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Selective fixation of the medial malleolus in unstable ankle fractures

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ABSTRACT

Background: Whilst the lateral malleolus appears to be crucial in controlling anatomical reduction of the talus, the role of the medial malleolus is less clear. Medial sided complications including infection, damage to local structures and symptomatic hardware are not without morbidity. This study compares the outcomes of patients with bimalleolar or trimalleolar ankle fractures who underwent fibular nail stabilisation with or without medial malleolar fixation.

Methods: From a prospective single-centre trauma database, we identified 342 patients over a nine-year period who underwent fibular nail insertion to stabilise a bimalleolar or trimalleolar ankle fracture. Isolated lateral malleolar fractures were excluded. Demographic data, clinical outcomes, radiographic evaluation, return to work and sport, and patient reported outcomes, including Olerud-Molander Ankle Score (OMAS), EuroQol-5D (EQ-5D) and Manchester-Oxford Foot Questionnaire (MOXFQ) were collected.

Results: This study included 247 patients with a mean age of 66.7 years (range, 25–96 years), of whom 200 were female (81%). Medial malleolar fixation was not performed in 54 cases (22%). There was no significant difference between groups with respect to failure of fixation ($p = 0.634$) or loss of talar reduction ($p = 0.157$). No patient required surgery for a symptomatic medial malleolar non-union. Medial sided complications occurred in 32 (16%) of the fixation group, of whom 20 (10%) required further surgery. At a mean mid-term follow-up of 4.8 years (range, 8 months – 9 years) there was no significant difference between the non-fixation and fixation groups with respect to the median OMAS (85 vs 80; $p = 0.885$) or median EQ-5D (0.80 vs 0.81; $p = 0.846$). Patient satisfaction was not significantly different between the two groups (85/100 vs 87/100; $p = 0.410$).

Conclusion: Non-operative management of the medial malleolar component of an unstable ankle fracture treated with a fibular nail may reduce the rate of post-operative complications without compromising the patient reported outcome.

Introduction

Wound infection and prominent painful metalwork are common complications following open reduction and internal fixation (ORIF) of unstable ankle fractures, particularly in elderly patients and those with vulnerable soft tissues [1–3]. The fibular intramedullary nail offers minimally invasive fracture stabilisation, with a proven reduction in wound complications, secondary procedures, and has greater biomechanical strength [4–7].

With the increasing use of the fibular nail in our service, we have noted a persistent rate of medial-sided wound and metalwork problems, despite the substantial reduction in lateral-sided wound complications. This has also been noted by other authors, who report medial sided wound infection in up to 30% of infected cases, [8] as well as the risk of persistent post-operative pain, and potential injury to the tibialis posterior tendon (TPT) [9]. Non-operative management of the medial malleolus has been shown to have potential advantages in a previous randomised controlled trial [10]. Our own experience, and a review of the literature, led to the gradual adoption of a policy of non-operative management of the medial malleolus where fibular fixation alone had resulted in a reduced and stable mortise, particularly in high risk patients.

The aim of this study was to compare complications, reoperation rates and patient reported outcomes, between patients managed with and without medial malleolar fixation in combination with fibular intramedullary nailing. This study was reviewed by the local NHS Research Ethics Service and registered with the local musculoskeletal quality improvement group.

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Patients and methods

A retrospective analysis of a prospectively collected trauma database complied between 2008 and 2016 was performed. This identified 342 patients over 16 years of age who underwent fibular nail stabilisation of an unstable ankle fracture, for whom complete clinical and radiographic data were available. Isolated lateral malleolar fractures and injuries with a purely ligamentous medial component were excluded, leaving a total study cohort of 247 cases for review. Patient records were assessed for demographic data, complications, subsequent treatments and/or procedures.

Radiographic analysis

Ankle fractures were classified according to the Arbeitsgemeinschaft für Osteosynthesefragen (AO) and Lauge-Hansen systems [11,12]. Medial malleolar fractures were further classified from the pre-reduction anteroposterior radiograph using the Herscovici system [13]. Intra-operative image intensifier radiographs were assessed for medial malleolar reduction quality following fibular stabilisation. Post-operative radiographs were scrutinised for malleolar union, loss of talar reduction, and construct failure requiring revision surgery.

