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PROTOCOL

Functional orthosis versus cast immobilization for weightbearing stable Weber B ankle fractures with concomitant unstable gravity stress tests

A PROTOCOL FOR A TWO-YEAR MULTICENTRE RANDOMIZED CONTROLLED NONINFERIORITY TRIAL

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Aims

Treatment of Weber B ankle fractures that are stable on weightbearing radiographs but unstable on concomitant stress tests (classified SER4a) is controversial. Recent studies indicate that these fractures should be treated nonoperatively, but no studies have compared alternative nonoperative options. This study aims to evaluate patient-reported outcomes and the safety of fracture treatment using functional orthosis versus cast immobilization.

Methods

A total of 110 patients with Weber B/SER4a ankle fractures will be randomized (1:1 ratio) to receive six weeks of functional orthosis treatment or cast immobilization with a two-year follow-up. The primary outcome is patient-reported ankle function and symptoms measured by the Manchester-Oxford Foot and Ankle Questionnaire (MOxFQ); secondary outcomes include Olerud-Molander Ankle Score, radiological evaluation of ankle congruence in weightbearing and gravity stress tests, and rates of treatment-related adverse events. The Regional Committee for Medical and Health Research (approval number 277693) has granted ethical approval, and the study is funded by South-Eastern Norway Regional Health Authority (grant number 2023014).

Discussion

Randomized controlled trials are needed to evaluate alternative nonoperative treatment options for Weber B/SER4a ankle fractures, as current clinical guidelines are based on biomechanical reasoning. The findings will be shared through publication in peer-reviewed journals and presentations at conferences.

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Introduction

Ankle stability should inform the choice between nonoperative treatment and surgery in Weber B/supination-external rotation (SER) fractures.[1–5] The primary determinant of ankle stability is the competency of the deltoid ligament.[1–3,6] Recent studies indicate that partial deltoid ligament injury is common,[2,7,8] determined by weightbearing radiographs deemed stable (no increase in medial clear space), while concomitant gravity stress radiographs demonstrate instability (due to an increase in medial clear space) (Figure 1). It is suggested that this is referred to as a Weber B/SER4a injury, and is due to partial deltoid ligament injury where the deep posterior tibiotalar ligament is intact.[2,7] Previous research has suggested that nonoperative treatment may be effective for these fractures. Although prospective studies

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Table I. Inclusion and exclusion criteria.

Inclusion criteria	Exclusion criteria
Isolated Weber type B fractures deemed stable on weightbearing radiographs (medial clear space increase of < 1.0 mm comparing injured versus uninjured ankle)	Fracture of the medial malleolus, pre-hospital closed fracture reduction, open fracture, a fracture resulting from high-energy trauma, multitrauma, or pathological fracture
Concomitant gravity stress test evaluated as unstable (medial clear space increase of 1.0 mm or more comparing injured versus uninjured ankle)	Fracture of the posterior malleolus involving 25% or more of the joint surface or with a step of the intra-articular surface
Available for stability evaluation within 14 days after injury	
	Neuropathy or generalized joint disease such as rheumatoid arthritis
Aged 18 to 80 years	Patients assumed not compliant (i.e. substance abuse, significant cognitive and psychiatric disorders)
Pre-injury walking ability without aids	
	Previous history of ipsilateral ankle fracture
	Previous history of ipsilateral major ankle/foot surgery
	Residence outside one of the participating hospitals' catchment areas (not available for follow-up)

have emerged,[7] the evidence is primarily based on retrospective studies with varying follow-up protocols and limited statistical power.[8–11] No randomized controlled trials (RCTs) have been conducted on this topic.

There is debate among authors on the best nonoperative treatment for these fractures, with some advocating for cast immobilization and others reporting successful outcomes using various orthoses and orthotic devices.[2,8] The argument for cast immobilization is based on the fear of post-traumatic osteoarthritis due to potential instability,[2] but there is no formal evidence to support this. The British Orthopaedic Association Standards for Trauma recommend cast immobilization for partially unstable fractures,[12] but this approach carries risks such as muscle atrophy, deep vein thrombosis, and joint stiffness. More functional treatment options may avoid these concerns, offer better cost-effectiveness,[13] and may be preferred by patients.[14] A RCT comparing patient-reported outcomes and the safety of functional orthosis versus cast immobilization is needed to determine the best treatment approach for these fractures.

