NEW YORK STATE OF OPPORTUNITY.

Workers' Compensation Board

Medical Treatment Guidelines

Ankle and Foot Injuries

January 2021

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Contributors

The NYS Workers' Compensation Board would like to thank the members of the New York Workers' Compensation Board Medical Advisory Committee (MAC). The MAC served as the Board's advisory body to adapt the American College of Occupational and Environmental Medicine (ACOEM) Practice Guidelines to a New York version of the Medical Treatment Guidelines (MTG). In this capacity, the MAC provided valuable input and made recommendations to help guide the final version of these Guidelines. With full consensus reached on many topics, and a careful review of any dissenting opinions on others, the Board established the final product.

Medical Advisory Committee

Joseph Canovas, Esq.
Special Counsel
New York State AFL-CIO

Kenneth B. Chapman, MD
Director Pain Medicine, SIUH Northwell Health Systems
Assistant Clinical Professor, NYU Langone Medical Center
Adjunct Assistant Professor, Hofstra Medical School

Nicholas D'Angelo, DPM
ABPS, Board Certified in Foot Surgery
NYSPMA, Board of Trustees
NYSPMA, Insurance Committee Chair

Lev Ginsburg, Esq.
Senior Director of Government Affairs
The Business Council of New York State

Emilio A. Goez, DPM, FACAS, FASPS
St. Barnabas Hospital Health System, Medical Co-Director, The Center for Wound Healing and Hyperbaric Medicine
Board Certified, Board of Foot and Ankle Surgery
Fellow, American Society of Podiatric Surgeons, the American College of Foot and Ankle Surgeons and the American Professional Wound Care Association

Robert Goldberg, DO
Attending Physician, Department of Rehabilitation, Beth Israel Hospital and Medical Center of NYC
Professor of Physical Medicine and Rehabilitation and Health Policy
Clinical Associate Professor of Rehabilitation Medicine, New York Medical College
Clinical Professor of Rehabilitation Medicine, Philadelphia College of Osteopathic Medicine
Member, Council on Medical Education of the American Medical Association

Charles M. Lombardi, DPM
Director of Podiatry, Department of Orthopaedics & Rehabilitation, New York-Presbyterian/Queens
Clinical Assistant Professor of Podiatry in Surgery, Cornell University Medical College, New York
Clinical Associate Professor of Surgery, External Faculty, New York College of Podiatric Medicine
Director of Podiatric Medical Education, New York-Presbyterian/Queens, New York.

Joseph Pachman, MD, PhD, MBA, MPH
Licensed Psychologist and Physician
Board Certified in Occupational Medicine

Fellow in ACOEM
Vice President and National Medical Director, Liberty Mutual

Elain Sobol Berger, MD, Esq.
Medical Director and Senior Policy Advisor
NYS Workers' Compensation Board

James A. Tacci, MD, JD, MPH (FACOEM, FACPM)
University of Rochester Medical Center
Attending Physician, Strong Occupational & Environmental Medicine, Strong Memorial Hospital
Associate Professor of Clinical Environmental Medicine, Department of Environmental Medicine
Associate Professor and Preventive Medicine Residency Director,Department of Public Health Sciences
Medical Director, URMC Travel Medicine / Passport Health of Upstate New York

Edward C. Tanner, MD
Chair, Department of Orthopaedics at Rochester General Hospital
Past President, New York State Society of Orthopaedic Surgeons (NYSSOS)
Member, American Academy of Orthopaedic Surgeons (AAOS)
Member, American Association of Hip and Knee Surgeons (AAHKS)

Contributors to ACOEM Ankle and Foot Disorders Guideline

Editor-in-Chief:
Kurt T. Hegmann, MD, MPH, FACOEM, FACP

Assistant Editor:
Matthew A. Hughes, MD, MPH

Evidence-based Practice Ankle and Foot Panel Chair:
Nelson S. Haas, MD, MPH, FACOEM

Evidence-based Practice Ankle and Foot Panel Members:
Patrick J. Beecher, MD, MPH, MBA, FACOEM
Mark Easley, MD
Hannah Edwards, MD, MPH
Harold Hoffman, MD, FRCPC
Steven Mandel, MD, FACOEM
RobRoy L. Martin, PhD, PT, CSCS
Pete Thomas, DPM, QME

The Evidence-based Practice Ankle/Foot Panel represents expertise in occupational medicine, neurology, podiatric surgery, foot and ankle surgery, physical therapy, and rehabilitation science.

Guidelines Methodology Consultant:
Kurt T. Hegmann, MD, MPH, FACOEM, FACP

Research Conducted By:
Kurt T. Hegmann, MD, MPH, FACOEM, FACP
Matthew A. Hughes, MD, MPH
Jeremy J. Biggs, MD, MSPH
Matthew S. Thiese, PhD, MSPH
Ulrike Ott, PhD, MSPH
Kristine Hegmann, MSPH, CIC
Atim Effiong, MPH
Holly Diane Uphold

Specialty Society and Society Representative Listing:
ACOEM acknowledges the following organizations and their representatives who served as reviewers of the "Ankle and Foot Disorders Guideline". Their contributions are greatly appreciated. By listing the following individuals or organizations, it does not infer that these individuals or organizations support or endorse the ankle and foot treatment guidelines developed by ACOEM.

2011 External Reviewers
American Physical Therapy Association
Stephanie Albin, DPT, FAAOMPT, OCS
Thomas G. McPoil, PT, PhD, ATC, FAPTA

American Podiatric Medical Association
Clinical Practice Advisory Committee (CPAC)

California Orthopaedic Association
Carol Frey, MD

Other Reviewers:
Kathryn L. Mueller, MD, MPH, FACOEM

2015 External Reviewers
American Academy of Physical Medicine & Rehabilitation

American Association of Occupational Health Nurses
Kimberly Olszewski, DNP, CRNP, COHNS-CM, FAAOHN

American College of Foot and Ankle Surgeons
Andrew J. Meyr, DPM, FACFAS

American Occupational Therapy Association
Michelle L. Bradshaw, DC, OTR/L
Julie Dorsey, OTD, OTR/L, CEAS

American Physical Therapy Association

American Podiatric Medical Association
James R. Christina, DPM

American Society of Anesthesiologists
Andres Navedo, MD

California Orthopedic Association
Eric Gokcen, MD
F. Ray Nickel, MD, MPH
Tye Ouzounian, MD
Steven Ross, MD
Ronald Smith, MD

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A. General Guideline Principles

The principles summarized in this section are key to the intended application of the New York State Medical Treatment Guidelines (MTG) and are applicable to all Workers' Compensation Medical Treatment Guidelines.

A.1 Medical Care

Medical care and treatment required as a result of a work-related injury should be focused on restoring functional ability required to meet the patient's daily and work activities and return to work, while striving to restore the patient's health to its pre-injury status in so far as is feasible.

A.2 Rendering of Medical Services

Any medical provider rendering services to a workers' compensation patient must utilize the Treatment Guidelines as provided for with respect to all work-related injuries and/or illnesses.

A.3 Positive Patient Response

Positive results are defined primarily as functional gains which can be objectively measured. Objective functional gains include, but are not limited to, positional tolerances, range of motion, strength, endurance, activities of daily living (ADL), cognition, psychological behavior, and efficiency/velocity measures which can be quantified. Subjective reports of pain and function should be considered and given relative weight when the pain has anatomic and physiologic correlation.

A.4 Re-Evaluate Treatment

If a given treatment or modality is not producing positive results, the provider should either modify or discontinue the treatment regime. The provider should evaluate the efficacy of the treatment or modality two to three weeks after the initial visit and three to four weeks thereafter. Recognizing that treatment failure is at times attributable to an incorrect diagnosis should prompt the clinician to reconsider the diagnosis in the event of an unexpected poor response to an otherwise rational intervention.

A.5 Education

Education of the patient and family, as well as the employer, insurer, policy makers and the community should be a primary emphasis in the treatment of work-related injury or illness. Practitioners should develop and implement effective educational strategies and skills. An education-based paradigm should always start with communication providing reassuring information to the patient. No treatment plan is complete without addressing issues of individual and/or group patient education as a means of facilitating self-management of symptoms and prevention of future injury.

Time Frames

A.6 Acuity

Acute, Subacute and Chronic are generally defined as time frames for disease stages:

- Acute – Less than one month
- Subacute - One to three month, and
- Chronic - greater than three months.

A.7 Initial Evaluation

Initial evaluation refers to the acute time frame following an injury and is not used to define when a given physician first evaluates an injured worker (initial encounter) in an office or clinical setting.

A.8 Diagnostic Time Frames

Diagnostic time frames for conducting diagnostic testing commence on the date of injury. Clinical judgment may substantiate the need to accelerate or decelerate the time frames discussed in this document.

A.9 Treatment Time Frames

Treatment time frames for specific interventions commence once treatments have been initiated, not on the date of injury. Obviously, duration may be impacted by disease process and severity, patient compliance, as well as availability of services. Clinical judgment may substantiate the need to accelerate or decelerate the time frames discussed in this document.

A.10 Delayed Recovery

For those patients who fail to make expected progress six to 12 weeks after an injury, re-examination in order to confirm the accuracy of the diagnosis and re-evaluation of the treatment program should be performed. Assessment for potential barriers to recovery (yellow flags/psychological issues) should be ongoing throughout the care of the patient. However, at six to 12 weeks, alternate treatment programs, including formal psychological or psychosocial evaluation, should be considered. Referrals to mental health providers (i.e.: psychology/psychiatry) for the evaluation and management of delayed recovery do not indicate or require the establishment of a psychiatric or psychological condition. The evaluation and management of delayed recovery does not require the establishment of a psychiatric or psychological claim.

Treatment Approaches

A.11 Active Interventions

Active interventions emphasizing patient responsibility, such as therapeutic exercise and/or functional treatment, are generally emphasized over passive modalities, especially as treatment progresses. Generally, passive and palliative interventions are viewed as a means to facilitate progress in an active rehabilitation program with concomitant attainment of objective functional gains.

A.12 Active Therapeutic Exercise Program

Active therapeutic exercise program goals should incorporate patient strength, endurance, flexibility, range of motion, sensory integration, coordination, and education as clinically indicated. This includes functional application in vocational or community settings.

A.13 Diagnostic Imaging and Testing Procedures

Clinical information obtained by history taking and physical examination should be the basis for selection and interpretation of imaging procedure results. All diagnostic procedures have variable specificity and sensitivity for various diagnoses.

When a diagnostic procedure, in conjunction with clinical information, provides sufficient information to establish an accurate diagnosis, a second diagnostic procedure will be redundant if it is performed only for diagnostic purposes. At the same time, a subsequent

diagnostic procedure (that may be a repeat of the same procedure, when the rehabilitation physician, radiologist or surgeon documents the study was of inadequate quality to make a diagnosis) can be a complementary diagnostic procedure if the first or preceding procedures, in conjunction with clinical information, cannot provide an accurate diagnosis, and is permissible under the MTG.

It is recognized that repeat imaging studies and other tests may be warranted by the clinical course and to follow the progress of treatment in some cases. It may be of value to repeat diagnostic procedures (e.g., imaging studies) during the course of care to reassess or stage the pathology when there is progression of symptoms or findings, prior to surgical interventions and therapeutic injections when warranted, and post-operatively to follow the healing process. Regarding CT examinations, it must be recognized that repeat procedures result in an increase in cumulative radiation dose and associated risks.

A.14 Surgical Interventions

Contemplation of surgery should be within the context of expected functional outcome. The concept of "cure" with respect to surgical treatment by itself is generally a misnomer. All operative interventions must be based upon positive correlation of clinical findings, clinical course and imaging and other diagnostic tests. A comprehensive assimilation of these factors must lead to a specific diagnosis with positive identification of pathologic condition(s). For surgery to be performed to treat pain, there must be clear correlation between the pain symptoms and objective evidence of its cause. In all cases, shared decision making with the patient is advised. The patient should be given the opportunity to understand the pros and cons of surgery, potential for rehabilitation as an alternative where applicable, evidence-based outcomes, and specific surgical experience.

A.15 Pre-Authorization

All diagnostic imaging, testing procedures, non-surgical and surgical therapeutic procedures within the criteria of the Medical Treatment Guidelines and based on a correct application of the Medical Treatment Guidelines are considered authorized, with the exception of the following procedures: Lumbar Fusion, Artificial Disc Replacements, Vertebroplasty, Kyphoplasty, Electrical Bone Growth Stimulators, Spinal Cord Stimulators, Intrathecal Drug Delivery (Pain Pumps), Osteochondral Autograft, Autologous Chondrocyte Implantation, Meniscal Allograft Transplantation and Knee Arthroplasty (Total or Partial Knee Joint Replacement). These are not included on the list of pre-authorized procedures. Providers who want to perform one of these procedures must request pre-authorization from the carrier before performing the procedure.

Second or subsequent procedures (the repeat performance of a surgical procedure due to failure of, or incomplete success from the same surgical procedure performed earlier, if the Medical Treatment Guidelines do not specifically address multiple procedures) also require pre-authorization.

A.16 Personality/Psychological/Psychosocial Evaluations

In select patients, diagnostic testing procedures may be useful when there is a discrepancy between diagnosis, signs, symptoms, clinical concerns or functional recovery. Psychological testing should provide differentiation between pre-existing depression versus injury-caused depression, as well as post-traumatic stress disorder, and other psychosocial issues that may include work or non-work-related issues when such conditions are identified in the patient.

For those patients who fail to make expected progress six to 12 weeks after an injury and whose subjective symptoms do not correlate with objective signs and tests, re-

examination in order to confirm the accuracy of the diagnosis should be made. Formal psychological or psychosocial evaluation may be considered.

A professional fluent in the primary language of the patient is strongly preferred. When such a provider is not available, services of a professional language interpreter must be provided.

Frequency: One time visit for evaluation. If psychometric testing is indicated by findings in the initial evaluation, time for such testing should not exceed an additional two hours of professional time.

A.17 Personality/Psychological/Psychosocial Intervention

Following psychosocial evaluation, when intervention is recommended, such intervention should be implemented as soon as possible. This can be used alone or in conjunction with other treatment modalities.

- Time to produce effect: two to eight weeks.
- Optimum duration: six weeks to three months.
- Maximum duration: three to six months. Counseling is not intended to delay but to enhance functional recovery. For select patients, longer supervision may be required, and if further counseling is indicated, documentation of the nature of the psychological factors, as well as projecting a realistic functional prognosis, should be provided by the authorized treating practitioner every four to six weeks during treatment.

A.18 Functional Capacity Evaluation (FCE)

Functional Capacity Evaluation is a comprehensive or more restricted evaluation of the various aspects of function as they relate to the patient's ability to return to work. Areas such as endurance, lifting (dynamic and static), postural tolerance, specific range-of-motion, coordination and strength, worker habits, employability, as well as psychosocial, cognitive, and sensory perceptual aspects of competitive employment may be evaluated. Components of this evaluation may include: (a) musculoskeletal screen; (b) cardiovascular profile/aerobic capacity; (c) coordination; (d) lift/carrying analysis; (e) job-specific activity tolerance; (f) maximum voluntary effort; (g) pain assessment/psychological screening; (h) non-material and material handling activities; (i) cognitive; (j) visual; and (k) sensory perceptual factors.

In most cases, the question of whether a patient can return to work can be answered without an FCE.

When an FCE is being used to determine a return to a specific job site, the treating physician is responsible for understanding and considering the job duties. FCEs cannot be used in isolation to determine work restrictions. The authorized treating physician must interpret the FCE in light of the individual patient's presentation and medical and personal perceptions. FCEs should not be used as the sole criteria to diagnose malingering.

An FCE may be considered at time of maximal medical improvement (MMI), following reasonable prior attempts to return to full duty throughout course of treatment, when the treating physician is unable to make a clear determination on work status on case closure.

A.19 Return to Work

For purposes of these guidelines, return to work is defined as any work or duty that the patient is able to perform safely. It may not be the patient's regular work. Ascertaining a

return to work status is part of medical care, and should be included in the treatment and rehabilitation plan. It is normally addressed at every outpatient visit. A description of the patient's status and task limitations is part of any treatment plan and should provide the basis for restriction of work activities when warranted. Early return to work should be a prime goal in treating occupational injuries. The emphasis within these guidelines is to move patients along a continuum of care and return to work, since the prognosis of returning an injured worker to work drops progressively the longer the worker has been out of work.

A.20 Job Site Evaluation

The treating physician may communicate with the employer or the employer's designee, either in person or by telephone, to obtain information regarding the demands of the patient's pre-injury job, including a description of the exertional demands of the job, the need for repetitive activities, load lifting, static or awkward postures, or any other factors that would pose a risk of re-injury or impedance of convalescence. When returning to work at the patient's previous job task/setting is not feasible, given the clinically determined restrictions on the patient's activities, inquiry should also be made about modified duty work settings, and a similar set of questions should be posed by the physician about work activities/demands in modified duty jobs.

Ideally, the physician would gain the most information from an on-site inspection of the job settings and activities; but it is recognized that this may not be feasible in most cases. If job videos/CDs/DVDs are available from the employer, these can contribute valuable information.

Frequency: one or two calls

- 1st call: Patient is in a functional state where the patient can perform some work.
- 2nd call: Patient has advanced to a state where the patient is capable of enhanced functional demands in a work environment.

The physician shall document the conversation.

Other

A.21 Guideline Recommendations and Medical Evidence

The Workers' Compensation Board and its Medical Advisory Committee have not independently evaluated or vetted the scientific medical literature used in support of the guidelines, but have relied on the methodology used by the developers of various guidelines utilized and referenced in these Guidelines.

A.22 Experimental/Investigational Treatment

Medical treatment that is experimental/investigational and not approved for any purpose, application or indication by the FDA is not permitted under these Guidelines.

A.23 Injured Workers As Patients

In these Guidelines, injured workers are referred to as patients recognizing that in certain circumstances there is no doctor-patient relationship.

A.24 Scope of Practice

These Guidelines do not address scope of practice or change the scope of practice.

Ankle and Foot Injuries

Effective Date: 01/01/21

B. Introduction

This guideline addresses common and potentially work-related ankle and foot injuries. It encompasses assessment; including identification of “red flags” or indicators of potentially-serious injury or disease; diagnosis; diagnostic studies for identification of clinical pathology and management. Red flags include fracture, dislocation, malignancy, metabolic disorders, infection, and other conditions.

B.1 History Taking and Physical Examination

B.1.a History Taking and Physical Examination

History taking and physical examination establish the foundation/basis for and dictate subsequent stages of diagnostic and therapeutic procedures. When findings of clinical evaluations and those of other diagnostic procedures are not consistent with each other, the objective clinical findings should have preference. The medical records should reasonably document the following:

B.1.b History of Present Injury

- Mechanism of injury: This includes details of symptom onset and progression, and symptoms that may arise from postural or functional accommodation to the Ankle-Foot injury;
- Relationship to work: This includes a statement of the probability that the illness or injury is work-related;
- Prior occupational and non-occupational injuries: To the same area including specific prior treatment;
- Ability to perform job duties and activities of daily living; and
- Exacerbating and alleviating factors for symptoms; not limited to the Ankle-Foot.

B.1.c Past History

- Past medical history includes, but is not limited to, neoplasm, gout, arthritis, and diabetes;
- Review of systems includes, but is not limited to, symptoms of rheumatologic, neurologic, endocrine, neoplastic, and other systemic diseases;
- Smoking history;
- Vocational and recreational pursuits;
- Prior imaging studies; and
- Past surgical history.

B.1.d Physical Examination

Examination of a joint should include the joint above and below the affected area, including the opposite side for comparison. Physical examination should include

accepted tests and exam techniques applicable to the joint or area being examined, including:

- Visual inspection - Examine both feet and look for and note asymmetries and for deformities suggestive of degeneration, malformation, fracture, or dislocations. Observe for signs of serious injuries, e.g., degloving injuries, lacerations, puncture wounds, open wounds and crush injuries;
- Palpation;
- Range of motion/quality of motion (active and passive); The range of motion (ROM) of the foot and ankle should be determined both actively and passively. Compare mobility of the affected and unaffected side;
- Strength (weakness / atrophy);
- Joint integrity / stability - Stress the ligaments to assess the stability and compare to contralateral unaffected side;
- Examination for deformity/displacement; and
- Assess neurologic (motor, sensory and reflexes) and vascular status (integrity of distal circulation, peripheral pulses, skin temperature) of the foot and ankle, as clinically indicated. Observe for signs of serious injuries, e.g., degloving injuries, lacerations, puncture wounds open wounds and crush injuries.

B.2 Assessing Red Flags

Certain findings, “red flags” raise suspicion of potentially serious medical conditions. Assessment (history and physical examination) should include evaluation for red flags. In the foot and ankle these findings or indicators may include: fracture, dislocations, infection or inflammation, tumor, tendon rupture and neurological or vascular compromise including compartment syndrome. Further evaluation/consultation or urgent/emergency intervention may be indicated, and the New York Ankle and Foot Injury Medical Treatment Guidelines incorporate changes in clinical management triggered by the presence of “red flags”.

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	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 May have sustained laceration, or direct trauma	Decreased sensation in feet and ankles Loss of vibratory or positional sense Altered sensation in a dermatomal distribution Absent ankle jerk 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	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 May have overlying signs of trauma including laceration, open wounds, puncuture wounds or crush
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 metatarsal or metatarsophalangeal joint 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	Flatfoot deformity, particularly when unilateral; tenderness of the posterior medial malleolus,

	progressive flatfoot deformity (with or without pain) May have sustained laceration, open wounds, crush injuries, or direct trauma May have degloving injury	asymmetrical flatfoot, difficulty with ipsilateral heel raise May have overlying signs of trauma including laceration, open wounds, puncture wounds, or crush injuries

B.3 Diagnostic Criteria and Differential Diagnosis

For most cases presenting with true foot and ankle disorders, diagnostic 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.

B.3.a Diagnostic Testing and Procedures

One diagnostic imaging procedure may provide the same or distinctive information as obtained by other procedures. Therefore, prudent choice of procedure(s) for a single diagnostic procedure, a complementary procedure in combination with other procedures(s), or a proper sequential order in multiple procedures will ensure maximum diagnostic accuracy, minimize adverse effect to patients and promote cost effectiveness by avoiding duplication or redundancy.

All diagnostic imaging procedures have a significant percentage of specificity and sensitivity for various diagnoses. None is specifically characteristic of a certain diagnosis. Clinical information obtained by history taking and physical examination should be the basis for selection and interpretation of imaging procedure results.

When a diagnostic procedure, in conjunction with clinical information, provides sufficient information to establish an accurate diagnosis, the second diagnostic procedure will be redundant if it is performed only for diagnostic purposes. At the same time, a subsequent diagnostic procedure (that may be a repeat of the same procedure, when the rehabilitation physician, radiologist or surgeon documents that the study was of inadequate quality to make a diagnosis) can be a complementary diagnostic procedure if the first or preceding procedures, in conjunction with clinical information, cannot provide an accurate diagnosis. Usually, preference of a procedure over others depends upon availability, a patient's tolerance, and/or the treating practitioner's familiarity with the procedure.

It is recognized that repeat imaging studies and other tests may be warranted by the clinical course and to follow the progress of treatment in some cases. It may be of value to repeat diagnostic procedures (e.g. imaging studies) during the course of care to reassess or stage the pathology when there is progression of symptoms or findings, prior to surgical interventions and therapeutic injections when warranted, and post-operatively to follow the healing process. Regarding CT examinations, it must be recognized that repeat procedures result in an increase in cumulative radiation dose and associated risks.

When indicated, the following can be utilized for further evaluation of foot and ankle injuries, based upon the mechanism of injury, symptoms, and patient history.

Table 2. Diagnostic Criteria for Non-Red Flag Conditions

Probable Diagnosis or Injury	Mechanism	Unique Symptoms	Unique Signs
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
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
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 plantar flexion or dorsal flexion	Pain over muscle/tendon unit on motion or resisted motion of tendon unit Tenderness of involved tendon
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
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
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
Heel spur	Degenerative change Idiopathic	Pain at heel with weight bearing First steps upon rising in the morning very painful in heel	Point tenderness over plantar calcaneus
Metatarsal stress fracture	Repetitive load	Pain in the dorsal forefoot on weight bearing	Point tenderness over metatarsal shaft
Toe fracture	Direct trauma	Pain at fracture site (possibly)	Point tenderness Deformity Hematoma
Crush injury	Direct trauma	Ranges from nonspecific pain to pain at fracture site	Point tenderness Deformity Hematoma Swelling
Nonspecific foot or ankle pain	Unknown	Nonspecific pain in foot or ankle	None

C. Conditions: This guideline addresses the following Foot and Ankle Disorders

C.1 Achilies Tendinopathy

C.2 Achillies Tendon Rupture

C.3 Ankle Tendinopathies

C.4 Tenosynovitis

C.5 Plantar Heel Pain (Plantar Fasciitis)

C.6 Foot Ulceration

C.7 Wound Care, Subungual Hematoma, Contusions

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C.11 Tarsal Tunnel Syndrome (TTS)

C.12 Ankle Sprain

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C.14 Foot Neuroma (Morton's Neuroma)

C.15 Bunions / Halus Valgus

C.16 Hammer Toe

C.17 Ankle and Foot Fractures

C.18 Hindfoot Fractures / calcaneus, Talus)

C.19 Forefoot and Midfoot Fractures (Tarsal, Metatarsal, Phalnageal)

C.1 Achilles Tendinopathy

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. The Achilles tendon plantar flexes the ankle and facilitates walking. Achilles tendon disorders can make walking difficult.

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.

C.1.a Diagnostic Studies

Although diagnosing of non-rupture Achilles disorders is largely based on a careful history and examination, diagnostic imaging may be required to verify a clinical suspicion or to exclude other musculoskeletal disorders.

C.1.a.i X-ray for Diagnosis of Achilles Tendon Disorders, Retrocalcaneal Bursitis, or Blunt Trauma or Suspected Fracture

Recommended – for diagnosing insertional Achilles tendon disorders or retrocalcaneal bursitis or evaluating blunt trauma or suspected fracture.

Rationale for Recommendation: 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 mid-portion tendon disorders. X-ray may reveal calcaneal spur, prominent posterior calcaneal tuberosity, or ossification of the Achilles tendon. For other Achilles disorders, ultrasound or MRI are more effective. Therefore, plain radiographic film studies are recommended only for insertional Achilles tendinopathy or traumatic injury.

C.1.a.ii Ultrasound for Diagnosis of Achilles Tendinopathy

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

Rationale for Recommendation: Ultrasound is frequently used to diagnose midportion tendinopathy.

C.1.a.iii Magnetic Resonance Imaging (MRI) for Diagnosis of Achilles Tendinopathy

Recommended - for evaluating Achilles tendinopathies including paratendonitis, tendinosis, and retrocalcaneal bursitis.

Rationale for Recommendation: MRI can demonstrate thickened paratenon with adhesions and offers extensive information on the internal structure of the tendon and surrounding tissues. MRI may be

helpful in differentiating inflammatory from degenerative changes in soft tissue.

C.1.a.iv CT for Diagnosis of Achilles Tendinopathy

Not Recommended - for diagnosing Achilles tendinopathy.

Rationale for Recommendation: CT is not helpful in differentiating inflammatory from degenerative changes in soft tissue. As CT has limitations when compared to MRI, it is not recommended.

C.1.b Medications

For most patients, ibuprofen, naproxen, or other older generation nonsteroidal anti-inflammatory drugs (NSAIDs) are recommended as first-line medications. Acetaminophen (or the analog paracetamol) may be a reasonable alternative to NSAIDs for patients who are not candidates for NSAIDs, although most evidence suggests acetaminophen is modestly less effective. There is evidence that NSAIDs are as effective for relief of pain as opioids (including tramadol) and less impairing.

C.1.b.i Non-steroidal Anti-inflammatory Drugs (NSAIDs) for Treatment of Acute, Subacute, Chronic, or Post-operative Achilles Tendinopathy Pain

Recommended - for treatment of acute, subacute, chronic, or post-operative Achilles tendinopathy pain.

Indications: For acute, subacute, chronic, or post-operative Achilles tendinopathy, NSAIDs are recommended for treatment. Over-the-counter (OTC) agents may suffice and should be tried first.

Frequency/Duration: As needed use may be reasonable for many patients.

Indications for Discontinuation: Resolution of foot/ankle pain, lack of efficacy, or development of adverse effects that necessitate discontinuation.

C.1.b.ii NSAIDs for Patients at High-Risk of Gastrointestinal Bleeding

Recommended – concomminent use of cytoprotective classes of drugs: misoprostol, sucralfate, histamine Type 2 receptor blockers, and proton pump inhibitors for patients at High-Risk of gastrointestinal bleeding.

Indications: For patients with a high-risk factor profile who also have indications for NSAIDs, cytoprotective medications should be considered, particularly if longer term treatment is contemplated. At-risk patients include those with a history of prior gastrointestinal bleeding, elderly, diabetics, and cigarette smokers.

Frequency/Dose/Duration: Proton pump inhibitors, misoprostol, sucralfate, H2 blockers recommended. Dose and frequency per

manufacturer. There is not generally believed to be substantial differences in efficacy for prevention of gastrointestinal bleeding.

Indications for Discontinuation: Intolerance, development of adverse effects, or discontinuation of NSAID.

C.1.b.iii NSAIDs for Patients at Risk for Cardiovascular Adverse Effects

Patients with known cardiovascular disease or multiple risk factors for cardiovascular disease should have the risks and benefits of NSAID therapy for pain discussed.

Recommended - Acetaminophen or aspirin as the first-line therapy appear to be the safest regarding cardiovascular adverse.

Recommended - If needed, NSAIDs that are non-selective are preferred over COX-2 specific drugs. In patients receiving low-dose aspirin for primary or secondary cardiovascular disease prevention, to minimize the potential for the NSAID to counteract the beneficial effects of aspirin, the NSAID should be taken at least 30 minutes after or eight hours before the daily aspirin.

Evidence for the Use of NSAIDs and Acetaminophen

C.1.b.iv Acetaminophen for Treatment of Acute, Subacute, or Chronic Achilles Tendinopathy Pain

Recommended - for treatment of acute, subacute, or chronic Achilles Tendinopathy Pain, particularly in patients with contraindications for NSAIDs.

Indications: All patients with foot/ankle pain, including acute, subacute, chronic, and postoperative.

Dose/Frequency: Per manufacturer's recommendations; may be utilized on an as-needed basis. There is evidence of hepatic toxicity when exceeding four gm/day.

Indications for Discontinuation: Resolution of pain, adverse effects or intolerance.

C.1.b.v Systemic Corticosteroids (oral or intermuscular preparations) for Treatment of Acute, Subacute, Chronic, or Postoperative Achilles Tendinopathy

Not Recommended - for the treatment of acute, subacute, chronic, or postoperative Achilles tendinopathy.

C.1.b.vi Opioids for Treatment of Acute, Subacute, or Chronic Achilles Tendinopathy Pain

Not Recommended - for treatment of acute, subacute, or chronic Achilles tendinopathy pain.

C.1.b.vii Opioids for Treatment of Pain for Postoperative Achilles Tendinopathy

Recommended - for short-term (not to exceed seven days) use to treat pain after Achilles tendon surgery or for patients who have encountered surgical complications.

Indications: Postoperative pain management.

Frequency/Dose/Duration: Frequency and dose per manufacturer's recommendations; total treatment length usually ranges from a few days to a maximum of seven days.

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 for Recommendations: 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 recommended for routine use.

C.1.b.viii Vitamin Therapy for Treatment of Achilles Tendinopathy

Not Recommended - as a therapeutic intervention or for prevention of Achilles tendinopathy.

C.1.b.ix High-dose Vitamin Therapy for Treatment of Achilles Tendinopathy

Not Recommended - for prevention of Achilles tendinopathy.

C.1.b.x Topical NSAIDs for Acute, Subacute, or Chronic Achilles Tendinopathy

Recommended - for treatment of acute, subacute, or chronic Achilles tendinosis.

Indications: Mild, moderate, or severe Achilles tendinopathy.

Frequency/Duration: Frequency per manufacturer's recommendation.

Indications for Discontinuation: Resolution, intolerance, adverse effects, or lack of benefits.

C.1.b.xi Topical NSAIDs for Postoperative Achilles Tendinopathy

Not Recommended - for treatment of postoperative Achilles tendinosis.

Evidence for the Use of Topical NSAIDs

C.1.b.xii Lidocaine Patches for Acute, Subacute, Chronic, or Postoperative Achilles Tendinopathy

Not Recommended - for the treatment of acute, subacute, chronic, or postoperative Achilles tendinopathy.

C.1.c Treatments

C.1.c.i Cryotherapy / Heat

C.1.c.i.a Cryotherapy for Acute, Subacute, Chronic, or Postoperative Achilles Tendinopathy

Recommended - for acute, subacute, chronic, or postoperative Achilles tendinopathy.

Indications: All patients with Achilles tendinopathy.

Frequency/Duration: Approximately three to five self-applications per day as needed.

Indications for Discontinuation: Resolution, adverse effects, noncompliance.

C.1.c.i.b Heat Therapy for Acute, Subacute, Chronic, or Postoperative Achilles Tendinopathy

Recommended - for acute, subacute, chronic, or postoperative Achilles tendinopathy.

Indications: All patients with Achilles tendinopathy.

Frequency/Duration: Approximately three to five self-applications per day as needed.

Indications for Discontinuation: Resolution, adverse effects, noncompliance.

Evidence for the Use of Cryotherapy and Heat for Achilles Tendinopathy

C.1.c.ii Mobilization / Immobilization

C.1.c.ii.a Night Splints for Acute, Subacute, or Chronic Achilles Tendinopathy

Not Recommended - for treatment of acute, subacute, or chronic Achilles tendinopathy.

C.1.c.ii.b Night Splints and Walking Boots for Postoperative Achilles Tendinopathy

Recommended - for postoperative Achilles tendinopathy patients.

Evidence for the Use of Night Splinting for Achilles Tendinopathy

C.1.c.iii Rehabilitation

Rehabilitation (supervised formal therapy) required as a result of a work-related injury should be focused on restoring functional ability required to meet the patient's daily and work activities and return to work; striving to restore the injured worker to pre-injury status in so far as is feasible.

Active therapy requires an internal effort by the patient to complete a specific exercise or task. Passive therapy are those interventions not requiring the exertion of effort on the part of the patient, but rather are dependent on modalities delivered by a therapist. Generally passive interventions are viewed as a means to facilitate progress in an active therapy program with concomitant attainment of objective functional gains. Active interventions should be emphasized over passive interventions.

The patient should be instructed to continue both active and passive therapies at home as an extension of the treatment process in order to maintain improvement levels.

Assistive devices may be included as an adjunctive measure incorporated into the rehabilitation plan to facilitate functional gains.

C.1.c.iii.a Therapeutic Exercise – Physical / Occupational Therapy

Recommended to improve function, including range of motion and strength.

Frequency/Dose/Duration: Total numbers of visits may be as few as two to three for patients with mild functional deficits or up to 12 to 15 with more severe deficits with documentation of ongoing objective functional improvement.

When there are ongoing functional deficits, more than 12 to 15 visits may be indicated if there is documentation of functional improvement towards specific objective functional goals (e.g., increased grip strength, key pinch strength, range of motion, advancing ability to perform work activities). As part of the rehabilitation plan a home exercise program should be developed and performed in conjunction with the therapy.

Indications for Discontinuation: Resolution of achilles tendinopathy pain, intolerance, lack of efficacy or noncompliance.

Evidence for the Use of Exercise for Achilles Tendinopathy

C.1.c.iii.b Extracorporeal Shockwave Therapy for Chronic Mid-portion Achilles Tendinopathy

Recommended - as an adjunct to an eccentric exercise for chronic, recalcitrant Achilles tendinopathy.

Indications: Moderate to severe, recalcitrant Achilles tendinopathy. Patients should have failed NSAIDs, eccentric exercises, therapy, and local injection(s).

Frequency/Duration: Three to four weekly sessions over three to four consecutive weeks.

Indications for Discontinuation: Completion of course, resolution of symptoms, adverse effects, intolerance, noncompliance.

C.1.c.iii.c Extracorporeal Shockwave Therapy for Acute, Subacute, or Postoperative Achilles Tendinopathy

Not Recommended - for treatment of acute, subacute, or postoperative Achilles tendinopathy.

Evidence for the Use of Extracorporeal Shockwave Therapy for Achilles Tendinopathy

C.1.c.iii.d Acupuncture for Acute, Subacute, Chronic, or Postoperative Achilles Tendinopathy

Not Recommended - for the treatment of acute, subacute, chronic, or postoperative Achilles tendinopathy.

C.1.c.iii.e Dry Needling for Acute, Subacute, or Chronic Achilles Tendinopathy

Not Recommended - for treatment of acute, subacute, or chronic Achilles tendinopathy.

Rationale for Recommendation: As there are other effective treatments, dry needling is not recommended for treatment of Achilles tendinopathy.

C.1.c.iii.f Massage and Tendon Mobilization for Acute, Subacute, Chronic, or Postoperative Achilles Tendinopathy

Not Recommended - for treatment of acute, subacute, chronic or postoperative Achilles tendinopathy.

C.1.c.iii.g Therapeutic Ultrasound for Acute, Subacute, Chronic, or Postoperative Achilles Tendinopathy

Not Recommended - for treatment of acute, subacute, chronic, or postoperative Achilles tendinopathy.

C.1.c.iii.h Iontophoresis with Glucocorticosteroid for Acute, Subacute, or Chronic Achilles Tendinopathy

Recommended - for treatment of acute, subacute, or chronic Achilles tendinopathy.

Indications: Acute, subacute, or chronic Achilles tendinopathy.

Frequency/Duration: Four treatments over two weeks with dexamethasone or other glucocorticoid. Therapy should include a concurrent eccentric exercise program.

Indications for Discontinuation: Resolution, adverse effects, intolerance, noncompliance.

C.1.c.iii.i Iontophoresis with Glucocorticosteroid for Postoperative Achilles Tendinopathy

Not Recommended - for treatment of postoperative Achilles tendinopathy.

C.1.c.iii.j Iontophoresis with NSAIDs for Acute, Subacute, Chronic, or Postoperative Achilles Tendinopathy

Not Recommended - for treatment of acute, subacute, chronic, or postoperative Achilles tendinopathy.

Rationale for Recommendations: Although evidence is minimal for efficacy in acute and subacute Achilles tendinopathy, iontophoresis with glucocorticosteroids is recommended for acute, subacute, or chronic Achilles tendinopathy, although the treatment has not been specifically tested among those patients.

Evidence for the Use of Iontophoresis for Achilles Tendinopathy

C.1.c.iii.k Phonophoresis for Acute, Subacute, Chronic, or Postoperative Achilles Tendinopathy

Not Recommended - for treatment of acute, subacute, chronic, or postoperative Achilles tendinopathy.

C.1.c.iii.l Low-level Laser Therapy for Select Chronic Achilles Tendinopathy

Recommended - for treatment of select patients with chronic Achilles tendinopathy.

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

Frequency/Duration: Twelve sessions over eight weeks. Therapy should include a concurrent active therapeutic exercise program.

Indications for Discontinuation: Resolution, adverse effects, intolerance, noncompliance.

C.1.c.iii.m Low-level Laser Therapy for Acute, Subacute, or Postoperative Achilles Tendinopathy

Not Recommended - for treatment of acute, subacute, or postoperative Achilles tendinopathy.

Evidence for the Use of Low-level Laser Therapy for Achilles Tendinopathy

C.1.c.iv Injection Therapy

C.1.c.iv.a Glucocorticosteroid Injections (Low-Dose) for Paratendon Bursitis

Recommended - as therapy for treatment paratendon bursitis.

Indications: Treatment with other interventions such as NSAIDs and exercises should have been attempted previously and either failed or results were unsatisfactory. `

Frequency/Duration: Up to three injections of glucocorticosteroid over three weeks, with second and third injections performed if the first provides decrease in pain and increased function.

Indications for Discontinuation: Resolution, intolerance, adverse effects, or lack of benefits.

C.1.c.iv.b Glucocorticosteroid Injections (Low-Dose) for Acute, Subacute, Chronic or Postoperative

Not Recommended - for treatment of acute, subacute, chronic or postoperative Achilles tendinopathy.

Evidence for the Use of Glucocorticosteroid Injections

C.1.c.iv.c Platelet Rich Plasma Injections for Achilles Tendinopathy

Not Recommended - for treatment of Achilles tendinopathy.

Evidence for the Use of Platelet Rich Plasma

C.1.c.iv.d Glycosaminoglycan Polysulfate Local Injection (GAGPS) for Acute, Subacute, or Postoperative Achilles Tendinopathy

Not Recommended - for treatment of acute, subacute, or postoperative Achilles tendinopathy.

Rationale for Recommendations: There is limited evidence that GAGPS may be beneficial for patients with chronic symptoms of Achilles tendon conditions.

Evidence for the Use of Glycosaminoglycan Injections

C.1.c.iv.e Subcutaneous Heparin Injection for Acute, Subacute, or Chronic Achilles Tendinopathy

Not Recommended - for treatment of acute, subacute, or chronic Achilles tendinopathy.

Evidence for the Use of Heparin Injections

Actovegin Injections
Actovegin injection (deproteinized hemodialysate from calf blood) into the paratendon for acute and chronic mid-portion Achilles tendinopathy.

C.1.c.iv.f Actovegin Injection for Acute, Subacute, or Chronic Achilles Tendinopathy

Not Recommended - for the treatment of acute, subacute or chronic Achilles tendinopathy.

Evidence for the Use of Actovegin Injections

C.1.c.iv.g Prolotherapy, including Polidocanol and Hypertonic Glucose Injections for Acute, Subacute, Chronic or Postoperative Achilles Tendinopathy

Not Recommended - for the treatment of most acute, subacute or chronic and postoperative Achilles Tendinopathy.

Evidence for the Use of Polidocanol Injections

C.1.c.iv.h Apoprotinin Injection for Acute, Subacute, or Chronic Achilles Tendinopathy

Not Recommended - for treatment of acute, subacute, or chronic Achilles tendinopathy.

Evidence for the Use of Apoprotinin Injections

C.1.c.iv.i High-volume Image-guided Injection for Chronic Achilles Tendinopathy

Not Recommended - for treatment of chronic Achilles Tendinopathy.

C.1.c.v Surgery

C.1.c.v.a Surgery for the Treatment of Chronic Achilles Tendinopathy without Rupture

Recommended - for select cases of chronic Achilles tendinopathy without rupture.

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

C.1.c.v.b Surgery for the Treatment of Acute or Subacute Achilles Tendinopathy Without Rupture

Not Recommended - for acute or subacute Achilles tendinopathy without rupture.

Rationale for Recommendations: Surgery is not recommended until a course of at least six months of other non-operative treatments without demonstrated efficacy has been attempted and the patient's symptoms are sufficient to warrant the risks of surgical intervention.

C.1.c.vi Other

C.1.c.vi.a Orthotic Devices (Such as Heel Lifts, Heel Pads or Heel Braces) for Acute, Subacute, Chronic, or Postoperative Achilles Tendinopathy

Not Recommended - for treatment of acute, subacute, or chronic Achilles tendinopathy.

Evidence for the Use of Orthotic Devices for Achilles Tendinopathy

C.2 Achilles Tendon Rupture

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. There is generally no history of prior symptoms (pain, stiffness) prior to rupture.

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), and a positive squeeze test of the calf muscle that fails to elicit plantar flexion. Specific imaging is not required for most acute rupture cases.

There are no other specific diagnostic criteria for Achilles tendon rupture. Acute rupture refers to rupture that presents for evaluation within four weeks, whereas chronic rupture refers to ruptures that present for evaluation four to six weeks or more after an acute injury.

Upon establishment of the diagnosis, initial treatment is symptomatic until the definitive care plan is established. This may include immobilization, relative rest, NSAIDs, acetaminophen and cryotherapy.

C.2.a Diagnostic Studies

Diagnosis of an Achilles tendon rupture is generally made through clinical history and physical examination findings.

X-ray is generally not used for the diagnosis of acute Achilles rupture, although it may be helpful in identifying tendon calcification.

C.2.a.i Routine X-ray for Diagnosis of Acute Achilles Rupture

Not Recommended - to diagnose acute Achilles tendon rupture.

Indications: Achilles tendon ruptures resulting from direct trauma or if suspected rupture involves the calcaneal insertion, or among patients with reasonable suspicion of tendon calcification. Ruptures of the tendon at the calcaneal insertion are reported to be rare, although if suspected radiography may detect avulsion of the bony insertion.

C.2.a.ii Ultrasound for Diagnosis of Acute Achilles Tendon Rupture

Recommended - for the diagnosis of acute Achilles tendon rupture.

Indications: Clinical suspicion of rupture is high but uncertain.

Rationale for Recommendation: It is recommended as the main confirmatory diagnostic test for Achilles ruptures, particularly when there is diagnostic uncertainty.

C.2.a.iii MRI for Diagnosis of Acute Achilles Tendon Rupture

Recommended - for the evaluation of acute Achilles tendon rupture.

Indications: Clinical suspicion of rupture is high but uncertain.

Rationale for Recommendation: MRI is recommended for select use as an alternative when clinical suspicion for rupture is high. It is sometimes used to evaluate the Achilles tendon particularly where there is diagnostic uncertainty, although ultrasound has been generally preferred.

C.2.b Medications

For most patients, ibuprofen, naproxen, or other older generation nonsteroidal anti-inflammatory drugs (NSAIDs) are recommended as first-line medications. Acetaminophen (or the analog paracetamol) may be a reasonable alternative to NSAIDs for patients who are not candidates for NSAIDs, although most evidence suggests acetaminophen is modestly less effective. There is evidence that NSAIDs are as effective for relief of pain as opioids (including tramadol) and less impairing.

C.2.b.i NSAIDs for Treatment of Acute, Subacute, Chronic, or Postoperative Achillies Tendon Rupture pain

Recommended - for treatment of acute, subacute, chronic, or postoperative Achillies tendon rupture pain.

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Indications: For acute, subacute, chronic, or postoperative Achillies tendon rupture, NSAIDs are recommended for treatment. Over-the-counter (OTC) agents may suffice and should be tried first.

Frequency/Duration: As needed use may be reasonable for many patients.

Indications for Discontinuation: Resolution of foot/ankle pain, lack of efficacy, or development of adverse effects that necessitate discontinuation.

C.2.b.ii NSAIDs for Patients at High-Risk of Gastrointestinal Bleeding

Recommended concomminent use of cytoprotective classes of drugs: misoprostol, sucralfate, histamine Type 2 receptor blockers, and proton pump inhibitors for patients at High-Risk of gastrointestinal bleeding.

*Indication*s: For patients with a high-risk factor profile who also have indications for NSAIDs, cytoprotective medications should be considered, particularly if longer term treatment is contemplated. At-risk patients include those with a history of prior gastrointestinal bleeding, elderly, diabetics, and cigarette smokers.

Frequency/Dose/Duration: Proton pump inhibitors, misoprostol, sucralfate, H2 blockers recommended. Dose and frequency per manufacturer. There is not generally believed to be substantial differences in efficacy for prevention of gastrointestinal bleeding.

Indications for Discontinuation: Intolerance, development of adverse effects, or discontinuation of NSAID.

C.2.b.iii NSAIDs for Patients at Risk for Cardiovascular Adverse Effects

Patients with known cardiovascular disease or multiple risk factors for cardiovascular disease should have the risks and benefits of NSAID therapy for pain discussed.

Recommended - Acetaminophen or aspirin as the first-line therapy appear to be the safest regarding cardiovascular adverse.

Recommended - If needed, NSAIDs that are non-selective are preferred over COX-2 specific drugs. In patients receiving low-dose aspirin for primary or secondary cardiovascular disease prevention, to minimize the potential for the NSAID to counteract the beneficial effects of aspirin, the NSAID should be taken at least 30 minutes after or eight hours before the daily aspirin.

C.2.b.iv Acetaminophen for Treatment of Acute, Subacute, or Chronic Achilles Rupture Pain

Recommended for treatment of acute, subacute, or chronic Achilles rupture pain, particularly in patients with contraindications for NSAIDs.

Indications: All patients with foot/ankle pain, including acute, subacute, chronic, and postoperative.

Dose/Frequency: Per manufacturer's recommendations; may be utilized on an as-needed basis. There is evidence of hepatic toxicity when exceeding four gm/day.

Indications for Discontinuation: Resolution of pain, adverse effects or intolerance.

C.2.b.v Opioids for Pain from Acute or Postoperative Achilles Tendon Repair

Recommended limited use of opioids (not to exceed seven days) for the treatment of acute Achilles tendon rupture is a treatment option for select patients presenting with acute or moderate to severe pain related to Achilles rupture. Limited use of opioids for a few days (not to exceed seven days) is also recommended for select patients who have undergone recent Achilles tendon repair or those who encountered surgical complications.

Indications: Acute rupture or postoperative pain management for patients with moderate to severe pain.

Frequency/Dose/Duration: Frequency and dose per manufacturer's recommendations; may be taken scheduled or as needed; generally taken for 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 one week. Generally should be utilized to supplement pain relief in addition to an NSAID or acetaminophen to reduce total need for opioid and the 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 for Recommendations: Opioids are recommended for brief select use in postoperative patients with primary use at night to facilitate adequate postoperative sleep

C.2.b.vi Opioids for Pain from Subacute or Chronic Achilles Tendon Repair

Not Recommended for treatment of pain from subacute or chronic Achilles tendon repair.

Rationale for Recommendation: Opioids are not recommended for routine use.

C.2.b.vii Prophylaxis for Prevention of Deep Venous Thrombosis

Recommended - for the prevention of deep venous thrombosis.

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.

C.2.b.viii Thrombosis Prophylaxis for Prevention of Deep Venous Thrombosis

Not Recommended to prevent deep venous thrombosis.

Evidence for the Use of DVT Prophylaxis for Achilles Tendon Rupture Repair

C.2.c Treatments

C.2.c.i Cryotherapy / Heat

C.2.c.i.a Self-application of Cryotherapy or Heat Therapy for Acute, Subacute, Chronic, or Postoperative Achilles Tendon Rupture

Recommended - for treatment of acute, subacute, chronic, or postoperative Achilles tendon rupture.

Indications: Acute, subacute, chronic, or postoperative patients with Achilles tendon rupture.

Frequency/Duration: Approximately three to five self-applications per day as needed.

Indications for Discontinuation: Resolution, adverse effects, noncompliance.

Rationale for Recommendation: Ice may be of short-term benefit in reducing swelling and pain for acute rupture. Heat

may be helpful for healing for a few days after the rupture or surgery.

C.2.c.ii Rehabilitation

Therapy

Rehabilitation (supervised formal therapy) required as a result of a work-related injury should be focused on restoring functional ability required to meet the patient's daily and work activities and return to work; striving to restore the injured worker to pre-injury status in so far as is feasible.

Active therapy requires an internal effort by the patient to complete a specific exercise or task. Passive therapy are those interventions not requiring the exertion of effort on the part of the patient, but rather are dependent on modalities delivered by a therapist. Generally passive interventions are viewed as a means to facilitate progress in an active therapy program with concomitant attainment of objective functional gains. Active interventions should be emphasized over passive interventions.

The patient should be instructed to continue both active and passive therapies at home as an extension of the treatment process in order to maintain improvement levels.

Assistive devices may be included as an adjunctive measure incorporated into the rehabilitation plan to facilitate functional gains.

C.2.c.ii.a Therapeutic Exercise - Physical / Occupational Therapy

Recommended – to improve function, including range of motion and strength.

Frequency/Dose/Duration: Frequency of visits is usually individualized based on severity of the limitation. Two to three visits per week for two weeks are often used to initiate an exercise program. Total numbers of visits may be as few as two to three for mild patients or up to 12 to 15 with documentation of objective functional improvement.

As part of the rehabilitation plan, patients should be instructed to continue both active and passive therapy, at home as an extension of the treatment process in order to maintain improvement.

Indications: All postoperative and conservatively managed Achilles rupture patients.

Indications for Discontinuation: Resolution of pain, intolerance, lack of efficacy or noncompliance.

C.2.c.ii.b Postoperative TENS for Achilles Tendon Repair

Not Recommended - as a postoperative treatment for Achilles tendon rupture.

Rationale for Recommendation: There is no defined benefit of TENS for promoting the healing process.

C.2.c.iii Surgery

C.2.c.iii.a Surgery for Treatment of Achilles Tendon Rupture

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 equivocal superiority of surgical compared to non-operative treatment.

C.2.c.iii.b Non-Operative Management of Achilles Tendon Rupture with Functional Splinting and Casting

Recommended - for Achilles tendon rupture. Non-operative management may be indicated in many cases, particularly for select patients with low physical demands where risk factors may outweigh benefits.

Evidence for the Use of Non-operative and Surgical Repair for Achilles Tendon Rupture

Surgical Repair - Open and Percutaneous Methods
Surgical repairs have included two basic approaches – open and percutaneous methods.

C.2.c.iii.c Open and Percutaneous Operative Approaches

Recommended - for patients undergoing operative repair. There is no recommendation of one approach over the other.

C.2.c.iii.d Augmented Surgical Repair for Acute Ruptures

Not Recommended - for acute ruptures unless primary repair is not possible.

C.2.c.iii.e Augmented Surgical Repair for Chronic or Neglected Ruptures

Not Recommended - for chronic or neglected ruptures.

Evidence for the Use of Surgical Technique for Achilles Tendon Rupture

C.2.c.iii.f Early Weight Bearing for Postoperative Rehabilitation of Achilles Tendon Repair

Recommended - as a primary treatment method for postoperative rehabilitation of Achilles tendon ruptures for functional bracing or rigid immobilization.

Indications: All postoperative nonaugmented Achilles tendon repairs concomitant with functional bracing or rigid casting.

Frequency/Duration: Initiate postoperative to two weeks.

Indications for Discontinuation: Rerupture, surgical complications, physical ability.

Rationale for Recommendation: 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, and has no demonstrated increase in complication rates.

C.2.c.iii.g Functional Bracing for Postoperative Rehabilitation of Achilles Tendon Repair

Recommended - as a primary treatment method for postoperative care of Achilles tendon ruptures.

Indications: All postoperative Achilles tendon repairs.

Frequency/Duration: Apply zero to two weeks postoperative.

Indications for Discontinuation: Discomfort, noncompliance, device intolerance.

Evidence for the Use of Postoperative Management for Achilles Tendon Rupture

C.3 Ankle Tendinopathies (Other than Achilles Tendinopathy)

The ankle's tendinous compartments are susceptible to stenosing tenosynovitis, similar to those of the wrist. 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. 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.

C.4 Tenosynovitis (Including Stenosing Tenosynovitis)

Patients with tendinopathy present with localized ankle pain that is augmented by movement. Occassionally, pain may extend along the affected tendon sheath.

Initial care usually involves limitation of the physical factors thought to be contributing. Walking casts or boots, splints, or braces for tendinoses may be helpful especially in moderate to severe cases. NSAIDs are often prescribed for initial treatment.

C.4.a Diagnostic Studies

There are no tests that are typically performed for tenosynovitis. X-rays are usually not helpful. Boney deformities may contribute to the tenosynovitis and occult fractures may occur.

C.4.b Medications

For most patients, ibuprofen, naproxen, or other older generation nonsteroidal anti-inflammatory drugs (NSAIDs) are recommended as first-line medications. Acetaminophen (or the analog paracetamol) may be a reasonable alternative to NSAIDs for patients who are not candidates for NSAIDs, although most evidence suggests acetaminophen is modestly less effective. There is evidence that NSAIDs are as effective for relief of pain as opioids (including tramadol) and less impairing.

C.4.b.i Non-Steroidal Anti-inflammatory Drugs (NSAIDs) for Acute, Subacute or Chronic Ankle Tenosynovitis

Recommended - for treatment of acute, subacute, or chronic ankle tenosynovitis.

Indications: For acute, subacute, chronic, or postoperative ankle compartment tenosynovitis, NSAIDs are recommended for treatment. Over-the-counter (OTC) agents may suffice and should be tried first.

Frequency/Duration: As needed use may be reasonable for many patients.

Indications for Discontinuation: Resolution of foot/ankle pain, lack of efficacy, or development of adverse effects that necessitate discontinuation.

C.4.b.ii NSAIDs for Patients at High-Risk of Gastrointestinal Bleeding

Recommended – concomminent use of cytoprotective classes of drugs: misoprostol, sucralfate, histamine type 2 receptor blockers, and proton pump inhibitors for patients at High-Risk of gastrointestinal bleeding.

*Indication*s: For patients with a high-risk factor profile who also have indications for NSAIDs, cytoprotective medications should be considered, particularly if longer term treatment is contemplated. At-risk patients include those with a history of prior gastrointestinal bleeding, elderly, diabetics, and cigarette smokers.

Frequency/Dose/Duration: Proton pump inhibitors, misoprostol, sucralfate, H2 blockers recommended. Dose and frequency per manufacturer. There is not generally believed to be substantial differences in efficacy for prevention of gastrointestinal bleeding.

Indications for Discontinuation: Intolerance, development of adverse effects, or discontinuation of NSAID.

C.4.b.iii NSAIDs for Patients at Risk for Cardiovascular Adverse Effects

Patients with known cardiovascular disease or multiple risk factors for cardiovascular disease should have the risks and benefits of NSAID therapy for pain discussed.

Recommended - Acetaminophen or aspirin as the first-line therapy appear to be the safest regarding cardiovascular adverse.

Recommended - If needed, NSAIDs that are non-selective are preferred over COX-2 specific drugs. In patients receiving low-dose aspirin for primary or secondary cardiovascular disease prevention, to minimize the potential for the NSAID to counteract the beneficial effects of aspirin, the NSAID should be taken at least 30 minutes after or eighthours before the daily aspirin.

Evidence for the Use of NSAIDs for Compartment Tenosynovitis

C.4.b.iv Acetaminophen for Tenosynovitis Pain

Recommended - for treatment of acute, subacute, or chronic Achilles Tenosynovitis Pain, particularly in patients with contraindications for NSAIDs.

Indications: All patients with foot/ankle pain, including acute, subacute, chronic, and postoperative.

Dose/Frequency: Per manufacturer's recommendations; may be utilized on an as-needed basis. There is evidence of hepatic toxicity when exceeding four gm/day.

Indications for Discontinuation: Resolution of pain, adverse effects or intolerance.

C.4.c Treatments

C.4.c.i Mobilization / Immobilization

C.4.c.i.a Walking Boots, Casts, Splints, and Braces for Acute and Subacute Ankle Tenosynovitis

Recommended - for treatment of acute and subacute ankle tendinoses.

Indications: Patients with tendinosis.

Frequency/Duration: Worn while ambulating.

Indications for Discontinuation: Failure to respond or resolution.

C.4.c.ii Rehabilitation

Rehabilitation (supervised formal therapy) required as a result of a work-related injury should be focused on restoring functional ability required to meet the patient's daily work activities and return to work; striving to restore the injured worker to pre-injury status in so far as is feasible.

Active therapy requires an internal effort by the patient to complete a specific exercise or task. Passive therapy are those interventions not requiring the exertion of effort on the part of the patient, but rather are dependent on modalities delivered by a therapist. Generally passive interventions are viewed as a means to facilitate progress in an active therapy program with concomitant attainment of objective functional gains. Active interventions should be emphasized over passive interventions.

The patient should be instructed to continue both active and passive therapies at home as an extension of the treatment process in order to maintain improvement levels.

Assistive devices may be included as an adjunctive measure incorporated into the rehabilitation plan to facilitate functional gains.

C.4.c.ii.a Therapy to Address Residual Deficits, Particularly Postoperatively

Recommended - for the treatment of residual deficiits associated with acute, subacute, chronic, or postoperative tenosynovitis.

Frequency/Dose/Duration –Total numbers of visits may be as few as two to three for patients with mild functional deficits or up to 12 to 15 with more severe deficits with documentation of ongoing objective functional improvement.

When there are ongoing functional deficits, more than 12 to 15 visits may be indicated if there is documentation of functional improvement towards specific objective functional goals (e.g., increased grip strength, key pinch strength, range of motion, advancing ability to perform work activities). As part of the rehabilitation plan a home exercise program should be developed and performed in conjunction with the therapy.

Indications for Discontinuation: Resolution of pain, intolerance, lack of efficacy or noncompliance.

C.4.c.ii.b Other Non-Operative Interventions Including Manipulation and Mobilization, Massage, Deep Friction Massage, or Acupuncture for Acute, Subacute, or Chronic Ankle Tenosynovitis

Not Recommended - for the treatment of acute, subacute, or chronic ankle tenosynovitis.

C.4.c.ii.c Iontophoresis for Acute and Subacute Ankle Tenosynovitis

Recommended - for ankle tenosynovitis using glucocorticosteroids and sometimes NSAIDs.

Indications: Patients with ankle tendinosis. Generally those who either fail to respond adequately to NSAIDs, splints, and activity modifications or decline injection.

Dose: Glucocorticosteroid is generally used.

Frequency/Duration: Generally two to three treatments to ascertain efficacy; an additional four to six treatments may be scheduled if efficacious. If improvements continue at six appointments, an additional four to six treatments are reasonable.

Indications for Discontinuation: Failure to respond, development of adverse effects, resolution.

Rationale for Recommendation: Iontophoresis with either a glucocorticoid or NSAID is recommended for select patients who fail to respond to other treatments or who decline injection.

C.4.c.iii Injection Therapy

C.4.c.iii.a Glucocorticosteroid Injections for Acute, Subacute, or Chronic Ankle Tendinosis

Recommended - for treatment of acute, subacute, or chronic ankle tendinosis.

Indications: Ankle symptoms of pain over a compartment. Generally, at least one week of non-invasive treatment to determine if condition will resolve without invasive treatment. It is reasonable to treat cases with an initial injection. An adjuvant injectable anesthetic is typically used.

Frequency/Duration: It is recommended that a single injection be scheduled, and the results evaluated to document improvement. Failure of a response within one to two weeks should result in reanalysis of the diagnosis and consideration of repeat injection. Recurrence of symptoms

months later should result in consideration of re-injection. Repeat injections can be considered when there is decreased pain and increased function from the previous injection. More than three 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.

Evidence for the Use of Glucocorticosteroid Injections for Ankle Tendinoses

C.4.c.iv Surgery

C.4.c.iv.a Surgical Release for Subacute or Chronic Ankle Tenosynovitis

Not Recommended - for patients with subacute or chronic ankle tenosynovitis who fail to respond to non-operative interventions including injections.

C.5 Plantar Heel Pain ("Plantar Fasciitis")

Heel pain is the most common area of pain in the foot. Plantar heel pain, known as "plantar fasciitis," is common. Other names for plantar heel pain include painful heel syndrome, heel spur syndrome, runner's heel, subcalcaneal pain, calcaneodynia, plantar fasciopathy, and calcaneal periostitis. 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.

Plantar fasciitis generally responds well to conservative management, with more than 90% of patients resolving over a six to 12 month period with non-surgical intervention.

Initial management of plantar heel pain is non-invasive. More than 90% of plantar heel pain will resolve with non-invasive measures over a six to 12 month period. Possibly, the most important non-operative treatment is reassuring the patient that 95% of those with plantar fasciitis will have resolution of symptoms in 12 to 18 months.

Plantar Fasciitis Diagnostic Criteria (Appendix D.2 – Table 3)

C.5.a Diagnostic Studies

Imaging plays a limited role in routine clinical practice and is generally reserved for select cases to rule out other causes of heel pain or to establish the diagnosis of plantar fasciitis when it is in doubt.

Plain radiographs are utilized for diagnosing plantar fasciitis.

C.5.a.i Use of X-Ray for Diagnosis of Plantar Heel Pain

Recommended – for diagnosing suspected fracture in patients with plantar heel pain.

Indication: Evaluation of plantar heel pain when calcaneal fracture or osseous tumor is suspected, or to rule out other causes of heel pain. Plain films should not be obtained solely to identify the presence of heel spurs.

C.5.a.ii MRI for Diagnosis of Select Patients with Plantar Fasciitis

Recommended - for the evaluation of select patients with plantar fasciitis.

Indications: Suspected plantar fascial rupture, avascular necrosis of talar dome, and stress fracture of the talar neck particularly if heel pain is not improving.

Rationale for Recommendation: 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, and osseous tumors.

Evidence for the Use of MRI for Plantar Fasciitis

C.5.a.iii SPECT-CT for Diagnosis of Plantar Fasciitis

Not Recommended - for the diagnosis of plantar heel pain.

C.5.a.iv Ultrasound for Diagnosis of Plantar Fasciitis

Recommended - for the evaluation of select patients with plantar fasciitis.

Indications: Evaluation of plantar heel pain when clinical diagnosis is uncertain or after no improvement from a course of conservative treatment of four to six weeks.

Rationale for Recommendation: 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.

C.5.b Medications

For most patients, ibuprofen, naproxen, or other older generation nonsteroidal anti-inflammatory drugs (NSAIDs) are recommended as first-line medications. Acetaminophen (or the analog paracetamol) may be a reasonable alternative to NSAIDs for patients who are not candidates for NSAIDs, although most evidence suggests acetaminophen is modestly less effective. There is evidence that

NSAIDs are as effective for relief of pain as opioids (including tramadol) and less impairing.

C.5.b.i Non-steroidal Anti-inflammatory Drugs (NSAIDs)
NSAIDs for Treatment of Acute, Subacute, Chronic, or Postoperative Plantar Fasciitis Pain

Recommended - for treatment of acute, subacute, chronic, or postoperative plantar fascitis pain.

Indications: For acute, subacute, chronic, or postoperative plantar fasciitis pain, NSAIDs are recommended for treatment. Over-the-counter (OTC) agents may suffice and should be tried first.

Frequency/Duration: As needed use may be reasonable for many patients.

Indications for Discontinuation: Resolution of foot/ankle pain, lack of efficacy, or development of adverse effects that necessitate discontinuation.

C.5.b.ii NSAIDs for Patients at High-Risk of Gastrointestinal Bleeding

Recommended – concomitant use of cytoprotective classes of drugs: misoprostol, sucralfate, histamine Type 2 receptor blockers, and proton pump inhibitors for patients at High-Risk of gastrointestinal bleeding.

*Indication*s: For patients with a high-risk factor profile who also have indications for NSAIDs, cytoprotective medications should be considered, particularly if longer term treatment is contemplated. At-risk patients include those with a history of prior gastrointestinal bleeding, elderly, diabetics, and cigarette smokers.

Frequency/Dose/Duration: Proton pump inhibitors, misoprostol, sucralfate, H2 blockers recommended. Dose and frequency per manufacturer. There is not generally believed to be substantial differences in efficacy for prevention of gastrointestinal bleeding.

Indications for Discontinuation: Intolerance, development of adverse effects, or discontinuation of NSAID.

C.5.b.iii NSAIDs for Patients at Risk for Cardiovascular Adverse Effects
Patients with known cardiovascular disease or multiple risk factors for cardiovascular disease should have the risks and benefits of NSAID therapy for pain discussed.

Recommended - Acetaminophen or aspirin as the first-line therapy appear to be the safest regarding cardiovascular adverse.

Recommended - If needed, NSAIDs that are non-selective are preferred over COX-2 specific drugs. In patients receiving low-dose aspirin for primary or secondary cardiovascular disease prevention, to minimize the potential for the NSAID to counteract the beneficial effects

of aspirin, the NSAID should be taken at least 30 minutes after or eight hours before the daily aspirin.

C.5.b.iv Acetaminophen for Treatment of Plantar Fasciitis Pain

Recommended - for treatment of acute, subacute, or chronic Plantar Fasciitis Pain, particularly in patients with contraindications for NSAIDs.

Indications: All patients with foot/ankle pain, including acute, subacute, chronic, and postoperative.

Dose/Frequency: Per manufacturer's recommendations; may be utilized on an as-needed basis. There is evidence of hepatic toxicity when exceeding four gm/day.

Indications for Discontinuation: Resolution of pain, adverse effects or intolerance.

Evidence for the Use of NSAIDs and Acetaminophen for Plantar Fasciitis

C.5.b.v Infliximab for Acute, Subacute, or Chronic Plantar Fasciitis

Not Recommended - for the treatment of acute, subacute, or chronic plantar fasciitis.

Evidence for the Use of Infliximab for Plantar Fasciitis

C.5.b.vi Opioids for Acute, Subacute, or Chronic Plantar Fasciitis Pain

Not Recommended - for the treatment of acute, subacute, or chronic plantar fasciitis.

C.5.b.vii Opioids for Post Op Plantar Fasciitis

Recommended – for limited use for a few postoperative days (not to exceed seven) for select patients with plantar fasciitis.

Indications: Postoperative pain management.

Frequency/Dose/Duration: Frequency and 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.

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.

Rationale for Recommendations: 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. They are not recommended for routine use.

Some patients may have insufficient pain relief with NSAIDs, thus judicious use of opioids in the immediate postoperative period may be helpful, particularly for nocturnal use. Opioids are recommended for brief select use in postoperative patients with primary use at night to achieve postoperative sleep while not impairing early rehabilitation.

Evidence for the Use of Opioids for Plantar Fasciitis

C.5.b.viii Oral or Intramuscular Glucocorticosteroids for Acute, Subacute, or Chronic Plantar Heel Pain

Not Recommended - for the treatment of acute, subacute, or chronic plantar heel pain.

Rationale for Recommendation: 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.

Evidence for the Use of Systemic Glucocorticosteroids for Plantar Heel Pain

C.5.b.ix Vitamins for Treatment or Prevention of Plantar Fasciitis

Not Recommended - for the treatment or prevention of plantar fasciitis.

Evidence for the Use of Vitamins for Plantar Fasciitis

C.5.b.x Lidocaine Patches for Acute, Subacute, Chronic, or Postoperative Plantar Fasciitis

Not Recommended - for the treatment of acute, subacute, chronic, or postoperative plantar fasciitis.

Evidence for the Use of Lidocaine Patch for Plantar Fasciitis

C.5.b.xi Topical NSAIDs for Acute, Subacute, or Chronic Plantar Fasciitis Pain

Recommended - for treatment of acute, subacute, or chronic plantar fascial pain syndromes.

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/Duration: Frequency according to manufacturer's recommendation. Topical NSAIDs have been used for one to three weeks.

Indications for Discontinuation: Resolution, intolerance, adverse effects, or lack of benefits.

Rationale for Recommendation: 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.

C.5.b.xii Topical NSAIDs for Postoperative Plantar Fasciitis

Not Recommended - for postoperative plantar fasciitis.

Evidence for the Use of Topical NSAIDs for Plantar Fasciitis

C.5.c Treatments

C.5.c.i Cryotherapy / Heat

C.5.c.i.a Cryotherapy for Acute, Subacute, Chronic, or Postoperative Plantar Heel Pain

Recommended - for treatment of acute, subacute, chronic, or postoperative plantar heel pain.

Indications: All patients with plantar heel pain.

Frequency/Duration: Approximately three to five self-applications per day as needed.

Indications for Discontinuation: Resolution, adverse effects, noncompliance.

C.5.c.i.b Heat Therapy for Acute, Subacute, Chronic, or Postoperative Plantar Heel Pain

Recommended - for treatment of acute, subacute, chronic, or postoperative plantar heel pain.

Indications: All patients with plantar heel pain.

Frequency/Duration: Approximately three to five self-applications per day as needed.

Indications for Discontinuation: Resolution, adverse effects, noncompliance.

Rationale for Recommendations: Ice and heat may help particularly with more acute symptoms.

Evidence for the Use of Cryotherapy and Heat for Plantar Heel Pain

C.5.c.ii Mobilization / Immobilization

C.5.c.ii.a Casting for Chronic Plantar Fasciitis

Not Recommended - as a treatment for chronic plantar fasciitis.

Evidence for the Use of Casting for Plantar Fasciitis

C.5.c.ii.b Night Splints for Plantar Heel Pain

Recommended - for subacute or chronic plantar heel pain.

Indications: Subacute or chronic plantar fasciitis requiring temporary pain and stiffness improvement.

Frequency/Duration: Nightly for duration of effectiveness (as determined by improvement in symptoms and function while under the care of a health care provider).

Indications for Discontinuation: Resolution, adverse effects, intolerance, noncompliance.

Evidence for the Use of Night Splints for Plantar Heel Pain

C.5.c.iii Rehabilitation

Rehabilitation (supervised formal therapy) required as a result of a work-related injury should be focused on restoring functional ability required to meet the patient's daily and work activities and return to work; striving to restore the injured worker to pre-injury status in so far as is feasible.

Active therapy requires an internal effort by the patient to complete a specific exercise or task. Passive therapy are those interventions not requiring the exertion of effort on the part of the patient, but rather are dependent on modalities delivered by a therapist. Generally passive interventions are viewed as a means to facilitate progress in an active therapy program with concomitant attainment of objective functional gains. Active interventions should be emphasized over passive interventions.

The patient should be instructed to continue both active and passive therapies at home as an extension of the treatment process in order to maintain improvement levels.

Assistive devices may be included as an adjunctive measure incorporated into the rehabilitation plan to facilitate functional gains.

C.5.c.iii.a Magnets for Acute, Subacute or Chronic Plantar Heel Pain

Not Recommended - for the treatment of acute, subacute, or chronic plantar heel pain.

Evidence for the Use of Magnets for Plantar Heel Pain

C.5.c.iii.b Stretching Exercises for Plantar Fasciitis

Recommended - for treatment of plantar fasciitis.

Indications: Acute, subacute, or chronic plantar fasciitis.

Frequency/Duration: Ten-minute stretches three times a day; no limit identified for duration.

Indications for Discontinuation: Resolution, adverse effects, intolerance, noncompliance.

Evidence for the Use of Stretching Exercises for Plantar Fasciitis

C.5.c.iii.c Heel Taping for Acute or Subacute Plantar Fasciitis or Heel Pain

Recommended - as a short-term treatment for acute or subacute plantar fasciitis or heel pain.

Indications: Patients with acute or subacute plantar fasciitis without adhesive allergies as a short-term intervention for pain relief.

Frequency/Duration: Daily application of tape for one to four weeks.

Indications for Discontinuation: Resolution, adverse effects, noncompliance, completion of four week course of treatment.

C.5.c.iii.d Heel Taping for Chronic Plantar Fasciitis or Heel Pain

Recommended - for the treatment of chronic plantar fasciitis or heel pain.

Rationale for Recommendations: The efficacy of taping is limited to modest short-term pain relief. Taping is generally limited to short-term use because of its potential for skin sensitization and breakdown. The use of taping is recommended as a short-term strategy as an adjunct with other non-operative treatments.

Evidence for the Use of Taping for Plantar Fasciitis

C.5.c.iii.e Acupuncture for Acute, Subacute, or Chronic Plantar Fasciitis

Not Recommended - treatment of acute, subacute, or chronic plantar fasciitis.

Evidence for the Use of Acupuncture for Plantar Fasciitis

C.5.c.iii.f Low Frequency Electrical Stimulation for Acute, Subacute, or Chronic Plantar Fasciitis

Not Recommended - for acute, subacute, or chronic plantar fasciitis.

