AMERICAN COLLEGE OF OCCUPATIONAL AND ENVIRONMENTAL MEDICINE

Ankle and Foot Disorders

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SUMMARY OF RECOMMENDATIONS

The Evidence-based Practice Ankle Disorders Panel's recommendations are based on critically appraised higher quality research evidence and on expert consensus observing First Principles when higher quality evidence was unavailable or inconsistent (see Methodology). The reader is cautioned to utilize the more detailed indications, specific appropriate diagnoses, temporal sequencing, preceding testing or conservative treatment, and contraindications that are elaborated in more detail for each test or treatment in the body of this Guideline in using these recommendations in clinical practice or medical management. These recommendations are not simple "yes/no" criteria.

All ACOEM guidelines include analyses of numerous interventions, whether or not FDA-approved. For non-FDA-approved interventions, recommendations are based on the available evidence; however, this is not an endorsement of their use. In addition, many of the medications recommended are utilized off-label. (For example, anti-epileptic agents have been used off-label since the 1960s to treat chronic pain.)

Recommendations are made under the following categories:

- Strongly Recommended, "A" Level
- Moderately Recommended, "B" Level
- Recommended, "C" Level
- Insufficient-Recommended (Consensus-based), "I" Level
- Insufficient-No Recommendation (Consensus-based), "I" Level
- Insufficient-Not Recommended (Consensus-based), "I" Level
- Not Recommended, "C" Level
- Moderately Not Recommended, "B" Level
- Strongly Not Recommended, "A" Level

Category	Recommendation	Evidence
Acetaminophen	Acetaminophen for Acute Achilles Rupture	Recommended, Insufficient Evidence (I)
	Acetaminophen for Acute Ankle Fracture Analgesia	Recommended, Insufficient Evidence (I)
	Acetaminophen for Acute, Subacute, or Chronic Achilles Tendinopathy Pain	Recommended, Insufficient Evidence (I)
	Acetaminophen for Acute, Subacute, or Chronic Ankle Sprain	Moderately Recommended, Evidence (B)
	Acetaminophen for Tarsal Tunnel Syndrome	Recommended, Insufficient Evidence (I)
	Acetaminophen for Acute, Subacute, Chronic, or Post-operative Plantar Fasciitis Pain	Recommended, Insufficient Evidence (I)
	Acetaminophen for Acute Paronychia	Recommended, Insufficient Evidence (I)

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Category	Recommendation	Evidence
	Acetaminophen for Charcot Joint	Recommended, Insufficient Evidence (I)
	Acetaminophen for Phalangeal or Metatarsal Fractures	Recommended, Insufficient Evidence (I)
Acupuncture	Acupuncture for Acute, Subacute, Chronic, or Post-operative Achilles Tendinopathy	No Recommendation, Insufficient Evidence (I)
	Acupuncture for Acute, Subacute, or Chronic Ankle Sprain	No Recommendation, Insufficient Evidence (I)
	Acupuncture for Acute, Subacute, or Chronic Plantar Fasciitis	No Recommendation, Insufficient Evidence (I)
	Acupuncture for Treatment of Tarsal Tunnel Syndrome	No Recommendation, Insufficient Evidence (I)
Antibiotics	Antibiotics for Acute Paronychia	No Recommendation, Insufficient Evidence (I)
	Antibiotics for Foot Ulceration	Recommended, Insufficient Evidence (I)
	Pre-operative Antibiotic Prophylaxis for Ankle Fractures	Recommended, Insufficient Evidence (I)
	Topical and Systemic Antibiotics for Secondary Infections in Chronic Paronychia	Recommended, Insufficient Evidence (I)
	Topical Antibiotics for Acute Paronychia	Recommended, Insufficient Evidence (I)
Antiemetics	Antiemetics for Achilles Bursitis or Tendinopathy	See the ACOEM Antiemetics Guideline
	Antiemetics for Achilles Tendon Rupture	See the ACOEM Antiemetics Guideline
	Antiemetics for Ankle and Foot Fractures	See the ACOEM Antiemetics Guideline
	Antiemetics for Ankle Sprains and Strains	See the ACOEM Antiemetics Guideline
	Antiemetics for Bunion	See the ACOEM Antiemetics Guideline
	Antiemetics for Charcot Arthropathy	See the ACOEM Antiemetics Guideline
	Antiemetics for Chronic Ulcer	See the ACOEM Antiemetics Guideline

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Category	Recommendation	Evidence
	Antiemetics for Hammertoe	See the ACOEM Antiemetics Guideline
	Antiemetics for Morton Neuroma	See the ACOEM Antiemetics Guideline
	Antiemetics for Paronychia	See the ACOEM Antiemetics Guideline
	Antiemetics for Plantar Fasciitis	See the ACOEM Antiemetics Guideline
	Antiemetics for Tarsal Tunnel Syndrome	See the ACOEM Antiemetics Guideline
Arthrography	Routine Use of Arthrography in Diagnosis of Acute Ankle Sprain	Not Recommended, Insufficient Evidence (I)
	Routine Use of Arthrography in Diagnosis of Subacute or Chronic Ankle Sprain	No Recommendation, Insufficient Evidence (I)
Balance Training	Balance/Proprioception Training for Prevention of Ankle Injury	Recommended, Evidence (C)
Bone Scan	Bone Scanning for Calcaneus Fracture	Recommended, Insufficient Evidence (I)
	Bone Scanning for Forefoot and Midfoot Fractures	Recommended, Insufficient Evidence (I)
	Bone Scans for Assessment of Acute Ankle Sprain	Recommended, Insufficient Evidence (I)
	Bone Scans for Assessment of Subacute or Chronic Ankle Sprain	No Recommendation, Insufficient Evidence (I)
Bracing	Ankle Brace (Orthosis) for Acute Ankle Sprain	Recommended, Insufficient Evidence (I)
	Ankle Support (Brace, Tape) for Prevention of Ankle Injury - Initial Injury	Recommended, Evidence (C)
	Ankle Support (Brace, Tape) for Prevention of Ankle Injury - Recurrent Injury	Recommended, Insufficient Evidence (I)
	Foot Waffle Support Brace for Foot Ulcerations	Not Recommended, Insufficient Evidence (I)
	Functional Bracing for Post-operative Rehabilitation of Achilles Tendon Repair	Moderately Recommended, Evidence (B)
	Splints, Walking Braces, Orthoses and Casts for Charcot Joint	Recommended, Insufficient Evidence (I)

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Category	Recommendation	Evidence
Casting	Cast Immobilization for Acute Mild to Moderate Ankle Sprain	Not Recommended, Insufficient Evidence (I)
	Cast Immobilization for Ankle Fractures	Moderately Recommended, Evidence (B)
	Cast Immobilization for Distal Tibial Extra-articular Fractures	Recommended, Insufficient Evidence (I)
	Cast Immobilization for Select Calcaneus Fractures	Recommended, Insufficient Evidence (I)
	Cast Immobilization for Severe Ankle Sprain	No Recommendation, Insufficient Evidence (I)
	Cast Immobilization for Tibial Shaft Fractures (Closed, Diaphyseal)	No Recommendation, Insufficient Evidence (I)
	Casting for Chronic Plantar Fasciitis	No Recommendation, Insufficient Evidence (I)
	Splints, Walking Braces, Orthoses and Casts for Charcot Joint	Recommended, Insufficient Evidence (I)
	Total Contact Casting for Foot Ulcerations	Recommended, Evidence (C)
Complementary and Alternative Medicine	Complementary and Alternative Medications for Diabetic Foot Ulcers	No Recommendation, Insufficient Evidence (I)
Compression	Compression Therapy for Acute Ankle Sprain	No Recommendation, Insufficient Evidence (I)
	Pneumatic Compression for Treatment of Ankle and Foot Edema	Recommended, Evidence (C)
	Reduced Localized Mechanical Compression/Pressure for Foot Ulcerations	Recommended, Insufficient Evidence (I)
	Use of Pneumatic Compression Device for Treatment of Calcaneus Fractures	Recommended, Evidence (C)
Contrast Bath	Contrast Bath Therapy for Acute Ankle Sprain	No Recommendation, Insufficient Evidence (I)
Corticosteroids	Systemic Corticosteroids for Treatment of Acute, Subacute, Chronic, or Post-operative Achilles Tendinopathy	Not Recommended, Insufficient Evidence (I)
Cryotherapy	Cryotherapy for Acute Ankle Sprain	Recommended, Insufficient Evidence (I)
	Cryotherapy for Acute, Subacute, Chronic, or Post-operative Achilles Tendinopathy	Recommended, Insufficient Evidence (I)

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Category	Recommendation	Evidence
	Cryotherapy for Acute, Subacute, Chronic, or Post-operative Plantar Heel Pain	Recommended, Insufficient Evidence (I)
	Self-application of Cryotherapy or Heat Therapy for Acute, Subacute, Chronic, or Post-operative Achilles Tendon Rupture	Recommended, Insufficient Evidence (I)
	Self-application of Ice or Heat for Treatment of Tarsal Tunnel Syndrome	Recommended, Insufficient Evidence (I)
CT Scan	Computed Tomography for Assessment of Acute Ankle Sprain	No Recommendation, Insufficient Evidence (I)
	Computed Tomography for Assessment of Subacute or Chronic Ankle Sprain	Recommended, Insufficient Evidence (I)
	Computed Tomography for Diagnosis and Classification of Ankle Fractures	Recommended, Insufficient Evidence (I)
	Computed Tomography for Diagnosis and Classification of Forefoot and Midfoot Fractures	Recommended, Insufficient Evidence (I)
	Computed Tomography for Diagnosis and Classification of Hindfoot Fractures	Recommended, Evidence (C)
	Computed Tomography for Diagnosis of Achilles Tendinopathy	Not Recommended, Insufficient Evidence (I)
	Computed Tomography Scans for Mid-tarsus Pain and Sprains	Recommended, Insufficient Evidence (I)
Diathermy	Diathermy for Acute Ankle Sprain	Moderately Not Recommended, Evidence (B)
	Diathermy for Management of Edema Associated with Calcaneus Fracture	No Recommendation, Insufficient Evidence (I)
	Diathermy for Subacute or Chronic Ankle Sprain	Not Recommended, Insufficient Evidence (I)
Drainage	Incision for Abscess Drainage in Acute Paronychia	Recommended, Insufficient Evidence (I)
Dressings	Wound Dressings for Management of Lower Extremity Ulcers	Recommended, Insufficient Evidence (I)
Education	Education for Acute, Subacute, Chronic, or Post-operative Achilles Tendinopathy	Recommended, Insufficient Evidence (I)
	Education for Effects of Acute, Subacute, Chronic or Post-operative Ankle Sprain Injury	Recommended, Insufficient Evidence (I)
	Education for Plantar Fascia Disorders	Recommended, Insufficient Evidence (I)

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Category	Recommendation	Evidence
	Exercise and Education for Achilles Tendon Rupture Rehabilitation	Recommended, Insufficient Evidence (I)
	Patient Education for Diabetic Foot Complications	Recommended, Insufficient Evidence (I)
Electrical Stimulation	Electrical Stimulation for Prevention of Muscle Atrophy	No Recommendation, Insufficient Evidence (I)
	High-voltage Pulsed Electrical Stimulation for Acute, Subacute, or Chronic Ankle Sprain	Not Recommended, Insufficient Evidence (I)
	Low-Frequency Electrical Stimulation for Acute, Subacute, or Chronic Ankle Sprain	Not Recommended, Evidence (C)
	Low-Frequency Electrical Stimulation for Acute, Subacute, or Chronic Plantar Fasciitis	No Recommendation, Insufficient Evidence (I)
	Post-operative TENS for Achilles Tendon Repair	No Recommendation, Insufficient Evidence (I)
Elevation	Intermittent Elevation for Acute Ankle Sprain	Recommended, Insufficient Evidence (I)
EMG	Electromyogram for Initial Evaluation, Diagnosis or Pre-operative Assessment of Tarsal Tunnel Syndrome	No Recommendation, Insufficient Evidence (I)
Exercise	Eccentric Exercises for Chronic Achilles Tendinopathy	Moderately Recommended, Evidence (B)
	Exercise and Education for Achilles Tendon Rupture Rehabilitation	Recommended, Insufficient Evidence (I)
	Exercises for Treatment of Tarsal Tunnel Syndrome	No Recommendation, Insufficient Evidence (I)
	Stretching Exercises for Acute, Subacute, or Post-operative Achilles Tendinopathy	Recommended, Insufficient Evidence (I)
	Stretching Exercises for Plantar Fasciitis	Recommended, Insufficient Evidence (I)
	Stretching/Strengthening Exercises for Prevention of Ankle Injury	No Recommendation, Insufficient Evidence (I)
Footwear	Changes in Shoewear for Treatment of Morton's Neuroma	Recommended, Insufficient Evidence (I)
	Shock-Absorbing Fitted Shoes for Prevention of Plantar Fasciitis	No Recommendation, Insufficient Evidence (I)
	Special Shoes for Prevention of Ankle Sprain or Recurrent Ankle Sprain	Recommended, Insufficient Evidence (I)

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Category	Recommendation	Evidence
Gait Training	Gait Training for Charcot Joint	Recommended, Insufficient Evidence (I)
Glucocorticosteroids	Oral or Intramuscular Glucocorticosteroids for Acute, Subacute, or Chronic Plantar Heel Pain	Not Recommended, Insufficient Evidence (I)
	Oral Systemic Glucocorticosteroids for Treatment of Tarsal Tunnel Syndrome	Recommended, Insufficient Evidence (I)
	Systemic Glucocorticosteroids for Acute, Subacute, or Chronic Ankle Sprain	Not Recommended, Insufficient Evidence (I)
Heat	Heat for Acute Ankle Sprain	No Recommendation, Insufficient Evidence (I)
	Heat Therapy for Acute, Subacute, Chronic, or Post-operative Achilles Tendinopathy	Recommended, Insufficient Evidence (I)
	Heat Therapy for Acute, Subacute, Chronic, or Post-operative Plantar Heel Pain	Recommended, Insufficient Evidence (I)
	Self-application of Cryotherapy or Heat Therapy for Acute, Subacute, Chronic, or Post-operative Achilles Tendon Rupture	Recommended, Insufficient Evidence (I)
	Self-application of Ice or Heat for Treatment of Tarsal Tunnel Syndrome	Recommended, Insufficient Evidence (I)
	Warm Compresses for Acute Paronychia	Recommended, Insufficient Evidence (I)
Hyperbaric Oxygen	Hyperbaric Oxygen for Diabetic Foot Ulcers	Recommended, Evidence (C)
	Hyperbaric Oxygen for the Management of Ankle or Foot Fractures	No Recommendation, Insufficient Evidence (I)
	Hyperbaric Oxygen Therapy for Acute Ankle Sprain	Not Recommended, Evidence (C)
	Hyperbaric Oxygen Therapy for Subacute or Chronic Ankle Sprain	Not Recommended, Insufficient Evidence (I)
Hypnosis	Hypnosis to Promote Healing of Ankle and Foot Fractures	No Recommendation, Insufficient Evidence (I)
Immobilization	Immobilization and Reduction for Closed Displaced Ankle Fractures	Recommended, Insufficient Evidence (I)
	Immobilization for Distal, Middle, or Proximal Phalanx Fractures	Recommended, Insufficient Evidence (I)
	Immobilization for Mild to Moderate Mid-tarsus Sprains	Recommended, Insufficient Evidence (I)

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Category	Recommendation	Evidence
	Immobilization for Non-displaced Ankle Fractures	Recommended, Insufficient Evidence (I)
Injections	Actovegin Injection for Acute, Subacute, or Chronic Achilles Tendinopathy	No Recommendation, Insufficient Evidence (I)
	Apoprotinin Injection for Acute or Subacute Achilles Tendinopathy	Not Recommended, Insufficient Evidence (I)
	Apoprotinin Injection for Chronic Achilles Tendinopathy	Not Recommended, Evidence (C)
	Autologous Blood Injection for Acute, Subacute, or Chronic Ankle Sprain	No Recommendation, Insufficient Evidence (I)
	Autologous Blood Injection for Acute, Subacute, or Chronic Plantar Fasciitis	Not Recommended, Evidence (C)
	Botulinum Injections for Treatment of Tarsal Tunnel Syndrome	Not Recommended, Insufficient Evidence (I)
	Botulinum Toxin A Injection for Acute or Subacute Plantar Fasciitis	Not Recommended, Insufficient Evidence (I)
	Botulinum Toxin A Injection for Select Chronic Plantar Fasciitis	Recommended, Evidence (C)
	Glucocorticosteroid Injections for Acute or Subacute Plantar Fasciitis	Not Recommended, Insufficient Evidence (I)
	Glucocorticosteroid Injections for Acute, Subacute, or Chronic Ankle Sprain	No Recommendation, Insufficient Evidence (I)
	Glucocorticosteroid Injections for Acute, Subacute, or Chronic Ankle Tendinosis	Recommended, Insufficient Evidence (I)
	Glucocorticosteroid Injections for Acute, Subacute, or Post-operative Achilles Tendinopathy	Not Recommended, Insufficient Evidence (I)
	Glucocorticosteroid Injections for Chronic Achilles Tendinopathy and Associated Paratendon Bursitis	Recommended, Insufficient Evidence (I)
	Glucocorticosteroid Injections for Chronic Plantar Fasciitis	Recommended, Evidence (C)
	Glucocorticosteroid Injections for Morton’s Neuroma	Recommended, Evidence (C)
	Glucocorticosteroid Injections for Tarsal Tunnel Syndrome	Recommended, Insufficient Evidence (I)
	Glycosaminoglycan Polysulfate Local Injection (GAGPS) for Acute, Subacute, or Post-operative Achilles Tendinopathy	No Recommendation, Insufficient Evidence (I)
	Glycosaminoglycan Polysulfate Local Injection (GAGPS) for Chronic Achilles Tendinopathy	Recommended, Evidence (C)

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Category	Recommendation	Evidence
	Guidance of Steroid Injection with Ultrasound or Scintigraphy for Plantar Fasciitis	Not Recommended, Evidence (C)
	High-volume Image-guided Injection for Chronic Achilles Tendinopathy	No Recommendation, Insufficient Evidence (I)
	Hyaluronic Acid Injections for Acute, Subacute, or Chronic Ankle Sprain	No Recommendation, Insufficient Evidence (I)
	Hyperosmolar Dextrose Injections for Plantar Fasciitis	No Recommendation, Insufficient Evidence (I)
	Insulin Injections for Treatment of Tarsal Tunnel Syndrome	Not Recommended, Insufficient Evidence (I)
	Platelet-Rich Plasma Injections for Achilles Tendinopathy	Moderately Not Recommended, Evidence (B)
	Platelet-Rich Plasma Injections for Acute, Subacute, or Chronic Ankle Sprain	No Recommendation, Insufficient Evidence (I)
	Platelet-Rich Plasma Injections for Plantar Fasciitis	No Recommendation, Insufficient Evidence (I)
	Polidocanol Injection for Acute, Subacute, or Post-operative Achilles Tendinopathy	No Recommendation, Insufficient Evidence (I)
	Prolotherapy Injections for Chronic Achilles Tendinopathy	No Recommendation, Insufficient Evidence (I)
	Sclerosant Injections for Morton's Neuroma	Not Recommended, Insufficient Evidence (I)
	Subcutaneous Heparin Injection for Acute or Subacute Achilles Tendinopathy	Not Recommended, Evidence (C)
	Subcutaneous Heparin Injection for Chronic Achilles Tendinopathy	Not Recommended, Insufficient Evidence (I)
Interferential Therapy	Interferential Therapy for Treatment of Ankle Edema	Moderately Not Recommended, Evidence (B)
Iontophoresis	Iontophoresis for Acute and Subacute Ankle Compartment Tenosynovitis	Recommended, Insufficient Evidence (I)
	Iontophoresis for Acute, Subacute, or Chronic Ankle Sprain	No Recommendation, Insufficient Evidence (I)
	Iontophoresis for Treatment of Tarsal Tunnel Syndrome	No Recommendation, Insufficient Evidence (I)
	Iontophoresis with Glucocorticosteroid for Acute, Subacute, or Chronic Achilles Tendinopathy	Recommended, Insufficient Evidence (I)

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Category	Recommendation	Evidence
	Iontophoresis with Glucocorticosteroid for Post-operative Achilles Tendinopathy	No Recommendation, Insufficient Evidence (I)
	Iontophoresis with Glucocorticosteroid or Acetic Acid for Acute, Subacute, or Chronic Plantar Fasciitis	No Recommendation, Insufficient Evidence (I)
	Iontophoresis with NSAIDs for Acute, Subacute, Chronic, or Post-operative Achilles Tendinopathy	No Recommendation, Insufficient Evidence (I)
Laser Therapy	Low-Level Laser Therapy for Acute Ankle Sprain	Moderately Not Recommended, Evidence (B)
	Low-level Laser Therapy for Acute, Subacute, or Chronic Plantar Fasciitis	No Recommendation, Insufficient Evidence (I)
	Low-level Laser Therapy for Acute, Subacute, or Post-operative Achilles Tendinopathy	No Recommendation, Insufficient Evidence (I)
	Low-level Laser Therapy for Select Chronic Achilles Tendinopathy	Recommended, Evidence (C)
	Low-Level Laser Therapy for Subacute or Chronic Ankle Sprain	Not Recommended, Insufficient Evidence (I)
Lidocaine	Lidocaine for Treatment of Morton's Neuroma	No Recommendation, Insufficient Evidence (I)
	Lidocaine Patches for Acute, Subacute, Chronic, or Post-operative Achilles Tendinopathy	No Recommendation, Insufficient Evidence (I)
	Lidocaine Patches for Acute, Subacute, Chronic, or Post-operative Plantar Fasciitis	No Recommendation, Insufficient Evidence (I)
	Lidocaine Patches for Acute, Subacute, or Chronic Ankle Sprain	No Recommendation, Insufficient Evidence (I)
	Lidocaine Patches for Treatment of Tarsal Tunnel Syndrome	Recommended, Insufficient Evidence (I)
Magnets	Magnets for Achilles Tendinopathy	Not Recommended, Insufficient Evidence (I)
	Magnets for Acute, Subacute or Chronic Plantar Heel Pain	Strongly Not Recommended, Evidence (A)
	Magnets for Acute, Subacute, or Chronic Ankle Sprain	No Recommendation, Insufficient Evidence (I)
	Magnets for Treatment of Tarsal Tunnel Syndrome	Not Recommended, Insufficient Evidence (I)
Manipulation / Mobilization	Manipulation and Mobilization of the Distal Lower Extremity for Treatment of Tarsal Tunnel Syndrome	Not Recommended, Insufficient Evidence (I)

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Category	Recommendation	Evidence
	Manipulation for Acute, Subacute, Chronic, or Post-operative Plantar Heel Pain	No Recommendation, Insufficient Evidence (I)
	Manipulation or Mobilization for Acute or Subacute Ankle Sprain	No Recommendation, Insufficient Evidence (I)
	Manipulation or Mobilization for Chronic Recurrent Ankle Sprain	No Recommendation, Insufficient Evidence (I)
	Manipulation or Mobilization for Treatment of Hallux Valgus	No Recommendation, Insufficient Evidence (I)
	Manipulation or Mobilization of the Distal Lower Extremity for Treatment of Morton's Neuroma	No Recommendation, Insufficient Evidence (I)
	Manual Therapy as Part of a Post-ankle Fracture Rehabilitation Program	Not Recommended, Evidence (C)
	Massage and Soft Tissue Mobilization for Acute, Subacute, Chronic, or Post-operative Plantar Fasciitis	No Recommendation, Insufficient Evidence (I)
	Massage and Tendon Mobilization for Acute, Subacute, Chronic, or Post-operative Achilles Tendinopathy	No Recommendation, Insufficient Evidence (I)
Massage	Massage and Soft Tissue Mobilization for Acute, Subacute, Chronic, or Post-operative Plantar Fasciitis	No Recommendation, Insufficient Evidence (I)
	Massage and Tendon Mobilization for Acute, Subacute, Chronic, or Post-operative Achilles Tendinopathy	No Recommendation, Insufficient Evidence (I)
Medications, Other	Autologous-derived Growth Factors for Select Non-healing Diabetic Ulcers	Recommended, Evidence (C)
	Becaplermin (Regranex) for Select Non-healing Diabetic Neuropathic Ulcers	Recommended, Evidence (C)
	Diuretics for Routine Treatment of Tarsal Tunnel Syndrome	Not Recommended, Insufficient Evidence (I)
	Glyceryl Trinitrate for Acute, Subacute, or Post-operative Achilles Tendinopathy	No Recommendation, Insufficient Evidence (I)
	Glyceryl Trinitrate for Treatment of Chronic Achilles Tendinopathy Pain	Recommended, Evidence (C)
	Granulocyte Colony-Stimulating Factor for Select Patients with Diabetic Foot Ulcers	Recommended, Insufficient Evidence (I)
	Infliximab for Acute, Subacute, or Chronic Plantar Fasciitis	Not Recommended, Insufficient Evidence (I)
	Low Molecular Weight Heparins for Diabetic Foot Ulcers	No Recommendation, Insufficient Evidence (I)

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Category	Recommendation	Evidence
	Prostacyclin Analogues (Iloprost) for Diabetic Ulcers	No Recommendation, Insufficient Evidence (I)
	Proteolytic Enzymes for Acute, Subacute or Chronic Ankle Sprain	Moderately Not Recommended, Evidence (B)
	Pyridoxine for Treatment of Tarsal Tunnel Syndrome	Not Recommended, Insufficient Evidence (I)
	Streptokinase/Streptodornase Preparations for Acute, Subacute, or Chronic Ankle Sprain	Not Recommended, Insufficient Evidence (I)
	Tacrolimus (0.1% Ointment) for Chronic Paronychia	Recommended, Evidence (C)
	Use of Nasal Spray Calcitonin for Post-fracture Osteopenia	Not Recommended, Evidence (C)
Medications, Topical	Antifungal and Glucocorticosteoid Creams for Chronic Paronychia	Recommended, Insufficient Evidence (I)
	Antifungals (Topical and Systemic) for Chronic Paronychia	Recommended, Insufficient Evidence (I)
	Benzydamine for Ankle Sprains	No Recommendation, Insufficient Evidence (I)
	Cold Gel for Ankle Sprain	No Recommendation, Insufficient Evidence (I)
	Comfrey Extract for Ankle Sprains	No Recommendation, Insufficient Evidence (I)
	Movelat for Acute, Subacute, or Chronic Ankle Sprain	No Recommendation, Insufficient Evidence (I)
	Topical Basic Fibroblast Growth Factors for Select Non-Healing Diabetic Neuropathic Ulcer	No Recommendation, Insufficient Evidence (I)
	Topical Glucocorticosteroid Creams for Chronic Paronychia	Recommended, Evidence (C)
	Topical Nerve Growth Factors for Select Non-Healing Diabetic Ulcers	Recommended, Insufficient Evidence (I)
	Topical NSAIDs for Acute Achilles Tendinopathy	Recommended, Insufficient Evidence (I)
	Topical NSAIDs for Acute Ankle Sprain	Moderately Recommended, Evidence (B)
	Topical NSAIDs for Acute, Subacute, or Chronic Plantar Fasciitis Pain	Recommended, Insufficient Evidence (I)
	Topical NSAIDs for Post-operative Achilles Tendinopathy	No Recommendation, Insufficient Evidence (I)

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Category	Recommendation	Evidence
	Topical NSAIDs for Post-operative Plantar Fasciitis	No Recommendation, Insufficient Evidence (I)
	Topical NSAIDs for Subacute or Chronic Achilles Tendinopathy	Recommended, Evidence (C)
	Topical NSAIDs for Subacute, Chronic, or Post-operative Ankle Sprain	No Recommendation, Insufficient Evidence (I)
	Wheat Grass Cream for Acute, Subacute, or Chronic Plantar Fasciitis	Moderately Not Recommended, Evidence (B)
Metatarsal Pads	Metatarsal Pads for Treatment of Morton's Neuroma	Recommended, Insufficient Evidence (I)
Mobilization	Early Mobilization for Acute Ankle Sprain	Moderately Recommended, Evidence (B)
	Early Mobilization for Ankle Fractures	Moderately Recommended, Evidence (B)
MRA	MR Angiography for Assessment of Acute Ankle Sprain	Not Recommended, Insufficient Evidence (I)
	MR Angiography for Assessment of Subacute or Chronic Ankle Sprain	No Recommendation, Insufficient Evidence (I)
MRI	MRI for Assessment of Acute Ankle Sprain	No Recommendation, Insufficient Evidence (I)
	MRI for Assessment of Subacute or Chronic Ankle Sprain	Recommended, Insufficient Evidence (I)
	MRI for Charcot Joint	Recommended, Insufficient Evidence (I)
	MRI for Diagnosis of Achilles Tendinopathy	Recommended, Insufficient Evidence (I)
	MRI for Diagnosis of Acute Achilles Tendon Rupture	Recommended, Insufficient Evidence (I)
	MRI for Diagnosis of Select Patients with Plantar Fasciitis	Recommended, Insufficient Evidence (I)
	MRI for Diagnosis of Tarsal Tunnel Syndrome	Recommended, Insufficient Evidence (I)
	MRI for Distal Lower Extremity and Ankle Fractures	Recommended, Insufficient Evidence (I)
	MRI for Follow-up Evaluation of Non-acute Calcaneus Fracture	Recommended, Evidence (C)

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Category	Recommendation	Evidence
	MRI for Suspected Acute Forefoot and Midfoot Fractures	Recommended, Insufficient Evidence (I)
	MRI for Suspected Acute Hindfoot Fractures	Recommended, Insufficient Evidence (I)
	Routine Use of MRI to Diagnose Tarsal Tunnel Syndrome	Not Recommended, Insufficient Evidence (I)
NCS	Nerve Conduction Studies for Diagnosis and Pre-operative Assessment of Tarsal Tunnel Syndrome	Recommended, Insufficient Evidence (I)
	Nerve Conduction Studies for Initial Evaluation of Tarsal Tunnel Syndrome	Not Recommended, Insufficient Evidence (I)
Needling	Dry Needling for Acute, Subacute, or Chronic Achilles Tendinopathy	Not Recommended, Insufficient Evidence (I)
Nerve Ablation	Nerve Ablation for Morton's Neuroma	Recommended, Insufficient Evidence (I)
Nonoperative	Medical Treatment for Charcot Joint	Recommended, Insufficient Evidence (I)
	Non-operative Management for Lower Extremity Stress Fractures	Recommended, Insufficient Evidence (I)
	Non-Operative Management for Non-displaced Metatarsal Fractures	Recommended, Insufficient Evidence (I)
	Non-operative Management for Non-displaced Tarsal-Metatarsal Injury (Lisfranc)	Recommended, Insufficient Evidence (I)
	Non-operative Management for Proximal Fifth Metatarsal Fractures	Recommended, Insufficient Evidence (I)
	Non-operative Management of Achilles Tendon Rupture with Functional Splinting and Casting	Recommended, Evidence (C)
	Non-operative Management of Non-displaced Talar Fractures	No Recommendation, Insufficient Evidence (I)
	Non-operative Management of Osteochondral Lesions of the Talus	Recommended, Insufficient Evidence (I)
	Non-operative Management of Syndesmotic Injuries	Recommended, Insufficient Evidence (I)
	Non-operative Management of Tibial Plafond and Pilon Fractures	Recommended, Insufficient Evidence (I)
	Nonoperative Treatments for Hammer Toe	Recommended, Insufficient Evidence (I)

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Category	Recommendation	Evidence
	Other Non-operative Interventions Including Manipulation and Mobilization, Massage, Deep Friction Massage, or Acupuncture for Acute, Subacute, or Chronic Ankle Tenosynovitis	No Recommendation, Insufficient Evidence (I)
NSAIDs	Acetaminophen for Acute Achilles Rupture	Recommended, Insufficient Evidence (I)
	Acetaminophen for Acute, Subacute, or Chronic Achilles Tendinopathy Pain	Recommended, Insufficient Evidence (I)
	Acetaminophen for Acute, Subacute, or Chronic Ankle Sprain	Moderately Recommended, Evidence (B)
	NSAIDs and Acetaminophen for Tarsal Tunnel Syndrome	Recommended, Insufficient Evidence (I)
	NSAIDs and Acetaminophen for Acute Ankle Fracture Analgesia	Recommended, Insufficient Evidence (I)
	NSAIDs and Acetaminophen for Acute, Subacute, Chronic, or Post-operative Plantar Fasciitis Pain	Recommended, Insufficient Evidence (I)
	NSAIDs for Acute Achilles Tendinopathy	Recommended, Evidence (C)
	NSAIDs for Acute Ankle Sprain	Strongly Recommended, Evidence (A)
	NSAIDs for Acute, Subacute, Chronic, or Post-operative Pain from Achilles Tendon Rupture	Recommended, Insufficient Evidence (I)
	NSAIDs for Acute, Subacute, or Chronic Ankle Compartment Tenosynovitis	Recommended, Insufficient Evidence (I)
	NSAIDs for Subacute or Chronic Achilles Tendinopathy or Post-operative Pain	Recommended, Insufficient Evidence (I)
	NSAIDs for Subacute, Chronic, or Post-operative Ankle Sprain	Recommended, Insufficient Evidence (I)
	NSAIDs or Acetaminophen for Acute Paronychia	Recommended, Insufficient Evidence (I)
	NSAIDs or Acetaminophen for Charcot Joint	Recommended, Insufficient Evidence (I)
	NSAIDs or Acetaminophen for Phalangeal or Metatarsal Fractures	Recommended, Insufficient Evidence (I)
Opioids	Limited Use of Opioids for Acute and Post-operative Pain Management	Recommended, Insufficient Evidence (I)
	Opioids for Acute, Subacute, or Chronic Plantar Fasciitis Pain	Not Recommended, Insufficient Evidence (I)

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Category	Recommendation	Evidence
	Opioids for Pain from Acute or Post-operative Achilles Tendon Repair	Recommended, Insufficient Evidence (I)
	Opioids for Pain from Subacute or Chronic Achilles Tendon Repair	Not Recommended, Insufficient Evidence (I)
	Opioids for Pain Treatment of Tarsal Tunnel Syndrome in Select Patients	Recommended, Insufficient Evidence (I)
	Opioids for Post-operative Plantar Fasciitis	Recommended, Insufficient Evidence (I)
	Opioids for Select Acute Ankle Sprains	Recommended, Evidence (C)
	Opioids for Select Postoperative Ankle Sprains	Recommended, Insufficient Evidence (I)
	Opioids for Treatment of Acute, Subacute, or Chronic Achilles Tendinopathy Pain	Not Recommended, Insufficient Evidence (I)
	Opioids for Treatment of Pain for Post-operative Achilles Tendinopathy	Recommended, Insufficient Evidence (I)
	Routine Use of Opioids for Treatment of Pain from Tarsal Tunnel Syndrome	Not Recommended, Insufficient Evidence (I)
Orthotics	Ankle-foot Orthotics for Treatment of Foot Drop	Recommended, Insufficient Evidence (I)
	Custom Orthoses for Acute, Subacute, or Chronic Plantar Fasciitis	No Recommendation, Insufficient Evidence (I)
	Foot Orthotics for Prevention of Ankle Injury	No Recommendation, Insufficient Evidence (I)
	Orthoses for Prevention of Plantar Fasciitis or Lower Extremity Disorders	No Recommendation, Insufficient Evidence (I)
	Orthotic Devices for Acute, Subacute, Chronic, or Post-operative Achilles Tendinopathy	No Recommendation, Insufficient Evidence (I)
	Orthotic Devices for Acute, Subacute, or Chronic Plantar Heel Pain	Recommended, Evidence (C)
	Orthotics and Special Shoes to Prevent Stress Fractures and Overuse Injuries	No Recommendation, Insufficient Evidence (I)
	Orthotics for Treatment of Hallux Valgus	Recommended, Evidence (C)
	Orthotics for Treatment of Morton’s Neuroma	Recommended, Insufficient Evidence (I)

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Category	Recommendation	Evidence
	Orthotics for Treatment of Tarsal Tunnel Syndrome	No Recommendation, Insufficient Evidence (I)
	Splints, Walking Braces, Orthoses and Casts for Charcot Joint	Recommended, Insufficient Evidence (I)
Phonophoresis	Phonophoresis for Acute, Subacute, Chronic, or Post-operative Achilles Tendinopathy	No Recommendation, Insufficient Evidence (I)
	Phonophoresis for Acute, Subacute, Chronic, or Post-operative Plantar Heel Pain	No Recommendation, Insufficient Evidence (I)
	Phonophoresis for Acute, Subacute, or Chronic Ankle Sprain	No Recommendation, Insufficient Evidence (I)
	Phonophoresis for Treatment of Tarsal Tunnel Syndrome	No Recommendation, Insufficient Evidence (I)
PT / OT	Physical or Occupational Therapy for Acute, Subacute, or Chronic Ankle Sprain	Recommended, Insufficient Evidence (I)
	Physical or Occupational Therapy for Chronic Ankle Instability (CAI)	Recommended, Insufficient Evidence (I)
	Physical or Occupational Therapy for Patients with Functional Debilities after Cast Removal	Recommended, Insufficient Evidence (I)
Radiation	Low-dose Radiation (Radiotherapy) for Chronic Plantar Heel Pain	No Recommendation, Insufficient Evidence (I)
Reduction	Conscious Sedation or Intraarticular Block for Non-operative Reduction Ankle Fractures	Recommended, Evidence (C)
	Hematoma Block or General Anesthesia for Non-operative Reduction Ankle Fractures	Recommended, Insufficient Evidence (I)
	Immobilization and Reduction for Closed Displaced Ankle Fractures	Recommended, Insufficient Evidence (I)
Rest	Rest for Treatment of Tarsal Tunnel Syndrome	No Recommendation, Insufficient Evidence (I)
Return to Work	Return-to-Work Programs for Treatment of Tarsal Tunnel Syndrome	Recommended, Insufficient Evidence (I)
	Work Restrictions for Treatment of Tarsal Tunnel Syndrome	No Recommendation, Insufficient Evidence (I)
Shockwave Therapy	Extracorporeal Shock Wave Therapy for Diabetic Foot Ulcers	Not Recommended, Evidence (C)
	Extracorporeal Shockwave Therapy for Acute or Subacute Plantar Fasciitis	Not Recommended, Insufficient Evidence (I)

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Category	Recommendation	Evidence
	Extracorporeal Shockwave Therapy for Acute, Subacute, or Post-operative Achilles Tendinopathy	Not Recommended, Insufficient Evidence (I)
	Extracorporeal Shockwave Therapy for Chronic Mid-portion Achilles Tendinopathy	Recommended, Evidence (C)
	Extracorporeal Shockwave Therapy for Chronic Plantar Fasciitis	Recommended, Insufficient Evidence (I)
	Extracorporeal Shockwave Therapy for Morton's Neuroma	No Recommendation, Insufficient Evidence (I)
	Intracorporeal Pneumatic Shockwave Therapy (IPST) for Select Chronic Plantar Fasciitis	Moderately Recommended, Evidence (B)
	Local Anesthesia with High Shockwave Therapy for Plantar Fasciitis	Recommended, Insufficient Evidence (I)
	Local Anesthesia with Low or Medium Shockwave Therapy for Plantar Fasciitis	No Recommendation, Insufficient Evidence (I)
	Radial Extracorporeal Shockwave Therapy for Acute or Subacute Plantar Fasciitis	Not Recommended, Insufficient Evidence (I)
	Radial Extracorporeal Shockwave Therapy for Chronic Plantar Fasciitis	No Recommendation, Insufficient Evidence (I)
	Ultrasound or Fluoroscopy Guidance for Shockwave Therapy for Plantar Fasciitis	Not Recommended, Insufficient Evidence (I)
SPECT	SPECT-CT for Diagnosis of Plantar Fasciitis	Not Recommended, Insufficient Evidence (I)
Splints	Night Splints and Walking Boots for Post-operative Achilles Tendinopathy	Recommended, Insufficient Evidence (I)
	Night Splints for Acute, Subacute, or Chronic Achilles Tendinopathy	No Recommendation, Insufficient Evidence (I)
	Night Splints for Plantar Heel Pain	Recommended, Insufficient Evidence (I)
	Nocturnal Splints for Treatment of Tarsal Tunnel Syndrome	No Recommendation, Insufficient Evidence (I)
	Splints, Walking Braces, Orthoses and Casts for Charcot Joint	Recommended, Insufficient Evidence (I)
Stretching	Passive Stretching for Contractures after Immobilization of Ankle Fractures	Moderately Not Recommended, Evidence (B)
Surgery	Arthroplasty for Charcot Joint	No Recommendation, Insufficient Evidence (I)

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Category	Recommendation	Evidence
	Augmented Surgical Repair for Acute Achilles Tendon Ruptures	Not Recommended, Evidence (C)
	Augmented Surgical Repair for Chronic or Neglected Achilles Tendon Ruptures	No Recommendation, Insufficient Evidence (I)
	Cryosurgery for Acute or Subacute Plantar Heel Pain	Not Recommended, Insufficient Evidence (I)
	Cryosurgery for Chronic Plantar Heel Pain	No Recommendation, Insufficient Evidence (I)
	Deltoid Ligament Repair Concurrent with ORIF for Unstable Ankle Fractures	Not Recommended, Insufficient Evidence (I)
	Open and Percutaneous Operative Approaches for Achilles Tendon Rupture	Recommended, Evidence (C)
	Operative Fixation for Closed Displaced Ankle Fractures	Recommended, Evidence (C)
	Operative Fixation for Displaced Distal Fibula Fractures	Recommended, Insufficient Evidence (I)
	Operative Fixation for Distal Tibial Extra-articular Fractures	Recommended, Insufficient Evidence (I)
	Operative Fixation for Syndesmotic Ruptures	Recommended, Insufficient Evidence (I)
	Operative Fixation for Tibial Shaft Fracture (Closed, Diaphyseal)	Recommended, Evidence (C)
	Operative Intervention for Osteochondral Lesions of the Talus	Recommended, Insufficient Evidence (I)
	Operative Management for Displaced Metatarsal Shaft Fractures	Recommended, Insufficient Evidence (I)
	Operative Management for Displaced Tarsal-Metatarsal Injury (Lisfranc)	Recommended, Insufficient Evidence (I)
	Operative Management for Distal, Middle, or Proximal Phalanx Fractures	Recommended, Insufficient Evidence (I)
	Operative Management for Lower Extremity Stress Fractures	No Recommendation, Insufficient Evidence (I)
	Operative Management for Select Calcaneus Fractures	Recommended, Insufficient Evidence (I)
	Operative Management of Displaced Talar Fractures	Recommended, Insufficient Evidence (I)
	Operative Management of Tibial Plafond and Pilon Fractures	Recommended, Insufficient Evidence (I)

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Category	Recommendation	Evidence
	Percutaneous Calcaneus Fenestration for Chronic Plantar Heel Pain	No Recommendation, Insufficient Evidence (I)
	Post-operative Care Dressing for Ankle Surgery	No Recommendation, Insufficient Evidence (I)
	Post-operative Management of Ankle Instability	Recommended, Insufficient Evidence (I)
	Post-operative TENS for Achilles Tendon Repair	No Recommendation, Insufficient Evidence (I)
	Pre-operative Antibiotic Prophylaxis for Ankle Fractures	Recommended, Insufficient Evidence (I)
	Prophylaxis for Prevention of Deep Venous Thrombosis After Surgical Treatment of Achilles Tendon Rupture	Recommended, Evidence (C)
	Radiofrequency Microtenotomy for Chronic Plantar Fasciitis	No Recommendation, Insufficient Evidence (I)
	Sheets of Cultured Allogeneic Keratinocytes for Non-healing Diabetic Ulcers	Recommended, Evidence (C)
	Specific Operative Procedures and Fixators for Ankle Surgery	No Recommendation, Insufficient Evidence (I)
	Surgery for Acute or Subacute Plantar Fasciitis	Not Recommended, Insufficient Evidence (I)
	Surgery for Hallux Valgus	Recommended, Evidence (C)
	Surgery for Hammer Toe	Recommended, Insufficient Evidence (I)
	Surgery for Select Chronic Recalcitrant Plantar Fasciitis	Recommended, Insufficient Evidence (I)
	Surgery for Select Mid-tarsus Sprains	Recommended, Insufficient Evidence (I)
	Surgery for the Treatment of Acute or Subacute Achilles Tendinopathy without Rupture	Not Recommended, Insufficient Evidence (I)
	Surgery for the Treatment of Chronic Achilles Tendinopathy without Rupture	Recommended, Insufficient Evidence (I)
	Surgery for Treatment of Achilles Tendon Rupture	Recommended, Evidence (C)
	Surgery for Treatment of Acute or Subacute Ankle Ligament Tear	Not Recommended, Insufficient Evidence (I)

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Category	Recommendation	Evidence
	Surgery for Treatment of Chronic Ankle Instability (CAI)	Recommended, Insufficient Evidence (I)
	Surgical Excision for Morton's Neuroma	Recommended, Insufficient Evidence (I)
	Surgical Management of Recurrent Acute Paronychia	Recommended, Insufficient Evidence (I)
	Surgical Management of Select Chronic Paronychia	Recommended, Insufficient Evidence (I)
	Surgical Procedures (Including Ostectomy) for Charcot Joint	Recommended, Insufficient Evidence (I)
	Surgical Release for Space Occupying Lesions in Tarsal Tunnel Syndrome	Recommended, Insufficient Evidence (I)
	Surgical Release for Subacute or Chronic Ankle Tenosynovitis	No Recommendation, Insufficient Evidence (I)
	Thigh Tourniquet for Ankle Surgery	Not Recommended, Evidence (C)
	Thrombosis Prophylaxis Method for Prevention of Deep Venous Thrombosis After Surgical Treatment of Achilles Tendon Rupture	No Recommendation, Insufficient Evidence (I)
	Tissue-engineered Skin Grafts for Non-healing Diabetic Ulcers	Moderately Recommended, Evidence (B)
	Treatment of Cancellous Bone Defect with Displaced Intra-Articular Calcaneus Fractures	No Recommendation, Insufficient Evidence (I)
	Use of Arthroscopy-Assisted ORIF for Distal Fibular Fractures	No Recommendation, Insufficient Evidence (I)
Taping	Ankle Support (Brace, Tape) for Prevention of Ankle Injury - Initial Injury	Recommended, Evidence (C)
	Ankle Support (Brace, Tape) for Prevention of Ankle Injury - Recurrent Injury	Recommended, Insufficient Evidence (I)
	Heel Taping for Acute or Subacute Plantar Fasciitis or Heel Pain	Recommended, Evidence (C)
	Heel Taping for Chronic Plantar Fasciitis or Heel Pain	No Recommendation, Insufficient Evidence (I)
	Tape, Elastic Wrap or Tubular Elastic for Acute Ankle Sprain	No Recommendation, Insufficient Evidence (I)
	Taping for Treatment of Foot Drop	No Recommendation, Insufficient Evidence (I)

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Category	Recommendation	Evidence
	Taping for Treatment of Tarsal Tunnel Syndrome	No Recommendation, Insufficient Evidence (I)
	Tubigrip for Acute Ankle Sprain	Not Recommended, Evidence (C)
Temperature Monitoring	Infrared Temperature Monitoring for Diabetic Foot Complications	Recommended, Evidence (C)
Tetanus	Tetanus Immunization Status for Open Fractures	Recommended, Insufficient Evidence (I)
Ultrasound	Low-Intensity Ultrasound for Postoperative Hallux Valgus	Not Recommended, Evidence (C)
	Routine Use of Diagnostic Ultrasound in Tarsal Tunnel Syndrome	Not Recommended, Insufficient Evidence (I)
	Therapeutic Ultrasound for Acute Ankle Sprain	Moderately Not Recommended, Evidence (B)
	Therapeutic Ultrasound for Acute, Subacute, Chronic, or Post-operative Achilles Tendinopathy	No Recommendation, Insufficient Evidence (I)
	Therapeutic Ultrasound for Acute, Subacute, Chronic, or Post-operative Plantar Fasciitis	Not Recommended, Evidence (C)
	Therapeutic Ultrasound for Subacute or Chronic Ankle Sprain	Not Recommended, Insufficient Evidence (I)
	Ultrasound for Diagnosis of Achilles Tendinopathy	Recommended, Insufficient Evidence (I)
	Ultrasound for Diagnosis of Acute Achilles Tendon Rupture	Recommended, Insufficient Evidence (I)
	Ultrasound for Diagnosis of Acute Ankle Sprain	Not Recommended, Insufficient Evidence (I)
	Ultrasound for Diagnosis of Plantar Fasciitis	Recommended, Insufficient Evidence (I)
	Ultrasound for Diagnosis of Subacute or Chronic Ankle Sprain	No Recommendation, Insufficient Evidence (I)
	Ultrasound for Treatment of Tarsal Tunnel Syndrome	No Recommendation, Insufficient Evidence (I)
	Ultrasound Imaging for Diagnosing Ankle Fracture	Recommended, Insufficient Evidence (I)
	Ultrasound or Fluoroscopy Guidance for Shockwave Therapy for Plantar Fasciitis	Not Recommended, Insufficient Evidence (I)

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Category	Recommendation	Evidence
	Ultrasound to Stimulate Bone Healing for Ankle and Foot Fractures	Moderately Not Recommended, Evidence (B)
	Use of Ultrasound As an Aid to Nerve Conduction Studies in Tarsal Tunnel Syndrome	Recommended, Insufficient Evidence (I)
Vacuum	Negative Pressure (Vacuum) Wound Care Systems for Lower-Extremity Ulcerations	Moderately Recommended, Evidence (B)
Vitamins	High-dose Vitamin Therapy for Treatment of Achilles Tendinopathy	Not Recommended, Insufficient Evidence (I)
	High-dose Vitamin Therapy for Treatment of Ankle Sprains	Not Recommended, Insufficient Evidence (I)
	Use of Vitamins (Other than Pyridoxine) for the Treatment of Tarsal Tunnel Syndrome	No Recommendation, Insufficient Evidence (I)
	Vitamin Therapy for Treatment of Achilles Tendinopathy	No Recommendation, Insufficient Evidence (I)
	Vitamin Therapy for Treatment of Ankle Sprains	No Recommendation, Insufficient Evidence (I)
	Vitamins for Treatment or Prevention of Plantar Fasciitis	No Recommendation, Insufficient Evidence (I)
Walking Boots	Walking Boots and Night Splints for Post-operative Achilles Tendinopathy	Recommended, Insufficient Evidence (I)
	Walking Boots for Acute Ankle Sprain	Not Recommended, Evidence (C)
	Walking Boots, Casts, Splints, and Braces for Acute and Subacute Ankle Compartment Tenosynovitis	Recommended, Insufficient Evidence (I)
Weight-bearing	Early Post-operative Weight-bearing for Ankle Fractures	Moderately Recommended, Evidence (B)
	Early Weight Bearing for Post-operative Rehabilitation of Achilles Tendon Repair	Strongly Recommended, Evidence (A)
	Early Weight Bearing in Non-operative Treatment for Achilles Tendon Rupture	No Recommendation, Insufficient Evidence (I)
	Immediate Non-weight Bearing (Rest) for Acute Ankle Sprain	Recommended, Insufficient Evidence (I)
X-ray	Routine Stress X-ray for Evaluation of Ligament Rupture in Acute Ankle Sprain	Not Recommended, Insufficient Evidence (I)
	Routine Stress X-ray for Evaluation of Ligament Rupture in Subacute or Chronic Ankle Sprain	No Recommendation, Insufficient Evidence (I)

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Category	Recommendation	Evidence
	Routine Use of X-ray for Diagnosis of Plantar Heel Pain	Not Recommended, Insufficient Evidence (I)
	Routine Use of X-ray for Diagnosis of Plantar Heel Pain with Suspected Fracture	Recommended, Insufficient Evidence (I)
	Routine Use of X-ray in Assessment of Acute Ankle Sprain	No Recommendation, Insufficient Evidence (I)
	Routine X-ray for Diagnosis of Acute Achilles Rupture	No Recommendation, Insufficient Evidence (I)
	Weight-bearing X-rays for Mid-tarsus Pain and Sprains	Recommended, Insufficient Evidence (I)
	X-ray for Diagnosis of Achilles Tendon Disorders, Retrocalcaneal Bursitis, or Blunt Trauma or Suspected Fracture	Recommended, Insufficient Evidence (I)
	X-ray for Suspected Acute Ankle Fractures	Recommended, Insufficient Evidence (I)
	X-ray for Suspected Acute Calcaneus Fractures	Moderately Recommended, Evidence (B)
	X-ray for Suspected Acute Forefoot or Midfoot Fractures	Recommended, Insufficient Evidence (I)
	X-ray for Suspected Acute Talus Fractures	Recommended, Insufficient Evidence (I)
	X-ray in Assessment of Acute Ankle Sprain when Fracture Suspected	Recommended, Insufficient Evidence (I)
	X-rays and Other Diagnostic Testing for Charcot Joint	Recommended, Insufficient Evidence (I)

WORKFLOWS

- Master Algorithm. ACOEM Guidelines for Care of Acute and Subacute Ankle and Foot Disorders
- Algorithm 1. Initial Evaluation of Ankle and Foot Disorders
- Algorithm 2. Initial and Follow-up Management of Ankle and Foot Disorders
- Algorithm 3. Initial and Follow-up Management of Achilles Tendinopathy
- Algorithm 4. Management of Achilles Tendon Rupture
- Algorithm 5. Management of Plantar Heel Pain
- Algorithm 6. Management of Tarsal Tunnel Syndrome
- Algorithm 7. Management of Acute Ankle Sprains
- Algorithm 8. Management of Ankle and Foot Fractures

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INTRODUCTION

All guidelines include analyses of numerous interventions whether or not they are approved by the U.S. Food and Drug Administration (FDA). For non-FDA-approved interventions, recommendations are based on the available evidence. This is not an endorsement of their use. Many of the medications recommended are utilized off-label.

The following is a general summary of the recommendations contained in this Guideline:

- Initially, perform a thorough assessment, seek red flags, and formulate a differential diagnosis. Assign a working pathological or tissue diagnosis when the likelihood of a specific disorder is high. If an accurate pathological or tissue diagnosis is not obvious, assign a symptomatic diagnosis. Additionally, assignment of a working diagnosis may be helpful.
- When red flags are present, take appropriate action, including referral. In the absence of red flags, focus on management of the ankle and/or foot disorder by monitoring for complications, facilitating healing, and relieving discomfort.
- The health care team should identify and eliminate causative factors and consider modifying symptom-provoking activities. Workstation ergonomic analyses and reduction of weight-bearing; force; awkward positioning; slip, trip, or fall hazards; and/or vibration may be helpful. Work technique and footwear should be considered; however, there is a paucity of information about what constitutes appropriate footwear in occupational environments. Footwear should fit well, be comfortable, and provide adequate protection.
- Assign activity limitations as appropriate. Discomfort may be relieved in the short-term by decreasing or modifying offending activities, administering analgesics, advising elevation of the affected limb, applying hot and cold compresses, using properly fitted footwear, using ankle or foot splints or supports and toe splints, and providing floor padding as appropriate. Individual treatment sections should be consulted for specific applications.
- Avoid immobilization except for short periods during post-operative recovery and initial stages of fracture healing. Apply measures to retain mobility as soon as possible when complete or partial immobilization of the ankle and/or foot is unavoidable.
- If symptoms that limit activities or require treatment persist beyond the expected time for recovery, reconsider the diagnosis and/or treatment approach. However, multiple ankle-foot conditions have poorly characterized, wide ranges for recovery times. If recovery is slower than expected, advance evaluation and consider referral, further diagnostic studies, and/or changes in management. Referrals to occupational physicians, physiatrists, physical therapists, occupational therapists, orthopedic surgeons, podiatrists, orthotists, or others should be considered, depending on the presentation of the patient.
- Investigate and address non-physical factors (i.e., psychiatric, psychosocial, psychophysiological, workplace, or socioeconomic issues), particularly when there is a delay in recovery or return to work without purely-objective physical findings to validate reasons for delays. These factors are often not overt and specific inquiries may be required to identify whether delayed recovery and return to work is due to physical or non-physical issues.

IMPACT

According to the U.S. Bureau of Labor Statistics, ankle and foot claims account for approximately 11% of all reports of non-fatal occupational injuries and illnesses involving days away from work; constitute less than half (44%) the claims pertaining to the lower extremity; and are more common than head, neck, arm and shoulder claims [(1)]. However,

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the cost of medical treatment of the ankle and foot is less than for most other areas of the body. For example, the average workers' compensation claim in Texas was $3,406, $3,702, $3,671, and $3,665 in 2010, 2011, 2012, and 2013, respectively [2]. But, the average cost for ankle and foot soft tissue claim was $1,313, $1,361, $1,619, and $1,677, for each respective year from 1999 to 2002 [3]. Overall, ankle and foot soft tissue claims accounted for approximately 3% of medical costs for soft tissue claims of defined areas [4].

This guideline addresses common and potentially work-related ankle and foot disorders. It encompasses assessment; including identification of "red flags" or indicators of potentially-serious injury or disease; diagnosis; special studies for identification of clinical pathology; work-relatedness; and management, including modified duty and activity, return to work, and an approach to delayed recovery. Red flags include fracture, dislocation, malignancy, metabolic disorders, infection, and other conditions.

BASIC PRINCIPLES AND DEFINITIONS

Acute, subacute, and chronic symptoms are generally defined as those present for less than 1 month, 1 to 3 months, and greater than 3 months, respectively.

Bunion: See hallux valgus.

Fasciitis: Inflammation of supportive band or covering [5].

Hallux Valgus: Lateral deviation of the great toe at the metatarsophalangeal joint with respect to the midline of the body, generally defined as over 15° and occurring in most cases with medial deviation of the first metatarsal [6,7].

Inflammation: A tissue reaction marked by redness, warmth, swelling, and pain, usually in response to injury or infection [5,8].

Ligament: A band or sheet of strong fibrous connective tissue connecting the articular ends of bones serving to bind them together and facilitate or limit motion [5].

Metabolic Disorder: Any pathologic condition of any chemical or physical process that take place within an organism [5].

Metatarsalgia: Pain in the forefoot at one or more of the metatarsal heads [5,9].

Morton's Neuroma (Interdigital Neuroma): A benign tumor of the neurovascular bundle of the intertarsal spaces that can be between any two distal metatarsal bones, although classically, "Morton's neuroma" describes the specific location only between the 3rd and 4th metatarsals [5,9].

Neuroma: A benign tumor composed of nerve cells [5].

Paratenon: tissue filling the space between a tendon and its sheath [10].

Plantar Fasciitis: Pain in the plantar aspect of the heel that may also be present along the fascia of the arch of the foot [9,11] determined by clinical criteria, and not clearly originating in the fascia of the plantar foot or caused by inflammation.

Referred Pain: Pain derived from pathology that is not at the location of the pain.

Retinaculum: A band or bandlike structure that holds an organ or a part in place [12].

Sprain: Injury, not necessarily permanent, of a ligament [5].

- S, Grade I: overstretching or slight tearing without instability.

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- S, Grade II: incomplete tearing.
- S, Grade III: complete tear or rupture.

Strain: Injury, not necessarily permanent, of a muscle or musculotendinous unit [5].

- S, Grade I: overstretching or slight tearing.
- S, Grade II: incomplete tearing.
- S, Grade III: complete tear or rupture.

Synovitis: Inflammation of synovium.

Tendinitis or Tendonitis: Inflammation of a tendon [5].

Tendinosis: A chronic degenerative tendon injury, unaccompanied by redness or heat. It is associated with pain and limited movement [13].

Tendinopathy: Any pathology of a tendon.

RISK AND CAUSATION

ACHILLES TENDON RUPTURE

Spontaneous rupture of the Achilles tendon is uncommon, with incidence rates reported between 4 and 37 per 100,000 person years [14,15,16,17,18,19]. However, these rates appear to be increasing in the general population [14,15], particularly among males in their 30s and 40s who participate in sporting activities [16], as well as in older persons involved in no sporting activity [15,18]. Achilles tendon ruptures most frequently affect males 4-fold more often than females [20]. It is estimated that approximately 75% of all Achilles ruptures are related to sports and of these injuries, 75% occur in recreational athletes [21,22,23], mostly during a game [24]. The incidence of patients experiencing Achilles tendon symptoms prior to acute rupture is unknown, although it appears low, around 5% [14].

The primary mechanism for Achilles tendon rupture is presumed to be trauma from tensile forces, such as those encountered when pushing off during sprinting or running, sudden forceful dorsiflexion of the foot with slipping, missing a stair, jumping, or landing on the foot after falling [25]. Rupture from unusual tensile forces may occur [26,27,28]. However, when the tendon is degenerated and at risk for rupture, an eventual rupture may also occur without extraordinary stress especially when the degeneration is more marked [29,30]. Approximately 80% of tendon ruptures occur 3-6cm above the calcaneal insertion [31]. Direct injury mechanisms are rare. The exact pathogenesis of acute Achilles tendon rupture as well as the mechanism of the healing process is unknown and controversial, although an underlying degenerative condition is believed to be uniformly present [25,32,33,34,35]. Similar to other ruptured tendons such as the supraspinatus (see Shoulder Disorders guideline), there are two predominate theories – mechanical and hypovascularity [32,34]. The mechanical theory hypothesizes tendon degeneration from "repetitive microtrauma" [36,37] and failure of the inhibitory mechanism of the musculotendinous unit [22]. The vascular theory includes evidence that there is low blood supply to the Achilles tendon in the area of rupture [36,38,39] which is similar to that found for other tendons in the body that rupture including the supraspinatus, bicipital, Achilles, and tibialis posterior [32,34,36,38,39] (see Shoulder Disorders guideline). Other factors associated with increased risk of Achilles tendon rupture include a 3- to 4-fold risk of rupture within 90 days after the use of fluoroquinolones [40,41] and 43-fold risk after use of fluoroquinolones concomitantly with steroids. However, the overall incidence of rupture among users of fluoroquinolones is low [41]. Additionally, there is

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suggestion of a genetic component related to sequence variants of the tenascin C (TNC) gene, which regulates the tissue's response to mechanical load.

ANKLE AND FOOT FRACTURES

Fractures of the foot and ankle are common injuries among the adult population. The incidence of ankle fractures has been estimated to be 107 to 184 per 100,000 person years [42], and accounts for approximately 9% of all fractures [43]. Causes of ankle and foot fractures include falls, twisting injuries, motor vehicle accidents, and sports related injuries [44,45,46]. In the occupational setting, there is little in the literature regarding the most common types of fractures, recovery and rehabilitation schedules, and workplace limitations [47]. Distal lower extremity, ankle, and foot fractures covered in this section include those of the distal tibia and fibula, the malleoli, talus, calcaneus, navicular, metatarsals, and phalanges; and Lisfranc fractures. Syndesmotic and osteochondral injury are also considered.

ANKLE SPRAINS

Injuries to the ankle are common and are a frequent reason for seeking acute care [48,49,50,51,52]. The ankle is the second most commonly injured body site after the knee for sports-related injuries, and ankle sprain is the most common ankle injury [49]. Ankle sprain is common in physically active populations, particularly among those who participate in basketball, soccer, football, or any sports which require participants to jump, land on one foot, and/or make sharp turns [53,54,55].

The ankle is a modified hinge joint formed by three bones – the tibia and fibula superiorly, and the talus inferiorly – and stabilized by several ligaments. The ankle is also known as the talocrural joint and primarily allows plantarflexion and dorsiflexion of the foot. The subtalar or talocalcaneal joint is the articulation between the talus and the calcaneus, and allows inversion and eversion. Both the talus and calcaneus articulate with the tarsal bones in the junction between hind and midfoot. There are distinctions between ankle and foot, although both ankle and foot may be injured together, and it may be hard in practice (and in the medical literature), to separate ankle and foot injuries [56].

The integrity of the ankle is maintained by three groups of ligaments [57]. Laterally the ligament complex is comprised of the anterior talofibular ligament (ATFL), the calcaneofibular ligament (CFL), and the posterior talofibular ligament (PTFL). Medially, the ankle is stabilized by the deltoid ligament complex. Axially, the ankle mortise is stabilized by ligaments of the syndesmosis and interosseous membrane fibers between the tibia and fibula [50,51,57,58,59]. Ankle sprain injuries involve tear of one or more ligaments in any of the three ligament groups. The majority of ankle sprains involve only the lateral ligaments, with approximately 15% involving the medial ankle [49,60]. Most mild and moderate lateral injuries involve the ATFL and CFL, and severe injuries may also involve the PTFL. These injuries usually result from plantarflexion and inversion of the foot with external rotation of the tibia. As the foot twists medially in relation to the lower leg, a progression of tears in a predictable sequence occurs [50,51,59].

The natural course of the lateral ankle sprain is rapid improvement. A systematic review of the natural history of ankle sprains from 31 prospective studies demonstrated rapid decrease in pain and improvement in function over the first 2-weeks post-injury [61]. However, 5 to 33% of patients still reported persistent or residual pain at 1 year. Reports of

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full recovery 3 years after an ankle sprain varied 36 to 85%. Up to one-third of patients experience subsequent sprain that appears related to severity of the sprain [61,62]. As the majority of patients with ankle sprain show significant improvement in the first 2 weeks, the effectiveness of interventions is difficult to judge. However, a significant proportion of persons will continue to have chronic changes from their pre-injury state. Those with recurrent sprain may exhibit ill-defined radiological differences in the talus and decreased ankle stability [63]. It is not clear whether the instability is a cause or an effect of recurrent sprain. This group may have a disproportionate influence of the outcomes in treatment studies.

Ten to 20% of patients with acute ankle sprain may develop chronic ankle instability (CAI) [64,65,66,67]. Chronic ankle instability from lateral ankle ligament injury may be characterized by recurrent sprains and/or a persisting feeling (for at least 6 months) that the ankle is unstable and will give way. Mechanical testing demonstrates increased laxity of the lateral ankle ligaments in some patients, but many have no objective findings, but still report functional instability related to what is thought to be a proprioception deficit [68,69,70]. Thus, the sense of instability may be the result of other factors, such as deficits in proprioception preceding or following the sprain. The cause of a proprioception deficit is unknown. A prevailing theory is that an alteration of afferent somatosensory information, reflex responses, and efferent motor measures result from destruction or functional alteration of nerve endings in the soft tissue, cartilage, and joints trauma can occur with ankle sprain trauma [68,69,70]. There are no quality trials that help identify who is at greater risk for CAI development.

ANKLE TENDINOPATHIES (OTHER THAN ACHILLES TENDINOPATHY)

The ankle's tendinous compartments are susceptible to stenosing tenosynovitis, similar to those of the wrist [71,72,73]. They may be affected by disease (e.g., rheumatic disorders, diabetes mellitus, and infection) and undergo age-related degenerative changes. Tendon subluxations, dislocations, and tears occur [74]. There are no quality trials addressing ankle tendinopathies other than Achilles tendinopathy. Guidance for these ankle-foot tendon disorders is based on analogies to other tendinopathies, particularly of the wrist.

CALCANEUS FRACTURE

The Calcaneus is the most frequently fractured tarsal bone and accounts for 60% of all tarsal bone fractures. Calcaneus fractures account for 1 to 2% of all fractures in adults, and often occur in industrial workers most typically jumping or falling from heights or involved in motor vehicle accidents [75,76,77,78,79,80]. The majority of calcaneus fractures occur in falls from a height of 6 feet or greater [81]. Displaced intraarticular fractures account for 60 to 75% of the total calcaneal fractures. Approximately 8 to 10% of all displaced intra-articular calcaneal fractures are bilateral [75,76,78,82,83]. These fractures typically occur due to axial loading in men 30 to 60 years of age and usually have a poor outcome [81,83,84]. The percentage of calcaneal fracture that occurs while at work has been estimated to be 36 to 50% [76].

CHARCOT JOINT (NEUROGENIC ARTHROPATHY)

Charcot joints are theorized to be caused by either: 1) a neuropathy with loss of position sense and chronic ongoing joint trauma; or 2) an autonomic neuropathy with secondary bone loss. The condition conveys a poor prognosis [85,86]. While any sensory peripheral

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neuropathy (e.g., alcoholism, polio, leprosy, syphilis) and some central nervous system conditions such as syringomyelia may cause the condition, the largest cause is diabetes mellitus [87,88,89]. The rate or progression is thought to correlate with the duration and severity of the underlying neuropathy [86,90,91], diabetic nephropathy [92], as well as, obesity [90,91,93] which conveys the risk and severity of joint trauma. Genetic factors have been suggested [94]. The condition may be associated with some fractures and/or dislocations often due to the insensate foot [95]. The onset may be relatively acute over a few weeks [96], or it may be insidious or both. While any joint may be affected, the most common are the ankle and knee. Work-related causes are extremely rare, but may theoretically include impacts of a toxic neuropathy or spinal cord injury. There are no quality studies to guide treatments, especially for workers, thus all recommendations are consensus-based.

FOOT DROP

Foot drop is a weakness in the dorsiflexion strength of the affected lower extremity resulting in an abnormal gait pattern [97]. Foot drop is most commonly caused by a variety of central and peripheral nervous system disorders, although any disorder affecting muscle strength may cause foot drop. Among these are stroke, central nervous system disorders (e.g., multiple sclerosis), muscular dystrophies, trauma (including surgical damage to nerves), spinal cord compression such as a herniated disc, autoimmune disorders (e.g., polyarteritis nodosa), ruptured anterior tibial tendon, and vascular disorders such as aneurysm [98,99,100,101,102,103]. The acute onset of foot drop after ipsilateral leg trauma may be a manifestation of compartment syndrome.

An estimated 20% of all stroke survivors experience foot drop, often a consequence of spastic hemiparesis from stroke [99,104]. There are many abnormalities associated with the gait cycle in patients with hemiparesis. Foot drop results in an abnormal gait pattern most often because the ankle of the weak side cannot undergo voluntary dorsiflexion [97]. Improving gait efficiency is a rehabilitation goal for hemiparetic stroke patients [105]. Addressing gait is important in persons with foot drop regardless of etiology. Other goals include increasing mobility and range of motion [106]. One trial found no differences between high and low dose botulinum A in spastic drop foot [106]. Another trial found lack of efficacy with an implanted peroneal nerve stimulator [100]. A minor proportion of cases of foot drop are considered occupational. Foot drop does not usually arise out of employment, but treatment, fitness for duty, and accommodation issues may be encountered by the occupational physician.

HAMMER TOE

Hammer toe syndromes normally occur in the sagittal plane [107]. The metatarsophalangeal joint is dorsiflexed, while the proximal interphalangeal joint is plantarflexed [108,109]. Hammer toe mostly affects the second toe. Risk factors are not defined in quality epidemiological studies, but theorized to include biomechanical dysfunction, hereditary factors, high-heeled or poor fitting shoes, and trauma.

FOOT NEUROMA

Morton's neuroma is a common neuralgia affecting the web spaces of the toes, typically the third toe [110,111]. The pain of Morton's Neuroma may be debilitating in cases where patients have difficulty walking or applying pressure on their foot out of fear of pain. The neuroma is associated with a pathology of the plantar digital nerve as it divides at the base of the toes

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to supply the sides of the toes. The prevalence of nerve thickening in an asymptomatic population was 54% [112]. The cause remains unclear and there are no established occupational causative factors. Histologic examination of intraoperative specimens and imaging shows neuronal thickening [113,114,115,116] and degenerative changes [117]. There are many different treatments that have been used for Morton's neuroma such as NSAIDs, corticosteroid injections, ablative procedures, and surgery [110,118].

FOOT ULCERATION

Foot ulcers that arise out of occupational trauma, burns, infection, or other occupational disease (i.e., occupational peripheral neuropathies) and exposures or from non-occupational origins, such as diabetes mellitus (with or without peripheral neuropathy), vascular insufficiency and non-occupational peripheral neuropathies, may be encountered in an occupational setting. Foot ulcers may be painless; but may be accompanied by pain, burning, or itching; and may be infected. Pressure ulcers develop as a result of pressure, force or friction concentrated on a small area over a bone of the foot [119,120]. Shear (tangential) force may be important. Treatment options for foot ulcerations include local wound care, surgical intervention and topical nerve growth factors [119]. Pressure-repllieving devices are often used [120]. Few research studies have investigated the pressure reducing properties of such devices.

PLANTAR HEEL PAIN

Heel pain is the most common area of pain in the foot [121,122,123]. Plantar heel pain, known as "plantar fasciitis," is common [124,125]. Other names for plantar heel pain include painful heel syndrome, heel spur syndrome, runner's heel, subcalcaneal pain, calcaneodynia, plantar fasciopathy, and calcaneal periostitis [126,127]. The cumulative incidence of plantar fasciitis is reported as up to 10% of the U.S. population. Plantar heel pain affects active and sedentary adults of all ages [124,128,129].

The pathophysiology of posterior-medial plantar heel pain, or "plantar fasciitis," is unclear and controversial [130,131,132,133]. Degeneration of the heel fat pad, pressure from spurs, bursitis, nerve entrapment, and other pathologies have been offered as explanations [131,132,133]. Histologic findings often demonstrate degeneration without inflammation [134]. Several surgical case series that include structural observations or tissue analysis are reported [132,135,136], but the selection of heel pain patients includes only the most recalcitrant cases that choose to resort to surgery; and the only controls are cadaveric. Case selection may be restricted and biased [137], and similar histology is found in cases and cadavers [135]. Calcaneal spurs have been described in association with plantar fasciitis; however, plantar heel pain may exist without the presence of a spur and asymptomatic spurs are common [138,139]. Thus, spurs are not sufficient or necessary to cause plantar heel pain [138,139]. In summary, various pathophysiological correlates with heel pain have been postulated, but there is no agreement in the literature on pathophysiology.

Plantar fasciitis is usually marked by pain in the inferior or plantar aspect of the medial heel most noticeable during weight-bearing activities, especially on the first weight-bearing step in the morning or upon standing after periods of sitting or recumbency [128,132,140,141,142]. Plantar fasciitis generally responds well to conservative management, with more than 90% of patients resolving over a 6 to 12 month period with non-surgical intervention [128,143,144,145].

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TARSAL TUNNEL SYNDROME

Tarsal tunnel syndrome (TTS) is a relatively infrequent condition defined as an entrapment neuropathy of the tibial nerve or one of its branches from its entry point under the flexor retinaculum below the medial malleolus to the end of its lateral and medial plantar and posterior calcaneal branches, which innervate the base of the foot. Anatomically, the lateral plantar nerve (similar to the ulnar nerve) innervates the 5th and lateral half of the 4th toe, as well as most of the deep muscles of the foot. The medial plantar nerve (similar to the median nerve of the wrist), innervates the great toe, 2nd and 3rd toes, and the medial aspect of the 4th toe. Often compared to carpal tunnel syndrome (CTS) in the literature, the anatomical characteristics of the tunnel and the accompanying tunnel contents are markedly different from the wrist. The position of the tibial nerve and vessels are relatively fixed in a compartment lying between two tendons, the flexor digitorum longus tendon superiorly and the flexor hallucis longus tendon inferiorly, with the flexor retinaculum forming the roof of the tarsal tunnel. Any excessive fat, mass, adjacent tenosynovitis, flexor retinaculum fibrosis, varicose veins, arthritides, compartment edema or space occupying object can hypothetically result in compression or traction of the tibial nerve.

TENOSYNOVITIS

Stenosing tenosynovitis involves hypertrophy of the retinaculum of the compartment with signs of tenosynovial and retinacular fibrosis usually present. Most cases are thought to be manifestations of a non-inflammatory condition caused by hypertrophy of the retinaculum and parietal layer of the tenosynovium with resulting symptoms of pain on use.

WORK-RELATEDNESS

A thorough work history is crucial to establishing work-relatedness (see General Approach to Initial Assessment and Documentation guideline). Determining whether a complaint of a foot or ankle disorder is work related requires careful analysis and weighing of all associated or apparently causal factors operative at the time. A predominance of work factors suggests that worksite intervention is appropriate. A cluster of cases in a work group suggests a greater probability of associated work-design or management factors.

Prolonged weight bearing may exacerbate Morton's neuroma, metatarsalgia, hallux valgus, and plantar fasciitis. However, a cause-effect relationship between any of these conditions and workplace factors has not been shown. Acute trauma at work can be associated with tendinitis, tenosynovitis, and ligament strains. Stress fractures can be related to a recent increase in walking or weight-bearing activities. The relation of "chronic strain" or degenerative joint disease to work in the absence of specific traumatic exposures has not been documented in well-designed studies.

Key factors to consider in disability duration are age and type of job, especially if the regular work includes activities likely to worsen the condition. It is important for the physician to clarify with patients and employers that:

- Even moderately heavy material handling may provoke foot and ankle symptoms caused by tendinitis, plantar fasciitis, heel spurs, metatarsalgia, and other conditions.
- Any restrictions are intended to allow for spontaneous recovery or time to build activity tolerance through exercise.

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INITIAL ASSESSMENT

For most cases presenting with true foot and ankle disorders, special studies are usually not needed until after a period of conservative care and observation. Most ankle and foot problems improve quickly once any red flags are ruled out. Routine testing, i.e., laboratory tests, plain-film radiographs of the foot or ankle, or special imaging studies are not recommended during the first month of activity limitation, except when a red flag that is noted on history or examination raises suspicion of a dangerous foot or ankle condition or of referred pain.

The initial evaluation should eliminate likely presence of red flags (see Table 1) and distal sources of foot and ankle pain. The absence of red flags eliminates the proximate need for special studies, referrals, or hospital admission, and allows reassurance of the patient during the period early in treatment and when spontaneous recovery is expected.

Foot and ankle complaints are classified as follows:

- **Potentially serious (red flag) foot and ankle conditions**: Fracture, dislocation, neurovascular compromise, tendon rupture, and neoplastic, inflammatory, metabolic, or infection disorders.
- **Mechanical disorders**: Derangements of the foot or ankle related to acute trauma, such as ligament strain.
- **Degenerative disorders**: Possible consequences of aging or repetitive use, or a combination thereof, such as degenerative arthritis and chronic tendinitis, tenosynovitis, or tendinosis.
- **Referred pain or paresthesias**
- **Nonspecific disorders**: Discomfort occurring in the foot or ankle that does not satisfy the diagnostic criteria of a serious condition, derangement, degeneration, or referred pain.

Physical examination evidence of neurovascular compromise that correlates with the medical history and test results may indicate a need for immediate consultation (see "red flags" in Table 1). The examination may further reinforce or reduce suspicion of tumor, infection, tendon rupture, metabolic disorder, fracture, or dislocation.

Diagnoses should be based on symptoms and examination and study findings, using rational, evidence-based criteria for the diagnosis whenever it exists. Ideally, the criteria for the diagnosis specifies how a pathologic state is determined (symptoms, dysfunction); and how to distinguish the pathological state deviates from the healthy state to cause the symptoms and dysfunction (abnormal examination and study findings). When assigning a diagnosis, the more specific the signs and symptoms, the more certain the diagnosis. When complaints and examination findings are diffuse, certainty of diagnosis must be low as many diagnoses may apply.

MEDICAL HISTORY

For foot and ankle injuries, the purpose of a medical history is to gather information that can be used to manage the case (see Medical History Questionnaire). The medical history is the foundation by which to identify the diagnosis, risk factors, complicating factors, causation, investigation plan, treatment recommendations, and fitness for work. A medical history requires a focused interview to obtain information about the main problem (presenting or chief complaint) – the issue that motivates the patient to seek attention. This

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is stated in a short sentence or phrase and usually volunteered by the patient early in the encounter.

The following information also needs to be obtained:

1. *Circumstances at onset of symptoms:* May help with formulation of a mechanism of injury/disease etiology.

- If there was a sudden onset, what was the nature of incident:
- bending, twisting, inversions, eversion
- trauma, blunt
- Symptoms at onset:
- acute or gradual onset;
- anatomic location;
- quantity;
- quality;
- duration;
- aggravating factors;
- alleviating factors;
- associated symptoms.
- Activities at onset:
- routine activities;
- unusual activities; or
- single incident or accident.

2. *Current status of the foot or ankle problem symptoms:* Has the main problem severity, location, or other characteristics changed?

- Quantity and quality: pain, weakness, limited motion, deformity, swelling, discoloration.
- Constant or intermittent symptoms.
- Aggravating and alleviating factors:
- time of day or week when symptoms increase or decrease;
- activities that increase or decrease symptoms;
- footwear that increases or decreases symptoms; and/or,
- factors that make the problem better or worse.
- Associated symptoms:
- Are the problems located primarily in the foot or ankle?
- Does the patient have pain or other problems elsewhere?
- Impact on function:
- Limitations in function due to the foot and ankle problems:
- What can't the patient do now?
- Is this problem limiting his or her activities?
- Can he or she walk or bear weight?

3. *Occupation:* What are the working conditions that may be involved in disposing persons to accidents, causing disease, or provoking symptoms?

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- Work situation:
- specific job duties;
- duration of individual tasks each day;
- time on feet daily;
- feet supports:
- footwear,
- orthotics, or
- assistive devices;
- physical factors:
- floor surfaces (regular or irregular, slippery, hard or soft);
- indoor or outdoor work; and
- weight-bearing activities (e.g., standing, walking, climbing stairs, ladders, or equipment, jumping);
- material handling (lifting, carrying, pushing, pulling);
- psychosocial factors – What does the patient like and dislike about the job?
- Are there good or bad relationships at work with co-workers and supervisors?
- Does the patient find his or her job stimulating, monotonous, and/or stressful?
- What is the patient concept of the cause of the problems? Is there a sense of blame and being wronged? Does the patient have or is the patient considering legal counsel?

4. Activities:

- Current work activities:
- What are the patient's current and past avocational (home and recreational) activities (hobbies, exercise, sports, volunteer activities), and family responsibilities (e.g., caring for a disabled family member)?
- Does the patient run, hike, jump, or climb?
- Have these activities changed lately?

5. Current treatments for foot and ankle problems:

- medications;
- foot, leg, and ambulation supports (footwear, orthotics, assistive devices); and
- physical modalities (e.g., physiotherapy, podiatry, etc.)

6. Patient goals:

- health condition;
- function;
- return to work; and
- finances.

7. General inquiry (review of systems) is used to detect concurrent conditions and avoid treatment pitfalls.

- Is there weight change, swelling, fever, or fatigue?

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- Problems in other body parts may indicate the need to examine these areas.

8. Past medical and health history:

- past diagnoses, treatment, and effects of treatment for the foot and ankle problems:
- previous similar episodes;
- previous investigations or consultations; and
- previous treatments with results of treatments.
- general medical conditions;
- surgery; and
- other medical or health conditions, activity intolerances, and medical treatment (e.g., medications).

Ambiguity in documentation can result in missed diagnoses, redundant testing and treatment, and delayed claim processing. The physician should be scrupulous in documentation, including noting which ankle or foot – left or right – is the subject of the patient's complaints. For example, if a worker has prior work-related claim that involves the opposite ankle or foot, confusion may develop as to what should be done for the "old" or the "new" injury.

PHYSICAL EXAMINATION

The physical examination should be guided by the medical history and encompass:

- General observation of the patient;
- Regional examination of the ankles and feet; and
- Neurovascular screening.

OBJECTIVE EXAMINATION FINDINGS

The physician should seek objective evidence of pathology that is consistent with the patient's subjective complaints. In many cases, truly objective findings such as swelling, deformity, atrophy, reflex changes, or spasm will be present. Observe for signs of serious injuries, e.g., degloving injuries, lacerations, puncture wounds open wounds and crush injuries. Any such findings should be thoroughly documented in the medical record both for reference during future visits and in support the patient's claims. For example, in the case of muscle spasm, the physician must document in which muscle the spasm has occurred (see Measurement).

SUBJECTIVE COMPONENTS OF THE EXAMINATION FINDINGS

For some patients with ankle or foot complaints there are no objective findings. Meticulous documentation of the patient's complaints at each visit is of the utmost importance in such cases, particularly if psychosocial complications appear to be present. Damage to tissue does not shift, and consistency of subjective examinations findings (e.g., tenderness, pain with manual muscle testing) may add to or detract from support for elements of the differential diagnosis. Consider palpating widely during multiple visits to determine consistency of findings. Tenderness, weakness, and specific changes in mobility should be predictable among visits. If symptoms and examination findings change unexpectedly,

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particularly in the absence of objective findings, suspect a non-anatomic/non-physiologic disorder.

MEASUREMENT

To accompany both symptoms and objective and subjective examination findings, quantification should be part of the examination and record. For example, when swelling is claimed or edema present, the extent of the swelling or edema should be recorded with tissue-pen outlines and photographs and with circumference measurements; when limited range of motion (ROM) is present, angles of movement should be measured; and when weakness is present, maximal weights lifted should be recorded.

ANATOMY

A full description of the ankle and foot is complex and beyond the scope of these *Guidelines*. The ankle and foot has 14 bones (not including those in the toes), many ligaments, tendons, and muscles, and can be separated into the hind-, mid-, and forefoot. The hindfoot contains the ankle (talocrural) and subtalar (talocalcanean) joints – the former is responsible for most of the plantarflexion and dorsiflexion of the foot – and the talus and calcaneus. The midfoot contains the remainder of the tarsal bones. Most supination, pronation, and rotation of the foot occur at the subtalar and mid-foot joints. The forefoot contains the tarsal bones and the toes. Additionally, the distal talofibial syndesmosis is part of the ankle [6,56].

The movements of the ankle and foot include:

- flexion (dorsiflexion) – upward movement of the foot at the ankle;
- extension (plantarflexion) – downward movement of the foot at the ankle;
- eversion – twisting of the foot with the sole facing laterally;
- inversion – twisting of the foot with the sole facing medially;
- abduction – movement of the foot in the axis of the lower leg so that the forefoot and toes move laterally;
- adduction – movement of the foot in the axis of the lower leg so that the forefoot and toes move medially;
- pronation – a combination of dorsiflexion, eversion, and abduction that moves the plantar aspect of the forefoot and toes to face laterally; and
- supination – a combination of plantar flexion, inversion, and adduction that moves the plantar aspect of the forefoot and toes toward the midline.

Dorsiflexion and plantar flexion are achieved by muscles with attachments anterior and posterior of the malleoli, respectively. The dorsiflexors include the tibialis anterior, extensor hallucis longus, and extensor digitorum longus. The plantar flexors include the peroneous longus and brevis, gastrocnemius, soleus, flexors hallucis and digitorum longi, and tibialis posterior. These muscles, along with the intrinsic muscles of the foot, are responsible for pronation and supination.

FOCUSED FOOT AND ANKLE EXAMINATION

Observation – Examine both feet and look for and note asymmetries. Note heel structure and position, including arch shape at rest and when the patient bears weight. Inspect medial and lateral dorsal and plantar aspects of the foot and ankle for skin integrity, edema, erythema, and/or ecchymosis that often occur over the injury site, and for deformities suggestive of degeneration, malformation, fracture, or dislocations. Observe for signs of

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serious injuries, e.g., degloving injuries, lacerations, puncture wounds, open wounds and crush injuries. The quality of findings may infer timing as well as location of ankle and foot disorders. Muscular atrophy arises only after weeks or months of problems. Ecchymosis may or may not betray diffusion of hemolysis that can take days to become evident. Observe weight-bearing skeletal alignment of the foot and ankle in relation to the whole body for local skeletal malalignment and correlated and compensatory motions and postures. Observe foot and ankle motion during gait, and during functional tasks (e.g., donning and doffing shoes), particularly those that are affected by the disorder. Usually, a person avoids placing weight on the injured or painful portion of the foot.

Palpation – Carefully palpate the ankles and feet for edema, tenderness, structural continuity, nodules and deformities including voids, and warmth. Close attention should be paid to the distal fibula, distal tibia, fifth metatarsal and calcaneocuboid joint because they are the areas most often injured in avulsion fractures. Palpation of the proximal fibula is also performed to help detect a Weber C ankle fracture. Palpate the tendons and their insertions, and the musculotendinous junctions. Always palpate bilaterally.

Range of Motion – The range of motion (ROM) of the foot and ankle should be determined both actively and passively. Check all axes of mobility (see Anatomy), and compare mobility of the affected and unaffected side. Expected mobility ranges can be found in sources such as the *AMA Guides to the Evaluation of Permanent Impairment*, and Hoppenfeld's *Physical Examination of the Spine and Extremities*.

Strength – Resisted ROM may be used to assess strength and the presence of injury in muscles, tendons, and their attachment points. Note weakness and distribution of pain and its anatomic correlation or lack thereof.

Joint Integrity – Stress the ligaments to assess the stability; include the anterior drawer tests of the ankle and talar tilt tests (supination of the ankle so that the lateral aspect of the talus faces down). The anterior drawer test is performed with the foot in neutral position, the foot held firmly at the heel, and posterior (sheer) force applied to the tibia. If significant anterior displacement of the foot relative to the distal tibia can be felt, it indicates a significant abnormality of the anterior talofibular ligament [(146)(147)]. The talar tilt test applies inversion force to the effected ankle while the lower leg is stabilized. A positive test indicates lateral ligamentous laxity. There should be comparable mobility in the contralateral side if both sides are normal. The squeeze test may is used to diagnose injury to the tibiofibular syndesmosis and involves placing the hands about 6 inches distal to the knee with thumbs on the fibula and fingers on the medial tibia, then squeezing the leg to bring the fibula and tibia together. Ankle or distal leg pain indicates syndesmotic injury [(6)].

Neurovascular Screening – Assess neurologic and vascular status of the foot and ankle (including skin temperature, peripheral pulses, and motor, reflex, and sensation of the foot and ankle and surrounding structures). Observe for signs of serious injuries, e.g., degloving injuries, lacerations, puncture wounds open wounds and crush injuries. Observe the skin for trophic changes. Examination of lumbosacral nerve root function also is in order because L5 radiculopathy can affect dorsiflexion and toe extensors and S1 radiculopathy can affect plantar flexion (see Low Back Disorders Guideline). Patients with peripheral neuropathy (e.g., diabetics) may have decreased sensation in the foot or ankle and neuropathic joints presenting as acute swelling or inflammation. Peripheral nerve entrapment may be manifested as foot drop if the peroneal nerve at the knee is involved or rarely, as tarsal

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tunnel syndrome, presenting as numbness of the plantar surface of the foot and toes. Foot drop can be seen in L5 neuropathy due to an L4-5 disc protrusion. Consider assessing the posterior tibial and dorsalis pedis pulses, and capillary refill time.

INITIAL CARE

Comfort is often a patient's first concern. Nonprescription analgesics, short-term non-weight bearing activities, cold application and elevation will provide sufficient pain relief for most patients with acute and subacute symptoms. If treatment response is inadequate (e.g., if symptoms and activity limitations continue), prescribed pharmaceuticals or physical methods can be added. Co-morbid conditions, side effects, costs, and clinician and patient preferences guide the physician's choice of recommendations.

AUDITING/MONITORING CRITERIA

The clinician is recommended to assure:

1. Patients with ankle sprains with Ottawa rules positive examination findings do not undergo x-rays. Target <10% undergo x-rays.
2. Patients with ankle sprains are provided active exercise or limited walking. Target >90%.
3. Patients with ankle sprains are prescribed NSAIDs. Target 90%.
4. Patients are prescribed eccentric exercises for Achilles tendinopathy without complete tear. Target >90%
5. Patients undergo postoperative weight bearing exercises within 2 weeks of Achilles tendon repair. Target 100%

ACHILLES TENDINOPATHY

OVERVIEW

Patients with tendinopathy present with localized ankle pain that is augmented by movement. Occasionally, pain may extend along the affected tendon sheath. Patients rarely have paresthesias unless there is an accompanying swelling or other mechanism to affect an adjacent nerve.

Pain from Achilles tendinopathy may occur at rest or during activity [(148)]. A history of activity may include running, jumping, and walking. Pain is the cardinal symptom of Achilles tendinopathy, which may manifest at the beginning and end of vigorous activity, but may become present throughout activity and in routine activities as it becomes more severe or chronic in nature. The pain may limit training or vigorous activity [(148)]. A detailed history of activity including running, jumping, and walking should be elicited.

The Achilles tendon should be palpated for tearing, rupture, tenderness, edema, and warmth. Calf-squeeze or knee flexion tests are done (see Achilles Rupture). Single-leg heel raise, hop in place, or hop forward may provoke Achilles tendon pain. Pain from Achilles disorder will be isolated to the Achilles tendon [(149)]. The Achilles tendon may have diffuse discomfort with swelling of the tendon mid-portion. Palpation may identify tenderness of both sides of the tendon. The medial side of the Achilles tendon is usually more tenderas the medial fibers are subjected to more stress. Achilles tendon swelling may be fusiform or sausage-like. Palpable or audible crepitus should be noted if present as this denotes paratenonitis. Crepitus is not usually present with intra-substance tendinopathy. A fixed

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thickening indicates paratenonitis. Intratendinous nodules or thickening that move with the tendon indicate tendinosis [25,148].

Tender nodules in the paratenon reflect hypertrophy of connective tissue. Decreased dorsiflexion at the ankle is due to tightness in the tendon complex [25]. Compression of the tendon at the calcaneal insertion with medial and lateral pinch that results in pain anterior to the tendon is indicative of retrocalcaneal bursitis. The Victorian Institute of Sport Assessment for Achilles tendinopathy (VISA-A) is a tool for assessing pain and function used in multiple studies cited in this guideline. There are other instruments for assessing pain and function.

DIAGNOSTIC RECOMMENDATIONS

X-RAY FOR DIAGNOSIS OF ACHILLES TENDON DISORDERS, RETROCALCANEAL BURSITIS, OR BLUNT TRAUMA OR SUSPECTED FRACTURE

Recommended

X-ray is recommended for diagnosing insertional Achilles tendon disorders or retrocalcaneal bursitis or evaluating blunt trauma or suspected fracture.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence Low

Rationale

There is no quality evidence for or against the use of x-ray for diagnosing Achilles tendinopathy. X-ray is non-invasive, has a low adverse-effect profile, but does result in radiation exposure and is of moderate cost. Radiography is poor at diagnosing soft-tissue disorders and in the absence of trauma or suspected fracture is not indicated as a first-line diagnostic tool for midportion tendon disorders. X-ray may reveal calcaneal spur, prominent posterior calcaneal tuberosity, or ossification of the Achilles tendon (Heckman et al., 2009). For other Achilles tendon disorders, ultrasound or MRI is more effective. Therefore, plain radiographic film studies are recommended only for insertional Achilles tendinopathy or traumatic injury.

ULTRASOUND FOR DIAGNOSIS OF ACHILLES TENDINOPATHY

Recommended

Ultrasound is recommended for diagnosing Achilles tendinopathy and may be particularly useful for differentiation of paratenonitis and tendinosis and for identifying fluid in the retrocalcaneal bursa.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence Moderate

Rationale

There are no quality randomized trials evaluating the use of ultrasound in the diagnosis of Achilles tendinopathy. However, ultrasound is frequently used to diagnose midportion

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tendinopathy, and can reveal local thickening of the tendon and/or irregular tendon structure with hypoechoic areas and/or irregular fiber orientation (Rompe et al., 2009). Ultrasound reveals fluid surrounding the tendon acutely and chronically and can show adhesions that can be visualized as thickening of the hypoechoic paratenon (Reddy et al., 2009). Although limited in its ability to distinguish tendon degeneration from partial rupture, ultrasound has a sensitivity of 0.8 and specificity of 0.4, (PPV = 0.49. NPV = 0.68) compared to clinical diagnosis (Tan et al., 2008). Ultrasound in non-invasive, has low adverse effects, and is of moderate cost. However, ultrasound may be less sensitive than MRI; therefore it is recommended when the clinical diagnosis is uncertain.

MAGNETIC RESONANCE IMAGING (MRI) FOR DIAGNOSIS OF ACHILLES TENDINOPATHY

Recommended

MRI is recommended for evaluating Achilles tendinopathies including paratendonitis, tendinosis, and retrocalcaneal bursitis.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence Moderate

Rationale

There are no quality randomized trials evaluating the use of MRI in the diagnosis of Achilles tendinopathy. MRI can demonstrate thickened paratenon with adhesions and offers extensive information on the internal structure of the tendon and surrounding tissues (Heckman et al., 2009). Compared to clinical diagnosis, MRI has a sensitivity of 0.95 and specificity of 0.5 (PPV = 0.56, NPV = 0.94) (Tan et al., 2008). MRI may be helpful in differentiating inflammatory from degenerative changes in soft tissue. MRI is more expensive than ultrasound, but may be more reliable because there is less chance for operator error and it provides a broader field of view relative to ultrasound. MRI is therefore recommended.

COMPUTED TOMOGRAPHY (CT) FOR DIAGNOSIS OF ACHILLES TENDINOPATHY

Not Recommended

CT is not recommended for diagnosing Achilles tendinopathy.

Strength of evidence Not Recommended, Insufficient Evidence (I)
Level of confidence Moderate

Rationale

There is no quality evidence for or against the use of CT imaging for the diagnosis of Achilles tendinopathy. While CT is non-invasive and has a low adverse effect profile, it results in radiation exposure and is of moderate to high cost. CT is not helpful in differentiating inflammatory from degenerative changes in soft tissue. As the role of CT has yet to be defined in the literature and has limitations when compared to MRI, it is not recommended.

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TREATMENT RECOMMENDATIONS

OVERVIEW

For each of the Achilles tendon disorders causing pain, the initial management is non-operative. It is believed that early intervention is critical, as management becomes more complicated and less predictable when the conditions become chronic [149].

Achilles tendon disorders, including Achilles tendinitis, tendinosis, or tendinopathy, are painful conditions affecting the Achilles tendon, which is the largest and strongest tendon in the body, connecting the soleus, and gastrocnemius muscles in the leg to the heel at the calcaneus bone [150]. The Achilles tendon plantar flexes the ankle and facilitates walking. Achilles tendon disorders can make walking difficult.

Proper management of Achilles tendon disorders should be distinguished on the basis of location – the distal insertion into the calcaneus (within 2cm of insertion) as opposed to the mid-portion of the tendon, often defined as the segment between 2cm and 6cm proximal to the calcaneal insertion, as these are different entities. Despite the differences that come with location, some studies do not clearly classify patients based on location. A distinction between acute, subacute, or chronic disorders is important in distinguishing between potential etiologies of pain and selecting the best intervention strategies, but the literature has inconsistent definitions of acuity [151].

The term “tendinopathy” in Achilles tendon disorders is the general reference term for the diagnosis of pain, swelling, and impaired performance [152]. The term “tendinosis” now refers to a non-inflammatory disorder of the midport of the tendon (2 to 6cms proximal to the insertion) with tendon degeneration confirmed histologically [151,153]; devascularization is common [25,148]. The morphological feature is increased interfibrillar glycosaminoglycans and changes in the collagen fiber structure and arrangement. It may be considered a failed healing response [126].

Paratenonitis is an inflammatory condition of the peritendinous structures, including the paratenon [148]. The Achilles tendon does not have a true tendon sheath, but a paratenon – a single layer of cells composed of fatty, mesentery-like areolar tissue that is highly vascularized [148]. **Insertional tendinosis** is an inflammatory process involving the distal 2cm and is often associated with **Haglund’s** deformity, which is a prominent posterior superior calcaneal tuberosity that contributes to changes in the overlying tissues (bursa, tendon). **Retrocalcaneal bursitis** is another source of calcaneal heel pain, caused by irritation of the retrocalcaneal bursa. The cause and pathogenesis of these disorders are unknown [149,150,151,153,154], although age appears to be an important factor. Associations between Achilles tendinopathy and sports are reported, but a cause-effect relationship between Achilles tendon problems and activities has not been established. Inactive individuals acquire Achilles tendon problems [153,154,155] – up to 30% of Achilles tendinopathy occurs in persons who do not participate in vigorous activity [126]. Compromise of microcirculation may play a role with Achilles tendinopathy, as well as other tendinopathies, such as patellar, supraspinatus, and bicipital tendinopathy [156] (see Shoulder Disorders guideline).

Many patients with mild symptoms require no specific limitations. Patients with moderate or severe Achilles tendinopathies may be allowed to limit activities that provoke symptoms, and should limit activities that pose a safety risk. Consider limitation of jumping, high-force

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loading of the Achilles tendon, climbing, or activities that require agility or balance. Complete rest is not indicated. Patients may return to their usual jobs, but some may require relative rest.

ACTIVITY MODIFICATION AND EXERCISE

EDUCATION

EDUCATION FOR ACUTE, SUBACUTE, CHRONIC, OR POSTOPERATIVE ACHILLES TENDINOPATHY

Recommended

Education is recommended for acute, subacute, chronic, or post-operative Achilles tendinopathy.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence Moderate

Indications

All patients with Achilles tendinopathy assigned eccentric exercises.

Frequency/Dose/Duration

One or 2 appointments to educate patients about the disorder, effects of activity, unhelpfulness of complete inactivity, prognosis, and to address other questions.

Indications for discontinuation

Recovery or demonstration of intolerance or lack of efficacy.

Rationale

Two moderate-quality studies compared more intense to less intense exercise (Silbernagel et al., 2001) or exercise to “active rest” (Silbernagel et al., 2007) for treatment of chronic Achilles tendinopathy. There was no difference between the effects of more intense and less intense exercise (Silbernagel et al., 2001). Eccentric exercises were found superior to concentric exercises (Mafi et al., 2001). (A low-quality study found eccentric exercises to have a better outcome over concentric exercises (Nielsen et al., 1990).) There is one high-quality study comparing eccentric exercise with non-intervention and with shockwave therapy (Rompe et al., 2007) that found exercise and shockwave therapy both superior to observation (Rompe et al., 2007). However, the equivalence of exercise to shock wave therapy was not reproducible (Rompe et al., 2008), challenging the reproducibility and integrity of the study findings. Additionally, in these studies, the uncertainty due to the instruments used to measure outcome (Robinson et al., 2001) was not addressed, with the differences in findings based primarily on statistics and without fully considering the variability introduced by the clinical measurement.

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There are no quality studies of exercise for treatment of acute, subacute, or post-operative Achilles pain. There are many additional studies that included exercise as part of the treatment, but did not have adequate controls to demonstrate the effects of exercise. Studies comparing exercise to other interventions generally used eccentric exercises. Stretching exercises and graded activity does not appear to differ in effect (Silbernagel et al., 2007) suggesting that allowing patients to engaging in activities according to their comfort level does not worsen outcome.

Exercise is non-invasive, has few adverse effects, may benefit the individual's overall health compared to inactivity, and is not costly when self-administered. Exercise may be taught quickly by clinicians or therapists and is moderately recommended. For acute pain, there is a lack of evidence for effectiveness, but it is reasonable to infer that this intervention may be beneficial. Post-operative patients may benefit from a few additional supervised visits to help guide exercise and activity levels.

EXERCISE

In the musculoskeletal literature, the term "exercise" is used to describe stretching, strengthening, and endurance programs. For Achilles tendinopathy, eccentric and concentric exercise are described, both of which are used to load the soleus and gastrocnemius muscles. Concentric exercise involves muscle contraction. Eccentric exercise allows muscle lengthening (stretching). It is possible that eccentric exercises result in increased oscillations in tendon force [32], reduction of tendon microcirculation [157], and promotion of tendon remodeling, including increased collagen fiber cross-linkage [126].

ECCENTRIC EXERCISES FOR CHRONIC ACHILLES TENDINOPATHY

Recommended

Eccentric exercises are moderately recommended for the treatment of chronic Achilles tendinopathy.

Strength of evidence Moderately Recommended, Evidence (B)
Level of confidence Moderate

Indications

Mild, moderate, or severe chronic Achilles tendinosis (Mafi et al., 2001, Silbernagel et al., 2001, Rompe et al., 2007).