Surgical technique and follow up

A total of 11 Orthopaedic trauma surgeons supervised the care of these patients over the study period. The surgical procedure to reduce and stabilise the fibula was performed as described by Bugler et al. using the Acumed fibular nail (Hillsboro, Oregon, USA) [4]. The nail is secured with one or two distal locking screws, inserted from anterior to posterior, and a proximal locking screw, inserted from the fibula into the tibia in a similar orientation to that of a syndesmosis screw. This technique allows control of both fibular length and rotation, and was employed in all of the cases, regardless of whether a syndesmosis injury was present and represents the standardised technique. A dynamic stress test was performed to assess the syndesmosis before insertion of the proximal locking screw. Once the implant was secured, the medial malleolus was assessed under fluoroscopy. In some cases where the mortise was congruent, and the medial malleolus was subjectively reduced within a few millimetres of an anatomical position, the decision was taken by the operating surgeon not to perform further open surgery on the medial side to expose and fix it. There was no attempt within this cohort to define medial malleolar position further, or to select or randomise cases. Medial malleolar fracture fixation, where considered necessary by the treating orthopaedic surgeon, was achieved with cancellous screws or a tension band wire construct as appropriate for fragment size and integrity. A radiographic example of a patient in the non-fixation group, demonstrating a well reduced medial malleolus fracture following fibular nail insertion is demonstrated (Figs. 1–3).

Regardless of medial side management, routine practice was to allow all patients immediately to bear full weight in a removable orthosis, with the exception of patients with a syndesmotic disruption or diabetic neuropathy who were kept non-weight bearing for up to eight weeks post-operatively. All patients received at least two post-operative clinical and radiographic reviews, the first at two weeks and the second between six and eight weeks. Subsequent review was at the discretion of the treating surgeon. Metalwork is not routinely removed in our centre, and was only removed at the patient's request when intolerably symptomatic.

Follow-up

Patients were contacted at a mean of 4.8 years post injury (range, 8 months – 10 years), either by postal questionnaire or structured telephone interview, to complete the EuroQol-5D (EQ-5D), [14] Olerud-Molander Ankle Score (OMAS) [15], Manchester Oxford Foot Questionnaire (MOXFQ) [16], return to work and sport, visual analogue scale (VAS) pain score and overall satisfaction score (5-point Likert scale).

Statistical analysis

Data was analysed using IBM SPSS software version 23.0 (Armonk, NY: IBM Corp). The Shapiro-Wilk test was used to assess normality of continuous data. Student's unpaired *t*-test was employed to analyse parametric continuous data and the Mann-Whitney U test was used to compare nonparametric continuous

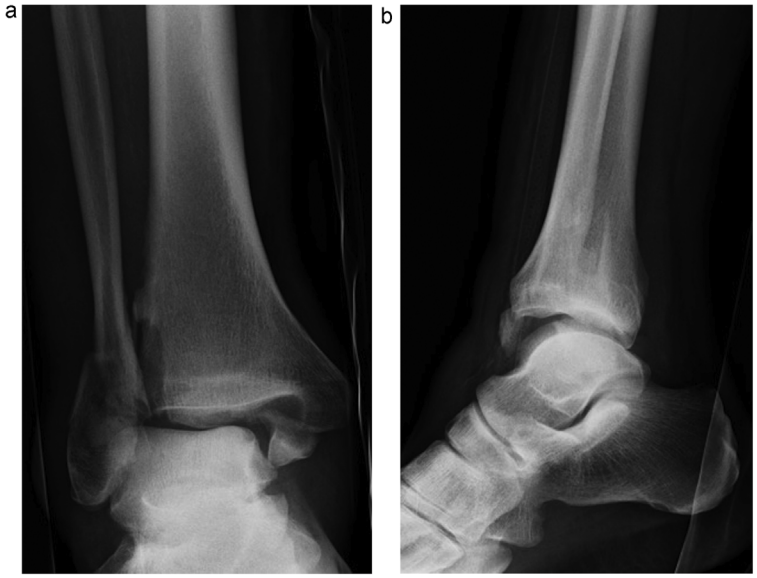

Fig. 1. Anteroposterior (a) and lateral (b) radiographs of a 56 year old male patient, demonstrating a supination-external rotation (SER) type/AO 44-B2 ankle fracture with talar shift and a Herscovici type B medial malleolar fracture. This patient had significant post-traumatic blistering both medially and laterally.

