Cast immobilisation versus surgery for unstable lateral malleolus fractures (SUPER-FIN): randomised non-inferiority clinical trial

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ABSTRACT

OBJECTIVE

To compare cast immobilisation with surgery using open reduction and internal plate fixation for unimalleolar Weber B ankle fractures with a congruent mortise on initial radiography but deemed unstable by external rotation stress testing.

DESIGN

Randomised, pragmatic, non-inferiority, clinical trial.

SETTING

One specialist university hospital trauma centre in Finland, 16 January 2013 to 7 July 2021.

PARTICIPANTS

840 skeletally mature patients (age ≥16 years) with an isolated Weber B fibula fracture on static radiographs. Fracture instability was assessed by standard external rotation stress test under fluoroscopy. 714 participants were excluded (569 with stable fracture, mortise incongruency, or fracture dislocation) and the remaining 126 patients with a congruent but unstable ankle mortise were randomised.

INTERVENTIONS

Participants were randomly allocated to receive either conventional cast immobilisation for six weeks (n=62) or surgical treatment with open reduction and internal plate fixation followed by cast immobilisation for six weeks (n=64).

MAIN OUTCOME MEASURES

The primary, non-inferiority outcome was the Olerud-Molander Ankle Score (OMAS; range 0-100 points; higher scores indicating better outcomes and fewer symptoms) at two years. The predefined non-inferiority margin for the primary outcome was set at −8 points. Secondary outcomes were ankle function, pain, health related quality of life, ankle range of motion, and radiographic outcome. Treatment related adverse events were also recorded.

RESULTS

121 out of 126 randomised participants (96%) completed the study. In the primary intention-to-treat analysis of 121 participants completing two year follow-up, the mean OMAS was 89 in the cast immobilisation group and 87 in the surgery group (between group mean difference 1.3 points, 95% confidence interval −4.8 to 7.3). No statistically significant between group differences were observed in any secondary outcomes. One participant in each group had radiographic evidence of non-union. In the surgery group, one participant had a superficial wound infection, one had delayed wound healing, and nine underwent procedures to remove hardware, two of whom developed postoperative infections (one deep and one superficial).

CONCLUSIONS

Cast immobilisation proved non-inferior to surgery for the treatment of unimalleolar Weber B ankle fractures with a congruent mortise on initial radiography but deemed unstable by external rotation stress testing. Overall, fewer treatment related harms occurred with cast immobilisation compared with surgery.

TRIAL REGISTRATION

ClinicalTrials.gov NCT01758796.

WHAT IS ALREADY KNOWN ON THIS TOPIC

Approximately two thirds of all ankle fractures are Weber B fractures of the lateral malleolus

Depending on the trauma and accompanying soft tissue injury, these fractures leave the ankle either stable or unstable

Surgery remains the main treatment for Weber B ankle fractures deemed unstable, despite recent trials and guidelines increasingly supporting non-operative options in selected patients

WHAT THIS STUDY ADDS

In patients with a unimalleolar Weber B ankle fracture with a congruent mortise on initial radiography but deemed unstable in external rotation stress testing, cast immobilisation results in non-inferior functional outcomes compared with surgery at two years post-injury

Patients should also be advised that surgery carries a risk of treatment related adverse events

Introduction

Ankle fractures are among the most common fractures in adults, with an annual incidence of up to 178 per 100 000 individuals.[1-3] Most (~60%) are isolated Weber B fractures of the lateral malleolus.[1-3] For these injuries, management decisions depend on whether the ankle mortise remains congruent. A Weber B fracture with a congruent mortise can generally be treated successfully with cast immobilisation, unless the talus shifts laterally or tilts, which results in loss of congruency visible on radiographs. Because incongruency disrupts normal joint loading and increases the risk of post-traumatic osteoarthritis, surgery is often considered necessary.[4-10]

That the ankles appear congruent on initial radiography yet later occult incongruency develops while patients are immobilised in a cast raises a major diagnostic challenge. Occult incongruency refers to talar lateral shift or tilt that emerges during cast immobilisation, when the ankle mortise widens despite a previously baseline radiograph showing congruency. This shifting or tilting is driven by associated ligamentous injury—particularly disruption of the deltoid ligament complex.[4-6 11-14] To pre-empt

such cases, several diagnostic strategies have emerged around the concept of stability and its assessment at presentation. Originally, clinicians relied on clinical judgement supplemented by plain radiographs and consensus based indicators.[7-9] To improve diagnostic performance, formalised stress testing under fluoroscopy—such as external rotation and gravity stress tests—were introduced.[5 6 13] Despite widespread adoption of ankle stability assessment, no universally accepted method exists, and thresholds for test positivity vary.[9 10 14]

More recently, the use of weightbearing radiographs has emerged as an alternative approach to the challenge of diagnosing occult incongruency.[15-20] At presentation, a fractured ankle with a congruent mortise is placed in a cast, the patient allowed to bear weight, and then congruency reassessed radiographically, typically 10 to 14 days after injury. This approach is now used in some regions, particularly the UK, to decide whether surgery is necessary.

