■ FOOT & ANKLE

Open reduction and fixation does not improve short-term outcome of medium-sized posterior fragments in AO type B ankle fractures: one-year results of the POSTFIX randomized controlled trial

A. L. Franx,
S. M. Verhage,
P. Krijnen,
E. L. L. Twiss,
I. B. Schipper,
J. M. Hoogendoorn

From Haaglanden Medical Center, The Hague, Netherlands

Aims

Guidelines for treatment of posterior malleolar fragments (PMFs) in trimalleolar fractures are scarce, mainly based on retrospective studies, and show varying advice. The need for fixation of smaller (< 25%) PMFs remains particularly controversial. This study aims to evaluate the superiority of fixation of medium-sized PMFs versus no fixation of the fragment.

Methods

A multicentre randomized controlled trial was conducted between January 2014 and January 2022 in two Dutch level 1 trauma centres (protocol registration: NCT02596529). Patients presenting with an AO-44-B3 fracture with a medium-sized (5% to 25%) PMF were 1:1 randomized online between open reduction and internal fixation (ORIF) (FIX) versus no fixation (NO-FIX) of the fragment. A total of 41 patients were allocated online to FIX via the posterolateral approach and 40 patients to NO-FIX. The primary outcome was functionality measured by the American Academy of Orthopaedic Surgeons (AAOS) questionnaire one year postoperatively. Secondary outcomes were osteoarthritis (OA) measured on radiographs and the Olerud and Molander ankle score, visual analogue scale pain, and EuroQol five-dimension questionnaire during follow-up. Quality of reduction was assessed by step-off on postoperative CT scan and radiograph. Complications were recorded.

Results

After one-year follow-up, no difference (p = 0.141) in AAOS was found after FIX (median 90 (IQR 68 to 95)) and NO-FIX (median 93 (IQR 85 to 97)). OA (≥ grade 2) was present in four (17%) of the cases after FIX and five (20%) after NO-FIX (p = 0.763). After one year, median pain scores were 20 (IQR 5 to 40) versus 10 (IQR 5 to 25) (p = 0.032), and perceived general median health scores were 80 (IQR 60 to 89) versus 83 (IQR 71 to 90) (p = 0.596) after FIX and NO-FIX, respectively. Postoperative step-off > 1 mm on CT scan was present in 56% after FIX versus 71% after NO-FIX (p = 0.193). Complication rates were 18% versus 5% (p = 0.071) after FIX and NO-FIX, respectively.

Conclusion

ORIF of medium-sized posterior fragments in AO type B trimalleolar fractures does not prompt superior functional or radiological results after one-year follow-up. Longer follow-up is needed to evaluate intermediate or long-term effects.

Cite this article: ***Bone Joint J*** **2025;107-B(4):461–469.**

Correspondence should be sent to A. L. Franx; email: adriaanfranx@hotmail.com

doi:10.1302/0301-620X.107B4.BJJ-2024-0521.R3 $2.00

Bone Joint J
2025;107-B(4):461–469.

Introduction

The optimal treatment of ankle fractures involving the posterior malleolus is contentious, lacking clear guidelines based on large clinical trials despite extensive literature. Fragment size has conventionally guided fixation decisions, yet evidence supporting this is inconclusive.[1-8] Biomechanical studies initially suggested that larger fragments lead to posterior instability and worse outcomes, but varied cut-off values were proposed.[9,10] Further studies were not able to demonstrate posterior instability in cadaveric ankles.[11-14] Subsequent retrospective studies failed to establish a consistent link between fragment size and function. Later studies suggested a shift of contact pressure pattern in case of a posterior malleolar fracture (PMF) and therefore the early induction of severe post-traumatic osteoarthritis (OA).[15,16] Two recent large retrospective cohort studies found a worse functional outcome if a persisting tibiotalar step-off was present after open reduction and internal fixation (ORIF), and therefore advised restoration of the articular surface.[7,8] However, no agreement was reached regarding which fragment size should be fixated. Recent prospective studies and reviews found mixed results regarding fixation necessity.[17-19] Traditionally, reduction of larger fragments is performed indirectly, followed by percutaneous screw fixation in an anteroposterior direction. It is often challenging to achieve anatomical reduction and fixation of smaller fragments percutaneously. An emerging approach involves posterior tibia exposure via a posterolateral approach for anatomical reduction and fixation, showing promising outcomes with fewer complications.[20-25] This multicentre trial aimed to compare functional and radiological outcomes after anatomical reduction and fixation of medium-sized PMF to no fixation of the PMF in type B ankle fractures.[26] It was hypothesized that ORIF of the PMF yields superior functional outcomes and fewer radiological signs of post-traumatic OA.

Methods

Study design and setting. This multicentre randomized controlled trial with a superiority design was conducted in two teaching hospitals in the Netherlands, both level-1 trauma centres (Haaglanden Medical Center, The Hague, and Leiden University Medical Center, Leiden, Netherlands). The study was initially started in the former centre, which was open for inclusion from January 2014. Due to the low inclusion rate, the latter centre was added as a participating hospital in 2019. As of early 2020, the inclusion gradually came to a stop due to COVID-19. After the COVID-19 pandemic, the inclusion remained problematic and was stopped in January 2022. This paper presents the outcomes during the first year of follow-up, which was completed in 2022. The Medical Ethics Committee of South-West Netherlands approved the study protocol (protocol number 13-068) in November 2013.[26] The study was registered prospectively in the Dutch National Trial Registration in 2013. The study protocol was retrospectively published and registered at ClinicalTrials.gov (NCT02596529).

Study population. All patients aged between 18 and 75 years presenting at the emergency department with a transsyndesmotic trimalleolar fracture (AO-44B3) with a medium-sized (5% to 25% of tibial articular surface, measured on lateral radiograph) PMF were eligible for participation in the study.

Table I. Inclusion and exclusion criteria.