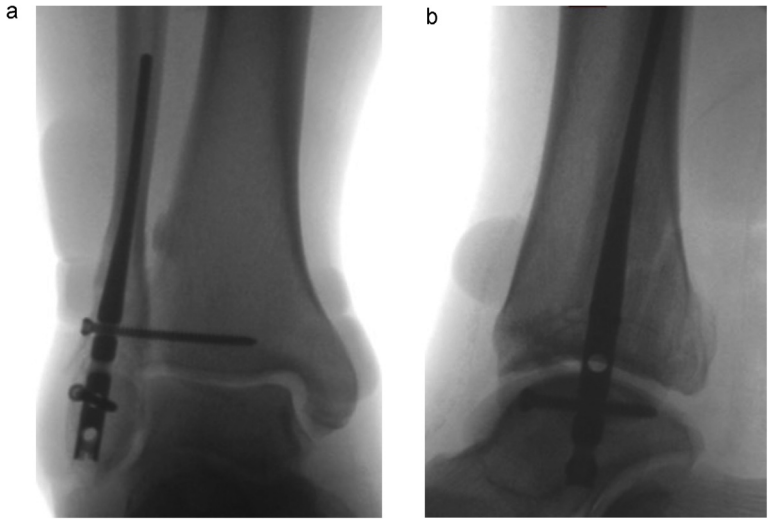

Fig. 2. Intra-operative anteroposterior (a) and lateral (b) fluoroscopy one day post-injury demonstrating an anatomically reduced medial malleolar fracture and anatomical mortise reduction post fibular nail insertion. The outline of fracture blistering can be seen on both radiographs.

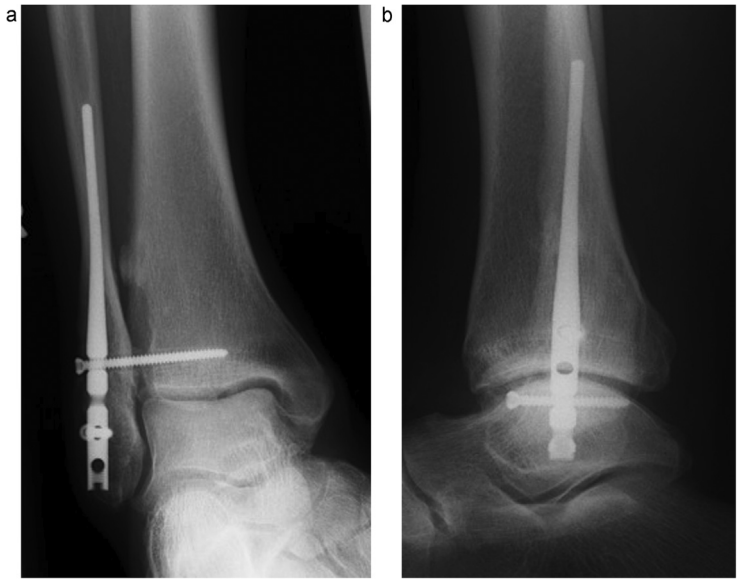

Fig. 3. Anteroposterior (a) and lateral (b) radiographs of the same patient, two years following surgery, demonstrating healed lateral and medial malleolar fractures with no significant evidence of post-traumatic osteoarthritis.

data. Categorical binary data were analysed using either the chi-square test (all observed frequencies in each cell > 5) or the Fisher's exact test (one cell had an observed frequency of ≤ 5). Two-tailed p values were reported, and statistical significance was set at p values of less than 0.05.

Results

Patients and injuries

Out of the total cohort of 247 cases, the medial malleolus was not fixed in 54 cases (22%) with the remaining 193 treated operatively with either 3.5 mm partially threaded cancellous screw(s) (n = 165, 85%) or a tension band wire construct (n = 28, 15%). The flow of patients is summarised in Fig. 4. The majority of patients were female (n = 200, 81%). There was a significant difference in the mean patient age of each group (fixation: 65 years, range 25–96 vs. non-fixation: 72 years, range 31–96, p = 0.003). Despite the overall higher mean age in the non-fixation group, 18 patients (33%) were aged under 65 years. There were 24 high-energy injuries and 17 open fractures. All of these were in the fixation group. The majority of medial malleolar fractures were B-type (n = 126, 51%) according to the Herscovici classification, occurring between the tip and the level of the plafond [13]. In the non-fixation group, there were proportionately more type A tip-avulsion fractures (non-fixation: 12 (22%) vs. fixation: 13 (7%), p = 0.032). Complete patient demographics and classification of injuries for each group are summarised in Table 1.