Overall, practices today are diverse. In our recent multi-register study,[21] we observed a sixfold variation in the incidence of surgery for isolated lateral malleolar fractures across six European countries between 2013 and 2022. Although surgical rates declined in some countries, they remained stable in others, highlighting marked heterogeneity in how clinicians judge which fractures require surgery.

We are aware of only one randomised trial to date that has compared surgery with cast immobilisation in patients with radiographically congruent Weber B fractures classified as unstable by external rotation testing.[8] At one year follow-up, that trial found functional outcomes to be equivalent between the two approaches. Nonetheless, differences in the incidence of adverse events prompted the authors to recommend consideration of surgery for younger patients.[8]

We conducted a prospective randomised parallel group non-inferiority trial to compare the outcomes of cast immobilisation with surgery in patients with a unimalleolar Weber B fracture with a congruent mortise deemed unstable after external rotation stress testing. Stringent criteria for defining instability were used to ensure that all mortises would be considered unstable across the range of previously used standards for assessing stability.

Box 1: Eligibility criteria

Inclusion criteria
- Skeletally mature (≥16 years) people
- Isolated Weber B fibula fracture and no widening of the mortise on static ankle radiography
  - Medial clear space <4 mm and ≤1 mm wider than the superior clear space
- Unstable ankle mortise on external rotation stress testing
  - Medial clear space ≥5 mm as measured between lateral border of medial malleolus and medial border of talus at level of talar dome
- Able to walk unaided before current trauma
- Enrolment <7 days after injury
- Provision of informed consent

Exclusion criteria
- Ankle fracture-dislocation
- Previous ankle fracture or deltoid ligament injury or other major fracture in ankle or foot area
- Bilateral ankle fracture
- Concomitant tibial fracture
- Pathological fracture
- Diabetic or other neuropathy
- Inadequate cooperation
- Inability to speak, understand, and read in language of clinical site (history of alcohol misuse, drug misuse, or psychological or psychiatric problems that are likely to invalidate informed consent)
- Permanent residence outside the catchment area of the hospital
- Open fracture
- Declined to participate

Methods

We conducted SUPER-FIN, a randomised, parallel group, non-inferiority trial comparing cast immobilisation for six weeks with surgery for Weber B ankle fractures deemed unstable, at Oulu University Hospital in Finland from 16 January 2013 to 7 July 2021. The reporting of this study follows the Consolidated Standards of Reporting Trials (CONSORT) guidelines for non-inferiority trials.[22] The trial protocol was approved by the institutional review board of Oulu University Hospital (EC 25/2012) and has been published.[23] The study was registered at ClinicalTrials.gov before the trial started. No changes were made to the study protocol after the trial started. All participants gave written informed consent.

Patients

Between December 2012 and March 2019, we prospectively assessed all skeletally mature patients (age ≥16 years) presenting to Oulu University Hospital with an ankle fracture for eligibility in two randomised controlled trials investigating unimalleolar Weber B fibula fractures: the previously published trial on stress negative fractures[24] and the present SUPER-FIN trial on stress positive fractures (see supplementary appendix 1, table 1 for the schedule of enrolment, interventions, and assessments). After confirming that an unimalleolar Weber B fracture was present and that the mortise was congruent on initial radiographs (medial clear space <4 mm and ≤1 mm wider than the superior clear space), we examined all patients for stability using the external rotation stress test. The test was performed in a clinical fluoroscopy suite without anaesthesia. A baseline fluoroscopic image was obtained with the leg positioned in approximately 10-15° of internal rotation and the ankle in neutral dorsiflexion. An external rotation force of 3.6-4.5 kg was then applied to the forefoot, and a second image was acquired to measure the medial clear space between the lateral border of the medial malleolus and the medial border of the talus at the level of the talar dome. We considered the ankle unstable when the medial clear space was ≥5 mm (see supplementary appendix 1, figure 1).[5 6 11-14] A calibration disc ensured standardised measurements.

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Based on the findings of the external rotation stress test, we classified fractures as stress negative or stress positive. Patients with stress negative fractures were included in a trial comparing cast immobilisation for three weeks versus six weeks.[24] The present SUPER-FIN trial, which began recruiting in January 2013, focused on patients with stress positive fractures. Running the two trials in parallel enabled consecutive enrolment across the full spectrum of radiographically congruent Weber B fractures. Box 1 details the inclusion and exclusion criteria.

Randomisation

A statistician with no clinical involvement in the trial prepared sequentially numbered, opaque, sealed envelopes with random permuted blocks (block size known only by the statistician) and no stratifications using a computerised random number generator. The envelopes were kept in a secure location. After obtaining patient consent, a surgeon member of the study group randomised participants in a 1:1 ratio to undergo either cast immobilisation or surgery by opening the next available numbered envelope. The surgeons carrying out randomisation were not involved in any further treatment of the participants.