Inclusion criteria
Age 18 to 75 years at time of inclusion
AO 44-B fracture with medium-sized (5% to 25%) posterior fragment
First ankle fracture of affected side
Exclusion criteria
Severely injured patients (ISS ≥ 16)
Multiple fractures or open fractures
Previous fracture to the ipsilateral ankle
Patients with pre-existent mobility problems
Pre-existing disability
Patients with follow-up in another hospital
Insufficient understanding of the Dutch language

ISS, Injury Severity Score.

Suprasyndesmotic fractures are regarded as a different entity and are therefore not reviewed in this study, since these injuries result from a different trauma mechanism (pronation – external rotation; PER) that generally results in injury of the interosseous membrane and ligament, which is not always present in trans-syndesmotic (supination – external rotation; SER) fractures. Most small posterior fragments (< 5% of the articular surface) are not fixed surgically, since these tend to have a more favourable outcome than medium-sized (5% to 25%) or large fragments (> 25%).[7] Current AO guidelines advise fixation of the PMF in case of displaced PMF, or if instability is persistent after lateral fixation.[27] However, the need for fixation of medium-sized PMF remains controversial.[7,17] Therefore, this study solely focuses on medium-sized fragments. Fragment size was measured on plain lateral trauma radiographs at the tibiotalar joint level by two independent observers (ALF, SMV). The complete inclusion and exclusion criteria are listed in Table I.

Recruitment, informed consent, and randomization. All eligible patients received detailed written information about the study, risks, and (non-)surgical management options. Upon written informed consent, participants were enrolled within one week after presentation by the study coordinator (SMV). Participants were allocated in a 1:1 ratio to one of the two interventions by an online randomization programme in blocks of six or eight patients, to ensure groups of approximately the same size. Patients were included and treated in the participating centre of first presentation. Blinding was not feasible due to the nature of the two different surgical approaches and the need for postoperative imaging.

Treatment protocol. All surgical interventions were performed by experienced surgeons familiar with both treatment protocols and fixation techniques. Preoperatively, 2 g cefazoline prophylaxis was administered intravenously. In case of non-fixation of the PMF, patients were operated on in supine position. The lateral malleolus was fixed with one or two lag screws and/or lateral plate fixation. The medial malleolus was fixed with one or two cancellous screws. In case of allocation to the fixation group, the participant was operated on in prone position. The posterolateral approach was used for fixation of both the lateral malleolus and the PMF.[25] The PMF was fixed with lag screws or a buttress or antiglide plate. The lateral and medial malleolus were fixed in the same manner as in the first group. After fixation, the syndesmosis was tested by a bone hook or

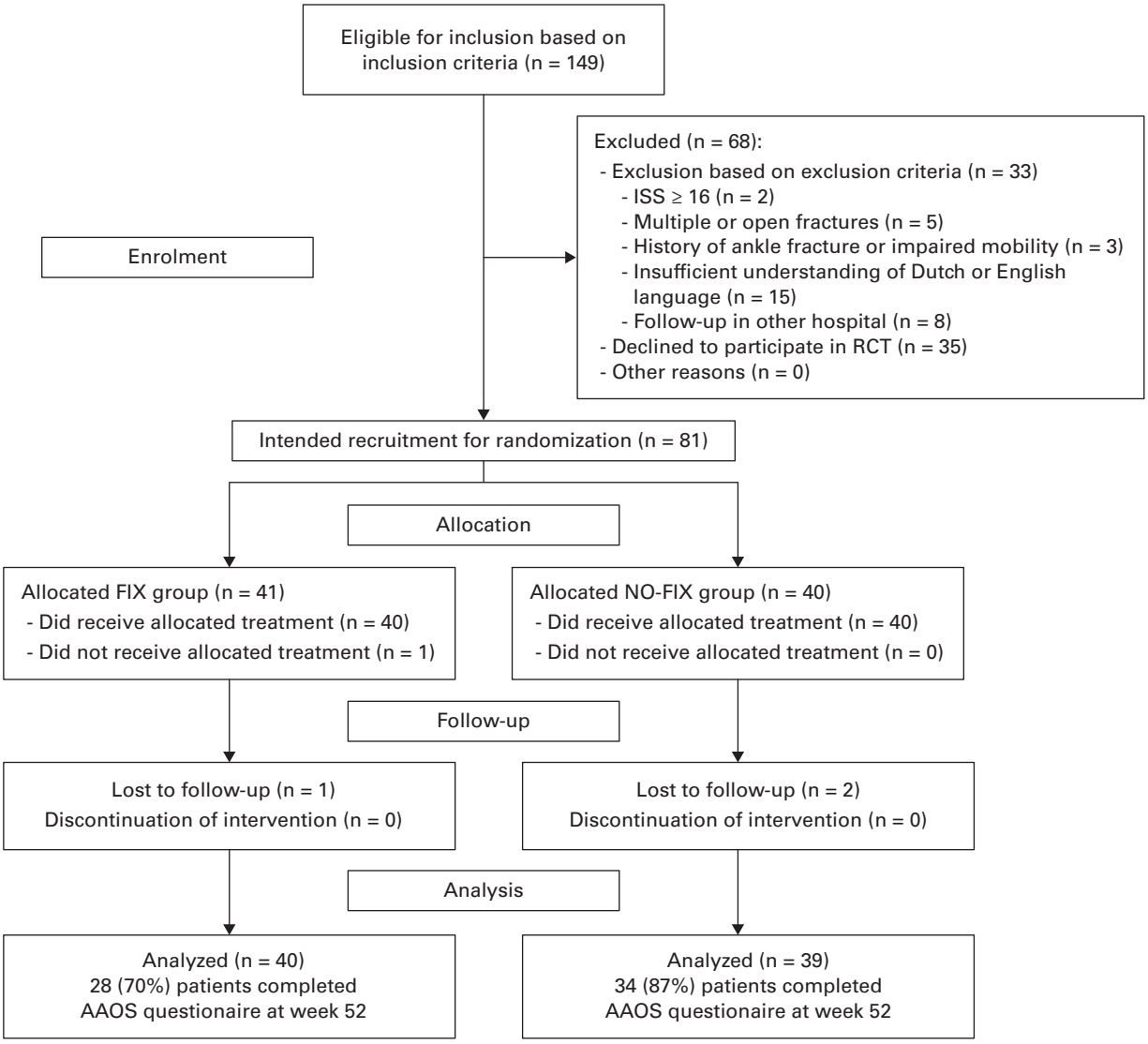

Fig. 1

Flowchart of inclusion and randomization. AAOS, American Academy of Orthopaedic Surgeons; ISS, Injury Severity Score; RCT, randomized controlled trial.

