Minimally Invasive Treatment Approaches in the Operative Management of Unstable Ankle Fractures

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Declaration

This thesis and its composition are my own work. The small contributions and assistance of other individuals have been appropriately indicated in the text and footnotes. Material published in peer-reviewed journals as a result of this thesis has been included in the appendix and referenced at the start of each chapter.

The research described in this thesis has been carried out by me, Thomas Henry Carter under the supervision of Mr Tim White and Mr Andrew Duckworth. I have not submitted this work in candidature for any other degree, diploma or professional qualification. It does not exceed the word limit of 60,000 words set by the College of Medicine and Veterinary Medicine.

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Table of Contents

TABLES AND FIGURES

Tables

Figures

LIST OF ABBREVIATIONS

AITFL	Anterior inferior tibiofibular ligament
AOFAS	American Orthopaedic Foot and Ankle Society
AO	Arbeitsgemeinschaft für Osteosynthesefragen
AP	Anteroposterior
ASA	American Society of Anaesthesiologists
ATFL	Anterior talofibular ligament
BMD	Bone mineral density
BMI	Body mass index
CCC	Close contact casting
CFL	Calcaneofibular ligament
CT	Computed tomography
DDL	Deep deltoid ligament
DLS	Distal locking screw
DVT	Deep vein thrombosis
ED	Emergency department
EQ-5D	EuroQol-5D
EOTU	Edinburgh Orthopaedic Trauma Unit
FAOS	Foot and Ankle Outcome Score
FHL	Flexor hallicus longus
FDA	Food and Drug Administration
IOL	Interosseous ligament
IQR	Interquartile range
ITF	Inferior transverse ligament
ITT	Intention to treat

LEFS	Lower Extremity Function Scale
MCID	Minimum clinically important difference
MIPO	Minimally invasive plate osteosynthesis
MMOLC	Medial malleolus osteoligamentous complex
MOON	Medial malleolus: Operative Or Non-operative
MOXFQ	Manchester-Oxford Foot Questionnaire
MRI	Magnetic resonance imaging
OA	Osteoarthritis
OMAS	Olerud-Molander Ankle Score
OR	Odds ratio
ORIF	Open reduction internal fixation
OTA	Orthopaedic Trauma Association
PA	Posteroranterior
PE	Pulmonary embolism
PITFL	Posterior inferior tibiofibular ligament
PIS	Patient information sheet
PLS	Proximal locking screw
PROM	Patient reported outcome measure
PTFL	Posterior talofibular ligament
PTOA	Post-traumatic osteoarthritis
RCT	Randomised controlled trial
SD	Standard deviation
SDL	Superficial deltoid ligament
SMFA	Short Musculoskeletal Functional Assessment
SN	Sural nerve

SORT-IT	Scottish Orthopaedic Research Trust Into Trauma
SPN	Superficial peroneal nerve
TBW	Tension band wire
TTC	Tibiotalarcalcaneal
TPT	Tibialis posterior tendon
VAS	Visual analogue scale
VTE	Venous thromboembolism

ACKNOWLEDGEMENTS

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I would also like to acknowledge the assistance of my colleagues in the EOTU and SORT-IT, a number of whom are co-authors on the peer reviewed publications included in the appendix. I would like to thank the SORT-IT for affording me the opportunity to conduct research into orthopaedic trauma. The two research assistants, Ms Debbie Ketchen and Miss Keri Swain have provided me with moral support and companionship, when needed the most. I would like to express my many thanks to Miss Katrina Bell, Mr Sam Mackenzie, Mr William Oliver Mr Marcus Hollyer and Miss Emma Gill for their assistance with data collection for the retrospective and prospective chapters of this thesis. Special thanks to Mrs Deborah MacDonald for her assistance with distribution and processing of postal questionnaires. In the biomechanical work, I would like to thank Dr Rob Wallace for his experience and time when testing the cadaveric specimens, in addition to Mr Iain Campbell and Mrs Laura Shiels for their assistance with processing and transporting cadaveric material between research sites. For the prospective RCT, I would like to acknowledge Dr Fergus Perks and Dr Nick Weir for their assistance with assessment of radiation doses and also Dr Cat Graham for her assistance with trial methodology and statistical advice. Finally, I would like to thank Acumed for the financial support, which allowed me to perform this research.

On a personal note, I would like to thank my patient wife Becky and our incredible yet not so patient children, Sam and Lottie. You all provided me with a reality check when I needed it the most. This thesis really was a team effort – thank you!

ABSTRACT

Ankle fractures account for approximately 10% of the acute orthopaedic workload and patients with unstable fracture patterns are typically offered surgery. Soft-tissue complications are unfortunately common and can result in significant morbidity. Consequently, there has been recent interest in minimally invasive treatment approaches, including intramedullary fixation of the fibula and treating well-reduced medial malleolar fractures non-operatively, following fibular stabilisation. This thesis aims to examine both concepts further through a series of retrospective, biomechanical and randomised controlled trial (RCT) investigations.

A prospective database of patients undergoing fibular intramedullary nail fixation of an unstable ankle fracture over an eight-year period was developed. This database was used to report on the outcome of fibular intramedullary nail fixation for these injuries and was also used to compare the outcome of those patients managed with or without medial malleolar fracture fixation after intramedullary fibular stabilisation. The primary short-term outcome was complications, including construct failure requiring revision surgery and medial sided complications. The primary mid-term outcome was the Olerud-Molander Ankle Score (OMAS). To further evaluate the performance of the fibular intramedullary nail against locking plate and interfragmentary screw fixation, a cadaveric biomechanical study was performed using six matched pairs of cadaveric lower limbs (mean age 86.5 years) with simulated AO/OTA 44-B type fractures. The specimens were randomised within each pair and tested to failure using a modification of a previously published protocol. Finally, a prospective RCT was carried out to compare fixation and non-fixation of an associated well reduced medial malleolar fracture (≤2 millimetres) after fibular fracture

stabilisation. The primary outcome measure was the OMAS one-year post randomisation. Secondary outcomes included further validated PROMs, complications, return to function and treatment satisfaction.

For the retrospective study of 342 patients (mean age of 64.6 years; range, 21-96), there were 20 fibular intramedullary nail fixation cases (6%) that required revision surgery for construct failure, and these were reviewed to classify failure according to 'surgeon error' (n=13) or 'device failure' (n=7). Risk factors for failure were identified, including suprasyndesmotic injuries and those constructs with the proximal locking screw (PLS) inserted >20mm above the plafond, which have informed technical refinements to improve patient care. After a mean follow-up of five years, outcome scores were collected from 229 patients, who in general reported a 'good' outcome according to a median OMAS of 80/100. From this database a refined cohort of 247 patients was analysed; 193 (78.1%) had received medial malleolar fracture fixation and 54 (21.9%) had not. Following retrospective review, there was no difference between the groups with respect to fixation failure (p=0.634) or loss of talar reduction (p=0.157). Medial sided soft tissue complications were more frequent following fixation and 10% of patients required surgery to address these. Medial sided radiographic union at the point of discharge was lacking in 16 (29.6%) patients in the non-fixation compared with 22 (11.4%) in the fixation group (p=0.002). The median mid-term OMAS was comparable between the two groups (p=0.885).

In a cadaveric setting, the fibular intramedullary nail and locking plate with interfragmentary screw fixation demonstrated comparable biomechanical properties including torque to failure, stiffness and energy absorbed (all p>0.05). The intramedullary nail failed primarily at the lateral ligament complex and at a greater angle of rotation (p=0.046), but the clinical significance of this latter finding is unclear.

Preliminary results from the prospective RCT are reported from 106 participants randomised to fixation (n=53) or non-fixation (n=53) of an associated well-reduced medial malleolar fracture after fibular stabilisation. The baseline demographics and injury characteristics were comparable (all $p>0.05$). One hundred patients (94.3%) were reviewed one year following surgery. There was no significant difference in the OMAS at any assessment point during the trial (all $p<0.05$) or any of the secondary outcomes at one year, including patients experiencing complications (64.0% vs. 62.0%; p=0.836). Whilst not statistically significant, more patients in the non-fixation group experienced a major complication (18.0% vs. 8.0%; p=0.137). Medial malleolar non-union was evident in three patients (6.0%) in the non-fixation group compared with no patients in the fixation group (p=0.242), and seven patients developed an asymptomatic pseudoarthrosis of the medial malleolus. Multivariate linear regression analysis identified smoking (p=0.006) and medial malleolar non-union (p=0.002) as predictive of a poor outcome according to the OMAS, but treatment group allocation was not (p=0.357).

The findings of this thesis support the use of the fibular intramedullary nail in the management of unstable ankle fractures. The mechanical failure rate, mid-term patient reported outcome and biomechanical properties are encouraging. Non-operative management of medial malleolar fractures as part of unstable fracture patterns is corroborated by both the retrospective and prospective data reported in this thesis. However, the prospective RCT remains under-powered and subsequent reporting of results upon trial completion is required to validate these findings.

LAY SUMMARY

Ankle fractures are common and potentially problematic injuries. In those injuries where the ankle joint is malreduced (not in a good position), patients generally need surgery, but this carries risk. Complications including infection and wound break down can cause long term problems. Some patients require more surgery to remove metalwork if it gets infected or causes irritation, but this carries further risk and does not always guarantee improvement. Consequently, there has been recent interest in minimally invasive treatment approaches to ankle fracture surgery. In these situations, the surgeon may make smaller incisions (cuts) and in some instances, if the bones are well aligned, may not need to insert metalwork into all of the bones that are broken. This may apply particularly to the bone on the inner aspect of the ankle, called the medial malleolus. This thesis aims to investigate these treatment approaches further.

A database of patients who underwent ankle fracture surgery with a fibular intramedullary nail was reviewed. This implant is inserted through small incisions and could be thought of as 'keyhole ankle surgery'. Patients were followed up five years after their surgery to record short-term complications and longer-term progress through the collection of a series of validated patient outcomes. The same database of patients was used to study a smaller group of 54 patients who in addition to a fibular intramedullary nail did not have the inner bone of their ankle (medial malleolus) treated surgically. This patient group was compared against a larger group of patients who received surgery to their medial malleolus, to assess complications and longer-term functional outcome. The fibular intramedullary nail was then tested biomechanically using cadaveric limbs against locking plate fixation, which is another implant that has previously been linked to soft tissue complications. The specimens were randomised within each pair to receive one of the two implants and tested using a previously published protocol. Finally, a randomised controlled trial (RCT) was conducted to recruit eligible patients with ankle fractures to receive either fixation or non-fixation of a well-aligned medial malleolar fracture after fixation of the fibular fracture. Participants were followed up over a one-year period.

Following review of the database of 342 patients, 20 (6%) required further surgery to re-fix the ankle. The majority were due to technical errors made by the surgeon. These cases were examined in detail to allow a greater understanding of the technique and make procedural refinements, in the hope of improving future patient care. The smaller group of 54 patients treated without fixation of the medial malleolar fracture performed equally well to those treated with fixation and had a lower rate of soft tissue complications. However, this study had some limitations including a lack of complete follow-up in some patients. Biomechanically, the fibular intramedullary nail was found to perform comparably to the locking plate. The nail benefits from being inserted through much smaller incisions, which may reduce soft-tissue complication rates clinically. Finally, results from the RCT are reported in the first 100 patients (50 in each group) to complete the one-year follow-up. Unfortunately, the trial was significantly affected by the COVID-19 pandemic but is now nearing completion. Provisional findings would suggest that there is no functional difference between the two groups one year after surgery or at any time point during the trial period.

The findings of this thesis support the use of the fibular intramedullary nail when managing unstable ankle fractures. Further work, including reporting of final results from the RCT contained within this thesis, is required to confirm that treating well-aligned medial malleolar fractures without surgery is beneficial for patients.

ETHICAL APPROVAL

The studies presented in Chapters 3, 5 and 6 were carried out following approval from the South-East Scotland Research Ethics Service (appendix 1 & 2). Whilst the cadaveric biomechanical work presented in Chapter 4 did not require formal ethical approval, the appropriate permissions were granted behalf of the local University anatomy department by Professor Tom Gillingwater.

1. INTRODUCTION AND LITERATURE REVIEW

Material from this chapter has been published in the Bone & Joint Journal (BJJ) in 2019[1], appendix 3 and the Bone & Joint Journal[360] in 2018[2] (appendix 4).

Carter TH, Duckworth AD, White TO. Medial malleolar fractures: current treatment concepts. Bone Joint J. 2019;101-B(5):512-21.

White TO, Carter TH. Ankle fractures: facts and fiction. Bone Joint J 360. 2018;7(4):3-8.

1.1 Introduction

Ankle fractures are the second most common orthopaedic trauma presentation in the United Kingdom (UK), accounting for approximately 10% of the acute workload[3]. In addition to the healthcare costs of managing patients with ankle fractures[4, 5], the impact of these injuries on patient quality of life should not be underestimated[6]. Despite their incidence and the developing experience of ankle fracture management, it is apparent that there are still opportunities for optimisation of patient care. Minimally invasive treatment approaches in the operative management of unstable ankle fractures may offer advantages over traditional practices, through the reduction of complications.

1.1.1 Defining the unstable ankle fracture

For the purpose of this thesis, only ankle fractures deemed unstable and therefore requiring surgical fixation have been included in the studies presented in each chapter. The ankle joint and its associated stability can be thought of as a ring, whereby the bones and ligamentous structures surrounding the ankle contribute to multi-directional stability[7]. If this ring is broken in two or more places, such as a bimalleolar ankle fracture or a lateral malleolar fracture with associated deep deltoid ligament injury, the talus is no longer reduced within the mortise and the injured ankle joint is deemed unstable. With an improved understanding of the biomechanics of the ankle joint and rehabilitation protocols, it is generally accepted that fractures with a single break in the ‘ring of stability’ can be managed non-operatively, often in a weightbearing orthosis[8-10]. These injuries will not be considered in this thesis.

1.2 Anatomy

The ankle joint complex describes the tibiotalar and inferior tibiofibular articulations of the lower limb. It can be divided anatomically by its osseous and soft tissue components.

1.2.1 Osseous anatomy

The ankle joint is an anatomically stable articulation, owing to the bony support and congruency afforded by the distal tibial and fibular articular surfaces which form the mortise (Figure 1.1). The superior, lateral and medial articular surfaces of the talus are tightly bound within the mortise to form the tibiotalar joint; a hinge-type synovial joint which primarily permits dorsiflexion (flexion) and plantarflexion (extension), with a normal range of motion from 13–33° of dorsiflexion to 23–56° of plantarflexion[11]. The distal tibiofibular joint, also referred to as the syndesmosis, is a non-synovial amphiarthrodial joint. Whilst it allows limited movement between the distal fibula and tibia it enables accessory gliding, a movement that is crucial in maintaining the ankle complex mechanics and provides additional structural support to the mortise[12]. The distal bony extensions of the mortise make up the three malleoli, described below.

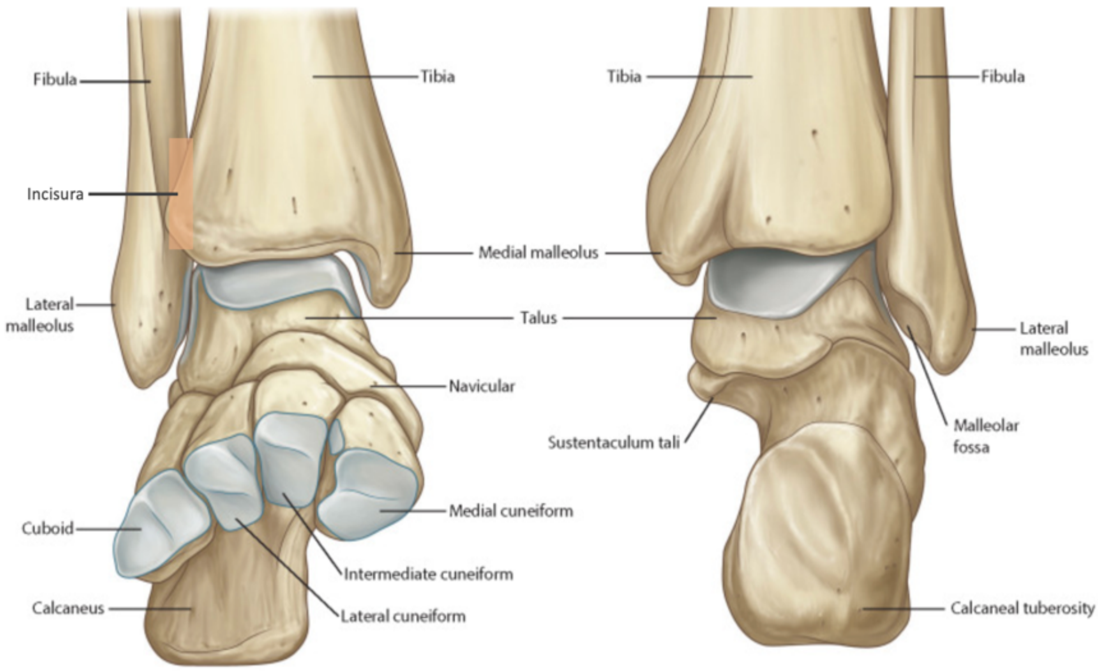

Figure 1.1: Osseous anatomy of the tibiotalar joint. Adapted from: Gray's Atlas of Anatomy. 2nd ed. Elsevier; 2015)[13].

The lateral malleolus is formed by the pyramidal shaped distal fibula and provides a lateral buttress to the tibiotalar joint. The lateral surface is convex and contiguous with the triangular diaphysis. The medial surface is similarly convex and articulates with the concaved lateral process of the talus. The posterior edge of the medial border of the fibula is flattened to allow passage of the peroneal tendons, through the malleolar fossa (Figure 1.1). The distal fibula is roughened along its distal tip, anterior and posterior borders, allowing attachment of the lateral ligament complex described below. The medial malleolus is formed by the pyramidal distal extension of the medial tibia. The detailed clinically relevant anatomy of the medial malleolus was first described in 1979 by Pankovitch and Shivaram[14], and consists of a convex and smooth medial subcutaneous surface and a smooth concaved articular surface, lined with hyaline cartilage (Figure 1.2).

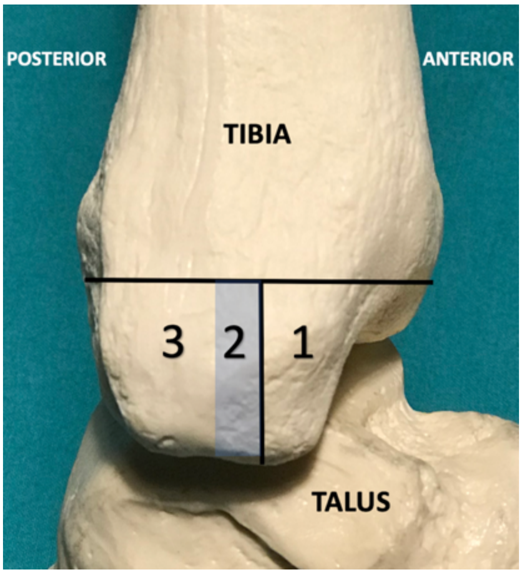

Figure 1.2: Osseous anatomy of the medial malleolus.

The anterior process (zone 1), extending to the very distal tip of the malleolus, also known as the anterior colliculus *(Latin: "mound")* is roughened for the attachment of the anterior fibres of the superficial deltoid ligament (SDL). Posterior to the anterior colliculus and separating it from the posterior colliculus (zone 3), lies the intercollicular groove (zone 2), which provides an attachment site for the deep anterior talotibial component of the deep deltoid ligament (DDL). The posterior colliculus in comparison is broader than the anterior colliculus, although has a smaller articular surface and provides attachment for the remaining components of the DDL. Finally, the tibial plafond terminates as the posterior malleolus and represents a lipped structure, which limits posterior talar translation and serves as an attachment for the posterior inferior tibiofibular ligament (PITFL) and joint capsule.

The talus is the second largest tarsal bone and is unique in two respects. It has no muscular attachments and has a large surface covering of hyaline cartilage (60%). It comprises three distinct articular surfaces as part of the tibiotalar joint, for articulation with the distal tibia, lateral and medial malleoli respectively. It articulates via a series of facets with the navicular and calcaneus.

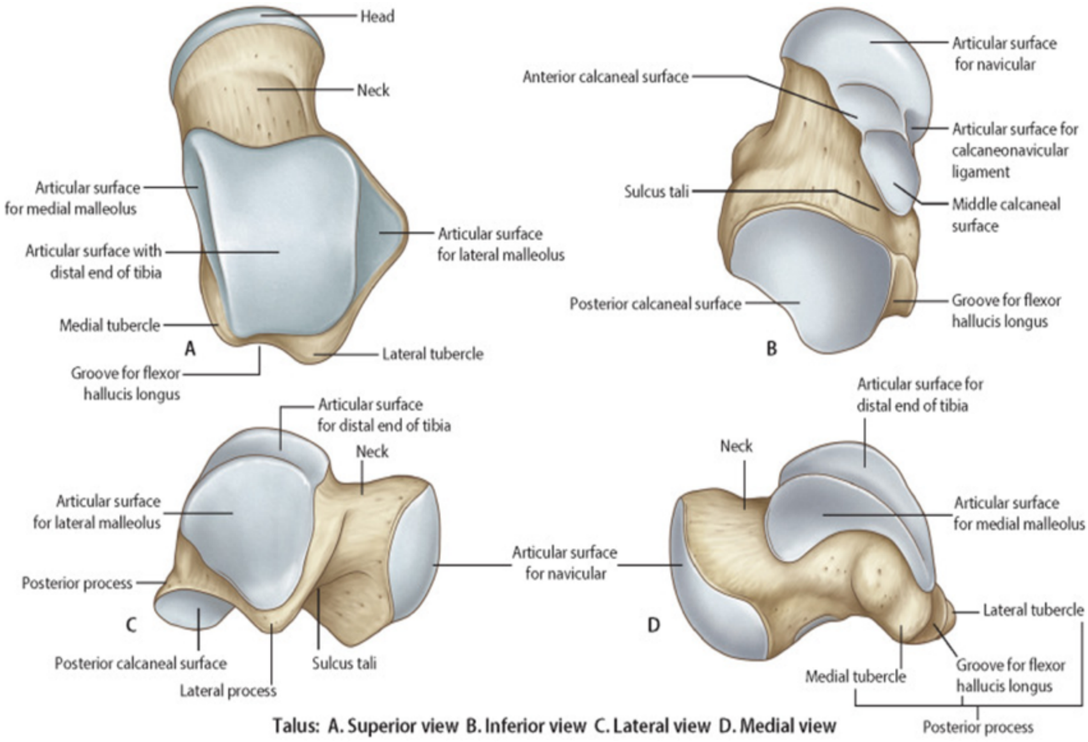

Figure 1.3: Osseous anatomy of the talus. Taken from: Gray's Atlas of Anatomy. 2nd ed. Elsevier; 2015)[13].

1.2.2 Ligamentous anatomy

During physiological loading of the ankle joint, the congruency of the articular surfaces limit talar rotation and translation, thereby affording primary stability[15]. Secondary stability is provided by the joint capsule and ligamentous structures, which are particularly crucial during the dynamic phases of ankle joint motion as the joint is progressively loaded and unloaded. These are broadly divided into two categories:

1. Ligaments of the lateral and medial ankle (Figure 1.4) – the lateral ligament complex comprises three distinct ligaments: the anterior talofibular ligament (ATFL), calcaneofibular ligament (CFL) and posterior talofibular ligament (PTFL). The ATFL is the principal stabilising ligament and resists anterior talar translation relative to the tibia. The CFL originates at the roughened posterior edge of the lateral malleolus and passes posteriorly as a thin, cord-like structure, inserting onto a small tubercle along the lateral calcaneus. The PTFL originates on the medial surfaces of the lateral malleolus and courses posteriorly to attach along the posterior aspect of the talus. The medial deltoid ligament takes origin from the medial malleolus and together with the malleolus is often referred to as the medial malleolus osteoligamentous complex (MMOLC)[16]. The deltoid ligament is anatomically divided into superficial (tibiocalcaneal, tibionavicular & superficial tibiotalar) and deep (anterior & posterior tibiotalar) components.

2. Ligaments of the distal tibiofibular joint – the syndesmosis is tightly bound by a series of four ligaments, comprising the anterior inferior tibiofibular ligament

(AITFL), posterior inferior tibiofibular ligament (PITFL), inferior transverse ligament (ITL) and interosseous ligament (IOL).

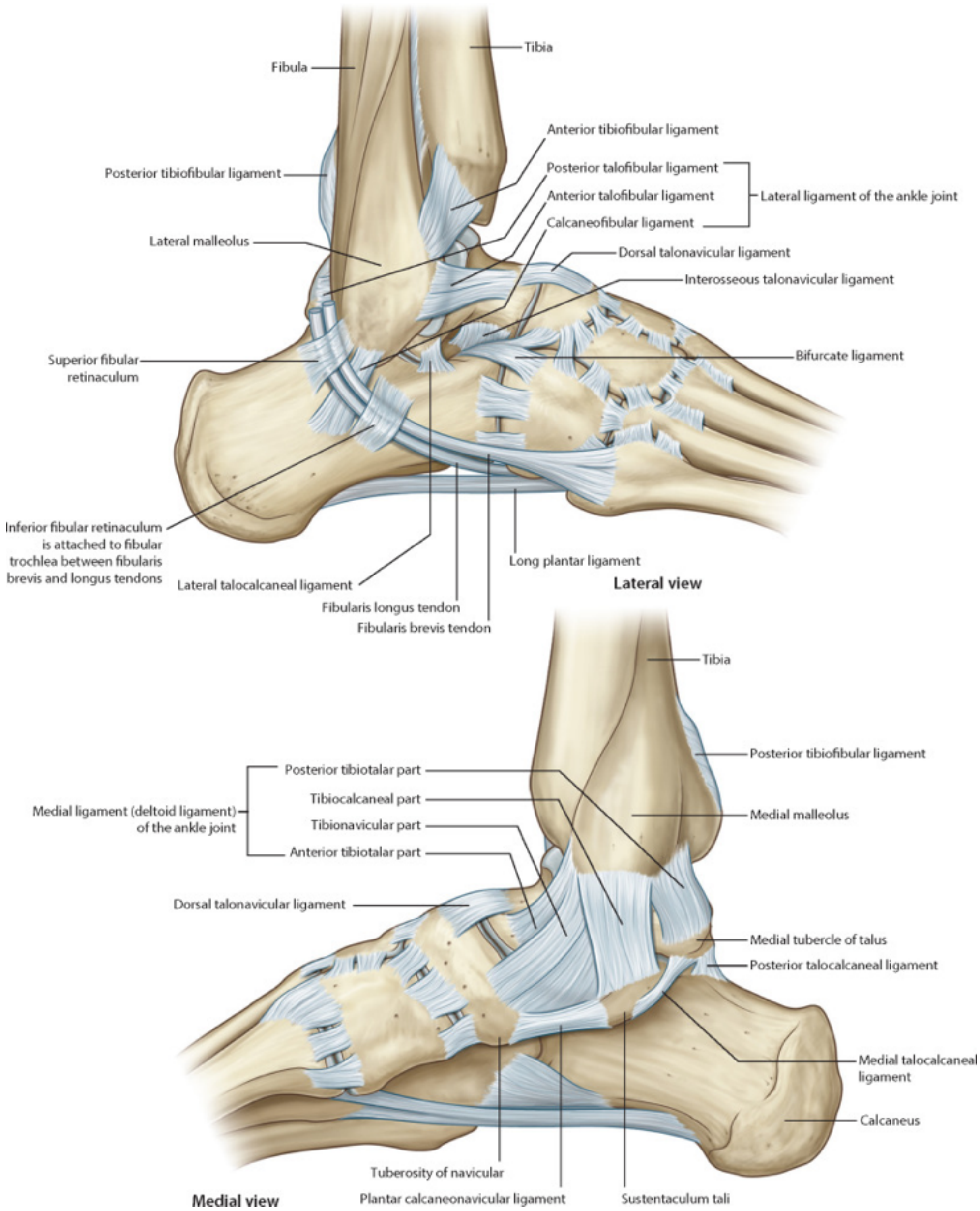

Figure 1.4: Ligamentous structures of the ankle joint. Taken from: Gray's Atlas of Anatomy. 2nd ed. Elsevier; 2015)[13].

1.3 Epidemiology of ankle fractures

Ankle fractures are common, with an annual incidence of 137.7/100,000/year reported in a major Scottish city between 2010 and 2011[17]. More recently in Norway, Elsoe et al included 9,767 patients over a 10-year period and found a mean incidence of 168.7/100,000/year with the overall incidence higher in women (179.5/100,000/year) compared with men (157.1/100,00/year)[18]. In this study, considerably more patients presented during the winter, when the weather conditions were particularly hazardous; this is in keeping with experiences in the UK[19]. Whilst young men and elderly women are particularly at risk[3, 20], traditionally giving rise to a classic bimodal distribution, this pattern now appears to be changing with a predominant bimodal distribution observed in women but a unimodal distribution amongst men with the incidence steadily decreasing with age (Figure 1.5)[18]. A universally observed trend is that of increasing fractures in the elderly, which has risen dramatically over the last 30 years and no doubt will continue to rise with an increasing life expectancy[20, 21]. Despite the predominant low-energy mechanism, elderly patients can present with more significant injuries, including complex and/or open fractures, often associated with significant morbidity. This has led some to re-think ankle fractures as the 'new geriatric hip fracture'[22].

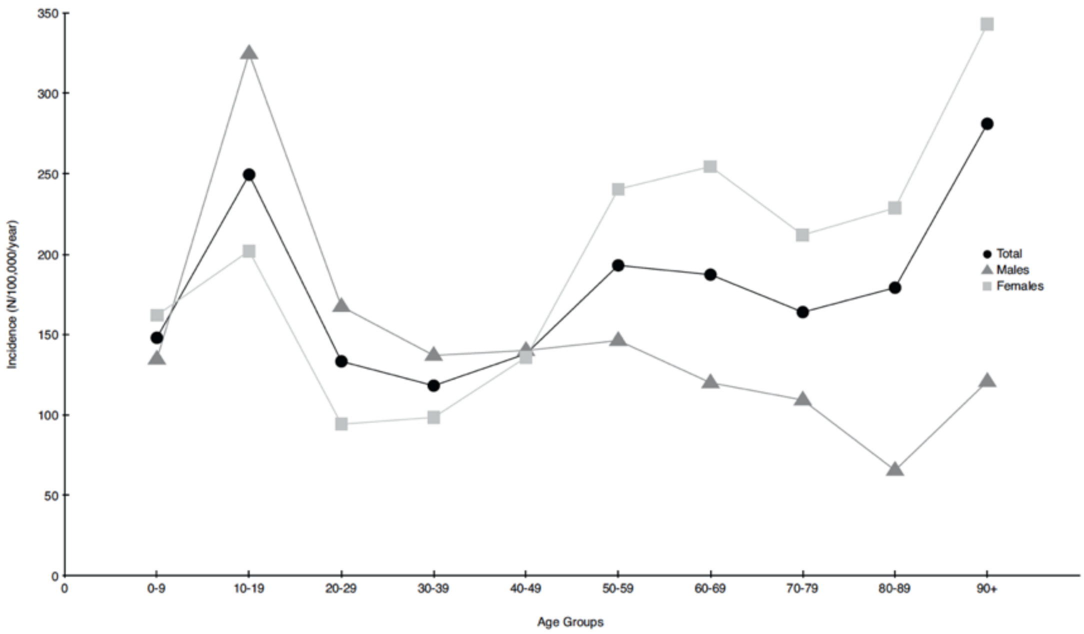

Figure 1.5: The incidence of ankle fractures per sex and age group over time. Taken from: Elsoe et al. Population-based epidemiology of 9767 ankle fractures. Foot Ankle Surg. 2018;24(1);34-9[18].

The three most common mechanisms of injury include simple falls from standing height (60%), sports (20%) and road traffic accidents (5-10%)[18]. Isolated fracture of one malleolus (unimalleolar), principally the lateral malleolus, is by far the most common trauma presentation (60-70%), with bimalleolar (15-20%) and trimalleolar (7-12%) fracture configurations comprising the remaining cases[18, 20, 23]. Approximately 2% of ankle fractures present with an associated open injury[20].

1.4 Assessment and classification of ankle fractures

1.4.1 Clinical assessment

Clinical assessment starts with a focused history and examination in the presenting environment, including questions regarding the mechanism of injury and early recognition of associated injuries. Documentation of relevant comorbidities that are associated with complications following ankle fracture including diabetes mellitus[24-28], peripheral neuropathy[27, 29, 30], peripheral vascular disease[27, 29, 31], steroid medication usage[27], chronic renal impairment[32], alcohol excess[33, 34], and tobacco smoking[24, 34, 35] is critical. Obesity in particular has been shown to be associated with a poor outcome following fixation, including a significantly increased risk of infection[36, 37] and diabetic patients have the highest risk of amputation for the management of a complication following ankle fracture fixation (OR 7.42)[38]. Examination of the skin integrity, circulation and sensation must be performed and clearly documented. Whilst in general, open fractures are associated with high energy injuries in younger patients, open ankle fractures frequently occur in the elderly population; around 12% of patients aged 60 years[39]. These cases classically present as a transverse laceration on the medial side of the ankle, where the delicate skin splits under tension[22]. Fractures of this nature are treated as per local open fracture management policy. In the presence of gross clinical deformity, neurovascular compromise, or threatened skin integrity, it is acceptable to reduce and hold these injuries expediently with a temporary plaster before radiographs are performed.

1.4.2 Imaging

In the absence of concerning clinical features described above, radiographs should be performed before attempting reduction of a fracture-dislocation. Standard anteroposterior (AP) and lateral radiographs centred on the ankle joint are recommended (Figure 1.6). In the presence of proximal fibular tenderness, radiographs of the knee must be obtained. If the adequacy of talar reduction is uncertain, a mortise view should be performed.

Figure 1.6: Standard AP and lateral radiographs of the elbow demonstrating a trimalleolar ankle fracture with talar shift.

Radiographs in the current plaster or splint should be taken to confirm talar reduction (Figure 1.7) before the patient is either transferred from the Emergency Department (ED) for ongoing Orthopaedic management or discharged home.

Malreduced ankle fractures are at risk of significant post-injury swelling, skin compromise and ongoing chondral injury, which must be identified and rectified early.

Figure 1.7: Post-manipulation radiographs demonstrating adequate talar reduction.

The neurovascular status must be assessed and documented following reduction. As discussed at the start of this thesis, initial radiographs may confirm a stable fracture configuration, with no evidence of talar shift. These injuries are routinely placed into a removable orthosis and allowed to weight bear as tolerated, with early outpatient review[8-10, 40]. Stress views (both manual and gravity assisted) have historically over-diagnosed instability resulting in a high false positive rate[41, 42] and are often poorly tolerated by patients; they are rarely used today in the UK to assess stability.

For more complex fracture patterns, including fractures of the posterior malleolus, computed tomography (CT) imaging of the ankle joint is recommended by some authors[43-45], with some demonstrating a change in management plan in approximately a quarter of cases (23%)[45]. CT imaging has been recommended for other clinical situations including syndesmotic injuries, plafond impaction, distal tibial proximal fracture extension and transitional ankle fractures in the adolescent population[46]. MRI has been used in experimental settings, largely aimed at assessing the integrity of the deltoid ligament and/or syndesmosis[47, 48], but due to cost and availability is not routinely used in clinical practice.

1.4.3 Classification systems

There have been numerous classifications of ankle fractures described. The first, by Percival Pott in 1758[49] simplifies the injury based on the number of malleoli involved: unimalleolar, bimalleolar or trimalleolar. Despite its simplicity, this system is commonly used in clinical practice due to its reproducibility amongst both junior and senior clinicians, although fails to differentiate between stable and unstable injuries. Danis and Weber later proposed their classification of fibular fractures based on the fracture location in relation to the distal tibiofibular joint[50]. Although this classification concentrates solely on the lateral malleolus, it does provide some guidance on fracture stability, with Weber-C (suprasyndesmotic) fractures in general being classified as unstable[50, 51].

AO/OTA classification

This classification system is used both in clinical practice and as a research tool[52]. To summarise, it numerically denotes the ankle joint and its corresponding malleoli as '44'. The level of the fracture in relation to the syndesmosis, as previously described in the Danis-Weber system[50], is recognised as A (infrasyndesmotic), B (transyndesmostic) or C (suprasyndesmotic). Further subsets describe the presence or absence of medial or posterior malleolar fractures and are given a number between 1 and 3 (Figure 1.8).

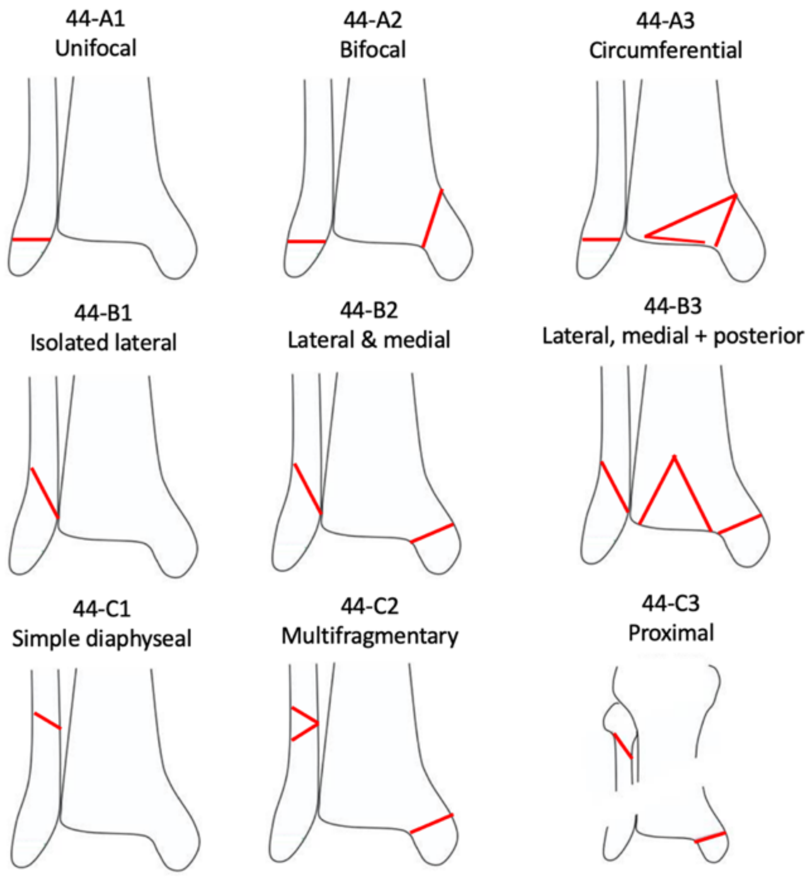

Figure 1.8: AO/OTA classification of ankle fractures[52].

Rodriguez et al performed a unique study, analysing videos from a social media platform of individuals sustaining potential ankle fractures[53], and found the AO/OTA system to more consistently predict fracture morphology (81%), compared with the Lauge-Hansen (65%) when studying 30 videos of injury and 26 cases of confirmed ankle injury[53]. Juto et al randomly selected 152 ankle fractures registered in the Swedish Fracture Register and assessed the inter-observer and intra-observer reliability of the AO/OTA system[54], noting a substantial agreement (0.6-0.8) in both instances according to the Cohen's kappa statistic. In a revised version of this system in 2018[55], more details regarding fracture morphology and/or ligamentous instability based on radiographic subluxation have been included.

Lauge-Hansen classification

This classification has become one of the most widely used systems and was created to guide the closed reduction of ankle fractures[56]. It describes firstly, the position of the foot at the time of injury (supination or pronation) and then secondly, the direction of the deforming force (abduction, adduction or external rotation). Thirteen possible fracture combinations were proposed from their work involving cadaveric tibiae (Table 1.1). Despite its popularity, this classification system has some limitations. Gardner et al evaluated its accuracy using MRI scans of patients with ankle fractures and found that 53% of fractures that were classifiable with the Lauge-Hansen system demonstrated patterns of ligamentous injury and fracture patterns that did not coincide with the described stages[57]. Kwon et al performed a study similar to that conducted by Rodriguez et al[53], analysing videos from a social media platform of individuals sustaining potential ankle fractures[58]. When matched against the confirmed fractures radiographically, the Lauge-Hansen system was only 58% accurate in predicting the fracture pattern based on the mechanism of injury. Others have found that the system may reliably predict injury to the syndesmosis with a sensitivity and specificity of 92% in both instances[59]. Despite limitations, it continues to be widely adopted in both the literature and clinical practice, as it frequently informs the type of treatment, including surgery, that is required.

Category	**Structures injured**
Supination external rotation (SER)	
- Stage I	Rupture of anterior inferior tibiofibular ligament
- Stage II	Oblique / spiral fracture of the distal fibula
- Stage III	Posterior inferior tibiofibular ligament / posterior malleolus avulsion
- Stage IV	Medial malleolus fracture / deltoid ligament rupture
Supination adduction (SAD)	
- Stage I	Transverse distal fibula fracture
- Stage II	Vertical fracture of the medial malleolus
Pronation external rotation (PER)	
- Stage I	Medial malleolus fracture / deltoid ligament rupture
- Stage II	Rupture of anterior inferior tibiofibular ligament
- Stage III	Oblique or spiral supra-syndesmostic fibula fracture
- Stage IV	Posterior inferior tibiofibular ligament / posterior malleolus avulsion
Pronation abduction (PAB)	
- Stage I	Medial malleolus fracture / deltoid ligament rupture
- Stage II	Rupture of anterior inferior tibiofibular ligament
- Stage III	Transverse or comminuted supra-syndesmostic fibula fracture

Table 1.1: The Lauge-Hansen classification of ankle fractures[56].

Medial malleolar fractures

Herscovici et al proposed their fracture classification for isolated fractures of the medial malleolus[60], based on a modification of the system proposed by Muller et al[61] and the previous work of Pankovich and Shivaram[14, 62]. The system simplifies fractures into four types based on the AP radiograph (Figure 1.9); type-A avulsion fractures of the medial malleolar tip, type-B fractures occurring between the tip and the level of the plafond, type-C fractures occurring at the level of the plafond and type-D fractures extending in a vertical direction from the medial corner of the plafond.

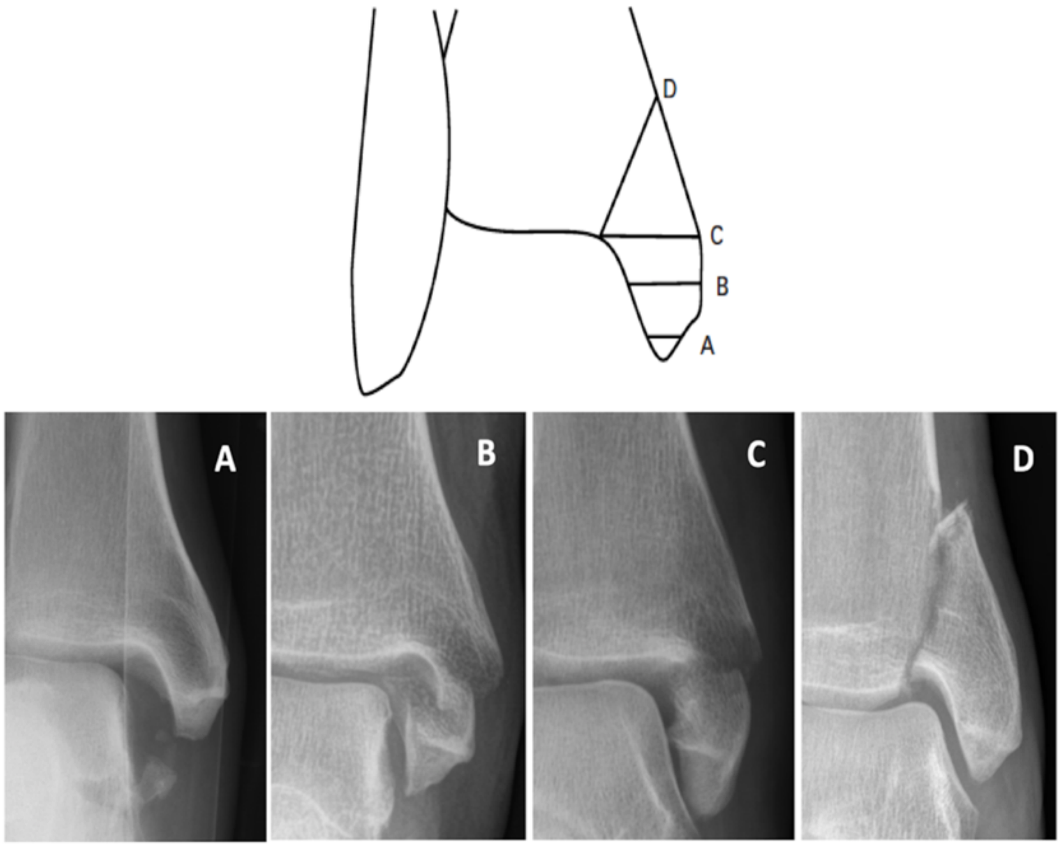

Figure 1.9: Herscovici classification of medial malleolar fractures with radiographic examples[60].

The main drawback of the classification is the utilisation of a single view radiograph (AP), when the medial malleolus is a 3-dimensional structure. The system recently underwent assessment for inter-observer reliability, intra-observer reproducibility and accuracy of diagnosis in a study by Aitken et al[63]. This study concluded that the classification was substantially reproducible (k = 0.64) but only moderately reliable (k = 0.54). Type-C fractures at the level of the tibial plafond were the most difficult to identify accurately amongst a group of suitably qualified observers. Additionally, 18% of fractures (out of a total cohort of 130 radiographs), were unclassifiable based on the current system. Despite these limitations, the system is the most utilised for classification of medial malleolar fractures to date.

Posterior malleolar fractures

The accuracy of posterior malleolar fracture fragment size measurement on the lateral radiograph has been fiercely contended[64, 65]. With the modern accessibility of non-contrast CT imaging, pre-operative scanning of ankle fractures has enabled to the development of classifications systems. The most widely used is the Haraguchi classification following a study of axial CT scans in 57 consecutive patients presenting with unstable ankle fractures[66]. Three types were described: type-1 wedge shaped fracture fragment involving the posterolateral corner of the plafond, type-2 transverse medial extension into the medial malleolus and type-3 small shell fracture of the posterior lip of the plafond. Whilst previously thought to be uncommon, a large fragment extending into the medial malleolus (type-2) was seen in almost 20% of cases, leaving the authors to conclude that CT scanning should be recommended for all injuries with a posterior malleolar fracture. Current work by Blom et al concluded that type 2 fractures were associated with a poorer clinical outcome according to the Foot and Ankle Outcome Score (FAOS) on multivariate analysis[67]. The Haraguchi classification system has been recently modified by Mason et al[44], to include an additional injury type, the posterior pilon. This modified system is becoming increasingly popular within the surgical literature[43, 68, 69].

1.5 Outcomes following operative management

It is recognised that patients undergoing surgical fixation of unstable ankle fractures do not universally return to their pre-injury baseline. Following surgery, recovery continues over a 12 month period[70] and at the end of this, approximately 60% of patients report ongoing pain and/or functional limitation as measured by validated patient reported outcome measures (PROMs)[71, 72]. Patients who experience significant complications following surgery invariably have poorer outcomes[73].

To identify areas for future research, it is important to understand the complications associated with the operative management of unstable ankle fractures. Complication rates of 40% are not uncommon in the published literature[29, 73, 74], ranging from mild metalwork associated pain/discomfort to significant deep peri-prosthetic infection requiring amputation. A significant proportion of complications are soft tissue in nature and future research should be aimed at reducing these rates.

1.5.1 Infection and wound healing

Infection is one of the most feared complications following ankle fracture fixation, due to the potential sequalae of sepsis control surgery (repeat debridement), long-term antibiotics, risk of construct failure, non-union and unfortunately in a small number of patients, amputation[24]. The development of infection is associated with a negative functional outcome and patient satisfaction[75, 76]. SooHoo et al conducted a large population based study including 57,183 patients undergoing surgical fixation post-ankle fracture over a 10-year period[31]. The overall post-operative wound infection rate, recorded from patients readmitted to hospital with infection was 1.44%, increasing to

4.57% in open fractures, 7.71% in complicated diabetes mellitus and 6.87% in patients with peripheral vascular disease. They found no difference in infection rates between fracture classification or institution (high volume vs. low volume). The overall low rate of 1.44% likely underestimates the true incidence of infection, as the authors only included patients readmitted and will not have captured infections diagnosed in the community or remote clinics.

Sun et al included 1,510 patients in a multi-centre study and found an overall inpatient diagnosed infection rate of 4.37% with a deep infection rate of 1.32% and superficial infection rate of 3.05%[37]. They defined a surgical site infection according to national guidelines, including a combination of clinical signs and bacterial culture results. Following multivariate analysis, significant risk factors for infection included older age, greater body mass index (BMI), high-energy injury, open injury, chronic heart disease, history of medical allergies and greater surgeon experience. This final risk factor was likely confounded by the fact that senior surgeons operated on the most complex fracture patterns. Unlike other authors[24, 25, 28, 34, 77], they did not find an association between infection and diabetes mellitus. Ovaska et al conducted a case-control study including 1,923 surgically managed ankle fractures over a four-year period and found an overall infection rate of 13.9% based on clinical signs and symptoms of surgical site infection[34]. Deep infection was diagnosed in 131 patients (6.8%). A single pathogenic organism was cultured in 67% of cases and the remaining 33% were polymicrobial. On univariate analysis, diabetes mellitus was found to be strongly associated with increased deep infection risk. Following multivariate analysis, increased risk of deep surgical site infection was associated with tobacco use, duration of surgery >90 minutes and application of a post-operative plaster outside the operating theatre. Schade et al reviewed early post-operative infections following ankle fixation (within 30 days of surgery)[25]. Significant risk factors for infection included diabetes (both insulin and non-insulin dependent), American Society of Anaesthesiologists (ASA) grade 3 or above and surgery in an inpatient setting (compared with outpatient/day surgery). These large studies provide robust data regarding the overall incidence of short-term infection requiring readmission to hospital but may have missed some infections presenting at outpatient follow up. Miller et al followed up 478 patients over an eight-year period in the outpatient setting[78]. They reported an infection rate of 3.2%, following a strict peri-operative protocol including delayed surgery until resolution of all blisters, five days of post-operative antibiotics and a minimum of six weeks non-weightbearing for all patients. Whilst the infection rate was low, the management protocol may be deemed somewhat unpractical for patients and in fact enforcement of weightbearing restrictions for all patients may have deleterious effects[79-81].

Infection and wound healing difficulties continue to present management challenges and future research should explore treatment approaches that aim to minimise these complications.

1.5.2 Symptomatic metalwork

Pain overlying metalwork following ankle fixation is unfortunately common, occurring in up to 1/3 of patients[73, 82] and many individuals request elective removal. Yet despite re-operation, up to 50% will notice no improvement in symptoms[82, 83]. Whilst it has not been possible to guarantee improvement in pain levels following removal, some authors have demonstrated functional benefit. Williams et al identified an improvement in the Short Musculoskeletal Functional Assessment (SMFA) score six months after elective removal in a cohort of 43 patients[84], although the clinical significance of this small improvement is debatable. Overall, 121 patients were approached and 78 failed to respond, which may represent significant responder bias. Sanders et al evaluated functional improvement in 179 patients undergoing implant removal below the level of the knee, including the ankle joint[85]. Whilst a statistically significant improvement in the Lower Extremity Function Scale (LEFS) was detected, the difference fell three points short of the minimum clinically important difference (MCID) and 31 patients (17.3%) experienced a post-operative surgical site infection. Additional risks, including infection, neurovascular injury, broken/retained implants and hypertrophic scarring have been reported following elective removal[83, 86, 87]. Reith et al specifically investigated patient satisfaction following elective metalwork removal in several clinical situations including post-ankle fracture fixation[87]. The overall patient reported complication rate in 332 patients was 10%, with the majority of these related to impaired wound healing. Despite this complication profile, overall patient satisfaction was high with 96% of patients stating they would choose implant removal again, especially if pain was the primary indication. The results of this study must be cautiously interpreted due to the high ‘drop-out’ rate of 36% of patients in the initial 565 cohort.

The economic burden of metalwork removal must be considered. Whilst metalwork removal following fracture fixation often used to be routine[88], the incidence following ankle fracture fixation now appears to be reducing[89]. Given current healthcare financial constraints, surgeons must counsel patients regarding the realistic result of metalwork removal and potential complications. Reducing the amount of metalwork implanted into the ankle at the time of fracture fixation has perceivable benefits if a comparable post-operative outcome is achievable.

1.5.3 Neurological injury

Neurological injury is reported following treatment of ankle fractures. When exposing the fibula through a lateral surgical approach, the superficial peroneal nerve (SPN), sural nerve (SN) and their respective branches are at risk of iatrogenic injury[90, 91]. The posterolateral approach, also used to access posterior malleolar fractures has also shown to place the SN at risk along the entire length of exposure[92]. Redfern et al performed a cross-sectional retrospective study investigating the rate of symptomatic SPN injury following both operative (n=56) and non-operative treatment (n=64) at a mean follow-up of two years[93]. In those patients undergoing ORIF surgery, 21% had ongoing pain, which was felt to be attributable to a SPN injury when examined clinically, compared with 9% in the non-operative group. Whilst SPN trauma at the time of injury could be expected to occur in both groups, iatrogenic injury during surgery likely explains the higher rate in the operative group. Given the anatomical course of the saphenous nerve and its two branches, a cadaveric study by Mercer et al recommended placing incisions around the medial malleolus as close to the malleolar tip as possible when fixing medial malleolar fractures in order to reduce the risk of nerve injury and painful neuroma formation[94]. Neuropathic pain secondary to ankle fracture fixation has been reported in up to 23% of patients following surgery and can result in significantly impaired health-related quality of life[95].

1.5.4 Post-traumatic osteoarthritis

In stark comparison to the hip and knee joints, up to 80% of osteoarthritis affecting the ankle is post-traumatic in origin (PTOA)[96-98]. Injuries including intra-articular fractures and high-grade ankle sprains result in pathological changes to articular congruity and subsequent joint malalignment, which stimulate degenerative processes and have shown to result in inferior patient outcome following fracture[99]. Furthermore, the initial chondral damage at the time of acute injury is felt to play a role in the development[99, 100]. Takakura et al included 18 patients with primary varus osteoarthritis treated with a distal opening wedge osteotomy and described one of the most common classification systems used today[101]. Takakura's classification is limited by its description of patients only with varus OA. A modification of the Kellgren and Lawrence classification system by Holzer et al, has been described in the more contemporary literature[102]. Lubbeke et al identified specific risk factors for the development of PTOA following internal fixation of unstable ankle fractures over an 18 year follow up period[103]. Advanced radiographic changes (Kellgren and Lawrence grades 3 and 4) developed in 36% of patients with specific risk factors including a Weber C fracture, presence of a medial malleolar fracture, age >30 years at the time of injury, BMI ≥25kg/m^2 and increasing duration of follow up following surgery (>20 years). Patients with ≥3 risk factors had a 60-70% probability of developing PTOA and the results of this study can be used to inform patients regarding their risk of future degeneration. However as with all longer-term studies there was a significant loss to follow up (34%), which makes examining outcomes in patients who develop PTOA following ankle fracture difficult.

1.5.5 Non-union

The FDA define a non-union as a fracture that persists at a minimum of nine months, without progression in the preceding three months. Whilst this encompasses all fractures, most, including malleolar fractures should unite before this and usually by six months. More pragmatically, fracture union can be defined clinically by the absence of motion and pain at the fracture site and radiographically by the presence of bridging callus in at least three of four cortices on orthogonal views. Interpretation of radiographic fracture union of the malleoli is difficult with plain XR, and CT can be used if there are clinical concerns. In this context, a general approach according to Frölke et al[104], defines a non-union as localised pain with either hypertrophic or atrophic radiographic changes, and a pseudoarthrosis as having similar radiographic appearances as non-union but without localised pain.

Malleolar non-union is uncommon following operative management but has a higher incidence in those injuries treated conservatively. Early work published by Mendelsohn et al in 1965 suggested that non-union of the medial malleolus (7%) was more common than that of the lateral malleolus (1%), following closed fracture management[105]. From their clinical series of 253 ankle fractures they concluded that non-union of the medial malleolus, although more common, was associated with far less pain and disability compared with the lateral equivalent, due to the development of a fibrous non-union. A more recent meta-analysis of aseptic fibular non-unions was performed by Bhadra et al[106]. Of the twelve studies included with an age range of 10-72 years, they found an overall incidence of fibular non-union of up to 5.4% (119 non-unions). Non-union was diagnosed in 80% of the cases based on persistent localised pain in the absence of radiographic union by 24 weeks post-injury. The authors also included studies with fractures managed conservatively both in isolation and in the presence of a tibial fracture treated with intramedullary nailing, which over-estimates the true incidence of non-union in isolated surgically treated ankle fractures. With these fractures excluded, the re-calculated incidence of fibular non-union in rotational ankle fractures was stated as 1%, with the distal fibula being the most common site (87%), due to exposure to shear, torsion, rotation, and compression forces in this region, permitted at the distal tibiofibular joint.

Medial malleolar non-union was first studied in detail by Banks et al in 1949[107], who concluded that non-union of the medial malleolus was not associated with inferior outcomes as long as the non-union was of a 'strong fibrous' composition and the tibiotalar alignment had been anatomically restored. Indications for intervention included significant ongoing localised pain, radiographic ankle instability and persistent tibialis posterior tenosynovitis. Malleolar non-union can be surgically managed using unicortical cancellous lag screw fixation with or without bone graft[108], bicortical screw stabilisation with autologous tibial bone grafting[109] tension-band wire (TBW) with or without bone graft[110, 111], or direct fragment excision[108]. The authors of these studies report good-excellent patient outcome with no further complications and union between four and seven months following non-union surgery. Functional outcomes and range of motion were comparable to patients receiving surgery for acute ankle fracture fixation[108].

1.6 Conservative management of unstable ankle fractures

The chapters contained within this thesis report on the operative management of unstable ankle fractures. Whilst is it generally accepted that in this clinical situation patient outcome is improved with operative intervention, there has been recent interest in conservative management, which should be acknowledged. Sanders at al conducted a small (n=81) multicentre randomised controlled trial comparing conservative and operative management of unstable isolated fibula fractures (SER4)[112]. They found no difference in functional outcome but did detect a higher rate of delayed union/non-union and ongoing displacement in those patients managed conservatively in cast. Willet at al conducted the Ankle Injury Management (AIM) trial across 24 sites[5], which compared close-contact casting (CCC) with internal fixation in 620 patients over the age of 60 years. With a 96% follow-up rate, the authors reported equivalent patient outcome at six months according to the OMAS. However, 23% of CCC patients required either further manipulation (n=10, 4%) or delayed internal fixation (n=52, 19%). A further 15% of patients went on to radiographic malunion. In the operative arm, 11% of patients experienced a wound related complication and 1% underwent further surgery to manage a soft-tissue complication. Whilst the authors suggested CCC is as effective as internal fixation, the study has been criticised due to the unpredictable nature of CCC in maintaining talar reduction[113, 114]. A subsequent mid-term follow up study reported the overall reoperation rate was twice as high in the CCC group compared with the internal fixation (31% vs. 16%)[115]. A recent systematic review and meta-analysis by Larsen et al concluded that for ankle fractures that do not demonstrate initial talar instability or in cases where the talus can be reduced and controlled by closed techniques, patient outcome was comparable to operative intervention[116]. The eight studies contained demonstrated considerable heterogeneity in terms of the included fracture patterns, patients, methodological quality and duration of follow-up, which must be acknowledged. Reducing the number of incisions around the ankle intuitively aims to reduce the soft tissue complication rate. However, an entirely conservative approach has resulted in sub-optimal outcomes primarily related to talar malreduction[5], which may impact on longer-term PTOA rates. With this in mind, research into the selective fixation of individual components of the acute ankle fracture represents an important area of future investigation. This approach to management may satisfy the ultimate goal of ankle fracture treatment; stable anatomical reduction with minimal incisions and early mobilisation[114].

1.7 Current treatment concepts in ankle fracture fixation

There are a range of strategies to consider when surgically managing unstable ankle fractures; the selection of which is typically determined by fracture pattern, bone quality, condition of the soft-tissue envelope, and surgeon experience. In order to highlight present-day practice and identify potential research areas, current treatment concepts are outlined below, including those techniques and implants that aim to reduce soft-tissue complications. These have been divided anatomically for clarity.

1.7.1 Lateral malleolus fixation

The fibula is considered by many as the key stabiliser of the ankle joint, following the combined biomechanical and clinical work of Yablon et al[117]. The current gold standard for fracture fixation is open reduction internal reduction (ORIF), with plates and screws. This treatment approach is unfortunately associated with high soft tissue complication rates as described earlier in this chapter. This has led to an awareness of percutaneous techniques, such as minimally invasive plate osteosynthesis (MIPO)[118-120] and intramedullary stabilisation[121-126].

Plate fixation

Traditionally, distal fibula fractures have been treated with plate fixation, commonly placed laterally, and supplemented with an interfragmentary lag screw or posterolateral as an anti-glide plate[127, 128]. Posterolateral plating has been shown to provide extra stability in elderly osteoporotic bone[137] and reduce soft tissue complications including requirement for metalwork removal[128, 129]. Previous concerns regarding peroneal tendon irritation[130], is less of an issue that previously thought[131]. Fixation challenges presented by osteoporotic patients have encouraged the use of locking plates[39, 132, 133]. Cadaveric biomechanical studies have demonstrated superior failure properties of locking plates with respect to torque to failure, angle at failure and maximal torque, that is independent of bone mineral density (BMD), compared with non-locking alternatives[134]. Others have not been able to corroborate similar findings when assessing differences in both bending and torsional stiffness in cadaveric fibulae fixed with locking and non-locking constructs[135-137], or in simulated comminuted suprasyndesmotic injury patterns[138]. Despite potential clinical advantages, some authors have found justification of the six-fold cost difference compared with semitubular plating (£674 vs. £105) difficult[139]. Tsukada et al performed a small prospective randomised controlled trial comparing locking plate (n=22) and non-locking plate (n=26) fixation for AO/OTA 44B type fractures over a 12 month follow up period[140]. They found no difference in clinical outcomes including fracture union, functional outcome or complications including infection and metalwork irritation. Similar findings have been reported when using low-profile locking plates[141, 142]. Some have reported unacceptably high rate of soft tissue complications following locking plate fixation[85], including three times higher wound complication rate (17.5% vs. 5.5%) and significant increase in major complications including further surgery to remove metalwork. One solution to the high soft tissue complication rate described is the MIPO technique, which has demonstrated positive outcomes in small retrospective series[118, 119]. However, ongoing concerns regarding infection (9%) and wound dehiscence (25%) have been reported by Bazarov et al[120] and anatomical studies have demonstrated risk of superficial peroneal nerve entanglement[143].

Plate fixation in high-risk patient groups, include the elderly, diabetics and those with neuropathy has been associated with high complication rates including loss of talar reduction, requirement for revision and amputation[77, 132]. In these situations, the insertion of multiple screws across the syndesmosis 'tibial-pro-fibular' has been recommended to achieve superior screw purchase. Whilst this technique is supported by biomechanical[144] and clinical data[145, 146], it still requires an extensive open approach, and with this the attendant soft-tissue complication profile. Alternatives to plate fixation, including intramedullary stabilisation may offer potential solutions.

Intramedullary stabilisation

Intramedullary fixation confers several benefits: firstly, the intramedullary nature of the implant offers biomechanical advantages through its load-sharing property, which may allow patients to mobilise earlier. Secondly, the implants are inserted percutaneously, with reduced insult to the overlying soft-tissue envelope. Intramedullary fixation of the fibula has historically been performed with a variety of implants including rods, single screws and unlocked nails[147-150]. Pritchett et al conducted the first randomised controlled trial comparing Rush rod fixation with AO plating of distal fibular fractures in two groups of elderly patients (n=25 per group)[150], reporting improved functional outcome in the intramedullary group, with less operative morbidity. Similarly, single screw fixation has previously been studied positively in both biomechanical[147] and clinical[151, 152] settings, with the benefits of reduced incision morbidity and cost. The development of surgical techniques and implants has advanced significantly over the last decade. Ramasamy et al analysed a small cohort of nine elderly patients managed with the Stainless Steel Taper (SST) nail (Biomet, Swansea, UK) and reported good-excellent outcomes in the majority of patients, with only one patient requiring further intervention (ankle arthrodesis)[153]. Rajeev at al reported their experience with the same SST nail in a group of 24 patients[154]. Whilst the authors reported a low complication rate, the mean OMAS was only 57, indicating that most patients experienced a poor functional outcome following surgery. Asloum et al published their experience with the Epifisa Nail (FH Orthopaedics Inc, New York, USA) in a prospective randomised controlled trial comparing the intramedullary nail with standard plate fixation[155]. Sixty patients were followed up over a one-year period and those patients in the nail group reported significantly better outcomes according to the OMAS and Kitaoka score, with less soft tissue complications. One drawback of this study was the high rate of cross-over from nail to plate fixation (seven patients) as the single-size Epifisa nail was too bulky for a narrow fibula to accept in some patients. The Acumed fibular intramedullary nail (Acumed, Hillsboro, Oregon, USA) was introduced to overcome some limitations of previous implants, by improving modularity and allowing trans-syndesmotic stabilisation. The fibular nail is supported by retrospective cohort studies[121-125, 156-159], biomechanical work[160, 161] and prospective randomised clinical trials[162, 163]. Whilst the increasing number of publications concerning the fibular nail represents a possible enthusiasm for the implant, the studies to date comprise small patient numbers (16-105 patients)[121-126] with limited short term follow-up (≤12 months)[121, 122, 155, 156, 158, 162, 164] and whilst they report improvements in soft tissue complications compared with plate fixation, they generally do not discuss or describe potential modes of treatment failure. This is an important component during the development of both new techniques and implants, that warrants further research.

Alternative fixation techniques

Lag screw only fixation has been investigated in both biomechanical[165] and clinical studies[166, 167]. Misaghi et al created fibula osteotomies in 40 sawbone models and assigned four groups of fixation technique: single lag screw, double lag screw, triple lag screw and a single lag screw combined with a 1/3 tubular neutralisation plate[165]. Double and triple lag screw fixation demonstrated similar biomechanical properties to lag screw and plate fixation, with no difference in torque to failure. Supporting evidence from two small clinical studies including 25[166] and 47[167] patients respectively demonstrated reduced soft tissue infection rates and metalwork related complications (5%) compared with lag screw and plate fixation (50%), when using a minimum of two lag screws in isolation. However, this technique relies on good bone quality with no comminution to enable satisfactory screw purchase, and a long oblique/spiral fracture pattern to permit multiple lag screw fixation, which limits its everyday applicability.

1.7.2 Medial malleolus fixation

Traditionally, the medial malleolus was considered to be the primary bony stabiliser of the ankle joint in an unstable fracture pattern[168], but was later challenged by the work of Yablon et al[117]. Herscovici et al recommended that isolated medial malleolar fractures could be safely treated non-operatively in a short-leg, non-weight bearing cast, with excellent functional and patient reported outcomes, regardless of initial fracture displacement from their series of 57 patients[60]. However more recently, displaced (≥2mm) isolated fractures[169] and/or those associated with a more unstable pattern such as bimalleolar fractures are generally managed operatively, commonly with either screw fixation, tension band wire construct or modern implants designs.

Screw fixation

Various types, diameters, lengths and configurations of screw fixation have been proposed. Traditional teaching by the AO group recommends two 4.0mm partially threaded cancellous screws inserted parallel and supplemented with washers in the case of porotic bone. In the majority of cases a 35–45mm screw is selected for fixation as longer than this risks bypassing the best quality cancellous bone for thread purchase[170]. In the relatively common clinical scenario of poor bone quality with inadequate purchase in metaphyseal bone, fully threaded cortical screws, engaging the far (lateral) cortex of the tibia have been described, with supportive clinical and biomechanical results[171-175]. A recent systematic review of the literature by Yammine et al has supported the use of fully threaded cortical (both unicortical and bicortical) over partially threaded screws due to shorter union times and lower rates of secondary intervention for metalwork removal[176]. Where cancellous lag screws are used, there is cadaveric biomechanical evidence to suggest that fully threaded cancellous screws generate more fracture site compression than partially threaded cancellous screws[177].