Interventions

Cast immobilisation

A trained plaster technician placed the injured ankle in a standard, padded synthetic cast below the knee, with the ankle immobilised at a 90° angle (see supplementary appendix 1, figure 2). All participants received both written and verbal instructions on care of the cast and recovery, as well as guidance from a physiotherapist on walking with crutches. Immediate partial weight bearing (~15-20 kg) was permitted, progressing to full weight bearing as tolerated from four weeks after injury. Participants were advised to contact the study hospital if they experienced any issues related to the cast or mobilisation. Cast immobilisation was continued for six weeks.

Surgery

For participants allocated to surgery, either a backslab or a circular cast was placed at the emergency department. For those with severe soft tissue injury, surgery was carried out as soon as the swelling subsided. On the day of surgery, all participants received standard preoperative antibiotics before skin incision. Surgery involved internal fixation, conducted according to standard principles for ankle fracture fixation (see supplementary appendix 1, table 2). All surgeries were performed during regular daytime hours by consultant orthopaedic trauma surgeons with at least five years (range 5-15 years) of experience in treating complex trauma or by orthopaedic residents under the direct supervision of a consultant. Postoperatively, the operated ankle was immobilised in a below-the-knee cast identical to that used in the cast immobilisation group. Written and verbal postoperative instructions, crutch assisted mobilisation, weightbearing guidance, and duration of cast immobilisation were identical to those for the cast immobilisation group. Participants were instructed to contact the study hospital with any concerns.

Clinical follow-ups

Clinical follow-up visits were scheduled at two, six, and 12 weeks, and again at two years after randomisation. Each visit included a clinical examination and weightbearing radiography (mortise and lateral projections) of the injured ankle. At the two week follow-up, the original cast was removed, the wound inspected, and stitches or staples (in the surgery group) removed. A new cast was then applied in both groups. All participants met with a physiotherapist at six and 12 weeks to guide rehabilitation.

Outcomes

The primary outcome was the Olerud-Molander Ankle Score (OMAS) at two years. OMAS is a validated, condition specific, patient reported outcome measure for ankle fracture symptoms (range 0-100; higher scores indicating better outcomes and fewer symptoms; minimal important difference 12 points).[26 27]

Secondary outcomes included the Foot and Ankle Outcome Score (FAOS, five subscales from 0 to 100, with higher scores indicating better function),[28] a visual analogue scale for pain and function (range 0-100, with higher scores indicating more severe pain or dysfunction),[29] the RAND 36-item health survey for health related quality of life (RAND-36, eight subscales from 0 to 100, with higher scores indicating better quality of life),[30] range of motion of the injured ankle measured using a goniometer,[31 32] and radiographically confirmed fracture union (yes or no). All secondary outcomes were assessed at two years.

Expected harms related to study treatments—including wound complications, venous thromboembolism, and loss of ankle joint congruity—were recorded as adverse events. Ankle congruity was assessed radiographically at two, six, and 12 weeks, and again at two years. At each follow-up visit, participants were systematically asked about harms and invited to report any negative effects. In addition to expected adverse events, we documented all unexpected adverse events, including secondary surgical procedures and their clinical indications.

After the final follow-up visit, two experienced orthopaedic surgeons with no access to clinical data or participants' reports independently analysed all radiographs for potential harms, such as implant failure, ankle joint incongruity, or fracture union. They also graded the radiographs (baseline and two years) for post-traumatic osteoarthritis using the modified Kellgren and Lawrence classification.[33]

Statistical analysis

The sample size calculation, detailed in the published protocol,[23] was based on a two arm design comparing surgery with non-operative treatment. At the time of planning the SUPER-FIN trial, no established estimate

existed for minimal clinically important difference in the OMAS. In the absence of empirical data, we organised a focus group discussion among clinical experts to determine an appropriate non-inferiority margin. Consensus was reached that a 10% difference on the 0-100 OMAS would represent a clinically meaningful difference. This 10% margin was chosen as the non-inferiority threshold. Based on results from our previous trial evaluating surgery for external rotation stress tested unstable ankle fractures,[34] the mean OMAS at two years was 79.6 (standard deviation (SD) 15.5), supporting the use of an 8 point margin in the SUPER-FIN trial. Assuming α=0.05, power 80% (1−β=0.8), and accounting for a 20% dropout rate, the required sample size was calculated to be 63 participants in each group (total n=126).