Frequency/Dose/Duration

One or 2 sets of exercises per day until symptom resolution and generally 1 or 2 appointments for exercise instruction (an additional 1 or 2 appointments for reinforcement is often needed in more chronic cases). Data suggest more intense exercise regimens result in superior outcomes (Silbernagel et al., 2001).

Indications for discontinuation

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Resolution, intolerance, adverse effects, or lack of benefits.

Rationale

Two moderate-quality studies compared more intense to less intense exercise (Silbernagel et al., 2001) or exercise to "active rest" (Silbernagel et al., 2007) for treatment of chronic Achilles tendinopathy. There was no difference between the effects of more intense and less intense exercise (Silbernagel et al., 2001). Eccentric exercises were found superior to concentric exercises (Mafi et al., 2001). (A low-quality study found eccentric exercises to have a better outcome over concentric exercises (Nielsen et al., 1990).) There is one high-quality study comparing eccentric exercise with non-intervention and with shockwave therapy (Rompe et al., 2007) that found exercise and shockwave therapy both superior to observation (Rompe et al., 2007). However, the equivalence of exercise to shock wave therapy was not reproducible (Rompe et al., 2008), challenging the reproducibility and integrity of the study findings. Additionally, in these studies, the uncertainty due to the instruments used to measure outcome (Robinson et al., 2001) was not addressed, with the differences in findings based primarily on statistics and without fully considering the variability introduced by the clinical measurement.

There are no quality studies of exercise for treatment of acute, subacute, or post-operative Achilles pain. There are many additional studies that included exercise as part of the treatment, but did not have adequate controls to demonstrate the effects of exercise. Studies comparing exercise to other interventions generally used eccentric exercises. Stretching exercises and graded activity does not appear to differ in effect (Silbernagel et al., 2007) suggesting that allowing patients to engaging in activities according to their comfort level does not worsen outcome.

Exercise is non-invasive, has few adverse effects, may benefit the individual's overall health compared to inactivity, and is not costly when self-administered. Exercise may be taught quickly by clinicians or therapists and is moderately recommended. For acute pain, there is a lack of evidence for effectiveness, but it is reasonable to infer that this intervention may be beneficial. Post-operative patients may benefit from a few additional supervised visits to help guide exercise and activity levels.

STRETCHING EXERCISES FOR ACUTE, SUBACUTE, OR POSTOPERATIVE ACHILLES TENDINOPATHY

Recommended

Stretching and loading exercises, particularly eccentric exercises, are recommended for the treatment of acute, subacute, or post-operative Achilles tendinopathy.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence Low

Indications

Mild, moderate, or severe acute, subacute and post-operative Achilles tendinosis.

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Frequency/Dose/Duration

One or 2 sets of exercises per day until symptom resolution and generally 1 or 2 appointments for exercise instruction (an additional 1 or 2 appointments for reinforcement is often needed in more chronic cases). Data suggest more intense exercise regimens result in superior outcomes (Silbernagel et al., 2001). Post-operative patients may require additional instruction during the recovery period.

Indications for discontinuation

Resolution, intolerance, adverse effects, or lack of benefits.

Rationale

Two moderate-quality studies compared more intense to less intense exercise (Silbernagel et al., 2001) or exercise to "active rest" (Silbernagel et al., 2007) for treatment of chronic Achilles tendinopathy. There was no difference between the effects of more intense and less intense exercise (Silbernagel et al., 2001). Eccentric exercises were found superior to concentric exercises (Mafi et al., 2001). (A low-quality study found eccentric exercises to have a better outcome over concentric exercises (Nielsen et al., 1990).) There is one high-quality study comparing eccentric exercise with non-intervention and with shockwave therapy (Rompe et al., 2007) that found exercise and shockwave therapy both superior to observation (Rompe et al., 2007). However, the equivalence of exercise to shock wave therapy was not reproducible (Rompe et al., 2008), challenging the reproducibility and integrity of the study findings. Additionally, in these studies, the uncertainty due to the instruments used to measure outcome (Robinson et al., 2001) was not addressed, with the differences in findings based primarily on statistics and without fully considering the variability introduced by the clinical measurement.

There are no quality studies of exercise for treatment of acute, subacute, or post-operative Achilles pain. There are many additional studies that included exercise as part of the treatment, but did not have adequate controls to demonstrate the effects of exercise. Studies comparing exercise to other interventions generally used eccentric exercises. Stretching exercises and graded activity does not appear to differ in effect (Silbernagel et al., 2007) suggesting that allowing patients to engaging in activities according to their comfort level does not worsen outcome.

Exercise is non-invasive, has few adverse effects, may benefit the individual's overall health compared to inactivity, and is not costly when self-administered. Exercise may be taught quickly by clinicians or therapists and is moderately recommended. For acute pain, there is a lack of evidence for effectiveness, but it is reasonable to infer that this intervention may be beneficial. Post-operative patients may benefit from a few additional supervised visits to help guide exercise and activity levels.

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MEDICATIONS

NSAIDS AND ACETAMINOPHEN

The use of oral NSAIDs and acetaminophen are well-described interventions for numerous soft-tissue and musculoskeletal injuries including ankle sprains [158]. The mechanism of action is unclear for musculoskeletal disorders that do not have significant components of inflammation, although some believe the mechanism nevertheless involves addressing some component of inflammation [159].

NSAIDS FOR ACUTE ACHILLES TENDINOPATHY

Recommended

NSAIDs are recommended for the treatment of acute, subacute, or chronic Achilles tendinopathy pain or post-operative pain or inflammation.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence High

Indications

Pain or inflammation associated with acute, subacute, or chronic Achilles tendinopathy, or post-operatively.

Frequency/Dose/Duration

Frequency and dose per manufacturer's recommendations; may be taken scheduled or as needed. As not all NSAIDs have been shown effective for treatment of Achilles tendinopathy, if one NSAID is not effective within 10 days, consider another of a different sub-class (i.e. salicylates, indoleacetates, propionates, phenylacetates, enolates, naphthylalkanones) in its place.

Indications for discontinuation

Resolution, intolerance, adverse effects, lack of benefits, or failure to progress over a trial of 2 weeks.

Rationale

Acetaminophen is an analgesic and has no therapeutic effect. There is no quality evidence for or against the use of acetaminophen for the treatment of pain from acute and subacute Achilles tendinopathy. There is one low-quality study comparing the effect of paracetamol with ibuprofen for acute sports injuries, which showed ibuprofen to be superior, although the study had several methodological problems (Bourne, 1980). However, there is quality evidence that acetaminophen is superior to placebo for treatment of other musculoskeletal disorders, including low back pain, and has a very low adverse-effect profile. However, patients using acetaminophen should be screened for the absence of liver disease and liver-disease risk factors, advised about dosing, and warned of potential hepatotoxicity (see

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Chronic Pain guideline for acetaminophen use). Oral acetaminophen is recommended for short-term as it is not invasive, has a lack of adverse effects when used as directed, and is low cost. There is one moderate-quality placebo-controlled study that showed improvement of pain and functional scores (Jakobsen et al., 1989, Jakobsen et al., 1988). This study considered multiple acute (less than 48-hours duration) soft-tissue disorders in young (mean age 20.5 years, range 19 to 25 years) military personnel. Of the 212 subjects, 71 had Achilles tendinosis that was treated with piroxicam, tenoxicam, or placebo. The study duration was 10 days. The tenoxicam group, but not the piroxicam group, experienced significantly better improvement than the placebo group. As the results for six disorders, including Achilles tendinopathy, were pooled in one analysis (Jakobsen et al., 1988), only the analysis of the Achilles tendinopathy sub-population (Jakobsen et al., 1989) applies to this section. There is one low-quality study comparing the effect of paracetamol with ibuprofen for acute sports injuries, which showed ibuprofen to be superior, although the study had several methodological problems (Bourne, 1980). A moderate-quality study of subacute and chronic Achilles tendinosis comparing piroxicam to placebo with both groups assigned stretching and strengthening exercises was negative (Astrom et al., 1992). In an additional study comparing indomethacin with injection of glycosaminoglycan (Sundqvist et al., 1987), the latter group fared significantly better than the former (NSAID) group; however, the study is not helpful for identification of efficacy of NSAIDs as there was no placebo control. There are no quality studies in post-operative patients; however, NSAIDs have been shown to be highly effective for several other post-operative conditions and thus are recommended (see Low Back Disorders; Hand, Wrist, and Forearm Disorders; and Hip and Groin Disorders guidelines). NSAIDs are not invasive, have low adverse effects particularly in employed populations, and are low cost, thus they are recommended. If NSAIDs are used to treat clinically evident or presumed inflammation, they should be administered on a scheduled basis. If NSAIDs are used for analgesia, they should be taken as needed.

Evidence

There are 4 moderate-quality RCTs incorporated in this analysis. There is 1 low-quality RCT in Appendix 1.

NSAIDS FOR SUBACUTE OR CHRONIC ACHILLES TENDINOPATHY OR POSTOPERATIVE PAIN

Recommended

NSAIDs are recommended for the treatment of acute, subacute, or chronic Achilles tendinopathy pain or post-operative pain or inflammation.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence High

Indications

Pain or inflammation associated with acute, subacute, or chronic Achilles tendinopathy, or post-operatively.

Frequency/Dose/Duration

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Frequency and dose per manufacturer's recommendations; may be taken scheduled or as needed. As not all NSAIDs have been shown effective for treatment of Achilles tendinopathy, if one NSAID is not effective within 10 days, consider another of a different sub-class (i.e. salicylates, indoleacetates, propionates, phenylacetates, enolates, naphthylalkanones) in its place.

Indications for discontinuation

Resolution, intolerance, adverse effects, lack of benefits, or failure to progress over a trial of 2 weeks.

Rationale

Acetaminophen is an analgesic and has no therapeutic effect. There is no quality evidence for or against the use of acetaminophen for the treatment of pain from acute and subacute Achilles tendinopathy. There is one low-quality study comparing the effect of paracetamol with ibuprofen for acute sports injuries, which showed ibuprofen to be superior, although the study had several methodological problems (Bourne, 1980). However, there is quality evidence that acetaminophen is superior to placebo for treatment of other musculoskeletal disorders, including low back pain, and has a very low adverse-effect profile. However, patients using acetaminophen should be screened for the absence of liver disease and liver-disease risk factors, advised about dosing, and warned of potential hepatotoxicity (see Chronic Pain guideline for acetaminophen use). Oral acetaminophen is recommended for short-term as it is not invasive, has a lack of adverse effects when used as directed, and is low cost. There is one moderate-quality placebo-controlled study that showed improvement of pain and functional scores (Jakobsen et al., 1989, Jakobsen et al., 1988). This study considered multiple acute (less than 48-hours duration) soft-tissue disorders in young (mean age 20.5 years, range 19 to 25 years) military personnel. Of the 212 subjects, 71 had Achilles tendinosis that was treated with piroxicam, tenoxicam, or placebo. The study duration was 10 days. The tenoxicam group, but not the piroxicam group, experienced significantly better improvement than the placebo group. As the results for six disorders, including Achilles tendinopathy, were pooled in one analysis (Jakobsen et al., 1988), only the analysis of the Achilles tendinopathy sub-population (Jakobsen et al., 1989) applies to this section. There is one low-quality study comparing the effect of paracetamol with ibuprofen for acute sports injuries, which showed ibuprofen to be superior, although the study had several methodological problems (Bourne, 1980). A moderate-quality study of subacute and chronic Achilles tendinosis comparing piroxicam to placebo with both groups assigned stretching and strengthening exercises was negative (Astrom et al., 1992). In an additional study comparing indomethacin with injection of glycosaminoglycan (Sundqvist et al., 1987), the latter group fared significantly better than the former (NSAID) group; however, the study is not helpful for identification of efficacy of NSAIDs as there was no placebo control. There are no quality studies in post-operative patients; however, NSAIDs have been shown to be highly effective for several other post-operative conditions and thus are recommended (see Low Back Disorders; Hand, Wrist, and Forearm Disorders; and Hip and Groin Disorders guidelines). NSAIDs are not invasive, have low adverse effects particularly in employed populations, and are low cost, thus they are recommended. If NSAIDs are used to treat

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clinically evident or presumed inflammation, they should be administered on a scheduled basis. If NSAIDs are used for analgesia, they should be taken as needed.

Evidence

There are 4 moderate-quality RCTs incorporated in this analysis. There is 1 low-quality RCT in Appendix 1.

ACETAMINOPHEN FOR ACUTE, SUBACUTE, OR CHRONIC ACHILLES TENDINOPATHY PAIN

Recommended

Acetaminophen is recommended for treatment of pain from acute, subacute, or chronic Achilles tendinopathy.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence Moderate

Indications

Pain associated with acute, subacute, or chronic Achilles tendinopathy.

Frequency/Dose/Duration

Frequency/dose per manufacturer's recommendations; may be taken as scheduled or as needed (FDA recommended daily doses is less than 4gm a day).

Indications for discontinuation

Resolution, intolerance, adverse effects, lack of benefits, or failure to progress over a trial of 2 weeks.

Rationale

Acetaminophen is an analgesic and has no therapeutic effect. There is no quality evidence for or against the use of acetaminophen for the treatment of pain from acute and subacute Achilles tendinopathy. There is one low-quality study comparing the effect of paracetamol with ibuprofen for acute sports injuries, which showed ibuprofen to be superior, although the study had several methodological problems (Bourne, 1980). However, there is quality evidence that acetaminophen is superior to placebo for treatment of other musculoskeletal disorders, including low back pain, and has a very low adverse-effect profile. However, patients using acetaminophen should be screened for the absence of liver disease and liver-disease risk factors, advised about dosing, and warned of potential hepatotoxicity (see Chronic Pain guideline for acetaminophen use). Oral acetaminophen is recommended for short-term as it is not invasive, has a lack of adverse effects when used as directed, and is low cost. There is one moderate-quality placebo-controlled study that showed improvement of pain and functional scores (Jakobsen et al., 1989, Jakobsen et al., 1988). This study considered multiple acute (less than 48-hours duration) soft-tissue disorders in young (mean

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age 20.5 years, range 19 to 25 years) military personnel. Of the 212 subjects, 71 had Achilles tendinosis that was treated with piroxicam, tenoxicam, or placebo. The study duration was 10 days. The tenoxicam group, but not the piroxicam group, experienced significantly better improvement than the placebo group. As the results for six disorders, including Achilles tendinopathy, were pooled in one analysis (Jakobsen et al., 1988), only the analysis of the Achilles tendinopathy sub-population (Jakobsen et al., 1989) applies to this section. There is one low-quality study comparing the effect of paracetamol with ibuprofen for acute sports injuries, which showed ibuprofen to be superior, although the study had several methodological problems (Bourne, 1980). A moderate-quality study of subacute and chronic Achilles tendinosis comparing piroxicam to placebo with both groups assigned stretching and strengthening exercises was negative (Astrom et al., 1992). In an additional study comparing indomethacin with injection of glycosaminoglycan (Sundqvist et al., 1987), the latter group fared significantly better than the former (NSAID) group; however, the study is not helpful for identification of efficacy of NSAIDs as there was no placebo control. There are no quality studies in post-operative patients; however, NSAIDs have been shown to be highly effective for several other post-operative conditions and thus are recommended (see Low Back Disorders; Hand, Wrist, and Forearm Disorders; and Hip and Groin Disorders guidelines). NSAIDs are not invasive, have low adverse effects particularly in employed populations, and are low cost, thus they are recommended. If NSAIDs are used to treat clinically evident or presumed inflammation, they should be administered on a scheduled basis. If NSAIDs are used for analgesia, they should be taken as needed.

Evidence

There are 4 moderate-quality RCTs incorporated in this analysis. There is 1 low-quality RCT in Appendix 1.

GLUCOCORTICOSTEROIDS

Oral or intramuscular (IM) glucocorticosteroids are often administered for musculoskeletal complaints with anti-inflammatory mechanism(s) as a rational for efficacy. There is limited efficacy for treatment of radiculopathy, but not low back pain (see Low Back Disorders guideline). However, the use of these medications for Achilles tendinopathy is not cited in quality studies. Injections are reviewed below.

SYSTEMIC CORTICOSTEROIDS FOR TREATMENT OF ACUTE, SUBACUTE, CHRONIC, OR POSTOPERATIVE ACHILLES TENDINOPATHY

Not Recommended

Oral or intramuscular steroid preparations are not recommended for the treatment of acute, subacute, chronic, or post-operative Achilles tendinopathy.

Strength of evidence Not Recommended, Insufficient Evidence (I)
Level of confidence Moderate

Rationale

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There is no quality evidence for use of corticosteroids for treatment of Achilles tendinopathy. As evidence is lacking and evidence of efficacy is present for several other treatments, oral or intramuscular steroid preparations are not recommended pending publication of quality studies.

OPIOIDS

Opioids are frequently used for musculoskeletal conditions; however, these are generally spine-related disorders. Use for treatment of Achilles tendinopathy has not been well described. Opioids are widely used post-operatively.

OPIOIDS FOR TREATMENT OF ACUTE, SUBACUTE, OR CHRONIC ACHILLES TENDINOPATHY PAIN

Not Recommended

Opioids are not recommended for treatment of acute, subacute, or chronic Achilles tendinopathy pain.

Strength of evidence Not Recommended, Insufficient Evidence (I)
Level of confidence High

Rationale

There is no quality evidence supporting the use of opioids for treating acute or chronic Achilles tendon pain. The vast majority of patients with Achilles tendinopathy do not have pain sufficient to require opioids. Patients with such degrees of pain should generally have investigations performed for alternative diagnoses. Opioids are not invasive, but have very high dropout rates and otherwise high rates of adverse effects. They are moderate to high cost depending on treatment duration (see Chronic Pain guideline) and are not recommended for routine use. Quality evidence for treating post-operative patients with opioids is absent. Some patients have insufficient pain relief with NSAIDs, thus judicious use of opioids may be helpful, particularly for nocturnal use. Opioids are recommended for brief use in select post-operative patients primarily at night to achieve sleep.

OPIOIDS FOR TREATMENT OF PAIN FOR POSTOPERATIVE ACHILLES TENDINOPATHY

Recommended

Opioids are recommended for short-term use to treat pain after Achilles tendon surgery.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence High

Indications

Post-operative pain management.

Frequency/Dose/Duration

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Frequency/dose per manufacturer's recommendations; total treatment length usually ranges from a few days to up to 2 weeks.

Indications for discontinuation

Sufficient pain management with other methods such as NSAIDs, resolution of pain, intolerance, adverse effects, lack of benefits, or failure to progress over a couple weeks.

Rationale

There is no quality evidence supporting the use of opioids for treating acute or chronic Achilles tendon pain. The vast majority of patients with Achilles tendinopathy do not have pain sufficient to require opioids. Patients with such degrees of pain should generally have investigations performed for alternative diagnoses. Opioids are not invasive, but have very high dropout rates and otherwise high rates of adverse effects. They are moderate to high cost depending on treatment duration (see Chronic Pain guideline) and are not recommended for routine use. Quality evidence for treating post-operative patients with opioids is absent. Some patients have insufficient pain relief with NSAIDs, thus judicious use of opioids may be helpful, particularly for nocturnal use. Opioids are recommended for brief use in select post-operative patients primarily at night to achieve sleep.

VITAMINS

The use of vitamins including B6, C, and E has been described for musculoskeletal conditions as an antioxidant or is hypothesized as a promoter of tendon healing processes.

VITAMIN THERAPY FOR TREATMENT OF ACHILLES TENDINOPATHY

No Recommendation

There is no recommendation for or against the use of vitamins as a therapeutic intervention or for prevention of Achilles tendinopathy in doses recommended by the U.S. FDA.

Strength of evidence No Recommendation, Insufficient Evidence (I)
Level of confidence Moderate

Rationale

There are no quality studies evaluating the use of vitamins to treat or prevent Achilles tendinopathy. If purchased in standard doses as a standard stock item at food and drug stores, vitamins are usually inexpensive. If taken in doses that do not substantially exceed U.S. FDA recommendations, vitamins are safe. However, custom vitamin mixtures or compounds and high doses of vitamins may be harmful and expensive.

HIGH-DOSE VITAMIN THERAPY FOR TREATMENT OF ACHILLES TENDINOPATHY

Not Recommended

The use of high doses (exceeding U.S. FDA recommendations) or expensive compounded preparation vitamins is not recommended for prevention of Achilles tendinopathy.

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Strength of evidence Not Recommended, Insufficient Evidence (I)
Level of confidence Moderate

Rationale

There are no quality studies evaluating the use of vitamins to treat or prevent Achilles tendinopathy. If purchased in standard doses as a standard stock item at food and drug stores, vitamins are usually inexpensive. If taken in doses that do not substantially exceed U.S. FDA recommendations, vitamins are safe. However, custom vitamin mixtures or compounds and high doses of vitamins may be harmful and expensive.

TOPICAL MEDICATIONS

TOPICAL NSAIDS FOR ACUTE OR SUBACUTE ACHILLES TENDINOPATHY

Recommended

Topical NSAIDs are recommended for treatment of acute or subacute Achilles tendinosis. Topical NSAIDs are meant to deliver medication locally and superficially in musculoskeletal disorders, including Achilles tendinopathy, to reduce pain, swelling, improve range of motion, and return the patient to full functional capacity as early as possible (Russell, 1991, Mason et al., 2004).

Strength of evidence Recommended, Evidence (C)
Level of confidence High

Indications

Mild, moderate, or severe Achilles tendinopathy. Only niflumic acid as a topical NSAID treatment for Achilles tendon disorders has been studied (Auclair et al., 1989); thus, there is no evidence of comparative superiority of any other topical NSAID.

Frequency/Dose/Duration

Frequency per manufacturer's recommendation. Niflumic acid was used for 1 week (Auclair et al., 1989) and piroxicam for 1 to 3 weeks (study of mixed acute disorders, 3% were Achilles tendonitis) (Russell, 1991).

Indications for discontinuation

Resolution, intolerance, adverse effects, or lack of benefits.

Rationale

There is one moderate-quality placebo-controlled trial that found efficacy of treatment with topical niflumic acid for Achilles tendon disorders (Auclair et al., 1989) that also demonstrated earlier functional return. The second placebo-controlled trial that used piroxicam to treat Achilles tendonitis also suggested efficacy; however, it included a small

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minority of Achilles tendinitis (3%), and a majority of other disorders – 51, 42, and 4%, respectively labeled as supraspinatus tendonitis, and ankle and acromioclavicular joint sprains (Russell, 1991). Additional support for the general effectiveness of topical NSAIDs in treating musculoskeletal disorders is derived from a systematic review of RCTs for multiple conditions without regard to type of disorder or anatomic location (Mason et al., 2004). However, this review contains no direct support for the use of topical NSAIDs in Achilles tendinopathy. Topical NSAIDs are not invasive, have low adverse effect rates, but may be moderate to high cost. They are recommended for treatment of acute or subacute Achilles tendinopathy. There is no evidence of efficacy in patient with chronic Achilles tendinosis. Post-operative patients may be reasonable candidates after the incision is well healed.

Evidence

There are 2 moderate-quality RCTs incorporated in this analysis.

TOPICAL NSAIDS FOR CHRONIC ACHILLES TENDINOPATHY

Recommended

Topical NSAIDs are recommended for treatment of chronic Achilles tendinosis. Topical NSAIDs are meant to deliver medication locally and superficially in musculoskeletal disorders, including Achilles tendinopathy, to reduce pain, swelling, improve range of motion, and return the patient to full functional capacity as early as possible (Russell, 1991, Mason et al., 2004).

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence High

Indications

Mild, moderate, or severe Achilles tendinopathy. Only niflumic acid as a topical NSAID treatment for Achilles tendon disorders has been studied (Auclair et al., 1989); thus, there is no evidence of comparative superiority of any other topical NSAID.

Frequency/Dose/Duration

Frequency per manufacturer's recommendation. Niflumic acid was used for 1 week (Auclair et al., 1989) and piroxicam for 1 to 3 weeks (study of mixed acute disorders, 3% were Achilles tendonitis) (Russell, 1991).

Indications for discontinuation

Resolution, intolerance, adverse effects, or lack of benefits.

Rationale

There is one moderate-quality placebo-controlled trial that found efficacy of treatment with topical niflumic acid for Achilles tendon disorders (Auclair et al., 1989) that also

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demonstrated earlier functional return. The second placebo-controlled trial that used piroxicam to treat Achilles tendonitis also suggested efficacy; however, it included a small minority of Achilles tendinitis (3%), and a majority of other disorders – 51, 42, and 4%, respectively labeled as supraspinatus tendonitis, and ankle and acromioclavicular joint sprains (Russell, 1991). Additional support for the general effectiveness of topical NSAIDs in treating musculoskeletal disorders is derived from a systematic review of RCTs for multiple conditions without regard to type of disorder or anatomic location (Mason et al., 2004). However, this review contains no direct support for the use of topical NSAIDs in Achilles tendinopathy. Topical NSAIDs are not invasive, have low adverse effect rates, but may be moderate to high cost. They are recommended for treatment of acute or subacute Achilles tendinopathy. There is no evidence of efficacy in patient with chronic Achilles tendinosis. Post-operative patients may be reasonable candidates after the incision is well healed.

Evidence

There are 2 moderate-quality RCTs incorporated in this analysis.

TOPICAL NSAIDS FOR POSTOPERATIVE ACHILLES TENDINOPATHY

No Recommendation

There is no recommendation for or against the use of topical NSAIDs for treatment of post-operative Achilles tendinosis.

Strength of evidence No Recommendation, Insufficient Evidence (I)
Level of confidence Low

Rationale

There is one moderate-quality placebo-controlled trial that found efficacy of treatment with topical niflumic acid for Achilles tendon disorders (Auclair et al., 1989) that also demonstrated earlier functional return. The second placebo-controlled trial that used piroxicam to treat Achilles tendonitis also suggested efficacy; however, it included a small minority of Achilles tendinitis (3%), and a majority of other disorders – 51, 42, and 4%, respectively labeled as supraspinatus tendonitis, and ankle and acromioclavicular joint sprains (Russell, 1991). Additional support for the general effectiveness of topical NSAIDs in treating musculoskeletal disorders is derived from a systematic review of RCTs for multiple conditions without regard to type of disorder or anatomic location (Mason et al., 2004). However, this review contains no direct support for the use of topical NSAIDs in Achilles tendinopathy. Topical NSAIDs are not invasive, have low adverse effect rates, but may be moderate to high cost. They are recommended for treatment of acute or subacute Achilles tendinopathy. There is no evidence of efficacy in patient with chronic Achilles tendinosis. Post-operative patients may be reasonable candidates after the incision is well healed.

Evidence

There are 2 moderate-quality RCTs incorporated in this analysis.

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LIDOCAINE PATCHES FOR ACUTE, SUBACUTE, CHRONIC, OR POSTOPERATIVE ACHILLES TENDINOPATHY

No Recommendation

There is no recommendation for or against the use of lidocaine patches for the treatment of acute, subacute, chronic, or post-operative Achilles tendinopathy.

Strength of evidence No Recommendation, Insufficient Evidence (I)
Level of confidence Low

Rationale

There are no quality studies of lidocaine patch use for treatment of Achilles tendinopathy. As the goal of most therapy for Achilles disorders is pain relief, this may represent a potential treatment on a short-term basis while other concomitant interventions, such as eccentric exercises, are being performed. However, there is insufficient evidence to make a recommendation for or against this treatment.

GLYCERYL TRINITRATE FOR TREATMENT OF CHRONIC ACHILLES TENDINOPATHY PAIN

Recommended

Topical glyceryl trinitrate is recommended for treatment of pain in select patients with moderate or severe chronic Achilles tendinopathy after other conservative treatment alternatives have failed (such as NSAIDs, exercises, and potentially injections). Topical application of glyceryl trinitrate has been used to stimulate collagen synthesis (Paoloni et al., 2004).

Strength of evidence Recommended, Evidence (C)
Level of confidence Low

Indications

Moderate or severe chronic Achilles tendinosis. Treatment with other interventions such as NSAIDs, exercises, and potentially injection(s) should have been attempted previously.

Frequency/Dose/Duration

Apply 1/4 of a 5mg/24-hour patch over site of maximal tenderness (2 to 6cm proximal to Achilles tendon insertion); replace patch every 24 hours for up to 6 months (Paoloni et al., 2004).

Indications for discontinuation

Resolution, intolerance, adverse effects, or lack of benefits.

Rationale

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There is one moderate-quality placebo-controlled RCT (Paoloni et al., 2004) with a 3-year follow-up report (Paoloni et al., 2007) for the continuous use of glyceryl trinitrate (GTN) patch over 24 weeks for chronic non-insertional Achilles tendon pain. This trial included common, conservative co-interventions. The authors found improvement in clinical condition of the GTN compared to the non-GTN group by most of their outcome measures, with differences statistically significant by 6 or 12 weeks (Paoloni et al., 2004). The numbers needed to treat by 6 or 12 weeks were in the neighborhood of 2 or 3, and by 24 weeks, numbers needed to treat were <2. The trial suggested less night and loading pain at 12 and 24 weeks, with sustained effects at 3-years in the intervention group. GTN is non-invasive, has few reported adverse effects compared to placebo, but is likely moderate to high cost over a 6-month course. There are no trials evaluating over-the-counter GTN topical ointments. Based on the limited evidence, this treatment appears hopeful, but currently there is insufficient quality evidence for a graded recommendation (A, B, C) in most Achilles' tendinosis patients. Therefore, it is recommended after treatments with demonstrated efficacy have proven ineffective or insufficient.

Evidence

There is 1 moderate-quality RCT with a second report of an extended evaluation period incorporated into this analysis.

GLYCERYL TRINITRATE FOR ACUTE, SUBACUTE, OR POSTOPERATIVE ACHILLES TENDINOPATHY

No Recommendation

There is no recommendation for or against the use of topical glyceryl trinitrate for treatment of acute, subacute, or post-operative Achilles tendinopathy.

Strength of evidence No Recommendation, Insufficient Evidence (I)
Level of confidence Low

Rationale

There is one moderate-quality placebo-controlled RCT (Paoloni et al., 2004) with a 3-year follow-up report (Paoloni et al., 2007) for the continuous use of glyceryl trinitrate (GTN) patch over 24 weeks for chronic non-insertional Achilles tendon pain. This trial included common, conservative co-interventions. The authors found improvement in clinical condition of the GTN compared to the non-GTN group by most of their outcome measures, with differences statistically significant by 6 or 12 weeks (Paoloni et al., 2004). The numbers needed to treat by 6 or 12 weeks were in the neighborhood of 2 or 3, and by 24 weeks, numbers needed to treat were <2. The trial suggested less night and loading pain at 12 and 24 weeks, with sustained effects at 3-years in the intervention group. GTN is non-invasive, has few reported adverse effects compared to placebo, but is likely moderate to high cost over a 6-month course. There are no trials evaluating over-the-counter GTN topical ointments. Based on the limited evidence, this treatment appears hopeful, but currently there is insufficient quality evidence for a graded recommendation (A, B, C) in most Achilles'

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tendinosis patients. Therefore, it is recommended after treatments with demonstrated efficacy have proven ineffective or insufficient.

ALLIED HEALTH INTERVENTIONS

EXTRACORPOREAL SHOCKWAVE THERAPY

EXTRACORPOREAL SHOCKWAVE THERAPY FOR CHRONIC MID-PORTION ACHILLES TENDINOPATHY

Recommended

Extracorporeal shockwave therapy is recommended as an adjunct to eccentric exercise for moderate to severe chronic, recalcitrant Achilles tendinopathy. Patients should have failed NSAIDs, eccentric exercises, physical or occupational therapy, and local injection(s) (Rompe et al., 2008, Rompe et al., 2009). Three to 4 weekly sessions are indicated over 3 to 4 consecutive weeks.

Strength of evidence Recommended, Evidence (C)
Level of confidence Low

Indications

Moderate to severe, recalcitrant Achilles tendinopathy. Patients should have failed NSAIDs, eccentric exercises, therapy, and local injection(s) (Rompe et al., 2008, Rompe et al., 2009).

Frequency/Dose/Duration

Three to 4 weekly sessions over 3 to 4 consecutive weeks, using 2,000 shocks at 0.1 to 0.2 J/mm2 administered in conjunction with an eccentric exercise program (Rompe et al., 2009, Rompe et al., 2008, Rompe, 2007, Rasmussen et al., 2008).

Indications for discontinuation

Completion of course, resolution of symptoms, adverse effects, intolerance, non-compliance.

Rationale

Evidence of efficacy for ESWT in treatment of patients with chronic Achilles tendinopathy is conflicting. There are two high-quality RCTs comparing ESWT with sham ESWT (Rasmussen et al., 2008, Costa et al., 2005) and one high-quality study comparing ESWT with a non-treated control group (Rompe, 2007). Adequacy of blinding of ESWT is unclear (Rasmussen et al., 2008, Costa et al., 2005). One sham-controlled trial failed to demonstrate efficacy (Costa et al., 2005) while another showed statistically significant functional improvement, but questionable clinical improvement (Rasmussen et al., 2008), raising questions of treatment effectiveness. The dosing and treatment intervals were different between the trial that failed to demonstrate efficacy (Costa et al., 2005) and those that did, which may have accounted for the variable effects. The trial with a non-treatment control group

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suggested ESWT was superior to non-treatment (Rompe, 2007); however, the level of benefit was modest and there was no superiority of the ESWT to eccentric exercises.

Two trials evaluated patients with chronic Achilles tendon disorders who failed other treatment (Rompe et al., 2009, Rompe et al., 2008). The first study compared ESWT and eccentric exercises and found statistically significant differences between the groups, with EWST patient outcomes superior (Rompe et al., 2008). The second study found a combination of eccentric exercises plus ESWT superior to exercises alone considering statistically significant differences alone (Rompe et al., 2009). However, although the groups receiving and not receiving ESWT had statistical differences, the clinical significance of the findings is uncertain because they were within the limits of reproducibility of one of the primary measurement instruments (Robinson et al., 2001). The investigators in these trials administered ESWT with timing and number of shocks similar to the authors of the successful sham ESWT study (Rasmussen et al., 2008).

The effectiveness of ESWT is unclear as the studies that showed differences between ESWT and non-ESWT groups were modest and may have reflected statistically rather than clinically significant differences. ESWT has not conclusively shown itself to be invasive in the literature cited in this section when administered as specified by the investigators (Rompe et al., 2009, Rompe et al., 2008, Rompe, 2007, Rasmussen et al., 2008). Tendon rupture was reported in one study (Costa et al., 2005); however, the circumstances of the ruptures cast doubt on whether ESWT was a contributing factor. There are no quality studies for treatment of acute, subacute, and post-operative Achilles tendinopathy patients, and given other treatment options, ESWT is not recommended for acute, subacute, or post-operative Achilles tendinopathy.

Evidence

There are 5 high-quality RCTs incorporated into this analysis.

EXTRACORPOREAL SHOCKWAVE THERAPY FOR ACUTE, SUBACUTE, OR POSTOPERATIVE ACHILLES TENDINOPATHY

Not Recommended

Extracorporeal shockwave therapy is not recommended for treatment of acute, subacute, or post-operative Achilles tendinopathy.

Strength of evidence Not Recommended, Insufficient Evidence (I)
Level of confidence Moderate

Indications

Moderate to severe recalcitrant Achilles tendinopathy. Patients should have failed NSAIDs, eccentric exercises, therapy, and local injection(s) (Rompe et al., 2008, Rompe et al., 2009).

Frequency/Dose/Duration

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Three to 4 weekly sessions over 3 to 4 consecutive weeks, using 2,000 shocks at 0.1 to 0.2 J/mm2 administered in conjunction with an eccentric exercise program.

Indications for discontinuation

Completion of course, resolution of symptoms, adverse effects, intolerance, non-compliance.

Rationale

Evidence of efficacy for ESWT in treatment of patients with chronic Achilles tendinopathy is conflicting. There are two high-quality RCTs comparing ESWT with sham ESWT (Rasmussen et al., 2008, Costa et al., 2005) and one high-quality study comparing ESWT with a non-treated control group (Rompe, 2007). Adequacy of blinding of ESWT is unclear (Rasmussen et al., 2008, Costa et al., 2005). One sham-controlled trial failed to demonstrate efficacy (Costa et al., 2005) while another showed statistically significant functional improvement, but questionable clinical improvement (Rasmussen et al., 2008), raising questions of treatment effectiveness. The dosing and treatment intervals were different between the trial that failed to demonstrate efficacy (Costa et al., 2005) and those that did, which may have accounted for the variable effects. The trial with a non-treatment control group suggested ESWT was superior to non-treatment (Rompe, 2007); however, the level of benefit was modest and there was no superiority of the ESWT to eccentric exercises.

Two trials evaluated patients with chronic Achilles tendon disorders who failed other treatment (Rompe et al., 2009, Rompe et al., 2008). The first study compared ESWT and eccentric exercises and found statistically significant differences between the groups, with EWST patient outcomes superior (Rompe et al., 2008). The second study found a combination of eccentric exercises plus ESWT superior to exercises alone considering statistically significant differences alone (Rompe et al., 2009). However, although the groups receiving and not receiving ESWT had statistical differences, the clinical significance of the findings is uncertain because they were within the limits of reproducibility of one of the primary measurement instruments (Robinson et al., 2001). The investigators in these trials administered ESWT with timing and number of shocks similar to the authors of the successful sham ESWT study (Rasmussen et al., 2008).

The effectiveness of ESWT is unclear as the studies that showed differences between ESWT and non-ESWT groups were modest and may have reflected statistically rather than clinically significant differences. ESWT has not conclusively shown itself to be invasive in the literature cited in this section when administered as specified by the investigators (Rompe et al., 2009, Rompe et al., 2008, Rompe, 2007, Rasmussen et al., 2008). Tendon rupture was reported in one study (Costa et al., 2005); however, the circumstances of the ruptures cast doubt on whether ESWT was a contributing factor. There are no quality studies for treatment of acute, subacute, and post-operative Achilles tendinopathy patients, and given other treatment options, ESWT is not recommended for acute, subacute, or post-operative Achilles tendinopathy.

Evidence

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There are 5 high-quality RCTs incorporated into this analysis.

ACUPUNCTURE

ACUPUNCTURE FOR ACUTE, SUBACUTE, CHRONIC, OR POSTOPERATIVE ACHILLES TENDINOPATHY

No Recommendation

There is no recommendation for or against the use of acupuncture for the treatment of acute, subacute, chronic, or post-operative Achilles tendinopathy.

Strength of evidence No Recommendation, Insufficient Evidence (I)
Level of confidence Low

Rationale

There is no quality evidence for or against the use of acupuncture for the treatment of Achilles tendinopathy. Acupuncture is minimally invasive, has minimal adverse effects, and depending on the number of treatments, may be moderately costly. There are other interventions with documented efficacy. Therefore, there is no recommendation for or against use of acupuncture for treatment of Achilles tendinopathy.

DRY NEEDLING FOR ACUTE, SUBACUTE, OR CHRONIC ACHILLES TENDINOPATHY

Not Recommended

Dry needling is not recommended for the treatment of acute, subacute, or chronic Achilles tendinopathy.

Strength of evidence Not Recommended, Insufficient Evidence (I)
Level of confidence Moderate

Rationale

There is no quality evidence for or against the use of dry needling techniques in treating Achilles tendon disorders. Dry needling is commonly used for the treatment of myofascial, back, neck, and other disorders (see Low Back Disorders, Chronic Pain, and Elbow Disorders guidelines), but is not well described for the treatment of Achilles tendinopathy. Dry needling is adequately invasive (where it should be avoided in treatment of Achilles tendinopathy) without evidence of efficacy, and is of moderate cost. As there are other effective interventions, dry needling is not recommended for treatment of Achilles tendinopathy.

MASSAGE

MASSAGE AND TENDON MOBILIZATION FOR ACUTE, SUBACUTE, CHRONIC, OR POSTOPERATIVE ACHILLES TENDINOPATHY

No Recommendation

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There is no recommendation for or against the use of massage or tendon mobilization for the treatment of acute, subacute, chronic or post-operative Achilles tendinopathy.

Strength of evidence No Recommendation, Insufficient Evidence (I)
Level of confidence Low

Rationale

There is no quality evidence for or against the use of massage or tendon mobilization to treat Achilles tendinopathy. It is possible for patients to self-administer these treatments, although there are no quality studies of self-administrations. Massage and tendon mobilization are not invasive, have minimal adverse effects, and depending on the number of treatments, are low to moderate cost. However, as there are other interventions with documented efficacy, there is no recommendation for or against use of these treatments for Achilles tendinopathy.

ULTRASOUND

THERAPEUTIC ULTRASOUND FOR ACUTE, SUBACUTE, CHRONIC, OR POSTOPERATIVE ACHILLES TENDINOPATHY

No Recommendation

There is no recommendation for or against the use of therapeutic ultrasound for the treatment of acute, subacute, chronic, or post-operative Achilles tendinopathy.

Strength of evidence No Recommendation, Insufficient Evidence (I)
Level of confidence Low

Rationale

Although cited as a potential treatment for Achilles tendinopathy, there is no quality evidence for or against the use of ultrasound. A recent small pilot study suggested support for continuing to investigate ultrasound as a potentially effective treatment, finding no difference between therapeutic ultrasound compared to eccentric exercises (Chester et al., 2008). Ultrasound is non-invasive, has low adverse effects, is moderate cost depending on the number of treatments, but there is no recommendation for its use pending publication of quality studies.

IONTOPHORESIS

IONTOPHORESIS WITH GLUCOCORTICOSTEROID FOR ACUTE, SUBACUTE, OR CHRONIC ACHILLES TENDINOPATHY

Recommended

Iontophoresis with glucocorticosteroid is recommended for the treatment of acute, subacute, or chronic Achilles tendinopathy. Four treatments over 2 weeks are indicated with dexamethasone (Neeter et al., 2003) or other glucocorticoid. Therapy should include a concurrent eccentric exercise program.

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Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence Moderate

Indications

Acute, subacute, or chronic Achilles tendinopathy.

Frequency/Dose/Duration

Four treatments over 2 weeks with dexamethasone (Neeter et al., 2003) or other glucocorticoid. Therapy should include a concurrent eccentric exercise program.

Indications for discontinuation

Resolution, adverse effects, intolerance, non-compliance.

Rationale

There is one moderate-quality, placebo-controlled RCT that compared iontophoresis using dexamethasone with saline for the treatment of acute and subacute Achilles tendinopathy (Neeter et al., 2003), which included the co-intervention of stretching and strengthening. Iontophoresis was applied twice a week for 2 weeks. Three performance and four pain outcomes were measured at baseline, 2 and 4 weeks, and 3 and 6 months. Of 24 measurement points after administration of treatment, only two showed statistically significant differences between the treatment and placebo groups. A short-treatment series of iontophoresis is non-invasive and has a low adverse-effect profile. Although evidence is minimal for efficacy in acute and subacute Achilles tendinopathy, iontophoresis with glucocorticosteroids is recommended for treatment of acute, subacute, or chronic Achilles tendinopathy, although it has not been specifically tested among those patients.

Evidence

There is 1 moderate-quality RCT incorporated into this analysis.

IONTOPHORESIS WITH GLUCOCORTICOSTEROID FOR POSTOPERATIVE ACHILLES TENDINOPATHY

No Recommendation

There is no recommendation for or against the use of iontophoresis with glucocorticosteroid for treatment of post-operative Achilles tendinopathy.

Strength of evidence No Recommendation, Insufficient Evidence (I)
Level of confidence Low

Rationale

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There is one moderate-quality, placebo-controlled RCT that compared iontophoresis using dexamethasone with saline for the treatment of acute and subacute Achilles tendinopathy (Neeter et al., 2003), which included the co-intervention of stretching and strengthening. Iontophoresis was applied twice a week for 2 weeks. Three performance and four pain outcomes were measured at baseline, 2 and 4 weeks, and 3 and 6 months. Of 24 measurement points after administration of treatment, only two showed statistically significant differences between the treatment and placebo groups. A short-treatment series of iontophoresis is non-invasive and has a low adverse-effect profile. Although evidence is minimal for efficacy in acute and subacute Achilles tendinopathy, iontophoresis with glucocorticosteroids is recommended for treatment of acute, subacute, or chronic Achilles tendinopathy, although it has not been specifically tested among those patients.

IONTOPHORESIS WITH NSAIDS FOR ACUTE, SUBACUTE, CHRONIC, OR POSTOPERATIVE ACHILLES TENDINOPATHY

No Recommendation

There is no recommendation for or against the use of iontophoresis with NSAIDs for treatment of acute, subacute, chronic, or post-operative Achilles tendinopathy.

Strength of evidence No Recommendation, Insufficient Evidence (I)
Level of confidence Low

Rationale

There is one moderate-quality, placebo-controlled RCT that compared iontophoresis using dexamethasone with saline for the treatment of acute and subacute Achilles tendinopathy (Neeter et al., 2003), which included the co-intervention of stretching and strengthening. Iontophoresis was applied twice a week for 2 weeks. Three performance and four pain outcomes were measured at baseline, 2 and 4 weeks, and 3 and 6 months. Of 24 measurement points after administration of treatment, only two showed statistically significant differences between the treatment and placebo groups. A short-treatment series of iontophoresis is non-invasive and has a low adverse-effect profile. Although evidence is minimal for efficacy in acute and subacute Achilles tendinopathy, iontophoresis with glucocorticosteroids is recommended for treatment of acute, subacute, or chronic Achilles tendinopathy, although it has not been specifically tested among those patients.

PHONOPHORESIS

PHONOPHORESIS FOR ACUTE, SUBACUTE, CHRONIC, OR POSTOPERATIVE ACHILLES TENDINOPATHY

No Recommendation

There is no recommendation for or against the use of phonophoresis for treatment of acute, subacute, chronic, or post-operative Achilles tendinopathy.

Strength of evidence No Recommendation, Insufficient Evidence (I)
Level of confidence Low

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Rationale

Phonophoresis is non-invasive, has few adverse effects, and is moderately expensive. However, there is no quality evidence evaluating phonophoresis for the treatment of patients with Achilles tendinopathy. Therefore, there is no recommendation for or against its use, pending publication of quality trials.

LOW-LEVEL LASER THERAPY

LOW-LEVEL LASER THERAPY FOR SELECT CHRONIC ACHILLES TENDINOPATHY

Sometimes Recommended

Low-level laser therapy is recommended for treatment of select patients with chronic Achilles tendinopathy. Patients should generally have failed NSAIDs, eccentric exercises, iontophoresis, and injection(s). Twelve sessions over 8 weeks are indicated. Therapy should include a concurrent eccentric exercise program.

Strength of evidence Recommended, Evidence (C)
Level of confidence Low

Indications

Chronic Achilles tendinopathy; patients should generally have failed NSAIDs, eccentric exercises, iontophoresis, and injection(s).

Frequency/Dose/Duration

Twelve sessions over 8 weeks (60mW/cm2, total dose 5.4J/session). Therapy should include a concurrent eccentric exercise program.

Indications for discontinuation

Resolution, adverse effects, intolerance, non-compliance.

Rationale

There is no quality trial evaluating LLLT versus sham treatment that did not include a co-intervention. There is one moderate-quality RCT evaluating treatment of patients with chronic Achilles tendinopathy that suggested benefits in pain intensity at 4, 8, and 12 weeks after an 8-week course of LLLT combined with eccentric exercises (Stergioulas et al., 2008). However, as the trial included eccentric exercises, it is unclear how much effect was attributable to LLLT and how much to exercises and whether adherence to exercise may have differed between the groups. LLLT is not invasive, has low adverse effects, but is high cost. LLLT is recommended for select patients who have failed treatments that have greater evidence of efficacy (or are considerably less costly) including NSAIDs, eccentric exercises, iontophoresis, or injection(s).

Evidence

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There is 1 moderate-quality RCT incorporated into this analysis.

LOW-LEVEL LASER THERAPY FOR ACUTE, SUBACUTE, OR POSTOPERATIVE ACHILLES TENDINOPATHY

No Recommendation

There is no recommendation for or against the use of low-level laser therapy for treatment of acute, subacute, or post-operative Achilles tendinopathy.

Strength of evidence No Recommendation, Insufficient Evidence (I)
Level of confidence Low

Rationale

There is no quality trial evaluating LLLT vs. sham treatment that did not include a co-intervention. There is one moderate-quality RCT evaluating treatment of patients with chronic Achilles tendinopathy that suggested benefits in pain intensity at 4, 8, and 12 weeks after an 8-week course of low laser therapy combined with eccentric exercises (Stergioulas et al., 2008). However, as the trial included eccentric exercises, it is unclear how much effect was attributable to LLLT and how much to exercises and whether adherence to exercise may have differed between the groups. LLLT is not invasive, has low adverse effects, but is high cost. LLLT is recommended for select patients who have failed treatments with greater evidence of efficacy or are considerably less costly, including NSAIDs, eccentric exercises, iontophoresis, and injection(s).

DEVICES

NIGHT SPLINTS

NIGHT SPLINTS FOR ACUTE, SUBACUTE, OR CHRONIC ACHILLES TENDINOPATHY

No Recommendation

There is no recommendation for or against the use of a night splint for the treatment of acute, subacute, or chronic Achilles tendinopathy. Splints that hold the foot in 90°of dorsiflexion during the night are sometimes used to reduce morning pain and stiffness from Achilles tendinopathy.

Strength of evidence No Recommendation, Insufficient Evidence (I)
Level of confidence Low

Rationale

There are no quality studies of patients treated with night splints compared to non-splinted controls. There also are no quality studies in post-operative patients. There are two moderate-quality studies that included splints for treatment of subacute and chronic Achilles tendinopathy. In both studies, there is no evidence that splinting provided any additive benefit over eccentric exercises alone (Roos et al., 2004, de Vos et al., 2007). This

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suggests splinting provides no added benefit. Night splints are non-invasive, have a minimal adverse effect profile, although they may provide some level of nuisance, and are low to moderate cost depending on the product and whether the device is custom made. There is no recommendation for or against use of these splints. Evidence suggests that other interventions, particularly exercises, are preferable. Post-operative patients generally require walking boots during rehabilitation.

NIGHT SPLINTS FOR POSTOPERATIVE ACHILLES TENDINOPATHY

Recommended

Night splints are recommended for postoperative Achilles tendinopathy patients.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence Low

Rationale

There are no quality studies of patients treated with night splints compared to non-splinted controls. There also are no quality studies in post-operative patients. There are two moderate-quality studies that included splints for treatment of subacute and chronic Achilles tendinopathy. In both studies, there is no evidence that splinting provided any additive benefit over eccentric exercises alone (Roos et al., 2004, de Vos et al., 2007). This suggests splinting provides no added benefit. Night splints are non-invasive, have a minimal adverse effect profile, although they may provide some level of nuisance, and are low to moderate cost depending on the product and whether the device is custom made. There is no recommendation for or against use of these splints. Evidence suggests that other interventions, particularly exercises, are preferable. Post-operative patients generally require walking boots during rehabilitation.

Evidence

There are 2 moderate-quality RCTs incorporated into this analysis.

WALKING BOOTS

WALKING BOOTS FOR POSTOPERATIVE ACHILLES TENDINOPATHY

Recommended

Walking boots are recommended for post-operative Achilles tendinopathy patients.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence Low

Rationale

Post-operative patients generally require walking boots during rehabilitation.

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MAGNETS

MAGNETS FOR ACHILLES TENDINOPATHY

Not Recommended

Magnets are not recommended for the treatment of acute, subacute, chronic, or post-operative Achilles tendon disorders.

Strength of evidence Not Recommended, Insufficient Evidence (I)
Level of confidence Low

Rationale

There are no quality studies available evaluating the use of magnets for treatment of Achilles tendon disorders. Magnets have been evaluated in quality studies involving the spine and hand and they have been found to be ineffective. Magnets are not invasive, have no adverse effects, and are low cost, but other interventions have documented efficacy. Thus, magnets are not recommended for the treatment of Achilles tendinopathy.

ORTHOTIC DEVICES

ORTHOTIC DEVICES FOR ACUTE, SUBACUTE, CHRONIC, OR POSTOPERATIVE ACHILLES TENDINOPATHY

No Recommendation

There is no recommendation for or against the use of orthotic devices such as heel lifts, heel pads, or heel braces for the treatment of acute, subacute, chronic, or post-operative Achilles tendinopathy. Orthotic devices are commonly used for Achilles tendinopathy and are designed to modify the foot posture or place the hindfoot in a neutral position to reduce the load on the tendon. These devices include heel lifts, pads, and braces (Rompe et al., 2008).

Strength of evidence No Recommendation, Insufficient Evidence (I)
Level of confidence Low

Rationale

There are no quality studies comparing orthotics with non-interventional or control groups. A low-quality study comparing groups that used heel pads, molefoam pads, or no device found no difference in the use of these devices (Lowdon et al., 1984). There is one moderate-quality study of one specific device; however, the study did not include a non-intervention group so improvement with intervention could not be differentiated from the natural course of the condition, failed to demonstrate superiority of splints to exercises, and splints provided no additive benefits when combined with exercises (Petersen et al., 2007). Capillary blood flow in Achilles paratenons (Knobloch et al., 2008) and tendons (Knobloch et al., 2008) of patients with Achilles tendinopathy who wore an AirCast AirHeel ankle splint was investigated with mixed results between the two studies in microcirculatory effects, but no clinical changes demonstrated in those who wore splints. These devices are usually non-

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invasive and low cost if not custom-made. Although they are often prescribed, there is insufficient evidence to support a recommendation for or against their use.

Evidence

There are 3 moderate-quality RCTs incorporated into this analysis. There is 1 low-quality RCT in Appendix 1.

HOT AND COLD THERAPIES

Cryotherapy and heat are commonly used for analgesia. Cryotherapy may reduce inflammation in acute musculoskeletal injuries, including Achilles tendinopathy [160].

CRYOTHERAPY FOR ACUTE, SUBACUTE, CHRONIC, OR POSTOPERATIVE ACHILLES TENDINOPATHY

Recommended

Cryotherapy is recommended for treatment of acute, subacute, chronic, or post-operative Achilles tendinopathy. Cryotherapy is commonly used for analgesia and may reduce inflammation in acute musculoskeletal injuries.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence Low

Indications

All patients with Achilles tendinopathy.

Frequency/Dose/Duration

Approximately 3 to 5 self-applications per day as needed.

Indications for discontinuation

Resolution, adverse effects, non-compliance.

Rationale

There is one moderate-quality study of cryotherapy considering tendon blood flow as an outcome (Knobloch et al., 2008). Clinical outcomes were not included and this study's usefulness is limited. There is no quality evidence for the use of cryotherapy or heat as treatments for Achilles tendinopathy. In a non-randomized prospective study, cryotherapy was demonstrated through Doppler ultrasound to result in temporary reduction in increased blood flow through the microcirculation (Knobloch et al., 2007). The use of ice has been implemented as part of a multi-intervention strategy (Mayer et al., 2007), although the individual contribution towards healing is unknown. Cryotherapy and heat are non-invasive, have few adverse effects, are not costly when self-administered, and are thus recommended.

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HEAT THERAPY FOR ACUTE, SUBACUTE, CHRONIC, OR POSTOPERATIVE ACHILLES TENDINOPATHY

Recommended

Heat is recommended for treatment of acute, subacute, chronic, or post-operative Achilles tendinopathy. Approximately 3 to 5 self-applications per day are indicated as needed.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence Low

Indications

All patients with Achilles tendinopathy.

Frequency/Dose/Duration

Approximately 3 to 5 self-applications per day as needed.

Indications for discontinuation

Resolution, adverse effects, non-compliance.

Rationale

There is one moderate-quality study of cryotherapy considering tendon blood flow as an outcome (Knobloch et al., 2008). Clinical outcomes were not included and this study's usefulness is limited. There is no quality evidence for the use of cryotherapy or heat as treatments for Achilles tendinopathy. In a non-randomized prospective study, cryotherapy was demonstrated through Doppler ultrasound to result in temporary reduction in increased blood flow through the microcirculation (Knobloch et al., 2007). The use of ice has been implemented as part of a multi-intervention strategy (Mayer et al., 2007), although the individual contribution towards healing is unknown. Cryotherapy and heat are non-invasive, have few adverse effects, are not costly when self-administered, and are thus recommended.

Evidence

There is 1 moderate-quality RCT incorporated into this analysis.

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INJECTION THERAPIES

GLUCOCORTICOSTEROIDS

GLUCOCORTICOSTEROID INJECTIONS FOR CHRONIC ACHILLES TENDINOPATHY AND ASSOCIATED PARATENDON BURSITIS

Sometimes Recommended

Low-dose glucocorticosteroid injections are recommended as an alternative therapy for the treatment of moderate or severe chronic Achilles tendinopathy and associated paratendon bursitis. Treatment with other interventions such as NSAIDs and exercises should have been attempted previously and either failed or yielded unsatisfactory results.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence Low

Indications

Moderate or severe chronic Achilles tendinopathy. Treatment with other interventions such as NSAIDs and exercises should have been attempted previously and either failed or yielded unsatisfactory results. There may be cases in the late subacute stage in which these injections may be appropriate if other treatments have failed; thus, there is overall no recommendation for patients in the subacute stage.

Frequency/Dose/Duration

Up to 3 injections of triamcinolone 20mg over 3 weeks (Fredberg et al., 2004), with 2nd and 3rd injections performed if the 1st does not yield complete relief, the problem continues to be incapacitating, conservative treatment options have been exhausted, and the patient understands and accepts that Achilles tendon rupture is possible and may necessitate surgery. Other glucocorticosteroids may be effective; however, one trial showed no effect of 1 methyl prednisolone injection (DaCruz et al., 1988) and quality trials with other glucocorticosteroids have not been reported.

Indications for discontinuation

Resolution, intolerance, adverse effects, or lack of benefits.

Rationale

One moderate-quality placebo-controlled RCT evaluating up to 3 triamcinolone injections under ultrasound guidance for treatment of Achilles tendinopathy (Fredberg et al., 2004), found evidence of short-term benefit. It is unclear if ultrasound guidance is necessary as the tissue is palpable. A second study found lack of efficacy (DaCruz et al., 1988). Glucocorticosteroid injections are invasive, have a low adverse-effect profile as a single low-dose injection, and are moderately costly. They are recommended as a treatment for select patients, after more conservative treatments have been attempted and found insufficient.

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Evidence

There are 2 moderate-quality RCTs incorporated into this analysis.

GLUCOCORTICOSTEROID INJECTIONS FOR ACUTE, SUBACUTE, OR POSTOPERATIVE ACHILLES TENDINOPATHY

Not Recommended

Low-dose glucocorticosteroid injections are not recommended for treatment of acute, subacute, or post-operative Achilles tendinopathy.

Strength of evidence Not Recommended, Insufficient Evidence (I)
Level of confidence Low

Rationale

One moderate-quality placebo-controlled RCT evaluating up to 3 triamcinolone injections under ultrasound guidance for treatment of Achilles tendinopathy (Fredberg et al., 2004), found evidence of short-term benefit. It is unclear if ultrasound guidance is necessary as the tissue is palpable. A second study found lack of efficacy (DaCruz et al., 1988). Glucocorticosteroid injections are invasive, have a low adverse-effect profile as a single low-dose injection, and are moderately costly. They are recommended as a treatment for select patients, after more conservative treatments have been attempted and found insufficient.

PLATELET-RICH PLASMA

PLATELET-RICH PLASMA (PRP) INJECTIONS FOR ACHILLES TENDINOPATHY

Not Recommended

Platelet-rich plasma injections are moderately not recommended for treatment of Achilles tendinopathy.

Strength of evidence Moderately Not Recommended, Evidence (B)
Level of confidence Moderate

Rationale

There is one high-quality trial for Achilles tendinopathy injections and it failed to demonstrate evidence of efficacy (de Vos et al., 2010). This procedure is invasive, has low adverse effects, is high cost, but with lack of efficacy is not recommended. As there is only one published clinical trial, this recommendation could change based on additional quality evidence, particularly as there may be some evidence of potential efficacy for some other tendinopathies (see Elbow Disorders and Knee Disorders guidelines).

Evidence

There is 1 high-quality RCT incorporated into this analysis.

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GLYCOSAMINOGLYCAN POLYSULFATE

GLYCOSAMINOGLYCAN POLYSULFATE LOCAL INJECTION (GAGPS) FOR CHRONIC ACHILLES TENDINOPATHY

Sometimes Recommended

Glycosaminoglycan polysulfate local injection is recommended as an alternative therapy for treatment of moderate or severe chronic Achilles tendinopathy. Treatment with other interventions such as NSAIDs and exercises should have been attempted previously and either failed or yielded unsatisfactory results.

Strength of evidence Recommended, Evidence (C)
Level of confidence Low

Indications

Moderate or severe chronic Achilles tendinopathy; treatment with other interventions such as NSAIDs and exercises should have been attempted previously and either failed or yielded unsatisfactory results.

Frequency/Dose/Duration

Up to 6 local injections into the paratendon area over a 2-week period; assess after 2 or 3 injections and if results are satisfactory, withhold and evaluate value of further injections while observing the clinical course.

Indications for discontinuation

Resolution, intolerance, adverse effects, or lack of benefits.

Rationale

There is one moderate-quality RCT evaluating glycosaminoglycan polysulfate for treatment of Achilles tendinopathy (Sundqvist et al., 1987). However, instead of being placebo controlled, it was controlled with indomethacin 50mg, 6 doses administered at time of injections in the placebo group. Six local injections of GAGPS into the paratendon area over a 2-week period (6 injections total) in patients with symptoms greater than 3 months demonstrated significant improvement from baseline at 4 weeks, with 53% responding to treatment (moderate or good) and 59% responding at 1 year. The comparison group received oral indomethacin, in which responders were 19% at 4 weeks and 12% at 52 weeks. Therefore, this suggests there is limited evidence that GAGPS may be beneficial for patients with chronic symptoms of Achilles tendon conditions. Glycosaminoglycan injections are invasive, have a low adverse effect profile, and are moderately costly as a series of injections is required.

Evidence

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There is 1 moderate-quality RCT incorporated into this analysis.

GLYCOSAMINOGLYCAN POLYSULFATE LOCAL INJECTION (GAGPS) FOR ACUTE, SUBACUTE, OR POSTOPERATIVE ACHILLES TENDINOPATHY

No Recommendation

There is no recommendation for or against the use of glycosaminoglycan polysulfate local injection for treatment of acute, subacute, or post-operative Achilles tendinopathy.

Strength of evidence No Recommendation, Insufficient Evidence (I)
Level of confidence Low

Rationale

There is one moderate-quality RCT evaluating glycosaminoglycan polysulfate for treatment of Achilles tendinopathy (Sundqvist et al., 1987). However, instead of being placebo controlled, it was controlled with indomethacin 50mg, 6 doses administered at time of injections in the placebo group. Six local injections of GAGPS into the paratendon area over a 2-week period (6 injections total) in patients with symptoms greater than 3 months demonstrated significant improvement from baseline at 4 weeks, with 53% responding to treatment (moderate or good) and 59% responding at 1 year. The comparison group received oral indomethacin, in which responders were 19% at 4 weeks and 12% at 52 weeks. Therefore, this suggests there is limited evidence that GAGPS may be beneficial for patients with chronic symptoms of Achilles tendon conditions. Glycosaminoglycan injections are invasive, have a low adverse effect profile, and are moderately costly as a series of injections is required.

HEPARIN

SUBCUTANEOUS HEPARIN INJECTION FOR ACUTE OR SUBACUTE ACHILLES TENDINOPATHY

Not Recommended

Heparin subcutaneous injection is not recommended for treatment of acute or subacute Achilles tendinopathy.

Strength of evidence Not Recommended, Evidence (C)
Level of confidence Low

Rationale

There is one moderate-quality study comparing subcutaneous heparin injection to placebo for insertional or calcaneal tendinitis (Larsen et al., 1987). No significant differences were found between the groups. This study was possibly confounded by including the co-intervention of physical work in both groups, although the impact is unclear. Heparin injections are invasive, are likely low risk to most patients at the described daily dose of 5,000 IU, and are moderately costly when considering a course of injections for at least 1 week. Due to the lack of demonstrated efficacy, they are not recommended. There is no evidence to support the use of heparin in chronic conditions.

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Evidence

There is 1 moderate-quality RCT incorporated into this analysis.

SUBCUTANEOUS HEPARIN INJECTION FOR CHRONIC ACHILLES TENDINOPATHY

Not Recommended

Heparin subcutaneous injection is not recommended for treatment of chronic Achilles tendinopathy.

Strength of evidence Not Recommended, Insufficient Evidence (I)
Level of confidence Low

Rationale

There is one moderate-quality study comparing subcutaneous heparin injection to placebo for insertional or calcaneal tendinitis (Larsen et al., 1987). No significant differences were found between the groups. This study was possibly confounded by including the co-intervention of physical work in both groups, although the impact is unclear. Heparin injections are invasive, are likely low risk to most patients at the described daily dose of 5,000 IU, and are moderately costly when considering a course of injections for at least 1 week. Due to the lack of demonstrated efficacy, they are not recommended. There is no evidence to support the use of heparin in chronic conditions.

ACTOVEGIN

ACTOVEGIN INJECTION FOR ACUTE, SUBACUTE, OR CHRONIC ACHILLES TENDINOPATHY

No Recommendation

There is no recommendation for or against the use of Actovegin injection for the treatment of acute, subacute or chronic Achilles tendinopathy.

Strength of evidence No Recommendation, Insufficient Evidence (I)
Level of confidence Low

Rationale

There is one moderate-quality placebo-controlled trial of Actovegin that showed a significantly greater improvement in acute pain and reduction of Achilles tendon diameter after a series of 3 injections into the paratendon for acute and subacute midportion Achilles tendinitis (Pforringer et al., 1994). The treatment group demonstrated complete resolution of pain while walking on tip-toes at the 3-month follow-up. This treatment is invasive, has a low reported adverse-effective profile, and is of moderate to high cost, but is not FDA approved for this use. Therefore, there is no recommendation for or against the use of these injections.

Evidence

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There is 1 moderate-quality RCT incorporated into this analysis.

PROLOTHERAPY

PROLOTHERAPY INJECTIONS FOR CHRONIC ACHILLES TENDINOPATHY

No Recommendation

There is no recommendation for or against the use of prolotherapy injections, including polidocanol and hypertonic saline, for the treatment of chronic Achilles tendinopathy.

Strength of evidence No Recommendation, Insufficient Evidence (I)
Level of confidence Low

Rationale

There is conflicting evidence on efficacy of prolotherapy injections for chronic Achilles tendinosis. One moderate- quality trial using hypertonic glucose suggested lack of efficacy (Yelland et al., 2010). Another suggested polidocanol was effective (Alfredson et al., 2005). Thus, the overall evidence conflicts when comparing treatment to placebo. A high-quality study showed no dose response of sclerosing injections but there was no placebo-controlled group and the trial cannot infer efficacy (Willberg et al., 2008). Thus with conflicting evidence, there is no recommendation for or against these injections.

Evidence

There is 1 high- and 2 moderate-quality RCTs incorporated into this analysis.

POLIDOCANOL

POLIDOCANOL INJECTION FOR ACUTE, SUBACUTE, OR POSTOPERATIVE ACHILLES TENDINOPATHY

No Recommendation

There is no recommendation for or against the use of polidocanol injection, including polidocanol and hypertonic saline, for acute, subacute, or post-operative Achilles tendinopathy.

Strength of evidence No Recommendation, Insufficient Evidence (I)
Level of confidence Low

Rationale

There is conflicting evidence on efficacy of prolotherapy injections for chronic Achilles tendinosis. One moderate- quality trial using hypertonic glucose suggested lack of efficacy (Yelland et al., 2010). Another suggested polidocanol was effective (Alfredson et al., 2005). Thus, the overall evidence conflicts when comparing treatment to placebo. A high-quality study showed no dose response of sclerosing injections but there was no placebo-controlled

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group and the trial cannot infer efficacy (Willberg et al., 2008). Thus with conflicting evidence, there is no recommendation for or against these injections.

Evidence

There is 1 high- and 2 moderate-quality RCTs incorporated into this analysis.

APROTININ

APOPROTININ INJECTION FOR ACUTE OR SUBACUTE ACHILLES TENDINOPATHY

Not Recommended

Aprotinin injection is not recommended for the treatment of acute or subacute Achilles tendinopathy.

Strength of evidence Not Recommended, Insufficient Evidence (I)
Level of confidence Low

Rationale

There is one moderate-quality placebo-controlled trial comparing aprotinin to placebo for the treatment of chronic midportion Achilles tendinopathy (Brown et al., 2004). A series of 3 weekly injections did not demonstrate any improvement of pain in the intervention group compared to placebo. However, this study allowed multiple co-interventions, including eccentric exercises in both groups, such that the impact of the intervention may be confounded. Regardless, as there was no improvement difference between the groups despite the co-interventions, it is unlikely that this intervention was effective as a treatment. It is invasive, has a small but serious risk for anaphylactic reaction as it is bovine in origin, and is likely moderate to high cost with multiple injections requiring several office visits. Therefore, aprotinin injection is not recommended.

APOPROTININ INJECTION FOR CHRONIC ACHILLES TENDINOPATHY

Not Recommended

Aprotinin injection is not recommended for the treatment of chronic Achilles tendinopathy.

Strength of evidence Not Recommended, Evidence (C)
Level of confidence Low

Rationale

There is one moderate-quality placebo-controlled trial comparing aprotinin to placebo for the treatment of chronic midportion Achilles tendinopathy (Brown et al., 2004). A series of 3 weekly injections did not demonstrate any improvement of pain in the intervention group compared to placebo. However, this study allowed multiple co-interventions, including eccentric exercises in both groups, such that the impact of the intervention may be confounded. Regardless, as there was no improvement difference between the groups

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despite the co-interventions, it is unlikely that this intervention was effective as a treatment. It is invasive, has a small but serious risk for anaphylactic reaction as it is bovine in origin, and is likely moderate to high cost with multiple injections requiring several office visits. Therefore, aprotinin injection is not recommended.

Evidence

There is 1 moderate-quality RCT incorporated into this analysis.

HIGH-VOLUME IMAGE-GUIDED

HIGH-VOLUME IMAGE-GUIDED INJECTION FOR CHRONIC ACHILLES TENDINOPATHY

No Recommendation

There is no recommendation for or against the use of high-volume image-guided injection for the treatment of chronic Achilles tendinopathy.

Strength of evidence No Recommendation, Insufficient Evidence (I)
Level of confidence Low

Rationale

There is no quality evidence for or against the use of high-volume injection into the tendon for chronic Achilles tendinopathy. However, this is only a recently described technique that borrows the hypothesis that reducing neovascularization will reduce pain and improve healing from other effective treatments. A small prospective study of 30 subjects demonstrated significant improvement in pain and function at 4 weeks, lasting out to 30 weeks (Chan et al., 2008). HVIGI is invasive, has uncertain adverse effect profile but may carry an increased risk for tendon rupture with the use of injected steroid, and is of moderate cost. Quality studies are necessary to evaluate this treatment.

SURGICAL CONSIDERATIONS

Quality, population-based studies for prognoses of Achilles tendinopathies have not been reported, and available published studies cited below are likely biased towards over-estimates of risk for surgery due primarily to selection and spectrum biases. It has been estimated that 24 to 45% of patients with chronic Achilles tendinopathy that fail 6 months of non-operative treatment have proceed to surgery [(161)]. For paratendonitis, surgery is rare, but if required, usually is performed through a longitudinal incision where the posterior and lateral aspects of the diseased paratenon are excised, sparing the anterior portion containing the vascular supply [(148)]. For mid-portion chronic tendinopathy, approximately 25% of patients have been estimated to fail non-operative measures. Surgical treatment consists of removing the areas of degenerated tendon, and may require tendon transfer if more than 50 to 75% of the tendon is removed [(148)]. For insertional tendinosis, 85 to 90% of cases improve with conservative measures. Surgical treatment frequently consists of a midline incision at the insertion and debriding calcific or degenerate regions.

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SURGERY FOR THE TREATMENT OF CHRONIC ACHILLES TENDINOPATHY WITHOUT RUPTURE

Sometimes Recommended

Surgery is recommended to treat select cases of chronic Achilles tendinopathy without rupture. There is no recommendation for any particular procedure over another. Surgery may be indicated for patients with moderate to severe chronic Achilles tendinopathy who have failed multiple non-surgical treatments and whose condition has lasted at least 6 months. Patients should generally have failed NSAID(s), eccentric exercises, iontophoresis, injection(s), or low-level laser therapy.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence Low

Indications

Patients with moderate to severe chronic Achilles tendinopathies who have failed multiple non-surgical treatments and whose condition has lasted at least 6 months. Patients should generally have failed NSAID(s), eccentric exercises, iontophoresis, injection(s) and low level laser therapy.

Rationale

There are no quality trials comparing surgical intervention(s) with continued non-operative interventions for patients with Achilles tendinopathy. Further, there are no trials comparing different surgical techniques. There are several studies that indicate surgical success as measured by satisfied or very satisfied scores is up to 85% (Rompe et al., 2008). Success rates at 7 months in a prospective study were higher at 88% for paratenonitis versus only 54% for those with intratendinous lesions, with complication rates of 6% versus 27% respectively (Paavola et al., 2002). Thus, while surgery appears to provide relief to the majority of patients, it is not without significant risk of complication, expense, and lack of comparison data to other non-surgical interventions. Therefore, surgery is not recommended until a course of at least 6 months of other non-operative treatments with demonstrated efficacy has been attempted and the patient's symptoms are sufficient to warrant the risks of surgical intervention.

SURGERY FOR THE TREATMENT OF ACUTE OR SUBACUTE ACHILLES TENDINOPATHY WITHOUT RUPTURE

Not Recommended

Surgery is not recommended for the treatment of acute or subacute Achilles tendinopathy without rupture.

Strength of evidence Not Recommended, Insufficient Evidence (I)
Level of confidence High

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Rationale

There are no quality trials comparing surgical intervention(s) with continued non-operative interventions for patients with Achilles tendinopathy. Further, there are no trials comparing different surgical techniques. There are several studies that indicate surgical success as measured by satisfied or very satisfied scores is up to 85% (Rompe et al., 2008). Success rates at 7 months in a prospective study were higher at 88% for paratenonitis versus only 54% for those with intratendinous lesions, with complication rates of 6% versus 27% respectively (Paavola et al., 2002). Thus, while surgery appears to provide relief to the majority of patients, it is not without significant risk of complication, expense, and lack of comparison data to other non-surgical interventions. Therefore, surgery is not recommended until a course of at least 6 months of other non-operative treatments with demonstrated efficacy has been attempted and the patient's symptoms are sufficient to warrant the risks of surgical intervention.

ACHILLES TENDON RUPTURE

OVERVIEW

Attention is initially focused on differential diagnosis for ankle and foot disorders through a focused history and examination [162] .

The cardinal symptom of an Achilles tendon rupture is a sudden pain in the posterior heel that is often accompanied by a “pop” heard emanating from the heel [25,161,163,164,165,166]. There is generally no history of prior symptoms (pain, stiffness) prior to rupture [14,166].

Diagnosis of an Achilles tendon rupture is most often based on loss of plantar flexion strength, palpation of a gap in the mid-portion of the tendon (proximal to the calcaneal insertion) [21,23,24], and a positive squeeze test of the calf muscle that fails to elicit plantar flexion [167]. The examiner may encounter resting dorsiflexion on the side of the rupture. Other examination findings include the Matles knee flexion test [168]. Specific imaging is not required for most acute rupture cases [25,163,164,166].

DIAGNOSTIC RECOMMENDATIONS

ROUTINE X-RAY FOR DIAGNOSIS OF ACUTE ACHILLES RUPTURE

No Recommendation

There is no recommendation for or against the routine use of x-ray to diagnose acute Achilles tendon rupture. X-ray is generally not widely used for the diagnosis of acute Achilles rupture, although it may be helpful in identifying tendon calcification (Gerster et al., 1977, Wick et al., 2008).

Strength of evidence No Recommendation, Insufficient Evidence (I)
Level of confidence Low

Indications

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Achilles tendon ruptures resulting from direct trauma or if suspected rupture involves the calcaneal insertion, or among patients with reasonable suspicion of tendon calcification (Gerster et al., 1977, Wick et al., 2008).

Rationale

There is no quality evidence that obtaining x-ray studies for the evaluation of acute Achilles rupture significantly improves or changes the course of treatment. A case report used x-ray to confirm the diagnosis of a suspected rupture in a 69-year old male with diffuse calcification of the Achilles tendon (Wick et al., 2008), although it is unknown if the management course was altered with this finding. While most ruptures are diagnosed by physical examination, in cases of uncertainty, MRI and ultrasound are preferred over x-ray. Ruptures of the tendon at the calcaneal insertion are reported to be rare, although if suspected, radiography may detect avulsion of the bony insertion (Lui, 2009). Therefore, although x-ray is inexpensive and is readily accessible, it is unlikely to provide diagnostic benefit except in cases where direct trauma may have resulted in increased likelihood of fracture, when suspected rupture involves the calcaneal insertion, or where there is reasonable clinical suspicion of tendon calcification such as among those with many cardiovascular risk factors or calcium pyrophosphate deposition disease.

ULTRASOUND FOR DIAGNOSIS OF ACUTE ACHILLES TENDON RUPTURE

Recommended

Ultrasound is recommended for the diagnosis of acute Achilles tendon rupture.
Ultrasound is widely used to evaluate Achilles tendon rupture, particularly when clinical suspicion of rupture is high but there is diagnostic uncertainty (Heckman et al., 2009, Cary, 2009).

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence Moderate

Indications

Clinical suspicion of rupture is high but uncertain.

Rationale

There are no quality trials comparing the use of ultrasound as a diagnostic test for acute Achilles tendon rupture. There are a number of case series that suggest ultrasound has a high sensitivity and specificity. A case series of 100 patients with suspected acute Achilles rupture compared pre-operative ultrasound with intraoperative findings. All suspected tears were confirmed by ultrasound and there was a high correlation of rupture size (Pearson r = 0.940) (Margetic et al., 2007). Another study comparing operative results with pre-operative ultrasound confirmed a high sensitivity and specificity, with one false negative out of 26 cases (Paavola et al., 1998). Ultrasound has been described as a tool to plan surgical intervention, although there are no trials found that demonstrate this utility. Ultrasound is not invasive, has no adverse effects, and is moderately costly. It is recommended as the

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main confirmatory diagnostic test for Achilles ruptures, particularly when there is diagnostic uncertainty.

MAGNETIC RESONANCE IMAGING (MRI) FOR DIAGNOSIS OF ACUTE ACHILLES TENDON RUPTURE

Sometimes Recommended

MRI is recommended for the evaluation of acute Achilles tendon rupture. MRI is recommended for select use as an alternative to ultrasound when clinical suspicion is high but uncertain, particularly when other issues are unclear such as requiring a broader field of view.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence Moderate

Indications

Clinical suspicion of rupture is high but uncertain.

Rationale

There are no quality trials evaluating the use of MRI in the diagnosis of Achilles tendon rupture. MRI has an advantage of providing a broader field of view compared to ultrasound. MRI is not invasive and has no adverse effects, but is high cost and more costly than ultrasound. MRI is therefore recommended for select use as an alternative when clinical suspicion is high but uncertain and particularly when other issues are unclear such as requiring a broader field of view.

TREATMENT RECOMMENDATIONS

OVERVIEW

Upon establishment of the diagnosis, initial treatment is symptomatic until the definitive care plan is established. This may include relative rest, NSAIDs, acetaminophen and cryotherapy. There are few quality trials for evaluation of any interventions for treatment of Achilles ruptures [25,163,169]. The optimal management of Achilles tendon rupture is controversial [14,23,24,25,163,170,171,172]. The objective of operative and non-operative management is to approximate the ruptured tendon ends. Non-operative management achieves this by keeping the foot in plantar flexion with a rigid cast or brace and allowing natural healing without sutures or other surgical intervention [25,161]. There are various protocols for rigid casting that differ in initial foot angle positions, duration of non-weight bearing, and timing of repositioning and activities. Functional braces or splints rather than casting have been described as an alternative to casting.

Workplace restrictions for an Achilles tendon rupture are dependent on treatment specifics. Historically, work limitations and rest have been prescribed [32]. However, there is quality evidence that early weight bearing post-operatively is beneficial to recovery; therefore, activity modification to safely allow weight bearing is recommended (see Rehabilitation).

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Numerous rehabilitation protocols are described for treating Achilles tendon rupture [23,24,163,171,172,173,174,175,176,177,178,179,180,181]. The goals of rehabilitation are to restore function, including ankle range of motion (ROM) in plantar flexion, dorsiflexion, ankle proprioception, and strength of the calf musculature, allowing full return to daily activities, sports, and occupation.

ACTIVITY MODIFICATION AND EXERCISE

EXERCISE AND EDUCATION FOR ACHILLES TENDON RUPTURE REHABILITATION

Recommended

A primarily home-based rehabilitation program (exercise and education) is recommended for treatment of Achilles tendon rupture.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence High

Indications

All post-operative and conservatively managed Achilles rupture patients.

Frequency/Dose/Duration

A written rehabilitation program including education and exercises with a clinician that usually includes participation in instruction and demonstration of exercises. Additional, occasional periodic measurements of functional recovery progress and provision of instruction of new activities (see Tables 6 and 7 for schedules). Three to 12 visits over the course of recovery of 3 to 6 months.

Rationale

There are no quality trials studying the influence of therapy on outcome after an Achilles tendon rupture. A retrospective study in German found no difference in functional outcomes measures between three groups that received no formal physiotherapy, physiotherapy for 3 to 6 weeks, and physiotherapy for more than 6 weeks. Review of protocols from the reviewed randomized trials regarding operative and non-operative treatment above found formal supervised physiotherapy was provided in only four of the studies (Moller et al., 2001, Moller et al., 2002, Saleh et al., 1992, Gigante et al., 2008). The majority of studies used widely diverse protocols for home exercises dependent on treatment methods. In general, functional rehabilitation can be performed following a written protocol performed sequentially over a 6-month period post injury. One or two initial visits to a physical therapist may be beneficial for instruction on a protocol, followed by periodic visits to measure progress and to provide additional coaching and instruction as new activities are added. A post-operative rehabilitation guideline derived from a well-detailed protocol by Kangas, with evidence based modifications from the reviewed quality trials, is shown in Tables 3 and 4.

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HOT AND COLD THERAPIES

SELF-APPLICATION OF CRYOTHERAPY FOR ACUTE, SUBACUTE, CHRONIC, OR POSTOPERATIVE ACHILLES TENDON RUPTURE

Recommended

Self-application of cryotherapy is recommended for treatment of acute, subacute, chronic, or post-operative Achilles tendon rupture.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence Low

Indications

Acute, subacute, chronic, or post-operative patients with Achilles tendon rupture.

Frequency/Dose/Duration

Approximately 3 to 5 self-applications per day as needed.

Indications for discontinuation

Resolution, adverse effects, non-compliance.

Rationale

There are no quality trials for modality applications in improving outcomes for Achilles tendon rupture. Cryotherapy (ice) and heat appear effective in treating musculoskeletal disorders involving other body parts. Ice may be of short-term benefit in reducing swelling and pain for acute rupture. Heat may be helpful particularly for healing particularly a few days after the rupture or surgery. These treatments are not invasive, have low adverse effects, are low cost, and thus are recommended.

SELF-APPLICATION OF HEAT THERAPY FOR ACUTE, SUBACUTE, CHRONIC, OR POSTOPERATIVE ACHILLES TENDON RUPTURE

Recommended

Self-application of cryotherapy or heat therapy is recommended for treatment of acute, subacute, chronic, or post-operative Achilles tendon rupture.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence Low

Indications

Acute, subacute, chronic, or post-operative patients with Achilles tendon rupture.

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Frequency/Dose/Duration

Approximately 3 to 5 self-applications per day as needed.

Indications for discontinuation

Resolution, adverse effects, non-compliance.

Rationale

There are no quality trials for modality applications in improving outcomes for Achilles tendon rupture. Cryotherapy (ice) and heat appear effective in treating musculoskeletal disorders involving other body parts. Ice may be of short-term benefit in reducing swelling and pain for acute rupture. Heat may be helpful particularly for healing particularly a few days after the rupture or surgery. These treatments are not invasive, have low adverse effects, are low cost, and thus are recommended.

MEDICATIONS

NSAIDS AND ACETAMINOPHEN

The use of oral NSAIDs is a well-described intervention for numerous soft-tissue and musculoskeletal injuries including ankle sprains [(158)]. The mechanism of action is unclear for typical musculoskeletal disorders that do not have traditional markers of inflammation, although some believe the mechanism of efficacy nevertheless involves addressing some component of inflammation [(159)].

NSAIDS FOR ACUTE, SUBACUTE, CHRONIC, OR POSTOPERATIVE PAIN FROM ACHILLES TENDON RUPTURE

Recommended

NSAIDs are recommended for treatment of pain from acute, subacute, chronic, or post-operative Achilles tendon rupture. There is no evidence that one NSAID is superior to another for treatment of Achilles rupture.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence High

Indications

Pain associated with acute, subacute, or chronic rupture, or for post-operative pain management.

Frequency/Dose/Duration

Frequency/dose per manufacturer's recommendations; may be taken as scheduled or as needed. There is no evidence one NSAID is superior to another for treatment of Achilles rupture.

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Indications for discontinuation

Resolution, intolerance, adverse effects, lack of benefits, or failure to progress over a trial of a few weeks.

Rationale

There are no quality trials for treatment of these patients with NSAIDs or acetaminophen. However, these medications have evidence of efficacy for treatment of numerous musculoskeletal disorders (see, for example, ankle sprains section and Shoulder Disorders and Low Back Disorders guidelines). NSAIDs and acetaminophen are not invasive, have low adverse effects and are low cost. They are recommended for treatment of these patients (see Hip and Groin Disorders guideline for discussion of gastroprotective and cardiovascular issues).

ACETAMINOPHEN FOR ACUTE ACHILLES RUPTURE

Recommended

Acetaminophen is recommended as an analgesia for pain as a result of acute Achilles tendon rupture. Clinicians are cautioned that an FDA advisory committee has recommended reduction in daily doses to below the prior recommendations of up to 4g a day.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence Low

Indications

Pain associated with acute Achilles tendon rupture.

Rationale

There are no quality trials for treatment of these patients with NSAIDs or acetaminophen. However, these medications have evidence of efficacy for treatment of numerous musculoskeletal disorders (see, for example, ankle sprains section and Shoulder Disorders and Low Back Disorders guidelines). NSAIDs and acetaminophen are not invasive, have low adverse effects and are low cost. They are recommended for treatment of these patients (see Hip and Groin Disorders guideline for discussion of gastroprotective and cardiovascular issues).

OPIOIDS

Opioids are frequently used to treat the pain of musculoskeletal conditions and are widely used in post-operative settings; however, most of the trials generally evaluated patients with spine-related disorders (see Low Back Disorders and Chronic Pain guidelines). Use of opioids for treatment of Achilles rupture has not been well described.

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OPIOIDS FOR PAIN FROM ACUTE OR POSTOPERATIVE ACHILLES TENDON REPAIR

Sometimes Recommended

Limited use of opioids for the treatment of acute Achilles tendon rupture is recommended as a treatment option for select patients presenting with acute or moderate to severe pain related to Achilles rupture, select patients who have undergone recent Achilles tendon repair, or patients who encountered surgical complications. Total length of treatment usually ranges from a few days to up to 2 weeks; should be utilized to supplement pain relief in addition to an NSAID or acetaminophen to reduce total need for opioid and consequent adverse effects.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence Moderate

Indications

Acute rupture or post-operative pain management for patients with moderate to severe pain.

Frequency/Dose/Duration

Frequency/dose per manufacturer's recommendations; may be taken as scheduled or as needed; generally short courses of a few days with subsequent weaning to nocturnal use if needed, then discontinuation. Total length of treatment usually ranges from a few days to up to 2 weeks; should be utilized to supplement pain relief in addition to an NSAID or acetaminophen to reduce total need for opioid and consequent adverse effects.

Indications for discontinuation

Sufficient pain management with other methods such as NSAIDs, resolution of pain, intolerance, adverse effects, lack of benefits, or failure to progress over a couple weeks.

Rationale

There is no quality evidence evaluating the use of opioids for the treatment of pain from acute Achilles tendon rupture. Approximating 50% of patients do not tolerate opioids (see Chronic Pain guideline). A large percentage of patients with Achilles tendon rupture do not report pain sufficient to require opioids. Opioids are not invasive, but have very high dropout rates and otherwise high rates of adverse effects, including very high associated death rates that have been reported to exceed motor vehicle crash death risks in two states (Hall et al., 2008, Centers for Disease Control and Prevention, 2006). Opioids are moderate to high cost depending on duration of treatment (see Chronic Pain guideline). They are not recommended for routine use. Some patients have insufficient pain relief with NSAIDs, thus judicious use of opioids for acute management may be helpful, particularly for nocturnal use. Opioids are recommended for brief, select use in post-operative patients with primary use at night to facilitate adequate post-operative sleep.

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OPIOIDS FOR PAIN FROM SUBACUTE OR CHRONIC ACHILLES TENDON REPAIR

Not Recommended

Opioids are not recommended for treatment of pain from subacute or chronic Achilles tendon repair.

Strength of evidence Not Recommended, Insufficient Evidence (I)
Level of confidence High

Rationale

There is no quality evidence evaluating the use of opioids for the treatment of pain from acute Achilles tendon rupture. Approximating 50% of patients do not tolerate opioids (see Chronic Pain guideline). A large percentage of patients with Achilles tendon rupture do not report pain sufficient to require opioids. Opioids are not invasive, but have very high dropout rates and otherwise high rates of adverse effects, including very high associated death rates that have been reported to exceed motor vehicle crash death risks in two states (Hall et al., 2008, Centers for Disease Control and Prevention, 2006). Opioids are moderate to high cost depending on duration of treatment (see Chronic Pain guideline). They are not recommended for routine use. Some patients have insufficient pain relief with NSAIDs, thus judicious use of opioids for acute management may be helpful, particularly for nocturnal use. Opioids are recommended for brief, select use in post-operative patients with primary use at night to facilitate adequate post-operative sleep.

SURGICAL CONSIDERATIONS

NONOPERATIVE MANAGEMENT

NONOPERATIVE MANAGEMENT OF ACHILLES TENDON RUPTURE WITH FUNCTIONAL SPLINTING AND CASTING

Recommended

Non-operative management with functional splinting and casting is recommended for Achilles tendon rupture. Non-operative management may be particularly selected for those with low physical demands and/or having co-morbidities that may preclude operative treatment.

Strength of evidence Recommended, Evidence (C)
Level of confidence Low

Rationale

There are five moderate-quality trials comparing non-operative management with surgical repair for ruptured Achilles tendons (Moller et al., 2001, Cetti et al., 1993, Moller et al., 2002, Metz et al., 2008, Twaddle et al., 2007, Moller et al., 2002, Metz et al., 2007). One trial suggested surgical management was superior to non-operative management for reducing risk of re-rupture (Moller et al., 2001, Moller et al., 2002), but did not have an important aspect of care (timing of casting and mobilization) held constant. In the other trials, there

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appeared to be a non-statistically significant trend towards higher re-rupture rates among the non-operative groups (there were no trials suggesting higher risk of re-rupture in the surgical groups) (Cetti et al., 1993, Metz et al., 2008, Twaddle et al., 2007, Metz et al., 2007).

Khan pooled data from three studies into a summary odds ratio and 95% confidence limit derived from the meta-analysis, which showed that non-surgical treatment was likely to result in 3.7 times more reruptures than surgical treatment; however, overall rerupture rates are low enough in surgical and non-surgical reapproximation methods to make 11 operations necessary to avoid one rerupture (Khan et al., 2005). Additionally, simple arithmetic summing of their data allowed calculation of an overall rerupture and infection rates, which are described above. The evidence indicates surgery reduces risk of re-rupture compared to non-operative treatment, but given a low overall rerupture rate, the effect is not dramatic.

One trial found no difference in lost time (Cetti et al., 1993), and two reported less lost time with the surgical group (Moller et al., 2001, Moller et al., 2002, Metz et al., 2008, Moller et al., 2002). A low-quality RCT also documented less lost time in the surgically repaired group (Nistor, 1981). One noted time-to-return-to-work favored the subset of population performing light work that received surgery (35.7 days versus 67.2 days), but the advantage was equivocal in sedentary and heavy job classifications. Overall, the studies suggest that persons in jobs that require mobility may benefit from surgical repair (Moller et al., 2001, Moller et al., 2002, Moller et al., 2002). One author suggested early mobilization is the most important factor in treating ruptured Achilles tendons (Twaddle et al., 2007). Möeller investigated differences in tendon healing based with MRI and ultrasound studies (Moller et al., 2002) and found no differences of partial defect, tendon thickness, homogenicity, tendinous edema, peritendinous reaction, or pattern of motion and the type of treatment received.

However, non-operative management appears to be effective in most patients (Moller et al., 2001, Cetti et al., 1993, Moller et al., 2002, Twaddle et al., 2007, Moller et al., 2002). There are few trials on casting and splinting or bracing. One moderate-quality study compared functional splinting with casting and reported higher satisfaction in the bracing compared with casting (Saleh et al., 1992). No differences in re-rupture rates or complications were found. There was a significant difference in dorsiflexion range of motion favoring the splinting group, although the clinical significance of this finding is unknown. The bracing group also self-reported shorter time required to be able to walk comfortably indoors and outdoors. However, this was a small study and was not a randomized crossover trial, which limits the utility to make a recommendation for one method over another. Thus, both methods are recommended as they are non-invasive, have similar long-term efficacy, and are reported as an effective treatment arm in other studies. Use of splinting is now becoming more common, with the primary advantage being patient preference.

One high-quality trial evaluated early weight bearing comparing non-operative immediate weight bearing using an orthosis to the use of a non-weight bearing rigid cast over a 12-week treatment period (Costa et al., 2006). Both groups were placed in the equinus position for 6 weeks followed by reduction of 1.5 inches every 2 weeks until the ankle was in a neutral position at 12 weeks. Evaluations at 3, 6, and 12 months did not demonstrate any

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significant differences in walking, stair climbing, return to work, return to sport, quality of life scores, or deficits in range of motion or torque. From this single study, it appears early weight bearing using the protocol described did not result in a significant benefit or adverse effect. Therefore, there is no recommendation for immediate weight bearing over rigid immobilization. Early weight bearing was found to provide functional improvement over rigid immobilization after surgical repair (see Post-Operative Care), but further evidence is needed to make a similar recommendation for non-operative care.

EARLY WEIGHT BEARING IN NONOPERATIVE TREATMENT FOR ACHILLES TENDON RUPTURE

No Recommendation

There is no recommendation for or against early weight bearing for non-operatively managed Achilles tendon ruptures.

Strength of evidence No Recommendation, Insufficient Evidence (I)
Level of confidence Low

Rationale

There are five moderate-quality trials comparing non-operative management with surgical repair for ruptured Achilles tendons (Moller et al., 2001, Cetti et al., 1993, Moller et al., 2002, Metz et al., 2008, Twaddle et al., 2007, Moller et al., 2002, Metz et al., 2007). One trial suggested surgical management was superior to non-operative management for reducing risk of re-rupture (Moller et al., 2001, Moller et al., 2002), but did not have an important aspect of care (timing of casting and mobilization) held constant. In the other trials, there appeared to be a non-statistically significant trend towards higher re-rupture rates among the non-operative groups (there were no trials suggesting higher risk of re-rupture in the surgical groups) (Cetti et al., 1993, Metz et al., 2008, Twaddle et al., 2007, Metz et al., 2007).

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SURGICAL REPAIR

Surgical repairs have included two basic approaches – open and percutaneous methods. There are more than 40 open techniques reported [182]. A number of augmentation techniques for open repair have been described purportedly resulting in strengthened repair and permitting earlier weight bearing after rupture. These include tendon transfers of the flexor hallucis longus, plantaris longus, semitendinosus and peroneus brevis or other methods such as gastrocnemiuous flap, dermal tissue graft, and fibrin glue [148,183,184,185,186,187,188,189,190]. Percutaneous techniques involve multiple smaller incisions through which the tendon is repaired. There are multiple techniques described [191,192,193], but few quality trials.

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SURGERY FOR TREATMENT OF ACHILLES TENDON RUPTURE

Recommended

Surgical repair is recommended for treatment of ruptured Achilles tendon. (The mixed results of the data supporting operative and non-operative care should be discussed with patients when covering treatment options. Discussion should include the numbers needed to treat or harm or likelihood that they will benefit from surgical care versus non-surgical care – 1 in 11, or be harmed by surgical care – 1 in 3), and the equivocal superiority of surgical compared to non-operative treatment.)

Strength of evidence Recommended, Evidence (C)
Level of confidence Moderate

Indications

A confirmed rupture of an Achilles tendon (based on history, physical examination, and imaging studies such as MRI and ultrasound) is the sole indication because repair is recommended in nearly all cases.

Rationale

There are five moderate-quality trials comparing non-operative management with surgical repair for ruptured Achilles tendons (Moller et al., 2001, Cetti et al., 1993, Moller et al., 2002, Metz et al., 2008, Twaddle et al., 2007, Moller et al., 2002, Metz et al., 2007). One trial suggested surgical management was superior to non-operative management for reducing risk of re-rupture (Moller et al., 2001, Moller et al., 2002), but did not have an important aspect of care (timing of casting and mobilization) held constant. In the other trials, there appeared to be a non-statistically significant trend towards higher re-rupture rates among the non-operative groups (there were no trials suggesting higher risk of re-rupture in the surgical groups) (Cetti et al., 1993, Metz et al., 2008, Twaddle et al., 2007, Metz et al., 2007).

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However, non-operative management appears to be effective in most patients (Moller et al., 2001, Cetti et al., 1993, Moller et al., 2002, Twaddle et al., 2007, Moller et al., 2002). There are few trials on casting and splinting or bracing. One moderate-quality study compared functional splinting with casting and reported higher satisfaction in the bracing compared with casting (Saleh et al., 1992). No differences in re-rupture rates or complications were found. There was a significant difference in dorsiflexion range of motion favoring the splinting group, although the clinical significance of this finding is unknown. The bracing group also self-reported shorter time required to be able to walk comfortably indoors and outdoors. However, this was a small study and was not a randomized crossover trial, which limits the utility to make a recommendation for one method over another. Thus, both methods are recommended as they are non-invasive, have similar long-term efficacy, and are reported as an effective treatment arm in other studies. Use of splinting is now becoming more common, with the primary advantage being patient preference.

One high-quality trial evaluated early weight bearing comparing non-operative immediate weight bearing using an orthosis to the use of a non-weight bearing rigid cast over a 12-week treatment period (Costa et al., 2006). Both groups were placed in the equinus position for 6 weeks followed by reduction of 1.5 inches every 2 weeks until the ankle was in a neutral position at 12 weeks. Evaluations at 3, 6, and 12 months did not demonstrate any significant differences in walking, stair climbing, return to work, return to sport, quality of life scores, or deficits in range of motion or torque. From this single study, it appears early weight bearing using the protocol described did not result in a significant benefit or adverse effect. Therefore, there is no recommendation for immediate weight bearing over rigid immobilization. Early weight bearing was found to provide functional improvement over rigid immobilization after surgical repair (see Post-Operative Care), but further evidence is needed to make a similar recommendation for non-operative care.

Because the functional results are superior, surgical repair is recommended for nearly all confirmed cases of Achilles tendon rupture (based on history, physical examination, and imaging studies such as MRI and ultrasound).

Evidence

There are 5 moderate-quality RCTs or quasi-randomized controlled trials incorporated into this analysis.

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OPEN AND PERCUTANEOUS OPERATIVE APPROACHES FOR ACHILLES TENDON RUPTURE REPAIR

Recommended

Open repair and percutaneous approaches are recommended for patients undergoing operative repair of Achilles tendon ruptures. There is no recommendation of one approach over the other.

Strength of evidence Recommended, Evidence (C)
Level of confidence Moderate

Rationale

There are two moderate-quality studies that compare open to a percutaneous approach for tenorrhaphy and both studies do not show clear evidence of superiority of one approach over the other (Lim et al., 2001, Gigante et al., 2008). In a moderate- quality trial of 60 repaired tendons, there were no differences found in functional recovery, rerupture or time to return to sports (Lim et al., 2001). However, there were more infections in the open repair group (21% versus 0%). In a second moderate-quality trial of 40 patients, equivocal results were again demonstrated between the two repair techniques, with no differences despite different post-operative immobilization durations (Gigante et al., 2008). Thus, there is currently insufficient evidence to recommend one approach over the other, and both are recommended. Potential advantages for percutaneous repairs include shorter procedure time completed under local anesthesia without a tourniquet (Gigante et al., 2008), cosmetic results, and fewer wound complications. There is one moderate-quality study on suture technique of end-to-end repair which found no difference in a reinforced continuous 6-strand suture technique compared with a simple Mason technique (Mortensen et al., 1992). Thus, there is no recommendation for any particular suture type or technique in end-to-end repairs.

There are two moderate-quality trials that compare open procedure end-to end suture techniques versus augmentation of repair using either a portion of the plantaris tendon or down-turned gastrocnemius fascia flap in patients with acute ruptures (Aktas et al., 2007, Pajala et al., 2009). From both trials, no additional advantages were gained from augmentation as measured by functional improvement or reruptures after long-term follow-up. Augmentation presumptively has higher risk of deep tissue infection, deep venous thrombosis, and delayed wound healing as the incision site may cross more poorly vascularized skin (Maffulli, 2005, Zell et al., 2000, Nilsson-Helander et al., 2008). These two trials did not demonstrate significant differences in adverse outcomes. Functional deficits at the tendon donor site may also be of concern (Hahn et al., 2008, Richardson et al., 2009), although the trials did not demonstrate these deficits. There is no quality evidence for or against the use of augmentation in repairing chronic or neglected ruptures. Increased tensile strength over suture alone is reported in cadaveric studies (Lee et al., 2008, Barber et al., 2008, Gebauer et al., 2007). Therefore, there is evidence that augmentation repair for acute injury tendon repair is not recommended due to lack of demonstrated benefit. There is insufficient evidence to recommend for or against using augmentation techniques for chronic or neglected ruptures, and there may be surgical situations in which the only option

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for repair is augmentation. Further studies regarding improvement of function, adverse effects including re-rupture rates, and donor site functional deficits are required.

AUGMENTED SURGICAL REPAIR FOR ACUTE ACHILLES TENDON RUPTURES

Not Recommended

Augmented repair is not recommended for acute ruptures unless primary repair is not possible.

Strength of evidence Not Recommended, Evidence (C)
Level of confidence Moderate

Rationale

There are two moderate-quality studies that compare open to a percutaneous approach for tenorrhaphy and both studies do not show clear evidence of superiority of one approach over the other (Lim et al., 2001, Gigante et al., 2008). In a moderate- quality trial of 60 repaired tendons, there were no differences found in functional recovery, rerupture or time to return to sports (Lim et al., 2001). However, there were more infections in the open repair group (21% versus 0%). In a second moderate-quality trial of 40 patients, equivocal results were again demonstrated between the two repair techniques, with no differences despite different post-operative immobilization durations (Gigante et al., 2008). Thus, there is currently insufficient evidence to recommend one approach over the other, and both are recommended. Potential advantages for percutaneous repairs include shorter procedure time completed under local anesthesia without a tourniquet (Gigante et al., 2008), cosmetic results, and fewer wound complications. There is one moderate-quality study on suture technique of end-to-end repair which found no difference in a reinforced continuous 6-strand suture technique compared with a simple Mason technique (Mortensen et al., 1992). Thus, there is no recommendation for any particular suture type or technique in end-to-end repairs.