Evidence for the Use of Electrical Stimulation for Plantar Fasciitis

C.5.c.iii.g Extracorporeal Shockwave Therapy for Chronic Plantar Fasciitis

Recommended - for chronic plantar fasciitis in select patients with chronic recalcitrant conditions.

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 six months of symptoms and fail therapy with active and passive exercises, NSAIDs, and glucocorticosteroid injection(s). The presence or absence of heel spur does not impact decision for use of ESWT.

Frequency/Duration: Treatment protocols vary; one to three treatment sessions with reported efficacy may be appropriate.

Indications for Discontinuation: Resolution, intolerance, noncompliance.

C.5.c.iii.h Extracorporeal Shockwave Therapy for Acute or Subacute Plantar Fasciitis

Not Recommended - for treatment of acute or subacute plantar fasciitis.

C.5.c.iii.i Ultrasound or Fluoroscopy Guidance for Shockwave Therapy for Plantar Fasciitis

Not Recommended - for treatment of plantar fasciitis.

C.5.c.iii.j Local Anesthesia with High Shockwave Therapy for Plantar Fasciitis

Recommended - in conjunction with high-energy ESWT for the treatment of plantar fasciitis.

C.5.c.iii.k Local Anesthesia with Low or Medium Shockwave Therapy for Plantar Fasciitis

Not Recommended - for the treatment of plantar fasciitis.

C.5.c.iii.l Radial Extracorporeal Shockwave Therapy for Chronic Plantar Fasciitis

Not Recommended - for the treatment of chronic plantar fasciitis.

C.5.c.iii.m Radial Extracorporeal Shockwave Therapy for Acute or Subacute Plantar Fasciitis

Not Recommended - for the treatment of acute or subacute plantar fasciitis.

Evidence for the Use of ESWT for Plantar Fasciitis

C.5.c.iii.n Iontophoresis with Glucocorticosteroid or Acetic Acid for Acute, Subacute, or Chronic Plantar Fasciitis

Not Recommended - for treatment of patients with acute, subacute, or chronic plantar fasciitis.

Evidence for the Use of Iontophoresis for Plantar Fasciitis

C.5.c.iii.o Low-level Laser Therapy for Acute, Subacute, or Chronic Plantar Fasciitis

Not Recommended - for treatment of acute, subacute, or chronic plantar fasciitis.

Evidence for the Use of Low-level Laser Therapy for Plantar Fasciitis

C.5.c.iii.p Manipulation for Acute, Subacute, Chronic, or Postoperative Plantar Heel Pain

Not Recommended - for treatment of acute, subacute, chronic, or postoperative plantar heel pain.

Evidence for the Use of Manipulation for Plantar Heel Pain

C.5.c.iii.q Massage and Soft Tissue Mobilization for Acute, Subacute, Chronic, or Postoperative Plantar Fasciitis

Not Recommended - for treatment of acute, subacute, chronic, or postoperative plantar fasciitis.

Evidence for the Use of Massage and Soft Tissue Mobilization for Plantar Fasciitis

C.5.c.iii.r Phonophoresis for Acute, Subacute, Chronic, or Post-operative Plantar Heel Pain

Not Recommended - for treatment of acute, subacute, chronic, or postoperative plantar heel pain.

Evidence for the Use of Phonophoresis for Plantar Heel Pain

C.5.c.iii.s Therapeutic Ultrasound for Acute, Subacute, Chronic, or Postoperative Plantar Fasciitis

Not Recommended - for treatment of acute, subacute, chronic, or postoperative plantar fasciitis.

Evidence for the Use of Therapeutic Ultrasound for Plantar Fasciitis

C.5.c.iii.t Low-dose Radiation (Radiotherapy) for Chronic Plantar Heel Pain

Not Recommended - for treatment of chronic plantar heel pain.

Evidence for the Use of Radiation Therapy for Plantar Heel Pain

C.5.c.iv Injection Therapy

C.5.c.iv.a Autologous Blood Injection for Acute, Subacute, or Chronic Plantar Fasciitis

Not Recommended - for treatment of acute, subacute, or chronic plantar fasciitis**.**

Evidence for the Use of Autologous Blood Injections for Plantar Fasciitis

C.5.c.iv.b Botulinum Toxin A Injection for Acute, Subacute or Chronic Plantar Fasciitis

Not Recommended - as a treatment for chronic plantar fasciitis.

Evidence for the Use of Botulinum Toxin A Injections for Plantar Fasciitis

C.5.c.iv.c Glucocorticosteroid Injections for Chronic Plantar Fasciitis

Recommended - for short-term relief of chronic or recalcitrant plantar fasciitis.

Indications: Moderate or severe plantar fasciitis, failed stretching, exercise and other non-operative options.

Frequency/Duration: A second injection may be performed if 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.

C.5.c.iv.d Glucocorticosteroid Injections for Acute or Subacute Plantar Fasciitis

Not Recommended - for treatment of acute or subacute plantar fasciitis.

C.5.c.iv.e Guidance of Steroid Injection with Ultrasound or Scintigraphy

Not Recommended - compared with palpation.

Evidence for the Use of Injected Glucocorticosteroids for Plantar Fasciitis

C.5.c.iv.f Hyperosmolar Dextrose Injections for Plantar Fasciitis

Not Recommended - for treatment of plantar fasciitis.

Evidence for the Use of Hyperosmolar Dextrose for Plantar Fasciitis

C.5.c.iv.g Platelet Rich Plasma Injections for Plantar Fasciitis

Not Recommended - for treatment of plantar fasciitis.

Evidence for the Use of Platelet Rich Plasma for Plantar Fasciitis

C.5.c.v Surgery

C.5.c.v.a Surgery for Select Chronic Recalcitrant Plantar Fasciitis

Recommended - for select chronic recalcitrant plantar fasciitis. There is no recommendation for any particular procedure or method over another.

Indications: Moderate to severe chronic plantar fasciitis patients who have failed multiple non-surgical treatments and whose condition has lasted at least six to 12 months. Patients should generally have failed NSAID(s), plantar

fascia stretching, injection(s) and failed other conservative treatment

Rationale for Recommendations: Surgery is recommended as an intervention after at least six 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.

C.5.c.v.b Surgery for Acute or Subacute Plantar Fasciitis

Not Recommended - for treatment of acute or subacute plantar fasciitis.

Evidence for the Use of Surgery for Plantar Fasciitis

C.5.c.vi Other

C.5.c.vi.a Orthotic Devices for Acute, Subacute, or Chronic Plantar Heel Pain

Recommended - for treatment of acute, subacute, or chronic plantar heel pain.

Indications: Patients with plantar fasciitis.

Duration/Frequency: Daily use for two to three months.

Indications for Discontinuation: Resolution, adverse effects, noncompliance.

C.5.c.vi.b Custom Orthoses for Acute, Subacute, or Chronic Plantar Fasciitis

Not Recommended - for acute, subacute, or chronic plantar fasciitis.

C.5.c.vi.c Orthoses for Prevention of Plantar Fasciitis or Lower Extremity Disorders

Not Recommended - for the prevention of plantar fasciitis or lower extremity disorders.

Evidence for the Use of Orthoses for Plantar Fasciitis

C.5.c.vi.d Cryosurgery for Subacute, Acute or Chronic Plantar Heel Pain

Not Recommended - for treatment of chronic plantar heel pain.

Evidence for the Use of Cryosurgery for Plantar Fasciitis

C.5.c.vi.e Intracorporeal Pneumatic Shockwave Therapy (IPST) for Select Chronic Plantar Fasciitis

Recommended - for treatment of select chronic plantar fasciitis.

Indications: 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 (i.e. NSAIDs, injection(s), stretching, other exercises and night splinting) and have a demonstrable heel spur.

Evidence for the Use of Intracorporeal Pneumatic Shock Therapy for Plantar Fasciitis

C.5.c.vi.f Percutaneous Calcaneus Fenestration for Chronic Plantar Heel Pain

Not Recommended - for treatment of chronic plantar heel pain.

Evidence for the Use of Percutaneous Bone Fenestration for Plantar Heel Pain

C.5.c.vi.g Radiofrequency Microtenotomy for Chronic Plantar Fasciitis

Not Recommended - for treatment of chronic plantar fasciitis.

Evidence for the Use of Radiofrequency Microtenotomy for Plantar Fasciitis

C.6 Foot Ulceration

C.6.a Physical Examination

The size, depth, 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.

Wagner Grading System:

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

C.6.b Diagnostic Studies

C.6.b.i X-Rays

Recommended - for those with questions of boney involvement, particularly concerns about osteomyelitis.

C.6.b.ii Bone Scans

Recommended – for those with question of boney involvement with indeterminate x-rays**.**

C.6.c Medications

Acetaminopthen and/or non-steroidal anti-inflammatory drugs (NSAIDs) for pain control are often not needed due to the propensity for the join to be denervated, but if needed are recommended.

For most patients, ibuprofen, naproxen, or other older generation NSAIDs are recommended as first-line medications. Acetaminophen (or the analog paracetamol) may be a reasonable alternative to NSAIDs for patients who are not candidates for NSAIDs, although most evidence suggests acetaminophen is modestly less effective. There is evidence that NSAIDs are as effective for relief of pain as opioids (including tramadol) and less impairing.

C.6.c.i Non-Steroidal Anti-Inflammatory Drugs

Recommended - for treatment of acute, subacute, chronic, or postoperative non-healing and/or infected ulcers

Indications: For acute, subacute, chronic, or postoperative pain. NSAIDs are recommended for treatment. Over-the-counter (OTC) agents may suffice and should be tried first.

Frequency/Duration: As needed use may be reasonable for many patients.

Indications for Discontinuation: Resolution of pain, lack of efficacy, or development of adverse effects that necessitate discontinuation.

C.6.c.ii NSAIDs for Patients at High-Risk of Gastrointestinal Bleeding

Recommended – concomminent use of cytoprotective classes of drugs: misoprostol, sucralfate, histamine Type 2 receptor blockers, and proton pump inhibitors for patients at High-Risk of gastrointestinal bleeding.

Indications: For patients with a high-risk factor profile who also have indications for NSAIDs, cytoprotective medications should be considered, particularly if longer term treatment is contemplated. At-risk patients include those with a history of prior gastrointestinal bleeding, elderly, diabetics, and cigarette smokers.

Frequency/Dose/Duration: Proton pump inhibitors, misoprostol, sucralfate, H2 blockers recommended. Dose and frequency per manufacturer. There is not generally believed to be substantial differences in efficacy for prevention of gastrointestinal bleeding

Indications for Discontinuation: Intolerance, development of adverse effects, or discontinuation of NSAID.

C.6.c.iii NSAIDs for Patients at Risk for Cardiovascular Adverse Effects

Patients with known cardiovascular disease or multiple risk factors for cardiovascular disease should have the risks and benefits of NSAID therapy for pain discussed.

Recommended - Acetaminophen or aspirin as the first-line therapy appear to be the safest regarding cardiovascular adverse.

Recommended - If needed, NSAIDs that are non-selective are preferred over COX-2 specific drugs. In patients receiving low-dose aspirin for primary or secondary cardiovascular disease prevention, to minimize the potential for the NSAID to counteract the beneficial effects of aspirin, the NSAID should be taken at least 30 minutes after or eight hours before the daily aspirin.

C.6.c.iv Acetaminophen for Treatment of Acute, Subacute, or Chronic Non-Healing and/or Infected Ulcers

Recommended - for treatment of acute, subacute, or chronic pain, particularly in patients with contraindications for NSAIDs.

Indications: All patients with pain, including acute, subacute, chronic, and postoperative.

Dose/Frequency: Per manufacturer's recommendations; may be utilized on an as-needed basis. There is evidence of hepatic toxicity when exceeding four gm/day.

Indications for Discontinuation: Resolution of pain, adverse effects or intolerance.

C.6.c.v Opioids for Pain from Acute, Subacute, Chronic or Postoperative Foot Ulcer

Recommended - Limited use of opioids (not to exceed seven days) for the treatment of select patients presenting with severe pain related to foot ulcer. Limited use of opioids for a few days (not to exceed seven days) is also recommended for select patients who have undergone recent surgical intervention.

Frequency/Dose/Duration: Frequency and dose per manufacturer's recommendations; may be taken scheduled or as needed; generally taken for 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 one week. Generally should be utilized to supplement pain relief in addition to an NSAID or acetaminophen to reduce total need for opioid and the 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.

C.6.c.vi Antibiotics

Recommended – for most non-healing and/or infected ulcers. Antibioitic selection should be tailored to the cultured or anticipated organism.

C.6.d Treatments

C.6.d.i Mobilization / Immobilization

C.6.d.i.a Total Contact Casting for Foot Ulcers

Recommended - for foot ulcers.

Indications – All patients with non-healing foot ulcerations are potential candidates.

Evidence for the Use of Total Contact Casting

C.6.d.i.b Foot Waffle Support Brace

Not Recommended - for patients with foot ulcers.

Evidence for the Use of the Foot Waffle Support Brace

C.6.d.ii Surgery

C.6.d.ii.a Surgical Debridement to Treat Lower Extremity Ulcers

Recommended – for the treatment of lower extremity ulcers; particularly for devascularized, callus, wound edge tissue and foreign debris.

C.6.d.iii Other

C.6.d.iii.a Negative Pressure (Vacuum) Wound Care Systems

Recommended - for the treatment of chronic lower extremity ulcers.

Indication: Chronic, non-healing lower extremity ulcers.

C.6.d.iii.b Hyperbaric Oxygen for Foot Ulcers

Recommended - for treatment of select foot ulcers.

Indications: Wagner's 2, 3, 4 foot ulcer(s) of more than three months duration.

Frequency: Treatments five days per week for eight weeks. May extend to ten weeks; maximum 40 treatments.

Evidence for the Use of Hyperbaric Oxygen

Evidence for the Use of Negative Pressure Therapy (Vacuum Devices)

C.7 Wound Care, Subungual Hematoma, Contusions

See Hand, Wrist, and Forearm guideline.

C.8 Charcot Joint (Neurogenic Arthropathy)

Refers to progressive degeneration of a weight bearing joint, a process marked by bony destruction, bone resorption, and eventual deformity due to loss of sensation secondary to neuropathy. Treatment includes addressing the underlying neuropathy.

C.8.a Diagnostic Studies

C.8.a.i X-Rays

Recommended – for diagnosing Charcot Joints.

C.8.a.ii MRIs

Recommended – to improve staging of Charcot joints**.**

C.8.b Medications

Acetaminopthen and/or non-steroidal anti-inflammatory drugs (NSAIDs) for pain control are often not needed due to the propensity for the join to be denervated, but if needed are recommended.

For most patients, ibuprofen, naproxen, or other older generation NSAIDs are recommended as first-line medications. Acetaminophen (or the analog paracetamol) may be a reasonable alternative to NSAIDs for patients who are not

candidates for NSAIDs, although most evidence suggests acetaminophen is modestly less effective. There is evidence that NSAIDs are as effective for relief of pain as opioids (including tramadol) and less impairing.

C.8.b.i NSAIDs for Treatment of Acute, Subacute, Chronic, or Postoperative Charcot Joint Pain

Recommended - for treatment of acute, subacute, chronic, or postoperative Charcot Joint pain.

Indications: For acute, subacute, chronic, or postoperative Charcot Joint pain, NSAIDs are recommended for treatment. Over-the-counter (OTC) agents may suffice and should be tried first.

Frequency/Duration: As needed use may be reasonable for many patients.

Indications for Discontinuation: Resolution of foot/ankle pain, lack of efficacy, or development of adverse effects that necessitate discontinuation.

C.8.b.ii NSAIDs for Patients at High-Risk of Gastrointestinal Bleeding

Recommended – concomminent use of cytoprotective classes of drugs: misoprostol, sucralfate, histamine Type 2 receptor blockers, and proton pump inhibitors for patients at High-Risk of gastrointestinal bleeding.

*Indication*s: For patients with a high-risk factor profile who also have indications for NSAIDs, cytoprotective medications should be considered, particularly if longer term treatment is contemplated. At-risk patients include those with a history of prior gastrointestinal bleeding, elderly, diabetics, and cigarette smokers.

Frequency/Dose/Duration: Proton pump inhibitors, misoprostol, sucralfate, H2 blockers recommended. Dose and frequency per manufacturer. There is not generally believed to be substantial differences in efficacy for prevention of gastrointestinal bleeding

Indications for Discontinuation: Intolerance, development of adverse effects, or discontinuation of NSAID.

C.8.b.iii NSAIDs for Patients at Risk for Cardiovascular Adverse Effects

Patients with known cardiovascular disease or multiple risk factors for cardiovascular disease should have the risks and benefits of NSAID therapy for pain discussed.

Recommended - Acetaminophen or aspirin as the first-line therapy appear to be the safest regarding cardiovascular adverse.

Recommended - If needed, NSAIDs that are non-selective are preferred over COX-2 specific drugs. In patients receiving low-dose

aspirin for primary or secondary cardiovascular disease prevention, to minimize the potential for the NSAID to counteract the beneficial effects of aspirin, the NSAID should be taken at least 30 minutes after or eight hours before the daily aspirin.

C.8.b.iv Acetaminophen for Treatment of Acute, Subacute, or Chronic Charcot Joint Pain

Recommended - for treatment of acute, subacute, or chronic Charcot Joint Pain, particularly in patients with contraindications for NSAIDs.

Indications: All patients with joint pain, including acute, subacute, chronic, and postoperative.

Dose/Frequency: Per manufacturer's recommendations; may be utilized on an as-needed basis. There is evidence of hepatic toxicity when exceeding four gm/day.

Indications for Discontinuation: Resolution of pain, adverse effects or intolerance.

C.8.c Treatments

C.8.c.i Rehabilitation

Therapy

Rehabilitation (supervised formal therapy) required as a result of a work-related injury should be focused on restoring functional ability required to meet the patient's daily and work activities and return to work; striving to restore the injured worker to pre-injury status in so far as is feasible.

Active therapy requires an internal effort by the patient to complete a specific exercise or task. Passive therapy are those interventions not requiring the exertion of effort on the part of the patient, but rather are dependent on modalities delivered by a therapist. Generally passive interventions are viewed as a means to facilitate progress in an active therapy program with concomitant attainment of objective functional gains. Active interventions should be emphasized over passive interventions.

The patient should be instructed to continue both active and passive therapies at home as an extension of the treatment process in order to maintain improvement levels.

Assistive devices may be included as an adjunctive measure incorporated into the rehabilitation plan to facilitate functional gains.

C.8.c.i.a Gait Training

Recommended – for treatment of Charcot Joints.

C.8.c.i.b Splings, Walking Braces, Orthoses and Casts in Select Patients

Recommended – for treatment of Charcot Joints.

C.8.c.ii Surgery

C.8.c.ii.a Surgical Procedures Including Ostectomy May Be Performed to Address Deformities That Place the Foot at Risk of Ulceration

Recommended – to address deformities that place foot at risk of ulceration.

C.8.c.ii.b Open Reduction Internal Fixation of Fractures

Recommended – open reduction internal fixation of fractures.

C.8.c.ii.c Fusion of Charcot Joints in Select Patients

Recommended – fusion of Charcot Joints.

C.8.c.ii.d Arthroplasty (Total Joint Replacement) for Charcot Joints

Not Recommended – for Charcot Joints.

C.9 Paronychia

Paronychia is an inflammatory disorder of the nail folds. It is generally classified as acute and chronic. Acute cases are caused by trauma to the nail folds or cuticle.

C.9.a Medications

For most patients, ibuprofen, naproxen, or other older generation nonsteroidal anti-inflammatory drugs (NSAIDs) are recommended as first-line medications. Acetaminophen (or the analog paracetamol) may be a reasonable alternative to NSAIDs for patients who are not candidates for NSAIDs, although most evidence suggests acetaminophen is modestly less effective. There is evidence that NSAIDs are as effective for relief of pain as opioids (including tramadol) and less impairing.

C.9.a.i NSAIDs for Treatment of Paronychia Pain

Recommended - for treatment of paronychia pain.

Indications: For paronychia pain, NSAIDs are recommended for treatment. Over-the-counter (OTC) agents may suffice and should be tried first.

Frequency/Duration: As needed use may be reasonable for many patients.

Indications for Discontinuation: Resolution of foot/ankle pain, lack of efficacy, or development of adverse effects that necessitate discontinuation.

C.9.a.ii NSAIDs for Patients at High-Risk of Gastrointestinal Bleeding

Recommended – concomminent use of cytoprotective classes of drugs: misoprostol, sucralfate, histamine Type 2 receptor blockers, and proton pump inhibitors for patients at High-Risk of gastrointestinal bleeding.

*Indication*s: For patients with a high-risk factor profile who also have indications for NSAIDs, cytoprotective medications should be considered, particularly if longer term treatment is contemplated. At-risk patients include those with a history of prior gastrointestinal bleeding, elderly, diabetics, and cigarette smokers.

Frequency/Dose/Duration: Proton pump inhibitors, misoprostol, sucralfate, H2 blockers recommended. Dose and frequency per manufacturer. There is not generally believed to be substantial differences in efficacy for prevention of gastrointestinal bleeding.

Indications for Discontinuation: Intolerance, development of adverse effects, or discontinuation of NSAID.

C.9.a.iii NSAIDs for Patients at Risk for Cardiovascular Adverse Effects

Patients with known cardiovascular disease or multiple risk factors for cardiovascular disease should have the risks and benefits of NSAID therapy for pain discussed.

Recommended - Acetaminophen or aspirin as the first-line therapy appear to be the safest regarding cardiovascular adverse.

Recommended - If needed, NSAIDs that are non-selective are preferred over COX-2 specific drugs. In patients receiving low-dose aspirin for primary or secondary cardiovascular disease prevention, to minimize the potential for the NSAID to counteract the beneficial effects of aspirin, the NSAID should be taken at least 30 minutes after or eight hours before the daily aspirin.

C.9.a.iv Acetaminophen for Treatment of Paronychia Pain

Recommended - for treatment of paronychia pain, particularly in patients with contraindications for NSAIDs.

Indications: All patients with foot/ankle pain, including acute, subacute, chronic, and postoperative.

Dose/Frequency: Per manufacturer's recommendations; may be utilized on an as-needed basis. There is evidence of hepatic toxicity when exceeding four gm/day.

Indications for Discontinuation: Resolution of pain, adverse effects or intolerance.

C.9.a.v Topical Anitbiotics for the Treatment of Acute Paronychia

Recommended – for treatment of acute paronychia.

C.9.a.vi Systemic Antibiotics for the Treatment of Complications of Paronychia

Recommended – for the treatment of complications of paronychia such as signs of systemic infection or surrounding cellulitis.

C.9.a.vii Topical and Systemic Antifungals for the Treatment of Select Patients with Chronic Paronychia Due to Fungal Infections

Recommended – for the treatment of chronic paronychia

C.9.a.viii Topical Glucocorticosteroid Cream for Treatment of Select Patients with Chronic Paronychia Not Due to Bacterial or Fungal Infections

Recommended – for treatment of select patients with chronic paronychia with chronic paronychia not due to bacterial or fungal infections.

C.9.a.ix Topical and Systemic Antibiotics for Treatment of Secondary Chronic Paronychia Due to Bacterial Infections

Recommended – for treatment of secondary chronic paronychia infections.

C.9.b Treatment

C.9.b.i Cryotherapy / Heat

Warm Compresses to Treat Acute Phase of Paronychia.

Recommended – for treatment of acute paronychia.

C.9.b.ii Surgery

C.9.b.ii.a En Bloc Excision of the Proximal Nail Fold and Eponychial Marsupialization, With or Without Nail Plate Removal

Recommended – for treatment of recurrent paronychias.

C.9.b.ii.b Surgical Management for Treatment of Chronic Paronychia for Those Who Fail Non-Operative Measures.

Recommended – surgical intervention, including en bloc excision of the proximal nail fold and eponychial marsupialization, with or without nail plate removal for treatment of chonic paronychia.

C.9.b.iii Other

C.9.b.iii.a Incision and Drainage of Abscess Formed in Respose to Acute Paronychia

Recommended – in response to acute paronychia.

C.10 Foot Drop

Foot drop is a weakness in the dorsiflexion strength of the affected lower extremity resulting in an abnormal gait pattern. 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. Foot drop results in an abnormal gait pattern most often because the ankle of the weak side cannot undergo voluntary dorsiflexion.

The acute onset of foot drop after ipsilateral leg trauma may be a manifestation of compartment syndrome. Acute cases of foot drop are urgencies if not emergencies due to the potential for significant enduring impairments.

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.

C.10.a Diagnostic Studies

Diagnostic studies to determine the cause of foot drop most often include MRI of the brain, spinal cord and/or MRI of the periphery and electrodiagnostic studies of the peripheral nerves as clinically indicated.

C.10.a.i Diagnostic Studies for Diagnosis of Foot Drop

Recommended – to determine cause of foot drop (see General Principles A.12 – Diagnostic Imaging and Testing Procedrues).

C.10.b Treatments

C.10.b.i Rehabilitation

Therapy

Rehabilitation (supervised formal therapy) required as a result of a work-related injury should be focused on restoring functional ability required to

meet the patient's daily and work activities and return to work; striving to restore the injured worker to pre-injury status in so far as is feasible.

Active therapy requires an internal effort by the patient to complete a specific exercise or task. Passive therapy are those interventions not requiring the exertion of effort on the part of the patient, but rather are dependent on modalities delivered by a therapist. Generally passive interventions are viewed as a means to facilitate progress in an active therapy program with concomitant attainment of objective functional gains. Active interventions should be emphasized over passive interventions.

The patient should be instructed to continue both active and passive therapies at home as an extension of the treatment process in order to maintain improvement levels.

Assistive devices may be included as an adjunctive measure incorporated into the rehabilitation plan to facilitate functional gains.

C.10.b.i.a Taping for Treatment of Foot Drop

Not Recommended - for the treatment of foot drop.

Rationale for Recommendation: Generally, braces are used for foot drop.

Evidence for the Use of Taping

C.10.b.ii Other

C.10.b.ii.a Ankle-foot Orthotics for Treatment of Foot Drop

Recommended - for the treatment of foot drop.

Evidence for use of Orthotics

C.11 Tarsal Tunnel Syndrome (TTS)

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. TTS is described by the constellation of symptoms of intermittent tingling, numbness or burning paresthesias in the toes and the plantar surface of the foot.

In the absence of neuropathic findings (sensory or motor involvement) four to six 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.

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.

C.11.a Diagnostic Studies

C.11.a.i Nerve Conduction Studies (NCS) for Diagnosis and Pre-operative Assessment of TTS Patients

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.

C.11.a.ii NCS for Initial Evaluation of TTS Patients

Not Recommended - for the initial evaluation and most TTS patients as NCS does not change the management of the condition during the first four to six weeks while conservative therapy is being tried.

C.11.a.iii Electromyography (EMG) for Initial Evaluation, Diagnosis or Pre-operative Assessment of TTS Patients

Not Recommended - 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.

Rationale for Recommendations: 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.

C.11.a.iv MRI for Diagnosis of TTS

Recommended - for the diagnosis of select cases of clinically suspected TTS that has failed conservative management or if a mass lesion is suspected.

C.11.a.v MRI to Diagnose TTS

Not Recommended - for the initial evaluation of TTS.

C.11.a.vi Use of Ultrasound as an Aid to NCS

Recommended - as an aid to 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.

C.11.a.vii Routine Use of Diagnostic Ultrasound

Not Recommended - as a routine diagnostic test for TTS.

Rational for Recommendations: The routine use of ultrasound for initial evaluation is not recommended. Ultrasound studies should be reserved for patients that have failed conservative therapy. Use as an adjunct to guide interventional therapies may be useful.

C.11.b Medications

For most patients, ibuprofen, naproxen, or other older generation nonsteroidal anti-inflammatory drugs (NSAIDs) are recommended as first-line medications. Acetaminophen (or the analog paracetamol) may be a reasonable alternative to NSAIDs for patients who are not candidates for NSAIDs, although most evidence suggests acetaminophen is modestly less effective. There is evidence that NSAIDs are as effective for relief of pain as opioids (including tramadol) and less impairing.

C.11.b.i Non-Steroidal Anti-inflammatory Drugs (NSAIDs) and Acetaminophen for TTS Pain

Recommended - for treatment of TTS

Indications: For TTS Pain, NSAIDs are recommended for treatment. Over-the-counter (OTC) agents may suffice and should be tried first.

Frequency/Duration: As needed use may be reasonable for many patients.

Indications for Discontinuation: Resolution of foot/ankle pain, lack of efficacy, or development of adverse effects that necessitate discontinuation.

C.11.b.ii NSAIDs for Patients at High-Risk of Gastrointestinal Bleeding

Recommended – concomminent use of cytoprotective classes of drugs: misoprostol, sucralfate, histamine Type 2 receptor blockers, and proton pump inhibitors for patients at High-Risk of gastrointestinal bleeding.

*Indication*s: For patients with a high-risk factor profile who also have indications for NSAIDs, cytoprotective medications should be considered, particularly if longer term treatment is contemplated. At-risk patients include those with a history of prior gastrointestinal bleeding, elderly, diabetics, and cigarette smokers.

Frequency/Dose/Duration: Proton pump inhibitors, misoprostol, sucralfate, H2 blockers recommended. Dose and frequency per manufacturer. There is not generally believed to be substantial differences in efficacy for prevention of gastrointestinal bleeding.

Indications for Discontinuation: Intolerance, development of adverse effects, or discontinuation of NSAID.

C.11.b.iii NSAIDs for Patients at Risk for Cardiovascular Adverse Effects

Patients with known cardiovascular disease or multiple risk factors for cardiovascular disease should have the risks and benefits of NSAID therapy for pain discussed.

Recommended: Acetaminophen or aspirin as the first-line therapy appear to be the safest regarding cardiovascular adverse.

Recommended: If needed, NSAIDs that are non-selective are preferred over COX-2 specific drugs. In patients receiving low-dose aspirin for primary or secondary cardiovascular disease prevention, to minimize the potential for the NSAID to counteract the beneficial effects of aspirin, the NSAID should be taken at least 30 minutes after or 8 hours before the daily aspirin.

C.11.b.iv Acetaminophen for Treatment of TTS Pain

Recommended - for treatment of TTS Pain, particularly in patients with contraindications for NSAIDs.

Indications: All patients TTS pain. Acetaminophen may provide enough mild analgesic relief to allow the patient to exercise or function at a higher level.

Dose/Frequency: Per manufacturer's recommendations; may be utilized on an as-needed basis. There is evidence of hepatic toxicity when exceeding four gm/day.

Indications for Discontinuation: Resolution of pain, adverse effects or intolerance.

C.11.b.v Oral Systemic Glucocorticosteroids for Treatment of TTS

Recommended - for treatment of TTS patients who decline tarsal tunnel injection.

Indications – Tarsal tunnel syndrome unresponsive to splinting. Most patients should be injected rather than given oral steroids. However, among those declining injection, oral glucocorticosteroids may be warranted.

Frequency/Dose: 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.

Opioids

Opioids have occasionally been used to treat patients with TTS. These medications have primarily been used for a few nights in the post-surgical period (see Non Acute Pain Guideline).

C.11.b.vi Routine Use of Opioids for Treatment of Pain from TTS

Not Recommended - for treatment of patients with pain from TTS.

Rationale for Recommendations: 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. They are not recommended for routine use. Opioids are recommended for brief, select use in postoperative patients with primary use at night to achieve sleep postoperatively.

C.11.b.vii Opioids for Pain Treatment of TTS in Select Patients Post Op

Recommended - limited use (not more than seven days) for select patients

Indications: 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.

Evidence for the Use of Opioids for TTS

C.11.b.viii Diuretics for Routine Treatment of TTS

Not Recommended - for routine treatment of TTS.

Rationale for Recommendation: Most of the medical conditions described as risk factors for TTS do not involve edema or swelling of the lower extremities.

C.11.b.ix Vitamins, Including Pyridoxine

Not Recommended - for the treatment of TTS in patients without vitamin deficiencies.

C.11.b.x Lidocaine Patches for Treatment of TTS

Recommended - for treatment of select cases of TTS.

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/Duration: Per manufacturer's recommendation.

Indications for Discontinuation: Resolution, intolerance, adverse effects, lack of benefits, or failure to progress over a trial of at least a couple weeks.

C.11.c Treatments

C.11.c.i Cyrotherapy / Heat

C.11.c.i.a Self-application of Ice or Heat for Treatment of TTS

Recommended - for the treatment of TTS.

Rationale for Recommendations: Ice and heat may help particularily with more acute symptoms.

C.11.c.ii Mobilization / Immobilization

C.11.c.ii.a Nocturnal Splints for Treatment of TTS

Not Recommended - nocturnal splinting for treatment of TTS.

C.11.c.iii Rehabilitation

Therapy

Rehabilitation (supervised formal therapy) required as a result of a work-related injury should be focused on restoring functional ability required to meet the patient's daily and work activities and return to work; striving to restore the injured worker to pre-injury status in so far as is feasible.

Active therapy requires an internal effort by the patient to complete a specific exercise or task. Passive therapy are those interventions not requiring the exertion of effort on the part of the patient, but rather are dependent on modalities delivered by a therapist. Generally passive interventions are viewed as a means to facilitate progress in an active therapy program with concomitant attainment of objective functional gains. Active interventions should be emphasized over passive interventions.

The patient should be instructed to continue both active and passive therapies at home as an extension of the treatment process in order to maintain improvement levels.

Assistive devices may be included as an adjunctive measure incorporated into the rehabilitation plan to facilitate functional gains.

C.11.c.iii.a Rest for Treatment of More Symptomatic Cases of TTS

Recommended - for the treatment of TTS.

Rationale for Recommendations: Ankle rest may be beneficial for the more symptomatic cases where aggrevating factors include constant standing or walking.

C.11.c.iii.b Exercise

Recommended - for the treatment of TTS.

Rationale for Recommendation: Exercise regimens for tendon gliding or nerve gliding may be appropriate with documentation of improved function and decreased pain.

C.11.c.iii.c Taping

Not Recommended - for the treatment of TTS.

C.11.c.iii.d Magnets

Not Recommended - for the treatment of TTS.

C.11.c.iii.e Acupuncture

Not Recommended - for the treatment of TTS.

Rationale for Recommendation: There are other interventions with documented efficacy. Therefore, the use of acupuncture for treatment of TTS is not recommended.

C.11.c.iii.f Manipulation and Mobilization of the Distal Lower Extremity

Not Recommended - for the treatment of TTS.

C.11.c.iii.g Ultrasound

Not Recommended - for the treatment of TTS

C.11.c.iii.h Iontophoresis

Not Recommended - for the treatment of TTS.

Rationale for Recommendation: Other treatments have documented efficacy and should be used preferentially.

C.11.c.iii.i Phonophoresis

Not Recommended - for the treatment of TTS.

Rationale for Recommendation: Other treatments have documented efficacy and should be used preferentially.

Evidence for the Use of Phonophoresis

C.11.c.iv Injection Therapy

C.11.c.iv.a Glucocorticosteroid Injections

Recommended - as part of a conservative management strategy for treatment of TTS.

Rationale for Recommendation: Injections are commonly reported as part of conservative therapy and as an additional mode for confirmation of suspected diagnosis of TSS. Thus, if a more conservative treatment strategy fails

to improve the condition, glucocorticosteroid injections may be useful.

C.11.c.iv.b Insulin Injections

Not Recommended - for the treatment of TTS.

C.11.c.iv.c Botulinum Injections

Not Recommended - for the treatment of TTS

C.11.c.v Surgery

C.11.c.v.a Surgical Release for Space Occupying Lesion

Recommended - Surgical release of posterior tibial nerve impingement at the tarsal tunnel upon failure of conservative treatment and in the presence of space occupying lesion. Surgical release for cases with nonspecific causes are otherwise expected to have mixed results and patients should be counseled regarding potential lack of benefit before consideration of surgery.

C.11.c.vi Other

C.11.c.vi.a Orthotics for Treatment of Select Patients with TTS

Recommended - selectively for those with TTS thought to be of biomechanical origin.

C.12 Ankle Sprain

Injuries to the ankle are common and are a frequent reason for seeking acute care.

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. The natural course of the lateral ankle sprain is rapid improvement. Ten to 20% of patients with acute ankle sprain may develop chronic ankle instability.

Classification systems for lateral ankle sprain severity are based on physical examination findings and are used to define the extent of ligament injury.

Sprain: Injury, not necessarily permanent, of a ligament.
- S, Grade I: overstretching or slight tearing without instability.
- S, Grade II: incomplete tearing.
- S, Grade III: complete tear or rupture.

Red flags, including fracture, should be considered.

C.12.a Diagnostic Studies

C.12.a.i Routine Use of Arthrography in Diagnosis of Acute, Subacute or Chronic Ankle Sprain

Not Recommended - for evaluation of acute, subacute or chronic ankle sprain.

Rationale for Recommendations: Arthrography is invasive, is associated with adverse effects including risks from dye and post-procedure pain. MRI, CT, and ultrasound have essentially replaced plain arthrography in current practice.

C.12.a.ii X-Ray in Assessment of Acute Ankle Sprain When Fracture is Not Suspected

Not Recommended - for evaluation of acute ankle sprain when fracture is not suspected.

C.12.a.iii X-Ray in Assessment of Acute Ankle Sprain When Fracture is Suspected

Recommended - if fracture is likely and the differential diagnosis reflects suspicion of fracture.

Rationale for Recommendations: 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.

Indications: Suspicion of fracture or if the history or physical is clinically suspicious for an injury other than an ankle sprain.

Views: Anteroposterior, lateral, and mortise radiographs should be obtained.

C.12.a.iv Routine Stress X-Ray for Evaluation of Ligament Rupture in Acute Ankle Sprain

Not Recommended - for evaluation of acute ankle ligament rupture.

C.12.a.v Routine Stress X-Ray for Evaluation of Ligament Rupture in Subacute or Chronic Ankle Sprain

Not Recommended - for evaluation of subacute or chronic ankle pain.

Rationale for Recommendations: 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. Therefore, x-ray is recommended for assessment of suspected ankle or foot fracture.

Evidence for the Use of X-ray for Evaluation of Ankle Fractures

C.12.a.vi CT for Assessment of Subacute or Chronic Ankle Sprain

Recommended - for the assessment of select patients with subacute or chronic ankle sprain.

Indications – Patients who have no improvement with non-operative therapy after four to six 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.

C.12.a.vii CT for Assessment of Acute Ankle Sprain

Not Recommended - for assessment of patients with acute ankle sprain.

C.12.a.viii Magnetic Resonance Arthrography (MRA) for Assessment of Subacute or Chronic Ankle Sprain

Not Recommended - for the assessment of subacute or chronic ankle sprain.

C.12.a.ix MRA for Assessment of Acute Ankle Sprain

Not Recommended - for the assessment of acute ankle sprain.

C.12.a.x Magnetic Resonance Imaging (MRI) for Assessment of Subacute or Chronic Ankle Sprain

Recommended - for the assessment of select patients with subacute or chronic ankle sprain.

Indications: Patients who have no improvement with non-operative therapy after four to six 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 For Recommendation: MRI is used to evaluate ligament, osteochondral injury such as talar dome lesions, fractures, ankle impingement, and other soft-tissue injuries.

C.12.a.xi MRI for Assessment of Acute Ankle Sprain

Not Recommended - for the assessment of acute ankle sprain.

C.12.a.xii Bone Scans for Assessment of Acute Ankle Sprain

Recommended - for select patients with acute ankle sprain.

Indications: Suspected stress fracture, infection, or tumor.

C.12.a.xiii Bone Scans for Assessment of Subacute or Chronic Ankle Sprain

Not Recommended - for patients with subacute or chronic ankle sprain.

C.12.a.xiv Ultrasound for Diagnosis of Subacute or Chronic Ankle Sprain

Not Recommended - for evaluation of patients with subacute or chronic ankle sprain.

C.12.a.xv Electrodiagnostic Studies of the Peroneal Nerve

Recommended – for select patients with recurrent / recalcentrant lateral sprains.

Indications –To rule out peroneal neuropath in Patients with Lateral sprains as a result of marked inversion injury.

C.12.b Medications

For most patients, ibuprofen, naproxen, or other older generation nonsteroidal anti-inflammatory drugs (NSAIDs) are recommended as first-line medications. Acetaminophen (or the analog paracetamol) may be a reasonable alternative to NSAIDs for patients who are not candidates for NSAIDs, although most evidence suggests acetaminophen is modestly less effective. There is evidence that NSAIDs are as effective for relief of pain as opioids (including tramadol) and less impairing.

C.12.b.i Acetaminophen for Treatment of Acute, Subacute, or Chronic Sprain Injury Pain

Recommended - for treatment of acute, subacute or chronic ankle sprain injury pain, particularly in patients with contraindications for non-steroidal anti-inflammatory (NSAIDs).

Indications: All patients with foot/ankle pain, including acute, subacute, chronic, and postoperative.

Dose/Frequency: Per manufacturer's recommendations; may be utilized on an as-needed basis. There is evidence of hepatic toxicity when exceeding four gm/day.

Indications for Discontinuation: Resolution of pain, adverse effects or intolerance.

C.12.b.ii Non-Steroidal Anti-inflammatory Drugs (NSAIDs)

NSAIDs for Treatment of Acute, Subacute, Chronic Ankle Sprain

Recommended - for treatment of acute, subacute, chronic, or postoperative Ankle Sprain.

Indications: For ankle sprain pain, NSAIDs are recommended for treatment. Over-the-counter (OTC) agents may suffice and should be tried first.

Frequency/Duration: As needed use may be reasonable for many patients.

Indications for Discontinuation: Resolution of foot/ankle pain, lack of efficacy, or development of adverse effects that necessitate discontinuation.

C.12.b.iii NSAIDs for Patients at High-Risk of Gastrointestinal Bleeding

Recommended – concomminent use of cytoprotective classes of drugs: misoprostol, sucralfate, histamine Type 2 receptor blockers, and proton pump inhibitors for patients at High-Risk of gastrointestinal bleeding.

Indications: For patients with a high-risk factor profile who also have indications for NSAIDs, cytoprotective medications should be considered, particularly if longer term treatment is contemplated. At-risk patients include those with a history of prior gastrointestinal bleeding, elderly, diabetics, and cigarette smokers.

Frequency/Dose/Duration: Proton pump inhibitors, misoprostol, sucralfate, H2 blockers recommended. Dose and frequency per manufacturer. There is not generally believed to be substantial differences in efficacy for prevention of gastrointestinal bleeding.

Indications for Discontinuation: Intolerance, development of adverse effects, or discontinuation of NSAID.

C.12.b.iv NSAIDs for Patients at Risk for Cardiovascular Adverse Effects

Patients with known cardiovascular disease or multiple risk factors for cardiovascular disease should have the risks and benefits of NSAID therapy for pain discussed.

Recommended - Acetaminophen or aspirin as the first-line therapy appear to be the safest regarding cardiovascular adverse.

Recommended - If needed, NSAIDs that are non-selective are preferred over COX-2 specific drugs. In patients receiving low-dose aspirin for primary or secondary cardiovascular disease prevention, to minimize the potential for the NSAID to counteract the beneficial effects of aspirin, the NSAID should be taken at least 30 minutes after or eight hours before the daily aspirin.

Evidence for the Use of Acetaminophen for Ankle Sprain

Evidence for the Use of NSAIDs for Ankle Sprain

C.12.b.v Opioids for Select Acute or Postoperative Ankle Sprain

Recommended - for no more than one week for select patients with severe pain related to acute ankle sprain. Limited use of opioids for no more than one week may be indicated for those that have undergone ankle ligament repair surgery or those who encountered surgical complications.

Indication: Highly selective use. Severe pain with acute ankle sprain and postoperative pain management. Generally to be used only with either demonstrated insufficient control of pain with NSAID or severe sprain/postoperative pain.

Frequency/Dose/Duration: Frequency and dose per manufacturer's recommendations; may be taken scheduled or as needed; generally suggested to be taken for short courses of a few days.

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 for Recommendation: The vast majority of patients with ankle sprain generally do not have pain sufficient to require opioids.

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 postoperative patients primarily at night to achieve postoperative sleep.

Evidence for the Use of Opioids for Ankle Sprain

C.12.b.vi Lidocaine Patches for Acute, Subacute, or Chronic Ankle Sprain

Not Recommended - for the treatment of acute, subacute, or chronic ankle sprain.

Evidence for the Use of Lidocaine Patches for Ankle Sprain

C.12.b.vii Topical NSAIDs for Acute Ankle Sprain

Recommended - for the treatment of acute ankle sprain.

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/Duration: requency per manufacturer's recommendation. Topical NSAID use has been reported for one to three weeks.

Indications for Discontinuation: Resolution, intolerance, adverse effects, or lack of benefits.

Rationale for Recommendation: Topical NSAIDs are used to deliver medication locally and superficially in musculoskeletal disorders, including ankle sprain disorders.

C.12.b.viii Topical NSAIDs for Subacute or Chronic Ankle Sprain

Not Recommended - for the treatment of subacute, or chronic ankle sprain.

Evidence for the Use of Topical NSAIDs for Ankle Sprain

C.12.c Treatments

C.12.c.i Rest, Ice, Compression, Elevation (RICE)

C.12.c.i.a Immediate Non-weight Bearing (Rest) for Acute Ankle Sprain

Recommended - as an initial intervention for acute ankle sprain for patients unable to tolerate weight.

Indications: 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/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.

Evidence for the Use of RICE for Ankle Sprain

C.12.c.i.b Cryotherapy for Acute Ankle Sprain

Recommended - for treatment of acute ankle sprains.

Indications: Acute ankle sprain.

Frequency/Duration: Self-application for 10 to 20 minutes every two hours for up to three days as needed.

Indications for Discontinuation: Resolution, adverse effects, noncompliance.

Evidence for the Use of Ice/Cryotherapy for Ankle Sprain

C.12.c.ii Cryotherapy / Heat

C.12.c.ii.a Heat for Acute Ankle Sprain

Not Recommended - for the treatment of acute ankle sprain.

Evidence for the Use of Heat for Ankle Sprain

C.12.c.iii Immobilization

C.12.c.iii.a Ankle Brace (Orthosis) for Acute Ankle Sprain

Recommended - for treatment of acute ankle sprain with optional use as needed by the patient for mild and moderate sprains.

Evidence for the Use of Ankle Brace Support (Pneumatic/Gel) for Ankle Sprain
Evidence for the Use of Ankle Support or Brace for Ankle Sprain

C.12.c.iii.b Walking Boot for Acute Ankle Sprain

Not Recommended - of acute ankle sprains.

C.12.c.iii.c Walking Boot for Select Cases of Severe Ankle Sprain

Recommended - for select cases of severe ankle sprains.

Evidence for the Use of Walking Boots for Ankle Sprain

C.12.c.iii.d Early Mobilization for Acute Ankle Sprain

Recommended - for acute ankle sprains without fracture.

Indications: Acute ankle sprains (severe sprains should undergo no more than three weeks of immobilization, splints should be sufficient for immobilization; ankle sprains that are mild or moderate should not undergo immobilization.

Rationale for Recommendations: Early mobilization is recommended over immobilization for most patients

C.12.c.iii.e Immobilization for Acute Mild to Moderate Ankle Sprain

Not Recommended - for patients with acute mild to moderate ankle sprain as splints should be sufficient.

Rationale for Recommendation: Mild acute sprains are generally self-limited and respond well to early mobilization and other therapies; therefore, casting is not recommended.

C.12.c.iii.f Immobilization for Severe Ankle Sprain

Recommended – splinting for immobilization for severe ankle sprain.

Indications: Severe ankle sprain.

Frequency/Duration: Application of a splint for ten days to three weeks after a 48 hour period of elevation and non-weight bearing.

Rationale for Recommendation: Casting is restrictive of activity, including return to work, impairs driving performance more than bracing, and is associated with risk for deep venous thrombosis. Cast immobilization is therefore not recommended. Splinting is recommended for immobilization of severe ankle sprain.

Evidence for the Use of Early Mobilization for Ankle Sprain

C.12.c.iv Rehabilitation

Rehabilitation (supervised formal therapy) required as a result of a work-related injury should be focused on restoring functional ability required to meet the patient's daily and work activities and return to work; striving to restore the injured worker to pre-injury status in so far as is feasible.

Active therapy requires an internal effort by the patient to complete a specific exercise or task. Passive therapy are those interventions not requiring the exertion of effort on the part of the patient, but rather are dependent on modalities delivered by a therapist. Generally passive interventions are viewed as a means to facilitate progress in an active therapy program with concomitant attainment of objective functional gains. Active interventions should be emphasized over passive interventions.

The patient should be instructed to continue both active and passive therapies at home as an extension of the treatment process in order to maintain improvement levels.

Assistive devices may be included as an adjunctive measure incorporated into the rehabilitation plan to facilitate functional gains.

C.12.c.iv.a Therapy – Active

Therapeutic Exercise

Recommended – for select patients with acute, subacute or chronic ankle sprain

Frequency/Dose/Duration –Total numbers of visits may be as few as two to three for patients with mild functional deficits or up to 12 to 15 with more severe deficits with documentation of ongoing objective functional improvement.

When there are ongoing functional deficits, more than 12 to 15 visits may be indicated if there is documentation of functional improvement towards specific objective functional

goals (e.g., increased grip strength, key pinch strength, range of motion, advancing ability to perform work activities). As part of the rehabilitation plan a home exercise program should be developed and performed in conjunction with the therapy.

C.12.c.iv.b Therapy - Passive

Rest, Ice, Compression, Elevation (RICE)

C.12.c.iv.b.i Immediate Non-weight Bearing (Rest) for Acute Ankle Sprain

Recommended - as an initial intervention for acute ankle sprain for patients unable to tolerate weight.

Indications: 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/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.

Evidence for the Use of RICE for Ankle Sprain

C.12.c.iv.b.ii Cryotherapy for Acute Ankle Sprain

Recommended - for treatment of acute ankle sprains.

Indications: Acute ankle sprain.

Frequency/Duration: Self-application for 10 to 20 minutes every two hours for up to three days as needed.

Indications for Discontinuation: Resolution, adverse effects, noncompliance.

Evidence for the Use of Ice/Cryotherapy for Ankle Sprain

C.12.c.v Cryotherapy / Heat

C.12.c.v.a Heat for Acute Ankle Sprain

Not Recommended - for the treatment of acute ankle sprain.

Evidence for the Use of Heat for Ankle Sprain

C.12.c.v.b Compression Therapy for Acute Ankle Sprain

Not Recommended - for acute ankle sprains.

C.12.c.v.c Tubigrip for Acute Ankle Sprain

Not Recommended - for acute ankle sprains.

C.12.c.v.d Tape, Elastic Wrap or Tubular Elastic for Acute Ankle Sprain

Not Recommended - for acute ankle sprains.

Evidence for the Use of Compression Bandage, Wrap, or Tape for Ankle Sprain

C.12.c.v.e Intermittent Elevation for Acute Ankle Sprain

Recommended - for controlling edema of acute ankle sprains.

Indications: Acute ankle sprain that manifest significant edema.

Indications for Discontinuation: Resolution, adverse effects, noncompliance.

Evidence for the Use of Elevation for Ankle Sprain

C.12.c.v.f Contrast Bath Therapy for Acute Ankle Sprain

Not Recommended - for the treatment of acute ankle sprain.

Evidence for the Use of Contrast Bath for Ankle Sprain

C.12.c.v.g High-Voltage Pulsed Current for Acute Ankle Sprain

Not Recommended - for acute ankle sprains.

C.12.c.v.h Magnets for Acute, Subacute, or Chronic Ankle Sprain

Not Recommended - for treatment of acute, subacute, or chronic ankle sprain.

Evidence for the Use of Magnets for Ankle Sprain

C.12.c.v.i Diathermy for Acute, Subacute, or Chronic Ankle Sprain

Not Recommended - for the treatment of acute, subacute, or chronic ankle sprain.

Evidence for the Use of Diathermy for Ankle Sprain

C.12.c.v.j Low Frequency Electrical Stimulation for Acute, Subacute, or Chronic Ankle Sprain

Not Recommended - for acute, subacute, or chronic ankle sprain.

C.12.c.v.k High-voltage Pulsed Electrical Stimulation for Acute, Subacute, or Chronic Ankle Sprain

Not Recommended - as a treatment for acute, subacute, or chronic ankle sprain.

Evidence for the Use of Electrical Stimulation for Ankle Sprain

C.12.c.v.l Iontophoresis for Acute, Subacute, or Chronic Ankle Sprain

Not Recommended - for treatment of acute, subacute, or chronic ankle sprain.

Evidence for the Use of Iontophoresis for Ankle Sprain

C.12.c.v.m Low-level Laser Therapy for Acute, Subacute, or Chronic Ankle Sprain

Not Recommended - for treatment of acute, subacute, or chronic ankle sprain.

Evidence for the Use of Low-level Laser Therapy for Ankle Sprain

C.12.c.v.n Phonophoresis for Acute, Subacute, or Chronic Ankle Sprain

Not Recommended - for treatment of acute, subacute, or chronic ankle sprain.

Evidence for the Use of Phonophoresis for Ankle Sprain

C.12.c.v.o Therapeutic Ultrasound for Acute, Subacute, or Chronic Ankle Sprain

Not Recommended - for the treatment of acute, subacute, or chronic ankle sprain.

Evidence for the Use of Therapeutic Ultrasound for Ankle Sprain

C.12.c.v.p Acupuncture for Acute, Subacute, or Chronic Ankle Sprain

Not Recommended - for treatment of acute, subacute, or chronic ankle sprain.

Evidence for the Use of Acupuncture for Ankle Sprain

C.12.c.v.q Hyperbaric Oxygen Therapy for Acute, Subacute, or Chronic Ankle Sprain

Not Recommended - for treatment of acute, subacute, or chronic ankle sprain.

Evidence for the Use of Hyperbaric Oxygen for Ankle Sprain

C.12.c.v.r Manipulation or Mobilization for Acute or Subacute Ankle Sprain

Not Recommended - for the treatment of acute or subacute ankle sprain.

C.12.c.v.s Manipulation or Mobilization for Chronic Recurrent Ankle

Not Recommended - for the treatment of chronic recurrent ankle sprain.

Evidence for the Use of Manipulation and Mobilization for Ankle Sprain

C.12.c.vi Injection Therapy

C.12.c.vi.a Autologous Blood Injection for Acute, Subacute, or Chronic Ankle Sprain

Not Recommended - as a treatment for acute, subacute, or chronic ankle sprain.

Evidence for the Use of Autologous Blood Injections for Ankle Sprain

C.12.c.vi.b Glucocorticosteroid Injections for Acute, Subacute, or Chronic Ankle Sprain

Not Recommended - for treatment of acute, subacute, or chronic ankle sprain.

Evidence for the Use of Injected Glucocorticosteroids for Ankle Sprain

C.12.c.vi.c Hyaluronic Acid Injections for Acute, Subacute, or Chronic Ankle Sprain

Not Recommended - for the treatment of acute, subacute, or chronic ankle sprains.

Evidence for the Use of Hyaluronic Acid for Ankle Sprain

C.12.c.vi.d Prolotherapy Injections for Acute, Subacute, Chronic or Ankle Sprains

Not Recommended - for the treatment of most acute, subacute or chronic and postoperative ankle sprains.

Evidence for the Use of Polidocanol Injections

C.12.c.vi.e Platelet Rich Plasma Injections for Acute, Subacute, or Chronic Ankle Sprain

Not Recommended - for the treatment of acute, subacute, or chronic ankle sprains.

Evidence for the Use of Platelet Rich Plasma for Ankle Sprain

C.12.c.vii Surgery

C.12.c.vii.a Surgery for Treatment of Acute or Subacute Ankle Ligament Tear

Not Recommended - for routine lateral ligament tear associated with acute or subacute ankle sprain.

C.12.c.vii.b Surgery for Treatment of Chronic Ankle Instability (CAI)

Recommended - for select cases of chronic ankle instability.

Indications: Chronic ankle instability of at least three months duration, lateral ankle ligament laxity, and failure of non-operative therapies including therapy and use of ankle orthosis.

Rationale for Recommendations: Persistent functional instability of a chronic nature may be considered for ligament reconstruction.

Evidence for the use of Surgical Intervention for Chronic Ankle Instability

Evidence for the Use of Acute Surgical Repair for Ankle Ligament Tear

C.12.c.vii.c Postoperative Management of Ankle Instability

Recommended - Short-term cast immobilization with early mobilization and therapy for ankle instability.

Rationale for Recommendation: Immobilization or early motion and therapy are described as frequent postoperative management techniques.

Evidence for the Use of Postoperative Management for Ankle Instability

C.13 Mid-Tarsus Pain and Sprains

Mid-tarsus or mid-foot pain and sprains frequently involve the ligaments of the mid-foot. A primary diagnostic focus is to eliminate the diagnosis of midfoot fracture. 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).

C.13.a Diagnostic Studies

C.13.a.i Weight Bearing X-Rays

Recommended – AP and lateral views without obliques; often bilateral for comparative purposes:

- Often normal in mild injuries (Grade 1 Sprains).
- Generally abnormal in moderate (Grade 2 Sprains).
- Always abnormal in severe injuries (Grade 3 Sprains).

C.13.a.ii CT Scans

Recommended – in uncertain cases and in select pre-operative cases.

C.13.b Treatments

C.13.b.i Mobilization / Immobilization

C.13.b.i.a Inmobilization in a Short-Leg Walking Boot or Cast

Recommended – for mild to moderate cases without diastasis.

Duration of Therapy – four to six weeks with repeat x-rays and evaluation for stability at two weeks.

C.13.b.ii Surgery

C.13.b.ii.a Surgery

Recommended – for all severe cases, unstable injuries, and those with significant diastasis)e.g. >2mm).

C.14 Foot Neuroma (Morton's Neuroma)

Morton's Neuroma is a common neuralgia affecting the web spaces of the toes, typically the third toe. 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 to supply the sides of the toes. There are many different treatments that have been used for Morton's Neuroma such as NSAIDs, corticosteroid injections, ablative procedures, and surgery.

A careful history and physical examination is considered the most important diagnostic approach and in most cases needs no further diagnostic testing.

C.14.aTreatment

C.14.a.i Rehabilitation

C.14.a.i.a Extracorporeal Shockwave Therapy

Not Recommended - for Morton's Neuroma.

Evidence for the Use of Extracorporeal Shockwave Therapy for Morton's Neuroma

C.14.a.i.b Manipulation or Mobilization of the Distal Lower Extremity for Treatment of Morton's Neuroma

Not Recommended - for treatment of Morton's Neuroma.

Evidence for the Use of Manipulation and Mobilization

C.14.a.ii Injection Therapy

C.14.a.ii.a Glucocorticosteroid Injections for Select Morton's Neuroma

Recommended - for Morton's Neuroma.

Indications: select cases where pain and/or debility are significant and changing shoe wear, and/or orthotics fail to sufficiently control symptoms.

Rationale for Recommendation: Up to three injections to attempt to reduce symptoms is a reasonable intervention to

try before surgery. Ongoing injections are not recommended.

Evidence for the use of Glucocorticosteroid Injections

C.14.a.ii.b Sclerosant Injections for Morton's Neuroma

Not Recommended - for Morton's Neuroma.

C.14.a.iii Surgery

C.14.a.iii.a Ablation for Morton's Neuroma

Recommended - for Morton's Neuroma.

Indications: Select cases where pain and/or debility are significant and changing shoe wear, orthotics and glucocorticoid injection(s) fail to sufficiently control symptoms.

C.14.a.iii.b Surgical Excision and/or Decompression for Morton's Neuroma

Recommended - where pain and/or debility are significant and changing shoe wear, orthotics and glucocorticoid injection(s) fail to sufficiently control symptoms.

Rationale for Recommendations: Ablative procedures or surgery are recommended in select cases where pain and/or debility are significant and changing shoe wear, orthotics and glucocorticoid injection(s) fail to sufficiently control symptoms.

Evidence of the Use of Surgery

C.14.a.iv Other

C.14.a.iv.a Changes in Shoewear for Treatment of Morton's Neuroma

Recommended - for treatment of Morton's Neuroma.

Indications: Essentially all patients should be advised to wear stiff-soled, wide toe box shoes with a low heel and soft insert.

C.14.a.iv.b Orthotics for Treatment of Morton's Neuroma

Recommended - for treatment of Morton's Neuroma.

C.14.a.iv.c Metatarsal Pads for Treatment of Morton's Neuroma

Recommended - for treatment of Morton's Neuroma.

Rationale for Recommendation: An attempt at an orthosis or a metatarsal pad is recommended.

Evidence for use of Orthotics

C.15 Bunions / Hallux Valgus

Hallux valgus ("bunion") is a lateral deviation of the great toe at the metatarsophalangeal joint with respect to the midline of the body, generally defined as over 14.5 degrees; and occurring in most cases with medial deviation of the first metatarsal.

The feet should show valgus deviation of the great toe beyond the first metatarsophalangeal joint.

C.15.a Diagnostic Studies

A careful history and physical examination is considered the most important diagnostic approach and in most cases needs no further diagnostic testing for preliminary treatment.

C.15.a.i X-Rays

Recommended – to evaluate alternate conditions such as osteoarthrosis, gout and degenerative joint disease. Also, x-rays are useful for measuring angles and surgical planning.

C.15.b Treatments

C.15.b.i Rehabilitation

C.15.b.i.a Low Intensity Ultrasound

Not Recommended - for postoperative osteotomy hallux valgus treatment.

Evidence for the Use of Ultrasound

C.15.b.i.b Manipulation or Mobilization for Treatment of Hallux Valgus

Not Recommended - for treatment of hallux valgus.

Evidence for the Use of Manipulation and Mobilization

C.15.b.ii Surgery

C.15.b.ii.a Surgery for Hallux Valgus

Recommended - for Hallux Valgus.

Indications: Select cases of mostly moderate hallux valgus where pain and/or debility are significant and changing shoe wear and orthotics fail to sufficiently control symptoms.

Evidence of the Use of Surgery

C.15.b.iii Other

C.15.b.iii.a Orthotics for Treatment of Hallux Valgus

Recommended - for treatment of Hallux Valgus.

Indications: Use of orthoses for hallux valgus should generally be limited to one of two 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 for Recommendation: Orthotics are recommended for those with symptoms insufficiently controlled by changing shoewear when possible.

Evidence for Use of Orthotics

C.16 Hammer Toe

Hammer toe syndromes normally occur in the sagittal plane. The metatarsophalangeal joint is dorsiflexed, while the proximal interphalangeal joint is plantarflexed. Hammer toe mostly affects the second toe.

C.16.a Treatment

C.16.a.i Non-Operative Treatments Include Footwear Modifications to Improve Toe Box/Room, Padding, Corticosteroid Injections, and Orthoses.

Recommended – for treatment of hammer toe.

C.16.a.ii Operative Treatment (Arthroplasty, Flexor Tendon Transfer, Flexor Tenotomy, Extensor Tendon Lengthening and Metatarsophalangeal Joint Capsulotomy, Fusion, and Diaphysectomy)

Recommended – for hammer toes with insufficient results from non-operative procedures.

C.17 Ankle and Foot Fractures

The initial evaluation of a patient with ankle injury should seek to identify conditions that require immediate treatment. These conditions include open fracture, vascular compromise, compartment syndrome, and joint dislocation.

In general, undisplaced or minimally displaced injuries are treated non-operatively, whereas displaced or unstable injuries are treated operatively. 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.

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. 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.

C.17.a Diagnostic Studies

C.17.a.i X-Ray for Suspected Acute Ankle Fractures

Recommended – as a first-line study.

Indications: Suspicion of fracture.

Rationale for Recommendation: X-ray is the recommended initial imaging study for suspected fracture.

Evidence for the Use of Ottawa Ankle and Foot Rules for Ankle Sprain

C.17.a.ii MRI for Distal Lower Extremity and Ankle Fractures

Recommended – for investigation of distal lower extremity and ankle fractures.

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

Rationale for Recommendation: MRI 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. MRI is recommended for these select circumstances.

Evidence for the Use of MRI for Evaluation of Ankle Fractures

C.17.a.iii CT for Diagnosis and Classification of Ankle Fractures

Recommended – for investigation of distal lower extremity and ankle fractures.

Indications: Suspected occult and complex ankle fractures; to gain greater clarity of fracture displacement. If intraarticular displacement is considered, then axial views are recommended in addition to any coronal views.

Rationale for Recommendation: 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.

Evidence for the Use of CT for Evaluation of Ankle Fractures

C.17.a.iv Ultrasound Imaging for Diagnosing Ankle Fracture

Recommended – for evaluation of soft-tissue injury associated with select displaced fractures or suspected malleolar stress fractures.

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, and in detection of suspected occult or stress fractures. Also used for suspected stress fracture of the distal tibia.

Rationale for Recommendation: Ultrasound imaging may be a useful adjuvant to clinical assessment of patients with regards to selection for further radiological examination, and is therefore recommended in select patients.

Evidence for the Use of Ultrasound for Evaluation of Ankle Fractures

C.17.b Medications

C.17.b.i Pre-Operative Antibiotic Prophylaxis for Ankle Fractures

Recommended – for closed or open ankle fracture surgery.

Evidence for the Use of Antibiotic Prophylaxis for Ankle Fractures

C.17.b.ii Use of Nasal Spray Calcitonin for Post-fracture Osteopenia

Not Recommended – for prophylaxis of post-fracture osteopenia.

Evidence for the Use of Calcitonin Prophylaxis for Post-fracture Osteopenia

C.17.b.iii DVT Prophylaxis

See discussion of DVT prophylaxis in the Achilles tendon rupture section.

Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) and Acetaminophen
For most patients, ibuprofen, naproxen, or other older generation NSAIDs are recommended as first-line medications. Acetaminophen (or the analog paracetamol) may be a reasonable alternative to NSAIDs for patients who are not candidates for NSAIDs, although most evidence suggests acetaminophen is modestly less effective. There is evidence that NSAIDs are as effective for relief of pain as opioids (including tramadol) and less impairing.

C.17.b.iv Non-Steroidal Anti-inflammatory Drugs (NSAIDs) for Acute Ankle Fracture Analgesia

Recommended - for treatment of pain associated with ankle fracture.

Indications: For acute, subacute, chronic, or postoperative ankle fracture, NSAIDs are recommended for treatment. Over-the-counter (OTC) agents may suffice and should be tried first.

Frequency/Duration: As needed use may be reasonable for many patients.

Indications for Discontinuation: Resolution of foot/ankle pain, lack of efficacy, or development of adverse effects that necessitate discontinuation.

C.17.b.v NSAIDs for Patients at High-Risk of Gastrointestinal Bleeding

Recommended - concomminent use of cytoprotective classes of drugs: misoprostol, sucralfate, histamine Type 2 receptor blockers, and proton pump inhibitors for patients at High-Risk of gastrointestinal bleeding.

*Indication*s: For patients with a high-risk factor profile who also have indications for NSAIDs, cytoprotective medications should be considered, particularly if longer term treatment is contemplated. At-risk patients include those with a history of prior gastrointestinal bleeding, elderly, diabetics, and cigarette smokers.

Frequency/Dose/Duration: Proton pump inhibitors, misoprostol, sucralfate, H2 blockers recommended. Dose and frequency per manufacturer. There is not generally believed to be substantial differences in efficacy for prevention of gastrointestinal bleeding.

Indications for Discontinuation: Intolerance, development of adverse effects, or discontinuation of NSAID.

C.17.b.vi NSAIDs for Patients at Risk for Cardiovascular Adverse Effects
Patients with known cardiovascular disease or multiple risk factors for cardiovascular disease should have the risks and benefits of NSAID therapy for pain discussed.

Recommended - Acetaminophen or aspirin as the first-line therapy appear to be the safest regarding cardiovascular adverse.

Recommended - If needed, NSAIDs that are non-selective are preferred over COX-2 specific drugs. In patients receiving low-dose aspirin for primary or secondary cardiovascular disease prevention, to minimize the potential for the NSAID to counteract the beneficial effects of aspirin, the NSAID should be taken at least 30 minutes after or eight hours before the daily aspirin.

C.17.b.vii Acetaminophen for Treatment of Acute, Subacute, or Chronic Acute Ankle Fracture Pain

Recommended - for treatment of acute, subacute, or chronic acute ankle fracture pain, particularly in patients with contraindications for NSAIDs.

Indications: All patients with foot/ankle pain, including acute, subacute, chronic, and postoperative.

Dose/Frequency: Per manufacturer's recommendations; may be utilized on an as-needed basis. There is evidence of hepatic toxicity when exceeding four gm/day.

Indications for Discontinuation: Resolution of pain, adverse effects or intolerance.

Evidence for the Use of NSAIDs and Acetaminophen for Foot and Ankle Fractures

C.17.b.viii Limited Use of Opioids for Acute and Postoperative Pain Management

Recommended – for limited use (less than seven days) for acute and postoperative pain management as adjunctive therapy to more effective treatments.

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

Frequency/Duration: Prescribed as needed throughout the day, then later only at night, before weaning off completely.

Rationale for Recommendation: 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 postoperative patients with primary use at night to achieve sleep postoperatively.

Evidence for the Use of Opioids for Foot and Ankle Fractures

C.17.b.ix Tetanus Immunization Status for Open Fractures

Recommended – updating of tetanus immunization status as necessary.

Indications: Wounds that are not clean if more than five years have elapsed since last tetanus immunization.

Rationale for Recommendation: 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 five years since last immunization, rather than ten years. Patients without a completed immunization series of three injections should receive tetanus immune globulin along with immunization.

Evidence for the Use of Tetanus Immunization for Open Foot and Ankle Fractures

C.17.b.x Analgesia for Non-Operative Reduction Ankle Fractures

Recommended – for performing non-operative closed reduction of ankle fractures.

Rationale for Recommendation: 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.

Evidence for the Use of Non-operative Reduction Analgesia for Ankle Fractures

C.17.c Treatments

C.17.c.i Mobilization / Immobilization

C.17.c.i.a Cast Immobilization for Ankle Fractures

Recommended - for the management of ankle fractures.

Indications: All ankle fractures.

Frequency/Duration: Immobilization generally for six to eight weeks.

Rationale for Recommendation: Cast immobilization is recommended for all patients and the use is dependent on physician and patient preference.

C.17.c.i.b Early Mobilization for Ankle Fractures

Recommended - in the management of postoperative and stable non-operative ankle fractures.

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

Frequency/Duration: Early mobilization can be started within one to three days postoperatively.

Rationale for Recommendation: Early mobilization is recommended for most patients with stable or repaired malleolar ankle fracture.

C.17.c.i.c Early Postoperative Weight-bearing for Ankle Fractures

Recommended - Early weight-bearing of operatively fixated ankle fractures postoperatively.

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

Rationale for Recommendation: Early weight-bearing may provide improvement in functional recovery short-term, does not appear to result in increased adverse events.

Evidence for the Use of Immobilization, Early Mobilization, Early Weight-bearing for Ankle Fractures

C.17.c.ii Rehabilitation

C.17.c.ii.a Electrical Stimulation for Prevention of Muscle Atrophy

Not Recommended - for prevention of muscle atrophy in ankle and foot fracture management.

Evidence for the Use of Electrical Stimulation for Ankle and Foot Fractures

C.17.c.ii.b Therapy for Patients with Functional Deficits after Cast Removal

Recommended - after cast removal for ankle fractures.

C.17.c.ii.c Manual Therapy as Part of a Post-ankle Fracture Rehabilitation Program

Recommended - as part of an active post-ankle fracture rehabilitation program.

C.17.c.ii.d Passive Stretching for Contractures After Immobilization of Ankle Fractures

Not Recommended - for contractures after immobilization of ankle fractures.

Frequency/Dose/Duration : Frequency of visits is usually individualized based on severity of the limitation. Two to three visits per week for two weeks are often used to initiate an exercise program. Total numbers of visits may be as few as two to three for mild deficits or for more severe deficits, up to 12 to 15 with documenation of objective functional improvement.

Evidence for the Use of Therapy for Ankle Fractures

C.17.c.ii.e Ultrasound to Stimulate Bone Healing for Ankle and Foot Fractures

Not Recommended - for ankle and foot fracture management.

Evidence for the Use of Ultrasound Stimulation for Ankle and Foot Fractures

C.17.c.ii.f Hyperbaric Oxygen for the Management of Ankle or Foot Fractures

Not Recommended - for management of ankle or foot fractures.

Evidence for the Use of Hyperbaric Oxygen for Ankle and Foot Fractures

C.17.c.iii Fracture Care

Malleolar Ankle Fractures
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. Non-union of the distal fibula fracture is rare 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.

C.17.c.iii.a Immobilization for Non-displaced Ankle Fractures

Recommended - for the treatment of non-displaced and reduced stable ankle fractures.

C.17.c.iii.b Immobilization and Reduction for Closed Displaced Ankle Fractures

Recommended – for select non-comminuted closed displaced ankle fractures.

Indications: Non-comminuted closed displaced ankle fractures with post-reduction displacement less than two to three mm and less than 25% posterior malleolus articular surface involvement.

C.17.c.iii.c Operative Fixation for Closed Displaced Ankle Fractures

Recommended – for unstable closed displaced ankle fractures.

Indications: Generally severe lateral fracture with medial malleolar involvement. Comminuted closed displaced ankle fractures with post-reduction displacement more than 2 to 3mm and more than 25% posterior malleolus articular surface involvement

Rationale for Recommendations: In the absence of severe systemic comorbidities, the results after open reduction and internal fixation of malleolar fractures in patients above and below 60 years of age are nearly identical, while nonoperative treatment of unstable fractures leads to significantly inferior outcomes. Therefore, the general indications for surgery in elderly patients should not differ from those in younger patients. Individual fracture treatment is tailored depending on bone quality, skin conditions, comorbidities and functional demand of the patient. To avoid complications, it is imperative to consider and treat comorbidities such as diabetes and osteoporosis.

Evidence for the Management of Malleolar Ankle Fractures

Tibial Shaft Fractures (Diaphyseal)

C.17.c.iii.d Operative Fixation for Tibial Shaft Fracture (Closed, Diaphyseal)

Recommended – for definitive management of displaced tibial shaft fracture.

Indications: Displaced, comminuted distal tibial shaft fracture.

C.17.c.iii.e Cast Immobilization for Tibial Shaft Fractures (Closed, Diaphyseal)

Recommended – case may be indicated in select patients with closed, stable, tibial fracture.

Evidence for the Management of Tibial Shaft Fractures

Distal Tibial Extra-Articular Fractures

C.17.c.iii.f Operative Fixation (i.e., Fracture Plating, Intramedullary Nail) for Distal Tibial Extra-Articular Fractures

Recommended – in select patients.

Indications: Open fractures, initial shortening >15mm, angular deformity after initial manipulation >5° in any plane.

C.17.c.iii.g Cast Immobilization for Distal Tibial Extra-Articular Fractures

Recommended – in select circumstances for distal extra-articular tibial fractures.