As elective removal of symptomatic metalwork following fracture fixation remains an issue[73, 82, 83] and the insertion of implants, including screws can cause iatrogenic injury to local structures[178, 179], approaches to inserting less metalwork around the ankle remains an area of active interest. Buckley et al have challenged the concept of double screw fixation for all medial malleolar fractures[180], in a RCT comparing single screw (SS) with double screw (DS) fixation in unstable fracture patterns. They reported no difference in the primary outcome measure (Short Form Survey-36 questionnaire) or secondary outcomes including failure of fixation, operating time, length of hospital stay or complications between the two groups. The most striking finding was that 14 patients in the DS group crossed over into the SS group intraoperatively as the surgeon felt that the fragment was too small to safely fix with two screws. Mandel et al supported this concept with their large retrospective study of 196 patients, finding no difference between SS and DS fixation in any of their primary or secondary outcome measures[181]. These two studies lend support to SS fixation, especially if the fragment is too small to accommodate two screws safely. It may be that even in unstable ankle fractures, well-reduced medial malleolar fractures may not require screw fixation at all, as long as the fibula has been securely stabilised. This concept was investigated by Hoelsbrekken et al[182], who randomised 100 patients into either internal fixation or non-operative treatment a well-reduced (<2mm displacement) medial malleolar following plate fixation of the fibula. Eighty-two patients were followed up over a mean period of 39 months. There was no difference in the OMAS, AOFAS score or pain VAS between the two groups and the non-union rate in the non-operative was 9% compared with 0% in the fixation group, but this did not negatively affect patient reported outcome. On retrospective review, three of the four patients had a poorly reduced fracture of >2mm displacement, which is a crucial to consider when applying the results to clinical practice and agrees with the findings of Hanhisuanto et al[169]. This study was limited by a 20% loss to follow-up, but the results certainly ask questions of the necessity for internal fixation of well-reduced medial malleolar fractures, even in unstable injury patterns and represents an area of future research interest.

TBW fixation

Distal, transverse fractures can be managed well with TBW constructs, offering reliable fracture union and a lower revision rate, compared with lag screw fixation (5% vs 24%)[183]. Cadaveric biomechanical work has demonstrated that cancellous lag screws provide only 47% of the strength (resisted fracture displacement in tension) of a TBW construct in B-type fractures[184]. TBW constructs are also recommended for fixation of small fragments, which are not large enough to accept a screw, or in poor bone quality, where thread purchase may be challenging[184]. In severely comminuted fractures, TBW constructs may act as a 'raft' to support the zone of comminution. Previous studies have reported reasonable overall patient reported outcomes, but with a high rate of medial sided pain and metalwork removal[185-187], it is generally accepted that this technique should be used in reserve. In an attempt to overcome soft-tissue complications, stainless steel wire has been replaced with knotless systems, through a combination of low-profile wires and tapes. Biomechanical[188, 189] and clinical studies[190] investigating these constructs have demonstrated promising results, with a reduction in implant removal compared with traditional TBW (0% vs 8%)[190] but to date the cost-effectiveness of these more expensive interventions remains unproven.

Zones of fixation

Due to the anatomical relationship of important structures with the medial malleolus, including the tibialis posterior tendon (TPT) and associated neurovascular bundle, the 'safe zone' for screw insertion has been described by Femino et al[178]. The TPT travels intimately around the posterior colliculus; abrasion at this level can lead to pain, attrition and subsequent late rupture. Three zones of screw insertion are described based on a lateral view of the ankle (Figure 1.10) and relate to the three colliculi of the malleolus as previously discussed. Screw placement in zone 3 resulted in significant risk of injury to the TPT. Based on this finding surgeons should consider the necessity of placing screws outwith the anterior colliculus. Zhang et al supported the findings of this study following CT imaging analysis of 215 ankles[191]. These findings support a move away from DS fixation for medial malleolar fractures.

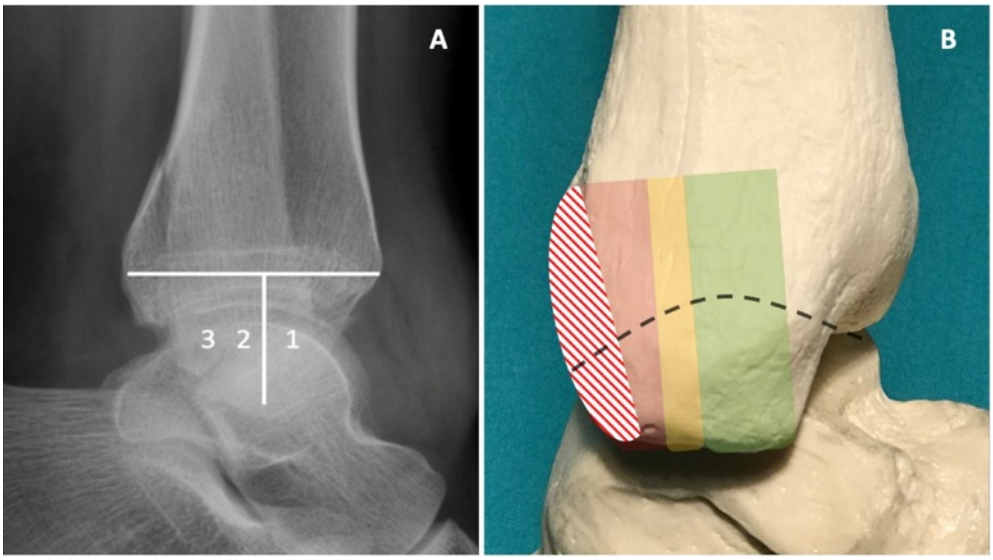

Figure 1.10: Lateral ankle radiograph (A) and sawbone model (B) demonstrating the safe zone (zone 1 - green) of the medial malleolus.

Plate fixation

Vertical shear fractures are inherently unstable and given the partial articular nature of the fracture pattern some authors have reclassified these injury patterns as a 'pilon variant'[192]. Divergent partially threaded screws have been shown to provide superior biomechanical qualities to that of parallel screws[193]. More recently, antiglide plate fixation has been investigated through a series of biomechanical studies. Wegner et al compared four fixation groups using synthetic distal tibiae[194]. Anti-glide plating supplemented with bicortical screw fixation perpendicular to the simulated fracture was significantly stiffer and able to withstand higher loads to failure than fixation with bicortical, parallel unicortical or divergent unicortical screws. Jones et al supported these findings when comparing a similar modified construct against traditional antiglide plating (without compression screws) and a precontoured medial malleolar hook plate[195], demonstrating significantly superior stiffness in the modified antiglide plating group. Given the relative rarity of these injuries, level-1 prospective randomised data is difficult to gather and therefore the majority of conclusions are drawn from laboratory studies[194-196].

Alternative implants

Alternative implants including headless compression screws (HCS) have been studied. Barnes et al followed up 44 patients managed with HCS fixation over a mean period of 35 weeks[197]. None of the patients developed a non-union or required further surgery to remove symptomatic metalwork. Despite this, 23% of patients still described discomfort around the screw entry point, despite satisfactory radiographs. This suggests that patient discomfort following fixation is likely related to the scar tissue and may explain why symptoms persist even following elective removal[82]. Similar findings have been published by Bulut et al[185] and Tekin et al[198], who reported low rates of metalwork removal[185, 198] but overall no significant difference in patient reported outcome[185]. Bioabsorbable implants have shown promise when compared against conventional metallic screws[199, 200], with reduction in the requirement for metalwork removal, but overall, no difference in time to fracture union or patient outcome. There have been previous concerns regarding inflammatory reactions, implant fracture and cost. Currently there does not appear to be strong enough evidence to support routine use but this represents an area of future research interest.

1.7.3 Posterior malleolus fixation

The management of posterior malleolar fractures remains controversial[201, 202]. Previously, fragment size has been used to guide the requirement for fixation based on cadaveric laboratory studies measuring associated changes in joint contact pressures[203, 204]. Some have questioned the validity of this concept[201]. Ongoing sagittal talar displacement is associated with a higher rate of post-traumatic osteoarthritis[205], but interestingly fragment size is not. CT imaging has changed how surgeons think about both fracture morphology and classification, including the impact this has on guiding management[44, 66, 67]. Given the site of tibial attachment of the PITFL, there is evidence to suggest that fixation of a large posterior malleolar fracture reduces the necessity for syndesmotic stabilisation[43, 206, 207]. There are currently no high-quality RCTs investigating posterior malleolar fixation, although the POSTFIX multicentre trial is ongoing and aims to provide clarity on the potential benefits of internal fixation of medium sized fragments (5-25% tibial articular surface) in Weber B-type injuries[208]. Posterior malleolar fractures can be treated with either plate or screw fixation.

Plate fixation

Plate fixation and in particular the posterolateral approach was popularised by Talbot et al[209] and later by Tornetta et al[210]. Plate fixation is felt to offer improved resistance to fracture displacement compared with screw fixation (both AP and PA)[211]. O'Connor et al retrospectively compared 27 patients managed with either posterior buttress plating or AP screws and found superior post-operative SMFA scores in the plating group, but no difference in ankle joint range of motion or radiographic degeneration at mid-term follow up[212]. Verhage et al studied 52 patients managed with posterior plating (n=40) or screw fixation (n=12) via a posterolateral approach[213]. All fractures reduced anatomically, and the syndesmosis was deemed to be stable after fixation in 82% of patients, obviating additional stabilisation. Complications included superficial infection (n=1), SN injury (n=2) and radiographic PTOA (n=4), with one patient progressing to ankle replacement two years after surgery. Similar complication profiles have been described in recent systematic reviews[214, 215] and large retrospective work[69]. More significant complications, including major vascular injury resulting in trans-tibial amputation have been reported following the posterior plating[216]. It appears that a combined posterolateral approach with posterior plating improves radiographic outcomes, including anatomical restoration of the articular surface[213, 217], although articular reduction may be improved simply during screw fixation with technical modification (Figure 1.11). The lack of data to suggest clinically important superiority of posterior plating over screw fixation, combined with the attendant complication profile requires future investigation.

Screw fixation

Screw fixation offers the advantage of smaller incisions, reduced soft-tissue trauma and is supported by positive patient reported outcomes[218]. Screws can be inserted either anterior to posterior (AP) or posterior to anterior (PA). AP screws are generally introduced through percutaneous incisions with the patient safely positioned supine. The fragment is reduced closed through ligamentotaxis, exploiting the posterior capsular attachment during ankle dorsiflexion. Additional technical modifications can improve articular reduction without the necessity of large incisions (Figure 1.11).

Figure 1.11: Posterior malleolar fracture fixation with AP screws following fracture reduction using a percutaneously periosteal elevator.

However, this minimally invasive approach does not allow direct visualisation of fracture reduction or removal of incarcerated fragments. Additionally, screw insertion may cause iatrogenic injury to the anterior anatomic structures at the ankle[219]. Similarly, purely percutaneously inserted screws from posterior to anterior (PA) place the sural nerve and FHL muscle belly at risk of injury[220]. Consequently, some authors have reported excellent outcomes with PA screw fixation through a small posterolateral approach, with equivalent outcomes to posterior plating[217] and improved outcomes compared with AP screw fixation[221]. Kang et al reported positive patient reported outcomes in individuals managed with percutaneous partially threaded cannulated screw fixation (PA) at six months and one year, when retrospectively compared against a group of patients treated conservatively[222]. However, there was no difference in time to union and the significant difference in outcome was not maintained after two years. Current understanding would suggest that not all posterior malleolar fractures need fixing and future research is likely to focus on appropriate selection of those that do and with this in mind, fragment specific fixation[67, 214, 223].

1.7.4 Syndesmosis stabilisation

Ankle fractures with associated syndesmotic injury occurs in approximately 20% of operatively managed cases[224]. There remains a degree of uncertainty concerning the diagnosis and appropriate management of syndesmosis injuries, which continues to stimulate debate[225-230]. Stabilisation can be performed with screw fixation or a suspensory device. As previously discussed, a more 'anatomical' approach to syndesmosis stabilisation by tensioning the PITFL through posterior malleolar fracture fixation, is felt to provide sufficient stability without the need for trans-syndesmotic fixation[201, 206, 227, 231]. Further research in this area is awaited.

Screw fixation

Screw fixation is currently considered as the 'gold standard' for syndesmosis stabilisation[224]. Debate continues regarding optimal screw diameter (3.5mm or 4.5mm). Biomechanical studies have not consistently demonstrated significant differences in load to failure or fibula displacement between the two sizes when tested under laboratory conditions[232, 233]. Once the ligamentous components of the syndesmosis have healed, screw breakage is often inevitable. Smaller 3.5mm screws are at higher risk of breakage[234], although given the dynamic nature of the syndesmosis this may in fact improve function[235, 236]. Larger 4.5mm screws have been shown to lead to higher rates of soft-tissue irritation, requiring elective removal[237]. Biomechanical testing has demonstrated greater load to failure during external rotation stress testing, when using double screw fixation compared with a single screw[238], but the clinical significance of this is remains unclear. The number of cortices engaged by the screw(s) has been a popular topic of research. A number of biomechanical[239] and clinical[240] studies comparing three or four cortices of fixation have found no difference with regards to laboratory tested stability and clinical outcomes, although tricortical screw fixation has been shown to provide more 'dynamic' fixation and therefore may result in less requirement for elective removal[241].

Elective screw removal internationally is dependent on specific hospital protocols and occurs in around 50% of cases[224]. Whilst some authors have not witnessed syndesmosis widening upon elective removal[236, 242], others have reported unexpectedly high rates of recurrent diastasis and infection, therefore questioning the necessity of the secondary procedure[243]. A recent systematic review by Dingemanns et al included two RCTs and nine case-control series comparing syndesmosis screw retention and elective removal[243]. The review concluded by finding no evidence that screw removal significantly improved functional outcome compared with retention. They hypothesised that the vast majority of retained screws were likely broken and/or loose and in some instances patients with retained screws outperformed those who underwent elective removal[235, 236, 244]. Other authors have claimed more explicitly that removal of intact retained screws improves patient outcome, but removal of broken or loose screws does not and consequently should be avoided[245]. To reduce the requirement for re-operation, bioabsorbable screws have been investigated against titanium screws by Sun et al in a prospective RCT[246]. Both implants provided similar mid-term functional outcome, but there was a significantly higher complication rate in the bioabsorbable screw group including heterotopic ossification and foreign body reaction requiring surgical intervention. Despite the high rate of secondary intervention following screw stabilisation, some authors have established a practice of ‘safe and cost-effective’ removal in the outpatient setting[247].

Suspensory device repair

The syndesmosis is a dynamic joint, permitting fibular rotation and translation. Consequently, suspensory devices including suture button repair have been shown to recreate the native biomechanics of the syndesmosis, reduce implant breakage, and decrease malreduction[225, 248-250]. Recently, Raeder at al conducted a prospective randomised trial including 97 patients randomised to either suture button (SB) or 4.5mm quadricortical syndesmosis screw (SS) fixation[225]. At mid-term follow up, both groups reported excellent outcomes according to the AOFAS and OMAS, which were both statistically significantly better in the SB group, but not clinically significant with only a five-point median difference in the OMAS. Similar differences in functional outcome were observed at earlier outcome points including six months, one year and two years. Radiographic osteoarthritis was three times higher in the SS compared with SB group, which may be an important determinant of function in the longer term. A similar trial again conducted by Raeder et al[251], randomised 113 patients to SB or SS fixation (3.5mm tricortical screw). The authors found no significant difference according to the AOFAS, OMAS, MOXFQ, complications or radiographic parameters, therefore concluding that SS fixation was in fact a favourable cheaper alternative to SB fixation. They hypothesised that the more flexible nature of the smaller diameter screw may explain the differences in outcome, compared with the more rigid 4.5mm quadricortical SS fixation[225].

Several systematic reviews have been performed comparing SB and SS fixation[229, 248, 250]. These have suggested that SB repair result in less constrained syndesmotic reduction which therefore may permit movement that is more physiologically representative of the native joint[250] and have a lower rate of re-intervention for removal[229, 248], although soft-tissue irritation from the suture button knot continues to be a major indication for unplanned surgery[252]. Despite the differences in rates of implant removal, patient reported is often comparable[229]. SB devices are currently substantially more expensive than SS fixation and further work in this area based on cost-effectiveness analyses is required. The necessity of elective removal, dependant on local protocol would be expected to be a confounding factor in these calculations.

1.8 Limitations of the evidence and directions for research

Debate regarding the management of each component of the unstable ankle fracture continues, for example, screw fixation versus suture button repair of the syndesmosis[225, 226, 229, 251, 253] and the necessity of posterior malleolar fixation based on size and/or fracture morphology[43, 68, 208, 213, 254]. Whilst these have been acknowledged in this introductory chapter, it is beyond the scope of this thesis to address each one. It is clear from the literature that there is emphasis on techniques and implants aimed at reducing the incidence of complications following fixation, many of which are soft tissue in nature. Treatment of lateral and medial malleolar fractures may be addressed through minimally invasive techniques and/or approaches to management, which may improve patient outcomes. These will be investigated further in this thesis.

1.8.1 Lateral malleolus fixation

Whilst both conventional non-locking and locking plate fixation provide satisfactory stabilisation of the fractured fibula, concerns regarding soft tissue complications have encouraged the development of percutaneous intramedullary techniques[147-149] and implants[123-125, 155, 157, 158, 162-164, 255]. However, there are limited data on the longer-term surveillance of patients treated with intramedullary stabilisation with majority of the literature comprised of studies with a maximum follow up duration of 12 months[121, 122, 155, 156, 158, 162, 164]. Future research is required to assess longer term patient outcome to ensure satisfactory results continue beyond this short-term assessment period. Whilst the biomechanical properties of the fibular intramedullary nail have been compared with neutralisation plate fixation[161], comparisons with locking plate fixation are limited to supra-syndesmotic injuries only[160]. As the intramedullary nail was introduced to overcome some of the management challenges presented by patients with poor bone quality, further biomechanical work comparing intramedullary and locking plate fixation for common osteoporotic fibular fractures will add to the understanding of the implant's capabilities.

1.8.2 Medial malleolus fixation

There has been a recent shift away from the philosophy that unstable medial malleolar fractures require fixation with two screws to prevent fracture fragment rotation. Buckley et al and Mandel et al demonstrated the clinical equivalence of single screw fixation in their prospective and retrospective studies respectively[180, 181]. Hoelsbrekken et al advanced this concept further in their prospective RCT[182], by comparing the outcome of patients treated with or without fixation of a well-reduced medial malleolar fracture following fibular stabilisation. This is the only study of its kind to date and was limited by the small sample size and lack of pre-operative PROMs. Successful union of medial malleolar fractures without the requirement for internal fixation addresses three potential operative complications: post-operative infection, damage to local structures and removal of symptomatic metalwork, which have all shown to be substantial and latterly not necessarily improved following elective removal[24, 82, 95, 178, 179, 197]. This treatment concept warrants further research and lends itself well to both retrospective cohort and prospective RCT investigation.

1.8.3 Thesis aims and hypotheses

To address the current limitations of the literature, this thesis will aim to:

1. Investigate the longer-term outcome of patients managed with a fibular intramedullary nail, including examination of failed fixation cases in order identify procedural refinements that might improve future patient care.
2. Compare the biomechanical failure properties of the fibular intramedullary nail with a locking plate and interfragmentary lag screw construct in a cadaveric setting.
3. Compare the outcome of patients treated with or without internal fixation of a well-reduced medial malleolar fracture following fibular stabilisation in both a retrospective and prospective setting.

The work in this thesis aims to test to following hypotheses:

1. Fibular intramedullary nail fixation results in satisfactory patient outcome beyond short-term follow up with an acceptable rate of mechanical failure and low soft tissue complication rate.
2. Locking plate and interfragmentary lag screw fixation is superior to fibular intramedullary nail fixation when tested to failure in a cadaveric setting.
3. Internal fixation of well-reduced medial malleolar fractures following fibular stabilisation is superior to non-fixation.

2. PATIENTS AND METHODS

2.1 Patients and database construction

All studies presented in this thesis were performed at the Edinburgh Orthopaedic Trauma Unit (EOTU). For each of the planned studies (excluding Chapter 4: cadaveric biomechanical study) the following data were collected as a minimum following review of electronic healthcare records and where possible, patient consultation: patient demographics including age and sex, side injured, mechanism of injury, chronic medical co-morbidities, medications, allergies, smoking and alcohol consumption, ASA grade and pre-injury functional status including mobility, employment and physical activity. The presenting fracture configuration and any associated injuries, including open fractures were classified following review of records and digitalised radiographs. A summary of the classifications used is found in Section 2.2 of this chapter and have previously been discussed in Chapter 1, Section 1.4. Details of anaesthesia, surgical management, post-operative immobilisation, weightbearing restrictions, physiotherapy, complications and subsequent treatments including the requirement for further surgical intervention were recorded. The prospective nature of the RCT presented in Chapter 6 allowed for additional data to be collected. A methodological overview of each study is described below.

2.1.1 Chapter 3. Modes of failure of the fibular intramedullary nail

Following advice from the South-East Scotland Research Ethics Service, formal ethical approval was not required for this study (appendix 1). An existing prospective database of surgically managed ankle fractures presenting to the EOTU, between 2002 and 2016 was used to identify those patients with an unstable ankle fracture that underwent fixation with a fibular intramedullary nail. Due to an electronic organisational upgrade including the digitalisation of radiographs, patients between 2002 and the beginning of 2008 did not have accessible radiographs for comprehensive review and were therefore excluded. Patients were further excluded if they lacked complete electronic clinic notes and/or radiographs at the following key timepoints: time of injury, intra-operative fluoroscopy, two weeks post-operative and six to eight weeks post-operative. Patients were contacted for the collection of mid-term outcome scores via postal questionnaire[a], or structured telephone interview for non-responders. The primary short-term outcome was mechanical failure requiring revision surgery. The primary mid-term outcome was the OMAS[256], which has been described in detail in Section 2.5. The detailed methodology for this study is found in Chapter 3, Section 3.4.

2.1.2 Chapter 4. Biomechanical comparison of the fibular intramedullary nail versus locking plate and lag screw fixation in the management of distal fibula fractures

Formal ethical approval was not required for this cadaveric biomechanical study. Permission was obtained from the head of anatomy at the University of Edinburgh[b,c]. Specimens were tested at the local University Orthopaedic engineering department and

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[a] Thank you to Mrs Deborah MacDonald for her help with processing postal questionnaire.

[b] Thank you to Professor Gillingwater for permission to use cadaveric specimens supplied by the University of Edinburgh anatomy department.

[c] I would like to express my gratitude to the donors and their families; without whom this study would not have been possible.

accompanied by a certified anatomist in possession of a Human Tissue Authority (HTA) anatomy licence, both during transportation and mechanical testing[d].

Six matched pairs of cadaveric lower limbs intact from foot to knee joint were supplied by the local University anatomy department. They were thawed from -20^{o}C to room temperature for 24 hours prior to preparation. Upon thawing the proximal tibia was disarticulated from the knee joint at the level of the proximal tibiofibular joint. The remaining stages of preparation and testing were initially identical to the technique described by Smith et al[161], except for the substitution of a 1/3 tubular neutralisation plate for a pre-contoured distal fibular locking plate. The technique was modified after an initial failure of proximal specimen fixation. This is described as part of the detailed study methodology in Chapter 4, Section 4.4.

2.1.3 Chapter 5. Medial malleolar fracture fixation in combination with fibular intramedullary nailing: a retrospective review

Following advice from the South-East Scotland Research Ethics Service, formal ethical approval was not required as this study (appendix 1). The same existing prospective database of all surgically managed ankle fractures presenting to the EOTU, described in Chapter 3 was analysed. The database was further refined by excluding patients without an associated medial malleolar fracture. Electronic healthcare records and radiographs were analysed to document post-operative complications. Patients were contacted for the collection of mid-term outcome scores via postal questionnaire

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[d] Thank you to Mr Iain Campbell, Anatomy manager at the University of Edinburgh for supervision of specimens both during transportation and mechanical testing. Thanks also to Mrs Laura Shiels for her help with storage and preparation of specimens.

or structured telephone interview for non-responders. The primary short-term outcome was difference in complications between the two groups. The primary mid-term outcome was the OMAS[256]. The detailed methodology for this study is found in Chapter 5, Section 5.4.

2.1.4 Chapter 6. Prospective RCT: MOON trial

This study was a fully registered prospective randomised, controlled, unblinded, single centre trial including patients with unstable fractures of the ankle joint. Ethical approval was granted by the South-East Scotland Research Ethics Service (appendix 2). The inclusion criteria were adult patients (≥16 years) who had sustained a closed, isolated unstable (bimalleolar or trimalleolar) fracture of the ankle joint, which required surgical fixation. Patients were excluded if they did not have capacity to consent to treatment, were unable to comply with follow-up at the study centre over a one-year period, had an associated lower limb injury, open fracture, neurovascular injury or significant involvement of the distal tibial plafond ('pilon' type injury). Further exclusion criteria included vertically unstable medial malleolar fractures (supination-adduction type injuries) and those patients who either declined or were medically unfit for surgery. Patients engaged in a current pharmacological clinical study and those patients in which the treating consultant felt that inclusion was not in the patient's best interest were also excluded. The primary outcome was the OMAS[256] recorded one year following surgery (date of randomisation). Secondary outcome measures comprised both surgeon and patient reported outcomes, in addition to complications.

Recruitment to this trial was suspended in February 2020 due to the worldwide SARS-CoV-2 virus pandemic. Recruitment then re-started on the 15th of June 2020 after appropriate authorisations. The final patient was recruited in August 2020, with final outcome score data collected at the end of August 2021. Consequently, the results presented in this chapter of the thesis include the first 100 participants to complete both one-year questionnaire and radiographic follow-up.

Power analysis

A power calculation was performed by an independent statistician, employed through the local University Clinical Research Facility[e]. It has been shown that a difference of 10 points in the OMAS represents the MCID for conditions around the foot and ankle, including osteoarthritis[256]. The multicentre AIM trial by Willet et al[5] set a between groups equivalence margin of 6 points with respect to the OMAS. Therefore, to show a clinically relevant difference of 10 points in the OMAS at one year between the two groups, a power calculation indicated a total sample of 128 participants would be required (64 in each group) assuming a common standard deviation (SD) of 20 points, 80% power and 5% level of significance. To account for loss to follow-up this number was increased by 20% to 154 participants (77 in each group). In the event of participant cross over between groups, intention to treat (ITT) analyses were to be performed. The detailed methodology for this study is found in Chapter 6, Section 6.4.

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[e] Thank you to Dr Cat Graham for help with the power calculation and statistical guidance.

2.2 Radiographic classification

In all studies, the presenting radiographs were reviewed, firstly to confirm injury and secondly to classify the fracture. For complex fractures, CT scanning was arranged at the discretion of the treating surgeon. Associated injuries identified radiographically elsewhere in the body were documented. In relation to the MOON trial (Chapter 6), patients with injuries that might have impacted on rehabilitation including significant lower limb or spinal injuries were excluded at the first point of clinical assessment.

Detailed radiographic assessment was performed using calibrated digitalised radiographs viewed on the Picture Archiving and Communication System (PACS, Rochester, NY: Carestream Health, Inc). Classification of fractures and detailed measurements were performed by me and two other senior orthopaedic registrars[f] . The assistance of other individuals in this situation is acknowledged in each chapter.

2.2.1 Ankle fractures

Standard AP and lateral radiographs of the ankle joint from the time of injury and post-reduction were used to classify all injuries. It was important to use both as the post-reduction radiograph, in plaster was frequently more useful for classification and measurement of an associated fracture of the posterior malleolus than the radiograph at the time of injury. The same was true for medial malleolus fracture classification. Fractures were classified according to the Lauge-Hansen[56] system in all studies

[f] Thank you to Mr Samuel Mackenzie and Miss Katrina Bell for assistance with radiographic classification and measurements.

(Chapter 1, Section 1.4; Table 1.1). In the MOON trial (Chapter 6), the AO/OTA[52] fracture classification was also included (Chapter 1, Section 1.4; Figure 1.8).

2.2.2 Fibular nail construct assessment

Intraoperative and postoperative radiographs were assessed for adequacy of fracture reduction and implant position in Chapter 3. Reduction quality was assessed using the criteria described by Burwell and Charnley[257], and described as either 'anatomical', 'fair' or 'poor'. The accuracy of the measurements was improved by first calibrating against the known major diameter of the cortical locking screws (3.5mm). Assessment of the fibular nail construct included measurement of nail length, width, number of distal locking screws (DLS) and number of proximal locking screws (PLS). The length of the PLS was also recorded, as was the distance from the centre of the most inferior PLS to the articular margin of the tibial plafond (Figure 2.1).

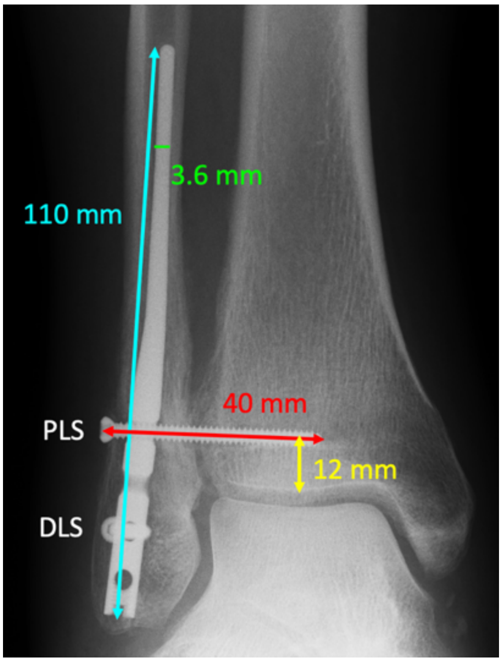

Figure 2.1: Radiographic assessment of the fibular intramedullary nail construct.

2.2.3 Medial malleolar fractures

Standard AP and lateral pre-operative radiographs were used to classify all medial malleolar fractures using the Herscovici classification[60] (Chapter 1, Section 1.4; Figure 1.9). For patients to be eligible for randomisation in the MOON trial (Chapter 6) their associated medial malleolar fracture required to be well reduced following fibular stabilisation. Based on the findings from previous studies[169, 182], fracture reduction was considered acceptable within two millimetres of an anatomical position when assessed using AP fluoroscopy with the ankle in neutral flexion. In Chapter 6 (MOON trial) a non-union was defined as localised pain with radiographic changes consistent with non-union at the 12-month assessment point. A pseudoarthrosis was used to describe the same radiographic features, but without localised pain, as per Frölke et al[104].

2.3 Surgical techniques

2.3.1 Fibular intramedullary nailing

The Acumed Fibula Rod (Hillsboro, Oregon, USA) was used in all cases that involved intramedullary stabilisation of the fibula. This device is a solid titanium implant available in two diameters (3mm and 3.6mm) and three lengths (110mm, 145mm and 180mm). Where possible, the wider nail was used with a length that allowed passage of the nail at least 20mm beyond the fracture. In younger patients the diameter of the fibular diaphysis can limit access for the wider nail and a 3mm diameter was selected to reduce the risk of periprosthetic fracture during impaction.

Although the technique can be modified at various stages to help reduce the fibular fracture and improve implant position, the overall technique followed a series of key steps. A smooth 1.6mm guide wire was initially placed at the fibular tip and visualised using both anteroposterior and lateral intra-operative fluoroscopy. The wire was advanced approximately 20mm under fluoroscopic guidance. An opening power reamer was then passed over the Kirschner wire to open up the distal fibula. T-handled reamers of increasing size were then passed across the fracture site and into the proximal fragment. The smaller reamer (3.1mm) allowed passage of the smaller nail (3.0mm), whereas the larger reamer (3.7mm) allowed passage of the 3.6mm nail. An appropriately sized nail between 110mm and 185mm was then inserted using the jig until the distal end of the nail was flush with the fibular tip. In most cases the insertion of the nail indirectly reduced the fibular fracture. The jig was then externally rotated by 30 degrees from the horizontal to allow for some internal rotation of the distal fragment during fracture reduction and permit anatomical placement of the trans-syndesmotic screw (fibula-pro-tibia). The nail was first locked distally with either one or two 3.5mm DLS(s) inserted through the targeted guide in an anterior to posterior direction, with care taken to abut, but not penetrate the posterior cortex of the fibula, reducing the risk of peroneal tendon irritation. Restoration of fibular length and rotation was achieved by back slapping the nail once it had been locked distally whilst applying controlled rotatory refinements. The final construct was then secured by inserting either one or two PLS(s) using the targeted guide from a lateral to medial direction. The PLS(s) passed across the syndesmosis are routinely inserted regardless of whether a syndesmotic diastasis was present or not. The selection of nail length, nail width, number of DLS and PLS was left to the discretion of the operating surgeon and was dictated by the fracture morphology and anatomy of the fibula.

2.3.2 Fibular plating

The pragmatic nature of the MOON trial presented in Chapter 6 allowed the surgeon to select the technique of fibular fracture fixation. Where open reduction and internal fixation was performed, the majority of cases utilised a 1/3 tubular plate, supplemented by an interfragmentary lag screw. In this technique, a standard approach to the distal fibula was taken through skin and subcutaneous fat, with care taken not to injure the SPN. Sharp dissection down to the level of the fracture allowed the fracture site to be visualised and cleared of periosteum and haematoma. Where possible the fracture was reduced and help with reduction forceps. An appropriately sized interfragmentary 3.5mm cortical lag screw was then inserted after preparing the near cortex with a 3.5mm drill and the far cortex with a 2.5mm drill. A 1/3 tubular plate of appropriate length was used in neutralisation mode and secured with proximal bicortical screws and distal cancellous screws. The stability of the syndesmosis was then assessed with either an external rotation test or via attempted manual translation of the fibula, whilst evaluating the joint fluoroscopically. In the case of osteoporotic bone, a pre-contoured distal fibular locking plate, with or without interfragmentary lag screw fixation was used in a small number of cases in Chapter 6. The technique was similar to that described for the 1/3 tubular plate fixation, except for the substitution of plate type and locking screws distally. Locking plates were used in the biomechanical study outlined in Chapter 4 and followed the same surgical principles.

2.3.3 Medial malleolar fracture fixation

The technique for fixation of an associated medial malleolar fracture was left to the discretion of the treating surgeon in Chapters 3, 5 and 6. Generally, the fracture was approached through a direct medial incision, based over the malleolar tip. Superficial dissection through skin and then careful dissection through subcutaneous fat allowed identification and protection of the long saphenous vein. The fracture site was then identified and cleared of both haematoma and any infolding periosteum. The fracture was reduced with pointed reduction forceps and fixed with either one or two partially threaded cancellous screws in most cases. In some instances, where the malleolar fragment was comminuted or the fragment size precluded the safe insertion of a screw, a TBW construct was used.

2.3.4 Posterior malleolar fracture fixation

Fixation of an associated posterior malleolar fracture was left to the discretion of the treating surgeon in Chapters 3, 5 and 6. In the vast majority of cases, an associated fracture was fixed if it contributed to posterior talar instability either demonstrated at the time of injury or when stressed intra-operatively. Fixation was achieved with either AP cancellous screws or posterior tibial buttress plating. In some instances, cannulated screws were inserted after over-drilling temporary guidewires, which had the advantage of improved temporary fracture reduction and control over screw placement. Posterior buttress plating was performed through a standard posterolateral approach, exploiting the internervous plane between flexor hallicus longus (tibial nerve) and the peroneal compartment (SPN).

2.4 Post-operative management

2.4.1 Immobilisation

The default immobilisation device in the EOTU was a removable orthosis, especially for those patients included in Chapter 6. This was routinely fitted by a physiotherapist in the immediate post-operative period. In select cases where the bone quality was poor or the patient was not compliant with weightbearing restrictions, a plaster was applied. Plaster casts were historically routinely applied in our service, but with a greater understanding of the benefits of early weightbearing in removal orthoses this practice now applies only to select cases[79, 81, 258-262].

2.4.2 Weightbearing status

The default weightbearing status in the EOTU was for full immediate weightbearing after surgery, especially for those patients included in Chapter 6. This was based on mounting evidence of the benefits of this intervention[79, 81, 258-262]. Indications for non-weightbearing included a confirmed radiographic syndesmosis injury, history of peripheral neuropathy, poor patient compliance or in select situations where the treating surgeon felt that non-weightbearing would be in that particular patient's best interest. In this situation the patient was advised against weightbearing for between six and eight weeks.

2.4.3 Metalwork removal

Metalwork was not routinely removed following ankle fracture surgery in the EOTU unless specifically requested by the patient due to ongoing well-localised symptoms.

2.5 Outcome measures

2.5.1 Patient reported outcome measures (PROMs)

The primary PROM used throughout this thesis was the OMAS[256]. Other outcome measures used included the Manchester-Oxford Foot Questionnaire (MOXFQ)[263] and the EuroQol-5D (EQ-5D)[264].

PROMs have several potential benefits, predominantly the shift of focus away from surgeon to patient assessment of outcome. It is possible to collect PROMs remotely, allowing repeated collection of surveillance outcome data during a clinical trial, without the requirement for regular outpatient review. This may have logistical and financial benefits for both the patient and research department. One potential drawback of using PROMs is the reliance on the patient to first be able to read the questions, understand what is asked of them and then be able to accurately select which option is relevant to them. Indeed, some authors have suggested that the typical readability of written PROMs are up to seven years above that of the average adult literacy in the UK[265]. Allowing a family member or friend to help them complete the PROMs may represent 'proxy respondent bias' and must be considered[266]. Details of each outcome measure, including the limitations are discussed below.

Olerud Molander Ankle Score

The OMAS[256] was developed for the evaluation of patient symptoms following ankle fracture (Figure 2.2). It has been retrospectively well validated[71, 72, 267], translated into a number of languages[268, 269] and is the focus of a number of current large multicentre lower limb trauma trials[5, 9, 270]. This outcome tool includes nine questions: the first three focus on primary complaints (pain, stiffness, swelling), the middle four focus on patient function (stair climbing, running, jumping, squatting), and the final two questions focus on the impact on everyday life (mobility and current level of employment/activity). A final score is awarded from 0-100 with 100 representing the best possible outcome. When the score was developed in 1984, the authors correlated the final score with an outcome category: 0-30 (poor); 31-60 (fair); 61-90 (good); 91-100 (excellent). A recent study by Garratt et al[271] found the OMAS to have acceptable levels of internal consistency, test-retest reliability and correlated strongly with other lower limb injury outcome scoring systems and measures of general health, including the EQ-5D. Whilst the OMAS focuses primarily on physical limitations, it fails to measure the impact of ankle trauma on mental/emotional well-being, i.e., it has poor psychometric qualities[272], which makes collection of a general health outcome data, such as the EQ-5D all the more important.

Olerud Molander Ankle Score (OMAS)

Please answer the following ten questions about your ankle and the effects your injury has had on your daily life. Please try to answer all of the questions.

Pain

☐ None ☐ While walking on even surface indoors
☐ While walking on uneven surface ☐ Constant and severe
☐ While walking on even surface outdoors

Stiffness

☐ None ☐ Stiffness

Swelling

☐ None ☐ Only evenings ☐ Constant

Stair-climbing

☐ No problems ☐ Impaired ☐ Impossible

Running

☐ Possible ☐ Impossible

Jumping

☐ Possible ☐ Impossible

Squatting

☐ No problems ☐ Impossible

Supports

☐ None ☐ Taping, wrapping ☐ Stick or crutch

Work, activities of daily life

☐ Same as before injury ☐ Loss of tempo
☐ Change to a simpler job/part-time work ☐ Severely impaired work capacity

TOTAL SCORE: ……./100

Figure 2.2: The Olerud Molander Ankle Score (OMAS).

Manchester-Oxford Foot Questionnaire

The MOXFQ[263] is a validated assessment tool for foot and ankle surgery (Figure 2.3)[263, 273-275]. It includes 16 questions, divided into three subscales: walking/standing (seven items), pain (five items) and social interaction (four items). Each question is scored from 0-4 with 0 indicating the best outcome. The overall score out of 64 is then converted to a metric score out of 100 (MOXFQ-Index), where 100 denotes the worst score. The MCID has been defined as a change of 13 points for each of the three domains[274]. The MOXFQ has since been used in other foot and ankle trauma studies, and found to have superior responsiveness when compared to the American Orthopaedic Foot and Ankle Society (AOFAS) score[275] and Self-Reported Foot and Ankle Outcome Score (SEFAS)[276]. It has also been found to correlate well with general heath outcome measures including the EQ-5D[277]. This allows for direct assessment and comparison of global foot and ankle outcome rather than the individual domains and has been statistically validated[278]. The main drawback of the MOXFQ is the absence of the word 'ankle' in the questions, which currently asks questions pertaining to the 'foot'. It was therefore essential to instruct patients when completing this PROM to answer based on their current assessment of their foot-ankle as a single unit. As with the OMAS, none of the questions directly assess mental health, which may be a significant determinant of outcome, particularly pain.

Manchester-Oxford Foot Questionnaire (MOXFQ)

During the past 4 weeks this has applied to me:

	None of the time	Rarely	Some of the time	Most of the time	All of the time
1. I have pain in my foot	☐	☐	☐	☐	☐
2. I avoid walking long distances because of pain in my foot	☐	☐	☐	☐	☐
3. I change the way I walk due to pain in my foot	☐	☐	☐	☐	☐
4. I walk slowly because of pain in my foot	☐	☐	☐	☐	☐
5. I have to stop and rest my foot because of pain	☐	☐	☐	☐	☐
6. I avoid some hard or rough surfaces because of pain in my foot	☐	☐	☐	☐	☐
7. I avoid standing for a long time because of pain in my foot	☐	☐	☐	☐	☐
8. I catch the bus or use the car because of pain in my foot	☐	☐	☐	☐	☐
9. I feel self- conscious about my foot	☐	☐	☐	☐	☐
10. I feel self-conscious about the shoes I have to wear	☐	☐	☐	☐	☐
11. The pain in my foot is worse in the evening	☐	☐	☐	☐	☐
12. I get shooting pains in my foot	☐	☐	☐	☐	☐
13. The pain in my foot prevents me from carrying out my work/everyday activities	☐	☐	☐	☐	☐
14. I am unable to do all my social and recreational activities because of pain in my foot	☐	☐	☐	☐	☐

	None	Very mild	Mild	Moderate	Severe
15. During the past 4 weeks how would you describe the pain you usually have in your foot?	☐	☐	☐	☐	☐

	No nights	Only 1 or two nights	Some nights	Most nights	Every night
16. During the past 4 weeks have you been troubled with pain from your foot at night?	☐	☐	☐	☐	☐

RAW SCORE: ……./64 METRIC SCORE……./100

Figure 2.3: The Manchester-Oxford Foot Questionnaire (MOXFQ).

EuroQol-5D

The EQ-5D[264] is a widely used multi-attribute utility instrument (MAUI). It is a valuable tool in the assessment of health-related quality of life (HrQOL), and provides an overall score between -0.59 and +1, where 0 is equal to the state of death and +1 indicates the best possible outcome (Figure 2.4). The three-level (3L) version of the EQ-5D was used and comprises five dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. A supplementary step in completion of the EQ-5D allows the patient to subjectively record an overall assessment of their general health using a visual analogue scale graded between 0-100, with 100 indicating the best possible health. The EQ-5D is quick to complete and unlike the OMAS and MOXFQ, includes a brief assessment of the individual's current mental health.

Euro-Qol-5D-3L Questionnaire

Please answer every question by marking the answer with a cross or a tick.
If you are unsure how to answer a question please give the best answer you can.

MOBILITY

☐ I have no problems walking about
☐ I have some problems walking about
☐ I am confined to bed

SELF CARE

☐ I have no problems with self care
☐ I have some problems with self care
☐ I am unable to wash or dress myself

USUAL ACTIVITIES

☐ I have no problems performing my usual activities
☐ I have some problems performing my usual activities
☐ I am unable to perform my usual activities

PAIN/DISCOMFORT

☐ I have no pain or discomfort
☐ I have moderate pain or discomfort
☐ I have extreme pain or discomfort

ANXIETY/DEPRESSION

☐ I am not anxious or depressed
☐ I am moderately anxious or depressed
☐ I am extremely anxious or depressed

Please indicate, by marking a line, on this scale how good or bad your health is today with 0 being the worst health imaginable and 100 being the best health.

0 10 20 30 40 50 60 70 80 90 100

Figure 2.4: The EuroQol-5D-3L (EQ-5D) score.

2.5.2 Subjective outcome measures

Subjective outcome measures have been used throughout this thesis, but mainly in Chapter 6 and included general health and pain. Where appropriate, patient return to function (employment and physical activity), in weeks was recorded.

2.5.3 Patient reported experience measures (PREMs)

PREMs are used to collect data on patients' views of their experience whilst receiving treatment. They do not reflect the outcome of care, but the process of receiving care[279]. Whilst several validated PREM questionnaires have been recently developed, to prevent over burdening patients, overall satisfaction with the process of care was used as the only PREM in this thesis. Patients were asked to award of score between 0-100, with 100 indicating 'extremely satisfied'. Although patient satisfaction is frequently used as an assessment tool in clinical studies and by healthcare policy makers, it is often difficult to distinguish between satisfaction with the process of care and satisfaction with the overall treatment outcome. It must be remembered that satisfaction can be significantly affected by a number of factors, including but not limited to pre-operative expectations, pain relief, staff communication and patient mental health status[280, 281].

3. INVESTIGATING MODES OF FAILURE OF THE FIBULAR INTRAMEDULLARY NAIL

Material from this chapter has been published in the Journal of Orthopaedic Trauma (JOT) in 2019[282], appendix 5.

Carter TH, Mackenzie SP, Bell KR, Bugler KE, MacDonald D, Duckworth AD, et al. Optimizing Long-Term Outcomes and Avoiding Failure With the Fibula Intramedullary Nail. J Orthop Trauma. 2019;33(4):189-95.

3.1 Aims and Hypothesis

The aim of this chapter was to retrospectively review both the short and mid-term outcome of patients presenting with acute ankle fractures who underwent fibular intramedullary nail stabilisation within a single orthopaedic trauma service.

The hypothesis was that given the intramedullary nature of the device, the fibular nail provides satisfactory stability with an acceptable rate of mechanical failure and longer-term patient reported outcome.

3.2 Chapter Summary

Review of a single-centre prospective trauma database identified all patients managed over an eight-year period with a fibular intramedullary nail. The mean age of the 342 patients included was 64.6 years (range, 21-96; SD, 17.1) and there were 251 women (73.4%). The most common mechanism of injury was a fall from standing height (n=302, 88.3%). There were 21 open fractures (6.1%) and 60 patients (17.5%) had a syndesmosis injury. The primary short-term outcome was mechanical failure requiring revision. The primary mid-term outcome was the OMAS.

Twenty cases (5.8%) required revision due to mechanical failure at a mean interval of 3.5 weeks between index procedure and revision. Thirteen (3.8%) were due to surgeon error and seven (2.0%) were due to device failure. Eight cases of surgeon error resulted in a recurrence of syndesmotic diastasis (n=8). Five failures (1.5%) occurred due to inadequate fracture reduction and/or poor technical execution. Seven device failures (2.0%) occurred due to failure of the PLS. Positioning the PLS >20mm above the plafond was significantly associated with an increased risk of mechanical failure (p=0.003). A further 16 patients (4.7%) required re-operation due to lateral sided metalwork irritation or infection control. At a mean follow up of 5.1 years (range, 0.7-8.4) the median OMAS was 80/100. Mechanical failure resulted in poorer outcomes in general and significantly so in respect of the OMAS (p=0.045).

This chapter explored risk factors for mechanical failure of the fibular intramedullary nail and has identified procedural refinements to reduce the incidence of future failure. These include performing a dynamic stress test of the syndesmosis, inserting two PLSs in cases of confirmed syndesmosis injury and/or poor bone quality, exploiting the denser subchondral bone within 20mm of the tibial plafond, and engagement of the fibular nail itself with the PLS head when the lateral fibular cortex provides insufficient purchase. Clinical and biomechanical comparisons with other implants such as locking plates may provide further evidence for the efficacy of the intramedullary nail.

3.3 Chapter Introduction

Open reduction and internal fixation (ORIF) of unstable ankle fractures is the most common surgical strategy for their management globally. Over the last two decades an increasing use of the fibular intramedullary nail has been observed within the EOTU; a pattern which has resonated within the recent literature. The fibular intramedullary nail is supported by retrospective[121, 122, 125, 126, 156, 159, 164, 255, 283], prospective RCT[162, 163] and biomechanical data[160, 161]. Whilst the device was reserved for the management of ankle fractures in elderly patients based on the results from the prospective RCT by White et al[162], with added familiarity, the indications have been expanded to now include younger, more active patients. With increasing practice and knowledge of the implant capabilities, an evolution of the design and surgical technique has been witnessed in the EOTU, progressing from a fully unlocked to a locked, length stable construct with improved rotational control (Figure 3.1).

With the development of any implant and/or surgical technique, the reporting of fixation failures and patient outcome is essential to allow greater understanding and further refinement. This chapter investigates the short and mid-term outcome of unstable ankle fractures managed with fibular intramedullary nail fixation. The incidence of failure, in addition to the modes and risk factors are presented. Finally, patient reported outcome at mid-term follow up is evaluated.

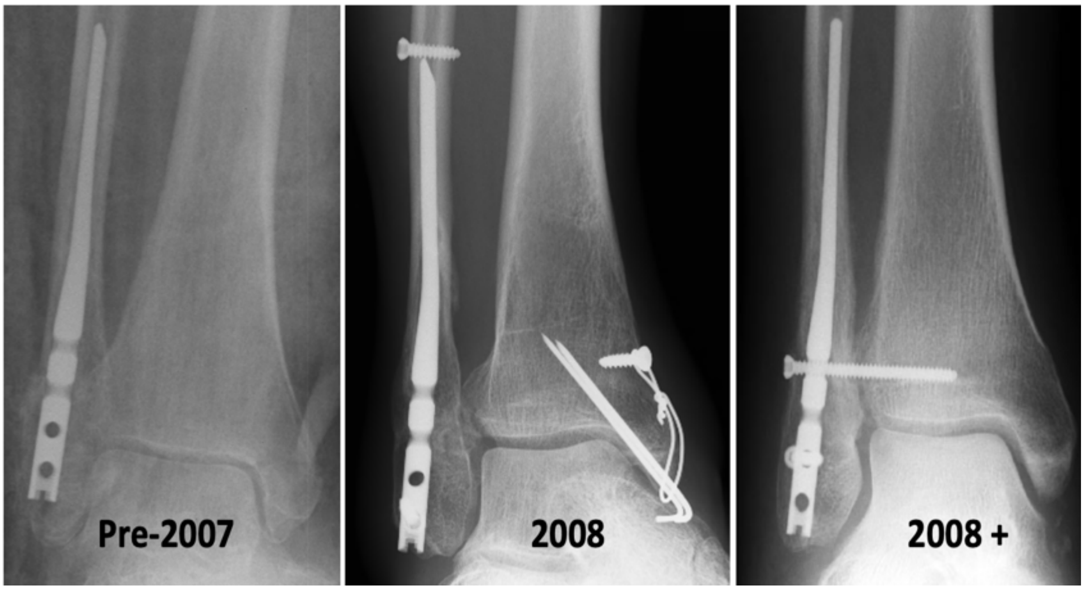

Figure 3.1: The evolution of the fibular intramedullary nail technique.

3.4 Patients and Methods

3.4.1 Patients and database construction

A retrospective analysis of a prospectively collected single centre trauma database, described in Chapter 2, Section 2.1, containing 362 cases was performed. Patients were excluded if they lacked a minimum of six weeks post-operative radiographic follow up (n=20). This identified a study cohort of 342 fractures in 342 patients, who were managed according to the surgical principles described in the paper by Bugler et al (2012)[124] and outlined in Chapter 2, Section 2.3. Electronic patient records were assessed for demographics, injury characteristics, operative data, complications including mechanical failure, subsequent treatments and/or procedures. The patient selection and outcome process are summarised in Figure 3.2.

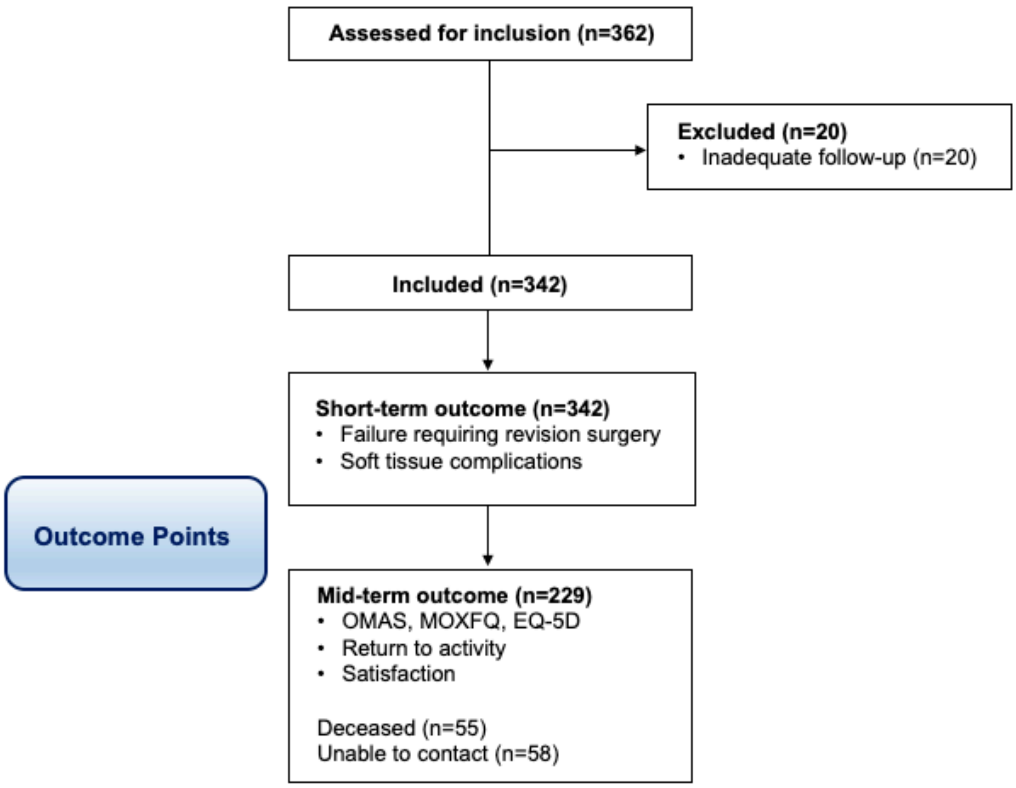

Figure 3.2: Flowchart that demonstrates the patient selection and outcome process.

3.4.2 Radiographic classification

Ankle fractures were classified according to the Lauge-Hansen[56] system (Chapter 1, Section 1.4; Table 1.1). Assessment was made of both the quality of reduction and the fibular nail construct itself (Chapter 2, Section 2.2). Post-operative radiographs were evaluated for talar malreduction and fixation failure requiring revision surgery, by two authors (THC and TOW)[g]. Failures were divided into two categories: surgical error or device failure. Surgical errors were subdivided into inadequate reduction/poor nail insertion technique, or the failure to prescribe or maintain post-operative protection of a syndesmotic injury. A failure was attributed to the device if it occurred following appropriate operative technique and satisfactory post-operative management. Device failures were subdivided into the location at which the construct had failed: the intramedullary nail, DLS(s), or PLS(s).

3.4.3 Surgical management

Patient care was supervised by a total of twelve fellowship trained orthopaedic trauma consultants and the surgical procedures were performed by 52 surgeons of mixed grade from junior registrar to senior consultant level. The technique for fibular intramedullary nailing has been described in Chapter 2, Section 2.3. Post-operative management followed the principles outlined in Chapter 2, Section 2.4.

[g] Thank you to Mr Tim White for assistance with the assessment of radiographs.

3.4.4 Outcome assessment

Short-term outcome

All patients underwent short-term follow up at the study centre, including a minimum of a two week and a six to eight week post-operative outpatient review. The primary short-term outcome was failure defined as any case that required revision surgery due to an inadequate mechanical construct. Complications including re-operation for the removal of symptomatic metalwork and/or for the treatment of infection were recorded.

An AP and lateral radiograph of the ankle joint was performed to assess for fixation failure, metalwork position and to monitor fracture union. For those patients making satisfactory progress at the six to eight week review appointment, it was not uncommon for patients to be discharged even if radiographic union was not established. Patients were provided with contact information to arrange further outpatient review in the event of complications and/or concerns.

Mid-term outcome

Mid-term outcome was primarily collected via postal questionnaire[h], followed by a structured telephone review for non-responders[i]. Two validated lower limb PROMs were collected: the OMAS[256] and the MOXFQ[263]. The EQ-5D[264] was used as a marker

[h] Thank you to Mrs Deborah MacDonald, database and clinical research manager at the University of Edinburgh, for assistance with sending and processing postal questionnaires.

[i] Thank you to Mr Marcus Hollyer and Miss Emma Gill, medical students at the University of Edinburgh, for assistance with data collection.

of general health status. Patients were asked to complete a health and pain VAS, in addition to rating their overall satisfaction with treatment. Each outcome measure has been discussed in Chapter 2, Section 2.5.

If the patient was in employment and/or engaged in physical activity before their injury they were asked to record the number of weeks, it took them following surgery to return. Finally, patients were asked to provide details regarding subsequent surgery as a result of a persistent problem following their surgery or injury.

3.4.5 Statistical analysis

Data analysis was performed using IBM SPSS software version 23.0 (Armonk, NY: IBM Corp). Data normality was assessed using the Shapiro-Wilk test. Student's unpaired t-test was used to analyse parametric continuous data and the Mann-Whitney test was used for continuous data that did not follow a normal distribution. Categorical binary data including surgical construct parameters (i.e., nail length and number of locking screws) were analysed using either the chi-square test (all observed frequencies in each cell >5) or the Fisher's exact test (one cell had observed frequency of ≤5). Spearman correlation was used to measure the strength of association between two continuous variables. Two-tailed p-values were reported and a p-value of <0.05 was considered significant.

3.5 Results

3.5.1 Patient demographics and injury characteristics

The mean age of the 342 patients was 64.6 years (range, 21-96; SD, 17.1; Table 3.1). There were 251 women (73.4%) and 91 men (26.6%). The median number of comorbidities per patient was 3 (IQR, 2-5), with diabetes mellitus being the most common (17.5% of cohort). Obesity defined by a BMI of $\geq$30 kg/m^2 was present in 13.2% of the study cohort. Twenty-one patients (6.1%) had confirmed osteoporosis at the time of injury and were taking prescribed pharmacological treatment. The majority of patients (74.3%) took regular medications with a median number of medications per patient of 4 (IQR, 2-7). One quarter (24.9%) of patients were smokers at the time of injury and 7.3% (n=25) drank alcohol in excess of recommended limits, defined as >14 units/week. Over half of the patients (54.1%) were classified as an ASA grade 2. The majority (75.4%) were independently mobile and 60.5% were retired.

The right ankle was injured in 56.7% (n=194) of cases (Table 3.2). Twenty-six fractures (7.6%) were sustained through a high energy injury mechanism. The most common mechanism of injury was a fall from standing height (n=302, 88.3%). There were 21 open fractures (6.1%) and a syndesmotic injury was present in 60 cases (17.5%). According to the Lauge-Hansen classification there were 270 (78.9%) supination-external rotation (SER) type fractures, 46 (13.4%) pronation-abduction (PAB) fractures, 19 (5.6%) pronation-external rotation (PER) fractures and seven (2.1%) supination-adduction (SAD) fractures. An associated medial malleolar and posterior malleolar fracture were present in 73% (n=248) and 43% (n=146) of cases respectively.

(n/% unless otherwise stated)	Total Cohort (n=342)
Mean age (range; SD)	64.6 (21-96, 17.1)
Sex	
- Man	91 (26.6)
- Woman	251 (73.4)
Median comorbidities (IQR)	3 (1-4)
- Diabetes	61 (17.5)
- Insulin dependent diabetes	25 (7.3)
- Immunosuppression	10 (2.9)
- Steroid use	14 (3.8)
- Renal impairment	29 (8.5)
- Peripheral neuropathy	20 (5.9)
- Ischaemic heart disease	51 (14.9)
- Obesity (BMI 30+)	45 (13.2)
- Osteoporosis	21 (6.1)
Regular medication	254 (74.3)
Median number of medications	4 (2-7)
Smoker	85 (24.9)
Alcohol excess (>14 units/week)	25 (7.3)
ASA grade	
- 1	55 (16.1)
- 2	185 (54.1)
- 3	91 (26.6)
- 4	11 (3.2)
Pre-injury mobility status	
- Independent	258 (75.4)
- Walking stick or frame	79 (23.1)
- Wheelchair	5 (1.5)
Pre-injury employment status	
- Employed	105 (30.7)
- Unemployed	30 (8.8)
- Retired	207 (60.5)

Table 3.1: Patient demographics.

(n/% unless otherwise stated)	Total Cohort (n=342)
Side of injury	
- Right	194 (56.7)
- Left	148 (43.3)
High energy injury mechanism	26 (7.6)
Mechanism of injury	
- Fall from standing height	302 (88.3)
- Fall from height	19 (5.6)
- Assault	2 (0.6)
- Sport	6 (1.8)
- Road traffic accident	8 (2.2)
- Other	5 (1.5)
Open fracture	21 (6.1)
Lauge-Hansen classification	
- SER	270 (78.9)
- PAB	46 (13.4)
- PER	19 (5.6)
- SAD	7 (2.1)
Syndesmosis diastasis	60 (17.5)
Associated medial malleolar fracture	248 (72.5)
Associated posterior malleolar fracture	146 (42.7)

Table 3.2: Injury characteristics.

3.5.2 Surgical management

Surgery was performed under image intensifier guidance according to the technique outlined in Chapter 2, Section 2.3. An anatomical or fair fracture reduction was achieved with the fibular intramedullary nail in 330 cases (96.5%); in 148 cases (43.3%) the reduction was anatomical and in 182 cases the reduction was fair (53.2%) according to the criteria described by Burwell and Charnley (Chapter 2, Section 2.2). Twelve cases (3.5%) were classified as a poor reduction and of these two cases required revision surgery for mechanical failure and are included in Table 3.4. Further peri-operative data including grade of surgeon, post-operative immobilisation and weightbearing status are presented in Table 3.3

(n/% unless otherwise stated)	**Total Cohort (n=342)**
Grade of surgeon	
- Consultant	73 (21.3)
- Fellow	25 (7.4)
- Registrar	244 (71.3)
Post-operative immobilisation	
- Plaster cast	183 (53.5)
- Removable orthosis	159 (46.5)
Post-operative weightbearing status	
- Full	187 (54.7)
- Partial	50 (14.6)
- Non	105 (30.7)

Table 3.3: Peri-operative data.

3.5.3 Short-term outcome

Mechanical construct failure

Mean short-term follow up was six months (range, 6 weeks–7 years). Twenty cases (5.8%) required revision surgery due to mechanical failure of the fibular intramedullary nail construct (Table 3.4). Of these failures, 13 (3.8%) were due to 'surgeon error' and seven (2.0%) were due to 'device failure'. All failures occurred within 12 weeks of surgery, with a mean period of 3.5 weeks from index procedure to revision. The mean patient age in this group was lower than that of the total cohort at 62.0 years (range, 24-93 years; SD, 15.0). The median number of comorbidities was equal with three comorbidities per patient in both the failure and non-failure groups. There was a comparable incidence of specific medical comorbidities in the failures group compared with the total cohort, including diabetes (n=3, 15%), obesity (n=2, 10%), renal impairment (n=1, 5%) and peripheral neuropathy (n=1, 5%).

The majority of cases of 'surgeon error' were secondary to either inadequate identification or protection of the syndesmosis leading to recurrence of syndesmotic diastasis, which occurred in eight cases (40% of failures; patient 1-8 in Table 3.4) and resulted in a post-operative radiographic diastasis (Figure 3.3). Seven of the eight cases were revised to reduce the syndesmosis and secure with the addition of a second PLS, which was inserted either through the alignment jig or freehand if there was concern about the screw being inserted too close to the articular margin of the tibiotalar joint.

Case	Age	Injury	Description of failure	Revision procedure(s)
Surgeon error: inadequate identification or protection of a syndesmosis injury				
1	56	SER	Recurrence of syndesmotic diastasis	Addition of 2nd PLS
2	87	PAB	Recurrence of syndesmotic diastasis	Addition of 2nd PLS
3	24	PER	Recurrence of syndesmotic diastasis	Addition of 2nd PLS
4	40	SER	Recurrence of syndesmotic diastasis	Addition of 2nd PLS
5	54	SER	Recurrence of syndesmotic diastasis	Addition of 2nd PLS
6	54	SER	Recurrence of syndesmotic diastasis	Conversion to plate and screws with 3x trans-syndesmotic screws
7	37	PAB	Recurrence of syndesmotic diastasis	Addition of 2nd PLS
8	48	PAB	Recurrence of syndesmotic diastasis	Addition of 2nd PLS
Surgeon error: fracture malreduction or poor nail insertion technique				
9	63	SER	Failure to engage distal fragment	Conversion to plates and screws
10	60	SER	Failure to engage distal fragment	Circular frame fixation
11	78	SER	Inadequate talar reduction	Conversion to plate and screws
12	61	SER	Inadequate talar reduction	Conversion to plate and screws
13	56	PAB	Inadequate talar reduction	Nail revision with two PLS
Device failure: all PLS related				
14	93	SER	PLS back out	Addition of 2nd PLS
15	74	SER	PLS back out	Addition of 2nd PLS
16	86	PAB	PLS back out	Addition of 2nd PLS
17	60	PAB	PLS back out	Conversion to Steinman pins + cast
18	68	SER	PLS back out	PLS re-tightened to engage nail
19	66	SER	PLS back out	Conversion to plate and screws
20	72	SER	PLS back out	Further failure with conversion to DC plate and screws

Table 3.4: A summary of mechanical construct failures.

Figure 3.3: Post-operative diastasis requiring revision surgery.

Poor intra-operative technique resulted in mechanical failure in a further five cases (25% of failures group). In two cases the fibula was poorly reduced, resulting in no engagement of the distal fragment with the intramedullary nail, followed by subsequent catastrophic failure (Figure 3.4). One of these cases ultimately required the application of a circular frame to achieve stability and union. In the other three cases the talus had not been adequately reduced, with two cases requiring early revision to conventional plate and screw fixation. The fifth case was revised by simply inserting a second PLS to facilitate talar reduction through medialisation of the fibula.

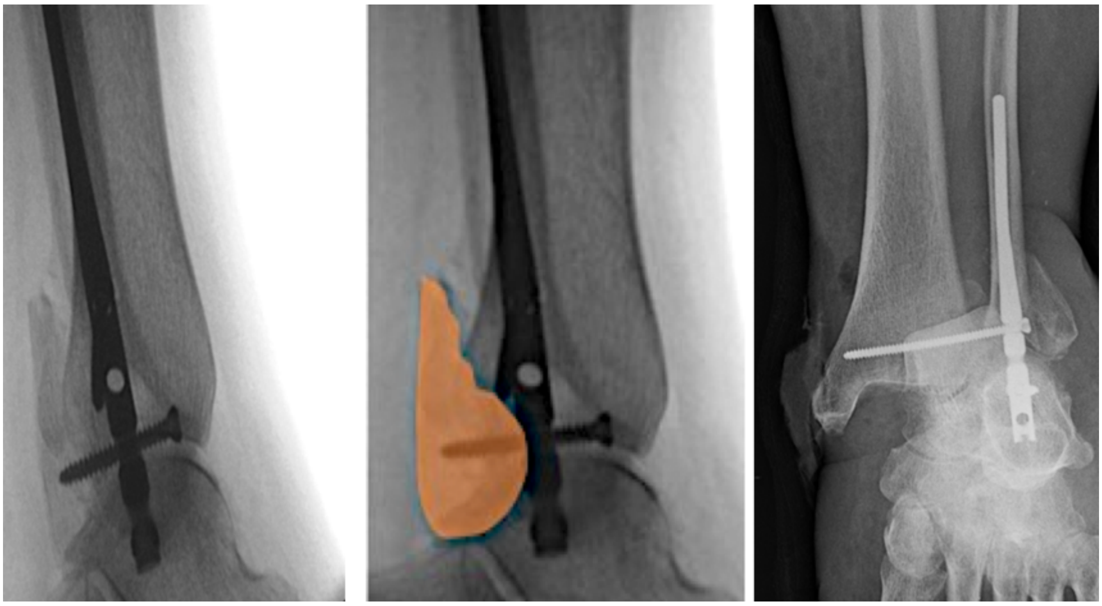

Figure 3.4: Poor fracture reduction with missed distal fragment resulting in early failure.