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chronic or neglected ruptures, and there may be surgical situations in which the only option for repair is augmentation. Further studies regarding improvement of function, adverse effects including re-rupture rates, and donor site functional deficits are required.

AUGMENTED SURGICAL REPAIR FOR CHRONIC OR NEGLECTED ACHILLES TENDON RUPTURES

No Recommendation

There is no recommendation for or against the use of augmented repair for chronic or neglected ruptures.

Strength of evidence No Recommendation, Insufficient Evidence (I)
Level of confidence Low

Rationale

There are two moderate-quality studies that compare open to a percutaneous approach for tenorrhaphy and both studies do not show clear evidence of superiority of one approach over the other (Lim et al., 2001, Gigante et al., 2008). In a moderate- quality trial of 60 repaired tendons, there were no differences found in functional recovery, rerupture or time to return to sports (Lim et al., 2001). However, there were more infections in the open repair group (21% versus 0%). In a second moderate-quality trial of 40 patients, equivocal results were again demonstrated between the two repair techniques, with no differences despite different post-operative immobilization durations (Gigante et al., 2008). Thus, there is currently insufficient evidence to recommend one approach over the other, and both are recommended. Potential advantages for percutaneous repairs include shorter procedure time completed under local anesthesia without a tourniquet (Gigante et al., 2008), cosmetic results, and fewer wound complications. There is one moderate-quality study on suture technique of end-to-end repair which found no difference in a reinforced continuous 6-strand suture technique compared with a simple Mason technique (Mortensen et al., 1992). Thus, there is no recommendation for any particular suture type or technique in end-to-end repairs.

There are two moderate-quality trials that compare open procedure end-to end suture techniques versus augmentation of repair using either a portion of the plantaris tendon or down-turned gastrocnemius fascia flap in patients with acute ruptures (Aktas et al., 2007, Pajala et al., 2009). From both trials, no additional advantages were gained from augmentation as measured by functional improvement or reruptures after long-term follow-up. Augmentation presumptively has higher risk of deep tissue infection, deep venous thrombosis, and delayed wound healing as the incision site may cross more poorly vascularized skin (Maffulli, 2005, Zell et al., 2000, Nilsson-Helander et al., 2008). These two trials did not demonstrate significant differences in adverse outcomes. Functional deficits at the tendon donor site may also be of concern (Hahn et al., 2008, Richardson et al., 2009), although the trials did not demonstrate these deficits. There is no quality evidence for or against the use of augmentation in repairing chronic or neglected ruptures. Increased tensile strength over suture alone is reported in cadaveric studies (Lee et al., 2008, Barber et al., 2008, Gebauer et al., 2007). Therefore, there is evidence that augmentation repair for

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acute injury tendon repair is not recommended due to lack of demonstrated benefit. There is insufficient evidence to recommend for or against using augmentation techniques for chronic or neglected ruptures, and there may be surgical situations in which the only option for repair is augmentation. Further studies regarding improvement of function, adverse effects including re-rupture rates, and donor site functional deficits are required.

DEEP VENOUS THROMBOSIS (DVT) PROPHYLAXIS

Thromboembolic events following lower-limb immobilization for musculoskeletal conditions have been reported as a common adverse effect [194,195,196], although the greatest reported risks have been among hip and knee arthroplasty and hip fracture patients (see Hip and Groin Disorders guideline). The incidence of symptomatic deep venous thrombosis after surgical treatment of Achilles tendon rupture has been reported to be between 7 and 19% [16,195]. Incidence of asymptomatic thromboembolic events based on ultrasound phlebography or color Doppler has been reported to be approximately 34% [16,196] with no differences reported between surgical or non-operative treatment groups [196]. Despite the high number of asymptomatic events, few progress to clinically symptomatic venous thrombosis or post-thrombotic syndrome [197]. There are no widely accepted recommendations for thromboprophylaxis in patients with lower limb injury or surgery [196].

PROPHYLAXIS FOR PREVENTION OF DEEP VENOUS THROMBOSIS

Recommended

Prophylaxis is recommended for the prevention of deep venous thrombosis.

Strength of evidence Recommended, Evidence (C)
Level of confidence High

Indications

Patients with predisposing risks for developing venous thrombosis events. High-risk populations are not well defined currently, and therefore require a high degree of physician and patient judgment. A low threshold for prophylaxis may be appropriate for patients with prior history of thrombolic and thromboembolic events, delayed rehabilitation or ambulation, obesity, diabetes, or other coagulation disorders.

Rationale

There is no quality evidence that prophylaxis is beneficial in preventing symptomatic deep venous thrombosis. However, there is one high-quality study that demonstrated a significantly reduced risk of venography diagnosed DVT (asymptomatic events) in patients with immobilized lower limbs treated for fractures or Achilles tendon ruptures (Lassen et al., 2002), although the analysis did not describe prevention of symptomatic DVT. Another high-quality trial of DVT prophylaxis with a different low molecular weight heparin (dalteparin) did not demonstrate a difference in total thromboembolic events as diagnosed by ultrasound phlebography compared with placebo (Lapidus et al., 2007). Furthermore, these two studies differed in duration of immobilization (6 weeks versus 3 weeks). Asymptomatic venous thrombosis events appear to be common after immobilization for Achilles rupture

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repair, although the incidence of symptomatic events is much lower, and quality evidence for strategies to prevent symptomatic DVT have not been established. Therefore, there is no recommendation for routine use of prophylaxis for Achilles rupture patients. A low threshold for use of prophylaxis may be indicated in patients with additional risk factors for venous thrombosis, such as previous thromboembolism, visible varicose veins, hypertension, hypercholesterolemia, current use of oral contraceptives, current hormone-replacement therapy, diabetes mellitus, or current smoking (Lassen et al., 2002) (see Hip and Groin Disorders guideline for discussion of DVT prophylaxis).

Evidence

There are 2 high-quality RCTs incorporated into this analysis.

THROMBOSIS PROPHYLAXIS FOR PREVENTION OF DEEP VENOUS THROMBOSIS

No Recommendation

There is no recommendation for or against the use of the most common types of prophylaxis, including warfarin, heparin, low molecular weight heparin, graded compression stockings, aspirin, or Factor Xa to prevent deep venous thrombosis.

Strength of evidence No Recommendation, Insufficient Evidence (I)
Level of confidence Low

Rationale

There is no quality evidence that prophylaxis is beneficial in preventing symptomatic deep venous thrombosis. However, there is one high-quality study that demonstrated a significantly reduced risk of venography diagnosed DVT (asymptomatic events) in patients with immobilized lower limbs treated for fractures or Achilles tendon ruptures (Lassen et al., 2002), although the analysis did not describe prevention of symptomatic DVT. Another high-quality trial of DVT prophylaxis with a different low molecular weight heparin (dalteparin) did not demonstrate a difference in total thromboembolic events as diagnosed by ultrasound phlebography compared with placebo (Lapidus et al., 2007). Furthermore, these two studies differed in duration of immobilization (6 weeks versus 3 weeks). Asymptomatic venous thrombosis events appear to be common after immobilization for Achilles rupture repair, although the incidence of symptomatic events is much lower, and quality evidence for strategies to prevent symptomatic DVT have not been established. Therefore, there is no recommendation for routine use of prophylaxis for Achilles rupture patients. A low threshold for use of prophylaxis may be indicated in patients with additional risk factors for venous thrombosis, such as previous thromboembolism, visible varicose veins, hypertension, hypercholesterolemia, current use of oral contraceptives, current hormone-replacement therapy, diabetes mellitus, or current smoking (Lassen et al., 2002) (see Hip and Groin Disorders guideline for discussion of DVT prophylaxis).

Evidence

There are 2 high-quality RCTs incorporated into this analysis.

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REHABILITATION

Postoperative management is controversial, with debate over rigid immobilization versus functional bracing, the timing for initiating weight bearing, the optimal initial plantarflexion angle of the foot, the progression of dorsiflexion allowance, and the length of time required in cast or brace [25,35,163,166,198,199]. Prolonged immobilization carries an increased risk of complications including joint stiffness, muscle atrophy, scar adhesion and deep venous thrombosis [176]. Immobilization of the muscle body in a shortened position (equinus) has been demonstrated to produce atrophy within 4 weeks [200,201].

EARLY WEIGHT-BEARING FOR POSTOPERATIVE REHABILITATION OF ACHILLES TENDON REPAIR

Recommended

Early weight bearing is strongly recommended as a primary treatment method for post-operative rehabilitation of Achilles tendon ruptures for functional bracing or rigid immobilization.

Strength of evidence Strongly Recommended, Evidence (A)
Level of confidence High

Indications for discontinuation

Rerupture, surgical complications, physical ability.

Rationale

There is one high-quality and two moderate-quality trials comparing early weight bearing post-operatively with non-weight bearing rehabilitation protocols (Costa et al., 2006, Suchak et al., 2008, Costa et al., 2003). These studies all report benefits of early weight bearing without increases in adverse effects. The high-quality trial allowed weight bearing beginning at two weeks compared to non-weight bearing plus ROM exercises for 6 weeks and found higher functional and quality of life scores (RAND-36 Scale) at 6 weeks than the controls. Two moderate-quality studies also found immediate weight bearing was well tolerated with no significant differences in complication rates (Costa et al., 2003) and resulted in faster recovery times as measured by resumption of normal walking (12.5 versus 18 weeks, p = 0.027) and stair climbing (13 versus 22 weeks, p = 0.023) (Costa et al., 2006). Thus, there is strong evidence that early immobilization is beneficial for short-term functional recovery, may result in increased mobility of the patient with improved quality of life, can be achieved with no incremental cost increase, and has no demonstrated increase in complication rates. There is no evidence that early weight bearing reduces the other risks reported with prolonged immobilization – stiffness in the ankle joint, calf atrophy, DVT and embolism, rerupture, deep infection, or skin necrosis (see Hip and Groin Disorders guideline for DVT prophylaxis).

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FUNCTIONAL BRACING FOR POSTOPERATIVE REHABILITATION OF ACHILLES TENDON REPAIR

Recommended

Functional splinting (bracing) is moderately recommended as a primary treatment method for post-operative care of Achilles tendon ruptures.

Strength of evidence Moderately Recommended, Evidence (B)
Level of confidence Moderate

Indications

All post-operative Achilles tendon repairs.

Frequency/Dose/Duration

Apply 0 to 2 weeks post-operative.

Indications for discontinuation

Discomfort, non-compliance, device intolerance.

Rationale

There are five moderate-quality trials comparing non-operative management with surgical repair for ruptured Achilles tendons (Moller et al., 2001, Cetti et al., 1993, Moller et al., 2002, Metz et al., 2008, Twaddle et al., 2007, Moller et al., 2002, Metz et al., 2007). One trial suggested surgical management was superior to non-operative management for reducing risk of re-rupture (Moller et al., 2001, Moller et al., 2002), but did not have an important aspect of care (timing of casting and mobilization) held constant. In the other trials, there appeared to be a non-statistically significant trend towards higher re-rupture rates among the non-operative groups (there were no trials suggesting higher risk of re-rupture in the surgical groups) (Cetti et al., 1993, Metz et al., 2008, Twaddle et al., 2007, Metz et al., 2007).

Khan pooled data from three studies into a summary odds ratio and 95% confidence limit derived from the meta-analysis, which showed that non-surgical treatment was likely to result in 3.7 times more reruptures than surgical treatment; however, overall rerupture rates are low enough in surgical and non-surgical reapproximation methods to make 11 operations necessary to avoid one rerupture (Khan et al., 2005). Additionally, simple arithmetic summing of their data allowed calculation of an overall rerupture and infection rates, which are described above. The evidence indicates surgery reduces risk of re-rupture compared to non-operative treatment, but given a low overall rerupture rate, the effect is not dramatic.

One trial found no difference in lost time (Cetti et al., 1993), and two reported less lost time with the surgical group (Moller et al., 2001, Moller et al., 2002, Metz et al., 2008, Moller et al., 2002). A low-quality RCT also documented less lost time in the surgically repaired group

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(Nistor, 1981). One noted time-to-return-to-work favored the subset of population performing light work that received surgery (35.7 days versus 67.2 days), but the advantage was equivocal in sedentary and heavy job classifications. Overall, the studies suggest that persons in jobs that require mobility may benefit from surgical repair (Moller et al., 2001, Moller et al., 2002, Moller et al., 2002). One author suggested early mobilization is the most important factor in treating ruptured Achilles tendons (Twaddle et al., 2007). Möeller investigated differences in tendon healing based with MRI and ultrasound studies (Moller et al., 2002) and found no differences of partial defect, tendon thickness, homogenicity, tendinous edema, peritendinous reaction, or pattern of motion and the type of treatment received.

However, non-operative management appears to be effective in most patients (Moller et al., 2001, Cetti et al., 1993, Moller et al., 2002, Twaddle et al., 2007, Moller et al., 2002). There are few trials on casting and splinting or bracing. One moderate-quality study compared functional splinting with casting and reported higher satisfaction in the bracing compared with casting (Saleh et al., 1992). No differences in re-rupture rates or complications were found. There was a significant difference in dorsiflexion range of motion favoring the splinting group, although the clinical significance of this finding is unknown. The bracing group also self-reported shorter time required to be able to walk comfortably indoors and outdoors. However, this was a small study and was not a randomized crossover trial, which limits the utility to make a recommendation for one method over another. Thus, both methods are recommended as they are non-invasive, have similar long-term efficacy, and are reported as an effective treatment arm in other studies. Use of splinting is now becoming more common, with the primary advantage being patient preference.

One high-quality trial evaluated early weight bearing comparing non-operative immediate weight bearing using an orthosis to the use of a non-weight bearing rigid cast over a 12-week treatment period (Costa et al., 2006). Both groups were placed in the equinus position for 6 weeks followed by reduction of 1.5 inches every 2 weeks until the ankle was in a neutral position at 12 weeks. Evaluations at 3, 6, and 12 months did not demonstrate any significant differences in walking, stair climbing, return to work, return to sport, quality of life scores, or deficits in range of motion or torque. From this single study, it appears early weight bearing using the protocol described did not result in a significant benefit or adverse effect. Therefore, there is no recommendation for immediate weight bearing over rigid immobilization. Early weight bearing was found to provide functional improvement over rigid immobilization after surgical repair (see Post-Operative Care), but further evidence is needed to make a similar recommendation for non-operative care.

POSTOPERATIVE TRANSCUTANEOUS ELECTRICAL NERVE STIMULATION (TENS) FOR ACHILLES TENDON REPAIR

No Recommendation

There is no recommendation for or against the use of TENS as a post-operative treatment for Achilles tendon rupture.

Strength of evidence No Recommendation, Insufficient Evidence (I)
Level of confidence Low

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Rationale

There are two moderate-quality reports from the same trial population of 20 surgically repaired tendons that describe the use of burst TENS in the post-operative period to stimulate tendon healing (Burssens et al., 2005, Burssens et al., 2003). The treatment group received 30-minute TENS treatment sessions 5 times a week in the second and third week post-operatively while the control received sham TENS sessions. The author reported increased numbers of fibroblasts (Burssens et al., 2003) and increased collagen production and deposition (Burssens et al., 2005) in the TENS group compared with the control. However, no clinical or functional outcomes were provided, making these results of unknown application. Thus, although TENS treatment is non-invasive with few reported adverse effects, there is no defined benefit for promoting the healing process and therefore, there is no recommendation for or against its use.

ANKLE AND FOOT FRACTURE

OVERVIEW

The physician should attempt to obtain detailed information on mechanism of injury, symptoms, previous injury, and pertinent past medical history. The mechanism of injury includes defining forces associated with the injury. Symptoms and the progress of symptoms over time should be documented, including pain at initial injury, ability to continue work activities, and pain quality over time [(202)].

A careful observation of the exposed extremity and systematic examination should be performed, including observation for soft tissue trauma, laceration, foreign body, edema, ecchymosis, deformity, and open fracture. Palpation of bony structures should include the length of the tibia and fibula, the medial and lateral malleoli, mortise syndesmosis, anterior calcaneus, lateral and posterior talus and the base of fifth metatarsal. Range-of-motion testing includes plantar flexion, and dorsiflexion. Pain in the heel of the foot may signify calcaneal fracture. The calcaneal squeeze test will elicit pain.

Ankle fractures are most often caused eversion and inversion of the ankle. Rupture of the distal tibiofibular syndesmosis frequently occurs in association with external rotation ankle injuries and may give a history of pain in the high ankle [(203)]. Calcaneus fractures are most often associated with falls from heights or motor vehicle crashes [(75)]. The patient will have significant pain in the foot/ankle with a history of a high impact injury. Because of axial transmission of force, these patients should be evaluated for spinal and visceral injuries. Tarsal fractures occur with both inversion and eversion type injuries and are characterized by pain in the hind and mid foot [(204)]. Distal phalanx fractures are associated with a crush injury or perpendicular shearing force injury to the toe. The history of stress fractures often includes increased physical activity or increase in intensity of activity preceding symptoms [(205,206,207,208)]. Navicular stress fracture and metatarsal stress fractures present as insidious onset of midfoot pain or forefoot pain with weight bearing [(204,209)].

It is important that clinicians understand the basic anatomy of the ankle and foot in order to assess injuries. The physician performing an initial evaluation of a patient with ankle injury should seek to identify conditions that require immediate treatment [(210)]. It is best to have a systematic approach to assessing a patient with ankle/foot injuries. Conditions that require

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immediate attention include open fracture, vascular compromise, compartment syndrome, and joint dislocation.

Most ankle fractures are produced by abnormal motion of the talus, which either pushes off, or, by means of ligamentous attachments, pulls off an alveolus [211]. There are multiple classification systems for describing fracture around the ankle and distal lower extremity although most practitioners now refer to the AO/Weber system and the Lauge-Hansen system. The AO/Weber classification system describes the location and type of fracture by the level of fibular fracture relative to the syndesmosis or plafond. (The plafond is the inferior surface of the tibia and fibula – literally, the "base plate.") According to this system, a Type A fracture is below the level of syndesmosis, Type B fracture is at the level of syndesmosis, and Type C fracture is above the syndesmosis. Type A is most commonly caused by internal rotation and adduction. Type B commonly results from external rotation, and is associated with or without tibiofibular ligament Type C are commonly from adduction (C-1), causing mediolateral oblique break above a ruptured tibiofibular ligament. Type C-2 results from abduction and external rotation, producing more extensive interosseous rupture and more extensive fracture high on the fibular. Type C injuries can also be associated with deltoid ligament rupture [211,212,213].

The Lauge-Hansen classification system is described as a tool to predict the mechanism and injury pattern of ankle fractures based on the position of the foot and the deforming force at the time of injury and on the x-ray findings [214,215,216,217]. These patterns include supination-external rotation, pronation external rotation, and supination adduction.

Both of these classification systems are noted to have significant shortfalls and therefore are used as guides rather than absolute rules in determining management course. Isolated medial malleolar fractures and pilon fracture do not fit into the Weber classification system. Further, the Weber Classification has not been found to be an accurate predictor of complex bimalleolar and trimalleolar fractures, and the Lauge-Hansen classification prediction model has been demonstrated to have significant discrepancies of predicted injury with actual injury [213,214,215,218,219,220]. Ultimately, the outcome of ankle and foot fractures is dependent on proper identification of mechanism of injury and restoration of ankle function through accurate realignment of normal articulations, and stable reconstruction of the syndesmosis and joint surface [221,222,223,224]. Stability of the ankle injury is assessed by the integrity of the "ring" around the ankle joint, consisting of the syndesmosis, lateral malleolus, medial malleolus, and stabilizing ligaments. A disruption in one place along the ring is generally considered stable, whereas integrity compromise in two locations is unstable and may result in dislocation and poor outcome if not managed appropriately. In general, undisplaced or minimally displaced injuries are treated non-operatively, whereas displaced or unstable injuries are treated operatively [42,225]. Complications of ankle and foot fractures include decreased range of motion, post-traumatic osteoarthritis, pain, persistent pain despite hardware removal, progressive talar instability, and malunions with concomitant syndesmotic widening [42,226,227,228,229,230].

DISTAL TIBIA AND FIBULA FRACTURES

Tibial fractures usually result from injuries associated with rotation and high force, and therefore isolated fractures of the distal tibia metaphysis are uncommon. Tibial fractures involving the tibial plafond result from low or high-energy injuries, and can be described with either classification scheme or as a pilon fracture.

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Pilon fractures of the tibia result from a high-energy injury such as a fall from heights or motor vehicle accident. The resultant high-energy forces are transmitted axially, causing the talus to impact the tibial articular surface, resulting in fracture of the distal tibia [46]. Pilon fractures are often associated with other fractures of the fibula and malleolar fractures, as well as syndesmotic disruption, resulting in challenging orthopedic management scenarios [231]. Intra-articular tibial fractures may result in posttraumatic osteoarthritis and decreased ankle function [46,232]. The fractures may be simple or comminuted. As fractures of the ankle resulting from axial force may appear deceptively-simple if only limited x-ray views are obtained, multiple x-ray views of the ankle or a CT scan should be obtained in the context of a fracture resulting from high-axial-force.

FIBULA FRACTURE

Fractures of the fibula are commonly caused by eversion injuries with ankle sprain, and may be in isolation or associated with tibia fractures. The Maisonneuve fracture, considered to be one of the most unstable ankle injuries [233], occurs when an external rotational force is applied to the fixed foot. The course of damaged tissue runs from the tibia, fractured at the ankle, up through the interosseous membrane and ends with a fracture of the proximal third of the fibula, and may result in unstable syndesmosis and bony avulsion or disruption of the syndesmotic ligaments [234,235,236].

MALLEOLAR FRACTURES

Malleoloar fractures have varied presentations, ranging from isolated fibular fracture with no displacement to trimalleolar fracture with dislocation and vascular compromise [223]. Isolated lateral malleolar fractures usually result from supination-external rotation (SER) injury and may include deltoid ligament rupture [237]. Isolated medial malleolar fractures may appear stable initially but have a tendency to displace [47]. Stress fractures of the medial malleolus and distal fibula are rare but may occur [205]. Posterior malleolar fractures are often missed and are highly variable [238].

A displaced fracture of only one malleolus is associated with ligamentous injury of either the syndesmotic ligament, deltoid ligament complex, or both [211]. A single break in the “ring” is usually stable, allowing for conservative treatment [211,239].

HIND FOOT FRACTURES

TALUS FRACTURE

The talus is a small, irregularly shaped bone whose surface area is covered 60 to 70% with articular cartilage. It transfers vertical weight bearing forces to horizontal support structures of the foot through major articulations with the heel and ankle [240]. Because of its key position, diagnosis and treatment of talus fractures is critical for foot and ankle function. Fracture of the talus may involve the head, neck, body, or lateral process (snowboarder fracture). Half of all talus fractures are of the neck, which are extra-articular [240]. Complications of talus fractures include infection, malunion, posttraumatic arthritis, osteonecrosis, and talar collapse. Avascular necrosis is the most clinically significant complication [241]. Osteochondral injuries occur where bone and cartilaginous fragments separate from the dome of the talus. These should be suspected when chronic pain, stiffness, weakness or instability continues for weeks to months following ankle trauma [223,242]. Physical findings may include effusion, pain, crepitus, pain with palpation of the corresponding ankle gutter, pain or limited motion of the ankle joint [243].

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CALCANEUS FRACTURE

The Calcaneus is the most frequently fractured tarsal bone and accounts for 60% of all tarsal bone fractures. Calcaneus fractures account for 1 to 2% of all fractures in adults, and often occur in industrial workers most typically jumping or falling from heights or involved in motor vehicle accidents [75,76,77,78,79,80]. The majority of calcaneus fractures occur in falls from a height of 6 feet or greater [81]. Displaced intraarticular fractures account for 60 to 75% of the total calcaneal fractures. Approximately 8 to 10% of all displaced intra-articular calcaneal fractures are bilateral [75,76,78,82,83]. These fractures typically occur due to axial loading in men 30 to 60 years of age and usually have a poor outcome [81,83,84]. The percentage of calcaneal fracture that occurs while at work has been estimated to be 36 to 50% [76].

MIDFOOT FRACTURES

NAVICULAR FRACTURES

There are three types of fractures of the navicular including avulsion, tuberosity, and body fractures. Fractures of the body are more severe as they are related to disruption of the talonavicular and cuneonavicular joints [244].

TARSAL METATARSAL FRACTURES

Injuries to the tarsal metatarsal complex includes injury to all of the bones and joints directly or indirectly involved in a tarsometatarsal fracture-dislocation, including cuneiforms, cuboid, and navicular [245]. Fracture and dislocation of the base of the metatarsals-tarsal joint is also known as a Lisfranc injury, and is usually a result of stepping into a hole, twisting the foot or from a fall from height. Frequent cause of Lisfranc injury is when the patient has their foot on the brake and is involved in a car accident.

METATARSAL FRACTURES

Metatarsal fractures are usually the result of inversion injury, fall from height or dropping an object on the forefoot [244,246,247]. Risk factors for poor outcomes include displacement greater than 2mm, high body mass index, female gender, and diabetes [246].

FIFTH METATARSAL INJURIES

Fifth metatarsal injuries are the most common foot fracture. Fifth metatarsal fractures are characterized by where they occur relative to the tuberosity. Avulsion fractures of the tuberosity are the most common fractures of the proximal 5th metatarsal. They occur after forced inversion with the foot and ankle in plantar flexion [248]. Metatarsal head fractures are rare; they often have a history of direct trauma [204].

JONES FRACTURE

Fractures at the metaphyseal-diaphyseal border are known as a Jones fracture. They are often associated with both eversion and inversion ankle injuries. Stress fractures typically occur in the diaphysis of the metatarsal.

PHALANGEAL FRACTURES

Injuries to the toes are usually secondary to stubbing injuries and direct blows from crush injuries [244].

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STRESS FRACTURES

Stress fractures are thought to occur from overuse with excessive and repetitive muscular forces being applied to the bone. The two most common areas for stress fractures are the calcaneus and metatarsals [244]. Stress fractures of the medial malleolus and distal fibula also are reported but are infrequent [205,206,207,208]. These appear to be caused by combination of muscular forces and axial loading. Stress fractures may also occur in the navicular bone [206,207,208,209,249].

DIAGNOSTIC RECOMMENDATIONS

X-RAY FOR SUSPECTED ACUTE ANKLE FRACTURES

Recommended

X-ray is recommended for suspected acute ankle fracture as a first-line study. Anteroposterior, lateral, and mortise radiographs should be obtained.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence High

Indications

Suspicion of fracture; Ottawa rules to determine likelihood of acute fracture. Presence of acute ankle edema greater than 13 to 15mm compared to uninjured ankle may indicate occult fracture.

Rationale

There are no quality studies comparing x-ray to clinical examination for evaluation of suspected fracture. However, x-ray is the recommended initial imaging study for suspected fracture. For ankle and foot sprain injuries, the Ottawa Ankle Rules are widely used as a screening tool to predict the absence of fracture (see Ankle Sprain for further discussion). X-ray is recommended for all acute fractures as an initial diagnostic study.

Evidence

There are no quality studies incorporated into this analysis.

MAGNETIC RESONANCE IMAGING (MRI) FOR DISTAL LOWER EXTREMITY AND ANKLE FRACTURES

Recommended

MRI is recommended for investigation of distal lower extremity and ankle fractures. MRI may be indicated for acute or subacute fracture to evaluate soft tissue/ligament trauma in complex displaced or comminuted, or if stability of fracture is uncertain and MRI will guide management decisions.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence Moderate

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Indications

For acute or subacute fracture to evaluate soft tissue/ligament trauma in complex displaced or comminuted, or if stability of fracture is uncertain and MRI will guide management decision.

Rationale

There is no quality evidence that MRI is superior to radiographs for the initial detection of ankle fractures and should not be used as a first-line imaging technique. Upon confirmation of displaced, comminuted, or unstable fracture, MRI may be an important diagnostic technique for the evaluation of suspected injuries of soft tissues related to distal fibular, tibial, and malleolar fractures, such as to the syndesmotic ankle ligament complex, extensor tendons, deltoid ligament, or tibial nerve (Koval et al., 2007). MRI is recommended for these select circumstances.

Evidence

There are no quality studies incorporated into this analysis.

COMPUTED TOMOGRAPHY (CT) FOR DIAGNOSIS AND CLASSIFICATION OF ANKLE FRACTURES

Sometimes Recommended

CT is recommended for investigation of distal lower extremity and ankle fractures. CT may be indicated for suspected occult and complex ankle fractures to gain greater clarity of fracture displacement, articular involvement, and subluxation of affected joints (Catalano et al., 2004, Harness et al., 2006, Katz et al., 2001). If intraarticular displacement is considered, then axial views are recommended in addition to any coronal views (Ogawa et al., 2009).

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence Moderate

Indications

Suspected occult and complex ankle fractures; to gain greater clarity of fracture displacement, articular involvement, and subluxation of affected joints (Catalano et al., 2004, Harness et al., 2006, Katz et al., 2001). If intraarticular displacement is considered, then axial views are recommended in addition to any coronal views (Ogawa et al., 2009).

Rationale

There are no quality diagnostic studies for use of CT in distal lower extremity and ankle fractures. CT should be considered when x-ray images are negative, but on the basis of physical findings, an occult fracture is strongly suspected. CT may also be useful for evaluation of complex comminuted fractures, providing superior depiction of distal tibial

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articular surface involvement, fragment positioning, and diagnosis of subluxations (Catalano et al., 2004, Harness et al., 2006). The value of CT has been demonstrated – a 2001 study showed the use of CT scanning for evaluation of articular step off and gaping, comminution, and treatment influenced observers to change treatment plans developed from radiographs and resulted in increased interobserver reliability in the proposed management of these injuries (Katz et al., 2001). Thus, the use of CT imaging is recommended.

Evidence

There are no quality studies incorporated into this analysis.

ULTRASOUND IMAGING FOR DIAGNOSING ANKLE FRACTURE

Sometimes Recommended

Ultrasound imaging is recommended for evaluation of soft-tissue injury associated with select displaced fractures or suspected malleolar stress fractures. Ultrasound may be used for evaluation of soft-tissue injury associated with select displaced fractures to assess stability of fracture, particularly of the deltoid ligaments with medial and bimalleolar fractures (Chen et al., 2008), assessment of interosseous membrane injury associated with Weber type B and C ankle fractures (Christodoulou et al., 1995), and in detection of suspected occult or stress fractures. Also used for suspected stress fracture of the distal tibia (Wang et al., 1999, Delacerda, 1981).

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence Low

Indications

Evaluation of soft-tissue injury associated with select displaced fractures to assess stability of fracture, particularly of the deltoid ligaments with medial and bimalleolar fractures (Chen et al., 2008), assessment of interosseous membrane injury associated with Weber type B and C ankle fractures (Christodoulou et al., 1995), and in detection of suspected occult or stress fractures. Also used for suspected stress fracture of the distal tibia (Wang et al., 1999, Delacerda, 1981).

Rationale

There are no quality trials evaluating the use of ultrasound for evaluation of ankle fractures. The sensitivity and specificity for diagnosis of the rupture of the interosseous membrane is reported at 88 and 94% compared with intraoperative findings (Christodoulou et al., 1995). There is no report of sensitivity and specificity for other disorders found. Ultrasound imaging may be a useful adjuvant to clinical assessment of patients with regards to selection for further radiological examination (Chen et al., 2008), and is therefore recommended in select patients.

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Evidence

There are no quality studies incorporated into this analysis.

TREATMENT RECOMMENDATIONS

OVERVIEW

The initial treatment of foot and ankle fractures is dictated by injury type (displaced or stable, open or closed) and by concomitant soft tissue injury [47]. Closed, stable injuries are generally treated non-operatively. Open fractures require emergent debridement and antibiotic prophylaxis. Closed unstable fractures generally require operative management. Management should be initiated for severe swelling, compartment syndrome, and skin integrity breakdown from fracture blisters.

Management of non-displaced and stable fractures has traditionally been non-operative with good results. There is continued debate regarding treatment for particular fractures types that are not clearly stable or unstable [250]. Non-union of the distal fibula fracture is rare [251] lending support to a trial of conservative management for non-displaced and stable displaced fractures. Reduction failure or delayed union may require surgical intervention. Posterior malleolar fractures are often missed and are highly variable [238]. A systematic review found no consensus on fragment size and surgical indication, and concluded that restoration of medical and lateral constraints of the ankle play the major role in development of post-traumatic osteoarthritis [252]. A case series with 13-year follow-up demonstrated fixation for fractures less than 25% of posterior malleolus may not be indicated, as both groups had similar outcomes [253].

Distal lower extremity, ankle, tarsal, and foot fractures will most often result in limited or non-weight bearing for a period of time. Management of edema for some fractures, particularly hindfoot and midfoot fractures, may require prolonged elevation of the injured leg. Casting, walking boot, or external hardware can impair ability to drive, walk, perform prolonged standing, climb stairs, work at heights, climb ladders, and other similar safety sensitive activities. The length of time of restrictions depends on the fracture, intervention, and healing rate of the patient, but can last from several weeks to several months.

No quality evidence exists for specific follow-up care of ankle fractures outside of identified recommendations listed in this section. Changes in ankle girth should be monitored for reduction in swelling after the immediate injury. Changes in tissue volume may necessitate re-casting or device adjustments. The fracture should be monitored for reduction failure with subsequent radiographic studies.

ACTIVITY MODIFICATION AND EXERCISE

EARLY MOBILIZATION FOR ANKLE FRACTURES

Recommended

Early mobilization is moderately recommended in the management of post-operative and stable non-operative ankle fractures.

Strength of evidence Moderately Recommended, Evidence (B)
Level of confidence Moderate

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Indications

Stabilized malleolar fractures with or without surgery and closed ankle fractures with adequate fixation and stabilization.

Frequency/Dose/Duration

Early mobilization can be started within 1 to 3 days post-operatively (Dogra et al., 1999, Lehtonen et al., 2003, Franke et al., 2008, Egol et al., 2000, Sondenaa et al., 1986).

Rationale

There are 10 moderate-quality trials comparing early motion/mobilization with cast immobilization post operatively (Dogra et al., 1999, Lehtonen et al., 2003, Franke et al., 2008, Hedstrom et al., 1994, Ahl et al., 1986, Tropp et al., 1995, Egol et al., 2000, Sondenaa et al., 1986, DiStasio et al., 1994, Vioreanu et al., 2007, Vioreanu et al., 2006). Four of the studies demonstrated near-term benefit in pain, swelling, functional improvement, and early return to work (Egol et al., 2000, Sondenaa et al., 1986, DiStasio et al., 1994, Vioreanu et al., 2007), while the other six studies demonstrated equivocal outcomes (Dogra et al., 1999, Lehtonen et al., 2003, Franke et al., 2008, Hedstrom et al., 1994, Ahl et al., 1986, Tropp et al., 1995). One of these equivocal studies included early motion for only the first 2 weeks post-operatively, and then the group was immobilized for 4 weeks (Dogra et al., 1999). Pertaining to adverse effects of early motion, one study demonstrated an increase in superficial wound infections (Lehtonen et al., 2003) and another reported infections although power was insufficient for significance (Vioreanu et al., 2007). There were no reports of increased non-union or delayed union from early mobilization. Of these nine studies, early weight-bearing was included as a co-intervention in four of the trials. In the six studies where early weight-bearing was not allowed (Dogra et al., 1999, Tropp et al., 1995, Egol et al., 2000, Sondenaa et al., 1986, DiStasio et al., 1994, Vioreanu et al., 2007), early motion alone provided positive benefit in four studies (Egol et al., 2000, Sondenaa et al., 1986, DiStasio et al., 1994, Vioreanu et al., 2007). There is one trial that compared early weight-bearing with and without early motion that demonstrated no significant differences (Hedstrom et al., 1994). A low-quality trial of early mobilization in tibial plafond fracture with external fixators demonstrated no benefit over no mobilization (Marsh et al., 2006). Thus, there is quality evidence that early motion in the immediate post-operative may provide additional benefit in early return to work and functional recovery, and has few adverse effects other than higher risk for superficial wound infection. Therefore, early mobilization is recommended for most patients with stable or repaired malleolar ankle fracture.

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NONOPERATIVE MANAGEMENT

CAST IMMOBILIZATION FOR ANKLE FRACTURES

Recommended

Cast immobilization is moderately recommended for the management of ankle fractures.

Strength of evidence Moderately Recommended, Evidence (B)
Level of confidence High

Indications

All ankle fractures.

Frequency/Dose/Duration

Immobilization generally for 6 to 8 weeks (Dogra et al., 1999, Lehtonen et al., 2003, Franke et al., 2008, Hedstrom et al., 1994, Ahl et al., 1986, Ahl et al., 1989, Tropp et al., 1995, Honigmann et al., 2007, van Laarhoven et al., 1996).

Rationale

There are nine moderate-quality trials that compared cast immobilization to other methods, including orthosis, removable cast, and splint with and without early motion and early weight-bearing that demonstrated equivocal results (Dogra et al., 1999, Lehtonen et al., 2003, Franke et al., 2008, Hedstrom et al., 1994, Ahl et al., 1986, Ahl et al., 1989, Tropp et al., 1995, Honigmann et al., 2007, van Laarhoven et al., 1996). Cast immobilization is recommended for all patients and the use is dependent on physician and patient preference.

IMMOBILIZATION FOR NONDISPLACED ANKLE FRACTURES

Recommended

Non-operative management is recommended for the treatment of non-displaced and reduced stable ankle fractures.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence High

Indications

Non-displaced distal fibula, lateral malleolar, or pilon fractures; select non-displaced medial malleolar fracture.

Rationale

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There are no quality trials comparing non-operative with operative treatment for initially non-displaced or minimally displaced fractures. There are three moderate-quality trials that compare operative to non-operative treatment for displaced fractures after closed reduction (Makwana et al., 2001, Bauer et al., 1985, Phillips et al., 1985). A moderate-quality trial that compared operative to non-operative treatment of displaced stable fractures found similar outcomes in fixation time (6 weeks), similar union rates, and same sick-leave duration (Bauer et al., 1985). Long-term outcomes were also similar in development of arthrosis, function, and residual pain. However, the study results may be biased as significant crossover occurred after randomization as non-reducible fractures were treated operatively, but considered in the non-operative group analysis. Another moderate-quality trial comparing non-operative to open reduction and internal fixation (ORIF) care in severe ankle fractures demonstrated higher scores on the author's measurement scale for the ORIF group (Phillips et al., 1985). A moderate-quality trial demonstrated better functional outcome and range of motion at long-term follow up with ORIF for fractures that were satisfactorily reduced under general anesthesia (Makwana et al., 2001). However, there were no differences in patient satisfaction. The types of ankle fractures were otherwise not clear. The study results suggested persons over 55 years old benefit from ORIF. A low-quality trial demonstrated better functional results in non-operative group with early weight-bearing compared with ORIF (Rowley et al., 1986). Another low-quality trial of cast with early weight bearing was demonstrated to have higher functional scores than ORIF group in an elderly population (Salai et al., 2000).

A systematic review of more than 57,000 patients who had undergone ankle surgery with ORIF of lateral malleolar, bimalleolar, or trimalleolar ankle fracture demonstrated low short-term complication rates for pulmonary embolism (0.34%), mortality (1.07%), wound infection (1.44%), amputation (0.16%), and revision of ORIF (0.82%). Open injury, diabetes, and peripheral vascular disease were strong predictors of post-operative complications (SooHoo et al., 2009). Other adverse effects reported from ORIF include malunion, nonunion, syndesmotic widening, degenerative changes, and septic arthritis (Ng et al., 2009). Thus, non-operative management is recommended in select patients with non-severe fractures with minimal displacement after closed reduction. Operative fixation is recommended for patients with severe fractures, non-satisfactory closed reduction, unstable fracture, or aged 55 or greater. There are two moderate-quality trials comparing rigid immobilization with Aircast immobilization for lateral malleolar fractures that demonstrated similar functional and return to work outcomes, and both are recommended (Brink et al., 1996, Stuart et al., 1989).

IMMOBILIZATION AND REDUCTION FOR CLOSED DISPLACED ANKLE FRACTURES

Recommended

Closed reduction and immobilization is recommended for select non-comminuted closed displaced ankle fractures.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence High

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Indications

Non-comminuted closed displaced ankle fractures with post-reduction displacement less than 2 to 3mm and less than 25% posterior malleolus articular surface involvement (Rowley et al., 1986, Brink et al., 1996, Joukainen et al., 2007, Bauer et al., 1985). Generally lateral malleolar Weber A & B or Modified Lauge-Hansen severity class 1 or 2 are considered for reduction (Makwana et al., 2001, Brink et al., 1996, Phillips et al., 1985).

Rationale

There are no quality trials comparing non-operative with operative treatment for initially non-displaced or minimally displaced fractures. There are three moderate-quality trials that compare operative to non-operative treatment for displaced fractures after closed reduction (Makwana et al., 2001, Bauer et al., 1985, Phillips et al., 1985). A moderate-quality trial that compared operative to non-operative treatment of displaced stable fractures found similar outcomes in fixation time (6 weeks), similar union rates, and same sick-leave duration (Bauer et al., 1985). Long-term outcomes were also similar in development of arthrosis, function, and residual pain. However, the study results may be biased as significant crossover occurred after randomization as non-reducible fractures were treated operatively, but considered in the non-operative group analysis. Another moderate-quality trial comparing non-operative to open reduction and internal fixation (ORIF) care in severe ankle fractures demonstrated higher scores on the author's measurement scale for the ORIF group (Phillips et al., 1985). A moderate-quality trial demonstrated better functional outcome and range of motion at long-term follow up with ORIF for fractures that were satisfactorily reduced under general anesthesia (Makwana et al., 2001). However, there were no differences in patient satisfaction. The types of ankle fractures were otherwise not clear. The study results suggested persons over 55 years old benefit from ORIF. A low-quality trial demonstrated better functional results in non-operative group with early weight-bearing compared with ORIF (Rowley et al., 1986). Another low-quality trial of cast with early weight bearing was demonstrated to have higher functional scores than ORIF group in an elderly population (Salai et al., 2000). A systematic review of more than 57,000 patients who had undergone ankle surgery with ORIF of lateral malleolar, bimalleolar, or trimalleolar ankle fracture demonstrated low short-term complication rates for pulmonary embolism (0.34%), mortality (1.07%), wound infection (1.44%), amputation (0.16%), and revision of ORIF (0.82%). Open injury, diabetes, and peripheral vascular disease were strong predictors of post-operative complications . Other adverse effects reported from ORIF include malunion, nonunion, syndesmotic widening, degenerative changes, and septic arthritis . Thus, non-operative management is recommended in select patients with non-severe fractures with minimal displacement after closed reduction. Operative fixation is recommended for patients with severe fractures, non-satisfactory closed reduction, unstable fracture, or aged 55 or greater. There are two moderate-quality trials comparing rigid immobilization with Aircast immobilization for lateral malleolar fractures that demonstrated similar functional and return to work outcomes, and both are recommended (Brink et al., 1996, Stuart et al., 1989).

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CAST IMMOBILIZATION FOR TIBIAL SHAFT FRACTURES (CLOSED, DIAPHYSEAL)

No Recommendation

There is no recommendation for or against non-operative management of tibial shaft fractures.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence Low

Rationale

There is one moderate-quality trial comparing management of tibial shaft fracture using operative fixation using intramedullary nail to plaster cast. The plaster cast group was separated into those whose fractures were not displaced and a cast alone would suffice, and those whose fracture was displaced and underwent internal fixation using cerclage or screw in addition to the plaster cast (Karladani et al., 2000). The study demonstrated significantly reduced time to fracture union time and weight bearing for the group without the cast. The cast-only and cast-with-minimal internal-fixation groups both demonstrated 50% failure requiring ORIF for non-union. As the intramedullary nail appears to result in quicker healing time and return to activity, it is recommended. This study indicates that patients should be counseled on the likelihood of knee pain long-term (44% of subjects). Casting may be an alternative for some patients, but with counseling that nearly half may need surgical intervention for delayed union. There are no quality trials of one type of surgical fixation compared with another. A low-quality trial demonstrated plates to provide faster healing time compared with intramedullary nail (Fernandes et al., 2006). Described techniques include use of an intramedullary nail, external fixators, or plates and screws, and there is no recommendation of one over another, with use based on surgeon preference (Karladani et al., 2000, Fernandes et al., 2006). There appears to be no advantage to minimal fixation with screw or cerclage compared with casting (Karladani et al., 2000).

CAST IMMOBILIZATION FOR DISTAL TIBIAL EXTRA-ARTICULAR FRACTURES

Sometimes Recommended

Non-operative management is recommended in select circumstances for distal extra-articular tibial fractures.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence Moderate

Indications

Closed simple fractures with initial shortening <15mm, angular deformity after initial manipulation <5° in any plane (Zelle et al., 2006).

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Rationale

There are no quality trials comparing operative to non-operative treatment for distal extra-articular tibia fracture. A systematic review of 1,125 fractures demonstrated a low non-union rate for immobilization of 1.3 vs. 5.5% for intramedullary nailing, although there were more open fractures in the nailing group . There is one moderate-quality trial comparing the use of intramedullary nail with percutaneous locking compression plates (Guo et al., 2010), and another moderate-quality trial comparing intramedullary nail with fracture plate and screws (Im et al., 2005). There were no significant differences in functional outcomes between these interventions. Intramedullary nail was demonstrated to have few superficial infections and less angulation than plates and screws (Im et al., 2005), and shorter operating time and radiation exposure than percutaneous compression plate (Guo et al., 2010). However, there is no quality evidence that one technique is superior to the other and no recommendation is made regarding technique.

NONOPERATIVE MANAGEMENT OF TIBIAL PLAFOND AND PILON FRACTURES

Sometimes Recommended

Non-operative management for tibial plafond fractures is recommended in select patients.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence High

Indications

Non-displaced, non-comminuted, stable fracture; ability to obtain acceptable fracture alignment with closed reduction.

Rationale

Distal lower leg fractures that impinge on the articular surface with the talus are known as plafond fractures. As these fractures are often caused by axial forces driving the talus into the lower leg, they are often called “pilon” (hammer) fractures. In this section, the term “plafond fracture” will be used. There are no quality trials for operative fixation of tibial plafond fractures. A low-quality trial compared ORIF of tibial plafond fractures with external fixation with and without limited internal fixation and found no radiographic difference at 15 weeks follow-up, but did demonstrate higher wound complication rate in the ORIF group leading to 3 amputation surgeries (Wyrsch et al., 1996). These fractures are noted to have high complication rates from surgical reduction and fixation (Marsh et al., 2006). Numerous internal and external fixation techniques are described, but there is no recommendation for one method over others (Lee et al., 2008, Bozkurt et al., 2008, Dunbar et al., 2008, Evans et al., 2010, Gardner et al., 2008, Papadokostakis et al., 2008, Ruland et al., 2008, Wang et al., 2010).

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NONOPERATIVE MANAGEMENT OF SYNDESMOTIC INJURIES

Recommended

Non-operative management is recommended for stable syndesmotic injury.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence High

Indications

Absence of other destabilizing injury including ankle fracture or deltoid ligament injury (Zalavras et al., 2007, Lin et al., 2006).

Rationale

There are no quality trials for non-operative management of syndesmotic injuries. There is opinion that not all ankle syndesmotic injuries lead to ankle instability, and may not need repair in the absence of other destabilizing injury . Fixation is required in the presence of fracture . Thus, non-operative management is recommended for select patients. Operative repair is recommended for non-stable injuries, which include most syndesmotic rupture with concurrent fractures or deltoid ligament injury. There is one moderate-quality trial comparing tri-cortical screw fixation with quadri-cortical screw fixation that demonstrated no significant long-term differences, although tri-cortical fixation was demonstrated to achieve earlier partial weight bearing and less pain at 3 months follow-up (Hoiness et al., 2004). A low-quality trial comparing tri-cortical screw fixation with quadri-cortical screw fixation demonstrated no significant long-term differences (Moore et al., 2006). There are two moderate-quality trials comparing bioabsorbable screws with metallic screws for syndesmotic repair that demonstrated no differences in outcomes other than that those with metallic screws were more likely to have reoperation for screw removal (Kaukonen et al., 2005, Thordarson et al., 2001). A study of outcomes with retained compared to removed screws and broken screws demonstrated no clinical differences, calling into question the need for removal of screws . There are no other trials comparing use of other fixation techniques. Thus, there is insufficient quality evidence for recommendation of one fixation technique over another. Both metallic and bioabsorbable screws appear to provide effective treatment.

ANALGESIA FOR NONOPERATIVE REDUCTION ANKLE FRACTURES

Recommended

Adequate analgesia is recommended for performing non-operative closed reduction of ankle fractures.

Strength of evidence Recommended, Evidence (C)
Level of confidence Moderate

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Rationale

There are no quality trials evaluating reduction without analgesia. There is one quality trial that compared intraarticular block to conscious sedation for closed reduction of ankle fractures that demonstrated both techniques were effective in providing analgesia with no differences between the groups (White et al., 2008). There are no quality trials for other techniques. A non-randomized study reported similar efficacy of hematoma block with conscious sedation (Furia et al., 1997). There is insufficient evidence to recommend one technique over another, and all are recommended. Appropriate technique should be based on factors of physician experience and preference, patient history of intolerance to medications or level of anxiety, and availability of equipment and supplies.

MEDICATIONS

NSAIDS AND ACETAMINOPHEN

NSAIDS FOR ACUTE ANKLE FRACTURE ANALGESIA

Recommended

NSAIDs are recommended for analgesia of pain associated with fracture.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence High

Indications

Pain due to ankle fracture.

Frequency/Dose/Duration

Scheduled dosage rather than as needed is generally preferable.

Indications for discontinuation

Resolution of pain, lack of efficacy, development of adverse effects, particularly gastrointestinal effects.

Rationale

There is no quality evidence regarding the use of NSAIDs or acetaminophen to control pain associated with ankle fractures. However, these medications are thought to be effective for control of swelling and pain in the initial stages of injury, are not invasive, have low adverse effects, and are low cost, thus they are recommended. There is no quality evidence that selective COX-2 inhibiting NSAIDs have a negative effect on bone fracture union or functional recovery (Boursinos et al., 2009) as concerns of NSAIDs causing delayed recovery come from an early case report of indomethacin use (Sudmann et al., 1976).

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Evidence

There are no quality studies incorporated into this analysis.

ACETAMINOPHEN FOR ACUTE ANKLE FRACTURE ANALGESIA

Recommended

Acetaminophen is recommended for analgesia of pain associated with fracture.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence High

Indications

Pain due to ankle fracture.

Frequency/Dose/Duration

Scheduled dosage rather than as needed is generally preferable.

Indications for discontinuation

Resolution of pain, lack of efficacy, development of adverse effects, particularly gastrointestinal effects.

Rationale

There is no quality evidence regarding the use of NSAIDs or acetaminophen to control pain associated with ankle fractures. However, these medications are thought to be effective for control of swelling and pain in the initial stages of injury, are not invasive, have low adverse effects, and are low cost, thus they are recommended. There is no quality evidence that selective COX-2 inhibiting NSAIDs have a negative effect on bone fracture union or functional recovery (Boursinos et al., 2009) as concerns of NSAIDs causing delayed recovery come from an early case report of indomethacin use (Sudmann et al., 1976).

Evidence

There are no quality studies incorporated into this analysis.

CALCITONIN

USE OF NASAL SPRAY CALCITONIN FOR POSTFRACTURE OSTEOPENIA

Not Recommended

The use of nasal spray calcitonin is not recommended for prophylaxis of post-fracture osteopenia.

Strength of evidence Not Recommended, Evidence (C)

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Level of confidence Low

Rationale

A moderate-quality trial demonstrated nasal calcitonin obtained from salmon compared with placebo did not result in significant differences in bone mineralization 3 months after surgery (Petersen et al., 1998). Nasal salmon calcitonin is non-invasive, has few adverse effects, but is of high cost, and has not shown to be effective in preventing post-operative osteopenia; therefore, nasal calcitonin is not recommended.

OPIOIDS

LIMITED USE OF OPIOIDS FOR ACUTE AND POSTOPERATIVE PAIN MANAGEMENT

Sometimes Recommended

Limited use of opioids for acute and post-operative pain management from foot or ankle fracture is recommended as adjunctive therapy to more effective treatments (especially NSAIDs, acetaminophen, elevation, splinting).

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence Low

Indications

For acute injury and post-operative pain management, a brief prescription of opioids as adjuncts to more efficacious treatments (especially NSAIDs, acetaminophen, elevation, splinting) is often required, especially nocturnally.

Frequency/Dose/Duration

Prescribed as needed throughout the day, then later only at night, before weaning off completely

Indications for discontinuation

Resolution of pain, improvement to the point of not requiring these medications, intolerance or adverse effects, non-compliance, surreptitious medication use, or use beyond 2 to 3 weeks for less extensive procedures.

Rationale

There is no quality evidence for the use of opioids for the treatment of pain associated with acute fracture. Opioids are not invasive, but have adverse effects. They are moderate to high cost depending on duration of treatment (see Chronic Pain guideline). Quality evidence for treatment of post-operative patients with opioids is absent. Some patients have insufficient pain relief with NSAIDs, thus judicious use of opioids may be helpful, particularly for nocturnal use. Opioids are recommended for brief, select use in post-operative patients with primary use at night to achieve sleep post-operatively.

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Evidence

There are no quality studies incorporated into this analysis.

TETANUS IMMUNIZATION

TETANUS IMMUNIZATION STATUS FOR OPEN FRACTURES

Recommended

For open fractures, it is recommended that tetanus immunization status to be updated as necessary.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence High

Indications

Wounds that are not clean if more than 5 years have elapsed since last tetanus immunization (Centers for Disease Control and Prevention, 2009).

Rationale

There are no quality studies of tetanus immunization updating for these fractures. However, these immunizations are widely used and believed to have been successful on a population basis in reducing risk of tetanus over many decades. Tetanus immunizations are minimally invasive, have low adverse effects, and are low cost. As the adverse effects of not immunizing may be fatal, tetanus immunization updating for open wounds is recommended. Wounds that are not clean or burns should require immunization if more than 5 years since last immunization, rather than 10 years (Centers for Disease Control and Prevention, 2009). Patients without a completed immunization series of 3 injections should receive tetanus immune globulin along with immunization.

Evidence

There are no quality studies incorporated into this analysis.

ELECTRICAL THERAPIES

ELECTRICAL STIMULATION FOR PREVENTION OF MUSCLE ATROPHY AFTER ANKLE/FOOT FRACTURES

No Recommendation

There is no recommendation for or against the use of electrical stimulation for prevention of muscle atrophy in ankle and foot fracture management.

Strength of evidence No Recommendation, Insufficient Evidence (I)
Level of confidence Low

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Rationale

There are no quality trials for the use of electric stimulation of ankle or foot fractures. There is a low-quality trial of electrical stimulation added to post-operative ORIF for ankle fracture failed to reach statistical significance for any outcomes compared with no stimulation (Hernandez et al., 2006). It has not demonstrated clinical benefit in distal upper extremity fractures (Wahlstrom, 1984). This treatment can be invasive with implantable direct current electrodes or can be non-invasive, generally have low adverse effects, but may be costly depending on the frequency and type of treatments. There is no recommendation for the use of electrical stimulation devices for ankle and foot fractures.

ALLIED HEALTH INTERVENTIONS

HYPERBARIC OXYGEN FOR THE MANAGEMENT OF ANKLE OR FOOT FRACTURES

No Recommendation

There is no recommendation for or against the use of hyperbaric oxygen for management of ankle or foot fractures.

Strength of evidence No Recommendation, Insufficient Evidence (I)
Level of confidence Low

Rationale

There are no quality trials for the use of hyperbaric oxygen to treat ankle or foot fractures. Hyperbaric oxygen is non-invasive and generally safe, although it is high cost. It has been recommended for crush injuries of the upper extremity, although no quality evidence is available for the lower extremity. Therefore, there is no recommendation for the use of hyperbaric oxygen for routine patients for bone healing or prevention of avascular necrosis. In select patients with moderate to severe crush injuries or compartment syndrome, hyperbaric oxygen may be indicated as risks of these conditions are outweighed by potential benefits.

ULTRASOUND TO STIMULATE BONE HEALING FOR ANKLE AND FOOT FRACTURES

Not Recommended

Ultrasound is moderately not recommended for ankle and foot fracture management.

Strength of evidence Moderately Not Recommended, Evidence (B)
Level of confidence Moderate

Rationale

There is one high-quality trial for the use of ultrasound stimulation of ankle or foot fractures (Handolin et al., 2005). Ultrasound applied daily for 20 minutes compared to sham demonstrated no additional benefit in healing of lateral malleolar fractures fixed with bioabsorbable screw. Ultrasound stimulation is non-invasive, is of moderate to high cost

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depending on frequency and duration of treatment, and has low adverse effects. It is not recommended for routine use to promote bone healing.

HYPNOSIS TO PROMOTE HEALING OF ANKLE AND FOOT FRACTURES

No Recommendation

There is no recommendation for or against the use of hypnosis for the management ankle or foot fractures.

Strength of evidence No Recommendation, Insufficient Evidence (I)
Level of confidence Low

Rationale

There is one moderate-quality trial of hypnosis for promotion of fracture healing compared to a no-hypnosis group that demonstrated no significant differences as it was underpowered (Ginandes et al., 1999). Hypnosis is non-invasive, has low adverse effects, but is costly with multiple therapist visits. There is insufficient evidence for recommending hypnosis.

SURGICAL CONSIDERATIONS

SURGICAL REPAIR

OPERATIVE PROCEDURES AND FIXATORS FOR ANKLE AND FOOT FRACTURES

No Recommendation

There is no recommendation for or against the use of a specific operative product, including rods, plates, and metallic and bioabsorbable materials.

Strength of evidence No Recommendation, Insufficient Evidence (I)
Level of confidence Low

Rationale

A majority of the studies failed to find one approach superior to another and some provide conflicting results. Additionally, the variability of the types of fractures provides additional uncertainty regarding optimal intervention(s). Thus, there is no recommendation for or against the use of a specific product.

OPERATIVE FIXATION FOR CLOSED DISPLACED ANKLE FRACTURES

Recommended

Operative fixation is recommended for unstable closed displaced ankle fractures.

Strength of evidence Recommended, Evidence (C)
Level of confidence High

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Indications

Generally severe lateral fracture with medical malleolar involvement (Makwana et al., 2001, Brink et al., 1996, Phillips et al., 1985). Comminuted closed displaced ankle fractures with post-reduction displacement more than 2 to 3mm and more than 25% posterior malleolus articular surface involvement (Rowley et al., 1986, Brink et al., 1996, Joukainen et al., 2007, Bauer et al., 1985); patients 55 years of age or older (Makwana et al., 2001, Phillips et al., 1985).

Rationale

There are no quality trials comparing non-operative with operative treatment for initially non-displaced or minimally displaced fractures. There are three moderate-quality trials that compare operative to non-operative treatment for displaced fractures after closed reduction (Makwana et al., 2001, Bauer et al., 1985, Phillips et al., 1985). A moderate-quality trial that compared operative to non-operative treatment of displaced stable fractures found similar outcomes in fixation time (6 weeks), similar union rates, and same sick-leave duration (Bauer et al., 1985). Long-term outcomes were also similar in development of arthrosis, function, and residual pain. However, the study results may be biased as significant crossover occurred after randomization as non-reducible fractures were treated operatively, but considered in the non-operative group analysis. Another moderate-quality trial comparing non-operative to open reduction and internal fixation (ORIF) care in severe ankle fractures demonstrated higher scores on the author's measurement scale for the ORIF group (Phillips et al., 1985). A moderate-quality trial demonstrated better functional outcome and range of motion at long-term follow up with ORIF for fractures that were satisfactorily reduced under general anesthesia (Makwana et al., 2001). However, there were no differences in patient satisfaction. The types of ankle fractures were otherwise not clear. The study results suggested persons over 55 years old benefit from ORIF. A low-quality trial demonstrated better functional results in non-operative group with early weight-bearing compared with ORIF (Rowley et al., 1986). Another low-quality trial of cast with early weight bearing was demonstrated to have higher functional scores than ORIF group in an elderly population (Salai et al., 2000). A systematic review of more than 57,000 patients who had undergone ankle surgery with ORIF of lateral malleolar, bimalleolar, or trimalleolar ankle fracture demonstrated low short-term complication rates for pulmonary embolism (0.34%), mortality (1.07%), wound infection (1.44%), amputation (0.16%), and revision of ORIF (0.82%). Open injury, diabetes, and peripheral vascular disease were strong predictors of post-operative complications . Other adverse effects reported from ORIF include malunion, nonunion, syndesmotic widening, degenerative changes, and septic arthritis . Thus, non-operative management is recommended in select patients with non-severe fractures with minimal displacement after closed reduction. Operative fixation is recommended for patients with severe fractures, non-satisfactory closed reduction, unstable fracture, or aged 55 or greater. There are two moderate-quality trials comparing rigid immobilization with Aircast immobilization for lateral malleolar fractures that demonstrated similar functional and return to work outcomes, and both are recommended (Brink et al., 1996, Stuart et al., 1989).

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OPERATIVE FIXATION FOR TIBIAL SHAFT FRACTURE (CLOSED, DIAPHYSEAL)

Recommended

Operative fixation is recommended for definitive management of displaced tibial shaft fracture.

Strength of evidence Recommended, Evidence (C)
Level of confidence High

Indications

Displaced, comminuted distal tibial shaft fracture.

Rationale

There is one moderate-quality trial comparing management of tibial shaft fracture using operative fixation using intramedullary nail to plaster cast. The plaster cast group was separated into those whose fractures were not displaced and a cast alone would suffice, and those whose fracture was displaced and underwent internal fixation using cerclage or screw in addition to the plaster cast (Karladani et al., 2000). The study demonstrated significantly reduced time to fracture union time and weight bearing for the group without the cast. The cast-only and cast-with-minimal internal-fixation groups both demonstrated 50% failure requiring ORIF for non-union. As the intramedullary nail appears to result in quicker healing time and return to activity, it is recommended. This study indicates that patients should be counseled on the likelihood of knee pain long-term (44% of subjects). Casting may be an alternative for some patients, but with counseling that nearly half may need surgical intervention for delayed union.

There are no quality trials of one type of surgical fixation compared with another. A low-quality trial demonstrated plates to provide faster healing time compared with intramedullary nail (Fernandes et al., 2006). Described techniques include use of an intramedullary nail, external fixators, or plates and screws, and there is no recommendation of one over another, with use based on surgeon preference (Karladani et al., 2000, Fernandes et al., 2006, Keating et al., 1997). There appears to be no advantage to minimal fixation with screw or cerclage compared with casting (Karladani et al., 2000).

OPERATIVE FIXATION FOR DISTAL TIBIAL EXTRA-ARTICULAR FRACTURES

Sometimes Recommended

Operative fixation (i.e., fracture plating, intramedullary nail) is recommended for distal extra-articular tibial fractures in select patients.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence Low

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Indications

Open fractures, initial shortening >15mm, angular deformity after initial manipulation >5° in any plane (Zelle et al., 2006).

Rationale

There are no quality trials comparing operative to non-operative treatment for distal extra-articular tibia fracture. A systematic review of 1,125 fractures demonstrated a low non-union rate for immobilization of 1.3 vs. 5.5% for intramedullary nailing, although there were more open fractures in the nailing group (Zelle et al., 2006). There is one moderate-quality trial comparing the use of intramedullary nail with percutaneous locking compression plates (Guo et al., 2010), and another moderate-quality trial comparing intramedullary nail with fracture plate and screws (Im et al., 2005). There were no significant differences in functional outcomes between these interventions. Intramedullary nail was demonstrated to have few superficial infections and less angulation than plates and screws (Im et al., 2005), and shorter operating time and radiation exposure than percutaneous compression plate (Guo et al., 2010). However, there is no quality evidence that one technique is superior to the other and no recommendation is made regarding technique.

OPERATIVE MANAGEMENT OF TIBIAL PLAFOND AND PILON FRACTURES

Sometimes Recommended

Operative management for tibial plafond fractures is recommended in select patients.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence High

Indications

Displaced, comminuted, or inability to obtain acceptable fracture alignment with closed reduction.

Rationale

Distal lower leg fractures that impinge on the articular surface with the talus are known as plafond fractures. As these fractures are often caused by axial forces driving the talus into the lower leg, they are often called “pilon” (hammer) fractures. In this section, the term “plafond fracture” will be used. There are no quality trials for operative fixation of tibial plafond fractures. A low-quality trial compared ORIF of tibial plafond fractures with external fixation with and without limited internal fixation and found no radiographic difference at 15 weeks follow-up, but did demonstrate higher wound complication rate in the ORIF group leading to 3 amputation surgeries (Wyrsch et al., 1996). These fractures are noted to have high complication rates from surgical reduction and fixation (Marsh et al., 2006). Numerous internal and external fixation techniques are described, but there is no recommendation for one method over others.

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OPERATIVE FIXATION FOR SYNDESMOTIC RUPTURES

Recommended

Operative fixation is recommended for closed ankle fractures with unstable syndesmotic rupture.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence High

Indications

Closed ankle fractures with unstable syndesmosis, AO fracture type C and/or pathologic widening of more than 2mm of the syndesmosis at intra-operative testing (Hoiness et al., 2004).

Rationale

There are no quality trials for non-operative management of syndesmotic injuries. There is opinion that not all ankle syndesmotic injuries lead to ankle instability, and may not need repair in the absence of other destabilizing injury (Zalavras et al., 2007, Lin et al., 2006). Fixation is required in the presence of fracture (Zalavras et al., 2007). Thus, non-operative management is recommended for select patients. Operative repair is recommended for non-stable injuries, which include most syndesmotic rupture with concurrent fractures or deltoid ligament injury. There is one moderate-quality trial comparing tri-cortical screw fixation with quadri-cortical screw fixation that demonstrated no significant long-term differences, although tri-cortical fixation was demonstrated to achieve earlier partial weight bearing and less pain at 3 months follow-up (Hoiness et al., 2004). A low-quality trial comparing tri-cortical screw fixation with quadri-cortical screw fixation demonstrated no significant long-term differences (Moore et al., 2006). There are two moderate-quality trials comparing bioabsorbable screws with metallic screws for syndesmotic repair that demonstrated no differences in outcomes other than that those with metallic screws were more likely to have reoperation for screw removal (Kaukonen et al., 2005, Thordarson et al., 2001). A study of outcomes with retained compared to removed screws and broken screws demonstrated no clinical differences, calling into question the need for removal of screws (Hamid et al., 2009). There are no other trials comparing use of other fixation techniques. Thus, there is insufficient quality evidence for recommendation of one fixation technique over another. Both metallic and bioabsorbable screws appear to provide effective treatment.

OPERATIVE FIXATION FOR DISPLACED DISTAL FIBULA FRACTURES

Recommended

Operative fixation is recommended for displaced distal fibula fracture.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence High

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Indications

Distal fibula shaft fracture, unsatisfactory closed reduction.

Rationale

There are no quality trials comparing conservative management of distal fibular shaft fracture with operative care. There is one quality trial that compared rod with plate fixation that demonstrated faster return to full weight-bearing (Pritchett, 1993). However, these results are limited as the study was conducted in an elderly population and may not be applicable to the working population. Thus, operative fixation is recommended for displaced, unstable distal fibular fractures. There is insufficient quality evidence for recommendation of one technique over another.

USE OF ARTHROSCOPY-ASSISTED ORIF FOR DISTAL FIBULAR FRACTURES

No Recommendation

There is no recommendation for or against the use of arthroscopy-assisted ORIF for distal fibular fractures.

Strength of evidence No Recommendation, Insufficient Evidence (I)
Level of confidence Low

Rationale

There are no quality trials for arthroscopic-assisted ORIF compared with ORIF alone for the treatment of distal fibular fractures. Two low-quality trials demonstrated conflicting reports for arthroscopic-assisted ORIF. One trial demonstrated better clinical AOFAS scores in the arthroscopic-assisted ORIF group, as patients were diagnosed and treated for osteochondral lesions, and talofibular ligament disruptions (Takao et al., 2004). The other study found no differences in outcomes (Thordarson et al., 2001). Arthroscopy may improve detection of osteochondral deficits and ligament rupture; however, functional outcomes from chondroplasty or ligament repair in addition to ORIF are unknown. There is insufficient evidence to recommend for or against this technique.

DELTOID LIGAMENT REPAIR CONCURRENT WITH ORIF FOR UNSTABLE ANKLE FRACTURES

Not Recommended

Performing repair of torn deltoid ligament in association with ORIF for ankle fracture is not recommended.

Strength of evidence Not Recommended, Insufficient Evidence (I)
Level of confidence Moderate

Rationale

There is one moderate-quality trial-comparing repair of rupture deltoid ligament with no repair in patients undergoing ORIF for unstable ankle fractures of lateral malleolus that

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demonstrated no significant differences in outcomes at short- or long-term follow-up (17 months) (Stromsoe et al., 1995). The study suggests surgical repair of a ruptured deltoid ligament is not currently recommended as it can add to surgical time without evidence of clinical benefit, although there may be circumstances outside of the trial criteria of Weber B and C lateral malleolar fractures that warrant repair. The use of weight-bearing radiographs is reported to be an effective, pain-free, and reliable method to exclude the need for operative repair of isolated lateral malleolar fractures with possible deltoid injury (Weber et al., 2010). There is insufficient evidence for recommendation of deltoid repair associated with ankle fracture.

PREOPERATIVE ANTIBIOTIC PROPHYLAXIS FOR ANKLE FRACTURES

Recommended

Pre-operative antibiotic prophylaxis is recommended for closed or open ankle fracture surgery.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence Moderate

Rationale

There is one high-quality trial comparing multi-dose pre-operative intravenous cephalotin with placebo for closed ankle fractures that demonstrated no differences in post-operative infections or other outcomes; however, it is likely underpowered (Paiement et al., 1994). A systematic review of antibiotic prophylaxis for any long bone surgery with single-dose antibiotic prophylaxis demonstrated significantly reduced deep surgical site infection (risk ratio 0.40, 95% CI 0.24 to 0.67), superficial surgical site infections, urinary infections, and respiratory tract infections (Gillespie et al., 2010). However, no advantage to multi-dose antibiotic prophylaxis was reported. Single-dose prophylaxis is reported to be more cost effective than multi-dose regimens (Slobogean et al., 2010). Antibiotics are minimally invasive, have low adverse effects, are low to moderate cost, and in large studies prevent risk of infection. Thus, they are recommended.

POSTOPERATIVE CARE

POSTOPERATIVE CARE DRESSING FOR ANKLE SURGERY

No Recommendation

There is no recommendation for or against the use of post-operative dressing for ankle surgery.

Strength of evidence No Recommendation, Insufficient Evidence (I)
Level of confidence Low

Rationale

There is no quality evidence evaluating the post-operative use of dressings to manage ankle fractures. There is one low-quality trial that compared immobilization with back slab to wool

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and crepe bandage immediately post-operation that demonstrated no differences between the two groups (Reed et al., 1998). The use of post-operative dressings is non-invasive, has no adverse effects, and is low cost. There is no recommendation for dressing type.

PNEUMATIC COMPRESSION FOR TREATMENT OF ANKLE AND FOOT EDEMA

Recommended

Use of pneumatic compression of foot and ankle to reduce swelling is recommended for patients with significant post-operative edema.

Strength of evidence Recommended, Evidence (C)
Level of confidence Low

Indications

Excessive swelling after ankle fracture surgery.

Rationale

Three moderate-quality trials comparing pneumatic compression or cold compression devices with a regimen of ice, splint, and elevation for managing edema during the peri-operative period demonstrated effective reduction in swelling (Mora et al., 2002, Thordarson et al., 1997, Caschman et al., 2004). These devices are noninvasive, have no significant adverse effects, and are moderately costly when used in a hospital setting. They are recommended for patients who have significant peri-operative edema. There is no quantified definition of "significant edema" found in the quality trials; therefore, clinical judgement of appreciable edema is warranted.

INTERFERENTIAL THERAPY FOR TREATMENT OF ANKLE EDEMA

Not Recommended

Interferential therapy for the treatment of post-operative swelling following ORIF for displaced malleolar fracture is moderately not recommended.

Strength of evidence Moderately Not Recommended, Evidence (B)
Level of confidence Moderate

Rationale

There is one high-quality trial comparing interferential current therapy with sham before and after ankle surgery that demonstrated no difference in foot or ankle volumetric measures (Christie et al., 1990). Interferential therapy is non-invasive, has no side effects, is of moderate cost, but is of low efficacy and therefore is not recommended for use to control peri-operative ankle and foot swelling.

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REHABILITATION

EARLY MOBILIZATION FOR ANKLE FRACTURES

Recommended

Early mobilization is moderately recommended in the management of post-operative and stable non-operative ankle fractures.

Strength of evidence Moderately Recommended, Evidence (B)
Level of confidence Moderate

Indications

Stabilized malleolar fractures with or without surgery and closed ankle fractures with adequate fixation and stabilization.

Frequency/Dose/Duration

Early mobilization can be started within 1 to 3 days post-operatively (Dogra et al., 1999, Lehtonen et al., 2003, Franke et al., 2008, Egol et al., 2000, Sondenaa et al., 1986).

Rationale

There are 10 moderate-quality trials comparing early motion/mobilization with cast immobilization post operatively (Dogra et al., 1999, Lehtonen et al., 2003, Franke et al., 2008, Hedstrom et al., 1994, Ahl et al., 1986, Tropp et al., 1995, Egol et al., 2000, Sondenaa et al., 1986, DiStasio et al., 1994, Vioreanu et al., 2007, Vioreanu et al., 2006). Four of the studies demonstrated near-term benefit in pain, swelling, functional improvement, and early return to work (Egol et al., 2000, Sondenaa et al., 1986, DiStasio et al., 1994, Vioreanu et al., 2007), while the other six studies demonstrated equivocal outcomes (Dogra et al., 1999, Lehtonen et al., 2003, Franke et al., 2008, Hedstrom et al., 1994, Ahl et al., 1986, Tropp et al., 1995). One of these equivocal studies included early motion for only the first 2 weeks post-operatively, and then the group was immobilized for 4 weeks (Dogra et al., 1999). Pertaining to adverse effects of early motion, one study demonstrated an increase in superficial wound infections (Lehtonen et al., 2003) and another reported infections although power was insufficient for significance (Vioreanu et al., 2007). There were no reports of increased non-union or delayed union from early mobilization. Of these nine studies, early weight-bearing was included as a co-intervention in four of the trials. In the six studies where early weight-bearing was not allowed (Dogra et al., 1999, Tropp et al., 1995, Egol et al., 2000, Sondenaa et al., 1986, DiStasio et al., 1994, Vioreanu et al., 2007), early motion alone provided positive benefit in four studies (Egol et al., 2000, Sondenaa et al., 1986, DiStasio et al., 1994, Vioreanu et al., 2007). There is one trial that compared early weight-bearing with and without early motion that demonstrated no significant differences (Hedstrom et al., 1994). A low-quality trial of early mobilization in tibial plafond fracture with external fixators demonstrated no benefit over no mobilization (Marsh et al., 2006). Thus, there is quality evidence that early motion in the immediate post-operative may provide additional benefit in early return to work and functional recovery, and has few

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adverse effects other than higher risk for superficial wound infection. Therefore, early mobilization is recommended for most patients with stable or repaired malleolar ankle fracture.

EARLY POSTOPERATIVE WEIGHT-BEARING FOR ANKLE FRACTURES

Recommended

Early weight-bearing of operatively fixated ankle fractures postoperatively is moderately recommended.

Strength of evidence Moderately Recommended, Evidence (B)
Level of confidence Moderate

Indications

Stabilized malleolar fractures with or without surgery and closed ankle fractures with adequate fixation and stabilization.

Rationale

There are seven moderate-quality trials comparing early weight-bearing (prior to 6 weeks post ORIF) to delayed weight bearing (Lehtonen et al., 2003, Franke et al., 2008, Hedstrom et al., 1994, Ahl et al., 1986, Ahl et al., 1989, Honigmann et al., 2007, van Laarhoven et al., 1996). One trial demonstrated better functional results and earlier return to work with early weight-bearing using an orthosis (Franke et al., 2008). The remaining trials demonstrated equivocal results with no increase in dislocation or other deficit. There is also one low-quality trial that demonstrated the advantage of early weight-bearing over non-weight bearing (Ahl et al., 1993). Another low-quality trial found no difference in complications or healing between early mobilization, early weight-bearing, and cast immobilization with no weight bearing (Finsen et al., 1989, Finsen et al., 1989). Described methods for rehabilitation include full weight-bearing using a functional vacuum stabilized orthosis immediately post-operative (Hedstrom et al., 1994), at 2 weeks (Honigmann et al., 2007), or with graduated weight-bearing beginning with 20kg weight bearing on Day 2 (Franke et al., 2008). Other methods include weight bearing with walking cast on post-operative Day 1 (Hedstrom et al., 1994, Ahl et al., 1986, Ahl et al., 1989), or graduated weight-bearing in cast at 2 weeks with full weight-bearing at 4 weeks (Lehtonen et al., 2003). Athletes that underwent ORIF followed by early motion and early weight-bearing were able to return to their pre-injury level of competition within 2 to 4 months with minimal residual complaints or deficits (Jelinek et al., 2009, Porter et al., 2008). Early weight-bearing therefore may provide improvement in functional recovery short-term, does not appear to result in increased adverse events, is of low incremental cost difference, and is therefore recommended.

THERAPY FOR PATIENTS WITH FUNCTIONAL DEBILITIES AFTER CAST REMOVAL

Sometimes Recommended

Referral of patients with functional debilities or inability to return to work for therapy after cast removal for ankle fractures is recommended.

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Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence Moderate

Rationale

There is one moderate-quality trial of supervised physical therapy compared to usual care that demonstrated subjective and objective improvement in the supervised therapy group in persons under age 40 (Nilsson et al., 2009). However, no benefit was found when not adjusted for age group and treatment effect. The study may have been underpowered, but the observed effect was likely of small clinical benefit. A high-quality trial comparing exercises alone, exercise with short-duration passive stretches, and exercise with long-duration passive stretches demonstrated no differences among groups when considering outcomes of passive dorsiflexion, pain, return to usual work, or participation in sports and leisure activities (Moseley et al., 2005). A moderate-quality study comparing physical therapy with and without manual therapy after cast removal demonstrated no differences in outcomes after 4 weeks (Lin et al., 2008). There is also a low-quality study comparing exercises with and without manual therapy for 3 weeks that reported increased active range of motion in the manual therapy group (Wilson, 1991).

Some patients, such as the young or athletic, may recover quickly and not gain much from therapy. Other patients may benefit from formal therapy after removal of a cast or splint to address disabilities. A few appointments for educational purposes for select patients are recommended. The number of appointments is dependent on the degree of debility, with 1 or 2 educational appointments appropriate for mildly affected patients. Patients with severe debility or those unable to return to work may benefit from 8 to 12 appointments that include assignment of and guidance with progressive stretching and strengthening exercises.

MANUAL THERAPY AS PART OF A POST-ANKLE FRACTURE REHABILITATION PROGRAM

Not Recommended

Manual therapy is not recommended as part of an active post-ankle fracture rehabilitation program.

Strength of evidence Not Recommended, Evidence (C)
Level of confidence Low

Rationale

There is one moderate-quality trial of supervised physical therapy compared to usual care that demonstrated subjective and objective improvement in the supervised therapy group in persons under age 40 (Nilsson et al., 2009). However, no benefit was found when not adjusted for age group and treatment effect. The study may have been underpowered, but the observed effect was likely of small clinical benefit. A high-quality trial comparing exercises alone, exercise with short-duration passive stretches, and exercise with long-duration passive stretches demonstrated no differences among groups when considering

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outcomes of passive dorsiflexion, pain, return to usual work, or participation in sports and leisure activities (Moseley et al., 2005). A moderate-quality study comparing physical therapy with and without manual therapy after cast removal demonstrated no differences in outcomes after 4 weeks (Lin et al., 2008). There is also a low-quality study comparing exercises with and without manual therapy for 3 weeks that reported increased active range of motion in the manual therapy group (Wilson, 1991). Some patients, such as the young or athletic, may recover quickly and not gain much from therapy. Other patients may benefit from formal therapy after removal of a cast or splint to address disabilities. A few appointments for educational purposes for select patients are recommended. The number of appointments is dependent on the degree of debility, with 1 or 2 educational appointments appropriate for mildly affected patients. Patients with severe debility or those unable to return to work may benefit from 8 to 12 appointments that include assignment of and guidance with progressive stretching and strengthening exercises.

PASSIVE STRETCHING FOR CONTRACTURES AFTER IMMOBILIZATION OF ANKLE FRACTURES

Not Recommended

Passive stretching is moderately not recommended for contractures after immobilization of ankle fractures.

Strength of evidence Moderately Not Recommended, Evidence (B)
Level of confidence Moderate

Rationale

There is one moderate-quality trial of supervised physical therapy compared to usual care that demonstrated subjective and objective improvement in the supervised therapy group in persons under age 40 (Nilsson et al., 2009). However, no benefit was found when not adjusted for age group and treatment effect. The study may have been underpowered, but the observed effect was likely of small clinical benefit. A high-quality trial comparing exercises alone, exercise with short-duration passive stretches, and exercise with long-duration passive stretches demonstrated no differences among groups when considering outcomes of passive dorsiflexion, pain, return to usual work, or participation in sports and leisure activities (Moseley et al., 2005). A moderate-quality study comparing physical therapy with and without manual therapy after cast removal demonstrated no differences in outcomes after 4 weeks (Lin et al., 2008). There is also a low-quality study comparing exercises with and without manual therapy for 3 weeks that reported increased active range of motion in the manual therapy group (Wilson, 1991). Some patients, such as the young or athletic, may recover quickly and not gain much from therapy. Other patients may benefit from formal therapy after removal of a cast or splint to address disabilities. A few appointments for educational purposes for select patients are recommended. The number of appointments is dependent on the degree of debility, with 1 or 2 educational appointments appropriate for mildly affected patients. Patients with severe debility or those unable to return to work may benefit from 8 to 12 appointments that include assignment of and guidance with progressive stretching and strengthening exercises.

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ANKLE SPRAIN

OVERVIEW

The medical history should elicit information to establish the mechanism of injury, severity of forces, and disability immediately following the injury. Red flags, including fracture, should be considered. The examiner should determine if the injury is a result of inversion versus eversion of foot, the position of the foot at the time of injury, and if rotational forces or direct physical trauma was involved. Previous ankle injury should be noted, including duration of symptoms and any residual symptoms at the time of injury. The examiner should seek co-morbidity including osteoporosis, arthritis, movement disorders, diabetes, peripheral vascular disease, seizure disorder and use of seizure medications, and hyperthyroidism as they are risk factors for falls and weakened joints and bones [51].

The physician performing an initial evaluation of a patient with ankle sprain should seek a discrete diagnosis (see Table 7). A careful thorough history is required. The examination generally needs to focus on the bony structures, ligaments, soft tissue, range of motion, and vascular status. Likelihood of fracture is assessed using the Ottawa Ankle and Foot Rules. Other trauma may be present and the examiner should be alert for other injuries that may have been sustained in the incident.

A careful observation of the exposed extremity and systematic examination should be performed including observation for soft tissue trauma and laceration or foreign body, edema, and ecchymosis. Edema is non-specific and has not been correlated with severity of injury. However, ankle girth on the injured side of 13 to 15mm greater than on the uninjured side, measured around the medial and lateral malleoli, has been reported to have a positive predictive value for detecting fracture of 83% [254,255]. Ecchymosis indicates more significant trauma. Ecchymosis on the medial aspect of the ankle along the posterior tibial ligament suggests deltoid ligament rupture. Ecchymosis from the ankle extending proximally to the distal lower leg suggests syndesmotic injury. However, ecchymosis may track subcutaneously, can be widespread, and is not a good indicator of the type or location of an injury unless it is focused.

Palpation of bony structures should include the tibia and fibula, the medial and lateral malleoli, mortise, calcaneus, lateral and posterior talus, and the base of fifth metatarsal. Palpation of the ATFL, CFL, PTFL, and deltoid ligament is performed to identify tenderness and/or discontinuity. Palpation of the Achilles tendon is performed to rule out other causes of acute ankle pain. Range-of-motion testing for the ankle includes plantar flexion, and dorsiflexion.

The anterior drawer test is performed to assess the integrity of the ATFL. The maneuver is performed by grasping the heel in one hand and pulling it forward while stabilizing the tibia with the other [256,257]. Optimal results are described using a force of 30 N (about 7 pounds force) [258]. Laxity is dependent on joint positioning, with the most laxity and the least stiffness reported when the knee is positioned at 90° of flexion and the ankle at 10° of plantarflexion [259]. Results are compared with the non-injured ankle, with 8mm or more increased laxity considered a positive test. Sensitivity and specificity of this maneuver are reported to be 73% and 97% [260]. A high correlation with radiographic findings for ligament rupture has also been described [261]. Results of objective dynamic testing equipment for

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testing lateral ligament laxity are mixed and are not reported to provide significant benefit over routine examination in clinical management [262,263,264].

The talar tilt test assesses the calcaneofibular ligament through inversion of the foot, and the deltoid ligament through eversion. This maneuver is performed by grasping the heel in one hand and the forefoot with the other hand and moving the foot back and forth from eversion (or pronation) to inversion (or supination). Pain and laxity of more than 5 to 10° compared with the uninjured ankle is indicative of ligament injury [51].

Syndesmosis integrity (high ankle sprain) is tested by the side-to-side external rotation test and the squeeze test. The examiner stabilizes the injured leg laterally with one hand, and externally rotates the foot in the horizontal plain. For the squeeze test, the examiner squeezes circumferentially around the syndesmosis. Pain elicited in the anterior ankle with these maneuvers suggests syndesmotic injury or fracture [265]. The patient's ability to stand and bear weight is also examined. The ability to take 4 steps on the injured ankle is evaluated as part of the Ottawa Ankle and Foot Rules.

Classification systems for lateral ankle sprain severity are based on physical examination findings and are used to define the extent of ligament injury. According to the West Point Grading System, Grade I sprains are mild, the most common, and require the least amount of treatment and least time to recovery. The anterior talofibular (ATFL) ligaments are stretched but not torn, and there is no significant instability. Grade II sprains are more severe, include a partially torn ATF ligament and may also involve the calcaneofibular ligament (CFL). Grade III sprains are the most severe, resulting in complete rupture of one or more ligaments of ATFL, CFL, and or posterior talofibular ligament (PTFL) resulting in instability of the joint. Most reviewed studies did not indicate specific schema system used for grading injuries, although [50,266] summarize the West Point Ankle Sprain Grading System. For the purpose of this section, a Grade I sprain and a mild sprain are synonymous; a Grade II sprain and a moderate sprain are synonymous; and a Grade III sprain and a severe sprain are synonymous.

DIAGNOSTIC RECOMMENDATIONS

RADIOGRAPHS (X-RAYS)

The primary purpose of obtaining radiologic imaging for the acute ankle injury is to evaluate for the presence of ankle or foot fractures. Ankle fracture occurs in approximately 15% of patients with ankle sprain [267,268,269]. The Ottawa ankle rules (OAR) have become well established as a valuable instrument for primary care physicians in acute care settings for determining appropriate level of concern for excluding fracture without the use of x-ray [270,271,272,273,274,275]. A meta-analysis of 27 studies demonstrated a negative likelihood ratio of less than 1.4%, indicating that very few fractures are missed in application of these rules [274]. OAR has been validated to be 100% sensitive.

The Ottawa ankle rules state that x-ray films are indicated only if there is pain in malleolar zone:

1. tenderness along the tip of or the posterior edge of the distal 6 cm of the lateral malleolus of the medial and/or lateral malleolus; and/or

2. an inability to bear weight for 4 steps (2 steps on each leg) without assistance both immediately and in the clinical setting.

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The rule also states that x-ray films of the foot are indicated only if there is pain in the mid-foot and there is:

1. tenderness at the base of the fifth metatarsal and/or tenderness over the navicular bone; and/or

2. an inability to bear weight for 4 steps without assistance both immediately and in the clinical setting [276] .

ROUTINE USE OF X-RAY IN ASSESSMENT OF ACUTE ANKLE SPRAIN

No Recommendation

There is no recommendation for or against the routine use of x-ray for evaluation of acute ankle sprain when fracture is not suspected.

Strength of evidence No Recommendation, Insufficient Evidence (I)
Level of confidence Low

Indications

Suspicion of fracture (but not in the context of a diagnosis of sprain without an associated fracture) or if the history or physical is clinically suspicious for an injury other than an ankle sprain. The presence of acute edema measured at the malleoli >13 to 15mm compared to uninjured ankle may indicate an occult fracture.

Rationale

There are no quality studies evaluating the diagnostic value of x-ray for ankle sprain. Plain films are not required for the diagnosis of acute ankle sprain as x-ray is poor at diagnosing soft-tissue disorders. The use of plain film x-ray rather is utilized for evaluation of accompanying ankle or foot fracture, orientation of fracture plane(s), and magnitude of the involvement of the articular surfaces, which if present may alter management in favor of surgery. X-ray is indicated based on high clinical suspicion or as guided by the Ottawa ankle and foot rules. There are two quality trials for the use of Ottawa rules, but these do not validate the rules as a tool. A high-quality trial demonstrated that in a busy emergency or urgent care setting, registered nurse triage using the rules did not significantly improve total visit time compared to MD triage, although there was no difference in patient satisfaction. However, the applicability of the study results is uncertain as it did not compare inter-discipline rater reliability or validate the rules (Fan et al., 2006). A moderate-quality RCT demonstrated that trained nurses are able to apply the rules as well as house officers (Derksen et al., 2005). Ottawa rules appear to be a valuable screening instrument for ordering x-ray in the acute setting. However, an x-ray should also be considered if there is high clinical suspicion based on history and physical or ankle edema that is 13 to 15mm greater than the uninjured side (Clark et al., 1995, Clark et al., 1996). X-ray is non-invasive, has low adverse effect profile, but does result in radiation exposure, and is of moderate cost. Therefore, x-ray is recommended for assessment of suspected ankle or foot fracture.

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X-RAY IN ASSESSMENT OF ACUTE ANKLE SPRAIN WHEN FRACTURE SUSPECTED

Recommended

X-ray in the case of ankle sprain is recommended if fracture is likely and the differential diagnosis reflects suspicion of fracture.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence High

Indications

Suspected or encountered fracture (see Fractures section for further guidance).

Rationale

There are no quality studies evaluating the diagnostic value of x-ray for ankle sprain. Plain films are not required for the diagnosis of acute ankle sprain as x-ray is poor at diagnosing soft-tissue disorders. The use of plain film x-ray rather is utilized for evaluation of accompanying ankle or foot fracture, orientation of fracture plane(s), and magnitude of the involvement of the articular surfaces, which if present may alter management in favor of surgery. X-ray is indicated based on high clinical suspicion or as guided by the Ottawa ankle and foot rules. There are two quality trials for the use of Ottawa rules, but these do not validate the rules as a tool. A high-quality trial demonstrated that in a busy emergency or urgent care setting, registered nurse triage using the rules did not significantly improve total visit time compared to MD triage, although there was no difference in patient satisfaction. However, the applicability of the study results is uncertain as it did not compare inter-discipline rater reliability or validate the rules . A moderate-quality RCT demonstrated that trained nurses are able to apply the rules as well as house officers (Derksen et al., 2005). Ottawa rules appear to be a valuable screening instrument for ordering x-ray in the acute setting. However, an x-ray should also be considered if there is high clinical suspicion based on history and physical or ankle edema that is 13 to 15mm greater than the uninjured side (Clark et al., 1995, Clark et al., 1996). X-ray is non-invasive, has low adverse effect profile, but does result in radiation exposure, and is of moderate cost. Therefore, x-ray is recommended for assessment of suspected ankle or foot fracture.

ROUTINE STRESS X-RAY FOR EVALUATION OF LIGAMENT RUPTURE IN ACUTE ANKLE SPRAIN

Not Recommended

Routine use of talar-tilt and anterior drawer stress x-ray is not recommended for evaluation of acute ankle ligament rupture.

Strength of evidence Not Recommended, Insufficient Evidence (I)
Level of confidence Moderate

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Rationale

The use of stress x-ray is a widely debated topic (Lohrer et al., 2008). A study comparing the use of stress x-ray with visual confirmation of ATFL integrity demonstrated accuracy of stress plain films to be 53% for acute cases and 91% for chronic cases. This compares to 91% for diagnostic ultrasound and 97% for MRI (Oae et al., 2010). As initial treatment for all acute ankle sprains without fracture is non-operative clinical management does not depend on the degree of instability on stress views (Frost et al., 1999). For cases of chronic ankle instability, anterior drawer and talar tilt stress views are of unknown clinical utility as there is little correlation of measurement with clinical decision making, as there is wide variability in measurements compared with the uninjured ankle (Lohrer et al., 2008)(Martin et al., 1996). Stress films are non-invasive, but can result in significant patient discomfort, are less accurate than MRI or CT, and have uncertain clinical correlation. They are not recommended in the acute setting. There is insufficient evidence for a recommendation in the evaluation of chronic ligament instability.

ROUTINE STRESS X-RAY FOR EVALUATION OF LIGAMENT RUPTURE IN SUBACUTE OR CHRONIC ANKLE SPRAIN

No Recommendation

There is no recommendation for or against the use of talar-tilt and anterior drawer stress x-rays for evaluation of subacute or chronic ankle pain.

Strength of evidence No Recommendation, Insufficient Evidence (I)
Level of confidence Low

Rationale

The use of stress x-ray is a widely debated topic . A study comparing the use of stress x-ray with visual confirmation of ATFL integrity demonstrated accuracy of stress plain films to be 53% for acute cases and 91% for chronic cases. This compares to 91% for diagnostic ultrasound and 97% for MRI . As initial treatment for all acute ankle sprains without fracture is non-operative clinical management does not depend on the degree of instability on stress views . For cases of chronic ankle instability, anterior drawer and talar tilt stress views are of unknown clinical utility as there is little correlation of measurement with clinical decision making, as there is wide variability in measurements compared with the uninjured ankle . Stress films are non-invasive, but can result in significant patient discomfort, are less accurate than MRI or CT, and have uncertain clinical correlation. They are not recommended in the acute setting. There is insufficient evidence for a recommendation in the evaluation of chronic ligament instability.

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COMPUTED TOMOGRAPHY

COMPUTED TOMOGRAPHY (CT) FOR ASSESSMENT OF SUBACUTE OR CHRONIC ANKLE SPRAIN

Sometimes Recommended

CT is recommended for the assessment of select patients with subacute or chronic ankle sprain.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence High

Indications

Patients who have no limited improvement with non-operative therapy after 4 to 6 weeks, persistent pain with weight bearing, or chronic feeling of instability; ankle injuries that involve crepitus, catching or locking, as these symptoms may be associated with a displaced osteochondral fragment.

Rationale

There are no quality trials for use of CT in evaluating ankle sprain. A prospective study demonstrated CT with an accuracy of 91% compared with arthroscopic findings, but only localized the injury to the same location as arthroscopy 63% of the time (Oae et al., 2010). There is insufficient evidence for recommending MRI over CT or visa versa, and the study should be selected based on objective of clinical suspicion.

COMPUTED TOMOGRAPHY (CT) FOR ASSESSMENT OF ACUTE ANKLE SPRAIN

No Recommendation

There is no recommendation for or against the use of CT for assessment of patients with acute ankle sprain.

Strength of evidence No Recommendation, Insufficient Evidence (I)
Level of confidence Low

Rationale

There are no quality trials for use of CT in evaluating ankle sprain. A prospective study demonstrated CT with an accuracy of 91% compared with arthroscopic findings, but only localized the injury to the same location as arthroscopy 63% of the time. There is insufficient evidence for recommending MRI over CT or vice versa, and the study should be selected based on objective of clinical suspicion.

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MAGNETIC RESONANCE IMAGING (MRI)

MAGNETIC RESONANCE IMAGING (MRI) FOR ASSESSMENT OF SUBACUTE OR CHRONIC ANKLE SPRAIN

Sometimes Recommended

MRI is recommended for the assessment of select patients with subacute or chronic ankle sprain. MRI may be indicated for patients who have no limited improvement with non-operative therapy after 4 to 6 weeks, persistent pain with weight bearing, or a chronic feeling of instability; and ankle injuries that involve crepitus, catching, or locking, as these symptoms may be associated with a displaced osteochondral fragment.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence Moderate

Rationale

There are no quality randomized trials evaluating the use of MRI in the diagnosis of ankle sprain. A prospective study comparing MRI with visual confirmation of ATFL integrity demonstrated accuracy of 97% for MRI (Oae et al., 2010). In the acute setting however, MRI has not been demonstrated to provide additional benefit in clinical diagnosis or management compared to plain film x-ray (Nikken et al., 2005, Remplik et al., 2004). For cases of non-response to non-operative functional treatment in subacute and chronic stages, syndesmotic injuries and for chronic ankle instability, MRI should be considered as an imaging technique (Alparslan et al., 2008, Oae et al., 2010, Naran et al., 2008, Brown et al., 2004, Martin, 2008). There is insufficient evidence for recommending MRI over CT or visa versa, and the study should be selected based on objective of clinical suspicion.

MAGNETIC RESONANCE IMAGING (MRI) FOR ASSESSMENT OF ACUTE ANKLE SPRAIN

No Recommendation

There is no recommendation for or against the use of MRI for the assessment of acute ankle sprain.

Strength of evidence No Recommendation, Insufficient Evidence (I)
Level of confidence Low

Rationale

There are no quality randomized trials evaluating the use of MRI in the diagnosis of ankle sprain. A prospective study comparing MRI with visual confirmation of ATFL integrity demonstrated accuracy of 97% for MRI . In the acute setting however, MRI has not been demonstrated to provide additional benefit in clinical diagnosis or management compared to plain film x-ray . For cases of non-response to non-operative functional treatment in subacute and chronic stages, syndesmotic injuries and for chronic ankle instability, MRI should be considered as an imaging technique (Alparslan et al., 2008, Brown et al., 2004).

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There is insufficient evidence for recommending MRI over CT or visa versa, and the study should be selected based on objective of clinical suspicion.

MAGNETIC RESONANCE ARTHROGRAPHY (MRA)

MAGNETIC RESONANCE ARTHROGRAPHY (MRA) FOR ASSESSMENT OF SUBACUTE OR CHRONIC ANKLE SPRAIN

No Recommendation

There is no recommendation for or against the use of MRA for the assessment of subacute or chronic ankle sprain.

Strength of evidence No Recommendation, Insufficient Evidence (I)
Level of confidence Low

Rationale

There is no quality evidence for the use of magnetic resonance arthrography. MRA is generally used for MRI or CT equivocal or difficult lesions . MRA performed on 60 consecutive patients with ankle sprain revealed bone contusion that did not appear on MRI or plain film . However, the incidence and clinical importance of bone bruises associated with ankle sprain is unknown. MRA is invasive, costly, and of uncertain clinical utility. It is not recommended for acute evaluation of ankle sprain.

MAGNETIC RESONANCE ARTHROGRAPHY (MRA) FOR ASSESSMENT OF ACUTE ANKLE SPRAIN

Not Recommended

MRA is not recommended for the assessment of acute ankle sprain.

Strength of evidence Not Recommended, Insufficient Evidence (I)
Level of confidence Low

Rationale

There is no quality evidence for the use of magnetic resonance arthrography. MRA is generally used for MRI or CT equivocal or difficult lesions . MRA performed on 60 consecutive patients with ankle sprain revealed bone contusion that did not appear on MRI or plain film . However, the incidence and clinical importance of bone bruises associated with ankle sprain is unknown. MRA is invasive, costly, and of uncertain clinical utility. It is not recommended for acute evaluation of ankle sprain.

ARTHROGRAPHY

ROUTINE USE OF ARTHROGRAPHY IN DIAGNOSIS OF ACUTE ANKLE SPRAIN

Not Recommended

The routine use of arthrography is not recommended for evaluation of acute ankle sprain.

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Strength of evidence Not Recommended, Insufficient Evidence (I)
Level of confidence Low

Rationale

There are no quality randomized trials evaluating arthrography for ankle sprain. Arthrography was considered the gold standard for identifying ligament and osteochondral defects (Nilsson, 1983, Moller-Larsen et al., 1988). Arthrography has a specificity and sensitivity of 71 and 96% respectively when compared to surgical findings (van Dijk et al., 1998). Compared with physical examination in the acute setting, arthrography was more sensitive in detecting ligament rupture (Lahde et al., 1988), although another study found delayed physical examination at 48 hours provides information of diagnostic quality that is equal to that of arthrography, and causes less discomfort to the patient (van Dijk et al., 1996). Arthrography is invasive, is associated with adverse effects including risks from dye and post-procedure pain, and is costly. MRI, CT, and ultrasound have essentially replaced plain arthrography in current practice.

ROUTINE USE OF ARTHROGRAPHY IN DIAGNOSIS OF SUBACUTE OR CHRONIC ANKLE SPRAIN

No Recommendation

There is no recommendation for or against the routine use of arthrography for evaluation of subacute or chronic ankle sprain.

Strength of evidence No Recommendation, Insufficient Evidence (I)
Level of confidence Low

Rationale

There are no quality randomized trials evaluating arthrography for ankle sprain. Arthrography was considered the gold standard for identifying ligament and osteochondral defects (Nilsson, 1983, Moller-Larsen et al., 1988). Arthrography has a specificity and sensitivity of 71 and 96% respectively when compared to surgical findings . Compared with physical examination in the acute setting, arthrography was more sensitive in detecting ligament rupture (Lahde et al., 1988), although another study found delayed physical examination at 48 hours provides information of diagnostic quality that is equal to that of arthrography, and causes less discomfort to the patient (van Dijk et al., 1996). Arthrography is invasive, is associated with adverse effects including risks from dye and post-procedure pain, and is costly. MRI, CT, and ultrasound have essentially replaced plain arthrography in current practice.

BONE SCANS

BONE SCANS FOR ASSESSMENT OF ACUTE ANKLE SPRAIN

Sometimes Recommended

Bone scans are recommended for select patients with acute ankle sprain in cases of suspected stress fracture, infection, or tumor.

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Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence Low

Indications

Suspected stress fracture, infection, or tumor.

Rationale

There is no quality evidence for the use of bone scan in investigating ankle pain. Bone scan imaging for stress fracture may be of benefit in highly select patients. A bone scan is non-invasive, but does result in radiation exposure and is of high cost. Therefor there is no recommendation for or against its use.

BONE SCANS FOR ASSESSMENT OF SUBACUTE OR CHRONIC ANKLE SPRAIN

No Recommendation

There is no recommendation for or against the use of bone scans for patients with subacute or chronic ankle sprain.

Strength of evidence No Recommendation, Insufficient Evidence (I)
Level of confidence Low

Rationale

There is no quality evidence for the use of bone scan in investigating ankle pain. Bone scan imaging for stress fracture may be of benefit in highly select patients. A bone scan is non-invasive, but does result in radiation exposure and is of high cost. Therefor there is no recommendation for or against its use.

ULTRASOUND

ULTRASOUND FOR DIAGNOSIS OF ACUTE ANKLE SPRAIN

Not Recommended

Ultrasound is not recommended for evaluation of select patients with acute ankle sprain.