external rotatory stress under fluoroscopic control. If the syndesmosis was unstable, one or two trans-syndesmotic positioning screws were placed. A postoperative cast was applied based on the surgeon's preference. Non-weightbearing mobilization was instructed for six weeks after surgery in both groups. After six weeks, gradual weightbearing mobilization was allowed and physiotherapy was started. Low-molecular weight heparin (weight-dependent dosage) was administered daily as long as patients were immobilized in a cast.

Patients. The patient flow is described in Figure 1. Between January 2014 and January 2022, 41 patients were included in the fixation group (FIX) and 40 patients in the no fixation group (NO-FIX). No patients were excluded after randomization and three were lost to follow-up after one year. Patient characteristics at baseline are presented in Table II. Both groups mainly consisted of Lauge-Hansen[28] SER-4 fractures, with posterior fragments mostly classified as the posterolateral type, also known as Bartoníček[29] type 2 or Haraguchi[30] type 1. Median fragment size measured on CT scan was 16% (IQR 13 to 21) and 17% (IQR 13 to 20) of the tibial articular surface for FIX and NO-FIX, respectively. Presence of comminution of the PMF was 63% in both groups. In the FIX group, 90% of posterior fragments were fixed using a plate, and screws were used in 10%. External fixation prior to definitive fixation, due to persisting (sub)luxation after closed reduction and splinting with extensive soft-tissue oedema, was performed in 12 (29%) and seven cases (18%) in the FIX and NO-FIX groups, respectively. During definitive fixation, loose osteochondral fragments originating from the PMF that were too small to fix were extracted in 16 cases (39%) in the FIX group. This was not performed in any of the cases in the NO-FIX group, due to the different soft-tissue approach.

Table II. Baseline and treatment characteristics by treatment arm.

Characteristic	FIX	NO-FIX
Patients, n	41	40
Female, n (%)	33 (80)	26 (65)
Median age at trauma, yrs (IQR)	55 (32 to 63)	54 (36 to 62)
Mean BMI, kg/m² (SD)	29 (5)	28 (5)
ASA grade, n (%)		
I	8 (19)	11 (27)
II	31 (76)	26 (65)
III	2 (5)	3 (8)
IV	0 (0)	0 (0)
Lauge-Hansen classification, n (%)		
SER3	3 (7)	4 (10)
SER4	38 (93)	36 (90)
Bartonicek classification, n (%)		
1	0 (0)	0 (0)
2	31 (76)	29 (74)
3	10 (24)	9 (23)
4	0 (0)	1 (3)
Haraguchi classification, n (%)		
I	30 (73)	29 (74)
II	11 (27)	10 (26)
III	0 (0)	0 (0)
Radiograph: preoperative		
Median PMF size, % (IQR)	16 (12 to 18)	15 (12 to 17)
Median PMF step-off, mm (IQR)	3.1 (1.8 to 4.0)	2.4 (1.1 to 3.8)
Medial fracture, n (%)	30 (73)	28 (70)
CT scan: preoperative		
Median PMF fragment size, % (IQR)	16 (13 to 21)	17 (13 to 20)
Median PMF step-off, mm (IQR)	3.3 (2.8 to 4.1)	2.7 (1.7 to 3.4)
Median PMF gap, mm (IQR)	3.8 (2.4 to 6.1)	3.3 (1.6 to 4.5)
Chaput-Tillaux fragment, n (%)	7 (17)	7 (18)
Wagstaffe-Le Fort fragment, n (%)	5 (12)	9 (23)
Comminution PMF, n (%)	26 (63)	24 (62)
Loose cartilage PMF, n (%)	32 (78)	28 (72)
External fixation, n (%)	12 (29)	7 (18)

ASA, American Society of Anesthesiologists; PMF, posterior malleolar fragment; SER, supination – external rotation.

Outcomes and follow-up. Patients were followed up at six, 12, and 26 weeks, and one year post-surgery. The primary outcome, assessed at one year, was the patient-reported functional outcome using the American Academy of Orthopaedic Surgeons (AAOS) questionnaire.[31] The AAOS ankle questionnaire is a validated and widely used patient-reported functional outcome score, and was used to evaluate function 26 and 52 weeks postoperatively.[32] Another patient-reported, secondary outcome parameter was the functional outcome measured using the Olerud and Molander ankle score (OMAS).[33] The OMAS was used for short-term functional assessment during the first postoperative year. Both AAOS and OMAS are measured on a scale from 0 (worst function) to 100 (best function). Pain was measured using a visual analogue scale (VAS) ranging from 0 to 10, and general health perception was assessed using the EuroQol instrument ranging from 0 (worst imaginable health) to 100 (best imaginable health) at each visit.[34] In the study protocol, the American Orthopaedic Foot and Ankle Society (AOFAS) score and range of motion were also included as secondary outcomes.[31] Unfortunately, range of motion (which is required to determine AOFAS score) was documented poorly; therefore, this secondary outcome was not included in the analysis. To promote transparency, the raw data of the AOFAS score for the included patients are presented in the Supplementary Material. Radiological signs of OA were evaluated using the Kellgren and Lawrence Score, modified by Kijowski et al,[35] at one year post-surgery. At time of inclusion, fragment size was assessed independently by two trauma surgeons (SMV and JMH). In case of disagreement, a third trauma surgeon (JMH) was consulted in order to reach consensus. All other radiological parameters were scored by a researcher (ALF). Pre- and postoperative CT scans in sagittal view assessed fragment size and reduction quality using step-off. All complications that were documented in the medical charts were extracted from the hospital information system. These included, but were not limited to, infection, secondary dislocation, secondary intervention, hardware removal, pulmonary embolism, and deep venous thrombosis. Moreover, fixation type, duration of operation, and length of stay were recorded. An overview of all measurements during the follow-up period is provided in Table III.