Seven failures occurred due to device failure, all of which occurred at the interface between the intramedullary nail and the PLS. Backout of this screw with resultant loss of control of the distal fragment and subsequent talar displacement was the most common mode of failure related to the device itself (Figure 3.5). The mean age in this cohort of seven patients was 10 years older than the mean age of the total cohort at 74.1 years (range, 67-93; SD, 12.0). The radiographic bone quality was poorer in this group with evidence of osteopenia; three of the seven patients were on pharmacological treatment for osteoporosis. In this situation, the PLS had been left abutting the lateral cortex of the fibula, but given the poor bone quality, the screw head had lost cortical purchase and subsequently loosened over time. Four of these cases were salvaged by inserting a second PLS to supplement the construct. In one case the current PLS was simply reinserted in the more proximal hole and tightened to fully engage the nail itself (Figure 3.5). There were no cases of nail fracture or DLS failure.

Figure 3.5: PLS failure resulting in revision surgery.

Risk factors for construct failure

Variables were assessed for their association with construct failure and are presented in Table 3.5. Statistically significant injury factors included the presence of a syndesmotic injury ($p=0.006$) and a PAB type injury ($p=0.035$). Finally, placement of the PLS was important to the success of the operation, whereby insertion >20mm above the level of the plafond, in the distal tibial metaphysis was strongly associated with increased risk of failure ($p=0.003$). The number of PLS, DLS, length of screws and length and width of intramedullary nail were not associated with construct failure (all $p>0.05$; Table 3.5). Despite older patients in general having poorer bone quality, increasing age was not associated with risk of failure ($p=0.627$).

Variable	p-value
Patient factors	
- Sex	0.718[a]
- Age at surgery	0.627[b]
Injury factors	
- Associated syndesmotic injury	**0.006***[a]
- Pronation-Abduction (PAB) injury	**0.035***[a]
- Absence of associated posterior malleolar fracture fixation	0.262[a]
- Absence of associated medial malleolar fracture fixation	0.197[a]
Implant/construct factors	
- PLS sited >20mm above the plafond	**0.003***[a]
- Number of PLS (1 or 2)	0.831[a]
- Length of PLS (30-65mm)	0.337[b]
- Number of DLS (1 or 2)	0.367[a]
- Length of DLS (14-20mm)	0.442[b]
- Fibular nail length (110mm, 145mm, 180mm)	0.141[a]

Table 3.5: Factors associated with construct failure. (* statistical significance reached, [a] Chi-squared test, [b] Student's unpaired t-test).

Soft-tissue complications

Thirteen patients (3.8%) not included in the cohort of 20 failed cases required further surgery for removal of symptomatic metalwork; removal of nail and all locking screws (n=5, 1.5%), PLS alone (n=5, 1.5%) and DLS alone (n=3, 0.9%). The incidence of lateral sided infection was 3.2% (n=11). These cases were managed with oral antibiotics alone (n=6), intravenous antibiotics alone (n=2) or implant removal supplemented by intravenous antibiotics (n=3). Therefore, the overall rate of re-operation secondary to symptomatic lateral sided metalwork prominence or infection was 4.7% (n=16).

3.5.4 Mid-term outcome

Of the 342 patients in the study cohort, 55 (16.1%) had died at most recent follow up leaving 287 for potential review (Figure 3.2). PROMs were collected from 229 patients (79.8% response rate of available cohort, 67.0% total cohort) with a mean follow-up of 5.1 years (range, 0.7-8.4; SD, 3.3). All outcome score data apart from return to function was skewed and therefore analysed with non-parametric statistical tests (Table 3.6). Twelve patients in the failed fixation group were contacted and their outcome was compared against those patients with a successful primary procedure. The overall mid-term outcome was classified as ‘good’ (61-90 category)[256] with a median OMAS of 80 (IQR, 50-95) and mean of 71.0 (range, 0-100; SD, 28.0). Outcome scores were generally poorer in those patients requiring revision surgery, with statistical significance reached in the primary outcome measure (OMAS; $p=0.045$) and approaching significance in the MOXFQ ($p=0.064$). There was no difference in the EQ-5D ($p=0.105$), health VAS (0.556), pain VAS ($p=0.442$) or overall treatment satisfaction ($p=0.149$).

When assessing return to function, patients in general returned to employment quicker than sport with a mean interval of 16.8 and 22.8 weeks respectively. Of the four patients in the failures group who were working and/or engaged in sporting activity, two returned to these activities after revision surgery. Although the mean return to work in the failures group was quicker (Table 3.6), given that only two patients were included in this group, this apparent advantage is likely erroneous and was not deemed appropriate for further statistical analysis.

Outcome measure (median, IQR)	**Total Group (n=229/342, 67%)**	**Failure (n=12/20, 60%)**	**Non-Failure (n=219/322, 68%)**	**p-value [a]**
PROMs				
- *OMAS*	80 (50-95)	65 (36-75)	80 (50-97)	**0.045***
- *MOXFQ*	10.9 (0-44.0)	31.3 (9.4-79.7)	9.38 (0-42.2)	0.064
- *EQ-5D*	0.76 (0.69-1.00)	0.71 (0.65-0.84)	0.80 (0.69-1.00)	0.105
Health VAS	80 (70-100)	80 (61-90)	80 (70-100)	0.556
Pain VAS	90 (60-100)	85 (60-100)	90 (60-100)	0.442
Satisfaction	90 (80-100)	84 (57-92)	90 (79-100)	0.149
Mean return to function				
- *Employment*	16.8 (1-112, 26.5)	14 (12-16, 2.8)	26 (1-112, 60.9)	NT
- *Sport*	22.8 (0-112, 26.7)	48 (24-72, 25.6)	21 (0-112, 23.9)	NT

Table 3.6: Mid-term patient reported outcome comparison between groups. (* statistical significance reached, [a] Mann-Whitney U test, NT: not tested due to insufficient numbers).

3.6 Discussion

This chapter has assessed the short and mid-term outcome of a large cohort of patients managed with a fibular intramedullary nail. This is the first study to report the rate of mechanical failure requiring revision surgery and perform a detailed case analysis in order to describe key modes of failure. Finally, through the collection of mid-term patient reported outcome scores at a mean follow-up period of five years, the results from this chapter allow surgeons to counsel patients on the anticipated post-operative outcome.

Intramedullary stabilisation of the fibula is not a new concept. Previous authors have historically described fibular fixation using a variety of implants including compression screws and rods, with reasonable biomechanical and clinical outcomes[147-150]. From this principle, intramedullary nail devices were developed by implant companies, including Acumed (Hillsboro, OR, USA). The nailing technique described in this chapter has seen significant developments over the last two decades (Figure 3.1). Before 2008, in the EOTU, the intramedullary nail was routinely inserted with no locking screws and required supplementation with a moulded plaster to confer additional stability. Patients were prevented from weightbearing after surgery for many weeks. This unlocked construct provided no control over fibular length or rotation and fibular shortening was unsurprisingly very common; shortening has been shown to increase tibiotalar contact pressure[284], which can accelerate degenerative changes and is clearly a sub-optimal outcome following treatment. In an attempt to counteract this problem, the nail was locked with a single screw distally, inserted from anterior to posterior. A second bicortical screw was then inserted proximal to the nail tip, aimed at limiting proximal nail migration. Unfortunately, this screw was regularly inserted eccentrically, allowing the nail to bypass the screw and continue to permit fibular shortening. By the end of 2008 the 'gold standard' technique was presented, as described by Bugler et al (2012)[124] and since then has formed the basis for the patient management described in this chapter. This consisted of an intramedullary nail locked with a single distal locking screw (DLS) inserted in an anterior to posterior direction and a single proximal locking screw (PLS) inserted from lateral to medial across the syndesmosis, irrespective of whether a radiographic diastasis was present or not.

The finding of a 6% mechanical failure rate is difficult to compare to the current literature as few studies have focused on failure as a primary outcome. Additionally, no other studies have formulated a description of the modes of failure. In the study by Bugler et al[124], which included 105 patients, the authors reported a failure rate of 7% (seven patients), of whom five required revision surgery[124]. Appleton et al reviewed 37 patients as part of one of the first case series published in 2006[157]. Three patients (8%) required revision fixation, but it was felt that failure in these cases was secondary to failure of fixation of either the medial or posterior malleolus. White et al conducted a prospective randomised controlled trial comparing fibular intramedullary nailing (n=50) with traditional plating (n=50)[162]. They reported no mechanical failures in either group, but one case of loss of fracture reduction not requiring revision surgery in both groups. Dabash et al included 18 'high-risk' patients with underlying significant comorbidities including advanced diabetes, chronic renal disease, osteoporosis and alcohol excess[122]. Despite a poor rate of compliance with weightbearing restrictions, the authors did not encounter any cases of failed fixation. This observation serves as reassurance given the recognition of increase complications in this specific high-risk patient group.

The mid-term outcomes presented in this chapter, generally compare favourably to the findings of other authors. Rajeev et al reviewed 24 patients managed with an alternative locked nail construct (Biomet SST fibular nail, Biomet, Warsaw, Indiana) and reported a lower OMAS of 58, but this was in a predominantly older patient cohort with a mean age of 79 years[154]. At a mean follow up of six years, the study published by Bugler et al reported a mean OMAS of 65[124]. Al-Obaidi et al followed up 23 patients from an initial cohort of 39 treated with intramedullary nail fixation at one year and reported a mean OMAS of 54[121]. This value is lower than reported elsewhere, but their cohort included a greater proportion of open fractures, which may explain this poorer value. In agreement with the findings of this chapter, the authors describe a case of mechanical failure whereby the construct had been unable to maintain mortise containment through post-operative recurrence of syndesmotic diastasis and required revision fixation. In the study by White at al previously discussed[162], at the primary outcome point (one year following surgery) the mean OMAS was 62.5, compared with 58.9 in the plating group, which was not statistically significant. Two previous studies have demonstrated superior patient outcome as reported by the OMAS. In the study by Appleton et al[157] the authors reported an impressive OMAS at one year of 87. However, the reporting of this outcome measure was modified by the authors by excluding the ‘running and jumping’ category given the mean age of the patient population, making it difficult to make accurate comparisons with the results of the current study. More recently Badenhort et al reported a median OMAS of 100 at one year for both intramedullary nailing and traditional plate fixation as part of a RCT[163]. Given the high loss to follow-up and multiple missing data points, this should be interpreted with caution as it is uncommon for patients to return to their pre-injury function following surgery[71, 72].

3.6.1 Technical refinements

The results of this chapter have led to several important technical refinements. The under recognition of an associated syndesmosis injury resulted in a large proportion of failures. Although the insertion of a proximal locking screw into the tibia is a key step in the technique, it is recognised that this screw is unlikely to maintain syndesmotic reduction, especially if non-weightbearing restrictions are not prescribed or adhered to. Once the nail is locked distally and with the jig still attached, the integrity of the syndesmosis can be assessed intra-operatively by lateralising the jig whilst the surgeon stabilises the affected limb, resulting in a modified 'stress-test' (Figure 3.6). If this manoeuvre demonstrates a diastasis or a syndesmotic injury is evident on the pre-operative radiographs, the insertion of a second PLS is now recommended.

Figure 3.6: Intra-operative ‘stress-test’ of the syndesmosis with insertion of two PLS.

In patients without a confirmed diastasis, it is acceptable to insert a single PLS to control implant length and rotation. As PLS back-out in this study was related to screw position in the distal tibia, it is recommended to insert the most distal screw close to the tibial plafond and certainly within 20mm of the articular surface; this exploits the denser bone that is found in the subchondral zone of the tibia[285]. This principle is particularly valid in patients with poor quality bone, such as the elderly and those with established osteoporosis. However, due to anatomical concavity of the plafond, care must be taken to avoid inadvertent articular penetration and assessment of screw position on the lateral fluoroscopy view is critical. Finally, in situations where the lateral cortex of the fibula does not provide a sufficient purchase for the screw head, the screw should be driven in to engage the nail itself, to reduce the risk of screw backout and subsequent loss of fracture reduction.

3.6.2 Strengths and limitations

The main strength of this study is the documentation of both the short and mid-term outcomes from a large patient population managed according to a published surgical technique[124, 162]. This study is unique in that it begins to identify and describe modes of failure in an effort to further refine the surgical technique. A number of findings contained within this chapter have been practice changing in the EOTU, which in turn will hopefully improve patient care. In addition to data on general health outcomes, validated foot and ankle outcome scores have been collected, including the widely used OMAS and the more contemporary MOXFQ, adopted extensively in the recent foot and ankle literature[275, 278, 286].

The primary limitation relates to the retrospective design, with a loss to follow up of 33% of the total cohort. However, given the mean patient age and the length of follow up, half (16%) of these patients died during the follow up period. It was only possible to collect outcome scores from 12 patients in the 'failure' group due to patient mortality and lack of patient response to multiple contact attempts. National imaging archives were searched to look for evidence of late mechanical failure in this group of patients and no cases were identified. Whilst only the OMAS demonstrated statistical and clinical significance, favouring the non-failure group by a median score of 15 points, the remaining outcome scores failed to show any significant difference at mid-term follow up. Given the low numbers in both groups, this is likely to represent a type II error. As patients were not reviewed in the outpatient clinic, it has not been possible to report on the longer-term radiographic evidence of osteoarthritis. Despite this a median total cohort OMAS of 80 represents a 'good' outcome and a median EQ-5D of 0.76 is comparable, if not better than the median EQ-5D index population norm of

0.71 for 65-74 year olds living in the UK[287]. Finally, pre-operative CT imaging of select fracture patterns may have helped operative planning and reduced the incidence of mechanical failure through better understanding of the fracture complexity. Performing CT scans on failed fixation cases would have afforded a more detailed assessment of the mode of failure, in particular where reduction of the syndesmosis was not maintained, and this should be the focus of future research to better define the modes of failure.

3.6.3 Key conclusions

The fibular intramedullary nail provides secure fixation with good patient-reported outcomes when used in the management of unstable ankle fractures. Through analysis of failed fixation cases, technical refinements including a dynamic intra-operative assessment of the syndesmosis and using two PLSs in confirmed syndesmosis injury have been proposed to reduce the future risk of mechanical failure.

3.6.4 Directions for future research

Whilst the intramedullary nail has demonstrated an acceptable rate of mechanical failure and positive patient reported outcome at mid-term follow up, the implant itself and the technique for insertion does require a degree of familiarity and may not be suitable for all fracture patterns and complexities. Future studies that investigate its performance against other constructs commonly used in the management of ankle fractures, particularly in high-risk patient groups, are required to corroborate the findings of this chapter and define the capabilities of the intramedullary nail further.

4. BIOMECHANICAL COMPARISON OF THE FIBULAR INTRAMEDULLARY NAIL VERSUS LOCKING PLATE AND LAG SCREW FIXATION IN THE MANAGEMENT OF DISTAL FIBULA FRACTURES

Material from this chapter has been published in the Journal of Orthopaedic Trauma (JOT) in 2020[288], appendix 6.

Carter TH, Wallace R, Mackenzie SA, Oliver WM, Duckworth AD, White TO. The Fibular Intramedullary Nail Versus Locking Plate and Lag Screw Fixation in the Management of Unstable Elderly Ankle Fractures: A Cadaveric Biomechanical Comparison. J Orthop Trauma. 2020;34(11):e401-e6.

4.1 Aims and Hypothesis

With a mechanical failure rate of 5.8%, the results from Chapter 3 support the use of the fibular intramedullary nail in the treatment of unstable ankle fractures. The mean patient age presented in Chapter 3 was 64.6 years and 73% of patients were women. The incidence of confirmed osteoporosis, on regular pharmacological intervention was only 6.1% (21 patients), although it could be suspected that given the demographic described, this figure was likely to have been higher, although not formally diagnosed before injury. When ankle fractures occur in this clinical situation, surgeons not familiar with the fibular intramedullary nail may favour a distal fibular locking plate over conventional non-locking tubular alternatives. However, soft tissue complications occur more frequently with locking plates and therefore percutaneous intramedullary stabilisation is an attractive alternative. The aim of this chapter was to explore this concept further by comparing the biomechanical failure properties of the fibular intramedullary nail and distal fibular locking plate in a cadaveric setting.

The hypothesis was that locking plate and lag screw fixation is superior to fibular intramedullary nail fixation when tested to failure in a cadaveric setting.

4.2 Chapter Summary

This cadaveric biomechanical study included twelve fresh-frozen cadaveric lower limbs (six matched pairs), which were systematically prepared, through soft-tissue releases and a fibular osteotomy, to create a simulated AO/OTA 44-B type fracture. No injury was created on the medial side. The limbs were randomised within each pair to receive either a fibular intramedullary nail or a distal fibular locking plate supplemented with an interfragmentary lag screw. The limbs were secured on a custom-made foot plate with the foot held rigidly in 20 degrees of supination, axially loaded to 700N and subjected to progressive external rotation until failure.

The mean specimen age was 86.5 years (range, 61-97; SD, 13.0). The mean torque to failure was greater in the nail group (23.5 N·m) compared with the locking plate group (21.6 N·m) but did not reach statistical significance (p=0.463). The nail group failed at a significantly greater mean angle of rotation (66.5°) compared with the locking plate group (53.3°; p=0.046). There was no difference in construct stiffness (p=0.673) or energy absorbed (p=0.075) between groups. The locking plates failed by plate and screw pull off at the implant-bone interface (three proximal and three distal failures). This contrasted with the nail group, which failed almost exclusively at the lateral ligament complex, whilst the fracture-implant construct remained intact.

This chapter demonstrated that locking plate and lag screw fixation was not superior to fibular intramedullary nail fixation when tested to failure in a cadaveric setting using elderly specimens. The minimally invasive technique afforded by the intramedullary nail does not appear to negatively affect its biomechanical properties.

4.3 Chapter Introduction

Distal fibular locking plate technology has demonstrated biomechanical advantages when examined in osteoporotic cadaveric specimens[134, 289], although has not established comparable clinical merit in both retrospective[290] and prospective studies[140]. Their use has been questioned by some given the three-fold increase in wound complications[290] and substantial cost[139], compared with non-locking alternatives. Additionally, the benefit of locking plate technology has not been sufficiently demonstrated by studies performed in normal bone density[291]. Other authors claim there is no difference in complication rates between the two implants[142].

Only one biomechanical study has compared the fibular intramedullary nail to a locking plate construct. Switaj et al created an iatrogenic comminuted AO/OTA 44-C type fracture with syndesmotic injury in 20 cadaveric legs (10 matched pairs) and found no difference in syndesmotic diastasis during cyclic loading or torque to failure during progressive application of external rotation[160]. With the advantages of the minimally invasive technique over a large exposure for plate fixation in suprasyndesmotic injuries, the authors concluded that the fibular intramedullary nail was an attractive implant choice in this clinical situation. To date, no studies have compared the fibular intramedullary nail with a distal fibular locking plate in the setting of an AO/OTA 44-B type fracture. This fracture configuration is the most common injury pattern seen clinically in the elderly patient group (≥60 years) with evidence to suggest a rate of 70% of all presenting ankle fractures[39]. As locking plate fixation is currently regarded as the 'gold standard', this study aimed to test the hypothesis that locking plate and lag screw fixation is superior to fibular intramedullary nail fixation when tested to failure in a cadaveric setting.

4.4 Methods

4.4.1 Preparation of specimens

Following thawing and initial preparation described in Chapter 2, Section 2.1, a soft-tissue window was created from 20mm distal to the fibular tip and extended proximally approximately 120mm (Figure 4.1).

Figure 4.1: Soft tissue dissection to expose the fibula.

The limbs were inspected to rule out previous injury. An iatrogenic supination-external rotation type injury was created. Firstly, the fibres of the AITFL and PITFL were divided using sharp dissection (Figure 4.2). The lateral ligament complex and interosseous ligaments were preserved. An osteotomy line was templated, then cut using an oscillating saw, starting at the anterior margin of the fibula incisura and extended at a 45° angle in a proximal and posterior direction, as would be routinely seen in clinical practice (Figure 4.3). No injury was created on the medial side.

Figure 4.2: Following division of the AITFL using sharp dissection.

Figure 4.3: Osteotomy created at 45° angle to the long axis of the fibula.

The limbs were randomised within each pair, via a simple coin toss technique[292-294], to receive either a fibular intramedullary nail (Fibula Rod, Acumed, Hillsboro, OR, USA) or a pre-contoured distal fibular locking plate (Ankle3, Acumed, Hillsboro, OR, USA) supplemented with an interfragmentary lag screw (Figure 4.4)[j].

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[j] Thank you to Acumed for providing the implants and instrumentation trays.

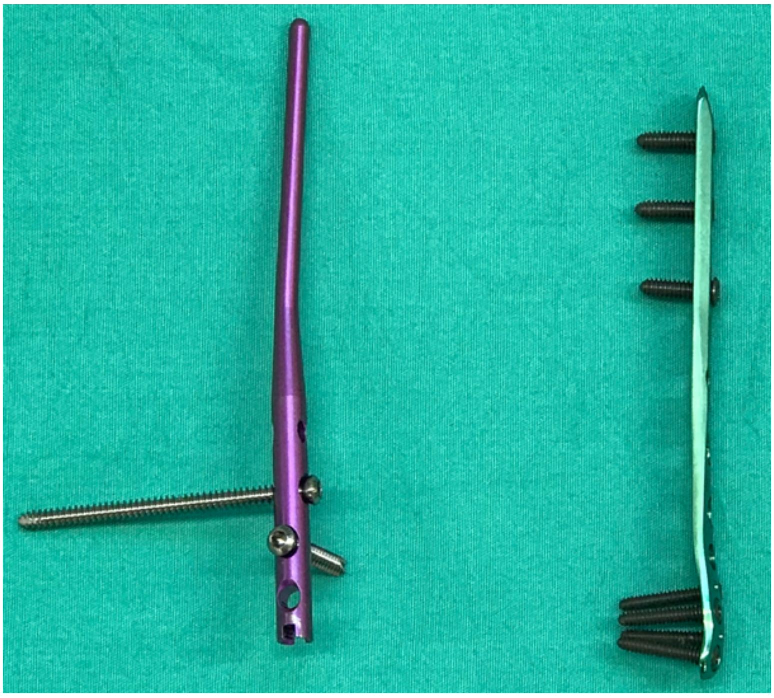

Figure 4.4: Fibular intramedullary nail and locking plate implants.

In the locking plate fixation group, the technique followed that described in Chapter 2, Section 2.3. An interfragmentary 3.5mm cortical screw was first inserted perpendicular to the osteotomy. An appropriately sided 6-hole (103mm length) distal fibular locking plate was secured against the lateral aspect of the fibula with four 2.7mm x 16mm unicortical locking screws distally and three 3.5mm x 12mm bicortical locking screws proximally. In the intramedullary nail group, the technique followed that described in Chapter 2, Section 2.3. Given the mean age of the cadaveric specimens and capacious intramedullary canals, the 3.6mm diameter x 110mm length nail was used in all cases. The construct was completed with a 3.5mm x 20mm DLS inserted in the most proximal of the two available holes, followed by a 3.5mm x 50mm PLS inserted across the syndesmosis in the most distal of the two available holes, with the jig positioned in 30^{o} of external rotation.

4.4.2 Mechanical testing

All limbs were tested at the local University department of Orthopaedic Engineering[k]. Each specimen was secured using a custom-made baseplate with a built in 20-degree angle. A 5mm threaded pin was inserted through the body of the calcaneus, parallel to the intermalleolar axis (Figure 4.5), supporting the foot in rigid supination. The specimens were secured proximally via a further 5mm threaded pin inserted through the tibia and then fibula approximately 5cm below the proximal tibiofibular joint as per the previous study by Smith et al[161].

Figure 4.5: Distal transcalcaneal fixation secured into custom-made 20^{o} baseplate.

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[k] Thank you to Dr Rob Wallace at the department of Orthopaedic engineering at the University of Edinburgh for assistance with the biomechanical testing and Mr Iain Campbell at the University of Edinburgh anatomy department for accompanying the specimens during transit and testing.

The proximal pin was secured by lowering the mobile arm of the testing apparatus to engage the threaded pin within the slotted flanges. Mechanical testing was performed using a Zwick/Roell z005 machine (Zwick Roell, GMBH & Co., Germany), with a 5kN load cell and a 100N·m torque cell. An initial pre-load of 5N was applied to secure the specimen. The specimen was then progressively loaded with 800N of force at a rate of 100N/second, to simulate single-leg stance. External rotation at a rate of 30 degrees/second was generated by rotating the proximal mobile arm of the testing apparatus in a clockwise direction for a left sided limb and anti-clockwise for a right sided limb. Measurements included torque to failure in newton-metres (N·m), angle at failure in degrees (^{o}), construct stiffness in newton-metres per degree of rotation (N·m/^{o}) and energy absorbed in Joules (J). The point of failure was defined as the first point at which the loaded specimen demonstrated a distinct reduction in torque with a corresponding increase in angle of rotation. Construct stiffness was calculated using the initial linear region of the torque vs. angle graph. Energy absorbed by the specimen to induce failure was calculated from the area under the curve. The specimens were visually inspected to describe the mode of failure.

4.4.3 Mechanical testing modification

When testing the first specimen, the 800N force applied through the proximal arm of the testing apparatus, followed by internal rotation caused the tibial pin to fracture the proximal tibial metaphysis. Examination of this specimen revealed diffuse poor bone quality with thin tibial cortices (Figure 4.6). Consequently, the method of proximal fixation and force applied to represent weightbearing was modified; the specimens were divided 25cm above the distal fibular tip, in the mid- to upper-tibial diaphyseal region, and the surrounding soft tissues were dissected free to allow access to both the tibia and fibula. The interosseous membrane was preserved. The force applied was reduced from 800N to 700N, again applied at a rate of 100N/second.

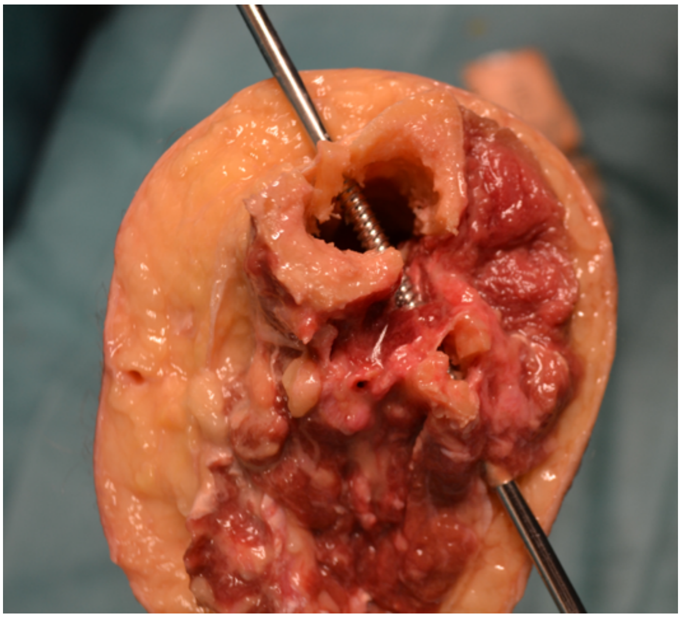

Figure 4.6: Failed proximal pin fixation due to tibial fracture.

The specimens were rigidly fixed proximally in custom-made 3mm thick metal pots filled with polymethylmethacrylate (PMMA) bone cement (Figure 4.7 & Figure 4.8). Once the bone cement had set, a 6mm hole was drilled through the metal pot, cement mantle and specimen, followed by passage of the original 5mm threaded pin. To account for slight vertical malalignment of the limb in the testing apparatus and to allow even distribution of load during compression, a 10mm ball bearing was placed between the slotted compression plate on the mobile arm of the Zwick machine and the specimen (Figure 4.9), as described by Zhao et al[295]. This series of modifications improved proximal tibial fixation and no further fractures were encountered. Distal fixation of the specimens, using the custom-made baseplate, remained unchanged. The final mechanical testing set-up is demonstrated in Figure 4.10.

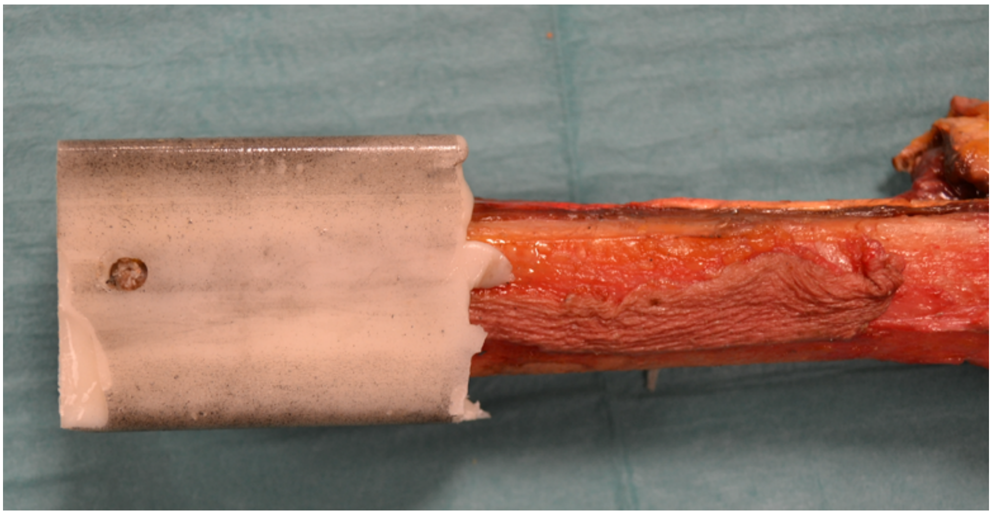

Figure 4.7: Proximal fixation with PMMA cement pot (view from the side).

Figure 4.8: Proximal fixation with PMMA cement pot (view from underneath).

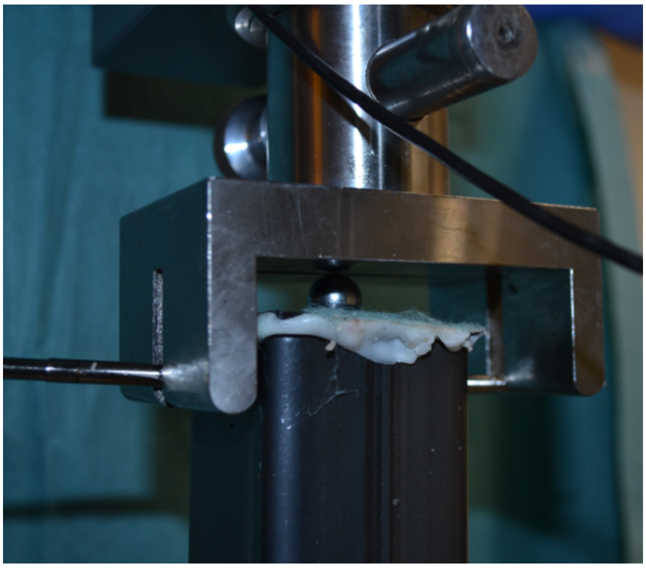

Figure 4.9: Modified proximal fixation technique with ball bearing.

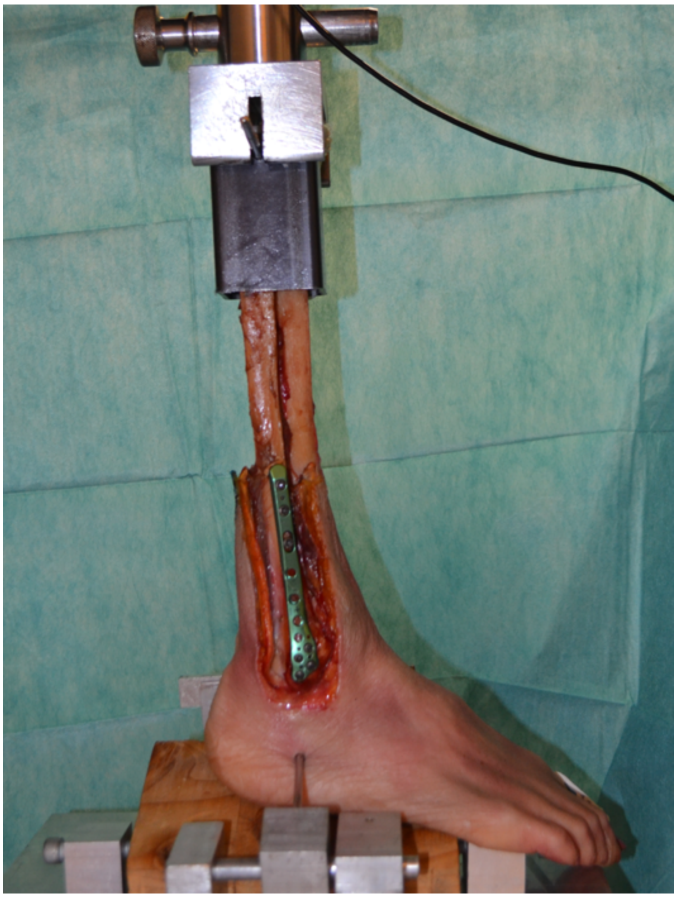

Figure 4.10: Final mechanical testing set-up following modification.

4.4.4 Statistical analysis

Data analysis was performed using IBM SPSS software version 23.0 (Armonk, NY: IBM Corp). Data normality was assessed using the Shapiro-Wilk test and all continuous data was found to follow a normal distribution. Despite this, due to the small sample size (six matched pairs) a non-parametric paired samples Wilcoxon rank-sum test was used to compare the two groups with respect to peak torque to failure, angle at failure, stiffness and energy absorbed. A p-value of <0.05 was considered significant. Post hoc power analysis was performed for each of the measured parameters using G*Power (version 3.9.1.6, Heinrich-Heine-Universität Düsseldorf). For a difference of 20% in torque to failure, angle at failure, construct stiffness and energy absorbed the power was 26%, 96%, 23% and 75% respectively.

4.5 Results

4.5.1 Specimens

The mean age at death of the six cadavers was 86.5 years (range, 61-97; SD, 13.0). Three (50%) were women. Limited available data on demographics, comorbidities and the mode of failure, following visual inspection are summarised in (Table 4.1).

Pair	Test number	Age (years)	Sex	Comorbidities	Mode of failure
1	1902	83	M	Pancreatic cancer, ischaemic heart disease	Nail: lateral ligaments Plate: proximal locking screws
2	1741	93	M	Pneumonia, frailty, chronic airways disease	Nail: lateral ligaments Plate: distal locking screws
3	1736	88	M	Pneumonia, interstitial lung disease	Nail: lateral ligaments Plate: distal locking screws
4	1911	61	W	Cervical cancer	Nail: lateral ligaments Plate: proximal locking screws
5	1907	97	W	Frailty, chronic kidney disease, dementia	Nail: fracture (osteotomy) site Plate: proximal locking screws
6	1904	97	W	Forehead squamous cell carcinoma, liver disease	Nail: lateral ligaments Plate: distal locking screws
Mean (range)		86.5 (61-97)	M:3 W:3		

Table 4.1: Demographic data and failure modes.

4.5.2 Biomechanical testing to failure

The mean torque to failure was 23.5N·m (range, 9.3-29.3; SD, 7.6) in the nail group versus 21.6N·m (range, 5.8-29.3; SD, 8.5) in the plate group (p=0.463,Table 4.2; Figure 4.11). The mean angle at failure was 66.5° (range, 46.0-75.0; SD, 10.4) in the nail group versus 53.3° (range, 48.0-62.0; SD, 6.0) in the plate group (p=0.046).

Construct stiffness was greater in the plate group, represented by a steeper gradient in the torque to failure curve (Figure 4.11) with a mean stiffness of 0.46N·m/° (range, 0.11-0.76; SD 0.22) versus 0.43N·m/° (range, 0.22-0.64; SD 0.15) in the nail group ($p=0.673$). The mean energy absorbed was greatest in the nail group with a mean of 865.2J (range, 233-1122; SD 351) versus 585.8J (range, 169-934; SD 249) in the plate group ($p=0.075$). A torque to failure curve for paired specimen four is displayed in Figure 4.12.

Pair	**Ultimate Torque to Failure (N·m)**			**Angle at Failure (°)**			**Stiffness (N·m/°)**			**Energy Absorbed (J)**		
	N	**P**	**p-val [a]**	**N**	**P**	**p-val [a]**	**N**	**P**	**p-val [a]**	**N**	**P**	**p-val[a]**
1	28.0	29.3		68.0	48.0		0.51	0.76		1122	562	
2	28.7	21.6		68.2	49.0		0.49	0.56		968	576	
3	23.8	24.0		75.0	62.0		0.41	0.34		1099	702	
4	29.3	20.7		69.8	54.0		0.64	0.53		1090	572	
5	9.3	5.8		46.0	48.0		0.22	0.11		233	169	
6	22.0	28.0		72.0	58.9		0.30	0.46		679	934	
	23.5 (9.3-29.3)	21.6 (5.8-29.3)	0.463	66.5 (46.0-75.0)	53.3 (48.0-62.0)	**0.046***	0.43 (0.22-0.64)	0.46 (0.11-0.76)	0.673	865.2 (233-1122)	585.8 (169-934)	0.075

Table 4.2: Biomechanical testing results. (N: nail, P: plate, [a] Wilcoxon rank-sum test, * statistical significance reached).

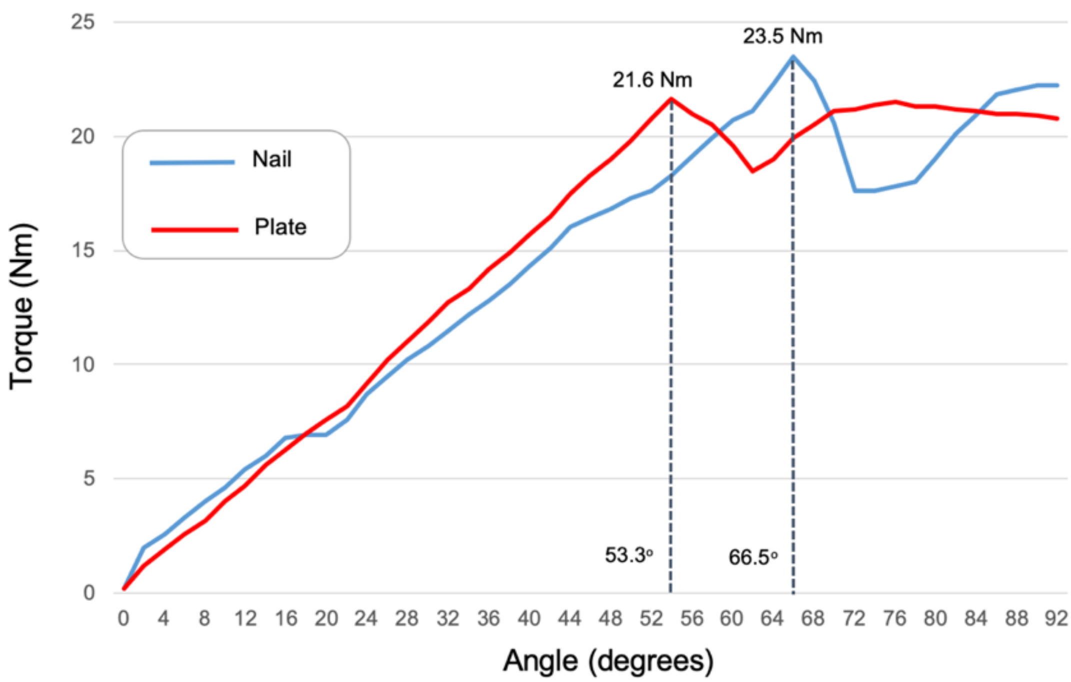

Figure 4.11: Mean torque to failure curve for all six matched pairs.

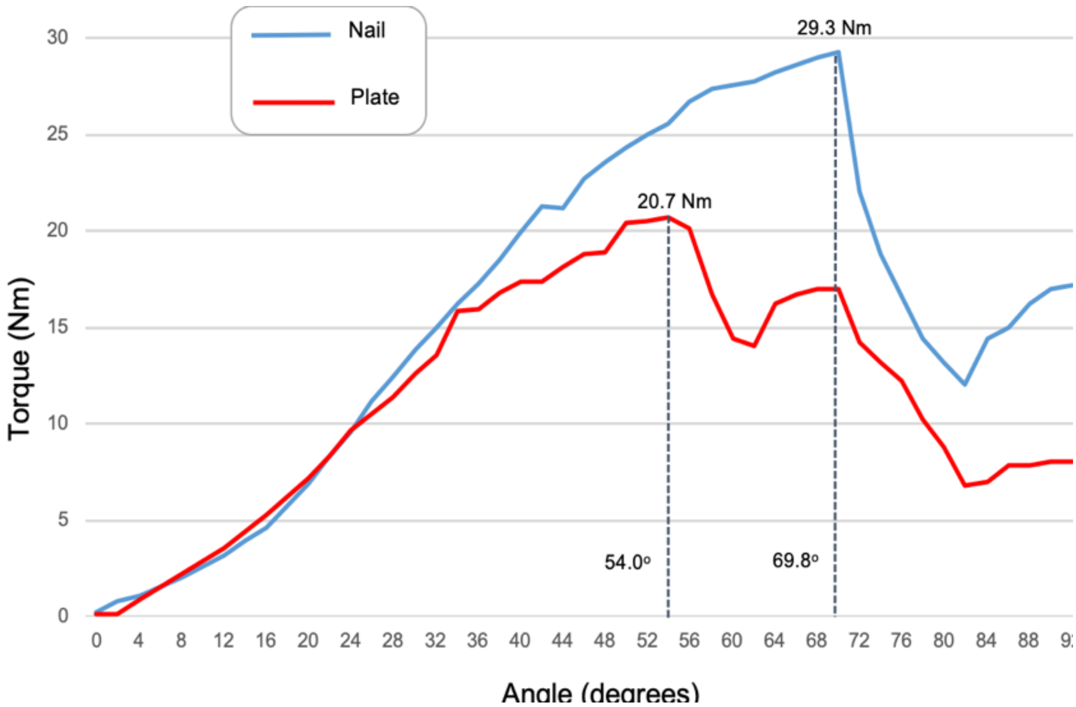

Figure 4.12: Torque to failure curve for paired specimen four.

4.5.3 Modes of failure

At the end of testing, each specimen was dissected and visually inspected to describe the mode of failure. Five of the six intramedullary nail specimens failed at the lateral ligament complex, either through a purely ligamentous avulsion or a bony avulsion from the distal fibula, at the insertion (Figure 4.13). One nail specimen failed at the osteotomy site with loss of reduction and spiral propagation of the fracture. In the plate fixation group, three specimens failed due to pull-out of the proximal locking screws with an associated fracture of the fibular diaphysis (Figure 4.14) and three failed distally through locking screw pull out (Figure 4.15).

Figure 4.13: Intramedullary nail failure with bony avulsion of lateral ligament complex.

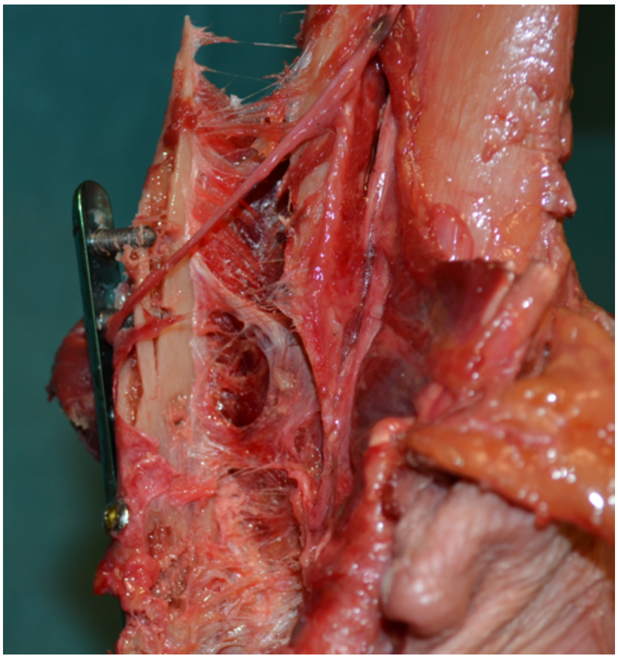

Figure 4.14: Plate failure with proximal locking screw pull-out and associated fracture.

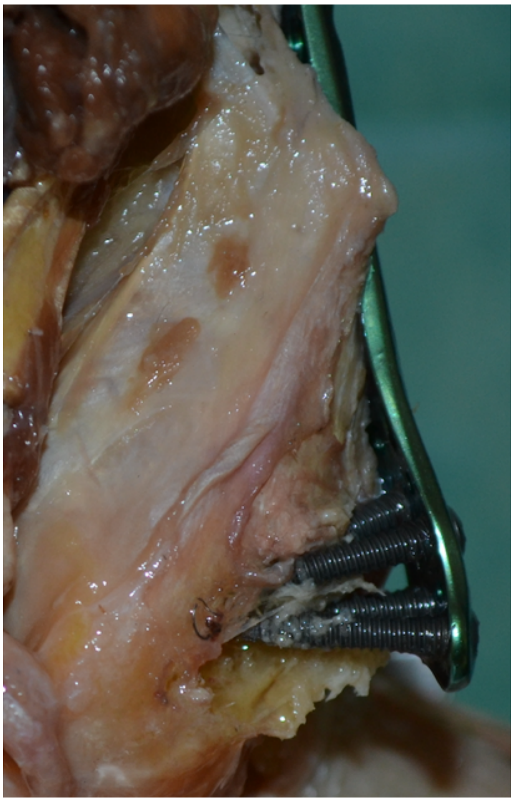

Figure 4.15: Plate failure with pull-out of distal locking screws from the fibula.

4.6 Chapter Discussion

This is the first investigation to directly compare the biomechanical properties of the fibular intramedullary nail and distal fibular locking plate in the management of AO/OTA 44-B type fractures when tested to failure in a cadaveric setting. Within the limitations of the small number of matched paired specimens tested locking plate and lag screw fixation was not found to be superior to fibular intramedullary nail fixation when measuring torque to failure, angle at failure, construct stiffness and energy absorbed. Statistical significance was reached with respect to angle at failure, favouring the intramedullary nail. The results of this study support the use of either an intramedullary nail or a locking plate in the management of AO/OTA B-type fractures. The decision on which implant to use should come down to local resources and experience with the specific techniques. The minimally invasive nature of the intramedullary nail, combined with the biomechanical findings of this chapter, make it an appealing implant to use, specifically in those patients with a compromised soft tissue envelope.

The values recorded for torque to failure in this study are similar to other published literature. Smith et al included ten matched lower limb pairs, comparing the fibular intramedullary nail with a 1/3 tubular non-locking plate supplemented with lag screw fixation[161]. The mean torque to failure was 28.4N·m in the fibular intramedullary nail group and 22.8N·m in the plate group ($p<0.05$). The specimens were on average 4.5 years younger, which may explain why the values are slightly higher than those in the current study. The mean difference in torque to failure between the two groups investigated in each study was lower in the current study, which may imply that distal fibular locking plate fixation is more effective than standard 1/3 tubular plate fixation in managing elderly distal fibula fractures. This concept has been demonstrated by Zahn et al, whereby locking plate fixation provided almost three times the torque to failure compared with non-locking plate constructs (11.2N·m vs. 4.3N·m)[134]. However, this study was limited by the use of unmatched specimen pairs and the fracture patterns were created by application of progressive axial load and torsion, which may have significantly limited the quality control of the material included. Conversely, Davis et al found that non-locking plates provided the greatest torque to failure, compared with locking alternatives[137]. Their study was however conducted using unmatched embalmed cadavers and not fresh-frozen specimens, which makes the findings of their study difficult to compare directly. The only published study to date, directly comparing the fibular intramedullary nail and locking plate fixation in matched cadaveric specimens was performed by Switaj et al (2016)[160]. This study included AO/OTA 44-C type injuries and found a greater torque to failure in the intramedullary nail group (29.6N·m vs. 28.1N·m), but without statistical significance. Angle at failure was comparable between groups, and significantly greater than that found in the current study. This may be explained by the difference in injuries included: type-C fractures were replicated iatrogenically by dividing the interosseous membrane and interosseous ligament, additional to releases of the AITFL and PITFL. Consequently, they are injuries with considerable rotational instability, conceivably permitting a greater angle of rotation before failure. Switaj et al concluded that the fibular intramedullary nail possessed similar failure characteristics to that of distal fibular locking plate fixation in the management of supra-syndesmotic injuries. The results of the current study build on these conclusions, through application of similar findings, but applied to a much more commonly presenting fracture pattern, especially in elderly osteoporotic bone[39].

4.6.1 Strengths and limitations

The main strength of this study is the investigation of two commercially available implants in a well-recognised and frequently managed pattern of ankle fracture (AO/OTA 44-B) in an elderly population. The injury was created in a uniform manner using a sequence of pre-determined steps, based on a previously published technique[161]. This is in contrast to inducing a fracture mechanically through the application of load and progressive axial rotation, as used in other studies[134]. This technique can lead to loss of injury standardisation and as a consequence, wastage of precious cadaveric material. The mechanical testing was supervised by a senior orthopaedic engineer, who advised on the technique modification following early specimen fixation failure.

This study has limitations. Firstly, the number of matched pairs was small and was due to the lack of suitable cadaveric pairs available from the local University anatomy department. Unpaired specimens were accessible, but it was felt that using specimens of this nature would affect the validity of the results obtained and were therefore not considered. Similar studies in the literature have included between seven and ten matched pairs (14-20 limbs)[127, 138, 160, 161, 289, 291]. There was also a lack of bone mineral density (BMD) assessment of the specimens and a previous history of osteoporosis was not accurately recorded for the cadavers studied. The strict inclusion of matched pairs should have minimised any variation in BMD between the two groups.

Whilst the specimens were directly inspected during preparation and no evidence of injury was detected, radiographs assessing for previous injury were not available. With respect to the implant techniques themselves, a transyndesmotic screw was inserted through the intramedullary nail as a way of controlling fibular length and rotation. This is a critical step in the published technique[124], and whilst important, it should be acknowledged that this screw was not used in the locking plate group, which was instead supplemented with an interfragmentary screw. This may have affected the biomechanical properties of the locking plate group and future study should involve a third group, which includes locking plate fixation with a transyndesmotic screw. Finally, it was not possible to perform cyclical loading of the specimens before testing torque to failure, due to limitations of the available orthopaedic engineering facilities. Cyclical loading may have delivered a more clinically accurate representation of weightbearing but requires additional equipment and is timely due to the repetitive nature of the investigation.

4.6.2 Key conclusions

Distal fibular locking plate and lag screw fixation is not superior to fibular intramedullary nailing when tested to failure in an AO/OTA 44-B type fracture pattern simulated in elderly cadaveric bone, including torque to failure, angle at failure, stiffness and energy absorbed by each construct. The minimally invasive nature of the intramedullary nail does not appear to negatively affect its biomechanical properties. Whilst both implants afford secure fixation, the percutaneous nature of the intramedullary nail make it an attractive treatment option, particularly in the elderly and other high-risk patient cohorts.

5. MEDIAL MALLEOLAR FRACTURE FIXATION IN COMBINATION WITH FIBULAR INTRAMEDULLARY NAILING: A RETROSPECTIVE REVIEW

Material from this chapter has been published in Injury, International Journal of the Care of the Injured in 2019[296], appendix 7.

Carter TH, Mackenzie SP, Bell KR, Hollyer MA, Gill EC, MacDonald DJ, et al. Selective fixation of the medial malleolus in unstable ankle fractures. Injury. 2019;50(4):983-9.

5.1 Aims and Hypothesis

At this stage the thesis moves away from fibular intramedullary nail fixation and investigates the third aim of the thesis; to compare the outcome of patients treated with or without internal fixation of a well-reduced medial malleolar fracture following fibular stabilisation. The aim of the study contained within this chapter was to retrospectively compare the outcome of patients with bimalleolar or trimalleolar ankle fractures who underwent fibular intramedullary nail stabilisation with or without medial malleolar fixation within a single orthopaedic trauma service.

The hypothesis was that internal fixation of well-reduced medial malleolar fractures following fibular stabilisation is superior to non-fixation according to patient reported outcomes (primary outcome measure: OMAS) and complication rates.

5.2 Chapter Summary

Review of a single-centre prospective trauma database identified all patients managed over an eight-year period with a fibular intramedullary nail. Patients without a medial malleolar fracture were excluded. The mean age of the 247 patients included was 66.7 years (range, 25-96; SD, 16.1 years) and 200 (81.0%) were women. Following fibular stabilisation, the medial malleolar fracture was internally fixed in 193 (78.1%) patients and managed conservatively in 54 (21.9%) patients. In general, patients in the non-fixation group were older, women, had more comorbidities and were lower demand. The primary short-term outcome was complications, in particular medial sided. The primary mid-term outcome was the OMAS.

There was no difference between the groups with respect to fixation failure (p=0.634) or loss of talar reduction (p=0.157). No patient in either group required further surgery for the management of a medial malleolar non-union. Medial sided soft tissue complications were more frequent in the fixation group, with 10% of patients requiring further surgery for medial complications. Evidence of medial sided radiographic union at the point of discharge was lacking in 16 (29.6%) patients in the non-fixation group compared with 22 (11.4%) in the fixation group (p=0.002), although no patient required further surgery to address a symptomatic non-union. The median OMAS at a mean follow-up of 4.8 years was comparable (p=0.885). This chapter has demonstrated equivalent mid-term patient reported outcome with reduced complication rates following the non-operative management of an associated medial malleolar fracture after intramedullary fibular stabilisation. Future high-quality prospective work is required to investigate whether a similar treatment approach to ankle fractures treated without intramedullary stabilisation is transferrable.

5.3 Chapter Introduction

Whilst isolated, stable fractures of the medial malleolus are frequently treated conservatively with good outcomes[60, 169], there has been recent interest in the non-operative management of medial malleolar fractures as part of unstable injury patterns, including bimalleolar and trimalleolar injuries[182]. With potential clinical and biomechanical advantages of the fibular intramedullary nail[122, 124, 156, 160-162, 255, 297], as demonstrated in Chapters 3 and 4 respectively, in addition to concerns regarding surgical incisions in vulnerable soft tissues, over recent years a similar management trend developed in the EOTU. This was particularly relevant after witnessing a reduction in lateral sided wound complications following the increased practice of intramedullary nail fixation, yet a continued rate of medial sided infection and request for removal of symptomatic medial sided metalwork. This development had stimulated some orthopaedic trauma surgeons in the EOTU to selectively leave well-reduced medial malleolar fractures without fixation following fibular stabilisation with an intramedullary nail, especially if there were concerns regarding the condition of the soft tissue envelope. This chapter compares the short and mid-term outcome between patients managed with and without medial malleolar fixation in combination with fibular intramedullary nailing.

5.4 Patients and Methods

5.4.1 Patients and database construction

A retrospective analysis of a prospectively collected single centre trauma database, described in Chapter 2, Section 2.1, containing 362 cases was performed. Patients were excluded if they did not have an associated medial malleolar fracture (n=95) or lacked a minimum of six to eight weeks post-operative radiographic follow-up (n=20), identifying a cohort of 247 fractures in 247 patients. Electronic records were assessed for demographics, injury characteristics, operative data, complications, subsequent treatments and/or procedures. The patient selection and outcome process are summarised in Figure 5.1.

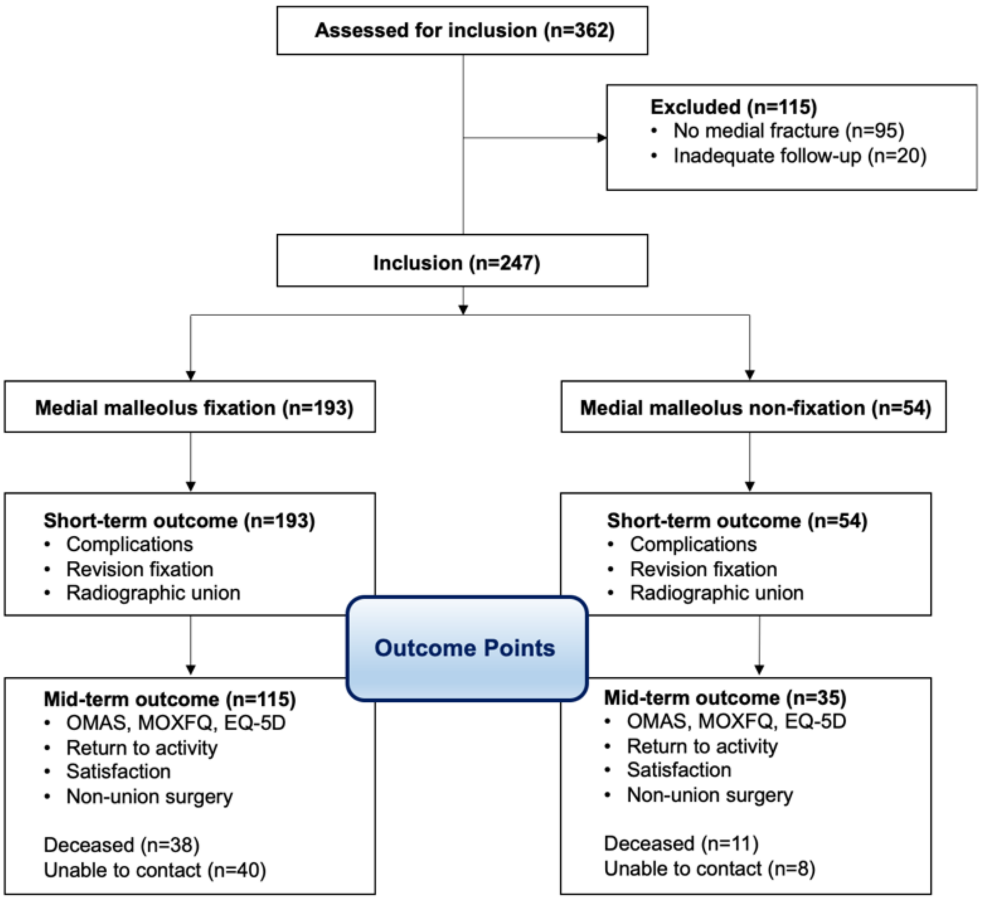

Figure 5.1: Flowchart that demonstrates the patient selection and outcome process.

As with the patients included in Chapter 3, fractures were classified according to the Lauge-Hansen[56] system (Chapter 1, Section 1.4; Table 1.1). Medial malleolar fractures were classified using the Herscovici system[63] (Chapter 1, Section 1.4; Figure 1.9). Retrospective assessment of the quality of medial malleolar reduction (non-fixation group only) was performed using the intra-operative AP fluoroscopy imaging and graded as 'anatomical' (undisplaced), good (≤2mm displacement) and poor (>2mm displacement). Post-operative radiographs were assessed for construct failure requiring revision surgery, loss of talar reduction and fracture union of both lateral and medial malleoli.

5.4.2 Surgical management

Patient care was supervised by a total of eleven fellowship trained Orthopaedic trauma consultants and the surgical procedures were performed by 42 surgeons of mixed grade from junior registrar to senior consultant level. The fibula was stabilised with an intramedullary nail according to the technique described in Chapter 2, Section 2.3 and Bugler et al[124]. Following fibula fixation, the medial malleolar fracture was then assessed intra-operatively by the operating surgeon. In cases where the mortise was reduced, and the medial malleolus was deemed well-reduced or within a few millimetres of the anatomical position, the decision was taken by the surgeon not to expose and fix the fracture. There was no attempt within this patient cohort to define medial malleolar reduction further, or to select or randomise cases intra-operatively. Where considered necessary, fixation was performed according to surgeon preference, either with cancellous screw(s) or a tension band wire construct, as described in

Chapter 2, Section 2.3. Post-operative management followed the principles outlined in Chapter 2, Section 2.4.

5.4.3 Outcome assessment

Short-term outcome

All patients underwent short-term follow-up at the study centre, including a minimum of a two week and a six to eight week post-operative outpatient review. Details of complications and secondary surgeries, including further operations to address failed fixation were recorded at each visit. The primary short-term outcome was complications with particular focus on medial sided complications, which included superficial or deep infection, wound dehiscence (with or without infection), metalwork prominence resulting in localised symptoms and medial malleolar non-union. Radiographic loss of talar reduction and the requirement for revision surgery in this situation was compared between the two groups.

An AP and lateral radiograph of the ankle joint was performed to confirm talar reduction, metalwork position and to monitor fracture union. For those patients making satisfactory progress at the six to eight week review appointment, it was not uncommon for discharge from the service even if radiographic union was not established. As it can take up to nine months to confirm radiographic fracture union, patients discharged before this point without confirmation of union were described as 'lacking radiographic union'. Patients were provided with contact information to arrange further outpatient review in the event of complications and/or concerns.

Mid-term outcome

Mid-term outcome at a mean follow-up of five years, was primarily collected via postal questionnaire[l], followed by a telephone review for non-responders[m]. Two validated lower limb PROMs were collected: the OMAS[256] and the MOXFQ[263]. The EQ-5D[264] was used as a marker of general health status. Patients were asked to complete a health and pain VAS, in addition to rating their overall satisfaction with treatment. Each outcome measure has been discussed in Chapter 2, Section 2.5.

If the patient was in employment and/or engaged in physical activity before their injury they were asked to record the number of weeks, it took them following surgery to return. Finally, patients were asked to provide details regarding subsequent surgery as a result of a persistent problem following their surgery or injury.

5.4.4 Statistical analysis

Data was analysed using IBM SPSS software version 23.0 (Armonk, NY: IBM Corp). Data normality was assessed using the Shapiro-Wilk test. Student's unpaired t-test was used to analyse parametric continuous data and the Mann-Whitney test was used for continuous data that did not follow a normal distribution. 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 observed frequency of ≤5). Two-tailed p-values were reported and a p-value of <0.05 was considered significant.

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[l] Thank you to Mrs Deborah MacDonald, database and clinical research manager at the University of Edinburgh, for assistance with sending and processing postal questionnaires.

[m] Thank you to Mr Marcus Hollyer and Miss Emma Gill, medical students at the University of Edinburgh, for assistance with data collection.

5.5 Results

5.5.1 Patient demographics and injury characteristics

The mean age of the 247 patients was 66.7 years (range, 25-96; SD, 16.1; Table 5.1). There were 200 women (81.0%) and 47 men (19.0%). There were proportionally more women in the non-fixation group (n=49, 91.7%) compared with the fixation group (n=151, 78.3%), but this did not reach statistical significance (p=0.070). The mean patient age in the non-fixation group was significantly higher than the fixation group (non-fixation: 72.1 years; range, 31-96; SD, 15 vs. fixation: 65.2 years; range, 25-96; SD, 17; p=0.014). Compared with the younger fixation group, patients in the non-fixation group in general had more comorbidities (p=0.099), were taking more regular medications (p=0.009), were less independently mobile (p=0.035) and the vast majority were retired (p=0.135). There were more patients with a higher ASA grade compared with the non-fixation group, but this failed to reach statistical significance (p=0.096; Table 5.1).

(n/% unless otherwise stated)	**Fixation (n=193, 78%)**	**Non-Fixation (n=54, 22%)**	**p-value**
Mean age (range, SD)			
Mean age (range, SD)	65.2 (25-96, 17)	72.1 (31-96, 15)	**0.003*[a]**
Sex			
- Man	42 (21.8)	5 (9.3)	0.070[b]
- Woman	151 (78.2)	49 (91.7)	
Mean comorbidities (range, SD)	2.9 (0-11, 2)	3.4 (0-8, 2)	0.099[a]
- Diabetes	30 (15.5)	13 (24.1)	0.144[b]
- Immunosuppression	5 (2.6)	3 (5.6)	0.378[c]
- Steroid use	6 (3.1)	4 (7.4)	0.232[c]
- Renal impairment	16 (8.3)	19 (16.7)	0.071[b]
- Peripheral neuropathy	15 (7.8)	3 (5.6)	0.770[c]
- Obesity (BMI 30+)	23 (11.9)	9 (16.7)	0.358[b]
Regular medication	148 (76.6)	47 (87.0)	**0.009*[b]**
Mean medications (range, SD)	4.0 (0-15, 4.0)	5.0 (0-21, 4.3)	0.114[a]
Smoker	32 (16.6)	4 (7.4)	0.125[c]
Alcohol excess (>14 units/week)	12 (6.2)	1 (1.9)	0.308[c]
ASA grade			
- 1	28 (14.5)	3 (5.6)	0.096[b]
- 2	96 (49.7)	27 (50.0)	
- 3	61 (31.6)	18 (33.3)	
- 4	8 (4.1)	6 (11.1)	
Pre-injury mobility status			
- Independent	149 (77.2)	34 (63.0)	0.095[b]
- Walking stick or frame	41 (21.2)	18 (33.3)	
- Wheelchair	3 (1.6)	2 (3.7)	
Pre-injury employment status			
- Employed	58 (30.1)	15 (27.8)	0.059[b]
- Unemployed	17 (8.8)	0 (0)	
- Retired	118 (61.1)	39 (72.2)	

Table 5.1: Patient demographics. (* statistical significance reached, [a] Student's unpaired t-test, [b] Chi-squared test, [c] Fisher's exact test).

With respect to injury characteristics there were several differences between the groups (Table 5.2). There were no fractures caused by a high energy injury mechanism in the non-fixation group compared with 24 (12.4%) in the fixation group (p=0.003). All fractures in the non-fixation group were caused by a fall from standing height (n=54, 100%). A fall from standing height was the most common mechanism in the fixation group (n=164, 85.0%) followed a fall from height (n=11, 5.7%) and road traffic accident (n=6, 3.1%). There were no open fractures in the non-fixation group compared with 17 (8.8%) in the fixation group (p=0.024). According to the Lauge-Hansen classification the most common injury pattern in both groups was a SER injury (fixation: n=150, 77.7% and non-fixation: n=46, 85.2%). There was no significant difference between groups with respect to injury classification (p=0.188). However, the numbers were low in the less common injury patterns, including PER and SAD classifications. A radiographic syndesmotic diastasis was present in proportionally more patients in the fixation group (n=37, 19.2%) compared with the non-fixation group (n=6, 11.1%), but this was not statistically significance (p=0.167). The same was true for the presence of a posterior malleolar fracture with proportionally more in the fixation group (n=91, 47.2%) compared with the non-fixation group (n=21, 38.9%; p=0.281). According to the Herscovici classification the most common type of medial malleolus fracture in both groups was the type-B injury (fixation: n=100, 51.8% and non-fixation: n=26, 48.1%). There were proportionately more type-A avulsion fractures in the non-fixation group (n=12, 22.2%) compared with the fixation group (n=13, 6.7%). Type-D fractures were more common in the fixation group (n=8, 4.1%) compared with the non-fixation group (n=1, 1.9%). These proportional group differences were statistically significant (p=0.008). The single type-D fracture in the non-fixation group did not have a characteristic infra-syndesmotic fibular fracture as typically seen in the SAD fracture pattern.

(n/% unless otherwise stated)	Fixation (n=193, 78%)	Non-Fixation (n=54, 22%)	p-value
Side of injury			0.272[b]
- Right	109 (56.5)	35 (64.8)	
- Left	84 (43.5)	19 (35.2)	
High energy injury mechanism	24 (12.4)	0 (0)	**0.003*[c]**
Mechanism of injury			0.102[b]
- Fall from standing height	164 (85.0)	54 (100.0)	
- Fall from height	11 (5.7)	0 (0)	
- Assault	2 (1.0)	0 (0)	
- Sport	5 (2.6)	0 (0)	
- Road traffic accident	6 (3.1)	0 (0)	
- Other	5 (2.6)	0 (0)	
Open fracture	17 (8.8)	0 (0.0)	**0.024*[c]**
Lauge-Hansen classification			0.188[b]
- SER	150 (77.7)	46 (85.2)	
- PAB	26 (13.5)	8 (14.8)	
- PER	9 (4.7)	0 (0)	
- SAD	8 (4.1)	0 (0)	
Syndesmosis diastasis	37 (19.2)	6 (11.1)	0.167[b]
Associated posterior malleolar fracture	91 (47.2)	21 (38.9)	0.281[b]
Medial malleolar fracture classification			0.008[b]
- A	13 (6.7)	12 (22.2)	
- B	100 (51.8)	26 (48.1)	
- C	72 (37.3)	15 (27.8)	
- D	8 (4.1)	1 (1.9)	

Table 5.2: Injury characteristics. (* statistical significance reached, [b] Chi-squared test, [c] Fisher's exact test).

5.5.2 Surgical management

Medial malleolar fracture fixation was performed in 193 (78.1%) cases with either 3.5mm partially threaded cancellous screw(s) (n=165, 85.5%) or a tension-band wire construct (n=28, 14.5%). In the remaining 54 (21.9%) cases the fracture was left without fixation following intramedullary stabilisation of the fibula. A radiographic example of a patient managed in the non-fixation group (n=54), demonstrating an anatomically reduced mortise and fracture of the medial malleolus, following fibular intramedullary nail fixation is demonstrated in Figure 5.2.