Strength of evidence Not Recommended, Insufficient Evidence (I)
Level of confidence Low

Rationale

There are no quality randomized trials for the use of ultrasound in the diagnosis of ankle sprain. A prospective study demonstrated lower accuracy of ultrasound compared with MRI and CT based on arthroscopic confirmation of surgical findings (Oae et al., 2010). Another comparative study of clinical and ultrasonographic findings found no correlation between usual clinical signs and type of ligament injury (Gremeaux et al., 2009). A prospective study

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of 110 patients with acute ankle sprain demonstrated that ultrasound detection of talocrural effusion is a sign to consider a sprain as severe (Guillodo et al., 2007). The long-term clinical utility versus routine care is not yet defined. Other studies have demonstrated utility of ultrasound for diagnosis of syndesmotic injury. Ultrasound is non-invasive, has low adverse effects, and is of moderate cost, but as ultrasonographic findings in the acute setting are unlikely to alter management, it is not recommended. Ultrasound for chronic ankle instability or assessment of ankle sprain that has not demonstrated improvement in 4 to 6 weeks may be reasonable, although there is insufficient information to recommend it over CT or MRI.

ULTRASOUND FOR DIAGNOSIS OF SUBACUTE OR CHRONIC ANKLE SPRAIN

No Recommendation

There is no recommendation for or against the use of ultrasound for evaluation of patients with subacute or chronic ankle sprain.

Strength of evidence No Recommendation, Insufficient Evidence (I)
Level of confidence Low

Rationale

There are no quality randomized trials for the use of ultrasound in the diagnosis of ankle sprain. A prospective study demonstrated lower accuracy of ultrasound compared with MRI and CT based on arthroscopic confirmation of surgical findings. Another comparative study of clinical and ultrasonographic findings found no correlation between usual clinical signs and type of ligament injury. A prospective study of 110 patients with acute ankle sprain demonstrated that ultrasound detection of talocrural effusion is a sign to consider a sprain as severe. The long-term clinical utility versus routine care is not yet defined. Other studies have demonstrated utility of ultrasound for diagnosis of syndesmotic injury. Ultrasound is non-invasive, has low adverse effects, and is of moderate cost, but as ultrasonographic findings in the acute setting are unlikely to alter management, it is not recommended. Ultrasound for chronic ankle instability or assessment of ankle sprain that has not demonstrated improvement in 4 to 6 weeks may be reasonable, although there is insufficient information to recommend it over CT or MRI.

TREATMENT RECOMMENDATIONS

OVERVIEW

The natural course of the lateral ankle sprain is rapid improvement. A systematic review of the natural history of ankle sprains from 31 prospective studies demonstrated rapid decrease in pain and improvement in function over the first 2-weeks post-injury [(61)]. However, 5 to 33% of patients still reported persistent or residual pain at 1 year. Reports of full recovery 3 years after an ankle sprain varied 36 to 85%. Up to one-third of patients experience subsequent sprain that appears related to severity of the sprain. As the majority of patients with ankle sprain show significant improvement in the first 2 weeks, the effectiveness of interventions is difficult to judge. However, a significant proportion of persons will continue to have chronic changes from their pre-injury state. Those with recurrent sprain may exhibit ill-defined radiological differences in the talus and decreased

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ankle stability. It is not clear whether the instability is a cause or an effect of recurrent sprain. This group may have a disproportionate influence of the outcomes in treatment studies.

Ten to 20% of patients with acute ankle sprain may develop chronic ankle instability (CAI) [64,65,66,67]. Chronic ankle instability from lateral ankle ligament injury may be characterized by recurrent sprains and/or a persisting feeling (for at least 6 months) that the ankle is unstable and will give way. Mechanical testing demonstrates increased laxity of the lateral ankle ligaments in some patients, but many have no objective findings, but still report functional instability related to what is thought to be a proprioception deficit [68,69,70]. Thus, the sense of instability may be the result of other factors, such as deficits in proprioception preceding or following the sprain. The cause of a proprioception deficit is unknown. A prevailing theory is that an alteration of afferent somatosensory information, reflex responses, and efferent motor measures result from destruction or functional alteration of nerve endings in the soft tissue, cartilage, and joints trauma can occur with ankle sprain trauma [68,69,70]. There are no quality trials that help identify who is at greater risk for CAI development.

Ankle sprain injuries often result in lost time from work and sport. Workplace limitations should be dictated by physical requirements of the job. Physical restrictions may include limited or progressive weight bearing. Walking is encouraged, but may require use of assistive devices. Activities that require sure footing such as working on irregular or inclined surface, climbing, or jumping should be avoided if they are likely to cause significant pain or feeling of instability. Accommodation may be requested for protective footwear or use of ankle-brace, which may impact a patient's ability to drive.

ACTIVITY MODIFICATION AND EXERCISE

EDUCATION

EDUCATION FOR EFFECTS OF ACUTE, SUBACUTE, CHRONIC OR POSTOPERATIVE ANKLE SPRAIN INJURY

Sometimes Recommended

Education is recommended for select patients with acute, subacute, chronic, or post-operative ankle sprain injury.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence Moderate

Frequency/Dose/Duration

One or 2 appointments to educate patients about the injury, effects of activity, unhelpfulness of complete inactivity, prognosis and addressing other questions. Additional appointments may be needed if education is combined with therapy treatments. Follow-up educational visit(s) for more severe disorders as part of a progression towards normal functional use is sometimes helpful.

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Indications for discontinuation

Achievement of education goals or non-compliance

Rationale

There are no quality studies specifically evaluating efficacy of patient education for utility or necessity in treatment of ankle sprain. Yet, for many disorders (e.g., criticality of maintaining splinting, cast management, monitoring for complications) education appears essential. Some physicians accomplish this in the course of extended patient visits, while others routinely refer patients to a therapist for education. Regardless of the approach, a few appointments for educational purposes are recommended for select patients. The number of appointments is dependent on the diagnosis, severity of the condition, and co-existing conditions. Although education is usually incorporated as part of the overall treatment plan, an additional 1 or 2 appointments for purely educational purposes may be helpful midway through a treatment course for the more severely affected patient. In addition, education is low cost and thus is recommended.

Evidence

There are no quality studies incorporated into this analysis.

EARLY MOBILIZATION

EARLY MOBILIZATION FOR ACUTE ANKLE SPRAIN

Recommended

Early mobilization is moderately recommended for acute ankle sprains without fracture.

Strength of evidence Moderately Recommended, Evidence (B)
Level of confidence High

Indications

Acute ankle sprains (severe sprains should undergo no more than 3 weeks of immobilization, splints should be sufficient for immobilization – see Immobilization for further discussion); ankle sprains that are mild or moderate should not undergo immobilization.

Rationale

There are five quality trials that compared early mobilization with cast immobilization (see Table in Immobilization) (Cooke et al., 2009, Lamb et al., 2009, Lamb et al., 2005, Dettori et al., 1994, Dettori et al., 1994, Beynnon et al., 2006, Ardevol et al., 2002, Eiff et al., 1994). There is evidence early mobilization provides short-term benefit in functional improvement, pain, and return to work. There are no trials demonstrating a negative treatment effect long-term for acute, moderate, or severe sprain injuries. Therefore, early mobilization is

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recommended over immobilization for most patients (see Immobilization for additional discussion).

There are no quality trials for casting of mild ankle sprains. Mild acute sprains are generally self-limited and respond well to early mobilization and other therapies; therefore, casting is not recommended. There are six quality trials that compared casting with early mobilization for moderate and severe acute ankle sprains. The moderate-quality CAST trial (Cooke et al., 2009, Lamb et al., 2009, Lamb et al., 2005), demonstrated below-the-knee casting of moderate and severe sprains for 10 days provided a statistical, but clinically indeterminate, short-term benefit compared with tubular bandage (control) in subjective ratings of pain, function, and symptoms in the first 12 weeks. There were no differences between casting and bracing however, and by 9 months there were no differences between groups. A moderate-quality study demonstrated short-term improvement in pain, swelling, and range of motion in the early mobilization group compared to casting for moderate and severe sprains, but did not demonstrate any long-term benefit of one over the other (Dettori et al., 1994, Dettori et al., 1994). Another moderate-quality trial demonstrated casting was less beneficial for moderate (Grade II) sprains, but was equivocal for severe sprains compared with bracing (Beynnon et al., 2006). A moderate-quality trial limited to severe ankle sprains demonstrated early mobilization resulted in short-term benefit in swelling, pain, stiffness and early return to sport compared with 3-week casting (Ardevol et al., 2002). There were no long-term differences measured at 12 months. Another moderate-quality trial demonstrated early mobilization after a 48-hour non-weight-bearing period provided subjective improvement in pain perception at 3 weeks, but no differences in improvement of swelling, residual pain, and function compared with casting (Eiff et al., 1994). However, early mobilization resulted in much faster return to full duty. No long-term differences were demonstrated in any of the quality trials.

Casting is non-invasive, but is restrictive of activity, including return to work, impairs driving performance more than bracing (Tremblay et al., 2009), and is associated with risk for deep venous thrombosis (Lamb et al., 2009). Total direct and indirect costs of casting based on the U.K. health care system are similar to the use of Aircast brace and more cost-effective than compression wrap (Cooke et al., 2009). Cast immobilization is therefore not recommended as an alternative to splinting and early mobilization treatment for severe and moderate ankle sprain.

REST, CASTING, AND IMMOBILIZATION

IMMEDIATE NON-WEIGHT-BEARING (REST) FOR ACUTE ANKLE SPRAIN

Recommended

Rest or non-weight bearing is recommended as an initial intervention for acute ankle sprain for patients unable to tolerate weight.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence Low

Indications

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Acute mild, moderate, and severe ankle sprain patients who are unable to tolerate weight bearing. A short period of up to 48-hours may be prescribed based on tolerance and ability to bear weight. Early mobilization is recommended.

Frequency/Dose/Duration

Up to 48 hours of non-weight bearing; early mobilization, progressive weight bearing as tolerated, addition of home therapeutic exercises.

Indications for discontinuation

Resolution, ability to tolerate weight.

Rationale

There are no quality trials comparing the effectiveness of using all RICE therapies concurrently with a control of no RICE therapy. RICE is frequently described as a co-intervention in numerous comparative trials. One moderate-quality trial that demonstrated the addition of therapeutic exercises to RICE resulted in improved short-term function with reduction in pain compared to RICE alone, although there were no differences in return to work, walking, or sports (Bleakley et al., 2010, Bleakley et al., 2007). Another moderate-quality trial demonstrated passive manipulation added to RICE protocol demonstrated improved dorsiflexion with reduction in pain compared to RICE alone, although there were no differences in return to work, walking, or return to sport (Green et al., 2001). There are no quality trials comparing immediate rest (non-weight bearing) to continued weight bearing. A moderate-quality trial demonstrated early mobilization through weight bearing with the assistance of ankle supports or compression wraps after a 48-hour non-weight-bearing period demonstrated improved return to full duty compared with immobilization (Eiff et al., 1994) (see Functional Treatment – Mobilization). Therefore, there is no evidence that rest is of benefit if weight bearing is tolerated in the immediate post-injury period. Despite the general acceptance of RICE or the individual therapies of RICE for acute ankle sprain, there is a lack of quality evidence for efficacy. A primary rationale for these modalities is to reduce edema. However, there was little correlation demonstrated in the available studies in reduction of edema as an indicator for functional or pain improvement (Sloan et al., 1989, Boyce et al., 2005, Bleakley et al., 2010, Bleakley et al., 2007). These treatments are not invasive, generally have few adverse effects, and are not costly when self-administered. Rest, ice, and elevation are therefore recommended. There is insufficient evidence for recommendation of compression.

INTERMITTENT ELEVATION FOR ACUTE ANKLE SPRAIN

Recommended

The use of intermittent elevation is recommended for controlling edema of acute ankle sprains.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence Low

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Indications

Acute ankle sprain that manifest significant edema.

Indications for discontinuation

Resolution, adverse effects, non-compliance.

Rationale

There is one moderate-quality study that demonstrated elevation is more effective in reducing edema after a single 30-minute treatment session than elevation used in conjunction with compression wrap or pneumatic brace, suggesting there is no added benefit for additional therapies in the immediate post-treatment period.(519) However, these results are of uncertain short-term clinical significance. The significance of changes in edema in the post-sprain recovery period is of undefined clinical significance, as little correlation is described in available trials (Sloan et al., 1989, Boyce et al., 2005, Bleakley et al., 2010, Bleakley et al., 2007). A prospective case series found no relationships between ankle-foot edema and ankle function in the acute phase of ankle sprain injury (Man et al., 2005).

CAST IMMOBILIZATION FOR ACUTE MILD TO MODERATE ANKLE SPRAIN

Not Recommended

Immobilization by cast is not recommended for patients with acute mild to moderate ankle sprain as splints should be sufficient. Walking boots are recommended for select severe cases of moderate sprains.

Strength of evidence Not Recommended, Insufficient Evidence (I)
Level of confidence High

Rationale

There are five quality trials that compared early mobilization with cast immobilization (see Table in Immobilization) (Cooke et al., 2009, Dettori et al., 1994, Dettori et al., 1994, Beynnon et al., 2006, Ardevol et al., 2002, Eiff et al., 1994). There is evidence early mobilization provides short-term benefit in functional improvement, pain, and return to work. There are no trials demonstrating a negative treatment effect long-term for acute, moderate, or severe sprain injuries. Therefore, early mobilization is recommended over immobilization for most patients (see Immobilization for additional discussion). There are no quality trials for casting of mild ankle sprains. Mild acute sprains are generally self-limited and respond well to early mobilization and other therapies; therefore, casting is not recommended. There are six quality trials that compared casting with early mobilization for moderate and severe acute ankle sprains. The moderate-quality CAST trial (Cooke et al., 2009), demonstrated below-the-knee casting of moderate and severe sprains for 10 days provided a statistical, but clinically indeterminate, short-term benefit compared with

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tubular bandage (control) in subjective ratings of pain, function, and symptoms in the first 12 weeks. There were no differences between casting and bracing however, and by 9 months there were no differences between groups. A moderate-quality study demonstrated short-term improvement in pain, swelling, and range of motion in the early mobilization group compared to casting for moderate and severe sprains, but did not demonstrate any long-term benefit of one over the other (Dettori et al., 1994, Dettori et al., 1994). Another moderate-quality trial demonstrated casting was less beneficial for moderate (Grade II) sprains, but was equivocal for severe sprains compared with bracing (Beynnon et al., 2006). A moderate-quality trial limited to severe ankle sprains demonstrated early mobilization resulted in short-term benefit in swelling, pain, stiffness and early return to sport compared with 3-week casting (Ardevol et al., 2002). There were no long-term differences measured at 12 months. Another moderate-quality trial demonstrated early mobilization after a 48-hour non-weight-bearing period provided subjective improvement in pain perception at 3 weeks, but no differences in improvement of swelling, residual pain, and function compared with casting (Eiff et al., 1994). However, early mobilization resulted in much faster return to full duty. No long-term differences were demonstrated in any of the quality trials. Casting is non-invasive, but is restrictive of activity, including return to work, impairs driving performance more than bracing (Tremblay et al., 2009), and is associated with risk for deep venous thrombosis . Total direct and indirect costs of casting based on the U.K. health care system are similar to the use of Aircast brace and more cost-effective than compression wrap (Cooke et al., 2009). Cast immobilization is therefore not recommended as an alternative to splinting and early mobilization treatment for severe and moderate ankle sprain.

CAST IMMOBILIZATION FOR SEVERE ANKLE SPRAIN

No Recommendation

There is no recommendation for or against the use of immobilization by cast.

Strength of evidence No Recommendation, Insufficient Evidence (I)
Level of confidence Low

Indications

Severe ankle sprain.

Frequency/Dose/Duration

Application of a sugar-tong splint for 10 days to 3 weeks after a 48-hour period of elevation and non-weight bearing.

Rationale

There are five quality trials that compared early mobilization with cast immobilization (see Table in Immobilization) (Cooke et al., 2009, Dettori et al., 1994, Dettori et al., 1994, Beynnon et al., 2006, Ardevol et al., 2002, Eiff et al., 1994). There is evidence early mobilization provides short-term benefit in functional improvement, pain, and return to

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work. There are no trials demonstrating a negative treatment effect long-term for acute, moderate, or severe sprain injuries. Therefore, early mobilization is recommended over immobilization for most patients (see Immobilization for additional discussion). There are no quality trials for casting of mild ankle sprains. Mild acute sprains are generally self-limited and respond well to early mobilization and other therapies; therefore, casting is not recommended. There are six quality trials that compared casting with early mobilization for moderate and severe acute ankle sprains. The moderate-quality CAST trial (Cooke et al., 2009), demonstrated below-the-knee casting of moderate and severe sprains for 10 days provided a statistical, but clinically indeterminate, short-term benefit compared with tubular bandage (control) in subjective ratings of pain, function, and symptoms in the first 12 weeks. There were no differences between casting and bracing however, and by 9 months there were no differences between groups. A moderate-quality study demonstrated short-term improvement in pain, swelling, and range of motion in the early mobilization group compared to casting for moderate and severe sprains, but did not demonstrate any long-term benefit of one over the other (Dettori et al., 1994, Dettori et al., 1994). Another moderate-quality trial demonstrated casting was less beneficial for moderate (Grade II) sprains, but was equivocal for severe sprains compared with bracing (Beynnon et al., 2006). A moderate-quality trial limited to severe ankle sprains demonstrated early mobilization resulted in short-term benefit in swelling, pain, stiffness and early return to sport compared with 3-week casting (Ardevol et al., 2002). There were no long-term differences measured at 12 months. Another moderate-quality trial demonstrated early mobilization after a 48-hour non-weight-bearing period provided subjective improvement in pain perception at 3 weeks, but no differences in improvement of swelling, residual pain, and function compared with casting (Eiff et al., 1994). However, early mobilization resulted in much faster return to full duty. No long-term differences were demonstrated in any of the quality trials. Casting is non-invasive, but is restrictive of activity, including return to work, impairs driving performance more than bracing (Tremblay et al., 2009), and is associated with risk for deep venous thrombosis . Total direct and indirect costs of casting based on the U.K. health care system are similar to the use of Aircast brace and more cost-effective than compression wrap (Cooke et al., 2009). Cast immobilization is therefore not recommended as an alternative to splinting and early mobilization treatment for severe and moderate ankle sprain.

EXERCISE

STRETCHING/STRENGTHENING EXERCISES FOR PREVENTION OF ANKLE INJURY

No Recommendation

There is no recommendation for or against the use of stretching or strengthening exercises for the prevention of initial or recurrent ankle injury.

Strength of evidence No Recommendation, Insufficient Evidence (I)
Level of confidence Low

Rationale

There are no quality trials for the use of stretching/strengthening exercises for the prevention of ankle injury. Stretching or strengthening exercises are of low cost, have no

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adverse effects, but are of unknown efficacy, and therefore there is no recommendation for or against their use pending quality trials.

BALANCE/PROPRIOCEPTION TRAINING FOR PREVENTION OF ANKLE INJURY

Recommended

Balance/proprioception training is recommended for prevention of initial and recurrent ankle injury.

Strength of evidence Recommended, Evidence (C)
Level of confidence Low

Rationale

There are two moderate-quality controlled trials that demonstrated benefit in reducing foot or ankle sprain injury after proprioception and balance training in healthy populations compared to control of no training (Emery et al., 2007, McGuine et al., 2006). Ankle sprain injuries were significantly reduced in high school athletes over the course of a season in the group that used a wobble board in training during the season (McGuine et al., 2006). A moderate-quality trial demonstrated home-based proprioception training to be effective in reducing recurrent ankle sprains compared with routine physiotherapy alone (Hupperets et al., 2009, Hupperets et al., 2008). A moderate-quality trial compared postural control techniques using either an internal focus of attention or an external focus of attention during training (Rotem-Lehrer et al., 2007). There were no differences between the techniques, and no recommendation for one technique is made over another. A low-quality trial compared training technique with proprioception and orthosis with no demonstrated differences (Stasinopoulos, 2004). Balance training is of low cost for exercises, and wobble boards can be inexpensive (McGuine et al., 2006). It is not clear which populations would benefit most from this training. Further studies in working populations are needed. Ankle support is low to moderate costs and has low adverse profile, and is recommended for short-term use.

MEDICATIONS

NSAIDS AND ACETAMINOPHEN

NSAIDS FOR ACUTE ANKLE SPRAIN

Recommended

NSAIDs are recommended for treatment of acute ankle sprain.

Strength of evidence Strongly Recommended, Evidence (A)
Level of confidence High

Indications

Pain associated with acute ankle sprain; also for subacute, chronic or post-operative management.

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Frequency/Dose/Duration

Frequency/dose per manufacturer's recommendations; may be taken as scheduled or as needed. There is no evidence one NSAID is superior to another for treatment of ankle sprain. OTC agents may suffice and tried first. There is no evidence for prolonged use, as quality trials demonstrated the greatest benefit within the first 2 weeks.

Indications for discontinuation

Resolution, intolerance, adverse effects, lack of benefits, or failure to progress over a trial of a few weeks.

Rationale

There are two high-quality (Ekman et al., 2006, Slatyer et al., 1997) and six moderate-quality placebo-controlled randomized trials (Ekman et al., 2002, Sloan et al., 1989, Bahamonde et al., 1990, Dreiser et al., 1993, Goldie et al., 1974, Moran, 1991) evaluating the use of NSAIDs in the treatment of acute ankle sprain. NSAIDs were demonstrated to improve function, pain scores with movement, and/or subjective patient global assessment over placebo in all of these studies except one (Goldie et al., 1974), which only studied the change in swelling as an outcome measure. NSAIDs demonstrated to be more effective than placebo include valdecoxib (Ekman et al., 2006), piroxicam (Slatyer et al., 1997, Bahamonde et al., 1990), celecoxib (Ekman et al., 2002), diclofenac (Bahamonde et al., 1990, Moran, 1991), nimesulide (Dreiser et al., 1993), and ibuprofen (Ekman et al., 2002, Sloan et al., 1989, Moran, 1991).

Four moderate-quality trials utilized reduction in swelling as an outcome measure. Three studies did not demonstrate any reduction in swelling compared with placebo (Bahamonde et al., 1990, Dreiser et al., 1993, Goldie et al., 1974). One study did find benefit as measured on a soft tissue swelling index for immediate versus delayed treatment with ibuprofen (Sloan et al., 1989). Thus, there is insufficient evidence to support the use of NSAIDs to treat swelling in acute ankle sprains.

There is no evidence of the superiority of one NSAID over another for any of the outcomes of analgesia, function, or swelling. There were no differences between celecoxib versus naprosyn (Petrella et al., 2004) or diclofenac (Nadarajah et al., 2006), diclofenac versus aspirin (Duncan et al., 1988), oxyphenbutazone versus diflunisal (Adams, 1978) or clonixin (Viljakka et al., 1983), diflunisal versus flurbiprofen (Finch et al., 1989), sulindac versus ibuprofen (Hayes et al., 1984), or modified dosing schedule of ibuprofen (McLatchie et al., 1985). There were no quality studies that compared placebo to OTC-strength NSAIDS. There are no quality studies in post-operative patients, however, NSAIDs have been shown to be highly effective for several other post-operative conditions and thus are recommended (see Low Back Disorders, Hand, Wrist, and Forearm Disorders, and Hip and Groin Disorders Guidelines). NSAIDs are not invasive, have low adverse effects particularly in employed populations, and are low cost, thus they are recommended. If NSAIDs are used to treat

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clinically evident or presumed inflammation, they should be administered on a scheduled basis. If NSAIDs are used for analgesia, they should be taken as needed.

NSAIDS FOR SUBACUTE, CHRONIC, OR POSTOPERATIVE ANKLE SPRAIN

Recommended

NSAIDs are recommended for treatment of subacute, chronic, or post-operative ankle sprain.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence High

Indications

Pain associated with acute ankle sprain; also for subacute, chronic or post-operative management.

Frequency/Dose/Duration

Frequency/dose per manufacturer's recommendations; may be taken as scheduled or as needed. There is no evidence one NSAID is superior to another for treatment of ankle sprain. OTC agents may suffice and tried first. There is no evidence for prolonged use, as quality trials demonstrated the greatest benefit within the first 2 weeks.

Indications for discontinuation

Resolution, intolerance, adverse effects, lack of benefits, or failure to progress over a trial of a few weeks.

Rationale

There are two high-quality (Ekman et al., 2006, Slatyer et al., 1997) and six moderate-quality placebo-controlled randomized trials (Ekman et al., 2002, Sloan et al., 1989, Bahamonde et al., 1990, Dreiser et al., 1993, Goldie et al., 1974, Moran, 1991) evaluating the use of NSAIDs in the treatment of acute ankle sprain. NSAIDs were demonstrated to improve function, pain scores with movement, and/or subjective patient global assessment over placebo in all of these studies except one (Goldie et al., 1974), which only studied the change in swelling as an outcome measure. NSAIDs demonstrated to be more effective than placebo include valdecoxib (Ekman et al., 2006), piroxicam (Slatyer et al., 1997, Bahamonde et al., 1990), celecoxib (Ekman et al., 2002), diclofenac (Bahamonde et al., 1990, Moran, 1991), nimesulide (Dreiser et al., 1993), and ibuprofen (Ekman et al., 2002, Sloan et al., 1989, Moran, 1991).

Four moderate-quality trials utilized reduction in swelling as an outcome measure. Three studies did not demonstrate any reduction in swelling compared with placebo (Bahamonde et al., 1990, Dreiser et al., 1993, Goldie et al., 1974). One study did find benefit as measured on a soft tissue swelling index for immediate versus delayed treatment with ibuprofen

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(Sloan et al., 1989). Thus, there is insufficient evidence to support the use of NSAIDs to treat swelling in acute ankle sprains.

There is no evidence of the superiority of one NSAID over another for any of the outcomes of analgesia, function, or swelling. There were no differences between celecoxib versus naprosyn (Petrella et al., 2004) or diclofenac (Nadarajah et al., 2006), diclofenac versus aspirin (Duncan et al., 1988), oxyphenbutazone versus diflunisal (Adams, 1978) or clonixin (Viljakka et al., 1983), diflunisal versus flurbiprofen (Finch et al., 1989), sulindac versus ibuprofen (Hayes et al., 1984), or modified dosing schedule of ibuprofen (McLatchie et al., 1985). There were no quality studies that compared placebo to OTC-strength NSAIDS. There are no quality studies in post-operative patients, however, NSAIDs have been shown to be highly effective for several other post-operative conditions and thus are recommended (see Low Back Disorders, Hand, Wrist, and Forearm Disorders, and Hip and Groin Disorders Guidelines). NSAIDs are not invasive, have low adverse effects particularly in employed populations, and are low cost, thus they are recommended. If NSAIDs are used to treat clinically evident or presumed inflammation, they should be administered on a scheduled basis. If NSAIDs are used for analgesia, they should be taken as needed.

ACETAMINOPHEN FOR ACUTE, SUBACUTE, OR CHRONIC ANKLE SPRAIN

Recommended

Acetaminophen is moderately recommended for treatment of pain from acute, subacute, or chronic ankle sprain.

Strength of evidence Moderately Recommended, Evidence (B)
Level of confidence Moderate

Indications

Pain associated with acute, subacute, or chronic ankle sprain pain.

Frequency/Dose/Duration

Frequency per manufacturer's recommendations; may be taken as scheduled or as needed. Clinicians are cautioned as an FDA advisory committee has recommended reductions in daily doses below prior recommendations of up to 4gm/day.

Indications for discontinuation

Resolution, intolerance, adverse effects, lack of benefits, or failure to progress over a trial of at least a couple of weeks.

Rationale

Acetaminophen is an analgesic with no significant anti-inflammatory effect. There are no quality placebo-controlled trials that address acetaminophen for ankle sprain. There is one high-quality trial that demonstrated equal efficacy of acetaminophen with over-the-counter

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(OTC) strength ibuprofen (Dalton et al., 2006), and two moderate-quality trials that found paracetemol equivalent to diclofenac 75mg twice daily for acute mild and moderate ankle sprains (Kayali et al., 2007). There is quality evidence that NSAIDs are effective (see NSAIDs). There is also quality evidence that acetaminophen is superior to placebo for treatment of other musculoskeletal disorders, including low back pain, and has a low adverse effect profile (see Chronic Pain guideline for discussion of acetaminophen).

OPIOIDS

OPIOIDS FOR SELECT ACUTE ANKLE SPRAIN

Sometimes Recommended

Limited use of opioids for no more than 1 week is recommended for select patients with severe pain related to acute ankle sprain.

Strength of evidence Recommended, Evidence (C)
Level of confidence Low

Indications

Highly selective use. Severe pain with acute ankle sprain and post-operative pain management. Generally to be used only with either demonstrated insufficient control of pain with NSAID or severe sprain/post-operative pain.

Frequency/Dose/Duration

Frequency/dose per manufacturer's recommendations; may be taken scheduled or as needed; generally suggested to be taken for short courses of a few days. Total length of treatment usually ranges from a few days for injuries to up to 2 weeks for post-surgical management.

Indications for discontinuation

Sufficient pain management with other methods such as NSAIDs, resolution of pain, intolerance, adverse effects, lack of benefits, or failure to progress over a couple weeks.

Rationale

There are two high-quality randomized placebo controlled trials that evaluate the use of Tramadol for treatment of ankle sprain (Hewitt et al., 2007, Ekman et al., 2006). Tramadol was demonstrated to be as effective as NSAIDs for short-term pain relief (Ekman et al., 2006), and as effective as hydrocodone with acetaminophen for pain at rest over the first 3 days post-injury (Hewitt et al., 2007). A low-quality trial concluded that codeine with acetaminophen was equivalent to diflunisal for acute ankle sprain analgesia (Aghababian, 1986).

The vast majority of patients with ankle sprain generally do not have pain sufficient to require opioids. Patients having such degrees of pain should generally have investigations

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performed for alternative diagnoses (see Table 7). Opioids (Tramadol) are not invasive, but have very high dropout rates and otherwise high rates of adverse effects. They are moderate to high cost depending on duration of treatment (see Chronic Pain guideline). They are recommended for short-term analgesia if NSAIDs are not tolerated or are insufficient.

Quality evidence for treatment of post-operative patients with opioids is absent. Some patients have insufficient pain relief with NSAIDs, thus judicious use of opioids may be helpful, particularly for nocturnal use. Opioids are recommended for brief select use in post-operative patients primarily at night to achieve post-operative sleep.

OPIOIDS FOR SELECT POSTOPERATIVE ANKLE SPRAIN

Sometimes Recommended

Limited use of opioids for no more than 1 week may be indicated for patients who have undergone ankle ligament repair surgery or those who encountered surgical complications.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence Low

Indications

Highly selective use. Severe pain with acute ankle sprain and post-operative pain management. Generally to be used only with either demonstrated insufficient control of pain with NSAID or severe sprain/post-operative pain.

Frequency/Dose/Duration

Frequency/dose per manufacturer's recommendations; may be taken scheduled or as needed; generally suggested to be taken for short courses of a few days. Total length of treatment usually ranges from a few days for injuries to up to 2 weeks for post-surgical management.

Indications for discontinuation

Sufficient pain management with other methods such as NSAIDs, resolution of pain, intolerance, adverse effects, lack of benefits, or failure to progress over a couple weeks.

Rationale

There are two high-quality randomized placebo controlled trials that evaluate the use of Tramadol for treatment of ankle sprain (Hewitt et al., 2007, Ekman et al., 2006). Tramadol was demonstrated to be as effective as NSAIDs for short-term pain relief (Ekman et al., 2006), and as effective as hydrocodone with acetaminophen for pain at rest over the first 3 days post-injury (Hewitt et al., 2007). A low-quality trial concluded that codeine with acetaminophen was equivalent to diflunisal for acute ankle sprain analgesia (Aghababian,

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1986). The vast majority of patients with ankle sprain generally do not have pain sufficient to require opioids. Patients having such degrees of pain should generally have investigations performed for alternative diagnoses (see Table 7). Opioids (Tramadol) are not invasive, but have very high dropout rates and otherwise high rates of adverse effects. They are moderate to high cost depending on duration of treatment (see Chronic Pain guideline). They are recommended for short-term analgesia if NSAIDs are not tolerated or are insufficient. Quality evidence for treatment of post-operative patients with opioids is absent. Some patients have insufficient pain relief with NSAIDs, thus judicious use of opioids may be helpful, particularly for nocturnal use. Opioids are recommended for brief select use in post-operative patients primarily at night to achieve post-operative sleep.

PROTEOLYTIC ENZYMES

The use of oral proteolytic enzymes such as hydrolase trypsin, endopeptidase bromelain, and flavonoid rutoside is described as a treatment for pain and swelling from ankle sprain [277,278,279].

PROTEOLYTIC ENZYMES FOR ACUTE, SUBACUTE OR CHRONIC ANKLE SPRAIN

Not Recommended

The use of oral proteolytic enzyme preparations is moderately not recommended for the treatment of acute, subacute, or chronic ankle sprain.

Strength of evidence Moderately Not Recommended, Evidence (B)
Level of confidence Moderate

Rationale

There are two placebo-controlled trials for proteolytic enzymes. A high-quality placebo-controlled trial demonstrated no difference between proteolytic enzymes and placebo in pain score, reduction in swelling, or range of motion measures (Kerkhoffs et al., 2004). A moderate-quality study found no differences in circumference or volume after 5 days of treatment (Craig, 1975). A low-quality trial compared enzymes and cast immobilization to placebo, with and without immobilization, with significant difference favoring enzymes, but had multiple methodological weaknesses and was of uncertain clinical significance (Brakenbury et al., 1983). Oral proteolytic enzymes are well tolerated (Kerkhoffs et al., 2004) and low cost, but are not efficacious and therefore are not recommended.

STREPTOKINASE/STREPTODORNASE

STREPTOKINASE/STREPTODORNASE PREPARATIONS FOR ACUTE, SUBACUTE, OR CHRONIC ANKLE SPRAIN

Not Recommended

Oral streptokinase/streptodornase preparations are not recommended for the treatment of acute, subacute, or chronic ankle sprain.

Strength of evidence Not Recommended, Insufficient Evidence (I)
Level of confidence Low

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Rationale

There is one moderate-quality trial for streptokinase/streptodornase (Varidase) that demonstrated benefit over placebo in the outcomes measures of pain and edema, although clinically the differences are of uncertain significance (Calandre et al., 1991). There is no recent medical literature on the use of this preparation for ankle sprain. This treatment has low reported side effects when used orally, but additional information is otherwise lacking. As the product is not available as an oral agent, there is no recommendation for or against its use.

SYSTEMIC GLUCOCORTICOSTEROIDS

SYSTEMIC GLUCOCORTICOSTEROIDS FOR ACUTE, SUBACUTE, OR CHRONIC ANKLE SPRAIN

Not Recommended

The use of oral or IM steroid preparations is not recommended for the treatment of acute, subacute, or chronic ankle sprain.

Strength of evidence Not Recommended, Insufficient Evidence (I)
Level of confidence High

Rationale

There is no quality evidence for use of these agents for treatment of ankle sprain. As evidence is lacking and evidence of efficacy is present for several other treatments for this condition, the use of glucocorticosteroids by oral or intramuscular routes is generally suggested to be avoided pending publication of quality studies.

Evidence

There are no quality trials incorporated into this analysis.

VITAMINS

VITAMIN THERAPY FOR TREATMENT OF ANKLE SPRAINS

No Recommendation

There is no recommendation for or against the use of vitamins as a therapeutic intervention or for prevention of ankle sprain in doses recommended by the U.S. FDA.

Strength of evidence No Recommendation, Insufficient Evidence (I)
Level of confidence Low

Rationale

There are no quality studies for the use of vitamins for purposes of either treatment or prevention of ankle sprain. If bought in standard doses as standard stock item at food and drug stores, vitamins are usually inexpensive. If taken in doses that do not substantially

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exceed U.S. FDA recommendations, vitamins are safe. However, custom vitamin mixtures or compounds and high doses of vitamins may be expensive and harmful and are not recommended.

Evidence

There are no quality trials incorporated in this analysis.

HIGH-DOSE VITAMIN THERAPY FOR TREATMENT OF ANKLE SPRAINS

Not Recommended

The use of high doses (exceeding U.S. FDA recommendations) or expensive compounded preparation vitamins is not recommended for prevention of ankle sprain.

Strength of evidence Not Recommended, Insufficient Evidence (I)
Level of confidence High

Rationale

There are no quality studies for the use of vitamins for purposes of either treatment or prevention of ankle sprain. If bought in standard doses as standard stock item at food and drug stores, vitamins are usually inexpensive. If taken in doses that do not substantially exceed U.S. FDA recommendations, vitamins are safe. However, custom vitamin mixtures or compounds and high doses of vitamins may be expensive and harmful and are not recommended.

Evidence

There are no quality trials incorporated in this analysis.

BENZYDAMINE

Benzydamine is a non-COX inhibitor anti-inflammatory used topically for oral and vaginal mucositis disorders [280] and has been investigated for the treatment of ankle sprain [281].

BENZYDAMINE FOR ANKLE SPRAINS

No Recommendation

There is no recommendation for or against the use of benzydamine for the treatment of acute, subacute, or chronic ankle sprain.

Strength of evidence No Recommendation, Insufficient Evidence (I)
Level of confidence Low

Rationale

There are no quality trials of benzydamine for the treatment of ankle sprains. A low-quality trial found no benefit of benzydamine over placebo (Elswood et al., 1985). Benzydamine

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applied topically has few side effects, is inexpensive, but is of unknown efficacy, and therefore there is insufficient evidence to recommend for or against this treatment.

Evidence

There are no quality trials incorporated into this analysis. There is 1 low-quality RCT in Appendix 1.

TOPICAL MEDICATIONS

Gels that produce a cold feeling (Menthol/Ethanol) – presumably by stimulating cold receptors in the skin – have been used for treatment of ankle sprain [282,283].

Comfrey extract ointment is used in the United States and Europe to treat wounds and as an anti-inflammatory, and has been described for ankle sprains [284,285,286,287]. The FDA banned the use of oral comfrey products due to pyrrolizidine alkaloid induced liver toxicity [288], but topical preparations are available.

The use of lidocaine patches has been described for various musculoskeletal disorders and has been reviewed in other guidelines (see Chronic Pain, Elbow Disorders, and Hand, Wrist and Forearm Disorders).

Movelat is marketed in Europe as an anti-inflammatory gel or cream composed of mucopolysaccharide polysulphuric acid ester with adrenocortical extract and salicylic acid. It has been described for the treatment of ankle sprain [289,290].

COLD GEL FOR ANKLE SPRAIN

No Recommendation

There is no recommendation for or against the use of medications (menthol/ethanol gels) that stimulate sensation of cold for treatment of ankle sprain.

Strength of evidence No Recommendation, Insufficient Evidence (I)
Level of confidence Low

Rationale

There is one moderate-quality placebo controlled trial for the use of cold gel in minor soft tissue injuries, which included minor ankle sprain as a subset (Airaksinen et al., 2003). The study demonstrated improved pain and subjective rating of functional disability scores in the cold gel group compared with placebo, although the results were likely of small clinical significance. There was no analysis for the ankle sprain subset of subjects. Cold gel has few adverse effects, is non-invasive, and is of low to moderate cost depending on length of use. There is no quality evidence of efficacy for ankle sprain and therefore there is no recommendation for or against its use.

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COMFREY EXTRACT FOR ANKLE SPRAINS

No Recommendation

There is no recommendation for or against the use of topical comfrey extract (Symphytum officinale) for the treatment of ankle sprains.

Strength of evidence No Recommendation, Insufficient Evidence (I)
Level of confidence Low

Rationale

There is one placebo-controlled moderate-quality study that suggested efficacy in improved analgesia and reduced swelling (Koll et al., 2004). There is one moderate-quality trial with two reports that demonstrated equivalency of comfrey gel to topical diclofenac gel in resting and active motion pain relief after 7 days of treatment (D'Anchise et al., 2007, Predel et al., 2005). As there is no ability to control the dose of nutraceutical and similar products, there is no recommendation for or against the use of comfrey to treat acute ankle sprain.

LIDOCAINE PATCHES FOR ACUTE, SUBACUTE, OR CHRONIC ANKLE SPRAIN

No Recommendation

There is no recommendation for or against the use of lidocaine patches for the treatment of acute, subacute, or chronic ankle sprain.

Strength of evidence No Recommendation, Insufficient Evidence (I)
Level of confidence Low

Rationale

There are no quality trials of lidocaine patch use for ankle sprain. As one goal of therapies for acute ankle sprain is pain relief, this may represent a potential treatment on a short-term basis while other concomitant interventions such as elevation, cryotherapy, and NSAIDs are utilized. Patches are low cost for a short-term trial; however, costs accumulate rapidly over time. Adverse effects of systemic absorption of topical anesthetics have prompted an FDA warning. There is no recommendation for lidocaine patches for ankle sprain.

Evidence

There are no quality trials incorporated into this analysis.

MOVELAT FOR ACUTE, SUBACUTE, OR CHRONIC ANKLE SPRAIN

No Recommendation

There is no recommendation for or against the use of topical creams (including Movelat) for the treatment of acute, subacute, or chronic ankle sprain.

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Strength of evidence No Recommendation, Insufficient Evidence (I)
Level of confidence Low

Rationale

There are two moderate-quality placebo-controlled quality trials of Movelat for the treatment of ankle sprains. One trial compared Movelat to placebo for mild and moderate acute sprain controlling for other co-interventions and demonstrated modest analgesic relief of pain at Day 9 only of an 11 day follow-up (Frahm et al., 1993). The other study compared Movelat as an adjunct to physiotherapy, and suggested a benefit of treatment, although an ill-defined scoring system was used and results were not supported by the analysis (Lester, 1981). Movelat applied topically has few side effects, is inexpensive, but is of unknown efficacy, and therefore there is insufficient evidence to recommend for or against this treatment.

TOPICAL NSAIDS FOR ACUTE ANKLE SPRAIN

Recommended

Topical NSAIDs are moderately recommended for the treatment of acute ankle sprain.

Strength of evidence Moderately Recommended, Evidence (B)
Level of confidence Moderate

Indications

Acute ankle sprain or patients with contraindications for oral treatment or who prefer not to take oral medications. No evidence of comparative superiority of one topical NSAID over another.

Frequency/Dose/Duration

Frequency per manufacturer's recommendation. Topical NSAID use has been reported for 1 to 3 weeks (Russell, 1991, Predel et al., 2005).

Indications for discontinuation

Resolution, intolerance, adverse effects, or lack of benefits.

Rationale

There are 3 high- and 3 moderate-quality placebo-controlled randomized trials for the use of topical NSAIDs in the treatment of ankle sprain injuries. All 3 high-quality RCTs demonstrated treatment benefit in analgesia and swelling reduction using daily ketoprofen patch (Mazieres et al., 2005), diclofenac gel (Predel et al., 2005), and ketorolac or etofenamate gel used over a 2-week period (Diebschlag et al., 1990). A moderate-quality trial demonstrated no benefit from Piroxicam gel over placebo for ankle sprains (Russell,

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1991), while a second moderate-quality study found niflumic acid gel to provide benefit in pain and functional improvement in the acute phase of injury (Dreiser et al., 1990). A third moderate-quality study found no treatment effect with flurbiprofen patch until 7 days post injury compared with placebo (Dreiser et al., 1994). There are no trials that demonstrate efficacy of one NSAID over another. One high-quality trial demonstrated increased efficacy in diclofenac gel formulated with lecithin compared to non-lecithin gel, although no placebo arm was included (Mahler et al., 2003). One moderate-quality trial demonstrated equivalent efficacy of NSAID gel with therapeutic ultrasound, although other studies found no benefit from ultrasound (see Physical Methods – Ultrasound) (Oakland, 1993). Topical NSAIDs are not invasive, have low adverse effect rates, but may cumulatively be moderate to high cost. They are recommended for treatment of acute ankle sprain, particularly in patients who do not tolerate or are poor candidates for oral treatment. Post-operative patients may be reasonable candidates after the incision is well healed.

TOPICAL NSAIDS FOR SUBACUTE, CHRONIC, OR POSTOPERATIVE ANKLE SPRAIN

No Recommendation

There is no recommendation for or against the use of topical NSAIDs fr the treatment of subacute, chronic, or post-operative ankle sprain.

Strength of evidence No Recommendation, Insufficient Evidence (I)
Level of confidence Low

Rationale

There are 3 high- and 3 moderate-quality placebo-controlled randomized trials for the use of topical NSAIDs in the treatment of ankle sprain injuries. All 3 high-quality RCTs demonstrated treatment benefit in analgesia and swelling reduction using daily ketoprofen patch (Mazieres et al., 2005), diclofenac gel (Predel et al., 2005), and ketorolac or etofenamate gel used over a 2-week period (Diebschlag et al., 1990). A moderate-quality trial demonstrated no benefit from Piroxicam gel over placebo for ankle sprains (Russell, 1991), while a second moderate-quality study found niflumic acid gel to provide benefit in pain and functional improvement in the acute phase of injury (Dreiser et al., 1990). A third moderate-quality study found no treatment effect with flurbiprofen patch until 7 days post injury compared with placebo (Dreiser et al., 1994). There are no trials that demonstrate efficacy of one NSAID over another. One high-quality trial demonstrated increased efficacy in diclofenac gel formulated with lecithin compared to non-lecithin gel, although no placebo arm was included (Mahler et al., 2003). One moderate-quality trial demonstrated equivalent efficacy of NSAID gel with therapeutic ultrasound, although other studies found no benefit from ultrasound (see Physical Methods – Ultrasound) (Oakland, 1993). Topical NSAIDs are not invasive, have low adverse effect rates, but may cumulatively be moderate to high cost. They are recommended for treatment of acute ankle sprain, particularly in patients who do not tolerate or are poor candidates for oral treatment. Post-operative patients may be reasonable candidates after the incision is well healed.

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DEVICES

SHOES, ORTHOTICS, AND WALKING BOOTS

SPECIAL SHOES FOR PREVENTION OF ANKLE SPRAIN OR RECURRENT ANKLE SPRAIN

Recommended

Appropriate activity-specific footwear is recommended for the prevention of ankle sprain or recurrent ankle sprain. There is no recommendation for the use of one type of shoe over another for prevention of ankle sprain or lower extremity disorders.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence Low

Rationale

There are two moderate-quality trials comparing the use of different running shoe types matched to foot arch (plantar shape) in military basic training settings, which did not demonstrate benefit in reducing injury or sprain (Knapik et al., 2010, Knapik et al., 2010). The application of these studies in the military is that no effort is needed to match shoe type with foot arch type. The practical applications in the working population are unclear. There is one moderate-quality trial that compared the use of high- and low-top basketball shoes in an athletic league (Barrett et al., 1993). There were no differences in incidence of injury between the groups over a 2-month college intramural season. There are myriad shoe types that are designed for workplace hazard or athletic event. The use or misuse of shoe type plausibly may result in injury when used improperly or for the wrong purpose. These devices are non-invasive, have few adverse effects, and are generally moderate cost for devices that are not custom designed. There is insufficient evidence for or against the use of one type of footwear over another as long as it is being used for the designed purpose.

WALKING BOOT FOR ACUTE ANKLE SPRAIN

Not Recommended

Walking boots are not recommended for treatment of acute ankle sprains.

Strength of evidence Not Recommended, Evidence (C)
Level of confidence Moderate

Rationale

There are no quality trials comparing the effectiveness of using all RICE therapies concurrently with a control of no RICE therapy. RICE is frequently described as a co-intervention in numerous comparative trials. One moderate-quality trial that demonstrated the addition of therapeutic exercises to RICE resulted in improved short-term function with reduction in pain compared to RICE alone, although there were no differences in return to work, walking, or sports (Bleakley et al., 2010, Bleakley et al., 2007). Another moderate-quality trial demonstrated passive manipulation added to RICE protocol demonstrated improved dorsiflexion with reduction in pain compared to RICE alone, although there were

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no differences in return to work, walking, or return to sport (Green et al., 2001). There are no quality trials comparing immediate rest (non-weight bearing) to continued weight bearing. A moderate-quality trial demonstrated early mobilization through weight bearing with the assistance of ankle supports or compression wraps after a 48-hour non-weight-bearing period demonstrated improved return to full duty compared with immobilization (Eiff et al., 1994) (see Functional Treatment – Mobilization). Therefore, there is no evidence that rest is of benefit if weight bearing is tolerated in the immediate post-injury period. A moderate-quality trial comparing a single 30-minute application of ice therapy to sham therapy demonstrated no significant benefit at 7 days (Sloan et al., 1989). However, there were no short-term outcome measures included and all subjects had NSAIDS and compression wrap. There is one moderate-quality study comparing continuous versus intermittent application of cold therapy that found two intermittent 10-minute intervals with a 10-minute break between applications every 2 hours for 3 days superior to 20-minute continuous application at same 2-hour intervals as measured by subjective pain with activity at 7 days (Bleakley et al., 2006). However, there were no differences in function, swelling, or pain at rest. Cold therapy has been demonstrated to be more effective in reducing edema than heat or contrast bath (Cote et al., 1988) and compression (Sloan et al., 1989). A low-quality study found no additional benefit from cold therapy or elastic tape when used with air-stirrup (Wilkerson et al., 1993). The use of cold therapy applied directly over elastic wrap as well as plaster and synthetic casting material has been demonstrated to effectively reduce skin temperature (Okcu et al., 2006), suggesting that application can be made regardless of immobilization or compression. There is no evidence that the use of ice hastens return to work or function . Cryotherapy is non-invasive, has low adverse effects when used for short periods or if precautions are taken to avoid freezing of soft tissues, is of low to high cost dependent on purchase or rental of equipment (Stockle et al., 1997), and is recommended. There is one moderate-quality study comparing compression using elastic wrap to no treatment for mild and moderate acute sprains that did not demonstrate significant benefit of compression wrap (Watts et al., 2001). Three moderate-quality trials demonstrated compression wrap (e.g., bandage, elastic wrap, tubigrip) to be less effective than ankle braces (Cooke et al., 2009, O'Hara et al., 1992, Boyce et al., 2005) while two trials found no difference between these treatments (Beynnon et al., 2006, Leanderson et al., 1999). However, one trial demonstrated the combination of compression wrap with ankle brace (Aircast) to be more effective than either treatment alone for mild (Grade I) sprains (Beynnon et al., 2006). A moderate-quality trial found no difference in tape versus compression wrap (Viljakka et al., 1983). A moderate-quality trial found no long-term differences between casting or semi-rigid immobilization (Dettori et al., 1994, Dettori et al., 1994). Compression wraps and a pneumatic compression device were found to be less effective than elevation in reducing acute edema (Rucinski et al., 1991). Compression wraps may provide additional benefit when used in conjunction with ankle braces. One moderate-quality trial compared non-orthosis ankle support to no treatment, which demonstrated tubular elastic (Tubigrip®) provided no therapeutic benefit for mild and moderate sprains (Watts et al., 2001). Three moderate-quality trials demonstrated elastic support (e.g. bandage, elastic wrap, tubigrip) to be less effective than ankle braces (Cooke et al., 2009, Boyce et al., 2005, O'Hara et al., 1992), while three trials found no difference between these treatments (Dettori et al., 1994, Dettori et al., 1994, Beynnon et al., 2006, Leanderson et al., 1999). One trial did find the combination of compression wrap with ankle brace (Aircast) to be more effective than either treatment alone for mild (Grade I) sprains (Beynnon et al.,

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2006). Functional strapping (taping) was demonstrated to provide short-term benefits in pain, swelling, stiffness, and feeling of instability for severe sprains compared with casting (Ardevol et al., 2002), but no long-term benefit was demonstrated. A moderate-quality trial found no difference in tape versus elastic wrap (Viljakka et al., 1983). A moderate-quality trial found no long-term differences between elastic wrap support and casting or semi-rigid immobilization (Dettori et al., 1994, Dettori et al., 1994). Taping, tubular elastic, and elastic bandage wrap for support are non-invasive, are generally of low to moderate cost, and have low adverse effects, but are of no therapeutic benefit for mild sprains and appear to be less effective than more rigid support for severe sprains. Therefore, there is insufficient evidence to recommend their routine use. There are no quality-controlled trials comparing the use of ankle bracing to a “no treatment” group. There are six moderate-quality trials that compared ankle braces to other functional treatments. Three moderate-quality trials demonstrated ankle braces to be more effective than elastic support (Cooke et al., 2009, O'Hara et al., 1992, Boyce et al., 2005), while three moderate quality studies found no differences between ankle brace and elastic wrap for moderate and severe sprains (Dettori et al., 1994, Dettori et al., 1994, Beynnon et al., 2006, Zwipp et al., 1992). There are three moderate-quality studies for ankle brace versus cast immobilization demonstrating benefit of brace over cast immobilization (Cooke et al., 2009, Boyce et al., 2005, Dettori et al., 1994, Dettori et al., 1994). Combined ankle brace with elastic wrap was found to beneficial over immobilization (Beynnon et al., 2006, Eiff et al., 1994). Ankle orthoses are non-invasive, are of moderate cost, and the quality evidence is mixed. There are no differences found in sprain recurrence between the different types of ankle supports used for early mobilization. It appears that mobilization is the most important factor; however, insofar as ankle braces and supports may aid and encourage increased mobilization, ankle braces and supports that allow some movement are recommended. One moderate-quality trial found a walking boot was inferior to a functional brace as part of a treatment program for severe lateral ankle injuries. (Prado 14) There is another moderate-quality study with three reports that included a walking boot as an intervention arm (Cooke et al., 2009). There were no short- or long-term benefits demonstrated compared with other functional and immobilization techniques. The walking boot was demonstrated to have the highest costs (direct, indirect) compared with casting, tubular bandage, or Aircast. Therefore, use of a walking boot for uncomplicated ankle sprains is not recommended. One moderate-quality sham-controlled trial found mostly negative results from use of compression stockings for treatment of ankle sprain (Bendahou M, 2014). There is one moderate-quality study that demonstrated elevation is more effective in reducing edema after a single 30-minute treatment session than elevation used in conjunction with compression wrap or pneumatic brace, suggesting there is no added benefit for additional therapies in the immediate post-treatment period (Rucinski et al., 1991). However, these results are of uncertain short-term clinical significance. The significance of changes in edema in the post-sprain recovery period is of undefined clinical significance, as little correlation is described in available trials (Sloan et al., 1989, Boyce et al., 2005, Bleakley et al., 2010, Bleakley et al., 2007). A prospective case series found no relationships between ankle-foot edema and ankle function in the acute phase of ankle sprain injury . Despite the general acceptance of RICE or the individual therapies of RICE for acute ankle sprain, there is a lack of quality evidence for efficacy. A primary rationale for these modalities is to reduce edema. However, there was little correlation demonstrated in the available studies in reduction of edema as an indicator for functional or pain improvement (Sloan et al., 1989, Boyce et al., 2005, Bleakley et al., 2010,

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Bleakley et al., 2007). These treatments are not invasive, generally have few adverse effects, and are not costly when self-administered. Rest, ice, and elevation are therefore recommended. There is insufficient evidence for recommendation of compression.

FOOT ORTHOTICS FOR PREVENTION OF ANKLE INJURY

No Recommendation

There is no recommendation for or against the use of foot orthotics for the prevention of ankle injury.

Strength of evidence No Recommendation, Insufficient Evidence (I)
Level of confidence Low

Rationale

There are no quality trials comparing the use of foot orthoses with "no use" for the prevention of ankle sprain. A low-quality study demonstrated no differences in injury prevention with the use of heel cup inserts (Fauno et al., 1993). There is one moderate-quality trial with two separate trials that compared custom soft orthotics with soft prefabricated orthotics, and custom semi-rigid orthotics with pre-fabricated semi-rigid orthotics (Finestone et al., 2004). There were no differences in incidence of injury between the groups. With the lack of a control group, prophylactic value of using orthotics is not defined. These devices are non-invasive, have few adverse effects, and are generally low cost for devices that are not custom-made. There is insufficient evidence for or against the use of foot orthotics for prevention of initial or recurrent ankle sprain.

COMPRESSION AND SUPPORT THERAPIES

COMPRESSION THERAPY FOR ACUTE ANKLE SPRAIN

No Recommendation

There is no recommendation for or against the use of compression therapy (i.e., tape, elastic wrap, tubular elastic, or pneumatic compression devices) for acute ankle sprains.

Strength of evidence No Recommendation, Insufficient Evidence (I)
Level of confidence Low

Rationale

There are no quality trials comparing the effectiveness of using all RICE therapies concurrently with a control of no RICE therapy. RICE is frequently described as a co-intervention in numerous comparative trials. One moderate-quality trial that demonstrated the addition of therapeutic exercises to RICE resulted in improved short-term function with reduction in pain compared to RICE alone, although there were no differences in return to work, walking, or sports (Bleakley et al., 2010, Bleakley et al., 2007). Another moderate-quality trial demonstrated passive manipulation added to RICE protocol demonstrated improved dorsiflexion with reduction in pain compared to RICE alone, although there were no differences in return to work, walking, or return to sport (Green et al., 2001). There are

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no quality trials comparing immediate rest (non-weight bearing) to continued weight bearing. A moderate-quality trial demonstrated early mobilization through weight bearing with the assistance of ankle supports or compression wraps after a 48-hour non-weight-bearing period demonstrated improved return to full duty compared with immobilization (Eiff et al., 1994) (see Functional Treatment – Mobilization). Therefore, there is no evidence that rest is of benefit if weight bearing is tolerated in the immediate post-injury period. There is one moderate-quality study comparing compression using elastic wrap to no treatment for mild and moderate acute sprains that did not demonstrate significant benefit of compression wrap (Watts et al., 2001). Three moderate-quality trials demonstrated compression wrap (e.g., bandage, elastic wrap, tubigrip) to be less effective than ankle braces (Cooke et al., 2009, Lamb et al., 2005, Lamb et al., 2009, O'Hara et al., 1992, Boyce et al., 2005) while two trials found no difference between these treatments (Beynnon et al., 2006, Leanderson et al., 1999). However, one trial demonstrated the combination of compression wrap with ankle brace (Aircast) to be more effective than either treatment alone for mild (Grade I) sprains (Beynnon et al., 2006). A moderate-quality trial found no difference in tape versus compression wrap (Viljakka et al., 1983). A moderate-quality trial found no long-term differences between casting or semi-rigid immobilization (Dettori et al., 1994, Dettori et al., 1994). Compression wraps and a pneumatic compression device were found to be less effective than elevation in reducing acute edema (Rucinski et al., 1991). Compression wraps may provide additional benefit when used in conjunction with ankle braces. Despite the general acceptance of RICE or the individual therapies of RICE for acute ankle sprain, there is a lack of quality evidence for efficacy. A primary rationale for these modalities is to reduce edema. However, there was little correlation demonstrated in the available studies in reduction of edema as an indicator for functional or pain improvement (Sloan et al., 1989, Boyce et al., 2005, Bleakley et al., 2010, Bleakley et al., 2007). These treatments are not invasive, generally have few adverse effects, and are not costly when self-administered. Rest, ice, and elevation are therefore recommended. There is insufficient evidence for recommendation of compression.

TUBIGRIP FOR ACUTE ANKLE SPRAIN

Not Recommended

Tubigrip is not recommended for acute ankle sprains.

Strength of evidence Not Recommended, Evidence (C)
Level of confidence Low

Rationale

There are no quality trials comparing the effectiveness of using all RICE therapies concurrently with a control of no RICE therapy. RICE is frequently described as a co-intervention in numerous comparative trials. One moderate-quality trial that demonstrated the addition of therapeutic exercises to RICE resulted in improved short-term function with reduction in pain compared to RICE alone, although there were no differences in return to work, walking, or sports (Bleakley et al., 2010, Bleakley et al., 2007). Another moderate-quality trial demonstrated passive manipulation added to RICE protocol demonstrated improved dorsiflexion with reduction in pain compared to RICE alone, although there were

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no differences in return to work, walking, or return to sport (Green et al., 2001). There are no quality trials comparing immediate rest (non-weight bearing) to continued weight bearing. A moderate-quality trial demonstrated early mobilization through weight bearing with the assistance of ankle supports or compression wraps after a 48-hour non-weight-bearing period demonstrated improved return to full duty compared with immobilization (Eiff et al., 1994) (see Functional Treatment – Mobilization). Therefore, there is no evidence that rest is of benefit if weight bearing is tolerated in the immediate post-injury period.

A moderate-quality trial comparing a single 30-minute application of ice therapy to sham therapy demonstrated no significant benefit at 7 days (Sloan et al., 1989). However, there were no short-term outcome measures included and all subjects had NSAIDS and compression wrap. There is one moderate-quality study comparing continuous versus intermittent application of cold therapy that found two intermittent 10-minute intervals with a 10-minute break between applications every 2 hours for 3 days superior to 20-minute continuous application at same 2-hour intervals as measured by subjective pain with activity at 7 days (Bleakley et al., 2006). However, there were no differences in function, swelling, or pain at rest. Cold therapy has been demonstrated to be more effective in reducing edema than heat or contrast bath (Cote et al., 1988) and compression (Sloan et al., 1989). A low-quality study found no additional benefit from cold therapy or elastic tape when used with air-stirrup (Wilkerson et al., 1993). The use of cold therapy applied directly over elastic wrap as well as plaster and synthetic casting material has been demonstrated to effectively reduce skin temperature (Okcu et al., 2006), suggesting that application can be made regardless of immobilization or compression. There is no evidence that the use of ice hastens return to work or function (Hubbard et al., 2004). Cryotherapy is non-invasive, has low adverse effects when used for short periods or if precautions are taken to avoid freezing of soft tissues, is of low to high cost dependent on purchase or rental of equipment (Stockle et al., 1997), and is recommended.

There is one moderate-quality study comparing compression using elastic wrap to no treatment for mild and moderate acute sprains that did not demonstrate significant benefit of compression wrap (Watts et al., 2001). Three moderate-quality trials demonstrated compression wrap (e.g., bandage, elastic wrap, tubigrip) to be less effective than ankle braces (Cooke et al., 2009, Lamb et al., 2009, Lamb et al., 2005, O'Hara et al., 1992, Boyce et al., 2005) while two trials found no difference between these treatments (Beynnon et al., 2006, Leanderson et al., 1999). However, one trial demonstrated the combination of compression wrap with ankle brace (Aircast) to be more effective than either treatment alone for mild (Grade I) sprains (Beynnon et al., 2006). A moderate-quality trial found no difference in tape versus compression wrap (Viljakka et al., 1983). A moderate-quality trial found no long-term differences between casting or semi-rigid immobilization (Dettori et al., 1994, Dettori et al., 1994). Compression wraps and a pneumatic compression device were found to be less effective than elevation in reducing acute edema (Rucinski et al., 1991). Compression wraps may provide additional benefit when used in conjunction with ankle braces.

One moderate-quality trial compared non-orthosis ankle support to no treatment, which demonstrated tubular elastic (Tubigrip®) provided no therapeutic benefit for mild and moderate sprains (Watts et al., 2001). Three moderate-quality trials demonstrated elastic

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support (e.g. bandage, elastic wrap, tubigrip) to be less effective than ankle braces (Cooke et al., 2009, Lamb et al., 2009, Lamb et al., 2005, Boyce et al., 2005, O'Hara et al., 1992), while three trials found no difference between these treatments (Dettori et al., 1994, Dettori et al., 1994, Beynnon et al., 2006, Leanderson et al., 1999). One trial did find the combination of compression wrap with ankle brace (Aircast) to be more effective than either treatment alone for mild (Grade I) sprains (Beynnon et al., 2006). Functional strapping (taping) was demonstrated to provide short-term benefits in pain, swelling, stiffness, and feeling of instability for severe sprains compared with casting (Ardevol et al., 2002), but no long-term benefit was demonstrated. A moderate-quality trial found no difference in tape versus elastic wrap (Viljakka et al., 1983). A moderate-quality trial found no long-term differences between elastic wrap support and casting or semi-rigid immobilization (Dettori et al., 1994, Dettori et al., 1994). Taping, tubular elastic, and elastic bandage wrap for support are non-invasive, are generally of low to moderate cost, and have low adverse effects, but are of no therapeutic benefit for mild sprains and appear to be less effective than more rigid support for severe sprains. Therefore, there is insufficient evidence to recommend their routine use.

There are no quality-controlled trials comparing the use of ankle bracing to a “no treatment” group. There are six moderate-quality trials that compared ankle braces to other functional treatments. Three moderate-quality trials demonstrated ankle braces to be more effective than elastic support (Cooke et al., 2009, Lamb et al., 2009, Lamb et al., 2005, O'Hara et al., 1992, Boyce et al., 2005), while three moderate quality studies found no differences between ankle brace and elastic wrap for moderate and severe sprains (Dettori et al., 1994, Dettori et al., 1994, Beynnon et al., 2006, Zwipp et al., 1992). There are three moderate-quality studies for ankle brace versus cast immobilization demonstrating benefit of brace over cast immobilization (Cooke et al., 2009, Boyce et al., 2005, Dettori et al., 1994, Dettori et al., 1994). Combined ankle brace with elastic wrap was found to beneficial over immobilization (Beynnon et al., 2006, Eiff et al., 1994). Ankle orthoses are non-invasive, are of moderate cost, and the quality evidence is mixed. There are no differences found in sprain recurrence between the different types of ankle supports used for early mobilization. It appears that mobilization is the most important factor; however, insofar as ankle braces and supports may aid and encourage increased mobilization, ankle braces and supports that allow some movement are recommended.

One moderate-quality trial found a walking boot was inferior to a functional brace as part of a treatment program for severe lateral ankle injuries. (Prado 14) There is another moderate-quality study with three reports that included a walking boot as an intervention arm (Cooke et al., 2009, Lamb et al., 2009, Lamb et al., 2005). There were no short- or long-term benefits demonstrated compared with other functional and immobilization techniques. The walking boot was demonstrated to have the highest costs (direct, indirect) compared with casting, tubular bandage, or Aircast. Therefore, use of a walking boot for uncomplicated ankle sprains is not recommended. One moderate-quality sham-controlled trial found mostly negative results from use of compression stockings for treatment of ankle sprain (Bendahou M, 2014).

There is one moderate-quality study that demonstrated elevation is more effective in reducing edema after a single 30-minute treatment session than elevation used in conjunction with compression wrap or pneumatic brace, suggesting there is no added

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benefit for additional therapies in the immediate post-treatment period (Rucinski et al., 1991). However, these results are of uncertain short-term clinical significance. The significance of changes in edema in the post-sprain recovery period is of undefined clinical significance, as little correlation is described in available trials (Sloan et al., 1989, Boyce et al., 2005, Bleakley et al., 2010, Bleakley et al., 2007). A prospective case series found no relationships between ankle-foot edema and ankle function in the acute phase of ankle sprain injury (Man et al., 2005).

Despite the general acceptance of RICE or the individual therapies of RICE for acute ankle sprain, there is a lack of quality evidence for efficacy. A primary rationale for these modalities is to reduce edema. However, there was little correlation demonstrated in the available studies in reduction of edema as an indicator for functional or pain improvement (Sloan et al., 1989, Boyce et al., 2005, Bleakley et al., 2010, Bleakley et al., 2007). These treatments are not invasive, generally have few adverse effects, and are not costly when self-administered. Rest, ice, and elevation are therefore recommended. There is insufficient evidence for recommendation of compression.

TAPE, ELASTIC WRAP, OR TUBULAR ELASTIC FOR ACUTE ANKLE SPRAIN

No Recommendation

There is no recommendation for or against the use of non-rigid support therapies (i.e., tape, elastic wrap, or tubular elastic) for acute ankle sprains.

Strength of evidence No Recommendation, Insufficient Evidence (I)
Level of confidence Low

Rationale

One moderate-quality trial compared non-orthosis ankle support to no treatment, which demonstrated tubular elastic (Tubigrip®) provided no therapeutic benefit for mild and moderate sprains (Watts et al., 2001). Three moderate-quality trials demonstrated elastic support (e.g. bandage, elastic wrap, tubigrip) to be less effective than ankle braces (Cooke et al., 2009, Lamb et al., 2009, Lamb et al., 2005, O'Hara et al., 1992, Boyce et al., 2005), while three trials found no difference between these treatments (Dettori et al., 1994, Dettori et al., 1994, Beynnon et al., 2006, Leanderson et al., 1999). One trial did find the combination of compression wrap with ankle brace (Aircast) to be more effective than either treatment alone for mild (Grade I) sprains (Beynnon et al., 2006). Functional strapping (taping) was demonstrated to provide short-term benefits in pain, swelling, stiffness, and feeling of instability for severe sprains compared with casting,(493) but no long-term benefit was demonstrated. A moderate-quality trial found no difference in tape versus elastic wrap (Viljakka et al., 1983). A moderate-quality trial found no long-term differences between elastic wrap support and casting or semi-rigid immobilization (Dettori et al., 1994, Dettori et al., 1994). Taping, tubular elastic, and elastic bandage wrap for support are non-invasive, are generally of low to moderate cost, and have low adverse effects, but are of no therapeutic benefit for mild sprains and appear to be less effective than more rigid support for severe sprains. Therefore, there is insufficient evidence to recommend their routine use.

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ANKLE BRACE (ORTHOSIS) FOR ACUTE ANKLE SPRAIN

Recommended

The use of semi-rigid pneumatic or gel ankle brace supports for treatment for acute ankle sprain is recommended, with optional use as needed by the patient for mild and moderate sprains.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence Low

Rationale

There are no quality-controlled trials comparing the use of ankle bracing to a "no treatment" group. There are six moderate-quality trials that compared ankle braces to other functional treatments. Three moderate-quality trials demonstrated ankle braces to be more effective than elastic support (Cooke et al., 2009, Lamb et al., 2009, Lamb et al., 2005, O'Hara et al., 1992, Boyce et al., 2005), while three moderate quality studies found no differences between ankle brace and elastic wrap for moderate and severe sprains (Dettori et al., 1994, Dettori et al., 1994, Beynnon et al., 2006, Leanderson et al., 1999). There are three moderate-quality studies for ankle brace versus cast immobilization demonstrating benefit of brace over cast immobilization (Cooke et al., 2009, Dettori et al., 1994, Dettori et al., 1994, Boyce et al., 2005). Combined ankle brace with elastic wrap was found to beneficial over immobilization (Beynnon et al., 2006, Eiff et al., 1994). Ankle orthosis are non-invasive, are of moderate cost, and the quality evidence is mixed. There are no differences found in sprain recurrence between the different types of ankle supports used for early mobilization. It appears that mobilization is the most important factor; however, insofar as ankle braces and supports may aid and encourage increased mobilization, ankle braces and supports that allow some movement are recommended.

ANKLE SUPPORT (BRACE, TAPE) FOR PREVENTION OF INITIAL ANKLE INJURY

Recommended

The use of ankle support (brace, tape) is recommended for the prevention of ankle injury.

Strength of evidence Recommended, Evidence (C)
Level of confidence Moderate

Rationale

There are two controlled moderate-quality trials that compare the incidence of ankle sprain injuries in healthy military populations using an ankle brace compared to “no brace” for intramural basketball participation (Sitler et al., 1994) and paratrooper training (Amoroso et al., 1998). Both studies demonstrated a lower incidence of ankle sprain in the brace group. Another moderate-quality trial compared bracing to taping for the prevention of sprain during a high school football season and found no difference between groups (Mickel et al., 2006). However, there was no control group to determine efficacy of prevention. There are two low-quality studies of high school athletes also suggesting preventive value of a lace-up

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brace (McGuine TA, 2011, McGuine TA, 2012). There are no quality trials for the use of ankle supports to prevent recurrent injury, but by inference, they may provide additional protection to persons with feelings of instability or who are involved in activities that are at high risk for ankle inversion. Ankle supports are non-invasive, have low adverse effects, and may be of moderate to high cost, particularly for daily taping or use of multiple braces over a season.

ANKLE SUPPORT (BRACE, TAPE) FOR PREVENTION OF RECURRENT ANKLE INJURY

Recommended

The use of ankle support (brace, tape) is recommended for the prevention of ankle injury.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence Moderate

Rationale

There are two controlled moderate-quality trials that compare the incidence of ankle sprain injuries in healthy military populations using an ankle brace compared to “no brace” for intramural basketball participation (Sitler et al., 1994) and paratrooper training (Amoroso et al., 1998). Both studies demonstrated a lower incidence of ankle sprain in the brace group. Another moderate-quality trial compared bracing to taping for the prevention of sprain during a high school football season and found no difference between groups (Mickel et al., 2006). However, there was no control group to determine efficacy of prevention. There are two low-quality studies of high school athletes also suggesting preventive value of a lace-up brace (McGuine TA, 2011, McGuine TA, 2012). There are no quality trials for the use of ankle supports to prevent recurrent injury, but by inference, they may provide additional protection to persons with feelings of instability or who are involved in activities that are at high risk for ankle inversion. Ankle supports are non-invasive, have low adverse effects, and may be of moderate to high cost, particularly for daily taping or use of multiple braces over a season.

MAGNETS

MAGNETS FOR ACUTE, SUBACUTE, OR CHRONIC ANKLE SPRAIN

No Recommendation

There is no recommendation for or against the use of magnets for treatment of acute, subacute, or chronic ankle sprain.

Strength of evidence No Recommendation, Insufficient Evidence (I)
Level of confidence Low

Rationale

There are no quality trials available for the use of magnets in the treatment of ankle sprain. Magnets have been evaluated in quality studies elsewhere involving the spine and hand and have been found to be ineffective. Magnets are not invasive, have no adverse effects, and

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are low cost, but are of unknown efficacy for sprains and therefore there is no recommendation for or against their use in the treatment of ankle sprain.

Evidence

There are no quality RCTs incorporated in this analysis.

ULTRASOUND

THERAPEUTIC ULTRASOUND FOR ACUTE ANKLE SPRAIN

Not Recommended

Therapeutic ultrasound is not recommended for the treatment of acute ankle sprain.

Strength of evidence Moderately Not Recommended, Evidence (B)
Level of confidence Moderate

Rationale

There are three moderate-quality placebo-controlled trials that demonstrated no clinical benefit from therapeutic ultrasound compared with sham ultrasound after 3 to 8 sessions as measured by pain, swelling, or functional improvement (Zammit et al., 2005, Nyanzi et al., 1999, Williamson et al., 1986). A low-quality trial demonstrated ultrasound plus ice to be more effective than elastoplast wrap in pain relief and functional recovery (Makuloluwe et al., 1977). There is one moderate-quality trial that demonstrated similar improvements in the ultrasound group compared with topical NSAIDs, although there was no control arm, so natural history for improvement cannot be excluded (Oakland, 1993). Ultrasound is non-invasive, has low adverse effects, is of moderate cost depending on numbers of treatments, but has low treatment efficacy and is therefore not recommended.

THERAPEUTIC ULTRASOUND FOR SUBACUTE OR CHRONIC ANKLE SPRAIN

Not Recommended

Therapeutic ultrasound is not recommended for the treatment of subacute or chronic ankle sprain.

Strength of evidence Not Recommended, Insufficient Evidence (I)
Level of confidence Moderate

Rationale

There are three moderate-quality placebo-controlled trials that demonstrated no clinical benefit from therapeutic ultrasound compared with sham ultrasound after 3 to 8 sessions as measured by pain, swelling, or functional improvement (Zammit et al., 2005, Nyanzi et al., 1999, Williamson et al., 1986). A low-quality trial demonstrated ultrasound plus ice to be more effective than elastoplast wrap in pain relief and functional recovery (Makuloluwe et al., 1977). There is one moderate-quality trial that demonstrated similar improvements in the ultrasound group compared with topical NSAIDs, although there was no control arm, so

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natural history for improvement cannot be excluded (Oakland, 1993). Ultrasound is non-invasive, has low adverse effects, is of moderate cost depending on numbers of treatments, but has low treatment efficacy and is therefore not recommended.

ALLIED HEALTH INTERVENTIONS

LOW-LEVEL LASER THERAPY

LOW-LEVEL LASER THERAPY FOR ACUTE ANKLE SPRAIN

Not Recommended

Low-level laser therapy is not recommended for treatment of acute ankle sprain.

Strength of evidence Moderately Not Recommended, Evidence (B)
Level of confidence Moderate

Rationale

There is one high-quality (de Bie et al., 1998) and one moderate-quality placebo-controlled trial (Stergioulas, 2004) for the use of LLLT in treating acute ankle sprain. A high-quality trial found no benefit in short- and long-term outcome measures from LLLT for acute ankle sprain. Rather, the sham intervention arm demonstrated higher functional scores and fewer lost days from work than the intervention arms. There were no differences in pain scores between the groups (de Bie et al., 1998). A moderate-quality study demonstrated reduction in ankle volume in the LLLT group compared to baseline for acute sprain, but there was no comparison between the intervention and sham and no-treatment groups (Stergioulas, 2004). Thus, the clinical significance of this finding is not defined. LLLT is not invasive, has low adverse effects, but is high cost, and has no demonstrated efficacy. Further quality studies are needed; therefore, LLLT is not recommended for ankle sprain.

LOW-LEVEL LASER THERAPY FOR SUBACUTE OR CHRONIC ANKLE SPRAIN

Not Recommended

Low-level laser therapy is not recommended for treatment of subacute or chronic ankle sprain.

Strength of evidence Not Recommended, Insufficient Evidence (I)
Level of confidence Moderate

Rationale

There is one high-quality (de Bie et al., 1998) and one moderate-quality placebo-controlled trial (Stergioulas, 2004) for the use of LLLT in treating acute ankle sprain. A high-quality trial found no benefit in short- and long-term outcome measures from LLLT for acute ankle sprain. Rather, the sham intervention arm demonstrated higher functional scores and fewer lost days from work than the intervention arms. There were no differences in pain scores between the groups (de Bie et al., 1998). A moderate-quality study demonstrated reduction in ankle volume in the LLLT group compared to baseline for acute sprain, but there was no

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comparison between the intervention and sham and no-treatment groups (Stergioulas, 2004). Thus, the clinical significance of this finding is not defined. LLLT is not invasive, has low adverse effects, but is high cost, and has no demonstrated efficacy. Further quality studies are needed; therefore, LLLT is not recommended for ankle sprain.

ACUPUNCTURE

ACUPUNCTURE FOR ACUTE, SUBACUTE, OR CHRONIC ANKLE SPRAIN

Not Recommended

There is no recommendation for or against the use of acupuncture for treatment of acute, subacute, or chronic ankle sprain.

Strength of evidence No Recommendation, Insufficient Evidence (I)
Level of confidence Low

Rationale

There are no quality trials of acupuncture for the treatment of ankle sprain. Acupuncture is minimally invasive, has minimal adverse effects, and, depending on numbers of treatments, is moderately costly. Other interventions have documented efficacy. Pending publication of quality studies, there is no recommendation for or against use of acupuncture for treatment of ankle sprain.

Evidence

There are no quality RCTs incorporated into this analysis.

HYPERBARIC OXYGEN THERAPY

HYPERBARIC OXYGEN THERAPY FOR ACUTE ANKLE SPRAIN

Not Recommended

Hyperbaric oxygen therapy is not recommended for treatment of acute ankle sprain.

Strength of evidence Not Recommended, Evidence (C)
Level of confidence Low

Rationale

There is one moderate-quality placebo controlled trial for hyperbaric oxygen therapy that failed to demonstrate any beneficial treatment effect from 2.0 atmospheres pressure as measured 72 hours post-treatment (Borromeo et al., 1997). Hyperbaric oxygen is non-invasive, is of moderate to high cost dependent on treatment facility and number of treatments, and has low risk for adverse effects, but has no demonstrated efficacy and is therefore not recommended.

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HYPERBARIC OXYGEN THERAPY FOR SUBACUTE OR CHRONIC ANKLE SPRAIN

Not Recommended

Hyperbaric oxygen therapy is not recommended for treatment of subacute or chronic ankle sprain.

Strength of evidence Not Recommended, Insufficient Evidence (I)
Level of confidence Low

Rationale

There is one moderate-quality placebo controlled trial for hyperbaric oxygen therapy that failed to demonstrate any beneficial treatment effect from 2.0 atmospheres pressure as measured 72 hours post-treatment (Borromeo et al., 1997). Hyperbaric oxygen is non-invasive, is of moderate to high cost dependent on treatment facility and number of treatments, and has low risk for adverse effects, but has no demonstrated efficacy and is therefore not recommended.

MANIPULATION AND MOBILIZATION

MANIPULATION OR MOBILIZATION FOR ACUTE OR SUBACUTE ANKLE SPRAIN

No Recommendation

There is no recommendation for or against the use of manipulation or mobilization for the treatment of acute or subacute ankle sprain.

Strength of evidence No Recommendation, Insufficient Evidence (I)
Level of confidence Moderate

Rationale

There is one moderate-quality trial that compared the addition of passive talocrural joint mobilization to a RICE protocol for acute ankle sprain (Green et al., 2001). The mobilization group demonstrated improvement in dorsiflexion range of motion. However, there is no correlation of improvement to other outcomes such as lost workdays, return to work, or return to sports or normal walking measures, making this finding of uncertain clinical significance. Another moderate-quality trial comparing a single session of mobilization plus movement with “no treatment” for subacute ankle sprain demonstrated immediate improvement of talocrural dorsiflexion (Collins et al., 2004). There were no other long-term or clinical outcomes reported, making the clinical significance of improved dorsiflexion and the intervention of unknown benefit. A high-quality cross-over trial comparing mobilization plus movement with “no treatment with or no weight bearing” also demonstrated improved talocrural movement, but conclusions of clinical utility are again limited (Vicenzino et al., 2006). An experimental trial of single intervention found limited evidence of potential efficacy, but no intermediate or long-term results (Yeo HK, 2011). A moderate-quality trial found minimal additive benefit of myofascial techniques to manipulation/mobilization (Truyols-Domi Nguez S, 2013). Manipulation is not invasive, is moderately costly, but may

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have adverse effects. There is no recommendation for or against manipulation of the ankle and foot joints for acute, subacute, or chronic ankle sprain as there is an absence of quality evidence.

MANIPULATION OR MOBILIZATION FOR CHRONIC RECURRENT ANKLE SPRAIN

No Recommendation

There is no recommendation for or against the use of manipulation or mobilization for the treatment of chronic recurrent ankle sprain.

Strength of evidence No Recommendation, Insufficient Evidence (I)
Level of confidence Low

Rationale

There is one moderate-quality trial that compared the addition of passive talocrural joint mobilization to a RICE protocol for acute ankle sprain (Green et al., 2001). The mobilization group demonstrated improvement in dorsiflexion range of motion. However, there is no correlation of improvement to other outcomes such as lost workdays, return to work, or return to sports or normal walking measures, making this finding of uncertain clinical significance. Another moderate-quality trial comparing a single session of mobilization plus movement with “no treatment” for subacute ankle sprain demonstrated immediate improvement of talocrural dorsiflexion (Collins et al., 2004). There were no other long-term or clinical outcomes reported, making the clinical significance of improved dorsiflexion and the intervention of unknown benefit. A high-quality cross-over trial comparing mobilization plus movement with “no treatment with or no weight bearing” also demonstrated improved talocrural movement, but conclusions of clinical utility are again limited (Vicenzino et al., 2006). An experimental trial of single intervention found limited evidence of potential efficacy, but no intermediate or long-term results (Yeo HK, 2011). A moderate-quality trial found minimal additive benefit of myofascial techniques to manipulation/mobilization (Truyols-Domi Nguez S, 2013). Manipulation is not invasive, is moderately costly, but may have adverse effects. There is no recommendation for or against manipulation of the ankle and foot joints for acute, subacute, or chronic ankle sprain as there is an absence of quality evidence.

HOT AND COLD THERAPIES

CRYOTHERAPY

CRYOTHERAPY FOR ACUTE ANKLE SPRAIN

Recommended

Cryotherapy is recommended for treatment of acute ankle sprains.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence Low

Indications

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Acute ankle sprain.

Frequency/Dose/Duration

Self-application for 10 to 20 minutes every 2 hours for up to 3 days as needed (Bleakley et al., 2006); may be applied over compression or casting materials (Okcu et al., 2006).

Indications for discontinuation

Resolution, adverse effects, non-compliance.

Rationale

There are no quality trials comparing the effectiveness of using all RICE therapies concurrently with a control of no RICE therapy. RICE is frequently described as a co-intervention in numerous comparative trials. One moderate-quality trial that demonstrated the addition of therapeutic exercises to RICE resulted in improved short-term function with reduction in pain compared to RICE alone, although there were no differences in return to work, walking, or sports (Bleakley et al., 2010, Bleakley et al., 2007). Another moderate-quality trial demonstrated passive manipulation added to RICE protocol demonstrated improved dorsiflexion with reduction in pain compared to RICE alone, although there were no differences in return to work, walking, or return to sport (Green et al., 2001). There are no quality trials comparing immediate rest (non-weight bearing) to continued weight bearing. A moderate-quality trial demonstrated early mobilization through weight bearing with the assistance of ankle supports or compression wraps after a 48-hour non-weight-bearing period demonstrated improved return to full duty compared with immobilization (Eiff et al., 1994) (see Functional Treatment – Mobilization). Therefore, there is no evidence that rest is of benefit if weight bearing is tolerated in the immediate post-injury period.

A moderate-quality trial comparing a single 30-minute application of ice therapy to sham therapy demonstrated no significant benefit at 7 days (Sloan et al., 1989). However, there were no short-term outcome measures included and all subjects had NSAIDS and compression wrap. There is one moderate-quality study comparing continuous versus intermittent application of cold therapy that found two intermittent 10-minute intervals with a 10-minute break between applications every 2 hours for 3 days superior to 20-minute continuous application at same 2-hour intervals as measured by subjective pain with activity at 7 days (Bleakley et al., 2006). However, there were no differences in function, swelling, or pain at rest. Cold therapy has been demonstrated to be more effective in reducing edema than heat or contrast bath (Cote et al., 1988) and compression (Sloan et al., 1989). A low-quality study found no additional benefit from cold therapy or elastic tape when used with air-stirrup (Wilkerson et al., 1993). The use of cold therapy applied directly over elastic wrap as well as plaster and synthetic casting material has been demonstrated to effectively reduce skin temperature (Okcu et al., 2006), suggesting that application can be made regardless of immobilization or compression. There is no evidence that the use of ice hastens return to work or function (Hubbard et al., 2004). Cryotherapy is non-invasive, has low adverse effects when used for short periods or if precautions are taken to avoid freezing

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of soft tissues, is of low to high cost dependent on purchase or rental of equipment (Stockle et al., 1997), and is recommended.

Despite the general acceptance of RICE or the individual therapies of RICE for acute ankle sprain, there is a lack of quality evidence for efficacy. A primary rationale for these modalities is to reduce edema. However, there was little correlation demonstrated in the available studies in reduction of edema as an indicator for functional or pain improvement (Sloan et al., 1989)(Boyce et al., 2005, Bleakley et al., 2010, Bleakley et al., 2007). These treatments are not invasive, generally have few adverse effects, and are not costly when self-administered. Rest, ice, and elevation are therefore recommended. There is insufficient evidence for recommendation of compression.

HEAT THERAPY

HEAT FOR ACUTE ANKLE SPRAIN

No Recommendation

There is no recommendation for or against the use of heat for the treatment of acute ankle sprain.

Strength of evidence No Recommendation, Insufficient Evidence (I)
Level of confidence Low

Rationale

There are no quality trials comparing heat with no treatment. There is one moderate-quality trial that demonstrated heat application resulted in increased edema compared with ice, although no functional differences were found between the groups (Cote et al., 1988). Heat treatments are not invasive, have no adverse effects, and are not costly when self-administered but there is no evidence for efficacy and therefore no recommendation for use in ankle sprain.

DIATHERMY FOR ACUTE ANKLE SPRAIN

No Recommendation

Diathermy is not recommended for the treatment of acute ankle sprain.

Strength of evidence No Recommendation, Insufficient Evidence (I)
Level of confidence Moderate

Rationale

There are five placebo-controlled high and moderate-quality trials for diathermy in the treatment of acute ankle sprain. A high-quality (Barker, 1985) and two moderate-quality trials (McGill, 1988, Pasila et al., 1978) demonstrated no benefit in pain, swelling, or functional recovery from a series of three diathermy treatments for acute ankle sprains of mild and moderate severity. There are two moderate-quality trials that reported benefit of diathermy. In a military population, a single session demonstrated reduction in swelling and

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pain measured immediately after the treatment was applied (Pennington et al., 1993). However, no long-term results were presented and there were baseline differences in the outcomes measures. Another trial utilizing 3 treatment sessions reported improvement in pain, swelling, and function, although the described statistical methods cause the results to be of uncertain clinical significance (Wilson, 1972). There is one moderate-quality study comparing the addition of diathermy to RICE, which demonstrated no additional benefit in reduction of pain or improvement of function. Therefore, while diathermy treatments are not invasive and have low complication rates, they are moderate to high cost depending on numbers of treatments, lacking evidence of efficacy and are not recommended.

DIATHERMY FOR SUBACUTE OR CHRONIC ANKLE SPRAIN

Not Recommended

Diathermy is not recommended for the treatment of subacute or chronic ankle sprain.

Strength of evidence Not Recommended, Insufficient Evidence (I)
Level of confidence Moderate

Rationale

There are five placebo-controlled high and moderate-quality trials for diathermy in the treatment of acute ankle sprain. A high-quality (Barker, 1985) and two moderate-quality trials (McGill, 1988, Pasila et al., 1978) demonstrated no benefit in pain, swelling, or functional recovery from a series of three diathermy treatments for acute ankle sprains of mild and moderate severity. There are two moderate-quality trials that reported benefit of diathermy. In a military population, a single session demonstrated reduction in swelling and pain measured immediately after the treatment was applied (Pennington et al., 1993). However, no long-term results were presented and there were baseline differences in the outcomes measures. Another trial utilizing 3 treatment sessions reported improvement in pain, swelling, and function, although the described statistical methods cause the results to be of uncertain clinical significance (Wilson, 1972). There is one moderate-quality study comparing the addition of diathermy to RICE, which demonstrated no additional benefit in reduction of pain or improvement of function. Therefore, while diathermy treatments are not invasive and have low complication rates, they are moderate to high cost depending on numbers of treatments, lacking evidence of efficacy and are not recommended.

CONTRAST BATH

CONTRAST BATH THERAPY FOR ACUTE ANKLE SPRAIN

No Recommendation

There is no recommendation for or against the use of contrast bath for the treatment of acute ankle sprain.

Strength of evidence No Recommendation, Insufficient Evidence (I)
Level of confidence Low

Rationale

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There are no quality trials comparing contrast bath with no treatment. There is one moderate-quality trial that included contrast bath as an intervention compared to cryotherapy and heat (Cote et al., 1988). There was less effect on edema compared to cold, but no functional outcomes were measured. A systematic review of contrast baths for musculoskeletal conditions, including ankle/foot disorders, concluded there is no relationship between physiological effects and functional outcomes. Contrast bath treatments are not invasive, have no adverse effects, and are not costly when self-administered, but there is insufficient evidence of their efficacy and therefore no recommendation for or against their use to treat ankle sprain.

ELECTRICAL THERAPIES

ELECTRICAL STIMULATION

LOW-FREQUENCY ELECTRICAL STIMULATION FOR ACUTE, SUBACUTE, OR CHRONIC ANKLE SPRAIN

Not Recommended

Low frequency electrical stimulation as a therapeutic measure is not recommended for acute, subacute, or chronic ankle sprain.

Strength of evidence Not Recommended, Evidence (C)
Level of confidence Low

Rationale

One moderate-quality trial compared low frequency electrical stimulation to sham stimulation and demonstrated no beneficial treatment effect over placebo (Man et al., 2007). There are no quality trials for high-voltage pulsed stimulation. A low-quality trial demonstrated no benefit over RICE therapy for high-voltage pulsed stimulation (Michlovitz et al., 1988). Low frequency electrical stimulation is non-invasive, is moderately costly with the purchase or rental of machine and supplies, and has low adverse effect profile, but is of no demonstrated efficacy and therefore is not recommended.

HIGH-VOLTAGE PULSED ELECTRICAL STIMULATION FOR ACUTE, SUBACUTE, OR CHRONIC ANKLE SPRAIN

Not Recommended

High-voltage pulsed stimulation as a therapeutic measure is not recommended for acute, subacute, or chronic ankle sprain.

Strength of evidence Not Recommended, Insufficient Evidence (I)
Level of confidence Low

Rationale

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One moderate-quality trial compared low frequency electrical stimulation to sham stimulation and demonstrated no beneficial treatment effect over placebo (Man et al., 2007). There are no quality trials for high-voltage pulsed stimulation. A low-quality trial demonstrated no benefit over RICE therapy for high-voltage pulsed stimulation (Michlovitz et al., 1988). Low frequency electrical stimulation is non-invasive, is moderately costly with the purchase or rental of machine and supplies, and has low adverse effect profile, but is of no demonstrated efficacy and therefore is not recommended.

IONTOPHORESIS

IONTOPHORESIS FOR ACUTE, SUBACUTE, OR CHRONIC ANKLE SPRAIN

No Recommendation

There is no recommendation for or against the use of iontophoresis for treatment of acute, subacute, or chronic ankle sprain.

Strength of evidence No Recommendation, Insufficient Evidence (I)
Level of confidence Low

Rationale

There is no quality evidence evaluating iontophoresis for treatment of patients with ankle sprain. A treatment series of iontophoresis is non-invasive, has low adverse effect profile, but is of moderate cost. Therefore, there is no recommendation for or against routine use pending publication of quality trials.

Evidence

There are no quality trials incorporated into this analysis.

PHONOPHORESIS

PHONOPHORESIS FOR ACUTE, SUBACUTE, OR CHRONIC ANKLE SPRAIN

No Recommendation

There is no recommendation for or against the use of phonophoresis for treatment of acute, subacute, or chronic ankle sprain.

Strength of evidence No Recommendation, Insufficient Evidence (I)
Level of confidence Low

Rationale

There is no quality evidence evaluating phonophoresis for treatment of patients with ankle sprain. Phonophoresis is non-invasive, has few adverse effects, and is moderately expensive. There is no recommendation pending publication of quality trials.

Evidence

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There are no quality studies incorporated into this analysis.

PULSED CURRENT

HIGH-VOLTAGE PULSED CURRENT FOR ACUTE ANKLE SPRAIN

No Recommendation

There is no recommendation for or against high-voltage pulsed current for acute ankle sprains.

Strength of evidence No Recommendation, Insufficient Evidence (I)
Level of confidence Low

Rationale

There are no quality trials comparing the effectiveness of using all RICE therapies concurrently with a control of no RICE therapy. RICE is frequently described as a co-intervention in numerous comparative trials. One moderate-quality trial that demonstrated the addition of therapeutic exercises to RICE resulted in improved short-term function with reduction in pain compared to RICE alone, although there were no differences in return to work, walking, or sports (Bleakley et al., 2010, Bleakley et al., 2007). Another moderate-quality trial demonstrated passive manipulation added to RICE protocol demonstrated improved dorsiflexion with reduction in pain compared to RICE alone, although there were no differences in return to work, walking, or return to sport (Green et al., 2001). There are no quality trials comparing immediate rest (non-weight bearing) to continued weight bearing. A moderate-quality trial demonstrated early mobilization through weight bearing with the assistance of ankle supports or compression wraps after a 48-hour non-weight-bearing period demonstrated improved return to full duty compared with immobilization (Eiff et al., 1994) (see Functional Treatment – Mobilization). Therefore, there is no evidence that rest is of benefit if weight bearing is tolerated in the immediate post-injury period. A moderate-quality trial comparing a single 30-minute application of ice therapy to sham therapy demonstrated no significant benefit at 7 days (Sloan et al., 1989). However, there were no short-term outcome measures included and all subjects had NSAIDS and compression wrap. There is one moderate-quality study comparing continuous versus intermittent application of cold therapy that found two intermittent 10-minute intervals with a 10-minute break between applications every 2 hours for 3 days superior to 20-minute continuous application at same 2-hour intervals as measured by subjective pain with activity at 7 days (Bleakley et al., 2006). However, there were no differences in function, swelling, or pain at rest. Cold therapy has been demonstrated to be more effective in reducing edema than heat or contrast bath (Cote et al., 1988) and compression (Sloan et al., 1989). A low-quality study found no additional benefit from cold therapy or elastic tape when used with air-stirrup (Wilkerson et al., 1993). The use of cold therapy applied directly over elastic wrap as well as plaster and synthetic casting material has been demonstrated to effectively reduce skin temperature (Okcu et al., 2006), suggesting that application can be made regardless of immobilization or compression. There is no evidence that the use of ice hastens return to work or function . Cryotherapy is non-invasive, has low adverse effects when used for short periods or if precautions are taken to avoid freezing of soft tissues, is of

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low to high cost dependent on purchase or rental of equipment (Stockle et al., 1997), and is recommended. There is one moderate-quality study comparing compression using elastic wrap to no treatment for mild and moderate acute sprains that did not demonstrate significant benefit of compression wrap (Watts et al., 2001). Three moderate-quality trials demonstrated compression wrap (e.g., bandage, elastic wrap, tubigrip) to be less effective than ankle braces (Cooke et al., 2009, O'Hara et al., 1992, Boyce et al., 2005) while two trials found no difference between these treatments (Beynnon et al., 2006, Leanderson et al., 1999). However, one trial demonstrated the combination of compression wrap with ankle brace (Aircast) to be more effective than either treatment alone for mild (Grade I) sprains (Beynnon et al., 2006). A moderate-quality trial found no difference in tape versus compression wrap (Viljakka et al., 1983). A moderate-quality trial found no long-term differences between casting or semi-rigid immobilization (Dettori et al., 1994, Dettori et al., 1994). Compression wraps and a pneumatic compression device were found to be less effective than elevation in reducing acute edema (Rucinski et al., 1991). Compression wraps may provide additional benefit when used in conjunction with ankle braces. One moderate-quality trial compared non-orthosis ankle support to no treatment, which demonstrated tubular elastic (Tubigrip®) provided no therapeutic benefit for mild and moderate sprains (Watts et al., 2001). Three moderate-quality trials demonstrated elastic support (e.g. bandage, elastic wrap, tubigrip) to be less effective than ankle braces (Cooke et al., 2009, Boyce et al., 2005, O'Hara et al., 1992), while three trials found no difference between these treatments (Dettori et al., 1994, Dettori et al., 1994, Beynnon et al., 2006, Leanderson et al., 1999). One trial did find the combination of compression wrap with ankle brace (Aircast) to be more effective than either treatment alone for mild (Grade I) sprains (Beynnon et al., 2006). Functional strapping (taping) was demonstrated to provide short-term benefits in pain, swelling, stiffness, and feeling of instability for severe sprains compared with casting (Ardevol et al., 2002), but no long-term benefit was demonstrated. A moderate-quality trial found no difference in tape versus elastic wrap (Viljakka et al., 1983). A moderate-quality trial found no long-term differences between elastic wrap support and casting or semi-rigid immobilization (Dettori et al., 1994, Dettori et al., 1994). Taping, tubular elastic, and elastic bandage wrap for support are non-invasive, are generally of low to moderate cost, and have low adverse effects, but are of no therapeutic benefit for mild sprains and appear to be less effective than more rigid support for severe sprains. Therefore, there is insufficient evidence to recommend their routine use. There are no quality-controlled trials comparing the use of ankle bracing to a “no treatment” group. There are six moderate-quality trials that compared ankle braces to other functional treatments. Three moderate-quality trials demonstrated ankle braces to be more effective than elastic support (Cooke et al., 2009, O'Hara et al., 1992, Boyce et al., 2005), while three moderate quality studies found no differences between ankle brace and elastic wrap for moderate and severe sprains (Dettori et al., 1994, Dettori et al., 1994, Beynnon et al., 2006, Zwipp et al., 1992). There are three moderate-quality studies for ankle brace versus cast immobilization demonstrating benefit of brace over cast immobilization (Cooke et al., 2009, Boyce et al., 2005, Dettori et al., 1994, Dettori et al., 1994). Combined ankle brace with elastic wrap was found to beneficial over immobilization (Beynnon et al., 2006, Eiff et al., 1994). Ankle orthoses are non-invasive, are of moderate cost, and the quality evidence is mixed. There are no differences found in sprain recurrence between the different types of ankle supports used for early mobilization. It appears that mobilization is the most important factor; however, insofar as ankle braces and supports may aid and encourage increased mobilization, ankle braces and supports that

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allow some movement are recommended. One moderate-quality trial found a walking boot was inferior to a functional brace as part of a treatment program for severe lateral ankle injuries. (Prado 14) There is another moderate-quality study with three reports that included a walking boot as an intervention arm (Cooke et al., 2009). There were no short- or long-term benefits demonstrated compared with other functional and immobilization techniques. The walking boot was demonstrated to have the highest costs (direct, indirect) compared with casting, tubular bandage, or Aircast. Therefore, use of a walking boot for uncomplicated ankle sprains is not recommended. One moderate-quality sham-controlled trial found mostly negative results from use of compression stockings for treatment of ankle sprain (Bendahou M, 2014). There is one moderate-quality study that demonstrated elevation is more effective in reducing edema after a single 30-minute treatment session than elevation used in conjunction with compression wrap or pneumatic brace, suggesting there is no added benefit for additional therapies in the immediate post-treatment period (Rucinski et al., 1991). However, these results are of uncertain short-term clinical significance. The significance of changes in edema in the post-sprain recovery period is of undefined clinical significance, as little correlation is described in available trials (Sloan et al., 1989, Boyce et al., 2005, Bleakley et al., 2010, Bleakley et al., 2007). A prospective case series found no relationships between ankle-foot edema and ankle function in the acute phase of ankle sprain injury . Despite the general acceptance of RICE or the individual therapies of RICE for acute ankle sprain, there is a lack of quality evidence for efficacy. A primary rationale for these modalities is to reduce edema. However, there was little correlation demonstrated in the available studies in reduction of edema as an indicator for functional or pain improvement (Sloan et al., 1989, Boyce et al., 2005, Bleakley et al., 2010, Bleakley et al., 2007). These treatments are not invasive, generally have few adverse effects, and are not costly when self-administered. Rest, ice, and elevation are therefore recommended. There is insufficient evidence for recommendation of compression.

INJECTION THERAPIES

AUTOLOGOUS BLOOD INJECTION FOR ACUTE, SUBACUTE, OR CHRONIC ANKLE SPRAIN

No Recommendation

There is no recommendation for or against the use of autologous blood injection as a treatment for acute, subacute, or chronic ankle sprain.

Strength of evidence No Recommendation, Insufficient Evidence (I)
Level of confidence Low

Rationale

There are no quality randomized trials for the use of autologous blood injection for the treatment of acute, subacute, or chronic ankle sprain. Adverse effects of autologous blood injection for plantar fasciopathy exist and include post-injection pain (53%) that may last up to 10 days and may require analgesia. These injections are of moderate cost related to procedure charges of venipuncture and injection, but are unknown efficacy. Thus, there is no recommendation for or against the use of autologous blood injection.

Evidence

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There are no quality trials incorporated into this analysis.

GLUCOCORTICOSTEROID INJECTIONS FOR ACUTE, SUBACUTE, OR CHRONIC ANKLE SPRAIN

No Recommendation

There is no recommendation for or against the use of glucocorticosteroid injection for routine treatment of acute, subacute, or chronic ankle sprain.

Strength of evidence No Recommendation, Insufficient Evidence (I)
Level of confidence Low

Rationale

There are no quality trials regarding glucocorticosteroid injection of ankle sprain. A low-quality trial found reduced skin temperature after local steroid injection compared to non-injected group, although there were no clinically significant differences (Nilsson, 1983). Recommendations for local injection of glucocorticosteroid in musculoskeletal conditions (i.e. epicondylalgia, plantar fasciitis, and shoulder impingement) are limited to focal pathology. There is no description found for injection of ankle ligaments. Injections are minimally invasive, are of moderate cost, with no evidence of efficacy, and have a potential risk for further ligament weakening. Therefore, there is no recommendation for or against the use of steroid injection for the treatment of ankle sprain.

