



Supplementary Material

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Table i. Core Outcome Set for distal Tibia and Ankle fractures randomized controlled trial review: example search strategy for Medline.

1	exp ankle/
2	exp ankle fractures/
3	exp ankle joint/
4	exp ankle injuries/
5	fractures, bone/
6	or/1-5
7	exp tibia/
8	exp tibial fractures/
9	exp fibula/
10	(or/7-9) and 6
11	Randomized controlled trials as topic/
12	randomized controlled trial/
13	random allocation/
14	double blind method/
15	single blind method/
16	clinical trial/
17	exp clinical trials as topic/
18	or/11-17
19	10 and 18
20	limit 19 to (english language and yr="2000 -Current")

Table ii. List of trials included in the review (n = 105).

First author	Year	Title
Ali	2017	Treatment of Extra-Articular Distal Tibial Fractures: Minimally invasive percutaneous plate osteosynthesis versus intramedullary nailing
An	2020	Clinical comparison of single-incision and dual-incision approaches for the treatment of distal tibial and fibular fractures: a randomised controlled trial
Andersen	2018	Randomised trial comparing suture button with single syndesmotic screw for syndesmosis injury
Asloun	2014	Internal fixation of the fibula in ankle fractures: a prospective, randomized and comparative study: plating versus nailing
Badenhorst	2020	Intramedullary fixation versus anatomically contoured plating of unstable ankle fractures: a randomised control trial
Boyle	2014	Removal of the syndesmotic screw after the surgical treatment of a fracture of the ankle in adult patients does not affect one-year outcomes
Buckley	2018	Single-screw fixation compared with double screw fixation for treatment of medial malleolar fractures: a prospective randomised trial
Buttenschoen	2001	The influence of vacuum-assisted closure on inflammatory tissue reactions in the postoperative course of ankle fractures
Carrozzo	2018	Beyond the pillars of the ankle: A prospective randomised CT analysis of syndesmosis' injuries in Weber B and C type fractures
Caschman	2004	The efficacy of the A-V impulse system in the treatment of posttraumatic swelling following ankle fracture
Costa	2018	Intramedullary nail fixation versus locking plate fixation for adults with a fracture of the distal tibia: the UK FixDT RCT
Daolagupu	2017	A comparative study of intramedullary interlocking nailing and minimally invasive plate osteosynthesis in extra articular distal tibial fractures
Dehghan	2016	Early weightbearing and range of motion versus non-weightbearing and immobilisation after open reduction and internal fixation of unstable ankle fractures: a randomised controlled trial
Egol	2000	Functional outcome of surgery for fractures of the ankle
Elwahab	2020	Is posterolateral plating better for fixation of Weber B distal fibular fractures than lateral plating: A randomized controlled clinical trial and a review of the literature
Erdem	2014	Comparison of lag screw versus buttress plate fixation of posterior malleolar fractures

Ewald	2015	Does ankle aspiration for acute ankle fractures result in pain relief? A prospective randomised double-blinded placebo-controlled trial
Fang	2016	Comparison of 3 Minimally Invasive Methods for Distal Tibia Fractures
Franke	2008	The dynamic vacuum orthosis: a functional and economical benefit?
Ge	2017	Preliminary effect of posterolateral ankle arthroscopy for ankle fractures in elderly patients
Georgiannos	2017	Fragility fractures of the ankle in the elderly: open reduction and internal fixation versus tibio-tal-calcaneal nailing: short-term results of a prospective randomised-controlled study
Gorodetskyi	2010	Use of Noninvasive Interactive Neurostimulation to Improve Short-Term Recovery in Patients with Surgically Repaired Bimalleolar Ankle Fractures: A Prospective, Randomized Clinical Trial
Guo	2010	A prospective, randomised trial comparing closed intramedullary nailing with percutaneous plating in the treatment of distal metaphyseal fractures of the tibia
Handolin (A)	2005	No long-term effects of ultrasound therapy on bioabsorbable screw-fixed lateral malleolar fracture
Handolin (B)	2005	Effect of ultrasound therapy on bone healing of lateral malleolar fractures of the ankle joint fixed with bioabsorbable screws
Handolin (C)	2005	The effect of low intensity ultrasound and bioabsorbable self-reinforced poly-L-lactide screw fixation on bone in lateral malleolar fractures
Hoelsbrekken	2013	Nonoperative treatment of the medial malleolus in bimalleolar and trimalleolar ankle fractures: a randomised controlled trial
Hoiness	2004	Tricortical Versus Quadricortical Syndesmosis Fixation in ankle fractures
Honigmann	2007	Aftertreatment of malleolar fractures following ORIF - functional compared to protected functional in a vacuum-stabilised orthosis: a randomised controlled trial
Hontzsch	2014	Evaluation of the effectiveness of the angular stable locking system in patients with distal tibial fractures treated with intramedullary nailing: a multicenter randomized controlled trial
Im	2005	Distal metaphyseal fractures of tibia: A prospective randomized trial of closed reduction and intramedullary nail versus open reduction and plate and screws fixation
Imran	2016	Comparison between Intramedullary Nailing (IMN) & Minimally Invasive Plate Osteosynthesis (MIPO) technique in distal tibia fractures in term of union