Figure 5.2: Radiographic example of a bimalleolar fracture-dislocation with a well-reduced medial malleolar fracture, maintenance of fracture reduction at six weeks and likely progression to union.

Intra-operative medial malleolar fracture reduction in the non-fixation group was assessed retrospectively from the AP fluoroscopy. An 'anatomical' reduction was achieved in 35 cases (64.8%), 'good' in 14 cases (26.0%) and 'poor' (>2mm displacement) in five cases (9.2%). In the 'poor' group the mean residual displacement was 2.9mm (range, 2.5-4.0mm). The mean age of these five patients was 75 years (range, 58-84 years). It was not possible to classify the medial malleolar fracture reduction quality pre-fixation in those treated with internal fixation. There was no significant difference between groups with respect to grade of operating surgeon (p=0.273) or post-operative weightbearing restrictions (p=0.673; Table 5.3). In the non-fixation group, there was a significantly higher proportion of patients fitted with a removable orthosis (non-fixation: n=36/54, 66.7% vs. fixation: n=79/193, 40.9%; p=0.001).

(n/% unless otherwise stated)	**Fixation (n=193, 78.1%)**	**Non-Fixation (n=54, 21.9%)**	**p-value** [b]
Grade of surgeon			
- Consultant	39 (20.2)	9 (16.7)	0.273
- Fellow	10 (5.2)	6 (11.1)	
- Registrar	144 (74.6)	39 (72.2)	
Post-operative immobilisation			
- Plaster cast	114 (59.1)	18 (33.3)	**0.001***
- Removable orthosis	79 (40.9)	36 (66.7)	
Post-operative weightbearing status			
- Full	112 (58.0)	28 (51.9)	0.672
- Partial	25 (13.0)	9 (16.7)	
- Non	56 (29.0)	17 (31.4)	

Table 5.3: Peri-operative data. (* statistical significance reached, [b] all Chi-squared test).

5.5.3 Short-term outcome

Soft tissue and metalwork complications

Medial sided soft tissue and metalwork associated complications were limited to the fixation group. Eighteen (9.1%) patients developed a medial sided infection, of which 14 (7.1%) were managed with at least one course of oral antibiotics alone, one (0.5%) with intravenous antibiotics and three (1.6%) with surgical debridement supplemented by intravenous antibiotics. Fourteen (7.3%) patients required surgery for removal of prominent medial sided metalwork. In total, 20 (10.4%) patients required further surgery for issues related to medial sided complications: 14 (7.3%) for symptomatic metalwork, three (1.6%) for infection control and three (1.6%) for revision fixation following primary medial sided failure (Figure 5.3).

Figure 5.3: Medial malleolar fracture fixation failure, requiring revision surgery.

Radiographic union

Evidence of medial malleolar fracture union at latest radiographic follow-up was lacking in 16 (29.6%) patients in the non-fixation group and 22 (11.4%) in the fixation group, which was statistically significant (p=0.002; Figure 5.4) These patients had satisfied outpatient discharge criteria, despite not demonstrating radiographic union. Since discharge, it is understood that none of these patients have required surgery for symptomatic malleolar non-union, confirmed by review of electronic patient records, the national radiographic archive and mid-term outcome data collection.

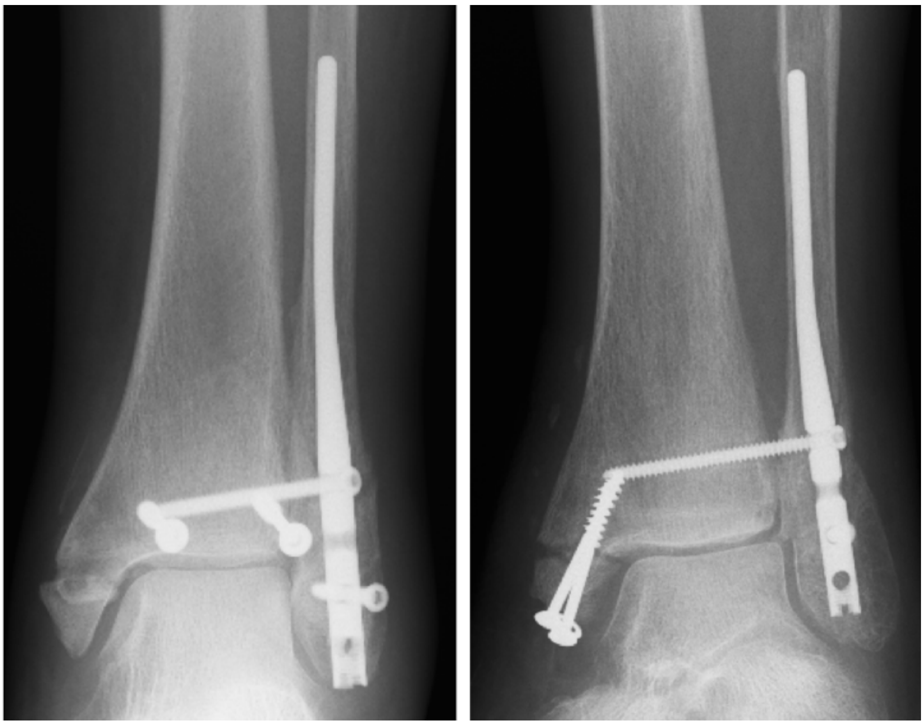

Figure 5.4: Medial malleolar fracture malreduction in both fixation and non-fixation groups six weeks following surgery, with no radiographic evidence of union at this early post-operative stage.

Construct failure and loss of talar reduction

Revision surgery for failed fixation was required in 15 cases (5.9%) of the total cohort. Eleven (5.7%) occurred in the fixation group and four (7.4%) in the non-fixation group (p=0.634). Post-operative talar displacement, not requiring further intervention occurred in three cases (1.2%): two (3.7%) in the non-fixation and one (0.5%) in the fixation group (p=0.157). These cases occurred in elderly, low-demand patients who made uneventful recoveries and in whom further surgery was not deemed appropriate.

5.5.4 Mid-term outcome

Of the 247 patients in the study cohort, 49 (19.8%) had died at most recent follow-up leaving 198 (81.2%) for potential review (fixation: 38 (19.7%) deceased and non-fixation: 11 (20.4%) deceased; Figure 5.1). PROMs were collected from 150 patients (75.8% response rate of available cohort, 60.7% total cohort) with a mean follow-up of 4.8 years (range, 0.7-10; SD, 3.5). All outcome score data was skewed and therefore analysed with non-parametric statistical tests (Table 3.6). There was no statistically significant difference in any outcome score or measurement of return to function between the two groups (all p>0.05).

Over the longer term no patient in either group required revision surgery for symptomatic medial malleolar non-union. Out of the five patients with a ‘poor’ medial malleolar fracture reduction, two were deceased and two were uncontactable. The single contactable patient with a medial malleolar reduction of 3mm reported an excellent outcome according to their OMAS (95), MOXFQ (0.0), and EQ-5D (1.0) scores.

Outcome measure (median, IQR)	**Fixation (n=115/193, 60%)**	**Non-Fixation (n=35/54, 64%)**	**p-value [a]**
PROMs			
- *OMAS*	80 (45-95)	85 (55-93)	0.885
- *MOXFQ*	9.4 (2.2-44.2)	17.2 (3.9-35.9)	0.380
- *EQ-5D*	0.81 (0.69-1.0)	0.80 (0.69-1.0)	0.846
Health VAS	80 (70-100)	81 (75-95)	0.306
Pain VAS	90 (60-100)	92 (69-100)	0.626
Satisfaction	87 (70-100)	85 (75-100)	0.410
Return to function (weeks)			
- *Employment*	8 (8-14)	6 (4-24)	0.476
- *Sport*	12 (10-28)	12 (8-41)	0.771

Table 5.4: Mid-term patient reported outcome comparison between groups. ([a] all Mann-Whitney U test).

5.6 Discussion

This chapter has compared the short and mid-term outcome of a group of patients managed with internal fixation of an associated medial malleolar fracture with a smaller group of patients treated non-operatively, following intramedullary fibular stabilisation. Internal fixation of medial malleolar fractures in this situation was not superior to non-fixation according to the mid-term primary outcome: the OMAS at a mean follow up of five years. Additionally, a reduction in medial sided soft tissue complications was found in the non-fixation group. Whilst a satisfactory outcome can be anticipated following conservative management of isolated medial malleolar fractures[60, 169], only one study has previously investigated this treatment approach in unstable ankle fractures. In the prospective randomised controlled trial by Hoelsbrekken et al (2013)[182], 82 patients were randomised to either fixation (n=37) or non-fixation (n=45) of an associated medial malleolar fracture following fibula stabilisation and followed up over a mean period of 39 months. The authors found no significant difference in the primary outcome measure (OMAS), reporting a mean score of 81 in the non-fixation group and 80 in the fixation group. In keeping with these findings, the results from this chapter suggest that there is no difference in patient reported outcome between the two groups. In particular, the OMAS score in this chapter (80 fixation and 85 non-fixation) was comparable to that published by Hoelsbrekken at al[182]. Furthermore, there was a reduced medial sided complication rate in the non-fixation group, lending support to non-operative management in a patient group with a somewhat different demographic, compared to the fixation group. It is important to acknowledge these differences as they may influence the interpretation of these findings and guide future research.

The average patient age in the non-fixation was significantly higher (72.1 years vs. 65.2 years) with a greater number of comorbidities. There were proportionately more patients in the non-fixation group with an ASA-4 grade, indicating that a greater proportion suffered with severe systemic disease, although this was not found to be statistically significant. Patients were less independently mobile and more likely to be retired in the non-fixation group; in summary they were of lower physical demand. In terms of the presenting injury, there were no high-energy injuries in the non-fixation group compared with 24 (12%) in the fixation group. Proportionately more patients in the non-fixation group presented with a type-A fracture according to the Herscovici classification. These fractures frequently involve a small bony avulsion, often at the attachment site of the superficial deltoid ligament on the tip of the anterior colliculus and given their size, are difficult to stabilise with screw fixation. A study by Tornetta et al established that fixation of these type-A fractures may not improve ankle stability, as the deep deltoid ligament attaches posteriorly and when intact safeguards talar reduction[298]. Treating these specific fractures conservatively is therefore not a new or unconventional treatment strategy. However, it had been previously suggested that these fractures may benefit from fixation to prevent a painful non-union[299]. Within the limitations of the data collected, with respect to clinically relevant non-union rates the results of this study do not support this statement. There is currently no well-defined maximum threshold for a type-A distal fracture and therefore a number of the type-A fractures identified in the non-fixation group might actually be classified as a smaller type-B injury, which are far more common in clinical practice (approximately 50%). This criticism of the Herscovici system has been noted as a consensus point in a recent appraisal of the classification by Aitken et al[63]. There were significantly more open fractures in the fixation group, frequently with a distinctive medial sided transverse laceration. During the study period, the local policy was to manage these injuries with wound debridement and as the fracture was already exposed, it was then reduced and internally fixed. Consequently, it is unsurprising that the medial sided wound complication rate was higher in the fixation group compared with those patients in the non-fixation group, which included no open fractures. Since this study, the safe management of an open medial malleolar fracture managed with a fibular intramedullary nail alone has been described in a recent case report[300].

There was no difference between groups with respect to post-operative weightbearing instruction following surgery with most patients permitted to bear full weight. Interestingly there was a significant difference in the number of patients fitted with a removable orthosis (moonboot) with proportionately more patients in the non-fixation group (64.8% vs. 40.9%; p=0.002). An explanation for this might be that the surgeons selecting patients to treat non-operatively were more engaged with the recent foot and ankle trauma surgery literature, which almost universally supports early weightbearing combined with range of movement exercises following ankle fracture fixation[79, 81, 258-260, 262]. A removable orthosis satisfies both recommendations.

5.6.1 Strengths and limitations

The main strength of this chapter is the documentation of both short and mid-term outcomes from a defined patient population managed in a single trauma service. In keeping with the strengths of Chapter 3, a series of validated measures of general health and lower limb outcomes have been collected[256, 263, 264]. Given the advanced age of the patient cohort and resultant mortality of nearly 20%, an overall contact rate of 67% is felt to be acceptable under these circumstances.

This study has limitations, the first of which is the retrospective design and disparity in the number of patients in each group. No significant difference in any patient reported outcome score has been demonstrated, which may represent a type II error. It was not possible to contact eight patients (15%) in the non-fixation group, who were understood to be alive at the time of collection. The advanced age of this group made contact by post and telephone difficult. Despite this, it is incorrect to assume that they would have experienced a comparable outcome to that of the contacted cohort. It has not been possible to present late radiographic follow-up of some patients, with 16 cases (29.6%) in the non-fixation group lacking radiographic evidence of union at the point of discharge. However, after searching electronic patient records and collecting outcome data, it is understood that no patient has required surgery for symptomatic non-union. Without further radiographs beyond nine months, it is impossible to define the non-union rate (or pseudoarthrosis in the absence of clinical pain). Similarly, assessment for development of PTOA given the nature and duration of follow up has not been feasible. This study is prone to selection bias, given the number of supervising surgeons involved. Nevertheless, this is a pragmatic scenario, representative of daily clinical practice. Finally, the findings can only be applied to those patients managed with a fibular intramedullary nail.

5.6.2 Key conclusions

Internal fixation of well-reduced medial malleolar fractures following fibular stabilisation is not superior to non-fixation according to patient reported outcome measures at a mean follow-up period of five years. Soft-tissue complications rates appear lower in the non-fixation group and consequently this treatment approach warrants future investigation.

5.6.3 Directions for future research

Given the inherent study limitations, including selection bias and inclusion of patients managed exclusively with a fibular intramedullary nail, a prospective RCT that investigates this minimally invasive treatment approach further, including alternative methods of fibular stabilisation would help to validate the findings of this chapter.

6. MEDIAL MALLEOLUS: OPERATIVE OR NON-OPERATIVE (MOON TRIAL) - PROSPECTIVE RANDOMISED CONTROLED TRIAL OF OPERATIVE VERSUS NON-OPERATIVE MANAGEMENT OF ASSOCIATED MEDIAL MALLEOLAR FRACTURES IN UNSTABLE FRACTURES OF THE ANKLE

Material from this chapter has been published in BMC Trials in 2019[301], appendix 8.

Carter TH, Oliver WM, Graham C, Duckworth AD, White TO. Medial malleolus: Operative Or Non-operative (MOON) trial protocol - a prospective randomised controlled trial of operative versus non-operative management of associated medial malleolus fractures in unstable fractures of the ankle. Trials. 2019;20(1):565.

6.1 Aims and Hypothesis

The primary aim of this chapter was to determine whether any difference exists in the primary outcome measure (OMAS) one-year post-randomisation between operative and non-operative management of well-reduced medial malleolar fractures following fibular stabilisation in patients undergoing surgical fixation of an unstable ankle fracture. The secondary aims were to determine if there were any differences between the two groups with regards to the secondary outcome measures including the MOXFQ, EQ-5D, complications, return to function and satisfaction.

The hypothesis was that internal fixation of well-reduced medial malleolar fractures following fibular stabilisation is superior to non-fixation, as measured by the OMAS at one-year post-randomisation. The null hypothesis was that there is no difference in outcome, as measured by the OMAS at one-year post-randomisation, between fixation and non-fixation of well-reduced medial malleolar fractures following fibular stabilisation.

6.2 Chapter Summary

A registered prospective randomised, single centre trial which included adult patients aged 16 years and older with operatively managed unstable ankle fractures was performed. Patients required an associated medial malleolar fracture to meet the inclusion criteria. Participants of the trial were randomised to either operative (fixation) or non-operative (non-fixation) management of their associated well-reduced medial malleolar fracture, following satisfactory fibular stabilisation. The choice of both lateral and medial sided fixation was left to surgeon discretion, as was the requirement for fixation of an associated posterior malleolar fracture. An acceptable closed reduction of the medial malleolus confirmed fluoroscopically was required (≤2 millimetres of displacement) to permit intra-operative randomisation. The primary outcome measure was the OMAS one-year post-randomisation (day of surgery). Secondary outcome measures included further validated PROMs, complications, return to function and treatment satisfaction.

There were 106 patients randomised to receive operative (n=53; 50.0%) or non-operative (n=53; 50.0%) management. The baseline demographics, fracture characteristics and peri-operative data for the two groups were comparable (all p>0.05), except for a significantly reduced tourniquet time in the non-fixation group with a mean difference of 21.7 minutes (p<0.001). Two (1.9%) patients died of unrelated causes and four (3.8%) were lost to follow-up, leaving 100 (94.3%) for review at the primary outcome endpoint. At one year following surgery the mean OMAS in the fixation group was 76.2 (range, 5-100; SD, 23.2) compared with 72.4 (range 5-100; SD, 22.5) in the non-fixation group (p=0.408). There was no statistically significant difference in the OMAS between the two treatment groups at any assessment point following randomisation (all p<0.05). Sixteen patients (32.0%) returned to their baseline OMAS or above in the non-fixation group compared with 14 patients (28.0%) in the fixation group (p=0.663). There were no statistically significant differences in any of the secondary outcome measures at one year following surgery, including the number of patients that experienced a complication (64.0% vs. 62.0%; p=0.836). Proportionately more patients in the non-fixation group experienced a major complication (18.0% vs. 8.0%; p=0.137) and more required further surgery to manage these complications (14.0% vs. 8.0%; p=0.525), although not statistically significant. Medial malleolar non-union was evident in three patients (6.0%) in the non-fixation group compared with no patients in the fixation group (p=0.242) and a further seven patients developed an asymptomatic pseudoarthrosis of the medial malleolus. Multivariate linear regression analysis identified patient smoking (p=0.006) and medial malleolar non-union (p=0.002) as predictive of a poor outcome at one year, but treatment group allocation was not (p=0.357).

As this trial is currently under-powered it is not possible to confirm or reject the null hypothesis. However, analysis of the data collected so far would suggest that internal fixation of an associated well reduced medial malleolar fracture following fibular stabilisation does not appear to be superior to non-fixation with respect to patient reported outcomes, complication rates, return to function and treatment satisfaction. Although not statistically significant, the more major complications including painful medial malleolar non-union and the requirement for re-operation are higher in the non-fixation group. Subsequent reporting of results from this trial when adequately powered will allow more accurate conclusions to be made in the absence of potential type II error.

6.3 Chapter Introduction

The results from the retrospective unmatched cohort study presented in Chapter 5 demonstrated equivalent patient reported outcome following the non-operative management of medial malleolar fractures following intramedullary fibular stabilisation with an intramedullary nail compared with internal fixation. This concept is supported by prospective data published by Hoelsbrekken et al[182]; a study that was limited by a lack of baseline PROMs and small sample size, although adequately powered according to the published power calculation.

A weakness of the retrospective study presented in Chapter 5 was the high rate of medial sided 'lacking radiographic union' in both the fixation and non-fixation groups, related primarily to a deficiency of radiographic surveillance, with many patients discharged from clinic between six and eight weeks following surgery. It was therefore difficult to quantify the true incidence of medial malleolar non-union and pseudoarthrosis in both groups, which remains a major limitation of the study and requires addressing in future research. The weaknesses highlighted in the discussion of Chapter 5 have been used to inform and carefully design the prospective RCT, presented in this chapter.

From the limited available literature to date, is it clear that further high-quality, prospective work is needed to determine if internal fixation of well-reduced medial malleolar fractures following fibular stabilisation is superior to non-fixation.

6.4 Patients and Methods

6.4.1 Patients and database construction

This was a registered single-centre, prospective RCT of adult patients (≥16 years of age) presenting with an unstable bimalleolar or trimalleolar fracture dislocation of the ankle joint (ClinicalTrials.gov ID: NCT 03362229). The trial protocol was published in advance of recruitment completion[301]. The main study centre was a large academic trauma centre providing Orthopaedic trauma care for a population of approximately 850,000. This trial was authorised by the appropriate ethical and clinical trial committees (REC: 17/SS/0124, IRAS: 222034; appendix 2).

Between October 2017 and September 2019, 106 adult patients with the ability to consent into a clinical trial were recruited. Due to the suspension of recruitment during the SARS-CoV-2 virus pandemic, it was not possible to recruit all 154 study participants before preparing and submitting this thesis. All patients presented with an unstable ankle fracture dislocation, requiring operative intervention. The inclusion and exclusion criteria are outline in Table 6.1. Daily screening of patient admissions lists identified a total of 609 patients presenting with unstable ankle fractures during the same study period (average 25 patients/month). Many patients were immediately ineligible as their injury did not include a fracture of the medial malleolus (n=207, 34.0%). The selection and flow of participants are summarised in Figure 6.1. The number of participants presented in this chapter falls below the planned recruitment of 154, including 20% loss to follow-up for reasons detailed in Chapter 2, Section 2.1. Future publication of the final results from this trial will be available after the submission of this thesis.

Inclusion criteria	Exclusion criteria
1. Age ≥16 years 2. Able to consent to treatment 3. Unstable fracture dislocation of the ankle joint requiring operative intervention 4. Closed injury 5. Weber B & Weber C fractures 6. Surgery date within two weeks of date of fracture	1. Unable to give informed consent 2. Unable to comply with follow-up 3. Additional lower limb injury 4. Open fracture 5. Associated neurovascular injury 6. Distal tibial intra-articular fractures 7. Medial malleolus vertical shear fractures 8. Isolated medial malleolus fracture 9. Medically unfit for surgery 10. Declining inclusion 11. Current engagement in a pharmaceutical/drug trial 12. Treating surgeon does not feel that inclusion in the trial is in the patients' best interest either due to fracture pattern or patient factors

Table 6.1: Inclusion and exclusion criteria for the trial.

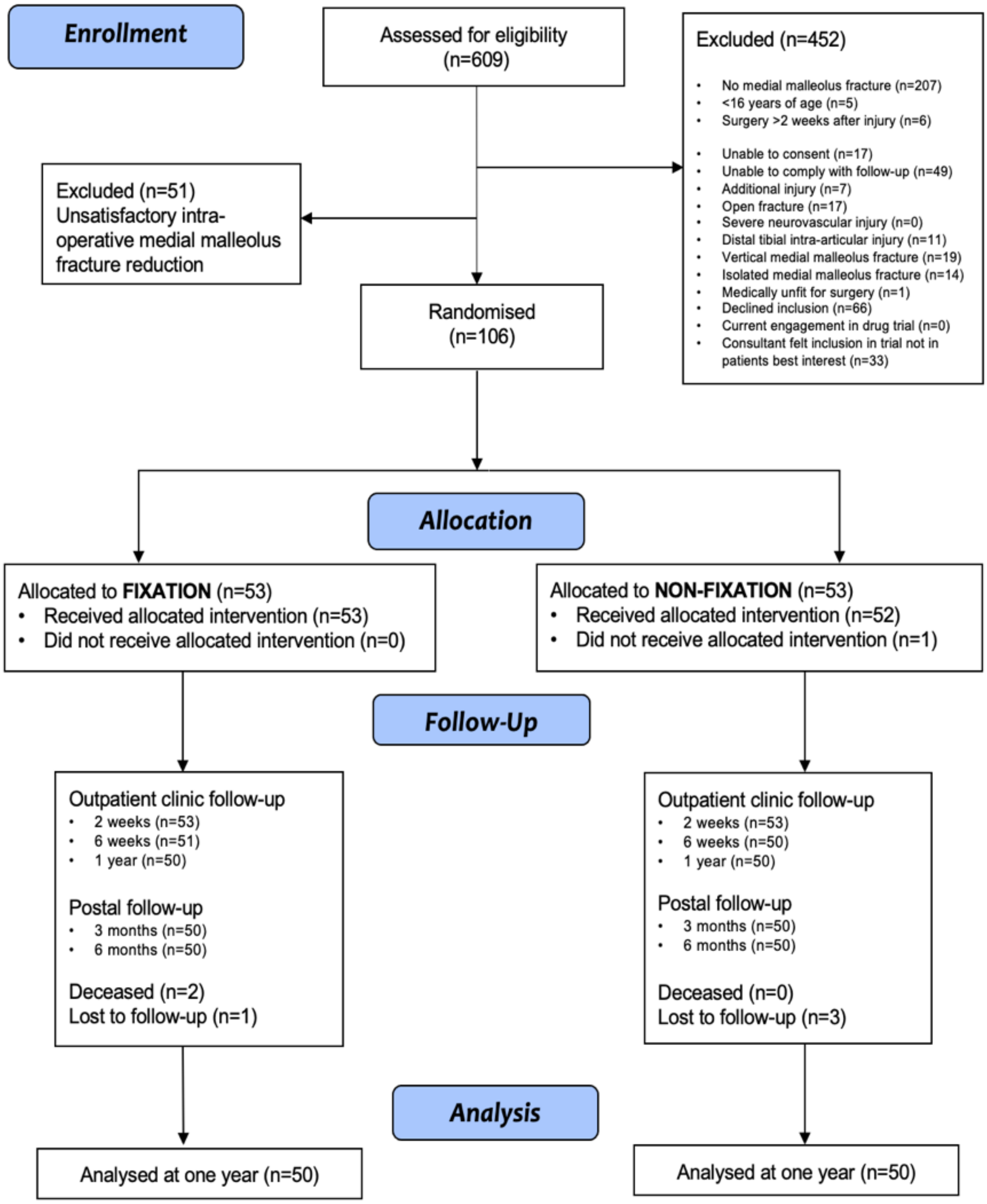

Figure 6.1: CONSORT diagram for recruitment and flow of the participants through the trial.

Demographic data was documented at the point of recruitment. This included age, sex, contact information, co-morbidities, medications, medical allergies, mobility status, smoking status, alcohol intake, BMI, occupation, employment status, pre-injury physical activity engagement including type and level of activity, mechanism of injury and the presence of any associated injuries. Participants were asked to complete a retrospective baseline EQ-5D and OMAS at presentation to assess pre-injury general and lower limb specific functional status, which was highlighted as a weakness of the previously published literature[182].

Consent process

The trial was introduced by a member of the on-call admitting team. A patient information sheet (PIS), containing full details of the trial was provided. Consent was taken during normal working hours by a member of the trial team, chiefly THC or WMO[n]. Patients were consented on the understanding that allocation of treatment group would occur during surgery, as detailed below. The signed consent form accompanied the participant to theatre, in addition to the next envelope in the randomisation sequence. Out of hours consent was taken by a member of the on-call team, who had been educated on the trial in advance of recruitment.

[n] Thank you to Mr William Oliver for assistance with recruitment of participants

Randomisation and allocation of treatment group

Randomisation was on a 1:1 basis, stratified by age (≥65 years or <65 years) and performed by an independent statistician (CG), employed through the local Clinical Research Facility[o]. Allocation of treatment occurred during surgery, following fibular stabilisation. The reduction quality of the medial malleolar fracture was verified by the operating surgeon and if deemed acceptable the opaque envelope was opened by an independent member of theatre staff. This revealed a sticker specifying 'FIXATION' or 'NON-FIXATION'. If the reduction of the medial malleolar fracture was not deemed satisfactory, the envelope was not opened and subsequently returned in order of the randomisation sequence. In this situation (n=51; Figure 6.1), the participant was excluded from the trial, and treated as per their supervising consultant's practice.

6.4.2 Radiographic classification and assessment of reduction quality

All radiographs were classified pre-operatively according to the Lauge-Hansen and AO/OTA classification systems[55, 56] (Chapter 1, Section 1.4). Medial malleolar fractures were classified pre-operatively according to the Herscovici classification system[60] (Chapter 2, Section 2.2). Following fibular stabilisation, the quality of medial malleolar fracture reduction was assessed fluoroscopically using an AP radiograph with the ankle in neutral position. A fracture was deemed to be acceptably reduced if there was no more than two millimetres of residual displacement as seen on the

[o] Thank you to Dr Cat Graham, statistician for assistance with randomisation and general statistical advice

radiograph (Chapter 2, Section 2.2). Examples of acceptable and unacceptable reductions are demonstrated in Figure 6.2 and Figure 6.3 respectively.

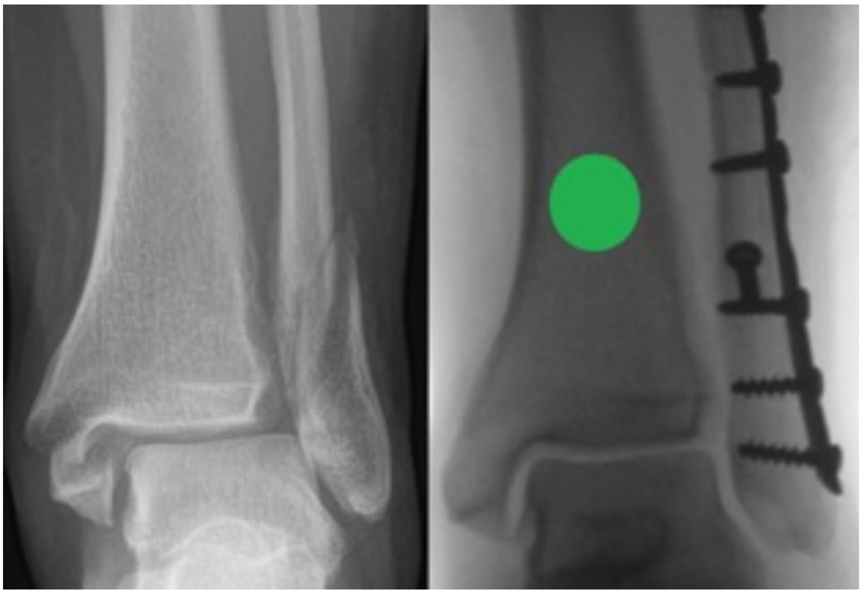

Figure 6.2: Acceptable medial malleolar fracture reduction.

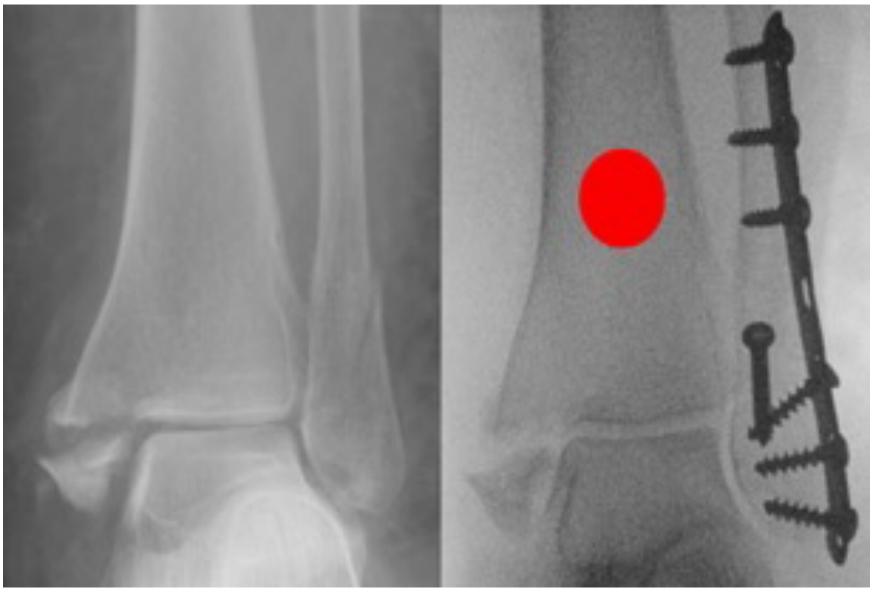

Figure 6.3: Unacceptable medial malleolar fracture reduction.

6.4.3 Management protocol

The median time to surgery was two days (range, 0-12), which was comparable between both groups (p=0.201). Peri-operative data are summarised in Table 6.5. The care of each participant was supervised by an orthopaedic trauma consultant. Surgery was performed by a consultant in six cases (5.7%) or a registrar/fellow in 100 cases (94.3%). The technique and choice of implant for stabilisation of the fibular fracture was at the discretion of the operating surgeon and included plate fixation (n=74, 69.8%), intramedullary nail (n=29, 27.4%) or syndesmosis screw-only fixation (n=3, 2.8%). Syndesmosis stabilisation was required in 23 cases (21.7%). Posterior malleolar fractures were addressed by the treating surgeon if they contributed to overall talar instability and were managed with 3.5mm partially threaded cancellous lag screws inserted in an anterior to posterior direction (n=5, 4.7%). Surgical techniques have been outlined in Chapter 2, Section 2.3.

Patients randomised to non-fixation (n=53) underwent no further surgical management of the associated medial malleolar fracture, whilst patients randomised to fixation (n=53) received internal fixation. The surgical approach and fixation technique was determined by the operating surgeon and comprised 3.5mm partially threaded cancellous lag screws (n=50, 94.3%), 3.5mm fully threaded cortical screws (n=2, 3.8%), or plate fixation (n=1, 1.9%). Post-operative immobilisation and weightbearing status was at the discretion of the treating surgeon and followed the principles outlined in Chapter 2, Section 2.4. Surgeons were advised not to allow the absence or presence of medial malleolar fracture fixation to influence their prescribed post-operative management.

The care of all participants during the trial was supervised by two orthopaedic consultants (TOW and ADD) with an interest in orthopaedic trauma[p]. Patients were reviewed in the outpatient clinic by one of three trauma research fellows (THC, WMO and KRB)[q]. Referral for physiotherapy was considered on an individual basis. Metalwork, including syndesmosis screws, was only removed in the clinical situation of intolerable discomfort or for control of deep infection.

6.4.4 Outcome assessment

Assessment points

All outpatient follow-up assessment was performed in the main study centre and included clinical and radiographic review. Participants were reviewed over a one-year period at the following timepoints: two weeks, six to eight weeks (depending on weightbearing status) and one year (52 weeks). The schedule of assessment points is summarised in Table 6.2. To minimise inconvenience, participants were contacted at both three (12 weeks) and six months (26 weeks) post-surgery to collect postal questionnaire outcome data.

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[p] Thank you to Mr Tim White and Mr Andrew Duckworth for dedicating research outpatient appointments for the review of trial participants

[q] Thank you to Mr William Oliver and Miss Katrina Bell for assistance with reviewing trial participants in the outpatient clinic

	Baseline/ Injury	**Week 2**	**Week 6-8**	**Week 12**	**Week 26**	**Week 52**
Informed Consent	X					
Demographics	X					
Inclusion/Exclusion Criteria	X					
Randomisation	X					
Radiographs	X	X	X			X
OMAS			X	X *(P)*	X *(P)*	X
MOXFQ			X	X *(P)*	X *(P)*	X
EQ-5D			X	X *(P)*	X *(P)*	X
Wound review +/- suture removal		X	X			
Pain score			X	X *(P)*	X *(P)*	X
Return to work & sport		X	X	X *(P)*	X *(P)*	X
Satisfaction		X	X	X *(P)*	X *(P)*	X
Complications		X	X	X *(P)*	X *(P)*	X

Table 6.2: Schedule of assessment points; *(P)* = collected via postal questionnaire.

Primary outcome

The primary outcome measure was the OMAS[256] at one year post randomisation (Chapter 2, Section 2.5). Eleven participants completed their one-year outcome scores via postal questionnaire due to outpatient appointment restrictions during the SARS-CoV-2 virus pandemic. They returned for outpatient radiographs when it was deemed safe, following completion of a satisfactory risk assessment.

Secondary outcomes

Secondary outcomes included both patient and surgeon reported outcome measures. The MOXFQ[263] and EQ-5D[264] were collected as measures of limb specific and general health outcome assessment respectively (Chapter 2, Section 2.5). Additionally, participants completed a health, pain and satisfaction VAS assessment, with a score of 100 indicating the best possible outcome. If applicable, return to function, including work and sport was recorded. Finally, treatment complications were documented and in general classified as minor if they did not require surgical intervention or major if they did[29]. Minor complications included superficial wound infection, wound dehiscence/delayed healing, asymptomatic prominent metalwork, localised ongoing pain (≥12 months after surgery) and pseudoarthrosis (painless radiographic evidence of non-union). Major complications included deep wound infection requiring debridement, failed fixation resulting in loss of talar reduction, non-union (painful radiographic evidence of non-union) and symptomatic metalwork, requiring removal. Given the nature of the study and the lack of data on the incidence of non-union, painful non-union of the medial malleolus was classed as a major complication, even if further surgery was not performed. Medical complications including VTE events were recorded separately.

Radiographic assessment using the intra-operative fluoroscopy was performed to determine the reduction quality of the medial malleolus fracture retrospectively and classed as ‘anatomical’, ‘good’ (≤2mm displacement) or ‘poor’ (>2mm displacement). AP and lateral radiographs of the ankle were performed at each outpatient clinic to assess for maintenance of talar reduction, fracture union and evidence of early PTOA.

Time to fracture union was assessed periodically according to planned follow-up visits and was based on the clinical absence of pain and radiographic evidence of endosteal healing. A binary timepoint of union by the second outpatient assessment point (six to eight weeks) was recorded to allow comparison between treatment groups. Given the duration of follow-up (12 months), it was possible to accurately define both a non-union and pseudoarthrosis based on the radiographic and clinical assessment. Evidence of PTOA was recorded according to the classification described by Holzer[102].

6.4.5 Statistical analysis

A power analysis demonstrated that 77 patients would be required in each treatment arm to detect a difference of 10 points (MCID) in the OMAS, accounting for a 20% increase to account for loss to follow-up (Chapter 2, Section 2.1)[r]. Outcomes between the two groups were compared using the Chi square test of proportions for binary variables or a Fisher's exact test if one cell in each analysis was <5. According to the normality of data, a Student's unpaired t-test was used to compare continuous variables with a normal distribution between two independent groups or a non-parametric equivalent (Mann-Whitney U test). A one-way ANOVA or non-parametric equivalent (Kruskal-Wallis test) was used when one variable had more than two categories. Pearson's correlation coefficient was used to analyse the correlation between two continuous variables. Factors associated with change in OMAS between pre-operative baseline and one year were identified through univariate analysis. To limit the number

[r] Thank you to Dr Cat Graham, statistician for her assistance with the power calculation and general statistical advice

of variables included in view of the sample size, only variables that showed a trend towards significance ($p<0.1$) or were significantly associated ($p<0.05$) with the OMAS change on univariate analysis were the included in a multivariate linear regression model using enter methodology. Two-tailed p-values were reported and a p-value of <0.05 was considered significant.

6.5 Results

Demographics

One hundred and six participants were randomised to either operative (n=53, 50.0%) or non-operative (n=53, 50.0%) management of their well reduced medial malleolar fracture following fibular fracture stabilisation (Figure 6.1). According to ITT principles, only one participant did not receive their allocated treatment; this patient was randomised to non-fixation, but the medial malleolar fracture was felt to re-displace following syndesmosis stabilisation and was therefore fixed. This participant was analysed according to their intended group allocation (non-fixation).

The mean age at injury was 56.5 years (range, 19-92; SD, 16.5). There was a substantial sex split with a strong majority of women (n=80, 75.5%) but no significant difference between the mean age at injury between the two sexes (p=0.613). Eighty-one patients (76.4%) had one or more comorbidities and the median number of comorbidities was 1 (range, 0-7). The most common ASA grade was 2 (n=47, 44.3%), followed by ASA 1 (n=39, 36.8%) and ASA 3 (n=20, 18.9%). Seventy-five patients (70.8%) took regular medication, 22 were current smokers (20.8%) and 20 (18.9%) consumed alcohol in excess of national recommendations (>14 units/week). The mean BMI was 28.5 (range, 18.7-48.8; SD, 5.6) and 35 patients (33.0%) were classified as obese (BMI>30). There were proportionately more obese patients in the non-fixation group, with a higher mean BMI, but this did not reach statistical significance (p=0.063). The demographics of both groups were well-balanced (all p>0.05; Table 6.3).

Injury characteristics

The right ankle was injured in the majority of cases (n=59, 55.7%). The most frequent mechanism of injury was a fall from standing height (n=88, 83.0%), followed by sports (n=10, 9.4%), fall from height (n=4, 3.8%), direct blow (n=3, 2.8%) and assault (n=1, 0.9%). Six patients had an associated injury including a contralateral undisplaced distal radius fracture, contralateral undisplaced radial head fracture, contralateral forearm abrasion, scalp laceration, peri-orbital haematoma and soft-tissue contusion to the contralateral leg. As per the exclusion criteria, there were no open fractures. Most fractures were trimalleolar (n=60, 56.6%) in configuration. The most common fracture pattern according to the Lauge-Hansen classification system was SER type-4 (n=92, 86.8%) and 44-B2 / 44-B3 (n=46, 43.4% each type) according to the AO/OTA classification system. Thirteen participants (12.3%) had a syndesmosis injury visible on their presenting radiographs. Sixty participants (56.6%) had a posterior malleolar fracture with a mean percentage involvement of the plafond, as measured on the lateral radiograph of 16.0% (range, 5-45; SD, 8.8). The most common medial malleolar fracture type according to the Herscovici classification was type B (n=67, 63.2%), followed by type C (n=34, 32.1%), type D (n=4, 3.8%) and type A (n=1, 0.9%). All the type D fractures were in the non-fixation group. Whilst most type D fractures are associated with a SAD injury pattern with a vertical fracture line, these fracturs were more oblique in orientation, but still classified as a type D according to the Herscovici system. The groups were well-balanced with respect to baseline injury characteristics (all p>0.05; Table 6.4)

Peri-operative data

There were no statistically significant differences between the two groups with respect to wait for surgery, grade of surgeon, anaesthetic type, fibular fixation technique, posterior malleolar fixation, post-operative immobilisation, weight bearing instruction, VTE prophylaxis or referral for post-operative physiotherapy (Table 6.5). Tourniquet time was significantly lower in the non-fixation group by a mean difference of 21.7 minutes (p<0.001). There were proportionately more patients managed non-weight bearing in the non-fixation group (18 patients, 34.0% vs. 9 patients, 17.0%), but this was not statistically significant (p=0.071) and may have represented the increased requirement for syndesmosis stabilisation in this group (14 patients, 17.0% vs. 9 patients, 26.4%; p=0.443). An example of a patient managed in the non-fixation group is presented in Figure 6.4.

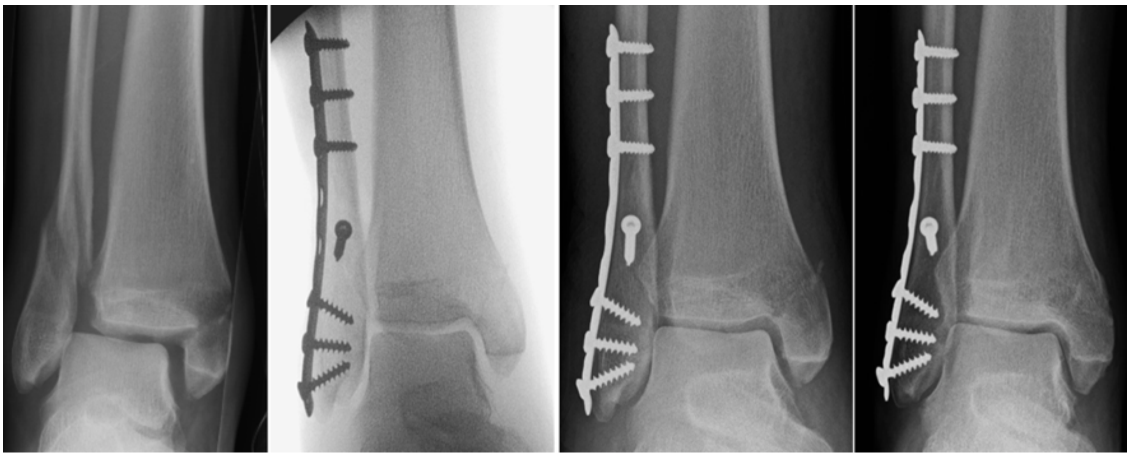

Figure 6.4: AP radiographs from a 53-year-old patient who was randomised to non-fixation following an anatomical intra-operative reduction and progressed to satisfactory radiographic union.

(n/% unless otherwise stated)	Fixation (n=53)	Non-Fixation (n=53)	p-value
Mean age (range, SD)	57.1 (27-87, 15.6)	55.9 (19-92, 17.5)	0.717[c]
Sex			0.176[a]
- Man	10 (18.9)	16 (30.2)	
- Woman	43 (81.1)	40 (69.8)	
Side of injury			
- Right	34 (64.2)	25 (47.2)	0.078[a]
- Left	19 (35.8)	28 (52.8)	
Smoker	10 (18.9)	12 (22.6)	0.632[a]
Number of cigarettes/day (range, SD)	16.4 (3-40,9.8)	15.8 (5-40, 8.4)	0.872[c]
Alcohol consumption (units/week)	19.1 (2-150, 29.3)	16.3 (2-80, 17.6)	0.630[c]
Alcohol excess (>14 units/week)	11 (20.8)	9 (17.3)	0.653[a]
BMI (range, SD)	27.7 (18.7-48.4, 5.4)	29.2 (19.5-45.0, 5.7)	0.194[c]
Obesity (BMI >30)	13 (24.5)	22 (41.5)	0.063[a]
Co-morbidities ≥1	39 (73.6)	42 (79.2)	0.492[a]
Mean comorbidities (range, SD)	1.7 (0-6, 1.3)	1.8 (0-7, 1.7)	0.796[c]
ASA grade			
- 1	18 (34.0)	21 (39.6)	
- 2	27 (50.9)	20 (37.7)	0.355[a]
- 3	8 (15.1)	12 (22.6)	
Pre-injury mobility			
- Independent	51 (96.2)	47 (88.7)	
- 1x walking stick	1 (1.9)	3 (5.7)	0.367[a]
- 2x walking stick	1 (1.9)	1 (1.9)	
- Walking frame	0	2 (3.8)	
Employed pre-injury	28 (52.8)	28 (52.8)	1.00[a]
Recreational activity pre-injury	29 (54.7)	23 (43.4)	0.244[a]
Mean pre-injury OMAS (range, SD)	94.7 (70-100, 9.4)	92.0 (50-100, 14.3)	0.267[c]

Table 6.3: Baseline patient demographics. (* statistical significance reached, [a] Chi-squared test, [b] Fisher's exact test, [c] Student's unpaired t-test).

(n/% unless otherwise stated)	**Fixation (n=53)**	**Non-Fixation (n=53)**	**p-value**
Associated injury	1 (1.9)	5 (9.4)	0.205[b]
Mechanism of injury			
- Fall standing height	43 (81.1)	45 (84.9)	
- Fall from height	3 (5.7)	1 (1.9)	0.666[a]
- Direct blow	1 (1.9)	2 (3.8)	
- Sport	5 (9.4)	5 (9.4)	
- Assault	1 (1.9)	0	
Lauge-Hansen classification			
- SER	48 (90.6)	44 (83.0)	
- PER	2 (3.8)	5 (9.4)	0.449[a]
- PAB	3 (5.7)	4 (7.5)	
- SAD	0	0	
AO/OTA classification			
- 44-B2	24 (45.4)	22 (41.5)	
- 44-B3	23 (43.4)	23 (43.4)	0.827[a]
- 44-C2	3 (5.7)	3 (5.7)	
- 44-C3	3 (5.7)	5 (9.4)	
Radiographic syndesmosis injury	6 (11.3)	7 (13.2)	0.767[a]
Posterior malleolar fracture	27 (50.9)	31 (58.5)	0.435[a]
Mean posterior malleolar fracture % (range, SD)	16.7 (5-40, 8.3)	15.8 (5-45, 9.3)	0.714[c]
Medial malleolar fracture			
- Type A	1 (1.9)	0	
- Type B	35 (66.0)	32 (60.4)	0.162[a]
- Type C	17 (32.1)	17 (32.1)	
- Type D	0	4 (7.5)	

Table 6.4: Baseline injury characteristics. (* statistical significance reached, [a] Chi-squared test, [b] Fisher's exact test, [c] Student's unpaired t-test).

(n/% unless otherwise stated)	Fixation (n=53)	Non-Fixation (n=53)	p-value
Median days to surgery (IQR)	2 (0-12)	2 (0-10)	0.150[c]
Anaesthetic			
- General	42 (79.2)	44 (83.0)	0.804[a]
- Spinal	11 (20.8)	9 (17.0))	
Grade of surgeon			
- Consultant	4 (7.5)	2 (3.8)	0.678[b]
- Trainee/fellow	49 (92.5)	51 (96.2)	
Fibular fixation			
- Plates and screws	39 (73.6)	35 (66.0)	
- Intramedullary nail	13 (24.5)	16 (30.2)	0.651[a]
- Syndesmosis screw	1 (1.9)	2 (3.8)	
Syndesmosis fixation	9 (17.0)	14 (26.4)	0.443[a]
Medial malleolar fracture fixation			
- 1x screw	25 (47.2)	n/a	
- 2x screw	27 (50.9)	n/a	n/a
- TBW	0	n/a	
- Plate	1 (1.9)	n/a	
Medial malleolar fracture reduction			
- Good (anatomical)	n/a	31 (58.5)	
- Fair (<2mm)	n/a	17 (32.1)	n/a
- Poor (>2mm)	n/a	5 (9.4)	
Posterior malleolus fixation	3 (5.7%)	2 (3.8%)	1.000[b]
Tourniquet used	50 (94.3)	50 (94.3)	1.000[a]
Mean tourniquet time (range, SD)	77.3 (40-124, 18.3)	55.6 (30-92, 14.9)	**<0.001*[d]**
Post-operative immobilisation			
- Moonboot	51 (96.2)	49 (92.5)	0.678[b]
- Plaster	2 (3.8)	4 (7.5)	
Post-operative weightbearing status			
- Full	44 (83.0)	34 (64.1)	
- Partial	0	1 (1.9)	0.071[a]
- Non	9 (17.0)	18 (34.0)	

Post-operative VTE prophylaxis	5 (9.4)	8 (15.1)	0.555[b]
Post-operative physiotherapy	35 (66.0)	34 (64.2)	0.834 [a]

Table 6.5: Peri-operative data. (* statistical significance reached, [a] Chi-squared test, [b] Fisher's exact test, [c] Mann-Whitney U test, [d] Student's unpaired t-test).

6.5.1 Primary outcome

At one year following surgery, 100 participants were available for review (94.3% follow-up rate). Two participants were deceased and four were lost to follow-up (Figure 6.1). Both deceased patients were in the fixation arm and died due to unrelated causes (cardiac event and metastatic bowel cancer). Outcome scores were all normally distributed. At the primary outcome endpoint, the mean OMAS was 74.3 (range, 5-100; SD, 22.8). Patients significantly improved from six-eight weeks (41.0) to one year (74.3), according to the mean OMAS ($p<0.001$) but were significantly worse than their pre-injury level of 93.4 (range, 50-100; SD, 12.1) one year after surgery ($p<0.001$). Thirty patients (30.0%) returned to their baseline OMAS or above.

The mean OMAS in the fixation group one-year post-randomisation was 76.2 (range, 5-100; SD, 23.2) compared with 72.4 (range, 5-100; SD, 22.5) in the non-fixation group ($p=0.408$). This mean difference of 3.8 was less than 10 points, which was defined as the MCID for the OMAS. There was no statistically significant difference in the OMAS between the two treatment groups at any assessment point following randomisation (Figure 6.5, Table 6.6). Sixteen patients (32.0%) returned to their baseline OMAS or above in the non-fixation group compared with 14 patients (28.0%) in the fixation group; this was not statistically significant ($p=0.663$).

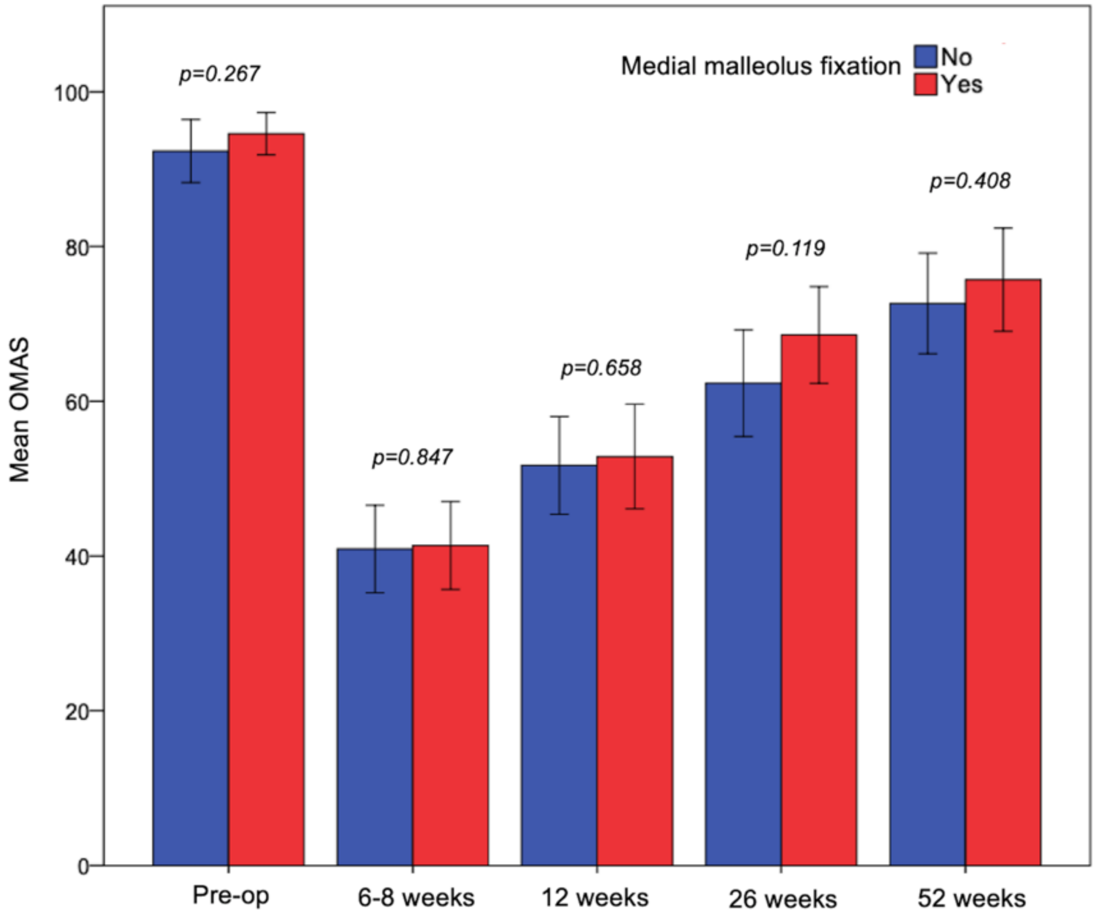

Figure 6.5: Change in OMAS over time with 95% confidence intervals.

Time Point	Outcome measure Mean (range, SD)	Fixation (n=50)	Non-fixation (n=50)	p-value[a]
Pre-op	*OMAS*	94.7 (70-100, 9.4)	92.0 (50-100, 14.3)	0.267
	EQ-5D	0.90 (0.27-1.0, 0.15)	0.86 (0.08-1.0, 0.24)	0.413
	Health VAS	80.2 (10-100, 16.9)	78.1 (0-100, 20.5)	0.577
	Pain VAS	95.7 (40-100, 12.9)	91.0 (10-100, 20.7)	0.168
6-8 weeks	*OMAS*	41.4 (5-85, 19.8)	40.6 (5-85, 19.7)	0.847
	MOXFQ	42.2 (6.3-87.5, 23.8)	48.3 (0-93.8, 23.4)	0.199
	EQ-5D	0.65 (-0.02 to 1.0, 0.21)	0.55 (-0.24 to 1.0, 0.27)	0.073
	Health VAS	81.2 (30-100, 15.5)	74.7 (30-100, 16.5)	**0.048***
	Pain VAS	82.4 (0-100, 21.4)	80.9 (30-100, 19.1)	0.723
	Satisfaction	95.1 (50-100, 10.2)	96.6 (50-100, 8.7)	0.432
12 weeks	*OMAS*	53.8 (20-10, 24.3)	51.7 (5-85, 22.0)	0.658
	MOXFQ	40.3 (0-85.9, 23.7)	47.5 (0-92.2, 24.2)	0.134
	EQ-5D	0.68 (-0.18 to 1.0, 0.23)	0.62 (-0.07 to 1.0, 0.26)	0.254
	Health VAS	79.0 (25-100, 14.5)	76.5 (0-100, 18.4)	0.460
	Pain VAS	75.4 (10-100, 21.5)	72.6 (15-100, 21.5)	0.512
	Satisfaction	88.5 (50-100, 14.3)	92.2 (60-100, 9.8)	0.133
26 weeks	*OMAS*	68.6 (10-100, 21.8)	61.1 (15-95, 25.3)	0.119
	MOXFQ	28.4 (0-100, 25.3)	35.9 (0-95.3, 26.8)	0.149
	EQ-5D	0.77 (0.07-1.0, 0.21)	0.67 (-0.24 to 1.0, 0.28)	0.065
	Health VAS	83.1 (30-100, 14.4)	78.7 (10-100, 17.4)	0.177
	Pain VAS	82.2 (10-100, 20.8)	74.4 (10-100, 24.2)	0.090
	Satisfaction	92.5 (40-100, 10.7)	92.4 (50-100, 10.2)	0.923
52 weeks	*OMAS*	76.2 (5-100, 23.2)	72.4 (5-100, 22.5)	0.408
	Change in OMAS	18.5 (-15-100, 22.9)	19.6 (-20 to 80, 21.2)	0.804
	MOXFQ	19.9 (0-93.8, 23.8)	22.9 (0-81.3, 21.3)	0.496
	EQ-5D	0.82 (0.62-1.0, 0.24)	0.77 (0.69-1.0, 0.24)	0.250
	Health VAS	85.8 (40-100, 14.1)	82.9 (10-100, 18.5)	0.371
	Pain VAS	89.1 (20-100, 20.0)	87.4 (0-100, 18.5)	0.663
	Satisfaction	96.0 (70-100, 7.2)	97.4 (50-100, 8.0)	0.361
	Return to work (wks)	8.2 (1-16, 4.7)	10.4 (0-20, 5.9)	0.149
	Return to sport (wks)	16.3 (7-39, 9.3)	18.5 (8-48, 13.1)	0.482

Table 6.6: Patient reported outcome measures at each assessment point by treatment group. (* statistical significance reached, [a] Student's unpaired t-test).

6.5.2 Secondary outcomes

Patient reported outcome measures

At one year following randomisation the mean MOXFQ for the total cohort was 21.4 (range, 0-93.8; SD, 22.5), the EQ-5D was 0.80 (range, -0.24 – 1.00; SD, 0.24), the health VAS was 84.3 (range, 10-100; SD, 16.4), the pain VAS was 88.2 (range, 0-100; SD, 19.2) and the mean satisfaction with treatment was 96.7 (range 50-100; SD, 7.6). Except for a significant difference in health VAS at 6-8 weeks following surgery, which favoured the fixation group (81.2 vs. 74.7; p=0.048), there were no statistically significant differences between the groups at any outcome point according to the secondary patient reported outcomes (Table 6.6).

Return to activity

By one year following randomisation 52 of the 56 participants who were working before their injury returned to work at a mean of 9.5 weeks (range, 0-26; SD, 5.5). Proportionately more patients in the non-fixation group returned to work (29, 58.0% vs. 23, 46.0%), but this was not statistically significant (p=0.091), nor was the time it took them to return to work (p=0.149), although return to work was quicker in the fixation group by a mean of 2.2 weeks (Table 6.6). Of the 56 participants who participated in physical activity before their injury, 53 returned to activity after a mean period of 17.3 weeks (range, 2-52; SD, 11.3). Proportionately more participants in the fixation group returned to sport (27, 54.0% vs. 26, 52.0%), but this was not statistically significant (p=0.801), nor was the time it took them to return to physical activity (p=0.482).

Complications

Ninety-eight complications were recorded in 63 patients (63.0%) during their treatment with a median of 1 complication per patient (IQR, 1-2). The vast majority of these were minor in nature and did not require surgical intervention (Table 6.7). Fifty-one patients (51.0%) experienced one or more minor complication(s), 11 patients (11.0%) experienced one or more major complication(s) and two patients (2.0%) experienced both; a breakdown of the number of patients experiencing a complication and the specific number of medial and lateral sided complications are presented in Table 6.7. The results have been presented in this way for clarity as there was some overlap between medial and lateral sided presentations. The most common complications were prominent metalwork (n=30, 30%), followed by localised pain (n=21, 21.0%) and superficial wound infection (n=13, 13.0%). All superficial infections improved with oral antibiotics and wound care alone (Figure 6.6). There were no medical complications including VTE.

Figure 6.6: Medial wound infection treated with oral antibiotics and regular wound care.

Thirty-two patients (64.0%) in the fixation group experienced one or more complication compared with 31 (62.0%) in the non-fixation group (p=0.836; Table 6.7). Proportionately more patients in the non-fixation group experienced a major complication (n=9, 18.0% vs. n=4, 8.0%; p=0.137), which largely related to symptomatic medial malleolar non-union (n=3, 6.0%) and an increased rate of further surgery to manage complications (n=7, 14.0%) including loss of talar reduction (n=3, 6.0%; Figure 6.7). The three patients that experienced a loss of talar reduction were all high-risk. The first was a 79-year-old osteoporotic woman who underwent plate fixation of the fibula, which failed rapidly with pull-out of the proximal screws. The second case was a 54-year-old heavy smoking woman, with an unrecognised syndesmosis injury who was permitted to weight bear immediately following surgery, eventually requiring revision syndesmosis fixation and subsequent removal of metalwork due to ongoing pain and infection. The third case was a 54-year-old man who was a heavy smoker and alcohol dependant. His fracture was under-treated and after it failed a CT scan demonstrated an unstable posteromedial pilon variant. He subsequently required a TTC nail arthrodesis (Figure 6.7).

Figure 6.7: Early post-operative loss of talar reduction requiring eventual TTC nail fixation.

(n/% unless otherwise stated)	Fixation (n=50)	Non-Fixation (n=50)	p-value
Patients with complication(s)	32 (64.0)	31 (62.0)	0.836[a]
Patients with minor complication(s)	29 (58.0)	24 (48.0)	0.316[a]
Superficial infection	8 (16.0)	5 (10.0)	0.564[a]
- Lateral	5 (10.0)	5 (10.0)	1.000[b]
- Medial	3 (6.0)	0	0.242[b]
Wound dehiscence	1 (2.0)	1 (2.0)	1.000[b]
- Lateral	1 (2.0)	1 (2.0)	1.000[b]
- Medial	0	0	n/a
Metalwork prominence	19 (38.0)	11 (22.0)	0.081[a]
- Lateral	15 (30.0)	11 (22.0)	0.362[a]
- Medial	11 (22.0)	0	**<0.001*[b]**
Localised pain	11 (22.0)	10 (20.0)	0.806[a]
- Lateral	4 (8.0)	6 (12.0)	0.505[a]
- Medial	10 (20.0)	4 (8.0)	0.084[a]
Pseudoarthrosis (painless)	0	7 (14.0)	**0.012*[b]**
- Lateral	0	0	n/a
- Medial	0	7 (14.0)	**0.012*[b]**
Patients with major complication(s)	4 (8.0)	9 (18.0)	0.137[b]
Failed fixation requiring revision	0	3 (6.0)	0.242[b]
Deep infection requiring surgery	1 (2.0)	0	1.000[b]
- Lateral	1 (2.0)	0	1.000[b]
- Medial	0	0	n/a
Non-union (painful)	0	3 (6.0)	0.242[b]
- Lateral	0	0	n/a
- Medial	0	3 (6.0)	0.242[b]
Medial malleolus non-union requiring surgery	0	1 (2.0)	1.000[b]
Removal of symptomatic metalwork	3 (6.0)	3 (6.0)	1.000[b]
- Lateral	1 (2.0)	3 (6.0)	0.212[b]
- Medial	2 (4.0)	0	0.189[b]
Further surgery to manage complications	4 (8.0)	7 (14.0)	0.525[b]

Table 6.7: Complications during treatment. (* statistical significance reached, [a] Chi-squared test, [b] Fisher's exact test).

Radiographic outcome and fracture union

Lateral malleolar fractures united without event in all participants, with no difference between groups in the proportion of patients achieving lateral malleolar union by the second post-operative outpatient review (p=0.761). Significantly more patients in the fixation group (n=41, 82.0%) achieved medial malleolar union by the same assessment point compared with the non-fixation group (n=29, 58.0%; p=0.013). At the primary endpoint, a medial malleolar pseudoarthrosis (Figure 6.8) occurred in seven patients in the non-fixation group (14.0% overall incidence), compared with no patients in the fixation group. A further three patients had a painful radiographic non-union (6.0%) with one requiring surgery for excision of the non-union fragment (Figure 6.9). In the non-fixation group 29 patients (58.0%) had a 'good' reduction, 16 patients (32.0%) had a 'fair' reduction, and five patients (10%) had a poor reduction.

Figure 6.8: Painless medial malleolar pseudoarthrosis, not requiring surgical intervention.

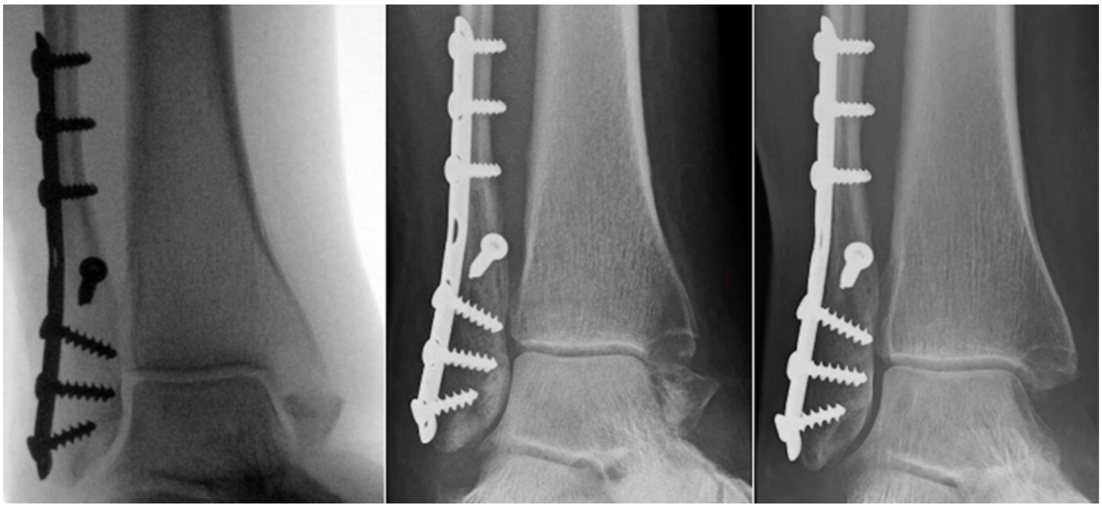

Figure 6.9: Symptomatic medial malleolar non-union following poor intra-operative reduction, eventually requiring excision of the fragment and deltoid ligament plication, with improvement in symptoms.

Pseudoarthrosis/non-union was associated with a poor intra-operative reduction quality with only one non-union occurring in the ‘anatomical’ reduction group (3.4%). The rate of pseudoarthrosis/non-union increased following a ‘fair’ reduction (6/16, 37.5%) and ‘poor’ reduction (3/5, 60.0%; p<0.001). Reduction quality was also associated with the development of a pseudoarthrosis (p=0.029), but not non-union (p=0.091), although the numbers of patients with a non-union was small (n=3). Patient outcome was affected by reduction quality with a 20-point difference in the OMAS at one-year between the three groups (‘good’: 77.9, ‘fair’: 67.2, ‘poor’: 57.0), which trended towards, but did not reach statistical significance (p=0.081; one-way ANOVA).

Radiographic features of PTOA were present in 11 patients in each group at the primary outcome endpoint. Patients in the non-fixation group demonstrated higher grade changes with two patients classified as grade 4 compared with no patients in the fixation group, but this was not statistically significant (p=0.149).

6.5.3 Predictors of outcome

Univariate analysis identified a number of variables which trended towards (p<0.01) significant association with a change in OMAS over the year study period, whereby a larger difference represented a poorer outcome; smoking (p=0.006), obesity (p=0.069), Weber C injury (p=0.081), syndesmosis fixation (p=0.010), poor intra-operative medial malleolar fracture reduction (p=0.098), and the development of a major complication (p=0.023), including a medial malleolar non-union (p=0.001). Pseudoarthrosis of the medial malleolar was not significant (p=0.882).