With respect to the intra-operative reduction of the medial malleolar fracture, in the non-fixation group the majority were displaced less than 2 mm following fibular fixation (n = 49, 91%), with anatomical reduction in two thirds of cases (n = 35, 65%). In five cases the residual displacement of the medial malleolar fracture was greater than 2 mm, with a mean displacement of 2.9 mm (range, 2.5–4 mm).

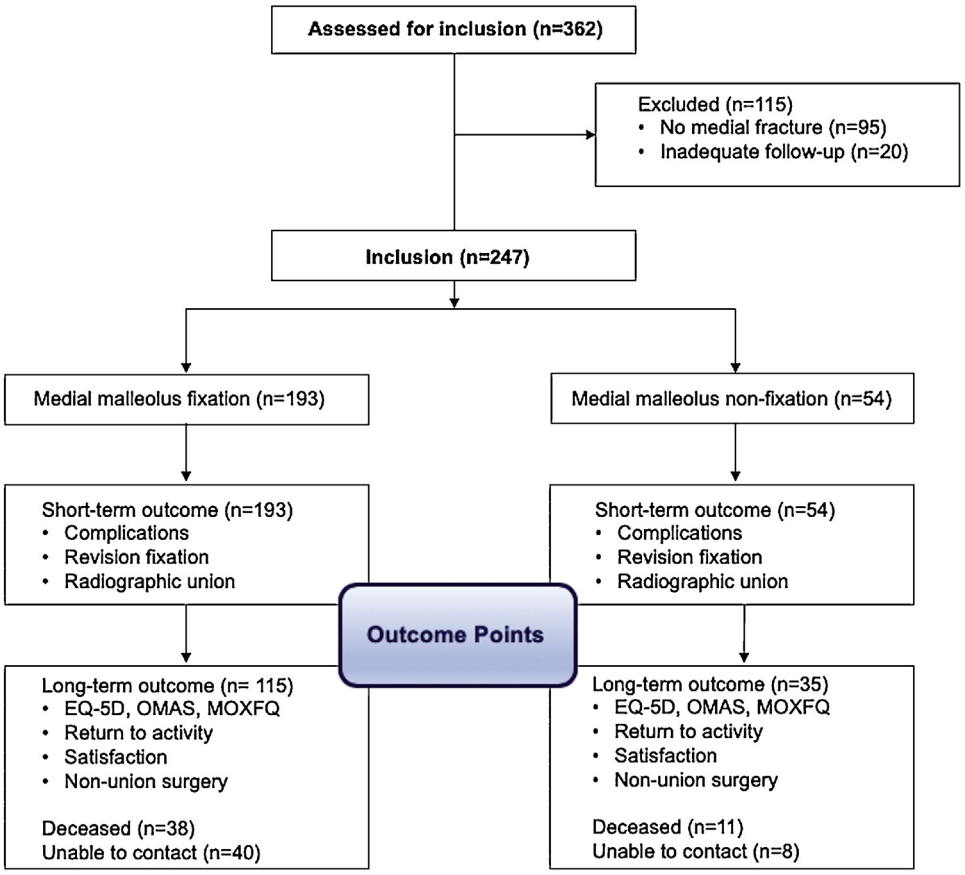

Fig. 4. Selection and flow of patients in the study.

Surgical construct failure

Revision surgery for failed fixation was required in 15 cases; 11 (6%) in the fixation group and four (7%) in the non-fixation group ($p = 0.634$). Revision surgery in the non-fixation group was due to different factors in each case. An elderly patient with a poor fibular nail technique in early 2008 required a hind-foot nail arthrodesis three week after her primary procedure. In a second case, the ankle joint was inadequately reduced, and the patient underwent revision surgery two days later with a subsequent good outcome. The remaining two fixations failed secondary to pull-out of the proximal 'syndesmotic' screw in osteoporotic metaphyseal bone. This was recognised as a failure of the fibular nail construct and not the absence of medial malleolar fixation. Post-operative talar displacement that did not require revision surgery occurred in three further cases: one (0.5%) in the fixation and two (4%) in the non-fixation group ($p = 0.157$). These cases occurred in elderly, low-demand patients whom made uneventful recoveries and where revision surgery could have introduced unwarranted risk without significant potential benefit. Three patients required revision surgery for failed medial malleolar fixation (one tension band-wire construct and two failed cancellous screw fixation) (Fig. 5).