The trial was designed to determine whether cast immobilisation is non-inferior to surgery in terms of the primary outcome (OMAS at two years post-randomisation). The primary analysis followed the intention-to-treat principle, with participants analysed in their randomised groups. We estimated the treatment effect on an intention-to-treat basis as the absolute difference between groups in the OMAS (primary outcome) with corresponding 95% confidence intervals (CIs) at two years after randomisation (primary time point). We considered cast immobilisation to be non-inferior to surgery if the lower limit of the CI was greater than −8.0. The primary analysis used Student's *t* test. In sensitivity analyses, we also performed analysis of covariance, adjusting for potential baseline confounders, including age, sex, smoking status, and signs of medial injury. Reporting adheres to the CONSORT statement.[22]

According to the CONSORT statement for non-inferiority and equivalence,[22] secondary outcomes may be analysed using either a superiority or an equivalence framework. In our trial, all secondary outcomes were assessed under a superiority hypothesis. As the trial was not powered for these comparisons, we considered these analyses as hypothesis generating. We analysed secondary outcomes on an intention-to-treat basis and expressed treatment effects as between group differences with corresponding 95% CIs and P values. Continuous outcomes (FAOS, visual analogue scale, RAND-36, and range of motion) were analysed using Student's *t* test or Welch's *t* test, depending on the equality of variances. Categorical variables (eg, treatment related adverse events) were analysed with χ^2 test or Fisher's exact test, with Wilson's method to calculate CIs for absolute risk differences.

In addition to the intention-to-treat analyses, we also performed per protocol and as treated analyses for both primary and secondary outcomes. An independent statistician unaware of the group assignments carried out all the analyses according to the published trial protocol.[23] The data were analysed using IBM SPSS Statistics version 25 or higher.

Blinding

Blinding of participants and outcome assessors was not possible owing to the nature of the interventions. However, we interpreted the results of the trial according to a blinded data interpretation scheme,[35] to which we made minor refinements. Before the completion of follow-up, the writing committee agreed on a prespecified plan for interpreting the trial results (https://clinicaltrials.gov/ProvidedDocs/96/NCT01758796/SAP_000.pdf). An independent statistician then carried out data analyses and chaired the subsequent blinded data interpretation meeting. In the meeting, the blinded results from the analyses were presented, with treatment groups labelled as group A and group B. We considered the results in light of the prespecified interpretation plan and agreed in writing on the appropriate interpretation. Thereafter, we broke the randomisation code and signed the minutes. Finally, we sent the minutes to an independent group of scientists for external review (see supplementary appendix 2).

Patient and public involvement

This trial was conceived and initiated in 2011, at a time when structured patient and public involvement was not yet an established element of trial design. As a result, no patients or members of the public were involved in the design process of this study, setting the research question, or the outcome measures nor were they involved in the analysis, interpretation, and writing of the results.

Results

Recruitment took place between 16 January 2013 and 1 March 2019. Final (two year) follow-up assessments were completed on 7 July 2021. Of the 840 patients assessed for eligibility, 687 patients were excluded as non-eligible and 27 eligible patients declined to be randomised (box 1, fig 1, and supplementary appendix 1, table 3). A total of 126 participants underwent randomisation; 62 were assigned to cast immobilisation and 64 were assigned to undergo surgery. However, two randomised participants (one in each group) were found ineligible after randomisation (fracture-dislocation) and were thus excluded. Also, one participant allocated to surgery crossed over to cast immobilisation owing to persisting skin blisters at the surgical site on day 7 after randomisation. Three participants were lost to follow-up, one from the cast immobilisation group and two from the surgery group (fig 1). The baseline characteristics of the two groups were broadly similar (table 1), except for some imbalances in smoking status and signs of medial injury. Supplementary appendix 1, table 4 provides a summary of missing data.

Primary outcome

In the primary intention-to-treat analysis, the mean OMAS at two years was 89 in the cast immobilisation group and 87 in the surgery group (between group mean difference 1.3 points, 95% CI −4.8 to 7.3) (fig 2