Jansen	2018	Active controlled motion in early rehabilitation improves outcome after ankle fractures: a randomised controlled trial
Joukainen	2007	Bioabsorbable screw fixation for the treatment of ankle fractures
Kariya	2020	Outcome and complications of distal tibia fractures treated with intramedullary nails versus minimally invasive plate osteosynthesis and the role of fibula fixation
Kearney	2019	Ankle injury rehabilitation (AIR): a feasibility randomised controlled trial comparing functional bracing to plaster cast in the treatment of adult ankle fractures
Kearney	2021	Use of cast immobilisation versus removable brace in adults with an ankle fracture: multicentre randomised controlled trial
Keene (A)	2016	The immediate effects of different types of ankle support introduced 6 weeks after surgical internal fixation for ankle fracture on gait and pain: a randomised crossover trial
Keene (B)	2016	The Ankle Injury Management (AIM) trial: a pragmatic, multicentre, equivalence randomised controlled trial and economic evaluation comparing close contact casting with open surgical reduction and internal fixation in the treatment of unstable ankle fractures in patients aged over 60 years
Kho	2020	Intramedullary nailing as an alternative to plate fixation in patients with distal fibular fracture
Kim	2018	A Prospective Randomized Study on Operative Treatment for Simple Distal Tibial Fractures-Minimally Invasive Plate Osteosynthesis Versus Minimal Open Reduction and Internal Fixation
Kimmel	2012	Rest easy? Is bed rest really necessary after surgical repair of an ankle fracture?
Konrad	2005	Tourniquets may increase postoperative swelling and pain after internal fixation of ankle fractures
Kortekangas	2014	Syndesmotic fixation in supination-external rotation ankle fracture: a prospective randomised study
Kortekangas	2015	A prospective randomised study comparing TightRope and syndesmotic screw fixation for accuracy and maintenance of syndesmotic reduction assessed with bilateral computed tomography
Kortekangas	2018	Three week versus six week immobilisation for stable Weber B type ankle fractures: randomised, multicentre, non-inferiority clinical trial
LaFlamme	2015	A prospective randomised multicentre trial comparing clinical outcomes of patients treated surgically with a