Radiographic evidence of medial malleolar fracture consolidation at latest radiographic follow-up was lacking in 16 patients (30%) in the non-operative group and 22 patients (11%) in the fixation group ($p = 0.002$). These patients had been reviewed in the outpatient clinic at between six and eight weeks post-operatively, found to be making satisfactory clinical progress, and were therefore discharged from service before confirmed radiographic union. None of these patients have required revision surgery for symptomatic malleolar non-union as confirmed by review of electronic patient records, the national picture archiving service (PACS) and patient questionnaires.

Soft tissue and metalwork complications

Medial side soft tissue and metalwork complications were limited to the fixation group (193 patients) where 18 (9%) developed infection and 14 (7%) required metalwork removal due to painful medial prominence. Examples of this are demonstrated radiographically (Figs. 6 & 7). Of the infected cases, 14 were managed with at least one course of oral antibiotics alone, one with intravenous antibiotics only and three with revision surgery supplemented by intravenous antibiotics. With respect to secondary procedures, twenty patients in total (10%) required a return to the theatre for issues related to medial sided metalwork: 14 for symptomatic prominence, three for sepsis control and three for revision fixation.

Patient reported outcomes

Of the 247 patients in the study cohort, 49 had died, leaving 198 patients for review (Fig. 4). Patient reported outcome measures were collected from 150 patients (76% response rate) with a mean follow up of 4.8 years (range, 8 months – 10 years). There was no statistical difference in any outcome score between groups, demonstrating comparable functional results regardless of medial malleolar treatment, summarised in Table 2. No patient in either group had required revision surgery for symptomatic non-union at the time of collection. When analysed separately, the outcome scores available for patients that had a medial sided avulsion injury (type-A fracture, $n = 12$) treated non-operatively were equivalent

Table 1
Comparisons between non-fixation and fixation groups – demographics and injury classification.

	Total	Non-Fixation	Fixation	*p-value*
Number of patients	247	54 (22%)	193 (78%)	
Age at surgery (years)	66.7	72.1	65.2	**0.003**[*,a]
Sex (n, %)				
- Male	47 (19%)	5 (9%)	42 (22%)	0.070[b]
- Female	200 (81%)	49 (91%)	151 (78%)	
High energy injury (n, %)	24 (10%)	0 (0%)	24 (12%)	**0.003**[*,c]
Open fracture (n, %)	17 (7%)	0 (0%)	17 (9%)	**0.024**[*,c]
Lauge-Hansen (n, %)				
- SER	196 (79%)	46 (85%)	150 (78%)	0.188[b]
- PER	9 (4%)	0	9 (5%)	
- PAB	34 (14%)	8 (15%)	26 (13%)	
- SAD	8 (3%)	0	8 (4%)	
AO/OTA (n, %)				
- 44-B2/B3	204 (83%)	46 (85%)	158 (82%)	0.172[b]
- 44-C1	9 (3%)	0 (0%)	9 (5%)	
- 44-C2	34 (14%)	8 (15%)	26 (13%)	
Syndesmosis diastasis (n, %)	43 (17%)	6 (11%)	37 (19%)	0.167[b]
Posterior malleolus fracture (n, %)	112 (45%)	21 (39%)	91 (47%)	0.281[b]
Medial malleolus (n, %)				
- A	25 (10%)	12 (22%)	13 (7%)	**0.008**[*,b]
- B	126 (51%)	26 (48%)	100 (52%)	
- C	87 (35%)	15 (28%)	72 (37%)	
- D	9 (4%)	1 (2%)	8 (4%)	

SER: Supination-External Rotation, PER: Pronation-External Rotation, PAB: Pronation-Abduction, SAD: Supination-Adduction. AO/OTA: AO/Orthopaedic Trauma Association. Herscovici medial malleolus fracture classification: A - tip avulsion, B - level between tip and plafond, C - level of plafond, D - vertical extension.
[a] Student's unpaired *t*-test.
[b] Chi-square test.
[c] Fisher's exact test.
[*] Statistical significance reached.

to those patients with a non-avulsion injury (non type-A fracture, n = 42) treated non-operatively (all p values >0.05).