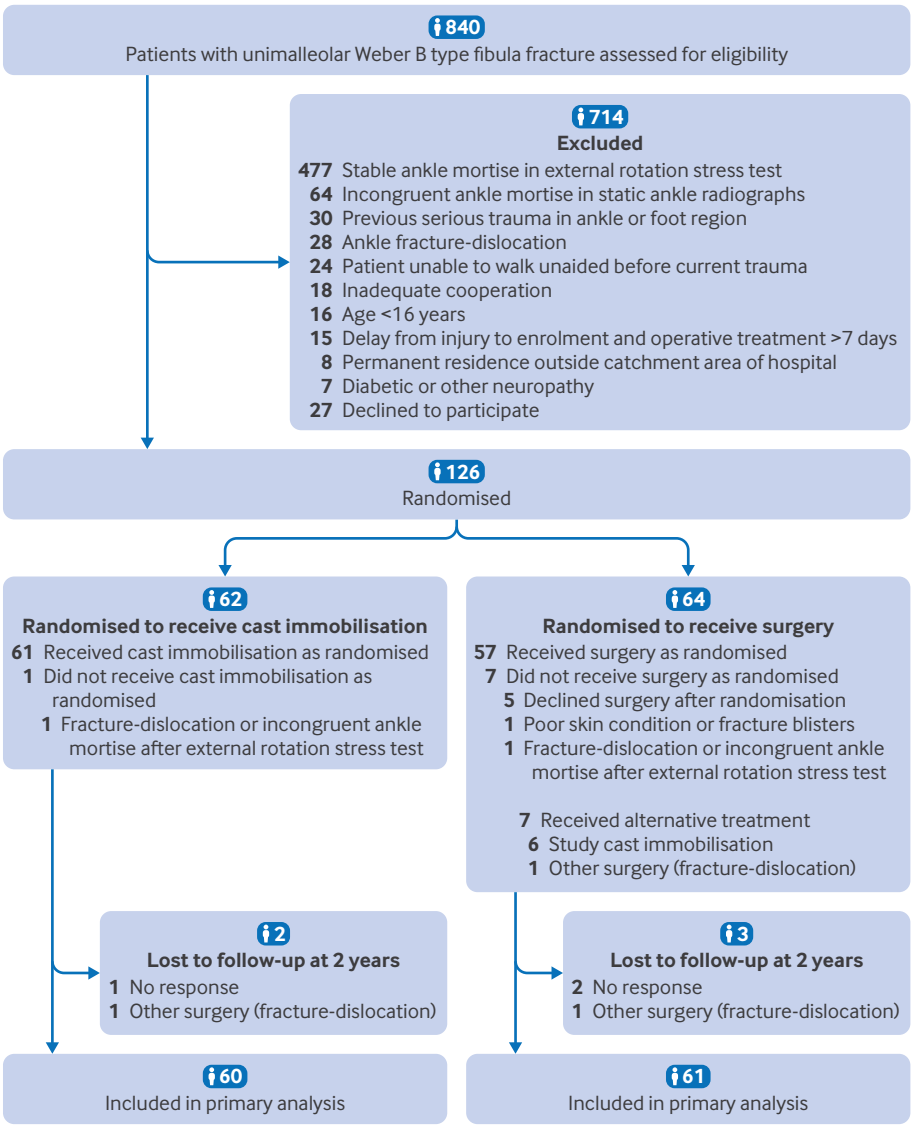

Fig 1 | Trial flow chart

and table 2). Per protocol, as treated, and sensitivity analyses—including analysis of covariance adjusting for baseline covariates such as smoking status and signs of medial injury—were consistent with the findings of the primary analysis (see supplementary appendix 1, table 5B and C and table 6).

Secondary outcomes

Table 2 and supplementary appendix 1, tables 7-10 show the data for all secondary outcomes. We did not observe any statistically significant between group differences in any of the secondary outcomes at two years, the primary outcome assessment time point.

Radiographic outcomes

Ankle radiographs were available for 55 of the 61 eligible participants (90%) in the cast immobilisation group and 58 of 63 (92%) in the surgery group at two years. No participant in either group experienced a loss of congruence of the ankle mortise. One participant in each group had a radiographically confirmed non-union, but both declined secondary surgery (see supplementary appendix 1, table 11). Most participants in both groups had either normal or mild-to-moderate features of post-traumatic osteoarthritis (Kellgren and Lawrence grade 1 or 2), and the progression of ankle osteoarthritis did not differ between the groups over the two year follow-up (see supplementary appendix 1, table 12).

Treatment related adverse events

One participant in each group had a radiographically confirmed non-union. In the surgery group, additional complications included superficial wound infection (n=1 participant), delayed wound healing (n=1), and hardware removal procedures (n=9), with two of the hardware removal procedures resulting in complicated postoperative infection (one deep and one superficial).

Table 1 | Baseline characteristics of participants with Weber B ankle fracture and congruent mortise randomised to receive cast immobilisation or surgery. Values are number (percentage) unless stated otherwise

Characteristic	Cast immobilisation (n=61)*	Surgery (n=63)*
Mean (SD) age at fracture (years), (range)	46 (18), (19-83)	43 (19), (16-82)
Age >50 years	26 (43)	26 (41)
Sex:		
Men	34 (56)	38 (60)
Women	27 (44)	25 (40)
Smoking status:		
Non-smoker	34 (56)	29 (46)
Former smoker	9 (15)	3 (5)
Current smoker	8 (13)	22 (35)
Missing	10 (16)	9 (14)
Level of education†:		
Basic (ISCED 2)	6 (10)	11 (18)
Upper secondary (ISCED 3 and 4)	26 (43)	29 (46)
Short cycle tertiary (ISCED 5)	17 (28)	16 (25)
Bachelor, master, or doctoral (ISCED 6-8)	7 (12)	4 (6)
Did not want to answer or missing information	5 (8)	3 (5)
Injury setting (ICD-10):		
Leisure activity	44 (72)	51 (81)
Working for income	9 (15)	4 (6)
Sports activity	4 (7)	6 (10)
Other	4 (7)	2 (3)
Mean (SD) pain‡ in external rotation stress test (NRS)§	5.6 (2.7)	5.2 (2.8)
Mean (SD) width of medial clear space¶ in external rotation stress test (mm)§	5.9 (0.8)	6.0 (0.9)
No of clinical signs of medial injury**:		
None	8 (13)	3 (5)
One	10 (16)	12 (19)
Two	21 (34)	19 (30)
Three	22 (36)	27 (43)
Missing	0	2 (3)
Median (range) delay from trauma to enrolment (days)	2 (0-6)	2 (0-7)