		static or dynamic implant for acute ankle syndesmosis rupture
Lehtola	2021	Suture button versus syndesmosis screw fixation in pronation-external rotation ankle fractures: a minimum 6-year follow-up of a randomised controlled trial
Lehtonen	2003	Use of a cast compared with a functional ankle brace after operative treatment of an ankle fracture: a prospective randomised study
Li	2014	Treatment of distal tibial shaft fractures by three different surgical methods: a randomized, prospective study
Li	2016	Minimally invasive treatment of medial malleolus fracture by implanting a hollow screw under C-arm X-ray
Li	2018	Percutaneous compression cannulated screw fixation for ankle fractures
Lin	2008	Manual therapy in addition to physiotherapy does not improve clinical or economic outcomes after ankle fracture
Mahendra	2018	Reamed intramedullary nailing versus anatomic plating by MIPO in distal tibia extra-articular metaphyseal fracture
Makwana	2001	Conservative versus operative treatment for displaced ankle fractures in patients over 55 years of age
Marsh	2006	Tibial plafond fractures treated by articulated external fixation: a randomised trial of postoperative motion versus nonmotion
Mauffrey	2012	A randomised pilot trial of "locking plate" fixation versus intramedullary nailing for extra-articular fractures of the distal tibia
Mayich	2013	Role of patient information handouts following operative treatment of ankle fractures: a prospective randomized study
Mittal	2017	Surgery for Type B Ankle Fracture Treatment: a Combined Randomised and Observational Study (CROSSBAT)
Molund	2020	Compared to conventional physiotherapy, does the use of an ankle trainer device after Weber B ankle fracture operation improve outcome and shorten hospital stay? A randomised controlled trial
Mora	2002	The role of pulsatile cold compression in edema resolution following ankle fractures: a randomized clinical trial
Moseley	2005	Passive stretching does not enhance outcomes in patients with plantarflexion contracture after cast immobilisation for ankle fracture: a randomised controlled trial

Moseley	2015	Rehabilitation after immobilisation for ankle fracture. The EXACT randomised clinical trial
Nilsson	2009	Effects of a training program after surgically treated ankle fracture: a prospective randomised controlled trial
Noh	2012	Outcomes of operative treatment of unstable ankle fractures: a comparison of metallic and biodegradable implants
Pan	2018	Surgical effects and prognosis of non-rigid internal fixation for ankle fractures combined with tibiofibular syndesmotic injuries
Park	2018	Comparison of clamp reduction and manual reduction of syndesmosis in rotational ankle fractures: a prospective randomised trial
Park	2019	Comparison of the use of evaporative coolants and ice packs for the management of preoperative edema and pain in ankle fractures: a prospective randomised controlled trial
Park	2020	Necessity of interfragmentary lag screws in precontoured lateral locking plate fixation for supination-external rotation lateral malleolar fractures
Park (A)	2021	Early weight-bearing versus nonweightbearing after operative treatment of an ankle fracture
Park (B)	2021	Comparison between headless compression screws and tension band wires for the fixation of medial malleolar fractures: a prospective randomised trial
Pawar	2014	A comparative study of intramedullary interlocking nail and locking plate fixation in the management of extra articular distal tibial fractures
Polat	2015	Intramedullary nailing versus minimally invasive plate osteosynthesis for distal extra-articular tibial fractures: a prospective randomised clinical trial
Prasad	2017	Comparative study of intramedullary interlocking nailing and minimally invasive percutaneous plate osteosynthesis (MIPO) in extra articular distal tibial fracture
Raeder	2020	Better outcome for suture button compared with single syndesmotic screw for syndesmosis injury: five-year results of a randomised controlled trial
Rashid	2013	To evaluate the efficacy of mobilisation techniques in post-traumatic stiff ankle with and without paraffin wax bath
Rayan	2018	Open reduction internal fixation versus external fixation with limited internal fixation for displaced comminuted closed pilon fractures: A randomised prospective study
Salai	2000	The epidemic of ankle fractures in the elderly – is surgical treatment warranted?