Discussion

In this study, we have demonstrated that medial malleolar fractures can be successfully managed non-operatively following satisfactory fibular stabilisation with an intramedullary device, with a reduced rate of post-operative complications.

There exists a long-standing debate regarding the role of the medial malleolus on ankle joint stability, with many acknowledging the lateral malleolus as the primary bony stabiliser. This concept was first popularised by Yablon et al in the 1970s, who eloquently stated that "the talus always faithfully follows the lateral malleolus upon reduction" [17]. Kimizuka et al. developed this further, assessing tibiotalar loading during weight bearing and concluded that 90% of loading occurs at the central zone of the plafond, with only 10% shared equally between the lateral and medial malleoli [18]. More recent biomechanical analysis has highlighted the importance of restoration of lateral malleolar integrity on tibiotalar loading, with 1 mm of lateral shift decreasing contact area by 40% [19].

The principle of non-fixation of the medial malleolus was first described by Lindenbaum and later by Hernigou who reported successful outcomes after excision of the medial malleolus, following acute trauma [20,21]. Tornetta et al. stimulated the debate further when describing the 'anterior colliculus' fracture of the medial malleolus and concluded that due to the posterior attachment of the deep deltoid ligament, fixation of these fractures may not provide additional stability to ankle joint [22]. The complications associated with medial malleolar fixation are well-recognised, with attempts to reduce infection and metalwork prominence through percutaneous approaches and headless compression screws, demonstrating promising results in small studies [23,24]. Unfortunately, for those patients who develop metalwork related pain, outcomes following surgery can be significantly affected, even following elective removal [25].

The study by Herscovici et al. from which medial malleolar fracture classification was described, included 57 isolated medial malleolar fractures treated non-operatively with union rates of 96% reinforced by both good clinical and patient outcomes after a minimum radiographic follow-up of two years [13]. The mean patient age in their study was 39.7 years, which is much younger than the 72.1 years in non-fixation group of the present study. This finding reflects the initial preference in our service for non-

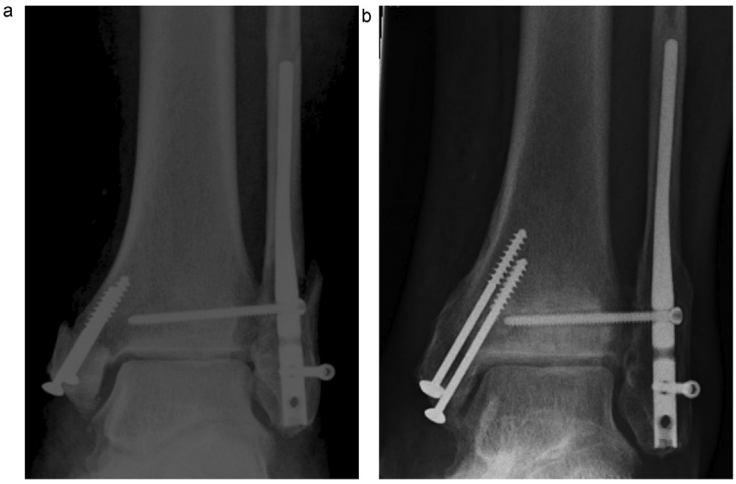

Fig. 5. Anteroposterior radiograph of 52-year-old male patient at two weeks post-operative stage demonstrating failed medial malleolar fixation (a). Anteroposterior radiograph from the same patient three months following revision surgery demonstrating satisfactory medial and lateral malleolar union, and an anatomical mortise (b).

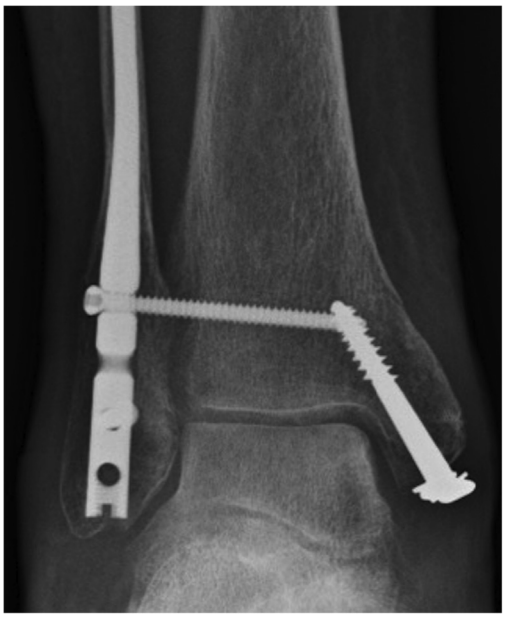

Fig. 6. Anteroposterior radiograph of a 67 year-old female patient following treatment of a supination-external rotation (SER) type/AO 44-B2 fracture, requiring elective removal of prominent medial metalwork after fracture consolidation at ten months post-operative stage.