Percentages may not total 100 because of rounding.
ICD-10=International Statistical Classification of Diseases and Related Health Problems, 10th revision; ISCED=International Standard Classification of Education; NRS=numerical rating scale.
*One participant in each group was excluded after randomisation owing to a fracture-dislocation.
†ISCED is a statistical framework for organising information on education maintained by United Nations Educational, Scientific, and Cultural Organization (Unesco).
‡Self-reported scale (0-10) measuring pain intensity (0=no pain, 1-3=mild pain, 4-6=moderate pain, and 7=10 severe pain).[25]
§Performed at the emergency department by the on-call surgeon to evaluate ankle fracture stability.[26]
¶Width according to McConnell et al,[5] Park et al,[13] and Gill et al.[6]
**Clinical signs of medial injury (yes or no) at the emergency department according to McConnell et al[5]: swelling, ecchymosis, and tenderness.

Supplementary appendix 1, tables 13 and 14 list all recorded adverse events.

Discussion

This randomised, controlled non-inferiority trial found that at two years, cast immobilisation was non-inferior to surgery for treating unimalleolar Weber B ankle fractures with a congruent mortise on initial radiographs but deemed unstable on external rotation stress testing. Additionally, treatment related adverse events were more frequent in the surgical group.

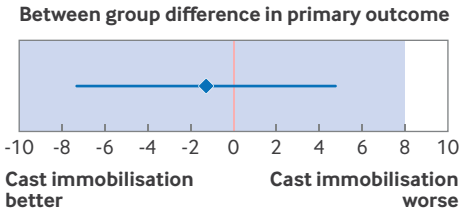

Fig 2 | Between group difference in primary outcome, Olerud-Molander Ankle Score at two year follow-up. Error bar indicates two sided 95% confidence interval. The shaded area indicates the zone of non-inferiority

Strengths and weaknesses in relation to other studies

Our result of an equivalent functional outcome between cast immobilisation and surgery in the treatment of external rotation test positive fibular fractures is in line with the only previous randomised controlled trial, by Sanders et al.[8] The overall incidence of adverse events after initial surgery in our trial was also in line with the results of Sanders et al's trial[8]: 23% (14/61) *v* 24% (10/41).[8] However, a difference emerged in adverse events after initial cast immobilisation. Although we observed no other adverse events apart from one (asymptomatic) non-union, Sanders et al reported "compromised fracture healing" in 40% (16/40) of participants in the cast immobilisation group.[8] This increased risk of adverse events in the cast immobilisation group prompted the authors to recommend surgery for younger patients.[8]

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Table 2 | Primary and secondary outcome measures at two years in participants with Weber B ankle fracture and congruent mortise randomised to receive cast immobilisation or surgery

	Cast immobilisation		Surgery		
Variable	No	Mean (SD)	No	Mean (SD)	Difference (95% CI)
Primary outcome					
Olerud-Molander Score (0-100)*	60	89 (17)	61	87 (16)	1.3 (−4.8 to 7.3)
Secondary outcomes					
Foot and Ankle Outcome Score (0-100)†:					
Pain	60	92 (12)	60	91 (11)	0.8 (−3.5 to 5.1)
Symptoms	60	83 (16)	60	84 (15)	−0.8 (−6.6 to 4.9)
Activities of daily living	60	95 (9)	60	96 (7)	−0.7 (−3.6 to 2.1)
Sport and recreation function	60	87 (20)	60	86 (21)	1.0 (−6.4 to 8.5)
Quality of life	60	83 (21)	60	81 (20)	2.0 (−5.3 to 9.3)
Visual analogue scale (0-100)‡:					
Pain	59	9.5 (17)	60	12.1 (19)	−2.6 (−9.1 to 3.9)
Function	59	11.3 (15)	60	12.2 (18)	−0.9 (−6.9 to 5.1)
RAND-36 item health survey (0-100)§:					
Physical function	60	88 (17)	61	87 (17)	0.3 (−5.9 to 6.5)
General health	60	73 (21)	61	72 (20)	0.8 (−6.5 to 8.1)
Mental health	59	80 (16)	61	79 (18)	0.8 (−5.3 to 6.9)
Role function (physical)	60	80 (34)	61	85 (32)	−4.4 (−16.3 to 7.5)
Vitality	59	70 (20)	61	70 (22)	−0.2 (−7.8 to 7.3)
Bodily pain	60	72 (24)	61	76 (25)	−4.1 (−12.9 to 4.7)
Social function	60	87 (22)	61	88 (22)	−0.8 (−8.8 to 7.2)
Role function (emotional)	60	88 (28)	61	85 (32)	3.1 (−7.8 to 13.9)
Range of motion¶:					
Ankle dorsiflexion	52	29 (6)	54	31 (5)	−1.7 (−3.8 to 0.5)
Ankle plantarflexion	52	53 (9)	54	53 (7)	0.0 (−3.0 to 3.1)

CI=confidence interval; SD=standard deviation.
*Higher scores indicate better outcomes, assessing pain, stiffness, swelling, activities of daily living, and physical function.
†Higher scores indicate better function.
‡Higher scores indicate more severe pain and poorer ankle function.
§Higher scores indicate better health related quality of life.
¶Measured using a goniometer.