This is a noninferiority trial with the primary objective of investigating whether patient-reported ankle function and radiological outcomes of functional orthosis treatment are adequately close to those of cast immobilization for Weber B/SER4a ankle fractures with no additional harm. Noninferiority is proven if ankle function in the functional orthosis group is within the predefined noninferiority margin of the cast immobilization group and without an appreciable increase in harm. Secondary objectives include evaluating if functional orthosis treatment has advantages (superiority) compared to cast immobilization, such as increased patient comfort, faster return to daily activities, or fewer complications.

Methods

Study design. This is the research protocol for an ongoing, preregistered, randomized, controlled, multicentre noninferiority study comparing the use of a functional orthosis for six weeks (as the new treatment) with the use of cast immobilization for six weeks (as the reference treatment) for partially unstable Weber B/SER4a ankle fractures. The protocol is developed in adherence with the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) statement.[15] When submitting this protocol, 39 patients were enrolled in the study. Inclusion started in May 2022, and we anticipate reaching our recruitment target of 110 patients within two years.

Study setting. Potential participants will be recruited from the Departments of Orthopaedic Surgery at three Norwegian hospitals: Østfold Hospital Trust, Innlandet Hospital Trust, Gjøvik Hospital, and Møre og Romsdal Hospital Trust, Aalesund Hospital. The catchment areas of the participating centres comprise approximately 500,000 persons. All centres are the only ones to treat ankle fractures in their catchment area.

Eligibility criteria. Patients are eligible if they present to one of the participating hospitals and comply with the inclusion and exclusion criteria presented in Table I.

Interventions

First presentation and diagnosis. An on-call medical doctor or nurse will apply a below-knee back slab with stirrup slab plaster cast when a Weber B fracture with medial clear space (MCS) measurements of 7.0 mm or less is identified on plain, non-weightbearing radiographs. The patient will keep the cast until final stability evaluations are performed after a minimum of three and a maximum of 14 days after injury. This delay is to enhance pain reduction, ensure proper weightbearing, and for swelling to settle. Figure 1 displays a flow diagram indicating the clinical pathway for Weber B fractures, eligibility assessment, and follow-up.

Stability evaluations. An on-call radiographer will obtain bilateral weightbearing and gravity stress radiographs. For weightbearing radiographs, the cast is removed, and then the foot must be plantigrade with a minimum of 50% of the total body weight loaded on the injured limb.