Multivariate linear regression analysis, controlling for these variables was performed (r^2=0.367). Smoking (p=0.006) and medial malleolar non-union (p=0.002) were the only variables predictive of a poor outcome, according to the overall change in OMAS at one year. Treatment allocation was not predictive of outcome (p=0.357). The same seven variables were entered into a separate model to predict the final OMAS at one-year (r^2=0.219); in keeping with results of the first model, smoking (p=0.023) and medial malleolar non-union (p=0.016) were predictive of a poor outcome (low OMAS).

6.6 Chapter Discussion

This is the largest prospective RCT in the literature comparing operative and non-operative management of associated medial malleolar fractures following fibular stabilisation in patients undergoing surgical fixation of an unstable ankle fracture. Despite being currently underpowered, it includes 18 more patients at the primary outcome endpoint than the only other published trial[182]. The patient reported outcome according to the OMAS was comparable between the two groups, both at the primary outcome endpoint and all other assessment points during the study. Additionally, there was no difference in the overall complication rate, although despite not demonstrating statistical significance, proportionately more patients in the non-fixation group experienced a major complication. The conclusions of this trial must be considered cautiously in context of the underpowered nature, especially as this study was not powered to detect a difference in complications.

In 2013 Hoelsbrekken et al performed the only other prospective RCT in the literature including 82 patients, comparing fixation (n=37) and non-fixation (n=45) of well-reduced medial malleolar fractures (<2mm displacement) following fibular stabilisation[182]. In keeping with the results presented in this chapter, there was no difference in the OMAS between the fixation (80) and non-fixation groups (81) at a minimum follow-up of two years. Interestingly the trial by Hoelsbrekken et al reported a higher rate of infection in the non-fixation group (9% vs 5%), which is the opposite to the results of the current study, whereby lateral sided infection was comparable, but medial infection was greater in the fixation group, as was localised medial sided pain following surgery. Two patients in the fixation group required further surgery for symptomatic medial sided metalwork; in one patient the screw had completely backed out and was threatening the skin and in the second patient the screw had caused localised inflammation to the tibialis posterior tendon, a complication which has been previously reported[178, 179]. At the time of surgery there was evidence of tenosynovitis of the tibialis posterior tendon, which improved significantly after screw removal. Three patients in the non-fixation group required further surgery to remove symptomatic lateral sided metalwork, compared with only one patient in the fixation group. Whilst not directly related to the medial sided treatment allocation re-operations of this nature increased the re-operation rate for the non-fixation group.

Despite the significant contribution of ankle fractures to the orthopaedic workload, there are few studies reporting the rates of medial malleolar non-union. Within the confines of the available literature[60, 182], published radiographic rates of between 4-9% are comparable to those in the present study (6%). Only one patient required further surgery, equating to a 2% risk of reintervention to treat medial malleolar non-union. The risk of developing a pseudoarthrosis/non-union was directly related to the quality of the fracture reduction at the time of surgery; in anatomically reduced fractures (n=29) only one patient developed a pseudoarthrosis (3%). Multiple linear regression analysis identified patient smoking and non-union as being strongly predictive of a poor outcome according to the OMAS, but the development of pseudoarthrosis was not. It may have been more correct to not define pseudoarthrosis as a minor complication in this chapter, but as the longer-term implications of this are unclear it was felt appropriate to include. Whilst it has been conclusively demonstrated that smoking has significant negative effects on bone healing[302], it was not possible with the number of patients in the current study to demonstrate a statistically significant association between smoking and non-union, although smokers were proportionately at higher risk of medial malleolar pseudoarthrosis/non-union than non-smokers (20% vs. 8%; p=0.096). Given that both factors may contribute to a poorer post-operative patient outcome, it would be reasonable to not consider conservative management of medial malleolar fractures in patients who smoke, especially as lateral malleolar non-union was not an observed problem in either group. Post-operative loss of talar reduction occurred in three patients, all of whom were in the non-fixation group. It was felt that early loss of reduction was secondary to under-treatment of the fibular fracture or under-appreciation of the severity of injury including an unrecognised syndesmosis injury and an unstable posteromedial pilon variant, all of which were in high-risk patients.

An advantage of non-fixation was a reduced mean tourniquet time of 21 minutes compared with fixation of the medial malleolar fracture. This may have potential benefits for increasing theatre utilisation and reducing complications associated with prolonged tourniquet use in lower limb fracture surgery including wound infection[303] and post-operative pain[304].

6.6.1 Strengths and limitations

The primary strength of this trial is the excellent compliance with randomised treatment allocation, with 99% of the 106 participants receiving their allocated intervention according to the ITT principle. The follow-up rate at the primary outcome endpoint of 94% serves as an additional strength. Based on the limitations of previous research in this area, the inclusion of pre-injury PROMs has enabled new measurements of patient recovery including the difference in OMAS over the study period, as well as reporting the percentage of patients returning to their baseline score following injury; an outcome metric which may be helpful when counselling patients with unstable ankle fractures prior to surgery. With only 30% of patients returning to the same patient-reported baseline reminds us that ankle fractures are not benign injuries.

The most significant limitation of the trial is the fact that it is currently under-powered by 28 patients; therefore, the absence of a statistically significant difference between the OMAS at one year may represent a type II error. The reasons for this have been explained in Chapter 2, Section 2.1 and the trial is now fully recruited (154 patients); the trial team remain active with data collection but continue to face challenges given the unpredictable nature of the SARS-CoV-2 virus pandemic. Another limitation of the study is the lack of surgeon and patient blinding but given the nature of the intervention this was not feasible. Acceptable medial malleolar fracture reduction based on AP intra-operative fluoroscopy was well-defined before the trial commenced and based on the surgeon's assessment after fibular stabilisation. The subjective nature of this unfortunately resulted in five patients being included in the non-fixation group that should have been excluded according to the study protocol but were analysed, in respect of the pragmatic nature of the study. Three of these patients went on to develop a pseudoarthrosis/non-union, which as a result has likely over-estimated the true incidence of non-union for the described study cohort. Furthermore, we do not have data on medial malleolar reduction quality for all the fixation cases as a number of surgeons unfortunately did not save the appropriate intra-operative fluoroscopy prior to internal fixation.

A final comment on clinical equipoise must be considered. Whilst the study team designed and conducted the trial with genuine clinical equipoise and educated all trauma consultants on the nature of the trial in advance of recruitment, it was evident that a small number of senior surgeons lacked equipoise as the trial progressed. Consequently, some patients under the care of these surgeons were excluded from the trial as that surgeon felt strongly for or against the principle of non-fixation of medial malleolar fractures. Whilst some surgeons felt that the medial malleolus should always be fixed, there were several occasions where surgeons excluded patients as they felt it was not in their patient's best interest to be included; they had decided in advance that they would treat the medial malleolar fracture non-operatively, usually secondary to concerns regarding a poor soft tissue envelope. The study team acknowledge this, but do not feel that this had a significant impact on the data collected.

6.6.2 Key conclusions

Internal fixation of well-reduced medial malleolar fractures following fibular stabilisation does not appear to be superior to non-fixation when examined under randomised controlled trial conditions although further data collection is required to confirm this statistically. Proportionally more patients treated without fixation experienced a major complication including the requirement for further surgery. Medial malleolar non-union and smoking are predictive of a poor outcome according to the OMAS one year following surgery.

6.6.3 Directions for future research

To draw firm conclusions from this trial, ongoing data collection is required. If the remaining results follow a similar trend to those currently presented then it is likely that each treatment approach results in equivalent patient reported outcome after one year. Future research should focus on patients with an ‘anatomical’ medial malleolar fracture reduction in a more tightly controlled trial. Allowing a fracture displacement threshold of two millimetres has undeniably increased the inclusion of unsuitable patients, according to the study protocol, although do provide useful data through their inclusion.

7. CONCLUSIONS

The aims of this thesis have been satisfied by the findings of each chapter. With respect to the first aim, the large retrospective review of 342 patients managed with a fibular intramedullary nail (Chapter 3) found a rate of mechanical failure of 6% and allowed for the examination of 20 failed fixation cases in detail. This has led to several procedural refinements, which have been adopted within the EOTU and have been shared with Acumed to make implant modifications. These include the provision of headless locking screws within the nail, to prevent screw back out and local soft-tissue irritation. Longer-term outcomes collected at a mean follow-up of five years provide useful prognostic data, which addresses a limitation of the published literature.

The second aim related to the biomechanical failure properties of the fibular intramedullary nail compared with locking plate fixation (Chapter 4). Whilst the fibular nail is a popular implant choice in the EOTU, it is acknowledged that most UK centres will be more familiar with locking plate fixation for elderly ankle fractures. The results of this chapter have demonstrated comparable failure properties, in particular torque to failure. Whilst the angle at failure was significantly higher in the nail group, the clinical significance of this is uncertain and likely reflects the lesser fixation constraint of the intramedullary device compared with the more rigid fixation afforded by locking plates. An important conclusion to take away is that the proven soft tissue benefits of the intramedullary nail do not appear to be offset by a lesser biomechanical performance.

The third and final aim was addressed by investigations in both a retrospective and prospective setting. Whilst the retrospective review of patients with medial malleolar fractures treated non-operatively following intramedullary fibular stabilisation (Chapter 5) would suggest comparable mid-term outcome to those patients treated with fixation, this study was subject to the typical limitations of retrospective study designs, including a large loss to follow-up and lack of radiographic surveillance, making it difficult to draw firm conclusions regarding medial malleolar union. This treatment concept was then prospectively investigated in the RCT presented in Chapter 6. Whilst the findings of this study remain underpowered due to the impact of the SARS-CoV-2 virus pandemic, the results to date would suggest that internal fixation is not superior to non-fixation, although it is not possible to either accept or reject the null hypothesis at present. Additional data collection is required to ensure that this finding is not a type II error. Future research in this area may need to take on a more restricted approach and only include anatomically reduced fractures. It is clear from these results and the literature so far that a poorer fracture reduction decreases the likelihood of fracture union, and that painful non-union is predictive of a poorer outcome at one year. Peer-reviewed publication of the final results of this RCT will add greatly to the current evidence base.

REFERENCES

1. Carter TH, Duckworth AD and White TO. Medial malleolar fractures: current treatment concepts. *Bone Joint J* 2019; 101-B: 512-521. 2019/05/01. DOI: 10.1302/0301-620x.101B5.BJJ-2019-0070.

2. White TO and Carter TH. Ankle fractures: facts and fiction. *Bone Joint J 360* 2018; 7: 3-8. Review. DOI: 10.1302/2048-0105.74.360623.

3. Court-Brown CM and Caesar B. Epidemiology of adult fractures: A review. *Injury* 2006; 37: 691-697. 2006/07/04. DOI: 10.1016/j.injury.2006.04.130.

4. Murray AM, McDonald SE, Archbold P, et al. Cost description of inpatient treatment for ankle fracture. *Injury* 2011; 42: 1226-1229. 2010/09/28. DOI: 10.1016/j.injury.2010.08.023.

5. Willett K, Keene DJ, Mistry D, et al. Close Contact Casting vs Surgery for Initial Treatment of Unstable Ankle Fractures in Older Adults: A Randomized Clinical Trial. *JAMA* 2016; 316: 1455-1463. 2016/10/12. DOI: 10.1001/jama.2016.14719.

6. McKeown R, Kearney RS, Liew ZH, et al. Patient experiences of an ankle fracture and the most important factors in their recovery: a qualitative interview study. *BMJ Open* 2020; 10: e033539. DOI: 10.1136/bmjopen-2019-033539.

7. Lampridis V, Gougoulias N and Sakellariou A. Stability in ankle fractures: Diagnosis and treatment. *EFORT Open Rev* 2018; 3: 294-303. 2018/06/29. DOI: 10.1302/2058-5241.3.170057.

8. Jain N, Symes T, Doorgakant A, et al. Clinical audit of the management of stable ankle fractures. *Ann R Coll Surg Engl* 2008; 90: 483-487. 2008/09/04. DOI: 10.1308/003588408X301145.

9. Kortekangas T, Haapasalo H, Flinkkilä T, et al. Three week versus six week immobilisation for stable Weber B type ankle fractures: randomised, multicentre, non-inferiority clinical trial. *BMJ* 2019: k5432. DOI: 10.1136/bmj.k5432.

10. Rydberg EM, Zorko T, Sundfeldt M, et al. Classification and treatment of lateral malleolar fractures - a single-center analysis of 439 ankle fractures using the Swedish Fracture Register. *BMC Musculoskeletal Disorders* 2020; 21. DOI: 10.1186/s12891-020-03542-5.

11. Castro MD. Ankle biomechanics. *Foot Ankle Clin* 2002; 7: 679-693. 2003/01/09.

12. Hertel J. Functional Anatomy, Pathomechanics, and Pathophysiology of Lateral Ankle Instability. *Journal of athletic training* 2002; 37: 364-375.

13. Drake R, Vogl A and Mitchell A. *Gray's Atlas of Anatomy*. 2 ed.: Elsevier Health Sciences, 2015.

14. Pankovich AM and Shivaram MS. Anatomical basis of variability in injuries of the medial malleolus and the deltoid ligament. I. Anatomical studies. *Acta Orthop Scand* 1979; 50: 217-223. 1979/04/01.

15. Stormont DM, Morrey BF, An KN, et al. Stability of the loaded ankle. Relation between articular restraint and primary and secondary static restraints. *Am J Sports Med* 1985; 13: 295-300. 1985/09/01. DOI: 10.1177/036354658501300502.

16. Davidovitch RI and Egol KA. The medial malleolus osteoligamentous complex and its role in ankle fractures. *Bull NYU Hosp Jt Dis* 2009; 67: 318-324. 2009/12/17.

17. Court-Brown C. Rockwood and Green's fractures in Adults. *Rockwood and Green's fractures in Adults*. Walters Kluwer, 2015.

18. Elsoe R, Ostgaard SE and Larsen P. Population-based epidemiology of 9767 ankle fractures. *Foot Ankle Surg* 2018; 24: 34-39. 2018/02/08. DOI: 10.1016/j.fas.2016.11.002.

19. Al-Azzani W, Adam Maliq Mak D, Hodgson P, et al. Epidemic of fractures during a period of snow and ice: has anything changed 33 years on? *BMJ Open* 2016; 6: e010582-e010582. DOI: 10.1136/bmjopen-2015-010582.

20. Court-Brown CM, McBirnie J and Wilson G. Adult ankle fractures--an increasing problem? *Acta Orthop Scand* 1998; 69: 43-47. 1998/04/03.

21. Salai M, Dudkiewicz I, Novikov I, et al. The epidemic of ankle fractures in the elderly--is surgical treatment warranted? *Arch Orthop Trauma Surg* 2000; 120: 511-513. 2000/09/30.

22. Toole WP, Elliott M, Hankins D, et al. Are low-energy open ankle fractures in the elderly the new geriatric hip fracture? *J Foot Ankle Surg* 2015; 54: 203-206. 2014/12/10. DOI: 10.1053/j.jfas.2014.10.015.

23. Jensen SL, Andresen BK, Mencke S, et al. Epidemiology of ankle fractures. A prospective population-based study of 212 cases in Aalborg, Denmark. *Acta Orthop Scand* 1998; 69: 48-50. 1998/04/03.

24. Zalavras CG, Christensen T, Rigopoulos N, et al. Infection following operative treatment of ankle fractures. *Clin Orthop Relat Res* 2009; 467: 1715-1720. 2009/02/20. DOI: 10.1007/s11999-009-0743-8.

25. Schade MA and Hollenbeak CS. Early Postoperative Infection Following Open Reduction Internal Fixation Repair of Closed Malleolar Fractures. *Foot Ankle Spec* 2018; 11: 335-341. 2017/10/17. DOI: 10.1177/1938640017735887.

26. Koval KJ, Zhou W, Sparks MJ, et al. Complications after Ankle Fracture in Elderly Patients. 2007; 28: 1249-1255. DOI: 10.3113/fai.2007.1249.

27. Leyes M, Torres R and Guillen P. Complications of open reduction and internal fixation of ankle fractures. *Foot Ankle Clin* 2003; 8: 131-147, ix. 2003/05/23.

28. Wukich DK, Lowery NJ, McMillen RL, et al. Postoperative infection rates in foot and ankle surgery: a comparison of patients with and without diabetes mellitus. *J Bone Joint Surg Am* 2010; 92: 287-295. 2010/02/04. DOI: 10.2106/JBJS.I.00080.

29. Zaghloul A, Haddad B, Barksfield R, et al. Early complications of surgery in operative treatment of ankle fractures in those over 60: a review of 186 cases. *Injury* 2014; 45: 780-783. 2014/01/07. DOI: 10.1016/j.injury.2013.11.008.

30. Simske NM, Benedick A, Audet MA, et al. Ankle fractures in patients over age 55 years: Predictors of functional outcome. *OTA International* 2020; 3.

31. SooHoo NF, Krenek L, Eagan MJ, et al. Complication rates following open reduction and internal fixation of ankle fractures. *J Bone Joint Surg Am* 2009; 91: 1042-1049. 2009/05/05. DOI: 10.2106/JBJS.H.00653.

32. Gougoulias N, Oshba H, Dimitroulias A, et al. Ankle fractures in diabetic patients. *EFORT Open Rev* 2020; 5: 457-463. 2020/09/22. DOI: 10.1302/2058-5241.5.200025.

33. Tonnesen H, Pedersen A, Jensen MR, et al. Ankle fractures and alcoholism. The influence of alcoholism on morbidity after malleolar fractures. *J Bone Joint Surg Br* 1991; 73: 511-513. 1991/05/01. DOI: 10.1302/0301-620X.73B3.1670461.

34. Ovaska MT, Makinen TJ, Madanat R, et al. Risk factors for deep surgical site infection following operative treatment of ankle fractures. *J Bone Joint Surg Am* 2013; 95: 348-353. 2013/02/22. DOI: 10.2106/JBJS.K.01672.

35. Nasell H, Ottosson C, Tornqvist H, et al. The impact of smoking on complications after operatively treated ankle fractures--a follow-up study of 906 patients. *J Orthop Trauma* 2011; 25: 748-755. 2011/09/03. DOI: 10.1097/BOT.0b013e318213f217.

36. Benedick A, Audet MA and Vallier HA. The effect of obesity on post-operative complications and functional outcomes after surgical treatment of torsional ankle fracture: A matched cohort study. *Injury* 2020; 51: 1893-1898. 2020/06/15. DOI: 10.1016/j.injury.2020.05.006.

37. Sun Y, Wang H, Tang Y, et al. Incidence and risk factors for surgical site infection after open reduction and internal fixation of ankle fracture: A retrospective multicenter study. *Medicine (Baltimore)* 2018; 97: e9901. 2018/02/15. DOI: 10.1097/MD.0000000000009901.

38. Pincus D, Veljkovic A, Zochowski T, et al. Rate of and Risk Factors for Intermediate-Term Reoperation After Ankle Fracture Fixation: A Population-Based Cohort Study. *J Orthop Trauma* 2017; 31: e315-e320. 2017/06/15. DOI: 10.1097/BOT.0000000000000920.

39. Gauthé R, Desseaux A, Rony L, et al. Ankle fractures in the elderly: Treatment and results in 477 patients. *Orthopaedics & Traumatology: Surgery & Research* 2016; 102: S241-S244. DOI: 10.1016/j.otsr.2016.03.001.

40. Gougoulias N and Sakellariou A. When is a simple fracture of the lateral malleolus not so simple? how to assess stability, which ones to fix and the role of the deltoid ligament. *Bone Joint J* 2017; 99-B: 851-855. 2017/07/01. DOI: 10.1302/0301-620X.99B7.BJJ-2016-1087.R1.

41. Koval KJ, Egol KA, Cheung Y, et al. Does a positive ankle stress test indicate the need for operative treatment after lateral malleolus fracture? A preliminary report. *J Orthop Trauma* 2007; 21: 449-455. 2007/09/01. DOI: 10.1097/BOT.0b013e31812eed25.

42. Egol KA, Amirtharajah M, Tejwani NC, et al. Ankle stress test for predicting the need for surgical fixation of isolated fibular fractures. *J Bone Joint Surg Am* 2004; 86-A: 2393-2398. 2004/11/04.

43. Stringfellow TD, Walters ST, Nash W, et al. Management of posterior malleolus fractures: A multicentre cohort study in the United Kingdom. *Foot and Ankle Surgery* 2020. DOI: 10.1016/j.fas.2020.08.003.

44. Mason LW, Marlow WJ, Widnall J, et al. Pathoanatomy and Associated Injuries of Posterior Malleolus Fracture of the Ankle. *Foot & Ankle International* 2017; 38: 1229-1235. DOI: 10.1177/1071100717719533.

45. Kumar A, Mishra P, Tandon A, et al. Effect of CT on Management Plan in Malleolar Ankle Fractures. *Foot Ankle Int* 2018; 39: 59-66. 2017/12/13. DOI: 10.1177/1071100717732746.

46. Rammelt S and Boszczyk A. Computed Tomography in the Diagnosis and Treatment of Ankle Fractures: A Critical Analysis Review. *JBJS Rev* 2018; 6: e7. 2018/12/19. DOI: 10.2106/JBJS.RVW.17.00209.

47. Bäcker HC, Vosseller JT, Bonel H, et al. Weightbearing Radiography and MRI Findings in Ankle Fractures. *Foot & Ankle Specialist* 2020: 193864002092157. DOI: 10.1177/1938640020921571.

48. Hermans JJ, Wentink N, Beumer A, et al. Correlation between radiological assessment of acute ankle fractures and syndesmotic injury on MRI. 2012; 41: 787-801. DOI: 10.1007/s00256-011-1284-2.

49. Pott P. Some few general remarks on fractures and dislocations. 1758. *Clin Orthop Relat Res* 2007; 458: 40-41. 2007/05/03. DOI: 10.1097/BLO.0b013e31803dd063.

50. Weber BG. [Malleolar fractures]. *Schweiz Med Wochenschr* 1967; 97: 790-792. 1967/06/17.

51. Danis R. Les fractures malleolaires. *Danis R (ed) Theorie et Pratique de l'Osteosynthese*. Paris, France: Masson, 1949, p. 133-165.

52. Marsh JL, Slongo TF, Agel J, et al. Fracture and dislocation classification compendium - 2007: Orthopaedic Trauma Association classification, database and outcomes committee. *J Orthop Trauma* 2007; 21: S1-133. 2008/03/07.

53. Rodriguez EK, Kwon JY, Herder LM, et al. Correlation of AO and Lauge-Hansen Classification Systems for Ankle Fractures to the Mechanism of Injury. *Foot & Ankle International* 2013; 34: 1516-1520. DOI: 10.1177/1071100713491730.

54. Juto H, Möller M, Wennergren D, et al. Substantial accuracy of fracture classification in the Swedish Fracture Register: Evaluation of AO/OTA-classification in 152 ankle fractures. 2016; 47: 2579-2583. DOI: 10.1016/j.injury.2016.05.028.

55. Meinberg E, Agel J, Roberts C, et al. Fracture and Dislocation Classification Compendium—2018. *Journal of Orthopaedic Trauma* 2018; 32: S1-S10. DOI: 10.1097/bot.0000000000001063.

56. Lauge-Hansen N. Ligamentous ankle fractures; diagnosis and treatment. *Acta Chir Scand* 1949; 97: 544-550. 1949/03/23.

57. Gardner MJ, Demetrakopoulos D, Briggs SM, et al. The Ability of the Lauge-Hansen Classification to Predict Ligament Injury and Mechanism in Ankle Fractures: An MRI Study. *Journal of orthopaedic trauma* 2006; 20: 267-272. DOI: 10.1097/00005131-200604000-00006.

58. Kwon JY, Chacko AT, Kadzielski JJ, et al. A novel methodology for the study of injury mechanism: ankle fracture analysis using injury videos posted on YouTube.com. *J Orthop Trauma* 2010; 24: 477-482. 2010/07/27. DOI: 10.1097/BOT.0b013e3181c99264.

59. Hermans JJ, Wentink N, Beumer A, et al. Correlation between radiological assessment of acute ankle fractures and syndesmotic injury on MRI. *Skeletal Radiology* 2012; 41: 787-801. DOI: 10.1007/s00256-011-1284-2.

60. Herscovici D, Jr., Scaduto JM and Infante A. Conservative treatment of isolated fractures of the medial malleolus. *J Bone Joint Surg Br* 2007; 89: 89-93. 2007/01/30. DOI: 10.1302/0301-620X.89B1.18349.

61. Muller M.E NF, Koch P, Schatzker J. . *Tibia/Fibula. The Comprehensive Classification of Fractures of Long Bones*. Springer-Verlag, 1990.

62. Pankovich AM and Shivaram MS. Anatomical basis of variability in injuries of the medial malleolus and the deltoid ligament. II. Clinical studies. *Acta Orthop Scand* 1979; 50: 225-236. 1979/04/01.

63. Aitken SA, Johnston I, Jennings AC, et al. An evaluation of the Herscovici classification for fractures of the medial malleolus. *Foot Ankle Surg* 2017; 23: 317-320. 2017/12/06. DOI: 10.1016/j.fas.2016.10.003.

64. Ferries JS, DeCoster TA, Firoozbakhsh KK, et al. Plain radiographic interpretation in trimalleolar ankle fractures poorly assesses posterior fragment size. *J Orthop Trauma* 1994; 8: 328-331. 1994/08/01. DOI: 10.1097/00005131-199408000-00009.

65. Buchler L, Tannast M, Bonel HM, et al. Reliability of radiologic assessment of the fracture anatomy at the posterior tibial plafond in malleolar fractures. *J Orthop Trauma* 2009; 23: 208-212. 2009/06/12. DOI: 10.1097/BOT.0b013e31819b0b23.

66. Haraguchi N, Haruyama H, Toga H, et al. Pathoanatomy of posterior malleolar fractures of the ankle. *J Bone Joint Surg Am* 2006; 88: 1085-1092. 2006/05/03. DOI: 10.2106/JBJS.E.00856.

67. Blom RP, Hayat B, Al-Dirini RMA, et al. Posterior malleolar ankle fractures. *Bone Joint J* 2020; 102-B: 1229-1241. 2020/08/31. DOI: 10.1302/0301-620X.102B9.BJJ-2019-1660.R1.

68. Bergman C, Morin M and Lawson K. Anatomy, Classification, and Management of Ankle Fractures Involving the Posterior Malleolar Fragment: A Literature Review. *Foot & Ankle Orthopaedics* 2019; 4: 247301141988772. DOI: 10.1177/2473011419887724.

69. Jeyaseelan L, Bua N, Parker L, et al. Outcomes of posterior malleolar fixation in ankle fractures in a major trauma centre. *Injury* 2020. DOI: 10.1016/j.injury.2020.12.006.

70. Egol KA, Tejwani NC, Walsh MG, et al. Predictors of short-term functional outcome following ankle fracture surgery. *J Bone Joint Surg Am* 2006; 88: 974-979. 2006/05/03. DOI: 10.2106/JBJS.E.00343.

71. Nilsson G, Jonsson K, Ekdahl C, et al. Outcome and quality of life after surgically treated ankle fractures in patients 65 years or older. *BMC Musculoskelet Disord* 2007; 8: 127. 2007/12/22. DOI: 10.1186/1471-2474-8-127.

72. Shah NH, Sundaram RO, Velusamy A, et al. Five-year functional outcome analysis of ankle fracture fixation. *Injury* 2007; 38: 1308-1312. DOI: 10.1016/j.injury.2007.06.002.

73. Macera A, Carulli C, Sirleo L, et al. Postoperative Complications and Reoperation Rates Following Open Reduction and Internal Fixation of Ankle Fracture. *Joints* 2018; 6: 110-115. 2018/07/28. DOI: 10.1055/s-0038-1653949.

74. Ebraheim NA, Mekhail AO and Gargasz SS. Ankle fractures involving the fibula proximal to the distal tibiofibular syndesmosis. *Foot Ankle Int* 1997; 18: 513-521. 1997/08/01. DOI: 10.1177/107110079701800811.

75. Hoiness P, Engebretsen L and Stromsoe K. The influence of perioperative soft tissue complications on the clinical outcome in surgically treated ankle fractures. *Foot Ankle Int* 2001; 22: 642-648. 2001/08/31. DOI: 10.1177/107110070102200805.

76. Schepers T, De Vries MR, Van Lieshout EMM, et al. The timing of ankle fracture surgery and the effect on infectious complications; A case series and systematic review of the literature. *International Orthopaedics* 2013; 37: 489-494. DOI: 10.1007/s00264-012-1753-9.

77. Wukich DK, Crim BE, Frykberg RG, et al. Neuropathy and poorly controlled diabetes increase the rate of surgical site infection after foot and ankle surgery. *J Bone Joint Surg Am* 2014; 96: 832-839. 2014/05/31. DOI: 10.2106/JBJS.L.01302.

78. Miller AG, Margules A and Raikin SM. Risk factors for wound complications after ankle fracture surgery. *J Bone Joint Surg Am* 2012; 94: 2047-2052. 2012/11/23. DOI: 10.2106/JBJS.K.01088.

79. Black JD, Bhavikatti M, Al-Hadithy N, et al. Early weight-bearing in operatively fixed ankle fractures: a systematic review. *Foot (Edinb)* 2013; 23: 78-85. 2013/06/04. DOI: 10.1016/j.foot.2013.05.002.

80. Smeeing DP, Houwert RM, Briet JP, et al. Weight-bearing and mobilization in the postoperative care of ankle fractures: a systematic review and meta-analysis of randomized controlled trials and cohort studies. *PLoS One* 2015; 10: e0118320. 2015/02/20. DOI: 10.1371/journal.pone.0118320.

81. Dehghan N, McKee MD, Jenkinson RJ, et al. Early Weightbearing and Range of Motion Versus Non-Weightbearing and Immobilization After Open Reduction and Internal Fixation of Unstable Ankle Fractures: A Randomized Controlled Trial. *J Orthop Trauma* 2016; 30: 345-352. 2016/04/06. DOI: 10.1097/BOT.0000000000000572.

82. Brown OL, Dirschl DR and Obremskey WT. Incidence of hardware-related pain and its effect on functional outcomes after open reduction and internal fixation of ankle fractures. *J Orthop Trauma* 2001; 15: 271-274. 2001/05/24.

83. Jacobsen S, Honnens de Lichtenberg M, Jensen CM, et al. Removal of internal fixation--the effect on patients' complaints: a study of 66 cases of removal of internal fixation after malleolar fractures. *Foot Ankle Int* 1994; 15: 170-171. 1994/04/01. DOI: 10.1177/107110079401500402.

84. Williams BR, McCreary DL, Chau M, et al. Functional Outcomes of Symptomatic Implant Removal Following Ankle Fracture Open Reduction and Internal Fixation. *Foot & Ankle International* 2018; 39: 674-680. DOI: 10.1177/1071100718757719.

85. Sanders FRK, Backes M, Dingemans SA, et al. Functional outcome of implant removal following fracture fixation below the level of the knee: a prospective cohort

study. *Bone Joint J* 2019; 101-b: 447-453. 2019/04/02. DOI: 10.1302/0301-620x.101b4.Bjj-2018-0745.R1.

86. Jung HG, Kim JI, Park JY, et al. Is Hardware Removal Recommended after Ankle Fracture Repair? *Biomed Res Int* 2016; 2016: 5250672. 2016/11/08. DOI: 10.1155/2016/5250672.

87. Reith G, Schmitz-Greven V, Hensel KO, et al. Metal implant removal: benefits and drawbacks--a patient survey. *BMC Surg* 2015; 15: 96. 2015/08/08. DOI: 10.1186/s12893-015-0081-6.

88. Bostman O and Pihlajamaki H. Routine implant removal after fracture surgery: a potentially reducible consumer of hospital resources in trauma units. *J Trauma* 1996; 41: 846-849. 1996/11/01.

89. Partio N, Huttunen TT, Mäenpää HM, et al. Reduced incidence and economic cost of hardware removal after ankle fracture surgery: a 20-year nationwide registry study. *Acta Orthopaedica* 2020; 91: 331-335. DOI: 10.1080/17453674.2020.1733749.

90. Solomon LB, Ferris L, Tedman R, et al. Surgical anatomy of the sural and superficial fibular nerves with an emphasis on the approach to the lateral malleolus. *Journal of Anatomy* 2001; 199: 717-723. DOI: 10.1046/j.1469-7580.2001.19960717.x.

91. Halm JA and Schepers T. Damage to the Superficial Peroneal Nerve in Operative Treatment of Fibula Fractures: Straight to the Bone? Case Report and Review of the Literature. *The Journal of Foot and Ankle Surgery* 2012; 51: 684-686. DOI: 10.1053/j.jfas.2012.05.021.

92. Jowett AJL, Sheikh FT, Carare RO, et al. Location of the Sural Nerve During Posterolateral Approach to the Ankle. *Foot & Ankle International* 2010; 31: 880-883. DOI: 10.3113/fai.2010.0880.

93. Redfern DJ, Sauvé PS and Sakellariou A. Investigation of Incidence of Superficial Peroneal Nerve Injury Following Ankle Fracture. *Foot & Ankle International* 2003; 24: 771-774. DOI: 10.1177/107110070302401006.

94. Mercer D, Morrell NT, Fitzpatrick J, et al. The course of the distal saphenous nerve: a cadaveric investigation and clinical implications. *Iowa Orthop J* 2011; 31: 231-235. 2011/11/19.

95. Rbia N, Van Der Vlies CH, Cleffken BI, et al. High Prevalence of Chronic Pain With Neuropathic Characteristics After Open Reduction and Internal Fixation of Ankle Fractures. *Foot & Ankle International* 2017; 38: 987-996. DOI: 10.1177/1071100717712432.

96. Weatherall JM, Mroczek K, McLaurin T, et al. Post-traumatic ankle arthritis. *Bull Hosp Jt Dis (2013)* 2013; 71: 104-112. 2013/09/17.

97. Ewalefo SO, Dombrowski M, Hirase T, et al. Management of Posttraumatic Ankle Arthritis: Literature Review. *Current Reviews in Musculoskeletal Medicine* 2018; 11: 546-557. DOI: 10.1007/s12178-018-9525-9.

98. Valderrabano V, Horisberger M, Russell I, et al. Etiology of Ankle Osteoarthritis. *Clinical Orthopaedics and Related Research®* 2009; 467: 1800-1806. DOI: 10.1007/s11999-008-0543-6.

99. Stufkens SA, Knupp M, Horisberger M, et al. Cartilage Lesions and the Development of Osteoarthritis After Internal Fixation of Ankle Fractures. *The Journal of Bone & Joint Surgery* 2010; 92: 279-286. DOI: 10.2106/jbjs.h.01635.

100. Delco ML, Kennedy JG, Bonassar LJ, et al. Post-traumatic osteoarthritis of the ankle: A distinct clinical entity requiring new research approaches. *Journal of Orthopaedic Research* 2017; 35: 440-453. DOI: 10.1002/jor.23462.

101. Takakura Y, Tanaka Y, Kumai T, et al. Low tibial osteotomy for osteoarthritis of the ankle. Results of a new operation in 18 patients. *J Bone Joint Surg Br* 1995; 77: 50-54. 1995/01/01.

102. Holzer N, Salvo D, Marijnissen ACA, et al. Radiographic evaluation of posttraumatic osteoarthritis of the ankle: the Kellgren–Lawrence scale is reliable and correlates with clinical symptoms. *Osteoarthritis and Cartilage* 2015; 23: 363-369. DOI: 10.1016/j.joca.2014.11.010.

103. Lübbeke A, Salvo D, Stern R, et al. Risk factors for post-traumatic osteoarthritis of the ankle: an eighteen year follow-up study. *International Orthopaedics* 2012; 36: 1403-1410. DOI: 10.1007/s00264-011-1472-7.

104. Frölke JPM and Patka P. Definition and classification of fracture non-unions. *Injury* 2007; 38: S19-S22. DOI: 10.1016/s0020-1383(07)80005-2.

105. Mendelsohn HA. Nonunion of malleolar fractures of the ankle. *Clin Orthop Relat Res* 1965; 42: 103-118. 1965/09/01.

106. Bhadra AK, Roberts CS and Giannoudis PV. Nonunion of fibula: a systematic review. *Int Orthop* 2012; 36: 1757-1765. 2012/05/31. DOI: 10.1007/s00264-012-1556-z.

107. Banks SW. The treatment of non-union of fractures of the medial malleolus. *J Bone Joint Surg Am* 1949; 31A: 658-662. 1949/07/01.

108. Khurana S, Karia R and Egol KA. Operative treatment of nonunion following distal fibula and medial malleolar ankle fractures. *Foot Ankle Int* 2013; 34: 365-371. 2013/03/23. DOI: 10.1177/1071100712473740.

109. Madhu T. A modified operative technique for enhanced compression of medial malleolar non-union. *Injury Extra* 2005; 36: 520-525.

110. John R. Tension Band Wiring Is As Effective As A Compression Screw In A Neglected, Medial Maleolus Non-Union: A Case-Based Discussion & Literature Review. *Journal of Orthopaedic Case Reports* 2017; 7: 72-75.

111. Kanakis TE, Papadakis E, Orfanos A, et al. Figure eight tension band in the treatment of fractures and pseudarthroses of the medial malleolus. *Injury* 1990; 21: 393-397. 1990/11/01.

112. Sanders DW, Tieszer C, Corbett B, et al. Operative versus nonoperative treatment of unstable lateral malleolar fractures: a randomized multicenter trial. *J Orthop Trauma* 2012; 26: 129-134. 2012/02/15. DOI: 10.1097/BOT.0b013e3182460837.

113. Ramasamy A, Humphrey J and Robinson AHN. The Ankle Injury Management (AIM) trial: the way forward or off target? *Bone Joint J* 2019; 101-B: 1466-1468. 2019/12/04. DOI: 10.1302/0301-620X.101B12.BJJ-2019-0901.

114. Younger A. Close contact casting may result in similar outcomes compared with plate fixation for unstable ankle fractures in patients over 60 years old. *Evid Based Med* 2017; 22: 99. 2017/04/05. DOI: 10.1136/ebmed-2017-110683.

115. Keene DJ, Lamb SE, Mistry D, et al. Three-Year Follow-up of a Trial of Close Contact Casting vs Surgery for Initial Treatment of Unstable Ankle Fractures in Older Adults. *JAMA* 2018; 319: 1274. DOI: 10.1001/jama.2018.0811.

116. Larsen P, Rathleff MS and Elsoe R. Surgical versus conservative treatment for ankle fractures in adults – A systematic review and meta-analysis of the benefits and harms. *Foot and Ankle Surgery* 2019; 25: 409-417. DOI: 10.1016/j.fas.2018.02.009.

117. Yablon IG, Heller FG and Shouse L. The key role of the lateral malleolus in displaced fractures of the ankle. *J Bone Joint Surg Am* 1977; 59: 169-173. 1977/03/01.

118. Iacobellis C, Chemello C, Zornetta A, et al. Minimally invasive plate osteosynthesis in type B fibular fractures versus open surgery. 2013; 97: 229-235. DOI: 10.1007/s12306-013-0292-x.

119. Abdelgaid SM, Moursy AF, Elgebaly EAA, et al. Minimally Invasive Treatment of Ankle Fractures in Patients at High Risk of Soft Tissue Wound Healing Complications. *The Journal of Foot and Ankle Surgery* 2018; 57: 557-571. DOI: 10.1053/j.jfas.2017.11.041.

120. Bazarov I, Kim J, Richey JM, et al. Minimally Invasive Plate Osteosynthesis for Treatment of Ankle Fractures in High-Risk Patients. *The Journal of Foot and Ankle Surgery* 2018; 57: 494-500. DOI: 10.1053/j.jfas.2017.11.004.

121. Al-Obaidi B, Wiik AV, Bhattacharyya R, et al. Fibular nails for open and closed ankle fractures: Results from a non-designer level I major trauma centre. *J Orthop Surg (Hong Kong)* 2019; 27: 2309499019832420. 2019/02/26. DOI: 10.1177/2309499019832420.

122. Dabash S, Eisenstein ED, Potter E, et al. Unstable Ankle Fracture Fixation Using Locked Fibular Intramedullary Nail in High-Risk Patients. *J Foot Ankle Surg* 2019 2019/01/08. DOI: 10.1053/j.jfas.2018.08.033.

123. Karkkola S, Kortekangas T, Pakarinen H, et al. Fibular nailing for fixation of ankle fractures in patients at high risk of surgical wound infection. *Foot and ankle surgery* 2019. DOI: 10.1016/j.fas.2019.10.005.

124. Bugler KE, Watson CD, Hardie AR, et al. The treatment of unstable fractures of the ankle using the Acumed fibular nail: development of a technique. *J Bone Joint Surg Br* 2012; 94: 1107-1112. 2012/07/31. DOI: 10.1302/0301-620X.94B8.28620.

125. Peeperkorn S, Nijs S and Hoekstra H. Why Fibular Nailing Can Be an Efficient Treatment Strategy for AO Type 44-B Ankle Fractures in the Elderly. *J Foot Ankle Surg* 2018; 57: 961-966. 2018/06/20. DOI: 10.1053/j.jfas.2018.03.033.

126. Tracey J, Vovos TJ, Arora D, et al. The Use of Modern Intramedullary Nailing in Distal Fibula Fracture Fixation. *Foot Ankle Spec* 2018: 1938640018803734. 2018/10/03. DOI: 10.1177/1938640018803734.

127. Minihane KP, Lee C, Ahn C, et al. Comparison of lateral locking plate and antiglide plate for fixation of distal fibular fractures in osteoporotic bone: a biomechanical study. *J Orthop Trauma* 2006; 20: 562-566. 2006/09/23. DOI: 10.1097/01.bot.0000245684.96775.82.

128. Kilian M, Csörgö P, Vajczikova S, et al. Antiglide versus lateral plate fixation for Danis-Weber type B malleolar fractures caused by supination-external rotation injury. *Journal of Clinical Orthopaedics and Trauma* 2017; 8: 327-331. DOI: 10.1016/j.jcot.2017.06.005.

129. Vance DD, Swindell HW, Greisberg JK, et al. Outcomes Following Posterior and Posterolateral Plating of Distal Fibula Fractures. *Foot & Ankle Specialist* 2019; 12: 246-252. DOI: 10.1177/1938640018788433.

130. Weber M and Krause F. Peroneal tendon lesions caused by antiglide plates used for fixation of lateral malleolar fractures: the effect of plate and screw position. *Foot Ankle Int* 2005; 26: 281-285. 2005/04/15. DOI: 10.1177/107110070502600403.

131. Ahn J, Kim S, Lee J-S, et al. Incidence of Peroneal Tendinopathy After Application of a Posterior Antiglide Plate for Repair of Supination External Rotation Lateral Malleolar Fractures. 2016; 55: 90-93. DOI: 10.1053/j.jfas.2015.07.007.

132. Rammelt S. Management of ankle fractures in the elderly. *EFORT Open Rev* 2016; 1: 239-246. 2017/05/04. DOI: 10.1302/2058-5241.1.000023.

133. Strauss EJ and Egol KA. The management of ankle fractures in the elderly. *Injury* 2007; 38 Suppl 3: S2-9. 2007/10/18. DOI: 10.1016/j.injury.2007.08.005.

134. Zahn RK, Frey S, Jakubietz RG, et al. A contoured locking plate for distal fibular fractures in osteoporotic bone: A biomechanical cadaver study. 2012; 43: 718-725. DOI: 10.1016/j.injury.2011.07.009.

135. Hallbauer J, Grafenstein A, Rausch S, et al. Biomechanical analysis of polyaxial locking vs. non-locking plate fixation of unstable fractures of the distal fibula: A cadaver study with a bone only model. *Foot Ankle Surg* 2018; 24: 326-329. 2018/02/08. DOI: 10.1016/j.fas.2017.03.008.

136. Hallbauer J, Klos K, Gräfenstein A, et al. Does a polyaxial-locking system confer benefits for osteosynthesis of the distal fibula: A cadaver study. *Orthopaedics & Traumatology: Surgery & Research* 2016; 102: 645-649. DOI: 10.1016/j.otsr.2016.03.014.

137. Davis AT, Israel H, Cannada LK, et al. A biomechanical comparison of one-third tubular plates versus periarticular plates for fixation of osteoporotic distal fibula fractures. *J Orthop Trauma* 2013; 27: e201-207. 2012/12/20. DOI: 10.1097/BOT.0b013e318281a565.

138. White NJ, Corr DT, Wagg JP, et al. Locked plate fixation of the comminuted distal fibula: a biomechanical study. *Can J Surg* 2013; 56: 35-40. 2012/11/29. DOI: 10.1503/cjs.012311.

139. Lyle SA, Malik C and Oddy MJ. Comparison of Locking Versus Nonlocking Plates for Distal Fibula Fractures. *J Foot Ankle Surg* 2018 2018/04/24. DOI: 10.1053/j.jfas.2017.11.035.

140. Tsukada S, Otsuji M, Shiozaki A, et al. Locking versus non-locking neutralization plates for treatment of lateral malleolar fractures: a randomized controlled trial. 2013; 37: 2451-2456. DOI: 10.1007/s00264-013-2109-9.

141. Herrera-Perez M, Gutierrez-Morales MJ, Guerra-Ferraz A, et al. Locking versus non-locking one-third tubular plates for treating osteoporotic distal fibula fractures: a comparative study. *Injury* 2017; 48 Suppl 6: S60-S65. 2017/11/23. DOI: 10.1016/S0020-1383(17)30796-9.

142. Moriarity A, Ellanti P, Mohan K, et al. A comparison of complication rates between locking and non-locking plates in distal fibular fractures. *Orthopaedics & Traumatology: Surgery & Research* 2018; 104: 503-506. DOI: 10.1016/j.otsr.2018.03.001.

143. Neubauer T, Heidari N, Weinberg AM, et al. The risk of nerve injury with minimally invasive plate osteosynthesis of distal fibula fractures: an anatomic study. 2011; 131: 1409-1412. DOI: 10.1007/s00402-011-1318-1.

144. Panchbhavi VK, Vallurupalli S and Morris R. Comparison of Augmentation Methods for Internal Fixation of Osteoporotic Ankle Fractures. *Foot & Ankle International* 2009; 30: 696-703. DOI: 10.3113/fai.2009.0696.

145. Panchbhavi VK, Mody MG and Mason WT. Combination of Hook Plate and Tibial Pro-Fibular Screw Fixation of Osteoporotic Fractures: A Clinical Evaluation of Operative Strategy. *Foot & Ankle International* 2005; 26: 510-515. DOI: 10.1177/107110070502600702.

146. Eyre-Brook AI, Ring J, Chadwick C, et al. A Comparison of Fibula Pro-Tibia Fixation Versus Hindfoot Nailing for Unstable Fractures of the Ankle in Those Older Than 60 Years. *Foot & Ankle Specialist* 2021: 193864002110173. DOI: 10.1177/19386400211017373.

147. Bankston AB, Anderson LD and Nimityongskul P. Intramedullary screw fixation of lateral malleolus fractures. *Foot Ankle Int* 1994; 15: 599-607. 1994/11/01. DOI: 10.1177/107110079401501105.

148. Ray TD, Nimityongskul P and Anderson LD. Percutaneous intramedullary fixation of lateral malleolus fractures: technique and report of early results. *J Trauma* 1994; 36: 669-675. 1994/05/01. DOI: 10.1097/00005373-199405000-00012.

149. Kara AN, Esenyel CZ, Sener BT, et al. A different approach to the treatment of the lateral malleolar fractures with syndesmosis injury: the ANK nail. *J Foot Ankle Surg* 1999; 38: 394-402. 1999/12/30.

150. Pritchett JW. Rush rods versus plate osteosyntheses for unstable ankle fractures in the elderly. *Orthop Rev* 1993; 22: 691-696. 1993/06/01.

151. Loukachov VV, Birnie MFN, Dingemans SA, et al. Percutaneous Intramedullary Screw Fixation of Distal Fibula Fractures: A Case Series and Systematic Review. *The Journal of Foot and Ankle Surgery* 2017; 56: 1081-1086. DOI: https://doi.org/10.1053/j.jfas.2017.05.024.

152. Ebraheim NA, Vander Maten JW, Delaney JR, et al. Cannulated Intramedullary Screw Fixation of Distal Fibular Fractures. *Foot & Ankle Specialist* 2019; 12: 264-271. DOI: 10.1177/1938640018790082.

153. Ramasamy PR and Sherry P. The role of a fibular nail in the management of Weber type B ankle fractures in elderly patients with osteoporotic bone—a preliminary report. *Injury* 2001; 32: 477-485. DOI: 10.1016/s0020-1383(01)00030-4.

154. Rajeev A, Senevirathna S, Radha S, et al. Functional outcomes after fibula locking nail for fragility fractures of the ankle. *J Foot Ankle Surg* 2011; 50: 547-550. 2011/06/04. DOI: 10.1053/j.jfas.2011.04.017.

155. Asloum Y, Bedin B, Roger T, et al. Internal fixation of the fibula in ankle fractures: a prospective, randomized and comparative study: plating versus nailing. *Orthop Traumatol Surg Res* 2014; 100: S255-259. 2014/04/09. DOI: 10.1016/j.otsr.2014.03.005.

156. Ashman BD, Kong C, Wing KJ, et al. Fluoroscopy-guided reduction and fibular nail fixation to manage unstable ankle fractures in patients with diabetes: a

retrospective cohort study. *Bone Joint J* 2016; 98-B: 1197-1201. 2016/09/03. DOI: 10.1302/0301-620X.98B9.37140.

157. Appleton P, McQueen M and Court-Brown C. The Fibula Nail for Treatment of Ankle Fractures in Elderly and High Risk Patients. *Techniques in Foot & Ankle Surgery* 2006; 5: 204-208. DOI: 10.1097/01.btf.0000221100.31792.c2.

158. Challagundla SR, Shewale S, Cree C, et al. Intramedullary fixation of lateral malleolus using Fibula Rod System in ankle fractures in the elderly. *Foot Ankle Surg* 2018; 24: 423-426. 2018/02/08. DOI: 10.1016/j.fas.2017.04.015.

159. Kho D-W, Kim H-J, Kim B-J, et al. Intramedullary nailing as an alternative to plate fixation in patients with distal fibular fracture. *Orthopaedics & Traumatology: Surgery & Research* 2020; 106: 149-154. DOI: 10.1016/j.otsr.2019.10.009.

160. Switaj PJ, Fuchs D, Alshouli M, et al. A biomechanical comparison study of a modern fibular nail and distal fibular locking plate in AO/OTA 44C2 ankle fractures. *J Orthop Surg Res* 2016; 11: 100. 2016/09/16. DOI: 10.1186/s13018-016-0435-5.

161. Smith G, Mackenzie SP, Wallace RJ, et al. Biomechanical Comparison of Intramedullary Fibular Nail Versus Plate and Screw Fixation. *Foot Ankle Int* 2017: 1071100717731757. 2017/10/04. DOI: 10.1177/1071100717731757.

162. White TO, Bugler KE, Appleton P, et al. A prospective randomised controlled trial of the fibular nail versus standard open reduction and internal fixation for fixation of ankle fractures in elderly patients. *Bone Joint J* 2016; 98-B: 1248-1252. 2016/09/03. DOI: 10.1302/0301-620X.98B9.35837.

163. Badenhorst D, Terblanche I, Ferreria N, et al. Intramedullary fixation versus anatomically contoured plating of unstable ankle fractures: a randomized control trial. *Int Orthop* 2020; 44: 561-568. 2020/01/26. DOI: 10.1007/s00264-020-04482-4.

164. Coifman O, Bariteau JT, Shazar N, et al. Lateral malleolus closed reduction and internal fixation with intramedullary fibular rod using minimal invasive approach for the treatment of ankle fractures. *Foot Ankle Surg* 2017 2018/02/08. DOI: 10.1016/j.fas.2017.08.008.

165. Misaghi A, Doan J, Bastrom T, et al. Biomechanical Evaluation of Plate Versus Lag Screw Only Fixation of Distal Fibula Fractures. *J Foot Ankle Surg* 2015; 54: 896-899. 2015/05/21. DOI: 10.1053/j.jfas.2015.03.011.

166. McKenna PB, O'Shea K and Burke T. Less is more: lag screw only fixation of lateral malleolar fractures. *International Orthopaedics* 2007; 31: 497-502. DOI: 10.1007/s00264-006-0216-6.

167. Tornetta P, 3rd and Creevy W. Lag screw only fixation of the lateral malleolus. *J Orthop Trauma* 2001; 15: 119-121. 2001/03/10. DOI: 10.1097/00005131-200102000-00008.

168. Hughes J. The medial malleolus in ankle fractures. *Orthop Clin North Am* 1980; 11: 649-660. 1980/07/01.

169. Hanhisuanto S, Kortekangas T, Pakarinen H, et al. The functional outcome and quality of life after treatment of isolated medial malleolar fractures. *Foot Ankle Surg* 2017; 23: 225-229. 2017/12/06. DOI: 10.1016/j.fas.2016.06.004.

170. Labronici PJ, Pires RE, Franco MV, et al. Medial Malleolar Fractures: An Anatomic Survey Determining the Ideal Screw Length. *Ann Med Health Sci Res* 2016; 6: 308-310. 2017/05/16. DOI: 10.4103/amhsr.amhsr_41_16.

171. Parada SA, Krieg JC, Benirschke SK, et al. Bicortical fixation of medial malleolar fractures. *Am J Orthop (Belle Mead NJ)* 2013; 42: 90-92. 2013/02/23.

172. King CM, Cobb M, Collman DR, et al. Bicortical fixation of medial malleolar fractures: a review of 23 cases at risk for complicated bone healing. *J Foot Ankle Surg* 2012; 51: 39-44. 2011/12/27. DOI: 10.1053/j.jfas.2011.09.007.

173. Kupcha P and Pappas S. Medial malleolar fixation with a bicortical screw: technique tip. *Foot Ankle Int* 2008; 29: 1151-1153. 2008/11/26. DOI: 10.3113/FAI.2008.1151.

174. Ricci WM, Tornetta P and Borrelli J, Jr. Lag screw fixation of medial malleolar fractures: a biomechanical, radiographic, and clinical comparison of unicortical partially threaded lag screws and bicortical fully threaded lag screws. *J Orthop Trauma* 2012; 26: 602-606. 2012/03/23. DOI: 10.1097/BOT.0b013e3182404512.

175. Meeks BD, Kiskaddon EM, Boin MA, et al. The Role of Far Cortical Endosteal Fixation for the Treatment of Medial Malleolus Fractures: A Biomechanical Study. *The Journal of Foot and Ankle Surgery* 2020; 59: 2-4. DOI: https://doi.org/10.1053/j.jfas.2018.12.042.

176. Yammine K, Karam K and Assi C. Cortical versus cancellous screws in treating medial malleolar fractures: A systematic review of comparative clinical and biomechanical studies. *The Foot* 2019; 40: 81-86. DOI: 10.1016/j.foot.2019.05.002.

177. Parker L, Garlick N, McCarthy I, et al. Screw fixation of medial malleolar fractures: a cadaveric biomechanical study challenging the current AO philosophy. *Bone Joint J* 2013; 95-B: 1662-1666. 2013/12/03. DOI: 10.1302/0301-620X.95B12.30498.

178. Femino JE, Gruber BF and Karunakar MA. Safe zone for the placement of medial malleolar screws. *J Bone Joint Surg Am* 2007; 89: 133-138. 2007/01/04. DOI: 10.2106/JBJS.F.00689.

179. DeMill SL, Bussewitz BW and Philbin TM. Injury to the Posterior Tibial Tendon After Open Reduction Internal Fixation of the Medial Malleolus. *Foot Ankle Spec* 2015; 8: 360-363. 2015/05/01. DOI: 10.1177/1938640015583308.

180. Buckley R, Kwek E, Duffy P, et al. Single-Screw Fixation Compared With Double Screw Fixation for Treatment of Medial Malleolar Fractures: A Prospective Randomized Trial. *J Orthop Trauma* 2018; 32: 548-553. 2018/09/14. DOI: 10.1097/BOT.0000000000001311.

181. Mandel J, Behery O, Narayanan R, et al. Single- vs 2-Screw Lag Fixation of the Medial Malleolus in Unstable Ankle Fractures. *Foot & Ankle International* 2019: 107110071984099. DOI: 10.1177/1071100719840995.

182. Hoelsbrekken SE, Kaul-Jensen K, Morch T, et al. Nonoperative treatment of the medial malleolus in bimalleolar and trimalleolar ankle fractures: a randomized controlled trial. *J Orthop Trauma* 2013; 27: 633-637. 2013/03/05. DOI: 10.1097/BOT.0b013e31828e1bb7.

183. Ebraheim NA, Ludwig T, Weston JT, et al. Comparison of surgical techniques of 111 medial malleolar fractures classified by fracture geometry. *Foot Ankle Int* 2014; 35: 471-477. 2014/02/15. DOI: 10.1177/1071100714524553.

184. Johnson BA and Fallat LM. Comparison of tension band wire and cancellous bone screw fixation for medial malleolar fractures. *J Foot Ankle Surg* 1997; 36: 284-289. 1997/07/01.

185. Bulut T and Gursoy M. Isolated Medial Malleolus Fractures: Conventional Techniques Versus Headless Compression Screw Fixation. *J Foot Ankle Surg* 2018; 57: 552-556. 2018/03/20. DOI: 10.1053/j.jfas.2017.12.005.

186. Kochai A, Turker M, Cicekli O, et al. A comparative study of three commonly used fixation techniques for isolated medial malleolus fracture. *Eklem Hastalik Cerrahisi* 2018; 29: 104-109. 2018/07/18. DOI: 10.5606/ehc.2018.61449.

187. Ostrum RF and Litsky AS. Tension band fixation of medial malleolus fractures. *J Orthop Trauma* 1992; 6: 464-468. 1992/01/01.

188. Fowler TT, Pugh KJ, Litsky AS, et al. Medial malleolar fractures: a biomechanical study of fixation techniques. *Orthopedics* 2011; 34: e349-355. 2011/08/06. DOI: 10.3928/01477447-20110627-09.

189. Clyde J, Kosmopoulos V and Carpenter B. A biomechanical investigation of a knotless tension band in medial malleolar fracture models in composite Sawbones(R). *J Foot Ankle Surg* 2013; 52: 192-194. 2012/12/21. DOI: 10.1053/j.jfas.2012.11.001.

190. Downey MW, Duncan K, Kosmopoulos V, et al. Comparing the Knotless Tension Band and the Traditional Stainless Steel Wire Tension Band Fixation for Medial Malleolus Fractures: A Retrospective Clinical Study. *Scientifica (Cairo)* 2016; 2016: 3201678. 2016/06/14. DOI: 10.1155/2016/3201678.

191. Zhang K, Chen Y, Qiang M, et al. The morphology of medial malleolus and its clinical relevance. *Pak J Med Sci* 2014; 30: 348-351. 2014/04/29.

192. Haller JM, Ross H, Jacobson K, et al. Supination adduction ankle fractures: Ankle fracture or pilon variant? *Injury* 2020. DOI: 10.1016/j.injury.2020.01.008.

193. Amanatullah DF, Khan SN, Curtiss S, et al. Effect of divergent screw fixation in vertical medial malleolus fractures. *J Trauma Acute Care Surg* 2012; 72: 751-754. 2012/04/12. DOI: 10.1097/TA.0b013e31823b8b9f.

194. Wegner AM, Wolinsky PR, Robbins MA, et al. Antiglide plating of vertical medial malleolus fractures provides stiffer initial fixation than bicortical or unicortical screw fixation. *Clin Biomech (Bristol, Avon)* 2016; 31: 29-32. 2015/10/21. DOI: 10.1016/j.clinbiomech.2015.10.005.

195. Jones DA, Cannada LK and Bledsoe JG. Are Hook Plates Advantageous Compared to Antiglide Plates for Vertical Shear Malleolar Fractures? *Am J Orthop (Belle Mead NJ)* 2016; 45: E98-102. 2016/03/19.

196. Toolan BC, Koval KJ, Kummer FJ, et al. Vertical shear fractures of the medial malleolus: a biomechanical study of five internal fixation techniques. *Foot Ankle Int* 1994; 15: 483-489. 1994/09/01. DOI: 10.1177/107110079401500905.

197. Barnes H, Cannada LK and Watson JT. A clinical evaluation of alternative fixation techniques for medial malleolus fractures. *Injury* 2014; 45: 1365-1367. 2014/07/22. DOI: 10.1016/j.injury.2014.05.031.

198. Tekin AC, Cabuk H, Dedeoglu SS, et al. Anterograde Headless Cannulated Screw Fixation in the Treatment of Medial Malleolar Fractures: Evaluation of a New Technique and Its Outcomes. *Med Princ Pract* 2016; 25: 429-434. 2016/06/12. DOI: 10.1159/000447426.

199. Tang J, Hu JF, Guo WC, et al. Research and application of absorbable screw in orthopedics: a clinical review comparing PDLLA screw with metal screw in patients with simple medial malleolus fracture. *Chin J Traumatol* 2013; 16: 27-30. 2013/02/07.

200. May H, Alper Kati Y, Gumussuyu G, et al. Bioabsorbable magnesium screw versus conventional titanium screw fixation for medial malleolar fractures. *Journal of Orthopaedics and Traumatology* 2020; 21. DOI: 10.1186/s10195-020-00547-7.

201. Solan MC and Sakellariou A. Posterior malleolus fractures: worth fixing. *Bone Joint J* 2017; 99-B: 1413-1419. 2017/11/03. DOI: 10.1302/0301-620X.99B11.BJJ-2017-1072.

202. White TO. In defence of the posterior malleolus. *Bone Joint J* 2018; 100-B: 566-569. 2018/04/28. DOI: 10.1302/0301-620X.100B5.BJJ-2017-1440.R1.

203. Macko VW, Matthews LS, Zwirkoski P, et al. The joint-contact area of the ankle. The contribution of the posterior malleolus. *J Bone Joint Surg Am* 1991; 73: 347-351. 1991/03/01.

204. Hartford JM, Gorczyca JT, McNamara JL, et al. Tibiotalar contact area. Contribution of posterior malleolus and deltoid ligament. *Clin Orthop Relat Res* 1995: 182-187. 1995/11/01.

205. Odak S, Ahluwalia R, Unnikrishnan P, et al. Management of Posterior Malleolar Fractures: A Systematic Review. *The Journal of Foot and Ankle Surgery* 2016; 55: 140-145. DOI: 10.1053/j.jfas.2015.04.001.

206. Fitzpatrick E, Goetz JE, Sittapairoj T, et al. Effect of Posterior Malleolus Fracture on Syndesmotic Reduction: A Cadaveric Study. *J Bone Joint Surg Am* 2018; 100: 243-248. 2018/02/07. DOI: 10.2106/JBJS.17.00217.

207. Baumbach SF, Herterich V, Damblemont A, et al. Open reduction and internal fixation of the posterior malleolus fragment frequently restores syndesmotic stability. *Injury* 2019; 50: 564-570. DOI: 10.1016/j.injury.2018.12.025.

208. 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: 94. 2017/02/25. DOI: 10.1186/s12891-017-1445-0.

209. Talbot M, Steenblock TR and Cole PA. Posterolateral approach for open reduction and internal fixation of trimalleolar ankle fractures. *Can J Surg* 2005; 48: 487-490. 2006/01/19.

210. Tornetta P, 3rd, Ricci W, Nork S, et al. The posterolateral approach to the tibia for displaced posterior malleolar injuries. *J Orthop Trauma* 2011; 25: 123-126. 2011/01/20. DOI: 10.1097/BOT.0b013e3181e47d29.

211. Anwar A, Zhang Z, Lv D, et al. Biomechanical efficacy of AP, PA lag screws and posterior plating for fixation of posterior malleolar fractures: a three dimensional finite element study. *BMC Musculoskeletal Disorders* 2018; 19. DOI: 10.1186/s12891-018-1989-7.

212. O'Connor TJ, Mueller B, Ly TV, et al. "A to p" screw versus posterolateral plate for posterior malleolus fixation in trimalleolar ankle fractures. *J Orthop Trauma* 2015; 29: e151-156. 2014/08/28. DOI: 10.1097/BOT.0000000000000230.

213. Verhage SM, Boot F, Schipper IB, et al. Open reduction and internal fixation of posterior malleolar fractures using the posterolateral approach. *The Bone & Joint Journal* 2016; 98-B: 812-817. DOI: 10.1302/0301-620x.98b6.36497.

214. Verhage SM, Hoogendoorn JM, Krijnen P, et al. When and how to operate the posterior malleolus fragment in trimalleolar fractures: a systematic literature review. *Arch Orthop Trauma Surg* 2018; 138: 1213-1222. 2018/05/13. DOI: 10.1007/s00402-018-2949-2.

215. Veltman ES, Halma JJ and De Gast A. Longterm outcome of 886 posterior malleolar fractures: A systematic review of the literature. *Foot and Ankle Surgery* 2016; 22: 73-77. DOI: 10.1016/j.fas.2015.05.003.

216. Sandelin H, Tukiainen E and Ovaska M. Amputation following internal fixation of an ankle fracture via the posterolateral approach – a case report. *Acta Orthopaedica* 2017; 88: 358-360. DOI: 10.1080/17453674.2016.1262679.

217. Erdem MN, Erken HY, Burc H, et al. Comparison of Lag Screw Versus Buttress Plate Fixation of Posterior Malleolar Fractures. *Foot & Ankle International* 2014; 35: 1022-1030. DOI: 10.1177/1071100714540893.

218. Wang Z, Sun J, Yan J, et al. Comparison of the efficacy of posterior-anterior screws, anterior-posterior screws and a posterior-anterior plate in the fixation of posterior malleolar fractures with a fragment size of ≥ 15 and < 15%. *BMC Musculoskeletal Disorders* 2020; 21. DOI: 10.1186/s12891-020-03594-7.

219. Peng J, McKissack H, Yu J, et al. Anatomic Structures at Risk in Anteroposterior Screw Fixation of Posterior Malleolar Fractures: A Cadaver Study. *Foot and Ankle Surgery* 2020. DOI: 10.1016/j.fas.2020.03.010.

220. Czerwonka N, Momenzadeh K, Stenquist DS, et al. Anatomic Structures at Risk During Posterior to Anterior Percutaneous Screw Fixation of Posterior Malleolar Fractures: A Cadaveric Study. *Foot & Ankle Specialist* 2020: 193864002094300. DOI: 10.1177/1938640020943004.

221. Vidović D, Elabjer E, Muškardin IVA, et al. Posterior fragment in ankle fractures: anteroposterior vs posteroanterior fixation. *Injury* 2017; 48: S65-S69. DOI: 10.1016/s0020-1383(17)30743-x.

222. Kang C, Hwang D-S, Lee J-K, et al. Screw Fixation of the Posterior Malleolus Fragment in Ankle Fracture. *Foot & Ankle International* 2019; 40: 1288-1294. DOI: 10.1177/1071100719865895.

223. Mason LW, Kaye A, Widnall J, et al. Posterior Malleolar Ankle Fractures: An Effort at Improving Outcomes. *JB JS Open Access* 2019; 4: e0058. 2019/07/25. DOI: 10.2106/jbjs.Oa.18.00058.

224. Schepers T. Acute distal tibiofibular syndesmosis injury: a systematic review of suture-button versus syndesmotic screw repair. *International Orthopaedics* 2012; 36: 1199-1206. DOI: 10.1007/s00264-012-1500-2.

225. Raeder BW, Figved W, Madsen JE, et al. Better outcome for suture button compared with single syndesmotic screw for syndesmosis injury: five-year results of a randomized controlled trial. *Bone Joint J* 2020; 102-B: 212-219. 2020/02/06. DOI: 10.1302/0301-620X.102B2.BJJ-2019-0692.R2.

226. Andersen MR, Frihagen F, Hellund JC, et al. Randomized Trial Comparing Suture Button with Single Syndesmotic Screw for Syndesmosis Injury. *J Bone Joint Surg Am* 2018; 100: 2-12. 2018/01/04. DOI: 10.2106/JBJS.16.01011.

227. Mak MF, Stern R and Assal M. Repair of syndesmosis injury in ankle fractures: Current state of the art. *EFORT Open Rev* 2018; 3: 24-29. 2018/04/17. DOI: 10.1302/2058-5241.3.170017.

228. Fort NM, Aiyer AA, Kaplan JR, et al. Management of acute injuries of the tibiofibular syndesmosis. *Eur J Orthop Surg Traumatol* 2017; 27: 449-459. 2017/04/10. DOI: 10.1007/s00590-017-1956-2.

229. Zhang P, Liang Y, He J, et al. A systematic review of suture-button versus syndesmotic screw in the treatment of distal tibiofibular syndesmosis injury. *BMC Musculoskeletal Disorders* 2017; 18. DOI: 10.1186/s12891-017-1645-7.

230. Carr JC, 2nd, Werner BC and Yarboro SR. An Update on Management of Syndesmosis Injury: A National US Database Study. *Am J Orthop (Belle Mead NJ)* 2016; 45: E472-E477. 2016/12/23.