Sanders	2012	Operative versus nonoperative treatment of unstable lateral malleolar fractures: a randomised multicentre trial
Sanders	2019	Improved reduction of the tibiofibular syndesmosis with tightrope compared with screw fixation: results of a randomised controlled study
Schubert	2020	Effect on overall health status with weightbearing at 2 weeks vs 6 weeks after open reduction and internal fixation of ankle fractures
Shannon	2017	Allgower-Donati versus vertical mattress suture technique impact on perfusion in ankle fracture surgery: a randomised clinical trial using intraoperative angiography
Sim	2019	Effect of hospital length of stay on tourniquet use during internal fixation of ankle fractures: randomised controlled trial
Smeeing	2020	Weight-bearing or non-weight-bearing after surgical treatment of ankle fractures: a multicentre randomized controlled trial
Sultan	2014	Compression stockings in the management of fractures of the ankle
Sun	2014	A prospective, randomised trial comparing the use of absorbable and metallic screws in the fixation of distal tibiofibular syndesmosis injuries
Tahir	2020	A multicentre randomised controlled trial comparing plating with intramedullary nailing for extra-articular distal tibial fractures
Takao	2004	Diagnosis and treatment of combined intra-articular disorders in acute distal fibular fractures
Thordarson (A)	2001	The role of ankle arthroscopy on the surgical management of ankle fractures
Thordarson (B)	2001	Bioabsorbable versus stainless steel screw fixation of the syndesmosis in pronation-lateral rotation ankle fractures: a prospective randomised trial
Tsukada	2013	Locking versus non-locking neutralisation plates for treatment of lateral malleolar fractures: a randomised controlled trial
Vallier	2012	Factors influencing functional outcomes after distal tibia shaft fractures
van den Berg	2018	Functional bracing treatment for stable type B ankle fractures
van der Velde	2013	Reducing the potential for tourniquet-associated reperfusion injury
van Gerven (A)	2020	Omitting Routine Radiography of Traumatic Ankle Fractures After Initial 2-Week Follow-up Does Not Affect Outcomes: The WARRIOR Trial: A Multicentre Randomized Controlled Trial

van Gerven (B)	2020	Reduction of routine use of radiography in patients with ankle fractures leads to lower costs and has no impact on clinical outcome: an economic evaluation
Vicenti	2020	The impact of lag screw in the healing time of distal tibia fractures treated with minimally invasive plate osteosynthesis: A randomized clinical trial
Vidovic	2017	Posterior fragment in ankle fractures: anteroposterior vs posteroanterior fixation
Vioreanu	2007	Early mobilisation in a removable cast compared with immobilization in a cast after operative treatment of ankle fractures: a prospective randomised study
Wani	2017	Operative Management of Distal Tibial Extra-Articular Fractures - Intramedullary Nail Versus Minimally Invasive Percutaneous Plate Osteosynthesis
White	2016	A prospective randomised controlled trial of the fibular nail versus standard open reduction and internal fixation for fixation of ankle fractures in elderly patients
Willet	2016	Close contact casting vs surgery for initial treatment of unstable ankle fractures in older adults: a randomised clinical trial
Winge	2018	Would complications after ankle surgery. Does compression treatment work? A randomised, controlled trial
Xian	2018	Novel elastic syndesmosis hook plate fixation versus routine screw fixation for syndesmosis injury
Zhan	2016	Anterior-inferior tibiofibular ligament anatomical repair and augmentation versus trans-syndesmosis screw fixation for the syndesmotic instability in external-rotation type ankle fracture with posterior malleolus involvement: A prospective and comparative study
Zyskowski	2021	Is early full weight bearing safe following locking plate ORIF of distal fibula fractures?

Table iii. Expanded definitions of terms used in Table II.

Term	Definition
Body structure and function	
Body structure	Anatomical structure of organs, bones and joints – e.g., organs, limbs and their components
Radiological fracture assessments	Including radiograph – e.g. anteroposterior, medial and/or lateral radiograph assessment; and other scanning techniques - e.g. CT scan. Outcomes include alignment, bone union (including mal- or nonunion, and time to achieve union), bone mineral density, and assessments of clear space and overlap
Body function	Physiological, musculoskeletal and psychological functioning of body systems – e.g. joint function and blood tests
Ankle swelling and alignment assessments	Assessment of ankle swelling and alignment. Includes amount of swelling and time taken for swelling to resolve
Blood chemistry	Any assessment of blood chemistry including pH and elements – e.g. serum sodium, calcium
Calf muscle assessments	Assessments of calf muscle strength (including assessments of force), size, and extent of muscle atrophy
Joint range of motion	Assessments of active and passive joint range of motion – e.g. ankle inversion, eversion, plantar- and dorsi-flexion.
Activities	Ability to perform an activity or task. Includes basic (e.g. weightbearing, step length, ability to walk) and instrumental activities of daily living (e.g. washing, dressing, walking), and physical activities (e.g. swimming, running)
Ankle function	Multi-domain assessments which emphasise activity and produce a single (index score). Examples of discrete outcomes include the Olerud-Molander Ankle Score (OMAS) (pain, swelling, stiffness, physical activities), Foot Function Index (FFI) (pain, disability, activity limitation), Musculoskeletal Functional Assessment (MFA) (activities, participation, emotional wellbeing), and the Short-MFA (SMFA) (dysfunction, bother)
Basic activities of daily living	Assessments of basic activities such as ability weight-bear and walk. This includes ambulation assessments and perceived difficulty with basic activities. Examples of discrete outcomes include time to weightbearing, walking speed (aided and unaided), perceived difficulty walking in an ankle support