A closer examination, however, suggested that many of these events may have been of limited clinical significance. Of the 16 events,[8] eight involved radiographic misalignment (such as widening of the medial clear space to ≥5 mm) and eight were classified as delayed union solely because bridging callus was absent at 12 weeks—a notably conservative definition. Only two participants ultimately required secondary surgery for early loss of reduction or progressive incongruency, whereas healing occurred in the remainder—including all delayed unions—by 12 months without further intervention.

The authors' decision to recommend surgery on the basis of a composite outcome (compromised fracture healing), a construct that has not subsequently gained widespread acceptance, likely reflects a cautiousness rooted in the longstanding concern within orthopaedics that even minor deviations in anatomy or fracture healing may increase the risk of poor functional outcomes and post-traumatic osteoarthritis. Indeed, this concern may be particularly warranted for many types of fractures, especially complex ones. That said, evidence is also accumulating to suggest that minor deviations in anatomy or fracture healing for unimalleolar fibular fractures may be less consequential than in other contexts. Although surgery generally better restores the anatomy and stability of a fractured ankle, both our trial and that of Sanders et al[8] showed equivalence of function after cast immobilisation and surgery. Moreover, in a recent randomised trial in adults older than 60 years presenting with ankle fractures deemed overtly unstable, casting still yielded functional outcomes that were equivalent to surgery, despite a clearly inferior initial stability and despite inferior restoration of mortise anatomy.[36 37] (It should be noted that the casting was of a high standard: close-contact casting.) As for the development of post-traumatic ankle osteoarthritis, our analysis showed that 98% of participants in both groups had either no or only mild-to-moderate (Kellgren and Lawrence grade 1 or 2) radiographic features of osteoarthritis and that progression of osteoarthritis did not differ between the groups (see supplementary appendix 1, table 12).

Overall, our findings—comparable function and risk of osteoarthritis in the cast immobilisation and surgery groups—align with existing data: post-traumatic ankle osteoarthritis is primarily related to the more severe ankle fracture types of bimalleolar and trimalleolar fractures and fracture dislocations and not to unimalleolar Weber B fractures with congruent ankle mortise.[38-40] Moreover, even if post-traumatic radiographic changes are apparent, their association with clinical symptoms is weak.[4] In fact, current evidence on post-traumatic ankle osteoarthritis, from studies with follow-ups of longer than 30 years, shows that the development of debilitating post-traumatic ankle osteoarthritis is unlikely in patients

with unilateral Weber B ankle fractures.[40-42] We will, however, continue to follow-up our participants.

Strengths and limitations of this study

Strengths of this trial include the robustness of the primary analysis and the precision of the effect estimate. Although concerns about sample size and non-inferiority margins are common in non-inferiority trials, our point estimates excluded a clinically meaningful treatment benefit in favour of surgery. Thus, our finding of non-inferiority for cast immobilisation was not based on absence of evidence but rather on evidence of absence of a clinically relevant difference—regardless of the non-inferiority margin.

We also used the only validated tool for assessing ankle function after fracture (OMAS)[26 27] and achieved a high follow-up rate (96%) at two years—a time point generally considered sufficient to capture longer term outcomes, including functional recovery and early post-traumatic osteoarthritis.[4] Although more granular data on short term recovery, such as return to work or sport, would undoubtedly have added value from a patient perspective, these patterns are generally quite well established through earlier studies, particularly the randomised controlled trial by Sanders et al,[8] which showed that both operative and non-operative groups improved substantially within the first six months, with trajectories converging by 12-24 weeks and remaining comparable thereafter. Our aim was to assess longer term comparative effectiveness.

Regarding limitations, single centre trials conducted by experts (here, investigators with extensive track records in studying ankle fractures[2 11 24 34 43 44]) are typically believed to enhance internal validity at the expense of external validity (generalisability). We argue that concerns about generalisability are mitigated in this case because we prospectively enrolled consecutive patients into two complementary trials of radiographically congruent Weber B fractures—one focusing on stress negative fractures[24] and the present SUPER-FIN trial focusing on stress positive fractures—thus spanning the full spectrum of these injuries. At the time of the trial, our study hospital was the sole provider of treatment for ankle fractures in a catchment area covering about 740 000 inhabitants and about 51% of Finland's total area, ensuring a highly representative sample. Thus, while our data are robust and internally valid (reflecting efficacy or a best case scenario), the findings are also likely to accurately represent the broader patient population. A further limitation is that we did not incorporate patient and public involvement as we conceived and initiated our trial in 2011, at a time when this information was not yet an established requirement of trial design. Future trials should address this from the outset to better align outcome selection with patients' priorities and enhance real world relevance.