Table III. Measurements during follow-up.

Measurement	Postoperative	6 wks	12 wks	26 wks	52 wks	5 yrs
Radiograph	X	X			X	X
CT scan	X					
OMAS		X	X	X	X	
AAOS				X	X	X
VAS						
Pain		X	X	X	X	X
General health		X	X	X	X	X

AAOS, American Academy of Orthopaedic Surgeons; OMAS, Olerud and Molander ankle score; VAS, visual analogue scale.

Sample size. In this study, functional outcome as measured by the AAOS score after one year was used as the primary outcome parameter. A Cochrane review suggested a difference of ten points to be clinically relevant.[36] For the sample size calculation, we adopted this ten-point difference, with a significance level of 5% and a SD of 15 points. To the best of our knowledge, the only study in the literature reporting a SD for AAOS is by Johanson et al,[32] which reports a SD of 16. We pragmatically chose to use a SD of 15 points. To achieve 80% power, group samples of at least 36 patients were needed. To account for 15% drop-out, group samples of 42 patients were needed (84 in total).

Statistical analysis. The analysis was performed on the basis of the intention-to-treat principle. Baseline characteristics of the study groups are described using summary statistics. Normality tests for all continuous outcome measures were performed. Normally distributed continuous outcome measures are reported as mean and SD and were compared using an unpaired *t*-test. Skewed outcomes are reported as median and IQR, and were analyzed using the Mann-Whitney U test. Scores on the OMAS, VAS pain, and VAS general health of the two groups during the follow-up were compared using linear mixed models (F-test). Categorical data were analyzed using the chi-squared test. All data were analyzed using SPSS Statistics for Windows v. 29 (IBM, USA). Statistical testing was two-tailed and a p-value < 0.05 was used as threshold for statistical significance.

Table IV. Outcome measures by treatment arm.

Outcome measure	FIX	NO-FIX	p-value
Patients, n	41	40	
Median AAOS (IQR)			
Week 26	81 (71 to 86)	86 (73 to 96)	0.038*
Week 52	90 (68 to 95)	93 (85 to 97)	0.141*
Median OMAS (IQR)			0.366†
Week 6	30 (5 to 33)	30 (15 to 49)	
Week 12	45 (35 to 60)	63 (25 to 80)	
Week 26	65 (45 to 70)	65 (40 to 85)	
Week 52	73 (45 to 90)	75 (54 to 95)	
Median VAS pain (IQR)			0.032†
Week 6	30 (10 to 50)	20 (10 to 39)	
Week 12	30 (18 to 50)	15 (5 to 40)	
Week 26	35 (15 to 50)	10 (10 to 30)	
Week 52	20 (5 to 40)	10 (5 to 25)	
Median VAS health (IQR)			0.596†
Week 6	70 (55 to 80)	70 (58 to 81)	
Week 12	70 (54 to 81)	80 (75 to 85)	
Week 26	70 (70 to 89)	80 (43 to 85)	
Week 52	80 (60 to 89)	83 (71 to 90)	
Radiograph: postoperative, n (%)	41 (100)	40 (100)	
Step-off > 1 mm, n (%)	9 (23)	24 (59)	< 0.001‡
CT scan: postoperative, n (%)	36 (90)	28 (68)	0.016‡
Step-off > 1 mm, n (%)	20 (56)	20 (71)	0.193‡
Radiograph: week 52, n (%)	24 (60)	25 (63)	0.752‡
Osteoarthritis ≥ grade 2, n (%)	4 (17)	5 (20)	0.763‡
Osteoarthritis grade, n (%)			
Grade 0	8 (33)	9 (36)	
Grade 1	12 (50)	11 (44)	
Grade 2	3 (13)	4 (16)	
Grade 3	1 (4)	1 (4)	
Grade 4	0 (0)	0 (0)	

*Mann-Whitney U test.
†F-test.
‡Chi-squared test.
AAOS, American Academy of Orthopaedic Surgeons; OMAS, Olerud and Molander ankle score; VAS, visual analogue scale.

Table V. Complications and secondary interventions by treatment arm.

Event	FIX	NO-FIX	p-value*
Patients, n	41	40	
Total complications, n (%)	7 (18)	2 (5)	0.071
Infection	4 (10)	2 (5)	
DVT/PE	2 (5)	0 (0)	
Other	1 (3)	0 (0)	
Hardware removal, n (%)	4 (10)	9 (22)	0.143

*Chi-squared test.
DVT, deep vein thrombosis; PE, pulmonary embolism.

Results

Patient-reported outcomes. Overall, 70% of all questionnaires were completed by the participants (69% at week 6, 61% at week 12, 73% at week 26, 77% at week 52). Median AAOS scores after one year did not differ: 90 (IQR 68 to 95) and 93 (IQR 85 to 97) in the groups with and without fixation, respectively (p = 0.141, Mann-Whitney U test; Table IV). The median AAOS score at week 26 was slightly better in the group without fixation of the PMF: 86 (IQR 73 to 96) versus 81 (IQR 71 to 86) in the fixation group (p = 0.038, Mann-Whitney U test). OMAS scores improved over time but showed no difference between the groups (p = 0.366, F-test). Pain scores decreased during follow-up in both groups, and were lower in the group without fixation (p = 0.032, F-test). Perceived health improved during follow-up, but did not differ between the groups (p = 0.596, F-test). All patient-reported outcome variables are presented in Table IV and Figure 2.