HYALURONIC ACID INJECTIONS FOR ACUTE, SUBACUTE, OR CHRONIC ANKLE SPRAIN

No Recommendation

There is no recommendation for or against the use of hyaluronic acid injection for the treatment of acute, subacute, or chronic ankle sprains.

Strength of evidence No Recommendation, Insufficient Evidence (I)
Level of confidence Low

Rationale

There is one moderate-quality trial with two reports that compared periarticular injection of hyaluronic acid to placebo (Petrella et al., 2009, Petrella et al., 2007). The study demonstrated benefit in total change in pain scores from baseline for weight bearing and walking over 90-day period. However, it was unclear if there was significant difference in pain scores at each interval, as baseline scores were not presented. Patient satisfaction scores were favorable to injection at 4 and 8 days. Hyaluronic acid injection is mildly invasive, is of moderate cost related to the procedure, has low incidence of adverse events (Petrella et al., 2009, Petrella et al., 2007), but is of uncertain clinical significance; therefore, there is no recommendation for or against its use.

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PLATELET-RICH PLASMA (PRP) INJECTIONS FOR ACUTE, SUBACUTE, OR CHRONIC ANKLE SPRAIN

No Recommendation

There is no recommendation for or against the use of platelet rich plasma injection for the treatment of acute, subacute, or chronic ankle sprains.

Strength of evidence No Recommendation, Insufficient Evidence (I)
Level of confidence Low

Rationale

There are no quality trials for ankle sprain platelet rich plasma (PRP) injection. This intervention consists of obtaining 30 to 60cc of autologous blood, centrifuging, and injecting 3 to 6cc of PRP. This procedure reportedly is low risk for adverse effects, moderately costly, and may require repeat injection. The clinical efficacy is currently undefined. Therefore, there is no recommendation for or against the use of PRP injection for ankle sprain.

SURGICAL CONSIDERATIONS

SURGERY FOR TREATMENT OF ACUTE OR SUBACUTE ANKLE LIGAMENT TEAR

Not Recommended

Surgical repair is not recommended for routine lateral ligament tear associated with acute or subacute ankle sprain.

Strength of evidence Not Recommended, Insufficient Evidence (I)
Level of confidence Low

Rationale

There are six moderate-quality trials that compared operative repair with non-operative management of acute rupture of the lateral ligaments. No quality clinically important evidence has been demonstrated to recommend initial surgical repair over non-operative care. Three of the quality-trials compared surgery to functional treatment (Pijnenburg et al., 2003, Povacz et al., 1998, Freeman, 1965, Freeman, 1965). Seven low-quality trials compared surgical repair to functional treatment with all finding no clinically significant long-term differences. Two studies suggest limited benefit of operative intervention (Gronmark et al., 1980) as measured by percentage of subjects symptomless at long-term follow-up, and number with fear of giving way (Korkala et al., 1987). Four trials suggest limited benefit of functional treatment as measured by higher percentage of subjects symptomless (Moller-Larsen et al., 1988), increased range-of-motion short-term (Zwipp et al., 1992, Sommer et al., 1989) and faster return to sport (Specchiulli et al., 2001). One trial found no differences in any outcome measure (van den Hoogenband et al., 1984). There were no differences in objective long-term functional outcomes demonstrated between the treatment groups. Subjectively, one study found functional treatment to result in patients becoming symptomless sooner than the surgical group (Freeman, 1965, Freeman, 1965),

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but another study has reported the functional group had a higher incidence of feeling ankle instability (Pijnenburg et al., 2003), although no differences in sprain recurrence were demonstrated. One study found less reinjury in the surgical repair group, but more osteoarthrosis after surgery (Pihlajamaki H, 2010). Patients in a functional group using an ankle orthosis (Aircast) returned to work significantly faster than the operative group (1.6 weeks versus 7.0 weeks, p <0.001) (Povacz et al., 1998). There are two quality trials that compared cast immobilization with operative repair (Freeman, 1965, Freeman, 1965, Evans et al., 1984), and seven low-quality trials that compared surgical repair to cast immobilization. Five studies demonstrated no differences between the two treatment types (Moller-Larsen et al., 1988, Zwipp et al., 1992, van den Hoogenband et al., 1984, Clark et al., 1965, Niedermann et al., 1981). Two studies suggest limited benefit of operative intervention (Gronmark et al., 1980) as measured by percentage of subjects symptomless at long-term follow-up, and number with fear of giving way (Korkala et al., 1987). There were no long-term differences between the groups demonstrated in either study. Cast mobilization resulted in fewer reports of residual instability than operative repair (Evans et al., 1984). Surgical repair is invasive, high cost, results in more lost-time from work, and has higher risk of adverse events than non-operative treatment. There is insufficient evidence that operative repair of ankle ligament ruptures provides significant long-term clinical benefit compared with non-operative care, and is therefore not recommended as an initial treatment for acute lateral ligament rupture of the ankle. Persistent functional instability of a chronic nature may be considered for ligament reconstruction. There are no quality-trials for repair of chronic ankle instability.

SURGERY FOR TREATMENT OF CHRONIC ANKLE INSTABILITY (CAI)

Sometimes Recommended

Ligament reconstruction is recommended for select cases of chronic ankle instability.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence Moderate

Indications

Chronic ankle instability confirmed with either anterior talofibular ligament (ATFL) or calcaneofibular ligament (CFL) abnormality on MRI and/or stress x-rays. The confirmed instability case should also meet all of the following: 1) chronic ankle instability of at least 4 months duration, 2) failure of strengthening and balance exercises, and 3) failure of ankle support brace.

Rationale

There are six moderate-quality trials that compared operative repair with non-operative management of acute rupture of the lateral ligaments. No quality clinically important evidence has been demonstrated to recommend initial surgical repair over non-operative care. Three of the quality-trials compared surgery to functional treatment (Pijnenburg et al., 2003, Povacz et al., 1998, Freeman, 1965, Freeman, 1965). Seven low-quality trials

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compared surgical repair to functional treatment with all finding no clinically significant long-term differences. Two studies suggest limited benefit of operative intervention (Gronmark et al., 1980) as measured by percentage of subjects symptomless at long-term follow-up, and number with fear of giving way (Korkala et al., 1987). Four trials suggest limited benefit of functional treatment as measured by higher percentage of subjects symptomless (Moller-Larsen et al., 1988), increased range-of-motion short-term (Zwipp et al., 1992, Sommer et al., 1989) and faster return to sport (Specchiulli et al., 2001). One trial found no differences in any outcome measure (van den Hoogenband et al., 1984). There were no differences in objective long-term functional outcomes demonstrated between the treatment groups. Subjectively, one study found functional treatment to result in patients becoming symptomless sooner than the surgical group (Freeman, 1965, Freeman, 1965), but another study has reported the functional group had a higher incidence of feeling ankle instability (Pijnenburg et al., 2003), although no differences in sprain recurrence were demonstrated. One study found less reinjury in the surgical repair group, but more osteoarthrosis after surgery (Pihlajamaki H, 2010). Patients in a functional group using an ankle orthosis (Aircast) returned to work significantly faster than the operative group (1.6 weeks versus 7.0 weeks, $p < 0.001$) (Povacz et al., 1998).

There are two quality trials that compared cast immobilization with operative repair (Freeman, 1965, Freeman, 1965, Evans et al., 1984), and seven low-quality trials that compared surgical repair to cast immobilization. Five studies demonstrated no differences between the two treatment types (Moller-Larsen et al., 1988, Zwipp et al., 1992, van den Hoogenband et al., 1984, Clark et al., 1965, Niedermann et al., 1981). Two studies suggest limited benefit of operative intervention (Gronmark et al., 1980) as measured by percentage of subjects symptomless at long-term follow-up, and number with fear of giving way (Korkala et al., 1987). There were no long-term differences between the groups demonstrated in either study. Cast mobilization resulted in fewer reports of residual instability than operative repair (Evans et al., 1984). Surgical repair is invasive, high cost, results in more lost-time from work, and has higher risk of adverse events than non-operative treatment. There is insufficient evidence that operative repair of ankle ligament ruptures provides significant long-term clinical benefit compared with non-operative care, and is therefore not recommended as an initial treatment for acute lateral ligament rupture of the ankle.

Thus, repair is recommended for select patients with chronic ankle instability confirmed with either anterior talofibular ligament (ATFL) or calcaneofibular ligament (CFL) abnormality on MRI and/or stress x-rays. The confirmed instability case should also meet all of the following: 1) chronic ankle instability of at least 4 months duration, 2) failure of strengthening and balance exercises, and 3) failure of ankle support brace.

Evidence

There are no quality RCTs incorporated into this analysis.

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REHABILITATION

THERAPY FOR ACUTE, SUBACUTE, OR CHRONIC ANKLE SPRAIN

Recommended

Therapy is recommended for select patients with acute, subacute, or chronic ankle sprain.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence Moderate

Indications

Acute, subacute, or chronic ankle sprain.

Frequency/Dose/Duration

Self-directed, home-based exercise and stretching program is recommended for ankle sprain. Most patients with acute sprains need no therapy. Supervised programs of 1 or 2 therapy sessions may be indicated for patients who require initial supervision; education; need motivation or help in overcoming fear avoidance; have significant impairments or functional limitations; or need to return to a high level of activity. Up to 12 appointments may be needed for chronic sprains, persistent ankle instability or for acute severe sprains. Follow-up educational visit(s) for more severe disorders as part of a progression towards normal functional use is sometimes helpful.

Indications for discontinuation

Achievement of rehabilitation goals or non-compliance.

Rationale

There is no quality assessment of the efficacy of exercises for treatment of ankle sprain/instability as the available literature has significant methodological flaws. The two highest quality studies conflict regarding a partial assessment of the utility of supervised exercises (van Rijn et al., 2009, van Rijn et al., 2007, Cleland JA, 2013). One moderate-quality trial compared supervised physical therapy (balance exercises, walking, running, jumping) to home-based exercises (van Rijn et al., 2009, van Rijn et al., 2007). Subjects in the home-based program reported less than 20% compliance, essentially allowing for comparison of a no treatment control to supervised physical therapy. For mild and moderate ankle sprains, there were no differences in outcomes at any interval. An analysis of benefit by sprain severity demonstrated a modest benefit from supervised physical therapy for those with severe sprains measured at 4 weeks in the outcomes of pain while walking on hard and rough surfaces, and the feeling of instability while walking on rough surface. However, the prevalence of these reported symptoms in the population was small, making the findings of little or no clinical significance (van Rijn et al., 2009). Another moderate-quality trial compared early rehabilitation with physical therapy (defined as therapeutic exercises that included muscle strengthening, neuromuscular training, and sports specific functional

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exercises) to standard RICE therapy (no physical therapy) for mild and moderate acute ankle sprain (Bleakley et al., 2010, Bleakley et al., 2007). The study demonstrated benefit as measured in subjective functional scores over the first 2 weeks of injury, but found no differences in pain, swelling, re-injury rate or physical activity. A low-quality trial demonstrated no differences between ankle-heel stretching protocols and natural history (Youdas et al., 2009). A low-quality trial demonstrated reduced sprain recurrence with use of wobble-board post-acute injury (Wester et al., 1996). A low-quality study demonstrated balance training with an external focus of attention improved postural sway (Laufer et al., 2007). Another low-quality trial demonstrated no benefit from use of imagery rehearsal (Christakou et al., 2007). Two other moderate-quality trials comparing supervised physical therapy to home based exercises found no differences in short-term outcomes measures (Bassett et al., 2007, Holme et al., 1999). Re-injury rates were reported lower in the supervised physical therapy group at 1 year (Holme et al., 1999).

The natural history of ankle sprain is improvement. Therefore, supervised therapy is not recommended for all patients with ankle sprain. A few appointments for educational purposes for patients with severe injury are recommended. The numbers of appointments are dependent on the degree of debility, with 1 or 2 educational appointments appropriate for most affected patients. Patients with severe debility or those unable to return to work may necessitate 8 to 12 appointments that particularly emphasize progressive strengthening exercises. Additionally, while routine use may be of limited benefit, those patients who have muscle weakness or other debilities may also derive benefit from therapy including self-training exercises, particularly if unable to return to work. Therefore, therapy is recommended for select patients.

There are two moderate-quality trials for chronic ankle instability comparing rehabilitation techniques including exercises (Hale et al., 2007) and intense training using a bi-directional bicycle pedal (Hoiness et al., 2003), with both studies demonstrated benefit in postural sway measures. Low-quality trials have demonstrated improvement in postural sway in subjects with chronic ankle instability from interventions of balance and control exercises (Bernier et al., 1998), elastic resistance exercises (Han et al., 2009), stochastic coordination training (Ross et al., 2007), proprioception and strength training (Powers et al., 2004), and Dura-disc and mini-trampoline training (Kidgell et al., 2007). None of these studies demonstrated clinical correlation of improved postural sway with reduced subjective or objective findings.

There are no quality studies that have demonstrated improved postural sway outcomes result in improved clinical outcomes, such as recurrence of injury. Rehabilitation techniques are non-invasive, have low adverse effects, and are of moderate to high cost dependent on the duration and frequency of treatment sessions. Rehabilitation techniques are numerous, and there are no quality comparison trials to determine what techniques produce the highest benefit in postural sway improvement. Because the quality evidence is currently limited to improved postural balance, but lacking in evidence of other clinical improvements (McKeon et al., 2008), the use of physical rehabilitation methods is a consensus recommendation prior to surgical intervention.

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THERAPY FOR CHRONIC ANKLE INSTABILITY (CAI)

Recommended

Therapy is recommended for treatment of chronic ankle instability.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence Moderate

Rationale

There is no quality assessment of the efficacy of exercises for treatment of ankle sprain/instability as the available literature has significant methodological flaws. The two highest quality studies conflict regarding a partial assessment of the utility of supervised exercises (van Rijn et al., 2009, van Rijn et al., 2007, Cleland JA, 2013). One moderate-quality trial compared supervised physical therapy (balance exercises, walking, running, jumping) to home-based exercises (van Rijn et al., 2009, van Rijn et al., 2007). Subjects in the home-based program reported less than 20% compliance, essentially allowing for comparison of a no treatment control to supervised physical therapy. For mild and moderate ankle sprains, there were no differences in outcomes at any interval. An analysis of benefit by sprain severity demonstrated a modest benefit from supervised physical therapy for those with severe sprains measured at 4 weeks in the outcomes of pain while walking on hard and rough surfaces, and the feeling of instability while walking on rough surface. However, the prevalence of these reported symptoms in the population was small, making the findings of little or no clinical significance (van Rijn et al., 2009). Another moderate-quality trial compared early rehabilitation with physical therapy (defined as therapeutic exercises that included muscle strengthening, neuromuscular training, and sports specific functional exercises) to standard RICE therapy (no physical therapy) for mild and moderate acute ankle sprain (Bleakley et al., 2010, Bleakley et al., 2007). The study demonstrated benefit as measured in subjective functional scores over the first 2 weeks of injury, but found no differences in pain, swelling, re-injury rate or physical activity. A low-quality trial demonstrated no differences between ankle-heel stretching protocols and natural history (Youdas et al., 2009). A low-quality trial demonstrated reduced sprain recurrence with use of wobble-board post-acute injury (Wester et al., 1996). A low-quality study demonstrated balance training with an external focus of attention improved postural sway (Laufer et al., 2007). Another low-quality trial demonstrated no benefit from use of imagery rehearsal (Christakou et al., 2007). Two other moderate-quality trials comparing supervised physical therapy to home based exercises found no differences in short-term outcomes measures (Bassett et al., 2007, Holme et al., 1999). Re-injury rates were reported lower in the supervised physical therapy group at 1 year (Holme et al., 1999). The natural history of ankle sprain is improvement. Therefore, supervised therapy is not recommended for all patients with ankle sprain. A few appointments for educational purposes for patients with severe injury are recommended. The numbers of appointments are dependent on the degree of debility, with 1 or 2 educational appointments appropriate for most affected patients. Patients with severe debility or those unable to return to work may necessitate 8 to 12 appointments that particularly emphasize progressive strengthening exercises. Additionally, while routine use may be of limited benefit, those patients who have muscle weakness or other debilities may also derive benefit from therapy including self-training exercises,

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particularly if unable to return to work. Therefore, therapy is recommended for select patients. There are two moderate-quality trials for chronic ankle instability comparing rehabilitation techniques including exercises (Hale et al., 2007) and intense training using a bi-directional bicycle pedal (Hoiness et al., 2003), with both studies demonstrated benefit in postural sway measures. Low-quality trials have demonstrated improvement in postural sway in subjects with chronic ankle instability from interventions of balance and control exercises (Bernier et al., 1998), elastic resistance exercises (Han et al., 2009), stochastic coordination training (Ross et al., 2007), proprioception and strength training (Powers et al., 2004), and Dura-disc and mini-trampoline training (Kidgell et al., 2007). None of these studies demonstrated clinical correlation of improved postural sway with reduced subjective or objective findings. There are no quality studies that have demonstrated improved postural sway outcomes result in improved clinical outcomes, such as recurrence of injury. Rehabilitation techniques are non-invasive, have low adverse effects, and are of moderate to high cost dependent on the duration and frequency of treatment sessions. Rehabilitation techniques are numerous, and there are no quality comparison trials to determine what techniques produce the highest benefit in postural sway improvement. Because the quality evidence is currently limited to improved postural balance, but lacking in evidence of other clinical improvements, the use of physical rehabilitation methods is a consensus recommendation prior to surgical intervention.

POSTOPERATIVE MANAGEMENT OF ANKLE INSTABILITY

Recommended

Short-term cast immobilization with early mobilization and therapy is recommended for ankle instability.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence Moderate

Rationale

There are two moderate-quality trials that compared early mobilization and physical therapy with 6-weeks cast immobilization for post-operative management for ligament reconstruction (Karlsson et al., 1999, Karlsson et al., 1995). There were no long-term differences between the groups, although results may be limited due to the sample sizes of each study. The early mobilization group demonstrated better range of motion at 6-weeks, although there were no differences in patient subjective functional scores. A pooled analysis of these two studies found the functional group had a statistically significant earlier return to work and sport than the casting group (de Vries et al., 2006). Thus, there is insufficient evidence to recommend one treatment over the other, and both are recommended according to informed preference of patient and clinician.

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PREVENTION OF INJURY

ANKLE SUPPORT (BRACE, TAPE) FOR PREVENTION OF INITIAL ANKLE INJURY

Recommended

The use of ankle support (brace, tape) is recommended for the prevention of ankle injury.

Strength of evidence Recommended, Evidence (C)
Level of confidence Moderate

Rationale

There are two controlled moderate-quality trials that compare the incidence of ankle sprain injuries in healthy military populations using an ankle brace compared to “no brace” for intramural basketball participation (Sitler et al., 1994) and paratrooper training (Amoroso et al., 1998). Both studies demonstrated a lower incidence of ankle sprain in the brace group. Another moderate-quality trial compared bracing to taping for the prevention of sprain during a high school football season and found no difference between groups (Mickel et al., 2006). However, there was no control group to determine efficacy of prevention. There are two low-quality studies of high school athletes also suggesting preventive value of a lace-up brace (McGuine TA, 2011, McGuine TA, 2012). There are no quality trials for the use of ankle supports to prevent recurrent injury, but by inference, they may provide additional protection to persons with feelings of instability or who are involved in activities that are at high risk for ankle inversion. Ankle supports are non-invasive, have low adverse effects, and may be of moderate to high cost, particularly for daily taping or use of multiple braces over a season.

ANKLE SUPPORT (BRACE, TAPE) FOR PREVENTION OF RECURRENT ANKLE INJURY

Recommended

The use of ankle support (brace, tape) is recommended for the prevention of ankle injury.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence Moderate

Rationale

There are two controlled moderate-quality trials that compare the incidence of ankle sprain injuries in healthy military populations using an ankle brace compared to “no brace” for intramural basketball participation (Sitler et al., 1994) and paratrooper training (Amoroso et al., 1998). Both studies demonstrated a lower incidence of ankle sprain in the brace group. Another moderate-quality trial compared bracing to taping for the prevention of sprain during a high school football season and found no difference between groups (Mickel et al., 2006). However, there was no control group to determine efficacy of prevention. There are two low-quality studies of high school athletes also suggesting preventive value of a lace-up brace (McGuine TA, 2011, McGuine TA, 2012). There are no quality trials for the use of ankle supports to prevent recurrent injury, but by inference, they may provide additional

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protection to persons with feelings of instability or who are involved in activities that are at high risk for ankle inversion. Ankle supports are non-invasive, have low adverse effects, and may be of moderate to high cost, particularly for daily taping or use of multiple braces over a season.

BALANCE/PROPRIOCEPTION TRAINING FOR PREVENTION OF ANKLE INJURY

Recommended

Balance/proprioception training is recommended for prevention of initial and recurrent ankle injury.

Strength of evidence Recommended, Evidence (C)
Level of confidence Low

Rationale

There are two moderate-quality controlled trials that demonstrated benefit in reducing foot or ankle sprain injury after proprioception and balance training in healthy populations compared to control of no training (Emery et al., 2007, McGuine et al., 2006). Ankle sprain injuries were significantly reduced in high school athletes over the course of a season in the group that used a wobble board in training during the season (McGuine et al., 2006). A moderate-quality trial demonstrated home-based proprioception training to be effective in reducing recurrent ankle sprains compared with routine physiotherapy alone (Hupperets et al., 2009, Hupperets et al., 2008). A moderate-quality trial compared postural control techniques using either an internal focus of attention or an external focus of attention during training (Rotem-Lehrer et al., 2007). There were no differences between the techniques, and no recommendation for one technique is made over another. A low-quality trial compared training technique with proprioception and orthosis with no demonstrated differences (Stasinopoulos, 2004). Balance training is of low cost for exercises, and wobble boards can be inexpensive (McGuine et al., 2006). It is not clear which populations would benefit most from this training. Further studies in working populations are needed. Ankle support is low to moderate costs and has low adverse profile, and is recommended for short-term use.

FOOT ORTHOTICS FOR PREVENTION OF ANKLE INJURY

No Recommendation

There is no recommendation for or against the use of foot orthotics for the prevention of ankle injury.

Strength of evidence No Recommendation, Insufficient Evidence (I)
Level of confidence Low

Rationale

There are no quality trials comparing the use of foot orthoses with “no use” for the prevention of ankle sprain. A low-quality study demonstrated no differences in injury prevention with the use of heel cup inserts (Fauno et al., 1993). There is one moderate-

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quality trial with two separate trials that compared custom soft orthotics with soft prefabricated orthotics, and custom semi-rigid orthotics with pre-fabricated semi-rigid orthotics (Finestone et al., 2004). There were no differences in incidence of injury between the groups. With the lack of a control group, prophylactic value of using orthotics is not defined. These devices are non-invasive, have few adverse effects, and are generally low cost for devices that are not custom-made. There is insufficient evidence for or against the use of foot orthotics for prevention of initial or recurrent ankle sprain.

SPECIAL SHOES FOR PREVENTION OF ANKLE SPRAIN OR RECURRENT ANKLE SPRAIN

Recommended

Appropriate activity-specific footwear is recommended for the prevention of ankle sprain or recurrent ankle sprain. There is no recommendation for the use of one type of shoe over another for prevention of ankle sprain or lower extremity disorders.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence Low

Rationale

There are two moderate-quality trials comparing the use of different running shoe types matched to foot arch (plantar shape) in military basic training settings, which did not demonstrate benefit in reducing injury or sprain (Knapik et al., 2010, Knapik et al., 2010). The application of these studies in the military is that no effort is needed to match shoe type with foot arch type. The practical applications in the working population are unclear. There is one moderate-quality trial that compared the use of high- and low-top basketball shoes in an athletic league (Barrett et al., 1993). There were no differences in incidence of injury between the groups over a 2-month college intramural season. There are myriad shoe types that are designed for workplace hazard or athletic event. The use or misuse of shoe type plausibly may result in injury when used improperly or for the wrong purpose. These devices are non-invasive, have few adverse effects, and are generally moderate cost for devices that are not custom designed. There is insufficient evidence for or against the use of one type of footwear over another as long as it is being used for the designed purpose.

STRETCHING/STRENGTHENING EXERCISES FOR PREVENTION OF ANKLE INJURY

No Recommendation

There is no recommendation for or against the use of stretching or strengthening exercises for the prevention of initial or recurrent ankle injury.

Strength of evidence No Recommendation, Insufficient Evidence (I)
Level of confidence Low

Rationale

There are no quality trials for the use of stretching/strengthening exercises for the prevention of ankle injury. Stretching or strengthening exercises are of low cost, have no

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adverse effects, but are of unknown efficacy, and therefore there is no recommendation for or against their use pending quality trials.

BUNIONS (HALLUX VAGUS)

DIAGNOSTIC RECOMMENDATIONS

X-RAYS TO DIAGNOSE BUNIONS

Recommended

X-rays are useful for measuring angles and surgical planning and are recommended.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence Low

TREATMENT RECOMMENDATIONS

DEVICES

ORTHOTICS FOR TREATMENT OF HALLUX VALGUS

Recommended

Orthotics are recommended for treatment of hallux valgus.

Strength of evidence Recommended, Evidence (C)
Level of confidence Low

Indications

Insufficient control or management by changing shoe wear. May be needed without changing shoe wear among those with prescribed shoewear (e.g., specified safety shoes). Use of orthoses for hallux valgus should generally be limited to 1 of 2 conditions: 1) There should be demonstrable hyperpronation or radiographic evidence of hyperpronation with a talar flexion angle of 30 degrees or more on a standing study; or 2) there should be pain localized to the plantar aspect of the hallux metatarsal head with or without bunion pathology.

Rationale

There is one moderate quality trial that found custom orthotics were superior to no treatment over 6 months. However, they were inferior to surgery at both 6- and 12-months (Torkki M, 2001). Thus, orthotics are recommended for those with symptoms insufficiently controlled by changing shoewear when possible. A custom made splint in Iran has also been trialed (Mirzashahi B, 2012). A pragmatic comparative trial found no difference between manual manipulative treatment and a night splint at one month although better outcomes were reported with manual therapy at one month and sustainability was not reported (du Plessis M, 2011).

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ALLIED HEALTH INTERVENTIONS

LOW-INTENSITY ULTRASOUND FOR BUNIONS

Not Recommended

Low-intensity ultrasound is not recommended for postoperative osteotomy hallux valgus treatment.

Strength of evidence Not Recommended, Evidence (C)
Level of confidence Low

Rationale

One trial suggests a lack of post-operative efficacy and thus low intensity ultrasound is not recommended for treatment of patients having undergone osteotomy for hallux valgus (Zacherl M, 2009).

MANIPULATION OR MOBILIZATION FOR TREATMENT OF BUNIONS

No Recommendation

There is no recommendation for or against the use of manipulation or mobilization for treatment of hallux valgus.

Strength of evidence No Recommendation, Insufficient Evidence (I)
Level of confidence Low

Rationale

There are no sham-controlled studies. A pragmatic comparative trial found no difference between manual manipulative treatment and a night splint at 1 week, although better outcomes were reported at 1 month and sustainability was not reported (du Plessis M, 2011). Thus, there is no recommendation.

SURGICAL CONSIDERATIONS

SURGERY FOR BUNIONS

Recommended

Surgery is recommended for bunions (hallux valgus).

Strength of evidence Recommended, Evidence (C)
Level of confidence Low

Indications

Select cases of mostly moderate or severe hallux valgus where there is failure of at least 3 months of nonoperative care (i.e., orthotics and changing shoe wear) and/or there is valgus angle progression leading to hammer toe, stiffness, and/or overlapping toes.

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Rationale

There is one moderate quality trial comparing surgery (chevron procedure) with orthosis with no treatment and found the best results with surgery (Torkki M, 2001). There are no other quality sham-controlled trials or comparative trials with non-operative treatments. There are many comparative trials comparing operative approaches (Pentikainen I, 2015, Pentikainen IT, 2012, Glazebrook M, 2014, Matricali GA, 2014, Park CH, 2013, Park CH, 2013, Faber FW, 2013, Windhagen H, 2013, Giannini S, 2013, Radwan YA, 2012, Klos K, 2011, Deenik AR, 2007, Deenik A, 2008, Saro C, 2007, Easley ME, 1996, Resch S, 1994, Klosok JK, 1993). The moderate quality comparative study reported osteotomy was superior to either orthotics or no treatment. Thus, surgery is recommended where there is failure of at least 3 months of nonoperative treatment including orthotics and changing shoe wear.

CHARCOT JOINT (NEUROGENIC ARTHROPATHY)

OVERVIEW

Diagnostic testing usually includes x-rays [291]. MRIs have been shown to provide more information, are hypothesized to improve staging [291], have not been shown to change management, but may be selectively recommended. Medical treatment includes addressing the underlying neuropathy to attempt to reduce systemic impacts. Splints, walking braces, orthoses and casts [292] should be tailored to the specific cause-condition. Acetaminophen and/or NSAIDs for pain control are often not needed due to the propensity for the joint to be denervated (see Chronic Pain guideline for other neuropathic pain medication options).

Surgical procedures including ostectomy may be performed to address deformities that place the foot at risk of ulceration, which if ulceration occurs increases risk of amputation [293,294]. Fractures require treatment that may include open reduction internal fixation. Fusion is also performed for some cases [295,296]. Arthroplasty (total joint replacement) has been traditionally viewed as contraindicated for Charcot joints due to underlying neuropathy that increases the failure rate. Although there are a few case reports suggesting potential success, there are no quality studies on arthroplasty for Charcot joints [297,298,299,300].

TREATMENT RECOMMENDATIONS

X-RAYS TO DIAGNOSE CHARCOT JOINT

Recommended

X-rays are recommended for diagnosing Charcot joint.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence High

MAGNETIC RESONANCE IMAGING (MRI) FOR CHARCOT JOINT

Sometimes Recommended

MRIs are selectively recommended for diagnosing Charcot joint.

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Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence Low

Rationale

MRIs have been shown to provide more information, are hypothesized to improve staging (Chantelau E, 2006), have not been shown to change management, but may be selectively recommended.

MEDICAL TREATMENT FOR CHARCOT JOINT

Recommended

Medical treatment includes addressing the underlying neuropathy to attempt to reduce systemic impacts and is recommended.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence High

GAIT TRAINING FOR CHARCOT JOINT

Recommended

Gait training by a therapist is recommended for patients with Charcot joint.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence Low

ORTHOTICS FOR CHARCOT JOINT

Recommended

Splints, walking braces, orthoses, and casts are recommended for patients with Charcot joint.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence Low

Rationale

Splints, walking braces, orthoses and casts (De Souza L, 2008) should be tailored to the specific cause-condition and are recommended.

ACETAMINOPHEN FOR CHARCOT JOINT

Recommended

Acetaminophen and/or NSAIDs are recommended for pain control.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence Low

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Rationale

Acetaminophen and/or NSAIDs for pain control are often not needed due to the propensity for the joint to be denervated, but if needed are recommended. (see Chronic Pain guideline for other neuropathic pain medication options).

NSAIDS FOR CHARCOT JOINT

Recommended

Acetaminophen and/or NSAIDs are recommended for pain control.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence Low

Rationale

Acetaminophen and/or NSAIDs for pain control are often not needed due to the propensity for the joint to be denervated, but if needed are recommended. (see Chronic Pain guideline for other neuropathic pain medication options).

OSTECTOMY FOR CHARCOT JOINT

Recommended

Surgical procedures including ostectomy are recommended.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence High

Rationale

Surgical procedures including ostectomy may be performed to address deformities that place the foot at risk of ulceration, which if ulceration occurs increases risk of amputation and are recommended.

OPEN REDUCTION INTERNAL FIXATION FOR CHARCOT JOINT

Recommended

Fractures require treatment that may include open reduction internal fixation and are recommended.

Strength of evidence Recommended, Evidence (C)
Level of confidence High

FUSION FOR CHARCOT JOINT

Recommended

Fusion is also performed for some cases and is recommended.

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Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence Moderate

ARTHROPLASTY FOR CHARCOT JOINT

No Recommendation

T**here is no recommendation for arthroplasty for Charcot joints**.

Strength of evidence No Recommendation, Insufficient Evidence (I)
Level of confidence Low

Rationale

Arthroplasty (total joint replacement) has been traditionally viewed as contraindicated for Charcot joints due to underlying neuropathy that increases the failure rate. Although there are a few case reports suggesting potential success, there are no quality studies and there is no recommendation for arthroplasty for Charcot joints (Babazadeh S, 2010, Bae DK, 2009, Parvizi J, 2003, Lee KB, 2008).

FOOT DROP

OVERVIEW

A history adequate to exclude uncontrolled comorbidities should be conducted. History of slipping, tripping, and falling should be obtained at assess risk and need for treatment and accommodations. **Acute trauma followed by foot drop and lower leg pain may mark compartment syndrome, which is one of the surgical emergent causes of foot drop.** The patient should be questioned about problems with balance, fall history, near-fall history, environmental hazards, use of assistive devices, and limitations in ability to stand.

Assessment of foot drop should exclude diagnoses that need aggressive or highly restrictive treatment, or involve untreated systemic disease (see above). Acute cases of foot drop are urgencies if not emergencies due to the potential for significant enduring impairments. In the absence of an obvious traumatic cause in an otherwise healthy person, the patient with foot drop should be assessed for cardiovascular and cerebrovascular disease, diabetes, inflammatory disorders, and peripheral neuropathy. The affected leg should be examined thoroughly and, if possible, damaged or diseased nerves, muscles, and blood vessels should be identified [301,302].

The back, groin, and legs of a patient with foot drop should be examined for signs of trauma, tumor, and vascular insufficiency. Consider examining strength and sensation of the entire leg, but focus on clues for involved myotomes, dermatomes, and tendons. Pulses throughout the leg should be checked. Palpation for pulsatile masses may reveal aneurysm.

Strength and sensation of the legs should be evaluated. Observation of gait, including use of stairs and ability to maneuver around obstacles may show opportunities for eliminating slip, trip, and fall hazards.

Diagnostic studies to determine the cause of foot drop most often include MRI of the brain [303], spinal cord [304,305,306] and/or MRI of the periphery [307] and electrodiagnostic studies of the peripheral nerves [308,309,310].

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TREATMENT RECOMMENDATIONS

ANKLE-FOOT ORTHOTICS FOR TREATMENT OF FOOT DROP

Recommended

Ankle-foot orthotics (AFOs) are recommended for the treatment of foot drop.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence Moderate

Rationale

Although there are no quality trials, ankle-foot orthotics for foot drop have been used successfully for many years (Hausdorff JM, 2008) and thus they are recommended since they facilitate walking ability. Evaluation for orthotics should include evaluation of the footwear that is to be worn by the patient, including the nature of the fore-soles. Fronts of shoes and boots can catch on carpets and low-lying irregular surfaces, and modifications of shoes and boots may mitigate slip, trip, and fall risks posed by footwear.

TAPING FOR TREATMENT OF FOOT DROP

No Recommendation

There is no recommendation for or against the use of taping for the treatment of foot drop.

Strength of evidence No Recommendation, Insufficient Evidence (I)
Level of confidence Low

Rationale

There are no quality trials and thus there is no recommendation for or against the use of taping. Generally, braces are used for foot drop.

FOOT NEUROMA (MORTON'S NEUROMA)

OVERVIEW

A history consistent with Morton's neuroma is that of pain, sometimes radiating, between two rays of the forefoot. The discomfort is often provoked or worsened with compression and weight-bearing activity.

A careful history and physical examination is considered the most important diagnostic approach and in most cases, generally needs no further diagnostic testing [311,312]. Other testing that has been used includes MRI, ultrasound and digital nerve testing [311,312,313], however, there is no evidence these are effective and there is no recommendation for or against routine use of imaging studies.

The feet should undergo a standard evaluation. Morton's neuroma is marked by tenderness between adjacent metatarsal heads and provocation with compression of the affected forefoot. Mulder's click, defined as a painful click palpated between the metatarsal heads

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when the forefoot is compressed, is pathognomonic for Morton's neuroma. There may be widening and dullness of the toe interspace due to the mass effect of the neuroma.

DIAGNOSTIC RECOMMENDATIONS

X-RAYS TO DIAGNOSE FOOT NEUROMA

Recommended

A careful history and physical examination is considered the most important diagnostic approach and in most cases, generally needs no further diagnostic testing for preliminary treatment. However, x-rays are commonly needed to evaluate alternate conditions such as osteoarthrosis, gout and degenerative joint disease. Also, x-rays are useful for measuring angles and surgical planning and are recommended.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence Low

TREATMENT RECOMMENDATIONS

MEDICATIONS

LIDOCAINE FOR TREATMENT OF MORTON'S NEUROMA

No Recommendation

There is no recommendation for or against the use of lidocaine for treatment of Morton's Neuroma.

Strength of evidence No Recommendation, Insufficient Evidence (I)
Level of confidence Low

Rationale

There are no quality trials and thus there is no recommendation for or against the use of lidocaine.

DEVICES

CHANGES IN SHOE WEAR FOR TREATMENT OF MORTON'S NEUROMA

Recommended

Shoewear changes are recommended for treatment of Morton's Neuroma.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence Low

Indications

Essentially all patients should be advised to wear stiff-soled, wide toe box shoes with a low heel and soft insert.

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Rationale

There are no quality studies showing demonstrable success, however, changes in shoe wear have long been used, are non-invasive and appear to have some clinical efficacy, thus, an attempt at changing shoewear is recommended.

ORTHOTICS FOR TREATMENT OF MORTON'S NEUROMA

Recommended

Orthotics are recommended for treatment of Morton's Neuroma.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence Low

Rationale

There are no quality studies showing demonstrable success, although one trial suggested no difference between a supination vs. pronation orthosis (Kilmartin TE, 1994). However, orthotics have long been used, are non-invasive and appear to have some clinical efficacy, thus, an attempt at an orthosis or a metatarsal pad is recommended.

METATARSAL PADS FOR TREATMENT OF MORTON'S NEUROMA

Recommended

Metatarsal pads are recommended for treatment of Morton's neuroma.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence Low

Rationale

There are no quality studies showing demonstrable success, although one trial suggested no difference between a supination vs. pronation orthosis (Kilmartin TE, 1994). However, orthotics have long been used, are non-invasive and appear to have some clinical efficacy, thus, an attempt at an orthosis or a metatarsal pad is recommended.

ALLIED HEALTH INTERVENTIONS

MANIPULATION OR MOBILIZATION OF THE DISTAL LOWER EXTREMITY FOR TREATMENT OF MORTON'S NEUROMA

No Recommendation

There is no recommendation for or against the use of manipulation or mobilization of the distal lower extremity for treatment of Morton's Neuroma.

Strength of evidence No Recommendation, Insufficient Evidence (I)
Level of confidence Low

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Rationale

There are no sham-controlled, quality studies addressing efficacy of manipulation and mobilization for treatment of Morton's neuroma and thus there is no recommendation.

EXTRACORPOREAL SHOCKWAVE THERAPY FOR MORTON'S NEUROMA

No Recommendation

There is no recommendation for or against the use of extracorporeal shockwave therapy for Morton's Neuroma.

Strength of evidence No Recommendation, Insufficient Evidence (I)
Level of confidence Low

Rationale

There is only one pilot study identified with some trending but statistically negative results that may be underpowered (Fridman R, 2009). Thus there is need for full trials prior to a possible evidence-based recommendation and there is no recommendation for or against the use of extracorporeal shockwave therapy for Morton's Neuroma.

INJECTION THERAPIES

GLUCOCORTICOSTEROID INJECTIONS FOR MORTON'S NEUROMA

Recommended

Glucocorticosteroid injections are recommended for Morton's Neuroma.

Strength of evidence Recommended, Evidence (C)
Level of confidence Low

Indications

Select cases where pain and/or debility are significant and changing shoe wear, and/or orthotics fail to sufficiently control symptoms.

Rationale

There is one moderate-quality trial suggesting efficacy of a glucocorticoid injection at 3 months compared with placebo. Long-term results are unclear, and may well not be present. Still, up to 3 injections to attempt to reduce symptoms is a reasonable intervention to try before surgery. Ongoing injections are not recommended.

SCLEROSANT INJECTIONS FOR MORTON'S NEUROMA

Not Recommended

Sclerosant and alcohol injections are not recommended for Morton's Neuroma.

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Strength of evidence Not Recommended, Insufficient Evidence (I)
Level of confidence Low

Rationale

There are no quality trials of sclerosing agents including alcohol. Case series have variously suggested efficacy and lack of efficacy, thus considering the intervention is destructive of tissue, it is not recommended.

SURGICAL CONSIDERATIONS

NERVE ABLATION FOR MORTON'S NEUROMA

Recommended

Nerve ablation is recommended for Morton's Neuroma.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence Low

Indications

Select cases where pain and/or debility are significant and changing shoe wear, orthotics and glucocorticoid injection(s) fail to sufficiently control symptoms.

Rationale

There are no quality sham-controlled trials for any ablative or surgical procedures. There are no comparative trials with non-operative treatments. The only trials compare operative approaches (Akermark C, 2013, Colgrove RC, 2000, Nashi M, 1997). Procedural results thus are unclear, although case series report successful treatments. Ablative procedures or surgery are recommended in select cases where there is failure of at least 3 months of nonoperative care (e.g., oral nonopioid analgesics, orthotics, wide toe-box shoes, metatarsal pads, glucocorticoid injections).

SURGICAL EXCISION FOR MORTON'S NEUROMA

Recommended

Surgical excision and/or decompression is recommended for Morton's Neuroma.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence Moderate

Indications

Select cases where there is failure of at least 3 months of nonoperative care (e.g., oral nonopioid analgesics, orthotics, wide toe-box shoes, metatarsal pads, glucocorticoid injections).

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Rationale

There are no quality sham-controlled trials for any ablative or surgical procedures. There are no comparative trials with non-operative treatments. The only trials compare operative approaches (Akermark C, 2013, Colgrove RC, 2000, Nashi M, 1997). Procedural results thus are unclear, although case series report successful treatments. Ablative procedures or surgery are recommended in select cases where there is failure of at least 3 months of nonoperative care (e.g., oral nonopioid analgesics, orthotics, wide toe-box shoes, metatarsal pads, glucocorticoid injections).

FOOT ULCERATION

OVERVIEW

A history adequate to exclude uncontrolled comorbidities should be conducted. Ensure that the patient is free of fever and chills, compromise of skin in other areas than the affected foot, and sensory changes.

Assessment of foot ulcer should exclude diagnoses that need aggressive or highly restrictive treatment, or involve inadequately treated underlying disease. The patient should be assessed for cardiovascular disease, diabetes, inflammatory disorders, peripheral neuropathy, systemic and localized infection. The affected foot should be checked for infection or gangrene. Ulcers are graded by the depth with different systems [301,302], but most commonly with the Wagner grading system [314]:

- Grade 0 – No ulcer in a high-risk patient
- Grade 1 – Superficial ulcer involving the full skin thickness but not underlying tissues
- Grade 2 – Deep ulcer, penetrating down to ligaments and muscle, but no bone involvement or abscess formation
- Grade 3 – Deep ulcer with cellulitis or abscess formation, often with osteomyelitis
- Grade 4 – Localized gangrene
- Grade 5 – Extensive gangrene involving the whole foot

The size, depth, and location of and condition of the area surrounding an ulcer should be recorded. Check for exudate, odor, tunneling, undermining, sinus tracts, necrosis or eschar formation, infection, and signs of healing (granulation and epithelialization). Assess the wound margins and areas around the wound, including for induration, and tracking of infection or inflammation. Determine the stage of each ulcer.

Sensation of the foot and bone and joint deformities should be carefully assessed. Evaluation of perfusion of the foot and ankle, including dorsalis pedis and posterior tibial pulses, and of capillary refill is helpful. Footwear should be assessed for good repair, provision of comfort and support, and freedom from protruding, abrasive, or sharp features.

X-rays are indicated for those with concerns about possible underlying boney involvement, particularly including concerns about osteomyelitis . Bone scans are also indicated for those with further questions of boney involvement, particularly with indeterminate x-rays.

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DIAGNOSTIC RECOMMENDATIONS

X-RAYS TO DIAGNOSE FOOT ULCERATIONS

Recommended

X-rays are indicated for those with concerns about possible underlying boney involvement, particularly including concerns about osteomyelitis and are Recommended.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence Low

BONE SCANS TO DIAGNOSE FOOT ULCERATIONS

Recommended

Bone scans are also indicated for those with further questions of boney involvement, particularly with indeterminate x-rays, and are Recommended.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence Low

TREATMENT RECOMMENDATIONS

OVERVIEW

Treatment options for foot ulcerations include local wound care, surgical intervention and topical nerve growth factors [(119)]. Pressure-relieving devices are often used [(120)]. Few research studies have investigated the pressure reducing properties of such devices.

NONOPERATIVE INTERVENTIONS

WOUND DRESSINGS FOR MANAGEMENT OF LOWER EXTREMITY ULCERS

Recommended

Wound dressings are recommended for management of lower extremity ulcers.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence Low

Indications

All lower extremity ulcers, usually on a daily basis. There is no convincing evidence of superiority of any particular product (Jeffcoate WJ, 2009).

Rationale

While there are multiple moderate-quality studies, none compared wound dressings with no wound dressings. One comparative trial found no differences between 3 types of dressings and concluded that the least expensive should then be utilized (Jeffcoate WJ, 2009). One high-quality trial of an antimicrobial dressing reported lower bacterial burdens

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at 4 weeks, but only modest, non-significant reductions in wound size. (Sibbald 12) One moderate-quality trial of dressings of Hydrofiber® with ionic silver or calcium alginate found modestly better healing with silver (Jude EB, 2007). However, another similar trial found no material differences (Trial C, 2010). Wound dressings are not invasive, generally have relatively low adverse effects, may be costly over time but are recommended. With almost no head-to-head trials for comparison, there is no recommendation for a particular formulation or product.

INFRARED TEMPERATURE MONITORING FOR DIABETIC FOOT COMPLICATIONS

Recommended

Infrared temperature monitoring is recommended for prevention of diabetic foot complications.

Strength of evidence Recommended, Evidence (C)
Level of confidence Low

Indications

Diabetics at risk of foot ulcers and amputations, particularly those with at least moderately severe peripheral neuropathy and/or arterial insufficiency.

Rationale

One moderate quality trial found no evidence patient education reduced diabetic foot infections or amputations (Lincoln NB, 2008). However, other moderate-quality trials have found that education changes patient behaviors (Corbett CF, 2003, Borges WJ, 2008). A moderate-quality trial found use of infrared temperature monitoring to be effective in preventing recurrent foot ulcers when added to footwear, diabetic education and regular foot care (Lavery LA, 2007). These interventions are not invasive, have no significant adverse effects, and are low cost; thus they are recommended.

PATIENT EDUCATION FOR DIABETIC FOOT COMPLICATIONS

Recommended

Patient education is recommended for prevention of diabetic foot complications.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence Low

Indications

Diabetics at risk of foot ulcers and amputations, particularly those with peripheral neuropathy and/or arterial insufficiency.

Rationale

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One moderate quality trial found no evidence patient education reduced diabetic foot infections or amputations (Lincoln NB, 2008). However, other moderate-quality trials have found that education changes patient behaviors (Corbett CF, 2003, Borges WJ, 2008). A moderate-quality trial found use of infrared temperature monitoring to be effective in preventing recurrent foot ulcers when added to footwear, diabetic education and regular foot care (Lavery LA, 2007). These interventions are not invasive, have no significant adverse effects, and are low cost; thus they are recommended.

PHYSICAL MODALITIES AND DEVICES

REDUCED LOCALIZED MECHANICAL COMPRESSION/PRESSURE FOR FOOT ULCERS

Recommended

Reduced localized mechanical compression/pressure is recommended for foot ulcers.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence High

Indications

All patients with foot ulcerations for which ulceration is not healing. Also recommended for prevention in particularly susceptible patients at high risk of complications (e.g., select workers with diabetes mellitus with peripheral neuropathy; frail elderly with compromised immune, dermatological, vascular systems).

Rationale

There are no quality trials on a general approach to reduction in localized mechanical compression or pressure/ force. These interventions include assessing whether there are poorly fitting shoes, and lack of movement producing sustained localized mechanical compression. Yet, approaches to reduce these forces are widely used, assumed to be of major importance, and assumed to have efficacy as localized pressure is generally presumed to be a causal factor. These techniques are not invasive, have low adverse effects, and are generally low cost. They are recommended for treatment of foot ulcerations, as well as prevention in susceptible populations. There are wound care systems but no quality trials to evaluate their efficacy.

Evidence

There are no quality RCTs incorporated into this analysis.

NEGATIVE PRESSURE (VACUUM) WOUND CARE SYSTEMS FOR CHRONIC FOOT ULCERS

Recommended

Negative pressure (vacuum) wound care systems are moderately recommended for the treatment of chronic lower extremity ulcers.

Strength of evidence Moderately Recommended, Evidence (B)

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Level of confidence Moderate

Indications

Chronic, non-healing lower extremity ulcers, including those associated with diabetes mellitus and venous stasis (Vuerstaek JD, 2006).

Rationale

There are multiple moderate-quality trials suggesting efficacy of negative pressure therapy for chronic leg ulcers, mostly diabetic-related. Two moderate-quality trials suggested improved wound healing with a vacuum-assisted device compared with moist gauze therapy (Blume PA, 2008, Mouës CM, 2004). Other moderate-quality trials suggested better wound healing and fewer amputations (Armstrong DG et al., 2005, Vuerstaek JD, 2006). A trial of -75mmHg vs. -125mmHg found no differences at 4 weeks (Lavery LA, 2014). Another trial found no differences between mechanically and electrically powered devices (Armstrong DG, 2012). There are various wound care systems and no quality comparative controls to suggest one is superior to another. Wound care systems are not invasive, have low adverse effects, are moderately costly, and with evidence of efficacy are recommended.

TOTAL CONTACT CASTING FOR FOOT ULCERS

Recommended

Total contact casting is recommended for foot ulcers.

Strength of evidence Recommended, Evidence (C)
Level of confidence Low

Indications

All patients with non-healing foot ulcerations are potential candidates although the moderate-quality data are all among diabetics.
Rationale

Total contact casting produced faster time to healing in a moderate quality trial (Lavery LA, 2014), thus it is recommended.

FOOT WAFFLE SUPPORT BRACE FOR FOOT ULCERS

Not Recommended

Foot Waffle Support Brace is not recommended for select patients with foot ulcers.

Strength of evidence Not Recommended, Insufficient Evidence (I)
Level of confidence Low

Rationale

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There is one low-quality RCT suggesting worse results with a foot waffle support brace compared with pillow support (Tymec AC, 1997) to attempt to reduce localized pressure. Foot waffle support braces are low cost, not invasive, but also do not appear effective and thus are not recommended.

Evidence

There is 1 low-quality RCT in Appendix 1.

MEDICATIONS

BECAPLERMIN (REGRANEX) FOR SELECT NONHEALING DIABETIC NEUROPATHIC ULCERS

Recommended

Becaplermin is recommended as adjuvant therapy to wound care for select non-healing diabetic neuropathic ulcers.

Strength of evidence Recommended, Evidence (C)
Level of confidence Low

Indications

Non-healing diabetic neuropathic ulcers that extend at least into the subcutaneous tissue, have adequate blood supply. Should only be used in addition to debridement, pressure relief and infection control.

Rationale

There are trials comparing becaplermin with placebo for adjuvant treatment of diabetic ulcers (Steed DL, 2006, Wieman TJ, 1998, Blume P, 2011, Niezgoda JA, 2005, d'Hemecourt PA, 1998, Bhansali A, 2009). While the trials often have methodological weaknesses, they overall appear to be associated with modestly superior wound healing rates. Becaplermin is non-invasive, has some adverse effects, is labor-intensive and is high cost; however, in select circumstances is recommended as an adjuvant to good ulcer care to speed healing.

There is one moderate-quality trial suggested faster resolution of a diabetic ulcer with a combination of autologous-derived growth factors plus collagen and oxidized regenerated cellulose for select non-healing diabetic neuropathic ulcers. This combination therapy is non-invasive, has some adverse effects, is labor-intensive and is high cost, however, in select circumstances is recommended as an adjuvant to speed healing.

One low-quality randomized controlled trial assessing topical nerve growth factor (TNGF) suggested fairly strong efficacy (Landi F, 2003). Topical Nerve Growth Factors are not invasive, has adverse effects and is costly, but is recommended for select patients. There is one low quality trial regarding topical basic fibroblast growth factor and thus insufficient evidence for a recommendation.

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AUTOLOGOUS-DERIVED GROWTH FACTORS FOR SELECT NONHEALING DIABETIC ULCERS

Recommended

Autologous-derived growth factors are recommended as adjuvant therapy to wound care with collagen and oxidized regenerated cellulose for select non-healing diabetic ulcers.

Strength of evidence Recommended, Evidence (C)
Level of confidence Low

Indications

Non-healing diabetic neuropathic ulcers of at least 4 weeks duration unresponsive to moist gauze treatment that extend at least into the subcutaneous tissue, have adequate blood supply (Kakagia DD, 2007). Should only be used in addition to a dressing of collagen and oxidized regenerated cellulose, debridement, pressure relief, and infection control.

Rationale

There are trials comparing becaplermin with placebo for adjuvant treatment of diabetic ulcers (Steed DL, 2006, Wieman TJ, 1998, Blume P, 2011, Niezgoda JA, 2005, d'Hemecourt PA, 1998, Bhansali A, 2009). While the trials often have methodological weaknesses, they overall appear to be associated with modestly superior wound healing rates. Becaplermin is non-invasive, has some adverse effects, is labor-intensive and is high cost; however, in select circumstances is recommended as an adjuvant to good ulcer care to speed healing.

There is one moderate-quality trial suggested faster resolution of a diabetic ulcer with a combination of autologous-derived growth factors plus collagen and oxidized regenerated cellulose for select non-healing diabetic neuropathic ulcers (Kakagia DD, 2007). This combination therapy is non-invasive, has some adverse effects, is labor-intensive and is high cost, however, in select circumstances is recommended as an adjuvant to speed healing.

One low-quality randomized controlled trial assessing topical nerve growth factor (TNGF) suggested fairly strong efficacy (Landi F, 2003). Topical Nerve Growth Factors are not invasive, has adverse effects and is costly, but is recommended for select patients. There is one low quality trial regarding topical basic fibroblast growth factor and thus insufficient evidence for a recommendation.

TOPICAL NERVE GROWTH FACTORS FOR SELECT NONHEALING DIABETIC ULCERS

Recommended

Topical nerve growth factors are recommended for select patients with foot ulcers.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence Low

Indications

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Foot ulcerations that are: (i) 1-30cm2 (Landi F, 2003) and (ii) either not healing after approximately 2-3 weeks, or occurring in those with high risk of complications (e.g., advanced diabetes mellitus with peripheral neuropathy; frail elderly with compromised immune, dermatological, vascular systems).

Rationale

There are trials comparing becaplermin with placebo for adjuvant treatment of diabetic ulcers (Steed DL, 2006, Wieman TJ, 1998, Blume P, 2011, Niezgoda JA, 2005, d'Hemecourt PA, 1998, Bhansali A, 2009). While the trials often have methodological weaknesses, they overall appear to be associated with modestly superior wound healing rates. Becaplermin is non-invasive, has some adverse effects, is labor-intensive and is high cost; however, in select circumstances is recommended as an adjuvant to good ulcer care to speed healing. There is one moderate-quality trial suggested faster resolution of a diabetic ulcer with a combination of autologous-derived growth factors plus collagen and oxidized regenerated cellulose for select non-healing diabetic neuropathic ulcers (Kakagia DD, 2007). This combination therapy is non-invasive, has some adverse effects, is labor-intensive and is high cost, however, in select circumstances is recommended as an adjuvant to speed healing. One low-quality randomized controlled trial assessing topical nerve growth factor (TNGF) suggested fairly strong efficacy (Landi F, 2003). Topical Nerve Growth Factors are not invasive, has adverse effects and is costly, but is recommended for select patients. There is one low quality trial regarding topical basic fibroblast growth factor and thus insufficient evidence for a recommendation.

Evidence

There is 1 low-quality RCT in Appendix 1.

TOPICAL BASIC FIBROBLAST GROWTH FACTORS FOR SELECT NONHEALING DIABETIC NEUROPATHIC ULCERS

No Recommendation

There is no recommendation for or against topical basic fibroblast growth factor for non-healing diabetic ulcers.

Strength of evidence No Recommendation, Insufficient Evidence (I)
Level of confidence Low

Rationale

There are trials comparing becaplermin with placebo for adjuvant treatment of diabetic ulcers (Steed DL, 2006, Wieman TJ, 1998, Blume P, 2011, Niezgoda JA, 2005, d'Hemecourt PA, 1998, Bhansali A, 2009). While the trials often have methodological weaknesses, they overall appear to be associated with modestly superior wound healing rates. Becaplermin is non-invasive, has some adverse effects, is labor-intensive and is high cost; however, in select circumstances is recommended as an adjuvant to good ulcer care to speed healing. There is one moderate-quality trial suggested faster resolution of a diabetic ulcer with a

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combination of autologous-derived growth factors plus collagen and oxidized regenerated cellulose for select non-healing diabetic neuropathic ulcers (Kakagia DD, 2007). This combination therapy is non-invasive, has some adverse effects, is labor-intensive and is high cost, however, in select circumstances is recommended as an adjuvant to speed healing. One low-quality randomized controlled trial assessing topical nerve growth factor (TNGF) suggested fairly strong efficacy (Landi F, 2003). Topical Nerve Growth Factors are not invasive, has adverse effects and is costly, but is recommended for select patients. There is one low quality trial regarding topical basic fibroblast growth factor and thus insufficient evidence for a recommendation.

GRANULOCYTE COLONY-STIMULATING FACTOR FOR DIABETIC FOOT ULCERS

Sometimes Recommended

Granulocyte colony-stimulating factor is recommended for treatment of particularly challenging diabetic foot ulcers.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence Low

Indications

At least moderate sized ulcers (0.5-3cm) with neuropathy (Kastenbauer T, 2003), threatening amputations (de Lalla F, 2001) and/or extensive cellulitis (Gough A, 1997).

Rationale

Overall literature is relatively sparse and somewhat conflicting, yet the higher quality studies suggest efficacy. One study suggested C-SCF was associated with faster reductions in pathogens (Kastenbauer T, 2003), one study found shortened hospital stays (Gough A, 1997) and another found fewer amputations (de Lalla F, 2001). Yet, another found no reduction in hospital stays (Yonem A, 2001). While there is somewhat conflicting literature, the higher quality literature suggests efficacy, thus G-CSF is recommended on a highly select basis for treatment of particularly difficult diabetic foot ulcers.

PROSTACYCLIN ANALOGUES (ILOPROST) FOR DIABETIC ULCERS

No Recommendation

There is no recommendation for or against prostacyclin analogues (iloprost) for treatment of diabetic foot ulcers.

Strength of evidence No Recommendation, Insufficient Evidence (I)
Level of confidence Low

Rationale

Prostacyclin analogues, including iloprost, have not been studied in quality studies and thus there is no recommendation.

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Evidence

There is 1 low-quality RCT in Appendix 1.

LOW-MOLECULAR-WEIGHT HEPARINS FOR DIABETIC FOOT ULCERS

No Recommendation

There is no recommendation for or against the use of low molecular weight heparins for treatment of diabetic foot ulcers.

Strength of evidence No Recommendation, Insufficient Evidence (I)
Level of confidence Low

Rationale

There is one exploratory trial suggesting potential efficacy. Additional, confirmatory studies are needed before an evidence-based recommendation is made.

ALLIED HEALTH INTERVENTIONS

COMPLEMENTARY AND ALTERNATIVE MEDICATIONS FOR DIABETIC FOOT ULCERS

No Recommendation

There is no recommendation for or against the use of complementary and alternative medications for treatment of diabetic foot ulcers.

Strength of evidence No Recommendation, Insufficient Evidence (I)
Level of confidence Low

Rationale

Complementary and alternative medications have not been studied in quality studies and thus there is no recommendation for their use.

HYPERBARIC OXYGEN FOR DIABETIC FOOT ULCERS

Recommended

Hyperbaric oxygen therapy is recommended for treatment of diabetic foot ulcers.

Strength of evidence Recommended, Evidence (C)
Level of confidence Low

Indications

Wagner's 2, 3, 4 foot ulcer(s) of more than 3 months duration (Löndahl M, 2010).

Frequency/Dose/Duration

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HBOT was used in one quality trial; regimen was 100% O2, 5min compression, 2.5 atmospheres for 85 min., 5min decompression. Treatments 5 days per week for 8 weeks. May extend to 10 weeks; maximum 40 treatments (Löndahl M, 2010).

Rationale

Hyperbaric oxygen therapy has been evaluated in one moderate-quality trial. Data suggest substantially improved rates of healing (Löndahl M, 2010). HBO is not invasive, usually has low adverse effects, and is costly, but it is recommended for treatment of select diabetic foot ulcers.

EXTRACORPOREAL SHOCK WAVE THERAPY FOR DIABETIC FOOT ULCERS

Not Recommended

Extracorporeal Shock Wave Therapy is not recommended for treatment of diabetic foot ulcers.

Strength of evidence Not Recommended, Evidence (C)
Level of confidence Low

Rationale

ESWT has been evaluated in a moderate-quality trial. Data do not show substantially improved rates of healing. ESWT is not invasive, has low adverse effects other than pain, but is costly and without clear evidence of benefit it is not recommended for treatment of diabetic foot ulcers.

SURGICAL PROCEDURES

TISSUE-ENGINEERED SKIN GRAFTS FOR NONHEALING DIABETIC ULCERS

Recommended

Tissue-engineered skin grafts are moderately recommended for highly select non-healing diabetic neuropathic ulcers.

Strength of evidence Moderately Recommended, Evidence (B)
Level of confidence Moderate

Indications

Non-healing diabetic neuropathic ulcers at least 1cm2 that extend at least into the subcutaneous tissue, have adequate blood supply and lasting at least 14 days. Should only be used in addition to debridement, pressure relief and infection control (Edmonds M, 2009, Sams HH, 2002).

Rationale

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Multiple moderate-quality RCTs have evaluated efficacy of tissue engineered skin grafts of various compositions (Edmonds M, 2009, Hanft JR, 2002, Sams HH, 2002) as adjuncts to wound care, all showing substantially better healing. Tissue grafts are not invasive, have low adverse effects, are costly but are recommended for select ulcers.

One moderate-quality trial found better healing using cultured allogeneic karatinocytes compared to Vaseline gauze (You HJ, 2012). This is a non-invasive treatment with low adverse effects, high cost but with significant evidence of efficacy and this thus recommended for highly select patients.

SHEETS OF CULTURED ALLOGENEIC KERATINOCYTES FOR NONHEALING DIABETIC ULCERS

Recommended

Sheets of cultured allogeneic keratinocytes are recommended for select non-healing diabetic ulcers.

Strength of evidence Recommended, Evidence (C)
Level of confidence Low

Indications

Non-healing diabetic ulcers of at least 1cm2 size, Wagner 1 or 2, transcutaneous oxygen of at least 40mmHg that have not responded to 6 weeks of treatment. Should only be used in addition to debridement, systemic antibiotic(s), pressure relief, and infection control (You HJ, 2012).

Rationale

Multiple moderate-quality RCTs have evaluated efficacy of tissue engineered skin grafts of various compositions (Edmonds M, 2009, Hanft JR, 2002, Sams HH, 2002) as adjuncts to wound care, all showing substantially better healing. Tissue grafts are not invasive, have low adverse effects, are costly but are recommended for select ulcers.

One moderate-quality trial found better healing using cultured allogeneic karatinocytes compared to Vaseline gauze (You HJ, 2012). This is a non-invasive treatment with low adverse effects, high cost but with significant evidence of efficacy and this thus recommended for highly select patients.

FOREFOOT AND MIDFOOT FRACTURES (TARSAL, METATARSAL, PHALANGEAL)

DIAGNOSTIC RECOMMENDATIONS

X-RAY FOR SUSPECTED ACUTE FOREFOOT OR MIDFOOT FRACTURES

Recommended

X-ray is recommended as a first-line study for suspected forefoot or midfoot fractures.

Strength of evidence Recommended, Insufficient Evidence (I)

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Level of confidence High

Indications

Suspicion of all forefoot and midfoot fractures.

Rationale

There are no quality trials for the use of x-ray for forefoot or midfoot fractures. However, x-ray assists in identifying fractures, orientation of fracture plane(s), magnitude of the involvement of the interphalangeal and metatarsal phalangeal joints, which if large enough may alter management in favor of surgery (see below). If fracture is clinically suspected in the setting of negative radiographs, follow-up radiographs may be helpful; after approximately 7 days there will be resorption at the fracture line, which will then be visible. X-ray is non-invasive, is lower cost than MRI or CT, and is recommended.

Evidence

There are no quality trials incorporated in this analysis.

MAGNETIC RESONANCE IMAGING (MRI) FOR SUSPECTED ACUTE FOREFOOT AND MIDFOOT FRACTURES

Recommended

MRI is recommended for suspected occult and stress fracture in select patients.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence Moderate

Indications

Generally reserved for suspicion of occult or stress fracture of the fore- or midfoot, however, CT is viewed as superior by some (Myerson MS, 2008).

Rationale

There is no quality evidence for the use of MRI for detecting forefoot or midfoot fractures. MRI should not be used as a first-line test. MRI may be an important diagnostic technique for the evaluation of suspected injuries of the navicular, tarsometatarsal joint (Lisfranc injury) and for early diagnosis of suspected stress fracture. MRI is also used for suspected occult fracture and for evaluation of avascular necrosis.

Evidence

There are no quality studies incorporated into this analysis.

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BONE SCANNING FOR FOREFOOT AND MIDFOOT FRACTURES

Sometimes Recommended

Bone scans are recommended for diagnosis of occult and stress fractures in select patients.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence Moderate

Indications

Generally reserved for suspicion of occult fracture of the tarsal and metatarsal bones, however, CT is viewed as superior by some (Myerson MS, 2008).

Rationale

There are no quality studies on bone scanning, and bone scans are not required to evaluate the majority of patients with forefoot and midfoot fractures. A bone scan may be reasonable for patients with high clinical suspicion but negative x-ray or CT scan. Technetium scanning may be positive for occult or stress fracture within 6 to 72 hours of pain onset (Born et al., 1997). MRI has become more widely used for early detection of stress fractures than bone scan.

Evidence

There are no quality studies incorporated into this analysis.

COMPUTED TOMOGRAPHY (CT) FOR DIAGNOSIS AND CLASSIFICATION OF FOREFOOT AND MIDFOOT FRACTURES

Recommended

CT is recommended for investigation of forefoot and midfoot fractures.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence Moderate

Indications

Evaluation of displaced or comminuted fracture of the tarsal and metatarsal bones to gain greater clarity of fracture displacement, articular involvement, and subluxation of affected joints. Generally, this is a second-line diagnostic tool after x-rays (Myerson MS, 2008).

Rationale

There is no quality evidence for the use of CT for detection of forefoot and midfoot fractures. CT should not be used as a first-line test. CT may be an important diagnostic

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technique to gain greater clarity of fracture displacement, articular involvement, and subluxation of affected joints, and is recommended for select patients.

Evidence

There are no quality studies incorporated into this analysis.

TREATMENT RECOMMENDATIONS

OVERVIEW

Initial management should include treatment of soft tissue injuries and pain control following completion of physical examination. Regional anesthesia may be administered to complete diagnostic assessment (passive range of motion, rotational alignment) and to perform closed reduction of the fracture, although not until neurovascular examination is documented. There are no quality trials for forefoot block techniques (see Metacarpal Fractures in Hand, Wrist, and Forearm Disorders guideline).

MEDICATIONS

NSAIDS FOR PHALANGEAL OR METATARSAL FRACTURES

Recommended

NSAIDs are recommended to control pain from phalangeal or metatarsal fractures.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence High

Indications

Pain due to phalangeal or metatarsal fracture.

Frequency/Dose/Duration

Scheduled dosage rather than as needed is generally preferable.

Indications for discontinuation

Resolution of pain, lack of efficacy, development of adverse effects particularly gastrointestinal.

Rationale

While there is no quality evidence, these medications are thought to be effective for control of swelling (NSAIDs) and pain in the initial stages of injury, are not invasive, have low adverse effects, are low cost, and thus are recommended. While there have been some concerns regarding delayed fracture healing, other studies have suggested no delayed bone healing (see Ankle Fractures). These concerns appear outweighed by pain management concerns.

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ACETAMINOPHEN FOR PHALANGEAL OR METATARSAL FRACTURES

Recommended

Acetaminophen is recommended to control pain from phalangeal or metatarsal fractures.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence High

Indications

Pain due to phalangeal or metatarsal fracture.

Frequency/Dose/Duration

Scheduled dosage rather than as needed is generally preferable.

Indications for discontinuation

Resolution of pain, lack of efficacy, development of adverse effects particularly gastrointestinal.

Rationale

While there is no quality evidence, these medications are thought to be effective for control of swelling (NSAIDs) and pain in the initial stages of injury, are not invasive, have low adverse effects, are low cost, and thus are recommended. While there have been some concerns regarding delayed fracture healing, other studies have suggested no delayed bone healing (see Ankle Fractures). These concerns appear outweighed by pain management concerns.

TARSAL-METATARSAL JOINT (LISFRANC) INJURY

NONOPERATIVE MANAGEMENT FOR NONDISPLACED TARSAL-METATARSAL INJURY (LISFRANC)

Sometimes Recommended

Non-operative management of non-displaced tarsal-metatarsal injury (Lisfranc) is recommended for select patients.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence Moderate

Indications

Fracture/joint dislocation displacement <2mm.

Frequency/Dose/Duration

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Non-weight-bearing cast for 6 weeks.

Rationale

There are no quality trials comparing non-operative treatment to fixation, bone screws, or plates for tarsal-metatarsal joint injuries. There is one moderate-quality trial comparing primary arthrodesis to primary ORIF that demonstrated no functional differences, but the study was discontinued secondary to higher number of secondary surgeries for hardware removal (Henning JA, 2009). It is unclear if removal was due to protocol or from symptomatic concerns. Twenty-two percent of eligible patients were enrolled in the study. Therefore, there is insufficient evidence to recommend primary arthrodesis as the initial procedure over primary ORIF. There are no quality studies defining acceptable limits of displacement for non-operative management, determining the ideal splint time or duration of internal or external fixation, making comparisons of fixation techniques or defining ideal post-operative rehabilitation protocols. Immobilization or fixation technique is therefore dictated by the physical and radiographic findings.

OPERATIVE MANAGEMENT FOR DISPLACED TARSAL-METATARSAL INJURY (LISFRANC)

Sometimes Recommended

Operative management is recommended for an unstable tarsal-metatarsal injury (fracture joint displacement with joint dislocation >2 mm).

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence Moderate

Indications

Fracture joint displacement with joint dislocation >2 mm (Myerson, 1999).

Frequency/Dose/Duration

Operative fixation with K-wire or screws, or primary arthrodesis; non-weight bearing for 6 to 12 weeks and edema management (see Ankle and Calcaneus Fractures) (Campbell, 2002, Myerson, 1999, Hatch et al., 2007, Henning JA, 2009). Toe-touch weight-bearing in walking boot for 8 weeks. May take 4 to 5 months to heal; therapy may be started. Removal of hardware prior to full activities (Myerson, 1999).

Rationale

There are no quality trials comparing non-operative treatment to fixation, bone screws, or plates for tarsal-metatarsal joint injuries. There is one moderate-quality trial comparing primary arthrodesis to primary ORIF that demonstrated no functional differences, but the study was discontinued secondary to higher number of secondary surgeries for hardware removal (Henning JA, 2009). It is unclear if removal was due to protocol or from symptomatic concerns. Twenty-two percent of eligible patients were enrolled in the study.

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Therefore, there is insufficient evidence to recommend primary arthrodesis as the initial procedure over primary ORIF. There are no quality studies defining acceptable limits of displacement for non-operative management, determining the ideal splint time or duration of internal or external fixation, making comparisons of fixation techniques or defining ideal post-operative rehabilitation protocols. Immobilization or fixation technique is therefore dictated by the physical and radiographic findings.

METATARSAL SHAFT FRACTURES

NONOPERATIVE MANAGEMENT FOR NONDISPLACED METATARSAL FRACTURES

Sometimes Recommended

Non-operative management is recommended for non-displaced metatarsal fractures.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence High

Indications

Non-displaced shaft fractures or with up to 3 to 4mm displacement in dorsal or plantar direction, angulation less than 10 degrees dorsally (Cakir et al., 2010, Hatch et al., 2007).

Frequency/Dose/Duration

Edema management with bulky dressing, elevation, splint if needed. Firm supportive shoe or fracture shoe with progressive weight bearing. Pain intolerance warrants short leg-walking cast for 2 to 3 weeks (Hatch et al., 2007). Repeat films at 1 week and 6 weeks.

Rationale

There are no quality studies comparing non-operative treatment, fixation, bone screws, or plates for metatarsal fractures. There also are no quality studies defining acceptable limits of displacement for non-operative management, determining the ideal splint time or duration of internal or external fixation, making comparisons of fixation techniques or defining ideal post-operative rehabilitation protocols. Immobilization or fixation technique is therefore dictated by the physical and radiographic findings.

Evidence

There are no quality studies incorporated into this analysis.

OPERATIVE MANAGEMENT FOR DISPLACED METATARSAL SHAFT FRACTURES

Sometimes Recommended

Operative management is recommended for displaced metatarsal shaft fractures.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence Moderate

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Indications

Multiple metatarsals fractured if displaced; shaft fracture near metatarsal head (Hatch et al., 2007).

Frequency/Dose/Duration

Percutaneous pinning or internal fixation with screws, plates; non-weight bearing 4 to 6 weeks. Progressive weight-bearing over next 4 to 6 weeks in fracture shoe/boot or walking cast. Full weight-bearing in shoes/stiff soled shoe after radiographic evidence of union (Campbell, 2002).

Rationale

There are no quality studies comparing non-operative treatment, fixation, bone screws, or plates for metatarsal fractures. There also are no quality studies defining acceptable limits of displacement for non-operative management, determining the ideal splint time or duration of internal or external fixation, making comparisons of fixation techniques or defining ideal post-operative rehabilitation protocols. Immobilization or fixation technique is therefore dictated by the physical and radiographic findings.

Evidence

There are no quality studies incorporated into this analysis.

PROXIMAL FIFTH METATARSAL FRACTURES

NONOPERATIVE MANAGEMENT FOR PROXIMAL FIFTH METATARSAL FRACTURES

Sometimes Recommended

Non-operative management of fifth metatarsal fractures (including Jones and avulsion) is recommended for select patients.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence High

Indications

Avulsion of tuberosity: non-displaced, <1 to 2mm step-off on articular surface or less than 30% of articular surface with cuboid (Hatch et al., 2007, Strayer et al., 1999, Zwitser et al., 2010); Jones Fracture: patient/clinician preference.

Frequency/Dose/Duration

Avulsion of tuberosity: edema management with bulky dressing, elevation, splint if needed; firm supportive shoe or fracture shoe with progressive weight bearing. Pain intolerance warrants short-leg walking cast for 2 to 3 weeks (Hatch et al., 2007, Strayer et al., 1999).

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Repeat films at 1 and 6 weeks. Jones Fracture: non-weight-bearing short-leg cast immobilization for 6 to 8 weeks, followed by hard-sole shoe or walking cast until union (Mologne et al., 2005).

Rationale

There are no quality studies comparing non-operative treatment, fixation, bone screws, or plates for avulsion fractures. A low-quality trial demonstrated Jones dressing resulted in faster return to activity than cast immobilization for avulsion fractures (Wiener et al., 1997). There also are no quality studies defining acceptable limits of displacement for non-operative management, determining the ideal splint time or duration of internal or external fixation, making comparisons of fixation techniques or defining ideal post-operative rehabilitation protocols. Immobilization or fixation technique is therefore dictated by the physical and radiographic findings. There is one quality trial for operative management compared with cast immobilization of Jones fractures that demonstrated shorter times to union and return to activity with screw fixation. The procedure is invasive with associated surgical risks and is high cost compared to conservative management. Conservative management may result in non-union (Myerson, 1999)(Mologne et al., 2005, Wiener et al., 1997). There is insufficient evidence for recommending one treatment over another, and should therefore be managed based on physician and patient preference.

OPERATIVE MANAGEMENT FOR DISPLACED METATARSAL SHAFT FRACTURES

Sometimes Recommended

Operative management for fifth metatarsal fractures (Jones, Avulsion) is recommended for select patients.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence Moderate

Indications

Avulsion of tuberosity: displaced >1 to 2mm step-off on the articular surface or more than 30% of articular surface with cuboid (Hatch et al., 2007, Strayer et al., 1999, Zwitser et al., 2010); Jones Fracture: patient/clinician preference.

Frequency/Dose/Duration

Avulsion of tuberosity: similar to other metatarsal shaft fractures treated operatively. Jones Fracture: non-weight bearing Jones splint for 2 weeks, followed by weight bearing in hard-sole shoe as tolerated (Mologne et al., 2005).

Rationale

There are no quality studies comparing non-operative treatment, fixation, bone screws, or plates for avulsion fractures. A low-quality trial demonstrated Jones dressing resulted in faster return to activity than cast immobilization for avulsion fractures (Wiener et al., 1997).

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There also are no quality studies defining acceptable limits of displacement for non-operative management, determining the ideal splint time or duration of internal or external fixation, making comparisons of fixation techniques or defining ideal post-operative rehabilitation protocols. Immobilization or fixation technique is therefore dictated by the physical and radiographic findings. There is one quality trial for operative management compared with cast immobilization of Jones fractures that demonstrated shorter times to union and return to activity with screw fixation. The procedure is invasive with associated surgical risks and is high cost compared to conservative management. Conservative management may result in non-union (Myerson, 1999, Mologne et al., 2005, Wiener et al., 1997). There is insufficient evidence for recommending one treatment over another, and should therefore be managed based on physician and patient preference.

PHALANGEAL FRACTURES

IMMOBILIZATION FOR DISTAL, MIDDLE, OR PROXIMAL PHALANX FRACTURES

Sometimes Recommended

Immobilization is recommended for treatment of select patients with distal, middle, or proximal phalanx fractures.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence High

Indications

Closed, non-displaced or stable after reduction, involves less than 25% of articular surface (Hatch, 2003). No established guides to the degree of acceptability of displacement, angulation, or rotation.

Frequency/Dose/Duration

Closed reduction after digital or hematoma block; obtain post-reduction film, repeat at 1 and 6 weeks; splint toe with buddy tape to adjacent toe until non-tender (3 to 4 weeks). Additional immobilization with a post-operative shoe or cast-boot should be considered.

Rationale

There are no quality studies for non-operative treatment, percutaneous fixation, bone screws, or plates for phalangeal fractures. There also are no quality studies defining acceptable limits of displacement for non-operative management, determining the ideal splint time or duration of internal or external fixation, making comparisons of fixation techniques or defining ideal post-operative rehabilitation impractical. Immobilization or fixation technique is therefore dictated by the physical and radiographic findings. It is generally limited to displaced fractures of the great toe or multiple toe fractures (see Phalangeal Fractures in Hand, Wrist, and Forearm Disorders guideline for analogous injury management).

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Evidence

There are no quality studies incorporated into this analysis.

OPERATIVE MANAGEMENT FOR DISTAL, MIDDLE, OR PROXIMAL PHALANX FRACTURES

Sometimes Recommended

Operative management is recommended for treatment of select patients with distal, middle, or proximal phalanx fractures (displaced fractures of great toe with poor reduction, unable to hold reduction with tape splinting).

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence High

Indications

Displaced fractures of great toe with poor reduction, unable to hold reduction with tape splinting.

Rationale

There are no quality studies for non-operative treatment, percutaneous fixation, bone screws, or plates for phalangeal fractures. There also are no quality studies defining acceptable limits of displacement for non-operative management, determining the ideal splint time or duration of internal or external fixation, making comparisons of fixation techniques or defining ideal post-operative rehabilitation impractical. Immobilization or fixation technique is therefore dictated by the physical and radiographic findings. It is generally limited to displaced fractures of the great toe or multiple toe fractures (see Phalangeal Fractures in Hand, Wrist, and Forearm Disorders guideline for analogous injury management).

Evidence

There are no quality studies incorporated into this analysis.

STRESS FRACTURES

Stress fractures are thought to be caused by repetitive loading to the bone rather than a discrete event. The etiology is thought to be related to intrinsic factors resulting in bone weakness such as rheumatoid arthritis, osteoporosis, or long-term corticosteroid use. Extrinsic factors that may contribute to stress fracture include vigorous athletic training regimens, and suboptimal footwear and nutritional status [315]. History of stress fractures often includes increased physical activity or increase in intensity of activity preceding symptoms [205,206,207,208]. Navicular stress fracture presents as insidious onset of midfoot pain. They are often slow to be diagnosed [209]. There may be tenderness over the dorsal aspect of the navicular bone in navicular stress fractures or over a metatarsal bone in metatarsal stress fractures. Diagnostic imaging includes x-ray which generally requires 2 to 4 weeks for a stress fracture to show up, MRI, and radionuclide bone scan [205,206,316].

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NONOPERATIVE MANAGEMENT FOR LOWER EXTREMITY STRESS FRACTURES

Recommended

Non-operative management is recommended for low-risk lower extremity stress fractures.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence High

Indications

Non-displaced stress fractures.

Frequency/Dose/Duration

All non-displaced stress fractures can be treated conservatively initially. Metatarsal: weight bearing with short leg cast, cast boot, or stiff soled shoe for 6 to 8 weeks. Calcaneus: activity restriction, heel-pad inserts, protected weight bearing. Fifth metatarsal: non-weight bearing for 6 to 8 weeks, same as Jones Fracture (see Fifth Metatarsal Fractures) (Gehrmann et al., 2006). Non-weight bearing may be required for up to 20 weeks in extreme cases (Karasick, 1994). Navicular: non-weight bearing cast until fracture is healed (6 weeks) but may require up to 8 months to return to full activity.

Rationale

There are no quality trials available for lower extremity stress fractures. Stress fractures are reported to respond well to activity restriction in most instances. Activity restriction is therefore recommended. Stress fractures that do not respond or that are displaced are treated operatively with fixation with and without graft. Athletes or persons that desire quicker return to activity often go straight to surgical intervention for stress fractures that are high-risk for non-union. Some high-risk fractures for non-union include talus, navicular, and fifth metatarsal (Chen et al., 2006, Weinfeld et al., 1997, Wilder et al., 2004, de Clercq et al., 2008, Jones et al., 2006, Gehrmann et al., 2006). There is insufficient evidence for recommendation of operative management.

Evidence

There are no quality studies incorporated into this analysis.

OPERATIVE MANAGEMENT FOR LOWER EXTREMITY STRESS FRACTURES

No Recommendation

There is no recommendation for or against the use of operative management of lower extremity stress fractures in select patients.

Strength of evidence No Recommendation, Insufficient Evidence (I)
Level of confidence Low

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Rationale

There are no quality trials available for lower extremity stress fractures. Stress fractures are reported to respond well to activity restriction in most instances. Activity restriction is therefore recommended. Stress fractures that do not respond or that are displaced are treated operatively with fixation with and without graft. Athletes or persons that desire quicker return to activity often go straight to surgical intervention for stress fractures that are high-risk for non-union. Some high-risk fractures for non-union include talus, navicular, and fifth metatarsal (Chen et al., 2006, Weinfeld et al., 1997, Wilder et al., 2004, de Clercq et al., 2008, Jones et al., 2006, Gehrmann et al., 2006). There is insufficient evidence for recommendation of operative management.

Evidence

There are no quality studies incorporated into this analysis.

HAMMER TOE

OVERVIEW

There are no quality trials to guide evidence-based treatment recommendations. Non-operative treatments include footwear modifications to improve toe box/room, padding, corticosteroid injections, and orthoses [123]. There are various surgical procedures used (arthroplasty, flexor tendon transfer, flexor tenotomy, extensor tendon lengthening and metatarsophalangeal joint capsulotomy, fusion, and diaphysectomy) [108,109]. Yet, there are no quality studies comparing surgery with no treatment or non-surgical options.

TREATMENT RECOMMENDATIONS

CORTICOSTEROID INJECTIONS FOR HAMMERTOE

Recommended

Non-operative treatments such as footwear modifications to improve toe box/room, padding, corticosteroid injections, and orthoses are recommended.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence Low

FOOTWEAR MODIFICATIONS FOR HAMMERTOE

Recommended

Non-operative treatments such as footwear modifications to improve toe box/room, padding, corticosteroid injections, and orthoses are recommended.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence Low

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ORTHOTICS FOR HAMMERTOE

Recommended

Non-operative treatments such as footwear modifications to improve toe box/room, padding, corticosteroid injections, and orthoses are recommended.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence Low

PADDING FOR HAMMERTOE

Recommended

Non-operative treatments such as footwear modifications to improve toe box/room, padding, corticosteroid injections, and orthoses are recommended.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence Low

SURGERY FOR HAMMERTOE

Recommended

Surgery is recommended for hammer toes with insufficient results from non-operative treatment.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence Low

Evidence

There are various surgical procedures used (arthroplasty, flexor tendon transfer, flexor tenotomy, extensor tendon lengthening and metatarsophalangeal joint capsulotomy, fusion, and diaphysectomy). Yet, there are no quality studies compared with no treatment or non-surgical options. There is one comparative study of operative treatments.

HINDFOOT FRACTURES (CALCANEUS, TALUS)

DIAGNOSTIC RECOMMENDATIONS

X-RAY FOR SUSPECTED ACUTE HINDFOOT FRACTURES

Recommended

X-ray is recommended as a first-line study for suspected hindfoot fractures.

Strength of evidence Moderately Recommended, Evidence (B)
Level of confidence High

Indications

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Suspicion of fracture.

Rationale

There are two quality diagnostic studies for the use of x-ray for calcaneus fractures (Knight et al., 2006, Ebraheim et al., 1996). A case-control diagnostic study demonstrated emergency department physicians were able to detect 97.5% of calcaneus fractures on lateral x-ray compared with CT confirmed diagnosis. Blinded radiologists reading the same films were 99.5% accurate compared with CT diagnosis (Knight et al., 2006). Another diagnostic study demonstrated x-ray to reveal more detail on articular depression and severity of rotational displacement of calcaneus fracture fragments than coronal CT (Ebraheim et al., 1996). Talus fractures are often difficult to see on x-ray, particularly of the lateral process. A 45° internal oblique view is beneficial. If clinically suspected in the setting of negative radiographs, follow-up radiographs may be helpful; after approximately 7 days there will be resorption at the fracture line, which will then be more easily visible (Furlong et al., 2004). Thus, x-ray should be the first diagnostic test for suspected hindfoot fracture and is recommended.

MAGNETIC RESONANCE IMAGING (MRI) FOR SUSPECTED ACUTE HINDFOOT FRACTURES

Recommended

MRI is recommended for suspected acute occult fracture of the calcaneus.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence Moderate

Indications

Generally reserved for suspicion of occult fracture of the talus neck or lateral process (Furlong et al., 2004). Patients whose plain images indicate osteochondral lesion and those who remain symptomatic after 6 weeks should undergo evaluation with MRI (Alexander et al., 1980, Canale et al., 1980, Flick et al., 1985)(Pettine et al., 1987).

Rationale

There is no quality evidence that MRI is superior to radiographs for the initial detection of hindfoot fractures and should not be generally used as a first-line test. MRI may be an important diagnostic technique for the evaluation of suspected injuries of the talar neck and lateral process. MRI is used for suspected occult fracture, as some talus fractures are not apparent on radiographs. MRI is also indicated for evaluation of avascular necrosis. For calcaneus fracture, there is one moderate-quality diagnostic study that compared MRI and CT findings of intra-articular calcaneus fractures with x-ray (Zeiss et al., 1991). MRI was demonstrated to be suboptimal for acute and subacute calcaneal injury compared to CT, but was more effective at diagnosis of soft tissue and avascular necrosis in patients with prolonged symptoms. Results of this study are limited by its small sample size of 29. In general, MRI is suboptimal compared with CT scan for calcaneus injury.

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MAGNETIC RESONANCE IMAGING (MRI) FOR FOLLOW-UP EVALUATION OF NONACUTE CALCANEUS FRACTURE

Recommended

MRI is recommended for calcaneus fractures for identification of complications in the non-acute fracture patient.

Strength of evidence Recommended, Evidence (C)
Level of confidence Moderate

Indications

Non-acute fracture patient with persistent pain more than 4 months after injury (Zeiss et al., 1991).

Rationale

There is no quality evidence that MRI is superior to radiographs for the initial detection of hindfoot fractures and should not be generally used as a first-line test. MRI may be an important diagnostic technique for the evaluation of suspected injuries of the talar neck and lateral process. MRI is used for suspected occult fracture, as some talus fractures are not apparent on radiographs. MRI is also indicated for evaluation of avascular necrosis. For calcaneus fracture, there is one moderate-quality diagnostic study that compared MRI and CT findings of intra-articular calcaneus fractures with x-ray (Zeiss et al., 1991). MRI was demonstrated to be suboptimal for acute and subacute calcaneal injury compared to CT, but was more effective at diagnosis of soft tissue and avascular necrosis in patients with prolonged symptoms. Results of this study are limited by its small sample size of 29. In general, MRI is suboptimal compared with CT scan for calcaneus injury.

BONE SCANNING FOR CALCANEUS FRACTURE

Sometimes Recommended

Bone scans are recommended for diagnosis of occult and stress fractures in select patients.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence High

Rationale

There are no quality studies on bone scanning and bone scans are not required for evaluation of the majority of patients with calcaneus fractures. A bone scan may be reasonable for those with high clinical suspicion but with negative x-ray and CT scan. Technetium scanning may be positive for occult or stress fracture within 6 to 72 hours of the onset of pain (Born et al., 1997).

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COMPUTED TOMOGRAPHY (CT) FOR DIAGNOSIS AND CLASSIFICATION OF HINDFOOT FRACTURES

Recommended

CT is recommended for investigation of hindfoot fractures.

Strength of evidence Recommended, Evidence (C)
Level of confidence High

Indications

CT is recommended for occult and complex distal extremity, ankle, and foot fractures to gain greater clarity of fracture displacement, articular involvement, and subluxation of affected joints (Catalano et al., 2004, Harness et al., 2006, Katz et al., 2001). If intraarticular displacement is considered, then axial views are recommended in addition to any coronal views (Ogawa et al., 2009). CT is indicated for evaluation of suspected subtalar joint fractures (Born et al., 1997, Haygood et al., 1997).

Rationale

A moderate-quality retrospective diagnostic study demonstrated CT to be superior to lateral x-ray in detecting articular displacement when coronal and axial images are obtained (Ebraheim et al., 1996). The same study suggests sagittal reconstruction for rotational abnormalities of the posterior facet should be considered for appropriate patients. CT scans are considered the gold standard (Daftary et al., 2005, Ogawa et al., 2009, Koval et al., 1993, Gilmer et al., 1986) and are used in several quality trials for diagnosing and characterizing calcaneus fractures (Kingwell et al., 2004, Knight et al., 2006, Howard et al., 2003, Thordarson et al., 1996, Buckley et al., 2002, Johal et al., 2009, Longino et al., 2001, Parmar et al., 1993). For other hindfoot fractures, CT should be considered when x-ray images are negative, but on the basis of physical findings an occult fracture is strongly suspected. CT may also be useful for evaluation of complex comminuted fractures, providing superior depiction of distal tibial articular surface involvement, fragment positioning, and diagnosis of subluxations (Catalano et al., 2004, Harness et al., 2006). The value of CT has been demonstrated – its use for evaluation of articular step off and gaping, comminution, and treatment has influenced observers to change treatment plans developed from radiographs and resulted in increased interobserver reliability in the proposed management of these injuries (Katz et al., 2001). Thus, the use of CT imaging is recommended.

TREATMENT RECOMMENDATIONS

MEDICATIONS

See Ankle Fracture section.

TALUS FRACTURES

Because of its key position, diagnosis and treatment of talus fractures is critical for foot and ankle function. Referral to specialist is indicated for all injuries due to the high potential for poor outcomes. Management includes evaluating the fracture closely with CT before

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deciding on conservative treatment. Non-displaced, non-rotated talar neck fractures can be treated with short-leg, non weight-bearing cast in neutral position for 6 to 12 weeks or until there is radiographic evidence that union has been achieved, followed by weight bearing in walker boot for 1 to 2 more months [317].

NONOPERATIVE MANAGEMENT OF NONDISPLACED TALAR FRACTURES

No Recommendation

There is no recommendation for or against non-operative management of non-displaced talar fractures (head, neck, body).

Strength of evidence No Recommendation, Insufficient Evidence (I)
Level of confidence Low

Rationale

There are no quality trials for talar head, neck, body, or lateral process fractures. Because of the key role the talus plays in locomotion, and the risk for significant disability and complication with these fractures, most are managed aggressively with open reduction and internal fixation (Chaney et al., 2001, Berlet et al., 2001, Thordarson, 2001). Referral to specialists is recommended for most, if not all, talus fractures.

Evidence

There are no quality studies incorporated into this analysis.

OPERATIVE MANAGEMENT OF DISPLACED TALAR FRACTURES

Recommended

Operative management is recommended for all displaced talar fractures (head, neck, body, lateral process).

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence High

Indications

All non-displaced, non-reducible fractures. Referral to specialist is indicated for all injuries due to the high potential for poor outcomes of these injuries. Emergent referral for talar neck fractures (Berlet et al., 2001).

Frequency/Dose/Duration

Post operative non-weight bearing casting for 6 to 12 weeks, changing every 3 weeks to evaluate soft tissue healing. Serial radiographs. Once union is apparent, non-weight bearing for another 4 to 8 weeks; if AVN of talar body is present, ensure protected weight bearing to prevent collapse of talar dome (Early, 2008, Berlet et al., 2001).

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Rationale

There are no quality trials for talar head, neck, body, or lateral process fractures. Because of the key role the talus plays in locomotion, and the risk for significant disability and complication with these fractures, most are managed aggressively with open reduction and internal fixation (Chaney et al., 2001, Berlet et al., 2001). Referral to specialists is recommended for most, if not all, talus fractures.

Evidence

There are no quality studies incorporated into this analysis.

NONOPERATIVE MANAGEMENT OF OSTEOCHONDRAL LESIONS OF THE TALUS

Recommended

Non-operative management of osteochondral lesions of the talus is recommended for select patients.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence Moderate

Indications

A non-operative approach is indicated for initial management of lateral lesions that radiographically appear to be a compression lesion with no visible fragment or there is a fragment but it is still attached. Medial lesions may also include nondisplaced fragment without attachment (Gobbi et al., 2006, Ferkel et al., 1990).

Frequency/Dose/Duration

Cast or brace immobilization and protected weight-bearing for 6 to 12 weeks, followed by increasing pain-free range-of-motion exercises and strengthening.

Rationale

There are no moderate- or high-quality trials comparing conservative management with operative repair. A systematic review of 32 lesser quality studies describing clinical outcomes reported a 45% success rate with non-operative treatment (Tol et al., 2000). There is no quality evidence that a trial of conservative therapy adversely affects surgery performed after conservative therapy has failed (Alexander et al., 1980, Flick et al., 1985). Therefore, a trial of conservative management is recommended initially. There are no quality trials regarding duration of conservative treatment, method of immobilization, weight-bearing status, use of NSAIDS, or the role of therapy. A trial of protected weight bearing for 6 to 12 weeks is reasonable (McGahan et al., 2010). There is one moderate-quality trial that compared three different surgical interventions for the treatment of osteochondral lesions of the talus (Gobbi et al., 2006). Chondroplasty, microfracture, and osteochondral autograft transplantation were all demonstrated to improve intragroup post-

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operative AOFAS and SANE scores from pre-operative baseline (p <0.001), with no significant difference between groups. There are no studies that compare these procedures with conservative management. Therefore, there is no recommendation for one procedure over another. Surgical treatment of Stage III and IV lesions yields good early results in 63% to 88% of patients (Alexander et al., 1980, Canale et al., 1980, Flick et al., 1985)(Pettine et al., 1987).

OPERATIVE INTERVENTION FOR OSTEOCHONDRAL LESIONS OF THE TALUS

Recommended

Operative intervention for osteochondral lesions of the talus is recommended for after an initial course of conservative management. Microfracture and osteochondral autograft are recommended.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence High

Indications

Confirmatory diagnostic evidence of an osteochondral lesion of the talus on x-ray, MRI and/or CT. Surgical considerations include either: 1) loose body or unstable or displaced lesion/defect or osteochondral fracture and/or 2) failure to heal or improve after 6 weeks of non-weight-bearing and other nonoperative treatment.

Rationale

There are no moderate- or high-quality trials comparing conservative management with operative repair. A systematic review of 32 lesser quality studies describing clinical outcomes reported a 45% success rate with non-operative treatment . There is no quality evidence that a trial of conservative therapy adversely affects surgery performed after conservative therapy has failed (Alexander et al., 1980). Therefore, a trial of conservative management is recommended initially. There are no quality trials regarding duration of conservative treatment, method of immobilization, weight-bearing status, use of NSAIDS, or the role of therapy. A trial of protected weight bearing for 6 to 12 weeks is reasonable . There is one moderate-quality trial that compared three different surgical interventions for the treatment of osteochondral lesions of the talus (Gobbi et al., 2006). Chondroplasty, microfracture, and osteochondral autograft transplantation were all demonstrated to improve intragroup post-operative AOFAS and SANE scores from pre-operative baseline (p <0.001), with no significant difference between groups. There are no studies that compare these procedures with conservative management. Therefore, there is no recommendation for one procedure over another. Surgical treatment of Stage III and IV lesions yields good early results in 63% to 88% of patients (Alexander et al., 1980).

Thus, surgical repair is recommended for select patients with confirmed diagnostic evidence of an osteochondral lesion of the talus on x-ray, MRI, and/or CT. Surgical considerations include either: 1) loose body or unstable or displaced lesion/defect or osteochondral

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fracture and/or 2) failure to heal or improve after 6 weeks of non-weight-bearing and other nonoperative treatment.

CALCANEUS INJURIES

Both non-surgical and surgical interventions are described to help regain anatomical reduction and alignment [318,319,320]. The majority of calcaneus fractures extend into the subtalar joint [204]. Calcaneocuboid joint injuries should be considered in the presence of calcaneus fracture [321]. Calcaneus fractures are often complicated by significant swelling secondary to soft tissue injury that may require delay in operative fixation and result in significant complications including fracture blister formation [47,322]. Clinical outcomes appear to be associated with restoration of Böhler's angle [76,319,323,324].

CAST IMMOBILIZATION FOR SELECT CALCANEUS FRACTURES

Sometimes Recommended

Non-operative cast immobilization is recommended for select calcaneus fractures.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence High

Indications

Non-displaced fracture, displaced extra-articular, displaced intra-articular.

Rationale

There are two moderate-quality trials that compared operative management (ORIF) to non-operative cast immobilization of non-reduced displaced intra-articular calcaneus fractures (Thordarson et al., 1996, Buckley et al., 2002). A low-quality prospective trial with 15-year follow-up demonstrated no significant benefit from surgery for non-displaced calcaneus fractures over non-operative care (Ibrahim et al., 2007, Parmar et al., 1993). There are two additional reports from the original trial and are considered as one trial in this analysis (Howard et al., 2003, O'Brien et al., 2004). The study, which included 424 fractures with intraarticular displacement greater than 2mm, demonstrated no differences in functional and pain assessment scores between groups. Upon stratification, females, patients not receiving workers' compensation, younger males, patients with a higher Böhler angle, patients with a lighter workload, and those with a single simple displaced intra-articular calcaneus fracture were demonstrated to have better results after operative treatment than after non-operative treatment. A second report demonstrated ORIF patients are more likely to develop complications, but workers' compensation patients developed a high incidence of complications regardless of the management strategy chosen (Howard et al., 2003). The third report demonstrated similar effect on subjective gait scores as the original report, with no differences between the non-stratified groups, but improved scores after stratification in the classifications of young males, non-workers' compensation, moderate workload before injury, and restoration of the Böhler angle to above 0 degrees (O'Brien et al., 2004). The second moderate-quality trial of 30 patients demonstrated surgical fixation results in lower pain scores and higher functional scores at 12 months. Thus, there is conflicting evidence for

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management recommendations, and both are recommended as treatment alternatives. Additional quality studies are needed.

There is evidence for consideration of non-operative management in workers' compensation patients (Buckley et al., 2002). Both operative and non-operative management have considerable potential for adverse effects, including secondary late fusion, compartment syndrome and fasciotomy, DVT and pulmonary embolism, and late-term arthrodesis. Surgical intervention also may result in superficial and deep infection, malposition of fixation, and hardware removal (Howard et al., 2003, Parmar et al., 1993, Radnay et al., 2009), and this should be taken into consideration when determining management technique. There is no quality evidence for costs of operative compared with non-operative care, although an economic study evaluated both direct and indirect costs, reporting operative management costs $19,000 CAN less per patient than non-operative management because of reduced lost time from work (Brauer et al., 2005). There is no quality evidence for one operative technique over another.

OPERATIVE MANAGEMENT FOR SELECT CALCANEUS FRACTURES

Sometimes Recommended

Operative management is recommended for select calcaneus fractures.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence High

Indications

Displaced, non-reducible extra-articular fractures, displaced intra-articular fractures.

Rationale

There are two moderate-quality trials that compared operative management (ORIF) to non-operative cast immobilization of non-reduced displaced intra-articular calcaneus fractures (Thordarson et al., 1996, Buckley et al., 2002). A low-quality prospective trial with 15-year follow-up demonstrated no significant benefit from surgery for non-displaced calcaneus fractures over non-operative care (Ibrahim et al., 2007, Parmar et al., 1993). There are two additional reports from the original trial and are considered as one trial in this analysis (Howard et al., 2003, O'Brien et al., 2004). The study, which included 424 fractures with intraarticular displacement greater than 2mm, demonstrated no differences in functional and pain assessment scores between groups. Upon stratification, females, patients not receiving workers' compensation, younger males, patients with a higher Böhler angle, patients with a lighter workload, and those with a single simple displaced intra-articular calcaneus fracture were demonstrated to have better results after operative treatment than after non-operative treatment. A second report demonstrated ORIF patients are more likely to develop complications, but workers' compensation patients developed a high incidence of complications regardless of the management strategy chosen (Howard et al., 2003). The third report demonstrated similar effect on subjective gait scores as the original report, with no differences between the non-stratified groups, but improved scores after stratification in

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the classifications of young males, non-workers' compensation, moderate workload before injury, and restoration of the Böhler angle to above 0 degrees (O'Brien et al., 2004). The second moderate-quality trial of 30 patients demonstrated surgical fixation results in lower pain scores and higher functional scores at 12 months. Thus, there is conflicting evidence for management recommendations, and both are recommended as treatment alternatives. Additional quality studies are needed. There is evidence for consideration of non-operative management in workers' compensation patients (Buckley et al., 2002). Both operative and non-operative management have considerable potential for adverse effects, including secondary late fusion, compartment syndrome and fasciotomy, DVT and pulmonary embolism, and late-term arthrodesis. Surgical intervention also may result in superficial and deep infection, malposition of fixation, and hardware removal (Howard et al., 2003, Parmar et al., 1993), and this should be taken into consideration when determining management technique. There is no quality evidence for costs of operative compared with non-operative care, although an economic study evaluated both direct and indirect costs, reporting operative management costs $19,000 CAN less per patient than non-operative management because of reduced lost time from work. There is no quality evidence for one operative technique over another.