Instrumental activities of daily living	Assessments of instrumental activities of daily living such as washing and dressing. Examples of discrete outcomes include the Foot and Ankle Disability Index (FADI), the Foot Ankle Outcome Score (FAOS) and the Ankle Osteoarthritis Scale (AOS) disability subscale
Physical activities	Assessments of physical activities such as running or swimming. An example of a discrete outcome is the FADI Sports subscale
Participation	Ability to participate in life and related activities, as influenced by their health. Includes returning to work or leisure activity, work stability, engaging with family, and usual social role
Participation in social and leisure activities	Multi-domain assessments which emphasise participation (work and leisure activity-related items), such as the Work Productivity and Activity Impairment (WPAI) questionnaire (work, daily life), or multi-item assessments with content specific to work, and work/ sport/ leisure activity performance. Discrete outcomes which assess participation in social life are included here - e.g. Assessment of Quality of Life (AQoL) Social Relationships subdomain
Return to work	Single item assessments of a person's return to work. This includes recorded duration of sick leave
Return to sport or leisure activity	Single item assessments of a person's return to sport or leisure activity.
Health-related quality of life	The influence of health and wellbeing on quality of life - how people feel, function, and live their lives. Uni- or multidimensional assessments, including symptoms, emotional wellbeing, and feelings of dependency. Assessment may be general/generic or specific
General health	Single item assessments of general or 'global' health.
Mental health	Single or multi-item assessments of mental health and emotional wellbeing
Multi-domain assessment	Multi-item assessments of how patients feel, function and lives their life. Discrete outcomes include total scores from the EQ-5D, AQoL questionnaire, and Short-Form 36-item and 12-item Health Status survey measures (SF-36 and SF-12)
Pain	Assessments of pain intensity, frequency, severity, or recovery. Includes single or multiple items (sub-domains) taken from existing measures - e.g. SF-36 Body Pain sub-domain
Physical health	Single or multi-item assessments of physical health
Processes of care	Outcomes related to the flow of patients through the care pathway (from the point of admission to discharge): e.g. duration of stay, duration of surgery, complications

Complications	Reporting of unintended outcomes and (serious) adverse events - including wound issues (infections (superficial, deep); dehiscence), surgical failure, reoperation (including implant removal), death, and secondary interventions including reoperations
Hospital-specific outcomes	Hospital outcomes including length of stay and radiation exposure
Surgery-specific outcomes	Surgery-specific outcome including duration of surgery, bleeding, incision perfusion and length of incision
Patient experiences	Patient's experiences of care and recovery. Includes satisfaction with outcomes (e.g. scar appearance) and perceptions of recovery
Satisfaction with care or treatment	Patient satisfaction with their care, treatment, or treating staff
Satisfaction with outcomes	Patient satisfaction with outcomes – e.g. scar appearance or comfort.
Perceptions of recovery	Patient perceptions of recovery – e.g. walking security
Economic assessment	Economic impact and resource use – including personal costs (e.g. informal care), work-related costs (e.g. absenteeism), direct healthcare unit costs (e.g. hospital days, prescription costs, implant cost, costs associated with treatment complications), secondary healthcare costs (e.g. medication use), and reporting of quality-adjusted life years (QALYs)

EQ-5D, EuroQol five-dimension questionnaire.