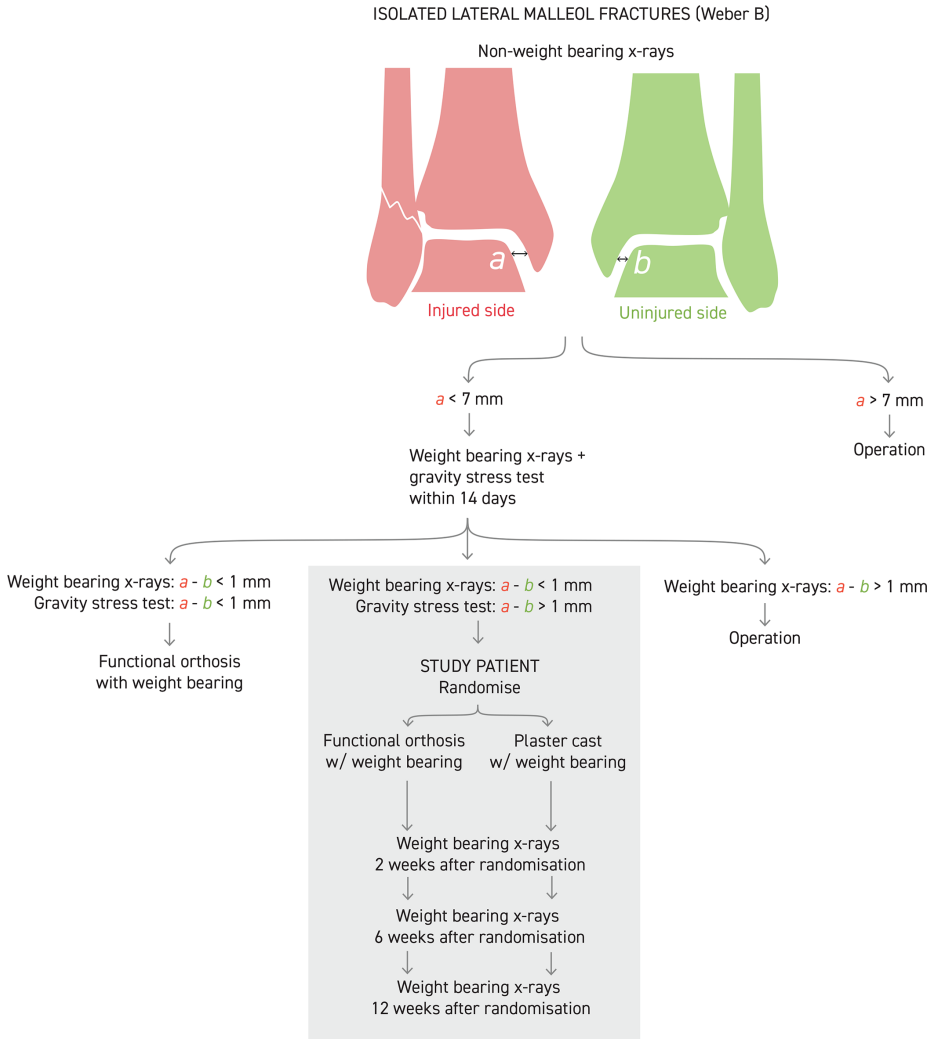

Fig. 1

The figure displays a flow diagram indicating the clinical pathway for Weber B fractures, eligibility assessment, and follow-up.

We will use a bathroom scale (Seca 877; Seca, Germany) to verify patients' ability to bear weight before radiography. During the gravity stress tests, patients are positioned lying on the side of the injured ankle, on a flat examination table, with the foot and distal half of the leg off the end of the table and instructed to relax.[16]

We consider the size of the MCS as an expression of ankle stability. We define the MCS as the distance between the medial border of the talus and the lateral border of the medial malleolus on a line parallel to and 5.0 mm below the talar dome, consistent with previous studies.[7,17] Trained orthopaedic residents or physiotherapists will review radiographs. The MCS is recorded in millimetres on mortise view radiographs. Satisfactory intra- and interobserver reliability of this method independent of rater experience is documented.[7] Stability is considered if the MCS measurement of the injured versus the uninjured ankle is less than 1.0 mm.

Treatment arms. Eligible patients will be randomly assigned to receive either functional orthoses or a cast for six weeks. A trained nurse will apply the appropriate treatment, either a standard, padded below-the-knee synthetic cast (3M ScotchCast Plus; 3M, USA) or a functional orthosis (AirCast Air-Stirrup; DJO Global, USA). The cast will immobilize the ankle joint at a 90° angle, and in cases where there is a risk of severe swelling, the use of the initial plaster cast may be extended for an additional one to two weeks. Both treatment groups will be allowed to bear weight on their injured ankle immediately after receiving the treatment, and all participants will receive education on self-management techniques such as crutch walking, using the cast or orthosis, proper loading techniques, and how to stay physically active while also managing pain and swelling. Participants will also receive a leaflet with exercises to promote circulation and

Table II. Schedule of follow-up and outcome assessments.

Outcome	Baseline (stability evaluation)	2 weeks	6 weeks	3 months	1 year	2 years
MOxFQ			x	x	x	x
OMAS			x	x	x	x
NRS patient satisfaction			x			
Ankle joint congruity	x	x	x	x		x
Radiological fracture union				x		x
Ankle ROM			x	x		x

MOxFQ, Manchester-Oxford Foot and Ankle Questionnaire; NRS, numerical rating scale; OMAS, Olerud-Molander Ankle Score; ROM, range of motion.

maintain joint range of motion (applicable to the orthosis group).

Concomitant care or interventions

Additional exercise therapy. For weeks 0 to six, supervised physiotherapy sessions will not be actively encouraged. However, participants will be advised to stay generally active within reasonable restrictions.

After week six, when the cast or orthosis is removed, supervised physiotherapy sessions will be left to the discretion of the clinical staff at each follow-up visit. However, a record of any additional rehabilitation and a history of any other interventions will be recorded on follow-up.

Adherence. Adherence and deviations from the treatment protocol will be addressed at each follow-up visit.