231. Miller MA, McDonald TC, Graves ML, et al. Stability of the Syndesmosis After Posterior Malleolar Fracture Fixation. *Foot Ankle Int* 2018; 39: 99-104. 2017/10/24. DOI: 10.1177/1071100717735839.

232. Markolf KL, Jackson SR and McAllister DR. Syndesmosis fixation using dual 3.5 mm and 4.5 mm screws with tricortical and quadricortical purchase: a biomechanical study. *Foot Ankle Int* 2013; 34: 734-739. 2013/02/14. DOI: 10.1177/1071100713478923.

233. Thompson MC and Gesink DS. Biomechanical comparison of syndesmosis fixation with 3.5- and 4.5-millimeter stainless steel screws. *Foot Ankle Int* 2000; 21: 736-741. 2000/10/07. DOI: 10.1177/107110070002100904.

234. Van Den Bekerom MPJ, Kloen P, Luitse JSK, et al. Complications of Distal Tibiofibular Syndesmotic Screw Stabilization: Analysis of 236 Patients. 2013; 52: 456-459. DOI: 10.1053/j.jfas.2013.03.025.

235. Hamid N, Loeffler BJ, Braddy W, et al. Outcome after fixation of ankle fractures with an injury to the syndesmosis. *The Journal of Bone and Joint Surgery British volume* 2009; 91-B: 1069-1073. DOI: 10.1302/0301-620x.91b8.22430.

236. Kaftandziev I, Spasov M, Trpeski S, et al. Fate of the syndesmotic screw—Search for a prudent solution. 2015; 46: S125-S129. DOI: 10.1016/j.injury.2015.10.062.

237. Peek AC, Fitzgerald CE and Charalambides C. Syndesmosis screws: How many, what diameter, where and should they be removed? A literature review. 2014; 45: 1262-1267. DOI: 10.1016/j.injury.2014.05.003.

238. Xenos JS, Hopkinson WJ, Mulligan ME, et al. The tibiofibular syndesmosis. Evaluation of the ligamentous structures, methods of fixation, and radiographic assessment. *J Bone Joint Surg Am* 1995; 77: 847-856. 1995/06/01. DOI: 10.2106/00004623-199506000-00005.

239. Nousiainen MT, McConnell AJ, Zdero R, et al. The influence of the number of cortices of screw purchase and ankle position in Weber C ankle fracture fixation. *J Orthop Trauma* 2008; 22: 473-478. 2008/08/02. DOI: 10.1097/BOT.0b013e31817ae635.

240. Wikeroy AK, Hoiness PR, Andreassen GS, et al. No difference in functional and radiographic results 8.4 years after quadricortical compared with tricortical syndesmosis fixation in ankle fractures. *J Orthop Trauma* 2010; 24: 17-23. 2009/12/26. DOI: 10.1097/BOT.0b013e3181bedca1.

241. Kortekangas T, Savola O, Flinkkila T, et al. A prospective randomised study comparing TightRope and syndesmotic screw fixation for accuracy and maintenance of syndesmotic reduction assessed with bilateral computed tomography. *Injury* 2015; 46: 1119-1126. 2015/03/15. DOI: 10.1016/j.injury.2015.02.004.

242. Gennis E, Koenig S, Rodericks D, et al. The Fate of the Fixed Syndesmosis Over Time. 2015; 36: 1202-1208. DOI: 10.1177/1071100715588186.

243. Dingemans SA, Rammelt S, White TO, et al. Should syndesmotic screws be removed after surgical fixation of unstable ankle fractures? a systematic review. *Bone Joint J* 2016; 98-B: 1497-1504. 2016/11/03. DOI: 10.1302/0301-620X.98B11.BJJ-2016-0202.R1.

244. Tucker A, Street J, Kealey D, et al. Functional outcomes following syndesmotic fixation: A comparison of screws retained in situ versus routine removal – Is it really necessary? 2013; 44: 1880-1884. DOI: 10.1016/j.injury.2013.08.011.

245. Manjoo A, Sanders DW, Tieszer C, et al. Functional and radiographic results of patients with syndesmotic screw fixation: implications for screw removal. *J Orthop Trauma* 2010; 24: 2-6. 2009/12/26. DOI: 10.1097/BOT.0b013e3181a9f7a5.

246. Sun H, Luo CF, Zhong B, et al. A prospective, randomised trial comparing the use of absorbable and metallic screws in the fixation of distal tibiofibular syndesmosis injuries: mid-term follow-up. *Bone Joint J* 2014; 96-B: 548-554. 2014/04/03. DOI: 10.1302/0301-620X.96B4.32171.

247. Sugi MT, Ortega B, Shepherd L, et al. Syndesmotic Screw Removal in a Clinic Setting Is Safe and Cost-effective. *Foot & Ankle Specialist* 2019: 193864001984332. DOI: 10.1177/1938640019843321.

248. Shimozono Y, Hurley ET, Myerson CL, et al. Suture Button Versus Syndesmotic Screw for Syndesmosis Injuries: A Meta-analysis of Randomized

Controlled Trials. *Am J Sports Med* 2019; 47: 2764-2771. 2018/11/27. DOI: 10.1177/0363546518804804.

249. McKenzie AC, Hesselholt KE, Larsen MS, et al. A Systematic Review and Meta-Analysis on Treatment of Ankle Fractures With Syndesmotic Rupture: Suture-Button Fixation Versus Cortical Screw Fixation. *J Foot Ankle Surg* 2019; 58: 946-953. 2019/09/03. DOI: 10.1053/j.jfas.2018.12.006.

250. Lee JS, Curnutte B, Pan K, et al. Biomechanical Comparison of Suture-Button, Bioabsorbable Screw, and Metal Screw for Ankle Syndesmotic Repair: A Meta-Analysis. *Foot and Ankle Surgery* 2020. DOI: 10.1016/j.fas.2020.03.008.

251. Ræder BW, Stake IK, Madsen JE, et al. Randomized trial comparing suture button with single 3.5 mm syndesmotic screw for ankle syndesmosis injury: similar results at 2 years. *Acta Orthopaedica* 2020: 1-6. DOI: 10.1080/17453674.2020.1818175.

252. Onggo JR, Nambiar M, Phan K, et al. Suture button versus syndesmosis screw constructs for acute ankle diastasis injuries: A meta-analysis and systematic review of randomised controlled trials. *Foot and Ankle Surgery* 2020; 26: 54-60. DOI: 10.1016/j.fas.2018.11.008.

253. Shimozono Y, Hurley ET, Myerson CL, et al. Suture Button Versus Syndesmotic Screw for Syndesmosis Injuries: A Meta-analysis of Randomized Controlled Trials. *The American Journal of Sports Medicine* 2019; 47: 2764-2771. DOI: 10.1177/0363546518804804.

254. Hoogendoorn JM. Posterior Malleolar Open Reduction and Internal Fixation Through a Posterolateral Approach for Trimalleolar Fractures. *JBJS Essent Surg Tech* 2017; 7: e31. 2018/09/21. DOI: 10.2106/JBJS.ST.17.00016.

255. Giordano V, Boni G, Godoy-Santos AL, et al. Nailing the fibula: alternative or standard treatment for lateral malleolar fracture fixation? A broken paradigm. *Eur J Trauma Emerg Surg* 2020 2020/03/08. DOI: 10.1007/s00068-020-01337-w.

256. Olerud C and Molander H. A scoring scale for symptom evaluation after ankle fracture. *Arch Orthop Trauma Surg* 1984; 103: 190-194. 1984/01/01.

257. Burwell HN and Charnley AD. The treatment of displaced fractures at the ankle by rigid internal fixation and early joint movement. *J Bone Joint Surg Br* 1965; 47: 634-660. 1965/11/01.

258. Vioreanu M, Dudeney S, Hurson B, et al. Early mobilization in a removable cast compared with immobilization in a cast after operative treatment of ankle fractures: a prospective randomized study. *Foot Ankle Int* 2007; 28: 13-19. 2007/01/30. DOI: 10.3113/FAI.2007.0003.

259. Tan EW, Sirisreetreerux N, Paez AG, et al. Early Weightbearing After Operatively Treated Ankle Fractures: A Biomechanical Analysis. *Foot Ankle Int* 2016; 37: 652-658. 2016/01/24. DOI: 10.1177/1071100715627351.

260. Egol KA, Dolan R and Koval KJ. Functional outcome of surgery for fractures of the ankle. A prospective, randomised comparison of management in a cast or a functional brace. *J Bone Joint Surg Br* 2000; 82: 246-249. 2001/02/07.

261. Thomas G, Whalley H and Modi C. Early mobilization of operatively fixed ankle fractures: a systematic review. *Foot Ankle Int* 2009; 30: 666-674. 2009/07/11. DOI: 10.3113/FAI.2009.0666.

262. Pyle C, Kim-Orden M, Hughes T, et al. Effect of Early Weightbearing Following Open Reduction and Internal Fixation of Unstable Ankle Fractures on Wound Complications or Failures of Fixation. *Foot & Ankle International* 2019: 107110071986793. DOI: 10.1177/1071100719867932.

263. Dawson J, Coffey J, Doll H, et al. A patient-based questionnaire to assess outcomes of foot surgery: validation in the context of surgery for hallux valgus. *Qual Life Res* 2006; 15: 1211-1222. 2006/09/27. DOI: 10.1007/s11136-006-0061-5.

264. Rabin R and de Charro F. EQ-5D: a measure of health status from the EuroQol Group. *Ann Med* 2001; 33: 337-343. 2001/08/09.

265. El-Daly I, Ibraheim H, Rajakulendran K, et al. Are Patient-reported Outcome Measures in Orthopaedics Easily Read by Patients? *Clinical Orthopaedics and Related Research®* 2016; 474: 246-255. DOI: 10.1007/s11999-015-4595-0.

266. Choi BC and Pak AW. A catalog of biases in questionnaires. *Prev Chronic Dis* 2005; 2: A13. 2005/01/27.

267. Ponzer S, Nasell H, Bergman B, et al. Functional outcome and quality of life in patients with Type B ankle fractures: a two-year follow-up study. *J Orthop Trauma* 1999; 13: 363-368. 1999/07/16.

268. Turhan E, Demirel M, Daylak A, et al. Translation, cross-cultural adaptation, reliability and validity of the Turkish version of the Olerud-Molander Ankle Score (OMAS). *Acta Orthopaedica et Traumatologica Turcica* 2017; 51: 60-64. DOI: 10.1016/j.aott.2016.06.012.

269. Nilsson GM, Eneroth M and Ekdahl CS. The Swedish version of OMAS is a reliable and valid outcome measure for patients with ankle fractures. 2013; 14: 109. DOI: 10.1186/1471-2474-14-109.

270. Weil NL, Termaat MF, Rubinstein SM, et al. WARRIOR-trial - is routine radiography following the 2-week initial follow-up in trauma patients with wrist and ankle fractures necessary: study protocol for a randomized controlled trial. *Trials* 2015; 16: 66. 2015/04/16. DOI: 10.1186/s13063-015-0600-x.

271. Garratt AM, Naumann MG, Sigurdsen U, et al. Evaluation of three patient reported outcome measures following operative fixation of closed ankle fractures. *BMC Musculoskelet Disord* 2018; 19: 134. 2018/05/04. DOI: 10.1186/s12891-018-2051-5.

272. McPhail SM, Dunstan J, Canning J, et al. Life impact of ankle fractures: qualitative analysis of patient and clinician experiences. *BMC Musculoskelet Disord* 2012; 13: 224. 2012/11/23. DOI: 10.1186/1471-2474-13-224.

273. Dawson J, Doll H, Coffey J, et al. Responsiveness and minimally important change for the Manchester-Oxford foot questionnaire (MOXFQ) compared with AOFAS and SF-36 assessments following surgery for hallux valgus. *Osteoarthritis and Cartilage* 2007; 15: 918-931. DOI: 10.1016/j.joca.2007.02.003.

274. Dawson J, Boller I, Doll H, et al. Minimally important change was estimated for the Manchester–Oxford Foot Questionnaire after foot/ankle surgery. *Journal of Clinical Epidemiology* 2014; 67: 697-705. DOI: 10.1016/j.jclinepi.2014.01.003.

275. Dawson J, Boller I, Doll H, et al. Responsiveness of the Manchester-Oxford Foot Questionnaire (MOXFQ) compared with AOFAS, SF-36 and EQ-5D assessments following foot or ankle surgery. *J Bone Joint Surg Br* 2012; 94: 215-221. 2012/02/11. DOI: 10.1302/0301-620X.94B2.27634.

276. Arbab D, Kuhlmann K, Schnurr C, et al. Comparison of the Manchester-Oxford Foot Questionnaire (MOXFQ) and the Self-Reported Foot and Ankle Outcome Score (SEFAS) in patients with foot or ankle surgery. *Foot Ankle Surg* 2018 2018/10/17. DOI: 10.1016/j.fas.2018.01.003.

277. Maher AJ and Kilmartin TE. An analysis of Euroqol EQ-5D and Manchester Oxford Foot Questionnaire scores six months following podiatric surgery. 2012; 5: 17. DOI: 10.1186/1757-1146-5-17.

278. Morley D, Jenkinson C, Doll H, et al. The Manchester-Oxford Foot Questionnaire (MOXFQ): Development and validation of a summary index score. *Bone Joint Res* 2013; 2: 66-69. 2013/05/16. DOI: 10.1302/2046-3758.24.2000147.

279. Kingsley C and Patel S. Patient-reported outcome measures and patient-reported experience measures. *BJA Education* 2017; 17: 137-144. DOI: 10.1093/bjaed/mkw060.

280. Ring D and Leopold SS. Editorial—Measuring Satisfaction: Can It Be Done? 2015; 473: 3071-3073. DOI: 10.1007/s11999-015-4485-5.

281. Graham B, Green A, James M, et al. Measuring Patient Satisfaction in Orthopaedic Surgery. 2015; 97: 80-84. DOI: 10.2106/jbjs.n.00811.

282. Carter TH, Mackenzie SP, Bell KR, et al. Optimizing Long-Term Outcomes and Avoiding Failure With the Fibula Intramedullary Nail. *J Orthop Trauma* 2019; 33: 189-195. 2018/12/19. DOI: 10.1097/BOT.0000000000001379.

283. Jordan RW, Chapman AWP, Buchanan D, et al. The role of intramedullary fixation in ankle fractures - A systematic review. *Foot Ankle Surg* 2018; 24: 1-10. 2018/02/08. DOI: 10.1016/j.fas.2016.04.004.

284. Thordarson DB, Motamed S, Hedman T, et al. The effect of fibular malreduction on contact pressures in an ankle fracture malunion model. *J Bone Joint Surg Am* 1997; 79: 1809-1815. 1997/12/31.

285. Kamer L, Noser H, Blauth M, et al. Bone Mass Distribution of the Distal Tibia in Normal, Osteopenic, and Osteoporotic Conditions: An Ex Vivo Assessment Using HR-pQCT, DXA, and Computational Modelling. *Calcif Tissue Int* 2016; 99: 588-597. 2016/08/31. DOI: 10.1007/s00223-016-0188-5.

286. Arbab D, Kuhlmann K, Schnurr C, et al. Comparison of the Manchester–Oxford Foot Questionnaire (MOXFQ) and the Self-Reported Foot and Ankle Outcome Score (SEFAS) in patients with foot or ankle surgery. *Foot and Ankle Surgery* 2018. DOI: 10.1016/j.fas.2018.01.003.

287. Szende A and Janssen B. Cross-Country Analysis of EQ-5D Data. In: Szende A, Janssen B and Cabases J (eds) *Self-Reported Population Health: An International Perspective based on EQ-5D*. Dordrecht (NL), 2014, pp.31-36.

288. Carter TH, Wallace R, Mackenzie SA, et al. The Fibular Intramedullary Nail Versus Locking Plate and Lag Screw Fixation in the Management of Unstable Elderly Ankle Fractures: A Cadaveric Biomechanical Comparison. *J Orthop Trauma* 2020; 34: e401-e406. 2020/10/17. DOI: 10.1097/BOT.0000000000001814.

289. Kim T, Ayturk UM, Haskell A, et al. Fixation of osteoporotic distal fibula fractures: A biomechanical comparison of locking versus conventional plates. *J Foot Ankle Surg* 2007; 46: 2-6. 2007/01/03. DOI: 10.1053/j.jfas.2006.09.009.

290. Schepers T, Lieshout EMMV, Vries MRD, et al. Increased rates of wound complications with locking plates in distal fibular fractures. *Injury* 2011; 42: 1125-1129. DOI: 10.1016/j.injury.2011.01.009.

291. Nguyentat A, Camisa W, Patel S, et al. A Biomechanical Comparison of Locking Versus Conventional Plate Fixation for Distal Fibula Fractures in Trimalleolar Ankle Injuries. *The Journal of Foot and Ankle Surgery* 2016; 55: 132-135. DOI: 10.1053/j.jfas.2015.08.017.

292. Schulz KF and Grimes DA. Generation of allocation sequences in randomised trials: chance, not choice. *The Lancet* 2002; 359: 515-519. DOI: 10.1016/s0140-6736(02)07683-3.

293. Kang M, Ragan BG and Park J-H. Issues in Outcomes Research: An Overview of Randomization Techniques for Clinical Trials. *Journal of Athletic Training* 2008; 43: 215-221. DOI: 10.4085/1062-6050-43.2.215.

294. Schulz KF. Assessing allocation concealment and blinding in randomised controlled trials: why bother? *Evidence-Based Nursing* 2001; 4: 4-6. DOI: 10.1136/ebn.4.1.4.

295. Zhao S, Arnold M, Ma S, et al. Standardizing compression testing for measuring the stiffness of human bone. *Bone Joint Res* 2018; 7: 524-538. 2018/09/28. DOI: 10.1302/2046-3758.78.BJR-2018-0025.R1.

296. Carter TH, Mackenzie SP, Bell KR, et al. Selective fixation of the medial malleolus in unstable ankle fractures. *Injury* 2019; 50: 983-989. 2019/03/19. DOI: 10.1016/j.injury.2019.03.010.

297. Tas DB, Smeeing DPJ, Emmink BL, et al. Intramedullary Fixation Versus Plate Fixation of Distal Fibular Fractures: A Systematic Review and Meta-Analysis of Randomized Controlled Trials and Observational Studies. *J Foot Ankle Surg* 2019; 58: 119-126. 2018/12/26. DOI: 10.1053/j.jfas.2018.08.028.

298. Tornetta P, 3rd. Competence of the deltoid ligament in bimalleolar ankle fractures after medial malleolar fixation. *J Bone Joint Surg Am* 2000; 82: 843-848. 2000/06/20.

299. Skie MC, Ebraheim NA, Woldenberg L, et al. Fracture of the anterior colliculus. *J Trauma* 1995; 38: 642-647. 1995/04/01.

300. Carter TH, Arthur CH, Duckworth AD, et al. To fix or not to fix: a novel approach to the safe management of unstable open medial malleolar fractures. *BMJ Case Rep* 2019; 12 2019/04/06. DOI: 10.1136/bcr-2018-228965.

301. Carter TH, Oliver WM, Graham C, et al. Medial malleolus: Operative Or Non-operative (MOON) trial protocol - a prospective randomised controlled trial of operative versus non-operative management of associated medial malleolus fractures in unstable fractures of the ankle. *Trials* 2019; 20: 565. 2019/09/14. DOI: 10.1186/s13063-019-3642-7.

302. Hernigou J and Schuind F. Tobacco and bone fractures: A review of the facts and issues that every orthopaedic surgeon should know. *Bone Joint Res* 2019; 8: 255-265. 2019/07/28. DOI: 10.1302/2046-3758.86.BJR-2018-0344.R1.

303. Su J and Cao X. Risk factors of wound infection after open reduction and internal fixation of calcaneal fractures. *Medicine (Baltimore)* 2017; 96: e8411. 2017/11/03. DOI: 10.1097/MD.0000000000008411.

304. Kruse H, Christensen KP, Moller AM, et al. Tourniquet use during ankle surgery leads to increased postoperative opioid use. *J Clin Anesth* 2015; 27: 380-384. 2015/05/17. DOI: 10.1016/j.jclinane.2015.03.034.

APPENDIX

Appendix 1

South East Scotland Research Ethics Service

Waverley Gate
2-4 Waterloo Place
Edinburgh
EH1 3EG

NHS Lothian

Mr Tom Carter
Orthopaedic Registrar + Research Fellow
Trauma & Orthopaedics
Royal Infirmary of Edinburgh

Date: 27/02/2017
Your Ref:
Our Ref: NR/161AB6
Enquiries to:
Direct Line: 0131 465 5679
Email:

Dear Mr Carter

Project Title: *Understanding the risk factors for failure following fibular intramedullary fixation of patients with unstable ankle fractures.*

You have sought advice from the South East Scotland Research Ethics Service on the above project. This has been considered on by the SESRES and you are advised that, based on the submitted documentation (email correspondence and documents submitted), it does not need NHS ethical review under the terms of the Governance Arrangements for Research Ethics Committees (A Harmonised Edition).

The advice is based on the following:

- *ethical approval is not required as your project is a service evaluation and not research*

If the project is considered to be health-related research you will require a sponsor and ethical approval as outlined in The Research Governance Framework for Health and Community Care. You may wish to contact your employer or professional body to arrange this. You may also require NHS management permission (R&D approval). You should contact the relevant NHS R&D departments to organise this.

For projects that are not research and will be conducted within the NHS you should contact the relevant local clinical governance team who will inform you of the relevant governance procedures required before the project commences.

This letter should not be interpreted as giving a form of ethical approval or any endorsement of the project, but it may be provided to a journal or other body as evidence that NHS ethical approval is not required. However, if you, your sponsor/funder feel that the project requires ethical review by an NHS REC, please write setting out your reasons and we will be pleased to consider further. You should retain a copy of this letter with your project file as evidence that you have sought advice from the South East Scotland Research Ethics Service.

Yours sincerely,

pp
Helen Newbery
Scientific Officer

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1

Headquarters
Waverley Gate, 2-4 Waterloo Place
Edinburgh EH1 3EG
Chair: Mr Brian Houston
Chief Executive: Tim Davison
Lothian NHS Board is the common name of Lothian Health Board

Appendix 2

Lothian NHS Board

South East Scotland Research Ethics Committee 2
Waverley Gate
2 - 4 Waterloo Place
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Telephone: 0131 465 5674
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NHS Lothian

Mr Timothy O White
Consultant Orthopaedic Trauma Surgeon & Clinical Lead for Trauma
NHS Lothian
Edinburgh Orthopaedic Trauma Unit
Royal Infirmary of Edinburgh, 51 Little France Crescent
Edinburgh
EH16 4SA

Dear Timothy White

Study title:	**Medial Malleolus: Operative Or Non-operative. A prospective randomized controlled trial of operative versus non-operative management of associated medial malleolus fractures in unstable fracture dislocations of the ankle joint**
REC reference:	**17/SS/0124**
IRAS project ID:	**222034**

Thank you for your letter of 22nd September 2017. I can confirm the REC has received the documents listed below and that these comply with the approval conditions detailed in our letter dated 15 September 2017

Documents received

The documents received were as follows:

Covering letter on headed paper [Covering letter for REC (following favourable outcome decision)]	2.0	22 September 2017
Participant consent form [Participant consent form]	2.0	22 September 2017
Participant information sheet (PIS) [Patient information sheet]	2.0	22 September 2017
Research protocol or project proposal [Study protocol]	2.0	22 September 2017
Validated questionnaire [EQ-5D health assessment]	Version 1.0	22 September 2017
Validated questionnaire [Manchester-Oxford Foot Questionnaire]	Version 1.0	

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IRAS Checklist XML [Checklist_02102017]		02 October 2017
Letter from statistician [Evidence of statistician review/feedback]		
Letters of invitation to participant [Letter of invitation to participant]	1.0	18 July 2017
Participant consent form [Participant consent form]	2.0	22 September 2017
Participant information sheet (PIS) [Patient information sheet]	2.0	22 September 2017
REC Application Form [REC_Form_18082017]		18 August 2017
Research protocol or project proposal [Study protocol]	2.0	22 September 2017
Summary CV for Chief Investigator (CI) [Summary CV TOW]		
Summary CV for student [Summary CV TC]		
Summary CV for supervisor (student research) [ADD summary CV]		15 August 2017
Summary, synopsis or diagram (flowchart) of protocol in non technical language [Participant flowchart (CONSORT)]	1.0	18 July 2017
Validated questionnaire [Olerud-Molander Scoring system (primary outcome measure)]		
Validated questionnaire [EQ-5D health assessment]	Version 1.0	22 September 2017
Validated questionnaire [Manchester-Oxford Foot Questionnaire]	Version 1.0	

You should ensure that the sponsor has a copy of the final documentation for the study. It is the sponsor's responsibility to ensure that the documentation is made available to R&D offices at all

17/SS/0124	**Please quote this number on all correspondence**

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Appendix 3

■ INSTRUCTIONAL REVIEW

Medial malleolar fractures

CURRENT TREATMENT CONCEPTS

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The medial malleolus, once believed to be the primary stabilizer of the ankle, has been the topic of conflicting clinical and biomechanical data for many decades. Despite the relevant surgical anatomy being understood for almost 40 years, the optimal treatment of medial malleolar fractures remains unclear, whether the injury occurs in isolation or as part of an unstable bi- or trimalleolar fracture configuration. Traditional teaching recommends open reduction and fixation of medial malleolar fractures that are part of an unstable injury. However, there is recent evidence to suggest that nonoperative management of well-reduced fractures may result in equivalent outcomes, but without the morbidity associated with surgery. This review gives an update on the relevant anatomy and classification systems for medial malleolar fractures and an overview of the current literature regarding their management, including surgical approaches and the choice of implants.

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The last decade has witnessed an exponential increase in the number of publications dealing with foot and ankle trauma, in particular, trauma involving the posterior malleolus and syndesmosis.[1] The medial malleolus was universally accepted as the primary ankle stabilizer until 1977, when Yablon et al[2] published a landmark study concluding that it is, in fact, the fibula that reliably guides and maintains talar reduction. The significance of the medial malleolus and supporting ligamentous structures has since been the subject of much clinical and biomechanical debate, with conflicting results. The findings of Yablon et al[2] were swiftly supported by Svend-Hansen et al,[3] who reported that isolated medial malleolar fixation in a bimalleolar injury resulted in poor long-term outcomes and post-traumatic osteoarthritis in most patients (55%). Pettrone et al[4] recorded improved outcomes with fixation of both malleoli compared with isolated medial fixation in bimalleolar injuries, in a series of 146 ankle fractures. Conversely, Earll et al[5] examined tibiotalar loading in 15 normal cadaveric ankles and concluded that sectioning the tibiocalcaneal division of the superficial deltoid ligament (SDL) in isolation increased tibiotalar contact pressures by 30%, although this structure is seldom repaired in clinical practice. A recent cadaveric biomechanical study by Lareau et al[6] noted a comparable decrease in medial tibiotalar contact pressures of 27.8% following screw fixation of an isolated medial malleolar osteotomy compared with non-fixation. An association between these biomechanical findings and the outcome in patients has not been confirmed.

Having familiarized themselves with one or two conventional techniques of fixation, many surgeons will have, understandably, not thought to question their approach to the management of medial malleolar fractures. With improvements in technology and a desire to reduce the complications of surgery, the medial malleolus is regaining attention.[7,8] This review provides an update on the relevant surgical anatomy and classification of the fractures, with an overview of the current literature on the management of medial malleolar fractures.

Clinical anatomy

The surgically important anatomy of the medial malleolus and associated ligamentous complex was well described by Pankovich and Shivaram in 1979[9] following cadaveric studies. Before this, attempts to define the anatomy and associated ligaments had been inconsistent and non-reproducible. The medial malleolus arises from the distal tibia as it terminates in a pyramidal process with a convex smooth medial surface felt subcutaneously, and a hyaline cartilage-lined concave articular surface. The anterior process, commonly referred to as the anterior colliculus (Latin for 'mound'), extends distally and is roughened for the attachment of the anterior fibres of the SDL. The intercollicular groove separates the anterior colliculus from the broader posterior colliculus, serving as an attachment for the posterior talotibial component of the deep deltoid ligament (DDL). The remaining components of the DDL originate from the posterior colliculus itself.

Together with the medial malleolus, the divisions of the deltoid ligament are collectively referred to as the medial malleolus osteoligamentous complex (MMOLC).[10] The SDL has three components: the naviculotibial, calcaneotibial, and superficial talotibial ligaments. The stronger

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Appendix

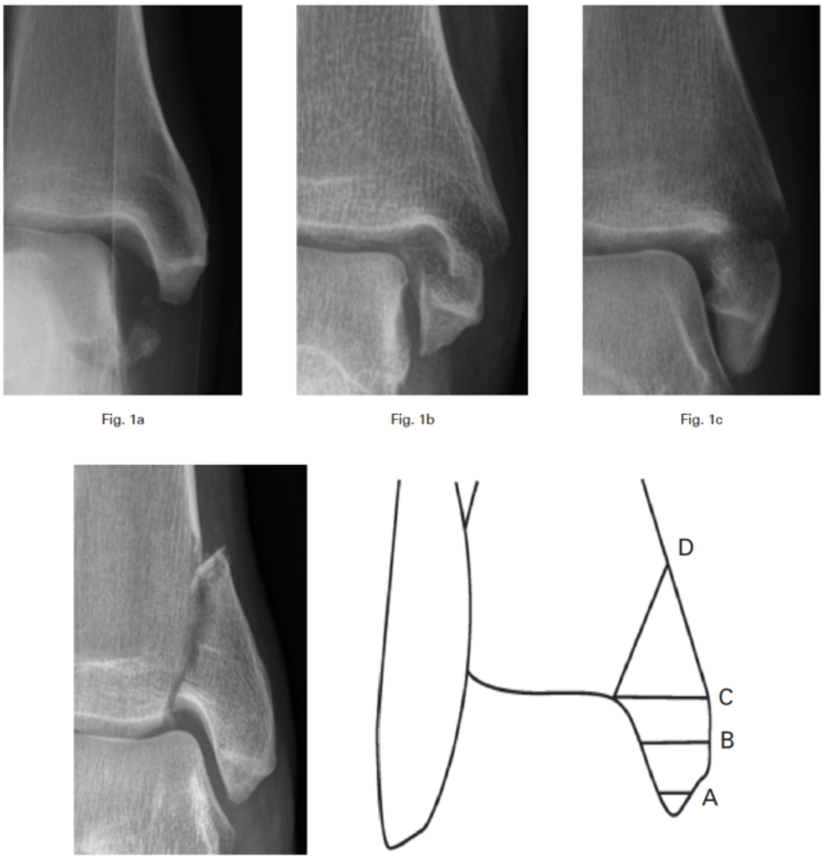

Fig. 1a Fig. 1b Fig. 1c Fig. 1d Fig. 1e

a) to d) Radiological examples for each Herscovici[14] type of medial malleolar fracture. e) An illustration of the classification.

DDL comprises the deep anterior talotibial ligament and the deep posterior talotibial ligament, which is the strongest and thickest ligament of the MMOLC. The tibialis posterior tendon lies within a deep fibrocartilage-lined groove and passes intimately around the posterior colliculus, providing additional stability to this zone of the malleolus. Combining the bony and ligamentous anatomy, Pankovich and Shivaram[11] proposed six clinical patterns of injury, with varying degrees of instability determined by the location of the fracture and the ligamentous disruption: 1) rupture of both the SDL and DDL with no associated fracture; 2) an isolated fracture of the anterior colliculus with no medial instability; 3) a fracture of the anterior colliculus with rupture of the deep posterior talotibial ligament, resulting in medial instability; 4) a fracture of the posterior colliculus with or without a fracture of the anterior colliculus; 5) a supracollicular fracture (vertical, oblique, or transverse) with an intact deltoid ligament; and 6) an avulsion 'chip' fracture considered as a sprain fracture of the SDL.

Classification of the fractures

Isolated fractures of the medial malleolus occur in only about 7% of fractures involving the ankle, although they are three times more common in combination with a lateral malleolar fracture (20%).[12,13] Herscovici et al[14] described a modification of the Müller classification system,[15] simplifying it into four distinct fractures based on the anteroposterior (AP) radiograph: type-A, avulsion fractures, occur at the tip of the malleolus; type-B fractures occur between the tip and the plafond; type-C fractures occur at the level of the plafond; and type-D fractures extend in an oblique-vertical direction from the plafond

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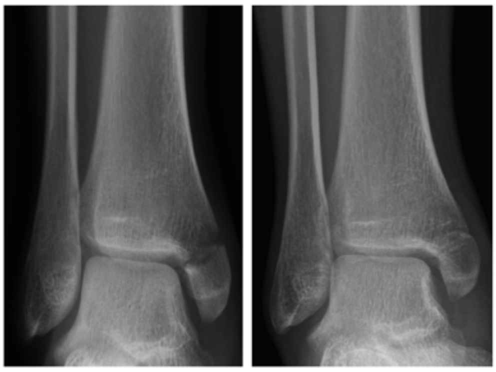

Fig. 2a Fig. 2b

a) Anteroposterior radiograph of a 27-year-old male patient with an isolated medial malleolar fracture without proximal fibular involvement. b) Clinical and radiological union after six weeks of weight-bearing in a removable orthosis.

(Fig. 1). This simplistic system has been adopted in much of the recent literature,[16-23] but as it is based only on AP imaging without considering the morphology of the fracture seen on a lateral radiograph or CT, some have questioned its intra- and interobserver reliability.

Aitken et al[12] studied the AP radiographs of 130 patients with medial malleolar fractures. Four blinded trauma surgeons examined these on two occasions separated by a six-week interval, classifying fractures according to the Herscovici system. Despite 18% of fractures being deemed 'unclassifiable', they reported the system to be substantially reproducible (k = 0.64) and moderately reliable (k = 0.54). Type-C fractures had the lowest intra- and interobserver agreement due to the variation in obliquity of the fracture line, which, if originating below the plafond, could easily be interpreted as a type-B fracture. Given the difficulties with interpreting or indeed identifying a medial malleolar fracture on a lateral radiograph, coupled with the associated radiation, costs, and preoperative delays of CT scanning, this system appears to be the current standard that will probably undergo modifications with the passage of time.

Nonoperative management

Isolated fractures. Herscovici et al[14] assessed outcome following the nonoperative management of isolated medial malleolar fractures in 57 patients, with a mean age of 40 years (17 to 69), all of whom were managed in a short-leg non-weight-bearing cast for six weeks. At a mean follow-up of 35.6 months (26 to 86), they reported a rate of nonunion of 4%, two patients, both of whom had type-C fractures that required fixation with bone grafting. The outcome according to the American Orthopaedic Foot and Ankle Society Score (AOFAS) was excellent, with a mean of 89.8 (69 to 100). There were no reports of medial instability, malalignment of the mortise, or post-traumatic degenerative changes. The authors concluded that conservative management of isolated medial fractures was safe, regardless of the initial displacement.

Hanhisuanto et al[21] compared the outcome of 46 patients with an isolated medial malleolar fracture treated conservatively with 60 patients who were treated operatively using either fixation with lag screws (57), Kirschner (K-)wire with a single screw (SS) (n = 1), K-wires alone (n = 1), or a tension band wire (TBW) (n = 1).[21] Those whose fracture was displaced by ≤ 2 mm were treated conservatively and those with more displacement or evidence of instability of the mortise underwent surgery. The mean Olerud–Molander Ankle Score (OMAS),[24] Foot and Ankle Outcome Score (FAOS),[25] and visual analogue scale (VAS) pain score were comparable in the two groups. However, this study was limited by a greater initial displacement in the operative cohort, as this may have signified a more severe underlying chondral injury. This study also lacks long-term radiological follow-up, and the rate of union in the two groups was not determined. However, reassuringly, satisfactory patient-reported outcomes would suggest that any asymptomatic nonunions, if present, would probably not require further intervention. Despite these limitations, this study provided support for the nonoperative management of a well-reduced medial malleolar fracture with ≤ 2 mm displacement. An example of successful nonoperative management from the authors' institution (Royal Infirmary of Edinburgh, Edinburgh, United Kingdom) is shown in Figure 2.

Stress fractures. Isolated stress fractures of the medial malleolus are rare, with a reported incidence of between 0.6% and 4% of all stress fractures of the lower limb. Most affect young, male, high-demand athletes.[26] They may not initially be evident on plain radiographs and further imaging, including CT, MRI, or bone scan, may be required to make the diagnosis. There is typically a vertically orientated fracture, possibly resulting from repetitive loading of the foot in an adducted position.[27] Two recent reviews by Caesar et al[26] and Irion et al[28] included a small number of low-quality studies. Although good outcomes and a high rate of union (97%) can be expected with nonoperative management for minor undisplaced fractures, the authors suggested some relative indications for surgery including: 1) high level of competition; 2) close proximity to competition; 3) evidence of fracture on plain radiographs; and 4) displacement of the fracture. Given the low incidence and significant variation in the performance level of athletes, the management of stress fractures of the medial malleolus should be considered on an individual basis.

'Unstable' displaced fractures. The recent literature involving the medial malleolus reveals conflicting opinions about the ideal management of an unstable injury. The nonoperative management of medial malleolar fractures following satisfactory fibular stabilization was the focus of a randomized controlled trial conducted in Norway by Hoelsbrekken et al.[7] They prospectively reviewed 82 patients with unstable bi- and trimalleolar fractures, who were randomized to be treated either with fixation (37) or non-fixation (45) of an associated well-reduced medial malleolar fracture following fixation of the lateral malleolus. Four patients (9%) in the non-fixation group developed a nonunion, but none required further surgery. The mean OMAS, AOFAS, and VAS pain scores were comparable between the groups. The rate of malunion (11% *vs* 7%) and radiological evidence of osteoarthritis (8% *vs* 2%) was higher in the fixation group, with the short follow-up available (mean,

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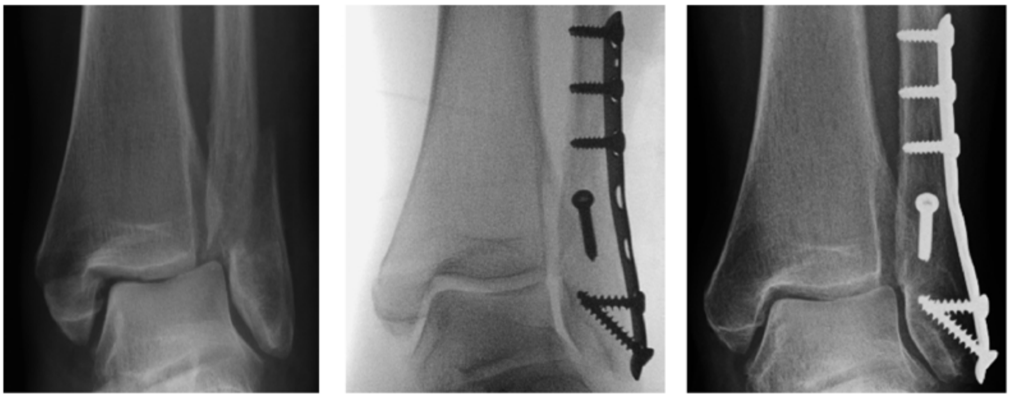

Fig. 3a Fig. 3b Fig. 3c

Anteroposterior radiographs of a 59-year-old female patient with a) a closed bimalleolar fracture. b) Following fibular fixation, the medial malleolus reduced anatomically. c) Maintenance of a satisfactory radiological outcome one year following surgery.

42.5 months (24 to 72)). These results may support a decision to leave a well-reduced medial malleolar fracture without fixation (Fig. 3) and may be particularly relevant in patients with a medial soft tissue injury, fracture blisters, or open wounds. This concept is supported by encouraging results from a recent retrospective study, which demonstrated positive patient reported outcome in 54 patients with a nonoperatively managed medial malleolar fracture following intramedullary fibular stabilisation.[29] Further prospective data in this area are awaited.[30]

Operative management

Surgical approach and reduction of the fracture. Traditionally, medial malleolar fractures have been fixed through an anteromedial approach beginning just proximal to the fracture and extending distally to cross the anterior one-third of the malleolus, terminating 2 cm distal to its tip. This approach places the great saphenous vein and nerve vulnerable to iatrogenic injury. Others prefer the more posteriorly sited direct medial approach, which reduces the risk of injury to these structures. Given the length and extensile nature of both incisions, they allow inspection and irrigation of the articular surface, retrieval of the periosteal flap that is often drawn into the fracture, and confirmation of fracture reduction through inspection of the tibial cortex and, if required, plafond margin.

More recently, minimally invasive approaches that reduce soft-tissue stripping have become popular, including a mini-arthrotomy technique involving a 3 cm incision at the superomedial aspect of the mortise, medial to the tendon of tibialis anterior.[17] This approach continues to allow articular inspection, irrigation, and reduction of the fracture, while fixation is performed through a separate stab incision. A purely percutaneous approach used in high-risk multi-comorbid patients through a 1 cm wound distal to the tip of the malleolus has shown promising results.[31] Weinraub et al[32] compared the rate of union of 32 patients undergoing purely percutaneous medial fixation with open reduction and internal fixation performed in 458 patients. Eight weeks postoperatively, the rate of union in the open reduction group was 92.4% compared with 71.9% in the percutaneous group ($p < 0.001$). The authors attributed this difference to the interposed periosteal flap, which becomes trapped during the rotational aspect of the injury and is clearly not retrieved during percutaneous fixation. They failed to report rates of infection or patient-reported outcome in either group. There is also likely to have been selection bias given the retrospective design and disparity in the size of the groups. Radiological follow-up was not performed beyond eight weeks, preventing comparison of nonunion rates. A purely percutaneous approach has theoretical advantages but relies on an acceptable closed reduction and would not be suitable for younger patients with grossly displaced fractures or impaction of the medial dome.

Many argue that it is the quality of the articular reduction that affects outcome. The arthroscopic assessment of reduction was the subject of a small case series involving 12 consecutive patients.[33] Despite encouraging results, the specialist nature of this intervention makes it unlikely to be adopted by most surgeons, who through standard open incisions can guide reduction by inspecting the external cortex and the anterior plafond. Reassuringly, and arguably more relevantly, most fractures (83%) with a satisfactory cortical reduction were also well reduced when assessed arthroscopically. The two patients (17%) with a poor intra-articular reduction had not complied with preoperative restrictions of weight-bearing, and underwent surgery more than two weeks after the injury with consequent impaction of the medial dome. Arthroscopically assisted reduction was possible in only one of these patients. Given that a modest improvement in reduction was only achieved in one patient, routine arthroscopic evaluation is unlikely to be advantageous in the compliant patient without significant delay to surgery.

Screw or TBW fixation. Most medial malleolar fractures requiring fixation are treated with screws. For fractures that

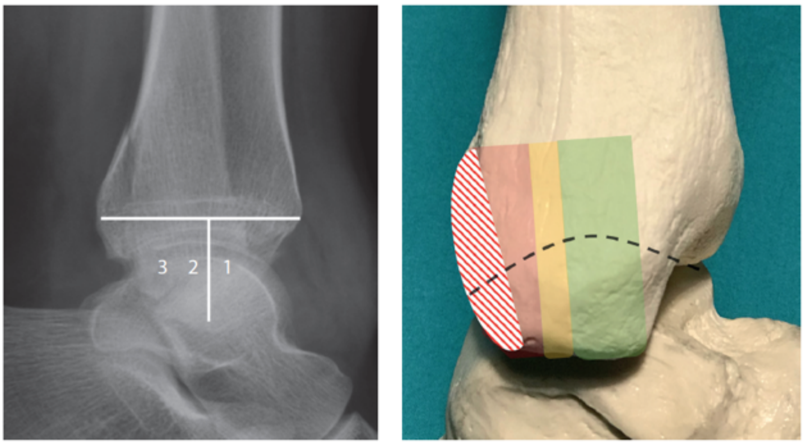

Fig. 4a Fig. 4b

a) Lateral radiograph and b) saw-bone model showing the three medial malleolar zones. Zone 1 (safe zone) is contained within the anterior colliculus (green). The intercollicular groove (yellow) separates the safe zone from zone 3 (red). The tibialis posterior tendon runs in its groove (red stripes).

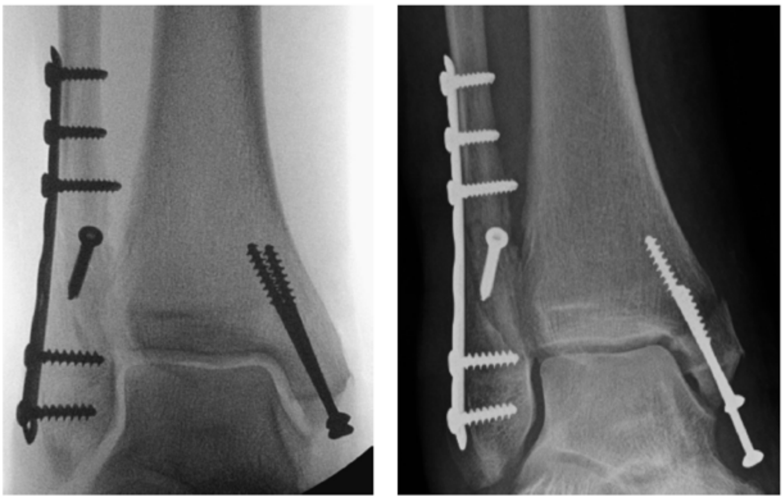

Fig. 5a Fig. 5b

a) Anteroposterior intraoperative fluoroscopy showing lag screw fixation of the medial malleolus in a 75-year-old male patient. b) Screw 'back-out' and loss of reduction, two weeks postoperatively.

preclude the use of a screw, such as distal avulsions or those with severe comminution, traditional AO teaching recommends TBW fixation.[34] This method has been supported by biomechanical and clinical data showing superior pull-out strength of TBW constructs compared with cancellous screws, although the technique has been modified by replacing the transosseous tunnels with proximal 'anchor screws'.[35,36]

Ebraheim et al[37] evaluated the outcome in relation to the technique of fixation that was used for transverse, oblique, and vertical medial malleolar fractures. They concluded that transverse fractures should be treated with TBW rather than lag screws given the lower rate of revision (5% *vs* 24%) and complications (16% *vs* 41%), but with radiological union being comparable for both techniques (79% *vs* 78%). Radiological

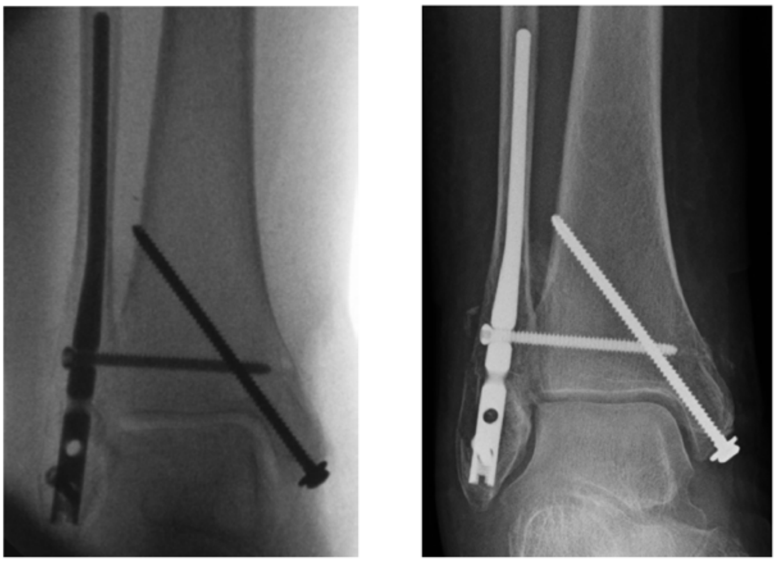

Fig. 6a Fig. 6b

a) Anteroposterior intraoperative fluoroscopy of a 78-year-old female patient with poor bone quality showing a bimalleolar fracture treated with percutaneous bicortical lag screw fixation of the medial malleolus. b) Six weeks postoperatively.

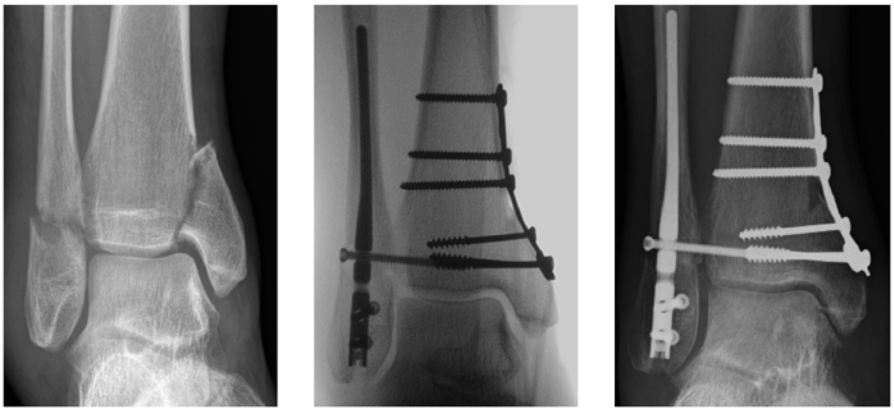

Fig. 7a Fig. 7b Fig. 7c

a) Anteroposterior radiograph of a 44-year-old male patient with a typical supination-adduction type of fracture. b) Intraoperative fluoroscopy following anti-glide plating with two partially threaded cancellous lag screws. c) Six months postoperatively.

and patient-reported outcomes were better following cancellous lag screw fixation of oblique fractures and buttress plating of vertically orientated fractures. Despite the potential biomechanical and clinical advantages, the authors did not comment on the unfortunately common drawback of TBW fixation involving symptomatic metalwork, with approximately 15% of patients requiring removal.[36,38] In an attempt to overcome this, some have replaced stainless steel wire with knotless systems, using a combination of low-profile wires and tapes, but with conflicting results in saw-bone biomechanical testing.[39,40]

Downey et al[41] compared a group of 18 patients treated with knotless tension band (KTB) fixation with 89 patients treated

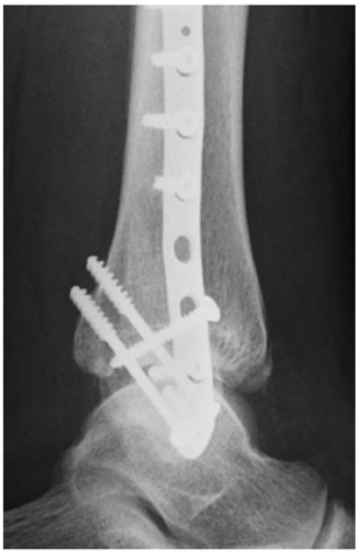

Fig. 8

Lateral radiograph of a 38-year-old male patient who had pain radiating to the sole of his foot due to irritation of the posterior tibial nerve following unsatisfactory fixation. The symptoms improved markedly after removal of the screws, which had been inserted with an incorrect trajectory.

with traditional TBW fixation. No patients required removal of metalwork in the KTB group compared with 8% in the TBW group, with comparable clinical outcomes and time to union. A rudimentary cost analysis suggested that despite the KTB implant costing three times that of the TBW, it was 13% cheaper due to the avoidance of secondary costs. Given the small number of patients in the study and higher initial costs of implants, further prospective data are required.

Screw fixation: length, type, and number. Parker et al[42] recently challenged the traditional AO approach to medial malleolar fixation, which recommends two parallel partially threaded cancellous lag screws. Using 21 randomized unpaired cadaveric tibiae, they measured compression at a simulated medial malleolar fracture site during fixation in four experimental groups using: A) a 4.0 mm × 45 mm × 15 mm partially threaded cancellous screw, B) a 4.0 mm × 45 mm fully threaded cancellous screw, C) a 4.0 mm × 45 mm fully threaded cancellous screw with a 4.0 mm glide hole; and D) a 4.0 mm × 30 mm × 16 mm partially threaded cancellous screw. The greatest compression at the fracture site was achieved by group B and the authors concluded that fully threaded cancellous screws achieve more purchase in the radiodense physeal scar compared with partially threaded screws of equivalent length (45 mm). The study was limited by the homogenous sample of elderly, osteoporotic cadaveric tibiae and the conclusions can only really pertain to this group. It may be that in younger patients with greater bone density, fully threaded screws might, in fact, function as distracting positional screws.

Excessively long screws can bypass the best-quality cancellous bone in which to gain good purchase, which may result in lower compression at the fracture site. Ricci et al[43] suggested screws of 40 mm to 45 mm in length should be used. Similarly, excessively short screws may not fully engage proximally, leading to the potential for distraction rather than the desired compression. Labronici et al[44] examined 116 cadaveric tibiae and reported that the mean distance from the medial malleolar tip to the distal tibial medullary canal was 55 mm, and concluded that screw length should be no more than 45 mm to achieve optimum purchase. They did not report the mean age of the specimens and no measurement of bone density was performed, but the large sample size strengthens the generalizability of these results and supports the findings of Parker et al,[42] who recommended 45 mm fully threaded screws.

The decision to use one or two screws has been recently investigated by Buckley et al,[23] who randomized 140 patients to either double screw (DS) or SS fixation, of whom 127 patients (91%) were followed-up. There was no significant difference at any time during the two-year follow-up period in the primary outcome measure (36-Item Short-Form Health Survey questionnaire) or secondary outcomes including operating time, length of stay in hospital, or complications between the groups. A syndesmosis screw failed in one patient in the SS group, and medial malleolar screw fixation failed in one patient in the DS group. Displacement of the medial malleolar fracture, which was subsequently treated conservatively, occurred in one patient in each group. A total of 14 patients randomized to the DS group crossed over to the SS group intraoperatively as the surgeon felt the fragment was too small for safe DS fixation. This is frequently encountered with the smaller fracture of the anterior colliculus, which commonly represents an SDL avulsion injury. These level 1 data conclude that SS fixation is efficacious in the treatment of most medial malleolar fractures and support the findings from a previous retrospective review.[45]

Screw fixation: zone of insertion. Fixation of medial malleolar fractures is not without risk. Damage to local structures including the tibialis posterior tendon, either from the tip of a screw posteriorly or the head of a screw distally, has been well described in small retrospective studies.[46] Femino et al[47] divided the medial malleolus into three zones from anterior to posterior and described the 'safe zone' for screw placement (Fig. 4). An oblique supracollicular fracture was created in ten unmatched cadaveric tibiae. Three screws were inserted parallel to the anterior tibial cortex, one in each of three zones: zone 1 (safe zone), anterior colliculus; zone 2, intercollicular groove; and zone 3, posterior colliculus. Screws placed in zone 3 resulted in 100% abutment of the tibialis posterior tendon and the tendon was injured in 50%. Screws in zone 2 were only a mean of 2 mm away from the groove containing the tendon. In large patients, the anterior colliculus may be capacious enough to accept two screws. In smaller patients, zone 2 screws should be inserted as close as possible to the posterior border of the anterior colliculus, identified as the tip of the malleolus. This can be confirmed on lateral fluoroscopy (Fig. 4). Inspection of the tibialis posterior tendon following insertion of such screws is recommended. Screws in the posterior colliculus should be removed electively following union of the fracture, to reduce

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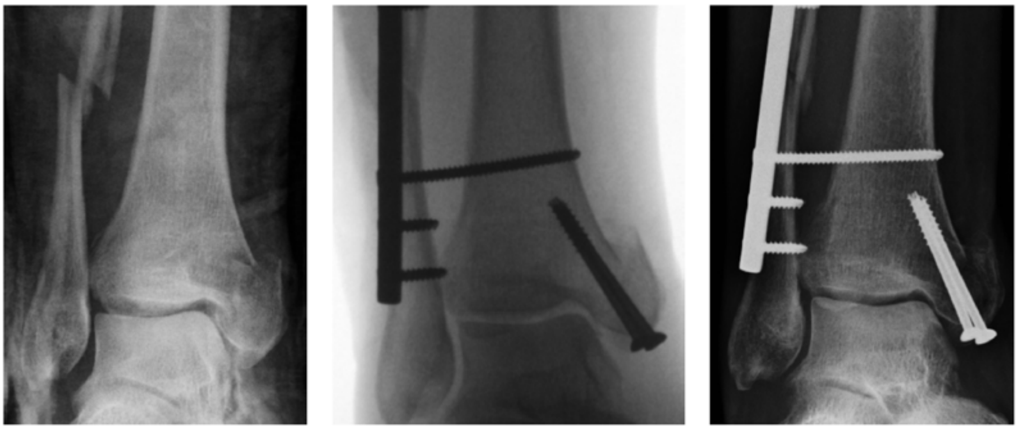

Fig. 9a Fig. 9b Fig. 9c

a) Anteroposterior radiograph demonstrating a comminuted medial malleolar fracture in a 48-year-old male patient. b) Poor intraoperative reduction with over-compression of the medial malleolus, c) resulting in malunion. The patient complained of medial-sided pain and the screws were removed six months postoperatively.

the risk of chronic attrition and tendon rupture. An additional key clinical point from this study relates to the trajectory of the screw, which should be parallel to the anterior tibial cortex. A screw that starts in the safe zone but has a posterior trajectory may produce similar morbidity.

These findings have been supported by Zhang et al,[48] who analyzed 3D CT scans in 215 patients without a previous fracture or congenital abnormality and found that, with a mean AP distance of 11.7 mm, the anterior colliculus could only accommodate two 4.0 mm screws safely in the largest patients. This work, in conjunction with the conclusions from the study by Buckley et al,[23] suggests that two screws may not be required.

Unicortical or bicortical fixation. The incidence of symptomatic metalwork following fixation of a medial malleolar fracture may be increased in patients with osteoporotic bone, especially when the maximum insertional torque of the screw has been exceeded through over-tightening and 'stripping'.[42] This leads to reduced compression and may predispose to screw 'back-out' (Fig. 5). Removal of screws does not always guarantee the resolution of symptoms.[49] The technique of bicortical lag screw fixation (Fig. 6) has been well described[50,51] and reported by Ricci et al[43] in a primarily clinical study supplemented with biomechanical testing. They included 92 patients (46 treated with partially threaded screws and 46 with a bicortical lag screw) and found a significantly lower rate of prominent medial metalwork and radiological loosening in the bicortical group. Biomechanical testing confirmed greater torque applied to the bicortical screws, which was indirectly extrapolated to greater compression at the fracture site. Supporting studies have shown superior biomechanical pull-out strength of bicortical fixation[16] and positive outcomes in high-risk patients, including those with osteoporosis, diabetes, peripheral vascular disease, and chronic renal impairment.[52]

Despite the encouraging clinical, radiological, and biomechanical evidence, bicortical fixation does not appear to have been widely adopted. Selecting a long fully threaded screw up to 120 mm in length may be somewhat unfamiliar to both surgeon and scrub nurse, but can be of significant benefit, particularly if there is concern about the compression achieved with standard, shorter, partially threaded screws.

Plate fixation. Vertical shear fractures of the medial malleolus are classically sustained in a supination-adduction injury. These are inherently unstable and usually require fixation. Partially threaded cancellous screws have long been used in these patients, with divergent screws providing better biomechanical qualities than parallel screws.[53] Wegner et al[54] compared four fixation groups for the treatment of a simulated vertical shear fracture in a synthetic bone model. Anti-glide plating (Fig. 7) was significantly stiffer and could withstand higher loads to failure than fixation with bicortical, parallel unicortical, or divergent unicortical screws. One drawback of anti-glide plating is the larger exposure and soft-tissue stripping, which is required. In patients with vulnerable soft tissues, bicortical screw fixation may provide enough stability without additional insult.

The traditional description of the anti-glide technique involves proximal-only screws within a standard one-third tubular plate. Jones et al[55] compared this technique with a modified construct including a further unicortical lag screw compressing the fracture. In a synthetic model, this configuration showed superior stiffness and maximum load to failure compared with the traditional technique and a more contemporary pre-contoured 'hooked' plate with no lag screw fixation. Given the low cost and accessibility, a configuration including one or more lag screw(s) should be the benchmark when using anti-glide plating (Fig. 7).

Alternative implants. In an attempt to reduce the rate of symptomatic metalwork, headless screws have been recently

Appendix

investigated by Barnes et al.[56] A total of 44 patients were reviewed clinically and radiologically at a median of 35 weeks (12 to 208) postoperatively. No patient had a nonunion and none required removal of metalwork, although the screws were removed in one as part of treatment for infection. Despite the adaptations in design, including the screw head lying flush with bone, nearly a quarter of patients (23%) complained of mild medial discomfort. This ongoing discomfort is likely to be related to scar tissue and may explain why symptoms do not always improve following removal of metalwork.[49]

In a small study by Tekin et al,[18] 12 patients were reviewed after antegrade, as opposed to retrograde, headless compression screw fixation of type-B fractures. No patients had a nonunion, prominent metalwork, instability, or infection and all had a good or excellent outcome with a mean AOFAS score of 95.0 (87 to 99). Bulut and Gursoy[20] compared headless compression screws with partially threaded lag screws and TBW fixation in the treatment of isolated medial malleolar fractures. There was significantly less medial-sided pain and removal of metalwork in the headless screw group, but no significant difference in the primary outcome measure (AOFAS; $p = 0.239$). Despite good clinical outcomes, there is a lack of supportive biomechanical evidence in the literature. A significant reduction in secondary intervention would be required to offset the greater initial cost of the screws.

Other devices, including low-profile malleolar sleds consisting of two prongs inserted in a retrograde manner from the tip of the malleolus and secured with proximal cancellous screws, have been introduced to reduce the incidence of symptomatic metalwork following TBW fixation of comminuted fractures.[57] These implants may have superior biomechanical properties, including higher pull-out strength, when compared with unicortical screw fixation in transverse fractures.[58] Absorbable implants might have a future role, specifically in reducing rates of re-operation, but have been associated with foreign body reaction, skin necrosis, and re-fracture.[59,60] Given the additional expense associated with these alternative implants, high-quality prospective studies are required to justify their routine clinical use, with high-risk patients most likely to benefit.

Complications. The fixation of medial malleolar fractures is not without risk. In addition to the routine risks of infection and implant-related pain, intra-articular screw penetration and inadvertent injury to the tibialis posterior tendon with its adjacent neurovascular bundle have been described (Fig. 8).[46,47,61] The challenge of achieving adequate fixation in comminuted or osteoporotic bone has been discussed. Due to the high rate of prominent metalwork following TBW fixation, most surgeons would use screw(s) whenever possible. Unfortunately, over-compression frequently results in over-reduction of the fracture, closing down the medial clear space or causing malalignment, both of which may produce inferior outcomes and continue to present a management challenge (Fig. 9).

In conclusion, the literature demonstrates that there is no single technique, operation, or implant that can be used universally in the treatment of medial malleolar fractures. With rising costs of health care and potential disruption to the busy lifestyles of our patients, there is an added incentive to 'get it right first time' while facilitating safe early mobilization and return to activity. Prominent metalwork is tolerated poorly, and new designs of implants have been developed with this in mind. Perhaps the introduction of these more expensive, complex devices is complicating the situation further. If we carefully consider the standard implants we routinely use and modify the technique, with bicortical screw fixation being a perfect example, the outcomes could potentially be improved more simply. In patients with severe fracture comminution, poor bone quality, or vulnerable soft tissues, we should question the need to intervene at all in a well-reduced medial fracture, especially in elderly patients. If fixation is required, respect should be paid to the 'safe zone' of the malleolus and one screw used where possible. Undoubtedly, more high-quality research is required to provide further direction.

Take home message

- Although the surgical anatomy is well understood, the optimal treatment of fractures of the medial malleolus remains unclear.
- Nonoperative management of well-reduced medial malleolar fractures may yield equivalent outcome to internal fixation, without the associated surgical morbidity.
- In the presence of poor bone quality, bicortical fixation should be considered for displaced fractures.
- The 'safe zone' of the medial malleolus must be respected in order to reduce the risk of iatrogenic injury to the tibialis posterior tendon.

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References

1. **White TO, Carter TH.** Ankle fractures: facts and fiction. *Bone & Joint 360* 2018;7(4):3–8.
2. **Yablon IG, Heller FG, Shouse L.** The key role of the lateral malleolus in displaced fractures of the ankle. *J Bone Joint Surg [Am]* 1977;59-A:169–173.
3. **Svend-Hansen H, Bremerskov V, Baekgaard N.** Ankle fractures treated by fixation of the medial malleolus alone. Late results in 29 patients. *Acta Orthop Scand* 1978;49:211–214.
4. **Pettrone FA, Gail M, Pee D, Fitzpatrick T, Van Herpe LB.** Quantitative criteria for prediction of the results after displaced fracture of the ankle. *J Bone Joint Surg [Am]* 1983;65-A:667–677.
5. **Earll M, Wayne J, Brodrick C, Vokshoor A, Adelaar R.** Contribution of the deltoid ligament to ankle joint contact characteristics: a cadaver study. *Foot Ankle Int* 1996;17:317–324.
6. **Lareau CR, Bariteau JT, Paller DJ, Koruprolu SC, DiGiovanni CW.** Contribution of the medial malleolus to tibiotalar joint contact characteristics. *Foot Ankle Spec* 2015;8:23–28.
7. **Hoelsbrekken SE, Kaul-Jensen K, Mørch T, et al.** Nonoperative treatment of the medial malleolus in bimalleolar and trimalleolar ankle fractures: a randomized controlled trial. *J Orthop Trauma* 2013;27:633–637.
8. **Kusnezov NA, Eisenstein ED, Diab N, Thabet AM, Abdelgawad A.** Medial malleolar fractures and associated deltoid ligament disruptions: current management controversies. *Orthopedics* 2017;40:e216-e222.
9. **Pankovich AM, Shivaram MS.** Anatomical basis of variability in injuries of the medial malleolus and the deltoid ligament. I. Anatomical studies. *Acta Orthop Scand* 1979;50:217–223.
10. **Davidovitch RI, Egol KA.** The medial malleolus osteoligamentous complex and its role in ankle fractures. *Bull NYU Hosp Jt Dis* 2009;67:318–324.
11. **Pankovich AM, Shivaram MS.** Anatomical basis of variability in injuries of the medial malleolus and the deltoid ligament. II. Clinical studies. *Acta Orthop Scand* 1979;50:225–236.
12. **Aitken SA, Johnston I, Jennings AC, Chua ITH, Buckley RE.** An evaluation of the Herscovici classification for fractures of the medial malleolus. *Foot Ankle Surg* 2017;23:317–320.
13. **Court-Brown CM, McBirnie J, Wilson G.** Adult ankle fractures--an increasing problem? *Acta Orthop Scand* 1998;69:43–47.
14. **Herscovici D Jr, Scaduto JM, Infante A.** Conservative treatment of isolated fractures of the medial malleolus. *J Bone Joint Surg [Br]* 2007;89-B:89–93.