Indications: Closed simple fractures with initial shortening <15mm, angular deformity after initial manipulation <5° in any plane.

Evidence for the Management of Tibial Extra-articular Fractures

Tibial Plafond (Pilon) Fractures

C.17.c.iii.h Non-operative Management of Tibial Plafond and Pilon Fractures

Recommended – in select patients.

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

C.17.c.iii.i Operative Management of Tibial Plafond and Pilon Fractures

Recommended – for tibial plafond fractures in select patients.

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

Rationale for Recommendations: Distal lower leg fractures that impinge on the articular surface with the talus are known as plafond fractures. These fractures are noted to have high complication rates from surgical reduction and fixation.

Evidence for the Management of Tibial Plafond and Pilon Fractures

Syndesmotic Ruptures
Operative treatment of unstable syndesmotic injury to restore the tibiofibular relationship.

C.17.c.iii.j Operative Fixation for Syndesmotic Ruptures

Recommended - for unstable syndesmotic rupture.

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.

C.17.c.iii.k Non-operative Management of Syndesmotic Injuries

Recommended - for stable syndesmotic injury.

Indications: Absence of other destabilizing injury including ankle fracture or deltoid ligament injury.

Rationale for Recommendations: 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.

Evidence for the Treatment of Syndesmotic Injury

Fibular Fracture

C.17.c.iii.l Operative Fixation for Displaced Distal Fibula Fractures

Recommended - for displaced distal fibula fracture.

Indications: Distal fibula shaft fracture, unsatisfactory closed reduction.

Rationale for Recommendation: Operative fixation is recommended for displaced, unstable distal fibular fractures.

Evidence for the Operative Management of Fibular Shaft Fractures

Arthroscopy with ORIF of Distal Fibular Fractures

C.17.c.iii.m Use of Arthroscopy Assisted ORIF for Distal Fibular Fractures

Not Recommended - for distal fibular fractures.

Evidence for the Use of Arthroscopy Evaluation During Distal Tibia Fracture Fixation ORIF

Deltoid Ligament Repair with ORIF of Lateral Ankle Fracture

C.17.c.iii.n Deltoid Ligament Repair Concurrent with ORIF for Unstable Ankle Fractures

Recommended – for patients with deltoid ligament disruption and high fibular fractures or in patients with concomitant syndesmotic fixation.

Evidence for the Repair of Deltoid Ligament with Lateral Ankle Fracture Fixation

C.17.c.iv Other

C.17.c.iv.a Pneumatic Compression for Treatment of Ankle and Foot Edema

Recommended - for patients with significant postoperative edema.

Indications: Excessive swelling after ankle fracture surgery.

Evidence for the Use of Pneumatic Compression for Edema Management

C.17.c.iv.b Interferential Therapy for Treatment of Ankle Edema

Not Recommended - for the treatment of postoperative swelling following ORIF for displaced malleolar fracture.

Evidence for the Use of Interferential Current Therapy for Postoperative Edema Management

C.18 Hindfoot Fractures (Calcaneaus, Talus)

C.18.a Diagnostic Studies

C.18.a.i X-ray

Recommended - as a first-line study for suspected acute hindfoot fractures.

Indications: Suspicion of fracture.

Views: Calcaneus: AP, lateral, and calcaneal view; Talus: AP, lateral, mortise, Broden views (45° internal oblique) and Canale views (talar neck).

Evidence for the Use of X-ray for Hindfoot Fractures

C.18.a.ii MRI

Recommended - for suspected acute occult fracture of the talus and calcaneus.

Indications – Generally reserved for suspicion of occult fracture of the talus neck or lateral process. Patients whose plain images indicate osteochondral lesion and those who remain symptomatic after six weeks should undergo evaluation with MRI.

C.18.a.iii MRI for Follow-up Evaluation of Non-acute Calcaneus Fracture

Recommended - for calcaneus fractures for identification of complications in the non-acute fracture patient.

Indications: Non-acute fracture patient with persistent pain more than four months after injury.

Rationale for Recommendations: 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. In general, MRI is suboptimal compared with CT scan for calcaneus injury.

Evidence for the Use of MRI for Hindfoot Fractures

C.18.a.iv Bone Scanning for Calcaneus Fracture

Recommended - for diagnosis of occult and stress fractures in select patients.

Rationale for Recommendation: A bone scan may be reasonable for those with high clinical suspicion but with negative x-ray and CT scan. Bone scans are utilized to diagnose occult calcaneus fractures and stress fractures of the calcaneus.

Evidence for the Use of Bone Scanning for Hindfoot Fractures

C.18.a.v CT for Diagnosis and Classification of Hindfoot Fractures

Recommended - for investigation of hindfoot fractures.

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. If intraarticular displacement is considered, then axial views are recommended in addition to any coronal views. CT is indicated for evaluation of suspected subtalar joint fractures.

Views: Coronal and axial.

Rationale for Recommendation: CT scans are considered the gold standard for diagnosing and characterizing calcaneus fractures. 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. 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.

Evidence for the Use of CT for Hindfoot Fractures

C.18.a.vi Follow-up Visits – Imaging

For talus fracture, if clinically suspected in the setting of negative radiographs, follow-up radiographs may be helpful; after approximately seven days there will be resorption at the fracture line, which will then be visible more easily. Follow-up radiography at six to eight weeks for confirmed talus fracture, looking for the Hawkins sign, a radiographic subchondral radiolucent band in the talar dome. This sign, visible in the anterior-posterior view, is indicative of viability at six to eight weeks post-fracture indicating that avascular necrosis is unlikely to develop.

C.18.b Medications

Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) and Acetaminophen

For most patients, ibuprofen, naproxen, or other older generation nonsteroidal anti-inflammatory drugs (NSAIDs) are recommended as first-line medications. Acetaminophen (or the analog paracetamol) may be a reasonable alternative to NSAIDs for patients who are not candidates for NSAIDs, although most evidence suggests acetaminophen is modestly less effective. There is evidence that NSAIDs are as effective for relief of pain as opioids (including tramadol) and less impairing.

C.18.b.i Non-Steroidal Anti-inflammatory Drugs (NSAIDs) and Acetaminophen for Hindfoot Fractures Analgesia

Recommended - for hindfoot fracture analgesia.

Indications: For hindfoot fracture analgesia, NSAIDs are recommended for treatment. Over-the-counter (OTC) agents may suffice and should be tried first.

Frequency/Duration: As needed use may be reasonable for many patients.

Indications for Discontinuation: Resolution of foot/ankle pain, lack of efficacy, or development of adverse effects that necessitate discontinuation.

C.18.b.ii NSAIDs for Patients at High-Risk of Gastrointestinal Bleeding.

Recommended – concomminent use of cytoprotective classes of drugs: misoprostol, sucralfate, histamine Type 2 receptor blockers, and proton pump inhibitors for patients at High-Risk of gastrointestinal bleeding.

*Indication*s – For patients with a high-risk factor profile who also have indications for NSAIDs, cytoprotective medications should be considered, particularly if longer term treatment is contemplated. At-risk patients include those with a history of prior gastrointestinal bleeding, elderly, diabetics, and cigarette smokers.

Frequency/Dose/Duration – Proton pump inhibitors, misoprostol, sucralfate, H2 blockers recommended. Dose and frequency per manufacturer. There is not generally believed to be substantial differences in efficacy for prevention of gastrointestinal bleeding.

Indications for Discontinuation – Intolerance, development of adverse effects, or discontinuation of NSAID.

C.18.b.iii NSAIDs for Patients at Risk for Cardiovascular Adverse Effects

Patients with known cardiovascular disease or multiple risk factors for cardiovascular disease should have the risks and benefits of NSAID therapy for pain discussed.

Recommended - Acetaminophen or aspirin as the first-line therapy appear to be the safest regarding cardiovascular adverse.

Recommended - If needed, NSAIDs that are non-selective are preferred over COX-2 specific drugs. In patients receiving low-dose aspirin for primary or secondary cardiovascular disease prevention, to minimize the potential for the NSAID to counteract the beneficial effects of aspirin, the NSAID should be taken at least 30 minutes after or 8 hours before the daily aspirin.

C.18.b.iv Acetaminophen for Treatment of Hindfoot Fracture Pain

Recommended - for treatment of hindfoot frracture pain, particularly in patients with contraindications for NSAIDs.

Indications: All patients with foot/ankle pain, including acute, subacute, chronic, and postoperative.

Dose/Frequency: Per manufacturer's recommendations; may be utilized on an as-needed basis. There is evidence of hepatic toxicity when exceeding four gm/day.

Indications for Discontinuation: Resolution of pain, adverse effects or intolerance.

Evidence for the Use of NSAIDs and Acetaminophen for Foot and Ankle Fractures

C.18.b.v Limited Use of Opioids for Acute and Postoperative Pain Management

Recommended – for limited use (less than seven days) in select patients for acute and postoperative pain management as adjunctive therapy to more effective treatments.

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

Frequency/Duration: Prescribed as needed throughout the day, then later only at night, before weaning off completely.

Rationale for Recommendation: Select 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 postoperative patients with primary use at night to achieve sleep postoperatively.

Evidence for the Use of Opioids for Foot and Ankle Fractures

C.18.b.vi Tetanus Immunization Status for Open Fractures

Recommended – updating of tetanus immunization status as necessary.

Indications: Wounds that are not clean if more than five years have elapsed since last tetanus immunization.

Rationale for Recommendation: 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 five years since last immunization, rather than ten years. Patients without a completed immunization series of three injections should receive tetanus immune globulin along with immunization.

Evidence for the Use of Tetanus Immunization for Open Foot and Ankle Fractures

C.18.b.vii Pre-Operative Antibiotic Prophylaxis for Ankle Fractures

Recommended – for closed or open ankle fracture surgery.

Evidence for the Use of Antibiotic Prophylaxis for Ankle Fractures

C.18.b.viii Use of Nasal Spray Calcitonin for Post-fracture Osteopenia

Not Recommended – for prophylaxis of post-fracture osteopenia.

Rationale for Recommendation: Nasal calcitonin obtained from salmon compared with placebo did not result in significant differences in bone mineralization 3 months after surgery.

Evidence for the Use of Calcitonin Prophylaxis for Post-fracture Osteopenia

C.18.b.ix DVT Prophylaxis

See discussion of DVT prophylaxis in the Achilles tendon rupture section.

C.18.c Treatments

C.18.c.i Rehabilitation

Therapy

Rehabilitation (supervised formal therapy) required as a result of a work-related injury should be focused on restoring functional ability required to meet the patient's daily and work activities and return to work; striving to restore the injured worker to pre-injury status in so far as is feasible.

Active therapy requires an internal effort by the patient to complete a specific exercise or task. Passive therapy are those interventions not requiring the exertion of effort on the part of the patient, but rather are dependent on modalities delivered by a therapist. Generally passive interventions are viewed as a means to facilitate progress in an active therapy program with concomitant attainment of objective functional gains. Active interventions should be emphasized over passive interventions.

The patient should be instructed to continue both active and passive therapies at home as an extension of the treatment process in order to maintain improvement levels.

Assistive devices may be included as an adjunctive measure incorporated into the rehabilitation plan to facilitate functional gains.

C.18.c.i.a Diathermy for Management of Edema Associated with Calcaneus Fracture

Not Recommended - for management of edema associated with calcaneus fractures.

Evidence for the Use of Diathermy for Edema Control

C.18.c.i.b Therapeutic Exercise - Physical / Occupational Therapy

Recommended – to improve function, including range of motion and strength.

Frequency/Dose/Duration –Total numbers of visits may be as few as two to three for patients with mild functional

deficits or up to 12 to 15 with more severe deficits with documentation of ongoing objective functional improvement.

When there are ongoing functional deficits, more than 12 to 15 visits may be indicated if there is documentation of functional improvement towards specific objective functional goals (e.g., increased grip strength, key pinch strength, range of motion, advancing ability to perform work activities). As part of the rehabilitation plan a home exercise program should be developed and performed in conjunction with the therapy.

C.18.c.ii Fracture Care

Talus Fractures
Because of its key position, diagnosis and treatment of talus fractures is critical for foot and ankle function.

C.18.c.ii.a Non-operative Management of Non-displaced Talar Fractures

Not Recommended - for non-displaced talar fractures (head, neck, body).

C.18.c.ii.b Operative Management of Displaced Talar Fractures

Recommended - for all displaced talar fractures (head, neck, body, lateral process).

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.

Rationale for Recommendations: Because of the key role the talus plays in locomotion, and the risk for significant disability and complication with these fractures referral to specialists for most, if not all, talus fractures is recommended.

Evidence for the Management of Talar Fractures

Osteochondral Lesions of the Talus

C.18.c.ii.c Non-Operative Management of Osteochondral Lesions of the Talus

Recommended - for select patients.

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.

Management: Cast or brace immobilization and protected weight-bearing for six to 12 weeks, followed by increasing pain-free range-of-motion exercises and strengthening.

C.18.c.ii.d Operative Intervention for Osteochondral Lesions of the Talus

Recommended - after an initial course of conservative management. Microfracture and osteochondral autograft are recommended.

Rationale for Recommendations: A trial of conservative management is recommended initially. A trial of protected weight bearing for six to 12 weeks is reasonable.

Evidence for the Use of Operative Management for Osteochondral Lesions

Calcaneus Fractures

C.18.c.ii.e Cast Immobilization for Select Calcaneus Fractures

Recommended - for select calcaneus fractures.

Indications: Non-displaced fracture, displaced extra-articular, displaced intra-articular.

C.18.c.ii.f Operative Management for Select Calcaneus Fractures

Recommended - for select calcaneus fractures.

Indications: Displaced, non-reducible extra-articular fractures, displaced intra-articular fractures.

Rationale for Recommendations: 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.

Evidence for the Management of Calcaneal Fractures

C.18.c.iii Other

C.18.c.iii.a Use of Pneumatic Compression Device for Treatment of Calcaneus Fractures

Recommended - for patients with significant edema after closed calcaneus fractures.

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/Duration: Pedal compression device used continuously until swelling subsides sufficiently to allow for surgery or to manage non-operatively.

Rationale for Recommendation: Pneumatic compression for edema management is recommended for management of acute calcaneus fracture management in select patients with significant edema.

Evidence for the Management of Edema Associated with Calcaneal Fractures

C.19 Forefoot and Midfoot Fractures (Tarsal, Metatarsal, Phalangeal)

C.19.a Diagnostic Studies

C.19.a.i X-ray for Suspected Acute Forefoot or Midfoot Fractures

Recommended - as a first-line study for suspected forefoot or midfoot fractures.

Indications: Suspicion of all forefoot and midfoot fractures.

Views : AP, lateral, and oblique.

Rationale for Recommendation: 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 seven days there will be resorption at the fracture line, which will then be visible.

Evidence for the Use of X-ray for Suspected Tarsal, Metatarsal, or Phalangeal Fractures

C.19.a.ii MRI for Suspected Acute Forefoot and Midfoot Fractures

Recommended - for suspected occult and stress fracture in select patients.

Indications: Generally reserved for suspicion of occult or stress fracture of the fore or midfoot, however, CT is viewed as superior by some.

Rationale for Recommendation: 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 for the Use of MRI for Suspected Tarsal Metatarsal and Phalangeal Fractures

C.19.a.iii Bone Scanning for Forefoot and Midfoot Fractures

Recommended - for diagnosis of occult and stress fractures in select patients.

Indications: Generally reserved for suspicion of occult fracture of the tarsal and metatarsal bones.

Rationale for Recommendation: Bone scans are not required for evaluation of 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.

Evidence for the Use of Bone Scan for Suspected Tarsal, Metatarsal, or Phalangeal Fractures

CT Imaging

C.19.a.iv CT for Diagnosis and Classification of Forefoot and Midfoot Fractures

Recommended – in select patients for investigation of forefoot and midfoot fractures.

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.

Rationale for Recommendation: CT should not be used as a first-line test. CT may be an important diagnostic technique to gain greater clarity of fracture displacement, articular involvement, and subluxation of affected joints, and is recommended for select patients.

Evidence for the Use of CT for Suspected Tarsal Metatarsal and Phalangeal Fractures

C.19.b Medications

Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) and Acetaminophen
For most patients, ibuprofen, naproxen, or other older generation nonsteroidal anti-inflammatory drugs (NSAIDs) are recommended as first-line medications. Acetaminophen (or the analog paracetamol) may be a reasonable alternative to NSAIDs for patients who are not candidates for NSAIDs, although most evidence suggests acetaminophen is modestly less effective. There is evidence that NSAIDs are as effective for relief of pain as opioids (including tramadol) and less impairing.

C.19.b.i Non-Steroidal Anti-inflammatory Drugs (NSAIDs) and Acetaminophen for Phalangeal or Metatarsal Fracture Pain Control

Recommended - for phalangeal or metatarsal fracture pain control.

Indications: For acute, subacute, chronic, or postoperative phalangeal or metatarsal fracture pain contorl, NSAIDs are recommended for treatment. Over-the-counter (OTC) agents may suffice and should be tried first.

Frequency/Duration: As needed use may be reasonable for many patients.

Indications for Discontinuation: Resolution of foot/ankle pain, lack of efficacy, or development of adverse effects that necessitate discontinuation.

C.19.b.ii NSAIDs for Patients at High-Risk of Gastrointestinal Bleeding.

Recommended – concomminent use of cytoprotective classes of drugs: misoprostol, sucralfate, histamine Type 2 receptor blockers, and proton pump inhibitors for patients at High-Risk of gastrointestinal bleeding.

*Indication*s: For patients with a high-risk factor profile who also have indications for NSAIDs, cytoprotective medications should be considered, particularly if longer term treatment is contemplated. At-risk patients include those with a history of prior gastrointestinal bleeding, elderly, diabetics, and cigarette smokers.

Frequency/Dose/Duration: Proton pump inhibitors, misoprostol, sucralfate, H2 blockers recommended. Dose and frequency per manufacturer. There is not generally believed to be substantial differences in efficacy for prevention of gastrointestinal bleeding.

Indications for Discontinuation: Intolerance, development of adverse effects, or discontinuation of NSAID.

C.19.b.iii NSAIDs for Patients at Risk for Cardiovascular Adverse Effects

Patients with known cardiovascular disease or multiple risk factors for cardiovascular disease should have the risks and benefits of NSAID therapy for pain discussed.

Recommended - Acetaminophen or aspirin as the first-line therapy appear to be the safest regarding cardiovascular adverse.

Recommended - If needed, NSAIDs that are non-selective are preferred over COX-2 specific drugs. In patients receiving low-dose aspirin for primary or secondary cardiovascular disease prevention, to minimize the potential for the NSAID to counteract the beneficial effects of aspirin, the NSAID should be taken at least 30 minutes after or eight hours before the daily aspirin.

C.19.b.iv Acetaminophen for Treatment of Acute, Subacute, or Chronic Phalangeal or Metatarsal Fracture Pain

Recommended - for treatment of acute, subacute, or chronic phalangeal or metatarsal fracture pain, particularly in patients with contraindications for NSAIDs.

Indications: All patients with foot/ankle pain, including acute, subacute, chronic, and postoperative.

Dose/Frequency: Per manufacturer's recommendations; may be utilized on an as-needed basis. There is evidence of hepatic toxicity when exceeding four gm/day.

Indications for Discontinuation: Resolution of pain, adverse effects or intolerance.

C.19.c Treatments

C.19.c.i Fracture Care

C.19.c.i.a Non-operative Management for Non-Displaced Tarsal-Metatarsal Injury (Lisfranc)

Recommended - for select patients.

Indications: Fracture/joint dislocation displacement <2mm.

Management: Non-weight bearing cast for six weeks.

C.19.c.i.b Operative Management for Displaced Tarsal-Metatarsal Injury (Lisfranc)

Recommended - for an unstable tarsal-metatarsal injury.

Indications: Fracture joint displacement with joint dislocation >2 mm.

Management: May take four to five months to heal; therapy may be started. Removal of hardware prior to full activities.

Rationale for Recommendations: Immobilization or fixation technique is dictated by the physical and radiographic findings.

Evidence for the Management of Lisfranc Injuries

C.19.c.i.c Non-Operative Management for Non-Displaced Metatarsal Fractures

Recommended - for non-displaced metatarsal fractures.

Indications: Non-displaced shaft fractures or with up to 3 to

4mm displacement in dorsal or plantar direction, angulation less than 10° dorsally.

C.19.c.i.d Operative Management for Displaced Metatarsal Shaft Fractures

Recommended - for displaced metatarsal shaft fractures.

Indications: Multiple metatarsals fractured if displaced; shaft fracture near metatarsal head.

Management: Percutaneous pinning or internal fixation with screws, plates; non-weight bearing four to six weeks. Progressive weight-bearing over next four to six weeks in fracture shoe/boot or walking cast. Full weight-bearing in shoes/stiff soled shoe after radiographic evidence of union.

Rationale for Recommendations: Immobilization or fixation technique is dictated by the physical and radiographic findings.

Evidence for the Management of Metatarsal Fractures

C.19.c.i.e Non-operative Management for Proximal Fifth Metatarsal Fractures (Including Joints and Avulsion).

Recommended - for select patients.

Indications: Avulsion of tuberosity: non-displaced, <1 to 2mm step-off on articular surface or less than 30% of articular surface with cuboid; Jones Fracture: patient/provider preference.

Management: Repeat films at one and six weeks. Jones Fracture: non-weight-bearing short-leg cast immobilization for one and six weeks, followed by hard-sole shoe or walking cast until union.

C.19.c.i.f Operative Management for Fifth Displaced Metatarsal Shaft Fractures (Jones, Avulsion)

Recommended - for select patients.

Indications: Avulsion of tuberosity: displaced >1 to 2mm step-off on the articular surface or more than 30% of articular surface with cuboid; Jones Fracture: patient/ provider preference.

Management: 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.

Rationale for Recommendations: Immobilization or fixation technique is dictated by the physical and radiographic findings.

Evidence for the Management of Proximal Fifth Metatarsal Injuries

C.19.c.i.g Immobilization for Distal, Middle, or Proximal Phalanx

Recommended - for treatment of select patients.

Indications: Closed, non-displaced or stable after reduction, involves less than 25% of articular surface.

Management: Closed reduction after digital or hematoma block; obtain post-reduction film, repeat at one and six weeks; splint toe with buddy taping to adjacent toe until non-tender (three to four weeks) excluding hallux. Additional immobilization with a postoperative shoe or cast-boot should be considered.

C.19.c.i.h Operative Management for Distal, Middle, or Proximal Phalanx Fractures

Recommended - for treatment of select patients.

Indications: Displaced fractures of great toe with poor reduction, unable to hold reduction with tape splinting.

Rationale for Recommendations: 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.

Evidence for the Management of Phalangeal Fractures

C.19.c.i.i Non-operative Management for Lower Extremity Stress Fractures

Recommended - for low risk lower extremity stress fractures.

Indications: Non-displaced stress fractures.

Management: All non-displaced stress fractures can be treated conservatively initially.

C.19.c.i.j Operative Management for Lower Extremity Stress Fractures '

Recommended –for lower extremity stress fractures (including navicular stress fractures) that do not respond or that are displaced.

Rationale for Recommendations: Stress fractures 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 .

Evidence for the Management of Stress Fractures

Appendices

Appendix D.1 – Definitions

Bunion: See hallux valgus.

Fasciitis: Inflammation of supportive band or covering.

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.

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

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.

Metatarsalgia: Pain in the forefoot at one or more of the metatarsal heads.

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.

Neuroma: A benign tumor composed of nerve cells.

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

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

Retinaculum: A band or bandlike structure that holds an organ or a part in place. (Stedman Medical Dictionary 15)

Sprain: Injury, not necessarily permanent, of a ligament.
S, Grade I: overstretching or slight tearing without instability.
S, Grade II: incomplete tearing.
S, Grade III: complete tear or rupture.

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

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

Tendinopathy: Any pathology of a tendon.

Appendix D.2 -Tables

Table 3. 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

Appendix D.3 - Evidence Tables

Evidence for the Use of NSAIDs and Acetaminophen

There are 4 moderate-quality RCTs incorporated in this analysis. There is 1 low-quality RCT in Appendix 2.

Author/Year Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments
NSAIDs vs. Placebo						
Jakobsen 1988 RCT	6.0	N = 212 Army personnel with acute soft tissue injuries <48 hours dxxxuration	Tenoxicam 20mg vs. piroxicam 20mg vs. placebo once daily for 10 days.	Significantly better improvement comparing tenoxicam with placebo: global judgment Day 2 (p = 0.025); median difference, -0.2; 95% CI, -0.4 to +0.0); tenderness Day 7 (p = 0.019; median difference, -0.5; 95% CI, -0.9; -0.1); functional limitation Day 10 (p = 0.0048; median difference, -0.3; 95% CI, -0.8 to -0.0).	"The use of tenoxicam 20 mg daily is superior to placebo and at least equal to piroxicam 20 mg daily in the treatment of some specific soft-tissue injuries."	Randomization, allocation, blinding details unclear. Data suggest NSAID superior for treatment of 6 acute injuries. Insufficient data for specific recommendation for Achilles tendinopathy.
Jakobsen 1989 (An analysis Achilles tendinopathy subgroup of Jakobsen 1988)	5.0	N = 115 Army personnel with tendinitis, periostitis or sprains <48 hours duration	Tenoxicam 20mg vs. placebo once daily for 10 days.	Clinical outcomes measured on 4-point scale (excellent, good, moderate, bad) based on spontaneous pain, tenderness, pain on movement, functional limitations, and adverse reactions. In tendonitis group, excellent or	In this 10-day trial for acute Achilles tendinopathy "[The authors] find the effect of tenoxicam 20 mg/ day in the treatment of tendinitis of the Achilles tendon to be convincingly superior to placebo." They found no significant	Randomization, allocation, baseline, blinding details unclear. Military population (mostly male) and included other soft tissue disorders. For acute Achilles tendonitis, 40 of 46 completed study. Data support NSAID superior to placebo.

				good results reached 71% vs. 31% in placebo (p = 0.008).	difference between piroxicam and placebo.	
NSAID plus Exercises vs. Placebo plus Exercise						
Astrom 1992 RCT	5.0	N = 70 non-rheumatic patients with painful Achilles tendinopathy	Piroxicam vs. placebo for 30 days, both groups with stretching and strengthening.	No differences at any time between groups in pain, swelling, muscle strength or ankle joint movement. Pain and tenderness improved in both groups.	"We conclude that a non-steroid anti-inflammatory agent (piroxicam) does not afford symptomatic relief in Achilles pain; a limited rate of success was noted, presumably due to the combined effect of rest, exercises and the placebo response."	Details of randomization, allocation, baseline comparability are sparse. Both groups underwent stretching and strengthening exercises, providing potentially major co-interventions. Data suggest no effect of NSAID.
Glucosaminoglycan Injection vs. NSAID						
Sundqvist 1987 RCT	6.0	N = 60 recreational athletes suffering from Achilles peri-tendinitis	Local injection glycosaminoglycan polysulfate (GAGPS) vs. indomethacin.	No difference in percentage with good response ratings in acute patients. Significant differences in chronic patients with GAGPS vs. indomethacin (59% vs. 12%, p <0.05).	"Local injections of GAGPS were shown to be more effective than high-dose indomethacin especially in chronic cases."	Allocation, blinding details unclear. Possible co-interventions (orthotics, physical therapy). Data suggest injection superior to NSAID.

Evidence for the Use of Topical NSAIDs

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

Author/Year Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments
Topical NSAIDS vs. Placebo						
Russell 1991 RCT	6.0	N = 214 with 1 unilateral acute soft tissue injury (recent sprained	Piroxicam 0.5% topical gel vs. placebo QID.	Piroxicam vs. placebo VAS Means Day 8. Spontaneous pain: 2.8 vs. 4.2, p <0.05; pain on	"This study demonstrates that piroxicam gel, administered on a q.i.d. basis	Allocation, blinding details unclear. Study included mixed diagnoses: Achilles 6

		ankle, sprained acromioclavicular joint, supraspinatus tendinitis or Achilles tendinitis)		movement: 5.0 vs. 9.5, p = 0.05; Pressure threshold ratio 0.79 vs. 0.58, p <0.05.	for a total daily dose of 20 mg, is effective treatment for patients suffering from musculoskeletal injuries (sprains and tendinitis) and is significantly more effective than placebo while offering toleration equal to placebo."	supraspinatus tendinitis 102/108, ankle sprains 84, AC sprain 6 subjects. No breakdown in analysis by specific disorder. Sample size too small for Achilles tendinitis subset to form firm conclusions.
Auclair 1989 RCT	5.0	N = 243 Achilles heel tendinitis	Niflumic acid gel (2.5%) applied to skin over tendon vs. placebo TID for 3 weeks.	Gel vs. placebo (p-value): pain improved on palpation (% and SD) 59.2 (35.8) vs. 48.0 (40.4) p = 0.028; attained previous sporting level 51 (44.7%) vs. 29 (28.7%) p = 0.015; global evaluation of efficacy by patient: Very good 21 (18.8%) 15 (13.8%) p = 0.043, Good 48 (42.9%) 39 (35.8%).	"The results of this study demonstrate the superiority of niflumic acid gel compared with placebo."	Randomization, allocation details not included. Blinding stated but is unclear. All subjects were also on rest from activities. Data suggest efficacy.

Evidence for the Use of Glyceryl Trinitrate Patches

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

Author/Year Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments
Paoloni 2004 RCT	5.5	N = 65 chronic non-insertional Achilles tendinopathy	Topical glyceryl trinitrate (GTN) patch (1/4 of a standard 5mg patch	GTN group had significantly less activity pain at 12, 24 weeks; less night pain and	"[C]ontinuous topical glyceryl trinitrate therapy can result in significantly decreased Achilles tendon tenderness by twelve weeks. For every 3-4 patients	Study included 84 tendons in 65 patients. Co-interventions: rest, heel wedges, prolonged static stretching,

			placed applied to effected tendon) vs. placebo patch for 24 weeks.	tenderness at 12 weeks only and pain with hop test at 24 weeks only.	treated with topical glyceryl trinitrate, one will have an excellent result at 24 weeks that would not have occurred with placebo."	eccentric stretching. Allocation and compliance unclear. Intervention a pro-drug of endogenous nitric oxide. Data suggest efficacy.
Paoloni 2007 RCT Follow-up of above study	5.5 (score from original)	N = 58 chronic non-insertional Achilles tendinopathy	Topical glyceryl trinitrate (GTN) patch vs. placebo patch; 3-year follow-up from 2004 study.	Of group treated previously with GTN, 88% asymptomatic vs. 67% rehab alone (p = 0.03).	"…suggests that this treatment provides more than simple analgesic effect on the tendon and that beneficial effects are present 3 years after therapy."	Of those that completed original study, 90% participated. No control for other treatments in interim period. Data suggest efficacy.

Evidence for the Use of Exercise for Achilles Tendinopathy

There are 2 high- and 3 moderate-quality RCTs incorporated into this analysis. There is 1 low-quality RCT in Appendix 2.

Author/Year Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments
Exercise vs. Other Intervention						
Rompe 2007 RCT	9.0	N = 75 with a chronic recalcitrant (>6 months) noninsertional Achilles tendinopathy;(25 in each group)	ESWT vs. eccentric exercises vs. no treatment in persons with chronic Achilles tendinopathy.	No differences between SWT and EE in any outcome measure. Both significantly better than wait and see for outcomes of VISA-A score, Likert score, load induced pain, and pain threshold.	"Both eccentric loading and repetitive low-energy SWT led to a successful outcome in 50% to 60% of patients. This is absolutely within the range of results of surgery."	Data suggest ESWT and eccentric exercises effective compared to no treatment.
Rompe J Bone Joint Surg Am 2008 RCT	8.5	N = 50 with chronic (≥6 months) recalcitrant insertional Achilles tendinopathy	ESWT (3 sessions over 3 weeks, 0.12mJ/mm^2 total energy) vs. daily regimen eccentric loading	Eccentric loading vs. ESWT: VISA-A score; 63.4±12.0 vs. 79.4±10.4, p = 0.005 (higher score better); Likert scale:	In this subset of "patients with recalcitrant insertional Achilles tendinopathy" results "demonstrate that the	No placebo control. All enrolled had failed local anesthetic injection, steroid injections, NSAIDs,

			exercises for 12 weeks.	3.7±1.5 vs. 2.8±1.6, p = 0.043; Loading pain scale: 5.0±2.3 vs. 3.0±2.3, p = 0.004 (favors ESWT); Tenderness at 3kg: 4.4±3.2 vs. 2.4±4.2, p = 0.031.	probability for recovery is significantly lower after eccentric loading as applied in the present study compared with repetitive low-energy shock wave therapy as applied."	physiotherapy and heel lifts. Data suggest ESWT superior to eccentric loading exercises.
Comparisons of Different Exercises and of Exercise versus Rest						
Sibernagel 2007 RCT	7.0	N = 42 with Achilles tendinopathy (as 4 dropped before final analysis, 38 patients with 51 tendons)	Tendon loading exercises with jumping, running during treatment vs. active rest (no physical activity that caused symptoms). Active group allowed to exercise to pain VAS of 5 as upper limit.	VISA-A score and pain not different between the groups at baseline or follow-up period of 12 months. No differences in rate of improvement between groups in any functional evaluations.	"No negative effects could be demonstrated from continuing Achilles tendon loading activity, such as running and jumping, with the use of a pain-monitoring model during treatment."	Results indicate activity modification based on pain levels does not impact results of eccentric exercise program.
Silbernagel 2001 RCT	5.5	N = 49 proximal achillodynia (44 involved Achilles tendons); 9 withdrew before study started	12 weeks of less-intense vs. more-intense exercise program for (eccentric/ concentric) in both arms in persons with chronic Achilles tendinopathy.	No significant changes between groups in any measures in the six-month follow-up period. Both groups improved from baseline.	"Measurement techniques and the treatment protocol with eccentric overload can be recommended for patients with chronic pain from the Achilles tendon. More patients achieved full recovery, had less pain during and after activity, and improved ankle range of motion in the experiment group."	Study had 49 patients (69 tendons). Randomization, details sparse. Controls received part of experiment exercise interventions. Results focused on changes from baseline, but data favored intense exercise group.
Mafi 2001	5.0	N = 44 painful chronic	Daily eccentric vs. concentric training	Patient satisfaction at 12 weeks	"Treatment with eccentric calf muscle training in	Small sample size; details sparse on

RCT		Achilles tendinosis	regimens for 12 weeks.	favored eccentric group: 82% vs. 36%, p <0.002.	patients with painful chronic Achilles tendinosis yielded good short term clinical results and significantly better results than concentric calf muscle training."	compliance, avoiding co-interventions. No blinding.

Evidence for the Use of Cryotherapy and Heat for Achilles Tendinopathy
There is 1 moderate-quality RCT incorporated into this analysis.

Author/Year Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments
Knobloch Am J Sports Med 2008 RCT	6.5	N = 60 healthy participants with no prior tendon problems	Cryotherapy with compression vs. cryotherapy alone	No adverse effects from cryotherapy. Cryotherapy plus compression vs. compression: no differences in superficial or deep blood flow with treatment, higher capillary flow in recovery with cryo/compression group.	"Intermittent administration of 3 x 10-minute cryotherapy and compression is superior to cryotherapy alone as far as Achilles tendon micro-circulation is concerned."	Baseline comparability unclear. Results of study are of uncertain clinical significance.

Evidence for the Use of Night Splinting for Achilles Tendinopathy
There are 2 moderate-quality RCTs incorporated into this analysis.

Author/Year Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments
Roos 2004 RCT	7.0	N = 44 with Achilles tendinopathy	Eccentric exercises (EE) vs. night splint vs. EE plus anterior night splint (90° dorsiflexion) over 12 weeks with 1-year follow-up.	All groups improved significantly across all times. No differences in pain between groups at any time. Clinically significant differences (>10 points) in mean pain score	"[E]ccentric exercises seem to improve function and reduce pain in primary care patients. The effects were apparent after 6 weeks and lasted for 1 year."	Small sample size with low power for 3 interventions. All intervention groups improved over time and similar at 1 year. Conclusion may not be complete as co-intervention of night splint. As no arm

				favored eccentric-only group over splint-only at 12 and 26 weeks (p value not reported).		comparing routine or no treatment, findings inconclusive for any intervention.
deVos 2007 RCT	6.0	N = 58 chronic midportion Achilles tendinopathy	Night splints plus eccentric exercises vs. eccentric exercises only for 12 weeks.	VISA-A score change: NS and EE only 50.1 to 68.8 and 49.4 to 67 (p <0.001)	"Splinting in addition to eccentric exercises did not lead to a significantly better outcome for patient satisfaction and VISA-A score. Both reduced pain and improved functional outcome."	Seventy (70) tendons in 58 patients. Patient mix included subacute and chronic conditions. Lack of details on co-intervention. Data suggest no difference.

Evidence for the Use of Orthotic Devices for Achilles Tendinopathy
There are 3 moderate-quality RCTs incorporated into this analysis. There is 1 low-quality RCT in Appendix 2.

Author/Year Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments
Petersen 2007 RCT	4.5	N = 100 with chronic Achilles tendinopathy	AirHeel brace vs. eccentric training vs. both combined.	AOFAS scores improved in all groups. No between-group differences. At 1-year follow-up, AOFAS scores improved 10-12% in all groups vs. baseline (p <0.001).	"This study could not demonstrate any significant differences between treatment with the AirHeel brace and an eccentric training program…"	Allocation, compliance details unclear. Data suggest orthotic provided no benefit.
Knobloch 2008 RCT	4.5	N = 116 with unilateral tendinopathy of main body of Achilles tendon	Eccentric exercise with and without use of AirHeel brace.	Excentric exercise plus AirHeel vs. excentric exercise alone – no difference	"Patient with tendinopathy of the main body of the AT experienced improved	Drop-out rate >20%. Effect on micro-circulation is of unknown clinical effect

				in superficial blood flow, paratenon blood flow. Blood flow at 2mm at insertion significantly reduced in excentric exercise alone (p <0.05). Oxygen saturation higher in excentric exercise plus AirHeel group (p <0.012)	clinical outcome with both management options. Tendon microcirculation was optimized in the combined group."	as demonstrated by equivalency of clinical outcomes. Data suggest no difference.
Knobloch 2008 RCT – 2nd report of above study	4.5	N = 116 with tendinopathy of Achilles tendon	Eccentric exercise with and without use of AirHeel brace.	Capillary blood flow in tendon and paratenon not significantly different at 2 or 8mm tissue depths at 12 positions. Pain reduced p <0.05 in combined treatment groups vs. those that dropped out (labeled non-compliant).	"No microcirculatory changes are evident in non-compliant and compliant patients with Achilles tendinopathy undergoing 12 weeks of eccentric training."	Second report of same study group. Initial report indicated compliance not known, but here reports 92/116 compliant, which appears to refer to those who completed study rather than compliance to exercise regimen or wearing AirHeel. Data suggest no difference.

Evidence for the Use of Extracorporeal Shockwave Therapy for Achilles Tendinopathy
There are 5 high-quality RCTs incorporated into this analysis.

Author/Year Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments
ESWT vs. Sham						

Rasmussen 2008 RCT	9.0	N = 48 assigned to non-operative treatment of chronic Achilles tendinopathy	ESWT vs. sham ESWT (ESWT: 1 session each week for 4 weeks, 2000 shots 0.21-0.51 ml/mm^2, 50 Hz); all patients assigned eccentric exercises.	AOFAS score increased more in intervention, 70 to 88 (p <0.05), than controls, 74 to 81. No difference in pain between groups.	"EWST appears to be a clinically relevant supplement to conservative treatment of tendinopathy. Currently, however, there is no convincing evidence for recommendation of ESWT."	Conservative treatment included stretching and eccentric exercise training as co-interventions. AOFAS score measures pain (40 points), function (50 points), alignment (10 points). Clinical significance set at 10 point difference. Baseline lower AOFAS scores in ESWT group than controls. Data suggest no superiority of ESWT compared to sham.
Costa 2005 RCT	8.0	N = 49 with chronic Achilles tendon pain	ESWT vs. sham ESWT (ESWT: 1500 shocks at 0.2J/mm^2, 1 a month for 3 months).	No differences between groups on pain at rest, during sports, ankle ROM, tendon or calf diameter, or functional scoring.	"Results of our study do not provide any evidence for use of shock wave therapy for treatment of chronic Achilles tendon pain. Complications in the treatment group included two tendon ruptures, suggesting caution in treating older patients with shock wave therapy."	Difference in median age 58 vs. 48 (control). Treatment was guided by ultrasound data. Data suggest no differences.
ESWT vs. Exercise						
Rompe 2009 RCT	9.0	N = 68 with chronic recalcitrant (>6 months) non-	Eccentric exercise vs. eccentric exercise plus shock wave	EE vs. EE + SWT at 4 months, Visa-A: 73 vs. 86.5 (p =	"The likelihood of recovery after 4 months was higher after a combined	No blinding of patients. Study shows both groups improved over

		insertional Achilles tendinopathy	therapy (3 visits over 3 weeks starting Week 4); 16 weeks follow-up. (ESWT: 2000 shocks at 0.1 J/mm^2, 1 a week for 3 weeks.)	0.016); Likert Scale (1-6): 2.9 vs. 2.1 (p = 0.035); Load-induced pain, (0-10) 3.9 vs. 2.4 (p = 0.045); 56% vs. 82% reported complete or good recovery (p = 0.001). All groups significantly better than baseline.	approach of both eccentric loading and SWT compared to eccentric loading alone. Eccentric training plus SWT should be offered to patients with chronic recalcitrant midportion tendinopathy of the Achilles tendon."	baseline. Still had 30% failure at 4 months. Of EE failures, 12/15 success with SWT at 12 months. Of EE+SWT failures, 3/6 success with surgery. Data suggest ESWT of additive benefit to eccentric exercises.
Rompe J Bone Joint Surg Am 2008 RCT	8.5	N = 50 chronic (≥6 months) recalcitrant insertional Achilles tendinopathy	ESWT (3 sessions over 3 weeks, 0.12 mJ/mm2 total energy) vs. daily regimen eccentric loading exercises for 12 weeks. (ESWT: 2000 shocks at 0.12 J/mm^2, 1 a week for 3 weeks.)	Eccentric loading vs. ESWT: VISA-A score; 63.4±12.0 vs. 79.4±10.4, p = 0.005 (higher score is better); Likert scale: 3.7±1.5 vs. 2.8±1.6 p = 0.043; Loading pain scale: 5.0±2.3 vs. 3.0±2.3, p = 0.004 (favors ESWT); Tenderness at 3 kg: 4.4±3.2 vs. 2.4±4.2, p = 0.031.	In this subset of "patients with recalcitrant insertional Achilles tendinopathy" the results "demonstrate that the probability for recovery is significantly lower after eccentric loading as applied in the present study compared with repetitive low-energy shock wave therapy as applied."	All enrolled had failed local anesthetic injection, steroid injections, NSAIDs, physiotherapy and heel lifts. Data suggest ESWT superior to eccentric exercise, however patients likely had prior exercise providing some potential bias against exercise group.
ESWT vs. No Treatment						

Rompe 2007 RCT	9.0	N = 75 chronic recalcitrant (>6 months) non-insertional Achilles tendinopathy (25 in each group)	ESWT vs. Eccentric Exercises vs. No treatment (ESWT: 2000 shocks at 0.1 J/mm^2, 1 a week for 3 weeks).	No differences between SWT and EE in any outcome measure. Both active treatments superior to wait and see for VISA-A score, Likert score, load induced pain, and pain threshold.	"Both eccentric loading and repetitive low-energy SWT led to a successful outcome in 50% to 60% of patients. This is absolutely within the range of results of surgery."	Data suggest ESWT and eccentric exercises effective compared to no treatment.

Evidence for the Use of Iontophoresis for Achilles Tendinopathy
There is 1 moderate-quality RCT incorporated into this analysis.

Author/Year Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments
Neeter 2003 RCT	6.0	N = 25 with acute (<3 months) pain from Achilles tendon)	Iontophoresis with dexamethasone 3ml suspension vs. iontophoresis with saline (4 treatments over 2 weeks); 1-year follow-up (volume specified, but not concentration; if dexamethasone suspension 0.4%, dose 12mg).	Performance and pain outcomes measured at 2 and 6 weeks, and 3 and 6 months. No differences between groups on toe-raising test, ROM, morning stiffness at any point. Of 16 measurement points for pain, treatment and control groups differed only at 6 month.	"[T]he experiment group (iontophoresis with dexamethasone) displayed better overall results compared with the control group in terms of less pain during and after physical activity and less pain during normal walking up and down stairs."	Small sample size. Some details sparse. All placed in program including stretching, strengthening making co-intervention a significant consideration. Lack of randomization, allocation, blinding details. Data suggest iontophoresis with steroid may be modestly better.

Evidence for the Use of Low-level Laser Therapy for Achilles Tendinopathy
There is 1 moderate-quality RCT incorporated into this analysis.

Author/Year Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments
Stergioulas 2008 RCT	7.0	N = 52 recreational athletes with chronic Achilles tendinopathy symptoms	Low level laser therapy (LLLT) with eccentric exercises (EE) vs. placebo LLLT with EE; 12 sessions, 8 weeks (60mW/ cm2, total 5.4 J per session.	Mean pain intensity scores LLLT plus EE vs. placebo plus EE (0, 4, 8, 12 weeks): 79.8 vs. 81.8, 53.6 vs. 71.5, 37.3 vs. 62.8, 33.0 vs. 53.0, p <0.001 at all intervals after baseline.	"Low-level laser therapy with the parameters used in this trial seems to be a safe and effective method for more rapid recovery when combined with an EE regimen…using power densities below 100mW/ cm2 seems to be important for obtaining good results."	Withdrawal rate 23% (12/52) although included in ITT. Randomization, allocation unclear. Not clear what amount of effect due to eccentric exercises. Data suggest LLLT may be of modest additive benefit to eccentric exercises.

Evidence for the Use of Glucocorticosteroid Injections

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

Author/Year Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments
Fredberg 2004 RCT	7.5	N = 48 (24 with Achilles tendinopathy; 24 with patellar tendinopathy) with diagnosis confirmed by ultrasound findings	Up to 3 injections of triamcinolone (20mg) injection vs. placebo under ultrasound guidance over 3-week period. Failures in placebo group received	No significant changes in placebo group over 6 months. All received steroids at 6 months. Subjects treated with steroid improved in all measures between 1 and 4 weeks, but outcomes deteriorated by 24 weeks. Those in placebo group which then received steroid had similar outcomes as	"Ultrasonographically guided injection of long acting steroid can normalize the ultrasonographic pathological lesions in the Achilles and patellar tendons, and has a dramatic [short-term] clinical effect but when combined with aggressive rehabilitation with running after a few days,	Study excluded 2/3 of patients referred to study (those without ultrasound findings). High treatment failure rate in all groups, with 25% in Achilles steroid, 50% patellar steroid groups going on to surgery. Data suggest short-term but questionable long-term efficacy.

			steroid protocol.	initially treated steroid group.	many will have relapse of symptoms."	
DaCruz 1988 RCT	4.0	N = 28 with Achilles paratendonitis	One peri-tendinous methyl-prednisolone 40mg injection vs. placebo.	Some evidence of short-term efficacy. Crossover of non-improving placebo group to treatment after 12 weeks. No significant differences between groups in pain scores, tenderness, activity level; 23 appeared to fail to respond to therapy, despite cross over.	"[I]t appears that locally-acting steroids have no role to play. Patients who did respond to treatment had only minimal signs and symptoms when they presented and recovered within six weeks."	Study of 36 tendons in 28 patients. Lack of details for randomization, blinding. Co-interventions with physiotherapy, heel lifts. Twenty-three percent dropout. Study states it is a crossover but details unclear. Data suggest lack of efficacy.

Evidence for the Use of Platelet Rich Plasma

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

Author/Year Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments
de Vos 2010 RCT	9.0	N = 54 patients, aged 18 to 70 years with chronic tendinopathy 2 to 7 cm above the Achilles tendon insertion	Eccentric exercises (usual care) with either a PRP injection (PRP group) vs. saline injection (placebo group). Randomization was stratified by activity level.	Mean VISA-A score improved after 24 weeks in the PRP group by 21.7 points (95% confidence interval [CI], 13.0-30.5) and in the placebo group by 20.5 points (95% CI, 11.6-29.4).	"Among patients with chronic Achilles tendinopathy who were treated with eccentric exercises, a PRP injection compared with a saline injection did not result in greater improvement in pain and activity."	Data suggest lack of efficacy.

Evidence for the Use of Glycosaminoglycan Injections

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

Author/Year Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments

Sundqvist 1987 RCT	6.0	N = 60 recreational athletes suffering from Achilles peri-tendinitis	Local injection glycosaminoglycan polysulfate (GAGPS) vs. indomethacin 50mg 3 times a week for 2 weeks.	No difference in percentage with good response ratings in acute patients. Significant differences in chronic patients with GAGPS vs. indomethacin (59% vs. 12%, p <0.05).	"Local injections of GAGPS were shown to be more effective than high-dose indomethacin especially in chronic cases."	Allocation, blinding details unclear. Sixty-six percent of participants had co-intervention of orthotic. Data suggest benefit in chronic conditions over indomethacin. No placebo.

Evidence for the Use of Heparin Injections

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

Author/Year Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments
Larsen 1987 RCT	6.5	N = 20 young males with acute calcaneal peritendinitis crepitans	Physical work plus heparin (5,000 IU) injection once daily for 5 days vs. physical work plus saline injections for acute Achilles calcaneal (insertional) pain.	During 1st week, total symptom score dropped 32% in heparin group and 34% in placebo from baseline. No difference between groups on outcomes measures over 2 week follow-up.	"The present study showed no certain effect of subcutaneous injections of heparin on the course of calcaneal peritendinitis."	Small sample size, blinding details unclear. Data suggest not effective.

Evidence for the Use of Actovegin Injections

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

Author/Year Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments
Pförringer 1994 RCT	6.5	N = 60 with Achilles paratendinitis	Actovegin (5ml solution of deproteinized hemodialys	Competitive and recreational "athletes" who had achillodynia no more than 3 months. Mean Achilles diameter reduction from 13.5mm	"Injection therapy with Actovegin ensures a high therapeutic	Conclusions state treatment effective for chronic pain, but cases

			ate from calf-blood) vs. placebo injections into paratendon (3 injection series at days 1, 3-4, 9-10).	to 9.8mm (active treatment), 27.2±10.4% reduction. Mean diameter decrease with placebo from 14.2 to 12.9mm, a decrease of 9.3±7.5%, p <0.0001. Severe and moderate pain provoked by stress while standing on tiptoes in 43.3% at baseline decreased to 0% in active drug group vs. 26.7% in placebo group.	success, both for acute and chronic Achilles paratendinitis. Due to the excellent low rate of side effects, a very favorable benefit/risk ratio is confirmed."	over 3 months were excluded. Treatment is not FDA approved.

Evidence for the Use of Polidocanol Injections

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

Author/Year Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments
Prolotherapy vs. Placebo Injections						
Yelland 2010 RCT	6.5	N = 43 with painful mid-portion Achilles tendinosis	Eccentric loading exercises (ELE) 12-week program (n = 15) vs. prolotherapy injections of hypertonic glucose with lignocaine alongside affected tendon (n = 14) vs. combined treatment (n = 14).	Mean (95% CI) increases in VISA-A scores at 12 months were 23.7 (15.6 to 31.9) for ELE, 27.5 (12.8 to 42.2) for prolotherapy and 41.1 (29.3 to 52.9) for combined treatment. At 6 weeks and 12 months, increases were significantly less for ELE than for combined treatment.	"For Achilles tendinosis, prolotherapy and particularly ELE combined with prolotherapy give more rapid improvements in symptoms than ELE alone but long-term VISA-A scores are similar."	Small sample sizes. No placebo. Baseline differences in pain duration (21 vs. 24 vs. 6 months). Some data suggest earlier improvement with prolotherapy or combined groups but nearly all data suggest no long-term differences.
Alfredson 2005 RCT	6.0	N = 20 with chronic painful mid-	Sclerosing injection (polidocanol) vs. lidocaine w/epi injection	Mean VAS scores during activity decreased 77±10 to	"Sclerosing injections with the substance Polidocanol, but not non-	Baseline comparison data sparse and higher pain scores in active

		portion Achilles tendinopathy	into neovascularization in chronic AT.	41±10 (p <0.005) vs. placebo 66±6 to 64±6, (p = 0.878) after 1 injection; 5 of 10 intervention group not satisfied after 1 injection; administered 2nd, all satisfied. All of placebo group crossed over after treatment failure; 90% satisfied after 1 injection (VAS 64±6 to 16±4, p <0.005). Outcome-observation period 3 months (range 6-20 weeks).	sclerosing injections with Lidocaine plus adrenaline, targeting the area with neo-vascularization of the Achilles tendon, led to significantly reduced pain during tendon-loading activity. Clinical improvement corresponded with elimination of the colour Doppler appearance of neo-vascularization ."	treatment group at baseline. Small sample size. Data suggest efficacy.
High vs. Low Dose Treatment						
Willberg 2008 RCT	9.5	N = 52 Achilles tendons (48 patients with chronic painful midportion Achilles tendinopathy)	Sclerosing injections with polidocanol: 5mg vs. 10mg (6-8 weeks between injections, up to 3 injections before initial evaluation) All had pain during loading of Achilles tendon and "long duration of symptoms": 26-month mean (range 6-72 months) in low-concentration group; 28-month mean (range 2-120 months) in	Mean VAS score improvement: 5mg vs. 10mg: 66±14 to 25±28, p <0.05, 66±21 to 24±31, p <0/05. No difference between groups in VAS improvement, number of treatments, adverse effects.	"We found no differences in the clinical results, number of treatments or volume injected when treating chronic painful midportion Achilles tendinopathy with sclerosing Polidocanol injections."	No placebo-control. Data suggest no differences, suggesting equal (in)efficacy.

			high-concentration.			

Evidence for the Use of Apoprotinin Injections
There is 1 moderate-quality RCT incorporated into this analysis.

Author/Year Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments
Brown 2006 RCT	6.5	N = 26 with Achilles tendinopathy	Apoprotinin (weekly injection x 3 weeks) plus eccentric exercises vs. placebo plus eccentric exercises.	No differences between treatment groups at any follow-up (2, 4, 12, or 52 weeks).	"Apoprotinin did not show any statistically significant benefit over placebo."	Thirty-three tendons in 26 patients. Allowed other conservative treatments to ensure enrollment (NSAIDs, heel pads, etc). Data suggest lack of efficacy.

Evidence for the Use of Non-operative and Surgical Repair for Achilles Tendon Rupture
There are 7 moderate-quality RCTs (one with two reports) incorporated into this analysis. There is 1 low-quality RCT in Appendix 2.

Author/Year Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments
Non-operative Functional Brace vs. Rigid Immobilization						
Saleh 1992 RCT	4.0	N = 40 with acute complete rupture of calcaneal tendon	Rigid cast (8 weeks) vs. functional splint (cast x 3 weeks, then splint x 6-8 weeks Sheffield splint).	Splint vs. cast (3, 6, 12 months): no differences in plantar strength or range of flexion at any period. Dorsiflexion ROM: 7.9 vs. 1.4, 13.2 vs. 3.8, 13.6 vs. 8.6 (all periods p <0.001) favor splint. Time to walk comfortably outdoors (cast vs. splint): 11 weeks vs. 6 weeks (p <0.001); time to walk comfortably indoors 15 weeks vs. 9 weeks (p	"Recovery of ankle dorsiflexion is quicker, without overstretching, and return to normal activities is more rapid. It was more popular with patients than a plaster cast. The risk of re-rupture did not appear to be increased."	No placebo or sham control. Lack of randomization, allocation, baseline comparability details. Lack of observer blinding. Data suggest functional splint superior assessed by patient preference, increased dorsiflexion range of motion. No difference in number that returned to sports.

				<0.001); 1 re-rupture in each group.		
Achilles Rupture Surgery vs. Non-operative Care						
Metz 2007, 2008 RCT	7.5	N = 83 acute Achilles tendon ruptures	Percutaneous surgery vs. non-operative treatment with immediate full weight bearing.	Mean days for return to work: nonoperative: 108, surgery: 58. Difference of 49 days, 95% CI, 4-94, p <0.05.	"Minimally invasive surgical treatment of acute AT rupture appears to have a lower risk of complications than does nonoperative treatment using functional bracing, although this difference is not statistically significant."	No blinding of assessor. Data suggest advantage in return-to-work time for surgery, although both groups able to bear weight after 1 week. Study not done in U.S.
Möller 2001 RCT	7.5	N = 112 with acute, complete rupture of Achillis tendon	Plaster immobilization (equinus position neutral for 4 weeks) vs. end-to-end surgical repair with functional orthosis (ROM-Walker brace, 2 weeks equinus cast, 2 weeks 30° equinus brace, 2 weeks 10° equinus, 2	Re-rupture after non-surgical treatment in 11 patients (20.8%), only 1 patient in surgical group (1.7%) (p = 0.0013). VAS quality of life scores favored surgical group for all follow up. VAS treatment results: 8 weeks – surgical: 89.2 (SD 10.3); non surgical: 74.9 (SD 19.1) (p <0.0001); 2	"…surgical treatment followed by early functional rehabilitation is a safe and reliable method of treatment. Conservative management resulted in failure in every fifth patient, and cannot be regarded as acceptable in healthy, active	First report of study population (see Möller 2002). Data suggest surgery particularly helpful for return to work in light jobs (35.7 days vs. 67.2 days), with no differences between heavy work (102.2 vs. 108.1 days) or sedentary jobs

			weeks 10° dorsiflexion).	years surgical group: 88.7 (SD 9.0); non surgical group: 70.3 (SD 20.1) (p = 0.0001).	patients under the age of 65."	(30.8 vs. 33.2 days).
Möller Scand J Med Sci Sports 2002 RCT	7.5	N = 112 with Achilles tendon rupture	Plaster immobilization (equinus position 4 weeks, neutral 4 weeks) vs. end-to-end surgical repair with functional orthosis (ROM-Walker brace, 2 weeks equinus cast, 2 weeks 30° equinus brace, 2 weeks 10° equinus, 2 weeks 10° dorsiflexion).	Re-rupture rates: non-surgical 11/53 (20.8%) vs. 1/59 surgical group (1.7%) p = 0.0013). Plantar flexion: no differences between groups in concentric muscle strength at 6 months, 1 and 5 years; dorsiflexion: no differences; endurance: no difference.	"If re-ruptures are avoided, surgical treatment followed by early functional rehabilitation and non-surgical treatment with a plaster for ATR appear to produce equally good results."	Study represents 2nd report on same population. No baseline comparison data provided. No blinding. Both groups had significant functional deficits compared to non-injured leg after 2 years.
Möller Knee Surg, Sports Traumatol 2002 RCT	6.0	N = 58 closed injury of tendon substance with injury no older than 7 days	Surgery (end-to-end suture) vs. progressive casting: healing evaluated by MRI and ultrasound.	No statistically significant differences between treatment groups in terms of positive healing findings on ultrasound or MRI at 6 or 12 months.	"Ultrasound (evaluation) performed during the healing after ATR detected no significant difference in the number of positive findings between the treatment groups. MRI findings after 1 year were well correlated	Intent of study was to describe healing process in terms of ultrasound and MRI studies. Baseline comparability unclear. Findings suggest no advantage to either protocol based on MRI or ultrasound

					with [ultrasound] findings, but no significant correlation was found between clinical parameters and the number of positive radiological findings."	(tendon thickness, tendon glide function, tendon defects).
Twaddle 2007 RCT	6.0	N = 50 acute ruptures of Achilles tendon	Surgery vs. non surgical intervention, both with controlled early motion (10 days cast than orthosis for both groups).	No significant differences in any outcome measures (musculoskeletal functional assessment instrument, dorsiflexion, plantar flexion, calf circumference, reruptures, complications) at measured follow-up at 8 weeks, 12 weeks, 24 weeks or 52 weeks.	"…there was no difference in any of the measured parameters for operatively and nonoperatively treated patients as long as both groups received early, controlled motion as part of their rehabilitation."	Randomization by coin toss. No blinding. Early motion orthosis did not include weight bearing until 6 weeks.
Cetti 1993 RCT	5.5	N = 111 acute ruptures of Achilles tendon	Surgery (end to end suture) + vs. progressive casting (casting 20° equinus for 6 weeks vs. 20° equinus, no weight bearing 4 weeks, neutral cast with 1-cm heel raise 4 weeks, heel raise alone 2 weeks).	Mean sick time (off work) for surgery group 6.2 weeks vs. 8.0 weeks (conservative) (p = NS). Complication rates not different. Rupture rates not significant (5% vs. 15%). Differences in ankle movement/calf atrophy favored surgical group at 12 months;	"Operative treatment using end to end suture of acute Achilles tendon rupture results in a higher resumption of sports activities at the same level as before the rupture. Major complications were equal in both groups. Operative treatment	Study appears to have excluded dropouts and noncompliant subjects as 156 were enrolled. Surgical technique varied. Data suggest benefit from surgery limited to faster return to sport.

				57.1% surgical group vs. 29.1% returned to level of sports at same level (p <0.05).	using end-to-end suture is preferable, while non-operative treatment is an acceptable alternative."	

Evidence for the Use of Surgical Technique for Achilles Tendon Rupture
There are 5 moderate-quality RCTs or quasi-randomized controlled trials incorporated into this analysis.

Author/Year Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments
Achilles Rupture Surgical Technique						
Pajala 2009 RCT	6.5	N = 60 acute Achilles tendon ruptures	End-to-end suture with and without augmentation (gastrocnemius fascia flap).	Twelve month follow-up: No differences in pain, stiffness, calf muscle weakness, ROM, or subjective satisfaction. Both groups 3 re-ruptures.	"...the augmented repair in cases of fresh complete Achilles tendon rupture does not have any advantage over simple end-to-end repair."	No assessor blinding noted. Data suggest no benefit to augmentation for acute rupture repair.
Gigante 2008 RCT	5.0	N = 40 acute Achilles tendon ruptures	Open vs. percutaneous repair of Achilles rupture.	Operating room time: 47 vs. 24 minutes for percutaneous repair (p <0.01). No differences in calf circumference or ankle ROM. Ankle circumference at 12 months open repair: 24.5 cm (SD 1.5) vs. percutaneous repair: 25.8 (SD 1.1) (p <0.01).	"...both the open and percutaneous technique are safe and effective in repairing the ruptured Achilles tendon, and that both afford nearly total restoration of clinical, US (ultrasound) and isokinetic patterns with the same rehabilitation protocol, despite slight differences in the duration of immobilization."	Allocation unclear. No baseline characteristics provided. Differences in immobilization duration. Casting 30 days open surgical group vs. 15 days for percutaneous. Data suggest comparable results.
Mortensen 1992 RCT	5.0	N = 57 acute Achilles tendon	Mason suture technique vs. continuous	No cases of infection or re-rupture in either group. No difference in metal	"[W]e did not find any clinical advantage in using a stronger and more extensive	No baseline comparison data. No blinding. Both groups had

		ruptures	6 strand suture technique.	marker separations of plantar repaired ends or planter flexion strength measured in 3 ankle positions between both groups found.	suture technique. Consequently, we recommend a simple suture technique."	cast immobilization post-op for 7 weeks. Data suggest comparable efficacy.
Lim 2001 Quasi-RCT	4.5	N = 66 ruptured Achilles tendons	Percutaneous vs. open repair (both groups receiving postoperative casting for mean of 12.6 weeks).	No differences in recovery duration to return activities of daily living, functional activity, sports at 8, 13, 26 weeks follow-up; 21% of open repairs had infection vs. 0% with percutaneous repair (p <0.05), No difference in re-ruptures (6% vs. 3%).	"…no difference in the numbers of re-ruptures between open and percutaneous groups, and the rate of injury to the sural nerve occurring during the repair is low, but nevertheless present."	Randomization based on medical record number (odd/even). No baseline comparison data presented. Sparse details. Data suggest comparable results.
Aktas 2007 RCT	4.0	N = 105 acute Achilles tendon ruptures	Single end-to-end with and without augmentation (use of plantaris tendon).	AOFAS hindfoot clinical outcome scores were 96.7 in Group 1 and 98.8 in Group 2. Return to preinjury level of sport activity: 58% Group 1 vs. 89% Group 2.	"Although functional outcomes of both treatment groups were the same, the end-to-end suturing technique provided a safer and more reliable treatment with a low risk of complications in the treatment of acute Achilles' tendon ruptures compared with the plantaris tendon augmentation technique."	Allocation and baseline results unclear. No blinding of assessment.

Evidence for the Use of Postoperative Management for Achilles Tendon Rupture

There are 2 high- and 7 moderate-quality RCTs incorporated into this analysis.

Author/Year Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments

Costa 2006 RCT	8.0	N = 96 Achilles tendon ruptures	Trial 1: early weight bearing vs. non-weight bearing in 48 operative patients. Trial 2: early weight bearing vs. non-weight bearing in 48 non-operative patients.	Trial 1: return to normal walking; treatment group: 22 weeks, control group: 25 weeks (p = 0.027). Return to normal stair climbing; treatment group: 22 weeks, control: 24 weeks (p = 0.023). Trial 2: return to normal walking (p = 0.765), climbing stairs (p = 0.484), return to sport (p = 0.631), quality of life (p = NS).	The study "[A]dvocates immediate weight-bearing mobilisation for the rehabilitation of all patients with rupture of the tendon Achilles."	Randomization, allocation, baseline comparability data not reported. Small sample with high dropout although intention to treat analysis reported. 2 trials in article. Two cases of rerupture in the 2 operative weight-bearing groups. Data suggest better results with earlier walking.
Suchak 2008 RCT	8.0	N = 110 Achilles tendon ruptures	Weight bearing vs. non weight bearing 2 weeks after surgery (both groups using same functional brace).	Quality of life RAND-36 scores: physical functioning weight bearing: 61.4 SD 29.4). Non weight bearing 47.6 (SD 34.4) (p = 0.03). Social functioning weight bearing: 72.7 (28.5). Non weight bearing: 60.7 (26.8) (p = 0.03). Vitality weight bearing 69.4 (23.7). Non weight bearing 60.6 (21.1) (p = 0.04). Role-emotional weight bearing 84.6 (32.0); on weight bearing 67.3 (43.1) (p = 0.02).	"The postoperative early weight-bearing protocol provided enhanced quality of life and activity level without an increase in complications in the early postoperative period."	Surgical repair techniques not uniform. Compliance quantified with sensors in orthotic brace. Results based on questionnaire rather than objective functional outcomes. Data suggest earlier return to weight bearing superior.
Kangas 2007 RCT	7.0	N = 50 acute Achilles tendon ruptures	Functional brace (braced neutral and plantar flexion) vs. cast immobilization post-surgical repair.	Elongation of AT occurred to lesser extent in early motion group rather than cast group (p = 0.054) at mean 60 weeks. AT elongation correlated significantly with clinical outcome (ρ = -.42, P = 0.17,	"Achilles tendon elongation was somewhat less in the early motion group and correlated with the clinical outcome scores. We recommend early functional postoperative treatment after	Data suggest less elongation of Achilles tendon after suture repair correlates with better clinical outcome. But does not show early mobilization significantly reduces elongation over

				patients with less AT elongation achieving a better clinical outcome.	Achilles rupture repair."	cast group; likely underpowered to detect a difference.
Kangas 2003 RCT	6.5	N = 50 acute Achilles tendon ruptures	Cast immobilization vs. functional brace and full weight bearing (after 3 weeks) after open repair.	At 3 months, difference in isometric strength deficit 25.2% weight bearing group vs. 24.1% cast group (p = NS). Pain relief, stiffness, subjective calf muscle weakness, footwear restrictions, and ROM not statistically significant over follow-up period.	"The isokinetic calf muscle strength results were somewhat better in the early motion group, whereas the other outcome results obtained in the two groups of patients were very similar. We recommend early functional postoperative treatment after Achilles rupture repair for athletes and well-motivated patients and for less-motivated patients and nonathletes."	Author conclusions related to differences within same group over time rather than between group deficit comparisons, which were not significant. Three reruptures; no difference between groups (6%).
Kauranen 2002 RCT	5.5	N = 30 acute Achilles tendon ruptures	Post-op functional treatment vs. early immobilization.	No differences found between groups in reaction time, speed of movement, tapping speed. Lateral coordination value of operated leg higher in plaster cast group than in active brace group 12 weeks after operation; p <0.05.	"It seems that the recovery of the above mentioned motor performance functions of the leg does not depend on whether the leg is in a plaster cast with the AT in tension or in an active brace during the early postoperative period after AT rupture repair."	Data limited to motor testing and motor performance, which may not correlate with functional outcomes of recovery studied by other researchers.
Cetti 1993 RCT	5.5	N = 111 acute Achilles tendon ruptures	Surgery (end to end suture) plus vs. progressive casting (casting 20° equinus for 6 weeks	Mean sick time (off work) for surgery group was 6.2 weeks vs. 8 weeks (conservative) (p = NS). Complication rates not different. Rupture rates were not significant (5% vs. 15%).	"Operative treatment using end to end suture of acute Achilles tendon rupture results in a higher resumption of sports activities at the same level as before the	Study appears to have excluded dropouts and noncompliant subjects as 156 were enrolled. Surgical technique varied. Data suggest benefit

			vs. 20° equinus, no weight bearing 4 weeks, neutral cast with 1-cm heel raise 4 weeks, heel raise alone 2 weeks)	Differences in ankle movement and calf atrophy favored surgical group at 12 months. 57.1% of surgical group vs. 29.1% returned to level of sports at same level (p <0.05).	rupture. Major complications were equal in both groups. Operative treatment using end-to-end suture is preferable, while non-operative treatment is an acceptable alternative."	from surgery limited to faster return to sport.
Cetti 1994 RCT	4.5	N = 60 acute Achilles tendon ruptures	Mobile cast (n = 30) vs. below knee rigid cast (n = 30) after operative repair (4-string suture).	60% of rigid cast patients reported discomfort from cast vs. 30% from mobile cast (p = 0.0037); 77% mobile cast found it "excellent," 20% rigid cast thought same (p <0.00005). Mean sick leave days: 53.4 rigid cast; 20.2 mobile cast (p = 0.0009). No difference in gait, ability to stand on toes at 12 months. Ankle mobility rated better in mobile cast group at 6 and 12 months (p <0.05).	"Operative treatment with a 4-string suture and use of a postoperative mobile cast proved safe and convenient and preferable to treatment with the traditional rigid below-knee cast."	Allocation and baseline results unclear. Reported results favor early mobilization after suture repair.
Mortensen 1999 RCT	4.5	N = 71 acute Achilles tendon ruptures	Cast x 2 weeks plus 6 weeks modifiable brace vs. equinus position cast x 6 weeks plus 2 weeks neutral cast (both groups after open repair).	Early motion vs. cast 16 months after operative treatment: sick leave in Days 43 (1-103)/68 (2-285); p <0.05, number of patients who returned to sports 22 (73%)/ 22 (76%); p = 1.00, months until sports resumed 4 (2-13)/7.5 (3-22); p <0.001, number who reached pre-injury level 17 (57%)/16 (55%); p = 1, months until preinjury level	"Early restricted motion appears to shorten the time needed for rehabilitation. There were no complications related to early motion in these patients. However, early unloaded exercises did not prevent muscle atrophy."	Allocation, baseline comparability unclear. No observer blinding. Timing of assessment may not have been same. Study suggests early motion advantageous in immediate post-op period, but results same by 16 month average follow-up (mean 16 months, 12-24

				reached 6 (2.5-13)/9 (6-14); p <0.001.		month range). Therefore, duration of differences unclear.
Costa 2003 RCT	4.0	N = 28 unilateral ruptures of Achilles tendon	Functional brace (immediate weight bearing) vs. progressive casting for 8 weeks following open end-to-end operative repair.	Time to return to sports (months): early loading: 6.0 (2.0 IQR) Cast: 8.0 (8.0 IQR). (-5.0, 3.5 95% CI for median difference). Flexion deficit degrees: Early loading plantar: 5.0 (3.5 IQR) Dorsal: -5.0 (4.25 IQR). Cast plantar: 5.0 (5.0 IQR) Dorsal 0.0 (0.0 IQR). (95% CI for median difference plantar: -10,0 dorsal: 0, 14) Peak torque deficit (% at 12 months); Early loading concentric: 13.5 (50.8 IQR) Eccentric: -1.5 (27.8 IQR). Cast concentric: 29.0 (23.5 IQR) Eccentric: 41.0 (26.0). (95% CI for median difference concentric: -56, 53 Eccentric -30, 45)	"(I)mmediate controlled weight-bearing mobilisation after Achilles repair is safe and may produce functional benefits for the patient."	Randomization, allocation, baseline comparability data not reported. Small sample with high dropout although intention to treat analysis reported. Data suggest shorter duration of functional deficits with earlier weight bearing.

Evidence for the Use of DVT Prophylaxis for Achilles Tendon Rupture Repair

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

Author/Year Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments
Lapidus 2007 RCT	10.0	N = 105 with Achilles	Low molecular weight heparin	Patients underwent modified Kessler end-to-	"Our study showed that DVT is common during immobilization after Achilles tendon rupture	Allocation method unclear. Diagnosis made with ultrasound

		tendon rupture	(5,000 u) vs. saline placebo for post-op DVT prophylaxis	end suture repair with casting. Incidence of DVT 34% LMWH group, 36% in placebo (p = 0.8). No difference in proximal DVT between groups.	surgery, and therefore effective thromboprophylaxis is desirable. [T]he daily administration of 5000 U of (low molecular weight heparin) did not affect the incidence of DVT."	with majority being asymptomatic. Thus, clinical significance of these findings unclear.
Lassen 2002 RCT	9.0	N = 440 ≥18 years or older undergoing elective hip replacement surgery	Low molecular weight heparin (5000 u) vs. saline placebo for post-surgical DVT prophylaxis.	Reviparin vs. placebo; Thrombosis- 17/189 (9%) vs. 35/188 (19%), OR 0.45 (0.24-0.82). Achilles tendon specific - 3/48 (6%) vs. 6/28 (21%), OR 0.24 (0.27-1.03). Bleeding events (14 vs. 12), major bleeding (2 vs. 1).	"[R]outine use of reviparin for prophylaxis against thrombosis during the period of leg immobilization after fracture of the leg or rupture of the Achilles tendon is beneficial. However, further evaluation is warranted before such treatment can be recommended for routine use."	Study included lower limb fractures and Achilles rupture patients with bracing and casting mean 7-8 weeks. Intent to treat based on 371 patients. Baseline between group differences in smoking rate. DVT diagnosis made on findings of venography. Data suggest fewer DVTs with treatment.

Evidence for the Use of NSAIDs for Compartment Tenosynovitis
There are no quality studies evaluating the use of NSAIDs for compartment tenosynovitis.

Evidence for the Use of Education for Plantar Fasciitis
There are no quality trials incorporated into this analysis.