Finally, although this trial was primarily a study of the management of Weber B ankle fractures with a congruent mortise deemed unstable, and not a study of stress testing in itself, our methodological choice to use the external rotation stress test also warrants further comment. The conventional method for assessing the stability of an isolated fibular fracture with a congruent ankle mortise has been one or another form of stress testing under fluoroscopy.[5 6 13] Notwithstanding, many clinicians still rely on clinical judgement complemented by plain radiography and consensus based indicators for instability (in particular, fracture gap >2 mm, particularly when accompanied by tenderness, swelling, and haematoma on the ankle's medial side).[40 45 46] Thus, there continues to be no universal operational consensus or agreed means for assessing and determining mortise instability.[9 10 14] For example, in an ongoing major pragmatic trial comparing cast immobilisation with surgery for unstable ankle fractures in the UK, the determination of instability (means and criteria) was left to the discretion of each recruiting surgeon.[47]

Given this general diversity of approaches and the inherent uncertainty it entails, to better standardise the assessment of stability and facilitate comparisons with earlier studies, we elected to use the external rotation stress test for stability in alignment with the trial by Sanders et al.[8] This test had the most robust evidence base,[5 6 11 13 14] showing equivalent diagnostic accuracy to the gravity stress test, the other most commonly used clinical test for ankle stability.[6 11 14] In previous studies assessing the treatment of these fractures using either the external rotation stress test or the gravity stress test,[5 19 24 48] the proportion of patients with an ankle mortise deemed unstable ranges from 35% to 65%. Of the 603 patients with an isolated Weber B ankle fracture and a congruent mortise we screened for eligibility, 21% (126 of 603) were deemed unstable, suggesting a more cautious screening process than previously.

Possible mechanisms and implications for clinicians or policymakers

The practice of surgically stabilising a unimalleolar Weber B ankle fracture deemed unstable stems largely from concern that casting may not provide adequate support. If so, this could risk occult incongruency. While such loss of congruency is a devastating treatment failure, it is rare in the context of isolated fibular fractures, as shown by our trial, Sanders et al's trial,[8] and other clinical populations.[15 19] In our cohort of more than 600 consecutive patients with Weber B fractures with a congruent mortise on initial radiography—including both this and our earlier randomised controlled trial[24]—no occult incongruency occurred. Taken together, these observations suggest that longstanding concern about occult instability may have contributed to decades of overtreatment.[49-51]

Encouragingly, accumulating evidence supports a simpler approach: rather than attempting to define fracture stability at the initial presentation, clinicians can place the ankle in a cast, allow early weight bearing, and confirm congruency with follow-up radiography within two weeks. The benefit of early weight bearing may be twofold: axial loading not only tests the ankle

under physiological conditions but may also help realign and stabilise the talus within the mortise, even in cases where the deltoid ligament is partially compromised.[17 52] Prospective studies using the early weightbearing radiograph protocol have reported rates of subsequent incongruency requiring surgery as low as 3-10%.[15-20] We performed weightbearing imaging at two weeks with the cast still in place, as the most relevant question is whether immobilisation provides adequate support. This pragmatic protocol confirms treatment adequacy without requiring cast removal simply to retest stability.

Together, our findings and those of previous studies show that a standard below-the-knee cast provides adequate stabilisation of an isolated unimalleolar fibular fracture with a congruent ankle mortise. This lends further support to the evolving concept that the treatment of ankle fractures should focus on obtaining and maintaining a congruent ankle mortise until fracture union, using the most conservative means possible.[36 37] Such an approach is supported by the current British Orthopaedic Association Standards for Trauma guidelines.[10]

Conclusion

The results of this randomised non-inferiority trial showed that in patients with a solitary Weber B fibula fracture and a congruent mortise on initial radiography that is deemed unstable in external rotation stress testing, cast immobilisation results in non-inferior functional outcomes compared with surgery at two years. Overall, fewer treatment related harms were observed with cast immobilisation than with surgery.

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Ethical approval: This study was conducted in accordance with the Declaration of Helsinki and was approved by the institutional review board of Oulu University Hospital (EC 25/2012).

Data sharing: The study protocol, including the statistical analysis plan, has been published.[23] The data underlying the primary findings in this paper and the code used to analyse the data are openly and publicly available at: https://doi.org/10.23729/fd-392c45f8-500c-32e5-adf9-f32f84b4e78a. Contact the corresponding author for problems with accessing the data.

Transparency: The lead author, guarantor (TK) affirms that the manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

Dissemination to participants and related patient and public communities: Upon publication of the trial results, a lay summary will be provided to participants. The findings will also be disseminated to the public through a press release, social media channels, traditional media, and presentations at scientific meetings.

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Supplementary information: Supplementary appendixes 1and 2