Primary outcome

The study's primary outcome is the difference in patient-reported ankle function measured by the Manchester-Oxford Foot and Ankle Questionnaire (MOxFQ).[18] The MOxFQ is a patient-reported questionnaire comprising 16 questions concerning foot and ankle function and quality of life.[19,20] It is scored on a scale of 0 to 64 points, with lower scores indicating fewer symptoms. We use the MOxFQ index,[21] where scores are converted to a scale of 0 to 100. There is no established minimal clinically important difference for the MOxFQ index. However, the minimal detectable change (MDC) was previously defined as five points.[22]

Secondary outcomes

Secondary outcomes related to the primary objective. Secondary outcomes include differences in patient-reported ankle function, as measured by the Olerud-Molander Ankle Score (OMAS: range 0 to 100, higher scores indicate fewer symptoms).[23] The OMAS is patient-reported and based on nine items emphasizing symptoms and ankle-specific functioning. Different studies have defined minimal clinically important difference as 8.8 and 9.5 points for patients with ankle fractures.[14] MDC is defined as 4.7 points.[8]

Furthermore, we will assess the radiological congruity/stability of injured versus normal ankles at two years. Ankles are considered congruent/stable if the MCS measurement of the injured versus the uninjured ankle is less than 1.0 mm. Congruity/stability will be measured on weightbearing radiographs and gravity stress radiographs. Sectra Picture Archiving and Communications System (Sectra, Sweden) will be used for radiograph measurements.

Expected complications or harms related to study treatment, including delayed fracture healing, symptomatic nonunion, and thromboembolic events, will be recorded as adverse events until study closure. Loss of congruence and conversion to surgery will be recorded as serious adverse events. At each follow-up visit, we will query about harms, and participants are asked to describe any negative effects of the trial treatment to record unexpected adverse events. Fracture union is considered if callus formation is present on radiographs with concurrent pain-free palpation over the fracture site. Delayed union and nonunion are recorded if a union cannot be found within 12 weeks and six months after fracture, respectively.

Secondary outcomes related to the secondary objectives. Other secondary outcomes include differences in a numerical rating scale of patient comfort at six weeks and ankle range of motion measurement using a goniometer at each follow-up visit after six weeks.

Demographic data and covariates. Sex, age at the time of injury, BMI, smoking status, and activity will be registered before randomization.

Participant timeline. Trial visits will be at two, six, and 12 weeks, and one and two years. The visits include a clinical examination and ankle radiographs. Site investigators (physiotherapists or orthopaedic residents) will manage the follow-up visits. Before each visit, participants will complete the questionnaires. The schedule of follow-up visits and outcome assessment is presented in Table II.

Sample size. The sample size was calculated based on the primary hypothesis of noninferiority of functional orthosis treatment versus cast immobilization two years

after randomization. A difference of 7.5 MOxFQ points constitutes our noninferiority limit. Based on preliminary results from another study conducted on ankle fractures at our hospital,[24] we used a standard deviation (SD) of 12 points MOxFQ score. To detect a mean difference in MOxFQ score of 7.5 points (SD 12) at two years with a significance level of 5% and power of 90% with equal allocation to two arms will require 44 patients in each arm of the trial. To tolerate 20% dropout, 55 patients will be recruited per arm.

Recruitment. Potential participants in this study will be identified when diagnosed with a Weber B ankle fracture in the emergency department of one of the participating hospitals. The site investigators will determine their eligibility based on the inclusion and exclusion criteria. Based on the incidence of ankle fractures and the catchment population of the participating centres, it is expected that 60 participants will be included per year, with a total inclusion period of two years. The study began in May 2022, and the two-year follow-ups are expected to be completed in 2026.

Allocation

Sequence generation. Patients will be evenly allocated (1:1 ratio) to either six weeks of cast immobilization or six weeks of functional orthosis. Randomization will be performed by site investigators using a web-based randomization system (WebCRF; Norway) developed and administered by the Unit of Applied Clinical Research, The Faculty of Medicine and Health Sciences, Norwegian University of Science and Technology, Trondheim, Norway. The system implements block randomization with varying block sizes stratified by patient age and BMI.

Concealment mechanism. Allocation concealment will be ensured, as the service will release the randomization code once the patient has been recruited into the trial; after all baseline measurements have been registered and written informed consent has been obtained.

Implementation. All patients who consent to participate and fulfil the inclusion criteria will be randomized. Randomization will be requested by the site investigator responsible for recruitment. The randomization result is displayed on the screen, and a copy is sent by email to the study coordinator.

Blinding. Blinding of participants is not possible due to the nature of the interventions. Blinding of site investigators and clinical staff at weeks 2 and 6 is not possible due to the nature of the interventions. Investigators responsible for 12-week and two-year follow-up consultations will be blinded to group allocation.