Evidence for the Use of Infliximab for Plantar Fasciitis
There are no quality trials incorporated into this analysis.

Evidence for the Use of Opioids for Plantar Fasciitis
There are no quality trials incorporated into this analysis.

Evidence for the Use of Systemic Glucocorticosteroids for Plantar Heel Pain
There are no quality trials incorporated into this analysis.

Evidence for the Use of Vitamins for Plantar Fasciitis
There are no quality trials incorporated into this analysis.

Evidence for the Use of Lidocaine Patch for Plantar Fasciitis
There are no quality trials incorporated into this analysis.

Evidence for the Use of Topical NSAIDs for Plantar Fasciitis
There are no quality trials incorporated into this analysis.

Evidence for the Use of Wheat Grass Cream for Plantar Fasciitis
There is 1 high-quality RCT incorporated into this analysis.

Author/Year Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments
Wheatgrass Cream vs. Placebo						
Young 2006 RCT	8.5	N = 80 with chronic plantar fasciitis	Wheatgrass cream vs. placebo cream.	VAS 1st-step pain improved from baseline to 6 weeks (wheatgrass p = 0.013; placebo p = 0.017), but NS between groups. Improvements continued to 12 weeks (wheatgrass p = 0.003; placebo p = 0.017). No changes in calf muscle strength and ankle dorsiflexion ROM.	"The topical application of wheatgrass cream is no more effective than a placebo cream for the treatment of chronic plantar fasciitis."	Data suggest lack of efficacy.

Evidence for the Use of Magnets for Plantar Heel Pain
There are 2 high-quality RCTs incorporated into this analysis. There is 1 low-quality RCT in Appendix 2.

Author/Year Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments
Winemiller 2005 RCT	9.5	N = 89 health care employees with non-specific feet pain for at least 30 days	Magnetic vs. sham-magnetic cushioned insoles for 8 weeks.	"All better" or "mostly better" at 4 8 weeks sham-magnetic vs. magnetic group: 33% vs. 32%; p = 0.98/ 33% vs. 32%; p = 0.86.	"This study provides convincing evidence that use of static magnets for a total of 8 weeks was not effective in relieving symptoms of nonspecific foot pain in the workplace."	Heterogeneous inclusion criteria. Non-specific diagnoses. No control for co-interventions. Data suggest lack of efficacy.

Winemiller 2003 RCT	9.0	N = 101 adults with diagnoses of plantar heel pain for at least 30 days	Magnetic vs. sham-magnetic cushioned insoles for non-specific foot pain for 8 weeks.	"All better" or "mostly better" at 8 weeks sham-magnetic vs. magnetic group: 33% vs. 35%; p = 0.78; VAS 4, 8 weeks (placebo vs. magnets) 4.2 vs. 4.4 p = 0.63, 3.9 vs. 3.9 p = 0.94.	"Static bipolar magnets embedded in cushioned shoe insoles do not provide additional benefit for subjective plantar heel pain reduction when compared to nonmagnetic insoles."	Randomization by drawing insoles from box. Acute pain included in study. Baseline differences in pain characteristics biased positively toward magnetic group. Data suggest lack of efficacy.

Evidence for the Use of Casting for Plantar Fasciitis
There are no quality trials evaluating the use of casting for plantar fasciitis.

Evidence for the Use of Night Splints for Plantar Heel Pain
There are 4 moderate-quality RCTs incorporated into this analysis. There is 1 low-quality RCT in Appendix 1.

Author/Year Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments
Batt 1996 RCT	5.0	N = 40 with plantar fasciitis	Standard treatment of anti-inflammatory medication, Viscoheel sofspot heel cushion, and stretching program for gastrocnemius and soleus muscles vs. Tension Night Splint.	Healed: Control 6/17 (35.3%) vs. TNS 16/ 16 (100%). After crossover, 8 of 11 (72.7%) controls asymptomatic after average 13 weeks.	"When used in combination with a visco-elastic heel pad, stretching program and nonsteroidal anti-inflammatory drugs, the TNS is an effective treatment of plantar fasciitis."	No blinding. Symptom chronicity not provided. Cure rates reported may indicate acute condition as no other studies have reported such efficacy of intervention.
Probe 1999 RCT	5.0	N = 116 with plantar fasciitis	Night splints vs. no splints in groups that received 1 month NSAIDs, Achilles stretching exercises, and shoe recommendations for 3 months.	At 19 months follow-up, 84% experienced improvement of symptoms. No statistical differences between treatment groups (p =	"No statistically significant improvement was seen to a standard nonoperative protocol with the addition of night splinting in this group of patients with	Lack of study details. No additional benefit of using commercial splints in study over other conservative measures (NSAID, Achilles

				0.95). Improvement rate, defined as decrease of 1 pain grade on 4-point scale in Group 1 was 66% and in Group 2 71% (p = 0.69).	symptoms of less than 12 months duration."	stretching). Study suggests lack of efficacy of night splints.
Powell 1998 RCT	4.5	N = 37 with chronic plantar fasciitis	Group A: splints for 1st month; Group B: for 2nd month. No splints used in either group for final 4 months of study.	Mayo Clinical Scoring System – significant differences found between Groups A and B (p = 0.0001) and between periods (p <0.0001 at 0, 1, 2, and 6 month follow-up visits).	"We demonstrated that dorsiflexion night splints can be an effective treatment in patients with recalcitrant plantar fasciitis."	Classified as cross-over but appears not true cross-over design, rather treatment delayed for 1-month in control group. Not blinded. Baseline differences. No washout for previous treatments.
Roos 2006 RCT	4.5	N = 43 with plantar fasciitis	Foot orthoses vs. orthoses plus night splints vs. night splints only.	All groups improved significantly in all 5 FAOS subscales across all times (p <0.04). No significant differences in pain among 3 groups at any time.	"Foot orthoses and anterior night splints were effective both short-term and long-term in treating pain from plantar fasciitis."	No baseline data presented; no blinding. Lack of details on co-interventions, compliance. No statistical differences in interventions. Study likely underpowered.

Evidence for the Use of Orthoses for Plantar Fasciitis

There is 1 high- and 7 moderate-quality RCTs incorporated into this analysis. There are 6 low-quality RCTs or crossover trials in Appendix 2.(208, 215, 217, 223, 225, 226) (Martin 01; Caselli 97; Kavros 05, Mejjad 04; Fauno 93; Lynch 98)

Author/Year Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments
Orthotics vs. Sham/No Treatment						
Landorf 2006	8.5	N = 136 with	Prefabricated orthoses vs. customized	ANCOVA adjusted differences	"Foot orthoses produce small short-term	Inclusion criteria for pain duration was at

RCT		plantar fasciitis	orthoses vs. sham orthoses. All had plaster molds of their feet. Sham orthosis fabricated "by molding a 6-mm, soft (120 kg/m^3) ethyl vinyl acetate foam over an unmolded cast of the foot…. [in such a way as] to provide minimal structural support for foot. Prefabricated orthosis was 3/4 length, retail mold made from firm-density polyethylene foam sufficiently thick to fill the arch area and prevent the orthosis from flattening." Custom orthotic made in commercial lab of semirigid polypropylene, had firm foam heel post "designed to provide significant support for the foot and influence the position of the foot relative to the leg."	between mean of Foot Health Status Questionnaire (95% CI); PF vs. sham, custom vs. sham, PF vs. custom. Pain 3-months: 8.7 (-0.1 to 17.6), 7.4 (-1.4 to 16.2), 1.3 (-7.6 to 10.2); Pain 12 months: 2.2 (-5.6 to 10.0), -0.1 (-7.8 to 7.7), 2.3 (-5.6 to 10.1); Function 3 months: 8.4 (1.0 to 15.8), 7.5(0.3 to 14.7), 0.9 (-6.3 to 8.1); Function 12 months: 5.5(-2.0 to 13.0), 4.3(-3.0 to 11.6), 1.2(-6.1 to 8.5)	benefits in function and may also produce small reductions in pain for people with plantar fasciitis, but they do not have long-term beneficial effects compared with a sham device. The customized and prefabricated orthoses... have similar effectiveness..."	least 4 weeks, with mean of 12 months. Data suggest modest function at 3 months over placebo but no differences in pain.
Orthoses: Custom vs. Fabricated						
Pfeffer 1999 RCT	6.5	N = 236 with proximal plantar fasciitis	Silicone heel pad vs. felt insert vs. rubber heel cap vs. custom-made "neutral" orthoses vs. no orthoses. All received AF and PF stretching exercises. Trial at 15 orthopedic foot/ankle centers; personnel at each center underwent	Percentages improved in each group: 1) silicone insert, 95%; 2) rubber insert, 88%; 3) felt insert, 81%; 4) stretching only, 72%; 5) custom orthosis, 68%. Multivariate analysis of mean pain score	"We conclude that, when used in conjunction with a stretching program, a prefabricated shoe insert is more likely to produce improvement in symptoms as part of the initial	Lack of blinding. Data suggest added benefit from orthosis plus stretching program, but percentages of improvement are of uncertain clinical significance as

			instructional video on obtaining molds; orthoses made at single production facility of 1/4 or 3/16 inch [6 to 9 mm] polypropylene.	changes showed all groups with significant improvement, no significant differences between groups.	treatment of proximal plantar fasciitis than a custom polypropylene orthotic device."	benefit response included the broad category of "all, much, or slightly better." No differences in mean pain scores.
Baldassin 2009 RCT	7.0	N = 142 adults (75% female) with plantar fasciitis, without anatomical alterations in feet	Prefabricated vs. custom foot orthoses for 8 weeks. Both prefabricated and custom orthoses made of ethylene vinyl acetate.	Significant improvement both groups for modified FFI, no difference between them, p <0.05. Cointerventions used 67% of the time, 40% performed stretching for Achilles tendon and 28% used other cointerventions.	"The low-cost prefabricated and customized foot orthoses, as used in this trial, had similar effectiveness in the treatment of noncomplicated plantar fasciitis after 8 weeks of use."	High dropout (~40%). No compliance data provided. Data suggest no differences in pain relief between prefabricated and custom EVA inserts.
Kelly 1998 RCT	5.0	N = 48 with primary lesser meta-tarsalgia	Bauerfiend Viscoped orthoses (group 1) vs. Langer Blueline orthoses (group 2) for 8 weeks for lesser metatarsalgia.	Mean reduction in VAS scores 13.6±23.3 for Group 1; 15.4±16.0 for Group 2. Symptom relief score 22.6±31.1 for Group 1; 40.2±34.7 for Group 2. Mean reduction of peak forefoot pressure 2.1±1.7 kPa in Group 1, 4.4±1.7 kPa in Group 2, p <0.001.	"The use of stock orthoses we feel is only acceptable providing that they are adjusted appropriately to each individual before being used. We continue to use the Langer Blueline insole because it is more efficacious (both subjectively and objectively), more economical, and better tolerated by patients."	Compliance of 40-56%. May not be applicable to heel pain. Data suggest lack of efficacy.
Orthotics vs. Other Therapies						
Chalmers 2000	7.5	N = 28 with rheumat	Supportive shoes worn alone vs. supportive shoes	Mean pain scores: final adjusted for baseline	"[Semi-rigid foot orthoses worn in supportive	Data suggest no differences

RCT		oid arthritis referred to therapy	worn with soft orthoses vs. supportive shoes worn with semi-rigid orthoses.	(mean±SD): Subortholen (2.88±0.44) vs. plastazote (4.27±0.45) vs. shoes (4.79±0.44), p = 0.006. Compared across treatments, change in pain for subortholen significantly different from change for plastazote and shoes alone, p = 0.027. No interventions had a significant effect on MTP joint synovitis or lower extremity function. No significant correlation between pain amount and amount of time intervention was worn.	shoes were shown to be an effective treatment for metatarsalgia secondary to RA…Soft orthoses did not provide significant pain relief and had limited durability. However, they may be clinically useful for clients who cannot tolerate more rigid materials."	in patient preference.
Pfeffer 1999 RCT	6.5	N = 236 with proximal plantar fasciitis	Silicone heel pad vs. felt insert vs. rubber heel cap vs. custom orthoses vs. no orthoses. All groups received AF and PF stretching exercises.	The percentages improved in each group were: 1) silicone insert, 95%; 2) rubber insert, 88%; 3) felt insert, 81%; 4) stretching only, 72%; and 5) custom orthosis, 68%. Multivariate analysis of mean pain score changes showed all groups with significant improvement, no significant differences between groups.	"We conclude that, when used in conjunction with a stretching program, a prefabricated shoe insert is more likely to produce improvement in symptoms as part of the initial treatment of proximal plantar fasciitis than a custom polypropylene orthotic device."	Lack of blinding. Data suggest added benefit from orthosis plus stretching program. Percentages of improvement are of uncertain clinical significance as benefit response included broad category of "all, much, or slightly better." No differences in mean pain scores.

Roos 2006 RCT	4.5	N = 43 with plantar fasciitis	Foot orthoses vs. orthoses plus night splints vs. night splints only.	All groups improved significantly in all 5 FAOS subscales across all times (p <0.04). No significant differences found in pain among 3 groups at any time.	"Foot orthoses and anterior night splints were effective both short-term and long-term in treating pain from plantar fasciitis."	No baseline data. No blinding. Lack of details on co-interventions, compliance. Study likely underpowered. No statistical differences in interventions.
Stratton 2009 RCT	4.5	N = 26 with plantar fasciitis symptoms ranging 1 week to 5 months	Low frequency electrical stimulation with orthoses and stretching vs. orthoses and stretching.	No intergroup differences in VAS, Activities of Daily Living Subscale of FAAM 4 weeks and 3 months after treatments. Both treatment arms showed statistically significant improvements compared to baseline.	"…the efficacy of using low-frequency electrical stimulation in the management of patients with plantar fasciitis is questionable."	Study included those with symptoms ranging 1 week to 6 months. Inclusion criteria required athletic activity 5 times a week for >90 minutes limiting general applicability. Randomization and allocation details sparse. Data suggest no added benefit from low frequency electrical stimulation.
Orthotics for Prevention						
Esterman 2005 RCT	4.0	N = 47 Royal Australian Air Force recruits with flexible flat feet embarking on 10-week basic training course	Orthotics vs. no orthotics for prevention in asymptomatic group.	Results not significant different but those with the orthotics had the least limb pain, the lowest rate of injuries, the best general foot health, and the best quality of life.	"The results of this pilot randomized controlled trial provide some tentative evidence that orthotics may improve lower limb pain and general foot health and decrease injury rates among military recruits with flexible flat feet."	Pilot study. Study performed on military recruits in basic training who were deemed to have "flat" feet. No blinding. Data suggest orthotics may have preventive benefit.

Evidence for the Use of Shock Absorbing Shoes for Plantar Fasciitis
There are 2 moderate-quality RCTs incorporated in this analysis. There is 1 low-quality RCT in Appendix 2.(229) (Fransen 97)

Author/Year Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments
Torkki 2002 RCT	6.5	N = 176 lower-limb overuse injuries	Individually adjusted footwear with good shock absorbing properties vs. subjects' own used footwear (control).	No differences between groups at 3 or 12 months follow-up for lower-limb pain intensity, number of painful days, or ability to work.	"[I]ndividually fitted shock-absorbing shoes seem to offer only rather small health benefits to subjects exposed to daily walking and having lower-limb overuse injuries."	Study of newspaper carriers in Finland. Study of lower limb "overuse injury." No control for other treatments. No analysis by disorder. Those in intervention expected improvement from treatment introducing potential bias for results (67% vs. 18%, p <0.001).
Milgrom 1992 RCT	4.0	N = 390 healthy recruits	Basketball shoes vs. marching boots and incidence of "overuse" injuries.	Basketball shoes vs. boots (14 weeks cumulative injuries); Femoral stress fracture (Fx) p = NS, tibial stress Fx p = NS, Metatarsal stress Fx 0 vs. 3.4% p = 0.03. Knee pain = NS, Achilles tendon pain = NS; foot problems 15.5% vs. 29.1 % p = 0.001.	"[M]odified basketball shoes in this study were not effective in lowering overall incidence of overuse injuries in the recruit population. The effect was limited to overuse injuries resulting from vertical impact loads."	Randomization, allocation unclear. No blinding. Study in military population. Data suggest basketball shoes (presumably with greater shock absorption) are superior to marching boots for prevention of foot overuse injuries.

Evidence for the Use of Stretching Exercises for Plantar Fasciitis
There are 4 moderate-quality RCTs (one with two reports) incorporated into this analysis.

Author/Year Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments

Pfeffer 1999 RCT	6.5	N = 236 with proximal plantar fasciitis	Silicone insert vs. rubber insert vs. felt insert vs. vs. custom orthosis vs. stretching only. Each group performed Achilles and plantar fascia stretching for approximately 10 minutes, twice a day. Follow-up at 8 weeks.	Percentages improved in each group: 1) silicone insert, 95%; 2) rubber insert, 88%; 3) felt insert, 81%; 4) stretching only, 72%; and 5) custom orthosis, 68%. Multivariate analysis of mean pain score changes showed all groups with significant improvement, no significant differences between groups.	"We conclude that, when used in conjunction with a stretching program, a prefabricated shoe insert is more likely to produce improvement in symptoms as part of the initial treatment of proximal plantar fasciitis than a custom polypropylene orthotic device."	Lack of blinding. Study suggests added benefit from orthosis plus stretching program. However, percentages of improvement are of unknown clinical significance as benefit response included broad category of "all, much, or slightly better." No differences in mean pain scores.
DiGiovanni 2003, 2006 RCT	4.5	N = 101 with chronic proximal plantar fasciitis for a duration >10 months	Plantar fascia tissue-stretching program vs. Achilles tendon-stretching (concentric) program; 8-week and 2-year follow-up.	Inclusion criteria was failure of non-operative treatments. Subject-relevant outcome measures all statistically better in positive responses for PF stretching vs. Achilles stretching. Overall better 82.6% vs. 55.6% (p = 0.01), >50% improvement in pain 82.6% vs. 58.3% (p = 0.03). Totally satisfied 91.3% vs. 60% (p = 0.006). At 8 weeks, Achilles group switched to PF stretching. At 2-year follow-up (attrition 40%) PF	"After eight weeks of treatment, the group managed with plantar fascial stretching exercises exhibited enhanced outcomes with regard to pain, function, and overall satisfaction compared with those of the group managed with standard Achilles tendon-stretching exercises. This study supports the use of the tissue-specific plantar fascia-stretching protocol as the	All groups received orthoses and NSAIDs. Baseline differences in duration of symptoms reported, (duration >in PF group, p<0.01) although the mean (years) not provided. Baseline pain scores not provided limiting comparison of change in scores (main outcome). High attrition (28%, 14/50) in Achilles stretching group. Lack of control group for Achilles limits

				stretching resulted in improvement of Achilles group; both groups improved with no differences.	key component of treatment for chronic plantar fasciitis."	conclusion for group treated with PF stretching at the 2 year follow-up as natural history is not ruled out.
Hyland 2006 RCT	4.5	N = 41 with plantar fasciitis	Stretching (plantar fascia, gastrocnemius) vs. calcaneal taping vs. sham taping vs. no treatment. Durations of symptoms unknown. Treatment effect measured after 1 week.	Stretch vs. taping vs. control vs. sham taping. VAS, PSFS stretching: 6.3±0.8 to 4.6±0.7, 5.6±1.1 to 4.9±1.2; taping: 7.0±0.8 to 2.7± 1.8, 4.5±6.2±1.8; control: 6.3±1.3 to 6.2±1.0; sham taping: 6.4±1.2 to 6.0±0.9, 5.3±0.5 to 5.4±0.6; pre- and post-intragroup difference $p<0.05$; intragroup: taping vs. stretching $p<0.06$, tape vs. sham and control $p<0.001$, stretch vs. sham and control p = NS.	"Calcaneal taping was shown to be a more effective tool for the relief of plantar heel pain than stretching, sham taping, or no treatment."	Randomization and allocation unclear. No blinding. Small sample size. Duration of symptoms at study entry unknown but suspect acute and subacute as previous treatment was a study exclusion criterion. Very short term study of only 1 week.
Radford 2007 RCT	5.5	N = 92 with plantar heel pain >3 months duration	Calf muscle stretching and sham ultrasound vs. sham ultrasound only. Required stretching 5 minutes per day.	No statistically significant differences between groups in first-step pain, foot pain, foot function, general foot health, or functional	"[A] two-week stretching program provides no statistically significant benefit in 'first-step' pain, foot pain, foot function or general foot health	Improvement in both groups occurred, but no between group differences. Short trial duration – only 5 minutes of intervention per day. Results suggest no

				measures in ROM.	compared to not stretching."	benefit of calf stretches using wedge technique.

Evidence for the Use of Taping for Plantar Fasciitis

There is 1 high- and 1 moderate-quality RCTs incorporated into this analysis. There is 1 low-quality RCT in Appendix 2.(226) (Lynch 98)

Author/Year Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments
Radford 2006 RCT	8.0	N = 92 with plantar heel pain	Low-Dye taping with sham ultrasound vs. sham ultrasound. Symptoms >4 weeks. Treatment effect measured over 1 week.	Taping vs. control: (adjusted mean difference 95% CI). First step pain; -12.3 (-22.4 to -2.2) p = 0.017. Foot pain, foot function, general foot health scores all non-significant between groups.	"Low-Dye is effective for the short-term treatment of the common symptoms of "first-step" pain in patients with plantar heel pain."	Short trial of 1 week. High level of adverse events in taping (28%) due to discomfort, allergic reactions. Data suggest no differences in outcomes measures except first step pain.
Hyland 2006 RCT	4.5	N = 41 with plantar fasciitis	Stretching (plantar fascia, gastrocnemius) vs. calcaneal taping vs. sham taping vs. no treatment. Durations of symptoms unknown. Treatment effect measured after 1 week.	Stretch vs. taping vs. control vs. sham taping; VAS, PSFS stretching: 6.3±0.8 to 4.6± 0.7, 5.6±1.1 to 4.9±1.2; taping: 7.0±0.8 to 2.7±1.8, 4.5±6.2±1.8; control: 6.3± 1.3 to 6.2±1.0. Sham taping: 6.4±1.2 to 6.0±0.9, 5.3±0.5 to 5.4±0.6 pre/post intra-group difference p <0.05; intra-group: taping vs. stretching p <0.06, tape vs. sham and control p <0.001, stretch vs. sham and control p = NS.	"Calcaneal taping was shown to be a more effective tool for the relief of plantar heel pain than stretching, sham taping, or no treatment."	Randomization and allocation unclear. No blinding. Small sample size. Duration of symptoms at study entry unknown but suspect acute and subacute as previous treatment was a study exclusion criteria. Very short term trial and follow-up of only one week limits utility of study for guidance.

Evidence for the Use of Acupuncture for Plantar Fasciitis
There is 1 high-quality RCT incorporated in this analysis.

Author/Year Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments
Zhang 2009 RCT	8.5	N = 53 with plantar fasciitis	Acupuncture needling of upper extremity at acupoint Daling (PC7) vs. acupoint Hegu (LI 4) in patients with symptoms >3 months; 10 treatments over 2-week period with 6-month follow-up.	Daling (palmar side of forearm, midpoint of wrist crease); Hegu (between 1st and 2nd metacarpal bones) at 1 month: Morning Pain VAS: 22.6±4.0 vs. 12.0± 3.0, p <0.05; overall pain VAS: 20.3±3.7 vs. 9.5±3.6, p <0.05; pressure pain threshold: 145.5±32.9 vs. -15.5±39.4, p <0.05	Study "demonstrates that acupoint PC 7 has a specific effect for treatment of plantar fasciitis, and that the methods of acupuncture treatment is both simple and safe."	Lack of placebo control limits conclusions on effectiveness of acupuncture vs. natural history. Some bias may be present as study conducted in culture where acupuncture is widely accepted as standard treatment.

Evidence for the Use of Electrical Stimulation for Plantar Fasciitis
There is 1 moderate-quality RCT incorporated into this analysis.

Author/Year Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments
Stratton 2009 RCT	4.5	N = 26 with plantar fasciitis	Low frequency electrical stimulation with orthoses and stretching vs. orthoses and stretching.	No intergroup differences in VAS, Activities of Daily Living Subscale of FAAM 4 weeks and 3 months after treatments. Both treatment arms statistically significant improvements compared to baseline.	"The efficacy of using low-frequency electrical stimulation in the management of patients with plantar fasciitis is questionable."	Study included patients with symptoms of 1 week to 6 months. Inclusion criteria: athletic activity 5 times per week for >90 minutes limiting generalizability. Randomization and allocation details sparse. Data suggest no added benefit from low frequency electrical stimulation.

Evidence for the Use of ESWT for Plantar Fasciitis

There are 9 high- and 14 moderate-quality RCTs (one with two reports) or quasi-RCTs incorporated into this analysis. There are 2 low-quality studies in the Appendix.(265, 266) (Furia 05, Alvarez 03)

Author/Year Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments
ESWT vs. Sham						
Haake 2003 RCT	10.0	N = 272 chronic plantar fasciitis with symptoms >6 months and failure of conservative treatment (non-specified)	ESWT vs. sham. Active treatment: 4,000 shocks 0.08 mJ/mm^2 x 3 treatments 2 week intervals; mepivacaine local used. Energy focused on insertion of fascia guided by ultrasound; 12 week at 12-month follow-up period; 320 mJ/mm^2; low energy flux.	Primary outcome: success on Roles and Maudsley Scale (score 1-2): 12 weeks – difference in success rates 3.6% (-8.0% to 15.1; p = 0.5927), OR 1.18 (0.675 to 2.07). 12 months: 91 of 113 (81%) ESWT vs. 87 of 115 (76%) placebo p >0.05. No significant effect of ESWT.	"We cannot recommend specific applications of extracorporeal shock wave therapy to be tested in further clinical studies because all major trials, using different shockwave variable and types of lithotripters, showed negative results."	Blinding of treat-ment method shown to be effective, 75% (therapy) vs. 65% (placebo) thought they were in treatment group. Local anesthesia with 2ml mepivacaine. Data suggest no benefit from ESWT given parameters.
Buchbinder 2002 RCT	9.5	N = 166 plantar fasciitis with symptoms range 8-900 weeks, mean 36-43 weeks; 12-week follow-up period; Dx of thickened insertion of plantar fascia (>4 mm) by ultrasound required	ESWT vs. sham. Active treatment: 2,000-2,500 shocks of variable energy (0.02-0.33mJ/mm2) dictated by pain tolerance) x 3 weekly treatments. No local used. Energy focused on insertion of fascia guided by ultrasound; ≤825 mJ/mm^2; low to medium energy flux.	At 6 and 12 weeks, significant improvements in overall pain in both active group placebo group although no differences between groups (mean±SD): 17.9±30.5 and 19.8±33.7 at 6 weeks (p = .74). 26.3±34.8 and 25.7±34.9 at 12 weeks (p = .99). No significant effect of ESWT.	"We found no evidence to support a beneficial effect on pain, function, and quality of life of ultrasound-guided ESWT over placebo in patients with ultrasound proven plantar fasciitis 6 and 12 weeks following treatment."	Use of anesthesia not noted. Focus of energy on thickest portion of plantar fascia vs. most tender point. Suggests ESWT provided no benefit given parameters of study at 6 or 12 weeks. Study included subacute and chronic conditions. No long-term follow-up.

Speed 2003 RCT	9.5	N = 88 adults with plantar fasciitis with symptoms >3 months (most failed analgesics, NSAIDs, injections, footwear, and orthotics); 6-month follow-up	ESWT vs. sham. Active treatment: 1,500 shocks of 0.12 mJ/mm2 x 3 treatment at monthly intervals. No local used. Energy focused on insertion of fascia guided by ultrasound and point of maximal tenderness on treatment application; 180 mJ/mm^2; low energy flux.	EWST vs. sham pain VAS (mean): 0/1/2/ 3/6 months: 73.6/ 62.5/51.6/41.4/34.7 vs. 70/63.7/48.1/47.1/29. No significant difference between groups with respect to changes seen in any outcome measures over 6-month period. No significant effect of ESWT.	"There appears to be no treatment effect of moderate dose ESWT in subjects with plantar fasciitis. The improvement shown with placebo may be simply an improvement in symptoms or a true placebo effect."	Use of anesthesia not noted. Data suggest lack of long term efficacy.
Gollwitzer 2007 RCT	9.0	N = 40 with chronic painful heel syndrome (symptoms >6 months); failed 4 conservative treatments; 12 week follow-up	ESWT vs. sham. Active treatment - 2000 shocks of 0.25 mJ/mm2 x 3 treatments at weekly intervals. No local used. Energy focused on at point of maximal tenderness; 500mJ/mm^2; low energy flux.	Final percent change from baseline in composite heel pain VAS score: 73.2% in the ESWT group vs. 40.5% in placebo group. Between-group difference not statistically significant. No differences in overall success rate. No significant effect of ESWT.	"In conclusion, ESWT with 3 repetitive applications of 2000 impulses of an electromagnetic shockwave device without local anesthesia appeared to be an effective, non-invasive treatment modality for proximal plantar fasciitis. This intervention was associated with negligible side effects."	Use of anesthesia was not indicated. Mann Whitney effect test to determine clinical significance of observed differences to justify conclusion. None of the clinical outcomes measures reached statistical significance.
Malay 2006 RCT	9.0	N = 172 volunteers with symptoms >6 months, failed 2 pharmaceutical and 2 non-pharmaceutical treatments. VAS > 5 (0-10	ESWT (115) vs. sham. Control (57) - Active treatment of 3500 impulses in single session (energy variable, total dose not reported). Energy Flux not specified.	Mean VAS change ESWT vs. placebo (1, 2, 3 months): -1.61 vs. 11.27 p = 0.34, -2.30 vs. -1.31 p = 0.26, -2.51 vs. -1.57 p = 0.45. Mean VAS change ESWT vs. placebo at 3 months: Spur absent; -3.67 vs. -2.19 p = 0.12, Spur present; -	"All assessments of the reduction of heel pain were found to be statistically significant when compared with placebo in participants who had already failed standard conservative treatments…with a single treatment	Study performed by manufacturer for FDA approval of Orthospec device (portable ESWT). Anesthesia not used. Study suggests delayed reduction in pain on assessor and

		scale); 3-month follow-up period		2.06 vs. -1.99, p = 0.96; Assessment of heel pain (responder vs. non-responder) at Months 1, 2, 3: 35.5% vs. 31.5% p = 0.61, 43.2% vs. 31.5% p = 0.14, 52.7% vs. 28.6% p = 0.003. Intervention subjects receiving higher-energy flux treatment and without heel spurs did better than those with heel spurs and those receiving lower-energy flux. Mixed statistically significant effects and few clinically-significant effects of ESWT.	session without the use of local anesthetics or systemic analgesics or sedatives."	patient report, but no improvement in function or activity after single treatment session. Effect seems greatest at 3 months. No long-term follow-up to determine if effect lasting.
Kudo 2006 RCT	8.5	N = 114 with plantar fasciitis symptoms >6 months, failed NSAIDs, stretching, and 2 other treatments ; VAS >5 (0-10 scale); 3-month follow-up	ESWT vs. sham. Active treatment 3800 impulses at variable energy (0.36 -0.64 mJ/mm2) in single treatment for total of 1,300 mJ/mm2 ED_+ or 2330 mJ/mm^2 ED; high energy flux.	Clinical success [No. of subjects (%)] active treatment group vs. placebo: 25/53 (47%) vs. 12/52 (23%); p = 0.0099. Adverse events through 3 months: pain during treatment (% incidence): 79.3 vs. 8.9; p = 0.000. Mixed, mostly non-statistically significant effects and questionable clinically-significant effects of ESWT.	"The results of this study confirm that high-energy ESWT, administered with the Dornier Epos Ultra is a safe and effective treatment for patients who have failed previous conservative nonsurgical treatments for chronic plantar fasciitis."	Local anesthesia with 5 ml lidocaine. Study suggests EWST provided benefit over placebo.
Marks 2008 RCT	8.5	N = 25 mean symptom duration 28.3 months,	ESWT (16) vs. Sham (9). Active treatment of 500 impulses day 1, 2000 impulses on day 4 and 7	VAS change >50%: ESWT 4/9 vs. sham 9/16 p = 0.44. VAS change overall: p = 0.75 between	"There appears to be a significant placebo effect with low-energy ESWT in	Randomization by drawing lots. Use of anesthesia not noted. Small sample size.

		failed NSAIDs, corticosteroid injections, physiotherapy; follow-up at 1, 6 months	at 0.16 mJ/mm2. No report on use of local or guidance method; 320 mJ/mm^2; low energy flux.	group mean Roles and Maudsley Scores: p = 0.22 between group mean. No significant effect of ESWT.	patients with heel pain, and there is also a lack of evidence for its efficacy compared to sham therapy."	Data suggest no clinically significant effect at 1 or 6 months.
Rompe 2003 RCT	7.5	N = 45 recreational runners with symptoms >12 months, failure of 3 non-operative treatments including NSAIDs, physiotherapy, orthotics; 12-month follow-up	ESWT vs. sham. Active treatment – 2,000 shocks of 0.16 mJ/mm2 x 3 treatments at weekly intervals. No local used. Energy focused on at point of maximal tenderness; 320 mJ/mm^2;low energy flux.	Mean reduction in self-assessment of pain on 1st walking in morning. Initial rating/6 months/1 year treatment vs. sham: 6.9±1.3/2.1± 2.0/1.5±1.7 vs. 7.0± 1.3/4.7±1.9, 4.4±1.7; p <0.0005 at 6, 12 months. Mean scores on AOFAS Ankle-Hindfoot Scale: 52.7 ±10.0/89.9±8.6/90.4 ±8.3 vs. 49.7±10.1/ 69.1±20.1, 75.4± 17.3; p = 0.0211. Subjective scale results: 4.0±0.0/ 2.1±0.8/1.9±0.6 vs. 4.0±0.0/3.0±1.0/2.7 ±1.1; p = 0.0445. Statistically significant positive effect of ESWT.	"The results of the current study revealed beneficial effects of low-energy extracorporeal shock wave therapy in long-distance runners with chronic plantar fasciitis. [W]e recommend shock wave therapy to any patient who has had unsuccessful conventional non-operative treatment over a period of at least 6 months, before considering an operative intervention."	Small sample size. No anesthesia used. Data suggest low energy ESWT showed beneficial vs. placebo in this group of runners over 12 month period.
Theodore 2004 RCT	7.5	N = 150 with plantar fasciitis with symptoms >6 months,	ESWT vs. sham. Active treatment 3800 impulses at variable energy (0.36 -0.64 mJ/mm2) in single treatment for total of 1,300	VAS: ESWT vs. sham (0, 5 days, 6 weeks, 3 months): 7.7 vs. 7.7, 5.0 vs. 5.7, 4.6 vs. 5.0, 3.4 vs. 4.1. Mean change from	"In conclusion, extracorporeal shock wave therapy has emerged as a safe treatment option for chronic plantar	Anesthesia through medial calcaneal nerve block with 5 ml of 1% lidocaine. Data suggest single treatment provides some

		failed stretching, failed NSAIDs and 2 other therapies; 12-month follow-up	mJ/mm2. Local anesthetic was used in conjunction with ultrasound guidance and modification with pain feedback. Study patients unblended at 3 months and placebo group was allowed to crossover; 1300 mJ/mm^2; medium to high energy flux.	baseline -4.4 vs. -3.6 p = 0.435. Roles & Maudsley (number reporting improvement from fair/poor to excellent/good at 3 months: 45/73 (63%) vs. 29/73 (40%), p = 0.0327. AOFAS Ankle-Hindfoot, SF-12: no differences. Statistically significant differences between groups noted in 3 months of blinded comparison. Some findings not statistical different and differences in VAS scores between groups less than 1.0. Mixed statistically significant, but positive short-term effect of ESWT, some statistically significant effects of questionable clinical significance.	fasciitis. This study demonstrates that electromagnetically generated, high-energy shock waves administered with ultrasound guidance during a single therapeutic session can safely produce clinical improvement by 3 months post treatment."	pain relief but minimal functional improvement at 3 months post single treatment. No long-term results available for control group.
Cosentino 2001 RCT	6.0	N = 60 talalgia associated with heel spur with symptoms >6 months, failure of other non-surgical treatments in past 6 months (non-	ESWT vs. sham. Active treatment 1200 impulses x 6 weekly treatments of 0.03-0.4 mJ/mm2. Energy directed to enthesophytosis with ultrasound. No local used. Energy flux not clearly specified, may have been between 36 and 480 mJ/mm^2.	No numerical statistics provided. ESWT significant decrease of VAS at rest, walking, after awakening and normal activity (p <0.0001) at treatment end, at 1, 3 months. Control (Group 2) no significant decrease of VAS (p = 0.47) at these points. Enthesitis	"Our results confirm the presence and size of bony spurs do not correlate with clinical symptoms and that ESWT can, in our opinion, be considered the best treatment for painful heel with heel spurs, owing to its lack	Randomization, allocation, baseline characteristics not well described. Blinding uncertain. No anesthesia used. Intervention group received variable levels of energy (0.03-0.4mJ/mm3). Suggests

		specific); 3-month follow-up period	Low to medium energy flux.	statistically significantly reduced in grade in intervention and compared to control group. No significant reduction in enthesophytosis size vs. control on x-ray.	of side effects and because it is repeatable and non-invasive treatment without anesthesia."	ESWT more effective than placebo in pain scores after treatment, lasting 3 months in patients with chronic plantar heel pain although study weaknesses reduce strength of conclusion.
Mehra 2003 RCT	6.0	N = 47 (23 plantar fasciitis, 24 tennis elbow); mean duration of symptoms 11 months; failure treatments : topical NSAIDs, steroid injection and/or surgery; 3 and 6 month follow-up	ESWT vs. sham. Active treatment – 2000 shocks of 2.5 bars of air pressure x 3 treatments at 2 week intervals. Local injection used. No guidance method reported.	Plantar fasciitis: mean pain score (13 patients ESWT) reduced from 5.9 to 1.9 at 6 months vs. 7.0 to 6.6 in control (no p-value provided); 12 patients (93%) showed significant improvement, 1 patient remained unchanged in treatment group. No improvement noted in control group.	"The mobile lithotripter is an effective form of treatment for tennis elbow and plantar fasciitis but warrants further larger studies."	Small sample size in PF treatment arm. Study details sparse. No anesthesia used. Data suggest ESWT is effective.
Ogden 2004 RCT	5.5	N = 384 plantar fasciitis (symptom duration not described) ; failure of 2 physical methods or pharmacol ogic treatments ; 12-month follow-up	ESWT vs. sham. Active treatment of 1500 shocks of variable energy (1400 at 0.22 mJ/mm2) in single session (total 324.25 J). Local block used. Guidance by point of maximal tenderness; 324 mJ/mm^2; low energy flux.	ESWT vs. sham: completely successful treatment 3 months; 3 months after treatment, 67/144 (47%) vs. 42/141 (30%) (p = 0.008). 1 year; 65/67 ESWT maintained successful result. 36/51 (71%) of non-randomized patients had a successful result.	"The application of electrohydraulic high-energy shock waves to the heel is a safe and effective noninvasive method to treat chronic plantar fasciitis, lasting up to and beyond one year."	FDA clinical trial. Multiple arms (randomized and non-randomized patients) combined in multiple analyses. Study similar to and may be same population as Ogden 2001. "Ankle-block" anesthesia used. Data

						suggest benefit of ESWT.
Rompe 1996 RCT	5.5	N = 36 with persistent symptoms of painful heel. Calcaneal spur, symptoms >12 months, unsuccessful conservative therapy (not specified)	ESWT vs. sham. Active treatment – 1000 shocks of 0.06 mJ/mm2 x 3 treatments at weekly intervals. No local used. Treatment guided by fluoroscopy; 60 mJ/mm^2; low energy flux.	ESWT vs. sham (3, 6 weeks): Night pain % reduction from baseline; 58.2% vs. 13.6 %, 57.4% vs. 8.1% (p <0.05). Resting pain % reduction from baseline: 75% vs. 36.6% (p <0.05), 79.6% vs.33.8% (p <0.01). Walking ability rated 1 to 5. Increase of 171.4% in Group I after 6 weeks of 178.6%; after 12 weeks 200%; after 24 weeks 185.7%. Sham: 0% (p <0.0001) and 4.8% (p <0.0005) at 3, 6 weeks.	"We found a significant decrease of pain and an increase of walking ability compared with a control group. After cross-over had been finished, all but 9 patients had improved -6 had become pain free - after ESWT, but, just as after surgery, the average time to maximum improvement was 6 months."	Small sample size. Randomization, allocation, baseline comparisons details sparse. No anesthesia was used. Data suggest low energy ESWT appears effective for chronic painful heel.
Ogden 2001 RCT	5.0	N = 302 with MSDs (260 random, 42 non-random) symptoms 6 months to 18 years; failed at least 3 conservative treatments	ESWT vs. sham. Active treatment of 1500 shocks of 18kV power in single session (repeat allowed in some cases). Local block used. Guidance by point of maximal tenderness.	ESWT vs. placebo (0, 12 weeks) VAS: 7.68 vs. 7.87, 3.13 vs. 4.37; Pain Self-assessment: 8.02 vs. 8.14, 3.48 vs. 4.20; Activity self-assessment: 3.49 vs.3.53, 1.72 vs. 1.88. No p-values provided between groups. Author states number of patients improved	"The results suggest that this therapeutic modality should be considered before any surgical options, and even may be preferable to cortisone injection, which has a recognized risk of rupture of the plantar fascia	Study is similar (may be same population as Ogden 2004). Randomization, allocation unclear. Lack of details for compliance, co-interventions; 42 non-randomized patients included for training. Unclear if

		; 1-year follow up		in all categories was significantly higher than placebo.	and recurrence of symptoms."	results are clinically significant but suggest modest clinical global improvement after ESWT.
rESWT vs. Sham						
Gerdesmeyer 2008 RCT	8.5	N = 254 chronic plantar fasciitis with symptoms >6 months, failed 2 pharmaceutical and 2 non-pharmaceutical treatments; VAS >5 (0-10 scale); follow-up at 3 and 12 months	Radial ESWT (rESWT) vs. sham. Active treatment of 2000 impulses x 3 sessions 2 weeks apart of 0.16 mJ/mm². Energy applied without anesthesia to the spot of greatest tenderness; 320 mJ/mm^2; low energy flux.	rEWST vs. placebo (VAS) % change from baseline: 12 weeks; -72.1 vs. -44.7, p = 0.0220, 12 months; -84.8 vs. -43.2, p = 0.0086; overall success heal pain (VAS), (n): 12 weeks ESWT (75) vs. placebo (49), p = 0.0020, 12 months ESWT (78) vs. placebo (51), p = 0.0014. Changes baseline to 12 weeks: SF-36 (%) -44.1 (-37.2±48.42) vs. -23.9 (-19.5±52.13), p = 0.0013; Roles & Maudsley Score excellent or good % - 58.40 vs. 41.5, p = 0.0031; patient global judgment (very satisfied or moderately satisfied) % - 63.16 vs. 46.36, p = 0.0045.	"Radial ESWT demonstrated safety and effectiveness. Radial ESWT can be strongly recommended for patients with therapy-resistant plantar painful heel syndrome."	No anesthesia used. Study performed by manufacturer for FDA approval of radial ESWT device. Randomization, allocation methods details sparse. Radial ESWT is alternative method of application with expanded energy field as compared to focused energy field of ESWT.
ESWT (Dose, Location, Frequency Studies)						
Rompe 2002 RCT	7.0	N = 112 intractable plantar heel pain with symptoms for 6 to 20 months; failure for	Three applications of 1000 impulses of low-energy shock waves of 0.08 mJ/mm^2 vs. those of three applications of ten impulses of	Scores for subjective variable for Group I vs. Group II: Modified Roles and Maudsley: (Excellent/Good at 6 months)	"In conclusion, the current pilot study revealed dose-related effects of low-energy extracorporeal shock-wave therapy in	Pilot study. No anesthesia was used. Authors opine the modified Roles and Maudsley scale is not valid for the foot. Data

		at least 6 months of conservative therapy; follow-up 3 and 6 months, 5 years	low-energy shock waves; 80 mJ/mm^2; low energy flux.	28/49 vs. 5/48, p<0.0001. Night pain at baseline (N): 31±8 vs. 30±10; p = 0.8681. 6 months: 6±10 vs. 32±9; p <0.0001. After 5 years: 4±8 vs. 11±15; p = 0.0015. Resting Pain at baseline: 27±14 vs. 26±14; p = 0.0890. 6 months: 7±10 vs. 25±13; p <0.0001. After 5 years: 4±9 vs. 11±12; p = 0.0033.	patients with chronic plantar fasciitis. The therapy with three applications of 1000 impulses appeared to be a useful, noninvasive treatment method with negligible side effects that reduced the necessity for a surgical procedure. Nevertheless, low-energy shock-wave application cannot be recommended as a first-line procedure for chronic heel pain."	suggest efficacy at 6 month follow-up. Efficacy at 5 years uncertain at 58% of low shock group had undergone surgery.
Dorotka 2006 RCT	6.5	N = 41 with chronic plantar fasciitis (radiologic evidence of heel spur), symptoms >6 months; failed conservative treatment with at least 3 different therapeutic modalities; follow-up at 6 and 12 weeks	Location of heel spur for ESWT by fluoroscopy vs. patient location for ESWT by maximal point of tenderness; 80 mJ/mm^2.	Pain at rest (VAS) before ESWT/ 6/ 12 weeks for Group 1 vs. Group 2: 67.0/ 83.8/ 74.6 vs. 67.7/ 104.5/ 119.0. No significant differences noted between Group 1 and 2.	"We found no noticeable differences in the clinical outcome between the groups. However, due to the longer lasting therapy sessions and the burden of additional radiation with fluoroscopy, we recommend patient location as a safe and effective technique for positioning the focus of ESWT in the treatment of plantar fasciitis with a calcaneal spur."	Both groups showed statistically significant improvement from baseline, although no difference between groups. Treatment protocol 1,000 impulses, lower than many other low energy ESWT studies. Lack of significant difference in localization suggests non-fluoroscopic technique is acceptable, if not preferred.

Tornese 2008 RCT	5.5	N = 51 subjects with history of at least 6 months of heel pain	Group A: perpendicular technique of ESWT vs. Group B: tangential technique of ESWT using 1800 pulses, of which at least 1400 were 0.22 mJ/mm2; ≥308 mJ/mm^2; low energy flux.	Mayo Clinical Scoring System (mean±SD): initial MCSS Group A (55.2±18.7) vs. Group B (53.5±20), p >0.05; 2 months follow-up MCSS Group A (83.9±13.7) vs. Group B (80±15.8), p >0.05; 8 months follow-up MCSS - Group A (90±10.5) vs. Group B (90.2±8.7), p >0.05.	"No differences in long-term outcome after extracorporeal shock wave therapy were found between the two treatment groups."	No placebo group for comparison. No anesthesia used. Randomization, allocation details not described. Both groups improved with no difference between two.
ESWT and Local Anesthesia						
Rompe 2005 RCT	10.0	N = 86 chronic plantar fasciitis, symptoms >6 months; failure of at least 3 conventional therapies for > 6 months (>or = 4weeks of PT and/or heel cord stretching, heel cushions/ orthotic devices, casting/night splints, >or = to 4 weeks course of NSAIDs, at least 2 local steroid	ESWT without local anesthesia (LA) vs. ESWT with LA. Treatment of 2,000 pulses at 0.09 mJ/mm^2 administered after localization of most-tender point in non-LA group. Anesthesia group received 2,000 pulses at 0.09 mJ/mm^2; 0 mJ/mm^2; low energy flux.	Mean changes from baseline at 3 weeks, 3 months, and 12 months Group I vs. Group II: 3 month mean change from baseline (95% CI) for Pain at 1st steps [0-10]: 4.7(4.0-5.4) vs. 2.6 (1.9-2.9). Between-group difference (95% CI): 2.1 (1.3-3.0); p <.001. Subjective rating scale [1-4]: 1.9 (1.6-2.1) vs. 1.2 (0.9-1.4). Between-group difference: 0.7 (0.3-1.1); p<.001. 12-month mean change from baseline (95% CI). Between-group difference (95% CI): Pain at first steps [0-10]: 5.0 (4.3-5.7) vs. 2.6 (1.9-3.3), 2.4 (1.4-	"We conclude that there is a positive treatment effect of repetitive low-energy ESWT as applied at 3-month follow-up in subjects with chronic plantar fasciitis. This positive treatment effect may be reduced by application of a local anesthetic to the painful area prior to low-energy ESWT." "[A] local anesthetic should not be used for blinding in randomized-controlled trials evaluating the clinical efficacy of repetitive low-energy ESWT for musculoskeletal disorders."	Anesthesia group received 4 ml mepivacaine injected in the origin of the plantar fascia. Data suggest efficacy of treatment is reduced with concomitant use of local anesthetic. Lack of sham control limits statement for treatment.

		injections); follow-up 3 weeks, 3 and 12 months		3.3); p <.001. Subjective rating scale [1-4]: 1.9 (1.6-2.2) vs. 1.2 (0.9-1.5), 0.7 (0.3-1.1); p <.001.		
ESWT vs. Other Therapies						
Hammer 2002, 2003 RCT	6.5	N = 47 chronic proximal plantar fasciitis with symptoms 6 to >12 months unsuccessful treatment of at least 6 months consisting of NSAIDs, heel cup, orthoses and/or shoe modifications, local steroid injections and electrotherapy (iontophoresis with diclofenac); follow-up 6, 12, 24 weeks	Three sessions of ESWT (3000 shockwaves/session of 0.2 mJ/mm2) at weekly intervals vs. in the patients of Group 2 treatment was continued for 12 weeks. Group 2 then were crossed-over to ESWT and followed for 2 years; 600 mJ/mm^2; low energy flux.	VAS (Mean±SD) score decreased t = 0 to t = 24 weeks (p <0.01) in both groups without significant difference between groups. VAS score at rest baseline/6/12/24 weeks for Group 1: 34.0±27.1/13.8±26.0/11.8±19.8/12.0 ±25.9. Group 2: 43.1 ±26.9/18.8±29.8/10.2±24.4/5.0±20.4. Everyday life Group 1: 78.2±17.5/28.2±31.4/29.0±31.6/22.6 ±33.6. Group 2: 70.4 ±22.2/37.1±32.8/26.0 ±30.1/11.9±23.5	"ESWT was able to decrease pain and increase the comfortable walking time significantly in patients with previous unsuccessful nonsurgical treatment for proximal plantar fasciitis. Up to 80% of the patients experienced a complete or nearly complete pain relief after a follow-up of six months."	ESWT group showed significant improvement over 24 month study. Control group showed no improvement over 12 weeks prior to crossover, where results became similar to ESWT group (no differences at last follow-up.)
Porter 2005 RCT	6.5	N = 132 proximal plantar fasciopathy with symptoms present for at least 6 weeks; follow-up at 3 and 12 months	ESWT 1000 impulses at 0.08mJ/mm2 x 3 weekly sessions vs. Intralesional corticosteroid injection. Inclusion criteria included symptoms of 6 weeks duration;	VAS pain scores, values for CSI (1.48; 0-7) significantly lower than ESWT (3.69; 0-8), and controls (3.58; 2-5) at 3 months. At 12 months, VAS scores for CSI (0.84; 0-7) and ESWT (0.84; 0-4)	"Corticosteroid injection is more efficacious and multiple times more cost-effective than ESWT in the treatment of plantar fasciopathy that has been symptomatic for	In this study both ESWT and CSI were used as first line therapy for acute symptoms. Results are therefore limited as no control for natural history of improvement

			80 mJ/mm^2; low energy density.	both significantly lower than controls (2.42; 1-4). Tenderness values at 3 months significantly higher for CSI (9.42; 7-11) than both ESWT (6.72; 4-11) and controls (7.63; 6-9); p <0.05 used throughout. Of 64 heels that received CSI, no infections or cases of rupture of plantar fascia.	more than 6 weeks."	in this disorder. Effects of CSI are short term.
Greve 2009 RCT	4.0	N = 32 plantar fascia >4mm thickness on ultrasound; symptoms ≥3 months; follow-up immediately after treatment and 3 months	ESWT (3,000 impulses at unspecified energy density for 3 weekly sessions vs. physiotherapy (ultrasound 1.2 W/cm2 twice weekly for 5 weeks plus stretching posterior leg; no energy flux specified.	No differences in two groups in parameters of pain duration after treatment, morning pain, pain with gait, use of analgesics.	"The two evaluated treatments were effective for reducing pain and incapacitation among patients with plantar fasciitis for at least three months after treatment."	Duration of disorder at study entry not specified. No control group. Lack of study details. Study suggests no difference in interventions of ESWT and physiotherapy.
Wang 2006 Quasi-RCT	4.0	N = 149 (168 heels) with chronic plantar fasciitis with symptoms for 6-38 months; follow-up 60-72 months treatment group, 34-64 months	ESWT (1500 impulses at 0.32 mJ/mm2 x single treatment) vs. conservative modalities. Outcomes measures reported at 3 to 6 years; 480 mJ/mm^2; medium energy flux.	Nearly 25% of ESWT group required second treatment. ESWT vs. Control: Final VAS 0.2 vs. 4.2, p <0.001. Mean function score (out of 30) - 29.6 (18-30) vs. 14.0 (10-17) p <0.001.	"ESWT is a new therapeutic modality that can safely and effectively treat patients with plantar fasciitis, with good long term results."	Quasi-randomization using odd/even medical chart number. Conservative management group included multiple modalities including NSAIDs, orthotics, PT, stretching, cortisone injection.

		control group				

Evidence for the Use of Iontophoresis for Plantar Fasciitis
There are 2 moderate-quality RCTs incorporated into this analysis.

Author/Year Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments
Osborne 2006 RCT	7.5	N = 31 medial calcaneal origin plantar fasciitis	0.4% dexamethasone vs. placebo (0.9% NaCl) vs. or 5% acetic acid. All groups with LowDye taping. 6 treatments over 2-week period. Final outcome at 2-weeks post treatment.	Numerical statistics not provided. Placebo/taping and acetic acid/taping groups significantly better than dexamethasone/taping for morning pain relief and reduction of worst pain in past 2 days at end of treatment. At 2 weeks post-treatment, no difference between groups in pain ratings, although placebo/taping lost all gains from baseline. No difference in functional improvement between dexamethasone/taping and acetic acid/taping at 4 weeks, but significant difference between AA/Taping and placebo/taping (p = 0.031).	"Six treatments of acetic acid iontophoresis combined with taping gave greater relief from stiffness symptoms than, and equivalent relief from pain symptoms to, treatment with dexamethasone/taping. For the best clinical results at four weeks, taping combined with acetic acid is the preferred treatment option compared with taping combined with dexamethasone or saline iontophoresis."	Co-intervention of stretching (gastrocnemius/ soleus). Small sample size with questionable baseline differences in duration of disease. Data results are of unknown clinical significance.
Gudeman 1997 RCT	6.0	N = 40 feet with plantar fasciitis	Group I: feet treated with traditional modalities and placebo iontophoresis. Group II: feet received	Group II had significantly greater improvement between pre-treatment and immediate post treatment than Group I; increase of 6.8±5.6 for Group II and 3.0±4.1 for Group I. At 1-month follow-up, no significant difference between groups. Difference in	"Based on these results, iontophoresis of dexamethasone for plantar fasciitis should be considered when more immediate results are needed."	Randomization and allocation unclear. Possible baseline difference in outcome measure. Baseline pain scores were

			traditional modalities plus iontophoresis with dexamethasone.	increase (control vs. treatment groups) between pre- and post testing statistically significant (p = 0.022), but difference in increase between pre- and follow-up testing not significant (p = 0.434).		mostly of mild severity.

Evidence for the Use of Low-level Laser Therapy for Plantar Fasciitis
There are 2 moderate-quality RCTs incorporated into this analysis.

Author/Year Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments
Kiritsi 2010 RCT	7.0	N = 30 unilateral plantar fasciitis	904 nm gallium-arsenide (GaAs) laser vs. sham laser, 18 sessions (3 x a week for 6 weeks).	LLLT vs. sham: VAS night rest- 48±9.4 to 21±24.3 vs. 49±9.4 to 38±10.3 p = 0.000 favoring LLLT change; VAS Daily Activities - 67±8.3 to 28±24.4 vs. 67±9.3 to 50±15.9, p = 0.001 favoring LLLT.	"We believe that 904 GaAs infrared (IR) laser therapy may contribute to plantar fasciitis healing and pain reduction. At this point, we should state that LLLT warrants further study as a treatment for plantar fasciitis."	Small sample size with 1/3 of control group withdrawing related to non-treatment reasons. Duration of baseline symptoms unknown, although inclusion criteria were 6 weeks or longer. No comparison of symptom duration between groups provided. Conclusions therefore limited.
Basford 1998 RCT	6.5	N = 32 plantar fasciitis >1 month duration	30mW .83µm gallium aluminum arsenide (GaA1As) laser vs. placebo.	No significant differences over study period between groups in terms of pain severity in morning, duration of painful walking on rising, exam, or medication, orthotic use.	"Low-intensity IR laser therapy appears safe but, at least within the parameters of this study, is not beneficial in the treatment of plantar fasciitis."	Randomization, allocation not described. Possible co-interventions of NSAIDs, orthoses. Data suggest lack of efficacy.

Evidence for the Use of Manipulation for Plantar Heel Pain
There are 2 moderate-quality RCTs incorporated into this analysis.

Author/Year Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments
Cleland 2009 RCT	5.0	N = 60 age 18 to 60 with chronic plantar heel pain	Manual physical therapy soft tissue mobilization, joint mobilization, manipulation) and ankle eversion exercises (MTEX) (n = 30) vs. electrophysical agents (iontophoresis with dexamethasone, ultrasound, and stretching/strengthening (EPAX) (n = 30); therapies 2 times week for 2 weeks, then once a week for 2 weeks.	EPAX vs. MTEX: 4, 26 weeks; Improvement in Lower Extremity Function Scale (LEFS- 0-80, higher is better): 7.5 vs. 21.0; p = 0.001; 12.9 vs. 22.8, p = 0.027. Improvement on Pain Scale from baseline (0-10) -1.4 vs. -2.9, p = 0.08; -2.8 vs. -3.4, p = 0.39.	"The results of this study provide evidence that MTEX is a superior management approach over an EPAX approach in the management of individuals with plantar heel pain at both the short- and long-term follow-ups. Future studies should examine the contribution of the different components of the exercise and manual physical therapy programs."	Multiple co-interventions used and lack of details for compliance to exercise/stretching regimens. Significance levels set by minimal clinically important difference for disability scores (9 points on scale). Study suggests both groups improved, but mobilization group demonstrated better disability scores. Actual clinical significance uncertain. Baseline pain scores moderate, and although change in score (improvement) significant at 6 weeks; clinical significance of VAS score of 3 vs. 2 is small.
Dimou 2004 RCT	4.5	N = 20 chronic plantar fasciitis	Manipulation (chiropractic adjustments twice weekly x 4 weeks) plus Achilles stretching (3 sessions daily) vs. orthotics.	Intergroup comparisons: Pain: no differences at Day 1, 1 or 2 months. Heel pain (leisure, work, sports); no differences at any interval.	"With the small sample size and methodological limitations of this trial, no firm conclusions can be drawn…[B]oth treatments appeared useful when used individually."	Lack of study details. Range of symptom duration was wide (8 weeks to 5 years). Small sample size with low power. Results inconclusive.

Evidence for the Use of Massage and Soft Tissue Mobilization for Plantar Fasciitis

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

Author/Year	Score	Sample Size	Comparison Group	Results	Conclusion	Comments

Study Type	(0-11)					
Cleland 2009 RCT	5.0	N = 60 age 18 to 60 with chronic plantar heel pain	Manual physical therapy soft tissue mobilization, joint mobilization, manipulation) and ankle eversion exercises (MTEX) (n = 30) vs. electro-physical agents (iontophoresis with dexamethasone, ultrasound, and stretching and strengthening (EPAX) (n = 30); therapies 2 times week for 2 weeks, then once a week for 2 weeks.	EPAX vs. MTEX: 4, 26 weeks; Improvement in Lower Extremity Function Scale (LEFS- 0-80, higher is better): 7.5 vs. 21.0; p = 0.001; 12.9 vs. 22.8, p = 0.027. Improvement on Pain Scale from baseline (0-10) -1.4 vs. -2.9, p = 0.08; -2.8 vs. -3.4, p = 0.39.	"The results of this study provide evidence that MTEX is a superior management approach over an EPAX approach in the management of individuals with plantar heel pain at both the short- and long-term follow-ups. Future studies should examine the contribution of the different components of the exercise and manual physical therapy programs."	Lack of details for compliance to exercise/stretching regimens and control for co-interventions. Significance levels set by minimal clinically important difference for disability scores (9 points on scale). Data suggest both groups improved, but mobilization group demonstrated better disability scores. Actual clinical significance uncertain. Baseline pain scores moderate, and although change in score (improvement) significant at 6 weeks; clinical significance of VAS score of 3 vs. 2 is small.

Evidence for the Use of Therapeutic Ultrasound for Plantar Fasciitis

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

Author/Year Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments
Crawford 1996 RCT	6.0	N = 19 with plantar heel pain (26 heels)	Ultrasound vs. placebo (0.5 w/cm2, 3 MHz, pulsed for 8 minutes); 8 treatments.	VAS ESWT vs. placebo: 6.7 vs. 7.5, 4.5 vs. 5.6 p >0.05	"Therapeutic ultrasound (at dosage described) is no more effective than placebo in the treatment of plantar heel pain."	Randomization, allocation methods unclear. Study details sparse. Treatment for 4 weeks. Data suggest no benefit from ultrasound at stated dosage.
Cleland 2009	5.0	N = 60 age 18 to 60	Manual physical therapy soft	EPAX vs. MTEX: 4, 26 weeks;	"The results of this study provide evidence	Lack of details for compliance to exercise/stretching

RCT		with chronic plantar heel pain	tissue mobilization, joint mobilization, manipulation) and ankle eversion exercises (MTEX) (n = 30) vs. electro-physical agents (iontophoresis with dexamethasone, ultrasound, and stretching and strengthening (EPAX) (n = 30); therapies twice a week for 2 weeks, then once a week for 2 weeks.	Improvement in Lower Extremity Function Scale (LEFS-0-80, higher is better): 7.5 vs. 21.0; p = 0.001; 12.9 vs. 22.8, p = 0.027. Improvement on Pain Scale from baseline (0-10) -1.4 vs. -2.9, p = 0.08; -2.8 vs. -3.4, p = 0.39.	that MTEX is a superior management approach over an EPAX approach in the management of individuals with plantar heel pain at both the short- and long-term follow-ups. Future studies should examine the contribution of the different components of the exercise and manual physical therapy programs."	regimens and control for co-interventions. Significance levels set by minimal clinically important difference for disability scores (9 points on scale). Data suggest both groups improved, but mobilization group demonstrated better disability scores. Actual clinical significance uncertain. Baseline pain scores moderate, and although change in score (improvement) significant at 6 weeks; clinical significance of VAS score of 3 vs. 2 is small.

Evidence for the Use of Radiation Therapy for Plantar Heel Pain
There is 1 moderate-quality RCT incorporated into this analysis.

Author/Year Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments
Heyd 2007 RCT	5.0	N = 130 with painful heel spurs	Total dose of 3.0 Gy given in 2 weekly fractions of 0.5 Gy (low dose [LD] group) vs. total dose of 6.0 Gy using 2 weekly fractions of 1.0 Gy (high dose [HD] group).	No statistically significant difference between both study groups	"Our prospective study demonstrated an equivalent efficacy of both fractionation schedules. More clinical and experimental trials are needed for evaluation of the minimum effective dose and optimization of the dose-fractionation schedules in anti-inflammatory RT."	Allocation method unclear. No control for co-interventions noted. No placebo group.

Evidence for the Use of Autologous Blood Injections for Plantar Fasciitis
There are 3 moderate-quality RCTs incorporated into this analysis.

Author/Year Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments
Injection Therapies – Autologous Blood vs. Glucocorticosteroid						
Lee 2007 RCT	5.5	N = 64 with chronic plantar fasciitis	Autologous blood 1.5mL vs. 20mg triamcinolone acetonide.	Mean VAS score at 0, 6 weeks, 3 months, 6 months for blood vs. steroid: 7.3±1.8 vs. 6.9±1.7 p = .3; 4.6±2.3 vs. 2.9±2.8 p = 0.011; 4.3±2.7 vs. 2.3±2.6 p = 0.005, 3.6±2.6 vs. 2.4±3.0 p = 0.094. Mean tenderness threshold scores at 0, 6 weeks, 3 months, 6 months for blood vs. steroid: 3.1±1.2 vs. 3.7±2.9 p = 0.167; 4.1±1.8 vs. 6.4±3.5 p = 0.003; 5.5±2.7 vs. 7.9±3.2 p = 0.003; 6.5±2.9 vs. 8.6±3.1 p = 0.008. Over 6-month follow-up, significant reduction in pain levels noted in both groups (p < 0.0001).	"Intralesional autologous blood injection is efficacious in lowering pain and tenderness in chronic plantar fasciitis, but corticosteroid is more superior in terms of speed and probably extent of improvement."	No placebo. Lack of blinding. Many co-interventions (rest, NSAIDs, stretching, repeat injections). Data suggest steroids more effective in short term for pain relief.
Kalaci 2009 RCT	5.5	N = 100 with plantar fasciitis	Group A: 2mL autologous blood only vs. Group B: anesthetic (2mL lidocaine) combined with peppering vs. Group C: corticosteroid (2mL triamcinolone) only vs. Group D: corticosteroid (2mL triamcinolone) combined with peppering.	Pain in affected heel on a 10 -cm VAS at 6 months (mean ± SD): Group A (3.53±3.06) vs. Group B (3.40±2.88) vs. Group C (1.52±2.14) vs. Group D (0.96±1.24). All improved from baseline (p = 0.000), C+D more effective than A+B (p <0.05). No difference between C+D. Modified roles/Maudsley score at 6 months: Group C, excellent and good 20/25; Group D, excellent and good 22/25, p = 0.24.	"[C]orticosteroid injection with peppering can be used as a first alternative in plantar fasciitis in cases in which other conservative methods failed."	Data suggest steroids equally effective with and without peppering from presented data. No placebo arm.

Kiter 2006 RCT	5.5	N = 45 with plantar heel pain	Peppering (10-15 injections with local) vs. autologous blood (2mL) vs. methylprednisolone acetate 40mg injection (all allowed up to 3 injections at monthly interval) followed for 6 months.	Peppering vs. autologous blood vs. steroid VAS (0-10): baseline 6.4±1.1 vs. 7.6 ±1.3 vs. 7.28±1.2. VAS: 6 months 2.2±2.2, 2.4±1.8, 2.57±2.9. All intragroup changes p <0.001, intergroup not significant.	"[P]eppering technique and autologous blood injection seem to be good alternatives to corticosteroid injection for the treatment of plantar heel pain, although the mechanism of cure is not completely understood."	Small sample size for each arm. Randomization by drawing lots. Author states demonstrated improvement in all groups, and therefore equal efficacy of treatment, but no placebo, limiting conclusions.

Evidence for the Use of Botulinum Toxin A Injections for Plantar Fasciitis
There are 4 moderate-quality RCTs incorporated into this analysis. (Babcock 05; Peterlein 12; Huang 10; Elizondo-Rodriguez 13)

Author/Year Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments
Injection Therapies – Botulinum Toxin A vs. Placebo						
Babcock 2005 RCT	6.5	N = 27 (43 feet) with plantar fasciitis	Botulinum toxin A 70 units vs. saline placebo.	Mean P-VAS pain scale score at 0, 3, 8 weeks for BTX-A vs. placebo: 5.1/2.7/1.6 vs. 4.9/4.7/4.4. Mean MFS score: 44/72/81 vs. 46/49/54. Compared with placebo injections, Botulinum toxin A group improved in all measures: Pain VAS (p <0.005), Maryland Foot Score (p = 0.001), Pain relief VAS (p <0.0005), pressure algometry response (p = 0.003).	"Botulinum toxin A injection for plantar fasciitis yields significant improvements in pain relief and overall foot function at both 3 and 8 weeks after treatment."	Data suggest Botulinum toxin A is effective for plantar fasciitis, although sample size is low, due to significant difference found at mid-study evaluation and subsequent termination of recruitment.

Peterlein 2012 RCT No mention of sponsorship, study medication donated by Ipsen Ltd. No COI, CP and RP are members of the research group botulinum toxin of the German Association of Neurology.	6.5	N = 40 with refractory plantar fasciitis for 4+ months and at least 2 previous conservative treatment fails. Median age 51.5 years.	BoNT-A 200 units in 2 mL 0.9% saline solution (n = 20) vs. saline placebo 2 mL (n = 20). Study duration: 18 weeks. Concomitant treatment prescribed for study was continued. Follow-up at baseline week 2, 6, 10, 14, and 18.	There were no significant differences between groups.	"In our study, we showed that fan-shaped local injections with 200 units of BoNT-A (Dysport) on the origin of the plantar fascia may decrease the 6-week pain score (VAS) and 18-week pain intensity, but this was not statistically significant when compared with the placebo group in patients with refractory plantar fasciitis."	Multicenter study with relatively small N and meaningful dropout. Data do no support treatment.
Huang 2010 RCT	6.0	N = 50 chronic unilateral plantar fasciitis	Botulinum toxin A 50 units vs. saline placebo under ultrasound guidance.	BTX-A vs. placebo 0, 3 weeks, 3 months. VAS (0-10): 5.9/3.4/2.0 for BTX-A group vs. 5.4/5.1/5.2 for placebo, p <0.001. Plantar fascia thickness (mm): 5.5/4.2/3.6mm for BTX-A vs. 5.5/5.6/5.6mm for placebo, p <0.001.	"[T]reatment of unilateral plantar fasciitis with [BTX-A] led to significant pain relief and a reduction in the plantar fascia thickness 3 weeks and 3 months post-injection."	No details for allocation, drop-out, co-interventions, and baseline chronicity of condition. Data suggest benefit from botulinum toxin A for chronic plantar pain. Ultrasound guidance vs. injection at point of maximal tenderness not addressed.

Elizondo-Rodriguez 2013 RCT No sponsorship or COI.	4.5	N = 40 with heel pain at insertion of plantar fascia or in anteromedial tuberosity of calcaneus having failed conservative treatment for 3 months. Mean age: Botox Group 41.6 years; Steroid Group 44.5 years.	Group A: botulinum toxin A 250 U (n = 19) vs. Group B: steroid injection, 2% lidocaine 2mL and 8mg dexamethasone 2mL (n = 17) Both groups received stretching exercises and attended 6 visits. Follow-up at 15 days following treatment and at 1, 2, 4, and 6 months.	Mean±SD VAS initial visit/final visit Group A vs. Group B: 7.1± 1.75 vs. 7.7±1.32 (NS)/1.1±1.50 vs. 3.8± 1.15 (p = 0.0005). Mean±SD Maryland Foot Ankle Score initial visit/final visit: 62.1±9.84 vs. 60.0± 11.87 (NS)/94.4± 10.64 vs. 79.2±14.96 (p = 0.0001). Mean±SD Foot and Ankle Disability Index score initial/final: 75.4±6.92 vs. 77.0±3.20 (NS)/95.0±7.27 vs. 83.0±6.41 (p = 0.000004). Mean±SD American Orthopaedic Foot and Ankle Society score initial/final: 46.0±14.83 vs. 46.8± 11.2 (NS)/ 93.2±9.31 vs. 74.8±10.29 (p = 0.00000006).	"[A] combination of BTX-A applications into the gastroc-soleus complex and plantar fascia stretching exercises yielded better results for the treatment of plantar fasciitis than intralesional steroids."	Data suggest Botox may be superior to steroids for treatment of plantar fasciitis. Results are seen early and persisted through the study period.