15. **Müller ME, Nazarian S, Koch P, Schatzker J.** *The Comprehensive Classification of Fractures of Long Bones.* Springer-Verlag, 1990.
16. **Pollard JD, Deyhim A, Rigby RB, et al.** Comparison of pullout strength between 3.5-mm fully threaded, bicortical screws and 4.0-mm partially threaded, cancellous screws in the fixation of medial malleolar fractures. *J Foot Ankle Surg* 2010;49:248–252.
17. **Saini P, Aggrawal A, Meena S, Trikha V, Mittal S.** Miniarthrotomy assisted percutaneous screw fixation for displaced medial malleolus fractures - a novel technique. *J Clin Orthop Trauma* 2014;5:252–256.
18. **Tekin AC, Đabuk H, Dedeoglu SS, et al.** Anterograde headless cannulated screw fixation in the treatment of medial malleolar fractures: evaluation of a new technique and its outcomes. *Med Princ Pract* 2016;25:429–434.
19. **Kochai A, Türker M, Çiçekli Ö, et al.** A comparative study of three commonly used fixation techniques for isolated medial malleolus fracture. *Eklem Hastalik Cerrahisi* 2018;29:104–109.
20. **Bulut T, Gursoy M.** Isolated medial malleolus fractures: conventional techniques versus headless compression screw fixation. *J Foot Ankle Surg* 2018;57:552–556.
21. **Hanhisuanto S, Kortekangas T, Pakarinen H, Flinkkilä T, Leskelä HV.** The functional outcome and quality of life after treatment of isolated medial malleolar fractures. *Foot Ankle Surg* 2017;23:225–229.
22. **Sohal HS, Garg RS, Jindal S, et al.** Minifragment T-plate fixation: an alternative method for medial malleolus fracture fixation. *J Foot Ankle Surg (Asia-Pacific)* 2016;3:10–14.
23. **Buckley R, Kwek E, Duffy P, et al.** Single-screw fixation compared with double screw fixation for treatment of medial malleolar fractures: a prospective randomized trial. *J Orthop Trauma* 2018;32:548–553.
24. **Olerud C, Molander H.** A scoring scale for symptom evaluation after ankle fracture. *Arch Orthop Trauma Surg* 1984;103:190–194.
25. **Roos E, Brandsson S, Karlsson J.** Validation of the foot and ankle outcome score for ankle ligament reconstruction. *Foot Ankle Int* 2001;22:788–794.
26. **Caesar BC, McCollum GA, Elliot R, Williams A, Calder JD.** Stress fractures of the tibia and medial malleolus. *Foot Ankle Clin* 2013;18:339–355.
27. **Sherbondy PS, Sebastianelli WJ.** Stress fractures of the medial malleolus and distal fibula. *Clin Sports Med* 2006;25:129–37.
28. **Irion V, Miller TL, Kaeding CC.** The treatment and outcomes of medial malleolar stress fractures: a systematic review of the literature. *Sports Health* 2014;6:527–530.
29. **Carter T, Mackenzie S, Bell K, et al.** Selective fixation of the medial malleolus in unstable ankle fractures. *Injury* 2019;11 [Epub ahead of print].
30. **Carter TH.** Medial Malleolus: Operative Or Non-operative (MOON). U. S. National Library of Medicine. https://clinicaltrials.gov/ct2/show/NCT03362229 (date last accessed 11 March 2019).
31. **Smith M, Medlock G, Johnstone AJ.** Percutaneous screw fixation of unstable ankle fractures in patients with poor soft tissues and significant co-morbidities. *Foot Ankle Surg* 2017;23:16–20.
32. **Weinraub GM, Levine P, Shi E, Flowers A.** Comparison of medial malleolar fracture healing at 8 weeks after open reduction internal fixation versus percutaneous fixation: a retrospective cohort study. *J Foot Ankle Surg* 2017;56:277–281.
33. **Swart EF, Vosseller JT.** Arthroscopic assessment of medial malleolar reduction. *Arch Orthop Trauma Surg* 2014;134:1287–1292.
34. **Schatzker J.** Screws and plates and their application. In: Müller ME, Allgöwer M, Schneider R, Willenegger H (eds.). *Manual of Internal Fixation: Techniques Recommended by the AO-ASIF Group.* Third ed. New York: Springer-Verlag, 1991:226–228.
35. **Johnson BA, Fallat LM.** Comparison of tension band wire and cancellous bone screw fixation for medial malleolar fractures. *J Foot Ankle Surg* 1997;36:284–289.
36. **Georgiadis GM, White DB.** Modified tension band wiring of medial malleolar ankle fractures. *Foot Ankle Int* 1995;16:64–68.
37. **Ebraheim NA, Ludwig T, Weston JT, Carroll T, Liu J.** Comparison of surgical techniques of 111 medial malleolar fractures classified by fracture geometry. *Foot Ankle Int* 2014;35:471–477.
38. **Ostrum RF, Litsky AS.** Tension band fixation of medial malleolus fractures. *J Orthop Trauma* 1992;6:464–468.
39. **Fowler TT, Pugh KJ, Litsky AS, Taylor BC, French BG.** Medial malleolar fractures: a biomechanical study of fixation techniques. *Orthopedics* 2011;34:e349-e355.
40. **Clyde J, Kosmopoulos V, Carpenter B.** A biomechanical investigation of a knotless tension band in medial malleolar fracture models in composite Sawbones®. *J Foot Ankle Surg* 2013;52:192–194.
41. **Downey MW, Duncan K, Kosmopoulos V, et al.** Comparing the knotless tension band and the traditional stainless steel wire tension band fixation for medial malleolus fractures: a retrospective clinical study. *Scientifica (Cairo)* 2016;2016:3201678.
42. **Parker L, Garlick N, McCarthy I, et al.** Screw fixation of medial malleolar fractures: a cadaveric biomechanical study challenging the current AO philosophy. *Bone Joint J* 2013;95-B:1662–1666.
43. **Ricci WM, Tornetta P, Borrelli J Jr.** Lag screw fixation of medial malleolar fractures: a biomechanical, radiographic, and clinical comparison of unicortical partially threaded lag screws and bicortical fully threaded lag screws. *J Orthop Trauma* 2012;26:602–606.
44. **Labronici PJ, Pires RE, Franco MV, et al.** Medial malleolar fractures: an anatomic survey determining the ideal screw length. *Ann Med Health Sci Res* 2016; 6:308–310.
45. **Shah Y, Syed T, Myszweski T, Zafar, F.** Comparison of outcome following either one or two screws for medial malleolar fracture fixation. *J Bone Joint Surg [Br]* 2010;92-B:255–256.
46. **DeMill SL, Bussewitz BW, Philbin TM.** Injury to the posterior tibial tendon after open reduction internal fixation of the medial malleolus. *Foot Ankle Spec* 2015;8:360–363.
47. **Femino JE, Gruber BF, Karunakar MA.** Safe zone for the placement of medial malleolar screws. *J Bone Joint Surg [Am]* 2007;89-A:133–138.
48. **Zhang K, Chen Y, Qiang M, et al.** The morphology of medial malleolus and its clinical relevance. *Pak J Med Sci* 2014;30:348–351.
49. **Brown OL, Dirschl DR, Obremskey WT.** Incidence of hardware-related pain and its effect on functional outcomes after open reduction and internal fixation of ankle fractures. *J Orthop Trauma* 2001;15:271–274.
50. **Parada SA, Krieg JC, Benirschke SK, Nork SE.** Bicortical fixation of medial malleolar fractures. *Am J Orthop (Belle Mead NJ)* 2013;42:90–92.
51. **Kupcha P, Pappas S.** Medial malleolar fixation with a bicortical screw: technique tip. *Foot Ankle Int* 2008;29:1151–1153.
52. **King CM, Cobb M, Collman DR, Lagaay PM, Pollard JD.** Bicortical fixation of medial malleolar fractures: a review of 23 cases at risk for complicated bone healing. *J Foot Ankle Surg* 2012;51:39–44.
53. **Amanatullah DF, Khan SN, Curtiss S, Wolinsky PR.** Effect of divergent screw fixation in vertical medial malleolus fractures. *J Trauma Acute Care Surg* 2012;72:751–754.
54. **Wegner AM, Wolinsky PR, Robbins MA, et al.** Antiglide plating of vertical medial malleolus fractures provides stiffer initial fixation than bicortical or unicortical screw fixation. *Clin Biomech (Bristol, Avon)* 2016;31:29–32.
55. **Jones DA, Cannada LK, Bledsoe JG.** Are hook plates advantageous compared to antiglide plates for vertical shear malleolar fractures? *Am J Orthop (Belle Mead NJ)* 2016;45:E98-E102.
56. **Barnes H, Cannada LK, Watson JT.** A clinical evaluation of alternative fixation techniques for medial malleolus fractures. *Injury* 2014;45:1365–1367.
57. **Maniar H, Kempegowda H, Tawari AA, et al.** Medial malleoli fractures: clinical comparison between newly designed sled device and conventional screws. *Foot Ankle Spec* 2017;10:296–301.
58. **Wegner AM, Wolinsky PR, Cheng RZ, et al.** Sled fixation for horizontal medial malleolus fractures. *Clin Biomech (Bristol, Avon)* 2017;42:92–96.
59. **Li ZH, Yu AX, Guo XP, et al.** Absorbable implants versus metal implants for the treatment of ankle fractures: a meta-analysis. *Exp Ther Med* 2013;5:1531–1537.
60. **Tang J, Hu JF, Guo WC, Yu L, Zhao SH.** Research and application of absorbable screw in orthopedics: a clinical review comparing PDLLA screw with metal screw in patients with simple medial malleolus fracture. *Chin J Traumatol* 2013;16:27–30.
61. **Giordano V, Gomes AF, Amaral NP, Albuquerque RP, Pires RE.** Preventing surgical complications: a survey on surgeons' perception of intra-articular malleolar screw misplacement in a cadaveric study. *Patient Saf Surg* 2011;5:24.

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A. D. Duckworth: Wrote the manuscript.
T. O. White: Wrote the manuscript.

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Appendix 4

FEATURE

Ankle fractures
facts and fiction

INTRODUCTION

Most orthopaedic surgeons have cut their teeth, at an early stage of training, by operating on ankle fractures. Some, contributing to a general trauma service, will continue to operate on ankle fractures throughout their careers. It is an area where many orthopaedic surgeons feel they have a degree of expertise, and yet ankle fractures are also an injury that can be unforgiving, with relatively high rates of complications,[1] which when suffered inevitably lead to an impaired outcome. It is certainly an injury where 'getting it right first time' pays dividends.[2] It is also an area that has experienced a resurgence of keen academic interest, with an exponential explosion in peer-reviewed publications in the last decade (Fig. 1). Some, like the Ankle Injury Management (AIM) trial, have been high-profile publications that have attracted interest from both within and outside of our own specialty.[3] Several areas, including the treatment of the posterior malleolus and the syndesmosis, arouse strongly felt opinions and have sparked heated controversy.[4] Yet, despite this heat, only a modest amount of light has been shed into the dark corners of the ankle, and even in some of the most routine areas of our practice there remains little clarity or consensus. This paper aims to review the existing literature and indicate where recent publications have added to the evidence base.

DIAGNOSING INSTABILITY

Isolated undisplaced lateral malleolar fractures are stable and are usually treated nonoperatively with good long-term outcomes.[5] In contrast, fractures with evident radiographic talar shift, and both bimalleolar and trimalleolar injuries, are unstable and usually require surgical intervention.

Diagnostic uncertainty commonly lies in between those poles – in distinguishing the stable isolated lateral malleolar fracture (supination-external rotation (SER) type 2) from the unstable SER type 4 injury with an associated deep deltoid ligament injury. Medial-sided tenderness and/or bruising may indicate a complete or partial deltoid ligament injury, but should be interpreted with caution.[6] Admission radiographs are a common trap for the unwary, as they are often taken with a plantar-flexed ankle. This brings the narrow, posterior part of the talus into the mortise, giving the illusion of talar shift (Fig. 2).

Stress radiographs, either gravity-assisted or manual, are still commonly used internationally, although they have poor diagnostic accuracy.[7,8] No consensus has been reached on the maximal medial clear space that should be considered normal, although 4 mm and 5 mm are

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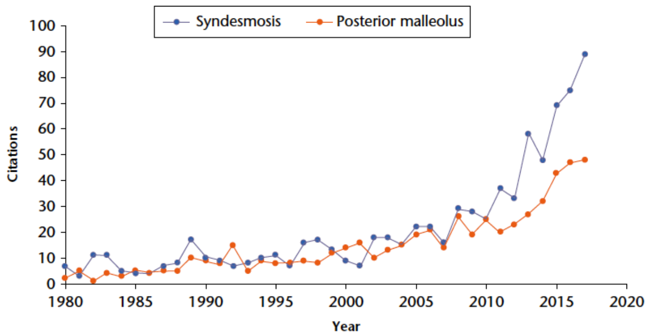

Fig. 1 Annual number of PubMed citations between 1980 and 2017 including the words 'syndesmosis' and 'posterior malleolus'.

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Fig. 2a Fig. 2b Fig. 2c Fig. 2d

Fig. 2 a) Anteroposterior ankle radiograph demonstrating apparent talar shift with increased medial clear space. b) Lateral ankle radiograph of the same patient, demonstrating plantar flexion of the talus, with the smaller posterior aspect of the talus articulating with the mortise. c) Anteroposterior radiograph of the same patient with the ankle now in d) a plantargrade (neutral) position with elimination of the initial apparent talar shift.

both commonly cited as indications for surgery; radiographic assessment is often inaccurate as the size of this medial clear space is significantly affected not only by ankle flexion, but also the position of rotation that the leg is held in at the moment the radiograph is taken.[9,10] Moreover, several clinical trials reporting on the outcomes of 'stress-positive' ankle fractures, which would commonly be treated surgically, have in fact shown satisfactory union and return to normal function with nonoperative treatment.[7,11,12] The high false positive rate for stress radiographs undoubtedly leads to unnecessary surgical treatment of stable ankle fractures, with unwarranted risk.[13] Unfortunately, no other investigation, including assessment of deep deltoid ligament competency using magnetic resonance imaging, has been shown to be effective.[12]

In the absence of a useful diagnostic investigation, the simple dynamic walking test, whereby the patient is permitted to weight-bear as tolerated in a removable orthosis applied in the Emergency Department, seems to be most accurate and simple to administer: a subsequent outpatient radiograph taken within two weeks will identify unstable fractures with new talar shift. This policy, widely adopted in many UK centres with a significant reduction in unnecessary surgery, is supported by the current British Orthopaedic Association Standards for Trauma (BOAST) guidelines.[14,15]

NONOPERATIVE MANAGEMENT

A successful outcome after ankle fracture can be anticipated where the talus is reduced anatomically under the mortise and held there until fracture union, regardless of how this is achieved. Surgical management, even in the elderly, has been traditionally recommended for unstable fractures.[16] However, as surgery in this patient group is associated with significant complications, including secondary loss of reduction and infection,[17,18] there has been a recent revival of interest in conservative management, including close-contact casting (CCC). Willet et al[3] conducted the multicentre AIM trial, comparing CCC with internal fixation in 620 patients over 65 years of age. They reported equivalent patient-related outcome at six-months, despite an overall 12% rate of wound complications in the operative group. In the CCC group, 25% of patients required further manipulation or conversion to internal fixation, with a further 15% going on to malunion. This trial has demonstrated a potential role for nonoperative management in the elderly, but with 40% of patients failing to achieve satisfactory union after initial management, surgeons may prefer to continue with the more dependable internal fixation.

PERCUTANEOUS FIXATION

Open surgical fixation has changed little in the last 50 years, and a standard AO technique is favoured for most ankle fracture surgery in young, healthy patients; this traditionally consists of open reduction, lag screw fixation if possible, and neutralization with a lateral or posterolateral plate. However, there are well-documented complications associated with open surgery, including: prominent metalwork often requiring further surgery for removal;[19] wound dehiscence and infection, particularly in the elderly, in diabetics, and those with neuropathy or poor compliance;[20] and construct failure in fragile bone, with complication rates reported of up to 30%. Any of these complications results in compromised overall outcome.[20] Delaying surgery for in-patient elevation to allow soft tissues to 'settle' is expensive and increases wound infection rates four-fold.[21] Locking-plate technology does not improve stability, and also increases wound complications.[22] An alternative strategy, of percutaneous fibular nailing (Figs 3 and 4), addresses each of these problems with soft-tissue preservation and more robust biomechanical stability.[23] Jain et al[24] reviewed the outcomes of 1008 patients from 17 studies of intramedullary ankle fixation and reported 98.5% union rates and 91.3% good or excellent outcomes. Two prospective randomized trials

Fig. 3 The fibular nail is inserted and secured through three small percutaneous incisions, leaving the swollen and blistered 'high-risk' skin undisturbed.

have confirmed that fibular nailing reduces wound problems and produces comparable or better clinical outcomes to plate fixation, whilst reducing overall cost.[1,25] Care must be taken to observe some technical considerations,[26] and pragmatic multicentre trials are needed to confirm generalizability of the technique following these smaller randomized studies.

THE MEDIAL MALLEOLUS

The significance of the medial malleolus on ankle joint stability has long been debated. A landmark paper by Yablon et al[27] stated that "the talus always faithfully follows the lateral malleolus upon reduction", and this is almost certainly true except for supination-adduction fractures. Isolated medial malleolar fractures are managed well with conservative treatment, even in the presence of initial displacement.[28,29] In contrast, fixation of these fractures carries operative morbidity, including wound infection, metalwork prominence, and possible damage to the posterior tibial tendon and local neurovascular structures.[30,31] Minimally invasive percutaneous techniques and headless screws have shown promising results in small cohort studies.[32-34] Extrapolating this principle to the management of the medial component of bimalleolar and trimalleolar fractures also seems to hold true: recent interest in conservative management of well-reduced medial malleolar fractures following fibular stabilization have demonstrated equivalent outcomes to fixation groups, with the avoidance of medial-sided wound dehiscence, infection, and nonunion.[35] It seems likely that fixation of the medial malleolus, particularly in weak, osteoporotic bone, may add little to the stability of inversion-type ankle fractures, and further level 1 data are needed to confirm this concept.

Fig. 4 Anteroposterior radiograph taken six weeks following surgery for treatment of an isolated lateral malleolus fracture.

THE POSTERIOR MALLEOLUS

Posterior malleolar fractures are attracting increasing attention (Fig. 1), with a current vogue for plating even small fragments.[4,36] Some principles related to this injury are well established: ankles where the talus remains subluxed posteriorly after fixation of the medial and lateral malleoli need adjuvant posterior fixation to replace and hold the talus in the mortise;[37] CT scans usually reveal larger and more complex fractures than is appreciated on plain radiographs;[38] and fixation of a large posterior fragment may provide secondary stabilization of the syndesmosis, via an intact posterior-inferior tibiofibular ligament (PITFL).[39,40] Beyond this, there is uncertainty and key issues remain to be established, including: whether any other posterior malleolar fractures benefit from fixation;[4] whether routine CT scans can assist in planning surgery given that the indications for fixation have not been established; and whether the additional risks and costs of posterior plating (surgery in the prone position, additional surgical and tourniquet time, additional implants, an extensile exposure) are worthwhile, in comparison with the known benefits and risks of standard syndesmosis fixation techniques.[41]

Commonly quoted indications for posterior malleolar surgery include fragment size, usually described in terms of the percentage of the plafond involved on lateral radiographs. However, this has not been shown to be of relevance, either in biomechanical[42-45] or clinical[46] studies. Furthermore, not one of the clinical trials[47-51] or systematic reviews[37,46,52] published to date has confirmed any benefit from surgical fixation for any size of posterior malleolar fragment, provided the talus is not subluxed after medial and lateral fixation. In contrast, fixation has been associated with a substantial rate of malunion,[50,53] and other complications in up to 20% of patients,[46,48,51,54-59] some devastating.[59] Prospective clinical trials by interested groups to establish in which patients fixation has efficacy, followed by pragmatic trials to show generalizability, are needed before widespread uptake of this practice is justified.

THE SYNDESMOSIS

Of all the contentious areas of ankle fracture treatment, the syndesmosis has attracted the greatest interest (Fig. 1) and controversy. An early and much-quoted paper by Sagi et al[60] showed that failure to reduce the syndesmosis anatomically resulted in impaired functional outcomes, and a huge volume of subsequent research has sought to determine the best way to assess, reduce, and stabilize the syndesmosis.

Complete assessment of the anatomy of the syndesmosis is impossible on standard radiographs and fluoroscopic images. This is due to the frustral shape of the mortise, which results in major changes in the measured medial clear space (by a factor of two) and tibiofibular overlap (by a factor of five) with only minor degrees of limb rotation,[10] the considerable anatomical variation in the shape of the incisura fibularis,[61] and the fact that rotation of the fibula can only be judged on axial imaging. Judging when the syndesmosis is truly unstable, therefore, is problematic because many surgeons assess this intraoperatively using an external rotation stress test, looking at the medial clear space. This is often abnormal even when the syndesmosis is intact,[62] resulting in the same issue of overdiagnosis as discussed above. With many studies on 'syndesmotic instability' presumably incorporating large proportions of patients with stable ankles, interpretation of the literature is difficult, and it is not, perhaps, surprising that some studies have shown that syndesmotic fixation in these patients is unnecessary[63] or can indeed be deleterious.[64] The hook test, directly assessing opening of the syndesmosis, is more accurate and is greatly to be preferred.[62]

Where syndesmotic instability is confirmed, assessing whether the surgical reduction of the syndesmosis has been adequate after closed surgery, using fluoroscopy, results in the same uncertainties, and several studies have confirmed that open reduction through

5

Appendix

an anterior arthrotomy allows a more accurate reduction.[60] The reduction is easier to confirm with the foot in neutral (as opposed to plantarflexion), but dorsiflexion to 'prevent' blocking the talus is an unnecessary but surprisingly tenacious dogma.[65,66]

Holding the reduction intraoperatively can be more difficult than is often appreciated: reduction clamps result in a tendency to over-compress the sydesmosis,[67,68] and careful positioning of the medial tine on the anterior third of the tibia is important to avoid posterior translation,[69] particularly where the incisura is shallow.[70] Manual compression and stabilization seems to result in a more predictable anatomical reduction.[71]

Definitive fixation of the reduced syndesmosis can be achieved with either screws or suture-buttons. Screws have been used successfully for decades, although much debate has ensued over the details of how many screws to use, of what diameter, and whether to engage three or four cortices; there seem to be no important differences between these strategies, although a large fragment screw can be expected to result in a higher rate of later irritation.[72] The evidence does not support routine removal, which is quite unnecessary and courts unnecessary complications.[73,74] More controversial is the recent popularization of suture button devices, with the conceptual advantage of more physiological tibiofibular movement. Two (relatively small) randomized controlled trials (RCTs)[75,76] and eight comparative studies[77-84] have been published, along with three meta-analyses.[85-87] Despite some enthusiastic abstracts, none of the RCTs or meta-analyses show a clinically important difference in either functional or radiographic outcome. Certainly, screws are more cost-effective.[88] There is a concept, repeatedly described in the literature, that the suture button minimizes malreductions by its very flexibility, allowing the fibula to 'self-centre' and find its correct position in the incisura during intraoperative tightening. Although attractive, there is, in fact, no evidence for this; comparative data have been skewed by one cohort trial in which different surgeons performed the two different procedures.[79] Complicating the issue further are recent papers that question whether in fact minor imperfections in reduction do result in a functional difference as has been assumed to date: up to 3 mm translation and 15° rotation appear to be well tolerated.[89] Again, large prospective trials with long-term follow-up will be needed to show whether the higher cost of the suture button is justified.

POSTOPERATIVE MOBILIZATION

Allowing patients to weight-bear early following ankle fracture surgery has been standard practice in many centres for decades, but remains surprisingly controversial in some regions. Cadaveric studies have shown that fixed bimalleolar and trimalleolar fractures remain intact when cycled to represent physiological postoperative weight-bearing.[90] This basic science has been clinically examined in a recently published RCT by Dehghan et al.[91] A total of 110 patients, without syndesmotic injury or operatively managed posterior malleolar fractures, were randomly allocated following fixation to an early weight-bearing group, beginning at two weeks, or a late weight-bearing group, beginning at six weeks. Ankle range of movement was significantly higher in the early weight-bearing group, with no increased risk of failure or infection. Interestingly, patients in the late weight-bearing group experienced a significantly greater rate of troublesome metalwork. The reason for the initial two-week period of non-weight-bearing in this trial is unclear, and a systematic review by Black et al[92] of 555 ankle fractures managed with immediate weight-bearing after surgery confirms this to be unnecessary. Immediate weight-bearing was, in fact, strongly associated with improved range of movement, shorter hospital stays, quicker return to work, and improved patient reported outcome measures. Further convincing evidence by Smeeing et al,[93] in a review of 25 studies including a total of 1376 participants, has demonstrated additional benefit of early ankle exercises combined with early weight-bearing. Our recommended practice is to allow all patients to weight-bear fully in a removable boot unless there is a confirmed syndesmotic injury or significant peripheral neuropathy, in which case patients are instructed to bear no weight for between six and eight weeks following surgery. All patients are strongly encouraged to perform early range of movement exercises, out of boot, to facilitate recovery.

VENOUS THROMBOEMBOLISM

There is now good evidence that thromboprophylaxis is not justified in the management of most ankle fractures. Despite this, there remains concern, driven by well-publicized case reports and the fear of litigation.[94] Most studies, meta-analyses, and guidelines are compromised because they use (surrogate) venographically detected deep vein thrombosis (DVT) as their primary outcome measure. Two recent trials have instead focused on 'clinically important VTE' (CIVTE). The first examined 265 patients with isolated lower limb fractures randomized to either Dalteparin 5000 IU daily for two weeks, or a placebo injection.[95] Interim analysis demonstrated two CIVTEs in the intervention group and three in the placebo group, offset by a slightly higher rate of minor bleeding in the heparin group. The overall rate of CIVTE, at 2%, was considerably lower than allowed for by the initial power calculations, and faced with the inability to complete recruitment to the trial, the steering committee opted to halt the study early. The second study examined 1435 injuries of the lower limb treated in cast, of which 479 were ankle fractures and 94 were tendo Achilles disruptions.[96] The study group received 2500 IU Dalteparin whilst they were in cast (a duration of between three and seven weeks), the control group received a placebo. In the final analysis, there were ten CIVTEs (1.4%) in the intervention group and 13 (1.8%) in the placebo group, which was not statistically significantly different. The conclusions that can be drawn from these two RCTs is that the incidence of CIVTE is low, and that prophylaxis is ineffective in reducing these events. Given the possible adverse effects of prophylaxis (such as haemorrhage and heparin-induced thrombocytopaenia), the risks are greater than the benefits for most patients, although there may be some patients at elevated risk of VTE for whom the risks of thromboprophylaxis might be justified. A precautionary principle seems reasonable, using risk assessment to identify patients with a personal or first-degree family history of a prothrombotic condition, a history of malignancy, morbid obesity, or prothrombotic drugs such as unopposed oestrogens.

CONCLUSION

Ankle fracture fixation is one of the most commonly undertaken orthopaedic procedures, and in healthy young patients many fractures can be treated successfully using standard AO techniques in a manner largely unchanged for half a century. However, this is a time of considerable academic interest and innovation, bringing with it the possibility of exciting advances in patient care, particularly in those 'unsolved' injuries with complex disruptions,

6

bone fragility, and compromised soft tissues. The concepts of ankle stability, syndesmotic function, and the role of the posterior malleolus are particularly fascinating and deserving of further research. As always, the challenge for our specialty is to train the next generation of surgeons to perform the operations that work well with understanding and skill, and to investigate critically those areas needing innovation and improvement.

REFERENCES

1. **Asloum Y, Bedin B, Roger T, et al.** Internal fixation of the fibula in ankle fractures: a prospective, randomized and comparative study: plating versus nailing. *Orthop Traumatol Surg Res* 2014;100(4 Suppl):S255–9.
2. **Briggs TWR.** *Getting It Right First Time - Improving the Quality of Orthopaedic Care within the National Health Service in England.* NHS England, 2012, 1–34.
3. **Willett K, Keene DJ, Mistry D, et al.** Close contact casting vs surgery for initial treatment of unstable ankle fractures in older adults: a randomized clinical trial. *JAMA* 2016;316:1455–1463.
4. **White TO.** In defence of the posterior malleolus. *Bone Joint J* 2018;100-B:566–569.
5. **Kristensen KD, Hansen T.** Closed treatment of ankle fractures. Stage II supination-eversion fractures followed for 20 years. *Acta Orthop Scand* 1985;56:107–109.
6. **DeAngelis NA, Eskander MS, French BG.** Does medial tenderness predict deep deltoid ligament incompetence in supination-external rotation type ankle fractures? *J Orthop Trauma* 2007;21:244–247.
7. **Egol KA, Amirtharajah M, Tejwani NC, Capla EL, Koval KJ.** Ankle stress test for predicting the need for surgical fixation of isolated fibular fractures. *J Bone Joint Surg [Am]* 2004;86-A:2393–2398.
8. **McConnell T, Creevy W, Tornetta P 3rd.** Stress examination of supination external rotation-type fibular fractures. *J Bone Joint Surg [Am]* 2004;86-A:2171–2178.
9. **Park SS, Kubiak EN, Egol KA, Kummer F, Koval KJ.** Stress radiographs after ankle fracture: the effect of ankle position and deltoid ligament status on medial clear space measurements. *J Orthop Trauma* 2006;20:11–18.
10. **Pneumaticos SG, Noble PC, Chatziioannou SN, Trevino SG.** The effects of rotation on radiographic evaluation of the tibiofibular syndesmosis. *Foot Ankle Int* 2002;23:107–111.
11. **Tornetta P 3rd, Axelrad TW, Sibai TA, Creevy WR.** Treatment of the stress positive ligamentous SE4 ankle fracture: incidence of syndesmotic injury and clinical decision making. *J Orthop Trauma* 2012;26:659–661.
12. **Koval KJ, Egol KA, Cheung Y, Goodwin DW, Spratt KF.** Does a positive ankle stress test indicate the need for operative treatment after lateral malleolus fracture? A preliminary report. *J Orthop Trauma* 2007;21:449–455.
13. **Toth MJ, Yoon RS, Liporace FA, Koval KJ.** What's new in ankle fractures. *Injury*. 2017;48:2035–2041.
14. **Gougoulias N, Sakellariou A.** When is a simple fracture of the lateral malleolus not so simple? how to assess stability, which ones to fix and the role of the deltoid ligament. *Bone Joint J* 2017;99-B:851–855.
15. **No authors listed.** British Orthopaedic Association Audit Standards for Trauma (BOAST) 12: The Management of Ankle Fractures. 2016. https://www.boa.ac.uk/wp-content/uploads/2016/09/BOAST-12-Ankle-Fractures.pdf (date last accessed 19 June 2018).
16. **Ehrenfreund T, Haluzan D, Dobric I, et al.** Operative management of unstable ankle fractures in the elderly: our institutional experience. *Injury* 2013;44 Suppl 3:S20–22.
17. **Zaghloul A, Haddad B, Barksfield R, Davis B.** Early complications of surgery in operative treatment of ankle fractures in those over 60: a review of 186 cases. *Injury*. 2014;45:780–783.
18. **Rammelt S.** Management of ankle fractures in the elderly. *EFORT Open Rev* 2017;1:239–246.
19. **Brown OL, Dirschl DR, Obremskey WT.** Incidence of hardware-related pain and its effect on functional outcomes after open reduction and internal fixation of ankle fractures. *J Orthop Trauma* 2001;15:271–274.
20. **Miller AG, Margules A, Raikin SM.** Risk factors for wound complications after ankle fracture surgery. *J Bone Joint Surg [Am]* 2012;94-A:2047–2052.
21. **Schepers T, De Vries MR, Van Lieshout EM, Van der Elst M.** The timing of ankle fracture surgery and the effect on infectious complications; a case series and systematic review of the literature. *Int Orthop* 2013;37:489–494.
22. **Schepers T, Van Lieshout EM, De Vries MR, Van der Elst M.** Increased rates of wound complications with locking plates in distal fibular fractures. *Injury* 2011;42:1125–1129.
23. **Smith G, Mackenzie SP, Wallace RJ, Carter T, White TO.** Biomechanical comparison of intramedullary fibular nail versus plate and screw fixation. *Foot Ankle Int* 2017;38:1394–1399.
24. **Jain S, Haughton BA, Brew C.** Intramedullary fixation of distal fibular fractures: a systematic review of clinical and functional outcomes. *J Orthop Traumatol* 2014;15:245–254.
25. **White TO, Bugler KE, Appleton P, et al.** A prospective randomised controlled trial of the fibular nail versus standard open reduction and internal fixation for fixation of ankle fractures in elderly patients. *Bone Joint J* 2016;98-B:1248–1252.
26. **Mackenzie SP.** The fibular nail experience: clinical and patient reported outcomes. *British Orthopaedic Association (BOA) Annual Congress*. Liverpool. 2017.
27. **Yablon IG, Heller FG, Shouse L.** The key role of the lateral malleolus in displaced fractures of the ankle. *J Bone Joint Surg [Am]*. 1977;59-A:169–173.
28. **Herscovici D Jr, Scaduto JM, Infante A.** Conservative treatment of isolated fractures of the medial malleolus. *J Bone Joint Surg [Br]* 2007;89-B:89–93.
29. **Hanhisuanto S, Kortekangas T, Pakarinen H, Flinkkila T, Leskela HV.** The functional outcome and quality of life after treatment of isolated medial malleolar fractures. *Foot Ankle Surg*. 2017; 23: 225-229.
30. **Zalavras CG, Christensen T, Rigopoulos N, Holtom P, Patzakis MJ.** Infection following operative treatment of ankle fractures. *Clin Orthop Relat Res* 2009;467:1715–1720.
31. **DeMill SL, Bussewitz BW, Philbin TM.** Injury to the posterior tibial tendon after open reduction internal fixation of the medial malleolus. *Foot Ankle Spec* 2015;8:360–363.
32. **Smith M, Medlock G, Johnstone AJ.** Percutaneous screw fixation of unstable ankle fractures in patients with poor soft tissues and significant co-morbidities. *Foot Ankle Surg* 2017;23:16–20.
33. **Weinraub GM, Levine P, Shi E, Flowers A.** Comparison of medial malleolar fracture healing at 8 weeks after open reduction internal fixation versus percutaneous fixation: a retrospective cohort study. *J Foot Ankle Surg* 2017;56:277–281.
34. **Bulut T, Gursoy M.** Isolated medial malleolus fractures: conventional techniques versus headless compression screw fixation. *J Foot Ankle Surg* 2018;57:552–556.
35. **Hoelsbrekken SE, Kaul-Jensen K, Mørch T, et al.** Nonoperative treatment of the medial malleolus in bimalleolar and trimalleolar ankle fractures: a randomized controlled trial. *J Orthop Trauma* 2013;27:633–637.
36. **Solan MC, Sakellariou A.** Posterior malleolus fractures: worth fixing. *Bone Joint J* 2017;99-B:1413-1419.
37. **Odak S, Ahluwalia R, Unnikrishnan P, Hennessy M, Platt S.** Management of posterior malleolar fractures: a systematic review. *J Foot Ankle Surg* 2016;55:140–145.
38. **Ferries JS, DeCoster TA, Firoozbakhsh KK, Garcia JF, Miller RA.** Plain radiographic interpretation in trimalleolar ankle fractures poorly assesses posterior fragment size. *J Orthop Trauma* 1994;8:328–331.
39. **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.
40. **Miller MA, McDonald TC, Graves ML, et al.** Stability of the syndesmosis after posterior malleolar fracture fixation. *Foot Ankle Int* 2018;39:99–104.
41. **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;468:1129–1135.
42. **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.
43. **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:347–351.
44. **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;18:271–278.
45. **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:1201–1206.
46. **Veltman ES, Halma JJ, de Gast A.** Longterm outcome of 886 posterior malleolar fractures: A systematic review of the literature. *Foot Ankle Surg* 2016;22:73–77.
47. **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:1348–1356.
48. **Langenhuijsen JF, Heetveld MJ, Ultee JM, Steller EP, Butzelaar RM.** Results of ankle fractures with involvement of the posterior tibial margin. *J Trauma* 2002;53:55–60.
49. **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;44:211–217.
50. **Xu HL, Li X, Zhang DY, et al.** A retrospective study of posterior malleolus fractures. *Int Orthop* 2012;36:1929–1936.

7

51. **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:812–817.

52. **van den Bekerom MP, Haverkamp D, Kloen P.** Biomechanical and clinical evaluation of posterior malleolar fractures. A systematic review of the literature. *J Trauma* 2009;66:279–284.

53. **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;36:673–678.

54. **Mingo-Robinet J, López-Durán L, Galeote JE, Martinez-Cervell C.** Ankle fractures with posterior malleolar fragment: management and results. *J Foot Ankle Surg* 2011;50:141–145.

55. **Choi JY, Kim JH, Ko HT, Suh JS.** Single oblique posterolateral approach for open reduction and internal fixation of posterior malleolar fractures with an associated lateral malleolar fracture. *J Foot Ankle Surg* 2015;54:559–564.

56. **Karbassi JA, Braziel A, Garas PK, Patel AR.** Open reduction internal fixation of posterior malleolus fractures and iatrogenic injuries: a cadaveric study. *Foot Ankle Spec* 2016;1938640016670242 (Epub ahead of print) PMID: 27654460.

57. **Patel A, Charles L, Ritchie J.** A complication of posterior malleolar fracture fixation. *J Foot Ankle Surg* 2016;55:383–386.

58. **Shi HF, Xiong J, Chen YX, Wang JF, Qiu XS, Huang J, et al.** Comparison of the direct and indirect reduction techniques during the surgical management of posterior malleolar fractures. *BMC Musculoskelet Disord* 2017;18:109.

59. **Sandelin H, Tukiainen E, Ovaska M.** Amputation following internal fixation of an ankle fracture via the posterolateral approach - a case report. *Acta Orthop* 2017;88:358–360.

60. **Sagi HC, Shah AR, Sanders RW.** The functional consequence of syndesmotic joint malreduction at a minimum 2-year follow-up. *J Orthop Trauma* 2012;26:439–443.

61. **Gardner MJ, Demetrakopoulos D, Briggs SM, Helfet DL, Lorich DG.** Malreduction of the tibiofibular syndesmosis in ankle fractures. *Foot Ankle Int* 2006;27:788–792.

62. **Stoffel K, Wysocki D, Baddour E, Nicholls R, Yates P.** Comparison of two intraoperative assessment methods for injuries to the ankle syndesmosis. A cadaveric study. *J Bone Joint Surg [Am]* 2009;91-A:2646–2652.

63. **Pakarinen HJ, Flinkkilä TE, Ohtonen PP, et al.** Syndesmotic fixation in supination-external rotation ankle fractures: a prospective randomized study. *Foot Ankle Int* 2011;32:1103–1109.

64. **Kortekangas TH, Pakarinen HJ, Savola O, et al.** Syndesmotic fixation in supination-external rotation ankle fractures: a prospective randomized study. *Foot Ankle Int* 2014;35:988–995.

65. **Pallis MP, Pressman DN, Heida K, Nicholson T, Ishikawa S.** Effect of ankle position on tibiotalar motion with screw fixation of the distal tibiofibular syndesmosis in a fracture model. *Foot Ankle Int* 2018;39:746–750.

66. **Tornetta P 3rd, Spoo JE, Reynolds FA, Lee C.** Overtightening of the ankle syndesmosis: is it really possible? *J Bone Joint Surg [Am]* 2001;83-A:489–492.

67. **Cherney SM, Haynes JA, Spraggs-Hughes AG, et al.** In vivo syndesmotic overcompression after fixation of ankle fractures with a syndesmotic injury. *J Orthop Trauma* 2015;29:414–419.

68. **Haynes J, Cherney S, Spraggs-Hughes A, et al.** Increased reduction clamp force associated with syndesmotic overcompression. *Foot Ankle Int* 2016;37:722–729.

69. **Cosgrove CT, Putnam SM, Cherney SM, et al.** Medial clamp tine positioning affects ankle syndesmosis malreduction. *J Orthop Trauma* 2017;31:440–446.

70. **Cherney SM, Spraggs-Hughes AG, McAndrew CM, Ricci WM, Gardner MJ.** Incisura morphology as a risk factor for syndesmotic malreduction. *Foot Ankle Int* 2016;37:748–754.

71. **Cosgrove CT, Spraggs-Hughes AG, Putnam SM, et al.** A novel indirect reduction technique in ankle syndesmotic injuries: a cadaveric study. *J Orthop Trauma* 2018 (Epub ahead of print) PMID: 29738403.

72. **Peek AC, Fitzgerald CE, Charalambides C.** Syndesmosis screws: how many, what diameter, where and should they be removed? A literature review. *Injury* 2014;45:1262–1267.

73. **Dingemans SA, Rammelt S, White TO, Goslings JC, Schepers T.** Should syndesmotic screws be removed after surgical fixation of unstable ankle fractures? a systematic review. *Bone Joint J* 2016;98-B:1497–1504.

74. **Schepers T, Van Lieshout EM, de Vries MR, Van der Elst M.** Complications of syndesmotic screw removal. *Foot Ankle Int* 2011;32:1040–1044.

75. **Kortekangas T, Savola O, Flinkkilä T, et al.** A prospective randomised study comparing TightRope and syndesmotic screw fixation for accuracy and maintenance of syndesmotic reduction assessed with bilateral computed tomography. *Injury* 2015;46:1119–1126.

76. **Laflamme M, Belzile EL, Bédard L, et al.** A prospective randomized multicenter trial comparing clinical outcomes of patients treated surgically with a static or dynamic implant for acute ankle syndesmosis rupture. *J Orthop Trauma* 2015;29:216–223.

77. **Kim JH, Gwak HC, Lee CR, et al.** A comparison of screw fixation and suture-button fixation in a syndesmosis injury in an ankle fracture. *J Foot Ankle Surg* 2016;55:985–990.

78. **Seyhan M, Donmez F, Mahirogullari M, et al.** Comparison of screw fixation with elastic fixation methods in the treatment of syndesmosis injuries in ankle fractures. *Injury* 2015;46(Suppl 2):S19–S23.

79. **Naqvi GA, Cunningham P, Lynch B, Galvin R, Awan N.** Fixation of ankle syndesmotic injuries: comparison of tightrope fixation and syndesmotic screw fixation for accuracy of syndesmotic reduction. *Am J Sports Med* 2012;40:2828–2835.

80. **Cottom JM, Hyer CF, Philbin TM, Berlet GC.** Transosseous fixation of the distal tibiofibular syndesmosis: comparison of an interosseous suture and endobutton to traditional screw fixation in 50 cases. *J Foot Ankle Surg* 2009;48:620–630.

81. **Thornes B.** Comparison of a novel Fiberwire-button construct versus metallic screw fixation in a syndesmotic injury model. *Foot Ankle Int* 2008;29:465.

82. **Coetzee JCEP.** Treatment of syndesmoses disruptions: a prospective, randomized study comparing conventional screw fixation vs TightRope fiber wire fixation—medium term results. *SA Orthop J* 2009;8:32–37.

83. **Kocadal O, Yucel M, Pepe M, Aksahin E, Aktekin CN.** Evaluation of reduction accuracy of suture-button and screw fixation techniques for syndesmotic injuries. *Foot Ankle Int* 2016;37:1317–1325.

84. **Neary KC, Mormino MA, Wang H.** Suture Button fixation versus syndesmotic screws in supination-external rotation type 4 injuries: a cost-effectiveness analysis. *Am J Sports Med* 2017;45:210–217.

85. **Inge SY, Pull Ter Gunne AF, Aarts CA, Bemelman M.** A systematic review on dynamic versus static distal tibiofibular fixation. *Injury* 2016;47:2627–2634.

86. **Chen B, Chen C, Yang Z, et al.** To compare the efficacy between fixation with tightrope and screw in the treatment of syndesmotic injuries: A meta-analysis. *Foot Ankle Surg* 2017 (Epub ahead of print) PMID: 29409259.

87. **Zhang P, Liang Y, He J, et al.** A systematic review of suture-button versus syndesmotic screw in the treatment of distal tibiofibular syndesmosis injury. *BMC Musculoskelet Disord* 2017;18:286.

88. **Ramsey DC, Friess DM.** Cost-effectiveness analysis of syndesmotic screw versus suture button fixation in tibiofibular syndesmotic injuries. *J Orthop Trauma* 2018;32:e198–203.

89. **Cherney SM, Cosgrove CT, Spraggs-Hughes AG, et al.** Functional outcomes of syndesmotic injuries based on objective reduction accuracy at a minimum 1-year follow-up. *J Orthop Trauma* 2018;32:43–51.

90. **Tan EW, Sirisreetreerux N, Paez AG, et al.** Early weightbearing after operatively treated ankle fractures: a biomechanical analysis. *Foot Ankle Int* 2016;37:652–658.

91. **Dehghan N, McKee MD, Jenkinson RJ, et al.** Early weightbearing and range of motion versus non-weightbearing and immobilization after open reduction and internal fixation of unstable ankle fractures: a randomized controlled trial. *J Orthop Trauma* 2016;30:345–352.

92. **Black JD, Bhavikatti M, Al-Hadithy N, Hakmi A, Kitson J.** Early weight-bearing in operatively fixed ankle fractures: a systematic review. *Foot* 2013;23:78–85.

93. **Smeeing DP, Houwert RM, Briet JP, et al.** Weight-bearing and mobilization in the postoperative care of ankle fractures: a systematic review and meta-analysis of randomized controlled trials and cohort studies. *PLoS One* 2015;10:e0118320 (Epub ahead of print) PMID: 25695796.

94. **Chen L, Soares D.** Fatal pulmonary embolism following ankle fracture in a 17-year-old girl. *J Bone Joint Surg [Br]* 2006;88-B:400–401.

95. **Selby R, Geerts WH, Kreder HJ, et al.** A double-blind, randomized controlled trial of the prevention of clinically important venous thromboembolism after isolated lower leg fractures. *J Orthop Trauma* 2015;29:224–230.

96. **van Adrichem RA, Nemeth B, Algra A, et al.** Thromboprophylaxis after knee arthroscopy and lower-leg casting. *N Engl J Med* 2017;376:515–525.

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Appendix

Appendix 5

ORIGINAL ARTICLE

Optimizing Long-Term Outcomes and Avoiding Failure With the Fibula Intramedullary Nail

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Objectives: To identify risk factors for fixation failure, report patient outcomes, and advise on modifications to the surgical technique for fibula nail stabilization of unstable ankle fractures.

Design: Retrospective review.

Setting: Academic orthopaedic trauma unit.

Patients: All 342 patients were identified retrospectively from a prospectively collected single-center trauma database over a 9-year period.

Intervention: Unstable ankle fractures managed surgically with a fibula nail.

Main Outcome Measurements: The primary short-term outcome was failure, defined as any case that required revision surgery because of an inadequate mechanical construct. The mid-term outcomes included the Olerud–Molander Ankle Score and the Manchester–Oxford Foot Questionnaire.

Results: Twenty failures occurred (6%), of which 7 (2%) were due to device failure and 13 (4%) due to surgeon error. Of the surgeon errors, 8 consisted of inappropriate weight-bearing after syndesmotic diastasis, and 5 were due to inadequate fracture reduction or poor nail placement. Proximal locking screw (PLS) pull-out was the cause of all device failures. Positioning the PLS >20 mm above the plafond significantly increased failure risk ($P = 0.003$). At a mean follow-up of 5.1 years (range, 8 months–8 years) the median Olerud–Molander Ankle Score and Manchester–Oxford Foot Questionnaire were 80 (interquartile range, 45) and 10.94 (interquartile range, 44.00), respectively. Patient outcome was not negatively affected by the requirement for revision surgery.

Conclusions: The fibula nail offers secure fixation and good patient-reported outcomes for unstable ankle fractures. Appropriate postoperative management and surgical technique, including careful placement of the PLS, is essential to minimize construct failure risk.

Key Words: trauma, ankle fracture, fibula nail, failure, patient outcome

Level of Evidence: Therapeutic Level IV. See Instructions for Authors for a complete description of levels of evidence.

(*J Orthop Trauma* 2019;33:189–195)

INTRODUCTION

Open reduction and internal fixation is the most common method used in the management of unstable ankle fractures. The incidence and severity of ankle fractures in the elderly is steadily rising.[1,2] In this multicomorbid patient group, high rates of postoperative complications are reported, including but not limited to infection, wound breakdown, implant prominence, and failed fixation.[3–7] Minimally invasive intramedullary fibula fixation using a series of percutaneous stab incisions (see **Figure**, **Supplemental Digital Content 1**, http://links.lww.com/JOT/A564, which demonstrates the small stab incisions) is supported by prospective randomized controlled trials, demonstrating a reduction in lateral sided infection and implant removal rates.[8] Recently published laboratory work has confirmed the superior biomechanical properties of this intramedullary technique.[9]

As with any method of fixation, correct technique and postoperative management is essential. The evolution of the fibula nail technique was described by Bugler et al[10] and emphasizes the importance of correct nail placement and the insertion of at least 2 locking screws; an anteroposterior distal locking screw (DLS), and a proximal locking screw (PLS) that traverses the fibula and syndesmosis to engage

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the tibia (see **Figure**, **Supplemental Digital Content 2**, http://links.lww.com/JOT/A565, which demonstrates the radiological outcome of a "gold-standard" technique). The reporting of patient outcome and the assessment of fixation failures is essential to allow a greater understanding of this method and to allow further refinement of the surgical technique.

This study aims to investigate the short- and mid-term outcomes of unstable ankle fractures managed with fibula nail fixation. The rates of failure, modes and risk factors for failure, as well as the patient-reported outcomes are presented.

PATIENTS AND METHODS

This study was reviewed by the local NHS Research Ethics Service and registered with the local musculoskeletal quality improvement group. A prospectively compiled trauma database between 2008 and 2016 was retrospectively reviewed, identifying 342 patients over the age of 16 years who had undergone fibula nail fixation of an unstable ankle fracture. All patients were managed according to the surgical principles outlined in the article by Bugler et al. Patient demographics, radiographic parameters, and outcomes including infection rates, interventions for infection, and further surgery for removal of implants were recorded.

Radiographic Analysis

Analysis of digitalized radiographs was performed using the Picture Archiving and Communication System (PACs, Rochester, NY: Carestream Health, Inc). Preoperative radiographs were classified according to Orthopaedic Trauma Association Classification and Lauge-Hansen systems,[11,12] and the presence of distal tibiofibula diastasis was noted. Intraoperative fluoroscopy images were scrutinized to establish adequacy of talar reduction and implant position. Radiographic criteria of reduction quality including talar reduction was classified as "anatomical," "fair," or "poor" according to Burwell and Charnley.[13] Surgical construct assessment included fibula nail length and width, number of DLS, number of PLS, length of PLS(s), and distance of the PLS from the tibial plafond (see **Figure**, **Supplemental Digital Content 2**, http://links.lww.com/JOT/A565, which demonstrates the radiological outcome of a "gold-standard" technique). Postoperative radiographs were assessed for talar malreduction and fixation failure requiring revision surgery. Failures were divided into 2 categories: (1) surgical error or (2) device failure. Surgical errors were subdivided into inadequate reduction/poor nail insertion technique, or the failure to prescribe or maintain postoperative protection of a syndesmotic injury. A failure was attributed to the device if it occurred after appropriate operative technique and satisfactory postoperative management. Device failures were subdivided into failure of the nail, DLS(s), or PLS(s). Correlation was sought between device failure, injury characteristics, and intraoperative markers of nail placement.

Management

A total of 52 surgeons performed the operations under the supervision of 12 Orthopaedic Trauma Consultants. Procedures were performed under thigh tourniquet control and after the administration of intravenous antibiotics. The first generation Acumed fibula nail (Hillsboro, OR) was used in all cases. This solid titanium implant is available in 2 diameters (3 and 3.6 mm) and 3 lengths (110, 145, and 180 mm). Where possible, the wider nail is used with a length that allows passage of the nail at least 20 mm beyond the fracture. Treatment of a bony medial malleolar component was at the discretion of the operating surgeon and included nonoperative management, 3.5 mm partially threaded cancellous screws, or tension band wire construct. Posterior malleolus fractures were predominantly managed operatively only if they contributed to posterior subluxation of the talus when assessed intraoperatively, using percutaneously inserted anteroposterior 3.5 mm partially threaded cancellous screws or application of a posterior tibial buttress plate. Postoperatively, patients were placed in a removable orthosis or cast and allowed to mobilize fully weight-bearing immediately, with the exception of those with a syndesmotic injury who were not permitted to weight-bear for 6–8 weeks.

Short-Term Follow-up

The primary short-term outcome failure was defined as any case that required revision surgery because of an inadequate mechanical construct. Patients underwent short-term follow-up assessment at our center, which is the single provider of orthopaedic trauma care in the region. All patients underwent at minimum of 2 postoperative clinical and radiographic reviews, the first at 2 weeks and the second between 6 and 8 weeks. Mean short-term follow-up was 6 months (range, 6 weeks–7 years). Complications including any subsequent surgeries were recorded. Subsequent review, including physiotherapy, was at the discretion of the treating surgeon. Implants were only removed if the patient was symptomatic.

Mid-term Follow-up

Patients were contacted either by postal questionnaire and/or structured telephone interview to complete a series of validated general and ankle specific patient-reported outcome measures, including the EuroQol-5D (EQ-5D),[14] with 1 indicating the best outcome, Olerud–Molander Ankle Score (OMAS),[15] with 100 indicating the best outcome and the Manchester–Oxford Foot Questionnaire (MOXFQ),[16] with 0 indicating the best outcome. Time to return to work and sport was recorded, along with a pain score and overall satisfaction recorded as a visual analogue scale (VAS), with 100 indicating the best possible outcome.

Statistical Analysis

Data were analyzed using IBM SPSS software version 23.0 (Armonk, NY: IBM Corp). The Shapiro–Wilk test was used to assess normality of continuous data. A Student unpaired t test was used to analyze parametric continuous data. The Mann–Whitney U test was used to compare nonparametric continuous data. Categorical binary data were analyzed using either the χ^2 test (all observed frequencies in each cell >5) or the Fisher 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

Demographics

In our study cohort of 342 patients, the mean age at surgery was 64.6 years (range, 21–96 years). There were 251 women (73%) and 91 men (27%). The median number of medical comorbidities was 3 [interquartile range (IQR), 3] per patient. Sixty-one patients (18%) had diabetes mellitus, of which 25 (7% of total cohort and 41% of diabetic group) were insulin-dependent and 20 patients (6% of total cohort and 33% of diabetic group) had peripheral neuropathy. Forty-five patients (13%) were obese with a body mass index >30 kg/m², 29 patients (8%) had chronic renal impairment, and 14 patients (4%) were taking long-term steroid medication at the time of surgery. A syndesmotic injury was present in 60 cases (18%). According to the Orthopaedic Trauma Association classification, there were 280 (82%) 44-B2/44-B3 fractures, 45 (13%) 44-C2 fractures, and 17 (5%) 44-C1 fractures. According to the Lauge-Hansen classification of ankle fractures, there were 270 (79%) supination-external rotation (SER) type fractures, 46 (13%) pronation-abduction (PAB) type fractures, 19 (6%) pronation-external rotation type fractures, and 7 (2%) supination-adduction type fractures.

Short-Term Outcome

Surgical Construct Failure

Construct failure occurred in 20 cases (6%). Thirteen (4%) of these were due to surgeon error and 7 (2%) due to device failure. Patient comorbidity was comparable with the total cohort with a median number of comorbidities of 3 (IQR, 4) per patient. Three patients (15%) had diabetes mellitus, of which 2 were insulin-dependent (10%) and 1 (5%) had peripheral neuropathy. Two patients (10%) were obese, 1 patient (5%) had chronic renal impairment and 1 patient (5%) was taking long-term steroid medication. A summary of failed cases and revision procedures is presented in Table 1. All failures occurred within 12 weeks of surgery and, in keeping with our patient demographic, were mainly in women (15 cases, 75%) with a mean age of 62.0 years (range, 24–93 years). Most surgeon errors were due to inadequate protection of a distal tibiofibula diastasis (8 cases, 40%), an issue that is not limited to the fibula nail (Fig. 1). Five cases failed because of poor intraoperative technique or talar reduction (Fig. 2). An "anatomical" or "fair" reduction quality was achieved with the fibula nail

TABLE 1. Fibular Nail Failures and Details of Revision Procedures

Case	Age	Injury	Description of Failure	Revision Procedure(s)
Surgeon error: malreduction or poor nail insertion technique				
1	63	SER	Failure to engage the distal fragment	Conversion to plates and screws
2	60	SER	Failure to engage the distal fragment	Conversion to ilizarov frame
3	78	SER	Inadequate talar reduction	Conversion to plates and screws
4	61	SER	Inadequate talar reduction	Conversion to plates and screws
5	56	PAB	Inadequate talar reduction	Nail revision with 2 PLS
Surgeon error: postoperative instructions				
6	56	SER	Inadequate syndesmotic protection	Addition of second PLS
7	87	PAB	Inadequate syndesmotic protection	Addition of second PLS
8	24	PER	Inadequate syndesmotic protection	Addition of second PLS
9	40	SER	Inadequate syndesmotic protection	Addition of second PLS
10	54	SER	Inadequate syndesmotic protection	Addition of second PLS
11	54	SER	Inadequate syndesmotic protection	Conversion to 4-hole 1/3 tubular plate and 3x trans-syndesmotic screws
12	37	PAB	Inadequate syndesmotic protection	Addition of second PLS
13	48	PAB	Inadequate syndesmotic protection	Addition of second PLS
Device failure: PLS related				
14	93	SER	PLS pull-out	Addition of second PLS to construct
15	74	SER	PLS pull-out	Addition of second PLS to construct
16	86	PAB	PLS pull-out	Addition of second PLS to construct
17	60	PAB	PLS pull-out	Conversion to steinman pins and cast
18	68	SER	PLS pull-out	PLS re-tightened to engage nail
19	66	SER	PLS pull-out	Conversion to plates and screws
20	72	SER	PLS pull-out	Addition of second PLS to construct Further failure with conversion to DC plate and screws

DCP, dynamic compression plate; PER, pronation-external rotation.

Appendix

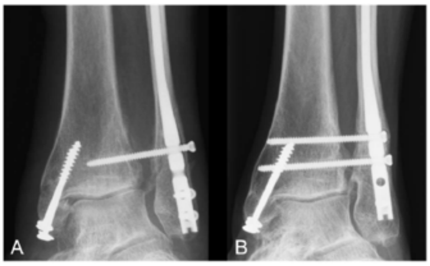

FIGURE 1. Anteroposterior radiograph from a 56-year-old patient who was allowed to fully weight-bear after surgery, despite recognized syndesmotic injury, demonstrating loosening of the PLS and a diastasis seen 4 weeks postoperatively (A). Final radiograph 2 years after revision surgery with deeper nail implantation, an additional PLS and non–weight-bearing restrictions for 8 weeks postoperatively (B).

device in 330 cases (96%), with 148 cases (43%) of anatomical reduction and 182 cases (53%) of fair reduction according to the Burwell and Charnley classification. Of the 12 cases of "poor" quality reduction, 2 required revision and are included in the failure cohort.

All 7 device failures occurred in relation to the PLS, in patients 60 years of age or older, with a mean age of 74 years (range, 60–93 years), 10 years older than the mean total study cohort (Fig. 3). Three of these patients had an established radiological diagnosis of osteoporosis, on pharmacological treatment.

More than half of these cases were salvaged by the addition of a second PLS or tightening of the PLS to engage the nail if the lateral fibula cortex was either comminuted or too porotic to achieve adequate buttress with the screw head. Both revision procedures were achieved through small stab incisions. There were no cases

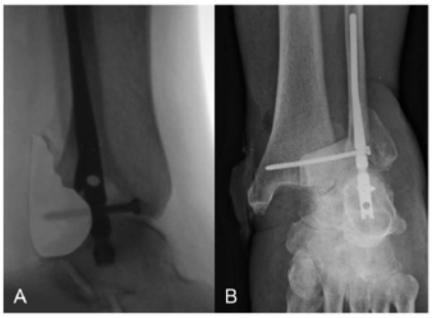

FIGURE 2. Intraoperative lateral radiograph demonstrating inadequate fracture reduction and stabilization, with the nail completely missing the distal fragment, highlighted in orange (A). The construct failed rapidly 10 days after surgery, with the talus after the unfixed lateral malleolar fragment posteriorly (B), eventually requiring a salvage arthrodesis. **Editor's Note:** A color image accompanies the online version of this article.

of nail breakage or DLS failure. Significant independent risk factors for construct failure include syndesmosis injury, PAB type fracture patterns and Weber-C injuries (see **Table, Supplemental Digital Content 3**, http://links.lww.com/JOT/A566, which summarizes the independent risk factors for construct failure). Constructs were more likely to fail if the PLS was inserted >20 mm above the level of the plafond ($P = 0.003$).

Soft-Tissue Complications

Thirteen patients (4%) required further surgery because of noninfected symptomatic implants, including removal of the fibula nail and all locking screw in 5 cases, the PLS in 5 cases, and the DLS in 3 cases. Lateral side infection occurred in 9 (3%) patients, 6 of whom required oral antibiotics, 2 required intravenous antibiotics, and 3 required removal of nail, supplemented by intravenous antibiotics. The overall reoperation rate for lateral soft-tissue prominence or infective complications was 5% (16 patients).

Mid-term Patient-Reported Outcomes

Out of the total cohort, 55 patients were deceased at the point of outcome score collection, leaving 287 for review. Patient-reported outcome measures were collected from 229 patients (80% response rate) with a mean follow-up of 5.1 years (range, 8 months–8 years). Out of the cohort of 20 failed cases, 3 were deceased, leaving 17 patients for review, of which 12 were contactable (71%).

Validated outcome scores in general demonstrated a good patient outcome with a median OMAS of 80 (IQR, 45) and MOXFQ of 10.94 (IQR, 44.00). Median patient satisfaction was 90 (IQR, 20). Patients requiring revision surgery presented a poorer outcome across all domains, but their outcome did not differ significantly compared with nonfailed cases, apart from in 1 score (OMAS). Pain and overall health scores were comparable between groups. Only 4 patients in the failure group were working and engaged in sport before their injury, of which 2 patients returned to work at a mean of 14 weeks. The same 2 patients returned to sport at 6 months and 18 months, respectively. Outcome scores for the total group, failures (n = 12), and nonfailures (n = 217) are summarized in Table 2.

DISCUSSION

This is the largest series in the literature reporting both the short- and mid-term outcome of fibula nail fixation for unstable fractures of the ankle. The fibula nail maintained a congruent ankle joint in 94% of cases, and overall patient satisfaction was high. Failure occurred principally due to both intraoperative and postoperative surgeon errors. However, for those patients with adequate talar reduction, appropriate nail insertion, and correct postoperative weight-bearing instruction, the failure rate was 2%. Both figures compare favorably with previous work reporting a failure rate of up to 14% for traditional open reduction and internal fixation in patients 50 years of age and older.[17]

This study supports and develops the findings of Bugler et al[10] that demonstrated a failure rate of 7% in an

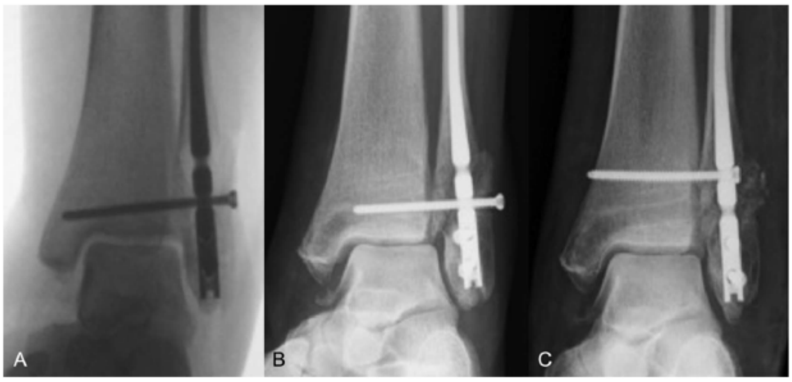

FIGURE 3. Intraoperative radiograph from a 68-year-old woman showing a reduced mortice (A). The head of the PLS is abutting the lateral fibula cortex. The osteoporotic cortex has not been of adequate strength, and the nail has displaced laterally, subsequently working the screw loose with loss of fracture reduction (B). Revised by engaging the nail with the PLS, using the more proximal hole, through a second stab incision (C).

earlier cohort of 105 fibula nails implanted with various screw configurations. This previous article demonstrated the importance of the PLS to the fibula nail construct, a concept that is further reinforced in this study. All 7 cases of device failure resulted from a loss of PLS hold in the distal fibula and/or tibial metaphyses, in a cohort of patients on average 10 years older than the total study group. This finding is possibly related to the relationship between increasing age and reduction in bone density as demonstrated by high-resolution quantitative computed tomography of cadaveric tibiae.[18] Similarly, PLS pull-out was related to screw position: a construct with a PLS sited more than 20 mm above the plafond and therefore in less dense tibial bone, had a significantly increased risk of failure (see **Figure, Supplemental Digital Content 2**, http://links.lww.com/JOT/A565, which demonstrates the zone of correct PLS insertion).

The introduction of new fixation techniques undoubtedly produces a learning curve, but despite the change in operative methodology since the introduction of the fibula nail in our center 14 years ago, and the fact 52 different surgeons of varying experience performed the procedures reported here, only 5 of the failures in the current study cohort were a direct result of technical error. We feel that this figure attests to the generalizability of the technique. Eight patients sustained a construct failure because of inadequate prescription of, or compliance with, restricted weight-bearing in the context of a syndesmotic injury. However, reassuringly, the majority of these surgical and management errors occurred in the first 5 years of the study, suggesting a general improvement in the understanding and application of both the device and surgical technique within our department over time. The patient-reported outcome scores in this study demonstrate worse outcomes in patients requiring revision surgery across all domains, although this was only statistically significant in the OMAS. This highlights the importance of "getting it right first time."

The main limitation of this study is the retrospective design. Furthermore, time to follow-up was variable with

TABLE 2. Patient-Reported Outcome Measures Comparing Failure and Nonfailure Groups

Outcome Measure	Total Group (Median, IQR)	Failure (Median, IQR)	Nonfailure (Median, IQR)	P*
EQ-5D	0.76 (0.31)	0.71 (0.39)	0.80 (0.31)	0.105
OMAS	80 (45)	65 (38)	80.00 (47)	0.045†
MOXFQ	10.94 (44.00)	31.25 (70.00)	9.38 (42.00)	0.064
VAS—pain/100	90 (40)	85 (40)	90 (40)	0.442
VAS—health/100	80 (30)	80 (29)	80 (30)	0.556
VAS—satisfaction/100	90 (20)	84 (35)	90 (21)	0.149

*Mann–Whitney *U* test.
†$P < 0.05$.
EQ-5D, EuroQol-5D.

a lack of longer-term clinical data and radiographs in some patients. These patients were often found to be making satisfactory progress at 6–8 weeks postoperatively and therefore discharged from the service. As our region, with a patient population of approximately 850,000 is served by a single orthopaedic center and shares a unified electronic patient database with local emergency departments and minor injury units, a recent electronic review enabled a comprehensive search to identify any complications not originally recorded. The decision to use the fibula nail was surgeon-dependent and based on a number of factors such as patient age, comorbidities, fracture configuration, and soft-tissue quality, rather than a prospectively agreed protocol. A prospective trial of this nature has since been published from our center.[8]

The study findings have also led to changes to, or refinements of, the recommended surgical technique:

1. As for all nailing procedures, selecting the optimal guide wire starting point at the beginning of the procedure is crucial. Errors include placement that is too medial, lateral, anterior, or posterior. This will result in inadequate fragment capture and stability or inadequate talar reduction. In the present series, in 2 cases, the nail was positioned so poorly in the distal fragment that it failed to grip it (Fig. 2), and in the remaining 3 cases, the nail entry point resulted in inadequate reduction of the talus. An entry point that is too medial pushes the lateral malleolus laterally during nail insertion, and with the talus faithfully after the lateral malleolus, results in residual displacement. Conversely, an overly lateral entry point results in medialization of the fibula, loss of talar reduction, and displacement of an associated medial malleolar fracture. Revision of this error, as with other long bone nailing procedures, involves opening out the entry point to facilitate correct nail trajectory (see **Figure**, **Supplemental Digital Content 4**, http://links.lww.com/JOT/A567, which summarizes the technical error and solution).
2. The base of the nail should be left flush with the cortex at the tip of the fibula, where it achieves optimal grip. Overinsertion leaves the base in the weaker cancellous bone of the fibula metaphysis where the grip is less satisfactory (see **Figure**, **Supplemental Digital Content 5**, http://links.lww.com/JOT/A568, which shows an example of nail overinsertion). Where it is necessary to implant the nail deeper in larger patients, end caps in the second generation of the fibula nails will increase cortical grip.
3. One DLS is adequate—no failures occurred in this cohort because of the DLS, only one of which was used in each case. After DLS insertion, the jig is back-slapped, and where necessary rotated, to ensure full fibula length and alignment is re-established.
4. If a single PLS is used, it should be implanted close to the plafond, exploiting the higher density subchondral bone, but being cautious to avoid damage to the plafond.
5. In the case of porotic bone or significant fibula comminution, the head of the PLS should be driven through the lateral fibula cortex, so that the head engages directly with the nail, providing a more robust buttress to lateral talar displacement. In addition, particularly in the elderly, it avoids the "broomstick in a bucket" phenomenon (also encountered in retrograde femoral nailing) whereby the capacious fibula metaphysis can move around the relatively thin nail.
6. The placement of 2 PLS is advised in patients with a demonstrable syndesmotic injury or markedly poor bone density. Intraoperative stress testing is performed by applying a lateral force vector to the fibula nail jig once the nail has been secured with a single, anteroposterior DLS. Rotatory movements of the foot or direct grasping/hooking of the fibula are unnecessary. If a diastasis is confirmed fluoroscopically, insertion of 2 PLS is recommended in addition to 6–8 weeks non–weight-bearing precaution in a removable orthosis.

This is the largest reported series of unstable ankle fractures managed with a fibula nail and demonstrates a low mechanical failure rate and high patient satisfaction. We have identified both surgeon- and implant-related modes of failure and have presented recommendations to optimize the surgical technique.