USE OF PNEUMATIC COMPRESSION DEVICE FOR TREATMENT OF CALCANEUS FRACTURES

Recommended

Use of pneumatic compression of foot to reduce swelling is recommended for patients with significant edema after closed calcaneus fractures.

Strength of evidence Recommended, Evidence (C)
Level of confidence Low

Indications

Patients with excessive swelling after closed displaced calcaneus fractures who are surgical candidates. Use in non-operative patients to reduce risk of other complications.

Frequency/Dose/Duration

Pedal compression device used continuously until swelling subsides sufficiently to allow for surgery or to manage non-operatively (Thordarson et al., 1999).

Indications for discontinuation

Achievement of desired swelling reduction, intolerance because of pain or discomfort.

Rationale

There is one moderate-quality trial comparing intermittent pneumatic pedal compression device after closed displaced calcaneus fractures compared to compression dressing and elevation (Thordarson et al., 1999). Compared to baseline, volumetric decrease was significantly greater in the pedal pneumatic compression group ($p = 0.02$). Faster resolution

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of pre-operative swelling allows earlier surgery and may reduce risk of developing fracture blister, but quality evidence is lacking for improvement of functional outcomes. There is a retrospective study of intermittent pneumatic compression for calcaneus fracture patients that reported decreased swelling and compartment pressures associated with calcaneus fractures (Myerson et al., 2000). Thus, pneumatic compression for edema management is recommended for management of acute calcaneus fracture management in select patients. There is no definition of significant edema found in the quality trials. Clinical judgement is therefore warranted.

DIATHERMY FOR MANAGEMENT OF EDEMA ASSOCIATED WITH CALCANEUS FRACTURE

No Recommendation

There is no recommendation for or against the use of diathermy for management of edema associated with calcaneus fractures.

Strength of evidence No Recommendation, Insufficient Evidence (I)
Level of confidence Low

Rationale

There are no quality trials for the use of diathermy for edema management of calcaneus fracture. There is no evidence that diathermy is more effective than elevation and ice, but it is more costly. There is no recommendation for the use of diathermy for edema management.

Evidence

There are no quality studies incorporated into this analysis.

TREATMENT OF CANCELLOUS BONE DEFECT WITH DISPLACED INTRA-ARTICULAR CALCANEUS FRACTURES

No Recommendation

There is no recommendation for or against the use of calcium phosphate paste or bone graft for treatment of displaced intra-articular fracture defects.

Strength of evidence No Recommendation, Insufficient Evidence (I)
Level of confidence Low

Rationale

There are no quality trials comparing functional outcomes after use of bone graft, bone cement, or calcium phosphate paste to correct bone defects during fixation of displaced intraarticular calcaneus fracture. A low-quality trial demonstrated less calcaneal collapse measured by Böhler angle with the use of calcium phosphate paste, although clinical outcomes were no different (Johal et al., 2009). Another low-quality trial demonstrated equivalency of bone cement to bone graft, although there was no comparison to a non-treatment group (Dickson et al., 2002). A cohort study comparing bone grafting to no

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grafting in displaced intraarticular calcaneus fractures found no objective radiographic or functional benefit from the use of bone graft (Longino et al., 2001).

There are few adverse effects from the use of bone cement or other synthetic products, but bone graft can result in a harvest surgical site with associated complications. This treatment is of moderate to high costs related to material and procedure costs, but is of unknown efficacy. There is no recommendation for the use of bone graft, bone cement, or calcium phosphate paste to fill displaced intraarticular calcaneus defects.

DEVICES

The use of foot orthotics for prevention of lower extremity disorders is considered elsewhere in this guideline (see Plantar Fasciitis). There is no recommendation for or against the use of orthotics and special shoes to prevent stress fractures and overuse injuries.

PHYSICAL METHODS AND REHABILITATION

There are no quality trials for physical methods and rehabilitation of hindfoot fracture (see Ankle Fracture section).

MID-TARSUS PAIN AND SPRAINS

OVERVIEW

Mid-tarsus or mid-foot pain and sprains frequently involve any of the ligaments of the mid-foot. A primary diagnostic focus is to eliminate the diagnosis of midfoot fracture (see also Midfoot fracture section). Metatarsalgia is included in this category as is metatarsophalangeal joint sprain. However, metatarsalgia is a broad categorization of forefoot pain that also includes numerous other conditions (e.g., Morton's neuroma). It is widely viewed as related to gait mechanics, anatomical variations, deformities and other largely non-occupational conditions [325,326] and aside from Morton's neuroma will not be addressed further.

- As there is almost no quality literature on these sprains, and none in typical working populations, most treatment recommendations are by analogy to ankle sprains and should be considered "Insufficient Evidence" recommendations (e.g., NSAID, ice). However, diagnostic and therapeutic approaches differ considerably, especially for Lisfranc injuries.
- Lisfranc injuries involve the tarsometatarsal joint(s) particularly at the bases of the first and second metatarsals. These are often complex injuries that can involve various combinations of the ligaments in the midfoot. Analogous injuries can occur to the other tarsometatarsal joints, are less common, are associated with a greater extent of injury, and may be progressive and sequential injuries. These injuries range in severity from mild sprains to dislocation/fractures (see detailed Lisfranc fractures in Midfoot fracture section below). Lisfranc injuries result from events such as falling from height, stepping in a hole, stepping off a curb, sporting events, and pushing on a brake during a motor vehicle accident [327,328,329]. While many of these injuries and sports and avocationally-related, some of these injuries are occupational.
- Midfoot pain should be carefully sought and located. Impaired weight-bearing is typical. The combination of midfoot pain, impaired weight bearing while in the context of an inciting event are usual characteristics [327]. Swelling and tenderness over the midfoot is

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common. Perhaps the most common provocative maneuver on examination is to passively pronate and abduct the forefoot to assess tarsometatarsal complex stability.

- Weight-bearing x-rays (AP and lateral views with/out obliques; often bilateral for comparative purposes) are often normal in mild injuries (grade 1 sprains), generally abnormal in moderate (grade 2), but are always abnormal in severe injures (grade 3) [328].
- CT scans are helpful in uncertain cases and in select preoperative cases [328,329].
- For mild to moderate cases without diastasis, immobilization in a short-leg walking boot or cast for 4-6 weeks is recommended [327,328,329,330], with repeat x-rays and evaluation for stability at 2 weeks [329].
- Some prefer to treat with complete non-weight bearing status due to the disability that may ensue in unsuccessfully treated cases, and is a reasonable option.

Surgery is recommended for all severe cases, unstable injuries, and those with significant diastasis [e.g., >2mm [329]]. Other than one quality study suggesting inferiority of ORIF [331], there are no other quality comparative trials for the more common operative techniques (screw fixation vs. arthrodesis vs. ligament reconstruction). There is not quality evidence to preferentially support immediate (24-48 hour surgery post-injury), however some surgeons prefer this often with percutaneous fixation techniques, while others opt to wait approximately one week for swelling to subside. It is helpful to coordinate with the surgeon regarding these preferences. Post-operative, non-weight bearing status is usually maintained for 8-12 weeks.

DIAGNOSTIC RECOMMENDATIONS

WEIGHT-BEARING X-RAYS FOR MID-TARSUS PAIN AND SPRAINS

Recommended

Weight-bearing x-rays (AP and lateral views with/out obliques; often bilateral for comparative purposes) are recommended.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence High

COMPUTED TOMOGRAPHY (CT) SCANS FOR MID-TARSUS PAIN AND SPRAINS

Recommended

CT scans are helpful in uncertain cases and in select pre-operative cases and are recommended.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence Moderate

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TREATMENT RECOMMENDATIONS

IMMOBILIZATION FOR MID-TARSUS PAIN AND SPRAINS

Recommended

For mild to moderate cases without diastasis, immobilization in a short-leg walking boot or cast for 4-6 weeks is recommended.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence Moderate

SURGERY FOR MID-TARSUS PAIN AND SPRAINS

Recommended

Surgery is recommended for all severe cases, unstable injuries, and those with significant diastasis [e.g., >2mm (Myerson MS, 2008)]. Other than one quality study suggesting inferiority of ORIF (Henning et al., 2009), there are no other quality comparative trials for the more common operative techniques (screw fixation vs. arthrodesis vs. ligament reconstruction). There is not quality evidence to preferentially support immediate (24-48 hour surgery post-injury), however some surgeons prefer this often with percutaneous fixation techniques, while others opt to wait approximately one week for swelling to subside. It is helpful to coordinate with the surgeon regarding these preferences. Post-operative, non-weight bearing status is usually maintained for 8-12 weeks.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence Moderate

PARONYCHIA

OVERVIEW

Paronychia is an inflammatory disorder of the nail folds. They are generally classified as acute and chronic. Acute cases are caused by trauma to the nail folds or cuticle. There are recurrent acute cases. However, chronic paronychia is increasingly thought to be an inflammatory condition of the nail folds that is analogous to eczema [(332,333)].

There are few quality trials of treatment of acute paronychia. If an abscess has formed, the primary treatment is incision in drainage. Systemic antibiotics have been reported as ineffective in a low-quality trial [(334)]. However, they are commonly prescribed and would be widely considered essential with a complicating condition such as diabetes mellitus, signs of systemic infection, or with a surrounding cellulitis. Thus, while antibiotics may not be needed for many cases, there also would be a low threshold for prescribing antibiotics.

Recurrent acute paronychias are thought to be recurrences of the same problems. These are often treated with surgery, especially en bloc excision of the proximal nail fold and eponychial marsupialization, with or without nail plate removal [(335)].

Chronic paronychia have been thought to be largely related to fungal infections and thus antifungals were common treatments, both topical and systemic [(336,337)]; however, that treatment option is usually the primary treatment for those thought to mainly have a fungal infection. One moderate-quality trial found superiority of terbinafine compared with

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itraconazole [338]. Instead, glucocorticosteroids are now thought to be the primary treatment. Topical glucocorticosteroid creams were found superior to anti-fungals in one RCT [339]. Tacrolimus 0.1% ointment has been found superior to steroids [340]. Topical antibiotics and systemic antibiotics have been used for secondary infections. The threshold for using an antibiotic in combination with a topical glucocorticosteroid is necessarily low, due to the potential for infectious complications.

Consideration of surgical management is recommended for patients who fail nonoperative measures, particularly including attempts to manage with glucocorticoids and anti-fungal(s). Surgical interventions include en bloc excision of the proximal nail fold and eponychial marsupialization, with or without nail plate removal [341].

TREATMENT RECOMMENDATIONS

ANTIBIOTICS FOR PARONYCHIA

No Recommendation

Antibiotics are commonly prescribed and would be widely considered essential with a complicating condition such as diabetes mellitus, signs of systemic infection, or with a surrounding cellulitis. Antibiotics may not be needed for many cases, but there also would be a low threshold for prescribing them.

Strength of evidence No Recommendation, Insufficient Evidence (I)
Level of confidence Low

INCISION AND DRAINAGE FOR PARONYCHIA

Recommended

If an abscess has formed, the primary treatment is incision and drainage.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence Low

WARM COMPRESSES FOR PARONYCHIA

Recommended

Warm compresses are recommended in the acute phase.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence Low

TOPICAL ANTIBIOTICS FOR PARONYCHIA

Recommended

The threshold for using an antibiotic in combination with a topical glucocorticosteroid is necessarily low, due to the potential for infectious complications.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence Low

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Indications

The threshold for using an antibiotic in combination with a topical glucocorticosteroid is necessarily low, due to the potential for infectious complications.

TOPICAL ANTIBIOTICS FOR CHRONIC PARONYCHIA

Not Recommended

Topical antibiotics and systemic antibiotics have been used for secondary infections and are recommended.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence Low

NSAIDS OR ACETAMINOPHEN FOR PARONYCHIA

Recommended

Pain management is generally not needed, but NSAIDs or acetaminophen may be used and are recommended.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence Low

SURGERY FOR ACUTE OR SUBACUTE PARONYCHIA

Recommended

Recurrent acute paronychias are thought to be recurrences of the same problems. These are often treated with surgery, especially en bloc excision of the proximal nail fold and eponychial marsupialization, with or without nail plate removal.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence Low

SURGERY FOR CHRONIC PARONYCHIA

Recommended

Consideration of surgical management is recommended, but only for those who fail non-operative measures, particularly including attempts to manage with glucocorticoids and anti-fungal(s). Surgical interventions include en bloc excision of the proximal nail fold and eponychial marsupialization, with or without nail plate removal.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence Low

ANTIFUNGALS FOR PARONYCHIA

Recommended

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Chronic paronychia have been thought to be largely related to fungal infections. Antifungals are common treatments, both topical and systemic, and are still recommended. However, that treatment option is usually the primary treatment for those thought to mainly have a fungal infection. One moderate-quality trial found superiority of terbinafine compared with itraconazole. Instead, glucocorticosteroids are now thought to be the primary treatment.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence Low

TOPICAL GLUCOCORTICOSTEROID COMBINED WITH ANTIFUNGAL FOR PARONYCHIA

Recommended

Antifungal and glucocorticosteoid creams have been combined and are recommended.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence Low

TOPICAL GLUCOCORTICOSTEROIDS FOR PARONYCHIA

Recommended

Glucocorticosteroids are now thought to be the primary treatment. Topical glucocorticosteroid creams were found superior to anti-fungals in one RCT, and thus they are recommended.

Strength of evidence Recommended, Evidence (C)
Level of confidence Low

TACROLIMUS FOR PARONYCHIA

Recommended

Tacrolimus 0.1% ointment has been found superior to steroids and is recommended.

Strength of evidence Recommended, Evidence (C)
Level of confidence Low

PLANTAR HEEL PAIN (PLANTAR FASCIITIS)

OVERVIEW

Plantar fasciitis is usually marked pain in the inferior or plantar aspect of either the center or medial heel. Pain may be reported distal towards the arch of the foot. As noted, it is most noticeable during weight-bearing activities, especially the first weight-bearing step of the day or after periods of sitting or recumbency [128,132,140,141,142].

Assessment of heel pain should exclude diagnoses that need aggressive or highly restrictive treatment, or involve systemic disease such as Achilles tendon rupture, plantar fascial rupture, systemic metabolic or inflammatory disorders, or calcaneal stress fracture. Additionally, before assigning a diagnosis of plantar fasciitis, plantar calcaneal and retro calcaneal bursitis, posterior tibial or medial calcaneal nerve entrapment, osseous tumor of

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the calcaneus, and S1 radiculopathy should also be eliminated [128,143,144,145]. (Some of these diagnoses may be controversial and pose diagnostic difficulties in themselves.) Distinguishing clinical features include location and duration of symptoms.

Examination usually reveals tenderness over the proximal central fascia, particularly near the insertion point at the calcaneal tuberosity. Stretching the plantar fascia by dorsi-flexing the toes may exacerbate the pain [124]. The calcaneal squeeze test is used to help identify a calcaneal stress fracture [143]. Plantar calcaneal bursitis pain can be elicited with palpation of the plantar center of the calcaneus. Additionally, the "windlass test" may be used, which has weight- and non-weight-bearing approaches:

- *Non-weight bearing* – With the patient sitting, the examiner stabilizes the ankle joint in neutral with one hand placed just behind the first metatarsal head then passively dorsiflexes the first metacarpophalangeal (MCP) joint while allowing the interphalangeal joint to plantarflex. Dorsiflexion of the first MTP joint is continued to its end of range or until the patient's pain is reproduced.
- *Weight bearing* – The patient stands on a step stool and positions the metatarsal heads of the foot to be tested just over the edge of the step. The subject is instructed to place equal weight on both feet. The examiner then passively extends the 1st MTP joint while allowing the interphalangeal joint to flex. Passive extension dorsiflexion of the 1st MTP joint is continued to its end of range or until the patient's pain is reproduced.

According to DeGarceau, sensitivity and specificity for the windlass test are 0.33 and 0.99, respectively [342]. Using DeGarceau's sensitivity and specificity, a person with plantar fasciitis may not have a positive test, but in the absence of a positive windlass test, plantar fasciitis is unlikely.

The diagnosis is evident from history and physical examination in most cases. There are no formally established diagnostic criteria. Diagnostic ultrasound or MRI may be used as a diagnostic tool, but no firm diagnostic criteria have been established. Hypoechogenicity of the plantar fascia on ultrasound, increased signal intensity of the plantar fascia on MRI, and plantar fascial thickness over 4 or 5mm by either method is likely to be abnormal. Plantar fascial thickness has been the subject of several radiographic studies in heel pain, some of which are summarized in Table 5. However, studies comparing subjects with heel pain to those without heel pain are often inadequately controlled and their findings are not conclusive.

Grasel considered a database of "1852 MR imaging studies of the ankle," selected 56 patients, but collected complete data sets on only 25 [343]. There was no comparison population. The authors' most-common finding was poorly circumscribed perifascial increase in STIR signal intensity superficial or deep to the plantar fascia (76% and 52%, respectively). Fifty-two percent of subjects had increased interfascial signal intensity, 56% had a bone marrow abnormality, and 25% had thickened plantar fascia. Grasel considered plantar fascia thicker than 5mm as abnormal. Kane stated that "plantar fasciitis was considered present when the plantar fascial thickness was greater than or equal to 4.5mm or when there was more than 1mm difference in plantar fascial thickness between the symptomatic and asymptomatic heels in association with decreased echogenicity and/or loss of definition of the antero-inferior border of the calcaneus" [344].

Imaging studies used to determine plantar fascial thickness select subjects from specific settings and are poorly controlled [343,345,346,347,348]. Only a minority of persons with plantar

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heel pain may have plantar fascia thicker than 5mm [343]. A reliable cutoff separating normally from abnormally thick plantar fascia is not clear. Given the variability of plantar fascial thickness in persons without heel pain, with thickness at the high end of the 95th percentile as much as 4.5mm, assuming a plantar fascial thickness of less than 4.5mm is abnormal is tenuous.

DIAGNOSTIC RECOMMENDATIONS

ROUTINE USE OF X-RAY FOR DIAGNOSIS OF PLANTAR HEEL PAIN

Not Recommended

The routine use of x-ray is not recommended for diagnosing plantar fasciitis or plantar heel pain as management is not altered.

Strength of evidence Not Recommended, Insufficient Evidence (I)
Level of confidence High

Rationale

There is no quality evidence evaluating the use of x-ray for the diagnosis of routine plantar heel pain consistent with the clinical diagnosis of plantar fasciitis. Radiography is poor at diagnosing soft-tissue disorders. For confirmation of ruptured fascia, ultrasound or MRI are more effective. X-ray is not invasive, has low adverse effects, and is low cost. X-ray is not recommended for routine evaluations except in cases of trauma or red flags.

ROUTINE USE OF X-RAY FOR DIAGNOSIS OF PLANTAR HEEL PAIN WITH SUSPECTED FRACTURE

Recommended

The use of x-ray is recommended for diagnosing plantar fasciitis or plantar heel pain when fractures are suspected including calcaneal stress fracture, osseous tumors, or non-routine confirmation of diagnosis.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence High

Indications

Evaluation of plantar heel pain when calcaneal fracture or osseous tumor is suspected. Plain films should not be obtained solely to indentify the presence of heel spurs, as the correlation between heel spurs and diagnosis or prognosis is believed to be poor. Lateral non-weight bearing x-ray focusing on soft tissue changes in plantar fascia thickness and fat reduction may provide diagnostic utility (Osborne et al., 2006), but ultrasound and MRI are considered superior. Plain x-rays are not indicated for routine evaluation of plantar heel pain as management is not altered.

Rationale

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There is no quality evidence evaluating the use of x-ray for the diagnosis of routine plantar heel pain consistent with the clinical diagnosis of plantar fasciitis. Radiography is poor at diagnosing soft-tissue disorders. For confirmation of ruptured fascia, ultrasound or MRI are more effective. X-ray is not invasive, has low adverse effects, and is low cost. X-ray is not recommended for routine evaluations except in cases of trauma or red flags.

MAGNETIC RESONANCE IMAGING (MRI) FOR DIAGNOSIS OF SELECT PATIENTS WITH PLANTAR FASCIITIS

Sometimes Recommended

MRI is recommended for the evaluation of select patients with plantar fasciitis. MRI may be useful in the diagnosis of causes of heel pain other than plantar fasciitis, including calcaneal stress fracture, plantar fascia rupture, perifascial fluid, calcaneal spurs, avascular necrosis of talar dome, joint fluid, ganglion cyst, stress fracture of the talar neck (Abdel-Wahab et al., 2008, Recht et al., 2001), and osseous tumors.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence Moderate

Indications

Suspected plantar fascial rupture, avascular necrosis of talar dome, and stress fracture of the talar neck particularly if heel pain is not improving (Grasel et al., 1999, Abdel-Wahab et al., 2008, Berkowitz et al., 1991, Recht et al., 2001, Theodorou et al., 2000).

Rationale

There are no quality trials evaluating the use of MRI for the diagnosis of plantar fasciitis. MRI may be useful in the diagnosis of causes of heel pain other than plantar fasciitis, including calcaneal stress fracture, plantar fascia rupture, perifascial fluid, calcaneal spurs, avascular necrosis of talar dome, joint fluid, ganglion cyst, stress fracture of the talar neck (Abdel-Wahab et al., 2008, Recht et al., 2001), and osseous tumors.

SPECT-CT FOR DIAGNOSIS OF PLANTAR FASCIITIS

Not Recommended

The use of SPECT-CT is not recommended for the diagnosis of plantar heel pain.

Strength of evidence Not Recommended, Insufficient Evidence (I)
Level of confidence Low

Rationale

There is no quality evidence supporting the use of SPECT-CT in investigating heel pain. SPECT-CT imaging for documenting increased metabolic activity is of unclear usefulness as there is no current accepted standard for interpretation of results, nor evidence that it will change outcome, nor is superior to less-expensive imaging methods. SPECT-CT is non-invasive but results in radiation exposure, is high cost, and is of undefined clinical utility. It is

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unlikely that SPECT-CT would result in changing or enhancing the treatment plan for plantar fasciitis, and is therefore not recommended.

ULTRASOUND FOR DIAGNOSIS OF PLANTAR FASCIITIS

Sometimes Recommended

Ultrasound is recommended for the evaluation of select patients with plantar fasciitis. Ultrasound may be useful when clinical diagnosis is uncertain or after no improvement from a course of conservative treatment of 4 to 6 weeks (Neufeld et al., 2008, Toomey, 2009).

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence Low

Indications

Evaluation of plantar heel pain when clinical diagnosis is uncertain or after no improvement from a course of conservative treatment of 4 to 6 weeks (Neufeld et al., 2008, Toomey, 2009).

Rationale

There are no quality trials for the use of ultrasound in diagnosing plantar fasciitis. However, ultrasound is frequently used to confirm suspected plantar fasciitis. Reported ultrasound findings include local thickening of the plantar fascia structure with hypoechoic areas (Kane et al., 2001, Sabir et al., 2005, Vohra et al., 2002, Tsai et al., 2000, Cardinal et al., 1996), fluid surrounding the tendon, and adhesions that can be visualized as thickening of the hypoechoic paratenon (Reddy et al., 2009). A threshold for considering plantar fascia thickened is not clear, but of the studies considered, the high end of the 95% confidence intervals for asymptomatic heel-thickness is above 4.5mm, and the low end for symptomatic heels is below 5.0mm. Thus, unless accompanied by a clinical correlation and other ultrasonographic findings, such as decreased echogenicity and/or loss of definition of the antero-inferior border of the calcaneus (Kane et al., 2001), use of plantar fascial thickness alone is not a reliable for diagnosis of plantar fasciitis. In addition to a lack of clear diagnostic criteria, findings on ultrasound are not likely to alter clinical management.

Ultrasound may be most helpful to identify fascial ruptures and plantar calcaneal bursitis. Ultrasound is non-invasive, has low adverse effects, and is of moderate cost. However, ultrasound may be less sensitive than MRI for suspected calcaneal fracture. Therefore, ultrasound is recommended for most cases when the clinical diagnosis is uncertain after a trial of presumptive conservative therapy where there is reasonable suspicion of symptomatic ruptures or plantar calcaneal bursitis. Ultrasound is not the primary diagnostic test for occult pathology or for suspected calcaneal fracture. However, it is recommended for cases of suspected plantar fascial rupture or plantar calcaneal bursitis if symptoms are not resolved after a trial of non-invasive therapy.

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TREATMENT RECOMMENDATIONS

OVERVIEW

There are no quality trials that include work or activity restrictions as an intervention. In general, avoidance of activities that are thought to exacerbate substantially symptoms such as prolonged walking or running may be beneficial [(142)], and no prolonged walking and/or running are work restriction may be specified as activity limitations. More commonly, activities may continue as before the onset of symptoms, but careful attention to stretching prior to weight bearing should be implemented.

EDUCATION

EDUCATION FOR PLANTAR FASCIA DISORDERS

Recommended

Education is recommended for select patients with acute, subacute, chronic, or post-operative plantar fascia and plantar heel pain. One or 2 appointments are indicated to educate patients about the disorder, effects of activity, unhelpfulness of complete inactivity, prognosis, and to provide detailed instructions for a stretching exercise program. Additional appointments may be needed if education is combined with physical or occupational therapy treatments. Follow-up educational visit(s) for more severe disorders as part of a progression towards normal functional use may be helpful.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence High

Indications

Achievement of education goals or non-compliance.

Frequency/Dose/Duration

One or 2 appointments to educate patients about the disorder, effects of activity, unhelpfulness of complete inactivity, prognosis, and to address other questions. These appointments are often combined with detailed instructions in a stretching exercise program. Additional appointments may be needed if education is combined with therapy treatments. Follow-up educational visit(s) for more severe disorders as part of a progression towards normal functional use is sometimes helpful.

Rationale

There are no quality trials evaluating efficacy of specific patient education for treating plantar fascia or heel pain disorders. Yet, education appears essential for optimizing doctor-patient alliance, reliable use of splints and performance of exercises, managing casts, and monitoring for infection and other problems. Some physicians accomplish this in the course of extended patient visits, while others routinely refer patients to a therapist for education. Regardless of the approach, a few appointments for educational purposes are recommended for select patients. The number of appointments needed is usually

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dependent on the diagnosis, severity of the condition, and co-existing conditions. A prospective series demonstrated that the addition of a multimedia presentation in the physician's office enhanced patient understanding of plantar fasciitis treatment protocols over surgeon-patient discourse (Beischer et al., 2008) and may be considered. Although education is usually incorporated as part of the overall treatment plan, an additional 1 or 2 appointments for purely educational purposes may be helpful midway through a treatment course for the more severely affected patient. Education is low cost and thus is recommended.

Evidence

There are no quality trials incorporated into this analysis.

ACTIVITY MODIFICATION AND EXERCISE

STRETCHING EXERCISES FOR PLANTAR FASCIITIS

Recommended

Stretching exercises of the plantar fascia and Achilles tendon are recommended for treatment of plantar fasciitis.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence High

Indications

Acute, subacute, or chronic plantar fasciitis.

Frequency/Dose/Duration

Ten-minute stretches 3 times a day; no limit identified for duration.

Indications for discontinuation

Resolution, adverse effects, intolerance, non-compliance.

Rationale

There is one moderate-quality trial with a 2-year follow-up report comparing plantar fascia stretching with Achilles stretching exercises (DiGiovanni et al., 2003, DiGiovanni et al., 2006). Heel pain in patients with chronic plantar pain who failed other conservative measures improved significantly with plantar fascia stretching exercises after 8 weeks of treatment compared with the Achilles stretching group. Stretching improved the subjects' reported pain but did not improve reported function to a statistically-significant level. Those in the Achilles group were crossed over to plantar stretching, and improved significantly over a 2-year period, similar to the first group. There was not a "no treatment" group to compare natural healing. Another moderate-quality trial comparing stretching to calcaneal taping, sham taping, and no treatment over a 1-week period found no benefit from

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gastrocnemius and plantar fascia stretching (Hyland et al., 2006). However, this study was limited to 1 week of treatment and follow-up. One moderate-quality study used stretching as a treatment arm to compare efficacy of orthotic interventions (Pfeffer et al., 1999). The stretching arm was as beneficial as a felt insert and custom orthosis. Another trial showed no statistically significant improvements between intervention (Achilles tendon-calf muscle stretching and sham ultrasound) and control (sham ultrasound only) groups after its 2-week period (Radford et al., 2007). Three trials offered a comparison between stretching and no stretching (Pfeffer et al., 1999, Hyland et al., 2006, Radford et al., 2007) without comparative benefit of stretching to the alternative treatment demonstrated in any of the trials. Two of the trials had participants who stretched stretch the plantar fascia (Pfeffer et al., 1999, Hyland et al., 2006) and one did not (Radford et al., 2007). Stretching is non-invasive, has no adverse effects, is self-administered and is of low cost, but has minimal evidence of efficacy. Given its low risk and cost, stretching is recommended.

MEDICATIONS

NSAIDS AND ACETAMINOPHEN

NSAIDs and acetaminophen are widely used for treatment of numerous soft-tissue and musculoskeletal injuries including ankle sprains [158] (see other MSD-related guidelines). The mechanism of action for NSAIDs is unclear for typical musculoskeletal disorders that mostly lack traditional markers of inflammation, although some believe the mechanism of efficacy nevertheless involves addressing some component of inflammation [159].

NSAIDS FOR ACUTE, SUBACUTE, CHRONIC, OR POSTOPERATIVE PLANTAR FASCIITIS PAIN

Recommended

NSAIDs are recommended treatment of acute, subacute, chronic, or post-operative plantar fasciitis pain.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence High

Indications

Pain associated with acute, subacute, chronic, or post-operative plantar fasciitis.

Frequency/Dose/Duration

Frequency/dose per manufacturer's recommendations; may be taken as scheduled or as needed. There is no evidence one NSAID is superior to another for treatment of plantar fasciitis or other musculoskeletal disorders.

Indications for discontinuation

Resolution, intolerance, adverse effects, lack of benefits, or failure to progress over a trial of a few weeks.

Rationale

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There are no quality trials of NSAID use specific for plantar fasciitis or for treatment of post-operative patients. A low-quality trial concluded Celecoxib may provide modest benefit over placebo, although the sample size was small and lacked methodological details (Donley et al., 2007). However, NSAIDs have been shown to be highly effective for several other musculoskeletal disorders and post-operative conditions. NSAIDs are not invasive, have low adverse effects particularly in employed populations, and are low cost, thus they are recommended.

Evidence

There are no quality trials incorporated into this analysis. There are 2 low-quality RCTs in Appendix 1 (Bourne, 1980, Donley et al., 2007).

ACETAMINOPHEN FOR ACUTE, SUBACUTE, CHRONIC, OR POSTOPERATIVE PLANTAR FASCIITIS PAIN

Recommended

Acetaminophen is recommended treatment of acute, subacute, chronic, or post-operative plantar fasciitis pain.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence High

Indications

Pain associated with acute, subacute, chronic, or post-operative plantar fasciitis.

Frequency/Dose/Duration

Frequency/dose per manufacturer's recommendations; may be taken as scheduled or as needed. There is no evidence one NSAID is superior to another for treatment of plantar fasciitis or other musculoskeletal disorders.

Indications for discontinuation

Resolution, intolerance, adverse effects, lack of benefits, or failure to progress over a trial of a few weeks.

Rationale

Acetaminophen is an analgesic and has no substantial anti-inflammatory effect. There is no quality evidence for or against the use of acetaminophen for the treatment of acute or subacute plantar fasciitis. There is one low-quality study comparing the effect of paracetamol with ibuprofen for acute sports injuries, which showed ibuprofen to be superior, although the study had several methodological problems (Bourne, 1980). However, there is quality evidence that acetaminophen is modestly superior to placebo for

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treatment of other musculoskeletal disorders, including low back pain, and has a low adverse effect profile (see Chronic Pain guideline for discussion of acetaminophen use). Acetaminophen is not invasive, has low adverse effects, and is low cost, thus by analogy with other musculoskeletal disorders, it is recommended.

Evidence

There are no quality trials incorporated into this analysis. There are 2 low-quality RCTs in Appendix 1 (Donley et al., 2007, Bourne, 1980).

INFLIXIMAB

Infliximab (Remicade) has been used for treatment of recalcitrant plantar fasciitis [349].

INFLIXIMAB FOR ACUTE, SUBACUTE, OR CHRONIC PLANTAR FASCIITIS

Not Recommended

Infliximab is not recommended for the treatment of acute, subacute, or chronic plantar fasciitis.

Strength of evidence Not Recommended, Insufficient Evidence (I)
Level of confidence Low

Rationale

Infliximab is a monoclonal antibody that acts as an anti-TNF factor used primarily for treatment of autoimmune disease such as rheumatoid arthritis and Crohn's disease. These medications have been used for treatment of other musculoskeletal disorders (see Chronic Pain and Low Back Disorders guidelines). There is no quality evidence for the use of Infliximab for the treatment of plantar fasciitis. Infliximab is administered as an infusion therapy and is therefore invasive, has a high adverse effect profile, and is high cost with no evidence of efficacy. Therefore, it is not recommended for routine or recalcitrant plantar fascial pain.

Evidence

There are no quality trials incorporated into this analysis.

OPIOIDS

OPIOIDS FOR ACUTE, SUBACUTE, OR CHRONIC PLANTAR FASCIITIS PAIN

Not Recommended

The use of opioids is not recommended for the treatment of acute, subacute, or chronic plantar fasciitis pain.

Strength of evidence Not Recommended, Insufficient Evidence (I)
Level of confidence High

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Rationale

There is no quality evidence for the use of opioids for the treatment of acute, subacute, or chronic plantar heel pain. The vast majority of patients with plantar fasciitis generally do not have pain sufficient to merit trialing with the risks of opioids. Patients having such degrees of pain are recommended to have investigations performed for alternative diagnoses as well as psychological issues (see Chronic Pain guideline). Opioids are not invasive, but have very high dropout rates (25 to 80%) and otherwise high rates of adverse effects. They are moderate to high cost depending on duration of treatment. They are not recommended for routine use.

OPIOIDS FOR POSTOPERATIVE PLANTAR FASCIITIS

Recommended

Limited use of opioids for a few post-operative days is recommended for select patients with plantar fasciitis. Opioids are generally suggested to be taken for short courses (a few days), with subsequent weaning to nocturnal use if needed, then discontinued. Duration usually ranges from a few days to up to 2 weeks.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence Moderate

Indications

Post-operative pain management.

Frequency/Dose/Duration

Frequency/dose per manufacturer's recommendations; may be taken as scheduled or as needed. Generally suggested to be taken for short courses (a few days), with subsequent weaning to nocturnal use if needed, then discontinued. Duration usually ranges from a few days to up to 2 weeks.

Indications for discontinuation

Sufficient pain management with other methods such as NSAIDs and acetaminophen, resolution of pain, intolerance, adverse effects, lack of benefits, or failure to progress over a couple weeks.

Rationale

Quality evidence for treatment of post-operative patients with opioids is absent. Some patients may have insufficient pain relief with NSAIDs, thus judicious use of opioids in the immediate post-operative period may be helpful, particularly for nocturnal use. Opioids are recommended for brief select use in post-operative patients with primary use at night to achieve post-operative sleep while not impairing early rehabilitation.

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Evidence

There are no quality trials incorporated into this analysis.

GLUCOCORTICOSTEROIDS

Oral or intramuscular glucocorticosteroids are occasionally administered for some musculoskeletal disorders, with efficacy believed to be largely through an anti-inflammatory mechanism. However, the use of these medications for plantar heel pain including plantar fasciitis is not reported in quality studies. Injections are reviewed below.

ORAL OR INTRAMUSCULAR GLUCOCORTICOSTEROIDS FOR ACUTE, SUBACUTE, OR CHRONIC PLANTAR HEEL PAIN

Not Recommended

Oral or intramuscular glucocorticosteroids are not recommended for the treatment of acute, subacute, or chronic plantar heel pain.

Strength of evidence Not Recommended, Insufficient Evidence (I)
Level of confidence Moderate

Rationale

There is no quality evidence for use of these agents for treatment of plantar fasciitis. These medications are either not invasive or minimally invasive, have adverse effects, and are low cost. As evidence is lacking and evidence of efficacy is present for several other treatments, the use of glucocorticosteroids by oral or intramuscular routes is not recommended.

VITAMINS

The use of vitamins including B6, C, and E is described for various musculoskeletal disorders as an antioxidant or is hypothesized as a promoter of tendon healing processes.

VITAMINS FOR TREATMENT OR PREVENTION OF PLANTAR FASCIITIS

No Recommendation

There is no recommendation for or against the short-term use of vitamins for the treatment or prevention of plantar fasciitis.

Strength of evidence No Recommendation, Insufficient Evidence (I)
Level of confidence Low

Rationale

There are no quality trials evaluating the use of vitamins for treating or preventing plantar fasciitis. Quality evidence increasingly documents lack of efficacy of vitamins for preventive cardiovascular purposes and increased risks of cancer has been reported, particularly for vitamin A and folate, raising serious questions about the antioxidant theory. Cost may be low, but with either compound formulations or cumulatively, costs may be considerable. Thus, there is no recommendation for or against short-term use of vitamins.

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Evidence

There are no quality trials incorporated into this analysis.

TOPICAL MEDICATIONS

The use of lidocaine patches has been described for various musculoskeletal disorders and has been reviewed in other guidelines (see Chronic Pain, Elbow Disorders, and Hand, Wrist and Forearm Disorders guidelines).

Topical NSAIDs are used to deliver medication locally and superficially in musculoskeletal disorders, including plantar heel disorders to reduce pain, swelling, improve range of motion and return to the patient to full functional capacity [350,351].

The use of wheat grass cream has been described for plantar fasciitis. Topical creams containing wheat grass are marketed for skin rejuvenation and healing.

LIDOCAINE PATCHES FOR ACUTE, SUBACUTE, CHRONIC, OR POSTOPERATIVE PLANTAR FASCIITIS

No Recommendation

There is no recommendation for or against the use of lidocaine patches for the treatment of acute, subacute, chronic, or post-operative plantar fasciitis.

Strength of evidence No Recommendation, Insufficient Evidence (I)
Level of confidence Low

Rationale

There are no quality trials of lidocaine patch use for plantar fasciitis. As one goal of therapies for plantar heel disorders is pain relief, this may represent a potential treatment on a short-term basis while other concomitant interventions, such as plantar fascia stretching exercises are being performed. However, lidocaine patches may be somewhat difficult to use on weight-bearing surfaces and with shoe wear. Patches are low cost for a short-term trial, but costs accumulate rapidly over time. Adverse effects of systemic absorption of topical anesthetics have prompted an FDA warning. There is no recommendation for or against lidocaine patches for plantar heel pain.

Evidence

There are no quality trials incorporated into this analysis.

TOPICAL NSAIDS FOR ACUTE, SUBACUTE, OR CHRONIC PLANTAR FASCIITIS PAIN

Recommended

Topical NSAIDs are recommended for treatment of acute, subacute, or chronic plantar fascial pain syndromes.

Strength of evidence Recommended, Insufficient Evidence (I)

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Level of confidence Low

Indications

Mild, moderate, or severe plantar fasciitis or in patients with contraindications for oral treatment. There is no evidence of comparative superiority of one topical NSAID versus another.

Frequency/Dose/Duration

Frequency per manufacturer's recommendation. Topical NSAIDs have been used for 1 to 3 weeks (Russell, 1991).

Indications for discontinuation

Resolution, intolerance, adverse effects, or lack of benefits.

Rationale

There are no quality trials of topical NSAIDs for treatment of plantar heel pain. Support is derived from evidence that topical NSAIDs may provide benefit to persons with Achilles tendinopathy, in addition to systematic review of RCTs covering multiple musculoskeletal conditions (see Achilles Tendinopathy). A systematic review of RCTs for multiple conditions has suggested effectiveness of topical NSAIDs for treatment of multiple musculoskeletal disorders (Mason et al., 2004). Topical NSAIDs are not invasive, have low adverse effect rates, but may cumulatively be moderate to high cost. They are recommended for treatment of acute, subacute, and chronic plantar fascial or plantar heel pain, particularly in patients who do not tolerate or are poor candidates for oral treatment. Post-operative patients may be reasonable candidates after the incision is well healed.

Evidence

There are no quality trials incorporated into this analysis.

TOPICAL NSAIDS FOR POSTOPERATIVE PLANTAR FASCIITIS

No Recommendation

There is no recommendation for or against the use of topical NSAIDs for post-operative plantar fasciitis pain.

Strength of evidence No Recommendation, Insufficient Evidence (I)
Level of confidence Low

Rationale

There are no quality trials of topical NSAIDs for treatment of plantar heel pain. Support is derived from evidence that topical NSAIDs may provide benefit to persons with Achilles

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tendinopathy, in addition to systematic review of RCTs covering multiple musculoskeletal conditions (see Achilles Tendinopathy). A systematic review of RCTs for multiple conditions has suggested effectiveness of topical NSAIDs for treatment of multiple musculoskeletal disorders (Mason et al., 2004). Topical NSAIDs are not invasive, have low adverse effect rates, but may cumulatively be moderate to high cost. They are recommended for treatment of acute, subacute, and chronic plantar fascial or plantar heel pain, particularly in patients who do not tolerate or are poor candidates for oral treatment. Post-operative patients may be reasonable candidates after the incision is well healed.

Evidence

There are no quality trials incorporated into this analysis.

WHEAT GRASS CREAM FOR ACUTE, SUBACUTE, OR CHRONIC PLANTAR FASCIITIS

Not Recommended

Wheat grass cream is moderately not recommended for treatment of acute, subacute, or chronic plantar fasciitis.

Strength of evidence Moderately Not Recommended, Evidence (B)
Level of confidence Moderate

Rationale

There is one high-quality RCT comparing topical wheat grass cream with placebo that found no differences in efficacy for pain or function (Young et al., 2006). Wheat grass cream is not invasive, has low adverse effects, and is inexpensive. However, it has a lack of efficacy and is therefore not recommended.

Evidence

There is 1 high-quality RCT incorporated into this analysis.

DEVICES

CASTING

CASTING FOR CHRONIC PLANTAR FASCIITIS

No Recommendation

There is no recommendation for or against the use of casting as a treatment for chronic plantar fasciitis.

Strength of evidence No Recommendation, Insufficient Evidence (I)
Level of confidence Low

Rationale

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There are no quality trials of immobilization with casting for plantar fasciitis. Mixed efficacy of cast immobilization (1 to 12 weeks) for recalcitrant plantar fasciitis as a last resort treatment prior to surgery is described in a case series report with 42% reporting total satisfaction and 46% reporting dissatisfaction (Tisdel et al., 1996). Casting is non-invasive, but is frequently not well tolerated and may have adverse effects including stiffness, recurrence of pain, venous thromboses, and is of unknown efficacy. The intervention could be high cost if it impaired or precluded performing occupational tasks. Therefore, there is no recommendation for or against the use of casting for chronic and subchronic plantar fascial heel pain.

TAPING

HEEL TAPING FOR ACUTE OR SUBACUTE PLANTAR FASCIITIS OR HEEL PAIN

Recommended

The use of heel taping is recommended as a short-term treatment for acute or subacute plantar fasciitis or heel pain.

Strength of evidence Recommended, Evidence (C)
Level of confidence Low

Indications

Patients with acute or subacute plantar fasciitis without adhesive allergies as a short-term intervention for pain relief.

Frequency/Dose/Duration

Daily application of tape for 1 to 4 weeks.

Indications for discontinuation

Resolution, adverse effects, non-compliance, completion of 4-week course of treatment.

Rationale

One high-quality trial of taping using the Low-Dye technique for plantar heel pain demonstrated modest benefit in “first-step” pain relief over a no-taping control at 1 week of follow-up (Radford et al., 2006). Taping failed to show improvement in other outcome measures however, including overall foot-pain, foot function, and general foot health status. Taping was limited by high adverse events (28%) including taping too tight, new pain, and allergic reaction to the tape. Low-Dye taping is described as an adjunct to other treatment arms in one moderate-quality study (Osborne et al., 2006), but no conclusions regarding its efficacy compared to other interventions or to no treatment can be made. There is one moderate-quality trial comparing calcaneal taping to stretching, sham taping, and no treatment for short-term treatment of plantar heel pain (Hyland et al., 2006). Calcaneal taping was demonstrated to be more effective in pain relief after 1 week of treatment than stretching, sham taping, and control. However, results are limited due to small sample size

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and short-term follow-up. Thus, the efficacy of taping is limited to modest short-term pain relief. Taping is non-invasive, is generally limited to short-term use by its potential for skin sensitization and breakdown, and is of moderate cost. Therefore, the use of taping is recommended as a short-term strategy as an adjunct with other non-operative treatments.

HEEL TAPING FOR CHRONIC PLANTAR FASCIITIS OR HEEL PAIN

No Recommendation

There is no recommendation for or against the use of heel taping for the treatment of chronic plantar fasciitis or heel pain.

Strength of evidence No Recommendation, Insufficient Evidence (I)
Level of confidence Low

Rationale

One high-quality trial of taping using the Low-Dye technique for plantar heel pain demonstrated modest benefit in “first-step” pain relief over a no-taping control at 1 week of follow-up (Radford et al., 2006). Taping failed to show improvement in other outcome measures however, including overall foot-pain, foot function, and general foot health status. Taping was limited by high adverse events (28%) including taping too tight, new pain, and allergic reaction to the tape. Low-Dye taping is described as an adjunct to other treatment arms in one moderate-quality study (Osborne et al., 2006), but no conclusions regarding its efficacy compared to other interventions or to no treatment can be made. There is one moderate-quality trial comparing calcaneal taping to stretching, sham taping, and no treatment for short-term treatment of plantar heel pain (Hyland et al., 2006). Calcaneal taping was demonstrated to be more effective in pain relief after 1 week of treatment than stretching, sham taping, and control. However, results are limited due to small sample size and short-term follow-up. Thus, the efficacy of taping is limited to modest short-term pain relief. Taping is non-invasive, is generally limited to short-term use by its potential for skin sensitization and breakdown, and is of moderate cost. Therefore, the use of taping is recommended as a short-term strategy as an adjunct with other non-operative treatments.

SPLINTING

NIGHT SPLINTS FOR PLANTAR HEEL PAIN

Recommended

The use of prefabricated night splints is recommended for subacute or chronic plantar heel pain requiring temporary pain and stiffness improvement.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence Low

Indications

Subacute or chronic plantar fasciitis requiring temporary pain and stiffness improvement.

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Frequency/Dose/Duration

Nightly for duration of effectiveness (as determined by improvement in symptoms and function while under the care of a clinician).

Indications for discontinuation

Resolution, adverse effects, intolerance, non-compliance.

Rationale

There are four moderate-quality trials evaluating efficacy of night splints (Batt et al., 1996, Powell et al., 1998, Probe et al., 1999, Roos et al., 2006). One study demonstrated improvement over no treatment after 1 month of treatment for chronic symptoms (Powell et al., 1998). However, this study had baseline differences between groups in the two arms of the study and the same splinting treatment was provided to both groups, with a crossover 1 month apart, limiting the strength of the conclusions. The other studies compared night splints to other conservative measures. One study demonstrated the combination of visco-elastic heel pad, stretching, and NSAIDs resulted in better "cure" rate than night splints, and those that failed night splints were nearly all cured after crossover (Batt et al., 1996). However, further evaluation after cure, which was generally within 13 weeks of use of splints, was not described. Chronicity of symptoms was not provided and exclusion criteria did not preclude acute plantar fascial pain, thus potential confounders were not controlled. Another study found no increased efficacy with the addition of night splints to NSAIDs, stretching, and shoe modifications after 3 months of treatment (Probe et al., 1999). A third study demonstrated no differences between orthoses, anterior night splints, or both interventions combined after 12 weeks of treatment (Roos et al., 2006). A low-quality trial compared custom made orthoses versus prefabricated orthoses versus night splints for treatment of acute and subacute plantar fascial pain and found no differences between the groups, concluding that all were effective as initial treatments (Martin et al., 2001). Thus, there is insufficient evidence that night splints are beneficial for chronic painful plantar pain. However, night splints are non-invasive, have few adverse effects (if not well tolerated can be discontinued) and are usually low to moderate cost if prefabricated. Thus, night splints are recommended for chronic and subacute plantar fascial heel pain.

ORTHOTICS AND SPECIAL SHOES

ORTHOTIC DEVICES FOR ACUTE, SUBACUTE, OR CHRONIC PLANTAR HEEL PAIN

Recommended

Orthotic devices (i.e., heel lifts, pads, heel cups, heel braces) are recommended for treatment of acute, subacute, or chronic plantar heel pain.

Strength of evidence Recommended, Evidence (C)
Level of confidence Low

Indications

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All patients with plantar fasciitis.

Frequency/Dose/Duration

Daily use for 2 to 3 months.

Indications for discontinuation

Resolution, adverse effects, non-compliance.

Rationale

There is one high-quality trial comparing custom and pre-fabricated orthoses with sham orthoses for treatment efficacy of plantar fasciitis (Landorf et al., 2006). In 136 patients with clinical plantar fasciitis, modest functional improvement at 3 months was demonstrated in both orthoses groups compared to sham, but the comparative improvement at 3 months was within the range of the clinical measuring method (Foot Health Status Questionnaire) ability to detect differences (intraclass correlation coefficients range, 0.74 to 0.92, and Cronbach α, 0.85 to 0.88), and the statistically significant effect disappeared at 12 months. There were no differences in symptom relief at 3 or 12 months. Thus, there is limited evidence for short-term functional benefit from the use of orthoses and no evidence of long-term benefit. (A low-quality crossover trial of orthoses for symptom relief of metatarsalgia related to rheumatoid arthritis demonstrated pain relief but no improvement in function (Mejjad et al., 2004).

There is one high-quality and three moderate-quality studies that compared custom-made orthoses to other prefabricated orthoses (Landorf et al., 2006, Baldassin et al., 2009, Pfeffer et al., 1999, Kelly et al., 1998). Despite advantages in pressure redistribution achieved with custom orthoses (Kelly et al., 1998), there were no advantages demonstrated in clinical outcomes including symptom relief at 8 weeks from the use of custom orthoses over prefabricated orthoses (Baldassin et al., 2009)(Pfeffer et al., 1999), or at 3 and 12 months (Landorf et al., 2006). However, patients with unusual foot anatomy may require custom-made orthoses.

One issue with some of the comparison trials is that custom-made and prefabricated orthoses may use different materials (Landorf et al., 2006, Kelly et al., 1998). Thus, the comparison is made of both production method and material of the orthotic. In one trial, both custom-made and prefabricated orthoses were made of the same material and showed similar effectiveness (Baldassin et al., 2009). Material characteristics such elasticity (ratio of force/unit area to fractional change in height) and thicknesses of the orthotics were usually not specified. In comparison with other treatments, orthoses were demonstrated to be equivalent in efficacy to night splints (Roos et al., 2006), supportive shoes (Chalmers et al., 2000), Achilles and plantar stretching exercises (Pfeffer et al., 1999), electrical stimulation (Stratton et al., 2009) and in a low-quality study, the airheel device (Kavros, 2005).

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There is one moderate-quality trial for orthotics and prevention of lower extremity disorders, which did not demonstrate benefit from using orthotics in a military population (Esterman et al., 2005). However, the study had multiple weaknesses, including low compliance making inference difficult to the general population. A low-quality randomized trial found demonstrated benefit in reducing acute leg and foot pain in referees during a tournament from the use of heel cups (Fauno et al., 1993).

Thus, the use of orthotic devices may provide some short-term benefit, but is not likely to result in dramatic improvements over natural healing. These devices are non-invasive, have few adverse effects, and are generally low cost for devices that are not custom-made; therefore, they are recommended. Custom orthoses also appear to have modest efficacy; however, there is no demonstrable improvement compared to other, commercially available orthoses, yet costs are higher. Thus, there is no recommendation for or against custom orthoses. There is insufficient evidence for orthotics for prevention and therefore, there is no recommendation for or against their use.

CUSTOM ORTHOSES FOR ACUTE, SUBACUTE, OR CHRONIC PLANTAR FASCIITIS

No Recommendation

There is no recommendation for or against the use of custom orthoses for acute, subacute, or chronic plantar fasciitis.

Strength of evidence No Recommendation, Insufficient Evidence (I)
Level of confidence Low

Rationale

There is one high-quality trial comparing custom and pre-fabricated orthoses with sham orthoses for treatment efficacy of plantar fasciitis (Landorf et al., 2006). In 136 patients with clinical plantar fasciitis, modest functional improvement at 3 months was demonstrated in both orthoses groups compared to sham, but the comparative improvement at 3 months was within the range of the clinical measuring method (Foot Health Status Questionnaire) ability to detect differences (intraclass correlation coefficients range, 0.74 to 0.92, and Cronbach α, 0.85 to 0.88), and the statistically significant effect disappeared at 12 months. There were no differences in symptom relief at 3 or 12 months. Thus, there is limited evidence for short-term functional benefit from the use of orthoses and no evidence of long-term benefit. (A low-quality crossover trial of orthoses for symptom relief of metatarsalgia related to rheumatoid arthritis demonstrated pain relief but no improvement in function (Mejjad et al., 2004).

There is one high-quality and three moderate-quality studies that compared custom-made orthoses to other prefabricated orthoses (Landorf et al., 2006, Baldassin et al., 2009, Pfeffer et al., 1999, Kelly et al., 1998). Despite advantages in pressure redistribution achieved with custom orthoses (Kelly et al., 1998), there were no advantages demonstrated in clinical outcomes including symptom relief at 8 weeks from the use of custom orthoses over prefabricated orthoses (Baldassin et al., 2009)(Pfeffer et al., 1999), or at 3 and 12 months

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(Landorf et al., 2006). However, patients with unusual foot anatomy may require custom-made orthoses.

One issue with some of the comparison trials is that custom-made and prefabricated orthoses may use different materials (Landorf et al., 2006, Kelly et al., 1998). Thus, the comparison is made of both production method and material of the orthotic. In one trial, both custom-made and prefabricated orthoses were made of the same material and showed similar effectiveness (Baldassin et al., 2009). Material characteristics such elasticity (ratio of force/unit area to fractional change in height) and thicknesses of the orthotics were usually not specified. In comparison with other treatments, orthoses were demonstrated to be equivalent in efficacy to night splints (Roos et al., 2006), supportive shoes (Chalmers et al., 2000), Achilles and plantar stretching exercises (Pfeffer et al., 1999), electrical stimulation (Stratton et al., 2009) and in a low-quality study, the airheel device (Kavros, 2005).

There is one moderate-quality trial for orthotics and prevention of lower extremity disorders, which did not demonstrate benefit from using orthotics in a military population (Esterman et al., 2005). However, the study had multiple weaknesses, including low compliance making inference difficult to the general population. A low-quality randomized trial found demonstrated benefit in reducing acute leg and foot pain in referees during a tournament from the use of heel cups (Fauno et al., 1993).

Thus, the use of orthotic devices may provide some short-term benefit, but is not likely to result in dramatic improvements over natural healing. These devices are non-invasive, have few adverse effects, and are generally low cost for devices that are not custom-made; therefore, they are recommended. Custom orthoses also appear to have modest efficacy; however, there is no demonstrable improvement compared to other, commercially available orthoses, yet costs are higher. Thus, there is no recommendation for or against custom orthoses. There is insufficient evidence for orthotics for prevention and therefore, there is no recommendation for or against their use.

ORTHOSES FOR PREVENTION OF PLANTAR FASCIITIS OR LOWER EXTREMITY DISORDERS

No Recommendation

There is no recommendation for or against the use of orthotic devices for the prevention of plantar fasciitis or lower extremity disorders.

Strength of evidence No Recommendation, Insufficient Evidence (I)
Level of confidence Low

Rationale

There is one high-quality trial comparing custom and pre-fabricated orthoses with sham orthoses for treatment efficacy of plantar fasciitis (Landorf et al., 2006). In 136 patients with clinical plantar fasciitis, modest functional improvement at 3 months was demonstrated in both orthoses groups compared to sham, but the comparative improvement at 3 months was within the range of the clinical measuring method (Foot Health Status Questionnaire)

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ability to detect differences (intraclass correlation coefficients range, 0.74 to 0.92, and Cronbach α, 0.85 to 0.88), and the statistically significant effect disappeared at 12 months. There were no differences in symptom relief at 3 or 12 months. Thus, there is limited evidence for short-term functional benefit from the use of orthoses and no evidence of long-term benefit. (A low-quality crossover trial of orthoses for symptom relief of metatarsalgia related to rheumatoid arthritis demonstrated pain relief but no improvement in function (Mejjad et al., 2004).

There is one high-quality and three moderate-quality studies that compared custom-made orthoses to other prefabricated orthoses (Landorf et al., 2006, Baldassin et al., 2009, Pfeffer et al., 1999, Kelly et al., 1998). Despite advantages in pressure redistribution achieved with custom orthoses (Kelly et al., 1998), there were no advantages demonstrated in clinical outcomes including symptom relief at 8 weeks from the use of custom orthoses over prefabricated orthoses (Baldassin et al., 2009)(Pfeffer et al., 1999), or at 3 and 12 months (Landorf et al., 2006). However, patients with unusual foot anatomy may require custom-made orthoses.

One issue with some of the comparison trials is that custom-made and prefabricated orthoses may use different materials (Landorf et al., 2006, Kelly et al., 1998). Thus, the comparison is made of both production method and material of the orthotic. In one trial, both custom-made and prefabricated orthoses were made of the same material and showed similar effectiveness (Baldassin et al., 2009). Material characteristics such elasticity (ratio of force/unit area to fractional change in height) and thicknesses of the orthotics were usually not specified. In comparison with other treatments, orthoses were demonstrated to be equivalent in efficacy to night splints (Roos et al., 2006), supportive shoes (Chalmers et al., 2000), Achilles and plantar stretching exercises (Pfeffer et al., 1999), electrical stimulation (Stratton et al., 2009) and in a low-quality study, the airheel device (Kavros, 2005).

There is one moderate-quality trial for orthotics and prevention of lower extremity disorders, which did not demonstrate benefit from using orthotics in a military population (Esterman et al., 2005). However, the study had multiple weaknesses, including low compliance making inference difficult to the general population. A low-quality randomized trial found demonstrated benefit in reducing acute leg and foot pain in referees during a tournament from the use of heel cups (Fauno et al., 1993).

Thus, the use of orthotic devices may provide some short-term benefit, but is not likely to result in dramatic improvements over natural healing. These devices are non-invasive, have few adverse effects, and are generally low cost for devices that are not custom-made; therefore, they are recommended. Custom orthoses also appear to have modest efficacy; however, there is no demonstrable improvement compared to other, commercially available orthoses, yet costs are higher. Thus, there is no recommendation for or against custom orthoses. There is insufficient evidence for orthotics for prevention and therefore, there is no recommendation for or against their use.

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SHOCK-ABSORBING FITTED SHOES FOR PREVENTION OF PLANTAR FASCIITIS

No Recommendation

There is no recommendation for or against the use of special fitted or shock absorbing shoes for prevention of plantar fasciitis or lower extremity disorders.

Strength of evidence No Recommendation, Insufficient Evidence (I)
Level of confidence Low

Rationale

There are two moderate-quality trials for the use of shock absorbing shoes for prevention of plantar heel pain (Torkki et al., 2002, Milgrom et al., 1992). A study of 176 newspaper carriers with lower limb overuse disorders randomized to shock absorbing athletic footwear or to continue their own footwear were followed over a 12-month period (Torkki et al., 2002). There was no control for "own footwear," and there was a large bias favoring the intervention group in which subjects "expected" to improve with the intervention. Regardless, there were no significant differences in outcomes at 3, 6, or 12 months. A study of military recruits randomized to basketball shoes or military boots during basic training demonstrated no benefit in overall incidence of lower extremity disorders, but was effective in reducing arch and plantar pain over a 14-week period (Milgrom et al., 1992). Fitted athletic shoes are non-invasive, have no adverse effects, and are inexpensive considering the duration of use is 6 months to 1 year, although there is no clear benefit to their use. Thus, there is no recommendation for or against the use of fitted shock absorbing shoes. A moderate-quality cross-over study utilized deep soft shoes as an intervention arm for metatarsalgia and demonstrated no improvement within the groups after a 12-week period (Chalmers et al., 2000).

MAGNETS

MAGNETS FOR ACUTE, SUBACUTE OR CHRONIC PLANTAR HEEL PAIN

Not Recommended

Magnets are strongly not recommended for the treatment of acute, subacute, or chronic plantar heel pain.

Strength of evidence Strongly Not Recommended, Evidence (A)
Level of confidence High

Rationale

There are two high-quality placebo controlled trials available for the use of magnets in plantar heel pain disorders (Winemiller et al., 2003, Winemiller et al., 2005). After an 8-week trial, no differences were found in pain scores or in the number reporting improvements (Winemiller et al., 2003). The same researcher also demonstrated in another high-quality trial no effect with magnetic insoles on non-specific foot pain (Winemiller et al., 2005). A low-quality study also found no difference between insoles with and without

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magnetic foil in 40 heels (Caselli et al., 1997). Magnets have been evaluated in quality studies elsewhere involving the spine and hand and have been uniformly found to be ineffective. Magnets are not invasive, have no adverse effects, and are low cost, but are not recommended for treatment of plantar heel pain.

HOT AND COLD THERAPIES

CRYOTHERAPY FOR ACUTE, SUBACUTE, CHRONIC, OR POSTOPERATIVE PLANTAR HEEL PAIN

Recommended

Cryotherapy is recommended for treatment of acute, subacute, chronic, or post-operative plantar heel pain.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence Low

Indications

All patients with plantar heel pain.

Frequency/Dose/Duration

Approximately 3 to 5 self-applications per day as needed.

Indications for discontinuation

Resolution, adverse effects, non-compliance.

Rationale

There are no quality trials for the use of heat or ice therapy. Ice and heat may help particularly with more acute symptoms. These treatments are not invasive, have no or minimal adverse effects, and are not costly; thus they are recommended.

Evidence

There are no quality trials incorporated in this analysis.

HEAT THERAPY FOR ACUTE, SUBACUTE, CHRONIC, OR POSTOPERATIVE PLANTAR HEEL PAIN

Recommended

Heat is recommended for treatment of acute, subacute, chronic, or post-operative plantar heel pain.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence Low

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Indications

All patients with plantar heel pain.

Frequency/Dose/Duration

Approximately 3 to 5 self-applications per day as needed.

Indications for discontinuation

Resolution, adverse effects, non-compliance.

Rationale

There are no quality trials for the use of heat or ice therapy. Ice and heat may help particularly with more acute symptoms. These treatments are not invasive, have no or minimal adverse effects, and are not costly; thus they are recommended.

Evidence

There are no quality trials incorporated in this analysis.

ALLIED HEALTH INTERVENTION

ACUPUNCTURE

ACUPUNCTURE FOR ACUTE, SUBACUTE, OR CHRONIC PLANTAR FASCIITIS

No Recommendation

There is no recommendation for or against the use of acupuncture for treatment of acute, subacute, or chronic plantar fasciitis.

Strength of evidence No Recommendation, Insufficient Evidence (I)
Level of confidence Low

Rationale

There are no quality controlled trials of acupuncture of the lower extremity for the treatment of plantar fasciitis. There is one high-quality study comparing the efficacy of acupuncture applied at one of two traditional acupoint sites in the upper extremity for relief of plantar fasciitis and heel pain of 3 months or greater duration (Zhang et al., 2009). Participants received 10 treatments over a 2-week period. There was greater benefit in pain score improvement at 1 month only in the acupoint Daling (PC7) group versus acupoint Hegu (LI 4) group. As this study had no placebo or “no treatment” comparison group, and with the inclusion criteria allowing subacute cases, the effectiveness of acupuncture at either acupoint is not distinguished from natural history. Acupuncture is minimally invasive, has minimal adverse effects, and, depending on numbers of treatments, is moderately

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costly. There are other interventions with documented efficacy. Therefore, there is no recommendation for or against the use of acupuncture for treatment of plantar fasciitis pending publication of quality trials.

MANIPULATION

MANIPULATION FOR ACUTE, SUBACUTE, CHRONIC, OR POSTOPERATIVE PLANTAR HEEL PAIN

No Recommendation

There is no recommendation for or against the use of manipulation for treatment of acute, subacute, chronic, or post-operative plantar heel pain.

Strength of evidence No Recommendation, Insufficient Evidence (I)
Level of confidence Low

Rationale

There are no quality trials comparing manipulation to natural history. There is one moderate-quality trial for the use of manipulation techniques compared to orthotics in the treatment of plantar heel pain; however, the study has a small sample size and methodological weaknesses, and was inconclusive (Dimou et al., 2004). A moderate-quality trial comparing mobilization and manipulation with electrical therapies demonstrated modest improvement in functional disability questionnaire scores, but the degree to which each person received manipulation is unclear, and the techniques used were not described, thus making conclusions regarding benefit of manipulation impossible (Cleland et al., 2009). Manipulation is not invasive, is moderately costly, but may have adverse effects, including migration of pain (Wyatt, 2006). There is no recommendation for or against manipulation of the ankle and foot joints as there is insufficient quality evidence.

MASSAGE

MASSAGE AND SOFT TISSUE MOBILIZATION FOR ACUTE, SUBACUTE, CHRONIC, OR POSTOPERATIVE PLANTAR FASCIITIS

No Recommendation

There is no recommendation for or against the use of massage or tendon mobilization for the treatment of acute, subacute, chronic, or post-operative plantar fasciitis.

Strength of evidence No Recommendation, Insufficient Evidence (I)
Level of confidence Low

Rationale

There are no quality trials comparing the use of manual therapy with no treatment. A moderate-quality trial comparing soft tissue mobilization, cryotherapy, and gastrocnemius stretching exercises to iontophoresis and ultrasound with exercises demonstrated manual physical therapy to be of greater benefit as measured by functional disability scores than

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electrical physiotherapy technique (Cleland et al., 2009). However, the magnitude of differences demonstrated was small, and are of uncertain clinical significance. It is possible for patients to self-administer these treatments, although there are no quality studies of self-administration. Massage and soft tissue mobilization are not invasive, have minimal adverse effects, and depending on numbers of treatments are low to moderate cost. As there are other interventions with documented efficacy, there is no recommendation for or against use of these treatments for plantar fasciitis.

PHONOPHORESIS

PHONOPHORESIS FOR ACUTE, SUBACUTE, CHRONIC, OR POSTOPERATIVE PLANTAR HEEL PAIN

No Recommendation

There is no recommendation for or against the use of phonophoresis for treatment of acute, subacute, chronic, or post-operative plantar heel pain.

Strength of evidence No Recommendation, Insufficient Evidence (I)
Level of confidence Low

Rationale

There is no quality evidence evaluating phonophoresis for treatment of patients with chronic plantar heel pain. Phonophoresis is non-invasive, has few adverse effects, and is moderately expensive. There is no recommendation for or against it use for plantar hell pain pending publication of quality trials.

Evidence

There are no quality trials incorporated into this analysis.

ULTRASOUND

THERAPEUTIC ULTRASOUND FOR ACUTE, SUBACUTE, CHRONIC, OR POSTOPERATIVE PLANTAR FASCIITIS

Not Recommended

Therapeutic ultrasound is not recommended for treatment of acute, subacute, chronic, or post-operative plantar fasciitis.

Strength of evidence Not Recommended, Evidence (C)
Level of confidence Low

Rationale

There is one moderate-quality trial that suggested no difference between therapeutic ultrasound and sham ultrasound after 8 treatments (Crawford et al., 1996). Ultrasound was also used in a treatment arm with iontophoresis, cryotherapy, and stretching and was found

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to be less beneficial than manual physical therapy (Cleland et al., 2009). Ultrasound is non-invasive, has low adverse effects, is moderate cost depending on numbers of treatments, but has low treatment efficacy and is therefore not recommended.

RADIOTHERAPY

LOW-DOSE RADIATION (RADIOTHERAPY) FOR CHRONIC PLANTAR HEEL PAIN

No Recommendation

There is no recommendation for or against the use of low-dose radiation (radiotherapy) for the treatment of chronic plantar heel pain.

Strength of evidence No Recommendation, Insufficient Evidence (I)
Level of confidence Low

Rationale

There are no quality placebo-controlled trials for radiation therapy. There is one moderate-quality trial comparing total radiation dose of 3.0 Gy vs. 6.0 Gy, which found no difference between the two groups (Heyd et al., 2007). The authors reported 87.7% of patients in both groups with improvement at 6 months, although nearly half had symptoms less than 6 months duration. A placebo-controlled protocol has been published with results pending until 2012 or later (Niewald et al., 2008). A prospective case series reported 77% success rates in 137 feet at 3 weeks and 24 months in patients with chronic plantar heel pain (Cavazos et al., 2009). Radiation therapy is non-invasive, has a potential adverse effect risk profile from radiation, and is moderately costly. Although potentially promising, further studies are needed, thus there is no recommendation for or against its use for treatment of chronic plantar heel pain.

IONTOPHORESIS

IONTOPHORESIS WITH GLUCOCORTICOSTEROID OR ACETIC ACID FOR ACUTE, SUBACUTE, OR CHRONIC PLANTAR FASCIITIS

No Recommendation

There is no recommendation for or against the use of iontophoresis with glucocorticosteroid or acetic acid for treatment of select patients with acute, subacute, or chronic plantar fasciitis.

Strength of evidence No Recommendation, Insufficient Evidence (I)
Level of confidence Low

Rationale

There are two moderate-quality placebo-controlled trials for iontophoresis using dexamethasone that provide conflicting results. A study of 40 heels comparing 0.4% dexamethasone with saline and combined with the co-interventions of stretching, exercises, ice, and orthoses demonstrated subjects that received 6 treatments over a 2-week period

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improved in function and pain scores at treatment end, but differences disappeared at 1-month post-treatment follow-up (Gudeman et al., 1997). Another study comparing dexamethasone to acetic acid and placebo with the co-intervention of Low-Dye taping demonstrated placebo to be more effective than dexamethasone in improving morning pain and worst pain in past 2 days at treatment end, but loss of effect at 4 weeks (Osborne et al., 2006). There was no difference between acetic acid and placebo in pain relief, although the acetic acid group demonstrated improved morning stiffness scores over placebo at 4 weeks. Thus, evidence for efficacy of iontophoresis with glucocorticoid or acetic acid is inconclusive, and at best appears to reflect modest short-term benefit. A treatment series of iontophoresis is non-invasive, has low adverse effect profile, but is of moderate cost. Treatment effects are short-lived after 2-week course. Therefore, no recommendation is made for or against its routine use.

INJECTION THERAPIES

AUTOLOGOUS BLOOD

AUTOLOGOUS BLOOD INJECTION FOR ACUTE, SUBACUTE, OR CHRONIC PLANTAR FASCIITIS

Not Recommended

Autologous blood injection is not recommended for treatment of acute, subacute, or chronic plantar fasciitis.

Strength of evidence Not Recommended, Evidence (C)
Level of confidence Low

Rationale

There are no quality trials comparing autologous blood injection to placebo. Three moderate-quality studies compared autologous blood injection to corticosteroid injection. Two of these studies found autologous blood injection to be less effective than steroid injection (Kalaci et al., 2009, Lee et al., 2007) while one demonstrated equal efficacy (Kiter et al., 2006). Two of these studies also compared the peppering technique with autologous blood and found no differences between the two treatments (Kalaci et al., 2009, Kiter et al., 2006). Adverse effects of autologous blood injection include post-injection pain (53%) lasting up to 10 days and may require analgesia. These injections are moderate cost related to procedure charges of venipuncture and injection. Autologous blood is demonstrated to be less effective than steroid injection, and is of unknown efficacy compared with placebo. Thus, autologous blood injection is not recommended.

BOTULINUM TOXIN A

BOTULINUM TOXIN A INJECTION FOR SELECT CHRONIC PLANTAR FASCIITIS

Sometimes Recommended

Botulinum toxin A injection is recommended as a treatment for select chronic plantar fasciitis. These injections may be useful for patients with chronic plantar pain (>6 months) and failure of multiple courses of NSAIDs, stretching exercises, and at least two steroid injections.

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Strength of evidence Recommended, Evidence (C)
Level of confidence Low

Indications

Chronic plantar pain (>6 months) and failure of multiple courses of NSAIDs, stretching exercises, and at least two steroid injections.

Frequency/Dose/Duration

One injection of 70 units in 2 divided doses; 40 units injected into tender region of heel medial to base of plantar fascia insertion, 30 units in most tender point of arch (Babcock et al., 2005). Alternatively, 1 injection of 50 units into plantar fascia under ultrasound guidance (Huang et al., 2010). The efficacy of repeat injections has not been studied in controlled trials (Babcock et al., 2005).

Rationale

There are two moderate-quality placebo controlled trials evaluating the use of Botulinum A for treatment of plantar fasciitis. A trial conducted in military personnel demonstrated significant pain relief and improved functional scores from a single injection of Botulinum Toxin A (BTX-A) versus saline into the plantar fascia up to 8 weeks post-injection (Babcock et al., 2005). This group was highly mobile (military transfers), and therefore long-term effects were not studied. The study was stopped at the interim analysis due to high therapeutic efficacy found with BTX-A in the short term, which means long-term benefit and harm was not assessed. Another trial demonstrated efficacy over saline after injection of Botulinum Toxin A into the plantar fascia thickening under ultrasound guidance.(299) Fatalities have been reported from the use of Botulinum Toxin A (Li et al., 2005), thus it should only be utilized with extreme caution. The agent induces muscle weakness and there is concern regarding long-term safety, especially with repeated dosing. Injection of BTX-A is high cost, and has not been studied in acute or subacute populations. It is recommended in highly select patients who have chronic plantar fasciitis and have failed multiple other treatments that have lower adverse effect profiles or are lower cost.

BOTULINUM TOXIN A INJECTION FOR ACUTE OR SUBACUTE PLANTAR FASCIITIS

Not Recommended

Botulinum Toxin A injection is not recommended for acute or subacute plantar fasciitis.

Strength of evidence Not Recommended, Insufficient Evidence (I)
Level of confidence Low

Rationale

There are four moderate-quality placebo controlled trials (Babcock et al., 2005). A trial conducted in military personnel demonstrated significant pain relief and improved

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functional scores from a single injection of Botulinum Toxin A (BTX-A) versus saline into the plantar fascia up to 8 weeks post-injection (Babcock et al., 2005). This group was highly mobile (military transfers), and therefore long-term effects were not studied. The study was stopped at the interim analysis due to high therapeutic efficacy found with BTX-A in the short term, which means long-term benefit and harm was not assessed. Another trial demonstrated efficacy over saline after injection of Botulinum Toxin A into the plantar fascia thickening under ultrasound guidance (Huang et al., 2010). Fatalities have been reported from use of Botulinum Toxin A (Li et al., 2005), thus use only with extreme caution. The agent induces muscle weakness and there is concern regarding long-term safety, especially with repeated dosing. Injection of BTX-A is high cost, and has not been studied in acute or subacute populations. It is recommended in highly select patients who have chronic plantar fasciitis and have failed multiple other treatments that have lower adverse effect profiles or are lower cost.

GLUCOCORTICOSTEROIDS

GLUCOCORTICOSTEROID INJECTIONS FOR CHRONIC PLANTAR FASCIITIS

Sometimes Recommended

Glucocorticosteroid injections are recommended for short-term relief of moderate or severe chronic plantar fasciitis for patients who have failed satisfactory management with NSAIDs, stretching, and other exercise. A 2nd injection may be performed if prior results are unsatisfactory, the problem is incapacitating, other options have been exhausted, and the patient understands and accepts that rupture is a possible complication and will likely necessitate surgery.

Strength of evidence Recommended, Evidence (C)
Level of confidence Moderate

Indications

Moderate or severe plantar fasciitis, failed satisfactory management with NSAIDs, stretching, and other exercise.

Frequency/Dose/Duration

Quality trials have utilized hydrocortisone 25mg, triamcinolone 20mg, betamethasone 5.7mg, and prednisolone acetate 25mg (Porter et al., 2005, Kalaci et al., 2009, Blockey, 1956, Crawford et al., 1999, Kriss, 2003). The tenderest point is generally included in the injection. A 2nd injection may be performed if prior results unsatisfactory, the problem is incapacitating, other options have been exhausted, and the patient understands and accepts that rupture is a possible complication and will likely necessitate surgery.

Indications for discontinuation

Resolution, intolerance, adverse effects, or lack of benefits.

Rationale

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There are two moderate-quality placebo-controlled trials of steroid injection for plantar fasciitis (Kalaci et al., 2009, Crawford et al., 1999). Kalaci compared injection with autologous blood, peppering with lidocaine, and injection or peppering with triamcinolone (dose in milligrams not specified) in 100 chronic plantar fasciitis patients (Kalaci et al., 2009). Both triamcinolone arms provided significantly better pain relief than autologous blood and peppering with lidocaine. It is unlikely that the use of peppering resulted in a treatment effect. A study of 106 patients with chronic plantar pain of 6 months median duration (range 1 to 120 months) had serious analysis reporting flaws, with four study arms, two of which received corticosteroids, two of which did not; two of which received tibial nerve blocks, two of which did not (Crawford et al., 1999). The authors claimed their subjects had a modest reduction in pain at 1 month after injection of 25mg prednisolone, but the comparison groups were not clear. At 1 month, the tibial nerve block groups did not do as well as the non-tibial nerve block groups, but the matter was not discussed. There was no difference among the groups at 3 or 6 months, suggesting that benefit of steroid injection or drawback of tibial nerve block may be short term. In contrast, the other study demonstrated no short-term benefit at 3 weeks, but did demonstrate a long-term benefit at 6 months post injection (Kalaci et al., 2009). A comparative trial of 22 heels found no significant differences between placebo and steroid. Heels were divided between placebo and 25mg hydrocortisone injection with no significant differences found at short- and long-term follow-up. This study has potential methodological flaws, including duration of plantar pain at initiation.

Two moderate-quality trials compared steroid injection to other treatments (Porter et al., 2005, Kriss, 2003). Injection of 20mg triamcinolone into the point of maximal tenderness in 76 heels was compared with soft anti-pronatory pad versus both treatments combined (Kriss, 2003). The steroid arms showed significant reduction in pain scores over anti-pronatory pad alone with early onset lasting 4 months. There was no statistical analysis presented between the steroid and steroid-pad groups, but a trend towards better scores in the injection alone group was presented. A trial of betamethasone (5.7mg) injected at the point of maximal tenderness demonstrated improved pain scores and tenderness threshold compared with 3 sessions of low-energy extracorporeal shock wave therapy at 3 months. These differences disappeared at the 12-month follow-up (Porter et al., 2005). One trial compared autologous blood injection with glucocorticosteroid injection and found the steroid injection superior (Lee et al., 2007).

A moderate-quality trial compared the use of ultrasound and scintigraphy guidance injection techniques versus palpation and injection at point of maximal tenderness and found no difference between the groups (Yucel et al., 2009). Thus, there is evidence that steroid injection provides short-term symptom relief lasting 4 to 6 months. Injection should be performed at the point of maximal tenderness by palpation rather than with ultrasound or other guidance techniques. Plantar fascia rupture post injection occurs in up to 10% of patients (Acevedo et al., 1998). However, this is likely high as none of the RCTs cited above reported ruptures among subjects in their corticosteroid arms. Ruptures may have long-term sequelae, including longitudinal arch strain, lateral plantar nerve dysfunction, stress fracture, hammer toe deformity, and antalgia (Acevedo et al., 1998, Sellman, 1994). Physicians and patients should carefully consider the benefits and risks compared to other

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conservative treatments, including temporizing, prior to glucocorticoid injection. Overall, corticosteroid injections are minimally invasive, are of moderate cost, and are recommended after other non-operative options have been tried for patients who have chronic or recalcitrant plantar fasciitis.

GLUCOCORTICOSTEROID INJECTIONS FOR ACUTE OR SUBACUTE PLANTAR FASCIITIS

Not Recommended

Glucocorticosteroid injections are recommended for short-term relief of moderate or severe chronic plantar fasciitis for patients who have failed satisfactory management with NSAIDs, stretching, and other exercise. A 2nd injection may be performed if prior results are unsatisfactory, the problem is incapacitating, other options have been exhausted, and the patient understands and accepts that rupture is a possible complication and will likely necessitate surgery.

Strength of evidence Not Recommended, Insufficient Evidence (I)
Level of confidence Moderate

Rationale

There are two moderate-quality placebo-controlled trials of steroid injection for plantar fasciitis (Kalaci et al., 2009, Crawford et al., 1999). Kalaci compared injection with autologous blood, peppering with lidocaine, and injection or peppering with triamcinolone (dose in milligrams not specified) in 100 chronic plantar fasciitis patients (Kalaci et al., 2009). Both triamcinolone arms provided significantly better pain relief than autologous blood and peppering with lidocaine. It is unlikely that the use of peppering resulted in a treatment effect. A study of 106 patients with chronic plantar pain of 6 months median duration (range 1 to 120 months) had serious analysis reporting flaws, with four study arms, two of which received corticosteroids, two of which did not; two of which received tibial nerve blocks, two of which did not (Crawford et al., 1999). The authors claimed their subjects had a modest reduction in pain at 1 month after injection of 25mg prednisolone, but the comparison groups were not clear. At 1 month, the tibial nerve block groups did not do as well as the non-tibial nerve block groups, but the matter was not discussed. There was no difference among the groups at 3 or 6 months, suggesting that benefit of steroid injection or drawback of tibial nerve block may be short term. In contrast, the other study demonstrated no short-term benefit at 3 weeks, but did demonstrate a long-term benefit at 6 months post injection (Kalaci et al., 2009). A comparative trial of 22 heels found no significant differences between placebo and steroid. Heels were divided between placebo and 25mg hydrocortisone injection with no significant differences found at short- and long-term follow-up. This study has potential methodological flaws, including duration of plantar pain at initiation.

Two moderate-quality trials compared steroid injection to other treatments (Porter et al., 2005, Kriss, 2003). Injection of 20mg triamcinolone into the point of maximal tenderness in 76 heels was compared with soft anti-pronatory pad versus both treatments combined (Kriss, 2003). The steroid arms showed significant reduction in pain scores over anti-pronatory pad alone with early onset lasting 4 months. There was no statistical analysis

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presented between the steroid and steroid-pad groups, but a trend towards better scores in the injection alone group was presented. A trial of betamethasone (5.7mg) injected at the point of maximal tenderness demonstrated improved pain scores and tenderness threshold compared with 3 sessions of low-energy extracorporeal shock wave therapy at 3 months. These differences disappeared at the 12-month follow-up (Porter et al., 2005). One trial compared autologous blood injection with glucocorticosteroid injection and found the steroid injection superior (Lee et al., 2007).

A moderate-quality trial compared the use of ultrasound and scintigraphy guidance injection techniques versus palpation and injection at point of maximal tenderness and found no difference between the groups (Yucel et al., 2009). Thus, there is evidence that steroid injection provides short-term symptom relief lasting 4 to 6 months. Injection should be performed at the point of maximal tenderness by palpation rather than with ultrasound or other guidance techniques. Plantar fascia rupture post injection occurs in up to 10% of patients (Acevedo et al., 1998). However, this is likely high as none of the RCTs cited above reported ruptures among subjects in their corticosteroid arms. Ruptures may have long-term sequelae, including longitudinal arch strain, lateral plantar nerve dysfunction, stress fracture, hammer toe deformity, and antalgia (Acevedo et al., 1998, Sellman, 1994). Physicians and patients should carefully consider the benefits and risks compared to other conservative treatments, including temporizing, prior to glucocorticoid injection. Overall, corticosteroid injections are minimally invasive, are of moderate cost, and are recommended after other non-operative options have been tried for patients who have chronic or recalcitrant plantar fasciitis.

GUIDANCE OF STEROID INJECTION WITH ULTRASOUND OR SCINTIGRAPHY

Sometimes Recommended

Ultrasound or scintigraphy imaging techniques to guide injection are not recommended as there is no added benefit compared with palpation (Yucel et al., 2009)**.**

Strength of evidence Not Recommended, Evidence (C)
Level of confidence Moderate

Rationale

There are two moderate-quality placebo-controlled trials of steroid injection for plantar fasciitis (Kalaci et al., 2009, Crawford et al., 1999). Kalaci compared injection with autologous blood, peppering with lidocaine, and injection or peppering with triamcinolone (dose in milligrams not specified) in 100 chronic plantar fasciitis patients (Kalaci et al., 2009). Both triamcinolone arms provided significantly better pain relief than autologous blood and peppering with lidocaine. It is unlikely that the use of peppering resulted in a treatment effect. A study of 106 patients with chronic plantar pain of 6 months median duration (range 1 to 120 months) had serious analysis reporting flaws, with four study arms, two of which received corticosteroids, two of which did not; two of which received tibial nerve blocks, two of which did not (Crawford et al., 1999). The authors claimed their subjects had a modest reduction in pain at 1 month after injection of 25mg prednisolone, but the comparison groups were not clear. At 1 month, the tibial nerve block groups did not do as

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well as the non-tibial nerve block groups, but the matter was not discussed. There was no difference among the groups at 3 or 6 months, suggesting that benefit of steroid injection or drawback of tibial nerve block may be short term. In contrast, the other study demonstrated no short-term benefit at 3 weeks, but did demonstrate a long-term benefit at 6 months post injection (Kalaci et al., 2009). A comparative trial of 22 heels found no significant differences between placebo and steroid. Heels were divided between placebo and 25mg hydrocortisone injection with no significant differences found at short- and long-term follow-up. This study has potential methodological flaws, including duration of plantar pain at initiation.

Two moderate-quality trials compared steroid injection to other treatments (Porter et al., 2005, Kriss, 2003). Injection of 20mg triamcinolone into the point of maximal tenderness in 76 heels was compared with soft anti-pronatory pad versus both treatments combined (Kriss, 2003). The steroid arms showed significant reduction in pain scores over anti-pronatory pad alone with early onset lasting 4 months. There was no statistical analysis presented between the steroid and steroid-pad groups, but a trend towards better scores in the injection alone group was presented. A trial of betamethasone (5.7mg) injected at the point of maximal tenderness demonstrated improved pain scores and tenderness threshold compared with 3 sessions of low-energy extracorporeal shock wave therapy at 3 months. These differences disappeared at the 12-month follow-up (Porter et al., 2005). One trial compared autologous blood injection with glucocorticosteroid injection and found the steroid injection superior (Lee et al., 2007).

A moderate-quality trial compared the use of ultrasound and scintigraphy guidance injection techniques versus palpation and injection at point of maximal tenderness and found no difference between the groups (Yucel et al., 2009). Thus, there is evidence that steroid injection provides short-term symptom relief lasting 4 to 6 months. Injection should be performed at the point of maximal tenderness by palpation rather than with ultrasound or other guidance techniques. Plantar fascia rupture post injection occurs in up to 10% of patients (Acevedo et al., 1998). However, this is likely high as none of the RCTs cited above reported ruptures among subjects in their corticosteroid arms. Ruptures may have long-term sequelae, including longitudinal arch strain, lateral plantar nerve dysfunction, stress fracture, hammer toe deformity, and antalgia (Acevedo et al., 1998, Sellman, 1994). Physicians and patients should carefully consider the benefits and risks compared to other conservative treatments, including temporizing, prior to glucocorticoid injection. Overall, corticosteroid injections are minimally invasive, are of moderate cost, and are recommended after other non-operative options have been tried for patients who have chronic or recalcitrant plantar fasciitis.

HYPEROSMOLAR DEXTROSE

HYPEROSMOLAR DEXTROSE INJECTIONS FOR PLANTAR FASCIITIS

No Recommendation

There is no recommendation for or against the use of hyperosmolar dextrose injections for treatment of plantar fasciitis.

Strength of evidence No Recommendation, Insufficient Evidence (I)

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Level of confidence Low

Rationale

There are no quality trials for plantar fascia hyperosmolar dextrose injection. In a case series of 20 consecutive patients treated with sonographically guided injections of hyperosmolar dextrose and lidocaine in patients with plantar fasciitis of 6 months duration, 16 reported good or excellent results with 4 unchanged (Ryan et al., 2009). This intervention has a low risk of adverse effects, is moderately costly as it may require a series of up to 3 injections. However, the clinical efficacy is currently undefined. Ultrasound guidance of injection was also described, although the necessity of this technique is also undefined. Therefore, there is no recommendation for or against the use of hyperosmolar dextrose injection into the plantar fascia.

Evidence

There are no quality trials evaluating the use of hyperosmolar dextrose injections for plantar fasciitis.

PLATELET-RICH PLASMA

PLATELET-RICH PLASMA (PRP) INJECTIONS FOR PLANTAR FASCIITIS

No Recommendation

There is no recommendation for or against the use of platelet-rich plasma injections for treatment of plantar fasciitis.

Strength of evidence No Recommendation, Insufficient Evidence (I)
Level of confidence Low

Rationale

There are no quality trials for plantar fascia platelet rich plasma (PRP) injection. This intervention consists of obtaining 30 to 60mL of autologous blood, centrifuging, and injecting 3 to 6mL of PRP under ultrasound guidance (Sampson et al., 2008). This procedure reportedly is low risk of adverse effects, is moderately costly, and may require repeat injection. There is a case series report suggesting therapeutic efficacy, which suggests future trials of this intervention are indicated. (A case series report of 9 patients with chronic plantar fasciitis treated with sonographically guided injections of platelet rich plasma demonstrated good or excellent relief at 2 months with continued relief at 12 months (Barrett et al., 2004). However, the clinical efficacy is currently undefined. Therefore, there is no recommendation for or against the use of platelet rich plasma injection into the plantar fascia.

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ELECTRICAL THERAPIES

ELECTRICAL STIMULATION

LOW-FREQUENCY ELECTRICAL STIMULATION FOR ACUTE, SUBACUTE, OR CHRONIC PLANTAR FASCIITIS

No Recommendation

There is no recommendation for or against the use of low frequency electrical stimulation for acute, subacute, or chronic plantar fasciitis.

Strength of evidence No Recommendation, Insufficient Evidence (I)
Level of confidence Low

Rationale

There is one moderate-quality trial that compared the addition of low-frequency electrical stimulation applied once a day for 4 weeks to a protocol that included plantar fascia stretching and prefabricated orthoses (Stratton et al., 2009). There were no differences between the groups, although the sample size was small and included acute, subacute, and chronic subjects. Low-frequency electrical stimulation is not invasive, is moderately costly with the purchase or rental of machine and supplies, and has low adverse effect profile, but appears to provide no benefit compared with orthosis and stretching. Thus, efficacy is unclear and no recommendation for or against its use is made.

SHOCKWAVE THERAPY

Shockwave therapy has been utilized for treatment of multiple chronic soft tissue disorders including Achilles tendinopathy, plantar fasciitis, epicondylitis, and calcific rotator cuff tendonitis. The mechanism of action is unknown, but shockwaves are purported to reduce pain and enhance healing [(126)]. Application and delivery of shockwave energy differs among studies. Focused shockwave therapy (fESWT) is the application of energy, whereas radial ESWT (rESWT) applies energy in a much broader tissue field. There have been challenges interpreting studies as the amount of energy delivered, method of focusing shockwaves, treatment frequency, timing, use of anesthetics, and outcomes vary among studies.

In ESWT, energy is imparted to tissue is a succession of usually 1,000 to 4,000 rapidly generated waves. Classification schemes for energy levels of shockwave therapy have been proposed by Mainz and Kassel [(352)], which are summarized in Table 6. Energy is expressed as energy flux density (EFD), or milliJoules passing through an area specified in square millimeters (mJ/mm^2), and measured in an area close to the center of the wave rather than at its lower-energy periphery.

The total energy delivered during an application of ESWT is a product EFD of each shock, the number of shocks, the area of the energy delivery for each shock (usually on the order of $20mm^2$), and the amount of energy absorbed by the tissue. Thus, a “low energy” application with a high number of shocks may impart more energy than a “high energy” application with a low number of shocks. No classification scheme to address this aspect of ESWT could be found. In lithotripsy, highly-focused shock waves are more effective. What if any bearing the transmission area has on treatment in musculoskeletal disorders is not addressed in the

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medical literature. Other areas of confusion when seeking an understanding of ESWT are that energy flux density may be reported in different ways and energy is distributed in the shock waves differently at different energy levels. EFD is reported as “total energy flux density (EFD)” or “positive energy flux density (EFD_+),” the latter being the amount of energy contained in only in the initial, rapid, positive-pressure compression wave (and does not include the longer negative-pressure wave that follows). EFD_+ is always smaller than EFD, and its comparative size may be dependent on EFD and the ESWT device [353,354,355,356]. Lower-energy EFDs have comparatively small proportions of their total energy in EFD_+ than do higher-energy EFDs [357]. EFD and EFD_+ may be recorded as the energy in the portion of the wave with sonic energy twice that of baseline, with pressure over 5 MPa (50 atmospheres), or in a “focal area” of the highest energy of 5mm diameter [354,355,356]. The different ways of measuring EFD may result in reporting differences of several-fold [353,358]. Lastly, the frequency of delivery of shock waves may affect secondary phenomena, such as formation of air bubble in tissue with the low-pressure portion of the energy wave that follows the high-pressure pulse, a phenomenon known as cavitation.

ESWT may induce frank tissue damage and pain at higher energy. One set of authors assert that energy flux levels of more than 0.34mJ/mm^2 require “regional nerve blocks combined with either intravenous sedation or general anesthesia [359].” However, in most studies, the authors do not indicate anesthesia was administered. Other than the assertion by Malay [359], a threshold for anticipating pain or administering anesthesia is not clear.

EXTRACORPOREAL SHOCKWAVE THERAPY FOR CHRONIC PLANTAR FASCIITIS

Recommended

Extracorporeal shockwave therapy (ESWT) is recommended as a treatment for chronic plantar fasciitis in select patients with chronic recalcitrant conditions.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence Low

Indications

Chronic plantar heel pain consistent with plantar fasciitis. In most studies of ESWT used for treatment of plantar fasciitis, patients often have at least 6 months of symptoms and fail therapy with active and passive exercises, NSAIDs, and glucocorticosteroid injection(s) (Ogden et al., 2001, Kudo et al., 2006, Rompe et al., 2003, Malay et al., 2006, Rompe et al., 1996, Theodore et al., 2004, Cosentino et al., 2001, Mehra et al., 2003)(Rompe JD, 2002, Ogden, 2004). The presence or absence of heel spur does not impact decision for use of ESWT (Cosentino et al., 2001).

Frequency/Dose/Duration

Treatment protocols vary; 1 to 3 treatment sessions with reported efficacy are 1,500 impulses at 0.22 mJ/mm2 to 3,800 impulses at 0.36 to 0.64mJ/mm2 (Ogden et al., 2001, Kudo et al., 2006, Malay et al., 2006, Theodore et al., 2004, Ogden, 2004). Serial sessions of 1,000 to 2,100 impulses at 0.16 mJ/mm2 or lower repeated over 3 sessions spaced in

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weekly or biweekly intervals is also reported (Rompe et al., 2007, Cosentino et al., 2001, Mehra et al., 2003).

Indications for discontinuation

Resolution, intolerance, non-compliance.

Rationale

There are multiple quality placebo-controlled trials providing conflicting outcomes for the efficacy of ESWT for the treatment of chronic plantar heel pain. Most of the high-quality studies failed to show superiority of ESWT to placebo (Haake et al., 2003, Buchbinder et al., 2002, Speed et al., 2003, Marks et al., 2008, Gollwitzer et al., 2007) however, there are two high-quality trials (Kudo et al., 2006, Malay et al., 2006) and seven moderate-quality trials (Ogden et al., 2001, Rompe et al., 2003, Rompe et al., 1996, Theodore et al., 2004, Cosentino et al., 2001, Mehra et al., 2003, Ogden, 2004) that suggested efficacy. Additionally, evidence for intermediate- and long-term harm was lacking.

Interpretation of these results is complicated by the wide variations in amount of energy delivered, treatment frequency, and use of local anesthetics. The optimal EFD for ESWT is unclear, as are the strata for energy flux delivery. Rompe used low energy (~0.08mJ/mm2), medium energy (~0.28mJ/mm2), and high energy (~0.60mH/mm2), in agreement with the Mainz classification (Gollwitzer et al., 2007). Quality trials have demonstrated low- and high-energy density delivery treatment regimens to be both effective and non-effective. Comparison of outcomes with total energy delivered is also inconsistent, as quality trials demonstrated total energy (EFD multiplied by the number of pulses at that EFD) between 60 mJ/mm2 (Rompe et al., 1996) and 2330mJ/mm2 (Kudo et al., 2006) to be both effective and ineffective. This energy range presumes EFD, not EFD+, reported by the study authors. Described protocols consisted of 3 treatment sessions, with varied impulse energy density (0.02 to 0.33mJ/mm2), number of impulses applied (1,500 to 4,000 per session), and spacing of treatment sessions (every third day to every other week). Thus, the optimal energy level of treatment is not well defined. There are three quality studies that demonstrated benefit from a single high-energy treatment session (Ogden et al., 2001, Malay et al., 2006, Theodore et al., 2004). One trial suggested a dose effect with increased impulses (Rompe et al., 2002).

Benefit of ESWT compared to corticosteroid injection in acute patients was compared (Porter et al., 2005). Both groups improved and no recommendation is made for either as an acute treatment. In comparison to mixed conservative therapies (Greve et al., 2009) one moderate-quality trial found no differences in outcomes measures, whereas two moderate-quality trials demonstrated ESWT more effective than serial conservative treatments of NSAIDs, orthotics, physiotherapy, stretching, and cortisone injections (Hammer et al., 2002, Hammer et al., 2003, Wang et al., 2006). These studies had multiple weaknesses limiting interpretation of results, but suggest for chronic conditions, ESWT may provide greater benefit than continuing with other non-operative treatments. ESWT may be invasive, particularly at high energy, when it may be performed with an injected anesthetic. Adverse effects from ESWT, particularly high-energy ESWT, may include erythema, pain, numbness,

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and tingling which are generally transient (Ogden et al., 2001, Kudo et al., 2006, Cosentino et al., 2001, Ogden, 2004, Haake et al., 2003). ESWT is moderate to high cost depending on numbers of treatments. However, the results of the studies are heterogenous, with more than a quarter of the high-quality studies and all seven moderate-quality studies showing efficacy. Thus, ESWT is recommended for treatment of chronic plantar fasciitis if more conservative measures have failed, particularly as if surgery is being considered.

A high-quality trial comparing radial ESWT (rESWT) with sham demonstrated efficacy in reduction of pain and improved function at 3 months and 1 year (Gerdesmeyer et al., 2008). There are no studies comparing rESWT versus ESWT. Another moderate-quality trial compared perpendicular to tangential application of energy, which demonstrated no difference in outcomes as both groups improved the same (Tornese et al., 2008). The study was missing a control group and therefore no recommendation is made for one technique over the other. Radial ESWT is similar to ESWT in other aspects, adverse effects, and cost. Based on the insufficient evidence of efficacy for ESWT, there is insufficient evidence for recommendation.

The use of ultrasound and fluoroscopy has been described to guide the location for ESWT application. The quality comparison trial found no difference in outcomes using fluoroscopy compared to palpation (Dorotka et al., 2006). Ultrasound was used in three high-quality studies that showed no benefit over sham treatment (Haake et al., 2003, Buchbinder et al., 2002, Speed et al., 2003), but has not been compared without ultrasound in the same study. Therefore, there is insufficient evidence that the use of ultrasound or fluoroscopy guidance provides additional benefit over application of energy at point of maximal tenderness, and is therefore not recommended.

Regarding the use of local anesthesia, a high-quality study compared the effect of local anesthesia block to no block in subjects receiving low-energy ESWT and found local block reduces the positive treatment effect of ESWT, with prolonged benefit at 3 months, suggesting pain associated with ESWT has a treatment effect (Rompe, 2005). However, two high-quality studies finding no effect of ESWT did not utilize a local block and still found no effect over placebo (Haake et al., 2003, Buchbinder et al., 2002). Thus, there is insufficient evidence for a recommendation for or against the use of local block with low- or medium-energy ESWT. Local anesthesia is typically used in high-energy ESWT, using the Mainz categorization, to over 0.60mJ/mm2, and is recommended for use with high-energy ESWT.

EXTRACORPOREAL SHOCKWAVE THERAPY FOR ACUTE OR SUBACUTE PLANTAR FASCIITIS

Not Recommended

Extracorporeal shockwave therapy (ESWT) is not recommended for treatment of acute or subacute plantar fasciitis.

Strength of evidence Not Recommended, Insufficient Evidence (I)
Level of confidence Moderate

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Rationale

There are multiple quality placebo-controlled trials providing conflicting outcomes for the efficacy of ESWT for the treatment of chronic plantar heel pain. Most of the high-quality studies failed to show superiority of ESWT to placebo (Haake et al., 2003, Buchbinder et al., 2002, Speed et al., 2003, Marks et al., 2008, Gollwitzer et al., 2007) however, there are two high-quality trials (Kudo et al., 2006, Malay et al., 2006) and seven moderate-quality trials (Ogden et al., 2001, Rompe et al., 2003, Rompe et al., 1996, Theodore et al., 2004, Cosentino et al., 2001, Mehra et al., 2003, Ogden, 2004) that suggested efficacy. Additionally, evidence for intermediate- and long-term harm was lacking.

Interpretation of these results is complicated by the wide variations in amount of energy delivered, treatment frequency, and use of local anesthetics. The optimal EFD for ESWT is unclear, as are the strata for energy flux delivery. Rompe used low energy (~0.08mJ/mm2), medium energy (~0.28mJ/mm2), and high energy (~0.60mH/mm2), in agreement with the Mainz classification (Gollwitzer et al., 2007). Quality trials have demonstrated low- and high-energy density delivery treatment regimens to be both effective and non-effective. Comparison of outcomes with total energy delivered is also inconsistent, as quality trials demonstrated total energy (EFD multiplied by the number of pulses at that EFD) between 60 mJ/mm2 (Rompe et al., 1996) and 2330mJ/mm2 (Kudo et al., 2006) to be both effective and ineffective. This energy range presumes EFD, not EFD+, reported by the study authors. Described protocols consisted of 3 treatment sessions, with varied impulse energy density (0.02 to 0.33mJ/mm2), number of impulses applied (1,500 to 4,000 per session), and spacing of treatment sessions (every third day to every other week). Thus, the optimal energy level of treatment is not well defined. There are three quality studies that demonstrated benefit from a single high-energy treatment session (Ogden et al., 2001, Malay et al., 2006, Theodore et al., 2004). One trial suggested a dose effect with increased impulses (Rompe et al., 2002).

Benefit of ESWT compared to corticosteroid injection in acute patients was compared (Porter et al., 2005). Both groups improved and no recommendation is made for either as an acute treatment. In comparison to mixed conservative therapies (Greve et al., 2009) one moderate-quality trial found no differences in outcomes measures, whereas two moderate-quality trials demonstrated ESWT more effective than serial conservative treatments of NSAIDs, orthotics, physiotherapy, stretching, and cortisone injections (Hammer et al., 2002, Hammer et al., 2003, Wang et al., 2006). These studies had multiple weaknesses limiting interpretation of results, but suggest for chronic conditions, ESWT may provide greater benefit than continuing with other non-operative treatments. ESWT may be invasive, particularly at high energy, when it may be performed with an injected anesthetic. Adverse effects from ESWT, particularly high-energy ESWT, may include erythema, pain, numbness, and tingling which are generally transient (Ogden et al., 2001, Kudo et al., 2006, Cosentino et al., 2001, Ogden, 2004, Haake et al., 2003). ESWT is moderate to high cost depending on numbers of treatments. However, the results of the studies are heterogenous, with more than a quarter of the high-quality studies and all seven moderate-quality studies showing efficacy. Thus, ESWT is recommended for treatment of chronic plantar fasciitis if more conservative measures have failed, particularly as if surgery is being considered.