Radiological outcome. Postoperative step-off measured on radiograph favoured the FIX group; a step-off > 1 mm was present in nine (23%) versus 24 (59%) (p < 0.001) cases. Postoperative CT scans were available in 64 cases (79%). Measured on CT scan, no significant difference in postoperative step-off was

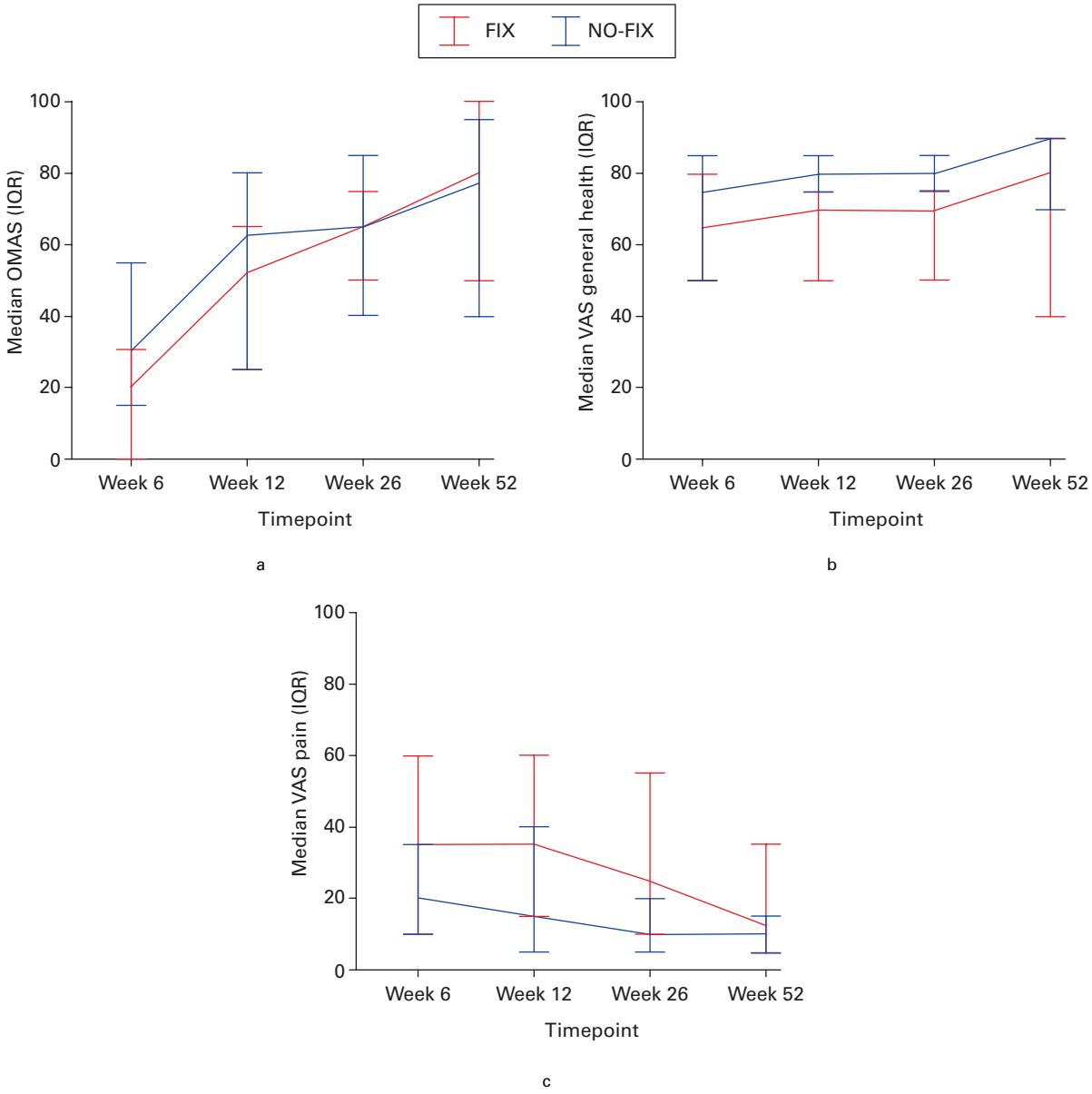

Fig. 2

Median a) Olerud and Molander ankle scores (OMAS), b) visual analogue scale (VAS) general health scores, and c) VAS pain scores with IQR.

found; a step-off > 1 mm was present in 20 (56%) versus 20 (71%) (p = 0.193, chi-squared test) cases for FIX and NO-FIX groups, respectively. After one-year follow-up, radiographs were obtained in 49 (60%) patients and were assessed for radiological signs of post-traumatic OA. OA (≥ grade 2) was present in four (17%) cases in the FIX group and five (20%) cases in the NO-FIX group (p = 0.763, chi-squared test) (Table IV). Rates of OA grades 1 to 4 are reported in Table IV.

Clinical outcome. Complication rates were 18% and 5% for the FIX and NO-FIX groups, respectively (p = 0.071, chi-squared test; Table V). The most common complications were infection and pulmonary embolism/deep venous thrombosis.

In the FIX group, four cases (10%) of infection were observed, three of which required reoperation and one treated successfully with oral antibiotics. Two cases of infection underwent external fixation prior to definitive fixation. In the NO-FIX group, two cases (5%) of infection were observed, one patient required reoperation, and one patient was treated successfully with oral antibiotics. One case of infection underwent external fixation prior to definitive fixation.

Pulmonary embolism/deep venous thrombosis rates were two cases (5%) in the FIX group and zero cases (0%) in the NO-FIX group. No cases of secondary dislocation, nonunion, or hardware failure were observed on radiograph or CT scan. Median operating time was 91 minutes (IQR 76 to 108) for FIX versus 67 minutes (IQR 47 to 88) for NO-FIX (p < 0.001, chi-squared test). Median length of stay was two days (IQR 1 to 5) for FIX and one day (IQR 1 to 2) for NO-FIX (p = 0.083,

Mann-Whitney U test). Union of the posterior fracture was achieved in all patients. Hardware was removed in four (10%) after fixation and in nine (22%) after no fixation of the PMF ($p = 0.143$, chi-squared test).