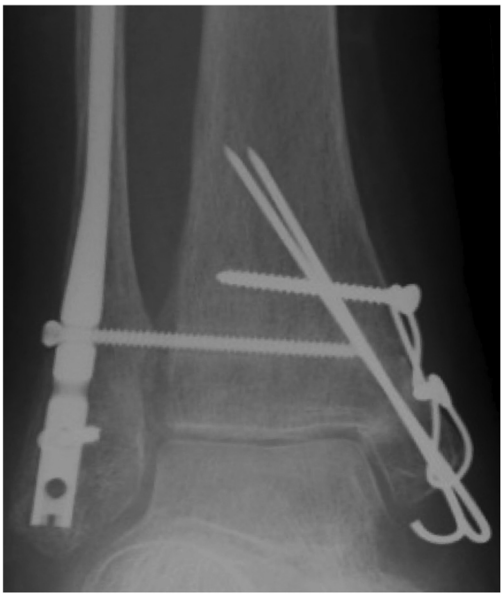

Fig. 7. Anteroposterior radiograph of a 66 year-old female patient following treatment of a supination-external rotation (SER) type/AO 44-B2 fracture, requiring elective removal of prominent medial metalwork after fracture consolidation at eight months post-operative stage. The Kirschner wires had been impacted at the time of surgery, but had backed out as the fracture healed.

operative medial malleolar management in the most elderly patients who usually had the poorest skin quality. However, following encouraging initial results, non-operative management has become more widely practiced to include a younger patient group, with 18 patients (33%) under the age of 65 years in this study. These results are therefore still applicable to the younger patient, especially if there are soft tissue concerns. Entirely closed management of unstable fractures in the over 65 age group has recently been the subject of the AIM trial [26]. Closed management was achieved by the application of a close-contact cast in theatre under a general or spinal anaesthetic, with subsequent restricted weight-bearing. The authors reported a significant reduction in the incidence of infection and wound complications compared with standard ORIF, with no difference in the OMAS at six months post injury. However, this was achieved at the expense of a 15% malunion rate, and a 26% rate of treatment failure: 70/311 patients required conversion to ORIF and a further 10 returned to theatre for re-manipulation. We believe that fibular nailing offers a more predictable maintenance of reduction (with an overall return to theatre rate of 6% in the present study), without the requirement for casting or restricted weight-bearing, which can be problematic in the elderly.

To our knowledge, only one prospective randomised controlled trial in this area has been conducted by Hoelsbrekken et al. [10]. This study compared outcomes of patients with bimalleolar and trimalleolar fractures randomised to fixation or non-fixation of the medial malleolar component. They found no difference with respect to patient reported outcome measures, complications or secondary intervention and a significantly lower tourniquet time in the non-fixation group. There was a higher rate of radiographic non-union in the non-fixation group, but without clinical correlation, in keeping with our own findings. Despite the positive trial conclusions, many appear cautious of adopting the practice, possibly due to the lack of long-term follow-up, and uncertainty regarding the possible development of post-traumatic osteoarthritis. On a similar prospective theme, there has been recent interest regarding the number of screws required for medial malleolar fixation. A trial published by Buckley et al. found no difference in patient outcome when one screw was used compared with two screws [27]. There was a significant intra-operative cross over from two screw to single screw fixation in 20% of cases as the surgeon felt the fragment was too small to safely accept two screws. This treatment concept is being slowly adopted in the authors' institution in the case of fixation of displaced fractures.