Data management. All data will be entered electronically using an electronic research register (MedInsight, Norway). This may be done at each participating site where the data originated. Original study forms will be entered electronically and kept on file at the participating site in locked cabinets. Access to the study data will be restricted to study group members. Participant files will be maintained in storage for a period of five years after the completion of the study.

Data analysis plan. Reporting of results will adhere to the Checklist for statistical Assessment of Medical Papers (CHAMP) statement.[25] A CONSORT chart illustrating participant flow throughout the study will also be produced. Stata Statistical Software v. 17 will be used for statistical analyses (StataCorp, USA). Treatment effects will be presented, with appropriate 95% confidence intervals (CIs), for both the unadjusted and adjusted analyses. The significance level is set to 5%. We will conduct intention-to-treat analyses as standard unless otherwise specified.

Demographic data. Demographic data will be summarized by treatment arms to check between-group comparability.

Primary analysis. The main analysis will investigate differences in the primary outcome, two years after randomization, between the two treatment groups. We plan to use repeated measures mixed model analyses for longitudinal data (both primary and secondary outcomes). If patient-reported data do not satisfy these analyses' assumptions, we will perform bootstrap procedures, or similar, on the mean patient-reported score difference for each time point instead. Noninferiority will be claimed if the higher CI limit for differences is less than the noninferiority margin. Simple linear and multiple regression will be used to control and adjust for confounding. Between-group comparisons for complications will be evaluated using chi-squared tests.

Secondary analyses. Descriptive statistics of OMAS at each timepoint will be calculated with between-group analyses following the method described in the primary analysis. An equivalence analysis of ankle congruity on weightbearing and gravity stress radiographs will be assessed using a predefined margin of 1.0 mm. Paired *t*-tests will be used to evaluate the difference in radiological MCS measurements of the injured ankle at two years versus the uninjured ankle at baseline.

Sensitivity analyses. Additionally, as-treated analyses will be conducted for the primary outcome. If noninferiority is proven, the results will be reviewed using alternative noninferiority margins to check if it will lead to different interpretations of between-group differences in patient-reported outcome data.

Reasons for ineligibility, non-compliance, withdrawal, or other protocol violations will be stated, and any patterns will be summarized.

Ethics. Ethical approval was obtained from the Regional Committee for Medical and Health Research (permission number: 277693). All data collection and management will agree with the terms in approvals. Participants must sign written informed consent forms before being randomized into the study. Participants will be informed, written and

oral, that participation in the studies is voluntary and that they can withdraw their consent at any time without it influencing further treatment.

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Discussion

The benefit of this study is advancing understanding of the most effective nonoperative treatment option for partially unstable Weber B/SER4a ankle fractures, as this is currently scarce. This study was designed as a noninferiority trial aiming to evaluate if the results of functional treatment are sufficiently close to those of cast immobilization without excess harm. Functional treatment may be advantageous by avoiding the risk of deep vein thrombosis, joint stiffness, and muscle atrophy associated with cast immobilization. However, it has been suggested that functional treatment may result in deep deltoid ligament healing in an elongated position, leading to subtle instability and an increased risk of post-traumatic osteoarthritis, but there is currently no evidence to support this claim. Although the follow-up period of two years may capture most harms related to both treatments, the development of post-traumatic osteoarthritis may take longer. Thus, we plan to extend the follow-up to longer than the two-year primary endpoint. Therefore, we consider that this study's results may help guide future clinical applications and treatment strategies for this patient group.

The results of this study will be published in international peer-reviewed journals and presented at national and international conferences. Both positive and negative results will be reported, and all authors will meet the criteria for co-authorship as defined by the International Committee of Medical Journal Editors.

Take home message

- Treatment choice for partially unstable Weber B/SER4a fractures is controversial, but the results of this randomized noninferiority trial may guide future treatment strategies for these common fractures.
- This study will investigate simple and feasible methods of fracture diagnosis and interventions that can be directly applied in routine clinical practice.
- A key secondary endpoint is the incidence of residual gravity stress instability rate at two years, which has been feared with functional treatment options but without formal evidence.

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- The datasets generated and analyzed in the current study are not publicly available due to data protection regulations. Access to data is limited to the researchers who have obtained permission for data processing. Further inquiries can be made to the corresponding author.

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