Evidence for the Use of Injected Glucocorticosteroids for Plantar Fasciitis
There are 6 moderate-quality RCTs incorporated into this analysis. There is 1 low-quality RCT in the appendix.(226) (Lynch 98)

Author/Year Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments
Glucocorticosteroid Injection vs. Placebo						
Crawford 1999 RCT	7.5	N = 106 with heel pain	Prednisolone acetate (25mg) plus 1ml of 2% lignocaine vs. 25mg prednisolone	Mean heel pain scores at baseline/1/3/6 months for local anesthetic alone: 5.5±2.1/4.0±2.9/3.7±	"A steroid injection can provide relief from heel pain in the short term. A single	Large drop-out rate, 48% at 6 months. Patients allowed to continue co-interventions

			acetate plus 1ml of 2% lignocaine given after a tibial nerve block vs. 2ml of 1% lignocaine hydrochloride vs. 2ml of 1% lignocaine hydrochloride given after a tibial nerve block; 6-month follow-up.	3.3/ 3.3±2.7. Corticosteroid plus LA plus tibial nerve block: 5.5±2.1/4.5±2.6/3.4±2.7/ 2.5±3.2. Corticosteroid and LA: 5.6±2.3/2.9±2.5/ 3.6±2.8/ 2.4±2.6. Local anesthetic plus tibial nerve block: 5.8±2.8/5.3±2.9/ 3.1±2.7/ 0.6±1.1. Outcomes favor steroid at 1 month (p = 0.02).	steroid injection does not offer a therapeutic benefit in the long term. There appears to be no increase in patient comfort from anaesthetizing the heel prior to infiltration."	although analysis controlled for co-variates. Statistical methods and analytical approach not specified. Data suggest glucocorticosteroid injection modestly superior to placebo.
Blockey 1956 RCT	6.0	N = 22 heels in 19 with pain in 1 or both heels	Hydrocortisone acetate 25mg injection vs. saline.	Steroid vs. saline group: relief at 1 week: 4/13 vs. 1/9. Relief at 2 months: 6/13 vs. 4/9. No statistical analysis provided but author states not significant.	"Hydrocortisone acetate may be the best substance to inject, but its advantage over saline has not been proved in this series."	Randomization, allocation methods unclear. Baseline comparisons not provided. All subjects given heel cups. One-hundred percent follow-up although at variable number of months for final visit (6-18 months). Small sample size. Data suggest no benefit from 25mg hydrocortisone, which may have been a suboptimal dosage.
Kalaci 2009 RCT	5.5	N = 100 with plantar fasciitis	Group A: 2mL autologous blood only vs. Group B: anesthetic (2mL of lidocaine) combined with peppering vs. Group C: corticosteroid (2mL of triamcinolone)	Pain in affected heel on a 10cm VAS at 6 months (mean ± SD): Group A (3.53±3.06) vs. Group B (3.40±2.88) vs. Group C (1.52±2.14) vs. Group D (0.96±1.24). All improved from baseline (p = 0.000),	"[C]orticosteroid injection with peppering can be used as a first alternative in plantar fasciitis in cases in which other conservative	Data suggest steroids appear equally effective with and without peppering from presented data. No placebo arm.

			only vs. Group D: corticosteroid (2 mL of triamcinolone) combined with peppering. Triamcinolone salt and dose not specified. 6-month follow-up.	C+D more effective than A+B (p <0.05). No difference between C+D. Modified roles and Maudsley score at 6 months: Group C, excellent and good 20/25; Group D, excellent and good 22/25, p = 0.24.	methods failed."	
Glucocorticosteroid Injection vs. Other Treatments						
Porter 2005 RCT	6.5	N = 132 plantar fasciopathy present for at least 6 weeks; follow-up at 3 and 12 months	Low-energy ESWT vs. intralesional corticosteroid injection. ESWT - 3 applications of 1000 pulses 0.08/mm2 flux density; Injection of 5.7 mg betamethasone (salt not specified) into maximal tender point.	VAS Scores at 0, 3, 12 months post treatment CSI: 5.47(2-8), 1.48 (0-7), 0.84 (0-7); ESWT: 5.52(3-8), 3.69 (0-8), 0.84 (0-4) p<0.05 at 3 months only favoring CSI TT (tenderness threshold, 0,3,12 months); CSI: 5.3(1-11), 9.42(7-11), 9.6 (7-11); ESWT: 5.2(3-7), 3.69(0-8), 9.54 (5-11); p>0.05 for all measurements	"Once plantar fasciopathy has persisted for more than 6 weeks, intralesional corticosteroid injection is more effective than ESWT within the first 3 months with regard to pain and tenderness, but at 12 month follow-up, there is no difference between the 2 treatments."	Randomization methods unclear. All had stretching as co-intervention. No true placebo included (compared with non-enrolled subjects). Effects of CSI appear short term. Inclusion criteria for most ESWT studies include failure of conservative treatment. In this case it was 1st line therapy.
Kriss 2003 RCT	4.5	N = 76 unilateral heel pain	Soft anti-pronatory pad vs. steroid injection (20mg triamcinolone hexacetonide) vs. both; 6-month follow-up period.	Mean difference in VAS Week 0, 1, 4, 8, 12, 24 (injection vs. injection plus pad vs. pad): Baseline: 76.1 vs. 66.3 vs. 71.7 p = 0.1; Week 1: -51.5 vs. -36.5 vs. -18.4 p = 0.001; Week 4: -65.3 vs.-49.3 vs. -20.3 p = 0.001; Week 8: -65.0 vs. -52.1 vs. -30.9 p = 0.05; Week 24: -63.7 vs. -61.3 vs. -50.6 p = 0.1. Difference in pain relief between 2 steroid groups and pad-only group stayed statistically	"Patients had significant and immediate pain relief following injection. This was maintained for the 6-month trial period. Orthoses also alleviate symptoms but within this trial group the benefit is delayed."	Randomization and baseline comparability unclear. No blinding. Analysis of between steroid groups not presented statistically. Data suggest benefit of injection compared with pad.

				significant for 4 months.		
Glucocorticosteroid Injection by Palpation vs. Imaging						
Yucel 2009 RCT	4.5	N = 35 heels in 27 patients with plantar fasciitis	Palpation guided (pg) 31.4% vs. ultrasound guided (ug) 42.9% vs. scintigraphy guided (sg) 25.7%. Using betamethasone dipropionate 3.215mg; 25-month follow-up.	VAS values – before treatment: ug (5.6±2.5), pg (6.4±2.7), sg (4.9±2.0); after treatment: ug (1.3±1.2), pg (2.2±2.5), sg (0.8±1.0). Plantar fascia, fat pad thickness, fascial echogenicity of groups: thickness before injection (mm): ug 4.2, pg 5.4, sg 3.5; fat pad thickness (mm) before injection: ug 6.9, pg 8.3, sg 8.7. Significant difference between ug and pg for plantar fascia thickness before injection, p = 0.017.	"All three methods were effective in the treatment of plantar fasciitis, and there was no statistically significant difference between these techniques in terms of plantar fascia thickness, fat pad thickness, and VAS value."	Randomization, allocation methods unclear. Baseline difference in outcome measures (plantar fascia thickness, fat pad thickness). Data suggest no difference between injection techniques. No placebo arm.

Evidence for the Use of Platelet Rich Plasma for Plantar Fasciitis
There are no quality trials evaluating the use of platelet rich plasma injections for plantar fasciitis.

Evidence for the Use of Cryosurgery for Plantar Fasciitis
There are no quality trials incorporated into this analysis.

Evidence for the Use of Intracorporeal Pneumatic Shock Therapy for Plantar Fasciitis
There is 1 high-quality RCT incorporated into this analysis.

Author/Year Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments
Dogramaci 2010 RCT	8.5	N = 50 clinically and radiologically confirmed plantar fasciitis	Intracorporeal pneumatic shock wave (IPST) vs. sham.	VAS ESWT vs. sham (0, 3 weeks, 6 months) 8.92 vs. 9.12, 2.60 vs. 5.04 p = 0.000, 2.04 vs. 7.16 p = 0.000; excellent/good vs. acceptable/poor	"Pneumatic lithotripter may be used safely and effectively in the treatment of chronic PF as an alternative to SWT devices	Chronic patients assessed at 3, 6 months. No mention of control for co-interventions. Data suggest highly effective treatment in small population. All

				92% vs. 24% (p <0.001).	before considering the surgery."	had radiographic spurs. Further studies needed to generalize for PF without spurs.

Evidence for the Use of Percutaneous Bone Fenestration for Plantar Heel Pain
There are no quality trials incorporated into this analysis.

Evidence for the Use of Surgery for Plantar Fasciitis
There are no quality trials incorporated into this analysis.

Evidence for the Use of Patient Education and Temperature Monitoring
There are 4 moderate-quality RCTs incorporated into this analysis. (Lavery 07; Lincoln 08; Corbett 03; Borges 08) There is 1 low-quality RCT in the Appendix. (Donohoe 00)

Author/Year Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments
Lavery 2007 RCT, multicenter trial Sponsored by the National Institute of Diabetes and Digestive and Kidney Diseases, National Institutes of Health. No mention of COI.	6.0	N = 173 with diabetic foot ulceration. Age range 40 – 80 years.	Standard therapy group: lower extremity evaluation by physician every 8 weeks, an education program about foot complications and self-care practices, and therapeutic insoles and footwear (n = 58) vs Structured foot exam group: standard therapy in addition to training to conduct a structured foot inspection twice a day using a mirror to see	Significant difference in times to develop ulcers (p = 0.011). Enhanced therapy significantly different from both standard therapy (p = 0.0059) and structured foot exam (p = 0.0055). Trend of survival better in enhanced therapy than standard therapy or structured foot exam (p = 0.0107). Decrease in risk of developing foot ulceration in enhanced therapy group (8.5%) vs. standard therapy	"Infrared temperature home monitoring, in serving as an "early warning sign," appears to be a simple and useful adjunct in the prevention of diabetic foot ulcerations."	Enhanced therapy group had fewer ulcers than other 2 groups and the other groups were 4 and 5 times more likely to develop ulcers.

			bottom of foot (n = 56) vs Enhanced therapy group: digital infrared thermometer to measure and record temperatures on each foot (n = 59). Follow-up for 15 months.	group (OR 4.48 [95% CI: 1.53–13.14], p = 0.008) and structured foot exam group (4.71 [1.60 – 13.85], p = 0.0061). Enhance therapy group contacted nurse due to foot problems than standard therapy (p = 0.030) or structured foot exam groups (p = 0.026).		
Lincoln 2008 RCT Sponsored by Diabetes UK. No COI.	6.0	N = 172 with diabetes and recently healed foot ulcers. Mean age 63.5 [12.1] years in the intervention group and 64.9 [10.9] years in control group.	Intervention group: education program (n = 87) vs Control group: usual care (n = 85). Follow-up 6 and 12 months.	At 12 months, intervention group followed more foot care behaviours vs. control group (median score: 42.0 vs. 38.7, p = 0.03). No significant difference in ulcer incidence at 6 (intervention 30%, control 21%) and 12 months (intervention 41%, control 41%).	"Even though the intervention was associated with improved foot care behaviour, there was no evidence that this programme of targeted education was associated with clinical benefit in this population when compared with usual care. The usefulness and optimal delivery of education to such a high-risk group requires further evaluation."	No apparent benefit in one on one eduction in prevention of diabetic foot ulcers.
Corbett 2003	4.5	N = 40 with type 2 diabetes.	Educational intervention: foot care education (n =	At baseline, risk for lower-extremity ulceration was	"A brief, individualized educational intervention	Pilot study. Sparse methodolog y and

RCT, prospective Sponsored by the AADE Education and Research Foundation and Carl M. Hansen Foundation/ Intercollegiate College of Nursing. No mention of COI.		Age range 26 – 91 years.	20) vs Control group (n = 20). Follow-up for 6 and 12 weeks.	high. Foot risk score 1.88 at baseline, 1.97 at 6 weeks, 1.87 at 12 weeks. At 12 weeks, intervention group had greater foot care knowledge (p = 0.029) and improved self-care practices (p = 0.007) vs. control group. At 12 weeks, intervention group improved significantly in self-efficacy (p = 0.014), reported foot self-care practices (p = 0.003), and foot care knowledge (p = 0.007).	about standard foot care topics improved patients' foot care knowledge and self-efficacy as well as reported self-care practices. Incorporating such interventions into routine home care services may enhance the quality of care and decrease the incidence of lower-extremity complications. ”	baseline comparability. Relatively small sample size.
Borges 2008 RCT No mention of sponsorship or COI.	4.0	N = 167 with type 2 diabetes who lived in a predominantly Mexican American community. Mean age 61.5 (11.4).	Intervention Group: 15-min intervention designed to improve diabetes self-efficacy and foot self-care behaviors (n = 55) vs Risk Assessment Group: 5-min foot risk assessment using a monofilament (the LEAP Abbreviated Diabetes Foot Screen), designed to encourage patients' involvement in assessing their feet (n = 55) vs	Significant increase of the foot self-care knowledge score after follow-up within control group (p < 0.05). Diabetes self-efficacy scores high at baseline and remained high after follow-up in all groups. There was a significant increase of diabetes self-efficacy score within control group (p < 0.05) and risk assessment group (p < 0.001). Baseline diabetes self-efficacy correlated with	“Recommendations for foot care education to prevent foot pathology indicate that the intervention should be simple, relevant, consistent, and repeated. Brief interventions delivered as patients interact with the health care system offer an opportunity for such interventions. The	Significiant difference regarding foot self care behaviors between groups at 1 month follow-up suggested that a brief eduction intervention may lead to increased preventive diabetic behaviors.

			Control group: Usual care (n = 57). Follow-up for 1 month.	self-reported foot self-care behaviors at baseline (p < 0.001) and follow-up (p < 0.05). Significant increase of self-reported foot self-care behaviors within intervention group (p <0.01) and control group (p < 0.05). Significant difference in observed self-care behavior scores between groups (p < 0.05). Applying lotion between toes was significant difference between groups (p < 0.01). Significant difference in item of checking bottom of foot (p < 0.05).	willingness of patients and emergency department staff to participate in the intervention and follow-up suggests that interventions delivered in this environment are not a burden."	

Evidence for the Use of Wound Dressings
There is 1 high (Sibbald 12) and 4moderate-quality RCTs (Jeffcoate 09; Jude 07; Trial 10; Piaggesi 10) incorporated into this analysis. There are 3 low-quality RCTs in the Appendix. (Veves 02; Jacobs 08; Shukrimi 08)

Author/Year Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments
Foams						
Sibbald 2012 RCT No mention of CO or Sponsorship.	8.5	N = 45 with leg and foot ulcers. Mean±SD age was 55.8±13.13 years.	Polyhexamethylene biguanide (PHMB) foam dressing (n=22) (vs. non-antimicrobial foam (n = 23). Follow-up 5 weeks.	Bacteriology at week 4 (polymicrobial organisms): detected in 5.3% of wounds treated with PHMB foam dressing vs. 33% control foam, p = 0.04).	"PHMB foam dressing successfully reduced chronic wound pain and bacterial burden."	Pilot RCT suggesting PHMB significantly decreased wound bacterial burden (p = 0.016) at 4 weeks

						compared to foam alone.
Jeffcoate 2009 RCT No mention of sponsorship or COI.	7.0	N = 317 with type 1 or type 2 diabetes with a chronic full - thickness foot ulcer, for at least 6 weeks and over age 18 or mean age was 60 years.	N-A or a non-adherent, knitted, viscose filament gauze (n = 106) vs. Inadine or an iodine-impregnated dressing both traditional dressings (n = 108) vs. Aquacel a newer product or hydrocolloid preparation (n = 103). Follow-up for 24 weeks.	At 12 weeks, incidences of healing for 3 dressings were; N-A/Inadine/and Aquacel; 25.5%/ 29.6%/and 28.2%. At week 24, number of ulcers managed in each group; N-A/Inadine/ and Aquacel; 30%/ 50%/55%. Overall healing rates for 3 dressings were: N-A/Inadine/and Aquacel; 39%/44%/ and 45%.	"As there was no difference in effectiveness, there is no reason why the least costly of the three dressings could not be used more widely across the UK National Health Service, thus generating potentially substantial savings."	Large sample size. High dropouts. Data suggest no difference in healing rates.
Jude 2007 RCT E.J. has received speaker's fees, research funding and fees for organizing education from ConvaTec.	6.0	N = 134 with non-ischaemic diabetic foot ulcer resulting from Type 1 or 2 diabetes mellitus or DM, all wounds ≥1cm^2. Mean age in AQAg and CA group; 58.9 ± 1.6 / and 61.1 ± 11.4.	AQAg, AQUACEL® Hydrofiber® dressing group, with 1.2% ionic silver left in place for up to 7 days (n = 67) vs. CA or Algosteril® calcium alginate dressing group, instructed to moisten it before use on dry wounds and to change daily (n = 67). Follow-up for 8 weeks.	Healing efficacy; primary end-point, healing speed, similar in AQAg-dressed and CA-dressed wounds; AQAg, (p = 0.993). 21 in AQAg group healed vs 15 in CA during 8 weeks. Wound infection; median time for clinical infection to resolve without recurring for AQAg and CA: 9 days for eight (88.9%) AQAg-resolved infections and 15 days, (p = 0.35) for 10 (76.9%; p = 0.48) CA-resolved infections. Safety; Of AQAg	"When added to standard care with appropriate off-loading, AQAg silver dressings were associated with favourable clinical outcomes compared with CA dressings, specifically in ulcer depth reduction and in infected ulcers requiring antibiotic treatment."	Ulcer depth was significantly decreased in Hydrofiber group compared to CA group (p = 0.04) but other outcome measures did not show statistical significance.

				patients, 25 (37%) experienced 1 or more adverse events, vs 26 (39%) of CA patients.		
Trial 2010 RCT No mention of sponsorship or COI.	5.5	N = 42 with locally infected chronic wounds, one of which is diabetic foot ulcers. The mean age was 68.9 for women and 66.5 for men.	Askina Calgitrol Ag or test dressing consists of a proprietary ionic silver alginate matrix and an absorbent polyurethane foam layer (n = 20) vs. Algosteril standard silver-free alginate dressing controlled and sustained over 72 hours (n = 22). Follow-up for 1 and 15 days.	Diabetic foot ulcers in 29% of participants. Chronic wounds: pressure ulcers (57%) or venous or mixed aetiology leg ulcers and diabetic foot ulcers (29%); few acute wounds (14%). Clinical scores of infection decreased significantly in both groups at day 15, 3.8± 2.9 in Askina Calgitrol Ag, (p = 0.001) vs 3.8 ±3.4 in Algosteril group, (p = 0.007). No adverse events recorded during study.	"The regression of local signs of infection, local tolerance, acceptability and usefulness were similar for the two dressings."	Similar efficacy between groups. Short follow-up. Dissimilar baseline data. Relatively small sample size (n = 42).
Piaggesi 2010 RCT Supported by a nonrestricted research grant from Oculus Innovative Sciences, manufacturers of Dermacyn Wound	4.0	N = 40 patients with diabetic ulcers greater than 5 cm2 area; Mean age was 62.05 years.	Group A treated with daily instillation of Dermacyn Wound Care (DWC) solution in amounts varying from 5-20mL (n = 20) vs. Group B-received same medication with povidone iodine diluted 50% with saline. Followed up weekly for 6 months or until	Healing rate (complete closure) at 6 months: 90% in Group A vs. 55% in group B (p = 0.002). Average healing time 10.5 weeks in Group A vs. 16.5 weeks in Group B (p = 0.007). Duration of antibiotic therapy significantly shorter in Group A vs. Group B; 10.1 weeks vs.	"The data from this study permit the observation that DWC should be considered as part of the integrated therapeutic approach in all the cases of infected DF ulceration, alongside surgery, systemic antibiotics, and revascularizatio	Data suggest faster healing.

Care. No COI.			complete closure of lesion.	15.8 weeks (p = 0.016).	n when needed."	

Evidence for the Use of Negative Pressure Therapy (Vacuum Devices)
There are 6 moderate-quality RCTs incorporated into this analysis. (Blume 08; Armstrong 12; Vuerstaek 06; Lavery 14; Armstrong 05; Moues 04) There is 1 low-quality RCT in the Appendix. (Mars 08)

Author/Year Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments
Blume 2008 RCT No mention of sponsorship or COI.	7.0	N = 341 with diabetes a stage 2 or 3 calcaneal, dorsal, or plantar foot ulcer ≥ 2 cm^2. Mean age of 58 years.	Negative pressure wound NPWT therapy or vacuum-assisted closure (n = 172) vs. Advanced moist wound therapy or AMWT, predominately hydrogels and alginates (n = 169). Follow-up at 3 and 9 months.	NPWT group significantly greater for complete ulcer closure vs AMWT group; 73/169 [43.2%] vs. 48/166 [28.9%], (p = 0.007). Fewer amputations observed in NPWT group or 4.1% vs AMWT group or 10.2%, (p = 0.035). Home care therapy days to total therapy days for NPWT was 9,471 of 10,579 (89.5%) vs 12,210 of 12,810 (95.3%) for AMWT.	"NPWT appears to be as safe as and more efficacious than AMWT for the treatment of diabetic foot ulcers."	Total wound closure in NPWT group 43.2% vs. AMWT 28.8% at 112 days.
Armstrong 2012 RCT, multicenter, prospective Sponsored by Spiracur, Inc. COI, two authors (DGA and WAM) have received research funding from both	6.5	N = 132 with noninfected, nonischemic, nonplantar lower extremity diabetic and venous wounds. Mean age of 65.0 ± 14.2 in the SNaP and 65.6 ± 15.6 in the VAC group.	The ultraportable mechanically powered Smart Negative Pressure (SNaP) Wound Care System vs Electrically powered Vacuum-Assisted Closure (VAC) Therapy System. Follow-up for 4, 8, 12, and 16 weeks.	SNaP group demonstrated non-inferiority vs. VAC group at 4, 8, 12, and 16 weeks: -33.08± 68.46 vs. -23.73± 76.51 - 44.62±78.35 vs. -40.7±85.28/-49.52± 78.94 vs. -39.56± 111.13/-52.91 ± 77.40 vs. -42.73±111.13; (p = 0.0030,	"[T]his study provides prospective, randomized controlled trial evidence that treatment of wounds with a mechanically powered NPWT device results in similar wound healing outcomes as treatment with an electrically	Similar efficacy between groups at all time points up to 16 weeks. Mean use devices: SNAP 10.2 minutes vs. VAC 18.22 minutes.

Spiracur, Inc. and KCI.				0.0130, 0.0051, and 0.0044).	powered NPWT device with what appears to be less impact on patient's quality of life."	
Vuerstaek 2006 RCT Sponsored by the Dutch department of Kinetic Concepts, Inc. (KCI). No COI.	5.5	N = 60 with chronic leg ulcers of >6 months duration. Age for SWC/VAC groups:23 (77)/ 23 (77).	Vacuum-assisted closure (VAC) group applied to wound during preparation stage, permanent negative pressure of 125mmHg exerted (n = 30) vs. Therapy or SWC group, conventional wound care techniques (n = 30). Follow-up for 12 months.	Treatment by VAC associated with significant faster time to complete healing, HR = 3.2; 95% CI, 1.7 – 6.2, (p < 0.000) and preparation time HR = 2.4; 95% CI, 1.2 – 4.7, (p < 0.01). Secondary outcome: median recurrence rate at month 4 (95% CI, 0.7 – 7.4) after VAC therapy vs. month 2 (95% CI, 0.5 – 3.6) in control group, (p = 0.47).	"V.A.C. therapy should be considered as the treatment of choice for chronic leg ulcers owing to its significant advantages in the time to complete healing and wound bed preparation time compared with conventional wound care."	VAC significantly better in complete wound healing compared to conservativ e group (median time 29 days vs. 45 days, p = 0.0001).
Lavery 2014 RCT No mention of Industry Sponsorship . COI, Dr. Lavery has research grants from KCI, Osirus, Health Point, ThermoTek, Integra, GlaxoSmith Kline, ConvaTec,	5.0	N = 40 with diabetic foot wounds, age 21-90 years, surgical lower extremity wounds, and ankle-brachial indices > 0.70. Mean±SD age 70.5±7.4 years (75mmHg) and 51.3±12.7 years (125mmHg).	Negative-pressure wound therapy with 75-mmHg continuous pressure with a silicone-covered dressing (75 mmHg) vs. 125mmHg with a polyurethane foam dressing. Both devices changed 3x/week. Follow up to 4 weeks or until surgical closure.	Mean±SD wound area and volume: 20.10±14.33cm2 (125mmHg) vs. 34.61±32.92cm2 (75mmHg), p = 0.08. No differences were found between treatments.	"[T]here was no difference in outcomes in wounds treated with low pressure (75 mmHg) with a silicone-coated interface and high pressure (125 mmHg) with a polyurethane foam interface."	Pilot study. No non-negative pressure group. Small sample size (n = 40). Similar efficacy between groups at 4 weeks.

and Innovative Therapies, Inc. He is on speaker's bureau for Shire, KCI, and Innovative Technologies and a consultant/ advisor for Innovative Therapies and Pamlab, L.L.C. He has stock ownership in Diabetica Solutions and Prizm Medical and holds patents with Diabetica Solutions.						
Armstrong 2005 RCT Sponsored by KCI USA. COI, two authors (DGA and LAL) have received research funding from KCI.	5.0	N = 162 patients with diabetic partial foot amputation wounds up to transmetatarsal level and evidence of adequate perfusion. Also corresponding to grade 2 or 3 of the University of Texas Diabetic Foot Wound Classification system. Mean age 59 (12.8).	Negative pressure wound therapy (NPWT) group (n = 77) received Vacuum-Assisted Closure (VAC) and dressing changes every 48 hours vs. Control group (n = 85) received dressing changes only everyday unless authorized by clinician. 16 week study, follow-ups at day 7, 14, 28, 42, 56, 84, and 112.	Patients within the NPWT group (56%) showed faster healing results than control group (39%). In wound closure 0.1702 (95% asymptotic CI (0.0184-0.322) when comparing NPWT to control group. Complete wound closure higher in NPWT than control group (p = 0.005). Wounds healed by surgical closure higher in NPWT at 40% than control group at 30%. Overall, VAC system	"In conclusion, our results indicate that NPWT as delivered through the VAC Therapy System seems to be a safe and effective treatment for complex diabetic foot wounds. Treatment with NPWT resulted in a higher proportion of wounds that healed, faster healing rates, and potentially fewer re-amputations than with standard	132/162 patients male. Proportional healing at 12 and 16 weeks similar. More frequent dressing changes in usual care group (QD vs. Q 48hrs), which may bias in favor of usual care. NPWT group had more complete and faster wound

				helped to reduce risk of second amputation in NPWT than in control group.	treatment. Future work should look at the effect of rapid healing on cost efficacy, length of hospital stay, and effectiveness, as well as quality of life."	healing vs. conventional treatment at 16 weeks and fewer amputations. High dropout rate.
Mouës 2004 RCT Sponsored in part by Plastic & Reconstructive Surgery Esser foundation, "Vereniging Trustfonds Erasmus University Rotterdam," and KCI International, Houten, the Netherlands.	4.0	N = 54 with full-thickness wound that could not be closed immediately because of infection, contamination, or chronic character. Mean age for VAC and Conventional group: 47.7± 9.6 / and 47.9±17.0.	Vacuum-assisted closure or VAC-therapy included polyurethane foam dressing with pore size of 400–600 mm (n = 29) vs. Treatment by conventional moist gauze therapy two times a day or more (n = 25). Follow-up for 20 days.	"Ready for surgical therapy" for VAC group 6.00±0.52 days (median±SEM) vs 7.00±0.81 days for conventional moist-treated wounds (p = 0.19). Wound surface reduction area was larger in VAC-treated group vs conservative group, (p < 0.05).	"In conclusion, this study shows a positive effect of vacuum-assisted closure therapy on wound healing, expressed as a significant reduction of wound surface area."	VAC group showed decrease in wound surface area 3.8±0.5%/day vs. conventional treatment group of 1.7±0.6 percent/day.

Evidence for the Use of Total Contact Casting
There is 1 moderate-quality RCT incorporated into this analysis. (Lavery 14)

Author/Year Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments
Lavery 2014 RCT	4.5	N = 73 with diabetes mellitus and grade UT1A or UT2A (University of Texas Ulcer Classification System) forefoot ulcer, no age information presented.	Shear-reducing cast walker (n = 27) vs. healing sandals (HS) with 8-mm Plastazote insole (n = 23) vs. total contact casts, TCCs, (n = 23) 12 week study. Follow-up every 7-10 days.	Mean±SD time to heal (weeks) HS vs. TCC vs. shear walker: 8.9±3.5 vs. 5.4±2.9 vs. 6.7±4.3 (p <0.001 TCC vs. HS). Mean±SD daily steps HS vs. TCC vs. shear walker: 4022±4652 vs.	"[P]atients treated with TCCs had the highest proportion of healed wounds and fastest healing time."	Diabetic population studied. Total contact cast associated with fastest healing time.

				1447±1310 vs. 1404±1234 (p = 0.014 HS vs. TCC, p = 0.007 HS vs. shear walker). Wounds healed per-protocol analysis HS vs. TCC vs. shear walker: 50.0% vs. 88.9% vs. 40.0% (p = 0.015 TCC vs. HS).		

Evidence for the Use of Growth Factors
There are 17 moderate-quality RCTs incorporated into this analysis. (Blume 11; Wieman 98; Niezgoda 05; Steed 06; d'Hemecourt 98; Hardikar 05; Bhansali 09; Fernandez-Montequin 09; Uchi 09; Viswanathan 06; Kusumanto 06; Lyons 07b; Fife 07; Brgido 06; Reyzelman 09; Purandare 07; Kakagia 07) There are 7 low-quality RCTs (Steed 95; Landi 03; Huang 14; Akbari 07; Eginton 03; Landsman 10; Richard 95) and 1 other study (Lyons 07) in the Appendix.

Author/Year Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments
Becaplermin						
Blume 2011 RCT No mention of sponsorship. COI: GAM501 and FCG are products in development by Cardium Therapeutics Inc., Lois A. Chandler is an employee of and owns stock options in Cardium Therapeutics, Inc. Robert L.	7.0	N = 129 patients with Wagner Classification Grade 1 cutaneous lower extremity ulcer between 1.5 and 10.0cm^2; mean age 56.9 years.	GAM501 Group-Ad5PDGF-B (Becaplermin) combined with Formulated Collagen Gel-Sub group, one treated at week 1, group 2 treated at weeks 1 and 4. Data analysis combined both groups (n = 72) vs. Formulated Collagen Gel (FCG) Group-Sub group, one treated at week one, group two treated at weeks 1 and 4. Data analysis	No significant difference for ulcer closure incidences between groups 31% in SOC, 45% in FCG and 41% in GAM501 (p >0.05). All groups showed significant increase in cumulative wound healing rates (decrease in radius of ulcer) from week 2 on compared to baseline. FCG showed a significant decrease in radius size vs. SOC from day 1 to week 1; 1.97 mm/week vs. 0.78 mm/week (p <0.05) and from day 1 to week 2;	"We conclude from this exploratory trial that a single application of GAM501 or FCG increases the healing rate of neuropathic DFUs for the first two weeks after treatment; whereas SOC with weekly visits seems to have a much smaller and delayed effect on wound healing rate."	At 1 week GAM501 and Formulated Collagen Gel improved healing rates vs. standard of care control.

Engler is a Consultant to and owns stock options in Cardium Therapeutics. Barbara K. Sosnowski is a named inventor of an applicable patent and currently an employee of Pfizer. Other authors were principal investigators and have no financial relationship with Cardium Therapeutics.			combined both groups (n = 33) vs. Standard of Care (SOC) Group (n = 19). Follow-up for 12 weeks.	1.37 vs. 0.63 (p <0.05). GAM501 did not show significant differences compared to SOC.		
Wieman 1998 RCT No mention of sponsorship. COI: T.J.W has served as a member of an advisory group for and has received research support and honoraria for speaking from Johnson & Johnson. TJW, JMS	6.5	N = 382 patients with type 1 or 2 diabetes and chronic low-extremity ulcers; mean age 58 years.	Becaplermin Gel 30 group: 30µg/g of 0.01% Regranex gel (n = 132) vs. Becaplermin Gel 100 group: 100µg/g of 0.01% Regranex gel (n = 123) vs. Placebo Group- Identical to vehicle component of gel with active drug, however it was saline. (n = 127). Follow-up for 20 weeks.	The 100 group showed a 50% incidence of complete healing at week 20 vs. 35% in placebo (p = 0.007) and 36% in the 30 group (p <0.05). The 100 group also showed a significantly decreased time to achieve complete healing vs. placebo; 86 days vs. 127 days (p = 0.013).	"Becaokernub gel 100 µg/g, in conjunction with good wound care, significantly increased the incidence of complete wound closure and significantly reduced the time to complete closure of chronic diabetic neuropathic ulcers."	Phase 3 trial suggesting becaplermin 100µg/g associated with better wound healing than placebo or beclaplermin 30µg/g.

and YS hold stock in Johnson & Johnson.						
Niezgoda 2005 RCT No mention of sponsorship or COI.	5.5	N = 90 patients with at least 1 diabetic foot ulcer; mean age 57.6 years.	OASIS Wound Matrix Group: an acellular biomaterial derived from pig small intestine submucosa in combination with standard care. (n = 50) vs. Regranex Group-Regranex with a secondary dressing and standard care. (n = 48). Follow-up for 12 weeks.	At 12 week follow-up 18 (49%) in OASIS group were considered healed vs. 10 (28%) patients in Regranex group (p = 0.055). In subgroup analysis, OASIS showed a significantly higher number of healed ulcers vs. Regranex for Plantar Ulcers; 14 (52%) vs. 3 (14%) (p = 0.14) and for Type 2 Diabetes; 12 (63%) vs. 8 (29%) (p = 0.034). There were 17 Complications/Adverse Events in OASIS group vs. 10 in Regranex group (p >0.05).	"In this study, OASIS was as effective as Regranex Gel in treating full-thickness diabetic foot ulcers and appears to be a viable treatment option for these patients."	Open label, unblinded. Wound care differed between groups. Baseline comparability in DM differed of unclear significance. Substantiation of blinding unclear. Patients followed up to 12 weeks, and given option of cross-over treatment if healing did not occur. Significantly more patients in OASIS group (49%) had type 1 diabetes than in Regranex Gel group (22%) (p = 0.018).
Steed 2006 RCT No mention of sponsorship or COI.	5.5	N = 118 with chronic, full-thickness, lower-extremity diabetic neurotrophic ulcers of at least 8 weeks.	PDGF group-rhPDGF-BB (Becaplermin) gel applied at dose equivalent to 2.2 micrograms until completely healed, or 20	Healing rates in gel group vs. placebo group at 6 weeks: 29 (48%) vs. 14 (25%); p = 0.01). Median reduction in wound area gel vs. placebo group:	"PDGF applied once daily was effective in healing chronic diabetic neurotrophic foot ulcers when used in conjunction with good wound care."	High dropout rate. PDGF effective vs. placebo for healing ulcer rate.

		Pooled from 10 centers. Mean age not provided.	weeks (n = 61) vs. Placebo Gel Group- Saline Gel (n = 57).	98.8% vs 82.1%; p = 0.09.		
d'Hemecourt 1998 RCT No mention of sponsorship or COI.	5.0	N = 172 patients with type 1 or 2 diabetes and chronic lower extremity diabetic ulcers. All received sharp debridement of ulcer; mean age 58.3 years.	Wound Care Group- good wound care alone – Sharp debridement of ulcers to remove calluses, fibrin and necrotic tissue (n = 68) vs. NaCMC Group- good wound care plus NaCMC gel (n = 70) vs. Becaplermin Group- 100µg/g of 0.01% Regranex gel plus good wound care (n = 34). Follow-up for 20 weeks.	22% of Patients in the wound care alone group achieved complete wound closure at 20 weeks compared to 36% of NaCMC group and 44% of the Becaplermin group. Mean time to achieve complete closure was 85 days in the Becaplermin group, 98 days in the NaCMC group and >141 days in the wound care group. P-values not given.	"In conclusion, the results presented here demonstrate that treatment with NaCMC gel does not impact wound healing negatively; NaCMC gel may have a beneficial effect on wound healing when compared with good wound care practice alone in patients with chronic diabetic ulcers of the lower extremity."	High dropout rate. P-values not provided and statistics not clear whether there was a significant relationship or not. Appears to show comparable results.
Hardikar 2005	5.0	N = 111 with type 1 or 2 diabetes mellitus, 18-80 years, <3 full-thickness chronic neuropathic ulcers of at least 4 weeks duration on lower extremity (Stages III-IV). Mean±SD age 54.5±9.9 (placebo group) and	Placebo gel (n = 58) vs. rhPDGF-based gel (n = 53). Both used 1.5mm layers of gel and covered with moist saline gauze. Dressings changed daily. Follow-up for 20 weeks.	Complete healing (achieving a functional score of 1) reported at end of 10 weeks: 71% (39/55) rhPDGF group vs.31% (18/58) placebo group, p <0.001). At 20 weeks: 85% (47/55) vs. 53% (31/58), p <0.05.	"[T]he efficacy assessed at 10 weeks in the present study showed that rhPDGF-based gel healed a greater percentage of patients and also healed patients faster and caused a greater reduction in the ulcer size than placebo."	Pragmatic RCT. Treatment administration not standardized. At 10 weeks, (39/55), 71% of rhPDGF had complete ulcer healing compared to (18/51) 31% in the placebo group. At 20 weeks, (47/55) 85% had

		54.7±9.0 years (treatment group).				complete ulcer healing compared to 31/58 (53%) in the placebo group.
Bhansali 2009 Prospective RCT No mention of sponsorship. No COI.	4.5	N = 20 patients with at least one neuropathic plantar ulcer of Wagner's grade ≥2; mean age 50.6 years.	Platelet-derived growth factor group (PDGF): A rh-PDGF-BB (Becaplermin) 0.01% Regranex gel (n = 10) vs. Standard Wound Care group (SWC) moist saline used (n = 10). Follow-up at 30, 60, 90, 120 and 150 days.	Mean duration of healing target ulcers 50.10 days in PDGF group and 86.10 days in SWC group; a 41.8% reduction in favor of PDGF group (p <0.02). Ulcers completely healed by 90 days in PDGF group vs. 120 days in SWC group (p <0.05). Reduction of size of ulcer did not show significant difference between groups.	"In conclusion, the results of this study suggest that within the setting of TCCoff-loaded patients with diabetic neuropathic large plantar ulcers, short-term use of rh-PDGF-BB gel reduced the time to complete healing considerably compared to SWC."	Small sample size (n = 20). Baseline wound size not comparable. Short-term use of PDGF-BB gel associated with increased wound healing vs. SWC by 30 days.
Autologous-derived growth factors						
Uchi 2009 RCT Supported by Kaken Pharmaceutical Co. Ltd. No mention of COI.	6.5	N=150 with non-ischaemic diabetic ulcers measuring ≤900 mm^2.	Placebo group (n = 51) vs. 0.001% bFGF group (n = 49) vs. 0.01% bFGF group (n = 50). Follow-up for 8 weeks.	Area of ulcer decreased by ≥75%: 57.5% (27/47) vs. 72.3% (34/47) vs. 82.2% (37/45) in the placebo, 0.001% bFGF and 0.01% bFGF groups, respectively (p = 0.025 between the 0.01% bFGF and placebo groups).	"The findings obtained in this trial showed wound healing accelerating effects of bFGF on diabetic ulcers."	Data suggest a dose-response relationships suggesting potential efficacy.
Fernandez-Montequin 2009 RCT Sponsored by The Ministry of Public Health of Cuba.	6.5	N = 149 with Wagner's grade 3 or 4 diabetic foot ulcers (DFUs). Age ≥18 years old.	Group I received rhEGF 75µg, 3 times per week (n = 53) vs. Group II received rhEGF 25 µg, 3 times per week (n = 48) vs. Group III or placebo	Ulcer closure occurred in 41 (77.4%), 25 (52.1%) and 27 (56.2%) from I, II and group III, respectively, (p = 0.018). The granulation tissue covering ≥50% of ulcer at 2	"It was concluded that recombinant human EGF (rhEGF) local injections offer a favourable risk–benefit balance in patients with advanced DFU."	Wagner's 3 or 4. High dropouts. Data suggest efficacy.

C.V.S. and P.A.L.S. are employees of the Centre for Biological Research, .B.A. works at CIGB itself and is author of patent that sustains project. J.I.F.M. is also coauthor.			administrated together with standardized good wound care, 3 times per week (n = 48). Follow-up for 3, 6 and 12 months.	weeks; achieved by 19/48 controls vs 44/53 in 75µg group, OR = 7.5; 95% (CI) 2.9-18.9 vs. 34/48 in 25µg group, OR = 3.7, 1.6-8.7.		
Viswanathan 2006 RCT Sponsored by Bharat Biotech International Limited. No mention of COI.	5.0	N = 60 with target ulcers no less than 2 cm and no more than 50 cm2 in area. Ages of 18 and 65 years.	Treatment group or rhEGF 30-g tubes twice daily until wound healed or until end of study (n = 30) vs. Placebo tubes water based and did not include active ingredient, twice daily (n = 29). Follow-up for 15 weeks.	90% of ulcers healed in 15 weeks vs. 22 weeks in the control group. Chances of non-healing within 15 weeks 14% in test group and 50% in control. Those with an ulcer area >6 cm in test group exhibited better healing vs. control (p <0.002).	"This phase III multicenter study established the safety and efficacy of rhEGF formulated gel and found the gel healed diabetic foot ulcers faster than treatment with placebo."	Phase 3 trial. Study group exhibited quicker healing times compared with placebo.
Kusumanto 2006 RCT Sponsored by Fornix BioSciences. No mention of COI.	5.0	N = 54 with diabetic foot ulcers and/or rest pain >2 weeks, failure of conventional treatment, serious limb ischemia, type 1 or 2 diabetes; Mean age 68.4 for control group and 68.7 for phVEGF group.	Control group (n = 27) vs. Vascular endothelial growth factor (2000 µg; $phVEGF_{165}$) treatment group (n = 27). Both groups received their allocated treatment at baseline and 28 days. Assessments at baseline, 7,	At final assessment, phVEGF group had significantly higher percentage of hemodynamic improvement and improvement in skin ulcer vs. control group; hemodynamic – 33% vs. 6%, (p = 0.05). Ulcer improvement – 33% vs. 0%, (p = 0.01).	"[W]e did not meet the primary end point of a reduced amputation rate. We did, however, demonstrate that intramuscular injections of the naked plasmid DNA encoding VEGF165 (phVEGF165) significantly improved wound healing and reduced	Longer ulcer duration in controls (5 vs. 3 months). No difference in amputations . Some data favor growth factor.

			14, 35, 42, 72 and 100 days.		hemodynamic insufficiency compared with placebo. Importantly, in the responders these clinical improvements resulted in improved physical functioning (mobility, and daily activities such as washing, dressing, and cleaning) and improved social functioning as detected by the RAND-36 questionnaire for QOL. Therefore "response" as defined in this study seems to be a meaningful notion."	
Lyons 2007 RCT Sponsored by Agennix, Inc. and the National Institute of Arthritis and Musculoskeletal and Skin Diseases of the National Institute of Health.	5.0	N = 46 with diabetes mellitus HbA_{1C} 6-13%, 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 0.5 to 10 cm^2, transcutaneous oxygen	2.5% Talactoferrin gel group (n = 15) vs. 8.5% Talactoferrin gel group (n = 15) vs. Placebo gel group (n = 16). Groups instructed to apply gel twice daily to ulcer for 12 weeks alongside typical wound care. Assessments at baseline, 30 days, 90 days and 180 days.	50% of participants in treatment groups reduced ulcer size ≥75% compared to 25% of participants in placebo group, approaching significance (p = 0.091). No statistically significant differences reported between varying percentages of talactoferrin gel.	"[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 2-same article as above. Small samples. High dropouts. Data suggest no differences in healing during treatments – modest differences appeared later.

		tension ≥30mm Hg or ankle-brachial index ≥0.7; Mean (±SD) age 58 (±10) for 2.5% gel group, 53 (±15) for 8.5% gel group and 56 (±14) for placebo gel group.				
Fife 2007 RCT Sponsored by Chrysalis BioTechnology Inc., Galveston, TX, a spinout of UTMB, Galveston. Dr. Carney's research related to this technology are monitored and managed by UTMB Conflicts of Interest Committee.	5.0	N = 60 with diabetic foot ulcers. Median age for the saline placebo, 1, and 10mg groups were 54.7, 59.6, and 53.7.	1 mg Chrysalin® twice weekly for up to 20 weeks or until ulcer reached complete closure, Bandages removed during twice-weekly visits for evaluation (n = 20) vs. 10mg Chrysalin® twice weekly for up to 20 weeks (n = 18) vs. Saline twice weekly for up to 20 weeks (n = 21). Follow-up for up to 20 weeks.	ITT population, 61% (11/18) of ulcers treated at 10mg dose achieved complete closure vs 52% (11/21) in 1mg dose and 48% (10/21) in saline-treated group. In PP population, incidence of complete ulcer closure was 57% (8/14) for 10mg dose, 45% (5/11) for 1mg dose and 33% (5/15) in saline placebo. Median time to 80% closure of 32 days for 10mg dose, 47 days for 1mg dose, and 57 days for saline control.	"These results indicate the potential safety and efficacy of Chrysalin® for treatment of diabetic foot ulcers."	Phase 1/2 study report. High dropouts. Data suggest efficacy.
Reyzelman 2009 RCT Supported by Wright Medical Technology,	4.5	N = 86 patients with diabetes and University of Texas (UT) grade 1 or 2 ulcer. Mean	Study Group-received single application of human acellular dermal regenerative tissue matrix graft (n = 47)	There was a significantly higher rate of complete ulcer closure in study group compared to control group; 32/46 69.6% vs. 18/39 46.2% (p =	"The results of this prospective, randomised, multicentre study indicate that diabetic foot ulcers treated with AM	Data suggest efficacy.

Inc. (Arlington, TN). Support included compensation to study personnel, providing AM therapy at no charge and statistical analysis. DGA and Orthopaedic Research & Reporting, Ltd received research funding from Wright Medical Technology, Inc.		Age was 56.3 years.	vs. Control Group: standard wound care management (n = 39). Follow-up for 12 weeks.	0.0289). No significant difference between groups for time it took to completely heal; 5.7 weeks vs. 6.8 weeks (p >0.05).	therapy have a two to three times higher probability of healing compared with those with standard of care management."	
Brigido 2006 RCT No mention of sponsorship or COI.	4.5	N = 28 diabetic patients with full-thickness wounds for at least 6 weeks. Mean age for Graftjacket / and Debridement group: 61.43 (7.18) / 66.21 (4.37).	A single application of Graftjacket tissue matrix, plus mineral oil-soaked fluff compression dressing (n = 14) vs. Control treatment of wound gel with gauze dressings (n = 14). Follow-up for 16 weeks.	12/14 patients treated with Graftjacket were healed by 16 weeks and only 4/14 patients in the control group. Average time to heal 11.92 weeks and 13.50 weeks for control group. Final ulcer area / depth / volume and number of ulcers healed in favor of Graftjacket, (p ≤0.001).	"Patients with chronic ulcers of various aetiologies who were treated with Graftjacket, a human acellular regenerative tissue matrix, showed a statistically significant higher percentage of wound closure by week 16 than the patients treated with sharp debridement only."	Pilot study. Data suggest efficacy.
Kakagia 2007 RCT No mention of	4.0	N = 54 diabetics with foot ulcers, or soft tissue defects, present >3 months;	Promogran only group (n = 18) vs. Autologous growth factors group (n = 18) vs. both Promogran	Both promogran and autologous growth factors treatment group demonstrated significantly greater reduction in all dimensions	"[W]e have shown that dressing nonhealing diabetic foot ulcers with modulators of the wound	Data suggest combination therapy superior and no differences between

sponsorship or COI.		Mean (±SD) age 58 (±10) for group A, 57 (±12) for group B and 61 (±9) for group C	and autologous growth factors group (n = 18). All groups received treatment for 8 weeks. Assessments at baseline and 8 weeks.	of wound compared to other two groups, (p <0.001).	environment in combination with the administration of autologous growth factors significantly accelerates the healing rate. It is suggested that rebalancing of the wound microenvironment by using dressings that inhibit proteases should initiate the repair process and increases the healing potential of autologous growth factors."	individual treatments.
Purandare 2007 RCT No mention of sponsorship or COI.	4.0	N = 50 patients with diabetic foot ulcers greater than 4 cm in diameter. Mean age was 56.29 years	Group A: Study drug (Tinospora cordifolia) administered in prepackaged numbered bottles for 1 month (n=25) vs. Group B- Placebo- same timeline with same medical treatment as well (n = 25). Follow-up for 3 months.	Seventeen patients in study group improved (73.9%) compared to 13 patients in the placebo group (59.1%), this difference was not significant between groups (p = 0.292). There was no significant difference between group A and B for mean change in wound severity score; 14.39 vs. 10.59 (p = 0.149), or change in mean ulcer depth; 2.17 vs. 1.36 (p = 0.096).	"Diabetic patients with foot ulcers on T. cordifolia as an adjuvant therapy showed significantly better final outcome with improvement in wound healing. Reduced debridements and improved phagocytosis were statistically significant, indicating beneficial effects of immuno-modulation for ulcer healing."	Sparse data. Non-significant results.

Evidence for the Use of Granulocyte Colony-stimulating Factor
There are 4 moderate-quality RCTs incorporated into this analysis. (Kastenbauer 03; Gough 97; DeLalla 01; Yonem 01)

Author/Year Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments
Kästenbauer 2003 RCT No mention of sponsorship or COI. Amgen Austria provided funding for Neumann who assisted in monitoring and analyzing the study.	6.5	N = 37 diabetic patients with moderate sized (diameter 0.5 – 3 cm) infected neuropathic (abnormal 10g-monofilament test) foot ulcer of Wagner's grade 2 or 3. Mean age G-CSF 60.8±11.1 years, placebo 58.2±8.1 years.	G-CSF 5µg/kg injected subcutaneously, stopped if neutrophil count >50.000/l and leukocyte count >75.000/l (n = 20) vs. placebo, 0.9% sterile saline injected subcutaneously (n = 17) for a 10 day in-hospital stay. All patients put on bed rest and treated with i.v. antibiotics (clindamycin and ciprofloxacin) until inflammation improved.	Mean±SD leukocyte count ($10^9 xL^{-1}$) at day 10: G-CSF 40.8±16.3 vs. placebo 9.3±8.3 (p = 0.00005).	"[A]ntibiotic and non-weight-bearing therapy (bed rest) accelerated the resolution of cellulitis in infected foot ulcers. Additional treatment with G-CSF had no further beneficial effect."	Small sample size. G-CSF associated with pathogen reduction faster than placebo leading to earlier resolution of cellulites.
Gough 1997 RCT No mention of sponsorship. COI, Gough was supported by a grant from Amgen Ltd, CA, USA.	6.0	N=40 diabetic patients with extensive cellulitis (acute spreading skin infection with involvement of subcutaneous tissues, characterized by erythema in association with purulent discharge with or without lymphangitis). Mean age G-CSF 65	G-CSF: initial dose of 5µg/kg daily and then lowered to 2.5µg/kg daily after 2 doses if neutrophil count higher than $25x10^9$/L and stopped if neutrophil $>50x10^9$/L (n = 20) vs. placebo, saline (n = 20) daily as an injection for 7 days. All patients received 4 antibiotics (ceftazidmine, amoxicillin, flucloxacillin, and	Median time to hospital discharge (days): G-CSF 10 vs. placebo 17.5 (p = 0.02). Median time to resolution of cellulitis (days): G-CSF 7 vs. placebo 12 (p = 0.03). Median time to withdrawal of intravenous antibiotics (days): G-CSF 8.5 vs. placebo 14.5 (p = 0.02). Median time to negative swab culture (days): G-CSF 4 vs. placebo 8 (p = 0.02).	"This study showed that in diabetic patients with foot infection G-CSF treatment significantly accelerated resolution of cellulitis, shortened hospital stay, and decreased antibiotic requirements."	Small sample size. G-CSf shortened hospital stay, accelerated wound healing (cellulitis), and decreased antibiotics. The mechanism may be related to increases in neutrophil superoxide production.

		years, placebo 66 years.	metronidazole) intravenously until cellulitis and ulcer discharge resolved. Patients followed until resolution of infection and discharge from hospital.			
De Lalla 2001 RCT No mention of sponsorship or COI.	4.5	N = 40 adult diabetic patients with limb-threatening infection (full-thickness ulcer, >2cm of cellulitis with or without lymphangitis, bone or joint involvement, and systemic toxicity). Mean age G-CSF 56.6±8.6 years, control group 59.8±9.6 years.	Conventional treatment: local treatment (debridement, daily inspection, cleaning with sterile water, disinfection with povidone iodine, surgical removal of necrotic tissues, and occlusive dressing of foot lesions, oral ciprofloxacin 750mg 2x/day plus clindamycin 300mg 4x/day) plus systemic antibiotic therapy (n = 20) vs. conventional treatment plus systemic antibiotic therapy plus glycosylated recombinant human granulocyte colony-stimulating factor (G-CSF) subcutaneously 263µg daily for 21 days (n = 20). Assessments weekly first 21 days and every	NS between groups for bacterial species or number of isolates per species. Mean±SD neutrophill counts: G-CSF 25,200±3,500 vs. control 6,500±4,400 cells/mm^3 (p=0.002). Amputations at 9 weeks: G-CSF 3 vs. control 9 (p=0.038)	"[T]he administration of G-CSF for 3 weeks as an adjunctive therapy for limb-threatening diabetic foot infection was associated with a lower rate of amputation within 9 weeks after the commencement of standard treatment."	Relatively small sample size. Comparable results in, both conventional therapy and G-CSF group. At 6 months the G-CSF group had fewer amputations (3) vs. (9) in the conventional treatment group.

			2 weeks for 6 weeks following. Follow-up for 6 months.			
Yönem 2001 RCT No mention of sponsorship or COI.	4.5	N = 30 diabetic patients with pedal cellulitis or Wagner's grade 2 or less lesion on their feet. Mean age G-CSF group 60.3+1.3 years, standard group 61.0±1.4 years.	Standard treatment: local wound care and parenteral antibiotherapy, ciprofloxacin and metronidazole intravenously (n = 15) vs. G-CSF 5µg/kg subcutaneously daily and stopped if neutrophil count >45x10^9/l in addition to standard treatment (n = 15). Patients were followed until hospital discharge.	Mean±SD neutrophil count post-treatment: G-CSF group 48700±1000 vs. standard group 4800±300 (p <0.001).	"Although G-CSF improves neutrophil function as well as increasing the absolute numbers, this improvement is not associated with shortening of duration of antibiotic administration, duration of hospital stay or need for amputation in diabetic foot infection"	Small sample size (n = 30), appears to lack efficacy GCSF increased neutrophil counts but was not associated with decreased antibiotic administration or shortened hospital stays.

Evidence for the Use of Prostacyclin Analogues (Iloprost)
There is 1 low-quality in the Appendix. (Sert 08)

Evidence for Low-Molecular Weight Heparins
There is 1 exploratory RCT incorporated into this analysis. (Rullan 08)

Author/Year Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments
Rullan 2008 RCT Supported by the Primary Health Care Management of Mallorca (Ib-Salut), Carlos III	8.0	N = 70 patients with diabetes and with a foot ulcer persisting for >3 months. Mean age 64.5 years.	Bemiparin Group-Administered at 3500 IU/day for first 10 days followed by 2500 IU/day for 3 months (n = 37) vs. Placebo Group: 0.2mL of isotonic saline administered for	Ulcer improvement rates at 3 months were significantly higher in the Bemiparin group compared to the Placebo group; 26/37 70.3% vs. 15/33 45.5 %, (p = 0.035). There was not a significant	"[T]his exploratory trial provides a 'proof of concept' of the potential usefulness of bemiparin in the treatment of diabetic foot ulcers."	"Exploratory trial." Data suggest efficacy.

Health Institute (RedIAPP network RD06/0018), Ministry of Health, Public Health Research Fund (FIS) (grant PI: 02/1704) and Laboratorios Farmacéuticos Rovi, S.A., Spain. No COI.			3 months (n = 33). Follow-up for 3 months.	difference between the two group for complete healing rates Bemiparin vs. Placebo; 35.1% vs. 33.3% (p=0.874). In the subgroup of Wagner grade II ulcers Bemiparin showed a significantly higher rate of complete healing compared to placebo; 50% vs. 0% (p=0.047).		

Evidence for the Use of Complementary and Alternative Medications
There are 3 low-quality RCTs in the Appendix. (Leung 08; Larijani 08; Bahrami 08)

Evidence for the Use of Hyperbaric Oxygen
There is 1 moderate-quality RCT incorporated into this analysis. (Londahl 10) There are 2 low-quality RCTs in the Appendix. (Wang 09; Duzgun 08)

Author/Year Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments
Löndahl 2010 RCT Sponsored by Thelma Zoegas Foundation, Region Skane Foundation and medical faculty of Lund University. No COI.	7.5	N = 94 with grade 2, 3, or 4 Wagner rated ulcers below foot lasting >3 months, diabetes, previous treatment at diabetes foot clinic <2 months; Mean age 69 for HBOT group; 68 for placebo group.	HBOT (100% O^2, 5min compression, 2.5 atmospheres 85 min., 5min decompression) vs. hyperbaric air treatments 5 days/week for 8 weeks. Treatment adjunctive to infection treatment, revascularization, off-loading, metabolic control.	Ulcer healing in 25/48 (52%) HBOT vs. 12/42 (29%) in sham group, p = 0.03. Sub analysis of those completing >35 sessions showed HBOT vs. placebo group healing at 1 year: 61% vs. 27%, (p = 0.009).	"…[A]djunctive treatment with HBOT facilitates healing of chronic foot ulcers in selected patients with diabetes."	Sham hyperbaric air. Data suggest NNT 3-4 to prevent non-healing ulcer with HBO.

Evidence for the Use of Extracorporeal Shock Wave Therapy

There are 3 low-quality RCTs in the Appendix. (Moretti 09; Wang 09; Petrofsky 10)

Evidence for the Use of Skin Grants
There are 11 moderate-quality RCTs incorporated into this analysis. (Edmonds 09; Hanft 02; Sams 02; You 12; Caravaggi 03; Uccioli 11; Gentzkow 96; Pollak 97; Veves 01; Han 10; Caputo 08) There are 2 low-quality RCTs in the Appendix. (Martson 03; Moustafa 07)

Author/Year Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments
Tissue Engineered Skin Grafts						
Edmonds 2009 RCT No mention of sponsorship. COI: Author has been reimbursed by Organogenesis, Inc., manufacturer of Apligraf Bi-Layered Cell Therapy, Bi-Layered Cell Therapy for attending conferences, and received honoraria for providing clinical expertise in meetings with regulatory agencies.	6.0	N = 82 patients with ulcer of neuropathic origin; mean age 58.7 years.	Apligraf group: Apligraf placed directly on base of target ulcer (n = 40) vs. Control Group-standard therapy, treated with same primary and secondary dressings as apligraf group (n = 42). Follow-up for 12 weeks.	There were more Apligraf patients who did not a have debridement at week 1; (p = 0.001), and after week 4; (p = 0.0273). Shorter wound healing time in Apligraf group compared to control group; (p = 0.059). At 12 week follow-up 51.5% of Apligraf group had complete closure compared to 26.3% in control group (p = 0.049).	"The overall results suggest that Apligraf, in combination with debridement, standard wound care, and offloading, should be considered in treating patients with nonhealing neuropathic diabetic foot ulcers."	Open label 1:1 prospective study.
Hanft 2002 RCT Sponsored by Advanced	5.0	N = 46 patients with type 1 or 2 diabetes and a plantar foot ulcer on the	HFDD group-application of Dermagraft at baseline and up to 7 additional applications	28 patients (14 each group) with ulcers of >6 weeks duration. HFDD group significantly	"The result s of this study suggest that the Dermagraft product is a	Wound closure significantly better in HFDD group

Tissue Science, Inc. No mention of COI.		heel or forefoot; Mean Age; not provided.		throughout study (n = 24) vs. CT group- Control group with standard dressing application (n = 22). Follow-up for 12 weeks.	greater number of complete wound closure vs. control group; 10 (71.4%) vs. 2 (14.3%) (p = 0.003). Time to complete wound closure significantly faster in HFDD group vs. control (p = 0.004).	safe and effective treatment for diabetic foot ulcers that are greater than 6 weeks' duration."	(71.4% vs. 14.3%, p = 0.003) and time to wound closure was better.
Sams 2002 RCT Supported by Organogenesis, INC. No mention of COI.	4.0	N= 22 patients diabetes and foot ulcer longer than 2-weeks in duration; mean age 53.6 years.		Graftskin group: graft contoured to ulcer base during surgery (n = 9) vs. Control: aggressive debridement, dressing change 2x/day, custom-made tridensity pressure-relieving footwear (based on ADA recommended treatment for diabetic ulcers (n = 8). Follow-up for 6 months (weekly first 12 weeks).	No statistically significant differences between groups. Graft skin group showed complete healing in 56% of patients at 12 weeks compared to 38% in the control group. There were no significant differences between groups in baseline ulcer history. No significant adverse events were attributable to either treatment group.	"Graftskin application appears to reduce healing time in difficult to heal diabetes-related neuropathic foot ulcers. The ease of application is exceptional. In our study, no serious side effects were associated with Graftskin."	17 treated due to 5 failing screening process after randomization. Small sample size (n = 17).
Allogeneic karatinocytes vs. vaseline gauze							

You 2012 RCT No mention of COI. Sponsorship, supported by grants from Tego Science (Seoul, Korea).	6.0	N = 59 type 1 or 2 diabetes, foot ulcer >1.0cm2 that did not exhibit healing for 6 weeks, Wagner grade 1 or 2, and transcutaneous oxygen pressure ≥40mmHg. Mean±SD age 63.5±9.0 years (treatment) and 62.4±9.4 years (control).	Keratinocyte group (n = 27) vs. vaseline gauze (n = 32). Follow-up weekly until wound closure or week 12.	Mean percentages of wound area reduction: 100±0 vs. 85±65% in treatment and control groups, Respectively, p <0.05. Complete wound healing: 85% of keratinocyte-treated group vs. 59% of control group, p<0.05.	"These results indicate that cultured allogeneic keratinocytes may offer a safe and effective treatment for diabetic foot ulcers."	No ITT analysis conducted. Keratinocyte group achieved 100% ulcer healing compared to control group (59%) at 12 weeks, p <0.005.
Other Skin Graft						
Caravaggi 2003 RCT Supported by a grant from Fidia Advanced Biopolymers. No mention of COI.	5.0	N = 79 patients with diabetic foot ulcer either plantar or dorsal; Mean Age not reported.	Autologous graft treatment: patients received autologous fibroblasts on Gyalograft3D which was grafted onto ulcer (n = 43) vs. Control Group treated with nonadherent paraffin gauze and scheduled	At final follow-up 65.3% in treatment group showed complete healing vs. 49.6% in control group (p = 0.191). In dorsal subgroup, treatment group showed significantly higher odds ratio (95% CI) for complete healing vs. control; 4.44 (1.09-17.7, p =	"The results of this clinical study clearly show that the use of total offloading is so important to the tissue repair process in plantar ulcers that the efficacy of fibroblasts on Hyalograft3D and keratinocytes	Open label. Data suggest improved healing in dorsal ulcers compared to standard care.

			for same treatment as graft group (n = 36). Follow-up for 11 weeks.	0.037). Mean healing time 63 days in treatment group vs. 77 days in control group (p >0.05).	on Laserskin cannot be differentiated from control techniques."	
Uccioli 2011 RCT Supported by Anika Therapeutics srl. No COI.	4.0	N = 160 patients with a diabetic ulcer without signs of healing for one month. Mean Age; not reported.	Treatment Group- Hyalograft 3D autograft, 2 weeks later, laserskin autograft was applied (n = 80) vs. Control Group- nonadherent paraffin gauze with secondary dressing (n = 80). Follow-up for 12 weeks.	No significant difference between treatment and control for ulcer healing at 12 weeks; 19 (24%) vs. 17 (21%) (p = 0.85). Mean time to complete healing not significant between groups; 50 vs. 58 days (p = 0.253). A 50% reduction in ulcer area achieved significantly sooner in treatment vs. control; Mean 40 days vs. 50 days (p = 0.018). No significant differences in adverse events between groups.	"[T]he results demonstrate the safety and effectiveness of autologous skin substitutes in the hard-to-heal diabetic dorsal foot ulcer population. The results permit the suggestion that such bioengineered substitutes are potentially useful in patients with hard-to-heal diabetic dorsal ulcers"	Pragmatic, open study. High dropout rate. Baseline comparability of initial ulcer size is different between the groups. Data suggest moderate efficacy.
Dermagraft						
Gentzkow 1996 RCT	5.0	N = 50 patients with Diabetic foot ulcers; Mean	Group A: One piece of dermagraft applied weekly	Complete closure was significantly higher in group A compared to the	"This study has provided pilot evidence of	Significant difference in mean age

No mention of sponsorship. COI: GDG and SDI are employed by and hold stock in Advanced Tissue Sciences, Inc. DPS, SJL, JJP, JJR and KSH receive funds from Advanced Tissue Sciences, Inc. for their participation as clinical investigators using Dermagraft to treat diabetic foot ulcers.		Age was 61.4 years.		for a total of 8 pieces (n = 12) vs. Group B- two pieces of Dermagraft applied every 2 weeks for a total of 8 pieces and 4 applications (n = 14) vs. Group C: One piece of Dermagraft applied every 2 weeks for a total of 4 pieces (n = 11) vs. Group D: Control group, conventional therapy and wound-dressing (n=13). Follow-up for 12 weeks.	control group; a, b, c, d respectively, 50% vs. 21.4% vs. 18.2% vs. 7.7% (p = 0.03 for A vs. D). Median time for complete wound closure was 12 weeks in Group A and >12 weeks in the remaining groups. Median closure time in Group A vs. Group B (p = 0.056). Median time to 50% closure was 2.5 weeks in group A compared with >12 weeks in group D (p = 0.0047).	effectiveness and has defined which treatment regimen should be used for pivotal studies of dermagraft as an active wound-healing agent for diabetic foot ulcers."	between groups. Potential randomization failure due to differences in baseline comparability. Control groups depicts duration of ulcers 37 weeks longer than in dermagraft group A and 46 weeks longer than group B and 44 weeks longer than group C.
Pollak 1997 RCT No mention of sponsorship or COI.	4.5	N = 281 patients with full-thickness diabetic ulcers of the plantar surface. Mean age was 55.4 years.		Control Group- Standard care with debridement, moist dressings and pressure relief (n = 142) vs. DG Group- Dermagraft added to ulcer with standard treatment (n = 139).	50.8% of patients in DG group showed complete wound healing at 12 weeks compared to 31.7% (p = 0.006). At week 32, DG group had a significantly higher healing.	"Thus, Dermagraft within the therapeutic range of metabolic activity, used in addition to a well-defined regimen of standard care, has been	At 12 weeks DG-TR group had more healed ulcers than control group (52% vs. 32%, p = 0.006). Time to healing for DG-TR group 13

			Primary follow-up for 12 weeks, secondary follow-up at 32 weeks.		demonstrated to provide significantly improved healing of diabetic foot ulcers compared to standard care alone.”	weeks vs. 28 weeks for control group. At week 32, DG-TR group sustained healing when compared to control group (58% vs. 42%), p = 0.04.
Apligraft						

Veves 2001 RCT No mention of sponsorship. COI: A.V. and V.F. are members of the Novartis advisory panel on Apligraf and have received honoraria for speaking arrangements from Novartis AF and Novartis AG, respectively. In addition, Organogenesis provided funds to laboratories of A.V. and V.F. to conduct studies on Apligraf. D.G.A. has accepted honoraria to speak on behalf of Novartis Pharmaceuticals	5.5	N=208 with type 1 or 2 diabetes and full-thickness neuropathic ulcers; mean age 57.1 years.		Graftskin Group: Graftskin applied after debridement directly over ulcer site and trimmed to fit ulcer. Graftskin could be reapplied from weeks 1-4 (n = 112) vs. Control Group-Standard care of American Diabetes Association, with complete dressing changes every week, and 2 secondary dressing changes 2x per day (n = 96). Follow-up at 1, 4 and 12 weeks.	Complete wound healing achieved in 63 (56%) of graftskin-treated patients compared with 36 (38%) control patients (p = 0.0042). Odds ratio (95% CI) of Graftskin compared to control was 2.14 (1.23-3.784). Median time to complete closure 65 days for graftskin which was significantly lower than 90 days in control group (p = 0.0026).	“In summary, in the present study we have shown, in a randomized prospective controlled fashion that weekly application of Graftskin for a maximum of 4 weeks results in a higher healing rate when compared with state-of-the-art currently available standard treatment and is not associated with any significant side effects.”	At 12 weeks, 56% of Graftskin groups achieved complete wound healing vs. 38% control group. There were twice as many amputations in the control group after 12 weeks.

Han 2010 RCT Sponsored by a grant of Korean Ministry of Knowledge Economy, Republic of Korea. No mention of COI.	4.5	N = 54 with diabetic foot ulcers >1.0cm2 that did not display signs of healing for 6 weeks. Mean age for treatment/ control group: 6.5 ±7.5/68.4 ± 8.7.		PLA cell treatment wound management and pressure off-loading, were set up to be identical for all (n = 28) vs. Control treatment only fibrinogen 0.3 – 1.0 mL + thrombin 0.3– 1.0mL, without cells, applied topically over debrided wounds (n = 26). Follow-up for 8 weeks.	Ulcer sizes of PLA group ranged between 1.2-7.6cm2 (mean area, 4.3±2.1cm2) with wound durations of 6-30 weeks (12.5±5.6 weeks). Ulcer size of control group ranged from 1.4-10.0cm2 (4.0 ±2.1cm2) with wound duration of 6-24 weeks (12.5±5.5 weeks). At 8 weeks, wound healing in 100% PLA cell-treated group and 16 (62%) in control, (p <0.05). Time for complete healing ranged from 17-56 days (mean, 33.8±11.6 days) in PLA cell-treated vs 28-56 days (42.1±9.5 days) in control, (p <0.05).	"In conclusion, uncultured PLA cell autografts stimulate the activity of diabetic fibroblasts and may offer a simple and effective treatment for diabetic ulcers."	Pilot study. Data suggest potential efficacy.

Caputo 2008 RCT Sponsored by Smith & Nephew Inc, Florida. No COI.	4.0	N = 41 with clinical signs of infection in the study ulcer. Mean age (range) 68.0 (33.0 – 95.0).	VERSAJETTM Hydrosurgery System (n = 22) vs. Conventional debridement with scalpel plus pulsed lavage (n = 19). Follow-up for 12 weeks.	At baseline median ulcer duration 1.2 months in both groups median surface area of 5.9cm2 and median area of devitalized tissue of 5.3cm2 in treatment group/surface area of 3.9cm2 and devitalized tissue of 3.7cm2. Wound closure between patients treated with Versajet vs conventional debridement (p = 0.733). At 12 weeks, wounds closed in 52.6% of Versajet group and 47.4% in controls.	"[T]he Versajet Hydrosurgery system is a quick and effective means of debriding lower extremity ulcers."	Ulcer size differed at baseline (5.9 v 3.9 cm^2) but favoring conventional. No difference in would closure rate. Versajet faster.

Evidence for use of Orthotics
There is 1 low-quality RCT in Appendix 2. (Hausdorff 08)

Evidence for the Use of Opioids for TTS

There are no quality studies evaluating the use of opioids for the treatment of pain from TTS.

Evidence for the Use of Phonophoresis
There are no quality studies evaluating phonophoresis for treating TTS patients.

Evidence for the Use of Return-to-work Programs for TTS
There are no quality studies incorporated into this analysis (see Chronic Pain guideline for additional studies).

Evidence for the Use of Ottawa Ankle and Foot Rules for Ankle Sprain
There is 1 moderate-quality RCT incorporated into this analysis.

Author/Year Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments
Nursing Assessment						
Derksen 2005 RCT	7.0	N = 106 ankle sprains	Application of Ottawa ankle and foot rules: specialized emergency nurse assessment (SEN) vs. house officer assessment (HO)	SEN group found indication of radiography in 60 (57%) of 106 patients vs. HO 69 (65%), p = 0.10. SEN vs. HO sensitivity of detecting fractures by means of OAR and OFR: 0.93 (CI 0.64-1.00)/0.93 (CI 0.64-1.00), p = 1.00. Specificity: 0.49 (CI 0.38-0.60)/0.39 (CI 0.29-0.50), p = 0.20. OAR and OFR overall results for lateral malleolus k = 0.30, medial malleolus k = 0.50, navicular k = 0.45, metatarsal vs. base k = 0.43.	"Specialized emergency nurses are able to assess ankle and foot injuries in an accurate manner with regard to the detection of acute fractures after a short, inexpensive course."	Randomized variable order of assessment. All patients assessed by both (quasi-cross over trial). Data suggest trained nurses are able to apply Ottawa rules.

Evidence for the Use of Education for Ankle Sprain
There are no quality studies incorporated into this analysis.

Evidence for the Use of Acetaminophen for Ankle Sprain
There is 1 high- and 1 moderate-quality RCTs incorporated into this analysis.

Author/Year Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments

Dalton 2006 RCT	8.5	N = 260 Grade I or II lateral ankle sprains	Acetaminophen Extended Release (1,300mg TID vs. ibuprofen 400mg TID) for mild and moderate acute ankle sprain.	No significant differences at 4 or 9 days on outcomes of pain on walking, ability to walk, swelling, bruising, ROM, satisfaction with treatment, negative anterior drawer, time to resume normal activity.	"Acetaminophen extended release 3,900 mg daily was comparable to ibuprofen 1,200 mg daily for treatment of grade I or II lateral ankle sprains. Both treatments were well tolerated."	Comparison is to OTC strength ibuprofen. Data suggest no difference in benefit for acute mild to moderate ankle sprain.
Kayali 2007 RCT	4.0	N = 100 1st or 2nd degree lateral ankle sprains within 48 hours of admission	Diclofenac sodium 75mg twice a day vs. paracetamol 500mg 3 times a day for 5 days for Grade I and II ankle sprains; follow-up 6 weeks.	Physician global mean assessment diclofenac sodium vs. paracetamol at Day 1, 10, and Week 6: 1.46±0.5 vs. 1.42±0.49, 3.18±0.5 vs. 3.14 ±0.53, 3.76±0.43 vs. 3.72± 0.45. ROM initial/last exam: 28.8°±9.3 vs. 30.2°±8.5 p = 0.43, 68.4°±3.1 vs. 67.6°±3.6 p = 0.03. No differences in swelling at any period.	"[D]iclofenac sodium and paracetamol are effective and well tolerated as a short term treatment alternatives for acute ankle injuries."	No placebo. Lack of randomization, allocation, baseline comparison and blinding details. Data suggest paracetamol is at least equivalent to NSAIDs for analgesia. No placebo arm.

Evidence for the Use of NSAIDs for Ankle Sprain

There are 4 high- and 14 moderate-quality RCTs incorporated into this analysis. (Lyrtzis 11) There are 4 low-quality RCTs in Appendix 2.(459-462) (Dupont 87; Fredberg 89; Aghababian 86; Andersson 83)

Author/Year Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments
NSAIDs vs. Placebo						

Slatyer 1997 RCT	8.5	N = 364 Australian Regular Army recruits with acute ankle sprains sustained during training	Piroxicam 40mg x 2 days, then 20mg x 5 days vs. placebo. 7-day trial with 6 month follow-up. All grades included.	Piroxicam vs. placebo "positive anterior drawer tests" Day 0, 3, 7, and 14 (%): 36/ 38 (χ^2 = 1.12, p = 0.57), 26/10 (χ^2 = 16.14, p = 0.001), 15/2 (χ^2 = 18.00, p = 0.001), 8/1 (χ^2 = 9.08, p = 0.001). VAS scores better Day 3, 7 (p <0.001). Subjects experiencing difficulty with activities at Day 14, 1 month, 3, and 6: p = 0.0001/ χ^2 = 50.58, p = 0.0001/ χ^2 = 88.02, p = 0.0001/ χ^2 = 64.96. p = 0.0001/ χ^2 = 16.90 favoring piroxicam.	"[N]onsteroidal anti-inflammatory agents should form an integral part of the treatment of acute ankle sprains."	Military training camp population. Clinical significance of improving positive anterior drawer sign unspecified. Study suggests benefits in pain scores at 2 weeks from NSAID but not in swelling. Suggests long-term benefit in reduction of difficulty with activities (difficulty in walking, running, jogging, forced march)
Ekman 2002 RCT	7.5	N = 445 Grade 1 or 2 ankle sprains within 48 hours and moderate to severe ankle pain	Celecoxib 200mg BID vs. ibuprofen 800mg TID vs. placebo, 10-day trial, Grade I, II sprains,	Patient global assessment 0-100 scale: celecoxib vs. placebo Day 4, 8, 11: 67 vs. 55 p <0.05, 82 vs. 72 p <0.05, 90 vs. 88 p = NS. Celecoxib vs. ibuprofen no differences between	"In managing acute ankle sprain- in providing pain relief and accelerating recovery, celecoxib 400 mg/day was	Randomization, allocation methods unclear. Study suggests both NSAIDs provide short-term benefit in weight-bearing pain,

			treated within 48 hours. Follow-up on Day 11.	groups. VAS weight bearing 0-100 scale: celecoxib vs. placebo Day 0, 4, 8, 11: 68.5 (14.1) vs. 71.3 (12.1), 35.3 (1.6) vs. 42.4 (1.6) p <0.05, 23.3 (1.8) vs.31.2 (1.8) p <0.05, 15.6 (1.8) vs. 19.9 (1.8) p = NS. Celecoxib vs. ibuprofen no differences between groups. Median return to normal function: celecoxib 5 days vs. ibuprofen 6 days vs. placebo 8 days, p = 0.001 for celecoxib vs. placebo, no difference between celecoxib and ibuprofen.	more effective as the maximum recommende d dose of ibuprofen (2400 mg/day)."	patient global assessment, and return to function over placebo acutely. Differences not significant after 1 week. Differences in clinical VAS scores of questionable significance.
Sloan Injury 1989 RCT	5.5	N = 122 acute ankle injuries within 6 hours of injury	Immediate ibuprofen (1,200mg loading, 2,400mg total per day) vs. placebo 1st 48 hours, than same ibuprofen schedule. Uniform background therapy of 20 minutes cooling, compression and elevation given to all patients using cooled anklet.	Immediate vs. delayed soft tissue swelling index: % improvement 49% vs. 37% p <0.01. Severity of injury: no data presented, favored immediate group p = 0.05; range of movement no differences; ability to bear weight no differences	"[I]mmediate medication with high-dose ibuprofen at 2400 mg/day should be considered in the routine treatment of moderate to severe ankle sprains, whether patients."	Patients treated within 6-hours. Study suggests immediate NSAIDs may be beneficial for immediate pain relief and swelling relief judged at 7 days vs. placebo.