Discussion

This study investigated if open anatomical reduction and fixation of medium-sized PMF fractures via a posterolateral approach in type B ankle fractures improves functional outcomes compared to no reduction and fixation. In both groups, clinically satisfactory outcomes were observed one year postoperatively. No statistically significant or clinically relevant difference was found in the primary outcome, the AAOS score after 52 weeks, after fixation and no fixation of the PMF. AAOS scores at week 26 and VAS pain scores during follow-up were superior after no fixation of the PMF. No difference in OMAS scores and perceived general health was found during follow-up. We observed no significant difference in radiological signs of OA between the two groups, at one year postoperatively. This may be explained by the short follow-up period of one year. It is likely that development of OA, and thus functional impairment, might occur later in life and hence the effects of (non-)surgical management could not yet be observed in this study.

Interestingly, in the FIX group, non-anatomical reduction (step-off > 1 mm) rates of the PMF appeared in 23% of cases when reviewed on fluoroscopy, but when step-off was assessed on CT scan, 56% of cases showed to be reduced non-anatomically (Table IV). This discrepancy may have contributed to the similar clinical outcome after the two treatment methods, since the two groups are relatively homogeneous regarding reduction of the PMF. In a study by Shi et al,[18] anatomical reduction rates evaluated on CT were 53% after ORIF and 31% after percutaneous AP screw fixation. The difference in anatomical reduction after ORIF in comparison to our results may be attributed to the larger fragments (25% of articular surface) in their study, which may be less challenging to reduce anatomically than small or comminuted fragments. It may be possible that in medium-sized fragments, ORIF via the posterolateral approach does not result in clinically significant superior fragment reduction, and therefore yields similar functional and radiological results as no fixation of the fragment. Suboptimal reduction in ORIF may be the result of using the reduction of the cortex from the fracture fragments as a proxy for articular reduction, causing the surgeon to rely on fluoroscopy when assessing articular reduction, which is known to be inaccurate. On the contrary, it is also possible that the discrepancy in quality of reduction on radiograph and CT scan is explained by the method of evaluation of CT scan, since the step-off was assessed on the sagittal image showing the largest step-off. Therefore, it is possible that a PMF that is reduced (nearly) anatomically, but with an irregularity in the joint surface of 1.1 mm on just one CT image, is regarded as non-anatomical, while this may be of little clinical consequence.

The optimal treatment for fractures of the PMF in trimalleolar ankle fractures remains a matter of debate. Initially, fragment size was thought to be the primary indicator for fixation of the PMF, with large fragments believed to cause posterior instability.[1,2,9,10] However, others have argued that posterior instability does not occur when the medial and lateral columns are restored after fixation of the medial and lateral malleoli.[11-14] Recent studies suggest that fragment displacement, not size, is the key risk factor for developing post-traumatic OA, which is strongly linked to poor functional outcomes.[4,7,8] Restoration of the distal tibial articular surface therefore seems essential in this type of injury.

The POSTFIX trial is the largest multicentre randomized clinical trial worldwide to analyze clinical and radiological effects using CT of open anatomical fixation of the PMF in type B trimalleolar fractures with medium-sized PMF. Strengths of this study are the randomized design, the use of multiple functional outcome measures, and the evaluation of reduction on postoperative CT scans. Moreover, to our knowledge, this is currently the largest prospective study evaluating medium-sized posterior fragments. Limitations are the short follow-up period, the absence of a cost-benefit analysis, and the lack of verification of the radiological measurements. In a previous study, we found moderate interobserver agreement for the assessment of PMF size.[37] Moreover, some of the study procedures that were common practice when the study was designed are not in line with current clinical practice in our centres. Specifically, evaluation of posterior fragment size for assessment of eligibility was performed on radiographs, since at the time of the study design this was common practice. During the course of the study, assessment of PMF using CT scan-based classification systems became more common. If we were to perform this study again now, we would base eligibility for inclusion on not just fragment size, but also fragment morphology (for instance, Bartonicek type 2). Furthermore, all patients were instructed to avoid weightbearing for six weeks, regardless of syndesmotic disruption, to evaluate the true effect of fixation itself instead of the postoperative procedure. Currently, our protocol has been changed to non-weightbearing for two weeks, followed by permissive weightbearing. Unfortunately, in only 60% of the cases were radiographs available after one year. Therefore, considering the availability of relatively few radiographs, a potential difference might have been missed. Another limitation is the availability of only 77% (28 in FIX group, 34 in NO-FIX group) of AAOS questionnaires at week 52, despite maximum effort to contact patients. Therefore, the analysis was underpowered, potentially resulting in missing a statistically significant difference. Conversely, the difference in AAOS scores between the study arms was merely three points, which does not meet the clinically relevant threshold of ten points.

Our findings are in agreement with other publications. Karaismailoglu et al[17] found comparable results one year postoperatively after randomization between ORIF and no treatment of the PMF fracture. Shi et al[18] found that ORIF yields clinically superior results compared to no fixation of the PMF fragment when assessed by the AOFAS questionnaire. However, this discrepancy with our results may be explained by the fact that they included only large fragments comprising more than 25% of the articular surface. Finally, in a recent systematic review on patient-reported outcomes after ORIF of the PMF compared to closed reduction and internal fixation (CRIF) or no fixation in bi- and trimalleolar ankle fractures, Miksch et al[19] found a statistically insignificant but clinically relevant difference in

favour of fixation. However, PMF sizes in the three included studies comparing ORIF to no fixation were heterogenous, sample sizes were small, and only one prospective trial was included. Moreover, in all of the previously mentioned studies not only type B (SER) but also type C (PER) injuries were included in the studies, which should be regarded as a different entity since, in contrast to type B fractures, syndesmotic disruption is common in these injuries. We are currently completing a prospective trial studying reconstruction of the syndesmosis by PMF fixation versus trans-syndesmotic screws, in type C fractures. Therefore, given that PER injuries were also included in the studies reviewed by Miksch et al,[19] no conclusions can be drawn regarding outcomes of (non)-fixational management of the PMF in SER injuries. To the best of our knowledge, this trial is the first study to solely focus on effects of PMF fixation in type B ankle fractures.