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A high-quality trial comparing radial ESWT (rESWT) with sham demonstrated efficacy in reduction of pain and improved function at 3 months and 1 year (Gerdesmeyer et al., 2008). There are no studies comparing rESWT versus ESWT. Another moderate-quality trial compared perpendicular to tangential application of energy, which demonstrated no difference in outcomes as both groups improved the same (Tornese et al., 2008). The study was missing a control group and therefore no recommendation is made for one technique over the other. Radial ESWT is similar to ESWT in other aspects, adverse effects, and cost. Based on the insufficient evidence of efficacy for ESWT, there is insufficient evidence for recommendation.

The use of ultrasound and fluoroscopy has been described to guide the location for ESWT application. The quality comparison trial found no difference in outcomes using fluoroscopy compared to palpation (Dorotka et al., 2006). Ultrasound was used in three high-quality studies that showed no benefit over sham treatment (Haake et al., 2003, Buchbinder et al., 2002, Speed et al., 2003), but has not been compared without ultrasound in the same study. Therefore, there is insufficient evidence that the use of ultrasound or fluoroscopy guidance provides additional benefit over application of energy at point of maximal tenderness, and is therefore not recommended.

Regarding the use of local anesthesia, a high-quality study compared the effect of local anesthesia block to no block in subjects receiving low-energy ESWT and found local block reduces the positive treatment effect of ESWT, with prolonged benefit at 3 months, suggesting pain associated with ESWT has a treatment effect (Rompe, 2005). However, two high-quality studies finding no effect of ESWT did not utilize a local block and still found no effect over placebo (Haake et al., 2003, Buchbinder et al., 2002). Thus, there is insufficient evidence for a recommendation for or against the use of local block with low- or medium-energy ESWT. Local anesthesia is typically used in high-energy ESWT, using the Mainz categorization, to over 0.60mJ/mm2, and is recommended for use with high-energy ESWT.

INTRACORPOREAL PNEUMATIC SHOCKWAVE THERAPY (IPST) FOR SELECT CHRONIC PLANTAR FASCIITIS

Recommended

Intracorporeal pneumatic shock therapy is moderately recommended for the treatment of select chronic plantar fasciitis (after failure of NSAIDs, injections, stretching, other exercises and night splinting; demonstrable heel spur).

Strength of evidence Moderately Recommended, Evidence (B)
Level of confidence Moderate

Indications

Failure of NSAIDs, injection(s), stretching, other exercises and night splinting; demonstrable heel spur.

Rationale

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There is one high-quality placebo-controlled trial performed as a pilot study that suggested pain relief and satisfaction compared with sham treatment in a small population of chronic plantar heel pain and radiographic spur (Dogramaci et al., 2010). Intracorporeal pneumatic shock therapy is invasive, requiring a rigid probe to be directly introduced into the calcaneal spur under fluoroscopic guidance, and is thus costly. This treatment has risk for hematoma, infection, or rupture. Thus, the use of IPST is recommended as an alternative to surgical intervention for recalcitrant plantar fasciitis among those patients who fail other non-operative treatments and have a heel spur.

ULTRASOUND OR FLUOROSCOPY GUIDANCE FOR SHOCKWAVE THERAPY FOR PLANTAR FASCIITIS

Not Recommended

Ultrasound or fluoroscopic guidance is not recommended over application of energy at the point of maximal tenderness for treatment of plantar fasciitis.

Strength of evidence Not Recommended, Insufficient Evidence (I)
Level of confidence Low

Rationale

There are multiple quality placebo-controlled trials providing conflicting outcomes for the efficacy of ESWT for the treatment of chronic plantar heel pain. Most of the high-quality studies failed to show superiority of ESWT to placebo (Haake et al., 2003, Buchbinder et al., 2002, Speed et al., 2003, Marks et al., 2008, Gollwitzer et al., 2007) however, there are two high-quality trials (Kudo et al., 2006, Malay et al., 2006) and seven moderate-quality trials (Ogden et al., 2001, Rompe et al., 2003, Rompe et al., 1996, Theodore et al., 2004, Cosentino et al., 2001, Mehra et al., 2003, Ogden, 2004) that suggested efficacy. Additionally, evidence for intermediate- and long-term harm was lacking.

Interpretation of these results is complicated by the wide variations in amount of energy delivered, treatment frequency, and use of local anesthetics. The optimal EFD for ESWT is unclear, as are the strata for energy flux delivery. Rompe used low energy (~0.08mJ/mm2), medium energy (~0.28mJ/mm2), and high energy (~0.60mH/mm2), in agreement with the Mainz classification (Gollwitzer et al., 2007). Quality trials have demonstrated low- and high-energy density delivery treatment regimens to be both effective and non-effective. Comparison of outcomes with total energy delivered is also inconsistent, as quality trials demonstrated total energy (EFD multiplied by the number of pulses at that EFD) between 60 mJ/mm2 (Rompe et al., 1996) and 2330mJ/mm2 (Kudo et al., 2006) to be both effective and ineffective. This energy range presumes EFD, not EFD+, reported by the study authors. Described protocols consisted of 3 treatment sessions, with varied impulse energy density (0.02 to 0.33mJ/mm2), number of impulses applied (1,500 to 4,000 per session), and spacing of treatment sessions (every third day to every other week). Thus, the optimal energy level of treatment is not well defined. There are three quality studies that demonstrated benefit from a single high-energy treatment session (Ogden et al., 2001, Malay et al., 2006, Theodore et al., 2004). One trial suggested a dose effect with increased impulses (Rompe et al., 2002).

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Benefit of ESWT compared to corticosteroid injection in acute patients was compared (Porter et al., 2005). Both groups improved and no recommendation is made for either as an acute treatment. In comparison to mixed conservative therapies (Greve et al., 2009) one moderate-quality trial found no differences in outcomes measures, whereas two moderate-quality trials demonstrated ESWT more effective than serial conservative treatments of NSAIDs, orthotics, physiotherapy, stretching, and cortisone injections (Hammer et al., 2002, Hammer et al., 2003, Wang et al., 2006). These studies had multiple weaknesses limiting interpretation of results, but suggest for chronic conditions, ESWT may provide greater benefit than continuing with other non-operative treatments. ESWT may be invasive, particularly at high energy, when it may be performed with an injected anesthetic. Adverse effects from ESWT, particularly high-energy ESWT, may include erythema, pain, numbness, and tingling which are generally transient (Ogden et al., 2001, Kudo et al., 2006, Cosentino et al., 2001, Ogden, 2004, Haake et al., 2003). ESWT is moderate to high cost depending on numbers of treatments. However, the results of the studies are heterogenous, with more than a quarter of the high-quality studies and all seven moderate-quality studies showing efficacy. Thus, ESWT is recommended for treatment of chronic plantar fasciitis if more conservative measures have failed, particularly as if surgery is being considered.

A high-quality trial comparing radial ESWT (rESWT) with sham demonstrated efficacy in reduction of pain and improved function at 3 months and 1 year (Gerdesmeyer et al., 2008). There are no studies comparing rESWT versus ESWT. Another moderate-quality trial compared perpendicular to tangential application of energy, which demonstrated no difference in outcomes as both groups improved the same (Tornese et al., 2008). The study was missing a control group and therefore no recommendation is made for one technique over the other. Radial ESWT is similar to ESWT in other aspects, adverse effects, and cost. Based on the insufficient evidence of efficacy for ESWT, there is insufficient evidence for recommendation.

The use of ultrasound and fluoroscopy has been described to guide the location for ESWT application. The quality comparison trial found no difference in outcomes using fluoroscopy compared to palpation (Dorotka et al., 2006). Ultrasound was used in three high-quality studies that showed no benefit over sham treatment (Haake et al., 2003, Buchbinder et al., 2002, Speed et al., 2003), but has not been compared without ultrasound in the same study. Therefore, there is insufficient evidence that the use of ultrasound or fluoroscopy guidance provides additional benefit over application of energy at point of maximal tenderness, and is therefore not recommended.

Regarding the use of local anesthesia, a high-quality study compared the effect of local anesthesia block to no block in subjects receiving low-energy ESWT and found local block reduces the positive treatment effect of ESWT, with prolonged benefit at 3 months, suggesting pain associated with ESWT has a treatment effect (Rompe, 2005). However, two high-quality studies finding no effect of ESWT did not utilize a local block and still found no effect over placebo (Haake et al., 2003, Buchbinder et al., 2002). Thus, there is insufficient evidence for a recommendation for or against the use of local block with low- or medium-energy ESWT. Local anesthesia is typically used in high-energy ESWT, using the Mainz categorization, to over 0.60mJ/mm2, and is recommended for use with high-energy ESWT.

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LOCAL ANESTHESIA WITH HIGH SHOCKWAVE THERAPY FOR PLANTAR FASCIITIS

Recommended

Local anesthesia is recommended when used in conjunction with high-energy ESWT for the treatment of plantar fasciitis.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence Low

Rationale

There are multiple quality placebo-controlled trials providing conflicting outcomes for the efficacy of ESWT for the treatment of chronic plantar heel pain. Most of the high-quality studies failed to show superiority of ESWT to placebo (Haake et al., 2003, Buchbinder et al., 2002, Speed et al., 2003, Marks et al., 2008, Gollwitzer et al., 2007) however, there are two high-quality trials (Kudo et al., 2006, Malay et al., 2006) and seven moderate-quality trials (Ogden et al., 2001, Rompe et al., 2003, Rompe et al., 1996, Theodore et al., 2004, Cosentino et al., 2001, Mehra et al., 2003, Ogden, 2004) that suggested efficacy. Additionally, evidence for intermediate- and long-term harm was lacking.

Interpretation of these results is complicated by the wide variations in amount of energy delivered, treatment frequency, and use of local anesthetics. The optimal EFD for ESWT is unclear, as are the strata for energy flux delivery. Rompe used low energy (~0.08mJ/mm2), medium energy (~0.28mJ/mm2), and high energy (~0.60mH/mm2), in agreement with the Mainz classification (Gollwitzer et al., 2007). Quality trials have demonstrated low- and high-energy density delivery treatment regimens to be both effective and non-effective. Comparison of outcomes with total energy delivered is also inconsistent, as quality trials demonstrated total energy (EFD multiplied by the number of pulses at that EFD) between 60 mJ/mm2 (Rompe et al., 1996) and 2330mJ/mm2 (Kudo et al., 2006) to be both effective and ineffective. This energy range presumes EFD, not EFD+, reported by the study authors. Described protocols consisted of 3 treatment sessions, with varied impulse energy density (0.02 to 0.33mJ/mm2), number of impulses applied (1,500 to 4,000 per session), and spacing of treatment sessions (every third day to every other week). Thus, the optimal energy level of treatment is not well defined. There are three quality studies that demonstrated benefit from a single high-energy treatment session (Ogden et al., 2001, Malay et al., 2006, Theodore et al., 2004). One trial suggested a dose effect with increased impulses (Rompe et al., 2002).

Benefit of ESWT compared to corticosteroid injection in acute patients was compared (Porter et al., 2005). Both groups improved and no recommendation is made for either as an acute treatment. In comparison to mixed conservative therapies (Greve et al., 2009) one moderate-quality trial found no differences in outcomes measures, whereas two moderate-quality trials demonstrated ESWT more effective than serial conservative treatments of NSAIDs, orthotics, physiotherapy, stretching, and cortisone injections (Hammer et al., 2002, Hammer et al., 2003, Wang et al., 2006). These studies had multiple weaknesses limiting interpretation of results, but suggest for chronic conditions, ESWT may provide greater benefit than continuing with other non-operative treatments. ESWT may be invasive,

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particularly at high energy, when it may be performed with an injected anesthetic. Adverse effects from ESWT, particularly high-energy ESWT, may include erythema, pain, numbness, and tingling which are generally transient (Ogden et al., 2001, Kudo et al., 2006, Cosentino et al., 2001, Ogden, 2004, Haake et al., 2003). ESWT is moderate to high cost depending on numbers of treatments. However, the results of the studies are heterogenous, with more than a quarter of the high-quality studies and all seven moderate-quality studies showing efficacy. Thus, ESWT is recommended for treatment of chronic plantar fasciitis if more conservative measures have failed, particularly as if surgery is being considered.

A high-quality trial comparing radial ESWT (rESWT) with sham demonstrated efficacy in reduction of pain and improved function at 3 months and 1 year (Gerdesmeyer et al., 2008). There are no studies comparing rESWT versus ESWT. Another moderate-quality trial compared perpendicular to tangential application of energy, which demonstrated no difference in outcomes as both groups improved the same (Tornese et al., 2008). The study was missing a control group and therefore no recommendation is made for one technique over the other. Radial ESWT is similar to ESWT in other aspects, adverse effects, and cost. Based on the insufficient evidence of efficacy for ESWT, there is insufficient evidence for recommendation.

The use of ultrasound and fluoroscopy has been described to guide the location for ESWT application. The quality comparison trial found no difference in outcomes using fluoroscopy compared to palpation (Dorotka et al., 2006). Ultrasound was used in three high-quality studies that showed no benefit over sham treatment (Haake et al., 2003, Buchbinder et al., 2002, Speed et al., 2003), but has not been compared without ultrasound in the same study. Therefore, there is insufficient evidence that the use of ultrasound or fluoroscopy guidance provides additional benefit over application of energy at point of maximal tenderness, and is therefore not recommended.

Regarding the use of local anesthesia, a high-quality study compared the effect of local anesthesia block to no block in subjects receiving low-energy ESWT and found local block reduces the positive treatment effect of ESWT, with prolonged benefit at 3 months, suggesting pain associated with ESWT has a treatment effect (Rompe, 2005). However, two high-quality studies finding no effect of ESWT did not utilize a local block and still found no effect over placebo (Haake et al., 2003, Buchbinder et al., 2002). Thus, there is insufficient evidence for a recommendation for or against the use of local block with low- or medium-energy ESWT. Local anesthesia is typically used in high-energy ESWT, using the Mainz categorization, to over 0.60mJ/mm2, and is recommended for use with high-energy ESWT.

LOCAL ANESTHESIA WITH LOW OR MEDIUM SHOCKWAVE THERAPY FOR PLANTAR FASCIITIS

No Recommendation

There is no recommendation for or against the use of local anesthesia when used in conjunction with low- or medium-energy ESWT for the treatment of plantar fasciitis.

Strength of evidence No Recommendation, Insufficient Evidence (I)
Level of confidence Low

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Rationale

There are multiple quality placebo-controlled trials providing conflicting outcomes for the efficacy of ESWT for the treatment of chronic plantar heel pain. Most of the high-quality studies failed to show superiority of ESWT to placebo (Haake et al., 2003, Buchbinder et al., 2002, Speed et al., 2003, Marks et al., 2008, Gollwitzer et al., 2007) however, there are two high-quality trials (Kudo et al., 2006, Malay et al., 2006) and seven moderate-quality trials (Ogden et al., 2001, Rompe et al., 2003, Rompe et al., 1996, Theodore et al., 2004, Cosentino et al., 2001, Mehra et al., 2003, Ogden, 2004) that suggested efficacy. Additionally, evidence for intermediate- and long-term harm was lacking.

Interpretation of these results is complicated by the wide variations in amount of energy delivered, treatment frequency, and use of local anesthetics. The optimal EFD for ESWT is unclear, as are the strata for energy flux delivery. Rompe used low energy (~0.08mJ/mm2), medium energy (~0.28mJ/mm2), and high energy (~0.60mH/mm2), in agreement with the Mainz classification (Gollwitzer et al., 2007). Quality trials have demonstrated low- and high-energy density delivery treatment regimens to be both effective and non-effective. Comparison of outcomes with total energy delivered is also inconsistent, as quality trials demonstrated total energy (EFD multiplied by the number of pulses at that EFD) between 60 mJ/mm2 (Rompe et al., 1996) and 2330mJ/mm2 (Kudo et al., 2006) to be both effective and ineffective. This energy range presumes EFD, not EFD+, reported by the study authors. Described protocols consisted of 3 treatment sessions, with varied impulse energy density (0.02 to 0.33mJ/mm2), number of impulses applied (1,500 to 4,000 per session), and spacing of treatment sessions (every third day to every other week). Thus, the optimal energy level of treatment is not well defined. There are three quality studies that demonstrated benefit from a single high-energy treatment session (Ogden et al., 2001, Malay et al., 2006, Theodore et al., 2004). One trial suggested a dose effect with increased impulses (Rompe et al., 2002).

Benefit of ESWT compared to corticosteroid injection in acute patients was compared (Porter et al., 2005). Both groups improved and no recommendation is made for either as an acute treatment. In comparison to mixed conservative therapies (Greve et al., 2009) one moderate-quality trial found no differences in outcomes measures, whereas two moderate-quality trials demonstrated ESWT more effective than serial conservative treatments of NSAIDs, orthotics, physiotherapy, stretching, and cortisone injections (Hammer et al., 2002, Hammer et al., 2003, Wang et al., 2006). These studies had multiple weaknesses limiting interpretation of results, but suggest for chronic conditions, ESWT may provide greater benefit than continuing with other non-operative treatments. ESWT may be invasive, particularly at high energy, when it may be performed with an injected anesthetic. Adverse effects from ESWT, particularly high-energy ESWT, may include erythema, pain, numbness, and tingling which are generally transient (Ogden et al., 2001, Kudo et al., 2006, Cosentino et al., 2001, Ogden, 2004, Haake et al., 2003). ESWT is moderate to high cost depending on numbers of treatments. However, the results of the studies are heterogenous, with more than a quarter of the high-quality studies and all seven moderate-quality studies showing efficacy. Thus, ESWT is recommended for treatment of chronic plantar fasciitis if more conservative measures have failed, particularly as if surgery is being considered.

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A high-quality trial comparing radial ESWT (rESWT) with sham demonstrated efficacy in reduction of pain and improved function at 3 months and 1 year (Gerdesmeyer et al., 2008). There are no studies comparing rESWT versus ESWT. Another moderate-quality trial compared perpendicular to tangential application of energy, which demonstrated no difference in outcomes as both groups improved the same (Tornese et al., 2008). The study was missing a control group and therefore no recommendation is made for one technique over the other. Radial ESWT is similar to ESWT in other aspects, adverse effects, and cost. Based on the insufficient evidence of efficacy for ESWT, there is insufficient evidence for recommendation.

The use of ultrasound and fluoroscopy has been described to guide the location for ESWT application. The quality comparison trial found no difference in outcomes using fluoroscopy compared to palpation (Dorotka et al., 2006). Ultrasound was used in three high-quality studies that showed no benefit over sham treatment (Haake et al., 2003, Buchbinder et al., 2002, Speed et al., 2003), but has not been compared without ultrasound in the same study. Therefore, there is insufficient evidence that the use of ultrasound or fluoroscopy guidance provides additional benefit over application of energy at point of maximal tenderness, and is therefore not recommended.

Regarding the use of local anesthesia, a high-quality study compared the effect of local anesthesia block to no block in subjects receiving low-energy ESWT and found local block reduces the positive treatment effect of ESWT, with prolonged benefit at 3 months, suggesting pain associated with ESWT has a treatment effect (Rompe, 2005). However, two high-quality studies finding no effect of ESWT did not utilize a local block and still found no effect over placebo (Haake et al., 2003, Buchbinder et al., 2002). Thus, there is insufficient evidence for a recommendation for or against the use of local block with low- or medium-energy ESWT. Local anesthesia is typically used in high-energy ESWT, using the Mainz categorization, to over 0.60mJ/mm2, and is recommended for use with high-energy ESWT.

RADIAL EXTRACORPOREAL SHOCKWAVE THERAPY FOR CHRONIC PLANTAR FASCIITIS

Sometimes Recommended

There is no recommendation for or against the use of radial ESWT (rESWT) for the treatment of chronic plantar fasciitis.

Strength of evidence No Recommendation, Insufficient Evidence (I)
Level of confidence Low

Rationale

There are multiple quality placebo-controlled trials providing conflicting outcomes for the efficacy of ESWT for the treatment of chronic plantar heel pain. Most of the high-quality studies failed to show superiority of ESWT to placebo (Haake et al., 2003, Buchbinder et al., 2002, Speed et al., 2003, Marks et al., 2008, Gollwitzer et al., 2007) however, there are two high-quality trials (Kudo et al., 2006, Malay et al., 2006) and seven moderate-quality trials (Ogden et al., 2001, Rompe et al., 2003, Rompe et al., 1996, Theodore et al., 2004,

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Cosentino et al., 2001, Mehra et al., 2003, Ogden, 2004) that suggested efficacy. Additionally, evidence for intermediate- and long-term harm was lacking.

Interpretation of these results is complicated by the wide variations in amount of energy delivered, treatment frequency, and use of local anesthetics. The optimal EFD for ESWT is unclear, as are the strata for energy flux delivery. Rompe used low energy (~0.08mJ/mm2), medium energy (~0.28mJ/mm2), and high energy (~0.60mH/mm2), in agreement with the Mainz classification (Gollwitzer et al., 2007). Quality trials have demonstrated low- and high-energy density delivery treatment regimens to be both effective and non-effective. Comparison of outcomes with total energy delivered is also inconsistent, as quality trials demonstrated total energy (EFD multiplied by the number of pulses at that EFD) between 60 mJ/mm2 (Rompe et al., 1996) and 2330mJ/mm2 (Kudo et al., 2006) to be both effective and ineffective. This energy range presumes EFD, not EFD+, reported by the study authors. Described protocols consisted of 3 treatment sessions, with varied impulse energy density (0.02 to 0.33mJ/mm2), number of impulses applied (1,500 to 4,000 per session), and spacing of treatment sessions (every third day to every other week). Thus, the optimal energy level of treatment is not well defined. There are three quality studies that demonstrated benefit from a single high-energy treatment session (Ogden et al., 2001, Malay et al., 2006, Theodore et al., 2004). One trial suggested a dose effect with increased impulses (Rompe et al., 2002).

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Regarding the use of local anesthesia, a high-quality study compared the effect of local anesthesia block to no block in subjects receiving low-energy ESWT and found local block reduces the positive treatment effect of ESWT, with prolonged benefit at 3 months, suggesting pain associated with ESWT has a treatment effect (Rompe, 2005). However, two high-quality studies finding no effect of ESWT did not utilize a local block and still found no effect over placebo (Haake et al., 2003, Buchbinder et al., 2002). Thus, there is insufficient evidence for a recommendation for or against the use of local block with low- or medium-energy ESWT. Local anesthesia is typically used in high-energy ESWT, using the Mainz categorization, to over 0.60mJ/mm2, and is recommended for use with high-energy ESWT.

RADIAL EXTRACORPOREAL SHOCKWAVE THERAPY FOR ACUTE OR SUBACUTE PLANTAR FASCIITIS

Not Recommended

Radial ESWT (rESWT) is not recommended for the treatment of acute or subacute plantar fasciitis.

Strength of evidence Not Recommended, Insufficient Evidence (I)
Level of confidence Moderate

Rationale

There are multiple quality placebo-controlled trials providing conflicting outcomes for the efficacy of ESWT for the treatment of chronic plantar heel pain. Most of the high-quality studies failed to show superiority of ESWT to placebo (Haake et al., 2003, Buchbinder et al., 2002, Speed et al., 2003, Marks et al., 2008, Gollwitzer et al., 2007) however, there are two high-quality trials (Kudo et al., 2006, Malay et al., 2006) and seven moderate-quality trials (Ogden et al., 2001, Rompe et al., 2003, Rompe et al., 1996, Theodore et al., 2004, Cosentino et al., 2001, Mehra et al., 2003, Ogden, 2004) that suggested efficacy. Additionally, evidence for intermediate- and long-term harm was lacking.

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Mainz classification (Gollwitzer et al., 2007). Quality trials have demonstrated low- and high-energy density delivery treatment regimens to be both effective and non-effective. Comparison of outcomes with total energy delivered is also inconsistent, as quality trials demonstrated total energy (EFD multiplied by the number of pulses at that EFD) between 60 mJ/mm2 (Rompe et al., 1996) and 2330mJ/mm2 (Kudo et al., 2006) to be both effective and ineffective. This energy range presumes EFD, not EFD+, reported by the study authors. Described protocols consisted of 3 treatment sessions, with varied impulse energy density (0.02 to 0.33mJ/mm2), number of impulses applied (1,500 to 4,000 per session), and spacing of treatment sessions (every third day to every other week). Thus, the optimal energy level of treatment is not well defined. There are three quality studies that demonstrated benefit from a single high-energy treatment session (Ogden et al., 2001, Malay et al., 2006, Theodore et al., 2004). One trial suggested a dose effect with increased impulses (Rompe et al., 2002).

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The use of ultrasound and fluoroscopy has been described to guide the location for ESWT application. The quality comparison trial found no difference in outcomes using fluoroscopy compared to palpation (Dorotka et al., 2006). Ultrasound was used in three high-quality studies that showed no benefit over sham treatment (Haake et al., 2003, Buchbinder et al., 2002, Speed et al., 2003), but has not been compared without ultrasound in the same study.

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Therefore, there is insufficient evidence that the use of ultrasound or fluoroscopy guidance provides additional benefit over application of energy at point of maximal tenderness, and is therefore not recommended.

Regarding the use of local anesthesia, a high-quality study compared the effect of local anesthesia block to no block in subjects receiving low-energy ESWT and found local block reduces the positive treatment effect of ESWT, with prolonged benefit at 3 months, suggesting pain associated with ESWT has a treatment effect (Rompe, 2005). However, two high-quality studies finding no effect of ESWT did not utilize a local block and still found no effect over placebo (Haake et al., 2003, Buchbinder et al., 2002). Thus, there is insufficient evidence for a recommendation for or against the use of local block with low- or medium-energy ESWT. Local anesthesia is typically used in high-energy ESWT, using the Mainz categorization, to over 0.60mJ/mm2, and is recommended for use with high-energy ESWT.

LOW-LEVEL LASER THERAPY

LOW-LEVEL LASER THERAPY FOR ACUTE, SUBACUTE, OR CHRONIC PLANTAR FASCIITIS

No Recommendation

There is no recommendation for or against the use of low-dose radiation (radiotherapy) for the treatment of chronic plantar heel pain.

Strength of evidence No Recommendation, Insufficient Evidence (I)
Level of confidence Low

Rationale

There are two moderate-quality studies providing conflicting results for the use of LLLT. A placebo-controlled trial suggested benefits for night pain and daily activity pain, although both groups improved significantly over the 6-week trial period (Kiritsi et al., 2010). The study had several weaknesses that limit conclusions. Another placebo controlled trial demonstrated no differences during or after 12 treatments of LLLT compared to the sham group in 32 patients (Basford et al., 1998). LLLT is not invasive, has low adverse effects, but is high cost, and demonstration of efficacy is conflicting. Further quality studies are needed; therefore no recommendation is made for its use to treat acute, subacute, or chronic plantar fasciitis or heel pain.

SURGICAL CONSIDERATIONS

SURGICAL RELEASE

SURGERY FOR ACUTE OR SUBACUTE PLANTAR FASCIITIS

Not Recommended

Surgical release is not recommended for treatment of acute or subacute plantar fasciitis.

Strength of evidence Not Recommended, Insufficient Evidence (I)
Level of confidence High

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Rationale

There are no quality randomized trials that compare sham surgery with surgical release, none that include surgery as a treatment arm for chronic plantar fasciitis, and none that compare efficacy of open versus endoscopic or other procedures. There is a dearth of case series reports of surgical plantar fascia release. Plantar fasciotomy is reported to have a complete pain relief success rate of 44% (Faraj et al., 2002), 50% (Davies et al., 1999), 61% (Conflitti et al., 2004), 68% (Hogan et al., 2004), and 69% (Jarde et al., 2003). Complete satisfaction is also reported between 48% (Davies et al., 1999) and 85% (Hogan et al., 2004). Average return to work or daily activities can range from 1.5 (Conflitti et al., 2004) to 7.85 months (Davies et al., 1999). Patients in the workers' compensation system have reportedly faired worse in satisfaction and lost time than those in non-workers' compensation systems (Bazaz et al., 2007). Fascial release is also associated with many adverse effects, including acute plantar fasciitis, forefoot stress fractures, and calcaneal and cuboid fractures (Cheung et al., 2006). Fascial release greater than 50% of the thickness may result in instability of the plantar arch (Jerosch et al., 2004) and result in lateral column pain symptoms (Brugh et al., 2002). There is no quality evidence on the added inclusion of spur excision or release of the abductor digiti quinti nerve with plantar release surgery. Thus, while surgery appears to provide complete relief to about half of patients, it is not without significant risk of complication, expense, and lack of comparison data to other non-surgical interventions.

Therefore, surgery is recommended as an intervention after at least 6 months of other non-operative treatments have been attempted and the patient's symptoms are sufficient to warrant the risks of surgical intervention. Patient education regarding suboptimal expected outcomes is recommended. There is no recommendation for or against procedure type (i.e. open vs. endoscopic) or the adjunct procedures (i.e. spur excision, neurolysis or release of abductor digiti quinti nerve).

SURGERY FOR SELECT CHRONIC RECALCITRANT PLANTAR FASCIITIS

Sometimes Recommended

Surgical release is recommended for select patients with moderate to severe chronic recalcitrant plantar fasciitis who have failed multiple non-surgical treatments and whose condition has lasted at least 6 to 12 months. Patients should receive pre-operative education regarding expected outcomes. There is no recommendation for any particular procedure or method over another.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence Low

Indications

Moderate to severe chronic plantar fasciitis patients who have failed multiple non-surgical treatments and whose condition has lasted at least 6 to 12 months. Patients should generally have failed NSAID(s), plantar fascia stretching, injection(s) and failed or refused other more conservative treatment. Patients should receive pre-operative education regarding expected outcomes.

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Rationale

There are no quality randomized trials that compare sham surgery with surgical release, none that include surgery as a treatment arm for chronic plantar fasciitis, and none that compare efficacy of open versus endoscopic or other procedures. There is a dearth of case series reports of surgical plantar fascia release. Plantar fasciotomy is reported to have a complete pain relief success rate of 44% (Faraj et al., 2002), 50% (Davies et al., 1999), 61% (Conflitti et al., 2004), 68% (Hogan et al., 2004), and 69% (Jarde et al., 2003). Complete satisfaction is also reported between 48% (Davies et al., 1999) and 85% (Hogan et al., 2004). Average return to work or daily activities can range from 1.5 (Conflitti et al., 2004) to 7.85 months (Davies et al., 1999). Patients in the workers' compensation system have reportedly faired worse in satisfaction and lost time than those in non-workers' compensation systems (Bazaz et al., 2007). Fascial release is also associated with many adverse effects, including acute plantar fasciitis, forefoot stress fractures, and calcaneal and cuboid fractures (Cheung et al., 2006). Fascial release greater than 50% of the thickness may result in instability of the plantar arch (Jerosch et al., 2004) and result in lateral column pain symptoms (Brugh et al., 2002). There is no quality evidence on the added inclusion of spur excision or release of the abductor digiti quinti nerve with plantar release surgery. Thus, while surgery appears to provide complete relief to about half of patients, it is not without significant risk of complication, expense, and lack of comparison data to other non-surgical interventions.

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Evidence

There are no quality trials incorporated into this analysis.

CRYOSURGERY

CRYOSURGERY FOR ACUTE OR SUBACUTE PLANTAR HEEL PAIN

Not Recommended

Cryosurgery is not recommended for treatment of acute or subacute plantar heel pain.

Strength of evidence Not Recommended, Insufficient Evidence (I)
Level of confidence Low

Rationale

There are no quality trials for percutaneous cryosurgery. A prospective case series reported 77% success in 137 feet at 3 weeks and 24 months in patients with chronic plantar heel pain (Cavazos et al., 2009). Cryosurgery is invasive, has an undefined adverse effect risk profile,

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and is moderately costly. Although potentially promising, further studies are needed, thus there is no recommendation for or against its use to treat plantar heel pain.

CRYOSURGERY FOR CHRONIC PLANTAR HEEL PAIN

No Recommendation

There is no recommendation for or against the use of cryosurgery for treatment of chronic plantar heel pain.

Strength of evidence No Recommendation, Insufficient Evidence (I)
Level of confidence Low

Rationale

There are no quality trials for percutaneous cryosurgery. A prospective case series reported 77% success in 137 feet at 3 weeks and 24 months in patients with chronic plantar heel pain (Cavazos et al., 2009). Cryosurgery is invasive, has an undefined adverse effect risk profile, and is moderately costly. Although potentially promising, further studies are needed, thus there is no recommendation for or against its use to treat plantar heel pain.

PERCUTANEOUS CALCANEUS FENESTRATION

PERCUTANEOUS CALCANEUS FENESTRATION FOR CHRONIC PLANTAR HEEL PAIN

No Recommendation

There is no recommendation for or against the use of percutaneous calcaneus fenestration for treatment of chronic plantar heel pain.

Strength of evidence No Recommendation, Insufficient Evidence (I)
Level of confidence Low

Rationale

There are no quality trials evaluating percutaneous bone fenestration for treatment of plantar heel pain. A prospective case series of 38 feet reported 100% success rates 12 months post-operatively in patients with chronic plantar heel pain (Cavazos et al., 2009). Percutaneous bone fenestration is invasive, has an undefined adverse effect risk profile, and is high cost as it is a surgical procedure performed with general or regional anesthesia. Although potentially promising, further studies are needed, and thus there is no recommendation for or against its use.

RADIOFREQUENCY MICROTENOTOMY

RADIOFREQUENCY MICROTENOTOMY FOR CHRONIC PLANTAR FASCIITIS

No Recommendation

There is no recommendation for or against the use of radiofrequency microtenotomy for treatment of chronic plantar fasciitis.

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Strength of evidence No Recommendation, Insufficient Evidence (I)
Level of confidence Low

Rationale

There are no quality trials evaluating radiofrequency microtenotomy for plantar fasciitis. A small prospective series showed positive benefits (Weil et al., 2008). Radiofrequency microtenotomy is invasive, has an undefined adverse effect risk profile, and is moderately costly. Although potentially promising, further studies are needed, thus there is no recommendation for or against its use.

Evidence

There are no quality trials incorporated into this analysis.

TARSAL TUNNEL SYNDROME (TTS)

OVERVIEW

TTS is described by the constellation of symptoms of intermittent tingling, numbness or burning paresthesias in the any of toes and the plantar surface of the foot. Case histories are mostly non-specific to exact dermatomal distribution of symptoms. As both medial and lateral plantar nerves travel in the same tunnel but may bifurcate and have lesions at different levels, impingement could theoretically cause symptoms in either one of the distributions or both distributions. There may also be a sensation of ankle pain, tightness and cramping. There may be a worsening of symptoms throughout the day with prolonged standing or walking, opposite of plantar fasciitis. Pain at night is also common which is similar to median nerve impingement at the carpal tunnel. There may be proximal radiation to the calf and leg with advanced nerve compression [360,361,362,363]. Similar to CTS patients being asked to complete a hand diagram to locate and rate symptoms, practitioners may ask patients to complete a foot diagram (Foot Wong-Baker Pain FACES Intensity Scale), which may be identify the different branches of the posterior tibial nerve that may be involved. Nerve identification is often useful in pre-treatment and follow-up evaluations [364].

TTS is often described as a complex condition difficult to diagnose and treat. This complexity is in part related to similar presentation of plantar and ankle pain as other foot and ankle disorders. In addition, anatomic variation in innervations of the plantar foot by the several nerves may result in variation of sensory and pain patterns, as well as variation in the level of bifurcation of posterior tibial nerve and artery as it traverses through the tunnel [365].

Physical findings reported in patients with clinical are minimal and include a Tinel's sign over the tarsal tunnel, local tenderness behind the medial malleolus, altered sensation of the plantar surface, and weakness of foot muscles as evidenced by reduced ability to fan the toes [360,366]. Evidence of pes planus, ankle trauma or bone deformity, arthritis, gout, edema, or palpable mass may increase the suspicion of TTS and support further diagnostic testing. Injection of the tarsal tunnel with lidocaine that provides pain relief is suggested in the literature, but is non-specific for nerve impingement as other disorders distal to the injection site are likely to similarly respond to an anesthetic nerve block. Inflation of a sphygmomanometer about the thigh to just above venous pressure may increase symptoms of the foot [360,367].

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One examination maneuver proposed for TTS is the “dorsiflexion-eversion test,” during which the examiner, with the patient seated and non-weight bearing, maximally dorsiflexes the ankle, everts the foot, and extends the toes maintaining the position for 5 to 10 seconds while tapping over the region of the tarsal tunnel to determine if a positive Tinel sign is present or if the patient complains of local nerve tenderness. This test was performed on 50 normal and 37 (44 feet) treated operatively for tarsal tunnel syndrome [366]. In the normal groups, no signs or symptoms were produced by the test. In the 44 symptomatic feet, the test increased numbness or pain in 36 feet (sensitivity 0.81, specificity 0.99). One issue with this examination maneuver is that there is no reliable standard of comparison. For example, electrophysiological studies, often considered a standard for locating nerve compression, is not reliable in TTS; and finding that persons who are awaiting an operation have discomfort more-easily provoked in the area of the operation than do persons who are not awaiting an operation may be fallacious. Thus, results of the dorsiflexion-eversion test should be interpreted with caution. A differential diagnosis for TTS should include interdigital neuroma, peripheral neuropathy, tenosynovitis, plantar fasciitis, plantar calluses, acute strain of the medial longitudinal arch, and peripheral vascular disease [368].

There are no well-established standard diagnostic criteria for TTS. Clinicians should maintain a high level of suspicion for TTS in patients presenting with pain and paresthesias of the plantar foot that worsen with prolonged standing and walking, or cause interruption of sleep.

DIAGNOSTIC RECOMMENDATIONS

NERVE CONDUCTION STUDIES

NERVE CONDUCTION STUDIES FOR PREOPERATIVE ASSESSMENT OF TARSAL TUNNEL SYNDROME

Recommended

Nerve conduction studies (NCS) are recommended for confirming the diagnosis of entrapment of the tibial nerve at the ankle for cases that do not improve with conservative treatment or if considering surgical release after excluding the possibility of other causes such as polyneuropathy and radiculopathy.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence High

Rationale

There are no quality trials evaluating the efficacy of electrodiagnostic methods, or how they affect the treatment outcomes of suspected TTS. A review of 317 articles by a task force of the American Association of Neuromuscular and Electrodiagnostic Medicine (AANEM) on the role of nerve conduction studies (NCS) and electromyography in the diagnosis of tarsal tunnel syndrome found only four studies meeting evidence criteria set by their panel (Patel et al., 2005). The review found nerve conduction studies were abnormal in some patients with suspected tarsal tunnel syndrome, although the study sizes were small in each case. Similar to CTS, sensory conduction was more likely to be abnormal than motor studies. AANEM recommendations for confirming tibial mononeuropathy at the level of the tarsal

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tunnel in patients with clinically suspected tarsal tunnel syndrome include: 1) tibial motor responses recorded over the abductor hallucis and abductor digiti minimi pedis muscles demonstrating prolonged distal onset latency; 2) medial and lateral plantar mixed NCSs demonstrating prolonged peak latency or slowed conduction velocity across the tarsal tunnel; and 3) medial and lateral plantar sensory NCSs demonstrating slowed conduction velocities across the tarsal tunnel and/or small amplitude or absent responses.

There is no quality evidence demonstrating the utility of needle EMG or surface EMG assessment in the diagnosis of TTS. Although this technique is used by many foot surgeons to confirm the diagnosis of tibial nerve impingement at the ankle, the utility as an early diagnostic test is not well defined. There is no well described benefit of EMG versus NCS or other tests, although by analogy to CTS, a utility for EMG for TTS is doubtful. Analyses of needle EMG by AANEM concluded with no recommendation for the use of EMG in diagnosis of TTS. Therefore, NCS is recommended for diagnosis of entrapment of the tibial nerve at the ankle and for pre-operative assessment, but is not recommended for initial evaluation and most TTS patients. There is also no recommendation for or against the use of EMG for initial evaluation, diagnosis or pre-operative assessment of TTS patients.

NERVE CONDUCTION STUDIES FOR INITIAL EVALUATION OF TARSAL TUNNEL SYNDROME

Not Recommended

NCS are not recommended for the initial evaluation of most TTS patients because NCS results do not change the management of the condition during the first 4 to 6 weeks while conservative therapy is being tried.

Strength of evidence Not Recommended, Insufficient Evidence (I)
Level of confidence High

Rationale

There are no quality trials evaluating the efficacy of electrodiagnostic methods, or how they affect the treatment outcomes of suspected TTS. A review of 317 articles by a task force of the American Association of Neuromuscular and Electrodiagnostic Medicine (AANEM) on the role of nerve conduction studies (NCS) and electromyography in the diagnosis of tarsal tunnel syndrome found only four studies meeting evidence criteria set by their panel (Patel et al., 2005). The review found nerve conduction studies were abnormal in some patients with suspected tarsal tunnel syndrome, although the study sizes were small in each case. Similar to CTS, sensory conduction was more likely to be abnormal than motor studies. AANEM recommendations for confirming tibial mononeuropathy at the level of the tarsal tunnel in patients with clinically suspected tarsal tunnel syndrome include: 1) tibial motor responses recorded over the abductor hallucis and abductor digiti minimi pedis muscles demonstrating prolonged distal onset latency; 2) medial and lateral plantar mixed NCSs demonstrating prolonged peak latency or slowed conduction velocity across the tarsal tunnel; and 3) medial and lateral plantar sensory NCSs demonstrating slowed conduction velocities across the tarsal tunnel and/or small amplitude or absent responses.

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ELECTROMYOGRAPHY FOR TARSAL TUNNEL SYNDROME

No Recommendation

There is no recommendation for or against the use of EMG for initial evaluation, diagnosis, or pre-operative assessment of TTS patients. Electromyography (as distinguished from a nerve conduction study) is not generally recommended as there is no quality evidence demonstrating the utility of EMG in the diagnosis of TTS.

Strength of evidence No Recommendation, Insufficient Evidence (I)
Level of confidence Low

Rationale

There are no quality trials evaluating the efficacy of electrodiagnostic methods, or how they affect the treatment outcomes of suspected TTS. A review of 317 articles by a task force of the American Association of Neuromuscular and Electrodiagnostic Medicine (AANEM) on the role of nerve conduction studies (NCS) and electromyography in the diagnosis of tarsal tunnel syndrome found only four studies meeting evidence criteria set by their panel (Patel et al., 2005). The review found nerve conduction studies were abnormal in some patients with suspected tarsal tunnel syndrome, although the study sizes were small in each case. Similar to CTS, sensory conduction was more likely to be abnormal than motor studies. AANEM recommendations for confirming tibial mononeuropathy at the level of the tarsal tunnel in patients with clinically suspected tarsal tunnel syndrome include: 1) tibial motor responses recorded over the abductor hallucis and abductor digiti minimi pedis muscles demonstrating prolonged distal onset latency; 2) medial and lateral plantar mixed NCSs demonstrating prolonged peak latency or slowed conduction velocity across the tarsal tunnel; and 3) medial and lateral plantar sensory NCSs demonstrating slowed conduction velocities across the tarsal tunnel and/or small amplitude or absent responses.

There is no quality evidence demonstrating the utility of needle EMG or surface EMG assessment in the diagnosis of TTS. Although this technique is used by many foot surgeons to confirm the diagnosis of tibial nerve impingement at the ankle, the utility as an early diagnostic test is not well defined. There is no well described benefit of EMG versus NCS or other tests, although by analogy to CTS, a utility for EMG for TTS is doubtful. Analyses of needle EMG by AANEM concluded with no recommendation for the use of EMG in diagnosis of TTS. Therefore, NCS is recommended for diagnosis of entrapment of the tibial nerve at

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the ankle and for pre-operative assessment, but is not recommended for initial evaluation and most TTS patients. There is also no recommendation for or against the use of EMG for initial evaluation, diagnosis or pre-operative assessment of TTS patients.

ULTRASOUND

ROUTINE USE OF DIAGNOSTIC ULTRASOUND FOR TARSAL TUNNEL SYNDROME

Not Recommended

Ultrasound is not recommended as a routine diagnostic test for TTS.

Strength of evidence Not Recommended, Insufficient Evidence (I)
Level of confidence Low

Rationale

There are no quality studies evaluating the efficacy of ultrasound imaging techniques for the initial diagnosis of TTS, or for the use of ultrasound in managing tarsal tunnel treatment courses. Ultrasound as an initial diagnostic test is not well described. There are efforts to correlate nerve size or swelling with other diagnostic criteria, but no quality data exist outlining sensitivity and specificity. Further, there are no comparison studies between MRI and ultrasound for making diagnostic or treatment decisions. The routine use of ultrasound for initial evaluation is therefore not recommended. Ultrasound studies reserved for patients that have failed conservative therapy or as an adjunct to guide interventional therapies however may be useful. When the diagnosis of TTS is highly suspected or confirmed by NCS, diagnostic nerve block, or glucocorticoid injection, the use of ultrasound can provide etiologic details such as inflammation of the nerve, soft tissue swelling, or soft tissue mass lesion .

DIAGNOSTIC ULTRASOUND WITH NERVE CONDUCTION STUDIES FOR TARSAL TUNNEL SYNDROME

Recommended

Ultrasound is recommended as an aid to nerve conduction studies (NCS) as it may be beneficial to identify suspected space-occupying lesions in the tarsal tunnel after failed conservative management, or as an adjunct to guide interventional therapies.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence Low

Rationale

There are no quality studies evaluating the efficacy of ultrasound imaging techniques for the initial diagnosis of TTS, or for the use of ultrasound in managing tarsal tunnel treatment courses. Ultrasound as an initial diagnostic test is not well described. There are efforts to correlate nerve size or swelling with other diagnostic criteria, but no quality data exist outlining sensitivity and specificity. Further, there are no comparison studies between MRI and ultrasound for making diagnostic or treatment decisions. The routine use of ultrasound

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for initial evaluation is therefore not recommended. Ultrasound studies reserved for patients that have failed conservative therapy or as an adjunct to guide interventional therapies however may be useful. When the diagnosis of TTS is highly suspected or confirmed by NCS, diagnostic nerve block, or glucocorticoid injection, the use of ultrasound can provide etiologic details such as inflammation of the nerve, soft tissue swelling, or soft tissue mass lesion (Vijayan et al., 2009, Girish et al., 2007, Hochman et al., 2004, Lee et al., 2005, Sofka et al., 2001).

MAGNETIC RESONANCE IMAGING

MAGNETIC RESONANCE IMAGING (MRI) FOR TARSAL TUNNEL SYNDROME

Recommended

MRI is recommended for the diagnosis of select cases of clinically suspected TTS that has failed conservative management or if a mass lesion is suspected.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence Low

Rationale

There are no quality studies evaluating the efficacy of MRI in identifying tarsal tunnel syndrome. However, MRI has taken a much more prominent role in recent years because of superior soft tissue resolution and the ability to noninvasively visualize the osseous structures, cartilage, and soft tissues. High-resolution of the tarsal tunnel allows visualization of the tibial nerve and plantar nerves in nearly their entire length, allowing demonstration of nerve compression by an adjacent structure (Campbell, 2006). The reviewed surgical case reports of TTS frequently implicate space occupying lesions impinging the tarsal fibro-osseous tunnel. MRI may have unique ability to visualize the described anomalies such as accessory muscles, venous dilation, ganglion cysts, neurilemoma, posttraumatic fibrosis and tenosynovitis. However, the presence of abnormal MRI findings in the lower legs of asymptomatic persons is unknown, so predictive values of abnormal findings, particularly minor abnormal findings, is unknown. Further, MR imaging demonstrated the presence and extent of impinging lesions in 17 of 19 patients who underwent surgery (Finkel, 1994). MRI is a moderate cost option with few side effects and is non-invasive with a high potential to direct treatment.

ROUTINE MAGNETIC RESONANCE IMAGING (MRI) FOR TARSAL TUNNEL SYNDROME

Not Recommended

The routine use of MRI is not recommended for the initial evaluation of TTS.

Strength of evidence Not Recommended, Insufficient Evidence (I)
Level of confidence High

Rationale

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There are no quality studies evaluating the efficacy of MRI in identifying tarsal tunnel syndrome. However, MRI has taken a much more prominent role in recent years because of superior soft tissue resolution and the ability to noninvasively visualize the osseous structures, cartilage, and soft tissues. High-resolution of the tarsal tunnel allows visualization of the tibial nerve and plantar nerves in nearly their entire length, allowing demonstration of nerve compression by an adjacent structure (Campbell, 2006). The reviewed surgical case reports of TTS frequently implicate space occupying lesions impinging the tarsal fibro-osseous tunnel. MRI may have unique ability to visualize the described anomalies such as accessory muscles, venous dilation, ganglion cysts, neurilemoma, posttraumatic fibrosis and tenosynovitis. However, the presence of abnormal MRI findings in the lower legs of asymptomatic persons is unknown, so predictive values of abnormal findings, particularly minor abnormal findings, is unknown. Further, MR imaging demonstrated the presence and extent of impinging lesions in 17 of 19 patients who underwent surgery (Finkel, 1994). MRI is a moderate cost option with few side effects and is non-invasive with a high potential to direct treatment.

TREATMENT RECOMMENDATIONS

OVERVIEW

In the absence of neuropathic findings (sensory or motor involvement), by inference from other neurological impingement syndromes, 4 to 6 weeks of conservative care before using invasive measures may be reasonable. The commonly prescribed conservative measures are intended to relieve pressure and pain. These include cold, taping, exercises (especially posterior tibial nerve stretching), anti-inflammatory medications, splints, orthotic devices and supportive footwear.

ACTIVITY MODIFICATION AND EXERCISE

EXERCISES FOR TARSAL TUNNEL SYNDROME

No Recommendation

There is no recommendation for or against the use of exercises for the treatment of TTS.

Strength of evidence No Recommendation, Insufficient Evidence (I)
Level of confidence Low

Rationale

Exercise regimens for tendon gliding or nerve gliding are prescribed but have not studied for TTS. Similar exercise regimens prescribed for CTS showed unclear benefit and no recommendation is made based on insufficient evidence. Additionally, as many believe physical activity is a risk factor for TTS and CTS, the logic of performing exercises for treatment is somewhat dissonant. Exercise programs are not invasive, have few if any adverse effects, and are low cost if performed independently after receiving initial instructions. However, no recommendation is made because of insufficient evidence.

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REST FOR TARSAL TUNNEL SYNDROME

No Recommendation

There is no recommendation for or against the use of rest for the treatment of TTS.

Strength of evidence No Recommendation, Insufficient Evidence (I)
Level of confidence Low

Rationale

There are no quality studies evaluating rest, ice, or taping, for symptomatic relief of TSS. Ankle rest or providing limitations of the affected leg is non-invasive, but can be moderate to high cost over time. Ankle rest may be beneficial for the more symptomatic cases where aggravating factors include constant standing or walking. Ice and heat may help particularly with more acute symptoms, although there is no evidence they help with other nerve impingement syndromes. Systematic reviews and case series reports using taping strategies for TTS were not found in the literature search and over time this intervention may be costly. However, taping may be helpful in the treatment of non-specific heel pain (Hyland et al., 2006) (see Heel Pain). Each of these treatments is not invasive and generally has few adverse effects. Self-applications of ice and heat are not costly.

TAPING FOR TARSAL TUNNEL SYNDROME

No Recommendation

There is no recommendation for or against the use of taping for the treatment of TTS.

Strength of evidence No Recommendation, Insufficient Evidence (I)
Level of confidence Low

Rationale

There are no quality studies evaluating rest, ice, or taping, for symptomatic relief of TSS. Ankle rest or providing limitations of the affected leg is non-invasive, but can be moderate to high cost over time. Ankle rest may be beneficial for the more symptomatic cases where aggravating factors include constant standing or walking. Ice and heat may help particularly with more acute symptoms, although there is no evidence they help with other nerve impingement syndromes. Systematic reviews and case series reports using taping strategies for TTS were not found in the literature search and over time this intervention may be costly. However, taping may be helpful in the treatment of non-specific heel pain (Hyland et al., 2006) (see Heel Pain). Each of these treatments is not invasive and generally has few adverse effects. Self-applications of ice and heat are not costly. Orthotics may be selectively recommended for those with TTS thought to be of biomechanical origin.

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MEDICATIONS

NSAIDS AND ACETAMINOPHEN

NONSTEROIDAL ANTI-INFLAMMATORY DRUGS (NSAIDS) FOR TARSAL TUNNEL SYNDROME

Recommended

A trial of NSAIDs is recommended to treat pain from TTS.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence Moderate

Rationale

There are no quality studies evaluating the effects of acetaminophen in treating TTS. However, acetaminophen may provide enough mild analgesic relief to allow the patient to exercise or function at a higher level. It is low cost, has few side effects, and is not invasive. There are no quality studies evaluating the effects of NSAIDs in treating TTS. Many of the review articles and case studies reviewed reported beneficial results from the use of NSAIDs. In addition, oral NSAIDs are useful in many soft tissue musculoskeletal conditions. However, NSAIDS have been shown to be ineffective for neuropathic pain including in the treatment of carpal tunnel syndrome (see Hand, Wrist, and Forearm Disorders guideline), so that true impingement of the posterior tibial nerve or its branches in the tarsal tunnel may have low response. Thus, while there is insufficient evidence, NSAIDS are recommended as an initial conservative treatment for tarsal tunnel syndrome particularly for cases where symptoms are thought to be able to be addressed by the NSAID.

ACETAMINOPHEN FOR TARSAL TUNNEL SYNDROME

Recommended

A trial of acetaminophen is recommended to treat pain from TTS.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence Moderate

Rationale

There are no quality studies evaluating the effects of acetaminophen in treating TTS. However, acetaminophen may provide enough mild analgesic relief to allow the patient to exercise or function at a higher level. It is low cost, has few side effects, and is not invasive. There are no quality studies evaluating the effects of NSAIDs in treating TTS. Many of the review articles and case studies reviewed reported beneficial results from the use of NSAIDs. In addition, oral NSAIDs are useful in many soft tissue musculoskeletal conditions. However, NSAIDS have been shown to be ineffective for neuropathic pain including in the treatment of carpal tunnel syndrome (see Hand, Wrist, and Forearm Disorders guideline), so that true impingement of the posterior tibial nerve or its branches in the tarsal tunnel may have low response. Thus, while there is insufficient evidence, NSAIDS are recommended as

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an initial conservative treatment for tarsal tunnel syndrome particularly for cases where symptoms are thought to be able to be addressed by the NSAID.

GLUCOCORTICOSTEROIDS

ORAL SYSTEMIC GLUCOCORTICOSTEROIDS FOR TARSAL TUNNEL SYNDROME

Sometimes Recommended

Oral glucocorticosteroids are recommended for treatment of patients with TTS that is unresponsive to splinting who decline tarsal tunnel injection.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence Low

Indications

Tarsal tunnel syndrome unresponsive to splinting. Most patients should be injected rather than given oral steroids (Wong et al., 2001); however, among those declining injection, oral glucocorticosteroids may be warranted.

Frequency/Dose/Duration

It is unclear what dose and duration of treatment is optimal. Inference is made from CTS literature. Two trials used 10 days of treatment with prednisolone acetate 25mg a day (Hui et al., 2001, Wong et al., 2001). A third trial used prednisolone 20mg a day for 2 weeks, then 10mg a day for 2 weeks (Chang et al., 1998, Mishra et al., 2006). Another used prednisolone 20mg a day for 1 week, then 10mg a day for 1 week (Chang et al., 1995). Another used prednisolone 20mg a day for 2 weeks on one of the treatment arms (Chang et al., 2002). There is some evidence that 2 weeks of treatment is as effective as 4 weeks (Chang et al., 2003, Chang et al., 2002). It is recommended that one course (10 to 14 days) of oral glucocorticosteroid be prescribed, rather than repeated courses. Prescriptions of low rather than high doses are recommended to minimize potential for adverse effects.

Rationale

There are no quality studies of glucocorticosteroid use in TTS patients. However, glucocorticosteroids have been used to treat CTS and have been shown to be effective (see Hand, Wrist, and Forearm Disorders guideline). Oral glucocorticosteroids are not invasive, have relatively few adverse effects for a short course and are low cost.

DIURETICS

DIURETICS FOR ROUTINE TREATMENT OF TARSAL TUNNEL SYNDROME

Not Recommended

Diuretics are not recommended for routine treatment of TTS.

Strength of evidence Not Recommended, Insufficient Evidence (I)

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Level of confidence Moderate

Rationale

There are no quality studies on the use of diuretics for TTS. Most of the medical conditions described as risk factors for TTS do not involve edema or swelling of the lower extremities. In the CTS literature, two quality studies of diuretics for treatment of CTS patients failed to find evidence of efficacy compared with placebo (Chang et al., 1998, Pal et al., 1988). Whether they are effective for treatment of patients with TTS accompanied by fluid retention states, such as third trimester pregnancy, has not been determined in quality studies, and use for select cases may be a reasonable intervention. Thus, diuretics are not recommended for routine treatment of CTS patients.

OPIOIDS

OPIOIDS FOR TARSAL TUNNEL SYNDROME

Sometimes Recommended

Limited use (a few days) of opioids is recommended for select patients who have undergone recent tarsal tunnel release and have large incisions or encountered significant complications and whose pain cannot be managed with other means.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence Low

Rationale

There are no quality studies of opioids for treatment of patients with TTS. The vast majority of patients with TTS do not have pain of sufficient intensity to require opioids. Patients having such degrees of pain should generally have investigations performed for alternative diagnoses. Opioids are not invasive, but have very high dropout rates and otherwise high rates of adverse effects. They are moderate to high cost depending on duration of treatment (see Chronic Pain guideline). They are not recommended for routine use. Opioids are recommended for brief, select use in post-operative patients with primary use at night to achieve sleep post-operatively.

Evidence

There are no quality studies evaluating the use of opioids for the treatment of pain from TTS.

ROUTINE USE OF OPIOIDS FOR TARSAL TUNNEL SYNDROME

Not Recommended

The routine use of opioids is not recommended for treatment of patients with pain from TTS.

Strength of evidence Not Recommended, Insufficient Evidence (I)

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Level of confidence High

Rationale

There are no quality studies of opioids for treatment of patients with TTS. The vast majority of patients with TTS do not have pain of sufficient intensity to require opioids. Patients having such degrees of pain should generally have investigations performed for alternative diagnoses. Opioids are not invasive, but have very high dropout rates and otherwise high rates of adverse effects. They are moderate to high cost depending on duration of treatment (see Chronic Pain guideline). They are not recommended for routine use. Opioids are recommended for brief, select use in post-operative patients with primary use at night to achieve sleep post-operatively.

Evidence

There are no quality studies evaluating the use of opioids for the treatment of pain from TTS.

VITAMINS

PYRIDOXINE FOR TARSAL TUNNEL SYNDROME

Not Recommended

Pyridoxine is not recommended for routine treatment of TTS in patients without vitamin deficiencies.

Strength of evidence Not Recommended, Insufficient Evidence (I)
Level of confidence Moderate

Rationale

There are no quality studies for the use of pyridoxine to treat TTS. However, review of this treatment for CTS did not show a clear benefit (see Hand, Wrist, and Forearm Disorders guideline). While vitamin B6 is relatively low risk and patients may use it without prescription, available evidence does not support its use for the routine treatment of TTS and thus it is not recommended. It may be a reasonable treatment option for those with presumptive pyridoxine deficiency (e.g., malnutrition, alcoholism, malabsorption, especially jejunal disorders such as sprue, etc.).

USE OF OTHER VITAMINS FOR TARSAL TUNNEL SYNDROME

No Recommendation

There is no recommendation for or against the use of other vitamins for the treatment of TTS.

Strength of evidence No Recommendation, Insufficient Evidence (I)
Level of confidence Low

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Rationale

There are no quality studies for the use of pyridoxine to treat TTS. However, review of this treatment for CTS did not show a clear benefit (see Hand, Wrist, and Forearm Disorders guideline). While vitamin B6 is relatively low risk and patients may use it without prescription, available evidence does not support its use for the routine treatment of TTS and thus it is not recommended. It may be a reasonable treatment option for those with presumptive pyridoxine deficiency (e.g., malnutrition, alcoholism, malabsorption, especially jejunal disorders such as sprue, etc.).

TOPICAL MEDICATIONS

LIDOCAINE PATCHES FOR TARSAL TUNNEL SYNDROME

Sometimes Recommended

Lidocaine patches are recommended for treatment of select cases of TTS. Lidocaine patches may be used for patients with moderate to severe TTS with pain as a central complaint and in whom other treatable causes of the pain have been eliminated. Patients generally should have previously been treated with likely more efficacious treatment strategies. Caution is warranted regarding widespread use of topical anesthetics for potential systemic effects from widespread administration.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence Low

Indications

Patients with moderate to severe TTS with pain as a central complaint and in whom other treatable causes of the pain have been eliminated. Generally should have previously been treated with likely more efficacious treatment strategies.

Frequency/Dose/Duration

Usually 3 patches per day; duration of use for chronic, localized pain may be as long as indefinitely, although most of these patients do not require indefinite treatment, as symptoms of TTS usually resolve, improve or require surgery. Caution is warranted regarding widespread use of topical anesthetics for potential systemic effects from widespread administration.

Indications for discontinuation

Resolution, intolerance, adverse effects, lack of benefits, or failure to progress over a trial of at least a couple weeks.

Rationale

Topical lidocaine has not been evaluated in quality studies of TTS. It has been suggested to improve pain associated with CTS (although the case diagnoses do not appear well

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substantiated in the available study as pain complaints as an overriding symptom among CTS patients raise concerns about alternate explanations for the symptoms) (Nalamachu et al., 2006). Lidocaine patches are not invasive and have a low adverse effects profile although some patients may experience local reactions such as skin irritation, redness, pain, or sores with use. Patches are also moderately or even high cost over time. While there are other lower cost topical treatments that provide analgesia, including heat, ice, and capsaicin, lidocaine patches may be a reasonable treatment option for pain related to TTS. Patients should be monitored to ensure that they are receiving benefit and to ascertain if there are any untoward local skin changes as a result of use.

HOT AND COLD THERAPIES

SELF-APPLICATION OF ICE OR HEAT FOR TARSAL TUNNEL SYNDROME

Recommended

Self-application of heat or ice is recommended for the treatment of TTS.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence Low

Rationale

There are no quality studies evaluating rest, ice, or taping, for symptomatic relief of TSS. Ankle rest or providing limitations of the affected leg is non-invasive, but can be moderate to high cost over time. Ankle rest may be beneficial for the more symptomatic cases where aggravating factors include constant standing or walking. Ice and heat may help particularly with more acute symptoms, although there is no evidence they help with other nerve impingement syndromes. Systematic reviews and case series reports using taping strategies for TTS were not found in the literature search and over time this intervention may be costly. However, taping may be helpful in the treatment of non-specific heel pain (Hyland et al., 2006) (see Heel Pain). Each of these treatments is not invasive and generally has few adverse effects. Self-applications of ice and heat are not costly.

DEVICES

NOCTURNAL SPLINTS FOR TARSAL TUNNEL SYNDROME

No Recommendation

There is no recommendation for or against the use of a trial of nocturnal splinting for treatment of TTS.

Strength of evidence No Recommendation, Insufficient Evidence (I)
Level of confidence Low

Rationale

There are no quality studies or reviews found on the benefit of splinting of the foot specifically for TTS. Nocturnal splinting of the wrist in a functionally neutral position has

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been found to be effective for CTS, although the mechanism of action is unknown. By inference from the CTS literature, nocturnal paresthesia and pain is also often described with TTS. However, the foot posture is less likely to be highly variable during sleep. Thus, although a trial of dorsal splinting of the foot may be beneficial, there is no recommendation for or against splinting.

MAGNETS FOR TARSAL TUNNEL SYNDROME

Not Recommended

Magnets are not recommended for the treatment of TTS.

Strength of evidence Not Recommended, Insufficient Evidence (I)
Level of confidence High

Rationale

Quality evidence in CTS suggests that magnets are not efficacious for treating pain associated with nerve impingement (Carter et al., 2002). There are no quality studies on the use of magnets for TTS. While magnets are not invasive, have no adverse effects, and are low cost, other interventions have been shown to be effective. Thus, magnets are not recommended for treatment of TTS.

ORTHOTICS FOR TARSAL TUNNEL SYNDROME

No Recommendation

There is no recommendation for or against the use of orthotics for the treatment of TTS.

Strength of evidence No Recommendation, Insufficient Evidence (I)
Level of confidence Low

Rationale

Orthotics are often prescribed to treat underlying alignment disorders (pes planus, valgus hindfoot deformity, varus hindfoot deformity, generalized joint hypermobility) which have been described as a possible etiology for TTS. It is hypothesized that these disorders result in increased strain on the flexor retinaculum, reducing the tarsal tunnel space causing impingement of the nerves (Francis et al., 1987). Orthotics are intended to reduce the stressors on the ligaments and reduce inflammation of the nerve. One case report of 14 patients with TTS and varus heel deformity were treated with lateral heel wedge orthotics (Radin EL, 1983). Eleven of the 14 patients did not respond to orthotics and went on to have surgical release. Another series report of 15 patients with pes planus and valgus hindfoot that were treated with orthotics showed a near 50% cure rate (Francis et al., 1987). Orthotics are non-invasive, have few if any side effects, but can be high cost for customized fitting and materials. Therefore, the lack of evidence of efficacy prevents a recommendation for or against the use of orthotics for TTS.

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ALLIED HEALTH INTERVENTIONS

ACUPUNCTURE FOR TARSAL TUNNEL SYNDROME

No Recommendation

There is no recommendation for or against the use of acupuncture for the treatment of TTS.

Strength of evidence No Recommendation, Insufficient Evidence (I)
Level of confidence Low

Rationale

There is no quality evidence of efficacy for acupuncture as a treatment for TTS. Acupuncture is minimally invasive, has minimal adverse effects, and is moderately costly. There are other interventions with documented efficacy. Therefore, there is no recommendation for or against use of acupuncture for treatment of TTS.

MANIPULATION AND MOBILIZATION FOR TARSAL TUNNEL SYNDROME

No Recommendation

There is no recommendation for or against the use of manipulation and mobilization of the distal lower extremity for the treatment of TTS.

Strength of evidence No Recommendation, Insufficient Evidence (I)
Level of confidence Low

Rationale

There are no quality studies of manipulation or mobilization of the lower extremity for the treatment of TTS. By inference from CTS, two quality studies suggested manipulation is ineffective for treatment of CTS (Davis et al., 1998, Burke et al., 2007). Manipulation is not invasive, is moderately costly, although it is unlikely to have adverse effects in the distal lower extremity. It is not recommended for treatment of TTS.

ULTRASOUND FOR TARSAL TUNNEL SYNDROME

Not Recommended

Ultrasound is not recommended as a routine diagnostic test for TTS.

Strength of evidence Not Recommended, Insufficient Evidence (I)
Level of confidence Low

Rationale

There are no quality studies for the use of ultrasound as a treatment for TTS. While there is a recommendation for its use in CTS patients, there is a lack of any case reports or systematic review for this treatment modality in TTS patients. Ultrasound is not invasive, has

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few adverse effects, but is moderate to high cost depending on the number of treatments (which were high in quality studies).

IONTOPHORESIS FOR TARSAL TUNNEL SYNDROME

No Recommendation

There is no recommendation for or against the use of iontophoresis for the treatment of TTS.

Strength of evidence No Recommendation, Insufficient Evidence (I)
Level of confidence Low

Rationale

There are no quality studies of iontophoresis for the treatment of TTS. Iontophoresis with glucocorticosteroid may be a reasonable option for treating patients who decline injection. However, oral glucocorticosteroids have quality evidence of efficacy and may be recommended preferentially as iontophoresis is believed to be less effective than glucocorticosteroid injections. Iontophoresis is not invasive, has low adverse effects, and is of moderate cost. However, other treatments have documented efficacy, and should be used preferentially.

PHONOPHORESIS FOR TARSAL TUNNEL SYNDROME

No Recommendation

There is no recommendation for or against the use of phonophoresis for the treatment of TTS.

Strength of evidence No Recommendation, Insufficient Evidence (I)
Level of confidence Low

Rationale

Phonophoresis has not been examined for the treatment of TTS in quality studies. It is believed to be less effective than glucocorticosteroid injections (Aygul et al., 2005). Phonophoresis is not invasive, has low adverse effects, and is moderately costly. However, other treatments have documented efficacy and should be used preferentially.

Evidence

There are no quality studies evaluating phonophoresis for treating TTS patients.

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INJECTION THERAPIES

GLUCOCORTICOSTEROID INJECTIONS FOR TARSAL TUNNEL SYNDROME

Recommended

Glucocorticosteroid injections are recommended as part of a conservative management strategy for the treatment of TTS.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence Moderate

Rationale

There are no quality studies evaluating the effects of corticosteroid injections in treating TTS. Injections are commonly reported as part of conservative therapy and as an additional mode for confirmation of suspected diagnosis of TSS. Corticosteroid injections are useful in other entrapment syndromes, particularly CTS (see Hand, Wrist, and Forearm Disorders guideline), and have been reported helpful for TTS. There are no data on recurrence or long-term benefits. This option is invasive, but low cost and has few side effects. Thus, if a more conservative treatment strategy fails to improve the condition, glucocorticosteroid injections may be useful. There is no quality information on the frequency or number of injections (see CTS in Hand, Wrist, and Forearm Disorders guideline).

INSULIN INJECTIONS FOR TARSAL TUNNEL SYNDROME

Not Recommended

Insulin injections are not recommended for the treatment of TTS.

Strength of evidence Not Recommended, Insufficient Evidence (I)
Level of confidence High

Rationale

There are no quality studies on TTS patients and the use of insulin injection into the tarsal tunnel. This technique has been described for CTS patients and by inference may have application to TTS. However, this treatment is invasive, requiring 7 weekly injections, may have adverse effects that also require ascertainment, and is moderate to high cost.

BOTULINUM INJECTIONS FOR TARSAL TUNNEL SYNDROME

Not Recommended

Botulinum injections are not recommended for the treatment of TTS.

Strength of evidence Not Recommended, Insufficient Evidence (I)
Level of confidence High

Rationale

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There is no quality evidence for the use of botulinum injections in TTS patients. However, there is one quality study which included CTS patients that does not show clear benefit, but did show weakness in two patients lasting a few weeks (Breuer et al., 2006). Botulinum injections are invasive, have adverse effects that include fatalities (Li et al., 2005), and are costly. These injections are not recommended for the management of TTS.

SURGICAL CONSIDERATIONS

SURGICAL RELEASE FOR SPACE-OCCUPYING LESIONS IN TARSAL TUNNEL SYNDROME

Sometimes Recommended

Surgical release of posterior tibial nerve impingement at the tarsal tunnel is recommended upon failure of conservative treatment and in the presence of a space-occupying lesion. Surgical release for cases with nonspecific causes are otherwise expected to have mixed results. Patients should be counseled regarding potential lack of benefit before consideration of surgery. There is no recommendation for any specific technique as there is a lack of quality evidence.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence Moderate

Rationale

Surgical intervention is controversial as there are no quality trials comparing surgery with conservative care methods, or any quality studies evaluating the overall efficacy of surgical intervention. Further, although surgical techniques have changed over time, there are no comparison studies of techniques. The majority of TTS cases described in the literature ultimately resulted in surgical release. Case reports and series generally report space occupying lesions are responsible for symptoms in many cases, although there is no data to indicate what percentage of overall TTS. There are few data reported on complications, efficacy of symptom relief, or correction of neurosensory deficits post surgery. Results of a case series (n = 32 feet) of patients undergoing surgical release and followed longitudinally 24 to 118 months found only 44% had good or excellent results with 48% dissatisfied with the results (Pfeiffer et al., 1994). Somewhat similar to CTS, no correlation was found between pre-operative electrodiagnostic results and clinical results (negative versus positive versus not done). The only reliable predictor of favorable result was identification of an anatomic lesion. Another case series (n = 34) comparing patients who had surgery with those who did not, report 50% efficacy of conservative treatment, whereas surgical decompression effectively relieved some symptoms in 79% of cases, although varied by diagnosis. The authors concluded aggressive treatment is warranted, although the prognosis overall is mixed, and should be preceded by a trial of conservative therapy prior to surgical release (Linscheid et al., 1970). Finally, the author in a case series of 108 ankles (72 patients) surgically released after failure of conservative treatment patients concluded that patients operated on sooner than 12 months after onset of symptoms had significantly higher postoperative scores on the Maryland Foot Score tool at 12 month follow-up than those with longer duration of symptoms, although both groups showed significant improvement in scores compared with preoperative measurements (Sammarco et al., 2003).

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RETURN TO WORK

WORK RESTRICTIONS FOR TARSAL TUNNEL SYNDROME

No Recommendation

There is no recommendation for or against the use of work restrictions for the treatment of TTS.

Strength of evidence No Recommendation, Insufficient Evidence (I)
Level of confidence Low

Rationale

There are no quality studies of workplace restrictions. Whether patients improve more quickly with activity limitations has not been shown. Additionally, there is no quality evidence that activities cause or worsen tarsal tunnel syndrome. Restrictions are not invasive, likely have few adverse effects, but may be moderate to high cost depending on length. There is no recommendation for or against workplace activity limitations.

RETURN-TO-WORK PROGRAMS FOR TARSAL TUNNEL SYNDROME

Recommended

Return-to-work programs are recommended for patients with TTS, particularly those with significant lost time.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence Low

Rationale

There are no quality studies that review the types of return-to work programs typically found in the U.S. These programs are thought to reduce morbidity and improve function. They are not invasive, have minimal potential for adverse effects and are not costly. Return-to-work programs are recommended for management of TTS patients with lost time, and may be helpful for proactive emphases on functional recovery.

Evidence

There are no quality studies incorporated into this analysis (see Chronic Pain guideline for additional studies).

TENOSYNOVITIS (INCLUDING STENOSING TENOSYNOVITIS)

OVERVIEW

Tendon entrapment generally has a simple presentation. Some occur after acute injury, but most occur without a specific inciting event.

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The ankle usually appears normal, although there may be visible tendon sheath edema. Edema is more common with inflammatory conditions (e.g., rheumatoid arthritis) or infections. Swelling and crepitus may indicate peritendinitis if there is no inflammatory or infectious disease. Tenderness occurs over the affected tendon and compartment. Pain in the affected compartment is generally present with provocative maneuvers (e.g., resisted use of the muscle-tendon unit).

There are no special tests that are typically performed for compartment tenosynovitis. X-rays are usually not helpful. The threshold for testing for confounding conditions such as diabetes mellitus and hypothyroidism should be low, particularly in the presence of and to prevent other morbidity. Yet, boney deformities may contribute to the tenosynovitis and occult fractures may occur also producing low thresholds for testing in certain circumstances. There are reports of MRI findings including tendinopathy, tendinosis, tenosynovitis, tears, subluxation and entrapment in ankle-foot tendinopathy [71,369,370]; however, the utility of MRI has not been demonstrated in quality studies.

TREATMENT RECOMMENDATIONS

OVERVIEW

Initial care usually involves limitation of the physical factors thought to be contributing. Walking casts or boots, splints, or braces for compartment tendinoses may be helpful especially in moderate to severe cases. NSAIDs are often prescribed for initial treatment. The efficacy and optimal timing of other treatment, such as corticosteroid and other injections, is unclear.

Follow-up visits are generally required every 1 or 2 weeks to evaluate efficacy of interventions until resolution of the condition.

MEDICATIONS

NSAIDS FOR ACUTE, SUBACUTE, OR CHRONIC ANKLE COMPARTMENT TENOSYNOVITIS

Recommended

NSAIDs (oral or topical) are recommended to control pain associated with acute, subacute, or chronic ankle compartment tenosynovitis.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence Moderate

Indications

Patients with ankle compartment tendinosis.

Frequency/Dose/Duration

Optimal dose is unknown and there are no quality studies comparing different NSAIDs. Regularly scheduled dosing is recommended for acute, significantly symptomatic presentations.

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Indications for discontinuation

Failure to respond, development of adverse effects, resolution.

Rationale

There are no quality studies that address the use of NSAIDs controlling pain associated with ankle compartment tenosynovitis. By analogy, NSAIDs are often used to treat pain associated with wrist compartment tendinoses (Jirarattanaphochai K, 2004, Mazieres et al., 2005, Piligian G, 2000, Hanlon DP, 1999, Idler RS, 1990, Steinberg D, 2015, Pantukosit S, 2001) and there is one quality study demonstrating efficacy of a ketoprofen patch versus placebo (Mazieres et al., 2005). As a NSAID patch has been demonstrated to be efficacious compared to placebo for the wrist, it is assumed that other topical forms are also efficacious. NSAIDs are not invasive, have low adverse effects in employed populations, and are low cost, thus they are recommended.

Evidence

There are no quality studies evaluating the use of NSAIDs for compartment tenosynovitis.

DEVICES

WALKING BOOTS, CASTS, SPLINTS, AND BRACES FOR ACUTE AND SUBACUTE ANKLE COMPARTMENT TENOSYNOVITIS

Recommended

Walking boots, casts, splints, and braces are recommended for treatment of acute and subacute ankle compartment tendinoses.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence Low

Indications

Patients with compartment tendinosis.

Frequency/Dose/Duration

Worn while ambulating.

Indications for discontinuation

Failure to respond or resolution.

Rationale

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There are no quality studies evaluating walking boots and splints/braces for compartment tenosynovitis. These are not invasive, have few adverse effects, and are not costly; thus, they are recommended.

ALLIED HEALTH INTERVENTIONS

IONTOPHORESIS FOR ACUTE AND SUBACUTE ANKLE COMPARTMENT TENOSYNOVITIS

Recommended

Iontophoresis treatments using glucocorticosteroids and sometimes NSAIDs are recommended for ankle compartment tenosynovitis.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence Low

Indications

Patients with ankle compartment tendinosis. Generally those who either fail to respond adequately to NSAIDs, splints, and activity modifications or decline injection.

Frequency/Dose/Duration

Glucocorticosteroid is generally used. However, quality studies of the elbow have documented successful treatment of lateral epicondylalgia with NSAIDs administered via iontophoresis (see Elbow Disorders guideline), thus they appear reasonable for this indication as well. Generally 2-3 appointments to ascertain efficacy; an additional 4-6 appointments may be scheduled if efficacious. If improvements continue at 6 appointments, an additional 4-6 appointments are reasonable.

Indications for discontinuation

Failure to respond, development of adverse effects, resolution.

Rationale

There are no quality studies evaluating iontophoresis for ankle compartment tenosynovitis. Iontophoresis is not invasive, has low adverse effects, but is moderate to high cost depending on the number of treatments. Iontophoresis with either a glucocorticoid or NSAID is recommended for select patients who fail to respond to other treatments or who decline injection.

MANIPULATION AND MOBILIZATION FOR ACUTE, SUBACUTE, OR CHRONIC ANKLE TENOSYNOVITIS

No Recommendation

There is no recommendation for or against the use of other non-operative interventions (i.e., manipulation and mobilization, massage, deep friction massage, or acupuncture) for the treatment of acute, subacute, or chronic ankle tenosynovitis as other interventions

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have proven efficacy and are preferentially indicated for initial and subsequent treatment options.

Strength of evidence No Recommendation, Insufficient Evidence (I)
Level of confidence Low

Rationale

There are no quality studies evaluating other non-operative interventions for ankle tenosynovitis. Other treatments have evidence of efficacy for treatment of the wrist and thus they are recommended by analogy.

MASSAGE FOR ACUTE, SUBACUTE, OR CHRONIC ANKLE TENOSYNOVITIS

No Recommendation

There is no recommendation for or against the use of other non-operative interventions like massage or deep friction massage for the treatment of acute, subacute, or chronic ankle tenosynovitis as other interventions have proven efficacy and are preferentially indicated for initial and subsequent treatment options.

Strength of evidence No Recommendation, Insufficient Evidence (I)
Level of confidence Low

Rationale

There are no quality studies evaluating other non-operative interventions for ankle tenosynovitis. Other treatments have evidence of efficacy for treatment of the wrist and thus they are recommended by analogy.

ACUPUNCTURE FOR ACUTE, SUBACUTE, OR CHRONIC ANKLE TENOSYNOVITIS

No Recommendation

There is no recommendation for or against the use of other non-operative interventions like acupuncture for the treatment of acute, subacute, or chronic ankle tenosynovitis as other interventions have proven efficacy and are preferentially indicated for initial and subsequent treatment options.

Strength of evidence No Recommendation, Insufficient Evidence (I)
Level of confidence Low

Rationale

There are no quality studies evaluating other non-operative interventions for ankle tenosynovitis. Other treatments have evidence of efficacy for treatment of the wrist and thus they are recommended by analogy.

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INJECTION THERAPIES

GLUCOCORTICOSTEROID INJECTIONS FOR ACUTE, SUBACUTE, OR CHRONIC ANKLE TENDINOSIS

Recommended

Glucocorticosteroid injections are recommended for treatment of acute, subacute, or chronic ankle tendinosis.

Strength of evidence Recommended, Insufficient Evidence (I)
Level of confidence Moderate

Indications

Ankle symptoms of pain over a compartment. Generally at least 1 week of non-invasive treatment to determine if condition will resolve without invasive treatment. It is reasonable to treat cases with an initial injection although there is no quality evidence to support that approach. Failure or suboptimal results with an initial injection result in a need for additional injection(s) in a minority of patients which is (are) usually successful (Anderson BC, 1991, Sakai N, 2002, Peters-Veluthamaningal C, 2009).

Frequency/Dose/Duration

Optimal dose is unknown. Studies in the wrist have utilized methylprednisolone acetate 40mg (Anderson BC, 1991, Goldfarb CA, 2007, Witt J, 1991), and triamcinolone acetonide 10mg (Sakai N, 2002, Peters-Veluthamaningal C, 2009). An adjuvant injectable anesthetic is typically used (Anderson BC, 1991, Sakai N, 2002, Jirarattanaphochai K, 2004). It is recommended that a single injection be scheduled and the results evaluated to document improvement (Peters-Veluthamaningal C, 2009). Failure of a response within 1-2 weeks should result in reanalysis of the diagnosis and consideration of repeat injection (Peters-Veluthamaningal C, 2009). Recurrence of symptoms months later should result in consideration of re-injection (Anderson BC, 1991, Lapidus PW, 1972). While there is no evidence-based maximum number of injections to treat an episode or over a lifetime, more than 3 injections in a year should be avoided due to tendon weakening and risk of rupture. Recurring injections on a year after year basis should also be similarly avoided.

Indications for discontinuation

If a partial response, consideration should be given to repeating the injection, typically at a modestly higher dose.

Rationale

There are no quality studies that address glucocorticosteroid injections for ankle tendinosis. By analogy, there is one moderate-quality study comparing glucocorticosteroid injections with placebo for treatment of de Quervain's stenosing tenosynovitis (Peters-Veluthamaningal C, 2009). The trial showed considerable benefits from active treatment

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that persisted for 12 months and allows for an evidence-based recommendation. Another high-quality trial found no additive benefit of NSAID in addition to injection to prevent recurrence but did not assess reductions in pain immediately after injection thus appears to have no bearing on use of NSAIDs for those purposes (Jirarattanaphochai K, 2004). (A low-quality trial found glucocorticosteroid injection superior to splinting in pregnant and lactating females (Avci S, 2002).) These injections are minimally invasive, have low adverse effects and are low to moderate cost. Thus, they are recommended to treat ankle tendinosis.

Evidence

There are no quality studies evaluating the use of glucocorticosteroid injections for ankle tendinosis.

SURGICAL CONSIDERATIONS

SURGICAL RELEASE FOR SUBACUTE OR CHRONIC ANKLE TENOSYNOVITIS

No Recommendation

There is no recommendation for or against the use of surgical release for patients with subacute or chronic ankle tenosynovitis who fail to respond to injection (Lapidus PW, 1972)**.**

Strength of evidence No Recommendation, Insufficient Evidence (I)
Level of confidence Low

Indications

Ankle tenosynovitis that fails to respond to non-operative interventions generally including at least 2 glucocorticosteroid injections. May be indicated without prior injection(s) if there is a clear contraindication for injections. Tendinous ruptures are often surgically treated.

Rationale

There are no quality studies evaluating the use of surgical release for ankle tenosynovitis. It may be a last resort for patients who have failed glucocorticosteroid injection(s) and other non-invasive treatments, but no recommendation is offered. A non-randomized study of 27 patients who underwent arthroscopic release for flexor hallucis longus tenosynovitis found 81% to have returned to the same level of activity prior to the injury (Corte-Real NM, 2012). In another study, 13 female ballet dances underwent operative release of the flexor hallucis longus tendon due to stenosing tenosynovitis. After a mean follow-up time of six years and six months, the authors found the treatment to be effective. All patients returned to dancing within 5 months, and 11 reached full participation (Kolettis GJ, 1996).

WOUND CARE, SUBUNGUAL HEMATOMA, AND CONTUSIONS

See Hand, Wrist, and Forearm guideline.

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FOLLOW-UP CARE

Patients with ankle and foot complaints should have re-evaluations dependent on their condition. Evaluations as frequently as three days after return to work, change in work limitations, or treatment may be appropriate, including to provide counseling on avoiding static positions, medication use, activity modification, and other concerns. Care should be taken to answer questions and make these sessions interactive so that the patient is fully involved in his or her recovery. These interactions may be done on site or by telephone. Most treatment tested in clinical trials is delivered for short periods, usually no more than 4 weeks, and the effect of treatment is usually evident within a month. When treatment has little or no effect, using the timeframes indicated in Table 4 for guidance, a change in treatment approach should be considered.

After a patient has accepted all reasonable medical treatment and the condition demonstrates stabilization, a point of **maximal medical improvement** (MMI), also known as a “medical end point” or “medical end result,” has been reached. When a point of maximal medical improvement is reached with full recovery, the patient should be discharged from treatment of the work-related ankle-foot problem. When a point of MMI is reached without full recovery, permanent activity limitations and ongoing treatment (if necessary) should be specified.

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TABLES

TABLE 1. RED FLAGS FOR POTENTIALLY SERIOUS ANKLE AND FOOT CONDITIONS

Disorder	Medical History	Physical Examination
Dislocation	Significant ankle or foot trauma Ankle or foot deformity with or without spontaneous reduction or self-reduction	Edema Deformity
Fracture	Significant trauma Abnormal mobility Deformity with or without spontaneous or self- reduction Painful swelling of ankle or foot	Edema Ecchymosis or hematoma Deformity Abnormal mobility Bony crepitus
Infection	Swelling, redness, localized warmth of ankle or foot Fever or chills Diabetes or immunosuppression (e.g., transplant, chemotherapy, HIV)	Visible and/or palpable mass Local tenderness, heat, swelling, erythema Systemic signs of infection (fever, tachycardia)
Inflammation	Inflammatory arthritis or autoimmune disease	Swelling, effusion, erythema, warmth, or edema
Metabolic disorder	Poor nutrition Changes in weight, appetite, energy level, skin, or bowel or bladder function Hair loss	
Acute gout	Sudden attack(s) of joint pain, redness, and swelling, usually monarticular, especially of the great toes Predisposing factors of being a man or post-menopausal woman, renal impairment, hyperuricemia, and use of diuretics or cytotoxic drugs [371]	Swelling Red, tender, warm first metatarsal joint
Neoplasm	Neoplastic disorder Unexplained weight loss, fatigue, masses	Palpable mass Deformity of ankle or foot
Rapidly progressive neurological compromise	Neuropathy, decreased or absent sensation Neurologic disease Diabetes Dislocation or fracture	Decreased sensation in feet and ankles Loss of vibratory or positional sense Altered sensation in a dermatomal distribution Absent ankle jerk

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	May have sustained laceration, or direct trauma	Motor loss in specific distribution Painless swelling (Charcot's joint)
Rapidly progressive vascular compromise	Diabetes Peripheral vascular disease or bypass grafts Dislocation or fracture May have sustained laceration, or direct trauma	Decreased or absent foot and ankle pulses Decreased capillary filling Cold, pale extremity
Tendon ruptures and evulsions		
Achilles	Sharp pain to the posterior distal calf or ankle, may be accompanied by loud pop Forceful plantarflexion of the foot, or unaccustomed and vigorous running, hiking, or climbing May have sustained laceration, open wounds, crush injuries, or direct trauma May have degloving injury Administration of fluoroquinolones or local injections [371]	Swelling and bruising Inability to point foot downward and stand or walk comfortably Positive Thompson test May have overlying signs of trauma including laceration, open wounds, puncture wounds, crush injuries
Peroneal	Pain and swelling of the lateral heel May have sustained laceration, open wounds, crush injuries, or direct trauma May have degloving injury	Impaired eversion strength [372] May have overlying signs of trauma including laceration, open wounds, puncture wounds, crush injuries
Tibialis, Anterior	Swelling and pain in the anterior ankle May have sustained laceration, open wounds, crush injuries, or direct trauma May have degloving injury	Anterior ankle tenderness, probable impaired dorsiflexion strength, tenderness at the first metatarsotarsal joint [373] May have overlying signs of trauma including laceration, open wounds, puncture wounds, crush injuries
Tibialis, Posterior	Medial ankle pain and swelling, particularly if behind the medial malleolus, new or progressive flatfoot deformity (with or without pain) May have sustained laceration, open wounds, crush injuries, or direct trauma May have degloving injury	Flatfoot deformity, particularly when unilateral; tenderness of the posterior medial malleolus [374,375], asymmetrical flat foot, difficulty with ipsilateral heel raise [376,377] May have overlying signs of trauma including laceration, open wounds, puncture wounds, crush injuries

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TABLE 2. NON-RED-FLAG CONDITIONS THAT CAN BE MANAGED BY PRIMARY CARE PHYSICIANS

Probable Diagnosis or Injury	Mechanism	Unique Symptoms	Unique Signs	Tests and Results
Ankle sprain	Inversion of ankle Eversion of ankle	Pain at or below lateral or medial malleolus Swelling over or near malleolus	Swelling at or below malleolus Tenderness over medial or lateral ankle ligament With severe sprain, positive drawer sign for instability	None (radiograph negative if obtained)
Forefoot sprain	Plantar flexion, dorsiflexion, or inversion beyond range	Dorsal foot pain Swelling of dorsal foot	Swelling in dorsum of foot Tenderness over dorsum of foot	None (radiograph negative if obtained)
Ankle or foot tendonitis	May be idiopathic, due to inflammatory conditions, and speculatively due to overuse	Heel cord pain Pain over specific tendon unit with plantarflexion or dorsiflexion	Pain over muscle/tendon unit on motion or resisted motion of tendon unit Tenderness of involved tendon	None
Neuroma	Idiopathic	Gradual onset of pain and paresthesias on both sides of web space	Reproduction of symptoms by pressing metatarsals together or pressing web space	None
Metatarsalgia	Idiopathic Degenerative changes Prolonged weight bearing	Gradual onset of pain under metatarsal heads with weight bearing	Reproduction of metatarsal pain on compression Decreased tissue padding under metatarsal heads	None
Bunion , hallux valgus	Degenerative change	Lateral deviation of first toe Pain in first toe from overlap with tight footwear	Lateral angulation of great toe	Metatarsal angle of >10°
Plantar fasciitis	Idiopathic	Pain across sole of foot Pain with 1st step upon rising in the morning	Tenderness on compression of plantar fascia	None
Heel spur	Degenerative change Idiopathic	Pain at heel with weight bearing	Point tenderness over plantar calcaneus	Radiograph positive for plantar

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		First steps upon rising in the morning very painful in heel		calcaneal spur (if obtained)
Metatarsal stress fracture	Repetitive load	Pain in the dorsal forefoot on weight bearing	Point tenderness over metatarsal shaft	Radiograph positive later in course of disorder Bone scan or spiral CT positive
Toe fracture	Direct trauma	Pain at fracture site (possibly)	Point tenderness Deformity Hematoma	Positive radiograph
Crush injury	Direct trauma	Ranges from nonspecific pain to pain at fracture site	Point tenderness Deformity Hematoma Swelling	Positive radiograph(s)
Nonspecific foot or ankle pain	Unknown	Nonspecific pain in foot or ankle	None	None

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TABLE 3. POSTOPERATIVE REHABILITATION PROTOCOL

	0-2 weeks	2-4 weeks	4-6 weeks	6-8 weeks	8-12 weeks	12-16 weeks	16-24 weeks
Foot/Ankle Position	Cast : Neutral (0°); Brace: neutral (0°)	Cast: Neutral (0°); Brace: neutral (0°)	Cast: Neutral (0°); Brace: neutral (0°)	Cast removed at 8 weeks; Brace removed at 6 weeks, 1cm heel raise for 2 to 4 more weeks.	No restriction on range of ankle movement	No restriction on range of ankle movement	No restriction on range of ankle movement
Weight Bearing	No recommendation with crutches on flat surface	Yes, flat surfaces, no tiptoes on stairs	Yes, flat surfaces, no tiptoes on stairs	Yes, flat surfaces, no tiptoes on stairs	Full	Full	Full
Physical Therapy Activities	None	Cast: ROM of toes, knee, hip joints. Isometric contraction of calf muscles. Brace: with leg dangling, active DF to neutral, passive PF	Cast: ROM of toes, knee, hip joints. Isometric contraction of calf muscles. Brace: with leg dangling, active DF to neutral, passive PF	At 8 weeks begin progressive heel raise; begin resistance exercises with tubing.	Begin closed chain exercises, stationary cycling, swimming	Eccentric/ concentric exercises. Closed chain exercises, stationary cycling, swimming	Jogging, sports specific activities, running. Full sport at 6 months.

Derived from [180,181] with modifications from [163,172,177,178,179].

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TABLE 4. NONOPERATIVE REHABILITATION PROTOCOL

	0-2 weeks	2-4 weeks	4-6 weeks	6-8 weeks	8-12 weeks	12-16 weeks	16-24 weeks
Foot/Ankle Position	Fixed Equinus (30° PF)	Cast: fixed at 15° plantar flexion at 2 weeks. Brace: allow 15-30° plantar flexion range	Cast: Fixed at neutral Brace: Allow 0°-30° Plantar flexion range	Cast and brace removed at 8 weeks, 1cm heel raise for 2 more weeks.	No restriction on range of ankle movement	No restriction on range of ankle movement	No restriction on range of ankle movement
Weight Bearing	None	No recommendation; with crutches on flat surface	Yes; flat surfaces, no tiptoes on stairs	Yes; flat surfaces, no tiptoes on stairs	Full	Full	Full
Physical Therapy Activities	None	Cast: ROM of toes, knee, hip joints. Isometric contraction of calf muscles. Brace: with leg dangling, active DF to neutral, passive PF	Cast: ROM of toes, knee, hip joints. Isometric contraction of calf muscles. Brace: with leg dangling, active DF to neutral, passive PF	8 weeks begin progressive heel raise. Begin resistance exercises with tubing.	Begin closed chain exercises, stationary cycling, swimming	Eccentric/ concentric exercises. Closed chain exercises, stationary cycling, swimming	Jogging, sports specific activities, running. Full sport at 6 months.

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TABLE 5. DIAGNOSIS OF PLANTAR FASCIITIS

Author/Year	Number of Subjects with Heel Pain (# of Painful Heels)	Plantar Fascial Thickness of Painful Heels (mm±SD)	Number of Controls (# of Heels)	Plantar Fascial Thickness of Controls	Comments
Abdel-Wahab 2008	17 (23)	4.9 ± 1.3	11 (22)	1.7 ± 0.06	Ultrasound, controls not matched
Berkowitz 1991	8 (9)	7.40 ± 1.17 sagittal 7.56 ± 1.01 coronal	5 age- and sex-matched; 5 unmatched	3.22 ± 0.44 sagittal 3.44 ± 0.53 coronal	MRI
Akfirat 2003	25	4.75	15	3.37 mm	Ultrasound
Cardinal 1996	15 (19)	5.2 ± 1.13	15 (11) asymptomatic heels of patients, and 15 asymptomatic persons	2.9 mm ± 0.70 2.6 mm ± 0.48	Ultrasound
Gibbon 1999	190 (297)	5.9 in unilaterally and 6.0 in bilaterally effected subjects	58	3.3mm in completely asymptomatic and 3.6 mm in unaffected side of unilateral subjects	Ultrasound
Kane 2001	28 (23)	5.7 ± 0.3	28 (5)	3.8±0.2	Ultrasound, longitudinal view, asymptomatic heels of patients served as control
Tsai 2000	102 (123)	5.47±1.09 in persons with bilateral heel pain; 5.61±1.19 in those with bilateral heel pain	33	3.83±0.7 in asymptomatic heels of heel-pain patients; 3.19±0.43 in asymptomatic subjects	Ultrasound, demographic characteristics documented included age, BMI, and sex, which were not different between heel pain patients and controls
Vohra 2002	109 (211)	5.35 in symptomatic bands		2.70 in asymptomatic bands	Ultrasound, thickness of lateral and medial bands measured and reported

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TABLE 6. CLASSIFICATION SCHEMES FOR ENERGY LEVELS OF SHOCKWAVE THERAPY

Classification Scheme	Energy Level	Energy Flux Density Range (mJ/mm^2)
Mainz	Low	0.08-0.27
	Medium	0.28-0.59
	High	>0.60
Kassel	Low	<0.12
	High	>0.12

TABLE 7. DIFFERENTIAL DIAGNOSIS OF ACUTE ANKLE SPRAIN

- Lateral ligament sprain
- Medial ligament sprain
- Syndesmotic injury
- Physeal fractures
- Osteochondral fractures
- Lateral process fracture of the talus
- Posterior process fracture of the talus
- Anterior process fracture of the calcaneus
- Fracture of the base of the fifth metatarsal
- Fracture of the base of the fifth metaphyseal-diaphyseal junction (Jones Fracture)
- Peroneal tendon subluxation/dislocation
- Malleolar fracture
- Calcaneocuboid joint sprain

APPENDIX 1: LOW-QUALITY RANDOMIZED CONTROLLED TRIALS AND NON-RANDOMIZED STUDIES

The following low-quality randomized controlled studies (RCTs) and other non-randomized studies were reviewed by the Evidence-based Practice Ankle and Foot Panel to be all-inclusive, but were not relied upon for purpose of developing this document's guidance on treatments because they were not of high quality due to one or more errors (e.g., lack of defined methodology, incomplete database searches, selective use of the studies and inadequate or incorrect interpretation of the studies' results, etc.), which may render the conclusions invalid. ACOEM's Methodology requires that only moderate- to high-quality literature be used in making recommendations [(378)].

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FOOT ULCERATIONS

Author/Year Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments
Patient Education						
(379) RCT No mention sponsorship or COI.	3.5	N = 1939 with diabetes. Age range 18.7 -95.8 years in intervention group and 18.0 -93.6 years in the control group.	Intervention group: explanatory practice visits and foot care education (n = 981) vs. Control group (n = 958). Follow-up for 6 months.	There was a significantly greater change of attitude about foot care in intervention group (p = 0.01). Intervention group had better attitudes towards personal foot care by 2.5% vs. 0.2% decrease in control group (p = 0.027). Small improvement in knowledge score within intervention group with mean percentage change of 1.1 (p = 0.015) and 1.3 in control group (p = 0.002).	"Provision of integrated care arrangements for the diabetic foot has a positive impact on primary care staffs' knowledge and patients' attitudes resulting in an increased number of appropriate referrals to acute specialist services."	Pragmatic RCT. Health care professionals. Knowledge of diabetic footcare improved in intervention group (p <0.001).
Wound Dressings						
(380) RCT Sponsored by Johnson & Johnson Wound Management.	3.5	N = 276 diabetics with a foot ulcer >30 days, rating grade 1 to 2 on Wagner scale and area ≥1cm; Mean age 58.3 years for both groups.	Promogran Group (n = 138) vs. Moistened gauze control Group (n = 138). Assessments at baseline and 12 weeks.	No significant results of improvement reported for Promogran group versus moistened gauze control group.	"[W]e have shown that Promogran, a wound dressing consisting of collagen and oxidized regenerated cellulose, was as effective as moistened gauze in promoting wound healing in diabetic foot ulcers,…"	Data suggest mostly comparable results. Sparse methodology.
(381) RCT	3.0	N= 40 diabetic patients with Wagner grade 1 or 2 ulcers.	Bensal HP group-Benzoic Acid 6%, Salicylic acid 3% and extract from	At 6 week follow-up wound diameter decreased in both	"In this tightly controlled and random study, Bensal HP not	Blinding only mentioned without details. Sparse baseline

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No mention of sponsorship or COI.		Mean age was not provided.	Q rubra, 3%. Application daily every 12 hours (n=20) vs. SSC Group- Silver Sulfadiazine cream. Application every 12 hours daily (n=20). Follow-up for 6 weeks.	groups; difference approached significance for Bensal HP vs. SSC group; 72.5% reduction vs. 54.7% (p = 0.059). Reductions significant in both groups compared to baseline (p = 0.016). Effect size of Bensal HP was 2.06 vs. 1.03 in SSC group.	only served as an adequate adjunct to generally accepted wound care, but also convincingly outperformed SSC used in the control."	comparability details.
(382) RCT No mention of sponsorship or COI.	1.5	N= 30 with Wagner's grade-II diabetic foot ulcers. Mean age: 52.1 years.	Honey dressing group (pH of 6.5, glucose 321mmol/l and specific gravity of 1.003) vs. standard dressing group (iodine solution 10%).	Mean healing time in standard dressing group vs. Honey group: 15.4 days (range 9-36 days) vs. 14.4 days (range 7-26 days); p<0.005	"Honey dressing is a safe alternative dressing for Wagner grade-II diabetic foot ulcers."	Sparse methodological and sample size.
Negative Pressure Therapy (Vacuum) Wound Care Systems						
(383) RCT No mention of sponsorship or COI.	3.0	N = 60 with non-ischemic diabetic foot ulcers, type 1 or 2 diabetes mellitus; Mean (±SD) age 51.5 (±7.6) for treatment group and 55.3 (±9.0) for control group	Compressed air massage group receiving 15-20 minutes of treatment (1 bar; 100kPa pressure) daily 5x a week until healed or administered skin graft (n = 30) vs. Control group (n = 30). Both groups received standard wound care for their ulcers.	Mean (±SD) time of ulcer healing in days significantly greater in air massage group versus control group: Air massage – 58.1 (±22.3) vs. control – 82.7 (±30.7), (p = 0.001). No significant results reported between groups for Wagner grade and ulcer size, Wagner size and time to healing and ulcer size and time to healing.	"Compressed air therapy can be viewed as a variant of pneumatic compression. It appears to be a safe and simple treatment modality, which, when added to standard medical and surgical management of infected diabetic ulcers, enhances ulcer healing. Further studies with this treatment modality are warranted"	Sparse descriptive data. Data suggest faster healing.
Foot Waffle Support Brace						
(120)	1.5	N=52 patients within age	Pillow positioned under both legs	Both groups Odds Ratio of 4.38 with	"[T]he results of this study did not	Data suggest use of foot

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RCT		range 27 to 90 years (M=66.6, SD=16.5)	from below knee to Achilles tendon region, leaving heels suspended above (Pillow group) vs. Foot waffle placed on each leg (Foot waffle group) Patient's position order supine then right lateral tilt or right lateral tilt then supine.	interface pressure >0mm Hg 4 times often with foot waffle than pillow. Significant difference between groups in skin changes (p = 0.036). Difference between groups in mean length of survival; pillow group vs. foot waffle (13 vs. 10 days)	support the use of the previously designed foot waffle for continuous heel elevation."	waffle device led to earlier development of foot ulcers although both groups ultimately developed foot ulcers.
Growth Factors						
Becaplermin						
(384) RCT No mention of sponsorship or COI.	3.0	N = 118 with chronic, full-thickness, lower-extremity diabetic neurotrophic ulcers of at least 8 weeks'; Mean Age was 60.8 years.	PDGF group- rhPDGF-BB (Becaplermin) gel applied at dose equivalent to 2.2 micrograms until completely healed, or 20 weeks (n = 61) vs. Placebo Gel Group- Saline Gel (n = 57). Follow-up for 20 weeks	At 20 weeks, 29 (48%) of patients treated with PDGF showed complete wound healing (functional assessment score of 1) compared with 14 (25%) of placebo group (p = 0.01). From day 68 to end of trial a difference of 30-40 days in time to complete wound healing observed in favor of PDGF group (p = 0.01).	"…demonstrated that repeated, once-daily, topical application of rhPDGF-BB is safe and stimulates rapid heating of chronic, full-thickness neurotrophic ulcers of the lower extremity in patients with diabetes mellitus.	Sparse study design details. Wound healing in experimental group was 2x vs. placebo.
Topical nerve growth factor (TNGF)						
(119) RCT	3.0	N = 38 patients with pressure ulcers on foot. Mean age of participants was 80.3 years.	2.5 S murine nerve growth factor used (topical nerve growth factor treatment, n=18) vs. (topical conventional treatment, n = 18). Balanced salt solution used as placebo and	Mean area (±SD) of ulcers between groups after 6 weeks treatment; treatment group vs. controls (274±329 mm2 vs. 526±334 mm2) p = 0.022. Reduction in ulcer area after adjustment for	"Topical application of nerve growth factor may be an effective therapy for patients with severe pressure ulcers."	1 patient from treatment group died and another from control group lost to follow-up. Topical treatment with NGF appears effective for treatment of

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			dropped on lesion in similar way with topical nerve growth factor solution. Both groups received same daily local care, NS irrigation, debriding enzymes, and opaque hydrocolloid occlusive barriers. Assessment at 6 weeks.	potential confounders; treatment vs. control group (6.5±0.3mm2 vs. 5.9±0.3 mm2) p <0.001		foot pressure ulcers
(385) RCT Sponsored by the Jinan City 2009 Technology Development Program. No mention of COI.	2.5	N = 60 with refractory chronic skin ulcers, which persisted for >1 month. Aged between 20 and 75 years with an average age of 50.6.	Group A or rhGM-CSF paste covered by alginate dressing (n = 20) vs Group B or rhGM-CSF only, applied to wounds (n = 20) vs Group C or Conventional vaseline dressing gauze applied (n = 20). Follow-up for 21 days.	Healing: highest healing rate of 56% for group A vs group C and B had a healing rate of 21 and 34%, respectively. Group showed significantly reduced pain vs groups B and C, (p <0.05).	"[T]he combined application of alginate dressing and rhGM-CSF for the treatment of refractory chronic skin ulcers demonstrated significant advantages."	Non-specific to diabetic ulcers. Sparse methods and baseline data combination of alginate and rhGM-CSF promoted faster wound healing compared to rhGM-CSF or conventional therapy.
(386) RCT No sponsorship or COI.	3.0	N = 18 patients with diabetic foot ulcers corresponding to grade 2 of University of Texas Diabetic Foot Wound Classification system. Mean Age 58.2 ± 8.07 Experimental group and 57.6 ± 8.02 Control group.	Experimental group (n = 9) received Vacuum-Compression Therapy (VCT) and conventional therapy vs. Control group (n = 9) received conventional therapy only. 12 sessions during 3 weeks, follow-up not clarified.	After 10 VCT sessions or conventional therapy sessions, surface area of foot ulcer diminished. Experimental showed a larger improvements in reduced surface area than control group. It is also believed that the VCT systems using negative pressure helps to improve oxygenation to tissues affected by vascular insufficiency and diabetes.	"Our results showed that VCT with conventional therapy more effectively healed diabetic foot ulcers than conventional therapy alone. VCT effectively prompted capillary filling and therefore helped patients with arterial circulation problems. Thus, for wound healing and limb preservation, we recommend VCT, in addition to conventional therapy, for	VCT administered 1 hour a day, 4 times a week for 10 sessions. Statistical data appear to be missing from the article. Small sample size (n = 18). Sparse methodology and comparable results.