Bahamonde 1990 RCT	5.5	N = 93 mild to severe sprained ankles	Diclofenac potassium 50mg TID vs. piroxicam 20mg vs. placebo (7-day trial) for acute ankle sprain (severity not specified, no torn ligaments).	Minimal statistical details provided. Volume of foot: no differences between 3 groups at 7 days. Pain at 2 days: lower VAS for diclofenac vs. placebo (p <0.0001) and piroxicam (p <0.0002). Differences continued to Day 3 vs. placebo, disappeared with piroxicam. Investigators assessment (excellent) higher for diclofenac p = 0.001.	"[D]iclofenac potassium was a good alternative to piroxicam for the treatment of stable (non-surgical) ligamentary injuries of the ankle, with a rapid onset of action and good overall tolerability by the patients."	Lack of randomization, allocation, compliance details. Suggests NSAIDs provide short-term benefit for acute sprains. Possible superiority of diclofenac vs. piroxicam at this dosage although conclusions limited by lack of presented data.
Dreiser 1993 RCT	5.0	N = 60 with symptoms and signs of traumatic distortion of the ankle	Nimesulide 100mg BID vs. placebo for acute ankle sprain.	Nimesulide vs. placebo (0-10) VAS at 0, 4, 8 days. Functional impairment: 2.7 vs. 2.8, 1.7 vs. 2.4 (p <0.01), 0.8 vs. 1.8 (p <0.001); Pain on passive movement: 2.6 vs. 2.7, 1.6 vs. 2.2 (p <0.01), 0.9 vs. 1.7 (p <0.001); Joint swelling: (units not specified) 19.3 vs. 21.8, 12.1 vs. 16.1 p >0.05, 5.7 vs. 5.7 p >0.05.	"Nimesulide 100 mg administered twice daily is an effective and safe short term treatment in the management of post-traumatic joint injuries."	Lack of randomization, allocation, baseline comparison, blinding details. Only included subjects with slight to moderate pain (>5 on 10 point VAS). Study suggests NSAIDs beneficial for pain relief over 8-day course for mild to moderately painful sprains. Clinical significance likely small.
Goldie 1974 RCT	4.0	N = 30 ankle sprains	Metopyramizol vs. phenylbutazone vs. placebo (dosages and schedule not stated), 7-day trial.	Mean improvement of foot volume: 60% metopyramizol vs. 51% phenylbutazone, vs. 56% placebo.	"The comparison between phenylbutazone and metopyramizol did not therefore yield any information as to the	Not clear if study was randomized. Sparse methodology details. Study suggests no benefit on ankle swelling. Conclusions limited by lack of methods details.

					preferred drug. The fact, however, that the reduction of swelling was the largest in the placebo group, might be an indication that Nature's own way in repair of tissue injury may be preferable to interference with drugs whose exact effect in the organism still remains unknown."	
Moran 1991 RCT	4.0	N = 60 ankle sprains suffering from moderate to severe inflammation and tenderness	Diclofenac Potassium 50 mg. t.i.d. vs. Ibuprofen 400 mg. t.i.d. vs. placebo for acute ankle sprain	Severity rating of 0 on Day 7 using 4-point scale: 0-none to 3 wincing and withdrawal) Diclofenac vs. ibuprofen vs. placebo: 12/20 vs. 8/21 vs. 1/19. p = 0.001, p = 0.004 respectively vs. placebo. Pain on passive movement rating of 0: 17/20 vs. 14/21 vs. 7/19 p <0.05 vs. placebo for both.	"[D]iclofenac potassium has been demonstrated to be effective in the treatment of acute ankle sprains."	Lack of randomization, allocation, baseline comparison, blinding details. Ibuprofen group appears to have had significant difference in baseline swelling. Data suggest NSAIDs may be superior to placebo for analgesia.
NSAIDs vs. Other Medications						
Petrella 2004 RCT	10.0	N = 397 acute 1st-degree or 2nd-degree ankle sprain	Celecoxib 200mg BID vs. naproxen 500mg BID, 7-day trial for acute Grade I, II sprains.	Mean VAS scores Day 4 and 8: celecoxib = 31.9±1.96/ 15.0±1.70, naproxen = 29.0± 1.91/15.3±1.65. Non-inferiority treatment differences (upper 95% CI) Day 4 (p = 0.1), and Day 8(p = 0.8). Patient global	"Celecoxib is as effective as naproxen in treating acute first-degree or second-degree ankle sprains but causes significantly	No placebo. Study suggests no difference in NSAID efficacy between Cox-2 inhibitor and naproxen.

				assessment Day 4 and 8 (%): celecoxib = 71%/89%, naproxen = 72%/90%. Celecoxib vs. naproxen AE of dyspepsia p = 0.032.	less dyspepsia."	
Ekman 2006 RCT	9.5	N = 829 acute 1st- or 2nd-degree ankle sprain	Valdecoxib 20mg once daily vs. valdecoxib 20mg twice daily vs. Tramadol 50mg 4 times daily vs. placebo for acute mild and moderate ankle sprain.	Valdecoxib 20mg bid vs. valdecoxib 20mg qd vs. tramadol 50mg 4 times vs. placebo. Patient global assessment good/very good: Day 4 no differences, Day 7 (76.4 vs. 67.3 vs. 59.6 vs. 55.5) p <0.001 for BID vs. placebo. APS questionnaire: 33.9 vs. 26.6 vs. 20.6 vs. 24.4 (p = 0.009 Day 4). Patient assessment of return to walking with/without pain Day 4 47.5/44.6/38.4/35.0) p = 0.002; Day 7 (79.4/72.5/ 67.3/63.9) p = 0.001. Tramadol treatment withdrawals due to adverse events vs. valdecoxib treatment (12.2% vs. 3.4%, p = 0.0005). Withdrawal rates due to adverse events similar in valdecoxib and placebo groups (3.4% vs. 2.4%, p = 0.75).	"…valdecoxib 20 mg bid was at least as effective as Tramadol 50 mg 4 times daily and significantly better than placebo."	Data suggest valdecoxib 20mg BID superior to placebo and trended towards better than tramadol for acute pain relief at Days 4 and 7. Data suggest no difference in tramadol and placebo at Day 4, with higher withdrawal rates in tramadol group.
Nadarajah 2006 RCT	9.5	N = 370 1st- or 2nd-degree ankle sprain ≤48 hours prior to1st dose of study	Celecoxib 200mg BID vs. diclofenac SR 75mg BID x 3 days for acute Grade I and II sprains.	VAS score on full weight bearing (celecoxib/diclofenac) : Day 4 (182/164) LS mean -0.8; final visit (188/177) LS mean -0.2.	"Celecoxib (400 mg loading, 200 mg bid) was as effective as diclofenac SR (75 mg bid)."	Study did not include a placebo group and allowed co-interventions of RICE, PT. Efficacy trial suggests no difference in two NSAIDs.

		medicatio n				
Lyrtzis 2011 RCT No COI or sponsor-ship.	7.0	N = 86 with acute Grade II sprains of the lateral collateral ligaments, age range 18 to 60	Group A, diclofenac, 75mg orally, twice a day, first 10 days (n = 42) Group B, paracetamol , 500mg, orally, 3 times a day (n = 44). All: RICE protocol, ankle bandage, for 10 days, elevation for first 3 days, start walking after 10 days. Follow-up: baseline, days 3 and 10.	Mean score for VAS pain scale: diclofenac vs. paracetamol: baseline/3rd day: 70.2/22.1 vs. 72.5/22.3, p < 0.001; baseline vs. baseline/10th day: 70.2/6.9 vs. 72.5/5.1,p < 0.001.	"[D]iclofenac and paracetamol had the same effect on pain reduction of ankle sprains but more acute ankle edema was present in patients who were treated with diclofenac than in patients who were treated with paracetamol."	Results suggest comparable efficacy for pain. Paracetamol associate with less swelling at 3 days, but otherwise did not differ.
Finch 1989 RCT	5.5	N = 50 acute ankle sprains or strains	Flurbiprofen 100mg vs. diflunisal 500mg BID x 18 days for acute ankle sprain <36 hours. All subjects had 7-day plaster cast immobilizati on.	Flurbiprofen vs. diflunisal physician assessment mean score changes: (only significant differences reported) measured Day 0, 7, 14, 21. Functional capability: Day 7 -1.96/-1.59 gait: Day 7 -1.22/-1.00, Day 14 -1.96/-1.77; Joint swelling: no differences; Ankle discoloration: no differences; Pain on passive motion: Day 7, -2.17/-1.81; Patient assessment mean scores. Pain while walking: no differences; Pain while standing: no	"Flurbiprofen and diflunisal appear to be effective and well-tolerated medications for the treatment of acute ankle sprains and strains."	No placebo. Lack of randomization, allocation details. No blinding. Co-intervention of casting for 7 days. Data suggest no differences.

				differences; p <0.05, p <0.01.		
Duncan 1988 RCT	5.0	N = 139 acute sprains and/or strains of knee or ankle	Diclofenac 75mg BID vs. aspirin 1.2g TID for acute ankle, knee injuries (<72 hours) for 3-10 days.	Diclofenac vs. aspirin mean (±SEM) for swelling, limitation of active ROM, pain on active motion: -1.17 (0.12)/-1.45 (0.11), -1.79 (0.11)/-1.88 (0.11), -1.96 (0.10)/-1.82 (0.10). Intragroup improvement from baseline p <0.001. Intergroup differences not significantly different; % returned to sport in 10 days: 83% vs. 82%, p >0.05).	"[D]iclofenac is useful in treating sports-related injuries and may allow an earlier return to playing fitness."	No placebo. Thirty-percent loss to follow-up/excluded from study. Data suggest no difference between ASA and diclofenac x.
Adams 1978 RCT	4.5	N = 37 acute, minor ligamento us injuries	Diflunisal 500mg twice daily vs. 200mg oxyphenbut azone 3 times daily (3-day trial, double-dummy, acute sprains classified as minor).	Spontaneous pain (rest) completely resolved in all patients by Day 3. Improvement (better/cured) in pain on movement: 16/17 diflunisal vs. 9/14 oxyphenbutazone p <0.01. Overall assessment (patient and physician): no differences at Day 1 or 3.	"[O]n the third day of treatment showed considerable improvement in the presenting symptoms and at this point diflunisal was statistically significantly better than oxyphenbutaz one in regard to relief of pain on movement of the joint."	Time elapsed from injury to entry into study significantly longer in oxybutazone group (median 13 vs. 4 hours). Sparse study details. Results suggest little clinical differences for acute pain relief. Medication off market.
Hayes 1984 RCT	4.5	N = 191 males >18 years old diagnosis of acute unilateral sprains or strains of ankle, hips, shoulders, or knees based on	Sulindac 200mg BID vs. ibuprofen 400mg TID, 4-day treatment.	Outcomes at 4 days: sulindac vs. ibuprofen mean rank for day pain, night, active motion, tenderness, ROM, and swelling: 86.3/91.0, 72.6/77.6, 88.5/87.4, 91.7/ 84.9, 83.2/93.3, 88.7/86.2. No differences reported.	"[S]ulindac has a place in the treatment of acute sprains and strains."	No placebo. Multiple co-interventions allowed. Data suggest no differences in treatments.

		history and physical findings				
McLatchie 1985 RCT	4.5	N = 144 Grade 1 and 2 inversion injuries to ankle sustained in sport	Ibuprofen 600mg QID vs. 1200mg BID vs. placebo for Grade I, II injuries; 7-day trial.	Ibuprofen QID vs. BID vs. placebo: Joint tenderness (0-8 scale): Day 3 no differences between any group. Day 7 VAS 2.44 vs. 2.647 vs. 3.182 (p <0.001). Mean level of training (0-3 scale): Day 3; 1.34 vs. 1.34 vs. 1.23, p <0.01 for ibuprofen vs. placebo. No difference between ibuprofen groups.	"[I]n soft tissue injuries to the lateral ligament complex caused by sporting activity a short course of high dose ibuprofen should be considered."	Trial conducted in athlete population. Randomization, allocation details sparse. No blinding. Data suggest NSAID superior to placebo although clinical differences appear to be small.
Kayali 2007 RCT	4.0	N = 100 1st or 2nd degree lateral ankle sprains within 48 hours of admission	Diclofenac sodium 75mg twice daily vs. paracetamol 500mg 3 times daily for 5 days for Grade I and II ankle sprains; follow-up for 6 weeks.	Physician global mean assessment for diclofenac sodium vs. paracetamol Day 1, 10, and Week 6: 1.46±0.5 vs. 1.42±0.49, 3.18±0.5 vs. 3.14±0.53, 3.76±0.43 vs. 3.72±0.45. ROM initial and last examination: 28.8°±9.3 vs. 30.2°±8.5 p = 0.43, 68.4°±3.1 vs. 67.6°±3.6 p = 0.03. No differences in swelling at any period.	"[D]iclofenac sodium and paracetamol are effective and well tolerated as a short term treatment alternatives for acute ankle injuries."	No placebo. Lack of randomization, allocation, baseline comparison and blinding details. Data suggest equivalency.
Viljakka 1983 RCT	4.0	N = 119 ankle sprains	Layer bandage vs. elastic adhesive tape. Oxyphenbutazone 100mg tid vs. clonixin 300mg TID vs. placebo.	No significant differences between layer bandage vs. elastic tape bandage in pain, tenderness, swelling, ROM. Elastic caused more rash, irritation or compression of skin. Examiners estimate of "Good" result: layer bandage (64%) vs. elastic (62%) vs. placebo 50%) vs.	"The layer bandage proved more stable in the lateral direction than the elastic adhesive tape bandage (p less than 0.001). Clonixin proved useful in controlling	Randomization, allocation, baseline comparability, blinding, compliance details sparse. Data suggest clonixin superior to oxyphenbutazone based on physician assessment but

				oxyphenbutazone (53%) vs. clonixin (84%). No differences between bandage groups. Placebo vs. oxyphenbutazone p >0.05. oxyphenbutazone vs. clonixin p <0.01, placebo vs. clonixin p <0.01.	swelling and in the authors opinion gave the best clinical results."	is of unclear clinical significance. Clonixin not available in U.S.

Evidence for the Use of Opioids for Ankle Sprain

There are 2 high-quality RCTs incorporated into this analysis. There is 1 low-quality RCT in Appendix 2.

Author/Year Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments
Hewitt 2007 RCT	9.5	N = 603 adults with ankle sprain and a diagnosis of partial ligament tear	Tramadol plus acetaminophen (37.5/375) QID vs. hydrocodone plus acetaminophen (7.5/650) qd vs. placebo for acute mild and moderate ankle sprain short term analgesia (5-day follow-up).	Tramadol/APAP vs. hydrocodone/APAP vs. placebo (pain relief score 0-4 scale) Immediate Mean Pain Relief: Tramadol better than placebo at 2, 3, 4 hours. Hydrocodone better than placebo at 1, 2, 3, 4 hours. Differences continued through Day 3. No differences between Tramadol and hydrocodone. Pain scores were at rest, not with movement (scores on 4 point scale). Total adverse events (95% CI): tramadol/acetaminophen 43.2% (36.2-50.2); hydrocodone/acetaminophen 36.5% (29.8-43.1); placebo 19.3% (13.9 -24.7). Discontinuation caused by adverse events: tramadol/acetaminophen 5.2%; hydrocodone/acetaminophen 4.4%; placebo	"One or 2 capsules of 37.5 mg tramadol/325 mg acetaminophen and 1 capsule of 7.5 mg hydrocodone/650 mg acetaminophen were well tolerated, had comparable clinical utility, and were more effective than placebo in the management of acute musculoskeletal pain caused by ankle sprain."	Study limited to short-term analgesia. Pain scores were at rest and not with activity, limiting overall conclusions.

				1.4%. Most common adverse events were somnolence, nausea, dizziness, and vomiting.		
Ekman 2006 RCT	9.5	N = 829 acute 1st- or 2nd-degree ankle sprain	Valdecoxib 20mg once daily vs. valdecoxib 20mg twice daily vs. Tramadol 50mg 4 times daily vs. placebo for acute mild and moderate ankle sprain.	Valdecoxib 20mg BID vs. valdecoxib 20mg qd vs. Tramadol 50mg 4 times vs. placebo. Patient global assessment good/very good: Day 4 no differences, Day 7 (76.4 vs. 67.3 vs. 59.6 vs. 55.5) p <0.001 for BID vs. placebo. APS questionnaire: 33.9 vs. 26.6 vs. 20.6 vs. 24.4 (p = 0.009 Day 4). Patient assessment of return to walking with/without pain Day 4 (47.5/44.6/38.4/35.0) p = 0.002; Day 7 (79.4/72.5/67.3/ 63.9) p = 0.001. Adverse events, any, (%): valdecoxib 20mg BID 33.0% vs. vadlecoxib 20mg qd 27.2% vs. tramadol 50mg QID 58.0% vs. placebo 43.1%. Adverse events, severe, (%): valdecoxib 20mg BID 2.1% vs. valdecoxib 20mg qd 1.7% vs. tramadol 50mg QID 7.5% vs. placebo 3.3%. Withdrawals due to adverse events: tramadol 12.2% vs. valdecoxib 3.4% (p = 0.0005); valdecoxib 3.4% vs. placebo 2.4% (p = 0.75). Adverse events included upper GI discomfort, GI-related adverse events, CNS-related adverse events, fatigue, accidental injury, asthenia, impaired	"Valdecoxib 20 mg bid was at least as effective as Tramadol 50 mg 4 times daily and significantly better than placebo."	Data suggest valdecoxib 20mg BID superior to placebo and trended towards better than tramadol for acute pain relief at Days 4 and 7. Data suggest no difference in tramadol and placebo at Day 4, with higher withdrawal rates in tramadol group.

				concentration, upper respiratory tract infection, pruritus, and rash.		

Evidence for the Use of Proteolytic Enzymes for Ankle Sprain
There is 1 high- and 1 moderate-quality RCT incorporated into this analysis. There is 1 low-quality RCT in Appendix 2.(465) (Brakenbury 83)

Author/Year Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments
Kerkhoffs 2004 RCT	8.0	N = 692 aged 16-53 years with acute unilateral sprain of the lateral ankle joint	Oral hydrolytic enzymes (various combinations) of phlogenzym, trypsin, bromelain, rutoside) vs. placebo.	Pain reduction at 7 days: Bromelain-trypsin 73.7%, Phlogenzym 60.3%, placebo 73.3%. Ankle swelling reduction: no significant differences found.	"Administration of proteolytic enzymes is no more effective than placebo in patients with an acute lateral ankle sprain treated functionally with a brace."	All patients treated with functional brace in addition to interventions. Data suggest lack of efficacy.
Craig 1975 RCT	4.5	N = 61 soft-tissue ankle injuries	Proteolytic enzymes (chymoral) vs. placebo taken for 5 days after acute ankle sprain.	Chymoral vs. placebo measurements for volume, horizontal circumference, diagonal circumference, and diameter: 60±41.608/75.42 ±57.274 (p = 0.2), 1.10± 0.8807/1.229±0.9019 (p = 0.4), 0.469±0.3631/0.466± 0.2842 (p = 0.9). Percent improved (%): 4.958±3.378/ 6.374±4.616 (p = 0.2).	"[N]o significant improvement in the treated series, there would appear to be no economic grounds for the continued use of these enzymes."	Allocation, blinding, baseline comparability, compliance details sparse or missing. Data suggest lack of efficacy.

Evidence for the Use of Streptokinase/Streptodornase for Ankle Sprain
There is 1 moderate-quality RCT incorporated into this analysis.

Author/Year	Score	Sample Size	Comparison Group	Results	Conclusion	Comments

Study Type	(0-11)					
Calandre 1991 RCT	6.5	N = 200 ankle sprains	Streptokinase 10,000 units plus Streptodornase 2500 units, 2 tabs po TID for 8 days vs. placebo (acute sprain, Grade II, III)	SS vs. placebo, Days 4, 8 mean (SE) (0 none, 1 mild, 2 moderate, 3 severe VAS score) Spontaneous pain: 0.41± 0.05 vs. 0.56±0.06 p = NS, 0.04±0.020 vs. 0.19±0.040, p <0.05; Mobilization pain: 1.26±0.06 vs. 1.70± 0.06, p <0.0001, 0.69±0.062 vs. 1.14±0.060, p <0.0001; edema: 1.38±0.072 vs. 1.96 ±0.060, p <0.0001, 0.60±0.062 vs. 1.41±0.070, p <0.0001.	"Oral (streptokinase +streptodornase) appears as a suitable alternative to NSAIDs because of its efficacy and low incidence of side effects."	Data suggest SK, SD may modestly reduce edema, pain over placebo. Clinical results however are of uncertain significance.

Evidence for the Use of Systemic Glucocorticosteroids for Ankle Sprain
There are no quality trials incorporated into this analysis.

Evidence for the Use of Vitamins for Ankle Sprain
There are no quality trials incorporated in this analysis.

Evidence for the Use of Cold Gel for Ankle Sprain
There is 1 high- and 1 moderate-quality RCT incorporated in this analysis.

Author/Year Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments
Cold Gel (Menthol/Ethanol)						
Gonzalez de Vega 2013 RCT	9.0	N = 449 with unilateral ankle sprain of the lateral ligaments; age range 17- 48	Traumeel ointment (T-O), 2 g (n = 152) vs. Traumeel gel (T-G) (n =150) vs. Diclofenac gel (D-G) (n = 147). Administered to ankle 3x/day for 14 days, paracetamol used as rescue medication for pain. Follow-up: baseline, days 4, 7, 14 and 42	No significant differences between groups for primary outcomes.	"T-O and T-G decreased pain and improved joint function to the same extent as D-G in acute ankle sprain, and were well tolerated."	No placebo, non-inferiority. Multicenter study. Large N. Data suggest comparable efficacy. However, less paracetamol use in diclofenac group (14.6% vs. 19.7%, 20.7%), suggesting potential confounding.

Airaksinen 2003 RCT	6.5	N = 74 sports-related soft tissue injuries	Cold Gel (Ice Power) vs. placebo gel (4 times a day for 14 days) for acute minor injuries (mixed, including ankle).	Cold gel vs. placebo: pain at rest (0-100 VAS): Day 1; 59±15 vs. 59±15, Day 7; 30 ±16 vs. 45±15, Day 14; 14± 13 vs. 26±18, Day 28; 7±12 vs. 13±14, p <0.001 at 1, 2, 4 weeks. Functional disability (0-100 VAS): Day 1; 63 vs. 62 Day 7; 31 vs. 48 p <0.001.	"[C]old gel caused significantly faster pain relief and significantly faster rehabilitation results after minor soft tissue injuries."	Heterogeneous injuries included, 23/74 of ankle. Severity of ankle sprain not specified other than minor. Clinical significance of pain and disability differences likely small. Skin temperature not measured (cold) objectively and thus not considered as part of cryotherapy. Data suggest modest efficacy.

Evidence for the Use of Comfrey Extract for Ankle Sprain

There are 3 moderate-quality RCTs incorporated into this analysis.

Author/Year Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments
Koll 2004 RCT	7.5	N = 143 unilateral acute ankle sprains	Comfrey extract gel vs. placebo (4 times daily application of 2g).	Comfrey vs. placebo, VAS: mean between injured/healthy foot at Day 4, 7; Pain: 2.37 vs. 3.35, p = 0.001, 1.44 vs. 2.85, p = 0.0001; swelling: 1.69 vs. 2.36, p = 0.0011, 1.09 vs. 1.90, p = 0.0001. Patient global efficacy (good/excellent) 61.3% vs. 50%, p = not reported.	"Compared to placebo, comfrey proved clinically and statistically superior concerning reduction of pain, swelling, movement limitation and global efficacy."	Lack of randomization, allocation, compliance details. Data suggest comfrey root extract superior to placebo gel for treatment of acute ankle sprains.
D'Anchise 2007 RCT	5.5	N = 164 acute unilateral ankle sprains (distortions)	Comfrey extract ointment (Kitta-Salbe®) vs. diclofenac gel (6-cm q.i.d. x 7 days for	Mean difference in tenderness values measured by tonometry of injured vs. contralateral ankle: comfrey extract minus diclofenac measured as	"The re-evaluation of the data showed superiority of the plant based ointment over the diclofenac gel in the	Second report of Predel 2005 (consider one study). Data suggest improvements in tenderness, but not in pain with movement or

			acute ankle sprain.	AUC 61.1 h* N/cm2 favoring comfrey extract (95% confidence interval: 19.08; 103.09 h x N/cm2). No differences in VAS for resting, movement pain.	treatment of distortions. It is encouraging and impressive to realize that a natural product seems to be an effective and safe alternative to the standard topical treatment with diclofenac."	at rest compared with topical NSAID. No control arm.
Predel 2005 RCT	5.5	N = 164 with acute unilateral ankle sprain (distortion)	Comfrey extract ointment (Kitta-Salbe®) vs. diclofenac gel (6-cm QID x 7 days for acute ankle sprain.	Comfrey vs. diclofenac VAS reduction (%) from baseline: Day 7; At rest: 92.01% vs. 84.96% (p >0.05); At motion: 83.2% vs.72.37% (p >0.05); Good/Excellent patient assessment: 84.2% vs. 70.8% p = 0.0111.	"It was confirmatorily shown that Comfrey extract is non-inferior to diclofenac. Moreover, the results of the primary and secondary variables indicate that Comfrey extract may be superior to Diclofenac gel."	No placebo. Randomization, allocation, compliance details sparse. Suggests comfrey root extract of equal efficacy.

Evidence for the Use of Lidocaine Patches for Ankle Sprain
There are no quality trials incorporated into this analysis.

Evidence for the Use of Movelat for Ankle Sprain
There are 2 moderate-quality trials incorporated into this analysis.

Author/Year Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments
Frahm 1993 RCT	6.0	N = 163 acute sprains of the knee	Movelat vs. placebo. 10cm cream BID for acute	Movelat vs. placebo-mean pain with movement (100mm VAS) Day 2, 4, 9, 11: 57.46 vs. 64.33, p = NS; 41.53 vs. 48.13, p = NS; 24.87 vs. 38.73,	"Treatment with the active cream lessened the pain on movement by 28% compared with the placebo, a statistically	Double-blinding details sparse. Data suggest topical Movelat cream has limited, if any, analgesic efficacy as only significant

		or ankle joint	mild, moderate ankle sprain.	p = 0.0065, 21.11 vs. 32.10, p >0.05. No differences in pain at rest, swelling, or physician assessment of efficacy or tolerability.	significant difference."	Day 9. No differences for pain at rest, edema, or subjective efficacy. Data suggests benefit clinically non-significant.
Lester 1981 RCT	5.5	N = 50 sprained ankles	Movelat vs. placebo.	Scoring system 1-4 (not defined) for movement limitation, swelling, pain, side effects created. Mean cumulative score (higher = better): Movelat gel group 12.1 (±3.8) vs. placebo gel group 9.7(±3.7), p <0.05.	"Movelat Gel as an adjunct to physiotherapy was shown to be superior to placebo gel and physiotherapy in alleviating the signs and symptoms of sprained ankle."	Randomization, allocation, compliance details sparse. Minimal statistical analyses presented. Data suggest cream may be effective, however, findings not clearly supported by details of analysis.

Evidence for the Use of Topical NSAIDs for Ankle Sprain

There are 4 high-quality RCTs (Predel 12) and 4 moderate-quality RCTs incorporated in this analysis. There is 1 low-quality study in Appendix 2.(485) (Campbell 94)

Author/Year Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments
Topical NSAIDs vs. Placebo						
Mazières 2005 RCT	9.0	N = 163 suffering painful (spontaneous pain >or = 50mm on a 0- to 100-mm VAS), benign (Grade I or II), recent (<2 days) ankle sprains as a model of general traumatic soft tissue injuries	Ketoprofen 100mg patch daily vs. placebo patch; 2-week trial for acute Grade I, II.	Ketoprofen vs. placebo Day 3, 7, 14. Spontaneous pain VAS (100mm): 33±19 vs. 40±22 p = 0.0053, 18±17 vs. 28±24 p = 0.007, 9±13 vs. 20±26 p = 0.006. Pain on active motion, VAS (100mm): 37±18 vs. 45± 22, 22±17 vs. 33±24 p = 0.192, 10±14 vs. 22±25 p = 0.0178. Ankle swelling (%): 3.9±3.7 vs. 4.0±3.4, p = 0.0476, 2.8±3.5 vs. 3.5±5.0, p = 0.0234, 1.9±2.8 vs. 2.2±3.6, p = 0.0765.	"This trial suggests that a 3- to 14-day treatment course by once-a-day 100-mg ketoprofen TDS patch is useful in post-traumatic painful soft tissue injuries, the duration depending on the results obtained, although 7-days seem optimal."	Data suggest modest short-term benefit of ketoprofen patch over placebo for acute injury.
Diebschlag 1990	8.5	N = 37 ankle sprains	Topical Ketorolac tromethamine 2% gel	Ketorolac vs. placebo: (% mean difference, 95% CI, p-value). Max volume change: -0.72	"Overall, this small study shows topical application of	Small sample size. Data suggest modest short-

RCT			vs. etofenamate gel 5% vs. placebo x 15 days for acute ankle sprain.	(-1.16 to -.28, p = 0.002; AUC: -0.84 (-1.17 to -0.51) p = 0.0001; Day 15 volume: -0.82 (-1.02 to -0.61) p = 0.0001. Ketorolac vs. etofenamate (% mean difference, 95% CI, p-value). Max Vol Change -0.02 (-.46 to 0.42) p = 0.92. AUC: 0.13 (-0.20 to 0.46) p = 0.44. Day 15 Volume: 0.13 (-0.08 to 0.33), p = 0.22. VAS pain on movement: no differences between groups Day 2. Lower scores Days 4, 8. Ketorolac lower than placebo at Day 4, 8.	ketorolac would seem to show excellent efficacy with few side-effects."	term benefits of ketorolac gel vs. placebo for ankle swelling. No superiority over etofenamate gel. No other functional outcomes measured.
Dreiser 1994 RCT	6.0	N = 131 outpatients, 18-70 years old, with acute pain in ankle joint caused by post-traumatic sprain	Flurbiprofen patch (40mg) vs. placebo patch twice daily.	Flurbiprofen vs. placebo at Day 0, 3, 7; spontaneous pain VAS: 64.0 vs. 63.3, 30.2 vs. 31.2, p >0.05, 14.0 vs. 17.6, p <0.05. Periarticular edema (cm): 1.93 vs. 1.79, p >0.05, 0.94 vs. 0.87, p >0.05, 0.42 vs. 0.54, p <0.05; overall efficacy (patient rating good/very good Day 7): 75% vs. 62% p = 0.14.	"After 7 days treatment, the 40 mg flurbiprofen patch proved superior to the control in the treatment of acute, uncomplicated ankle sprains with respect to both the subjective symptoms (pain) and the objective signs (oedema)."	Sparse details for randomization, allocation, baseline comparability and blinding. Data suggest benefit at 7 days over placebo but no benefit at 3 days. No difference in patient satisfaction.
Russell 1991 RCT	5.5	N = 200 acute soft tissue injuries (ankle or acromioclavicular sprains, supraspinatus, or Achilles tendinitis)	Piroxicam 0.5% gel 1gm applied QID vs. placebo gel.	Piroxicam vs. placebo: failure to complete study due to lack of efficacy: 6/100 vs. 42/100, p <0.001. Spontaneous pain: improvement from baseline in VAS Days 2-8 in both groups p <0.001, piroxicam significantly better than placebo p = 0.047. In sprain group,	"[P]iroxicam gel, administered on a q.i.d. basis for a total daily dose of 20 mg, is effective treatment for patients suffering from musculoskeletal injuries	Mixed MSDs limit conclusions for specific disorders. Study suggests topical NSAID is effective for tendinitis (shoulder) but did not demonstrate

				differences between placebo not significant.	(sprains and tendinitis) and is significantly more effective than placebo."	VAS difference in sprains.
Dreiser 1990 RCT	5.0	N = 60 recent uncomplicated ankle sprains	Niflumic acid gel 2.5% applied TID vs. placebo gel for 7 days; uncomplicated sprains with moderate-severe pain <3 days from injury.	Niflumic acid vs. placebo: Differences from baseline in VAS, Day 4; 31.9±3.31 vs. 22.35±3.761, p = 0.056. Day 8: 54.1±4.31 vs. 38.95 ±5.26, p = 0.03. Investigator rating of patient response Day 4: pain on palpation very much improved, much improved 9 vs. 3, p = 0.026. Pain on contraction much improved, improved 21 vs. 9, p = 0.017; functional disability much improved, improved 24 vs. 11, p = 0.002.	"A new 2.5% topical gel formulation of niflumic acid administered 3-times daily in the treatment of simple ankle sprains has been shown to be effective and well tolerated, with a significantly higher proportion of patients in the group treated with niflumic acid gel being healed at the end of the study."	Randomization, allocation, blinding methods unclear. Compliance uncertain. Results suggest topical niflumic acid superior to placebo.
Topical NSAIDs vs. Other						
Mahler 2003 RCT	8.5	N = 100 mild to moderate post-traumatic injuries (Grade 1 ankle, knee and muscle injuries)	Diclofenac (DHEP with lecithin) vs. DHEP plain gel for acute ankle sprain.	Pain on movement (VAS) for both groups decreased p <0.01. Lecithin decrease in absolute value Day 3, end of treatment: lecithin = -27.4mm/ gel = -16.8 mm/p = 0.025, lecithin = -48.3 mm/gel = -41.3mm/p = 0.036. Spontaneous pain (VAS) significant after 3 days: lecithin = -18.4mm/gel = -9.9mm/p <0.01. Pain on movement, spontaneous pain on movement significant Day 2 on, p <0.01.	"Due to the presence of lecithin in the new gel formulation, DHEP lecithin showed a faster and significantly more marked therapeutic effect compared with that of DHEP gel."	No placebo. Data suggest formulation with lecithin is more effective for pain relief in treatment of acute ankle sprains.
Predel 2012 RCT	8.0	N = 242 with acute ankle sprains (Grade I	DDEA 2.32% TID, (n = 80) vs. DDEA 2.32% BID,	Mean mm ± SD for POM (VAS): DDEA 2.32% tid vs. placebo: day 5: 49.7±21.5 vs. 25.4±14.8, p <0.0001;	"DDEA 2.32% gel twice daily (applied in the morning and evening) was	Three arms to study. Diclofenac decreased pain vs.

		and II); age range 18 to 81	2 tubes (n = 80) vs. placebo (n = 82). All given 3 tubes labeled morning, noon, evening; 1st dose at center, 2g of gel with fingertips on both sides of ankle ~1 min.; rescue med 500mg paracetamol. Follow-up: baseline, and days 2 to 8.	DDEA 2.32% bid vs. placebo: 49.1±19.3, p <0.0001.	well tolerated and provided lasting relief from pain, improved function, and reduced symptomatic healing time in un-complicated ankle sprain."	placebo although increasing from BID to TID showed little or no difference.
Oakland 1993 RCT	5.5	N = 220 acute lateral ankle ligaments injuries	Felbinac gel plus sham ultrasound placebo vs. placebo gel plus ultrasound vs. felbinac plus ultrasound for acute ankle sprains (severity not described).	Changes from baseline in VAS Pain: 21.5mm vs. 19.4mm vs. 16.5mm, p >0.05. Investigator Assessment (% moderate or better response) 84.5% vs. 83.5% vs. 86.5%. Full Weight Bearing: 73% vs. 77% vs. 80%, p >0.05	"[F]elbinac gel has a similar clinical efficacy to ultrasound in the treatment of acute injuries of the lateral ankle ligaments."	No placebo. Allocation, investigator blinding not described; 52 of 220 dropped out (results carried forward in analysis). Suggests ultrasound and topical NSAID of similar efficacy. No evidence of combined effect.

Evidence for the Use of Contrast Bath for Ankle Sprain

There is 1 moderate-quality trial incorporated in this analysis.

Author/Year Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments

Cote 1988 RCT	4.0	N = 30 post-acute sprained ankles	Cold bath (50-60°F) vs. heat bath (102-106°F) vs. contrast bath for acute ankle sprain (Grade I, II) swelling applied once daily (20 minutes) on post-injury Days 3, 4, 5. Outcomes measured 1-3 days post-treatment.	Ankle volume change pre- to post-treatment (mL): cold vs. heat vs. contrast mean (SD); Day 1: -1.3 (27.1) vs. 27.4 (25.2) vs. 27.4 (13.6); Day 3: 1.7 (14.2) vs. 28.7 (15.8) vs. 35.3(31.2). Total 3 day change: 3.3 (11.3) vs. 25.3 (19.5) vs. 26.5 (8.2), p <0.05 cold vs. heat, contrast. No difference between heat and contrast.	"[C]old therapy is clearly the most favorable of the three treatments if the therapeutic objective is to minimize edema before rehabilitative exercise during the third, fourth and fifth days post injury for first- and second-degree ankle sprains."	Small sample size. Details of allocation, baseline comparability missing. Age of injury not specified. Effect of treatment limited to edema as functional improvement and pain measures not included.

Evidence for the Use of Early Mobilization for Ankle Sprain

There are 6 moderate-quality RCTs (two with multiple reports) incorporated into this analysis. (Bendahou 14) There are 3 low-quality RCTs in Appendix 2.(147, 499, 500) (Zwipp 92; Cetti 94; Korkala 87)

Author/Year Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments
Cooke 2009 Lamb 2005, 2009 RCT	7.5	N = 584 16 years and older with acute severe ankle sprain	Tubular bandage vs. below-knee cast (10 days) vs. Aircast vs. Bledsoe boot. Inclusion criteria of inability to bear weight for 3 days as surrogate for Grade II, III sprains. Study is also known as CAST trial.	Tubular bandage results used as control; 4 weeks: below-knee cast better than tubular bandage for FAOS scores on pain, symptoms, activities of daily living scales. No differences between other interventions except Aircast superior for FAOS ADL scores; 12 weeks: casting better than control FAOS pain, ADL, sports, QoL scores; 9 months: no differences between groups in any measure.	"[I]nitially treated [non weight bearing ankle sprains] treated with 2-3 days of elevation, ice and non-weight bearing exercise, had a more rapid resolution of symptoms and return to normal activities in the first 3 months when treated with a below knee cast for 10 days than when treated with tubular bandage."	Three reports of same study. All evaluations by postal questionnaire. Compliance to protocols unclear. Co-interventions allowed (ice, NSAIDs, walking aids). Loss to follow-up between 23-27% across groups. Although some statistical differences, clinical differences in outcomes between 4 treatment arms small and of

						uncertain significance.
Ardevol 2002 RCT	6.0	N = 140 Grade III ruptures of lateral ankle ligaments	Cast immobilization (3 weeks) vs. functional treatment (strapping with controlled mobilization) for severe ankle sprains.	Functional treatment showed significant benefit over immobilization at 3, 6 months for pain, swelling, and at 3 months only for stiffness and subjective instability. Mean time to return to sport at same activity 70% vs.36% favoring functional treatment (p <0.01). No differences at 12 months except for relative reduction in talar tilt, also favored functional group.	"[F]unctional treatment is safe, associated with a more rapid recovery, and particularly suitable in athletic populations."	Both groups received multiple co-interventions with cryotherapy, physical therapy, proprioception training, and NSAIDs. Data suggest functional treatment is beneficial at 3 and 6 months but is equivocal at 12 months.
Beynnon 2006 RCT	5.5	N = 212 suffering 1st acute ankle ligament sprain injury (Grades I, II, or III)	Elastic wrap vs. bracing plus elastic wrap vs. casting for 1st time ankle sprains of Grades I, II, and III and excluded fractures.	Outcomes by severity grade and treatment. Grade I sprain: no casting group included. Elastic vs. brace vs. brace plus elastic: Days to return to normal walking 11.16 vs. 10.33 vs. 4.62, p = 0.008; Days to normal stair climbing: 12.05 vs. 11.43 vs. 5.46, p = 0.003. No difference between and elastic wrap and Air-Stirrup for return to normal walking (p = 0.84) and stair climbing (p = 0.98). No differences in secondary outcomes (return to full weight bearing, full capability in normal activities, work or athletics. Grade II sprain: no differences between	"…Air-Stirrup brace combined with an elastic wrap provided earlier return to preinjury function compared with treatment with the Air-stirrup brace alone, elastic wrap alone, or walking cast for 10 days followed by elastic wrap. At 6 months, all treatments produced comparable outcomes in terms of clinical testing, activity level, functional status, and patient satisfaction."	Several co-interventions (PT, RICE). High drop-out rate although ITT analyses. Data suggest brace with wrap superior to other treatments for mild sprains. Casting in Grade II sprains resulted in more days for recovery in multiple outcomes measures, whereas no difference in non-casting methods. Grade III sprains demonstrated equivalency of casting and bracing.

				3 non-casting treatments. Casting had significantly more days to normal walking (24.12 vs. 10.10, p = 0.001) and stair climbing (27.94 vs. 11.72, p = 0.001) than brace plus wrap, and return to full capability in work and athletics vs. elastic wrap. Grade III sprain: no differences any measure between brace and cast.		
Bendahou 2014 RCT	5.0	N=126 with recent ankle sprain without fracture or traumatic injury seen in ER. Mean age compression stockings 31+9 years, placebo 30±8 years.	Compression stockings (Venoflex) applied from tibia tuberosity to base of toes: class II with pressure between 15-20.3mm Hg (n = 61) vs. placebo: noncompressive stockings (n = 65). All patients received standard care consisting of RICE protocol, immobilization with same orthesis for 4-6 weeks, and acetaminophen or tramadol depending on pain severity, and rehabilitation (2-3 sessions per week of strengthening	No significant differences between groups.	"Compression stockings failed to significantly modify the time to return to normal painless walking in ankle sprain."	Baseline of more physical activity in compression group may have biased in favor of that group. Data suggest lack of efficacy of compression stockings.

			exercises, proprioception exercises, and weight-bearing postures). Follow-up 6-9 days after trauma, 15-30 days after trauma, and 90 days after trauma.			
Dettori 1994 a, b RCT	5.0	N = 64 moderate or severe lateral ankle sprain	Plaster cast immobilization vs. AirCast vs. elastic wrap (all for 2 weeks) for acute moderate and severe sprain. Each group had 3 weeks PT rehab post treatment.	Cast vs. air-stirrup vs. elastic: Median days return to work (full military duty) 32.4 vs. 29.6 vs. 29.4, p = 0.078; ROM, pain, swelling (2 weeks) significant difference favoring early motion groups vs. cast. Differences disappeared at 5 week follow-up. No differences in re-injury rate at 5-weeks. At 1-year, fewer subjective complaints in casting group. No differences in measures of pain, job performance, ADLs, need for bracing.	"Early ankle mobilization reduces swelling and pain, and increases ROM and strength compared to cast immobilization... There are no differences among those sustaining various degrees of ankle injury in subjective or functional complaints after 1 year. Those with severe double ligament tears perform as well as those with single ligament tears independent of the initial treatment."	Lack of study detail for randomization, allocation, compliance. 3-weeks PT rehab co-intervention. Data suggest short term advantage of early mobilization although results are of uncertain clinical significance. Study also found 44% of those with moderate or severe sprains were still symptomatic at 1-year independent of treatment type.
Eiff 1994 RCT	4.5	N = 138 lateral ankle sprains	Early mobilization (elastic wrap, Air-stirrup) vs. immobilization (sugar-tong plaster splint x 10 days with no weight bearing) for mild and moderate	Early mobilization vs. immobilization: % of patients with residual pain: No differences at 10 days. At 3 weeks, 57% vs. 87%. No differences at 6 weeks or 3,6,12 months; % of patients with residual swelling or improved activity:	"[I]n first-time lateral ankle sprains, although both immobilization and early mobilization prevent late residual symptoms and ankle instability, early mobilization	Sparse study details. Multiple co-interventions. Study suggests few clinically significant differences between immobilization vs. early mobilization after a 48-hour period of non-weight

			acute ankle sprains.	No differences in swelling or improved activity at any time; % return to work full duty: at 10 days 54% vs. 13%. At 3 weeks, no difference. 100% by 3 months.	allows earlier return to work and may be more comfortable for patients."	bearing and RICE although early return to work at full duty demonstrated with early mobilization.

Evidence for the Use of Tubular Elastic, Elastic Wrap, or Tape for Ankle Support
There are 10 moderate-quality RCTs (two with multiple reports) incorporated into this analysis. (Sultan 12) There are 7 low-quality RCTs in Appendix 2.(411, 416, 500-504) (Muwanga 86; Scotece 92; Cetti 84; Korkala 87; Nilsson 83; Brooks 81; Airaksinen 90)

Author/Year Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments
Cooke 2009 Lamb 2005, 2009	7.5	See Evidence Table for the Use of Early Mobilization for Ankle Sprain above.				
Ardevol 2002	6.0	See Evidence Table for the Use of Early Mobilization for Ankle Sprain above.				
Beynnon 2006	5.5	See Evidence Table for the Use of Early Mobilization for Ankle Sprain above.				
Sultan 2012 RCT	6.5	N = 36 with ankle sprains sustained within 72 hours of attending a fracture clinic; 18 years or older	Standard treatment, written and verbal information on ankle sprains, advice on RICE (rest, ice, compression, elevation), Tubigrip, worn for 7 weeks (n = 18) vs. Class II elastic stockings, same advice and	Mean (95% CI) for VAS: baseline vs. 4 weeks: Stocking: 65 (56-73) vs. 9 (5-13), p = 0.004; baseline vs. 8 weeks: 65 (56-73) vs. 5 (0-11), p = 0.002; Tubigrip: baseline vs. 4 weeks: 66 (59-73) vs. 21 (11-31), p = 0.004; baseline vs. 8 weeks: 66 (59-73) vs. 18 (10-26), p = 0.002. Mean (95% CI) for AOFAS: stocking vs. Tubigrip: 4 weeks: 94 (84-102) vs. 83 (70-90), p = 0.004; 8	"ES applied early following ankle sprain significantly improved recovery compared with Tubigrip. By 4 weeks, the ES patients experienced less pain, swelling and restriction in ankle movement. The functional outcome and SF12 at 4 and 8 weeks were also better."	Few baseline characteristics. ES significantly reduced ankle circumference following ankle sprain vs. tubigrip. Recovery time decreased and ankle ROM and movements at both 4 and 8 weeks.

			informatio n, fitted stockings to patient, wear continuous ly, day/night, for 7 days, wear during day remove at night for 6 weeks until pain free (n = 18). Follow-up: baseline, 4 and 8 weeks.	weeks: 99 (92-105) vs. 88 (78-95), p = 0.002. Mean (95% CI) for SF 12 scores improved with stocking group from 4 to 8 weeks: 112 (109-115) vs. 119 (118-121), p < 0.01.		
O'Hara 1992 RCT	5.5	N = 220 with and without acute ankle injuries	Ankle support (Malleotrai n) vs. standard care (rest, tubigrip) for mild and moderate acute sprains.	Support vs. standard: outcomes at 12-14 days; VAS: rest pain 178.5 vs. 235.8 p <0.05; speed of response rest pain: 9.13 vs. 11.38 days, p <0.05. Overall assessment: normal 88% vs. 67%, p <0.001.	"In patients with acute ankle injuries, a Malleotrain ankle support results in more rapid alleviation of symptoms than does Tubigrip and is acceptable to patients."	Data suggest benefit of using ankle support compared to tubigrip. Despite statistical significance of some factors, clinical significance is uncertain.
Dettori 1994 a, b	5.0	See Evidence Table for the Use of Early Mobilization for Ankle Sprain above.				
Boyce 2005 RCT	4.0	N = 50 presenting consecutiv ely within 24 hours a moderate or severe lateral ligament sprain after an ankle inversion injury	Elastic support bandage vs. Aircast ankle brace for acute Grade II, III sprains	Function measured by Karlsson scores: 10 days (35 for elastic vs. 50 for Aircast, p = 0.028) at 1 month (55 for elastic vs. 68 for Aircast, p = 0.029). No significant differences between groups for secondary outcome measures of swelling, pain at 10 days.	"[T]he use of an Aircast ankle brace in the treatment of moderate and severe lateral ligament ankle sprains, presenting within 24 hours of injury, produces a significant improvement in ankle joint function, at both 10 days and one month, compared	Lack of study details. Withdrawal rate >20%. No detail on co-interventions, compliance to treatments. Data suggest use of Aircast provides better functional outcomes but no differences in swelling or pain at 10 days.

					with standard management with an elastic support bandage."	
Leanderson 1999 RCT	4.0	N = 73 age 15-55 years old with acute Grade II or III ankle sprain, who sought medical care within 24 hours of injury	Air cushioned ankle brace (AirCast) vs. compression bandage for acute Grade II and III ankle sprains.	ROM discrepancy injured vs. uninjured foot decreased at follow-up; still decreased at 10 weeks (p <0.01). ROM in uninjured foot increased at follow-up (p <0.05). Figure-of-eight running times both groups between 2-10 week follow-up improved significantly from baseline (p <0.05), but no differences between groups.	"[T]he methods used in the present study are well suited for further studies of objective modalities of ankle joint function with the possible exception of the joint position sense test."	Sparse details for randomization methods, baseline comparability, control of cointerventions. Results are of uncertain clinical significance other than noting both groups improved throughout the follow-up period with no difference between interventions.
Viljakka 1983 RCT	4.0	N = 119 with ankle sprains	Layer bandage vs. elastic adhesive tape. Oxyphenbutazone 100mg TID vs. clonixin 300mg. TID vs. placebo. Severity of acute injury not specified.	No significant differences between layer vs. elastic tape bandage in pain, tenderness, swelling, ROM. Elastic caused more rash, irritation, skin compression. Examiner estimate of "good" result: layer bandage (64%) vs. elastic (62%) vs. placebo 50%) vs. oxyphenbutazone (53%) vs. clonixin (84%). No differences between bandage groups. Placebo vs.	"The layer bandage proved more stable in the lateral direction than the elastic adhesive tape bandage (p less than 0.001). Clonixin proved useful in controlling swelling and in the authors opinion gave the best clinical results."	Randomization, allocation, baseline comparability, blinding, compliance details sparse. Study suggests clonixin has advantage over oxyphenbutazone based on physician assessment but is of unknown clinical significance. Clonixin not available in U.S.

				oxyphenbutazone, p >0.05; oxyphenbutazone vs. clonixin, p <0.01, placebo vs. clonixin, p <0.01.		
Watts 2001 RCT	4.0	N = 400 with acute Grade I or II (mild to moderate) lateral ankle sprains	Double Tubigrip (elastic wrap) vs. no compression wrap for acute Grade I and II sprain.	In DTG group, 81 took pain killers vs. 50 in no-DTG group, p = 0.001; 54 DTG and 48 no-DTG group had to take days off work, p = 0.072. DTG average 3.37 days off work vs. 3.21 days for no-DTG, p = 0.94. Took average 2.65 days for DTG group to walk unaided vs. 2.32 days for no-DTG group, p = 0.23.	"This study suggests that the use of double tubigrip compression bandage in grade 1 and 2 ankle sprains does not shorten recovery time or number of days off work….(and) seems to be associated with an increase in the need for analgesia."	50% loss to follow-up. No details on co-interventions other than "therapy and analgesia." No details on compliance to intervention.

Evidence for the Use of Ankle Support or Brace for Ankle Sprain
There are 7 moderate-quality RCTs (two with multiple reports) incorporated into this analysis. There are 5 low-quality RCTs in Appendix 2.(499, 501-503, 505) (Zwipp 92; Cetti 84; Wilkerson 93; Scotece 92; Muwanga 86)

Author/Year Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments
Cooke 2009 Lamb 2005, 2009	7.5	See Evidence Table for the Use of Early Mobilization for Ankle Sprain above.				
Beynnon 2006	5.5	See Evidence Table for the Use of Early Mobilization for Ankle Sprain above.				
O'Hara 1992	5.5	See Evidence Table for the Use of Tubular Elastic, Elastic Wrap, or Tape for Ankle Support above.				
Dettori 1994 a, b	5.0	See Evidence Table for the Use of Early Mobilization for Ankle Sprain above.				
Eiff 1994	4.5	See Evidence Table for the Use of Early Mobilization for Ankle Sprain above.				
Boyce 2005	4.0	See Evidence Table for the Use of Tubular Elastic, Elastic Wrap, or Tape for Ankle Support above.				
Leanderson 1999	4.0	See Evidence Table for the Use of Tubular Elastic, Elastic Wrap, or Tape for Ankle Support above.				

Evidence for the Use of Walking Boots for Ankle Sprain
There are 2 moderate-quality RCT (with multiple reports) incorporated into this analysis. (Prado 14)

Author/Year Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments
Cooke 2009 Lamb 2005, 2009	7.5	See Evidence Table for the Use of Early Mobilization for Ankle Sprain above.				
Prado 2014 RCT	4.0	N = 104 with severe lateral ankle ligament injuries, average age 32.7, age range 15 to 64, (SD 12.2)	Group A, walking boot first 3 weeks, functional brace for an additional 3 weeks (n = 94) vs. Group B, functional brace only (n = 92). Rehab program: 4 weeks after injury, strengthening and proprioception exercises, limiting ankle inversion and plantarflexion to 10°; follow-up: baseline, 3, and 6 weeks following injury.	Mean ± SD for AOFAS score: Group A vs. Group B: first week after injury: 61±11.2 vs. 67±10.8, p = 0.00003, in favor of Group B. Mean±SD for VAS: Group A vs. Group B: 3 weeks: 1.7±1.2 vs. 1.4±1.2, p = 0.0348, in favor of Group B. Mean±SD for AOFAS score: Group A vs. Group B: 3 weeks: 79.5±9.2 vs. 84.8±8.8, p = 0.00004, in favor of Group B; 6 weeks: 90.5±10.6 vs. 94.3±6.6, p = 0.027, in favor of Group B.	"Conservative treatment of patients with acute, severe, first episode lateral ankle injuries using a functional brace showed slightly better functional results compared to those using a walking boot, as well as a shorter period of work absenteeism. Both treatment protocols allowed for the reestablishment of ankle stability."	Minimal baseline comparability. Functional brace showed a slight improvement over use of walking boot and faster return to work. Data support immediate use of functional brace over walking boot for 3 weeks.

Evidence for the Use of Heat for Ankle Sprain

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

Author/Year Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments

Cote 1988 RCT	4.0	N = 30 post-acute sprained ankles	Cold bath (50-60°F) vs. heat bath (102-106°F) vs. contrast bath for acute ankle sprain (Grade I, II) swelling applied once daily (20 mins) on post-injury days 3,4,5. Outcomes measured 1-3 days post treatment.	Ankle volume change pre- to post-treatment (mL): Cold vs. Heat vs. Contrast mean (SD), Day 1: -1.3 (27.1) vs. 27.4 (25.2) vs. 27.4 (13.6), Day 3: 1.7 (14.2) vs. 28.7(15.8) vs. 35.3 (31.2). Total 3 day change: 3.3 (11.3) vs. 25.3 (19.5) vs. 26.5(8.2), p <0.05 cold vs. heat, contrast. No difference between heat and contrast.	"[C]old therapy is clearly the most favorable of the three treatments if the therapeutic objective is to minimize edema before rehabilitative exercise during the third, fourth and fifth days post injury for first- and second-degree ankle sprains."	Small sample size. Details of allocation, baseline comparability missing. Age of injury not specified. Effect of treatment is limited to edema as functional improvement and pain measures were not included.

Evidence for the Use of Casting for Ankle Sprain

There are 6 moderate-quality RCTs or crossover trials (two with multiple reports) incorporated into this analysis. There are 5 low-quality RCTs in Appendix 2.(499-501, 510, 511) (Zwipp 92; Cetti 84; Korkala 87; van den Hoogenband 84; Gronmark 80)

Author/Year Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments
Immobilization vs. Early Mobilization						
Tremblay 2009 Crossover Trial	7.5	N = 48 healthy volunteers	Braking performance in walking cast vs. Aircast Walker vs. running shoe (control).	Adjusted mean total braking time (seconds): running shoe vs. walking cast vs. Aircast Walker undistracted; 0.604±0.051 vs. 0.636±0.60 vs. 0.639±0.05, p <0.05 vs. control. Distracted, 0.680±0.059 vs. 0.700±0.067 vs. 0.712±0.063, p <0.05 vs. control, p <0.05 vs. walking cast.	"[W]earing a walking cast or a removable Aircast Walker on the right lower limb increases the emergency braking time during simulated driving."	Data suggest reduced reaction times in emergency braking with and without distractions although findings were linked to lab situation in health subjects. Applicability to injured patients uncertain.
Cooke 2009 Lamb 2005, 2009	7.5	See Evidence Table for the Use of Early Mobilization for Ankle Sprain above.				

Ardevol 2002	6.0	See Evidence Table for the Use of Early Mobilization for Ankle Sprain above.
Beynnon 2006	5.5	See Evidence Table for the Use of Early Mobilization for Ankle Sprain above.
Dettori 1994 a, b	5.0	See Evidence Table for the Use of Early Mobilization for Ankle Sprain above.
Eiff 1994	4.5	See Evidence Table for the Use of Early Mobilization for Ankle Sprain above.

Evidence for the Use of RICE for Ankle Sprain

There are 2 moderate-quality RCTs (one with two reports) incorporated into this analysis.

Author/Year Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments
Combined RICE Therapies						
Bleakley 2007, 2010 RCT	7.0	N = 101 acute Grade 1 or 2 ankle sprain	PRICE vs. PRICE plus early therapeutic exercises. Intermittent cryotherapy protocol: 10 minute ice, 10 minute rest (control) or 10 minute exercises (intervention) then 10 minutes cryotherapy, 3 times a day, 1 week). Both groups received exercise protocol after Week 1: 30-minute session once a week, 4 weeks) for Grade I and II sprains; 16 week follow-up.	Treatment effect: control vs. exercise. Difference in lower extremity function score: Week 1; 5.28 (0.31-10.26) p = 0.008. Week 2; 4.92 (0.27-9.57) p = 0.0083. No difference after Week 2. Pain at rest, pain with activity, and swelling: no differences any interval. Re-injury rate 16 weeks 2/50 vs. 2/51. Physical activity: Time (hours/day) 1st week, control vs. exercise; walking-1.2 (0.9-1.4) vs. 1.6(1.3-1.9) p = 0.029. Step sitting, standing, p >0.05.	"[I]ncorporating therapeutic exercises during the first week after ankle sprain resulted in significant improvements in short term ankle function compared with a standard functional intervention."	Compliance <80%, >20% dropout in exercise group. Data suggest addition of therapeutic exercises to protection, RICE protocols provides short term functional benefit as measured on subjective lower extremity functional scale and in time spent walking. No difference in other outcomes measures.
Green 2001 RCT	6.5	N = 41 acute ankle inversion sprains <72	RICE vs. passive accessory joint mobilization +	At 4th treatment session, 68% of treatment group and 3 subjects from control released as	"Addition of talocrural mobilization to the RICE protocol in the management	Baseline differences in number of recurrent sprains (higher in experimental

		hours and no other injury to the lower limb	RICE for acute sprain.	attained full ROM in dorsiflexion, p <0.01. For dorsiflexion ROM, experimental group improved 10.9° (SEM = 1.9°) and control 5.8° (SEM = 1.1°). Stride speed increased more within 1st and 3rd treatment sessions for experimental group, p <0.05. Experiment group returned to work 6 days after injury, and the control group patients returned to work 5.3 days after injury.	of ankle inversion injuries necessitated fewer treatments to achieve pain-free dorsiflexion and to improve stride speed more than RICE alone."	group). Despite outcome improvements in dorsiflexion, does not appear to be a statistically significant difference in lost work days or return to work, sports, or normal walking. Thus, improved dorsiflexion ROM as an outcome measure is of unknown clinical importance.

Evidence for the Use of Immediate Post-injury Rest for Ankle Sprain
There is 1 moderate-quality RCT incorporated into this analysis.

Author/Year Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments
Eiff 1994	4.5	See Evidence Table for the Use of Early Mobilization for Ankle Sprain above.				

Evidence for the Use of Ice/Cryotherapy for Ankle Sprain
There are 6 moderate-quality RCTs incorporated into this analysis. (Sandoval 10) There are 4 low-quality RCTs in Appendix 2.(505, 518, 521, 522) (Stockle 97; Michlovitz 88; Wilkerson 93; Laba 89)

Author/Year Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments
Bleakley 2006 RCT	7.5	N = 89 mild/moderate acute ankle sprains	Cryotherapy (20 minutes continuous application every 2 hours repeated vs. 10 minutes continuous application, 10	Subjective measures of function, swelling, and pain at rest improved significantly for both groups. No intergroup differences with	"The application of an intermittent cryotherapy protocol after mild or moderate ankle sprain significantly reduced the	No placebo or sham. Baseline differences in pain at rest favoring intermittent (less pain) group was nearly

			minute break, 10 minutes application, repeated q 2 hours) up to 72 hours; 6 week follow-up.	exception of more pain relief with activity during Week 1 in intermittent group, although there were baseline differences between groups.	level of subjective pain on activity, one week after the injury, compared with a standard protocol. There was no significant difference in terms of function, swelling, or pain at rest."	significant p = 0.08 which weakens conclusion.
Okcu 2006 RCT	7.0	N = 44 healthy subjects (Group A) and subjects with Grade III inversion type acute ankle sprain (Group B)	Skin temperature measurement after cryotherapy: Robert Jones bandage vs. elastic bandage vs. plaster cast vs. synthetic cast.	All groups had significant temperature reduction after use of ice packs regardless of material. Average time to reach minimum temperature was 48 minutes (RJB), 42 min (elastic), 30 minutes (Plaster) and 38 minutes (synthetic cast). Time to cooling significantly faster in casting groups compared with RJB.	"A bandage or cast does not prevent measurable skin temperature lowering by frozen ice packs both in normal and swollen ankles."	Randomization variable was not treatment but immobilization technique. All subjects received ice packs and skin temperature was measured by thermistor. No differences found. Data suggest that cryotherapy results in skin temperature cooling regardless of material over injury.
Sloan Injury 1989 RCT	5.5	N = 122 acute ankle injuries within 6 hours of injury	Immediate ibuprofen (1200mg loading, 2400mg total per day) vs. placebo 1st 48 hours, than same ibuprofen schedule. A uniform background therapy of 20 minutes cooling, compression and elevation was given to all	Immediate vs. delayed soft tissue swelling index: % improvement 49% vs. 37% p <0.01. Severity of injury: no data presented, favored immediate group p = 0.05; range of movement no differences; ability to bear weight no differences	"[I]mmediate medication with high-dose ibuprofen at 2400 mg/day should be considered in the routine treatment of moderate to severe ankle sprains, whether patients."	Patients treated within 6-hours. Data suggest immediate NSAIDs may be beneficial for immediate pain relief and swelling relief judged at 7 days vs. placebo.

			patients using cooled anklet.			
Sloan Arch Emerg Med 1989 RCT	5.0	N = 143 ankle sprains within 24 hours of injury	Cryotherapy vs. sham cryotherapy (both with NSAIDs, elastic wrap).	At Day 7, improvement in swelling by 46% of cold therapy group and 40% of dummy therapy, p = 0.07; also, 88% of cold therapy group had improved by 2-4 scale points compared to 79% of dummy therapy, p = 0.15. Weight bearing, 36% of cold therapy group and 29% of dummy therapy showed improvements by 3-4 scale units, p = 0.64.	"[A] single 30-minute period of treatment in the accident and emergency department cannot be justified, though advice to paramedics, sports trainers and patients themselves to give and continue cold and compression is probably important."	Lack of randomization, allocation, baseline comparability details. All patients had NSAIDs, elastic wrap. Data suggest no benefit of single 30 minute cold treatment vs. placebo at 1 week.
Cote 1988 RCT	4.0	N = 30 post-acute sprained ankles	Cold (50-60°F) vs. heat bath (102-106°F) vs. contrast bath for acute ankle sprain (Grade I, II) swelling applied once daily (20 minutes) post-injury Days 3, 4, 5. Outcomes measured 1-3 days post-treatment.	Ankle volume change pre- to post-treatment (mL): cold vs. heat vs. contrast mean (SD); Day 1: -1.3 (27.1) vs. 27.4(25.2) vs. 27.4 (13.6); Day 3: 1.7 (14.2) vs. 28.7 (15.8) vs. 35.3 (31.2). Total 3 day change: 3.3 (11.3) vs. 25.3 (19.5) vs. 26.5(8.2) p <0.05 cold vs. heat, contrast. No difference between heat and contrast.	"[C]old therapy is clearly the most favorable of the three treatments if the therapeutic objective is to minimize edema before rehabilitative exercise during the third, fourth and fifth days post injury for first- and second-degree ankle sprains."	Small sample size. Details of allocation, baseline comparability missing. Age of injury not specified. Effect of treatment limited to edema as functional improvement; pain measures not included.

Sandoval 2010 RCT	4.5	N = 28 participants with lateral ankle sprain; age range 18 to 26 (21±2.5 years)	Control group (CG), convention treatment (cryotherapy) only (n = 10) vs. HVPC(+) (high-voltage pulsed current), conventional treatment and HVPC, using active electrodes with positive polarity (n = 8) vs. HVPC(-), conventional treatment and HVPC, using active electrodes with negative polarity (n = 10). Follow-up: baseline, final assessment at completion.	Mean ± SD for ROM: CG vs. HVPC(+) vs. HVPC(-): first: -13±8.2 vs. -2±9.5 vs. -6±5.5, p = 0.03.	"The results showed no significant differences between groups. However, they suggest a possible contribution of HVPC(-) to the acceleration of recovery during the initial healing phase of ankle sprain in humans."	Small groups. No significant differences in 3 groups but HVPC- trended towards improved recovery time. Possible underpowering.

Evidence for the Use of Compression Bandage, Wrap, or Tape for Ankle Sprain

There are 11 moderate-quality RCTs (one with three reports) incorporated into this analysis. (Lardenoye 12; Sultan 12) There are 7 low-quality RCTs in Appendix 2.(411, 416, 500-504) (Muwanga 86; Scotece 92; Cetti 84; Korkala 87; Nilsson 83; Brooks 81; Airaksinen 90)

Author/Year Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments
Cooke 2009 Lamb 2005, 2009	7.5	See Evidence Table for the Use of Early Mobilization for Ankle Sprain above.				
Beynnon 2006	5.5	See Evidence Table for the Use of Early Mobilization for Ankle Sprain above.				
O'Hara 1992	5.5	See Evidence Table for the Use of Tubular Elastic, Elastic Wrap, or Tape for Ankle Support above.				
Dettori 1994 a, b	5.0	See Evidence Table for the Use of Early Mobilization for Ankle Sprain above.				
Lardenoye 2012	5.0	N = 70 with grade	Tape group; first layer of latex free,	No statistically significant differences were	"In summary this study shows that	Semi-rigid brace is better than taping for

RCT		II or III ankle sprain; mean age for tape 30 years, mean age for brace 29.8 years	adhesive, bandage to protect skin; 2nd layer of 2.5cm non-elastic strapping tape used for support; 3rd layer of elastoplasts 6cm broad, elastic used for fixation (n = 35) vs. semi-rigid brace with air cushions to inflate and stabilize ligaments preventing twisting (n = 35). Follow-up: baseline, 2, 4, 8, and 12 weeks.	seen between both groups for the primary outcome.	treatment of acute lateral ankle sprain with a semi-rigid brace leads to less complications and a higher patient satisfaction than treatment with tape. In line with previous studies there is no difference regarding functional outcome and pain. Therefore using a semi-rigid brace should be considered for treatment of acute ankle sprains."	patient comfort in ankle sprain but no significant differences between 2 groups and a high dropout rate.
Rucinski 1991 RCT	4.5	N = 30 post-acute (>24 hours post-injury) 1st- and 2nd-degree sprained ankles	Elastic (Ace) wrap plus elevation vs. pneumatic compression device plus elevation vs. elevation (all 30 minute treatment sessions).	In volume measurements post treatment, the control (elevation) is only group with reduced measurement from baseline p <0.01.	"The results of this study suggest that for the post acute phase of a sprained ankle, elevation alone is superior to elastic wrapping and intermittent compression."	Small sample size. Exclusion criteria: those needing "cast immobilization" may bias generalizability. Suggests after single session, elevation most effective for controlling edema, but no short to long-term conclusions.
Boyce 2005 RCT	4.0	N = 50 presented consecutively within 24 hours moder	Elastic support bandage vs. Aircast ankle brace for acute Grade II, III sprains.	Function measured by Karlsson scores: 10 days (35 for elastic vs. 50 for Aircast, p = 0.028) at 1 month (55 for elastic vs. 68 for Aircast, p = 0.029). No significant differences	"[T]he use of an Aircast ankle brace in the treatment of moderate and severe lateral ligament ankle sprains, presenting within 24 hours	Lack of details. Withdrawal rate >20%. No detail on co-interventions, compliance to treatments. Data suggest Aircast provides better functional

		ate or severe lateral ligament sprain after an ankle inversion injury		between groups for secondary outcome measures of swelling, pain at 10 days.	of injury, produces a significant improvement in ankle joint function, at both 10 days and one month, compared with standard management with an elastic support bandage."	outcomes but no differences in swelling or pain at 10 days.
Leanderson 1999 RCT	4.0	N = 73 age 15-55 with acute Grade II or III ankle sprain, who sought medical care	Air cushioned ankle brace (Aircast) vs. compression bandage for acute Grade II and III ankle sprains.	ROM discrepancy in injured vs. uninjured foot decreased at follow-up; still decreased at 10 weeks (p <0.01). ROM uninjured foot increased at follow-up. Figure-of-eight running times for both groups between 2-10 week follow-up improved significantly from baseline, but no differences between groups.	"[T]he methods used in the present study are well suited for further studies of objective modalities of ankle joint function with the possible exception of the joint position sense test."	Sparse details for randomization, baseline comparability, control of co-interventions. Results of uncertain clinical significance other than noting both groups improved through follow-up: no difference between interventions.
Viljakka 1983 RCT	4.0	N = 119 ankle sprains	Layer bandage vs. elastic adhesive tape. Oxyphenbutazone 100mg TID vs. clonixin 300mg. TID vs. placebo. Severity of acute injury not specified.	No significant differences between layer vs. elastic tape bandage in pain, tenderness, swelling, ROM. Elastic: more rash, irritation or skin compression. Examiner estimate of "good" result: Layer bandage (64%) vs. elastic (62%) vs. placebo 50%) vs. oxyphenbutazone (53%) vs. clonixin (84%). No differences between	"The layer bandage proved more stable in the lateral direction than the elastic adhesive tape bandage (p less than 0.001). Clonixin proved useful in controlling swelling and in the authors opinion gave the best clinical results."	Randomization, allocation, baseline comparability, blinding, compliance details sparse. Data suggest clonixin has advantage over oxyphenbutazone based on physician assessment but is of unknown clinical significance. Clonixin is not

				bandage groups. Placebo vs. oxyphenbutazone, p >0.05. Oxyphenbutazone vs. clonixin, p <0.01, placebo vs. clonixin, p <0.01.		available in U.S.
Watts 2001 RCT	4.0	N = 400 acute Grade 1 or 2 (mild to moderate) lateral ankle sprains	Double Tubigrip (elastic wrap) vs. No compression wrap for acute Grade I and II sprain.	81 patients in DTG group and 50 in no-DTG group took pain killers, p = 0.001. 54 of DTG group, 48 of no-DTG group had to take days off work, p = 0.072. DTG group took average of 3.37 days off compared to 3.21 days for no-DTG group, p = 0.94. Took average 2.65 days for DTG group to walk unaided vs. 2.32 days for no-DTG group, p = 0.23.	"This study suggests that the use of double tubigrip compression bandage in grade 1 and 2 ankle sprains does not shorten recovery time or number of days off work….(and) seems to be associated with an increase in the need for analgesia."	Loss of 50% to follow-up. No details on co-interventions other than "therapy and analgesia." No details on compliance to intervention.
Sultan 2012 RCT	6.5	N= 36 aged 18 years or over with ankle sprains sustained within 72 hours. Mean age (range): stocking group 34 (20-	Tubigrip (n = 18) vs. class II below knee elastic stockings (ESs, Medi UK Ltd.) (n = 18) worn until patient pain-free and fully mobile. Follow-up at 4 weeks.	At 4 weeks: ES reduced mean ankle circumference to 22 (22-23) cm and calf circumference to 38 (37-39) cm compared with no change in either ankle or calf circumference using Tubigrip, p<0.05.	"Elastic compression improves recovery following ankle sprain."	Few baseline data. Data suggest elastic stockings superior to tubigrip for ROM and edema.

		59). Tubigrip group 30 (21-57).				

Evidence for the Use of Elevation for Ankle Sprain
There is 1 moderate-quality RCT incorporated into this analysis.

Author/Year Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments
Rucinski 1991	4.5	See Evidence Table for the Use of Compression Bandage, Wrap, or Tape for Ankle Sprain above.				

Evidence for the Use of Ankle Brace Support (Pneumatic/Gel) for Ankle Sprain
There are 9 moderate-quality RCTs (one with multiple reports) incorporated into this analysis.

Author/Year Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments
Ankle Brace Support (Pneumatic/Gel)						
Cooke 2009 Lamb 2005, 2009	7.5	See Evidence Table for the Use of Compression Bandage, Wrap, or Tape for Ankle Sprain above.				
Ardevol 2002	6.0	See Evidence Table for the Use of Early Mobilization for Ankle Sprain above.				
Beynnon 2006	5.5	See Evidence Table for the Use of Compression Bandage, Wrap, or Tape for Ankle Sprain above.				
O'Hara 1992	5.5	See Evidence Table for the Use of Compression Bandage, Wrap, or Tape for Ankle Sprain above.				
Dettori 1994 a, b	5.0	See Evidence Table for the Use of Compression Bandage, Wrap, or Tape for Ankle Sprain above.				
Eiff 1994	4.5	See Evidence Table for Immediate Post-injury Rest for Ankle Sprain above.				
Rucinski 1991	4.5	See Evidence Table for the Use of Compression Bandage, Wrap, or Tape for Ankle Sprain above.				
Boyce 2005	4.0	See Evidence Table for the Use of Compression Bandage, Wrap, or Tape for Ankle Sprain above.				
Leanderson 1999	4.0	See Evidence Table for the Use of Compression Bandage, Wrap, or Tape for Ankle Sprain above.				