In conclusion, no statistically or clinically significant difference in all functional and radiological outcome measures were observed after one-year follow-up. The short-term value of ORIF of medium-sized posterior fragments in type B ankle fractures therefore seems limited. Longer follow-up is needed to establish any possible intermediate or long-term differences.

Take home message

- Guidelines for the treatment of medium-sized posterior malleolar fractures in trimalleolar ankle fractures are scarce and show varying advice.
- No differences in functional or radiological outcomes were observed one year after randomization between fixation and no fixation of posterior fragments.
- Longer follow-up is needed to establish long-term effects.

Supplementary material

The supplementary material provides a raw data repository of American Orthopaedic Foot and Ankle Society scores, which were planned as a secondary outcome measure in this study, but were not analyzed and reported in the manuscript due to high levels of missing data.

References

1. **Lovisetti G**, **Irwin TA**. Posterior malleolus fracture. *J Am Acad Orthop Surg*. 2014;22(2):67.
2. **Odak S**, **Ahluwalia R**, **Unnikrishnan P**, **Hennessy M**, **Platt S**. Management of posterior malleolar fractures: a systematic review. *J Foot Ankle Surg*. 2016;55(1):140–145.
3. **Jaskulka RA**, **Ittner G**, **Schedl R**. Fractures of the posterior tibial margin: their role in the prognosis of malleolar fractures. *J Trauma*. 1989;29(11):1565–1570.
4. **De Vries JS**, **Wijgman AJ**, **Sierevelt IN**, **Schaap GR**. Long-term results of ankle fractures with a posterior malleolar fragment. *J Foot Ankle Surg*. 2005;44(3):211–217.
5. **Langenhuijsen JF**, **Heetveld MJ**, **Ultee JM**, **Steller EP**, **Butzelaar RMJM**. Results of ankle fractures with involvement of the posterior tibial margin. *J Trauma*. 2002;53(1):55–60.
6. **Broos PL**, **Bisschop AP**. Operative treatment of ankle fractures in adults: correlation between types of fracture and final results. *Injury*. 1991;22(5):403–406.
7. **Drijfhout van Hooff CC**, **Verhage SM**, **Hoogendoorn JM**. Influence of fragment size and postoperative joint congruency on long-term outcome of posterior malleolar fractures. *Foot Ankle Int*. 2015;36(6):673–678.
8. **Xu H**, **Li X**, **Zhang D**, **et al**. A retrospective study of posterior malleolus fractures. *Int Orthop*. 2012;36(9):1929–1936.
9. **Macko VW**, **Matthews LS**, **Zwirkoski P**, **Goldstein SA**. The joint-contact area of the ankle. The contribution of the posterior malleolus. *J Bone Joint Surg Am*. 1991;73-A(3):347–351.
10. **Hartford JM**, **Gorczyca JT**, **McNamara JL**, **Mayor MB**. Tibiotalar contact area. Contribution of posterior malleolus and deltoid ligament. *Clin Orthop Relat Res*. 1995;320:182–187.
11. **Harper MC**. Posterior instability of the talus: an anatomic evaluation. *Foot Ankle*. 1989;10(1):36–39.
12. **Harper MC**. Talar shift. The stabilizing role of the medial, lateral, and posterior ankle structures. *Clin Orthop Relat Res*. 1990;257:177–183.
13. **Harper MC**, **Hardin G**. Posterior malleolar fractures of the ankle associated with external rotation-abduction injuries. Results with and without internal fixation. *J Bone Joint Surg Am*. 1988;70-A(9):1348–1356.
14. **Raasch WG**, **Larkin JJ**, **Draganich LF**. Assessment of the posterior malleolus as a restraint to posterior subluxation of the ankle. *J Bone Joint Surg Am*. 1992;74-A(8):1201–1206.
15. **Vrahas M**, **Fu F**, **Veenis B**. Intraarticular contact stresses with simulated ankle malunions. *J Orthop Trauma*. 1994;8(2):159–166.
16. **Fitzpatrick DC**, **Otto JK**, **McKinley TO**, **Marsh JL**, **Brown TD**. Kinematic and contact stress analysis of posterior malleolus fractures of the ankle. *J Orthop Trauma*. 2004;18(5):271–278.
17. **Karaismailoglu B**, **Yıldırım O**, **Aslan L**, **et al**. Middle-sized posterior malleolus fractures: fixed versus non-fixed - a prospective randomized study. *Foot Ankle Surg*. 2023;29(4):329–333.
18. **Shi H-F**, **Xiong J**, **Chen Y-X**, **et al**. Comparison of the direct and indirect reduction techniques during the surgical management of posterior malleolar fractures. *BMC Musculoskelet Disord*. 2017;18(1):109.
19. **Miksch RC**, **Herterich V**, **Barg A**, **Böcker W**, **Polzer H**, **Baumbach SF**. Open reduction and internal fixation of the posterior malleolus fragment in ankle fractures improves the patient-rated outcome: a systematic review. *Foot Ankle Int*. 2023;44(8):727–737.
20. **Talbot M**, **Steenblock TR**, **Cole PA**. Posterolateral approach for open reduction and internal fixation of trimalleolar ankle fractures. *Can J Surg*. 2005;48(6):487–490.
21. **Tornetta P**, **Ricci W**, **Nork S**, **Collinge C**, **Steen B**. The posterolateral approach to the tibia for displaced posterior malleolar injuries. *J Orthop Trauma*. 2011;25(2):123–126.
22. **Miller AN**, **Carroll EA**, **Parker RJ**, **Helfet DL**, **Lorich DG**. Posterior malleolar stabilization of syndesmotic injuries is equivalent to screw fixation. *Clin Orthop Relat Res*. 2010;468(4):1129–1135.
23. **Gardner MJ**, **Brodsky A**, **Briggs SM**, **Nielson JH**, **Lorich DG**. Fixation of posterior malleolar fractures provides greater syndesmotic stability. *Clin Orthop Relat Res*. 2006;447:165–171.
24. **Forberger J**, **Sabandal PV**, **Dietrich M**, **Gralla J**, **Lattmann T**, **Platz A**. Posterolateral approach to the displaced posterior malleolus: functional outcome and local morbidity. *Foot Ankle Int*. 2009;30(4):309–314.
25. **Verhage SM**, **Boot F**, **Schipper IB**, **Hoogendoorn JM**. Open reduction and internal fixation of posterior malleolar fractures using the posterolateral approach. *Bone Joint J*. 2016;98-B(6):812–817.
26. **Verhage S**, **van der Zwaal P**, **Bronkhorst M**, **et al**. Medium-sized posterior fragments in AO Weber-B fractures, does open reduction and fixation improve outcome? The POSTFIX-trial protocol, a multicenter randomized clinical trial. *BMC Musculoskelet Disord*. 2017;18(1):94.
27. **Barbosa P**, **Bonnaire F**, **Kojima K**. Transsyndesmotic, posterior, lateral simple fractures, and deltoid rupture. AO Foundation. 2013. https://surgeryreference.aofoundation.org/orthopedic-trauma/adult-trauma/malleoli/transsyndesmotic-posterior-lateral-simple-fractures-and-deltoid-rupture (date last accessed 13 February 2025).
28. **Lauge-Hansen N**. Fractures of the ankle. II. Combined experimental-surgical and experimental-roentgenologic investigations. *Arch Surg (1920)*. 1950;60(5):957–985.
29. **Bartoníček J**, **Rammelt S**, **Kostlivý K**, **Vaněček V**, **Klika D**, **Trešl I**. Anatomy and classification of the posterior tibial fragment in ankle fractures. *Arch Orthop Trauma Surg*. 2015;135(4):505–516.
30. **Haraguchi N**, **Haruyama H**, **Toga H**, **Kato F**. Pathoanatomy of posterior malleolar fractures of the ankle. *J Bone Joint Surg Am*. 2006;88-A(5):1085–1092.
31. **Kitaoka HB**, **Alexander IJ**, **Adelaar RS**, **Nunley JA**, **Myerson MS**, **Sanders M**. Clinical rating systems for the ankle-hindfoot, midfoot, hallux, and lesser toes. *Foot Ankle Int*. 1994;15(7):349–353.
32. **Johanson NA**, **Liang MH**, **Daltroy L**, **Rudicel S**, **Richmond J**. American Academy of Orthopaedic Surgeons lower limb outcomes assessment instruments. Reliability, validity, and sensitivity to change. *J Bone Joint Surg Am*. 2004;86-A(5):902–909.
33. **Olerud C**, **Molander H**. A scoring scale for symptom evaluation after ankle fracture. *Arch Orth Traum Surg*. 1984;103(3):190–194.