In this study, we made no prospective attempt to define an acceptable (or unacceptable) degree of medial malleolar displacement. The quality of the medial malleolus fracture reduction was left to the discretion of the operating surgeon, who would presumably be influenced by a number of factors including age, comorbidities and skin condition. In most cases the medial malleolar fractures reduced spontaneously and were often impossible to discern on intra-operative fluoroscopy, with only 9% of fractures having >2 mm displacement on the anteroposterior intra-operative radiograph. Regardless of fracture displacement, patients in who maintained an adequate talar reduction had universally favourable outcomes. We had four cases requiring revision surgery for mechanical failure in the non-fixation group. The first failed case involved an inappropriate fibular nailing technique with no interlocking screws, performed in a frail, medically unwell patient in an attempt to provide stability with minimal operating time. This was the only case where the gold-standard technique described in the paper by Bugler et al. [4] was not employed and serves as a reminder of the important technical aspects of satisfactory fibular reduction and fixation to ensure a successful outcome.

This study is primarily limited by its retrospective nature and low number of patients in the non-fixation compared with the fixation group. We have been unable to contact eight patients (15%) in the non-fixation group and 11 patients (20%) were deceased at the time of outcome score collection. This may have introduced bias and we should not assume that all of these patients would have experienced an equivalent outcome to that of the contacted cohort. We have been unable to show a significant difference in any of the patient reported outcome scores, and this may represent a type II error. However, the functional outcome scores are comparable (Table 2) and where there is a difference, in the

Table 2
Patient reported outcome measures comparing medial malleolar non-fixation and fixation groups.

Outcome Measure	Non-fixation (median, IQR)	Fixation (median, IQR)	*p-value*[†]
EQ-5D	.80 (.31)	.81(.31)	0.846
OMAS	85 (38)	80 (50)	0.885
MOXFQ	17.2 (32)	9.4 (42)	0.380
VAS - Pain	92 (31)	90 (40)	0.626
VAS - Health	81 (20)	80 (30)	0.306
Return to Work (weeks)	6 (20)	8 (6)	0.476
Return to Sport (weeks)	12 (33)	12 (18)	0.771
Satisfaction	85 (25)	87 (30)	0.410

EQ-5D: EuroQol-5D, OMAS: Olerud-Molander Ankle Score, MOXFQ: Manchester-Oxford Foot Questionnaire, VAS: visual analogue scale.
[†] all p-values are using a Mann-Whitney U test.

OMAS, VAS health, VAS pain, return to work and satisfaction, the differences favour the non-fixation group. We feel it is highly unlikely that there is a real, undetected difference in favour of fixation. Furthermore, we aim to address these limitations with an on-going adequately powered prospective randomised trial. We acknowledge that there is also a lack of objective outcome measurements such as ankle joint range of movement assessment. Given the advanced age of many of our cohort, it was not feasible to arrange physical review for all patients. Consequently, we are unable to present late radiographic follow-up of some patients, with 16 not demonstrating radiographic evidence of union at discharge. However, after searching electronic patient records and collecting outcome data, no patient has required surgery for symptomatic non-union and it is likely that many or all progressed to uneventful union. This study is prone to selection bias, given the number of supervising surgeons involved. However, this pragmatic scenario is representative of daily clinical practice within both our centre and wider Orthopaedic trauma community. We have not specifically assessed development of post-traumatic radiographic osteoarthritis, which would represent a useful long-term finding in a prospective study. Finally, given the mode of intramedullary fibular fixation, the results of this study may not be applicable to ankle fractures treated with plate and screw fixation. This highlights an area for future prospective investigation.

The results and limitations of this retrospective pilot study have been used to inform a randomised controlled trial, currently in the recruitment stage, known as the MOON study – **M**edial Malleolus: **O**perative **O**r **N**on-operative (ClinicalTrails.gov ID NCT03362229). This trial will include adult patients with closed bimalleolar or trimalleolar ankle fractures and allows the surgeon to select their preferred method of fibular stabilisation and medial malleolus fixation (if randomised to fixation). It will expand on the current literature by inclusion of pre-injury functional outcome scores and an adequately powered sample size.

Conflicts statement

One of the senior authors has been involved in the design of the 2nd generation of the fibular nail manufactured by the company Acumed (Hillsboro, Oregon, USA). This author has not received financial rewards for this. Acumed sponsored The Edinburgh International Trauma Symposium (EITS) organised by the registered Scottish charity (SC142054), the Scottish Orthopaedic Research Trust Into Trauma (SORT-IT), between 2009 and 2014, and have provided research grants to SORT-IT.

Appendix A. Supplementary data

Supplementary material related to this article can be found, in the online version, at doi:https://doi.org/10.1016/j.injury.2019.03.010.

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