Evidence for the Use of Magnets for Ankle Sprain
There are no quality RCTs incorporated in this analysis.

Evidence for the Use of Diathermy for Ankle Sprain

There are 2 high- and 3 moderate-quality RCTs or quasi-RCTs incorporated into this analysis.

Author/Year Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments
Barker 1985 RCT	8.5	N = 82 mild ankle sprains	Diathermy vs. sham diathermy for acute ankle sprain (3 sessions, 45 minutes on consecutive days). Severity not specified, exclusion criteria: no fracture.	Outcomes measured at 1, 2, 3, 8, 15 days. ROM: No differences at any time. Volume: No differences at any time. Pain scores: No differences at any time. Gait Scores: no differences any time.	"All the quantitative measurements carried out in this trial have failed to show a statistically significant difference between the active and control groups."	Data suggest no short-term benefit from diathermy for mild ankle sprain with the stated protocol.
McGill 1988 RCT	8.0	N = 31 age 16-60 with lateral ligament sprain of ankle within 48 hours	Pulsed diathermy (3 daily 15 minute sessions) vs. placebo for acute Grade II sprains.	Diathermy vs. placebo (mean, SD): pain score 2.37±1.19 vs. 2.34±1.47. Number analgesics/day - 0.44 ± 0.51 vs. 0.29± 0.55. Time to weight bearing; 3.78±3.2 vs. 2.88±1.5. All differences not significant.	"No significant differences in terms of pain, swelling, or time to full weight-bearing have been shown."	Small sample size. Placebo group had proportionately more females. Data suggest no benefit over placebo.
Pennington 1993 RCT	6.5	N = 50 Grade I and II (no gross instability) sprained ankles	Diathermy vs. sham diathermy for acute mild and moderate ankle sprain (1 treatment session of 70 minutes).	Ankle edema (cc of water displacement) Placebo: 1,152±216 to 1,141±213. Diapulse: 1,295±255 to 1,251±255; mean difference: Placebo vs. Diapulse 11 vs. 44, p <0.01. Subjective improvement: 8/25 vs. 16/25	"[N]on-thermal pulsed, electromagnetic energy as delivered by Diapulse can be used to decrease swelling and pain in the acutely sprained ankle. This can be important in a population which is required to wear restrictive	Study purpose for short-term effect of diathermy in a military population. Minimal baseline comparability with heterogeneity in mean outcome measure of swelling. Data suggest benefit immediately after treatment

				favoring diathermy. No p-value given.	footwear and is expected to return to continued active training as rapidly as possible."	with diathermy but duration and long- term benefit is uncertain.
Pasila 1978 RCT	5.0	N = 321 recent ligamentous injuries of ankle and foot	Diapulse vs. curapuls vs. placebo for acute mild and moderate sprains. 20 minute treatment on 3 consecutive days. Diapulse 38W/sec, curapuls 40W/sec. Outcomes measured at Day 3.	No differences abduction, adduction, strength of forefoot. No differences recovery of impaired weight-bearing (heel, toe). Significant difference in mean change of limp 1.0 (diapulse) vs. 0.7 (placebo). Limp measured 0-3 scale, 0-no limp, 1-hardly noticeable, 2-noticeable, 3-crutches. No clinical significant differences.	"[L]ittle significant difference between recovery in the placebo group of patients and in those given shortwave treatment by either of the two devices used."	Randomization by drawing lots. No blinding noted although it is possible patients blinded. Data suggest no short term clinical benefit from diathermy.
Wilson 1972 Quasi-RCT	4.5	N = 40 with inversion injury of ankle during preceding 36 hours	Diapulse vs. placebo diapulse (1 hour treatment for 3 days) for acute mild and moderate sprains. Outcomes measured at 3 days.	Diapulse vs. placebo (at 3 days from baseline): Improvement of swelling – sum of scores all subjects (0-4 VAS) 38 to 14 (63.2%) vs. 38 to 26 (31.6%); Improvement of Pain: sum of scores for all subjects (0-4 VAS) 43 to	"High-frequency electrical treatment has a biological effect in recently-injured soft tissues. This is particularly noticeable in the reduction of pain and also disability."	Quasi-randomization (treatment machine randomized not subject). Allocation unclear. Author states statistical significance but results not reported and are of uncertain clinical significance as sum of all

				11 (74.4%) vs. 37 to 25 (32.4%); Improvement of disability (0-4 VAS): 46 to 6 (86.9%) vs. 41 to 23 (43.9%).		subjects were used rather than average improvement per subject.

Evidence for the Use of Electrical Stimulation for Ankle Sprain
There is 1 moderate-quality RCT incorporated into this analysis. There is 1 low-quality RCT in Appendix 2.

Author/Year Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments
Man 2007 RCT	4.5	N = 34 subjects recovering from ankle sprain	Neuromuscular electrical stimulation (NMES) vs. sub-motor NMES sham NMES	No significant differences among groups for adapted Hughston Clinic Subjective Rating Scale for Ankle Disorders scores between 1st and 3rd sessions, ankle volume or girth differences.	"…no differences were found between the NMES and submotor or sham ES groups in ankle-foot volumes in the early period after ankle sprain."	Baseline differences existed in outcomes measure of ankle girth. Lack of randomization, allocation details. Small sample size, low power. Data suggest lack of efficacy.

Evidence for the Use of Iontophoresis for Ankle Sprain
There are no quality trials incorporated into this analysis.

Evidence for the Use of Low-level Laser Therapy for Ankle Sprain
There is 1 high- and 1 moderate-quality RCT incorporated into this analysis.

Author/Year Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments

de Bie 1998 RCT	9.5	N = 217 acute lateral ankle sprains	Low-level laser therapy (5J/cm2 and 0.5J/cm2) vs. sham laser therapy, 12 treatments over 4 weeks for acute mild, moderate, and severe ankle sprain. Each of 3 groups received bracing and therapeutic exercises.	Perceived pain Day 5 (mean±SD) (low dose/high dose/sham): (2.8± 2.2/2.9±2.1/3.3±2.4) p = 0.6; Day 10 (2.0±2.0/2.1±1.9/1.7±1.9) p = 0.48; Day 14 (1.6±1.9/1.7±1.7/ 1.4±1.7) p = 0.42; Day 28 (0.6±1/ 0.8±1.2/0.4±1) p = 0.14. Function score Day 5 (25.1±15/24.7±15.1/ 25.7±114.8) p = 0.92; Day 10 (42.2±16.1/44.1±14.9/49. 9±15.9) p = 0.01; Day 14 (56.3±16.1/56.0 ±15.7/60.0±17.1) p = 0.03. Sick leave; 12.5±11.1/11.2±10.0/7.8± 9.2, p = 0.02. Outcome measures 1 year follow-up (mean ±SD/low/ high/placebo): (13.1±12.3/11.5± 10.7/7.8±9.3) p = 0.013.	"Laser treatment is not effective in the treatment of ankle sprains. On the basis of this trial, therapists should reconsider the use of laser therapy in the treatment of ankle sprains."	Co-interventions of elastic wrap, bracing, home exercises. No added benefit from laser therapy at low or high energy compared with sham. Treatment groups had significantly more absence days away from work and lower functional outcomes in first 4 weeks. Data suggest lack of efficacy.
Stergioulas 2004 RCT	5.0	N = 47 soccer players with 2nd degree ankle sprains	RICE vs. RICE and placebo laser vs. RICE and LLLT (820nm, 40mW at 16 hz) twice daily x 3 days for acute moderate grade ankle sprains.	Largest volume change in laser group: 40.3±2.4ml decreased after 24 hours (p <0.01), 56.4±3.1ml after 48 hours (p <0.002), 65.1±4.4ml after 72 hours (p <0.001).	"LLLT combined with RICE can reduce edema in second-degree ankle sprains."	Although significant difference from baseline in volumetric measurement of edema reduction in LLT group, no intergroup statistical analysis provided. Thus, unknown if LLLT provided benefit over placebo or RICE related to edema. Results limited to 72-hours post-treatment. Significance of edema reduction is of unknown clinical significance.

Evidence for the Use of Phonophoresis for Ankle Sprain
There are no quality studies incorporated into this analysis.

Evidence for the Use of Therapeutic Ultrasound for Ankle Sprain
There are 4 moderate-quality RCTs incorporated into this analysis. There is 1 low-quality study in Appendix 2.

Author/Year Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments
Nyanzi 1999 RCT	6.5	N = 58 ankle injuries	Ultrasound vs. sham ultrasound; 3 10-minute sessions on consecutive days. Energy 0.25 W cm^{-2}, 1:4 mark ratio at 3Mhz. Follow-up 2 weeks post last session. Acute sprains, severity not described.	Placebo vs. ultrasound: VAS (0-10cm): No differences any day (1-14). Intragroup placebo improved 4.8 to 0.7cm p <0.0001, ultrasound 4.9 to 0.9cm p <0.0001. Ankle swelling: No intergroup differences at any interval. Both groups improved significantly from baseline. No differences between dorsiflexion, plantar flexion, and weight bearing ability.	"[This study has shown that at the dose and duration used, ultrasound therapy offers no benefits over sham ultrasound (placebo) in the management of lateral ligament sprains of the ankle joint."	Study blinded to patient and researcher applying treatment. Allocation not described. Few baseline variables presented for comparison. Suggests ultrasound treatment does not provide therapeutic effect for acute ankle sprain. Grade of sprain uncertain, although all subjects eligible after fracture ruled out by radiograph.
Oakland 1993 RCT	5.5	N = 220 acute injuries of lateral ankle ligaments	Felbinac gel plus sham ultrasound placebo vs. placebo gel plus ultrasound vs. felbinac plus ultrasound for acute ankle sprains (severity not described).	Changes from baseline in VAS Pain: 21.5mm vs. 19.4mm vs. 16.5mm, p >0.05. Investigator Assessment (% moderate or better response) 84.5% vs. 83.5% vs. 86.5%; Full Weight bearing: 73% vs. 77% vs. 80%, p >0.05	"[F]elbinac gel has a similar clinical efficacy to ultrasound in the treatment of acute injuries of the lateral ankle ligaments."	Allocation, blinding of investigator not described; 52 of 220 dropped out although results carried forward in analysis. Study suggests ultrasound and topical NSAID of similar efficacy. No evidence of combined effect. No control arm.

Zammit 2005 RCT	5.0	N = 34 acute lateral ligament sprains of ankle joint	Ultrasound vs. sham ultrasound vs. control. All groups received elastic wrap (tubigrip), exercise, and ice; 6 sessions of ultrasound over 2 weeks, energy 0.25Wcm^2 for 10 minutes, sessions 4-6 increased to 0.5Wcm^2. Acute Grade I and II sprains.	Ultrasound vs. sham vs. control: Mean changes at 22 days. Pain (VAS cm): 3.9/4.0/4.2, p >0.05; Swelling reduction (cm): 1.0/1.3/1.2, p >0.05; Plantar flexion: 10°/5.2°/5/5°, p >0.05; Dorsiflexion: 4.7°/4.6°/8.8°, p >0.05.	"At the does and duration used in this study, ultrasound is not effective in the management of acute lateral ligament sprains of the ankle joint, with respect to the following outcomes: pain, swelling, range of motion during dorsiflexion and plantar flexion, and postural stability."	Randomization, allocation, baseline comparability details sparse. Data suggest no added benefit of ultrasound therapy to mild and moderate acute ankle sprains over placebo combined plus conservative measures of exercise, elastic wrap. Use of these modalities limits ability to differentiate effect of natural history.
Williamson 1986 RCT	4.0	N = 154 age 12-65 with history of inversion injury to lateral ligament of ankle	Ultrasound vs. sham ultrasound for acute mild and moderate ankle sprains. Treatment every other day until reaching end point of 0-1 on a 15 point scale for pain and degree of limitation.	No significant difference between groups for time spent on crutches or time taken off work. Both groups reached the end points at the same rate.	"Ultrasound treatment by the method used… does not hasten recovery after a lateral ligament sprain of the ankle."	Lack of randomization, allocation, baseline comparability, compliance details. High withdrawal rate. No additive effect of ultrasound to other methods demonstrated.

Evidence for the Use of Acupuncture for Ankle Sprain
There are no quality RCTs incorporated into this analysis.

Evidence for the Use of Hyperbaric Oxygen for Ankle Sprain
There is 1 moderate-quality RCT incorporated in this analysis.

Author/Year Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments

Borromeo 1997 RCT	6.0	N = 32 acute ankle sprains	Hyperbaric oxygen therapy 2 atmospheres absolute pressure vs. air 1.1 atmosphere absolute pressure treatment.	Regression analysis for oxygen vs. air, age, severity, time to initial treatment after injury: p = 0.152, p = 0.010, p = 0.0001, p = 0.995. Both groups significant reduction in pain during treatment (p <0.05): SEM for HBO = 0.19, SEM for air = 0.14.	"Analysis of objective measures of ankle function showed no difference between the subjects exposed to air and those exposed to HBO. Only two factors, subject age and initial severity of injury, affected time to recovery."	Multiple co-interventions (NSAID, RICE, splinting, elastic warp, PT). Small sample size. Data suggest no additional benefit for acute injury treated within 72 hours.

Evidence for the Use of Manipulation and Mobilization for Ankle Sprain
There is 1 high- and 5 moderate-quality RCTs or crossover trials incorporated into this analysis. (Truyols-Dominguez 13; Yeo 11; Cosby 11) There are 5 low-quality RCTs in Appendix 2.(544, 546-549) (Eisenhart 03; Pellow 01; Coetzer 01; Kohne 07; Lopez-Rodriguez 07)

Author/Year Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments
Vicenzino 2006 Crossover Trial	8.0	N = 16 recurrent lateral ankle sprains	Mobilization with movement (MWM)t: weight bearing vs. non-weight bearing vs. no treatment in those with history of recurrent ankle sprain (no active conditions).	Weight bearing vs. non-weight bearing vs. control: % improvement of posterior talar glide; 55% vs. 50% vs. 17%, p = 0.003 for both MWM techniques vs. control.	"[T]he application of the MWM treatment techniques improved posterior talar glide and talocrural dorsiflexion immediately after application in subjects with chronic recurrent lateral ankle sprain. [T]here appears to be little difference in treatment effect between the 2 MWM techniques."	Crossover trial. Reported double-blinding, but not feasible subject or intervention could be blinded. Results of uncertain clinical significance as no report of long-term outcomes regarding recurrence of sprain.
Truyols-Dominguez 2013 RCT	7.0	N = 50 with unilateral inversion ankle	Comparison group, manipulation/mobilization only (n = 25) vs. Experimental group, myofascial	Combined treatment group had greater improvement on each functional score domain. No p-values to report.	"This study provides evidence that, in the treatment of individuals' post–inversion ankle sprain, the addition of myofascial therapy to a plan of care consisting of	Addition of myofascial techniques to thrust and non-thrust manipulations in treatment of acute ankle sprain

		sprain; mean age for comparison group: 32, mean age for experimental group: 33.	manual therapy and manipulation/mobilization intervention (n = 25). Both groups: ankle and foot non-thrust mobilization and thrust manipulation, general exercises, and instruction to elevate and ice the ankle. Follow-up: baseline, post intervention, and 1-month		thrust and nonthrust manipulation and exercise may further improve outcomes compared to a plan of care solely consisting of thrust and nonthrust manipulation and exercise. However, though statistically significant, the difference in improvement in the primary outcome between groups was not greater than what would be considered a minimal clinically important difference. Future studies should examine the long-term effects of these interventions in this population."	associated with greater improvement of function and less pain at 4 weeks and at 1 month follow-up. However, differences modest.
Collins 2004 Crossover Trial	6.5	N = 16 subacute Grade II lateral ankle sprains	Mobilization with movement vs. placebo mobilization vs. no-treatment (single sessions).	Mean±SD for dorsiflexion (mm) MWM vs. placebo vs. control: Pre: 57.27 (p 0.017) ± 41.00 vs. 60.17± 38.49 vs. 58.29±32.67. Post: 68.93± 45.44 (p 0.017) vs. 62.07± 38.97 vs. 56.42± 33.48.	"Mulligan's dorsiflexion mobilization with movement technique significantly increases talocrural dorsiflexion initially after application in subacute ankle sprains."	Excluded for sample size. Randomized variable was treatment order. No long-term results; results of unknown clinical significance.
Green 2001 RCT	6.5	N = 41 acute ankle inversion sprains <72	RICE vs. passive accessory joint mobilization plus RICE for acute ankle sprain (max 6 treatment	Manipulation vs. control: attained full ROM after 4 sessions: 68% vs. 16%, p <0.01. Dorsiflexion ROM improvement: 10.9° (SEM = 1.9°) vs. 5.8° (SEM = 1.1°) after 1st treatment. Stride speed increased	"Addition of talocrural mobilization to the RICE protocol in the management of ankle inversion injuries necessitated fewer treatments to achieve pain-free dorsiflexion and to improve stride	Baseline differences in number of recurrent sprains (higher in experimental group). Despite outcome improvements in dorsiflexion, does not

		hours and no other injury to lower limb	sessions, once every other day).	more within 1st and 3rd treatment sessions for experimental group, p <0.05. Return to work: 5.3 vs. 6 days.	speed more than RICE alone."	appear statistically significant in lost work days or return to work, sports, normal walking. Thus, improved dorsiflexion ROM as an outcome measure of unknown clinical importance.
Yeo 2011 Experimental Trial	5.5	N= 13 with unilateral acute and subacute ankle supination injury (2-10 weeks). Mean age 29.5 years. Acute and subacute ankle sprains (2-10	Maitland's passive accessory mobilization of the talus on distal tibia and fibular (manual application of repetitive gentle oscillation of talus for 1 min, repeated 3 times) vs. manual contact control (hand contact on ankle) vs. no contact control. 3 study sessions scheduled at least 48 hours apart where all patients received the 3 conditions. Assessments	Ankle dorsiflexion index: increase of 9.6mm following treatment condition (p = 0.000), significant between treatment and manual contact control (p = 0.000) and no contact control (p = 0.000). Pressure pain threshold: increased 17.76% after treatment (p = 0.000), significant between treatment and manual contact control (p = 0.000) and no contact control (p = 0.002). Pain VAS scores: NS (p = 0.369). Ankle functional scores: NS (p = 0.475).	"[A]ccessory mobilisation of the ankle joint using the anterioreposterior glide technique produced an immediate and rapid onset hypoalgesic effect and an improvement in ankle dorsiflexion range of motion in subjects with an ankle supination injury."	Experimental design. No intermediate or longer term outcomes of meaningful clinical efficacy reported.

		weeks)	immediately after each intervention.			
Cosby 2011 RCT	4.5	N = 17 with acute lateral ankle sprain (Grade I and II); mean age 19.76±1.35	Treatment group, physical therapist guided 30 second grade III AP talocrural joint mobilizations, one mobilization/second vs. Control group, not treatment, no physical contact with physician. All participants: dorsiflexion ROM, posterior talar translation using a portable ankle arthrometer, and self-reported function. Follow-ups: baseline, immediate post-treatment, and 24-hour follow-up.	Mean±SD for dorsiflexion ROM: control vs. treatment: baseline: 7.36±6.38 vs. 6.49±6.43, p = 0.04; 24-hour: 9.94±4.0 vs. 8.82±7.29, p = 0.04. FADI-ADL (foot and ankle disability index-activities of daily living) control vs. treatment: baseline: 72.76±18.7 vs. 62.29±17.63, p = 0.004, 24-hour: 82.09±9.99 vs. 75.85±15.15, p = 0.004. FADI pain: baseline: 81.25±14.94 vs. 72.22±10.87, p = 0.03, 24-hour: 80.47±7.04 vs. 84.03±14.36, p = 0.03.	"A single bout of AP talocrural joint mobilizations may not have an immediate effect on ankle dorsiflexion ROM, posterior talar translation, or self-reported function; however, they may have an immediate effect on pain perception in individuals with an acute lateral ankle sprain."	Small N with few baseline characteristics. No significant decrease in pain perception between 2 groups at 24 hours. No significant followup to afford assessment of utility.

Evidence for the Use of Ankle Support (Brace, Tape) for Prevention of Ankle Sprain
There are 3 moderate-quality RCTs incorporated in this analysis. There are 3 low-quality RCTs in Appendix 2.(554) (Stasinopoulos 04; McGuine 11; McGuine 12)

Author/Year Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments
Amoroso 1998 RCT	6.0	N = 777 U.S. Army Airborne School volunteers	Outside boot ankle brace (Aircast) vs. no additional support in parachute jump training in military population.	Brace vs. control: Ankle inversion injuries 7/376 (3.79% vs. 1/369 (0.55%) p-0.04. No differences in ankle fractures, syndesmosis sprains, knee or leg sprains/strains.	"Inversion ankle sprains during parachute training can be significantly reduced by using an outside-the-boot ankle brace, with no increase in risk for other injuries."	Randomization based on odd/even military numbers. No baseline comparisons. Compliance not stated but inferred in this military population.
Mickel 2006 RCT	5.0	N = 93 ankle sprains in high school football players during a single season	Bracing (semi-rigid airsport brace) vs. taping for prevention of sprain in high school football league.	There was 0.83 ankle sprains per 1,000 exposures for brace group and 0.77 sprains per 1,000 exposures in tape group, p >0.05.	"Both of these prophylactic measures were well tolerated by the players, and the incidence of lateral ankle injuries was equal in both groups, whereas the cost to implement these measures was higher in the taping group."	Allocation, baseline details sparse. Study may not have been powered to detect differences. Cost discussion compares retail taping costs to wholesale device costs.
Sitler 1994 RCT	5.0	N = 1,601 U.S. Military Academy cadets with no pre-participation, clinical, functional, or radiographic evidence of ankle instability	Ankle stabilizer (Aircast) vs. no ankle stabilizer in healthy military recruits intramural basketball program.	Total number of ankle injuries for 2 years: ankle stabilizer 11, control 35, p <0.05. For contact injuries, those who wore ankle stabilizers had fewer ankle injuries compared to controls, p <0.01. The incidence of knee injury not significant between the 2 groups.	"The total number of ankle injuries as well as the number of single and combined anterior talofibular and calcaneofibular ligament injuries were significantly reduced with ankle stabilizer use. No significant difference existed between the ankle stabilizer and control groups in the frequency of knee injuries."	Randomization, allocation methods not described. Overall incidence lower with brace group. Study completed in young military population

Evidence for the Use of Balance Training/Proprioception for Prevention of Ankle Sprain
There are 4 moderate-quality RCTs (one with two reports) incorporated into this analysis. There are 8 low-quality RCTs (one with 2 reports) in Appendix 2.(554, 560-567) (Coughlan 07; Engebretsen 08; Mohammadi 07; Verhagen 04; Verhagen Br J Sports Med 05; Verhagen Clin Biomech 05; Wedderkopp 99; Melnyk 09; Stasinopoulos 04)

Author/Year Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments
Emery 2007 RCT	6.0	N = 920 high school basket-ball players	Wobble board training plus warm-up exercises vs. warm-up exercises in high school basketball league.	Control vs. training player exposure hours, number of injuries, injury rate/1000 hour, relative risk, 95% CI, statistically significant. All injury: 34955/39369, 141/130, 4.03 (3.4-4.76)/3.3 (2.76-3.92), 1/0.8, 0.57-1.11, p = 0.18. All acute injury: 34955/3969, 134/109, 3.83 (3.21-4.54)/2.77 (2.27-3.34), 1/0.71, 0.5-0.99, p = 0.047. Lower extremity injury: 34955/39369, 111/106, 3.18 (2.61-3.82)/2.69 (2.2-3.26), 1/0.83, 0.57-1.19, p = 0.3. Ankle injury: 34955/39369, 76/62, 2.46 (1.97-3.04)/1.57 (1.21-2.02), 1/0.71, 0.45-1.13, p = 0.15.	"A basketball-specific balance training program was effective in reducing acute-onset injuries in high school basketball. There was also a clinically relevant trend found with respect to the reduction of all, lower-extremity, and ankle sprain injury."	Randomization conducted by team rather than individual. Compliance less than 60%. No significant effect on ankle sprains but data suggest reduced acute injuries.
McGuine 2006 RCT	5.5	N = 765 high school soccer and basket-ball players	Balance training (wobble board) vs. control for high school basketball and soccer players.	"Taking part in the intervention program significantly reduced the risk of an ankle sprain (risk ratio, 0.56; 95% CI, 0.33-0.95; p = 0.033)."	"[B]alance training program, implemented throughout a sports season, will reduce the rate of ankle sprains by 39% in high school basketball and soccer players."	Subjects randomized as whole team. Method not described. No blinding of assessors. Suggests balance training program beneficial in reducing sprains.
Huppereets 2008, 2009 RCT	5.0	N = 522 active participants in sports with a	Home-based 8-week proprioceptive training (3	Effect of proprioceptive training program regression analysis showed lower recurrences of ankle sprain in intervention vs. control	"The use of a proprioceptive training programme after usual care of an ankle sprain is	No blinding, Low compliance rates (23% fully compliant, 29% partially).

		lateral ankle sprain up to 2 months prior to inclusion	sessions/week plus routine physiotherapy) vs. routine physiotherapy for prevention of recurrent sprain; 1-year follow-up.	(0.63/95%CI = 0.45-0.88). Effect of non-medically treated athletes' regression showed lower recurrence of ankle sprains in intervention vs. control. Self reported recurrences of ankle sprain (0.45, 0.28-0.72). Recurrences leading to loss of sports time (0.47, 0.23-0.96).	effective for the prevention of self reported recurrences. This proprioceptive training was specifically beneficial in athletes whose original sprain was not medically treated."	Data suggest home based training for proprioception may be beneficial in preventing recurrent ankle sprain.
Rotem-Lehrer 2007 RCT	5.0	N = 36 male volunteers with Grade 1 or 2 ankle sprains	Internal focus of attention (IFA) during postural control training vs. external focus (EFA) during postural control training.	Stability scores: overall/anterior posterior stability/medial lateral stability; pretraining, post-training, change score: IFA mean±SD for (95%): 13.5±4.1/11.9±5.5/-1.59 (-3.13 to -0.05), 8.3±3.2/6.8±3.2/ -1.43 (-3.13 to 0.28), 10.3±4.2/ 9.6±5.1/-0.69 (-1.99 to 0.61). EFA: 15.7±3.3/10.2±3.5/-5.45 (-6.62 to -3.97), 10.1±3.4/6.0±2.0/-4.14 (-5.75 to -2.54), 11.5±2.6/8.2±3.4/ -3.36 (-4.88 to -1.84).	"[E]xternal focus of attention is advantageous for the transfer of learning of a postural control task following an ankle injury."	Randomization, allocation details sparse. Blinding described but not of intervention or assessment. Results do not include injury recurrence or improvement and are thus of limited significance.

Evidence for the Use of Foot Orthotics for Prevention of Ankle Injury

There is 1 moderate-quality RCT incorporated into this analysis. There is 1 low-quality RCT in Appendix 2.

Author/Year Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments
Finestone 2004 RCT	4.0	N = 451 male infantry recruits	Trial 1: (n = 451) custom soft orthoses vs. soft prefabricated orthoses; Trial 2: (n = 423) semirigid biomechanical orthoses vs. semirigid	Injury incidence (%): custom soft vs. soft prefabricated vs. semirigid biomechanical vs. semirigid prefabricated: Stress fracture 9.1 vs. 8.9 vs. 9.7 vs. 9.1; Ankle sprain	"[F]indings suggest that if a foot orthosis is being dispensed as prophylaxis for overuse injuries in an active, healthy population, there is little justification for prescribing semirigid biomechanical orthoses. Their cost is	Reported as single trial, but groups randomized separately. Prevention study in military population. Reported as subject blinded, but

			prefabricated orthoses. Use in military training 14-week program.	9.9 vs. 10.7 vs. 9.3 vs. 8.0; Foot problems: 17.4 vs. 19.6 vs. 14 vs. 20.1. No differences between groups in any disorder.	high compared to other types of orthoses, without an advantage in comfort or a reduction in stress fractures, ankle sprains, and foot problems."	true blinding not described. Data suggest no effect of orthotic type in injury prevention. No control group.

Evidence for the Use of Foot Wear for Ankle Sprain

There are 3 moderate-quality RCTs incorporated into this analysis.

Author/Year Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments
Knapik 2010 RCT	5.5	N = 1,411 Marine Corps recruits	Motion control shoes for low arch-motion vs. cushion shoe for high arch vs. stability (control) running shoes; 12-week basic training (Marines).	Hazard ratio (men) intervention/control; Low arch: 0.91 (0.40-2.07) p = .82; High arch: 1.05 (0.53-2.10) p = .89; hazard ratio (women) intervention/ control: Low arch: 0.74 (0.31-1.76) p = .49; High arch: 1.11 (0.62-2.00) p = .72	"This prospective study demonstrated that assigning shoes based on the shape of the plantar foot surface had little influence on injuries even after considering other injury risk factors."	Lack of compliance, co-intervention details. Compliance assumed high (military training/shoe assignment tracked). Results suggest fitting shoe type to perceived plantar shape provides no additional benefit in preventing injuries, including sprains.
Knapik 2010 RCT	4.5	N = 2,702 U.S. Air Force Basic Military Training (BMT) recruits	Motion control shoes for low arch-motion vs. cushion shoe for high arch vs. stability (control) running shoes; 12-week basic training.	Training-related Injury Index: hazard ratio (men) intervention/control 1.17 (0.95-1.45) p = .14; Training-related Injury Index: hazard ratio (women) intervention/ control 1.26 (0.96-1.65) p = .09	"This prospective study demonstrated that assigning running shoes based on the shape of the plantar surface had little influence on the injury risk in BMT even after controlling for other injury risk factors."	Lack of compliance, co-intervention details. Compliance assumed high (military training/shoe assignment tracked). Results suggest fitting shoe type to perceived plantar shape provides no additional benefit in preventing injuries, including sprains.

Barrett 1993 RCT	4.0	N = 622 college intramural basketball players	High-top shoes vs. low-top vs. high top with inflatable air chambers for prevention of ankle sprain.	Injury rates per 10,000 player minutes, 95% CI (high-top air chamber vs. low-top vs. high-top): 2.69 (0.6-6.8) vs. 4.06 (1.2-10.3) vs. 4.8 (2.0- 9.8).	"The major finding of this study was that there was no difference between high- and low-top basketball shoes in the prevention of ankle sprains."	Allocation method, compliance unclear. Results suggest no difference after 2 months in college intramural population with shoe types.

Evidence for the Use of Stretching/Strengthening Exercises for Prevention of Ankle Injury
There are no quality RCTs incorporated into this analysis. There are 4 low-quality RCTs in Appendix 2.(562, 583-585) (Pope 00; Puls 07; Ekstrand 83; Mohammadi 07)

Evidence for the Use of Therapy for Ankle Sprain/Instability
There are 6 moderate-quality RCTs (two with two reports) incorporated into this analysis. (Cleland 13; Ismail 10) There are 9 low-quality RCTs in Appendix 2.(416, 588-591, 601) (Christakou 07; Laufer 07; Youdas 09; Chaiwanichsiri 05; Wester 96; Brooks 81; Kim 14; Collado 10; Asimenia 13)

Author/Year Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments
Van Rijn 2009, 2007 RCT	7.5	N = 107 adults with acute lateral ankle sprain	Physical therapy (PT) plus conventional care vs. conventional care only (education, home exercises, early weight bearing, tape, brace). Intervention group: 9 sessions of supervised PT consisting of individualized program of balance exercises, walking, running, and jumping. Home exercise	Outcomes after 3, 12 months follow-up (conventional/PT) AR%: re-sprain 3 months (14/10) - 4.2(-21.5 to 13.1%); re-sprain 12 months (16/13) 2.5 (-16.8 to 22.0%); reported instability 3 months (34/32) 1.2 (-17.4 to 19.7); instability 12 months (30/26) 3.5 (-22.9 to 15.8%); tested instability 3 months (26/18) - 11.5 (-32.6 to 9.5); full treatment appreciation 3 months (32/40) 22.8 (7.0 to 38.7%). Mild/moderate vs. severe sprain subgroups: pain (walking on flat) 2.2 vs. 1.3%, OR 1.1	"Usual care combined with supervised exercises compared with usual care alone at 3 months and 1-year follow-up after an acute lateral ankle sprain did not indicate clinically meaningful differences in the occurrence of re-sprains or in subjective recovery in patients consulting a GP or the emergency department. The results of (2009) study only partially support the	Of those in home exercise group, 82% reported rarely or never doing home exercises, essentially making this a study of supervised PT vs. "usual care," with no clinical benefit demonstrated by supervised PT. The 2009 study presented analysis for subset of severe ankle sprains in cohort and demonstrated modest statistical benefit but unknown clinical benefit at

			program not defined.	(0.1-2.0); pain (walking on rough) 2.5 vs. 2.3%, OR 1.7 (0.6-2.9); stability (walking on rough) 2.6 vs. 2.1%, OR 1.8 (0.6-2.9). No differences sprain recurrence between groups.	recommendations regarding the use of the ankle function score in the Acute Ankle Injury guideline of the Royal Dutch Society of Physiotherapists."	4 weeks, and no differences in any measure at 8 weeks or beyond.
Cleland 2013 RCT	7.5	N = 74 with inversion ankle sprain; mean age for home exercise program: 33.2, mean age for manual therapy and exercise: 37.1	Manual Therapy & Exercise (MTEX), mobilizing and strengthening, standing and functional exercises; seen by physical therapist (PT) twice weekly for 8 sessions (n = 37) vs. Home Exercise Program (HEP), manipulations of joints, home exercises, strengthening and balancing exercises; seen by PT for 4 sessions 1 per week (n = 37). Both treatments lasted 30 minutes, advice to stay active, and education on ice, compression and elevation. Follow-up: baseline, 4 weeks and 6 months.	Mean percent score for FAAM activities of daily living (ADL): MTEX vs. HEP: 4 weeks: 85% vs. 70%, p <0.05; 6 months: 95% vs. 85%, p <0.05. Mean percent score for FAAM sports: MTEX vs. HEP: 4 weeks: 75% vs. 65%, p <0.05; 6 months: 90% vs. 85%, p <0.05. Mean (95 CI) for FAAM ADL: Between group differences: baseline to 4 weeks: 11.7 (7.4 to 16.1), p <0.001 (in favor of MTEX); baseline to 6 months: 6.2 (0.98 to 11.5), p = 0.02 (in favor of MTEX). FAAM sports: baseline to 4 weeks: 13.3 (8.0 to 18.6), p <0.001 (in favor of MTEX), baseline to 6 months: 7.2 (2.6 to 11.8), p = 0.002 (in favor of MTEX).	"The results suggest that an MTEX approach is superior to an HEP in the treatment of inversion ankle sprains."	Good baseline comparability. Both groups had pain improvement from treatment with Manual therapy and exercise group having slightly better results for pain relief and function at 4 weeks and also 6 months vs. HEP group. However, as the intervention group had both active supervision of exercise as well as manual therapy, what was responsible for the modest differences is unclear.

Bleakley 2007, 2010 RCT	7.0	N = 101 acute Grade I or II ankle sprains	PRICE vs. PRICE plus early therapeutic exercises. Intermittent cryotherapy protocol: 10 minutes ice, 10 minutes rest (control) or 10 minutes exercises (intervention) then 10 minutes cryotherapy 3 times a day for 1 week. Both received exercise protocol after Week 1 for 30 minutes once a week, 4 weeks for Grade I and II sprains; 16 week follow-up.	Treatment effect: control vs. exercise; Difference in lower extremity function score: Week 1; 5.28 (0.31-10.26) p = 0.008. Week 2; 4.92 (0.27-9.57) p = 0.0083. No difference after Week 2. Pain at rest, pain with activity, swelling: all no differences at any interval. Reinjury rate at 16 weeks 2/50 vs. 2/51. Physical activity: Time (hours/day) spent first week, control vs. exercise; Walking-1.2(0.9-1.4) vs. 1.6(1.3-1.9) p = 0.029. Step sitting, standing p >0.05.	"[I]ncorporating therapeutic exercises during the first week after ankle sprain resulted in significant improvements in short term ankle function compared with a standard functional intervention."	Compliance <80%, >20% dropout in exercise group. Data suggest addition of therapeutic exercises to protection, RICE protocols provides short term functional benefit as measured on subjective lower extremity functional scale and in time spent walking. There was no difference in other outcomes measures.
Bassett 2007 RCT	6.0	N = 47 acute ankle sprains	Home PT vs. clinic based management.	Post-PT scores (mean±SD/ clinic/home): LLTQ recreational activity subscale (12.00±10.10/ 8.18±7.24) p >0.05; LLTQ ADL subscale (2.32±3.60/1.82±3.58) p >0.05; motor activity scale (5.14±1.28/5.73±1.08) p >0.05. Appointments (mean±SD/ clinic/home): attended (7.64±4.54/4.55±1.78) p = 0.005; recommended (8.44±4.12/ 4.68±1.78) p = 0.001; completed physical therapy	"Home based physical therapy intervention plus adherence enhancing adjuncts is a safe and viable option for patients with ankle sprains, and physical therapists should contemplate using it with patients who have problems attending regular clinic appointments."	No control group of PT vs. no PT. Wide inclusion criteria (all but non-English speakers eligible). Data suggest home PT for acute ankle sprain as effective as structured/supervised PT with higher compliance to regimen.

				intervention (15/21) p = 0.004.		
Holme 1999 RCT	4.0	N = 92 ankle sprain injuries obtained during sports activity	Supervised PT vs. education and home exercises.	Side-by-side percent differences similar in both groups for all variables, p >0.05. Re-injury data 12 months after injury: yes = 2 in training group, 11 in control group (p <0.05).	"Six weeks after an ankle injury a side-to-side difference in isometric ankle strength and postural control was demonstrated, which appeared to normalize after 4 months, with or without supervised physical therapy. Supervised rehabilitation may reduce the number of re-injuries, and therefore play a role in injury prevention."	Baseline difference possibly suggesting randomization failure; 30% lost to follow-up. Measured values of uninjured side not constant over study. Appeared to improve in both groups. No between-group comparisons provided as discussion limited to comparison of injured to un-injured ankle.
Ismail 2010 RCT	4.0	N = 36 athletes with lateral ankle sprain referred to physical therapy clinic; mean age for plyometric group 25.4±4.3, mean age for resistive group	Plyometric group, exercise program of jumping and hopping different directions with or without barrier, with single of double leg; 2 days/week (n = 19) vs. Resistive group, manual exercise for dorsiflexion, plantarflexion, eversion, and inversion; 3 to 5 seconds for 10 reps; heel and toe rise, towel curl, and marble pick up (10 reps each), 2 days/week (n	Mean±SD for functional tests: plyometric vs. resistive: post-test: climbing downstairs (sec): 13.7±2.6 vs. 16.6±2.3, p = 0.01; raising on heel (times): 47.7±3.5 vs. 38.58±4.4, p = 0.00; raising on toes (times): 46.1±4.4 vs. 41.5±6.6, p = 0.01; single-limb stance (sec): 65.9±6.4 vs. 56.7±3.9, p = 0.00.	"Plyometrics were more effective than resistive exercises in improving functional performance of athletes after lateral ankle sprain."	Small N, large dropout rate. Plyometrics better than resistive exercises for increased function of lateral ankle sprains in athletes.

		27.1±4.4	= 17) 6-week study with no other follow-up.			

Evidence for the Use of Rehabilitation for Chronic Ankle Instability
There are 2 moderate-quality RCTs incorporated into this analysis. There are 5 low-quality studies in Appendix 2.(596-599, 602) (Han 09; Ross 07; Bernier 98; Kidgell 07; Powers 04)

Author/Year Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments
Hoiness 2003 RCT	6.5	N = 20 recurrent ankle sprains and positive stress x-ray films	Bi-directional bicycle pedal vs. regular (unicycle) pedal in 6 week high intensity training program.	Test group improved performance to 80% maximum level after training, 72.5% before. The control group improved from 56.1% or 67.8%. Figure 8 running (seconds before/after): test group (12.41/12.17) p = 0.003 vs. control group (12.22/12.11) p = 0.078. Eversion torque (before/after): all ankles 60°s^{-1} (22.75/2.35) p = 0.037; unstable ankles 60°s^{-1} (22.50/25.50) p = 0.154; stable ankles 60°s^{-1} (23.00/25.20) p = 0.182.	"Short-term high-intensity training with a bi-directional pedal improves ankle performance and may be an option in the treatment of recurrent ankle sprains."	Bi-directional pedal tilts 20° sideways during loaded cycles. Small sample size. Results of uncertain clinical significance in general population (test group 0.2 seconds faster running on 40 meter figure 8 track). No significant difference in Karlsson functional scores, figure of 8 running times, or eversion torque angles despite intragroup improvements in intervention group.
Hale 2007 RCT	4.5	N = 48 with unilateral chronic ankle instability (CAI)	Chronic ankle instability (CAI) rehab vs. CAI control vs. healthy group.	CAI groups showed increase in COPV when evaluating eyes closed (p = 0.034) and eyes open (p = 0.029) when standing on involved limb vs. uninvolved limb. CAI rehab and control could reach further standing on uninvolved limb: posteromedial reach p = 0.047, posterolateral reach	"[P]ostural control and functional limitations exist in individuals with CAI. In addition, rehabilitation appears to improve these functional limitations. Finally, there is evidence to suggest the SEBT may be a	Sparse study details for randomization, allocation, baseline comparability. Data suggest rehab regimen may improve postural deficits although it is not clear from this study if findings correlate to improved function and reduced

				p = 0.007, lateral reach p = 0.025. The CAI rehab group showed improvement for the FADI-Sport change scores vs. CAI control (p = 0.009), and healthy (p <0.0005).	good functional measure to monitor change after rehabilitation for CAI."	recurrence of ankle injury.

Evidence for the Use of Autologous Blood Injections for Ankle Sprain
There are no quality trials incorporated into this analysis.

Evidence for the Use of Injected Glucocorticosteroids for Ankle Sprain
There are no quality trials incorporated into this analysis. There is 1 low-quality study in Appendix 2.(411) (Nilsson 83)

Evidence for the Use of Hyaluronic Acid for Ankle Sprain
There is 1 moderate-quality RCT (with two reports) incorporated into this analysis.

Author/Year Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments
Petrella 2007, 2009 RCT	7.0	N = 158 competitive athletes with acute Grade I or II lateral ankle sprains	Periarticular hyaluronic acid injection 1.2mL vs. saline placebo injection (both groups with RICE). Injection site at anterior talofibular ligament in delivering medication in AP, medial, lateral directions. Acute Grade I, II sprains treated <48 hours.	HA vs. PL at Day 4, 8, 30, 90, 712. HA more reduction in VAS from baseline for weight bearing and walking. No differences in patient global assessment. Increased patient satisfaction Day 4, 8. Baseline scores not presented so total change significantly different but uncertain if actual data different.	"HA treatment for acute sprain was highly satisfactory in the short term and the long term versus placebo. This was associated with reduced pain and more rapid return to sport, with few associated adverse events."	Blinding, allocation methods unclear. Lack of baseline data. Previous articles on methods were unclear. Suggests hyaluronic acid injection results in clinical improvement in total pain reduction over placebo with long-lasting effect. Reported results may be of small clinical significance.

Evidence for the Use of Platelet Rich Plasma for Ankle Sprain

There are no quality trials incorporated into this analysis.

Evidence for the use of Surgical Intervention for Chronic Ankle Instability
There are no quality RCTs incorporated into this analysis.

Evidence for the Use of Acute Surgical Repair for Ankle Ligament Tear
There are 6 moderate-quality RCTs (one with two reports) incorporated into this analysis. (Pihlajamaki 10) There are 9 low-quality RCTs in Appendix 2.(412, 499, 500, 510, 511, 605, 618, 619, 621) (Moeller-Larsen 88; Specchiulli 01; Sommer 89; Zwipp 92; Korkala 87; Niedermann 81; van den Hoogenband 84; Gronmark 80; Clark 65)

Author/Year Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments
Surgery vs. Non-operative Care						
Pijnenburg 2003 Quasi-RCT	6.0	N = 370 adults 18 to 45 years with painful ankle caused by an indirect supination injury	Surgical repair vs. functional treatment of lateral ligament rupture. Functional treatment either non-weight bearing cast for 5 days followed by elastic wrap or taping.	Operative vs. functional (%), Residual pain: 16 vs. 25, p <0.05, Giving way: 20% vs. 32%, p <0.016, Recurrent sprains: 22 vs. 34, p <0.022. Score of excellent and good: 86% vs. 74% (no P provided).	"We found operative treatment led to better results at the short and long term follow-up. We believe that operative treatment for lateral ligament ruptures can be adopted in selected cases when higher functional demands are required. If operative treatment is rejected or not available, taping is a good alternative."	Quasi-randomization (odd-even week of enrollment to study). Allocation not concealed. Study demonstrates mixed results as patient report of residual pain, recurrent sprains higher in conservative group, but no difference in subjective satisfaction with treatment.
Povacz 1998 RCT	6.0	N = 167 adults with isolated injury of ankle fibular collateral ligaments	Surgery plus cast for 6 weeks vs. ankle orthosis (6 weeks) using Aircast.	Pain at 2-year follow-up: Surgery vs. Aircast mild (29% vs. 21%), severe (3% vs. 3 %), none (68% vs. 77%). Overall results were not significantly different. Time to resume normal work activities (7.0 weeks vs. 1.6 weeks, p <0.0001).	"We recommend non-operative treatment of a sprain of the ankle in young adults, including those who are involved in athletic activities."	No difference in clinical outcome at 2 years for this particular injury. Patients returned to work earlier with nonoperative treatment.

Pihlajamaki 2010 RCT	5.5	N = 51 with an acute Grade-III lateral ligament rupture of ankle, age range 18-26 (mean, 20.4)	Surgical; ligament repair, talofibular ligament, anterior talofibular and calcaneofibular ligaments (n = 25) vs. Functional; functional light-weight orthotic device for 3 weeks; allowed dorsiflexion and plantar flexion, but resisted inversion and eversion of ankle (n = 26). After care: anti-inflammatory medication and crutches, mobilization and muscle strengthening exercises supervised by physiotherapist.	No significant differences to report between two groups in any outcome measure. All patients in both groups recovered preinjury activity level and reported they could walk and run normally.	"These findings indicate that, in terms of recovery of the preinjury activity level, the long-term results of surgical treatment of acute lateral ligament rupture of the ankle correspond with those of functional treatment. Although surgery appeared to decrease the prevalence of reinjury of the lateral ligaments, there may be an increased risk for the subsequent development of osteoarthritis."	Surgical vs. functional treatment of acute ankle ruptures have similar outcomes although surgical patients showed more degenerative cartilage changes post-surgery via MRI.
Evans 1984 RCT	5.0	N = 100 acute ruptures of ankle lateral ligaments	Suture repair plus cast (3 weeks) plus PT vs. cast plus PT.	Comparisons at 3 months and 2 years after injury. Operative repair vs. plaster cast only: Giving way only; 13 vs. 4. Recurrent sprains only; 13 vs. 11. Giving way and	"[E]arly mobilisation with the protection of a cast brace may achieve equal functional results with the advantage of earlier recovery."	Randomization, allocation details missing. Study demonstrated similar outcomes in both groups with higher symptomatic instability at 2

				recurrent sprains 3 vs. 4.		years in surgical group.
Jeong 2010 RCT No mention of sponsorship. No COI.	4.5	N = 100 with diabetic foot ulcers on various locations, type 1 or 2 diabetes, and no signs of healing for a month; Mean (±SD) age 64.5 (±8.1) for treatment group and 63.8 (±6.4) for control group.	Treatment group receiving blood bank platelet concentrate (ABO- and Rh-compatible) (n = 52) vs. Control group (n = 48). Both groups received 25ml or 12.5ml for 1st application and 25ml or 12.5ml 3-4 days post-op alongside standard wound care. Assessments at baseline and 12 weeks.	Mean (±SD) time for complete ulcer healing significantly lower in the treatment group versus the control group; 7.0(±1.9) weeks vs. 9.1 (±2.2) weeks, ($p<0.05$). Degrees of wound shrinkage significantly lower in treatment group versus the control; 96.3 (±7.8) vs. 81.6 (±19.7), ($p<0.05$).	"Although further investigations are needed to determine the ultimate value of the blood bankplatelet concentrate allograft, the present study demonstrates that this method may be used to treat diabetic foot ulcers. The use of a blood bank platelet concentrate may provide a simple, safe, and effective means of treating diabetic foot ulcers."	Data suggest efficacy.
Freeman 1965a, b RCT	4.0	N = 45 ankle sprains (46 ankles)	Ligament repair and immobilization vs. cast immobilization 6 weeks vs. strapping (tape) and mobilization.	Report of instability at 1 year (mobilization, immobilization, suture repair) 5/12 (41%) vs. 7/17 (41%) vs. 6/16 (37.5%). Average time to symptomless ankle: mobilization 12 weeks vs. 22 to 26 weeks after immobilization (with	"Mobilisation may be the treatment of choice for most, perhaps all, ruptures of the lateral ligament of the ankle."	Lack of randomization, allocation, baseline comparability method details. Data suggest quicker resolution of symptoms in mobilization group and no difference in subjective

				or without suture repair).		outcomes at 1 year.

Evidence for the Use of Postoperative Management for Ankle Instability
There are 2 moderate-quality RCTs incorporated in this analysis.

Author/Year Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments
Karlsson 1999 RCT	5.0	N = 30 chronic lateral ligament instability of the ankle	Post-ligament reconstruction: plaster cast x 6 weeks vs. cast x 7-10 days followed by Aircast (early mobilization) with early motion training. Subjects failed 3 months physiotherapy prior to study.	Cast vs. early motion: Functional results excellent or good (%) - 12/15 vs. 14/15, p >0.05; Sick leave 7 vs. 6 weeks (p >0.05).	"Early mobilization after ankle ligament surgery for chronic ligamentous instability should be preferred to postoperative immobilization."	Randomization, allocation, baseline comparability details sparse. Study demonstrates early mobilization may have better functional outcomes at 3 months and faster return to sport but no differences in long-term outcomes.
Karlsson 1995 RCT	4.0	N = 40 chronic lateral instability of the ankle	Post-ligament reconstruction: plaster cast vs. walking boot (6 weeks) with early motion training. Subjects failed 3-months physiotherapy prior to study.	Cast vs. early motion: functional results excellent or good (%) - 80% vs. 95%, p >0.05; dorsiflexion at 6 weeks: 5.4 vs. 15.2 (p <0.001), plantar flexion 16.2 vs. 38.5 (p <0.001). Both ROM measures at 2 years not different.	"Early range of motion training in an ankle joint brace is a safe method after anatomical reconstruction of the ankle ligaments in patients with chronic instability. The method allows the patients to return earlier to work and sports activities with preserved mechanical stability."	Lack of study details including randomization method, allocation, baseline comparability, compliance, and timing of assessments. No significant differences on long term follow-up but early ROM may result in quicker return to work and sports.

Evidence for use of Orthotics
There is 1 moderate-quality RCT incorporated into this analysis. (Kilmartin 94)

Author/Year Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments
Kilmartin 1994 RCT	4.5	N = 23 with unilateral pain in 3rd/4th metatarsal space which was irritated by exercise and relieved by rest. Mean age of participants was 43.	Supination Orthoses group (n = 10) vs. Pronation Orthoses group (n = 11). Patients followed up at 4, 8, 12 and 52 weeks.	At final follow-up, 5 patients in each group reported their symptoms were better than at baseline. Results not significant between groups for any measurement. Alternative treatment necessary for a number of patients (52% of participants) who were not helped at all by orthoses upon discharge from study.	"While this study has not demonstrated that compressed felt orthoses have any significant effect on Morton's neuroma, it does show that preventing subtalar joint pronation produces no significant benefit."	High dropout rate and small N with subjective measurements of patient responses. Pronation did not appear to be superior to supination.

Evidence for the use of Lidocaine
There is 1 low-quality RCT in Appendix 2. (Quiding 13)

Evidence for the use of Manipulation and Mobilization
There is 1 moderate-quality RCT incorporated into this analysis. (Govender 07)

Author/Year Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments
Govender 2007 RCT	4.5	N = 40 patients with diagnosed Morton's neuroma.	Group A: Placebo (de-tuned ultrasound) (n = 20) vs. Group B: Manipulative care-mobilized to remove palpated inter-metatarsal and midtarsal restrictions. Manipulation delivered to any areas of restriction found within ankle and foot joints (n = 20). Each group	NRS-101 showed Group B to have statistically significant improvement in perceived pain vs. Group A at 6 weeks (final visit). Mean scores: 25.4 and 40.7 (p = 0.03). Pain pressure threshold and pressure tolerance levels significantly improved Group B vs. Group A. 25.6	"These findings suggest the possibility of shortterm relief and efficacy for manipulation and mobilization in the treatment of Morton's neuroma, but they must be confirmed by future well-designed, high-quality, and methodologically	Small numbers, baseline comparability weak, non-blinded observer and questionnaire not specific to Morton's Neuroma. No clear sham

			received 6 treatments over 3 weeks. Data obtained at 1st, 3rd and final treatment visits.	vs. 19.1 for pain pressure (p = 0.02) and 36.0 vs. 28.5 for pressure tolerance (p = 0.02).	improved randomized clinical trials."	group, rather control is detuned US.

Evidence for the Use of Extracorporeal Shockwave Therapy for Morton's Neuroma
There is 1 moderate-quality RCT incorporated into this analysis. (Fridman 09)

Author/Year Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments
Fridman 2009 RCT	5.5	N = 25 with Morton's neuroma confirmed clinically and by ultrasound.	Active group treated with OSSATron device using 2,000 pulses at 21 kV directed inferior to neuroma (n = 13) vs. Sham Group: 5mL of bupivacaine hydrochloride but no shockwave therapy (n = 12). Follow-up at 1, 6, and 12 weeks post-treatment.	Active group had significant difference from baseline VAS pain after 12 weeks. (p<0.0001). Sham group had no differences from baseline (p=0.1218). 69% (9) of ESWT vs 40% (4) of sham achieved VAS 3 or less. No difference between groups.	"Owing to the success with this procedure (no complications and no post-treatment disability), we continue to offer extracorporeal shockwave therapy as an alternative to surgical excision for Morton's neuroma."	Pilot study, small numbers. Data suggest EST may be better than sham for Morton's Neuroma, but data suggest underpowering. Reproduction in full trial needed.

Evidence for the use of Glucocorticosteroid Injections
There is 1 moderate-quality RCT incorporated into this analysis. (Thomson 13)

Author/Year Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments

Thomson 2013 RCT	4.5	N = 131 patients who had a clinical diagnosis of Morton's neuroma.	Corticosteroid and anesthetic group (1mL methylprednisolone [40mg] and 1mL 2% lignocaine) (n = 64) vs. Anesthetic alone group (2 mL 1% lignocaine) (n = 67). Patients assessed at 1, 3 and 12 months via questionnaire.	Steroid group reported significantly higher FHT scores compared to control group (mean (SD)) at 1 month 61.1 (22.6) vs. 49.8 (25.4) (p = 0.002), and at 3 months, 64.7 (22.0) vs. 50.9 (27.2) (p = 0.002). Results significantly lower for MFPDS pain score (walking pain) for steroid group compared to control at 1 month 31.4 (20.3) vs. 42.0 (20.9) (p = 0.002) and at 3 months 30.5 (21.5) vs. 41.9 (26.3) (p= 0.004).	"The groups also differed significantly in this measure at one month after injection, and improvements with corticosteroid injection (significant and nonsignificant) were observed for measures of pain, function, and patient global assessment of general health at one and three months after injection."	Methylprednisolone better than control at 3 months.

Evidence of the Use of Surgery
There are 3 moderate-quality RCTs incorporated into this analysis. (Akermark 13; Colgrove 00; Nashi 97)

Author/Year Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments
Colgrove 2000 RCT	5.5	N = 44 patients with foot neuromas. Average age of participants was 49 in resection group and 46 in transposition group.	Resection procedure (R Group) (n = 22) vs. Transposition procedure (T Group) (n = 22). Follow-up via phone call 1, 3, 6, 12, 36-48 months to measure pain, 0-100 (0-no pain and 100-max pain)	Preoperative pain levels were 78 (T Group) vs. 77 (R Group). At 1 month is was 22 vs. 19, at 6 months 11 vs. 8, at 12 months 4 vs. 6 respectively. These results were not found to be significant. At final follow up (36-48 months) pain level was 2 (T Group) vs. 9 (R Group). This difference at final	"Excellent results can be obtained by performing either a resection or a transposition of the ION, but this review indicates that a long term asymptomatic result is more likely to be achieved by the use of the transposition procedure."	Transposition compared with resection showed better long-term results. Question baseline comparability as assessed from patient report and not

				follow up was significant (p = 0.02)		standardized.
Akermark 2013 Prospective RCT	4.5	N = 76 patients with a typical history and clinical diagnosis of primary Morton's Neuroma for at least 4 months.	Plantar Incisions (n = 35) vs. Dorsal Incisions (n = 41). Patients' follow-up at 3 months, 12 months and 33-34 months.	There was a significant reduction of VAS pain score compared with baseline in both groups at all follow-up periods. (p<0.001). There was no significant difference between groups at any follow-up for VAS scores. Restrictions in daily activities were reduced 77% in the plantar group and 67% in the dorsal group. These results were significant compared to baseline for both groups (p<0.001), with no significant difference between groups. There were 5 complications in the plantar group 6 in the dorsal group.	"This study showed that pain during daily activities was equally significantly reduced in both groups at all postoperative follow-ups, with clinically good results in the plantar and dorsal groups. Results from this and other studies confirm the results from our earlier published retrospective study on Morton's neuroma, that there is a difference in the types of complications between the 2 approaches.	No significant differences in plantar versus dorsal techniques at 34 weeks.
Nashi 1997 RCT	4.5	N = 52 patients with Morton's neuroma. Mean age among participants (44 female and 8 male) was 53 years.	Dorsal approach group (n = 26) vs. Plantar approach group (n = 26). Average follow-up was 3.1 years and minimum follow-up time was one year.	In first 2 weeks after operatation, 8 patients in dorsal group able to fully bear weight compared to 0 patients in plantar group. Average return to work time after surgery was 22 days in dorsal group with 37 days in plantar group. In dorsal group. 80% of	"The results of our study would appear to favour the dorsal approach because of the shorter in-patient period, earlier weight-bearing, a shorter time taken to return to work, a less painful scar and greater	Dorsal better than plantar approach for earlier hospital discharge and return to work. Far more females in study questioning baseline comparability.

				patients reported good or satisfied compared to 65% in plantar group.	patient satisfaction."	

Evidence for use of Orthotics

There are 2 moderate-quality RCTs incorporated into this analysis. (Torkki 01; DuPlessis 11)

Author/Year Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments
Torkki 2001 RCT	7.5	N = 211 patients with mild or moderate hallux valgus deformation (painful bunion with hallux valgus angle ≤35º intermetatarsal angle ≤15º. Mean age surgery 48±10 years, orthosis 49±10 years, control 47±9 years.	Surgery, chevron procedure followed by abduction splint for 6 weeks (n = 71) vs. functional foot orthosis, negative cast technique (n = 69) vs. control, no surgery or foot orthotics (n = 69). Follow-up at 6 months and 1 year after randomization.	Differences in adjusted group means (95% CI) at 6 months: pain in last 6 months (NS between groups); intensity of foot pain, surgery vs. control -20 (-28 to -12), orthosis vs. control -14 (-22 to -6), surgery vs. orthosis (NS); ability to work, significant in surgery vs. orthosis -1 (-9 to -7). Differences in adjusted group means (95% CI) at 12 months: pain in last 6 months surgery vs. control -22 (-42 to -1), orthosis vs. control (NS), surgery vs. orthosis -34 (-55 to -14); intensity of foot pain, surgery vs. control -19 (-28 to -10), orthosis vs. control (NS), surgery vs. orthosis -14 (-22 to -5); ability to work (NS between groups).	"[T]he chevron operation is an effective treatment for patients who have a mild to moderate hallux valgus deformity and bunion pain while walking as their main symptom."	Mild or moderate cases studied and studied worst foot. Data suggest surgery superior to orthosis. Orthosis minimally superior to no treatment at 6 months but not at 12 months.

Du Plessis 2011 RCT	6.0	N = 30 participants with symptomatic hallux (ces) with pain and disability being ≥30% on VAS pain scale and disability scale respectively; mean age 42.	Experimental group: Brantingham protocol: Mobilization, Mobilization with HVLA, Post-treatment cold therapy and Mobilization of other foot and ankle joints as indicated (n = 15) vs. Control Group: Night split which holds big toe in corrected position (n = 15). Follow-up at 1 week and 1 month.	No significant differences between groups at 1-week follow-up. At 1 month follow-up there significant difference between experimental group vs. control group for Pain scores; 1.2 vs. 17.7 (p<0.01) and for Foot function scores (FFI); 2.3 vs. 33.4 (p <0.01). Both groups showed statistically significant improvements in both outcome measures at the final follow up.	"This exploratory trial has demonstrated that a structured protocol of MMT (the Brantingham protocol) is possibly as effective as standard care (night splint) in the short-term (3 weeks) for symptomatic mild to moderate HAV. At the 1-month follow-up the MMT maintains its treatment effect without further treatment, but the night splint does not."	Pragmatic trial. Small sample size. Baseline comparability unclear. Suggests MMT is comparable to night splint at 1 seek but after that MMT sustained outcomes up to 1 month for mild to moderate HAV.

Evidence for the Use of Ultrasound
There is 1 moderate-quality RCT incorporated into this analysis. (Zacherl 09)

Author/Year Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments
Zacherl 2009 RCT	6.5	N = 44 participants (52 feet) with mild to moderate hallux valgus deformity; Mean age 53 years.	Verum Group-Daily transcutaneous low intensity pulsed ultrasound (LIPUS) (n = 26 feet) vs. Placebo Group-sham ultrasound device (n = 26 feet) Follow-up at 6 weeks and 1 year.	No significant difference between groups for the metatarsophalangeal-interphalangeal scale (p = 0.57). Also, no significant difference for treatment satisfaction between groups. VAS pain scale did not show significant improvement at	"Despite potential impact of LIPUS on bone formation, we found no evidence of an influence on outcome 6 weeks and 1 year after chevron osteotomy for correction of hallux valgus deformity."	LIPUS not associated with improvement in outcomes at 6 weeks or 1 year after chevron osteotomy.

				final follow-up (p = 0.80) nor did ROM in metatarsophalangeal joint (p = 0.36).		

Evidence for the use of Manipulation and Mobilization
There is 1 moderate-quality RCT incorporated into this analysis. (DuPlessis 11)

Author/Year Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments
Du Plessis 2011 RCT	6.0	N = 30 participants with symptomatic hallux (ces) with pain and disability being ≥ 30% on the VAS pain scale and disability scale respectively; Mean Age was 42 years.	Experimental group: Brantingham protocol: Mobilization, Mobilization with HVLA, Post-treatment cold therapy and Mobilization of other foot and ankle joints as indicated (n = 15) vs. Control Group: Night split which holds the big toe in a corrected position (n = 15), Follow-up at 1 week and 1 month	There were no significant differences between the two groups at 1-week follow-up. At the 1 month follow-up there was a significant difference between the experimental group vs. control group for Pain scores; 1.2 vs. 17.7 (p <0.01) and for Foot function scores (FFI); 2.3 vs. 33.4 (p <0.01). Both groups showed statistically significant improvements in both outcome measures at final follow up.	"This exploratory trial has demonstrated that a structured protocol of MMT (the Brantingham protocol) is possibly as effective as standard care (night splint) in the short-term (3 weeks) for symptomatic mild to moderate HAV. At the 1-month follow-up the MMT maintains its treatment effect without further treatment, but the night splint does not."	Pragmatic trial. Small sample size. Baseline comparability unclear. Suggests MMT is comparable to night splint at 1 seek but after that MMT sustained outcomes up to 1 month for mild to moderate HAV.

Evidence of the Use of Surgery
There is 1 moderate-quality RCT incorporated into this analysis. (Torkki 01)

Author/Year Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments

Torkki 2001 RCT	7.5	N = 211 patients with mild or moderate hallux valgus deformation (painful bunion with hallux valgus angle ≤ 35º intermetatarsal angle ≤15º. Mean age surgery 48±10 years, orthosis 49±10 years, control 47±9 years.	Surgery, chevron procedure followed by abduction splint for 6 weeks (n = 71) vs. functional foot orthosis, negative cast technique (n = 69) vs. control, no surgery or foot orthotics (n = 69). Follow-up at 6 months and 1 year after randomization.	Differences in adjusted group means (95% CI) at 6 months: pain in last 6 months (NS between groups); intensity of foot pain, surgery vs. control -20 (-28 to -12), orthosis vs. control -14 (-22 to -6), surgery vs. orthosis (NS); ability to work, significant in surgery vs. orthosis -1 (-9 to -7). Differences in adjusted group means (95% CI) at 12 months: pain in last 6 months surgery vs. control -22 (-42 to -1), orthosis vs. control (NS), surgery vs. orthosis -34 (-55 to -14); intensity of foot pain, surgery vs. control -19 (-28 to -10), orthosis vs. control (NS), surgery vs. orthosis -14 (-22 to -5); ability to work (NS between groups).	"[T]he chevron operation is an effective treatment for patients who have a mild to moderate hallux valgus deformity and bunion pain while walking as their main symptom."	Mild or moderate cases studied and studied worst foot. Data suggest surgery superior to orthosis. Orthosis minimally superior to no treatment at 6 months but not at 12 months.

Evidence for the Use of X-ray for Evaluation of Ankle Fractures
There are no quality studies incorporated into this analysis.

Evidence for the Use of MRI for Evaluation of Ankle Fractures
There are no quality studies incorporated into this analysis.

Evidence for the Use of CT for Evaluation of Ankle Fractures
There are no quality studies incorporated into this analysis.

Evidence for the Use of Ultrasound for Evaluation of Ankle Fractures
There are no quality studies incorporated into this analysis

Evidence for the Use of Antibiotic Prophylaxis for Ankle Fractures
There is 1 high-quality RCT incorporated in this analysis.

Author/Year Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments
Paiement 1994 RCT	9.0	N = 122 isolated closed ankle fractures undergoing ORIF	Cephalotin 1g (n = 60) vs. placebo (n = 62) IV every 6 hours for 24 hours.	Functional outcome at 1 year comparable, no pain or limp, and return to work and other activities not statistically different between groups; 1 deep tissue infection in placebo group.	"This series of ORIF of 122 patients with closed ankle fracture shows that the infection rate after such a clean orthopaedic procedure is relatively low, approximately 3%. Therefore, cephalotin prophylaxis does not seem justified in this patient population."	Intra-operative IV antibiotics did not result in any significant different outcome in terms of infection, return to work or pain in patients undergoing ORIF with an isolated closed ankle fracture. Appears likely underpowered.

Evidence for the Use of Calcitonin Prophylaxis for Post-fracture Osteopenia
There is 1 moderate-quality RCT incorporated in this analysis.

Author/Year Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments
Peterse n 1998 RCT	6.5	N = 24 ankle fractures requiring ORIF	Nasal salmon calcitonin 200 IU once daily for 12 weeks vs. placebo.	Bone mineralization at 3 months: placebo lost 14%, sCT 2.1% (NS) in injured leg. Uninjured: placebo lost 2.2%, sCT gained 8.6% at 1.5 months (p = 0.07).	"200 IU of nasal salmon calcitonin given daily could not inhibit the development of posttraumatic osteopenia in the injured legs, following ankle fractures, but a statistically significant effect was observed in the healthy legs."	No mention of co-interventions or compliance with medication on daily basis. Small numbers; drop outs after 3 months make changes seen not able to reach statistical significant in injured leg. Data suggest no benefit for osteopenia prophylaxis.

Evidence for the Use of NSAIDs and Acetaminophen for Foot and Ankle Fractures
There are no quality studies incorporated into this analysis.

Evidence for the Use of Opioids for Foot and Ankle Fractures
There are no quality studies incorporated into this analysis.

Evidence for the Use of Tetanus Immunization for Open Foot and Ankle Fractures
There are no quality studies incorporated into this analysis.

Evidence for the Use of Non-operative Reduction Analgesia for Ankle Fractures
There is 1 moderate-quality RCT incorporated into this analysis.

Author/Year Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments
White 2008 RCT	7.0	N = 42 closed, displaced ankle fracture requiring non-operative manipulation reduction	Conscious sedation vs. intraarticular block (12mL lidocaine) for reduction maneuver, application of splint.	Conscious sedation vs. block: 2/21 vs.6/21 required repeat analgesia, p = 0.15. No differences in duration, difficulty of performing procedure; both methods effective in reducing pain from baseline (p <0.001, p<0.0002), no differences between groups.	"Compared with conscious sedation, an intra-articular lidocaine block provides a similar degree of analgesia and sufficient analgesia to achieve successful closed reduction of an ankle fracture-dislocation with minimal medical risks. It is a safe and reasonable alternative to conscious sedation."	Small sample size. Suggests conscious sedation and hematoma block effective in providing analgesia for ankle fracture reduction.

Evidence for the Management of Malleolar Ankle Fractures

https://pdfs.semanticscholar.org/9b32/2345999312ca742f7257eefd998ffaa0fc01.pdf

There are 5 moderate-quality RCTs incorporated in this analysis. There are 2 low-quality RCTs in Appendix 2.

Author/Year Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments
Non-operative Management						
Bauer 1985 RCT	5.5	N = 111 intra-articular malleolar fractures (Weber types A, B, C) with stable syndesmosis	Closed reduction with cast immobilization vs. ORIF and Cast immobilization. Weeks 0-6, non-weight bearing, Cast	Cast vs. ORIF: hospitalization (days): 5.0 (0-19) vs. 9.5 (2-33); Cast treatment (weeks): 6.2 (4-16) vs. 6.6 (2.5-10); Sick leave (weeks): 14 (3-63) vs. 14 (4-49); full ROM	"[T]he initial results indicated a more favorable early course in the patients randomized to surgery. At follow-up examination, however, patients randomized to closed reduction had long-term	After randomization, 10 not treated according to protocol received other treatment (8 in non-operative had ORIF). Results suggest similar outcomes for operative vs. non-operative

			removed at 6 weeks, full weight bearing at 9-12 weeks.	(weeks): 12 (9-15) vs. 9 (6-12), p <0.01. No difference in degree of arthrosis operative vs. non-operative long term.	results comparable to those randomized to operation."	treatment. Loss of reduction in 8 patients subsequently needing ORIF suggests follow-up necessary when treating non-operatively.
Brink 1996 RCT	5.5	N = 66 stable lateral malleolar fractures. Supination-eversion Stage II	Aircast air-stirrup, with full weight bearing vs. DonJoy ROM Walker Brace, full weight bearing.	At 4 weeks 11/33 (34%) of Air and 4/33 (13%) able to do unlimited activity (p <0.05). Average time for return to work 6 weeks in both groups. No differences remained at 12 weeks.	"[B]oth dynamic braces provided good pain relief at 4 weeks, allowed return to work at 6 weeks, and resulted in healing at 12 weeks. The Aircast was found to be easier to use and more comfortable, but the R.O.M-Walker gave greater pain relief, increased range of motion, and earlier return of ambulation."	No blinding, no mention of co-interventions or lack thereof. Either brace appears sufficient; return to work equal in both groups. No clinical difference at 12 weeks between groups. Aircast cost $40 and ROM-Walker cost $110. For cost benefit Aircast seems better choice as they both returned to work on average at 6 weeks. However, pain control may dictate use of ROM-Walker in some patients.
Stuart 1989 RCT	4.0	N = 40 lateral Malleolar fractures, type II	Below-knee walking plaster and crutches (Group A) vs. pneumatic air stirrup and crutches (Group B) for 4-6 weeks.	Air cast group: Comfort at 24 hours better (p <0.05); swelling at 7 days better (p <0.00001). No difference in time to union. Arc of motion better (p <0.0001).	"We advocate the use of the Aircast pneumatic air stirrup in the cost-effective management of stable ankle fractures."	Lack of study details. Improvements not well correlated with long-term clinical or functional outcomes. Cost benefit showed similar overall costs; slightly more in air cast group. In Type II lateral malleolar fractures air cast appears superior.
Non-operative vs. Operative Management						
Phillips 1985	5.0	N = 138 closed severe	All underwent closed	For patients with initial satisfactorily	"In patients with severe fracture of the ankle that had	Poor compliance with follow-up. No blinding.

RCT		ankle fracture (Grade-4 supination- external rotation or pronation external rotation)	reduction. If satisfactory, closed treatment vs. ORIF. Unsatisfactory closed reduction: trial of reduction under general anesthesia, randomized to ORIF vs. or ASIF technique.	closed reduction, ORIF had better outcomes in ROM. Gait better if a medial malleolar fracture (p <0.05). For closed reduction: no difference between ORIF and ASIF. Better alignment by x-ray after surgery had better clinical outcome in both groups (p <0.01).	been satisfactorily reduced initially by closed manipulation, open reduction and internal fixation performed according to ASID guidelines gave significantly better results, as measured by our 150-point scoring system, than did closed treatment. Patients with a medial malleolar fracture and patients who were more than fifty years old both had less favorable results after closed treatment. The difference in the talocrural angle between the injured and normal sides was the only statistically significant radiographic indicator of a good prognosis."	Measurement scale more weighted by subjective than objective measures. Validity of scoring system unknown. Study suggests for severe ankle fractures, ORIF may be better option, particularly with medial malleolar fractures and in persons older than 55.
Makwana 2001 RCT	4.0	N = 47 displaced ankle fractures requiring reduction in patients age 55 and older	Acceptable post-reduction then closed treatment (CT) (below-knee plaster cast, elevation 48 hours, protected weight bearing 6 weeks, then full weight bearing) vs. ORIF: post-op below-knee cast,	Hospital stay: CT: 2.6 days, ORIF: 6.7 (p = 0.01). Immediate reduction: CT: 57%, ORIF 86% (p = 0.03). Loss of reduction: CT: 8/21 (38%), ORIF: 0/22 (p = 0.003). CRPS: CT: 0/21, ORIF 2/22 (11%).	"We recommend treating displaced ankle fractures in patients over the age of 55 years by open reduction and internal fixation."	No blinding, no mention of co-interventions, follow up ranged from 15-42 months. More smokers in the closed group. Study suggests in age group 55 and older ORIF has fewer treatment failures and better functional outcomes.

			leg elevated 48 hours, then protected weight bearing. Full weight bearing at 6 weeks.			