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					patients with diabetic foot ulcers and nonhealing wounds."	
[387] RCT, prospective	3.0	N = 10 diabetics with significant soft tissue defects of the foot.	Vacuum Assisted Closure device™ (VAC) Vs Conventional moist dressings. At enrollment, patients assigned to receive 1 treatment for first 2 weeks, after which they switched to other treatment for remaining 2 weeks. Follow-up for 2 and 4 weeks.	At 4 weeks, wound depth significantly changed from examination (3.1± 0.9) to termination (1.2±0.3); (p <0.05). At 2 weeks, VAC therapy significantly reduced wound depth (-49±11.1 vs. -7.7±5.2) and volume (-59±9.7 vs. -0.1±14.7) of wound vs. moist dressing (p <0.05 and p <0.005).	"[The] data from a small group of diabetic patients with large foot wounds demonstrate that negative-pressure wound dressings decrease wound depth and volume more effectively than moist gauze dressings over the first 4 weeks of therapy. We believe that this will ultimately result in more rapid complete wound healing and prevention of wound complications so frequently encountered in this population."	High dropout rate and small sample size. Crossover design.
[388] RCT Sponsored by Soluble Systems LLC. COI: Dr. Landsman is a paid consultant for Soluble Systems LLC.	3.5	N= 32 wounds (number of patients not specified) with forefoot or midfoot ulcer of Wagner Grade 1 or 2. Mean Age; 57.2 years.	TheraGauze (TG) group- treated with standard wound debridement as needed and dressing changes every other day with TheraGauze applied to wound surface (n = 16 wounds) vs. TheraGauze + Becaplermin (TG + B) Group- Same treatment as TG group, with the extra treatment of becaplermin (Regranex 0.01%) daily (n = 16 wounds). Weekly	Main outcome was percentage of wounds that achieved complete closure and rate of closure: 46.2% of wounds in both groups achieved closure at 12 weeks and 69.2% in TG+B group vs. 61.5% in TG group at 20 weeks (p >0.05). Rate closure higher during first 4 weeks compared to last 16. Average rate closure 0.37 cm2/week in TG	"In conclusion, we believe that this study illustrates that wounds are more likely to close and to close more quickly with regulation of moisture across the wound bed. Smart dressings that provide precise regulation of the wound environment will be expanded in the future as new applications that take	Comparable results in both groups suggesting becaplermin does not increase wound healing.

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			follow-up to Week 12, then bi-weekly to Week 20.	group vs. 0.41 cm2/week in TG +B group (p = 0.34).	advantage of this unique technology are explored."	
(389) RCT Sponsorship, supported by Farmitalia Caro Erba Laboratory, Milano, Italy. No mention of COI.	3.5	N = 17 suffering from chronic neuropathic ulcer of the plantar surface of foot. Typical neuropathic ulcer of Wagner grade I-III, more than 0.5 cm in the largest diameter. Mean age 61.9±10.0 years in treatment group.	bFGF vs. placebo applied daily for 6 weeks, then twice a week for 12 weeks.	Weekly reduction in ulcer perimeter and area was identical in both groups, as was rate of linear advance from entry to 6th week of treatment (bFGF: 0.053±0.048 mm vs. placebo: 0.116±1.129 mm): same result obtained at 11th week.	"Topical application of bFGF has no advantage over placebo for healing chronic neuropathic diabetic ulcer of the foot. Because diabetes causes significant wound-healing defects, we hypothesized that using a single growth factor might be insufficient to accelerate wound closure of diabetic ulcers."	Small sample size (n = 17). Sparse methodological details.
Autologous-derived Growth Factor						
(390) Dose-escalation study Sponsored by Agennix, Inc. and the National Institute of Arthritis and Musculoskeletal and Skin Diseases of the National Institute of Health.	N/A	N = 9 with diabetes mellitus with an HbA_{1C} from 6% to 13%, full thickness diabetic foot ulcer below that ankle that has not reduced in size ≥30% in past 4 weeks with typical treatments, post debridement size between .5-10 cm^2, transcutaneous oxygen tension ≥30 mm Hg or ankle-brachial index ≥0.7; Mean (±SD) age 57 (±6) for 1% gel group, 54 (±7) for 2.5% gel group and	1% Talactoferrin gel group (n=3) vs. 2.5% Talactoferrin gel group (n=3) vs. 8.5% Talactoferrin gel group (n=3). Groups instructed to apply gel twice daily to ulcer for 30 days alongside typical wound care. Assessments at baseline, weekly during treatment, weekly for 1 month after final treatment, and semimonthly for 3 months after final treatment.	No p-value statistics reported for this phase of the study. 2.5% and 8.5% talactoferrin selected for use in phase 2.	"[T]alactoferrin was a safe and well-tolerated treatment of diabetic neuropathic foot ulcers without associated adverse events or laboratory abnormalities. In addition, talactoferrin enhanced the rate of healing in these ulcers. A phase 3 will be required to confirm these results."	Study Phase 1-same article as below.

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		52 (±11) for 8.5% gel group.				
Prostacyclin Analogues (Iloprost)						
(391) RCT No mention of COI or Sponsorship.	2.5	N = 60 with type 2 diabetic patients (61.8 ± 9.7 years, mean ±SD) with diabetic foot ulcer and peripheral arterial occlusive disease, stage III or more by Wagner classification. Plus 15 healthy controls.	Group I: iloprost infusion (0.5-2 ng/kg/min for 6 h) for 10 consecutive days. (n = 30) vs. Group II: (n=30) treated same except iloprost treatment constituting a patient control group. 30 day follow-up.	Group I patients showed improvement in endothelial functions at 10th and 30th day (p = 0.002) in respect to group II.	"Ten-day iloprost infusion therapy to patients with diabetic foot ulcers seems to be efficient in the improvement of endothelial function, but, despite our positive clinical observation, this improvement does not affect the outcome of the amputation rates at 30 days follow up period."	Sparse details.
Complementary and Alternative Medications						
(392) RCT Sponsored by the University Grants Council of Hong Kong.	2.5	N = 80 with chronic foot ulcers, type 2 diabetes; Mean (±SD) age 66.3 (±12.6) for herbal group and 68.5 (±11.1) for placebo group	Herbal treatment group receiving a mixture of 12 herbs given 2x daily in a drink (n = 40) vs. Placebo control group (n=40). Both groups received typical antidiabetic treatment. Assessments at baseline, 1 week, 2, 3, and 4 weeks.	No statistically significant p-value results reported for limb salvage or healing of ulcers.	"[T]his study further supports the efficacy of the herbal supplement. The treatment group showed superiority over the placebo group in terms of: limb salvage, appearance of granulation tissue, and overall assessment of wound healing. Importantly, the study further supported the safety of the herbal formulation."	Article methods note inclusion is Type 2 DM, but table has some Type 1 enrolled. Sparse methods. Baseline differences in gangrenous tissue (none in 18% herbal vs. 35% placebo) concerning for randomization failure.
(393) RCT	2.0	N= 25 patients with diabetic foot ulcers; Mean Age was 53.6 years.	Semelil Group-Intravenous administration of ANGIPARS 4 mL daily for 28 days	Significant decrease in ulcer surface area for Semelil vs. Conventional	"This herbal extract by intravenous route in	Small sample size. Differing group sizes with only 9

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Supported by ParsRoos Co. No mention of COI.			(n = 16) vs. Conventional Therapy included betadine bath, antibiotic therapy, wound debridement. (n = 9). Follow-up for 4 weeks.	Therapy; 64% reductions vs. 25% reduction (p = 0.015). Treatment group showed decrease in wound size compared to baseline (479.93 mm2 to 198.93 mm2, (p<0.001)). No significant decrease in area in control group (p = 0.076).	combination with conventional therapy is more effective than conventional therapy by itself probably without side effect. However, further studies are required in the future to confirm these results in larger population."	controls reported.
(394) RCT No mention of sponsorship or COI.	1.0	N = 21 with diabetic foot ulcers. Age range from 18 to 75 years.	Group 1 received 100mg of oral ANGIPARS™ twice a day for 6 weeks, plus conservative treatment (n = 6) vs. Group 2 received ANGIPARS™ gel 3% added to oral form of same product and not conventional therapies (n = 6) vs. Group 3 or control, only conventional therapies performed (n = 9). Follow-up for 6 weeks.	Foot ulcer surface areas decreased from 375.00± 118.14 mm2 to 41.67±32.70mm2 in group 1, (p = 0.040); and from 916.67±228.64 mm2 to 137.50± 41.71mm2 in group 2 (p = 0.010). In group 3, ulcer surface areas reduced from 766.22±320.17 to 689.11±329.07, (p = 0.076).	"[I]n diabetic foot ulcers, either treatment with oral ANGIPARS™ capsules (100mg) twice a day or combination therapy with oral and topical forms, in conjunction with good wound care significantly increased the incidence of complete wound closure."	Phase 3 trial. Small sample size (21), and unequal group sizes. Baseline differences (ulcer surface area 375 vs. 917 vs. 766), concerning for randomization failure.
Hyperbaric Oxygen						
(395) RCT Sponsorship, supported by National Science Council (95-2314-B-182A-081), Tissue Regeneration Technologies, and National Health Research	3.5	N =72 with chronic diabetic foot ulcers. Mean±SD age was 58.6±12.6 years (ESWT); 63.4±10.3 years.	ESWT group received 300 100/cm2 impulses of shockwave at 0.11 mJ/cm2 energy flux density every 2 weeks for 6 weeks vs. hyperbaric oxygen therapy (HBO) group received HBO daily for 20 treatments via mask.	Completely healed in 31%, improved in 58%, and unchanged in 11% for the ESWT group vs. 22% completely healed, 50% improved, and 28% unchanged for HBO group.	"ESWT appears to be more effective than HBO in chronic diabetic foot ulcers"	Quasi-randomized (date of treatment). HBO administered by a "mask" in a chamber.

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Institute (NHRI-EX96-9423EP). No mention of COI.						
[396] RCT No sponsorship or COI.	2.5	N = 100 with foot wound that had been present for at least 4 weeks despite appropriate local and systemic wound care.	Standard therapy (ST) administrated 2 sessions per day, followed by 1 session on following day (n = 50) vs ST combined with HBOT standard therapy supplemented by hyperbaric oxygen treatments (n = 50). Follow-up for 4 to 5 months.	No patients in ST group who healed without surgery vs 33 (66%) of patients in group receiving HBOT healed without survery. Healing ST vs HBOT; (Ulcer grade 2)/(Ulcer grade 3)/and (Ulcer grade 4): (0 vs 6) / (0 vs 13) / and (0 vs 14).	"In conclusion, this study showed that the use of HBOT in the treatment of diabetic foot ulcers statistically significantly improved the prevalence of healing in foot ulcers of diabetic patients."	Multiple baseline differences concerning for randomization failure. Data suggest better results with HBO.
Extracorporeal Shockwave Therapy						
[397] RCT No COI. No mention of Sponsorship.	3.5	N = 30 with neuropathic diabetic foot ulcers. Mean±SD age: 56.8±7.5 years.	Standard care and shock wave therapy. Other group treated with standard care. Follow-up over 20 weeks.	Complete wound closure ESWT-treated vs. control: 53.33% vs. 33.33%. Healing times: 60.8 vs. 82.2; p <0.001.	"[ESWT] may be a useful adjunct in the management of diabetic foot ulceration."	Details sparse.
[395] RCT Sponsorship, supported by National Science Council (95-2314-B-182A-081), Tissue Regeneration Technologies, and National Health Research Institute (NHRI-EX96-9423EP).	3.5	N = 72 with chronic diabetic foot ulcers. Mean±SD age 58.6±12.6 years (ESWT); 63.4±10.3 years.	ESWT group received 300 100/cm^2 impulses of shockwave at 0.11 mJ/cm^2 energy flux density every 2 wk for 6 wk vs. hyperbaric oxygen therapy (HBO) group received HBO daily for 20 treatments via mask.	Completely healed in 31%, improved in 58%, and unchanged in 11% for the ESWT group vs.22% completely healed, 50% improved, and 28% unchanged for the HBO group.	"ESWT appears to be more effective than HBO in chronic diabetic foot ulcers"	Quasi-randomized (date of treatment). HBO administered by a "mask" in a chamber.

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No mention of COI.						
Electrical Stimulation						
(398) RCT No COI. No mention of Sponsorship.	1.0	N = 20 non-healing diabetic foot ulcers (mean duration 38.9±23.7 months. Mean±SD age: 48.4±14.6 years	Local dry heat (37°C; n = 10) vs. local dry heat + ES (n = 10) three times a week for 4 weeks.	Average wound area and volume decreased in ES + heat group: 68.4±28.6% and 69.3 ± 27.1%, respectively (both p<0.05), over the 1-month period.	"Local dry heat and ES work well together to heal chronic diabetic foot wounds; however, local heat would appear to be a relevant part of this therapy because ES alone has produced little healing in previous studies."	Sparse details. Attempted to study additive benefit of Electrical stimulation over dry heat alone.
Skin Grafts						
Dermagraft						
(399) RCT Supported by a research grant from Advanced Tissue Sciences, Inc. and Smith and Nephew, Inc. COI-W.A.M. is on speaker's bureau for Smith and Nephew, Inc., and has received honoraria and travel support for lectures and travel programs from Smith and Nephew, Inc. J.H. has received consulting fees for lectures and program sponsorship from Advanced	3.5	N= 314 patients with diabetes with a foot ulcer of at least 2 weeks duration. Mean Age was 55.7 years	Dermagraft Group: Dermagraft application with standard wound dressings (n = 163) vs. Control Group: Standard wound dressings (n = 151). Follow-up for 12 weeks.	There were 245 patients with chronic ulcers (>6 weeks duration). 39 (30%) of patients in dermagraft group had completely healed at 12 weeks compared to 21 (18%) in control group (p = 0.023). The dermagraft group had a significantly faster time to complete wound closure than the control group (p=0.04). No significant differences in the number of adverse events between groups.	"In conclusion, Dermagraft has been shown in this multicenter, prospective randomized study to be safe and effective for the treatment of chronic diabetic foot ulcers."	Some dissimilar baseline comparability data. Adverse events similar between groups. Dermagraft group had more complete ulcer healing at 12% compared to control group (30% vs. 18%, p = 0.023).

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Tissue Sciences, holds stock in ATIS, and has been a paid speaker for Smith and Nephew, Inc.						
Apligraft						
(400) RCT No mention of sponsorship. Dr. Manar Moustafa and Dr. Anthony Bullock were employed by the University of Sheffield through a grant obtained from CellTran Limited, Ms. Zoe Ince and Dr. David B Haddow are employees of Celltran and Professor Sheila MacNeil is a Founder Director of CellTran and R&D Director of CellTran.	3.5	N= 16 patients (21 Ulcers) with diabetic ulcers. Mean age was 52.4 years.	Active Group- received up to 12 active dressings (n = 8) vs. Placebo Group: initially received 6 placebo dressings followed up by up to 12 active dressings (n = 8). Follow-up for 12 weeks.	Ultimately, 12 patients each with 1 ulcer index were analyzed (7 active, 5 placebo). In the placebo group 1/5 ulcers completely healed and 4/7 in the active group. During follow-up, 3 of 4 completely healed ulcers in the active group recurred. Ulcer size reduction after treatment was greater in active group compared to the placebo group, however, these differences were not significant (p >0.05).	Repeated regular applications of the patient's keratinocytes, delivered on the carrier dressing, initiated wound healing in ulcers resistant to conventional therapy, with 19 out of 21 ulcers responding.	Partial cross-over. High dropouts.

FOOT DROP

Author/Year Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments
Orthotics						
(401) RCT	1.0	N = 24 with chronic hemiparesis whose walking was	Subjects walked for 6 minutes while wearing force-sensitive insoles, once with and once	Gait asymmetry index instantly improved by 28% or from 0.58±0.30 to 0.42±0.22) and	"The studied neuroprosthesis enhances gait and improves dynamic stability in chronic	Neuroprosthesis appeared to improve gait and stability in patients with foot

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		impaired by foot drop, with mean age 54.0 ± 5.2.	without the neuroprosthesis. Neuroprosthesis were conducted after using the device for 4 and 8 weeks. Follow-up for a total of 8 weeks.	by 45% (to 0.32± 0.20; p ± 0.001, after 8 weeks. Stride time variability decreased by 23% immediately (from 5.7±2.9% to 4.4± 1.3%) and by 33% (to 3.8 ± 1.4%; p < 0.002) after 8 weeks.	hemiparetic patients, supporting the idea that this is a viable treatment option in the rehabilitation of patients with foot drop."	drop but study elements were sparse and omitted many details.
Taping						
(402) RCT Cross-over	1.0	N = 14 with an increase in vertical navicular height of at least 10mm when foot was moved from relaxed calcaneal stance to subtalar neutral, mean age 23.8 ± 3.5.	LowDye taping, temporary felt orthotics, consisting of a spur and mini-stirrups, and adding calcaneal slings and reverse sixes which are anchored one third up leg and all subjects have participated in fitness activities (10 and 20 minutes). In control condition, subjects did not have tape or orthotics applied. Follow-up of exercise challenge (0, 10, and 20 minutes of controlled jogging).	Exercise challenge effect on each treatment technique: with tape, there was a significant reduction in mean percentage change in mean vertical navicular height from 19.0%-5.9% over first 10-minute period, but not over second l0-minute period (5.9%-3.5%). Tape and orthotic treatments produced approximately a 19% and 14% increase in vertical navicular height.	"Antipronation tape and temporary orthotics help to control excessive foot pronation initially after application and following exercise."	Crossover study with small N and few details on methodology.

MORTON'S NEUROMA

Author/Year Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments
Lidocaine Patches						
(403) RCT	3.0	N=27 patients with Morton neuroma	2mL Placebo vs. 1mg/mL lidocaine vs. 10mg/mL lidocaine.	Mean QST assessment value calculated for affected and non-affected foot. Difference between	"The present results may therefore suggest that lidocaine is relatively more	Crossover study with small N and minimal baseline characteristics. Some data

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		for at least 3 months confirmed by MRI.	Patients had 3 visits each. At each visit, a patient randomly assigned to one of three treatments and then immediately tested with QST assessments and a step-up test.	feet not significant for any group (p >0.10). Lidocaine (10mg/mL) showed significant effects compared to placebo for QST for 3 measurements, CDT measurement (p = 0.039), MDT measurement (p = 0.009) and wind up (p = 0.016). Mean pain intensity following injection was 4.1 after placebo, 2.0 after 1 mg/mL lidocaine and 1.2 after 10mg/mL lidocaine. Difference between placebo and lidocaine (1mg/mL) and lidocaine (10mg/mL) significant. (p <0.001).	effective on heat pain in damaged tissue and, although results were seen in only 3 patients, could be effective in patients with heat hyperalgesia, ie, in patients with pain resulting from sensitized heat nociceptors."	suggest possible efficacy.

ACHILLES TENDINOPATHY

Author/Year Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments
Exercise vs. Exercise						
(404) RCT	2.5	N = 17 athletic patients, chronic Achilles tendonitis	Eccentric vs. concentric exercise regimens daily for 12 weeks.	No differences in return-to activity ratings. Differences favoring eccentric in pain ratings 3.0 vs. 4.7 at 12 weeks.	"The subjective symptoms of pain with Achilles tendonitis were better controlled in the eccentric exercise group than in the concentric group."	Small sample size. Lack of study details.
NSAIDs						
(405) RCT	3.5	N = 60 acute sports injuries	Ibuprofen (1,600 mg) vs. paracetamol (3,600 mg) daily.	Days to return to sport in 1-5 days: Ibuprofen 14/28, paracetamol 5/27, (p <0.05).	"[I]f ibuprofen is given within two days of injury return to sporting activity is hastened, and our results support those of Muckle (1974)."	Sparse study details.
Orthotic Devices						

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(406) RCT	2.5	N = 33 age 11-51 years with unilateral Achilles tendinitis	Sorbothane heel pads for 2 months (n = 11) vs. soft sponge rubber pads of "Molefoam" (n = 10) vs. no pads (n = 12). All received 5 consecutive daily 5 minute ultrasound treatments.	All groups with improvement at 10 days and 2 months.	"Patients treated with ultrasound and exercises alone (group III) revealed the most significant improvement in the clinical findings, as characterized by a reduction in both swelling and tenderness."	All groups with ultrasound and exercise therapy. Data suggest possible randomization failure. Small sample size for 3 comparison groups. "No heel pad group" significantly shorter duration of symptoms. Outcomes measures were gain parameters that may have little clinical significance.

ACHILLES TENDON RUPTURE

Author/Year Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments
Achilles Rupture Surgery vs. Non-operative Care						
(21)	3.5	N = 105 closed acute ruptures of Achillis tendon	Surgery (end to end suture) vs. progressive casting.	"Absence from work varied depending on work. It averaged thirteen weeks (0-30) in surgically treated groups and nine weeks (0-44) in non-surgically treated groups (P <0.05)." No differences in plantar flexion strength or increases in tendon size.	"Results of both surgical and non-surgical treatment of acute ruptures of the tendo Achilles were good, and they confirmed the results reported previously. There were only minor differences in the groups, but the period of morbidity was shorter, the complaints were fewer, and no hospital stay was needed in the conservatively treated patients. ...The treatment of choice should be non-surgical."	Quasi randomized (odd-even day). No blinding of assessment. Casting group was quicker to return to work, although also had higher re-rupture rate (8% vs. 4%).

PLANTAR FASCIITIS

Author/Year Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments
MRI						

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(407) RCT	2.5	N = 43 patients (48 heels) with chronic courses of plantar fasciitis	MRI with a high field system vs. MRI with a low field system.	While thickness of plantar aponeurosis, soft tissue signal intensity changes, and soft tissue contrast medium uptake did not correlate with clinical outcome, presence of a calcaneal bone marrow edema highly predictive for satisfactory outcome (positive predictive value 0.94, sensitivity 0.89, specificity 0.8).	"This study indicates that in patients with chronic plantar fasciitis, the presence of calcaneal bone marrow edema on pretherapeutic MRI is a good predictive variable for a satisfactory clinical outcome of ESWA."	No non-MRI control group.
NSAIDs						
(405)	3.5	See NSAIDs in Evidence Table for Achilles Tendinopathy above.				
(408)	2.5	N = 29 with plantar fasciitis	NSAID (celecoxib 200mg q day) vs. placebo.	NSAID vs. Placebo (1, 2, 6 months); Pain (VAS improvement): 2.55 vs. 1.47, 3.73 vs. 2.97, 6.06 vs. 4.85, all p >0.05; Disability (VAS improvement): 1.92 vs. 0.88, 2.71 vs. 2.42, 4.96 vs. 3.81, all p >0.05.	"…the use of an NSAID may increase pain relief and decrease disability in patients with plantar fasciitis when used with a conservative treatment regimen."	Small sample size. Co-interventions (heel cup, stretching, and night splints) allowed. Details of randomization sparse. Baseline differences in outcome measures. No statistical differences in outcomes measures at 1, 2, 6 months.
Glucocorticosteroid Injections						
(409)	3.0	N = 103 with plantar fasciitis	Group 1 (n = 35) steroid injection 0.5ml	High treatment failures in injection group	"The results of this study show that	Lack of study details. No blinding. Lack

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RCT			dexamethasone plus 2 300mg capsules of etodolac a day vs. Group 2 (n = 33) viscoelastic heel cup plus acetaminophen vs. Group 3 (n = 35) LowDye taping plus custom orthoses.	(23%) and heel cup (42%). Final outcome of "excellent" or "fair" vs. "poor." Injection group 33% (9 of 27) Heel cup group 30% (7 of 23) vs. 70% (19 of 27) of orthoses group (p = 0.005).	mechanical control of the foot with taping and orthoses is more effective than either anti-inflammatory therapy with NSAIDs in combination with injections or accommodative therapy with heel cups in the conservative treatment of plantar fasciitis."	of control for co-interventions. Randomization and allocation unclear.
Magnets						
(410) RCT	2.5	N = 40 with medial plantar calcaneal heel pain	PPT/Rx Firm Molded Insole with magnetic foil vs. PPT/Rx Firm Molded Insole with no magnetic foil.	No significant difference between number of patients reporting improvement in each group (chi-squared = 1.22; p = NS). No significant difference in improvement made by magnetic foil group vs. PPT/Rx Firm Molded Insole group as measured by percentage difference in mean scores on foot function index.	"Approximately 58% of patients using the PPT/Rx Firm Molded Insole with magnetic foil for 4 weeks and 60% of patients using the PPT/Rx Firm Molded Insole alone for the same period reported improvement in foot function as measured by the foot function index. The magnetic foil offered no advantage over the insole."	Lack of method details. Unclear if this was an RCT.
Orthoses						
(411) RCT	3.5	N = 255 plantar heel tenderness, history of pain on rising in morning or after rest, no	Custom-made orthoses vs. OTC arch supports vs.	No statistically significant differences among	"Mechanical control of the foot is a successful	No blinding. High drop-out rate; 12 week study.

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	May have sustained laceration, or direct trauma	Motor loss in specific distribution Painless swelling (Charcot's joint)
Rapidly progressive vascular compromise	Diabetes Peripheral vascular disease or bypass grafts Dislocation or fracture May have sustained laceration, or direct trauma	Decreased or absent foot and ankle pulses Decreased capillary filling Cold, pale extremity
Tendon ruptures and evulsions		
Achilles	Sharp pain to the posterior distal calf or ankle, may be accompanied by loud pop Forceful plantarflexion of the foot, or unaccustomed and vigorous running, hiking, or climbing May have sustained laceration, open wounds, crush injuries, or direct trauma May have degloving injury Administration of fluoroquinolones or local injections [371]	Swelling and bruising Inability to point foot downward and stand or walk comfortably Positive Thompson test May have overlying signs of trauma including laceration, open wounds, puncture wounds, crush injuries
Peroneal	Pain and swelling of the lateral heel May have sustained laceration, open wounds, crush injuries, or direct trauma May have degloving injury	Impaired eversion strength [372] May have overlying signs of trauma including laceration, open wounds, puncture wounds, crush injuries
Tibialis, Anterior	Swelling and pain in the anterior ankle May have sustained laceration, open wounds, crush injuries, or direct trauma May have degloving injury	Anterior ankle tenderness, probable impaired dorsiflexion strength, tenderness at the first metatarsotarsal joint [373] May have overlying signs of trauma including laceration, open wounds, puncture wounds, crush injuries
Tibialis, Posterior	Medial ankle pain and swelling, particularly if behind the medial malleolus, new or progressive flatfoot deformity (with or without pain) May have sustained laceration, open wounds, crush injuries, or direct trauma May have degloving injury	Flatfoot deformity, particularly when unilateral; tenderness of the posterior medial malleolus [374,375], asymmetrical flat foot, difficulty with ipsilateral heel raise [376,377] May have overlying signs of trauma including laceration, open wounds, puncture wounds, crush injuries

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		history of trauma to heel within previous 3 months	tension night splints.	treatment groups in overall effectiveness during 12 weeks of treatment for plantar fasciitis. Overall success rate of treatment in present study lower than rates in studies in which multiple modalities used.	method of treating plantar fasciitis. Custom-made orthoses, over-the-counter arch supports, and tension night splints are all effective as initial treatments for plantar fasciitis. Patients in the present study demonstrated the best compliance with the use of custom-made orthoses, which may indicate that orthoses provide the best long-term results."	
(412) RCT	3.0	N = 50 plantar fasciitis of 4 weeks duration but less than 12 weeks	AirHeel device vs. prefabricated orthoses.	Changes from baseline to week 12 (VAS pain scores); AirHeel vs. 1st Step: -25.8 vs. -21.1 p = 0.075.	"Patients with a higher initial pain score seemed to respond better initially to the AirHeel (p = 0.015) than the 1st Step insert (p = 0.035)."	Intervention provided for acute phase of condition that has natural history of improvement in 90% of cases. No placebo for comparison to natural history. Co-intervention of plantar fascia stretching exercises.
(409)	3.0	See Glucocorticosteroid Injections above.				
(410)	2.5	See Magnets above.				
(413) Crossover Trial	5.0	N = 16 meta-tarsalgia due to rheumatoid arthritis	Orthotics vs. no orthotics.	Mean VAS scores lower for orthotic group (42.06±15.87 mm for gait	"[W]earing foot orthoses provided significant pain relief, but was	Population was RA patients with metatarsalgia. Orthotic use

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				without orthotics vs. 18.87±12.09mm for gait with orthotics), p = 0.008. No difference between right and left side for spatiotemporal variable values between groups.	not sufficient to improve gait in RA patients with metatarsalgia due to forefoot involvement. Limiting pain is the main reason why foot orthoses have been widely recommended, but has not fully addressed the problem of gait in RA patients."	resulted in less pain (metatarsalgia) related to RA. Study was excluded in the evidence table as it is a study of purely RA patients and no clear relationship with workers.
(414) Quasi-RCT	3.5	N = 121 soccer referees	Shock absorbing heal cup (SAH) vs. no heel cup in asymptomatic population.	Lower incidences of soreness in back, calf, and Achilles tendon for group wearing SAH compared to control group on days 2, 3, and 4, p <0.05.	"The occurrence of achillodynia, calf muscle soreness and back pain can be reduced by the use of shock absorbing heel insoles when used during a period of extreme strenuous activity. Other problems, however, like ankle, knee and thigh soreness were not improved by the use of SAH."	Study performed in sports referee group at 5-day soccer tournament. Pseudo-randomization (allocation by date born in month). High loss to follow-up (30/121).
Shock Absorbing Shoes						
(415) RCT	N/A	N = 30 with rheumatoid arthritis (RA) reporting chronic foot pain	Footwear vs. no footwear for 2 months.	Footwear group showed improvement on all measured variables. Control group showed slight deterioration for all variables except NWB	"These data suggest that off-the-shelf orthopedic footwear is beneficial for people with RA even when subjects were unselected on	Excluded, study of RA patients only.

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				pain. Footwear group improved for all gait variables.	basis of age, sex, disease duration, or disability as measured by the Stanford Health Assessment Questionnaire. ”	
Taping						
(409)	3.0	See Glucocorticosteroid Injections above.				
Extracorporeal Shockwave Therapy						
(416) RCT	2.0	N = 53 chronic plantar fasciitis	Single treatment vs. multiple treatments of ESWT	Mean pre-treatment VAS entire group 9.2±0.7; 4 weeks after treatment VAS score decreased to 3.4±1.9; after 12 weeks decreased to 2.4±1.8. Difference between pre-treatment, 12 week post-treatment VAS scores statistically significant (p <.05).	“The results of the current study revealed beneficial effects of extracorporeal shock wave therapy in patients with chronic plantar fasciitis.”	Treatment appeared effective in all groups but sample size too small for between group comparisons.
(417) RCT-Mixed	Excluded		ESWT vs. sham			Results included pooling of randomized and non-randomized subjects from combined studies. No conclusions specific to randomized population provided. Appears similar if not same

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						population as Ogden 2004. Study is excluded.

ANKLE SPRAINS

Author/Year Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments
NSAIDs						
(418) RCT	3.5	N = 67 acute ankle sprains, varying degree of severity	Ibuprofen 600mg, 4 times daily vs. placebo.	Ibuprofen vs. placebo VAS 0-4 (day 4, 8); Rest: 0.3 vs. 0.2, 0.2 vs. 0.2; Jumping: 0.7 vs. 1.0, 0.5 vs. 0.5; Walking: 1.8 vs. 1.9. 1.2 vs. 1.3.	"Although there were trends indicating a superiority of effectiveness in the treatment group, the differences between groups were not statistically significant."	Study not clear if it is a randomized trial. Allocation unclear. Reported no differences between placebo and ibuprofen group.
(419) RCT	3.0	N = 68 acute ankle joint injuries presented to casualty ward	Ibuprofen 600mg, 4 times daily vs. placebo for 4-6 days.	No difference in swelling reduction, number of patients taking additional analgesics (5/47 vs. 9/53).	"No difference between relief of pain and reduction of swelling was demonstrated. We cannot recommend routine treatment with ibuprofen for acute ankle joint injuries."	Drop outs (14) replaced by new patients. No data on compliance. Multiple co-interventions. Study suggests no difference between placebo and ibuprofen.
(420) RCT	2.5	N = 40 mild to moderate pain associated with Grade 2 ankle sprain	Diflunisal (1000mg loading, 500mg BID/TID) vs. codeine with acetaminophen	Severity of pain for diflunisal vs. acetaminophen at base line (%): none = 0/0, mild = 0/0, moderate = 100/100, severe = 0/0. After treatment: none = 21/28.5, mild = 73.7/62,	"[D]iflunisal and the combination of acetaminophen with codeine are equally effective in	Lack of study details regarding randomization, allocation, blinding, compliance. No statistical

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			(30/300 1 or 2 q 4 hours).	moderate = 5.3/9.5, severe = 0/0. "In a global assessment of efficacy and tolerability, 17(89%) of 19 patients rated diflunisal as very good or excellent, whereas only nine (43%) of 21 patients rated acetaminophen with codeine similarly."	relieving moderate pain associated with grade 2 ankle sprain."	analyses of results provided.
(421) RCT	2.5	N = 100 sprained ankles	Ibuprofen 800mg TID (compression vs. ace bandage) x 10 days vs. placebo (compression vs. ace) 2-week trial for acute sprain (injury extent non-defined).	No differences in swelling improvement between 4 groups found. No differences in pain at rest, walking, or tenderness. Minimal statistical analysis presented.	"Neither Ibuprofen nor high quality bandaging had a significant effect on the swelling, pain or tenderness."	Lack of randomization, allocation, baseline comparison, cointervention s and blinding details. Suggests no benefit from ibuprofen or elastic/compre ssion bandages.
Opioids						
(420)	2.5	See NSAIDs above.				
Proteolytic Enzymes						
(278) RCT	3.0	N = 400 males who attended ER within 24 hours of sprain	Proteolytic enzymes plus plaster cast vs. placebo plus plaster vs. enzymes plus Tubigrip vs. placebo plus Tubigrip.	Day 7, bruising significant difference favor placebo/Tubigrip vs. enzymes/ Tubigrip (p <0.01). Day 14, improvement in placebo/Tubigrip (89%) and placebo/ plaster (67%). Day 7, edema difference in favor of Tubigrip vs. plaster (p <0.05 in favor of placebo/ Tubigrip). No differences in between groups in dorsiflexion or plantar flexion.	"[T]hose who received a plaster cast and enzymes recovered faster than those in a cast alone. In addition, the power of dorsiflexion recovered faster in the Tubigrip group in those who received oral proteolytic enzymes."	Lack of study details regarding randomization, allocation, blinding, compliance. High drop-out rate (148/400). Results suggest little clinical significance between these treatments.
Benzydamine						
(281)	2.0	N = 86 presenting to accident and ER with ankle sprains	Tubigrip vs. benzydamine vs. placebo.	Mean scores for time from presentation Tubigrip vs. placebo vs.	"[I]nitial treatment of ankle sprains	Quasi-randomization (odd/even

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Quasi-RCT				benzydamine at 0, 2, 9 days: 7.9/8.8/8.4, 5.2/5.9/5.7, 2.6/2.4/ 2.45. Mean scores for improvement days 0-2, SEM: 2.71/2.93/2.7, 0.53/0.51/0.33. All made similar progress.	should include compressive support and rest followed by early active use of the joint. This topical agent appears to offer no advantage in the initial treatment of ankle sprains."	birth year), then randomized tubes of topical treatment. High loss to follow-up (34/86). Suggests no treatment effect from benzydamine for acute ankle sprains.
Topical NSAIDs						
[422] RCT	3.5	N = 100 to ER with acute ankle sprain	Ibuprofen cream 5% applied QID vs. placebo cream, 7-14 day trial, likely Grade I, II acute sprains.	Ibuprofen cream vs. placebo; significant difference in mean VAS score and walking ability Days 2 and 3 only.	"[T]he use of topical ibuprofen is associated with a statistically significant reduction in pain over the first 48 hours of treatment following an acute ankle sprain."	Results are of uncertain significance as 49% of randomized patients did not complete study and were not included in the analysis.
Glucocorticosteroid Injections						
[423] RCT	2.5	N = 178 injury to lateral ankle ligaments only, occurred within last 6 hours, patients 15-67 years of age	Elastic wrap (I) vs. elastic wrap plus cold pack, rubber pad (II) vs. elastic wrap, cold, rubber pad plus hydrocortisone local injection 4mg (III).	Injury severity determined by arthrography. Temperature: no ligament rupture, mean temperature less in Group III than I and II ($p < 0.005$). No difference Day 7. With ligament rupture: Day 1 and 3 no difference I vs. II. I vs. III found lower temperature in III at Day 1, 7 ($p < 0.05$). Pain: All without ligament rupture had more rapid pain relief after Day 1. With ruptures, I more pain than II and III after Day 1 ($p < 0.05$, $p < 0.001$).	"[A]nkle sprains should be treated conservatively with local cooling, anti-inflammatory medication and elastic wrapping regardless of the severity of the injury."	Randomization, allocation, baseline comparability, blinding details not described. Timing of assessments variable for long term follow-up (3-6 months). Multiple cointervention s (PT in groups II and III) make comparisons difficult for individual treatment

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						recommendations.
Early Mobilization						
[424] RCT	3.5	N = 200 rupture ankle ligaments	Surgery plus cast immobilization vs. surgery plus functional orthosis vs. cast immobilization vs. functional orthosis.	At 3 months, better ROM in primary functional group. No differences in subjective outcomes. At 12 months, no differences regarding joint stability, ROM, recurrence of injury, limitations, instability.	"[A]s a result of the trial, the only remaining surgical indications would seem to be dislocations of the foot and ankle, ankle ligament rupture with additional intra-articular pathology, and second-stage injuries or re-ruptures."	Possible confounding cointerventions including NSAIDs, PT. Minimal statistical analysis provided.
[425] RCT	3.0	N = 130 ruptured fibular ankle ligaments	Below-knee walking plaster for 6 weeks vs. mobile Pliton-80 bandage.	Positive "modified" Romberg test for plaster and pliton (Week 8/24): 30/17, 16/8. Intermittent pain and swelling of ankle for plaster and pliton (Week 8/24): 24/8, 6/4.	"[R]ecommend the mobile Pliton-80 bandage as the treatment of ruptures to the fibular ankle ligaments."	Randomization, allocation, baseline comparability, blinding, co-intervention details sparse. Differences between two treatments not statistically significant.
[426] RCT	2.5	N = 150 recent tears of lateral ligament of ankle	Bandaging (1-4 weeks) vs. plaster cast of 4 weeks (weight bearing at 1 week) vs. operative repair of ligament plus plaster cast of 4 weeks for severe acute first time ankle sprain.	No significant differences at 2-years in sprain recurrences, number of subjects reporting decrease in sporting activities, tenderness, or talar tilt on radiographs. "Fear of giving way" more common in non-operative treatments (52.8% bandage, 32% cast vs. 9% operative). total chi square = 15.36>13.816 = χ^2.001 (df = 2). Good/ excellent results based on age (15-40 and 41-50): total chi square = 8.75>6.635 =	"Patients over 40 should be treated conservatively, since the capacity for ligamentous regeneration appears significantly less good that that of young people. Severe ankle sprains in patients under 40 should be preferably be	Lack of study details. Only follow-up reported is at 2-years. Thus, unknown whether any short-term benefits. Suggests no significant differences at 2 years. Results limited to non-athletic populations.

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				χ^2.01 (df = 1). Significant difference in favor of younger group. No differences in interventions between age groups.	treated by operation."	
Tubular Elastic, Elastic Wrap, and Tape						
[427] RCT	3.5	N = 156 with acute ankle injuries	Tubigrip vs. strapping vs. Velcro strap (Nottingham Ankle support).	Tubigrip vs. strapping vs. Nottingham; support able to bear weight (%): 40 vs. 62 vs. 67. P value and ROM data not reported. Nottingham > both Tubigrip and strapping p = 0.001174. Feeling of confidence: data not reported, Nottingham > both Tubigrip and strapping p = 0.02.	"The Nottingham Ankle Support was a convenient, economical and effective method of treatment of a common condition. It allowed a greater range of movement at early follow-up than Tubigrip and eversion strapping."	Sparse details for randomization, allocation, cointerventions, compliance. Suggests Velcro strap support resulted in improved ROM and feeling of stability at 10 days.
[428] RCT	3.5	N = 184 healthy soldiers with acute Grade I or Grade II ankle sprain	Taping (unchanged 3 days) vs. gel cast x 3 days vs. taping (changed each day x 3 days).	3-day strap vs. 3-day gel cast vs. daily strap return to duty Day 3 (military) 24/54 vs. 20/59 vs. 36/54. No grade II sprains returned by Day 3.	"[A] treatment protocol of daily ankle strapping plus standard physical therapy modalities/exercise was more effective than a single ankle strapping and a gel-O-cast wrap…for Grade I and II ankle sprains."	Sparse study details. No baseline comparisons. Multiple cointerventions with PT and modalities. Some subjects had treatment repeated at end of 3-days for initial failure.
[425]	3.0	See Evidence Table for Early Mobilization above.				
[426]	2.5	See Evidence Table for Early Mobilization above.				
[423]	2.5	See Evidence Table for Glucocorticosteroid Injections above.				
[267]	1.5	N = 104 inversion injuries seen during a	No support vs. physiotherapy vs. double	Days off work: days at clinic (no support/ physiotherapy/double	"[M]obilisation, with early physiotherapy	Lack of study details; 241 entered trial

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RCT		10-week period at regional accident unit	Tubigrip support vs. immobilized.	Tubigrip support/ immobilized), 5.1: 23.6/6.0:21.4/7.5:21.5/4 1.0:25.0.	or even without, offers the most rapid return to functional activity."	with high drop-out or exclusion. Not clear how many randomized.
[429] RCT	1.0	N = 44 acute ankle sprains	Elastic bandage vs. elastic bandage plus intermittent pneumatic compression (compression 30 minutes a day, 5 days).	Results section did not include measurement data. After 5 IPC sessions, edema volume 33 mL (IPC) vs. 80 mL (control), p <0.001. Pain, ROM scores not presented but reported to be significantly improved in IPC group.	"Elastic bandage with IPC treatment is effective in decreasing edema, relieving pain, and increasing ankle joint motion after ankle sprains. All these factors improve limb function and lead to good results in the rehabilitation of ankle sprains."	Lack of study details (randomizatio n, allocation, baseline comparability, no blinding, compliance, co-interventions, follow-up). Suggests intermittent compression results in greater reduction of edema/improv ed ROM.
Ankle Support/Brace						
[427]	3.5	See Tubular Elastic, Elastic Wrap, and Tape above.				
[428]	3.5	See Tubular Elastic, Elastic Wrap, and Tape above.				
[424]	3.5	See Early Mobilization above.				
[425]	3.0	See Early Mobilization above.				
[430] RCT, cluster	3.0	N = 2081 high school football players	Laced-up Ankle brace, Don-Joy Ankle Stabilizing Brace; team-organized conditioning session, practice, competition until season is completed (n = 993) vs. Control, no intervention (n = 1088).	"The incidence of the acute ankle injury per 1000 exposures was significantly lower for the braced group compared to the control group: 0.48 vs. 1.12, p = 0.003." Injury rate (95% CI) for acute ankle injury without a previous history of ankle injury: control vs. braced; 0.91 (0.64, 1.28) vs. 0.40 (0.20, 0.81), p = 0.010; with a history of ankle injury: 2.91 (1.92, 4.41) vs. 1.05 (0.53, 2.09), p = 0.004.	"Players who used lace-up ankle braces had a lower incidence of acute ankle injuries but no difference in the incidence of acute knee or other lower extremity injuries. Braces did not reduce the severity of ankle, knee or other lower	Cluster randomization. Laceup braces associated with lower number of ankle injuries vs. placebo but ankle injury severity same between 2 groups.

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					extremity injuries."	
[431] RCT	2.0	N = 1460 male and female basketball players	Lace-up ankle brace, McDavid Ultraviolet 195; team-organized conditioning session, practice, competition until season is completed (n = 740) vs. Control, no intervention (n = 720).	"The overall incidence of acute ankle injury was lower in the braced group (0.47; 95% CI: 0.30, 0.74) than in the control group (1.41: 95% CI: 1.05, 1.89). The incidence of first-event acute ankle injury was lower in the braced group (0.83; 95% CI: 0.37, 1.84) than in the control group (1.79; 95% CI: 0.98, 3.27), p < 0.001, in favor of the braced group."	"Use of lace-up ankle braces reduced the incidence but not the severity of acute ankle injuries in male and female high school basketball athletes both with and without a previous history of an ankle injury."	Cluster randomization Baseline comparability limited with self-reported questionnaire.
[432] RCT	1.5	N = 34 Grade 2 inversion sprains	Elastic tape plus Air-stirrup vs. Air-stirrup plus room temp cooling device vs. Air-stirrup plus ice.	F-ratio calculated (ANOVA) for evaluation of significant difference among treatment methods not significant p = 0.055.	"Subjects who receive focal compression to the soft tissues around the periphery of the fibular malleolus… recover higher function than …uniform external compression. Application of cold with greater frequency and longer duration than typical…does not appear to increase the rate of recovery."	Quasi-randomization (date of injury with predetermined allocation). Lack of other methodological details. Follow-up period not specified. Study likely underpowered to detect any differences.
Casting						
[424]	3.5	See Evidence Table for Early Mobilization above.				
[425]	3.0	See Evidence Table for Early Mobilization above.				
[426]	2.5	See Evidence Table for Early Mobilization above.				

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(433) RCT	2.5	N = 150 acute ankle sprain injury	Surgical repair vs. cast immobilization (5 weeks) vs. tape bandage (elastic) x 4 weeks for proven lateral ligament tears	Surgical vs. cast vs. tape: Resumption of work activities (weeks): 9.7 vs. 6.8 vs. 2.5 (no p values given); Return to sports at 12 weeks: 35.7% vs. 47.4% vs. 81.4%	"The results...clearly showed the collective advantages of early mobilization with a Coumans-bandage. The long term results, as indicated by the one year follow-up, showed no significant differences and were completely normal in all three treatment groups."	Lack of details for randomization, allocation, cointerventions, compliance. Suggests short-term benefit of functional treatment over surgical repair. No differences long term.
(434) RCT	2.0	N = 95 rupture of lateral ligaments of ankle	Ligament repair and immobilization vs. cast immobilization 6 weeks vs. strapping (tape) and mobilization.	Results at follow-up (4-34 months range): Operation vs. strapping vs. cast: % free of symptoms 97% vs. 77% vs. 67%. (No p values given.)	"Young, physically active people, particularly active sportsmen and women, are recommended for primary suture combined with splinting in a plaster cast for at least 6 weeks. Strapping is preferred if conservative treatment is indicated."	Lack of methodological details. Follow-up times not same for each subject. Follow-up by postal questionnaire in proportion of subjects vs. clinical exam. No statistical analyses limits conclusions.
Cryotherapy						
(435) RCT	3.0	N = 60 foot or ankle trauma	Continuous cryotherapy vs. intermittent compression vs. cold packs 4 times daily for pre and post-	Percent of swelling compared with admission-lower percent is better (Int. Compression/continuous cooling/ice packs): Preoperative Ankle at 24	"It could be shown that both continuous cryotherapy and intermittent	Lack of details. Pre-, post-op cooling provided, but not all subjects received both (<50%) despite

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	May have sustained laceration, or direct trauma	Motor loss in specific distribution Painless swelling (Charcot's joint)
Rapidly progressive vascular compromise	Diabetes Peripheral vascular disease or bypass grafts Dislocation or fracture May have sustained laceration, or direct trauma	Decreased or absent foot and ankle pulses Decreased capillary filling Cold, pale extremity
Tendon ruptures and evulsions		
Achilles	Sharp pain to the posterior distal calf or ankle, may be accompanied by loud pop Forceful plantarflexion of the foot, or unaccustomed and vigorous running, hiking, or climbing May have sustained laceration, open wounds, crush injuries, or direct trauma May have degloving injury Administration of fluoroquinolones or local injections [371]	Swelling and bruising Inability to point foot downward and stand or walk comfortably Positive Thompson test May have overlying signs of trauma including laceration, open wounds, puncture wounds, crush injuries
Peroneal	Pain and swelling of the lateral heel May have sustained laceration, open wounds, crush injuries, or direct trauma May have degloving injury	Impaired eversion strength [372] May have overlying signs of trauma including laceration, open wounds, puncture wounds, crush injuries
Tibialis, Anterior	Swelling and pain in the anterior ankle May have sustained laceration, open wounds, crush injuries, or direct trauma May have degloving injury	Anterior ankle tenderness, probable impaired dorsiflexion strength, tenderness at the first metatarsotarsal joint [373] May have overlying signs of trauma including laceration, open wounds, puncture wounds, crush injuries
Tibialis, Posterior	Medial ankle pain and swelling, particularly if behind the medial malleolus, new or progressive flatfoot deformity (with or without pain) May have sustained laceration, open wounds, crush injuries, or direct trauma May have degloving injury	Flatfoot deformity, particularly when unilateral; tenderness of the posterior medial malleolus [374,375], asymmetrical flat foot, difficulty with ipsilateral heel raise [376,377] May have overlying signs of trauma including laceration, open wounds, puncture wounds, crush injuries

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			operative edema.	hours-42% vs. 64% vs. 82%; Post-operative ankle at 24 hours - 64% vs. 73% vs. 80%; Post-operative ankle at 4 days - 37% vs. 36% vs. 62%	impulse compression therapy lead to faster reduction of swelling compared with standard cool pack therapy."	randomization. No statistical analyses. Included heterogeneous disorders limiting conclusions. Suggests advantage of both treatments compared with standard ice pack application. Equipment costs moderate to high for rental or purchase.
(436) RCT	2.0	N = 30 young adults with Grade I or I1 lateral ankle sprains	Ice pack (30 minutes) vs. high voltage pulsed stimulation at 28 or 80 pulses per sec (pps). For grade I, II ankle sprain. All groups had ice, elevation, rest.	Ice and high voltage pulsed stimulation at 28 and 80pps tend to produce decrease in foot and ankle volume, increase in ROM in dorsiflexion, decrease in pain. No significant differences among groups in any measured parameters.	"HPVS did not further enhance the effects of ice, compression, and elevation."	Lack of study details for allocation, baseline comparability. Suggests no benefit from high voltage pulsed stimulation.
(432)	1.5	See Evidence Table for Ankle Support/Brace above.				
(437) RCT	1.0	N = 30 acute ankle sprain (no other associated condition) r eferred to physio-therapy	Ice vs. no ice (all subjects received ultrasound, exercises, ankle support) for moderate acute ankle sprain.	Rate of recovery (days) ice vs. no ice; Group 3 (able to stand without pain, pain with stairs or walking 10 steps): 4.6 vs. 3.0 days; Group 4 (unable to bear weight): 7.3 vs. 10.2 days	"This clinical trial reveals no significant differences between subjects with ankle sprain injuries who received ice therapy as part of a standard treatment programme and those that did not."	Randomization via coin toss. Duration of study, time of outcomes measurement, and frequency of interventions not described. Lack of overall details.
Electrical Stimulation						
(436)	2.0	See Evidence Table for Cryotherapy above.				

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Ultrasound						
[438] RCT	2.0	N = 80 mild or moderate ankle sprains	Immobilization with elastoplast vs. ultrasound and ice	Ultrasound vs. elastoplast recovery at Week 1, 2: 46.2%/26.6%, 86.4%/58.6%. P-values not provided.	"[T]he use of ice packs and ultrasound relieved the pain, swelling and loss of function more than in patients immobilized with elastoplast."	Lack of study details. No statistical analyses. Ultrasound group also had ice pack treatment. No definition of "recovery" as an outcome measure.
Manipulation and Mobilization						
[439] RCT	3.5	N = 30 acute Grade I, II sprains	Chiropractic manipulation of subtalar, talocrural joints (6 sessions for 2 weeks) vs. piroxicam 40mg x 2 days, then 20mg a day, 5 days.	No differences at 2 weeks or 6 weeks in NRS-101 questionnaire, McGill Pain questionnaire, Athletic Limitation Questionnaire, algometer or goniometer measurements.	"As there was no statistically significant difference found between the two treatment protocols, except for the number of fixations found at the ankle joint, it is suggested that these treatment protocols were equally effective."	Lack of study details. Partial blinding of observer (not on all outcomes). Co-interventions of ice, crepe bandage. Suggests no difference in treatment outcomes, although no control group limits conclusions vs. natural history.
[440] RCT	3.5	N = 30 subacute and chronic Grade I and Grade II ankle inversion sprains	Ankle mortise separation adjustment vs. placebo group for 8 treatment sessions over 4 weeks.	Although both groups showed improvement, statistically significant differences in favor of the adjustment group were noted with respect to reduction in pain, increased ankle range of motion, and ankle function.	"This study appears to indicate that the mortise separation adjustment may be superior to detuned ultrasound therapy in the management of subacute and chronic grade I and grade II inversion ankle sprains."	Methodology details sparse, 6 subjects excluded after inclusion of convenience sample. States placebo single-blind study, but blinding or placebo use unclear. Comparison: manipulation to detuned ultrasound. No placebo of "manipulation."

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[441] RCT	3.0	N = 55 with unilateral ankle sprains	Osteopathic manipulative treatment (single treatment) vs. control. Both groups received RICE, NSAIDs.	Mean±SD VAS score for treatment group vs. control group: 3.15± 1.4 vs. 3.5±2.8; p = 0.61. ROM (degrees): 42.5±14.4 vs. 39.0± 15.4.	"Data clearly demonstrate that a single session of OMT in the ED can have a significant effect in the management of acute ankle injuries."	Sparse details. Does not demonstrate clear benefit of manipulation at 1 week from single treatment except ROM. No difference in pain or edema.
[442] RCT	3.0	N = 30 recent sprain in chronic recurrent ankle sprain patients	Manipulation (6 sessions over 4-week period) vs. single manipulation (talocrural manipulation).	"Subjects in multiple manipulation treatment arm demonstrated statistically significant improvement in 2 measures of proprioception as well as ROM in dorsiflexion."	"[M]anual manipulation of the ankle is an effective treatment for chronic ankle sprains…It is suggested that careful manipulative therapy in conjunction with exercise may offer effective therapy for recurrent ankle sprain."	Lack of study details. Single blinding claimed of control group although blinding not of treatment. Results are of unknown clinical significance.
[443] RCT	3.0	N = 52 field hockey players with Grade II ankle sprain	Manipulation (2 techniques) vs. placebo technique; single treatment, immediate follow-up results.	"Intergroup comparison revealed statistically significant differences in the increase in percentage of posterior load on the manipulated foot, percentage of bilateral posterior load, percentage of anterior load on the manipulated foot, and percentage of bilateral anterior load."	"The application of caudal talocrural joint manipulation redistributed foot load in our sample of athletic individuals with grade II ankle sprain."	Lack of study details. Patients received both intervention and placebo, although order and washout not clear. Placebo questionable as subjects presumably could discriminate between manipulation and simply holding foot with same manipulation grip. Results of no clinical significance.

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Ankle Support for Prevention						
[444] RCT	2.0	N = 52 female volleyball players with ankle sprains	Technical training (land, takeoff technique) vs. proprioception vs. orthosis (ankle stirrup).	Ankle sprain recurrence during season (training vs. proprioception vs. orthosis): 2/18 (12%) vs. 3/17 (18%) vs. 6/17 (35%). No statistical analysis presented.	"All three preventive strategies were effective in athletes who had suffered ankle sprain once or twice only during their career."	Lack of study details. No compliance data for each intervention limits results. No statistical analyses presented.
Balance/Proprioception Training						
[445] RCT	3.5	N = 20 from active athletic population	Four week neuromuscular training program (proprioception, conditioning, strength) vs. no exercise group.	No significant differences in ankle joint position or velocity of postural control (p >0.05).	"The mechanisms by which neuromuscular training improves function in normal subjects and those with functional ankle instability do not appear to result in measurable changes in gait kinematics."	Randomization performed on matched pairs of healthy subjects (no previous injury). Results are of unknown clinical significance.
[446] RCT	3.0	N = 508 male soccer players with history of previous injury or reduced function in ankle, knee, hamstring or groin	Identified athletes at high risk for injury (previous injury). Intervention group (ankle, knee, groin training programs with wobble board, balance pad, other exercises 3 times a week for 10 weeks, then once a week during season) vs. no additional exercises.	Injury incidence (intervention vs. control) ankle: 10/102 (10%) vs. 14/107 (13%), RR 0.9 (0.5-1.3) p = 0.21. Knee, hamstring, groin (all have incidence ratio with p >0.05. Compliance with protocol 27.5% for ankle intervention.	"Although we were able to identify players with an increased injury risk through a comprehensive questionnaire, there was no effect of the targeted intervention on injury risk."	Randomization, allocation methods not described. No blinding. Cointerventions not controlled (shoes, orthotics, etc.). Low compliance rates (20-30%) lessen significance.

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[447] RCT	3.0	N = 80 male soccer players with previous ankle inversion sprain	Proprioception training (ankle disk) vs. evertor muscle strength training vs. orthosis (Aircast stirrup) vs. no treatment control for prevention of recurrent ankle sprain.	Number of incidence (injuries/1000 players), relative risk of injury (95% CI), and percent sprained. Proprioception: 0.13/0.003-0.93/5%. Strength: 0.5/0.11-1.87/20%. Orthosis: 0.25/0.03-1.25/10%. Control: 3.33/0.12-1.91/40%.	"Proprioceptive training, compared with no intervention, was an effective strategy to reduce the rate of ankle sprains among male soccer players who suffered ankle sprain."	Lack of details on randomization, allocation, baseline comparability, blinding, compliance, co-interventions. Small sample, power may have been insufficient as incidence lower in orthosis group although p = 0.06. Duration of regimens not indicated.
[448], [449] Cluster-RCT	3.0	N = 1,127 volleyball players (4 regions, 116 teams)	Normal training routines vs. addition of balance board training. Randomized by 4 geographic regions, all regional teams assigned to control or intervention).	Control group, 0.9 incidences of ankle injuries per 1000 hours, 95% CI of 0.6-1.2. In intervention group, 0.5 incidences of ankle injuries per 1000 hours, 95% CI 0.3-0.6. No differences between groups for total, training, match injury incidence. Costs per player: $93.87 vs. $47.09 (control)	"[P]roprioceptive balance board program was effective in preventing recurrence of ankle sprains. However, there seemed to be an increase in recurrence of overuse knee injuries. Positive effects of the balance board programme could only be achieved at certain costs."	Single study with two reports. Cluster randomization. Lack of study details. Studies suggest balance board training may reduce recurrent ankle sprains, but increases risk of knee injury in those that have had previous knee injury.
[450] RCT	3.0	N = 30 volleyball players	Balance program (14 exercises with balance board) vs. no balance program for 5.5 weeks.	Outcome measure is center of pressure (CoP) excursions measured by sway platform. No differences in any sway measures with and without eyes closed at end of training.	"The 5 1/2 week balance training programme applied in this study did not reduce CoP excursion in a general population of non-injured	Lack of randomization, allocation, compliance details. Small sample size. Non-randomized comparison group included.

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					and previously injured subjects."	Results are of unknown clinical significance as outcome measure is surrogate for ankle instability but did not measure injury.
[451] Cluster-RCT	3.0	N = 237 young female players in European handball (22 teams)	Ankle disk 10-15 minutes all practice sessions with 2 or more functional activities for all major muscle groups vs. usual practice in healthy subjects.	More ankle and finger sprains in control group compared to intervention, p <0.05.	"[T]he intervention programme used in this study had a significant effect on the number of injuries and the injury incidence in young female European Handball players."	Cluster randomization by team vs. individual player; included multiple injury outcomes. For ankle: 23 injuries in control vs. 6 in intervention, p <0.01. Effect cannot be made attributable to intervention in this study design.
[452] RCT	2.0	N = 26 healthy subjects	Whole body vibration training x 4 weeks vs. no training.	No differences in latencies and reflex activity in both long peroneal and tibialis muscles in response to ankle sprain simulation or ankle inversion motion.	"…it is unlikely that 4-weeks of whole body vibration training has beneficial effects on ankle joint stability in the case of an ankle inversion motion."	Lack of study details. Results are of unknown clinical significance as the subject population had no orthopedic injuries and outcomes measures did not include incidence of injury post training.
[444]	2.0	See Ankle Support for Prevention above.				
Foot Orthotics for Prevention						
[414]	3.0	See Evidence Table for Plantar Fascitis (Orthoses) above.				

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Stretching/Strengthening Exercises						
[453] Cluster-RCT	3.5	N = 1,589 male army recruits (39 platoons)	Stretching vs. no stretching for prevention of ankle sprain.	1538 recruits, 170 (11%) transferred to officer training before end of training. Incidence of lower-limb injury: 3.5 per 1,000 training days. Hazard ratio .95 (95% CI .77-1.18). Ligament sprain, ankle joint: control vs. stretch; 27 vs. 19 out of 175 and 158.	"[P]reexercise muscle stretching does not produce a clinically worthwhile reduction in the risk of lower-limb injury. Injury risk is strongly associated with age and 20mSRT scores. This suggests that fitness may be a modifiable risk factor for injury."	Cluster randomization as subjected assigned to platoon by surname. Platoons then randomized although method unclear. Lack of study details. Ankle specific analysis not presented.
[454] RCT	3.5	N = 30 healthy subjects	No training vs. Thera-band training 3 times a week vs. Thera-band 5 times a week for 6 weeks.	Primary outcome of postural control measured on force plate. There were no differences related to intervention.	"[F]ound no significant improvements in static postural control among healthy individuals related to a specific Thera-band training regiment after six weeks of training regardless if the exercises were performed three or five times per week."	Sparse study details. No compliance to training data presented. Study suggests Thera-band training provides no benefit to healthy population. Results are of uncertain clinical significance.
[455] RCT	1.5	N = 180 male soccer players	Warm-up exercise program (passing soccer ball, flexibility stretches, cool down) vs. control.	Prophylactic program vs. nonobservance prophylactic program vs. control number of injures: Strains 5/1/23, lower leg injuries (traumatic) 0/0/3, lower leg injuries (overuse) 1/0/7, ankle sprain in players with history of	"[T]he proposed prophylactic program, including close supervision and correction by doctors and physiotherapists, significantly	Sparse study details. Intervention appears to have reduced injury and ankle sprains.

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				previous strain 0/2/9 (p <0.05), reinjuries 0/0/13, knee sprains with ALRI 0/0/3, injuries due to fouls 1/0/6, injuries at training camp 1/0/8, injuries connected with prophylactic program 8/3/72, other injuries 12/0/21, total 20/3/93.	reduces soccer injuries."	
(447) 2007	3.0	See Balance/Proprioception Training above.				
Physical or Occupational Therapy						
Acute and Subacute						
(456) RCT	3.5	N = 20 athletes who sustained Grade II acute ankle sprains	Imagery rehearsal and physical therapy vs. physical therapy.	Total (heel and toe) risings between imagery rehearsal vs. control: 19.00±2.11 vs. 14.50±4.38, p <0.0167. No differences heel or toe raising individually or in single-leg hop, stairs or balance measures.	"Results revealed significant differences only in the variable of muscular endurance. This study partly supports the contribution of imagery to the functional rehabilitation of grade II ankle sprain."	Sparse study details for compliance, baseline comparability. Both groups with extensive PT (12 sessions over 4 week period). Study results suggest mental imagery techniques is of little benefit.
(457) RCT	3.5	N = 40 volunteers referred to treatment within 4 months after Grade 1 or 2 ankle sprain; no concurrent impairment	Balance training: external attention focus vs. internal attention focus: 4 sessions	Outcomes after 4 sessions of training measured on stability index: EFA group experienced significant decrease in Overall Stability Index (OSI) p = 0.030.	"[E]xternal focus of attention is advantageous for the learning of a postural control task following an ankle injury."	Military population. Lack of study details. Results are of unknown clinical significance.
(458) RCT	3.5	N = 27 acute inversion sprains	Ankle-heel stretch to improve dorsiflexion in mild and moderate ankle sprains: Group 1: 30 second	Active ankle dorsiflexion ROM: Mean improvement at 6 weeks (Group 1 vs. 2 vs. 3)- 16°±5°, 19°±6,° 18°±9°, p >0.05 for intergroup differences.	"We were unable to demonstrate a significant group effect. Therefore, we are unable to recommend	Lack of study details. Study demonstrated all subjects improved with no differences in groups.

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			stretch vs. Group 2: 1 minute stretch vs. Group 3: 2 minute stretch		with confidence that after an inversion ankle sprain subjects perform a minimum of 3 daily static heel-cord stretches each of 30 seconds duration."	
[459] RCT	3.0	N = 40 male athletes with Grade 2 ankle sprain	Star-excursion balance training plus PT vs. PT for moderate acute sprains. PT included heat, ultrasound, ROM exercises, strengthening and stretching exercises. Balance training 3 supervised sessions a week for 4 weeks.	Balance training vs. control. Single leg stance time (SLST): eyes closed: 11.76+6.25 to 18.10+8.99 p >0.05, vs. 14.65+18.43 to 39.91+22.51, p = 0.002. Eyes closed SLST: 58.68+38.99 to 72.39 +31.47 p >0.05 vs. 74.82+73.49 to 162.98 +108.5, p <0.007. No between-group comparisons provided. Sprain recurrence (3 month follow-up): 1/15 vs. 2/17.	"The 4 weeks program of Star Excursion Balance training is more effective in improving functional stability of the sprained ankle than the conventional therapy program."	Lack of study details. Clinical significance of single leg stance test is uncertain. Appears to include baseline differences in outcomes measures (SLST, recurrence of injury). No differences in sprain recurrence.
[460] Quasi-RCT	2.5	N = 61 primary ankle sprains	Wobble board + RICE vs. RICE	6/24 vs. 13/24 patients had recurrent sprains, p <0.05. After 1, 6, and 12 weeks, no significant difference between groups for edema.	"Wobble board training for a period of 12 weeks, beginning 1 week after the ankle sprain, was effective in reducing the number of recurrent distortions and in preventing functional instability of the ankle in patients with primary ankle sprain. No difference in edema or hematoma seen during	Quasi-randomization. Sparse study details.

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					recovery period (1, 6, 12 weeks)."	
[461] RCT	2.0	N= 30 with unstable ankles; ages ranged 20 to 22 (20.58±0.64)	Land group, rehab program on land (n = 15) vs. Aquatic group, rehab program in swimming pool (n = 15). Both groups: static (total stability, anterior-posterior, and medial and lateral indices computed) and dynamic balance test with Biodex Stability System (6 wks, 3x/wk); 20 min training program (45 secs/exercise, 15 secs rest). Follow up: pre- and post-training.	Mean ± SD for Balance Assessments: land vs. aquatic: injured: post-training: total stability index: 4.41±1.7 vs. 4.36±1.4, p < 0.01; anterior-posterior index: 3.76±1.4 vs. 3.23±1.3, p < 0.01; medial-lateral index: 3.41±0.9 vs. 3.12±1.1, p < 0.01.	"The findings of this study advocate the use of balance exercise program for rehabilitation of college-aged individuals with functional ankle instability. The results demonstrated that individuals with a previous ankle sprain experienced balance deficits. A balance training program performed on balance boards increased the balance ability of the participants. The performance of balance exercises can take place in either a pool or land environment, with the same positive effect."	Baseline data sparse, N relatively small. Study of hypothesis that prior ankle sprain led to functional defects and balance problems, then tested that those may benefit from balance training program. However, differences modest between groups and no assessment of preventive and/or major functional gain.
[462] RCT	1.5	N = 30 with ankle sprains	Control Group (Group A) (n = 10) vs. Muscle strengthening exercise group	Mean ± SD for muscle strengthening: Group A vs. Group B vs. Group C: plantar flexion: 45.8±21.6 vs. 75.2±26.4 vs. 71.6±26.3, p < 0.05; dorsiflexion: 18.4±7.3 vs.	"Applying combined muscle strengthening and proprioceptive exercises to	Three arms but poorly described and small N. Combination muscle strengthening

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			(Group B); plantar flexion, dorsiflexion, inversion and eversion, 10 minutes using TheraBands (n = 10) vs. Combined muscle strengthening and proprioceptive exercises group (Group C); same exercises as group B then proprioceptive exercises, marching in place for 50 seconds, 4 sets for 10 minutes (n = 10).	27.5±9.5 vs. 30.7±5.4, p < 0.05; inversion: 17.8±5.5 vs. 28.7±6.6 vs. 26.2±8.9, p < 0.05; eversion: 10.2±2.2 vs. 14.3±1.9 vs. 14.7±3.0, p < 0.05.	those who have functional ankle instability is more effective than applying only muscle strengthening exercises."	and proprioceptive exercises to patients with ankle instability more effective than muscle strengthening exercises alone.
(267) RCT	1.5	N = 104 inversion injuries during a 10-week period at regional accident unit	No support vs. physiotherapy vs. double Tubigrip support vs. immobilized	Days off work: days at clinic (no support/ physiotherapy/double Tubigrip support/ immobilized), 5.1:23.6/ 6.0:21.4/7.5:21.5/41.0:25.0.	"[M]obilisation, with early physiotherapy or even without, offers the most rapid return to functional activity."	Lack of study details; 241 entered trial. High drop-out or exclusion rate(s). Not clear how many randomized.
(463) RCT	1.0	N = 28 with ankle sprains; mean age in eccentric group: 25.1, mean age for concentric group: 23.3, mean age for control group: 24.4	Concentric reinforcement (CG), foot inverted and everted, 10 reps, 2 min. rest period, proprioceptive rehabilitation on Freeman plate (n = 9) vs. Eccentric reinforcement (EG), foot blocked in eversion position, physiotherapist grasped lateral part of patient's forefoot, push	Mean ± SD for peak torques: CG vs. EG: concentric mode: 29.11±11.8 vs. 38.6±16, p = 0.01, eccentric mode: 35.7±17.5 vs. 45.8±20.3, p = 0.01. Strength deficits for injured side vs. healthy side: concentric: CG vs. EG: -28% vs. 19%, p = 0.01; eccentric: -41% vs. 1.6%, p = 0.03.	"After the eccentric reinforcement in the EG group, the muscle strength was significantly greater during concentric movements. Eccentric rehabilitation therefore restored the strength of the injured evertor muscles. These results show the value of this	Placebo group, few baseline characteristics to compare. Eccentric reinforcement in EG group had greater strength during concentric movements.

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			inwards, patient resisting inversion movement, returning to the first position; 5 series of 10 reps with 2 min rest period (n = 9) vs. Control group, healthy volunteers, no treatment (n = 10). Four-week study with no follow-ups.		method, especially as the weakness of these muscles after sprains is one of the main risk factors contributing to instability and the recurrence of sprains."	
Chronic Ankle Instability						
(464) RCT	3.5	N = 40 (20 with chronic ankle instability, 20 healthy subjects)	Exercise CAI vs. exercise healthy normal vs. control CAI vs. control healthy normal.	Post training (change over the first 4 weeks): Treatment t = -5.51/ p = 0.001, ankle sprain history CAI vs. healthy normal t = -2.76/ p = 0.010.	"Balance was improved after 4 weeks of elastic resistance exercise in subjects with and without a history of lateral ankle sprains. Balance improvements persisted 4 weeks following the treatment cessation."	Recruitment method of subjects is vague with healthy and previously injured young adults as study population. Sparse methodological details. Results of unknown clinical significance.
(465) RCT	3.0	N = 30 functional ankle instability	Conventional coordination training (CCT) vs. stochastic resonance coordination training (SCT) vs. control (no training). Programs 6 weeks.	Center of pressure as outcomes measure: control vs. CCT - no pre or post-test differences. SCT group had less posttest COP than post-test pooled mean of control and CCT groups.	"[C]oordination training alone did not result in significantly better postural stability than subjects who did not participate in coordination training at posttest. Coordination training with SR stimulation enhanced	Randomization, allocation, compliance details sparse. Only portion of subjects blinded. Results are of unknown clinical significance.

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					postural stability."	
[466] RCT	2.5	N = 48 functional instability of ankle	Control (no treatment) vs. electrical stimulation sham treatment (peroneus longus and brevis) vs. 6 weeks of balance and coordination training.	Maximum inversion test showed passive position sense better than active position sense, p <0.05m, for joint position sense. No differences between groups for sway index. Modified equilibrium score anterior/posterior: condition F (1, 42) = 56.64, p <0.001; eyes, F (1, 42) = 1118.18, p <0.001, F (2, 42) = 5.19, p <0.01. Modified equilibrium score medial/lateral: condition F (1, 42) = 89.2, p <0.001; eyes F (1, 42) = 1212.81, p <0.001, F (2, 42) = 6.90, p <0.003.	"[P]ostural sway can be improved in subjects with functional instability of the ankle following 6 weeks of coordination and balance training."	Lack of study details (randomization, allocation, baseline comparability, no blinding, and compliance). Study results of improving postural sway is of uncertain clinical significance as no injury recurrence data provided.
[467] RCT	2.5	N = 20 athletes with functional ankle instability	Dura disc training vs. mini-trampoline training vs. control (routine daily activities) in subjects with hx of ankle inversion injury and ankle instability with injury in past 2 years. Balance training program 6 weeks.	Postural Sway (pretest vs. post-test) in mm. Control: 36.9±9.9 vs. 36.7±8.2; Mini-tramp: 56.8±20.5 vs. 33.3.±8.5, p = 0.003. Dura Disc: 41.3±2.6 vs. 27.2±4.8 p = 0.003.	"[R]esults indicate that not only is the mini-trampoline an effective tool for improving balance after LAS, but it is equally as effective as the dura disc."	Lack of randomization, allocation, co-intervention, compliance details. Small sample size with non-randomized comparison group included. Results are of unknown clinical significance as outcome measure is surrogate for ankle instability but did not measure injury.
[468] RCT	1.5	N = 38 self-reported unilateral functional a nkle instability	Strength vs. proprioception vs. proprioception plus strength vs. control (3	No differences in muscle fatigue measures or static balance measures.	"Strength training, proprioceptio n training, and the combination of the 2 failed to improve	Lack of study details (randomizatio n, allocation, baseline comparability, no blinding, compliance,

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			sessions a week for 6 weeks).		postural-stability characteristics in a group of subjects with functional ankle instability."	co-interventions, follow-up).
Surgical Repair						
[469] RCT	3.5	N = 200 arthro-graphically verified rupture of 1 or both lateral ankle ligaments	Surgery vs. cast immobilization vs. tape (non-elastic) for 5 weeks, Grade II, III acute sprains.	Tendency of patients treated with tape to start to work earlier than other 2 groups, difference not significant; no differences in talar tilt. Report ankles asymptomatic: 2 1/34 vs. 20/29 vs. 34/40, p <0.005 favoring tape.	"Patients treated with tape had fewer symptoms, fewer complaints when running, and more ankles recovered to the preinjury state. Therefore, in lateral ankle ligament rupture, tape bandages seem preferable."	Lack of details for randomization, allocation, baseline comparability, compliance. All sprains were confirmed by arthrography. Suggests benefit of non-elastic tape for faster recovery than surgery.
[470] Quasi-RCT	3.5	N = 100 Grade III injuries of lateral ankle ligament	Surgical repair vs. conservative care (taping x 40 days)	Surgical vs. taping: Ankle Hind-foot Scale (100 point scale): 79+16 vs. 82+11 p >0.05. Return to sports: 10 vs. 7 weeks, p <0.05. Ankle swelling: no differences at any time.	"[I]n the short term, surgical treatment does not show any advantage over functional treatment. Therefore, nonsurgical treatment is recommended for grade III ankle ligament tears."	Quasi-randomization (odd/even birth year), Many details sparse. Compliance, drop-out rate unknown. Results suggest no difference in functional outcomes although taping resulted in faster return to sports.
[471] RCT	3.5	N = 80 recent ruptures of fibular ligament	Surgery plus cast for 3 weeks vs. functional (strapping for 2 weeks)	Surgery vs. functional: Restriction in ROM at 6 weeks: 22/36 vs. 0/27. Restriction in ROM at 1-year: both groups full	"The comparably good results of functional and operative treatments	Sparse study details. Grade of sprains likely moderate and severe, but not

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				movement and normal stability.	reported by others are confirmed by our study."	specified. No statistical analysis.
(424)	3.5	See Early Mobilization above.				
(426)	2.5	See Early Mobilization above.				
(472) RCT	2.5	N = 444 acute ankle sprains	Surgery plus cast for 5 weeks vs. cast for 5 weeks; randomized portion likely moderate and severe sprains.	Outcomes measures: strapping (non-randomized Grade I) vs. plaster vs. operation. No differences in return to sport, functional recovery, pain when walking. Good Results: 76% plaster vs. 81% operative (p = NS).	"[T]here was no statistically significant difference between the results of conservative and operative treatment of rupture of the lateral ligaments of the ankle."	Sparse study details. Only 209/444 randomized. Results did not clearly indicate if randomized portion considered separately. High drop-out rate at 1-year follow-up (37%). No differences in treatment in any major indicator.
(433)	2.5	See Casting above.				
(434)	2.0	See Casting above.				
(473) RCT	1.5	N = 24 with injuries of the lateral ligaments of ankle	Surgical repair vs. cast immobilization.	Surgical vs. cast: Average return to full duty (weeks): 12 vs. 8, p not specified. Excellent results (time measured not indicated) 9/12 vs. 9/12	"In terms of function…there was no difference between the two groups. Surgical treatment, however, is associated with a greater morbidity."	Timing of outcome measures unclear. Duration of conservative group immobilization not defined. Operative group received PT. Suggests outcomes similar in functional measures. Earlier return to work in cast group.

ANKLE FRACTURES

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Author/Year Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments
Tibia Shaft Fractures – Operative Management						
(474) RCT	3.0	N = 45 with closed multi-fragmented tibial diaphyseal fractures AO classification type B or C	Nonreamed interlocking intramedullary nails (n = 23) vs. bridging plates (n = 22).	No infections. Healing time for nails group was 20.3 weeks, for plates 16.0 weeks (p = 0.019). No differences in mobility.	"[T]he healing times were significantly shorter in patients undergoing surgery with the bridging plate technique, and the functional results were not different among patients of both groups."	No blinding; overall lack of details. Healing times appear shorter in plate vs. nails for closed multi-fragmented diaphyseal fractures. Lack of co-interventions, weight-bearing status, compliance, physical therapies make drawing conclusion difficult.
Operative Care – Plafond						
(231) RCT	3.5	N = 39 with intra-articular fracture of the tibial plafond	Open reduction and internal fixation (n = 18) vs. external fixation and limited internal fixation (n = 20).	No statistical differences in radiographic or functional results measured by clinical scores between groups; 15 operative complications in 7/19 ORIF group; 4 in 4/20 external fixation with or without limited internal fixation. Follow-up on average 39	"[L]imited internal fixation combined with use of an external fixator is an equally effective and safer method of treatment for most fractures of the tibial plafond."	Lack of study details in paper resulted in lower score. In tibial plafond fractures class I-III limited internal fixation with external fixation appears to have fewer complications with similar outcomes when compared to ORIF.

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				months after injury.		
Syndesmosis Injury Operative Technique						
[203] RCT	3.0	N = 127 unstable malleolar fractures with fluoro-scopically confirmed tibiofibular instability	Fixation of syndesmosis, with 3.5mm screws through 3 cortices. Non-weight bearing 6-10 weeks (n = 59) vs. fixation of syndesmosis, with 3.5mm screws through 4 cortices. Non-weight bearing 6-10 weeks (n = 61).	Hardware failure: 3 = 5/59 (8%); 4 = 4/61 (7%). Loss of reduction: 3 = 3/59 (5%); 4 = 0/61 (0%). Screw removal: 3 = 4/59 (7%); 4 = 4/61 (7%). All 3 patients in 3 cortical fixation group who needed screw removals because of pain non-compliant with weight-bearing restrictions, intoxicated at time of surgery, and smokers.	"[E]ither three or four cortices of fixation are sufficient to stabilize the syndesmosis during healing."	Lack of study details. No blinding, no mention of co-interventions. Suggests no significant differences in technique, but 4 cortices may be a better choice in patients who are likely to be non-compliant.
Malleolar Ankle Fracture Management						
[229] RCT	3.5	N = 42 with displaced ankle fractures requiring reduction (Pre-sumably AO B and C level of fracture)	Closed reduction and long leg plaster cast 6 weeks with early weight bearing encouraged vs. ORIF using AO technique. Below-knee plaster cast 6 weeks with early weight bearing.	At 20 weeks from injury more of the closed reduction group regained normal movements and foot position.	"[I]f a good reduction can be achieved and maintained then closed treatment is as good as operative treatment in the short term and, indeed, seemed to result in a quicker return to normal gait."	No blinding, lack of details on co-interventions and baseline characteristics.
[230] RCT	1.5	N = 84 elderly patients with displaced closed tri-malleolar ankle fractures with manipu-lation under an-esthesia for reduction	Conservative therapy including short leg cast and mobilization vs. open reduction surgery.	Total ankle scores: 91.37±8.96 for non-operative group vs. 75.22±14.38 for operative	"[C]onsideration of a non-operative approach to the treatment of well-reduced	Randomization method uncertain. Overall lack of study details. Generalizabili

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				group, p = 0.001.	ankle fractures in the elderly."	ty may be limited to elderly population.
Ankle Fracture Operative Management: Procedures and Fixators						
(475) RCT	3.5	N = 43 closed non-comminuted fractures of lateral and/or medial malleolus and dis-locations	ORIF with biofix implants vs. ORIF with metal implants.	Patients with biodegradable rods scored an average of 94.5 point on Olerud's scale compared to 90.4 points scored for patients with the stainless steel implants. Biofix patients scored 89% compared to 84% for AO/ASIF patients on the linear analogue scale.	"Patients treated with the biodegradable material reported slightly less pain during the follow-up period and were found to have a slightly better function of the ankle joint… Biofix biodegradable implants can be used for the internal fixation of a limited number of fracture dislocations of the ankle joint (i.e., noncomminuted simple fractures in nonosteoporotic patients)."	Lack of study details. No blinding, no details on control of co-interventions. Suggests bioabsorbable rods have similar outcomes as metal implants.
(476) RCT	3.5	N = 37 displaced malleolar fractures aged 65 and older	Self-reinforced polyglycolide rods and screws (n = 16) vs. metallic screws and plates (n = 19)	Re-displacement occurred in 1/16 (6%) in biodegradable group. Exact reduction obtained in 15/16 (94%) biodegradable group and 16/19 (84%) metallic group.	"It seems that displaced malleolar fractures can be treated successfully also in elderly people using totally biodegradable self-reinforced polyglycolide rods and screws when comminution does not require plate fixation."	Lack of study details. Suggests biodegradable implants achieved similar outcomes to metallic screws and plates in elderly patients with displaced malleolar fractures.
(477)	3.5	N = 72 Weber type B distal fibular fractures surgically repaired	Arthro-scopically assisted open reduction and	AORIF: 30/41 (73.2%) had osteochondral	"In the treatment of distal fibular	No blinding, minimal baseline

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RCT			internal fixations (AORIF) (n = 41) vs. open reduction and internal fixation (ORIF) (n = 31).	lesions, 33/41(80.5%) had tibiofibular ligament disruption, 6/41 (14.6%) had no combined disorder found. Ankle Hind-Foot score: AORIF 91.0, ORIF 87.5 (p = 0.0106).	fractures, precisely diagnosing and treating the combined intra-articular disorders is important for gaining satisfactory clinical results."	characteristics included. No mention of co-interventions. At 1 year follow-up, AORIF patients appear to have better scores on Ankle Hind-Foot score. No increase in adverse events reported with AORIF over just ORIF.
(478) RCT	3.5	N = 155 closed displaced medial malleolar fractures	Polylactide (bioabsorbable) screws vs. stainless-steel screws (control group).	No significant difference between groups for ability to walk, p = 0.95, run, p = 0.14, jump, p = 0.27, or climb stairs, p = 0.13. At 1 year, average ankle score: 83 points for study group, 79 for control, p = 0.13.	"[P]olylactide screws are a safe and effective alternative to stainless-steel screws for the fixation of displaced medial malleolar fractures."	No blinding, no allocation concealment, follow-up timing was variable. Study suggests PLA screws are as effective as stainless-steel without increased adverse events in medial malleolar fixation.
(479) RCT	3.0	N = 32 supination eversion fractures	Fixation with biodegradable polyglycolic acid rods or screws vs. metal wires, staples, and pins.	Residual displacement after operative treatment lateral malleolus rod: 0/15 poor; screw 0/17 poor; nondegenerative 0/13 poor. Medial mall: rod 0/3 poor; screw 0/7 poor; nondegenerative 0/13 poor.	"Nondegradable fixation is easier to handle, gives better fracture stability, can be used in more severe fractures."	Lack of study details. Suggests no significant differences in clinical outcomes and choice of fixation hardware should be based on surgeon preference.

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				Tibialis posterior: rod 1/7 (14%) poor; screw 1/7 (14%) poor; non-degenerative 3/18 (17%) poor.		
(480) RCT	3.0	N = 29 closed displaced malleolar fx in alcoholics	Self-reinforced dyless polyglycolide (PGA) screws (Biofix) vs. metallic AO implants.	Difference in redisplacements significant between groups, 8/16 for PGA and 1/13 for metallic AO, p = 0.04. Wound infections: 4 superficial, 1 deep all in PGA group 5/16 (31%).	"The significantly higher rate of failures in the PGA group noted during the study caused us to discontinue it."	Large difference in post-operative hospital days between groups, PGA was 5.6 and metallic 3.8. There was a large dropout rate. Study suggests PGA was inferior to metallic implants.
(203)	3.0	See Syndesmosis Injury Operative Technique above.				
(481) RCT	2.5	N = 19 with SER or PER fractures with intact medial malleolus; no evidence of intra-articular pathology	Open plate fixation with arthroscopic visualization of joint vs. open plate fixation.	8/9 patients who had arthroscopy had evidence of articular damage to the dome of the talus. No difference in SF-36 scores or objective clinical findings between groups.	"Most patients who underwent arthroscopic examination of the ankle joint were found to have a variable degree of articular cartilage damage at the dome of the talus…with no significant difference noted between groups in subjective or objective outcomes."	Lack of study details. Does not appear to be clinically beneficial results from arthroscopic investigation of ankle joint in addition to open reduction and plate fixation in SER or PER fractures with an intact medial malleolus.
Post Operative Care – Dressings						
(482) RCT	4.5	N = 54 undergoing open reduction and internal fixation	Immobilization with backslab (n = 28) vs. wool and crepe bandage (n = 26) for 1 day	Significant difference between groups for closet angle to	"[E]ither a backslab or wool and crepe bandages may be applied after	Abstract with lack of details results in low-quality study. Study

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			for post-op pain management.	plantigrade patient could achieve 1st day of physiotherapy, 25.0° for backslab group, 48.3° for wool and crepe group, p = 0.04.	internal fixation of ankle fractures, depending upon the surgeon's preference."	suggests no difference in post-op management of ORIF ankle fracture between back slab or crepe bandage.
Calcaneal Fractures: Operative Care – Cancellous Bone Defect Filling						
[483] RCT	3.5	N = 47 displaced intra-articular calcaneal fractures closed	ORIF with a bioabsorbable calcium phosphate paste to fill voids vs. ORIF.	No difference between groups Bohler angles at 6 weeks and 3 months. At 6 months Bohler angle collapse was: BSM: 5.6 degrees, ORIF: 9.1 degrees (p = 0.03). At one year BSM: 6.2 degrees, ORIF: 10.4 degrees (p = 0.05). No difference in SF-36, general health, limb specific function, pain.	"The results of this study show that use of bioabsorbable calcium phosphate paste leads to less calcaneal collapse after operative management once weight bearing is begun. We suggest the use of a bioresorbable calcium phosphate paste to fill the cancellous bone defect and augment ORIF."	No blinding or mention of co-interventions. Drop-out rate >20%. Bioabsorbable group and less collapse of Bohler angle at 6 months and greater than 1 year. No clinical outcome differences noted at any times. Clinical correlation of findings warrant further study to see if any clinical benefits occur with less collapse of Bohler angle.
[484] RCT	3.0	N = 38 acute closed Type I fractures of radius, humorous, ulna, femur, tibia, or calcaneal, traumatic void requiring grafting	Grafting material: BoneSource (BS) mineral product vs. Autograft (AG) from iliac crest or other location.	All fractures healed by 12 months follow-up. Maintenance of reduction observed in BS: 10/12 (83%), AG 10/15 (67%). Pain over fracture site	"Data from this demonstrate that BoneSource was both safe and effective as a bone void filler. The BoneSource showed equal or better maintenance of reduction than	Small numbers, no blinding, no co-interventions, no mention of compliance with surgical after care. Study did not include

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				resolved at 6 months: BS: 10/13 (77%), AG 9/16 (56%). (NS).	the autograft group."	control of no grafting. Suggests no difference in bone graft materials.
Post-Operative Rehabilitation: Immobilization, Early Mobilization, Early Weight Bearing						
[485]; [486] RCT	3.5	N = 57 displaced ankle fractures including the lateral malleolus. Weber A, B, C. Treated operatively. All casts removed after 6 weeks	Cast for 3 days, then no cast. Non-weight bearing. (A) Early motion with daily flexion, extension, inversion, eversion exercises vs. (B) Non-weight bearing plaster cast for 6 weeks vs. (C) plaster walking cast first 6 weeks.	Report 1: No significant difference in bone mineral content between 3 different treatment groups. Report 2: No complications with fracture healing in any of the groups. No difference in mean ROM of ankle. Weeks lost from work: A) 9.5, B) 13.8, C) 12.9 (NS). Participants encouraged to bear as much weight as possible).	"It appears that the amount of early weight bearing and active exercises after ankle fracture obtainable in clinical practice does not modify the degree of post-traumatic osteopenia. [T]he three postoperative regimens did not discernibly influence the clinical outcome, the risk of complications, or the delay in returning to work."	No mention of compliance with exercises or weight bearing status measured. Data suggest no differences in post-fracture osteopenia. No functional differences from each protocol.
[487] RCT	3.0	N = 40 dislocated bi- or tri-malleolar fractures	Early weight bearing after 1 week of non-weight bearing in an orthosis vs. late weight bearing using dorsal splint.	Orthosis group had better dorsal flexion at 3 and 6 months, p <0.05 and better plantar flexion at 3 months, p <0.05 compared with dorsal splint group.	"When comparing the 4 postoperative regimes, only small differences between the groups were found. As early postoperative weight bearing considerably facilitates rehabilitation it is to be recommended."	Two different results included. Compliance with motion exercises or weight bearing status not noted. No increases in complications for early weight bearing at 18 months follow-up. Suggests no long-term differences

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						from each protocol.
[488] RCT	1.5	N = 27 ankle fractures, type not described but all treated non-operatively	Immobilization in plaster for 6 weeks (n = 10) vs. plaster immobilization along with compression stocking for 6 weeks (n = 10) vs. immediate mobilization (n = 7).	Difference in limb circumference between control limb and fractured one less for stocking group vs. immobilization alone at 12 weeks (1.03±0.72 cms vs. 0.37±0.46 cms), p <0.004, and 18 weeks (1.15±0.72cms vs. 0.45 ±0.30cms), p <0.03. Reduction in limb swelling not seen in early mobilization group. Circumference at 5cm and 10cm from lateral malleolus decreased in compression stocking group only at 12 and 18 weeks.	"[L]imb swelling may subside more rapidly in the immobilised fractured limb if a compression stocking is applied while the limb is in plaster."	Lack of details. Compression stocking while in a plaster cast may decrease overall calf swelling.
[232] RCT	1.5	N = 55 tibial plafond fractures with external and minimal internal fixation	Mobilization (MG) home exercises, non-weight bearing, 10 reps 3 times a day. Passive dorsiflexion with active plantarflexion vs. 8-12 weeks external fixation without any mobilization. (NMG).	In 31 patients who had follow-up after 2 years, no difference detected. NMG averaged 11.7 weeks in a fixator MG 15.5 weeks (p = 0.008).	"These results indicate that treatment protocols that use long periods of cross-joint external fixation that immobilizes the ankle as definitive treatment result in similar patient outcomes compared to otherwise identical treatment	No blinding noted. Unable to reliably record compliance with home mobilization exercises. Study likely underpowered.

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					protocols that incorporate and use an articulated hinged for ankle motion."	
Post-Operative Care – Physical Therapy						
(489) RCT	3.5	N = 10 ankle fracture treated operatively or conserva-tively with immobili-zation in cast for 6 weeks	Exercise plus manual therapy 3 times a week for 5 weeks vs. exercise only 3 times a week for 5 weeks	MT group: 5/5 at Week 5 had full dorsiflexion. 4/5 had full plantarflexion. Control group: 1/5 at Week 5 had full dorsiflexion. 2/5 had full plantarflexion.	"The results of this small pilot study suggest that the use of manual therapy techniques and exercise used in the mobilisation of fractured ankles post-cast immobilisation is more effective than the traditional physiotherapy approach of mobilising exercises alone."	Small sample size. At baseline, manual therapy group had a higher functional score compared to exercise-only group. Very small numbers. Lack of reporting on compliance to protocol. No baseline explanation of conservative vs. surgery for fracture management between groups.
Post-Operative Care – Electrical Stimulation						
(490) RCT	1.5	N = 24 closed ankle fractures requiring surgery	Cast plus percutaneous electrical stimulation (Myospare) for 6 weeks vs. cast for 6 weeks.	No adverse effects from Myospare reported. Reported trend (p >0.05) toward improvement in calf diameter as well as in dorsiflexion and plantarflexion in Myospare group.	"The use of the Myospare device under a cast in patients after surgical fixation of ankle fractures has been demonstrated as feasible and safe. In this pilot study a trend toward enhanced recov ery was apparent in the	Abstract description only. Sparse details.

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					treatment group."	
Calcaneal Fractures – Non-operative vs. Operative Care						
[491] Quasi-RCT	3.5	N = 80 non-displaced calcaneal fractures (included but not randomized) and displaced intra-articular calcaneal fractures	Non-operative (elevation for 5-7 day with mobilization, than non-weight bearing cast for 6-8 weeks vs. ORIF with post-op cast and non-weight bearing for 6-8 weeks.	Displaced fractures: increased pain scores on VAS correlated with significant delays in return to employment (p <0.002), return to full recreational activities (p <0.01), and reduced patient satisfaction (p <0.000002)	"[O]perative treatment of this joint is not likely to improve outcome."	Quasi-randomization (birth-year odd/even). Lack of detail on how many included in each group. No blinding or post-op compliance noted. Suggests non-displaced fractures superior to displaced fractures, regardless os treatment. In patients with displaced fractures, no significant differences in outcomes between surgery and cast.
[78] RCT	2.5	N = 46 with displaced intra-articular calcaneal fractures (15 year study follow-up)	Conservative treatment (C) of elevation for 5-7 days, movement as able, cast with non-weight bearing for 6-8 weeks vs. ORIF lateral approach. (Op) Plaster cast for 6 weeks, non-weight bearing 6-8 weeks.	AOFAS hindfoot score: C = 78.5, Op = 70.0 (p = 0.11). AOFAS foot function index: C = 24.4, Op = 26.9 (p = 0.66). Calcaneal fracture score: C = 70.1, Op = 63.5 (p = 0.41). Bohler's angle: C = 10.4° Op = 16.9° (p = 0.07). Height of calcaneus: C = 37.2 mm, Op = 38.2mm (p = 0.57). Grade of OA in subtalar	"At a mean follow-up of 15 years, we have shown no difference between conservative or operative patients using both functional and radiological outcomes."	Follow up of Parmar 93 study; 50% participation from original participants. No mention of interval injury, therapy or concurrent treatment of participants in study. Study did not find any clinical evidence of difference between operative

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				joint: (p = 0.54).		and non-operative treatment of displaced intra-articular calcaneal fractures at 15 years follow-up.
Metatarsal Fracture (Avulsion) – Operative Management						
[492] Quasi-RCT	3.0	N = 89 with avulsion fracture of 5th meta-tarsal (excluded Jones fractures)	Short leg cast vs. Jones Fracture soft dressing.	Cast vs. dressing: Average time to union (days) 43 vs. 45, p = ns. Average time return to pre-injury level activity (days): 46 vs. 33, p<0.05. Modified Foot score 86 vs. 92, p = NS.	"The Jones dressing proves to be an effective, non-debilitating treatment modality for avulsion fractures of the base of the fifth metatarsal. It allows patients an earlier return to full activity than when treated in a short leg cast, without the risk of compromising clinical or radiographic healing."	Quasi-randomization by even/odd day of injury presented. Baseline comparability details sparse. Loss to follow-up 35%. Study suggests no dressing for avulsion fracture may lead to quicker return to activity.

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National, Regional, Local Committee Affiliations—Past President, Michigan Occupational and Environmental Medicine Association; Past President, Detroit Occupational Physicians Association

Guidelines Related Professional Activities—Past Member, Health Services Policies, Procedures, Programs and Guidelines Review and Development Committee, General Motors Corporation; Past Member of Public Health Committee, Ingham County Medical Society; Past Member, Board of Trustees of the Michigan Mid-South Health Systems Agency; Past Member, Project Review Committee and Public Information Committee of Michigan Mid-South Health Systems Agency

Research Grants/Other Support—None

Financial/Non-Financial Conflict of Interest—None

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Research Grants/Other Support—None reported

Financial/Non-Financial Conflict of Interest—None reported

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National, Regional, Local Committee Affiliations—None

Guidelines Related Professional Activities— Activities related to the ACOEM Practice Guidelines research Grants/Other Support— Training grants and research grants primarily on the epidemiology of musculoskeletal disorders (e.g., CTS, shoulder tendinosis, LBP)

Financial/Non-Financial Conflict of Interest— Honoraria: Teaching honoraria from courses, ACPM and ACOEM-related; Consulting regarding how to reduce work-related injuries, causation and apportionment of injuries, work restrictions and work-relatedness injuries, and practice guidelines compliance; Clinical: Primary, secondary and tertiary clinical management of occupational injuries and diseases

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Guidelines Related Professional Activities—

Research Grants/Other Support—None

Financial/Non-Financial Conflict of Interest—None

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National, Regional, Local Committee Affiliations—None

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Research Grants/Other Support—None

Financial/Non-Financial Conflict of Interest—None

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National, Regional, Local Committee Affiliations—Medical Reviewer for following journals: Journal of Voice and Academy of Neurology – Practice Guidelines; *AADEP Disability Newsletter*; Expert Opinion Editor, *Practical Neurology*; Treasurer, New York Occupational and Environmental Medical Association

Other Guidelines Related Professional Activities—Member, ACOEM Evidence-based Practice Chronic Pain Panel; Member, ACOEM Evidence-based Practice Ankle/Foot Panel; Panel Member, Sports Concussion, American Academy of Neurology

Research Grants/Other Support—Sport Concussion Voice Disorders: Laryngeal EMG, Sjogren's Syndrome

Financial/Non-Financial Conflict of Interest—None

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Guidelines Related Professional Activities—Clinical Practice Guideline on Heel Pain – Plantar Fasciitis for Orthopaedic Section of the American Physical Therapy Association; Clinical Practice Guideline on Achilles Tendinopathy for Orthopaedic Section of the American Physical Therapy Association; Team Leader, Orthopaedic Section, American Physical Therapy Association's International Classification of Functioning and Disability Project

Research Grants/Other Support—Co-Investigator, "Ankle Proprioception after Total Ankle Replacement," DePuy Research Grant

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Financial/Non-Financial Conflict of Interest—None

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National, Regional, Local Committee Affiliations—None

Guidelines Related Professional Activities—ACFAS Clinical Practice Guidelines

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Financial/Non-Financial Conflict of Interest—None reported

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Guidelines Related Professional Activities—None

Research Grants/Other Support—None

Financial/Non-Financial Conflict of Interest—None

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