34. **EuroQol Group**. EuroQol - a new facility for the measurement of health-related quality of life. *Health Policy*. 1990;16(3):199–208.
35. **Kijowski R**, **Blankenbaker D**, **Stanton P**, **Fine J**, **De Smet A**. Arthroscopic validation of radiographic grading scales of osteoarthritis of the tibiofemoral joint. *AJR Am J Roentgenol*. 2006;187(3):794–799.
36. **Donken CCMA**, **Al-Khateeb H**, **Verhofstad MHJ**, **van Laarhoven CJHM**. Surgical versus conservative interventions for treating ankle fractures in adults. *Cochrane Database Syst Rev*. 2012;8:CD008470.
37. **Verhage SM**, **Rhemrev SJ**, **Keizer SB**, **Quarles van Ufford HME**, **Hoogendoorn JM**. Interobserver variation in classification of malleolar fractures. *Skeletal Radiol*. 2015;44(10):1435–1439.

Author information:
A. L. Franx, MD, PhD Candidate, General Surgery Resident
S. M. Verhage, MD, PhD, Trauma Surgeon
J. M. Hoogendoorn, MD, PhD, Trauma Surgeon
Department of Surgery, Haaglanden Medical Center, The Hague, Netherlands.

P. Krijnen, PhD, Clinical Epidemiologist, Department of Surgery, Leiden University Medical Center, Leiden, Netherlands; Acute Care Network West-Netherlands, Leiden, Netherlands.

E. L. L. Twiss, MD, Trauma Surgeon
I. B. Schipper, MD, PhD, Professor of Trauma Surgery, Trauma Surgeon
Department of Surgery, Leiden University Medical Center, Leiden, Netherlands.

Author contributions:
A. L. Franx: Formal analysis, Methodology, Writing – original draft, Project administration, Investigation.
S. M. Verhage: Methodology, Supervision, Conceptualization, Writing – review & editing.
P. Krijnen: Formal analysis, Methodology, Writing – review & editing.
E. L. L. Twiss: Writing – review & editing.
I. B. Schipper: Writing – review & editing.
J. M. Hoogendoorn: Conceptualization, Methodology, Supervision, Funding acquisition, Writing – review & editing.

Funding statement:
The authors disclose receipt of the following financial or material support for the research, authorship, and/or publication of this article: this study was made possible by a local research grant from the Haaglanden Medical Centre, as reported by all the authors.

ICMJE COI statement:
All the authors report a local research grant from the Haaglanden Medical Centre, related to this study.

Data sharing:
The data that support the findings for this study are available to other researchers from the corresponding author upon reasonable request.

Ethical review statement:
The Medical Ethics Committee South West Netherlands approved of the study protocols (protocol number 13-068). Informed consent was taken from all participants.

Open access funding:
The authors report that the open access funding for their manuscript was self-funded.

Trial registration number:
This trial is registered at ClinicalTrials.gov (protocol number NCT02596529).

This article was primary edited by M. Hossain.