Evidence for the Management of Tibial Shaft Fractures
There is 1 moderate-quality RCT incorporated in this analysis. There is 1 low-quality RCT in Appendix 2.

Author/Year Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments
Karladani 2000 RCT	4.5	N = 53 unilateral displaced and closed or Grade 1 open tibial shaft fractures	Intramedullary nail (Group I, n = 27) vs. cast only (Group IIa, n = 12) vs. cast plus additional minimal internal fixation (Group IIb, n = 14).	Mean time to union (mean±SD): Group IIa (25 weeks ±11), Group 2b (26 weeks ±8.3) 95% CI: -4.9-17.6; Group II (a and b) (25 weeks ±9.4) Group I (19 weeks ±8.2) 95% CI: 2.5-12; 6 patients in Group I and 16 in Group II had delayed union, p = 0.005.	"Delayed union, malunion, and restricted range of motion at the ankle joint were common complications when these fractures were treated with a cast. We recommend intramedullary nailing for these fractures."	Large portion crossed over as 14/26 (53.8%) in cast group required ORIF, making comparison groups nonhomogeneous. Data suggest cast only may not be appropriate for specific fracture types as >50% required ORIF.

Evidence for the Management of Tibial Extra-articular Fractures
There are 2 moderate-quality RCTs incorporated into this analysis.

Author/Year Study Type	Score (0-11)	Sample Size	Comparison Groups	Results	Conclusion	Comments
Im 2005 RCT	6.0	N = 78 distal metaphyseal fractures of tibia undergoing	Closed intramedullary nailing. (N) vs. ORIF with plates and screws (PS).	Duration of operation: N = 72 minutes, PS = 89 minutes (p = 0.02). Radiological union: N = 18 weeks, PS = 20 weeks (p = 0.89). Infections: N = 1 superficial infections,	"[L]ocked intramedullary nails have an advantage in restoration of motion and reduce wound problems, and	Suggests benefit of intramedullary nailing in less angulation. No differences in radiological union, and

		operative treatment		PS = 6 superficial, 1 deep (p = 0.03). Average angulation: N = 2.8°, PS = 0.9° (p = 0.01). Ankle dorsiflexion: N = 14°, PS = 7° (p = 0.001). Olerud Molander score: N = 88.5%, PS = 88.2% (p = 0.71).	anatomic plate and screws can restore alignment better than intramedullary nails."	Olerud Molander scores, suggesting both methods similar in functional outcomes. More infections with plates and screws.
Guo 2010 RCT	5.0	N = 111 distal closed metaphysical fractures, non-intraarticular	Intramedullary nail (IMN) vs. percutaneous locking compression plating (LCP).	IMN vs. LCP: Time to union (weeks) 17.7 vs. 17.6, p .0.05; AOFAS at 1 year, 86. vs. 83.9, p >0.05; Percent wanting hardware removed 84.1% vs. 92.7%, p >0.05; Operative time (minutes) 81.2 vs. 97.9, p <0.001; radiation use (minutes) 21.2 vs. 3.0, p <0.001.	"[B]oth a closed IMN and LCP with MIPO can be used safely to treat OTA type 42-A distal metaphyseal fractures of the tibia. Closed nailing has the advantage of shortened operating and radiation time and ease of removal of hardware."	Randomization, allocation details sparse, 85/111 completed study. Results suggest no differences in techniques for functional outcomes.

Evidence for the Management of Tibial Plafond and Pilon Fractures
There are no quality studies incorporated into this analysis. There is 1 low-quality RCT in Appendix 2.

Evidence for the Treatment of Syndesmotic Injury
There are 3 moderate-quality RCTs incorporated into this analysis. There is 1 low-quality RCT in Appendix 2.

Author/Year Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments
Høiness 2004 RCT	7.0	N = 64 closed ankle fractures with unstable syndesmosis. AO fracture type B and/or C	Tricortical fixation with two 3.5mm screws through 1 cortex of tibia after 2-3 days, 2-5kg weight bearing for 6 weeks. (TC) vs. Quadricortical fixation with 1 4.5mm screw through both tibial cortices. No weight	Olerud-Molander functional scores: TC-77, QC 66 (p = 0.025) at 3 months, at 1 year (NS). Pain: TC<QC (p = 0.017) at 3 months, at 1 year (NS). Dorsiflexion: No difference.	"[T]ricortical screw fixation of a ruptured syndesmosis is adequate and improves early function compared with the traditional transsyndesmotic fixation with bicortical holds in the tibia."	No blinding, mention of co-interventions, return to work or ADLs considered outside Olerud Molander score. Suggests tricortical screws for ruptured

			bearing for 8-12 weeks (QC).	No loss of fixation in any patient; 2 in TC had to have screws removed.		syndesmosis repair may provide early functional benefit through earlier mobilization by earlier partial weight bearing status. No long-term advantages demonstrated.
Thordarson 2001 RCT	6.0	N = 32 pronation lateral rotation fractures requiring fibular fixation of syndesmosis	PLA (polylactide) syndesmosis screw vs. fibular plate fixation. Stainless steel syndesmosis screw requiring removal of screw on average at 13.4 weeks post-op.	All uncomplicated healing of fibular fractures without loss of function. No evidence of displacement or osteolysis or sterile effusion. No wound complications from original surgery. All satisfied with surgery. No difference in subjective complaints, pain, walking tolerance. Average ROM: PLA 10° dorsiflexion, 38° plantarflexion. Stainless steel: 8° in dorsiflexion, 45° in plantarflexion.	"PLA syndesmotic screw is an attractive [option] to avoid the subsequent morbidity for the removal of the stainless steel screw."	No blinding, average age PLA group 34.7, in stainless steel 24.2. Study suggests both equally effective for syndesmotic stabilization with major benefit of eliminating need for hardware removal.
Kaukonen 2005 RCT	5.0	N = 40 lateral malleolar fracture with disrupted	Metallic screws (n = 18) vs. syndesmotic (bioabsorbable)	Mean operative time decreased in	"[P]LLA screws may be reliably used in the fixation of	No blinding or co-interventions noted. PLLA

		syndesmosis requiring screw placement	polylevolactic acid screw (n = 20).	metallic screw group by 15 minutes (p = -0.033). No difference in active ROM, return to sport activity, subjective measures.	syndesmotic ruptures without compromises in the incidence of local postoperative complications."	screws did not have increased adverse reactions, and had similar clinical outcomes as metallic screw. Study suggests both methods as effective, with advantage of PLA screws not requiring removal.

Evidence for the Operative Management of Fibular Shaft Fractures
There is 1 moderate-quality RCT incorporated in this analysis.

Author/Year Study Type	Score (0-11)	Sample Size	Comparison Groups	Results	Conclusion	Comments
Pritchett 1993 RCT	4.0	N = 50 unstable fibular fractures in elderly patients, supination-eversion Stage IV	Rush rods (n = 25) vs. AO plates (n = 25).	Rush Rod: 88% good or fair functional results. Full weight bearing was possible 6 weeks earlier. AO Plate: 76% had good or fair functional results. 2 deep infections and 2 non-unions resulting in 2 ankle fusions.	"The load sharing nature of the fixation allows early weight bearing, which is beneficial for many patients. Also, patients may return to their preoperative status (and hence, home) more rapidly with intramedullary fixation."	Lack of details. Intramedullary rod has potential to decrease morbidity with earlier weight bearing on fractured ankle. Reported less morbidity with rod vs. AO plate.

Evidence for the Repair of Deltoid Ligament with Lateral Ankle Fracture Fixation
There is 1 moderate-quality RCT incorporated in this analysis.

Author/Year Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments

Stromso e 1995 RCT	4.5	N = 50 Weber type-B or C with ruptured deltoid ligament; plaster slab 2-3 days, mobilization allowed on crutches with full weight bearing at or after 6 weeks.	No repair of deltoid ligament with ORIF vs. repair of deltoid ligament with ORIF.	Mean average operation time 75 minutes for suture group vs. 95 for ligament repair group. Mean hospital stay 6 days; absence from work 7 weeks. No difference in symptoms and clinical findings at review. All radiographs showed normal healing.	"[R]uptured deltoid ligament can be left unexplored without any effect either on early mobilisation or on the long-term result."	Assessor blinded at 17-month follow-up visit. Many details sparse. Difference in age between 2 groups. Study suggests repair of deltoid ligament in Weber type B or C fractures may not change clinical outcome.

Evidence for the Use of Operative Procedures and Fixators for Ankle Surgery
There are 4 moderate-quality RCTs incorporated into this analysis. There are 8 low-quality RCTs in Appendix 2.(688, 741, 744, 747, 749-752) (Dijkema 93; Kankare 96; Takao 04; Bucholz 94; Ahl 94; Moore 06; Kankare 95; Thordarson 01)

Author/Year Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments
Høiness 2004 RCT	7.0	N = 64 closed ankle fractures and unstable syndesmosis; AO fracture type B and/or C	Tricortical fixation with 2 3.5mm screws through 1 cortex of tibia after 2-3 days, 2-5kg weight bearing for 6 weeks. (TC) vs. Quadricortical fixation with 1 4.5mm screw through both tibial cortices. No weight bearing 8-12 weeks (QC).	Olerud-Molander functional scores: TC- 77, QC 66 (p = 0.025) at 3 months, at 1 year (NS). Pain: TC<QC (p = 0.017) at 3 months, at 1 year (NS). Dorsiflexion: No difference; no loss of fixation in any patient; 2 in TC had to have screws removed.	"[T]ricortical screw fixation of a ruptured syndesmosis is adequate and improves early function compared with the traditional transsyndesmotic fixation with bicortical holds in the tibia."	No blinding, no mention of co-interventions. No return to work or ADLs outside of Olerud Molander score. Suggests tricortical screws for ruptured syndesmosis repair may provide early functional benefit through earlier mobilization by earlier partial weight bearing status. However, no long-term advantage reported.
Joukainen 2007 RCT	5.5	N = 62 displaced ankle fractures needing operative treatment. Weber B or C	Bioabsorbable screws for fixation: SR-PLA70 screws (retains strength for 24 weeks vs. SR-PLLLA	Only difference in sick days: SR-PLA70 60, SR-PLLA 65 (p = 0.02). Operating time, at one year: ROM, pain, x-rays, Olerud-Molander score no statistical	"Both SR-PLA70 and SR-PLLA screw implants exhibited good biocompatibility."	No blinding and no information on co-interventions. Suggests SR-PLA70 and SR-PLLA bioabsorbable screws have similar outcomes. Lack of

			screws (retains strength for 36 weeks).	difference. No difference in return to sports or syndesmotic ossification.		comparison group limits conclusion regarding method vs. other fixation methods.
Rokkanen 1985 RCT	5.0	N = 44 displaced ankle fractures	Metallic implants (n = 22) vs. biodegradable implants (n = 22).	Mean operating time 34 minutes in metallic group and 42 minutes in biodegradable group; 1/22 (4.5%) had a non-anatomic reduction. Mean number of sick days equal between groups. No difference in "outcome" measures.	"[T]he biodegradable fixation method is advantageous because the removal procedure associated with metallic implants is avoided."	Lack of study details Suggests equivalency of biodegradable implants with metal implants in outcomes measures.
Kaukonen 2005 RCT	5.0	N = 40 lateral malleolar fractures with disrupted syndesmosis requiring screw placement	Metallic screws (n = 18) vs. syndesmotic (bioabsorbable) polylevolactic acid screw (n = 20).	Mean operative time was decreased in metallic screw group by 15 minutes (p = -.033). No difference in active ROM, return to sport activity, subjective measures.	"[P]LLA screws may be reliably used in the fixation of syndesmotic ruptures without compromises in the incidence of local postoperative complications."	No blinding or co-interventions. PLLA screws did not have increased adverse reactions; had similar clinical outcomes as metallic screw. Suggests both methods as effective; advantage of PLA screws no removal required.

Evidence for the Use of Postoperative Dressings for Ankle Surgery
There are no quality studies. There is 1 low-quality RCT in Appendix 2.(753) (Reed 98)

Evidence for the Use of Immobilization, Early Mobilization, Early Weight-bearing for Ankle Fractures
There are 13 moderate-quality RCTs (one with two reports) incorporated in this analysis. There are 4 low-quality RCTs (one with two reports) in Appendix 2.(652, 768-770, 773) (Finsen 89a; Finsen 89b; Ahl 93; Fitzgerald 94; Marsh 06)

Author/Year Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments
Dogra 1999	7.0	N = 52 bi-malleolar	Early mobilization	At 3 months: average pain and	"We have demonstrated	Lack of details for co-

RCT		ankle fractures requiring surgery	(EM) started 24 hours post-op: 10 minutes dorsiflexion and plantarflexion 4 times a day for 2 weeks. Then, below-knee plaster cast applied until Week 6 with partial weight-bearing vs. 6 weeks of plaster cast (IM).	Olerud score not different. ROM Plantar mean loss: EM = 12.31 degrees, IM = 12.69 (p = 0.83). Symmetrical gait: EM = 20/26 (77%); IM = 6/26 (23%) (p = 0.0001).	in our study that ankle remobilisation in the first 2 weeks after surgery does not make a difference to the early outcome at 12 weeks."	interventions and compliance with exercises or weight-bearing status. Suggests 2 weeks of early mobilization followed by 4 weeks of immobilization post-op for bi-malleolar fractures does not have a large clinical benefit at 12 weeks.
Honigmann 2007 RCT	6.5	N = 45 Weber A or B isolated malleolar fracture post-ORIF	Vacuum stabilized orthosis with full weight bearing after 2 weeks and walking without crutches at 3 weeks if able vs. partial weight bearing of 15kg for 6 weeks.	At discharge and 6 weeks, no difference between groups for ability to partially bear weight. Control group favored for mean difference of plantar flexion of 2.5° (p = 0.05) and inversion of 10° (p = 0.02) after 6 weeks.	"We observed that patients receiving surgical treatment for malleolar fractures of the types Weber A and B experienced no adverse events when being treated with a functional orthosis."	No blinding/lack of details on compliance with weight-bearing and co-interventions. Early mobilization appears to trend for earlier return to work with a mean of 37 days in orthosis group compared to 53 days in control (p = 0.79).
Van Laarhoven 1996 RCT	6.0	N = 81 ankle fractures AO A, B, and C managed by ORIF	Post-op management with weight bearing in a below-knee walking plaster cast vs. non-weight bearing with crutches.	Walking plaster group had small difference for subjective ankle score and linear analogue score compares to non-weight bearing, p = 0.03 and p = 0.02. AO type B and type C had no difference. No difference between groups at 12 months.	"Early application of a walking plaster did not result in an increased rate of complications such as wound dehiscence, superficial wound infection, arthritis, osteitis or secondary dislocation."	No blinding or discussion of compliance with weight bearing vs. non-weight bearing. No clinical difference at 12 months, thus benefits of early ambulation should not be discounted for fear of complications in ankle fractures AO types A, B and C.
Franke 2008	6.0	N = 27 Weber B fractures	Dynamic vacuum orthotic applied	Olerud Molander score 10 weeks: O = 95; C = 75 (p	"The orthosis is the prerequisite for	No blinding, no mention of co-interventions or

RCT		status post ORIF	for 6 weeks post-op to allow movement of 10-0-10° of upper ankle joint movement. Allowed 20kg weight bearing post-op Day 2, full weight bearing post-op Day 15 (O) vs. circular cast with dorsal window cut out to allow dorsal extension of talocrural joint; 6 weeks immobilization (C).	= 0.02). ROM in plantar flexion at 6 weeks: O>C (p = 0.005). Pain 10 weeks: C>O (p = 0.004). Wound healing complications: O = 2/14 (14%), C = 1/13 (8%). Return to work: O = 52 days (10-87), C = 76 days (45-95) (p = 0.02). Time spent by medical staff to treat O group, 3-4 times less than C group. Cost: O = 381 E, C = 419 E.	early return to work. Its application no only reduces the working time required by medical personnel but it is also likely to save on expenditure for treatment, aftercare and rehabilitation."	pain medication use. Orthosis does appear to provide benefit for return to work and activities. Wound complication rate similar between two groups.
Hedstrom 1994 RCT	5.0	N = 53 dislocated lateral malleolar fractures >2mm requiring ORIF	Post-op protocol of orthosis with active ankle movement and weight bearing vs. walking cast with no ankle movement.	Linear analogue scale results between groups better for orthosis patients at 3-month follow-up examinations, p = 0.02.	"[I]n this prospective randomized study it is not possible to show any clinical advantages by active ankle movements."	No blinding, lack of study details. Baseline difference in classification levels between groups with 5 supination eversion III in cast group and 2 in orthosis group. Suggests no difference in early ankle mobilization compared with cast.
Vioreanu 2007, 2006 RCT	5.0	N = 66 closed Weber A, B, C post ORIF; posterior splint until suture removed (10-14 days) and non-	Early mobilization (EM) at 2 weeks vs. immobilization. Both non-weight bearing until Week 6. Early motion group performed exercises 3 times a day for	Return to work: EM-67 days, LM-95 days. (p <0.05). No difference in SF-36 at 6 months; 3 post-op infections in EM. EM had better ROM at 6 weeks (p <0.05). No difference in swelling at 6 weeks. EM had	"[E]arly motion is consistently beneficial for all outcomes, including pain relief, range of motion, swelling, and return to work."	No blinding. Data suggest early mobilization is associated with earlier return to work and less muscle wasting.

		weight bearing	10 minutes, active and passive ROM with PT.	less muscle wasting (p <0.005) at 6 weeks.		
Ahl 1989 RCT	4.5	N = 99 dislocated lateral or bi-malleolar fracture (lateral and medial malleoli) with verified rupture of anterior tibiofibular ligament	Early weight-bearing group: starting 1st postoperative day. Below-knee cast for 7 weeks vs. late weight bearing group: 4th or 5th post-op week. Below-knee cast for 7 weeks.	No differences at 18-months between 2 groups for healing, arthrosis, roentgenographic stereophotogram metric analysis. No negative consequences in 14 patients with ruptured deltoid ligament that was not repaired.	"Early weight bearing does not result in fracture dislocation. No tendency to redislocation was revealed, supporting the opinion that a repair of the deltoid ligament is unnecessary."	Lack of blinding, No mention of co-interventions. Suggests no long-term consequences from early mobilization after surgical fixation. Also suggests no consequence of not repairing deltoid ligament although sample only included 14 with ruptured ligament.
DiStasio 1994 RCT	4.5	N = 61 active duty military patients with isolated closed ankle fractures	Six weeks of removable orthosis, starting PT 1 week post-op, 6 weeks non-weight bearing vs. 6 weeks short leg cast, starting PT at 6 weeks; 6 weeks non-weight bearing.	At 3 months post-op, short-leg cast group had lower scores compared to removable orthosis (p = 0.0001). Difference remained at 6 months (p = 0.0027). No difference in strength at 3 months, no difference in swelling at 3 months, no difference in functional testing at 3 months.	"The use of a removable orthosis for six weeks is advocated, with the patient non-weightbearing and following a formal physical therapy program emphasizing edema control, early motion, and strengthening."	Exact details of fracture and surgery lacking in study. Return to full duty was not different, but study done in military population. 6 weeks of removable orthosis and early physical therapy appears to have subjective benefit.
Ahl 1986 RCT	4.5	N = 46 dislocated fractures of fibula with pre-op verified ruptures of anterior tibiofibular ligament	Early weight bearing from 1st post-op day (n = 24) vs. late weight bearing from 4th post-op week (n = 22). Both groups had below-knee cast for 7 weeks.	All fractures healed "properly." No infections. No significant difference in swelling, circumference of ankle or calf, or range of motion at 3 or 6 months.	"[W]ith the use of this operative technique, using a minimum amount of osteosynthesis devices, an exact reconstruction of the ankle	Lack of details. No functional outcomes measured to see if early mobilization affected ADLs or return to work. Early weight bearing in stable lateral malleolus fractures without

					mortise can, as a rule, be achieved with sufficient stability to allow immediate postoperative weight bearing in a walking cast."	demonstrable adverse events.
Lehtonen 2003 RCT	4.5	N = 100 unstable and/or displaced Weber Type A or B with ORIF and casting for 6 weeks, non-weight bearing for 2 weeks, then partial weight bearing to 4 weeks, then full weight bearing at 6 weeks	Early mobilization in Aircast. Daily ROM exercises immediately postoperatively vs. immobilization group in below-knee cast for 2 weeks. Then in weight-bearing fiberglass cast until 6 weeks.	All fractures healed well. No difference in ankle swelling, atrophy of calf muscles, laxity of ankle joint, active ROM (NS). Overall complications rates between the cast group (16%) and the brace group (66%) was significant (p = 0.0005) with the majority of the increased complications in the brace group being wound infections.	"In conclusion, the results of this study show that the postoperative treatment of ankle fractures can be accomplished equally effectively both with use of a plaster cast and with a functional brace. The risk of postoperative wound complications associated with this treatment approach is considerably increased compared with that after conventional cast treatment."	No blinding, no mention of co-interventions or compliance with program. Mobilization began immediately post-op which may have contributed to increased wound complication rate seen in study.
Egol 2000 RCT	4.0	N = 60 unstable fractures requiring ORIF; Weber B fractures; all in plaster splint 2-3 days after surgery then	Function removable brace with early movement (active and passive exercises of ankle and subtalar joint by PT then at home 3x/day) vs.	All fractures clinically united at 6 weeks and radiographically united at 12 weeks. Early mobilization group had higher functional scores (0-100) at all follow up visits but only significant at 6	"We recommend the use of functional bracing and early exercises after operative treatment of fractures of the ankle."	Study excluded workers' compensation claims. No blinding, lack of study details on compliance with exercises, co-interventions, and randomization process. No mention of type of work in each

		randomized into groups (both groups non-weight bearing at least 6 weeks)	immobilization postoperatively in below the knee cast. PT after 6 weeks.	weeks 56.5 vs. 52.4 (p = 0.03). Return to work: Early mobilization mean days 53.8, immobilization 106.5 (p = 0.007).		group for RTW analyses. Suggests faster return to work with functional bracing and early mobilization with no increase in adverse events.
Sondenaa 1986 RCT	4.0	N = 43 ankle fractures requiring surgery	Primary mobilization group: plaster cast for 3 days. Full weight-bearing at 6 weeks vs. Immobilization group: plaster cast for 6 week with no weight bearing.	At 6 weeks, ROM greater in primary mobilization group (p <0.01). Swelling decreased in mobilization at 12 weeks (p <0.05). Pain less in mobilization group at 6, 12, 18 weeks follow-up; equal 1 year follow-up.	"Plaster immobilization after ankle fracture results in a minor increase in morbidity. If the patient is cooperative and fixation of the fracture stable, an early mobilization (1 week) is preferable."	Lack of study details. Compliance uncertain. Early mobilization appears to increase ROM, decrease pain and swelling in stable fractures.
Tropp 1995 RCT	4.0	N = 30 Weber B or C ankle fractures requiring ORIF	Double-hinged brace (received program for self training or mobility, muscular strength, and function immediately post-op) vs. plaster cast (post-op for 6 weeks, full weight bearing allowed with crutches for 2-4 weeks, then same self-training program at 6 weeks.	At 6 weeks 6/15 (40%) in brace group vs. 1/15 (7%) in cast group showed failure of syndesmotic staples. No correlation in displacement or fracture healing. No difference in ankle scores or ROM improvement compared to uninjured ankle at 12 months. No difference Olerud function scores. ROM: dorsiflexion better in brace group at 1 year (p <.05), no correlation with functional outcomes at 12 months.	"We conclude that the double-hinged brace is appreciated by the bearer. Higher ROM was noted in the brace group, but the obvious advantage of the brace is subjective to the bearer. There is a higher expense for the brace than for the plaster cast. Long-term results of brace and case treatment are comparable."	No blinding, no mention of co-interventions, no baseline characteristics provided. No mention of compliance with exercise program in either group or compliance with weight bearing status. Suggests earlier mobilization does not appear to increase adverse events after Weber B or C ankle fractures.

Evidence for the Use of Pneumatic Compression for Edema Management
There are 3 moderate-quality RCTs incorporated into this analysis.

Author/Year Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments
Thordarson 1997 RCT	6.0	N = 30 Weber B and C ankle fractures	Pneumatic pedal compression device pre-operatively vs. posterior splint, ice, elevation before surgery.	Compression group: change in volume Day 1-2: -88ml (p = 0.027), Day 1-3: -31ml (p = 0.049). Control group: change in volume Day 1-2: +33ml, Day 1-3: +32ml.	"Pneumatic pedal compression device resulted in a significant decrease in preoperative edema after ankle fractures compared with a control group."	No baseline characteristics provided. No blinding. Suggests compression device is effective in reducing pre-operative edema in ankle fracture patients.
Caschman 2004 RCT	5.5	N = 64 closed unilateral fractures unable to be operated on immediately secondary to edema but in need of surgery	Pneumatic compression in cast device (AVI) (n = 27) vs. elevation (control) pre-op (n = 27). Compression continuous until time of surgery and without elevation.	AVI vs. Elevation: mean final pre-op swelling (mm±SD): control (24.0± 16.6) vs. AVI (13.1±13.2), p = 0.030. A-V bladder: 3/27 (11%) had soft-tissue complications. 2/27 (7%) had blisters. Limb elevation: 12/27 (44%) had soft-tissue complications; 7/27 (26%) skin blisters, 2/27 (7%) post-op DVT. A-V bladder group went to surgery on average 3.5 days earlier than limb elevation group (not significant).	"[T]he A-V impulse in-cast system is of value in reducing preoperative swelling following ankle fracture, and this is associated with a reduction in delay of surgery and overall morbidity."	Suggests pneumatic compression superior to elevation alone for reducing edema pre-operatively and complications associated with fracture blister.
Mora 2002 RCT	5.5	N = 24 closed ankle fractures that required ORIF; Weber A, B, C and	Pulsatile cold compression (PCC) device applied to ankle, on bed rest with foot elevated vs. posterior	Circumferential decrease in cm: 24 hours = PCC-0.5, C-0.1 (p <0.001). 48 hours = PCC-0.9, C-0.4 (p <0.001). 72 hours = PCC-	"The Cryo/Cuff compression dressing and AutoChill system significantly decreased edema in	No blinding or mention of co-interventions. All patients 3 days post-injury when randomized. Pump system cost $150.

		medial malleolar fractures	molded splint, bed rest with elevation (C).	1.2, C-0.5 (p = 0.009). All patients had mean satisfaction score of 4 (1-4).	ankle fractures before surgery compared to splintage and elevation alone."	Clinical outcome measures (shorter operative time, functional outcomes after surgery, wound infection) not reported.

Evidence for the Use of Interferential Current Therapy for Postoperative Edema Management
There is 1 high-quality RCT incorporated into this analysis.

Author/Year Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments
Christie 1990 RCT	8.0	N = 24 receiving open reduction and internal fixation	Interferential therapy (electrotherapy) 20 minutes a day before casting and after surgery (2-4 days) vs. placebo.	Foot/ankle volumetric changes: no difference (p >0.05), no trend seen.	"The results of this double-blind study do not support the use of interferential therapy in the treatment of oedema."	Interferential therapy does not appear effective.

Evidence for the Use of Electrical Stimulation for Ankle and Foot Fractures
There are no quality studies incorporated into this analysis. There is 1 low quality RCT in Appendix 2.

Evidence for the Use of Therapy for Ankle Fractures
There are 2 high-quality and 1 moderate-quality RCTs incorporated with this analysis. There is 1 low-quality RCT in Appendix 2.(783)

Author/Year Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments
Moseley 2005 RCT	8.5	N = 150 plantarflexion contracture patients after ankle cast immobile-zation for fracture	Exercises plus short-duration passive stretch: 6 minutes a day broken into 12, 30-second stretches vs. exercises plus long-duration stretch: 30 minutes a day vs. exercises; 4 week home-based program. Up to 5 PT visits	No difference in main outcomes measures of passive dorsiflexion with knee bent and straight or Lower extremity functional scale. At 4 weeks, long-duration group felt more ready to return to sports and leisure activities (p =	"The addition of a program of passive stretches confers no benefit over exercise alone for the treatment of plantarflexion contracture after cast immobilization for ankle fracture."	Exercise program details sparse. No benefit found from passive stretching of either duration in addition to a 4 week exercise program for plantarflexion contractures after casting. Suggests treatment

			after cast removal. Included exercises for mobility, strengthening, stepping, weight bearing, balancing.	0.03) but not at 3 months.		emphasis should be on exercise compliance not stretching.
Lin 2008 RCT	8.0	N = 94 isolated ankle fractures: able to weight bear or partial-weight bear and referred to PT with some residual pain	PT and manual therapy with anterior-posterior joint mobilization over talus. Seen twice a week for 4 weeks for MT, maybe longer for PT vs. PT; twice a week for 1st week, then once a week for at least 4 more weeks.	No significant difference in primary outcomes of activity modifications or quality of life between groups. Control group had increase return to sports and activities over MT at 12 weeks. Fracture severity did not influence outcomes. Experimental group incurred an increase cost on average of $200.00AU more.	"When provided in addition to a physiotherapy programme, manual therapy did not enhance outcome in adults after ankle fracture."	No blinding of participant or therapist, but assessor was blinded. No mention of co-interventions. Manual therapy added costs but not any other benefits over PT in patients after ankle fractures with or without surgical fixation.
Nilsson 2009 RCT	6.0	N = 110 post-op ankle fracture fixations	Supervised PT 12-week program vs. usual care (education on home exercises, PT if ordered by MD).	Training vs. control; average PT visits: 17 vs. 7 (p <0.001). Olerud Molander Score: no differences when unadjusted. For <age 40; 78.1 vs. 65.5 at 6 mos, 86.5 vs. 72.8 at 12 mos, p = 0.028. SF-36 Physical Health: no differences; SF-36 Mental Health (MCS): no differences.	"The training model used in this study showed superior results compared to usual care regarding subjectively scored function and muscle strength in the plantar flexors and dorsiflexors in patients under the age of 40. However, only three out of nine outcome measures	Co-interventions allowed (usual care). Compliance with supervised program uncertain. Reported results only showed positive effect for 3 variables after adjustment for age group and treatment effect. No differences otherwise. Results appear likely of small clinical significance.

					showed a difference."	

Evidence for the Use of Ultrasound Stimulation for Ankle and Foot Fractures
There is 1 high-quality RCT incorporated into this analysis.

Author/Year Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments
Handolin 2005 RCT	9.0	N = 16 dislocated lateral malleolar fractures fixed with 1 bioabsorbable poly-L-lactide screw	Ultrasound machine daily for 20 minutes applied by patient at home vs. sham ultrasound daily for 20 minutes applied by patient at home.	All fractures fully healed. No foreign body reactions documented. No difference in Olerud-Molander scores.	"In conclusion, the six-week low-intensity ultrasound therapy had no effect on radiological bone morphology, bone mineral density or clinical outcome in bioabsorbable screw-fixed lateral malleolar fractures 10 months after the injury."	Small numbers. No mention of specific co-interventions. Sparse baseline characteristics presented. Suggests ultrasound of no benefit for fracture healing.

Evidence for the Use of Hyperbaric Oxygen for Ankle and Foot Fractures
There are no quality studies incorporated into this analysis.

Evidence for the Use of Hypnosis for Ankle and Foot Fractures
There is 1 moderate-quality RCT incorporated into this analysis.

Author/Year Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments
Ginandes 1999 RCT	4.5	N = 11 acute non-displaced lateral malleolar fractures	Six visits of hypnosis with therapist and daily hypnosis tapes for fracture healing vs. regular care.	At 12 weeks, both groups had normal healing as expected (mean±SEM): fracture line controls (13.7±1.31), fracture line hypnosis (11.6±2.06), fracture edge controls (12.5±1.65), fracture edge hypnosis (11.6±1.96). Self reported VAS lower in hypnosis group Week 1, p = 0.15, Week 3, p = 0.013, and Weeks 6 and 12. Week 9, hypnosis group regained more	"Despite a small sample size and limited statistical power, these data suggest that hypnosis may be capable of enhancing both anatomical and functional fracture healing."	Lack of study details. Small sample size. Results suggest no benefit from hypnosis in improving fracture healing.

				mobility to injured ankle compared to controls, p = 0.24. Hypnosis group better gait going down stairs Week 6, p = 0.24.		

Evidence for the Use of X-ray for Hindfoot Fractures

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

Author/Year Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments
Knight 2006 Diagnostic Comparison Study	8.0	N = 133 calcaneal fractures (CT diagnosis, x-ray comparisons) vs. case controls	CT-verified calcaneal fractures, then standard mediolateral foot and ankle projections used on the lateral foot or ankle radiographs vs. Negative lateral x-rays for evidence of calcaneal fractures.	Emergency physicians 97.9% accurate in diagnosing calcaneus fractures based on reviewing plain films without assistance from angles (97%-99%). K value when measured against gold standard was 0.96 (0.94-0.98). Radiologist had sensitivity of 98.5% and specificity of 100%. Bohler's angle had intraclass correlation of 0.84 (0.79-0.87). CAG intraclass correlation 0.52 (0.43-0.60).	"BA is somewhat helpful and the CAG is not useful in diagnosing calcareous fractures in the ED."	Trial randomized order of x-ray reading (case vs. control) by MD. Lateral x-rays appear to have acceptable specificity and sensitivity for diagnosing calcaneal fractures in acute trauma patients compared with CT. Use of angles did not add significant improvement in diagnosis.
Ebraheim 1996 Diagnostic Comparison Study	7.0	N = 35 lateral x-rays, coronal CT scans and intra-operative findings in calcaneal fractures	All patients had lateral x-rays, coronal CT, and surgery.	Good correlation between lateral x-rays and coronal CT images in 26/35 patients. In the other 9 there was evidence of articular depression and incongruity in lateral x-ray but not CT.	"The present study emphasizes that coronal CT images often fail to accurately reveal the articular depression and severity of rotational displacement of calcaneal	Imaging findings verified intra-operatively on all 35 patients. Study suggests coronal CT may underestimate severity of posterior talocalcaneal fractures.

					fracture fragments."	

Evidence for the Use of MRI for Hindfoot Fractures
There is 1 moderate-quality study incorporated in this analysis.

Author/Year Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments
Zeiss 1991 Diagnostic Comparison Study	5.5	N = 29 cadavers, calcaneal facture patients, and healthy volunteers	Use of MRI for indentifying both bone and soft tissue injury in calcaneal fracture.	Difficult to interpret MRI scans in fracture patients up to 4 months after injury. After 2 years with continued symptoms MRI useful in identifying possible problems in both bone and soft tissue.	"The usefulness of MRI evaluation of calcaneal fractures in acute and subacute evaluation will most likely be very limited to occasions where CT does not clearly define tendon displacement or when avascular necrosis or osteomyelitis in a concern. It could be more helpful in evaluation of persistent pain complicating healed fractures."	Data suggest MRI not helpful in acute or subacute calcaneal fracture or soft tissue injury evaluation. Can be helpful in chronic pain patient in identifying possible pain generating issues.

Evidence for the Use of Bone Scanning for Hindfoot Fractures
There are no quality studies incorporated into this analysis.

Evidence for the Use of CT for Hindfoot Fractures
There is 1 moderate-quality study incorporated into this analysis.

Author/Year Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments
Ebraheim 1996 Diagnostic Comparison Study	7.0	N = 35 calcaneal fractures (lateral x-rays, coronal CT scans and intraoperative findings)	All had lateral x-rays, coronal CT, and surgery.	Good correlation between lateral x-rays and coronal CT images in 26/35 patients. In other 9, evidence of articular depression and incongruity in lateral x-ray, but not CT.	"The present study emphasizes that coronal CT images often fail to accurately reveal the articular depression and severity of rotational displacement of	Imaging findings verified intra-operatively on all 35 patients. Study suggests coronal CT may underestimate severity of posterior talocalcaneal fractures.

					calcaneal fracture fragments."	

Evidence for the Management of Talar Fractures
There are no quality studies incorporated into this analysis.

Evidence for the Use of Operative Management for Osteochondral Lesions
There is 1 moderate-quality RCT incorporated into this analysis.

Author/Year Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments
Gobbi 2006 RCT	4.0	N = 32 osteochondral lesions of talus: Ferkel class 2b, 3 or 4	Chondroplasty (CP) vs. microfracture (MF) vs. osteochondral autograft transplantation (OAT).	No difference in Ankle-Hindfoot scale at 6 or 12 months. No difference in SANE scores at final follow-up. Pain less for CP group compared to MF and OAT at 24 hours post-op (p <0.001).	"On the basis of AHS and SANE ratings, no differences can be seen between chondroplasty, micro fracture, or OAT for patients with osteochondral lesions of the talus."	No blinding or mention of co-interventions or compliance with aftercare. No significant differences at 6 or 12 month follow-up between 3 groups. All 3 methods appear effective therapeutic options with similar outcomes. However, chondroplasty shown ineffective in knee.

Evidence for the Management of Calcaneal Fractures
There are 4 moderate-quality RCTs incorporated in this analysis. There are 2 low-quality RCTs in Appendix 2.(668, 805) (Parmar 93; Ibrahim 07)

Author/Year Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments
Non-operative vs. Operative Care						
Buckley 2002 RCT	5.5	N = 424 displaced intra-articular calcaneal fractures	Non-operative treatment involved no attempt at closed reduction, treated with ice, elevation, and rest vs. ORIF.	Outcomes after non-operative treatment not different for those after operative treatment. SF-36 score was non-op: 64.7 vs. ORIF: 68.7 (p = 0.13). VAS score: non-op:64.3, ORIF 68.6 (p = 0.12). Patients not in workers' comp	"Without stratification of groups, the functional results after nonoperative care of displaced intra-articular calcaneal fractures were equivalent to those after operative care. However, careful stratification of the patient	No blinding noted. Operative management trended towards better outcomes in subsets of study. Post-hoc analyses suggests good anatomic reduction provides a

				and managed operatively had significantly higher satisfaction scores (p = 0.001).	population and clinical outcome information distinguishes certain features that support surgical care for displaced intra-articular calcaneal fractures. Statistical analysis demonstrated that women, patients who were 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 calcaneal fracture have better results after operative treatment than after nonoperative treatment."	positive effect on outcomes. Data suggest no difference in general population between treatments, but ORIF may be superior to non-operative management in specific populations.
Howard 2003 RCT	5.5	N = 424 displaced intra-articular calcaneal fractures with disruption of posterior facet >2mm	Non-operative treatment (NOP). Pain management, RICE, non-weight bearing. PT and full weight bearing at 6 weeks vs. ORIF, lateral approach. Full weight	ORIF had more clinical complications than NOP. NOP 42.218 (19%) had complications that led to surgery; 2/218 (0.01%) had late compartment syndrome. 37/218 (16%) had secondary late fusion.	"Outcome scores in this study tend to support ORIF for calcaneal fractures. ORIF patients are more likely to develop complications, however. Certain patient populations have a high incidence of	Second report of Buckley 2002. No blinding, large drop out rate, no mention of co-interventions. Suggests non-operative management of displaced intra-articular calcaneal fractures with

			bearing and PT at 6 weeks.	1/218 developed CRPS. ORIF: 11/206 (0.5%) deep wound infections. 2/206 developed PE. 4/206 had compartment syndrome.	complications regardless of the management strategy chosen (WCB patients, Sanders type IV patients)."	disruption of posterior facet >2mm has fewer complications than ORIF.
O'Brien 2004 RCT	5.5	N = 319 patients with 351 displaced intra-articular calcaneal fractures	Non-operative management vs. ORIF measuring gait satisfaction scores at 2-8 years.	No difference in SF-36 scores between groups at 2 to 8 years follow-up (p = 0.22). Age <30 with ORIF = improvement in gait scores compared to non-op (p = 0.02). Quality of fracture reduction no different between groups. Bohler angle in non-op group of >15° compared to <0° had better gait scores (p = 0.00).	"[P]ersonal gait satisfaction scores were not significantly affected by treatment method in patients with DIACF at 2-8 years follow up. However, gait scores were better in patients treated with ORIF if they were younger than 30 years of age, had no worker's comp claims, had jobs requiring a moderate workload before injury and had restoration of Bohler angle to above 0 degrees."	Third report of same population (see Buckley 2002). Post-hoc analyses suggests restoration of Bohler angle is predictive of function. Data also suggests those with workers' comp claims have worse outcomes regardless of treatment type for this injury.
Thordarson 1996 RCT	4.0	N = 30 displaced intra-articular calcareous fractures Sanders Type II or III	Non-operative management with early mobilization and delayed weight bearing at 8 weeks vs. ORIF with early mobilization and delayed weight bearing.	Pain on extremes of motion in 25% of ORIF and 100% in non-operative group. Average functional score of 86.7 in ORIF group vs. 55.0 in non-operative group. (p <0.0001).	"Our study demonstrated markedly superior results with operative treatment of fractures versus non-operative treatment.	Follow-up 14 months for non-operative group, 17 months for ORIF. Significantly greater recovery after displaced intra-articular calcareous fractures Sanders Type II and III with ORIF

						compared to non-operative treatment with pain and functional scores.

Evidence for the Management of Edema Associated with Calcaneal Fractures
There is 1 moderate-quality RCT incorporated into this analysis.

Author/Year Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments
Thordarson 1999 RCT	6.0	N = 28 closed dislocated intra-articular calcaneal fractures	Intermittent pedal compression device, posterior splint, and leg elevation. Started 24 hours after injury. Compression 3 x cycles/minutes full time until surgery vs. compression dressing, posterior splint, and elevation.	All patients tolerated foot pump without need of ankle nerve block. Volumetric measurements: Day 1-2: Pump = -40mm, control = +76mm (p = 0.02); Day 1-3: pump = -96mm, control = +37mm (p = 0.02).	"In summary, we found that using a foot pump prior to surgery resulted in a significant decrease in preoperative edema in patients after an intraarticular calcaneus fracture in comparison with those in the control group."	No blinding or mention of baseline characteristics. Pedal pump appears beneficial in reducing post injury pre-op swelling in displaced intra-articular calcaneal fractures.

Evidence for the Use of Diathermy for Edema Control
There are no quality studies incorporated into this analysis.

Evidence for the Use of Bone Graft and Fillers for Calcaneal Fracture Defect
There are no quality studies incorporated into this analysis. There are 2 low-quality trials in Appendix 2.(803, 822) (Johal 09; Dickson 02)

Evidence for the Use of X-ray for Suspected Tarsal, Metatarsal, or Phalangeal Fractures
There are no quality trials incorporated in this analysis.

Evidence for the Use of MRI for Suspected Tarsal Metatarsal and Phalangeal Fractures
There are no quality studies incorporated into this analysis.

Evidence for the Use of Bone Scan for Suspected Tarsal, Metatarsal, or Phalangeal Fractures
There are no quality studies incorporated into this analysis.

Evidence for the Use of CT for Suspected Tarsal Metatarsal and Phalangeal Fractures
There are no quality studies incorporated into this analysis.

Evidence for the Management of Lisfranc Injuries
There is 1 moderate-quality RCT incorporated into this analysis.

Author/Year Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments
Henning 2009 RCT	5.0	N = 40 Lisfranc injuries, <3 months duration	Primary arthrodesis (PA) vs. ORIF	Study discontinued after 40 patients (planned for 60) secondary to hardware removal rates and secondary surgery (79 vs. 17%) favoring arthrodesis. No differences in functional outcomes, clinical assessments or patient satisfaction.	"PA resulted in a statistically significant decrease in the number of follow up surgeries compared to [primary] ORIF if hardware removal is routinely performed. If performed properly, patients are satisfied with either technique."	Small sample size. Baseline differences suggest potential randomization failure. Loss to follow-up 20%.

Evidence for the Management of Metatarsal Fractures
There are no quality studies incorporated into this analysis.

Evidence for the Management of Proximal Fifth Metatarsal Injuries
There is 1 moderate-quality RCT incorporated into this analysis. There is 1 low-quality RCT in Appendix 2.(826) (Wiener 97)

Author/Year Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments
Metatarsal Fracture (Jones) – Operative Management						
Mologne 2005 RCT	6.0	N = 37 acute Jones fractures	Cast immobilization vs. intramedullary screw fixation. Non-weight bearing cast 8 weeks, followed by walking cast or hard shoe until union. Post-op non-weight bearing with bulky Jones splint for 2 weeks.	8 of 18 (44%) in cast group had treatment failures vs. 1/19 (5.3%). Mean time to clinical union 7.5 weeks (surgery) vs. 14.5 weeks (cast), p <0.001. Mean time to running and jumping sports (weeks) 8.0 vs. 15.0 (cast), p <0.001	"Early surgical treatment results in a shorter time to clinical union and allows patients to return to sports and activities of daily living faster than with cast treatment."	Lack of details for allocation, blinding. No loss to follow-up. Suggests surgical fixation of acute Jones fracture provides fewer treatment failures and quicker time to healing and functional recovery.

Evidence for the Management of Phalangeal Fractures
There are no quality studies incorporated into this analysis.

Evidence for the Management of Stress Fractures
There are no quality studies incorporated into this analysis.

Evidence for the Use of Glucocorticosteroid Injections for Ankle Tendinoses
There are no quality studies evaluating the use of glucocorticosteroid injections for ankle tendinosis.

Evidence for Surgical Release
There are no quality studies incorporated into this analysis.

Evidence for the Use of MRI for Plantar Fasciitis
There are no quality studies incorporated into this analysis. There is 1 low-quality RCT in Appendix 2.(191) (Maier 00)

Evidence for the Use of NSAIDs and Acetaminophen for Plantar Fasciitis
There are no quality trials incorporated into this analysis. There are 2 low-quality RCTs in Appendix 2.(36, 201) (Donley 07; Bourne 80)

Evidence for the Use of Benzydamine for Ankle Sprain
There are no quality trials incorporated into this analysis. There is 1 low-quality RCT in Appendix 2.(469) (Elswood 85)

Evidence for the Use of Arthroscopy Evaluation during Distal Tibia Fracture Fixation ORIF
There are no quality RCTs incorporated into this analysis. There are 2 low-quality RCTs in Appendix 2.(737, 744) (Takao 04; Thordarson 01)

Evidence for the Use of Phonophoresis for Plantar Heel Pain
There are no quality trials incorporated into this analysis.

Evidence for the Use of Hyperosmolar Dextrose for Plantar Fasciitis
There are no quality trials evaluating the use of hyperosmolar dextrose injections for plantar fasciitis.

Evidence for the Use of Radiofrequency Microtenotomy for Plantar Fasciitis
There are no quality trials incorporated into this analysis.

Evidence for the Use of the Foot Waffle Support Brace
There is 1 low-quality RCT in Appendix 2. (Tymec 97)

Evidence for the Use of Taping
There is 1 low-quality RCT in Appendix 2. (Vicenzino 00)

Evidence for the Use of Cryotherapy and Heat for Plantar Heel Pain
There are no quality trials incorporated in this analysis.

Evidence for the use of Topical Nerve Growth Factors
There is 1 low-quality RCT in Appendix 2. (Landi 03)

Appendix D.4 - 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.(835) (Harris JOEM 08)

FOOT ULCERATIONS

Author/Year Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments
Patient Education						
Donohoe 2000 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						
Veves 2002 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.
Jacobs 2008 RCT No mention of sponsorship or COI.	3.0	N= 40 diabetic patients with Wagner grade 1 or 2 ulcers. Mean age was not provided.	Bensal HP group- Benzoic Acid 6%, Salicylic acid 3% and extract from 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.	At 6 week follow-up wound diameter decreased in both 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.	"In this tightly controlled and random study, Bensal HP not only served as an adequate adjunct to generally accepted wound care, but also convincingly outperformed SSC used in the control."	Blinding only mentioned without details. Sparse baseline comparability details.
Shukrimi 2008 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	Mean healing time in standard dressing group vs. Honey group: 15.4 days (range 9-36 days) vs. 14.4	"Honey dressing is a safe alternative dressing for Wagner grade-II diabetic foot ulcers."	Sparse methodological and sample size.

			(iodine solution 10%).	days (range 7-26 days); p<0.005		
Negative Pressure Therapy (Vacuum) Wound Care Systems						
Mars 2008 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						
Tymec 1997 RCT	1.5	N=52 patients within age range 27 to 90 years (M=66.6, SD=16.5)	Pillow positioned under both legs 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	Both groups Odds Ratio of 4.38 with 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	"[T]he results of this study did not support the use of the previously designed foot waffle for continuous heel elevation."	Data suggest use of foot waffle device led to earlier development of foot ulcers although both groups ultimately developed foot ulcers.

			or right lateral tilt then supine.	of survival; pillow group vs. foot waffle (13 vs. 10 days)		
Growth Factors						
Becaplermin						
Steed 1995 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)						
Landi 2003 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 dropped on	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.	"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 foot pressure ulcers

			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.	Reduction in ulcer area after adjustment for potential confounders; treatment vs. control group (6.5±0.3mm2 vs. 5.9±0.3 mm2) p <0.001		
Huang 2014 RCT Sponsored by the Jinan City 2009 Technology Developme nt 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.
Akbari 2007 RCT No sponsorshi p 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	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	"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	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.

			weeks, follow-up not clarified.	systems using negative pressure helps to improve oxygenation to tissues affected by vascular insufficiency and diabetes.	arterial circulation problems. Thus, for wound healing and limb preservation, we recommend VCT, in addition to conventional therapy, for patients with diabetic foot ulcers and nonhealing wounds."	
Eginton 2003 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	High dropout rate and small sample size. Crossover design.

					encountered in this population."	
Landsman 2010 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 follow-up to Week 12, then bi-weekly to Week 20.	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 group vs. 0.41 cm2/week in TG +B group (p = 0.34).	"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 advantage of this unique technology are explored."	Comparable results in both groups suggesting becaplermin does not increase wound healing.
Richard 1995 RCT Sponsorship, supported by Farmitalia Caro Erba Laboratory, Milano, Italy.	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.	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.	"Topical application of bFGF has no advantage over placebo for healing chronic neuropathic diabetic ulcer of the foot. Because diabetes causes significant wound-healing	Small sample size (n = 17). Sparse methodological details.

No mention of COI.		Mean age 61.9±10.0 years in treatment group.		placebo: 0.116±1.129 mm): same result obtained at 11th week.	defects, we hypothesized that using a single growth factor might be insufficient to accelerate wound closure of diabetic ulcers."	
Autologous-derived Growth Factor						
Lyons 2007 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 52 (±11) for 8.5% gel group.	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.
Prostacyclin Analogues (Iloprost)						
Sert 2008 RCT No mention of COI or	2.5	N = 60 with type 2 diabetic patients (61.8 ± 9.7 years, mean ±SD) with diabetic foot ulcer and	Group I: iloprost infusion (0.5-2 ng/kg/min for 6 h) for 10 consecutive days. (n = 30)	Group I patients showed improvement in endothelial functions at 10th and 30th	"Ten-day iloprost infusion therapy to patients with diabetic foot ulcers seems	Sparse details.

Sponsorship.		peripheral arterial occlusive disease, stage III or more by Wagner classification. Plus 15 healthy controls.	vs. Group II: (n=30) treated same except iloprost treatment constituting a patient control group. 30 day follow-up.	day (p = 0.002) in respect to group II.	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."	
Complementary and Alternative Medications						
Leung 2008 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.
Larijani 2008 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 (n =	Significant decrease in ulcer surface area for Semelil vs. Conventional	"This herbal extract by intravenous route in combination	Small sample size. Differing group sizes with only 9 controls reported.

Supported by ParsRoos Co. No mention of COI.			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).	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."	
Bahrami 2008 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±32.70 mm2 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						
Wang 2009 RCT Sponsorship, supported by National	3.5	N =72 with chronic diabetic foot ulcers. Mean±SD age was 58.6±12.6 years (ESWT);	ESWT group received 300 100/cm2 impulses of shockwave at 0.11 mJ/cm2 energy flux density every 2	Completely healed in 31%, improved in 58%, and unchanged in 11% for the ESWT 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.

Science Council (95-2314-B-182A-081), Tissue Regeneration Technologies, and National Health Research Institute (NHRI-EX96-9423EP). No mention of COI.		63.4±10.3 years.	weeks for 6 weeks vs. hyperbaric oxygen therapy (HBO) group received HBO daily for 20 treatments via mask.	vs. 22% completely healed, 50% improved, and 28% unchanged for HBO group.		
Duzgun 2008 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						
Moretti 2009 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.

Wang 2009 RCT Sponsorship, supported by National Science Council (95-2314-B-182A-081), Tissue Regeneration Technologies, and National Health Research Institute (NHRI-EX96-9423EP). No mention of COI.	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.
Electrical Stimulation						
Petrofsky 2010 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						
Martson 2003	3.5	N= 314 patients with diabetes with a	Dermagraft Group: Dermagraft	There were 245 patients with chronic	"In conclusion, Dermagraft	Some dissimilar baseline

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 Tissue Sciences, holds stock in ATIS, and has been a paid speaker for Smith and Nephew, Inc.		foot ulcer of at least 2 weeks duration. Mean Age was 55.7 years	application with standard wound dressings (n = 163) vs. Control Group: Standard wound dressings (n = 151). Follow-up for 12 weeks.	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.	has been shown in this multicenter, prospective randomized study to be safe and effective for the treatment of chronic diabetic foot ulcers."	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).

Apligraft						
Moustafa 2007 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						
Hausdorff 2008	1.0	N = 24 with chronic hemiparesis	Subjects walked for 6 minutes while	Gait asymmetry index instantly	"The studied neuroprosthesis enhances	Neuroprosthesis appeared to improve gait

RCT		whose walking was impaired by foot drop, with mean age 54.0 ± 5.2.	wearing force-sensitive insoles, once with and once without the neuroprosthesis. Neuroprosthesis were conducted after using the device for 4 and 8 weeks. Follow-up for a total of 8 weeks.	improved by 28% or from 0.58±0.30 to 0.42±0.22) and 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.	gait and improves dynamic stability in chronic hemiparetic patients, supporting the idea that this is a viable treatment option in the rehabilitation of patients with foot drop."	and stability in patients with foot drop but study elements were sparse and omitted many details.
Taping						
Vicenzino 2000 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,	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	"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.

			10, and 20 minutes of controlled jogging).	navicular height.		

MORTON'S NEUROMA

Author/Year Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments
Lidocaine Patches						
Quiding 2013 RCT	3.0	N=27 patients with Morton neuroma for at least 3 months confirmed by MRI.	2mL Placebo vs. 1mg/mL lidocaine vs. 10mg/mL lidocaine. 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.	Mean QST assessment value calculated for affected and non-affected foot. Difference between 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).	"The present results may therefore suggest that lidocaine is relatively more 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."	Crossover study with small N and minimal baseline characteristics. Some data suggest possible efficacy.

ACHILLES TENDINOPATHY

Author/Year Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments
Exercise vs. Exercise						
Niesen-Vertommen 1992 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						
Bourne 1980 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						
Lowdon 1984 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						

Nistor 1981	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						
Maier 2000 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						
Bourne 1980	3.5	See NSAIDs in Evidence Table for Achilles Tendinopathy above.				

Donley 2007	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						
Lynch 1998 RCT	3.0	N = 103 with plantar fasciitis	Group 1 (n = 35) steroid injection 0.5ml 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.	High treatment failures in injection group (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).	"The results of this study show that 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."	Lack of study details. No blinding. Lack of control for co-interventions. Randomization and allocation unclear.
Magnets						
Caselli 1997 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	"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	Lack of method details. Unclear if this was an RCT.

				foil group vs. PPT/Rx Firm Molded Insole group as measured by percentage difference in mean scores on foot function index.	period reported improvement in foot function as measured by the foot function index. The magnetic foil offered no advantage over the insole."	
Orthoses						
Martin 2001 RCT	3.5	N = 255 plantar heel tenderness, history of pain on rising in morning or after rest, no history of trauma to heel within previous 3 months	Custom-made orthoses vs. OTC arch supports vs. tension night splints.	No statistically significant differences among 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.	"Mechanical control of the foot is a successful 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."	No blinding. High drop-out rate; 12 week study.
Kavros 2005 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.
Lynch 1998	3.0	See Glucocorticosteroid Injections above.				
Caselli	2.5	See Magnets above.				

1997						
Mejjad 2004 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 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.	"[W]earing foot orthoses provided significant pain relief, but was 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."	Population was RA patients with metatarsalgia. Orthotic use 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.
Fauno 1993 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						
Fransen 1997 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 pain. Footwear group improved for all gait variables.	"These data suggest that off-the-shelf orthopedic footwear is beneficial for people with RA even when subjects were unselected on basis of age, sex, disease duration, or disability as measured by the Stanford Health	Excluded, study of RA patients only.

					Assessment Questionnaire."	
Taping						
Lynch 1998	3.0	See Glucocorticosteroid Injections above.				
Extracorporeal Shockwave Therapy						
Furia 2005 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.
Alvarez 2003 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 population as Ogden 2004. Study is excluded.

ANKLE SPRAINS

Author/Year Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments
NSAIDs						
Dupont 1987 RCT	3.5	N = 67 acute ankle sprains, varying degree of	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	Study not clear if it is a randomized trial. Allocation unclear. Reported no differences between placebo and ibuprofen group.

		severity			statistically significant."	
Fredberg 1989 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.
Aghababian 1986 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 (30/300 1 or 2 q 4 hours).	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, 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."	"[D]iflunisal and the combination of acetaminophen with codeine are equally effective in relieving moderate pain associated with grade 2 ankle sprain."	Lack of study details regarding randomization, allocation, blinding, compliance. No statistical analyses of results provided.
Andersson 1983 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	No differences in swelling improvement between 4 groups found. No differences in pain at rest, walking, or tenderness. Minimal	"Neither Ibuprofen nor high quality bandaging had a significant effect on the swelling, pain or tenderness."	Lack of randomization, allocation, baseline comparison, cointerventions and blinding details. Suggests no benefit from ibuprofen or

			for acute sprain (injury extent non-defined).	statistical analysis presented.		elastic/compression bandages.
Opioids						
Aghababian 1986	2.5	See NSAIDs above.				
Proteolytic Enzymes						
Brakenbury 1983 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						
Elswood 1985 Quasi-RCT	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. 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.	"[I]nitial treatment of ankle sprains 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."	Quasi-randomization (odd/even 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						

Campbell 1994 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						
Nilsson 1983 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 cointerventions (PT in groups II and III) make comparisons difficult for individual treatment recommendations.
Early Mobilization						
Zwipp 1992 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,	"[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.

				limitations, instability.		
Cetti 1984 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.
Korkala 1987 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 = χ^2.01 (df = 1). Significant	"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 treated by operation."	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.

				difference in favor of younger group. No differences in interventions between age groups.		
Tubular Elastic, Elastic Wrap, and Tape						
Muwanga 1986 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.
Scotece 1992 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.
Cetti 1984	3.0	See Evidence Table for Early Mobilization above.				
Korkala 1987	2.5	See Evidence Table for Early Mobilization above.				
Nilsson 1983	2.5	See Evidence Table for Glucocorticosteroid Injections above.				
Brooks 1981 RCT	1.5	N = 104 inversion injuries seen	No support vs. physiotherapy vs. double Tubigrip	Days off work: days at clinic (no support/ physiotherapy/double Tubigrip support/	"[M]obilisation, with early physiotherapy or even without, offers the most rapid return to functional activity."	Lack of study details; 241 entered trial with high drop-out or exclusion. Not

		during a 10-week period at regional accident unit	support vs. immobilized.	immobilized), 5.1: 23.6/6.0:21.4/7.5 :21.5/41.0:25.0.		clear how many randomized.
Airaksinen 1990 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 (randomization, allocation, baseline comparability, no blinding, compliance, co-interventions, follow-up). Suggests intermittent compression results in greater reduction of edema/improved ROM.
Ankle Support/Brace						
Muwanga 1986	3.5	See Tubular Elastic, Elastic Wrap, and Tape above.				
Scotece 1992	3.5	See Tubular Elastic, Elastic Wrap, and Tape above.				
Zwipp 1992	3.5	See Early Mobilization above.				
Cetti 1984	3.0	See Early Mobilization above.				
McGuine 2012 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	"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	"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 extremity injuries."	Cluster randomization. Laceup braces associated with lower number of ankle injuries vs. placebo but ankle injury severity same between 2 groups.

			intervention (n = 1088).	(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.		
McGuine 2011 RCT	2.0	N = 1460 male and female basket ball player s	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.
Wilkerso n 1993 RCT	1.5	N = 34 Grade 2 inversi on sprain s	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						
Zwipp 1992	3.5	See Evidence Table for Early Mobilization above.				

Cetti 1984	3.0	See Evidence Table for Early Mobilization above.				
Korkala 1987	2.5	See Evidence Table for Early Mobilization above.				
van den Hoogenband 1984 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.
Gronmark 1980 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						
Stöckle 1997 RCT	3.0	N = 60 foot or ankle trauma	Continuous cryotherapy vs. intermittent compression vs. cold packs 4 times daily for pre and post-operative edema.	Percent of swelling compared with admission-lower percent is better (Int. Compression/continuous cooling/ice packs): Preoperative Ankle at 24 hours-42% vs. 64% vs. 82%; Post-operative ankle at 24 hours - 64% vs.	"It could be shown that both continuous cryotherapy and intermittent impulse compression therapy lead to faster reduction of swelling compared with standard cool pack therapy."	Lack of details. Pre-, post-op cooling provided, but not all subjects received both (<50%) despite randomization. No statistical analyses. Included heterogeneous disorders limiting conclusions. Suggests advantage of both treatments compared with standard ice pack

				73% vs. 80%; Post-operative ankle at 4 days - 37% vs. 36% vs. 62%		application. Equipment costs moderate to high for rental or purchase.
Michlovitz 1988 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.
Wilkerson 1993	1.5	See Evidence Table for Ankle Support/Brace above.				
Laba 1989 RCT	1.0	N = 30 acute ankle sprain (no other associated condition) referred 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						
Michlovitz 1988	2.0	See Evidence Table for Cryotherapy above.				
Ultrasound						
Makuloluwe 1977 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						
Coetzer 2001 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.
Pellow 2001 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."
Eisenhart 2003 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.

Köhne 2007 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.
Lopez-Rodriguez 2007 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.
Ankle Support for Prevention						
Stasinopoulos 2004 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						
Coughlan 2007 RCT	3.5	N = 20 from active athletic population	Four week neuromuscular training program (proprioception, conditionin	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	Randomization performed on matched pairs of healthy subjects (no previous injury). Results are of unknown

			g, strength) vs. no exercise group.		ankle instability do not appear to result in measurable changes in gait kinematics."	clinical significance.
Engebretsen 2008 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.
Mohammadi 2007 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.

Verhagen 2004, Verhagen Br J Sports Med 2005 Cluster-RCT	3.0	N = 1,127 volley ball 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.
Verhagen Clin Biomech 2005 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 and previously injured subjects."	Lack of randomization, allocation, compliance details. Small sample size. Non-randomized comparison group included. Results are of unknown clinical significance as outcome measure is surrogate for ankle instability but did not measure injury.
Wedderkopp 1999 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.

Melnyk 2009 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.
Stasinopoulos 2004	2.0	See Ankle Support for Prevention above.				
Foot Orthotics for Prevention						
Fauno 1993	3.0	See Evidence Table for Plantar Fascitis (Orthoses) above.				
Stretching/Strengthening Exercises						
Pope 2000 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.
Puls 2007 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	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.

					five times per week."	
Ekstrand 1983 RCT	1.5	N = 180 male soccer player s	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 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.	"[T]he proposed prophylactic program, including close supervision and correction by doctors and physiotherapists, significantly reduces soccer injuries."	Sparse study details. Intervention appears to have reduced injury and ankle sprains.
Mohammadi 2007	3.0	See Balance/Proprioception Training above.				
Physical or OccupationalTherapy						
Acute and Subacute						
Christakou 2007 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	"Results revealed significant differences only in the variable of muscular endurance. This study partly supports the contribution of	Sparse study details for compliance, baseline comparability. Both groups with extensive PT (12 sessions over 4 week period).

				or toe raising individually or in single-leg hop, stairs or balance measures.	imagery to the functional rehabilitation of grade II ankle sprain."	Study results suggest mental imagery techniques is of little benefit.
Laufer 2007 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.
Youdas 2009 RCT	3.5	N = 27 acute inversion sprains	Ankle-heel stretch to improve dorsiflexion in mild and moderate ankle sprains: Group 1: 30 second stretch vs. Group 2: 1 minute stretch vs. Group 3: 2 minute stretch	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 with confidence that after an inversion ankle sprain subjects perform a minimum of 3 daily static heel-cord stretches each of 30 seconds duration."	Lack of study details. Study demonstrated all subjects improved with no differences in groups.
Chaiwanichsiri 2005 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	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	"The 4 weeks program of Star Excursion Balance training is more effective in improving functional stability of the sprained ankle than the	Lack of study details. Clinical significance of single leg stance test is uncertain. Appears to include baseline differences in outcomes

			included heat, ultrasound, ROM exercises, strengthening and stretching exercises. Balance training 3 supervised sessions a week for 4 weeks.	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.	conventional therapy program."	measures (SLST, recurrence of injury). No differences in sprain recurrence.
Wester 1996 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 recovery period (1, 6, 12 weeks)."	Quasi-randomization. Sparse study details.
Asimenia 2013 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	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	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

			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.		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."	preventive and/or major functional gain.
Kim 2014 RCT	1.5	N = 30 with ankle sprains	Control Group (Group A) (n = 10) vs. Muscle strengthening exercise group (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,	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. 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, $p < 0.05$.	"Applying combined muscle strengthening and proprioceptive exercises to those who have functional ankle instability is more effective than applying only muscle strengthening exercises."	Three arms but poorly described and small N. Combination muscle strengthening and proprioceptive exercises to patients with ankle instability more effective than muscle strengthening exercises alone.

			marching in place for 50 seconds, 4 sets for 10 minutes (n = 10).			
Brooks 1981 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.
Collado 2010 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 inwards, patient resisting inversion movement, returning to the first	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 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."	Placebo group, few baseline characteristics to compare. Eccentric reinforcement in EG group had greater strength during concentric movements.

			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.			
Chronic Ankle Instability						
Han 2009 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.
Ross 2007 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 postural stability."	Randomization, allocation, compliance details sparse. Only portion of subjects blinded. Results are of unknown clinical significance.
Bernier 1998 RCT	2.5	N = 48 functional instability of ankle	Control (no treatment) vs. electrical stimulation sham treatment (peroneus longus and brevis) vs. 6	Maximum inversion test showed passive position sense better than active position sense, p <0.05m, for joint position sense.	"[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

			weeks of balance and coordination training.	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.		improving postural sway is of uncertain clinical significance as no injury recurrence data provided.
Kidgell 2007 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.
Powers 2004 RCT	1.5	N = 38 self-reported unilateral function	Strength vs. proprioception vs. proprioception plus strength vs. control (3	No differences in muscle fatigue measures or static balance measures.	"Strength training, proprioception training, and the combination of the 2 failed to improve postural-stability characteristics in a	Lack of study details (randomization, allocation, baseline comparability, no blinding,

		al ankle instability	sessions a week for 6 weeks).		group of subjects with functional ankle instability."	compliance, co-interventions, follow-up).
Surgical Repair						
Møeller-Larsen 1988 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.
Specchiulli 2001 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.
Sommer 1989 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 movement and normal stability.	"The comparably good results of functional and operative treatments reported by others are confirmed by our study."	Sparse study details. Grade of sprains likely moderate and severe, but not specified. No statistical analysis.
Zwipp 1992	3.5	See Early Mobilization above.				
Korkala 1987	2.5	See Early Mobilization above.				

Niedermann 1981 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.
van den Hoogenband 1984	2.5	See Casting above.				
Gronmark 1980	2.0	See Casting above.				
Clark 1965 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

Author/Year Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments
Tibia Shaft Fractures – Operative Management						

Fernandes 2006 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						
Wyrsch 1996 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 months after injury.	"[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.
Syndesmosis Injury Operative Technique						
Moore 2006 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	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	"[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.

			screws through 4 cortices. Non-weight bearing 6-10 weeks (n = 61).	with weight-bearing restrictions, intoxicated at time of surgery, and smokers.		
Malleolar Ankle Fracture Management						
Rowley 1986 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 encourage d 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.
Salai 2000 RCT	1.5	N = 84 elderly patients with displaced closed tri-malleolar ankle fractures with manipu-lation under an-esthesia for reduction	Conservat ive therapy including short leg cast and mobilizatio n vs. open reduction surgery.	Total ankle scores: 91.37±8.96 for non-operative group vs. 75.22±14.38 for operative group, p = 0.001.	"[C]onsideration of a non-operative approach to the treatment of well-reduced ankle fractures in the elderly."	Randomization method uncertain. Overall lack of study details. Generalizability may be limited to elderly population.
Ankle Fracture Operative Management: Procedures and Fixators						
Dijkema 1993 RCT	3.5	N = 43 closed non-comminut ed	ORIF with biofix implants vs. ORIF	Patients with biodegradable rods scored an average of 94.5 point on Olerud's	"Patients treated with the biodegradable material reported slightly less pain	Lack of study details. No blinding, no details on control of co-

		fractures of lateral and/or medial malleolus and dis-locations	with metal implants.	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.	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)."	interventions. Suggests bioabsorbable rods have similar outcomes as metal implants.
Kankare 1996 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.
Takao 2004 RCT	3.5	N = 72 Weber type B distal fibular fractures surgically repaired	Arthro-scopically assisted open reduction and internal fixations (AORIF) (n = 41) vs. open reduction and internal fixation (ORIF) (n = 31).	AORIF: 30/41 (73.2%) had osteochondral 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).	"In the treatment of distal fibular fractures, precisely diagnosing and treating the combined intra-articular disorders is important for gaining satisfactory clinical results."	No blinding, minimal baseline 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.
Bucholz 1994 RCT	3.5	N = 155 closed displaced medial	Polylactide (bioabsorbable)	No significant difference between groups for ability to	"[P]olylactide screws are a safe and effective alternative to	No blinding, no allocation concealment, follow-up timing

		malleolar fractures	screws vs. stainless-steel screws (control group).	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.	stainless-steel screws for the fixation of displaced medial malleolar fractures."	was variable. Study suggests PLA screws are as effective as stainless-steel without increased adverse events in medial malleolar fixation.
Ahl 1994 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. Tibialis posterior: rod 1/7 (14%) poor; screw 1/7 (14%) poor; non-degenerative 3/18 (17%) 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.
Kankare 1995 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.
Moore 2006	3.0	See Syndesmosis Injury Operative Technique above.				
Thordarson 2001 RCT	2.5	N = 19 with SER or PER fractures with intact medial malleolus	Open plate fixation with arthroscopic visualization of joint	8/9 patients who had arthroscopy had evidence of articular damage to the dome of the talus. No difference in SF-36 scores or	"Most patients who underwent arthroscopic examination of the ankle joint were found to have a variable degree of articular cartilage	Lack of study details. Does not appear to be clinically beneficial results from arthroscopic investigation of ankle joint in

		; no evidence of intra-articular pathology	vs. open plate fixation.	objective clinical findings between groups.	damage at the dome of the talus…with no significant difference noted between groups in subjective or objective outcomes."	addition to open reduction and plate fixation in SER or PER fractures with an intact medial malleolus.
Post Operative Care – Dressings						
Reed 1998 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 for post-op pain management.	Significant difference between groups for closet angle to plantigrade patient could achieve 1st day of physiotherapy, 25.0° for backslab group, 48.3° for wool and crepe group, p = 0.04.	"[E]ither a backslab or wool and crepe bandages may be applied after internal fixation of ankle fractures, depending upon the surgeon's preference."	Abstract with lack of details results in low-quality study. Study 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						
Johal 2009 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.
Dickson 2002 RCT	3.0	N = 38 acute closed Type I fractures of radius, humorous, ulna,	Grafting material: BoneSource (BS) mineral product vs. Autograft	All fractures healed by 12 months follow-up. Maintenance of reduction observed in BS: 10/12 (83%), AG 10/15 (67%).	"Data from this demonstrate that BoneSource was both safe and effective as a bone void filler. The BoneSource showed equal or	Small numbers, no blinding, no co-interventions, no mention of compliance with surgical after care. Study did not include

		femur, tibia, or calcaneal, traumatic void requiring grafting	(AG) from iliac crest or other location.	Pain over fracture site resolved at 6 months: BS: 10/13 (77%), AG 9/16 (56%). (NS).	better maintenance of reduction than the autograft group."	control of no grafting. Suggests no difference in bone graft materials.
Post-Operative Rehabilitation: Immobilization, Early Mobilization, Early Weight Bearing						
Finsen 1989a; 1989b 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.
Ahl 1993 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 from each protocol.
Fitzgerald 1994	1.5	N = 27 ankle fractures,	Immobilization in plaster for	Difference in limb circumference between control	"[L]imb swelling may subside more rapidly in the	Lack of details. Compression stocking while in

RCT		type not described but all treated non-operatively	6 weeks (n = 10) vs. plaster immobilization along with compression stocking for 6 weeks (n = 10) vs. immediate mobilization (n = 7).	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.	immobilised fractured limb if a compression stocking is applied while the limb is in plaster."	a plaster cast may decrease overall calf swelling.
Marsh 2006 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 protocols that incorporate and use an articulated hinged for ankle motion."	No blinding noted. Unable to reliably record compliance with home mobilization exercises. Study likely underpowered.
Post-Operative Care – Physical Therapy						

Wilson 1991 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						
Hernandez 2006 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 recovery was apparent in the treatment group."	Abstract description only. Sparse details.
Calcaneal Fractures – Non-operative vs. Operative Care						
Parmar 1993 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	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

			bearing for 6-8 weeks.			displaced fractures, no significant differences in outcomes between surgery and cast.
Ibrahim 2007 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 joint: (p = 0.54).	"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 and non-operative treatment of displaced intra-articular calcaneal fractures at 15 years follow-up.
Metatarsal Fracture (Avulsion) – Operative Management						
Wiener 1997 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	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

					leg cast, without the risk of compromising clinical or radiographic healing.”	quicker return to activity.

Appendix D.5 - References

1. Statistics UDoLBoL. Table R21. Number of nonfatal occupational injuries and illnesses involving days away from work by part of body and selected events or exposures leading to injury or illness. *Injuries, Illnesses, and Fatalities*. 2005;Available at: http://www.bls.gov/iif/oshwc/osh/case/ostb1677.pdf.
2. US Department of Labor Bureau of Labor Statistics. Table R19. Number of nonfatal occupational injuries and illnesses involving days away from work by part of body and selected natures of injury or illness. *Injuries, Illnesses, and Fatalities*. 2004;Available at: http://www.bls.gov/iif/oshwc/osh/case/ostb1529.pdf.
3. US Department of Labor Bureau of Labor Statistics. Table R21. Number of nonfatal occupational injuries and illnesses involving days away from work by part of body and selected events or exposures leading to injury or illness. *Injuries, Illnesses, and Fatalities*. 2004;Available at: http://www.bls.gov/iif/oshwc/osh/case/ostb1531.pdf.
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