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REFERENCES

1. Toole WP, Elliott M, Hankins D, et al. Are low-energy open ankle fractures in the elderly the new geriatric hip fracture? *J Foot Ankle Surg.* 2015;54:203–206.
2. Rammelt S. Management of ankle fractures in the elderly. *EFORT Open Rev.* 2016;1:239–246.
3. Koval KJ, Lurie J, Zhou W, et al. Ankle fractures in the elderly: what you get depends on where you live and who you see. *J Orthop Trauma.* 2005; 19:635–639.
4. Zaghloul A, Haddad B, Barksfield R, et al. Early complications of surgery in operative treatment of ankle fractures in those over 60: a review of 186 cases. *Injury.* 2014;45:780–783.
5. Lynde MJ, Sautter T, Hamilton GA, et al. Complications after open reduction and internal fixation of ankle fractures in the elderly. *Foot Ankle Surg.* 2012;18:103–107.
6. Hoiness P, Engebretsen L, Stromsoe K. The influence of perioperative soft tissue complications on the clinical outcome in surgically treated ankle fractures. *Foot Ankle Int.* 2001;22:642–648.
7. Ashman BD, Kong C, Wing KJ, et al. Fluoroscopy-guided reduction and fibular nail fixation to manage unstable ankle fractures in patients with diabetes: a retrospective cohort study. *Bone Joint J.* 2016;98B:1197–1201.
8. White TO, Bugler KE, Appleton P, et al. A prospective randomised controlled trial of the fibular nail versus standard open reduction and internal fixation for fixation of ankle fractures in elderly patients. *Bone Joint J.* 2016;98B:1248–1252.
9. Smith G, Mackenzie SP, Wallace RJ, et al. Biomechanical comparison of intramedullary fibular nail versus plate and screw fixation. *Foot Ankle Int.* 2017;38:1394–1399.
10. Bugler KE, Watson CD, Hardie AR, et al. The treatment of unstable fractures of the ankle using the Acumed fibular nail: development of a technique. *J Bone Joint Surg Br.* 2012;94:1107–1112.
11. Marsh JL, Slongo TF, Agel J, et al. Fracture and dislocation classification compendium—2007: Orthopaedic Trauma Association classification, database and outcomes committee. *J Orthop Trauma.* 2007;21:S1–S133.
12. Lauge-Hansen N. Ligamentous ankle fractures; diagnosis and treatment. *Acta Chir Scand.* 1949;97:544–550.
13. Burwell HN, Charnley AD. The treatment of displaced fractures at the ankle by rigid internal fixation and early joint movement. *J Bone Joint Surg Br.* 1965;47:634–660.

14. *EuroQol-5D.* 2014. Available at: https://euroqol.org/. Accessed May 2018.
15. Olerud C, Molander H. A scoring scale for symptom evaluation after ankle fracture. *Arch Orthop Trauma Surg.* 1984;103:190–194.
16. Dawson J, Coffey J, Doll H, et al. A patient-based questionnaire to assess outcomes of foot surgery: validation in the context of surgery for hallux valgus. *Qual Life Res.* 2006;15:1211–1222.
17. Beauchamp CG, Clay NR, Thexton PW. Displaced ankle fractures in patients over 50 years of age. *J Bone Joint Surg Br.* 1983;65: 329–332.
18. Kamer L, Noser H, Blauth M, et al. Bone mass distribution of the distal tibia in normal, osteopenic, and osteoporotic conditions: an ex vivo assessment using HR-pQCT, DXA, and computational modelling. *Calcif Tissue Int.* 2016;99:588–597.

Appendix

Appendix 6

ORIGINAL ARTICLE

The Fibular Intramedullary Nail Versus Locking Plate and Lag Screw Fixation in the Management of Unstable Elderly Ankle Fractures: A Cadaveric Biomechanical Comparison

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Objectives: To compare the biomechanical failure properties of the fibular intramedullary nail with locking plate and lag screw fixation in the management of unstable elderly distal fibular fractures.

Methods: Twelve fresh-frozen cadaveric lower limbs (6 matched-pairs) were studied. A simulated OTA/AO 44-B fracture was created, then randomly allocated within each pair to intramedullary nail or locking plate fixation supplemented with an interfragmentary lag screw. The limbs were secured with the foot rigidly held in 20 degrees of supination, loaded to 700N and subjected to progressive external rotation until failure.

Results: The mean specimen age was 86.5 years (61–97). Mean torque to failure was greater in the intramedullary nail group, but did not reach statistical significance (23.5 N·m vs. 21.6 N·m; $P = 0.463$). The nail failed at a significantly greater angle of rotation compared with plate fixation (66.5 degrees vs. 53.3 degrees; $P = 0.046$). There was no significant difference between the groups with respect to construct stiffness ($P = 0.673$) or energy absorbed ($P = 0.075$). The locking plate specimens failed through plate and screw construct pull off at the implant-bone interface. In contrast, the intramedullary nail specimens failed at the lateral ligament complex, whereas the fracture-implant construct remained intact.

Conclusion: Intramedullary nailing and locking plate fixation have similar biomechanical characteristics when tested to failure. The benefits of the minimally invasive surgery offered by the intramedullary nail make it an attractive implant in the management of these patients.

Key Words: ankle fracture, trauma, fibular nail, locking plate

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INTRODUCTION

The fibular intramedullary nail has been recently reported to have a clinically acceptable mechanical failure rate of 6% and good long-term patient reported outcomes.[1] The implant benefits from a minimally invasive technique, resulting in fewer lateral sided soft tissue complications including infection and implant removal.[2,3] In elderly patients and/or those with a vulnerable soft tissue envelope, the clinical benefits have proven to be significant.[4–8]

Despite the recent enthusiasm for this surgical strategy, surgeons not conversant with the technique or implant, may prefer the greater familiarity of locking plate technology, especially in elderly, osteoporotic bone. Anatomical periarticular locking plate fixation has demonstrated biomechanical advantages when examined against standard neutralization and antiglide plating techniques in both cadaveric[9–12] and saw bone studies.[13] Some have reported superior biomechanical properties of antiglide plating with a posterolateral standard 1/3 tubular plate compared with a 1/3 tubular laterally sited locking plate,[14] but this technique is associated with peroneal tendon irritation and a high rate of implant removal.[15] However, the established biomechanical advantages of locking plates have been reported to come at the cost of a significant increase in the rate of wound complications due to the bulky design,[16,17] and the expense of the implant.[18]

The biomechanical properties of the modern fibular intramedullary nail were investigated in a study by Smith et al[19] and shown to compare favorably against standard

1/3 tubular neutralization plate and lag screw fixation. The only biomechanical study to date which compares the intramedullary nail with locking plate technology, examined a supra-syndesmotic (OTA/AO 44-C2) fracture, representing an important, but relatively uncommon pattern of injury.[20] No data are available for the more clinically relevant OTA/AO 44-B type fracture, which presents frequently in the elderly patient, occurring in approximately 70% of all ankle fractures occurring in patients >60 years of age.[21]

The aim of this study was to address this deficiency in the literature by comparing the biomechanical failure properties of the fibular intramedullary nail and locking plate with lag screw fixation in the management of OTA/AO 44-B elderly ankle fractures.

MATERIALS AND METHODS

Formal ethical review was not required for this cadaveric study. Consent for scientific investigation and medical photography had been provided by each donor. Permission to test and transport cadaveric material was obtained from the head of the anatomy department and the University of Edinburgh. The specimens were handled and transported in line with the Human Tissue Act, Scotland. Twelve fresh frozen lower limbs (6 matched pairs) from the knee joint to foot were acquired.

Preparation of Specimens

All specimens were thawed from −20°C to room temperature for 24 hours before preparation. First, the proximal tibia was disarticulated from the knee joint at the level of the proximal tibiofibular joint. The remaining stages of preparation and testing were based on the technique described by Smith et al.[19] A soft-tissue window including skin and subcutaneous fat was created 20 millimetres (mm) distal to the fibular tip and extended proximally by 120 mm. After inspection for evidence and exclusion of previous injury, an iatrogenic supination-external rotation type injury was created (OTA/AO 44-B type).[22] First, the fibers of the anterior and posterior tibiofibular ligaments were divided followed by an oblique fibular osteotomy taking origin from the anterior margin of the fibula incisura and extended at a 45-degree angle in a proximal and posterior direction. The medial malleolus and deltoid ligament were left intact to simulate successful medial sided fixation. The limbs were randomized within each pair to receive either an intramedullary nail (Fibula Rod first generation, Acumed, Hillsboro, OR) or a precontoured distal fibular locking plate (Ankle3, Acumed) with interfragmentary lag screw fixation (Fig. 1).

In the intramedullary nail group, the initial entry point at the tip of the fibula was found with a smooth Kirshner wire. The distal fibula was then prepared with an opening power reamer. T-handled reamers of increasing diameter were passed across the fracture site into the proximal fragment. The intramedullary nail comes in a selection of nail lengths and diameters. Given the advanced age of the specimens and the capacious nature of the fibular canal, a 110-mm × 3.6-mm diameter nail was selected for all specimens. With the base of the nail flush with the distal fibula, the implant was secured

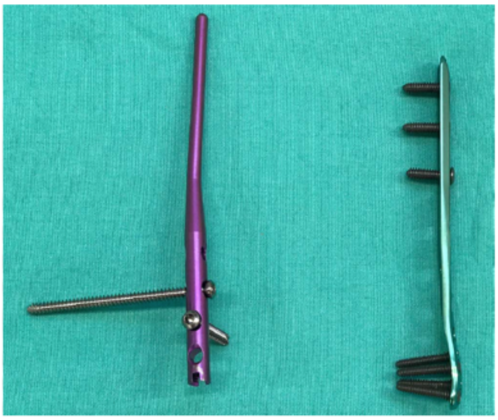

FIGURE 1. Fibular intramedullary nail and precontoured distal fibular locking plate implants.

with 2 locking screws. A 20-mm distal locking screw was inserted in the most proximal of the 2 available holes in an anterior to posterior direction. A single 50-mm proximal locking screw was inserted across the syndesmosis in the most distal of the 2 available holes, with the jig positioned in 30 degrees of external rotation, as per the recommended surgical technique. All syndesmotic screws were tricortical and did not reach the medial tibial border. Screw lengths were in keeping with the mean length of tricortical transyndesmotic screw, defined in the dataset of a large retrospective study published from the authors' institution.[1] This fibular nail construct is reflective of that used in routine clinical practice; the development of which is described in the instructional paper by Bugler et al,[23] and further refined following subsequent experience.[1] In the locking plate group, the osteotomy site was reduced and held with a pointed reduction clamp. A bicortical 3.5-mm fully threaded lag screw between 18 mm and 24 mm was inserted 90 degrees to the osteotomy site to provide interfragmentary compression. An appropriately sided 6-hole (103 mm length) precontoured distal fibular locking plate was then secured against the lateral aspect of the fibula with 4 2.7-mm × 16-mm unicortical locking screws distally and 3 3.5-mm × 12-mm bicortical locking screws proximally.

Mechanical Testing

The limbs were secured distally using a custom-made base plate with a built-in 20-degree angle and a 5-mm transcalcaneal threaded pin, inserted parallel to the intermalleolar axis. This allowed the foot to be held rigidly in supination. The technique for proximal fixation was modified from that described by Smith et al [19] by dividing each specimen 25 cm above the fibular tip and dissecting the surrounding soft tissues free. The proximal diaphysis of the tibia and fibula were then potted into a 3-mm thick steel box section using polymethylmethacrylate cement, followed by the

Appendix

insertion of a 5-mm threaded pin. This pin was inserted through the box section, cement mantle and tibial metaphysis (Fig. 2) and provided superior proximal fixation. The top compression plate was designed with slotted flanges at either side to provide a secure location for the threaded pin and allow rotation to be applied to the limb. A 10-mm ball bearing was placed between the compression plate and the cement pot to account for slight vertical misalignments of the limb.[24]

Mechanical testing was performed using a Zwick/Roell z005 mechanical testing machine with a 5 kN load cell and a 100 N·m torque cell (Zwick Roell, GMBH & Co, Germany). The proximal pin was secured by a controlled reduction of the gap between the compression surfaces until the pin was within the slotted flanges and a preload of 5 N was achieved. A compressive load was then applied to each specimen at a rate of 100 N/s up to 700 N to replicate bodyweight. The compressive load was maintained whereas an external rotation was applied at a rate of 30 degrees/s up to a maximum excursion of 90 degrees, simulating a supination-external rotation movement. Measurements included torque to failure in newton-meters (N·m), angle at failure in degrees (°), construct stiffness in newton-meters per degree of rotation (N·m/°) and energy absorbed in Joules (J). The point of failure was defined as the first point at which the loaded specimen demonstrated a distinct reduction in torque with a corresponding increase in angle of rotation. Each specimen was then visually inspected to describe the mode of failure.

FIGURE 2. Mechanical testing apparatus set-up. This example shows a distal fibular locking plate in a right-sided specimen.

Statistical Analysis

Data were analyzed using IBM SPSS software version 23.0 (Armonk, NY: IBM Corp.). Because of the small sample size, a nonparametric paired samples Wilcoxon rank-sum test was used to compare the 2 groups with respect to peak torque to failure, angle at failure, stiffness, and energy absorbed. Continuous data are presented as means and ranges. A P-value of <0.05 was considered statistically significant.

RESULTS

The mean age of the 6 cadavers included in this study was 86.5 years (61–97). There were 3 women and 3 men. The mean torque to failure was 23.5 Nm (9.3–29.3) in the intramedullary nail group versus 21.6 Nm (2.8–29.3) in plate fixation group (P = 0.463). Angle at failure was the only statistically significant finding between the 2 groups with a greater angle in the nail group (P = 0.046). Detailed test results are summarized (see **Table, Supplemental Digital Content 1**, http://links.lww.com/JOT/B68, which includes all 6 matched pairs) and a mean torque to failure curve for all 6 matched pairs is displayed in Fig. 3.

At the end of testing, each specimen was visually examined to describe the mode of failure. Five of the 6 nail specimens failed at the lateral ligament complex, either through ligamentous avulsion or a small bony avulsion from the distal fibula (Fig. 4). The iatrogenic fibula fracture remained reduced except for one specimen, which failed at the osteotomy site with subsequent loss of reduction and proximal spiral diaphyseal propagation of the fracture. In the plate fixation group, 3 specimens failed because of pull-out of the proximal locking screws with an associated diaphyseal fracture (Fig. 5) and 3 failed distally via locking screw pull out from the distal fibula (see **Figure, Supplemental Digital Content 2**, http://links.lww.com/JOT/B69, which demonstrates distal locking screw pull out).

DISCUSSION

Intramedullary stabilization of the fibula has gained recent popularity because of its minimally invasive technique, thus preserving the overlying soft tissue envelope. A recent systematic review by Jordan et al [25] and a meta-analysis of observational and randomized controlled trials by Tas et al 2 found that intramedullary fixation (mixed implants) was associated with equivalent functional outcomes and a significantly lower complication rate compared with plate fixation (mixed locking and nonlocking).

The results of this current biomechanical study support the use of either an intramedullary nail or a locking plate construct in the management of an OTA/AO 44-B ankle fracture created in a cadaveric setting. To our knowledge, this is the first study to compare directly the biomechanical failure properties of the 2 implants in this common fracture pattern. Despite the mean torque to failure favoring the intramedullary nail by 1.9 N·m, statistical significance was demonstrated

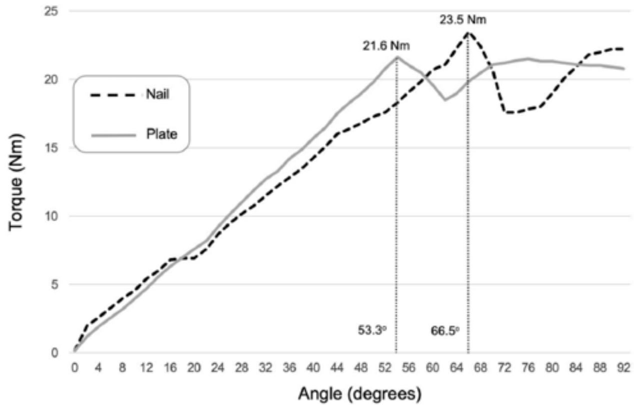

FIGURE 3. Mean torque to failure and angle at failure for all 6 matched pairs.

only in the angle of failure, which favored the intramedullary nail by a mean of 13.2 degrees.

The values recorded for torque to failure in this biomechanical study are comparable to that found by other authors. Smith et al[19] examined 10 matched pairs of cadaveric lower limbs with a mean age of 82 years. The mean torque to failure in the intramedullary nail fixation group was 28.4 N·m, compared with 22.8 N·m in the standard 1/3 tubular with lag screw fixation group ($P < 0.05$). Both values are slightly higher than the current study, but the specimen age was on average 4.5 years lower. The mean angle at failure was almost identical, with an angle of 53.4 degrees in the nail group versus 54.0° in the plate group. In the current study, we found the mean angle of failure to be significantly greater in the nail group compared with the plate group (66.5 degrees vs. 53.3 degrees).

Zahn et al[10] included 20 unpaired cadaveric lower limb specimens, comparing 10 locking plate and 10 nonlocking plate constructs following the creation of a simulated fracture through the application of progressive axial load and torsion. Conversely, the mean torque to failure in the locking plate group in their study was much lower at 11.2 N·m and just 4.3 N·m in the nonlocking plate group. However, this study was limited by the uncontrolled method of fracture creation and the use of unpaired specimens. Switaj et al[20] compared the fibular nail and distal fibular locking plate in suprasyndesmotic injuries (OTA/AO 44-C). After external rotation cyclic loading, the specimens were tested under torque to failure conditions. Torque to failure was greatest in the fibular nail group compared with the plate group, but as with our study, did not reach statistical significance (29.6 N·m vs. 28.1 N·m). Of interest, the angle at failure was comparable between the 2 groups: 91.6 degrees in the nail group and 93.5 degrees in the plate fixation group ($P = 0.73$). Both values are much higher than the angle at failure in the 2 groups included in our study and are most likely related to the suprasyndesmotic nature of the injury examined. In this work, the authors divided the interosseous membrane, interosseous ligament, and both the anterior and posterior tibiofibular ligaments, creating an unusually rotationally unstable injury. This would have permitted a greater angle of rotation before reaching the defined point of failure, even with the inclusion of a single 3.5-mm diameter syndesmotic screw.

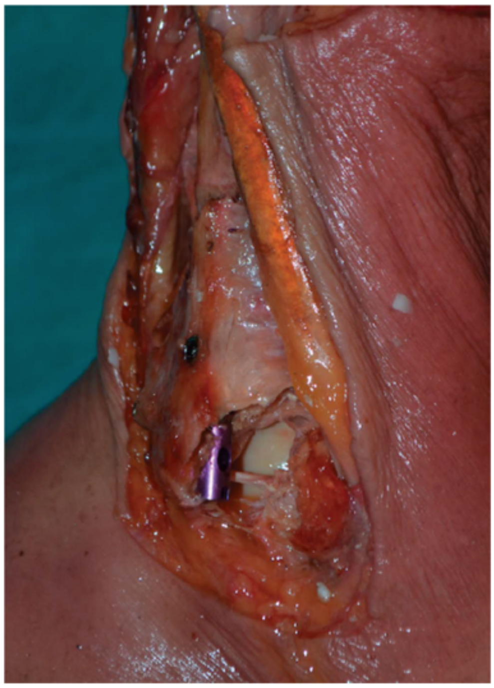

FIGURE 4. Failure of intramedullary nail specimen at the lateral ligament complex. In this example, a bony avulsion can be seen from the distal fibula, exposing the implant.

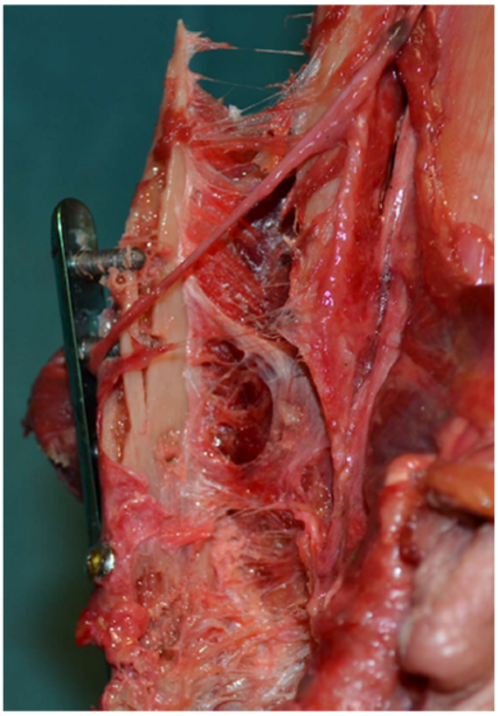

FIGURE 5. Failure of plate fixation at the proximal locking screws with associated diaphyseal fracture.

With respect to modes of failure in the present study, specimens in the intramedullary nail group failed consistently at the lateral ligament complex with either a pure ligamentous rupture or a bony avulsion from the distal fibula (Fig. 4) rather than from displacement of the fracture. This finding is in keeping with that from Smith et al,[19] where 9 of the 10 nail specimens failed in an identical manner. In the current study only one specimen failed at the level of the fracture (specimen 5), with proximal propagation of the osteotomy. Of note, this specimen was from the oldest female donor, aged 97 years, with particularly porotic bone quality on macroscopic inspection. The recorded torque to failure in this paired specimen was very low compared with the grouped means. This translated into a low angle at failure, stiffness and ultimately, the energy absorbed by the specimens from this individual during testing. There was an equal split of proximal and distal failure in the locking plate group. As the locking plate design intended and regardless of failure locality, the screws remained locked into the plate and simply pulled out from the distal metaphyseal bone (see **Figure**, **Supplemental Digital Content 2**, http://links.lww.com/JOT/B69, which demonstrates distal locking screw pull out) or produced a proximal fracture as the screws pulled out proximally (Fig. 5). This was different to the mode of failure described in the study by Smith et al,[19] in which the proximal cortical screws loosened, allowing the plate to cleanly pull off the fibula, without associated fracture.

The main strengths of this study are the inclusion of the most common pattern of ankle fracture in the elderly (OTA/AO 44-B), the use of matched limb pairs and the creation of a reproducible fracture pattern using a standardized surgical technique, which improves the reproducibility of the supination external rotation type injury studied. Previous studies have created an initial injury by applying progressive axial loading and torsion to a fresh limb, frequently producing an unpredictable fracture pattern, with no injury standardization.[10] This leads to subsequent wastage of cadaveric material and with it, associated costs. Specimen preparation and instrumentation was performed by experienced orthopaedic trauma surgeons and the biomechanical testing was supervised by a senior orthopaedic engineer, based on modifications from a previously published technique.[19]

The study has limitations. First, the sample size of 12 limbs (6 matched pairs) was small and was because of the limited availability of good quality matched pairs from the local university anatomy department. This number is slightly lower than previous studies in the area, which included 7 (14 limbs),[18] 8 (16 limbs),[9,14,26] and 10 (20 limbs)[19,20] matched pairs. Taking into account the costs of materials and the quality of the data produced, we feel that between 8 and 10 matched pairs is an appropriate sample size. We acknowledge that our sample falls just below this. Studies reporting on higher numbers (20 + limbs), include specimens that are both unmatched and isolated to the fibula only,[11] compared with the whole lower limb as in the current study. Unpaired specimens were available, but it was felt that this would affect the validity of the results and were therefore not considered for inclusion. Apart from angle at failure, we were unable to detect a statistically significant difference between the 2 implants and this may represent a type II error. Measurement of bone mineral density was not performed, but selected limbs were from an elderly population, with a mean age of 86.5 years. The strict inclusion of matched pairs likely eliminated significant variation of bone density between the 2 implant groups. All specimens were inspected for evidence of previous injury, but plain radiographs or more detailed imaging was not performed, mainly because of cost implications. Regarding implant selection, the fibular nail operative technique mandates a transyndesmotic screw is inserted regardless of an underlying syndesmotic injury, predominantly for rotational control of the implant within the fibula. We acknowledge that this transyndesmotic screw may have affected the biomechanical results, when compared with the locking plate group, which was not supplemented by a screw of this nature. It was not possible within the confines of this matched pair experiment to investigate this further and therefore this represents a future area of study. Finally, the mechanical testing equipment available did not provide capabilities for cyclical loading of specimens before testing torque to failure. This is perhaps more clinically representative of weight-bearing and must be acknowledged as another limitation.

Appendix

In summary, the results from this study demonstrate comparable biomechanical properties when testing the fibular intramedullary nail and distal fibular locking plate to failure, under experimental conditions for an OTA/AO 44-B fracture pattern simulated in elderly cadaveric ankles. Given the minimally invasive nature of the intramedullary nail, this device may provide superior overall clinical outcomes while maintaining equivalent mechanical stability to that of a locking plate in the management of elderly ankle fractures.

ACKNOWLEDGMENTS

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REFERENCES

1. Carter TH, Mackenzie SP, Bell KR, et al. Optimizing long-term outcomes and avoiding failure with the fibula intramedullary nail. *J Orthop Trauma.* 2019;33:189–195.
2. Tas DB, Smeeing DPJ, Emmink BL, et al. Intramedullary fixation versus plate fixation of distal fibular fractures: a systematic review and meta-analysis of randomized controlled trials and observational studies. *J Foot Ankle Surg.* 2019;58:119–126.
3. White TO, Bugler KE, Appleton P, et al. A prospective randomised controlled trial of the fibular nail versus standard open reduction and internal fixation for fixation of ankle fractures in elderly patients. *Bone Joint J.* 2016;98-B:1248–1252.
4. Dabash S, Eisenstein ED, Potter E, et al. Unstable Ankle fracture fixation using locked fibular intramedullary nail in high-risk patients. *J Foot Ankle Surg.* 2019;58:357–362.
5. Al-Obaidi B, Wiik AV, Bhattacharyya R, et al. Fibular nails for open and closed ankle fractures: results from a non-designer level I major trauma centre. *J Orthop Surg.* 2019;27:2309499019832420.
6. Rehman H, Gardner WT, Rankin I, et al. The implants used for intramedullary fixation of distal fibula fractures: a review of literature. *Int J Surg.* 2018;56:294–300.
7. Peeperkorn S, Nijs S, Hoekstra H. Why fibular nailing can Be an efficient treatment strategy for AO type 44-B ankle fractures in the elderly. *J Foot Ankle Surg.* 2018;57:961–966.
8. Challagundla SR, Shewale S, Cree C, et al. Intramedullary fixation of lateral malleolus using Fibula Rod System in ankle fractures in the elderly. *Foot Ankle Surg.* 2018;24:423–426.
9. Kim T, Ayturk UM, Haskell A, et al. Fixation of osteoporotic distal fibula fractures: a biomechanical comparison of locking versus conventional plates. *J Foot Ankle Surg.* 2007;46:2–6.
10. Zahn RK, Frey S, Jakubietz RG, et al. A contoured locking plate for distal fibular fractures in osteoporotic bone: a biomechanical cadaver study. *Injury.* 2012; 43: 718–725.
11. Knutsen AR, Sangiorgio SN, Liu C, et al. Distal fibula fracture fixation: biomechanical evaluation of three different fixation implants. *Foot Ankle Surg.* 2016; 22: 278–285.
12. Switaj PJ, Wetzel RJ, Jain NP, et al. Comparison of modern locked plating and antiglide plating for fixation of osteoporotic distal fibular fractures. *Foot Ankle Surg.* 2016;22:158–163.
13. Bariteau JT, Fantry A, Blankenhorn B, et al. A biomechanical evaluation of locked plating for distal fibula fractures in an osteoporotic sawbone model. *Foot Ankle Surg.* 2014;20:44–47.
14. Minihane KP, Lee C, Ahn C, et al. Comparison of lateral locking plate and antiglide plate for fixation of distal fibular fractures in osteoporotic bone: a biomechanical study. *J Orthop Trauma.* 2006; 20:562–566.
15. Weber M, Krause F. Peroneal tendon lesions caused by antiglide plates used for fixation of lateral malleolar fractures: the effect of plate and screw position. *Foot Ankle Int.* 2005;26:281–285.
16. Lyle SA, Malik C, Oddy MJ. Comparison of locking versus non-locking plates for distal fibula fractures. *J Foot Ankle Surg.* 2018; 57:664–667.
17. Schepers T, Van Lieshout EM, De Vries MR, et al. Increased rates of wound complications with locking plates in distal fibular fractures. *Injury.* 2011;42:1125–1129.
18. Nguyentat A, Camisa W, Patel S, et al. A biomechanical comparison of locking versus conventional plate fixation for distal fibula fractures in trimalleolar ankle injuries. *J Foot Ankle Surg.* 2016;55: 132–135.
19. Smith G, Mackenzie SP, Wallace RJ, et al. Biomechanical comparison of intramedullary fibular nail versus plate and screw fixation. *Foot Ankle Int.* 2017;38:1394–1399.
20. Switaj PJ, Fuchs D, Alshouli M, et al. A biomechanical comparison study of a modern fibular nail and distal fibular locking plate in AO/OTA 44C2 ankle fractures. *J Orthop Surg Res.* 2016;11:100.
21. Gauthé R, Desseaux A, Rony L, et al. Ankle fractures in the elderly: treatment and results in 477 patients. *Orthop Traumatol Surg Res.* 2016; 102:S241–S244.
22. Meinberg EG, Agel J, Roberts CS, et al. Fracture and dislocation classification compendium—2018. *J Orthop Trauma.* 2018;32:S1–S170.
23. Bugler KE, Watson CD, Hardie AR, et al. The treatment of unstable fractures of the ankle using the Acumed fibular nail: development of a technique. *J Bone Joint Surg Br.* 2012;94:1107–1112.
24. Zhao S, Arnold M, Ma S, et al. Standardizing compression testing for measuring the stiffness of human bone. *Bone Joint Res.* 2018;7:524–538.
25. Jordan RW, Chapman AWP, Buchanan D, et al. The role of intramedullary fixation in ankle fractures - a systematic review. *Foot Ankle Surg.* 2018;24:1–10.
26. White NJ, Corr DT, Wagg JP, et al. Locked plate fixation of the comminuted distal fibula: a biomechanical study. *Can J Surg.* 2013;56:35–40.

Appendix

Appendix 7

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Selective fixation of the medial malleolus in unstable ankle fractures

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Trauma
Medial malleolus
Patient outcome

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

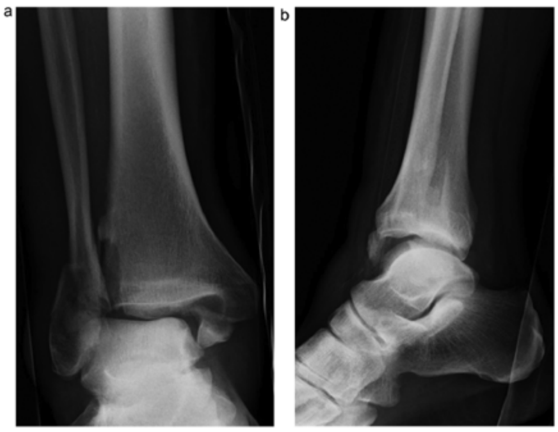

Fig. 1. Anteroposterior (a) and lateral (b) radiographs of a 56 year old male patient, demonstrating a supination-external rotation (SER) type/AO 44-B2 ankle fracture with talar shift and a Herscovici type B medial malleolar fracture. This patient had significant post-traumatic blistering both medially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

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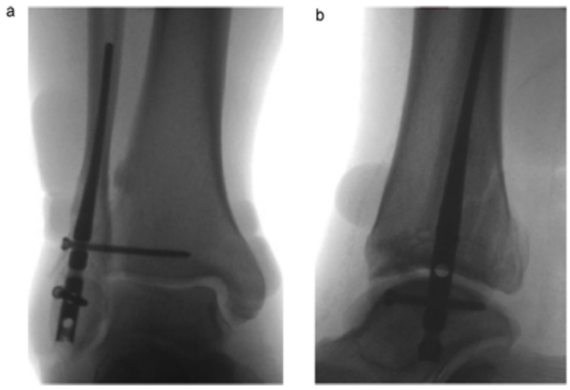

Fig. 2. Intra-operative anteroposterior (a) and lateral (b) fluoroscopy one day post-injury demonstrating an anatomically reduced medial malleolar fracture and anatomical mortise reduction post fibular nail insertion. The outline of fracture blistering can be seen on both radiographs.

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).

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Appendix

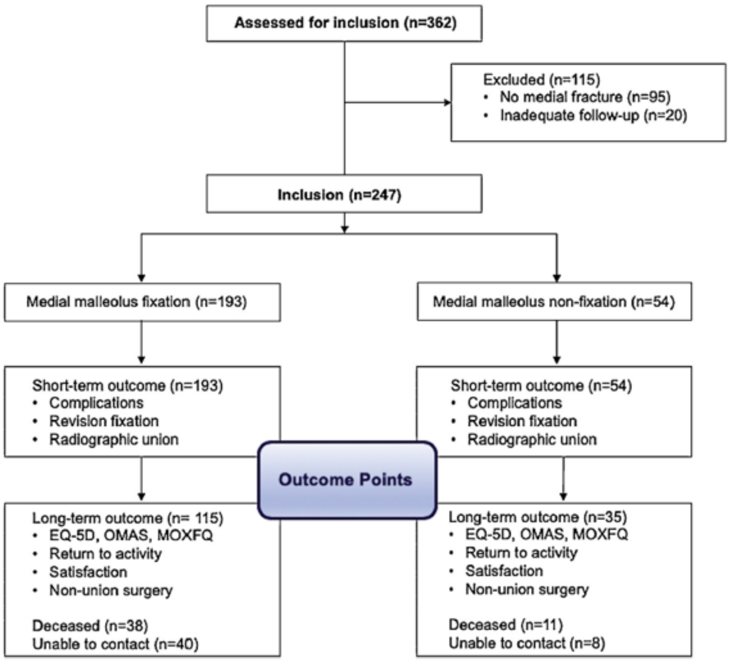

Fig. 4. Selection and flow of patients in the study.

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

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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-

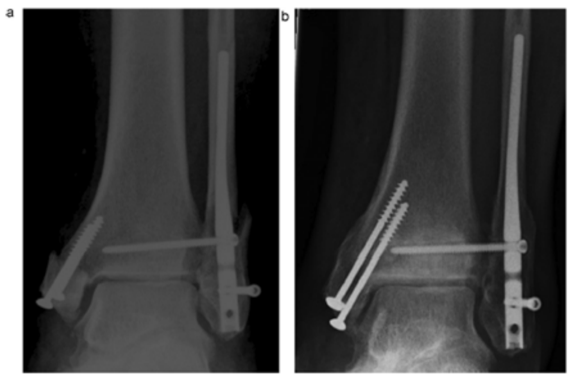

Fig. 5. Anteroposterior radiograph of 52-year-old male patient at two weeks post-operative stage demonstrating failed medial malleolar fixation (a). Anteroposterior radiograph from the same patient three months following revision surgery demonstrating satisfactory medial and lateral malleolar union,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

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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

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Appendix

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.

References

[1] Leyes M, Torres R, Guillen P. Complications of open reduction and internal fixation of ankle fractures. Foot Ankle Clin 2003;8:131–47 ix.
[2] Hoiness P, Engebretsen L, Stromsoe K. The influence of perioperative soft tissue complications on the clinical outcome in surgically treated ankle fractures. Foot Ankle Int 2001;22:642–8.
[3] SooHoo NF, Krenek L, Eagan MJ, Gurbani B, Ko CY, Zingmond DS. Complication rates following open reduction and internal fixation of ankle fractures. J Bone Joint Surg Am 2009;91:1042–9.
[4] Bugler KE, Watson CD, Hardie AR, et al. The treatment of unstable fractures of the ankle using the Acumed fibular nail: development of a technique. J Bone Joint Surg Br 2012;94:1107–12.
[5] White TO, Bugler KE, Appleton P, Will E, McQueen MM, Court-Brown CM. A prospective randomised controlled trial of the fibular nail versus standard open reduction and internal fixation for fixation of ankle fractures in elderly patients. Bone Joint J 2016;98-B:1248–52.
[6] Ashman BD, Kong C, Wing KJ, et al. Fluoroscopy-guided reduction and fibular nail fixation to manage unstable ankle fractures in patients with diabetes: a retrospective cohort study. Bone Joint J 2016;98-B:1197–201.
[7] Smith G, Mackenzie SP, Wallace RJ, Carter T, White TO. Biomechanical comparison of intramedullary fibular nail versus plate and screw fixation. Foot Ankle Int 20171071100717731757.
[8] Zalavras CG, Christensen T, Rigopoulos N, Holtom P, Patzakis MJ. Infection following operative treatment of ankle fractures. Clin Orthop Relat Res 2009;467:1715–20.
[9] DeMill SL, Bussewitz BW, Philbin TM. Injury to the posterior tibial tendon after open reduction internal fixation of the medial malleolus. Foot Ankle Spec 2015;8:360–3.
[10] Hoelsbrekken SE, Kaul-Jensen K, Morch T, et al. Nonoperative treatment of the medial malleolus in bimalleolar and trimalleolar ankle fractures: a randomized controlled trial. J Orthop Trauma 2013;27:633–7.
[11] Fracture and dislocation compendium. Orthopaedic trauma association committee for coding and classification. J Orthop Trauma 1996;10(Suppl. 1) 1–154 v-ix.
[12] Lauge-Hansen N. Ligamentous ankle fractures; diagnosis and treatment. Acta Chir Scand 1949;97:544–50.
[13] Herscovici Jr. D, Scaduto JM, Infante A. Conservative treatment of isolated fractures of the medial malleolus. J Bone Joint Surg Br 2007;89:89–93.
[14] listed. Na. EuroQol-5D. 2014.
[15] Olerud C, Molander H. A scoring scale for symptom evaluation after ankle fracture. Arch Orthop Trauma Surg 1984;103:190–4.
[16] Dawson J, Coffey J, Doll H, et al. A patient-based questionnaire to assess outcomes of foot surgery: validation in the context of surgery for hallux valgus. Qual Life Res 2006;15:1211–22.
[17] Yablon IG, Heller FG, Shouse L. The key role of the lateral malleolus in displaced fractures of the ankle. J Bone Joint Surg Am 1977;59:169–73.
[18] Kimizuka M, Kurosawa H, Fukubayashi T. Load-bearing pattern of the ankle joint. Contact area and pressure distribution. Arch Orthop Trauma Surg 1980;96:45–9.
[19] Lloyd J, Elsayed S, Hariharan K, Tanaka H. Revisiting the concept of talar shift in ankle fractures. Foot Ankle Int 2006;27:793–6.
[20] Lindenbaum BL. Loss of the medial malleolus in a bimalleolar fracture. A case report. J Bone Joint Surg Am 1983;65:1184–5.
[21] Hernigou P, Goutallier D. Absence of the medial malleolus. A case report with a 20-year follow-up study. Clin Orthop Relat Res 1991;141–2.
[22] Tornetta 3rd P. Competence of the deltoid ligament in bimalleolar ankle fractures after medial malleolar fixation. J Bone Joint Surg Am 2000;82:843–8.
[23] Smith M, Medlock G, Johnstone AJ. Percutaneous screw fixation of unstable ankle fractures in patients with poor soft tissues and significant co-morbidities. Foot Ankle Surg 2017;23:16–20.
[24] Barnes H, Cannada LK, Watson JT. A clinical evaluation of alternative fixation techniques for medial malleolus fractures. Injury 2014;45:1365–7.
[25] Brown OL, Dirschl DR, Obremskey WT. Incidence of hardware-related pain and its effect on functional outcomes after open reduction and internal fixation of ankle fractures. J Orthop Trauma 2001;15:271–4.
[26] Willett K, Keene DJ, Mistry D, et al. Close contact casting vs surgery for initial treatment of unstable ankle fractures in older adults: a randomized clinical trial. JAMA 2016;316:1455–63.
[27] Buckley R, Kwek E, Duffy P, et al. Single-screw fixation compared with double screw fixation for treatment of medial malleolar fractures: a prospective randomized trial. J Orthop Trauma 2018;32:548–53.

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Appendix

Appendix 8

Carter *et al. Trials* (2019) 20:565
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Trials

STUDY PROTOCOL Open Access

Medial malleolus: Operative Or Non-operative (MOON) trial protocol - a prospective randomised controlled trial of operative versus non-operative management of associated medial malleolus fractures in unstable fractures of the ankle

Thomas H. Carter[1*], William M. Oliver[1], Catriona Graham[2], Andrew D. Duckworth[1] and Timothy O. White[1]

Abstract

Background: There are limited data reporting the outcome of patients with non-operatively managed medial malleolus fractures compared to those treated surgically in the presence of fibular stabilisation for unstable fractures of the ankle. Conservative management could result in fewer complications, reduced surgical time and lower cost. The purpose of this study is to determine if any difference exists in patient reported and surgical outcomes 1 year after surgery between operative and non-operative treatment of medial malleolar fractures in combination with stabilisation of the lateral malleolus.

Methods/design: This is a single-centre, prospective, randomised controlled trial that aims to randomise 154 participants with an unstable ankle fracture to 'non-fixation' ($n = 77$) or 'fixation' ($n = 77$) of an associated well-reduced medial malleolus fracture following fibular stabilisation. The study will include patients ≥ 16 years of age with a closed bimalleolar or trimalleolar ankle fracture who are able to consent, complete questionnaires in the English language, and complete follow-up over a 1-year period. Randomisation will occur intra-operatively when the medial malleolus fracture is deemed 'well-reduced', with 2 mm or less of fluoroscopic displacement. The technique for fixation of both the medial and lateral malleoli is at the discretion of the operating surgeon. Patient-reported, observer-rated, and radiographic assessments will be collected at baseline and then at the following post-operative assessment points: 2 weeks, 6 weeks and 1 year. Postal questionnaire outcome data will be collected at 3 and 6 months. The primary outcome measure will be the Olerud Molander Ankle Score (OMAS) at 1 year following surgery. Secondary outcome measures will include the Manchester-Oxford Foot Questionnaire (MOXFQ), EuroQol-5D (EQ-5D), pain, treatment satisfaction, time to return to activity, operative tourniquet time, and complications.

(Continued on next page)

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Discussion: There is only one previous randomised trial comparing non-fixation with fixation of associated medial malleolus fractures but that was limited by the lack of baseline patient-reported outcome data and an inferior sample size. This current prospective trial aims to provide high-quality evidence regarding the requirement for medial malleolar fixation in unstable ankle fractures.

Trial registration: ClinicalTrials.gov, NCT03362229. Registered retrospectively on 5 December 2017.

Keywords: Randomised controlled trial, Ankle fractures, Medial malleolus, Fracture fixation, Trauma, Patient outcome

Background

Ankle fractures are the second most common orthopaedic trauma presentation, accounting for approximately 10% of all fractures presenting at hospital [1]. The annual incidence of ankle fractures is approximately 122–184/100,000 person years (1:800) [2]. According to the Arbeitsgemeinschaft für Osteosynthesefragen (AO) principles, unstable ankle fractures with associated medial malleolar fractures are treated with open reduction and internal fixation (ORIF) [3]. Screw fixation is recommended for the majority of medial fractures, although debate exists regarding the type of screw, the number of screws and the zone of insertion [4–9]. For fractures not amenable to screw fixation due to fragment size, morphology and/or poor bone quality, tension band wiring (TBW) is thought to provide superior fixation [10–12]. Symptomatic metalwork rates following both screw fixation and TBW of medial malleolar fractures are high, prompting development of more novel implants including headless screws, absorbable hardware and knotless systems, with encouraging results [13–18].

A number of retrospective studies have demonstrated that isolated medial malleolus fractures may be treated non-operatively with good patient-reported outcomes and union rates as high as 96% [19, 20]. With an operatively stabilised fibula and a well-reduced medial malleolus fracture, the same principles of non-operative management may be applicable [21]. Only one randomised controlled trial has been conducted on this subject by Hoelsbrekken et al. [22]. The authors recruited 100 patients, with 18 patients (18%) lost to follow-up, leaving 82 patients randomised to a non-operative group ($n = 45$) and an operative group ($n = 37$). There were 51 female (62%) and 31 male (38%) patients. There was no statistically significant difference between the two groups with respect to the Olerud Molander Ankle Score (OMAS) and the American Academy of Foot and Ankle Surgeons (AOFAS) ankle-hindfoot score at a mean follow-up of 44 months. Four cases (8%) of medial malleolar radiographic non-union occurred in the non-operative group, although none of the patients were symptomatic and did not require further treatment. This study was limited by the lack of baseline patient-reported outcome scores and the small sample size.

Building on the current evidence and by including baseline patient-reported outcomes and a larger sample size, the aim of the MOON trial is to determine if any difference exists in the primary outcome measure (OMAS) at the 1-year post-operative stage between non-operative treatment of the medial malleolus in combination with operative fixation of the lateral malleolus and operative fixation of both the medial and lateral malleoli in unstable fractures of the ankle. The secondary aim of this trial is to determine if any difference exists in the complication rate at 1 year post-injury between non-operative treatment of the medial malleolus in combination with operative fixation of the lateral malleolus and operative fixation of both the medial and lateral malleoli.

Methods

This single-centre, randomised controlled trial will follow the Consolidated Standards of Reporting Trials (CONSORT) statement [23]. It will be performed in the Edinburgh Orthopaedic Trauma service, Royal Infirmary of Edinburgh, Edinburgh, UK, and has been approved by the South-East Scotland Research Ethics Committee 2 (REC reference 17/SS/0124). The first patient was recruited following satisfactory ethical approval on 24 October 2017. The study was registered with the ClinicalTrials.gov database on 5 December 2017 (ClinicalTrials.gov identifier NCT03362229). This study is co-funded by the Scottish Orthopaedic Research Trust into Trauma (SORT-IT) and an educational grant provided by Acumed (Hillsboro, Oregon, USA). The planned flow of participants is summarised in Fig. 1.

Inclusion criteria

Inclusion criteria are: 1) age ≥ 16 years; 2) able to consent to treatment; 3) unstable fracture dislocation of the ankle joint requiring operative intervention; 4) closed injury; 5) Weber B and Weber C fractures; and 6) surgery date within 2 weeks of date of fracture.

Exclusion criteria

Exclusion criteria are: 1) patients unable to comply with post-operative data gathering including completing questionnaires in the English language; 2) additional

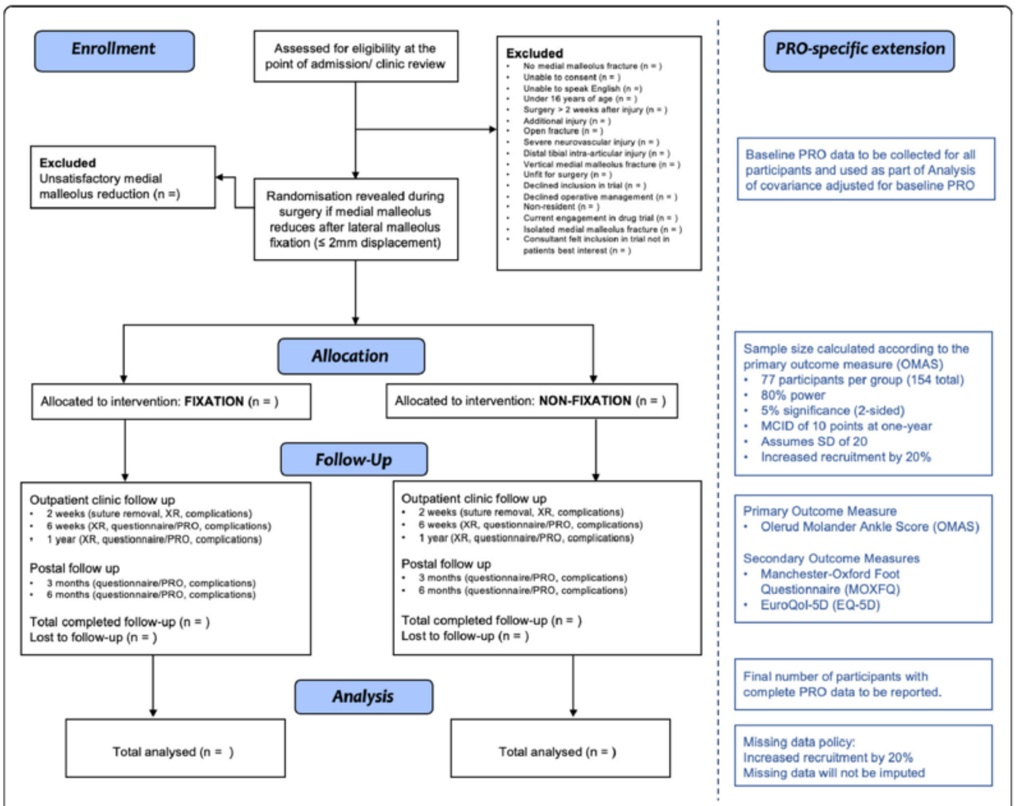

Fig. 1 Planned flow of participants. MCID minimal clinically important difference, PRO patient-reported outcome, SD standard deviation, XR x-ray

lower limb injury which may impact on patient rehabilitation; 3) open fracture; 4) confirmed severe associated neurovascular injuries; 5) distal tibial intra-articular fractures/pilon-type injuries; 6) supination-adduction type 2 (SAD-2) fracture configurations with a medial malleolus vertical shear fracture; 7) patients medically unfit for surgery; 8) patients declining operative management; 9) non-residents, unable to return to the unit for follow-up for a period of 1 year; 10) current engagement in a pharmaceutical/drug trial; and 11) where the treating surgeon does not feel that inclusion in the trial is in the patients' best interest either due to the fracture pattern or patient factors.

Sample size

The primary outcome measure will be the OMAS. In total, 154 patients (77 per arm) will be required with 80% power and 5% (two-sided) significance to detect a clinically meaningful difference of 10 points on the OMAS scale at 12 months between the two groups [24–26]. This assumes a standard deviation of 20 [27]. The sample size has been increased by 20% to account for any loss to follow-up.

Randomisation and allocation

Randomisation of treatment will be on a 1:1 ratio. Randomisation will be stratified according to age with a 'young group' (< 65 years) and an 'older group' (≥ 65 years). Based on retrospective data reporting the epidemiology of ankle fractures at our centre we will stratify on a 3:1 ratio between the 'young' and 'old'. This will be factored into the computer-generated randomisation schedule, which will utilise a block design of mixed block sizes and will be generated by an independent statistician employed through the local university research methodology department. A member of staff independent of the trial will use this list to create 154 opaque sequentially sealed envelopes clearly distinguishing those

Appendix

for the young and old groups separately. Contained within each envelope will be a sticker bearing the words 'Fixation' or 'Non-fixation', which will be placed onto the study consent form.

Participants will be identified by members of the on-call admitting team as they attend the local hospital emergency department (ED) or who are referred to the outpatient trauma clinic. The trial will be introduced by a member of staff and a patient information sheet (PIS) specific to the trial will be given to the patient to consider. Once the patient has had time to read and consider the information, they will be approached by a member of the research team (one of four) who will clarify any points of uncertainty. The patient will be asked to sign a consent form providing their permission to enter the study and the next available randomisation envelope (age-dependent) will accompany the consent form into the operating theatre with the patient. The participant will not be aware of the result of randomisation at the point of study enrolment. The envelope will remain unopened until the operating surgeon has confirmed that the reduction of the medial malleolus fracture on an anteroposterior view is acceptable following fibular stabilisation. The envelope will be opened by a member of theatre staff who is independent of the trial. In the event that the fracture is not well-reduced, the envelope is returned in sequence back to the study office and the patient is withdrawn from the study. In the case of a trimalleolar fracture with an associated posterior malleolar fracture, fracture fixation will be at the discretion of the operating surgeon and influenced by the size of the fragment, articular congruity and presence of posterior talar subluxation. Examples of an acceptable and unacceptable intra-operative medial malleolar reduction are shown in Figs. 2 and 3.

Interventions

Non-fixation

Participants randomised to non-fixation of their well-reduced medial malleolus fracture will not require further intervention on the medial side. Wound closure on the lateral side, post-operative immobilisation and weight bearing restriction will be at the discretion of the operating surgeon. As a general rule in our service we aim to fit all patients with a removable orthosis and allow them to immediately fully weight bear wherever possible, only restricting in the case of a syndesmotic injury or peripheral neuropathy for between 6 and 8 weeks. The presence or absence of medial malleolus fixation should not influence the surgeon's decision with respect to the post-operative management.

Fixation

Participants randomised to fixation of their well-reduced medial malleolus fracture will be treated with standard medial malleolar fixation techniques at the discretion of the operating surgeon, the most common of which involves one or two 3.5-mm partially threaded cancellous lag screw (35–45 mm length) inserted at 90° to the fracture, following a satisfactory open reduction. Other

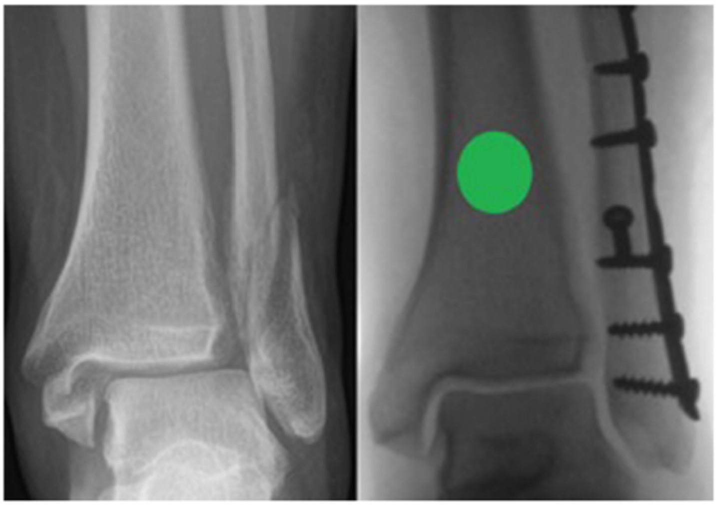

Fig. 2 Anteroposterior radiograph of a supination-external rotation stage IV fracture at the time of injury and following fibular stabilisation, demonstrating an anatomically reduced medial malleolus. This patient would be eligible for intra-operative randomisation

Appendix

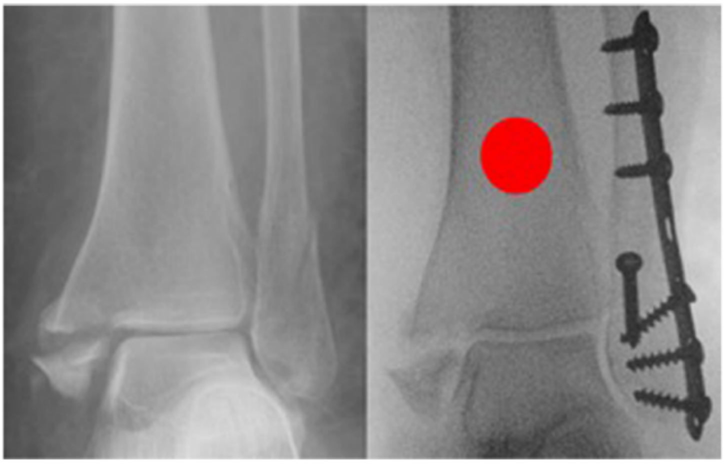

Fig. 3 Anteroposterior radiograph of a supination-external rotation stage IV fracture at the time of injury and following fibular stabilisation. The medial malleolus has not reduced to acceptable limits, likely incarcerated by soft tissue. This patient would not be eligible for intra-operative randomisation

techniques may include tension band wire construct and Kirschner wires, appropriate for size and integrity of the malleolar fragment. Wound closure and post-operative management are at the discretion of the operating surgeon as in the non-fixation trial arm.

Blinding

Given the invasive nature of surgery those patients randomised to 'Fixation' will have an additional surgical wound on the medial aspect of their ankle and those who are randomised to 'Non-fixation' will not. It is therefore not possible to blind either the surgical team or the patients in this trial.

Outcome assessment

All participants, regardless of randomisation, will be reviewed back in the research outpatient clinic at 2 weeks, 6 weeks and at 1 year post-intervention. During the 2-week post-operative assessment, the wounds will be inspected, sutures removed by a dressings nurse and the patient will undergo anteroposterior (AP) and lateral radiographs of the ankle joint to ensure satisfactory talar reduction and no displacement of the metalwork or fractures. Immediate complications including infection, wound dehiscence and venous thromboembolic (VTE) disease will be documented. The 6-week, 8-week and 1-year assessment points will include further weightbearing AP and lateral radiographs to assess fracture union, talar reduction and radiographic evidence of osteoarthritis. Patients will complete the patient-reported outcome measures of OMAS, Manchester-Oxford Foot Questionnaire (MOXFQ), EuroQol 5D (EQ-5D), pain and treatment satisfaction on visual analogue scales (VAS), and return to work and sport. Complications will be documented. Physiotherapy will be organised at the discretion of the clinician reviewing the patient in the clinic to begin following the 6-week assessment. Postal questionnaires will be sent out at 3 and 6 months after surgery collecting the same outcome scores. The schedule of enrolment, interventions, and assessments as per the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) is summarised in Fig. 4.

Primary outcome

The primary outcome measure will be the OMAS at 1 year following surgery [28]. This is a validated lower limb outcome score that has been used in large Health Technology Assessment (HTA)-funded trials concerning the ankle [24, 27]. This scoring system assesses patient-reported outcome across nine parameters: pain, stiffness, swelling, stair climbing, running, jumping, squatting, supports, and work/activities of daily living. A final score is calculated from 0 to 100, with 100 representing a better functional outcome. A recent study found that the OMAS had acceptable levels of internal consistency and test-retest validity, and correlated strongly with other lower limb injury outcome scoring systems and measures of general health, including the EQ-5D [29]. The primary null hypothesis is that there is no difference in outcome (primary outcome measure, OMAS) after 1 year between fixation of associated medial malleolus fractures and non-fixation in patients undergoing surgery for an unstable fracture of the ankle.

Appendix

	STUDY PERIOD						
	Enrolment	Allocation	Post-allocation				Close-out
TIMEPOINT	$-t_1$	0	*2 weeks*	*6 weeks*	**12 weeks*	**26 weeks*	*52 weeks*
ENROLMENT:							
Eligibility screen	X						
Informed consent	X						
Demographics	X						
Allocation		X					
INTERVENTIONS:							
FIXATION		X					
NON-FIXATION		X					
ASSESSMENTS:							
Wound review +/- removal of sutures			X	X			
OMAS		X		X	X	X	X
MOXFQ				X	X	X	X
EQ-5D		X		X	X	X	X
Pain score				X	X	X	X
Return to work & sport				X	X	X	X
Satisfaction				X	X	X	X
Complications			X	X	X	X	X

Fig. 4 Schedule of enrolment, interventions, and assessments. *Data collected through postal questionnaire. EQ-5D EuroQol 5D, MOXFQ Manchester-Oxford Foot Questionnaire, OMAS Olerud Molander Ankle Score

Secondary outcomes

Secondary outcome measures include: 1) MOXFQ (Isis Innovation Ltd., Oxford, UK) [30], a validated and reliable patient-reported outcome measure for surgery of the foot and ankle, consisting of 16 items from three domains: walking/standing (seven items), pain (five items) and social interaction (four items) where each item is scored on a five-point Likert scale ranging from no limitation to maximum limitation (0, 1, 2, 3, 4); a raw score out of 64 is then converted to a 0–100 metric score, with 100 representing a better functional outcome; 2) EQ-5D [31], a standardised instrument for use as a measure of health outcome; 3) pain assessment measured on a VAS from 0 to 100 with 100 indicating no pain; 4) treatment satisfaction measured on a VAS from 0 to 100 with 100 indicating extremely satisfied; 5) time taken to return to work and sport (if applicable); 6) operative tourniquet time; and 7) complications including superficial and deep infection, nerve injury, chronic pain, failure of fixation, non-union, metalwork complications and re-operation.

Statistical analysis

The analysis of primary outcome data will include participants who have completed their 12-month follow-up, and will be analysed on an intention-to-treat basis. Statistical analysis will be performed by a senior statistician who is independent of the study and employed through the local university research methodology department. The primary outcome measure (OMAS at 1 year) will be compared between the two treatment groups using a two-way sample *t* test or non-parametric equivalent, dictated by the normality of the data. An analysis of covariance adjusting for age and the baseline patient-reported outcome measure (OMAS) will be performed. This method will also be used to compare other continuous outcome measure scores. The OMAS will also be collected at multiple time points to calculate change in outcome over time. This will be determined by fitting a linear regression to the 6-week to 12-month values of each participant and comparing the slope of the regression line between treatment arms. Comparison of binary outcomes such as the presence of non-union, infection and re-operation will be compared between the two treatment groups using a binominal test for comparison of proportions. Two-tailed p values will be presented wherever possible and a p value < 0.05 will be used to indicate statistical significance.

Missing data

The study sample size has been increased by 20% to account for loss to follow-up at the primary outcome point (12 months). The primary outcome point will be collected at the final outpatient clinic appointment and, as such, it is anticipated that missing data for the primary outcome will be low. The participant dropout rate for each arm of the trial will be reported and compared. If the participant dropout rate at the primary outcome point is high, a sensitivity analysis may be performed. Missing data at the intermediate data collection points are most likely to occur at the 3- and 6-month assessment points as data collection is via postal questionnaire. However, by performing an analysis on change over time through fitting regression models the impact of missing data will be minimised.

Patient safety

Secondary outcome measures include complications, which will be closely monitored in both arms of the trial. This trial will be conducted in line with the Academic and Clinical Central Office for Research and Development (ACCORD) published guidelines: Identifying, Recording and Reporting Adverse Events for Clinical Investigations of Medical Devices.

Discussion

The most basic fracture classification system, devised by Pervical Pott, describes the number of malleoli involved—unimalleolar, bimalleolar and trimalleolar [32]. The lateral and medial malleoli are important contributors to ankle stability in conjunction with their associated ligaments—the lateral ligament complex and medial/deltoid ligament, respectively.

There has been considerable historical debate regarding the significance of the contribution of the medial malleolus to ankle joint stability. Yablon et al. concluded that the lateral malleolus was fundamental in anatomical reduction of bimalleolar fracture patterns with the talus 'always faithfully followed the lateral malleolus upon reduction' [33]. This was confirmed with cadaveric ankle stress testing which found that ankle stability was minimally affected upon sectioning of the deltoid ligament or fracture of the medial malleolus. Yablon's theory went against the views of others including Hughes who hypothesised it was in fact the medial malleolus which helped to re-establish a stable and congruent mortise [34]. The majority of surgeons therefore considered the medial malleolus to be the most important stabiliser and consequently unstable bimalleolar ankle fracture dislocations were commonly treated with open reduction and internal fixation of the medial malleolus in conjunction with closed reduction of the lateral malleolus.

When assessing load bearing in the ankle joint, the majority of the bodyweight is distributed over the central zone of the distal tibial plafond. During standing and walking, 90% of the loading occurs in this area with the remaining load being shared between the medial and lateral malleoli [35]. Consequently, good results have been published in patient cohorts with conservatively managed isolated medial malleolus fractures [19, 20]. Herscovici et al. identified 57 patients with conservatively managed isolated medial malleolus fractures, accepting any degree of fracture reduction [19]. Only two cases required further intervention with an overall union rate of 96%. Patients reported good outcomes as per the Short Form-36 (SF-36) and AOFAS ankle-hindfoot score. Importantly there were no cases of medial instability, skin compromise, malalignment of the mortise or post-traumatic degenerative changes after a mean 3-year follow-up. They concluded that isolated medial malleolus fractures could be treated non-operatively, but consideration should be given to fixation in the cases of bimalleolar and trimalleolar fracture dislocations, which were deemed more inherently unstable. More recently Hanhisuanto et al. concluded that medial malleolar reduction was critical for a good patient outcome when managed conservatively, defining 2 mm or less of displacement as the absolute acceptable cut-off [20].

Any operation, especially on the foot and ankle, is associated with a risk of surgical site infection (SSI), particularly in elderly patients who may have contributing risk factors such as diabetes, immunosuppression and peripheral vascular disease. Infection rates between 8% and 13% have been quoted, with up to 10% requiring further surgery for removal of metalwork or wound debridement [36, 37]. With this in mind, the benefits of minimising skin incisions and implantation of metalwork are clear.

Following a review of the recent literature, this randomised controlled trial will provide superior statistical power when assessing the impact of medial malleolus fixation on patient-reported and surgical outcomes following bimalleolar or trimalleolar fractures. Given the varied practice in ankle fracture surgery including implant selection for fibular stabilisation, medial malleolar fracture fixation, wound closure, post-operative immobilisation and weight-bearing restrictions, the study has a pragmatic design to reproduce day-to-day trauma care [38, 39].

One anticipated difficulty will be intra-operative randomisation. We have defined an acceptable reduction as no more than 2 mm of displacement as measured fluoroscopically on an AP view, based on the recent evidence [20, 22]. During surgery there will be subjective variability in the surgeon's accurate determination of displacement with the fluoroscopy equipment available. Therefore, the surgeon will have to decide whether the displacement is acceptable by assessing the overall shape and alignment of the mortise. Revealing the allocation of randomisation before the reduction has been assessed would create potential bias regarding the interpretation of reduction quality. It is crucial that the envelope is not opened until authorised to do so by the operating surgeon and this must be performed by an independent member of staff. A research co-ordinator will be present in theatre to ensure the result of randomisation is not revealed until the correct stage in the surgical procedure. If the patient is no longer eligible the envelope must be returned immediately to the study office in order to prevent disruption to the randomisation sequence.

A limitation of the study relates to the single-centre design. However, the study centre provides orthopaedic care to a population of approximately 850,000 and has 12 orthopaedic trauma consultants who collectively provide operative intervention for approximately 450 ankle fractures per year. The authors feel the results will therefore be reliably extrapolated to the wider orthopaedic community. Patient-reported outcome scores are being increasingly used in orthopaedic trials with clear benefits—the focus of outcome is centred on the patient, and outcome scores can be collected remotely. The OMAS (primary outcome) may be limited as it focuses more on physical symptoms (pain, stiffness and swelling) and patient performance (running, jumping, squatting), whilst neglecting the impact on emotional/mental well-being. It is therefore important to collect data on a general health outcome (EQ-5D) as part of the assessment in this prospective trial.

Trial status

The first patient was recruited on 24 October 2017. The expected date of completion is February 2021.

Abbreviations

ACCORD: Academic and Clinical Central Office for Research and Development; AO: Arbeitsgemeinschaft für Osteosynthesefragen; AOFAS: American Academy of Foot and Ankle Surgeons; AP: Anteroposterior; CONSORT: Consolidated Standards of Reporting Trials; ED: Emergency department; EQ-5D: EuroQol 5D; HTA: Health Technology Assessment; MOXFQ: Manchester-Oxford Foot Questionnaire; OMAS: Olerud Molander Ankle Score; ORIF: Open reduction and internal fixation; PIS: Patient information sheet; REC: Research Ethics Committee; SAD: Supination adduction; SF-36: Short Form-36; SORT-IT: Scottish Orthopaedic Trust into Trauma; SPIRIT: Standard Protocol Items: Recommendations for Interventional Trials; SSI: Surgical site infection; TBW: Tension band wiring; VAS: Visual analogue scale; VTE: Venous thromboembolic

Acknowledgements

This study is being conducted with the help of the Scottish Orthopaedic Research Trust into Trauma (SORT-IT) and the NHS Lothian health board.

Data storage

All paper records with patient-identifiable data will be kept in a locked cupboard in the study office. The Chief Investigator will be responsible for the key. All computer records will have limited access via usernames and passwords, and no identifiable data will leave the hospital computer system. Paper records will be kept for 5 years. All electronic data will be handled according to ACCORD guidelines on data protection and confidentiality.

Authors' contributions

TOW was primarily involved in the conception and design of the study and is the principal investigator. THC developed the study protocol, drafted the manuscript and acts as the main co-ordinating study investigator. ADD assisted with design of the study protocol and reviews patients in the trauma clinic. WMO assisted with manuscript preparation and acts as an additional study co-ordinator. CG assisted with design of the study and provided detailed statistical guidance. All authors have contributed to and approved the final submitted manuscript.

Authors' information

THC is enrolled in a postgraduate programme with the University of Edinburgh. This study will form part of a submitted thesis for the award of Doctor of Medicine (MD). All of the authors possess valid Good Clinical Practice (GCP) qualifications.

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Availability of data and materials

Not applicable.

Ethics approval and consent to participate

This study has been approved by the South-East Scotland Research Ethics Committee 2 (REC reference 17/SS/0124). Informed consent will be obtained from all study participants at the point of enrolment.

Consent for publication

Not applicable.

Competing interests

The authors declare they have no competing interests.

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References

1. Court-Brown CM, Caesar B. Epidemiology of adult fractures: a review. Injury. 2006;37:691–7. https://doi.org/10.1016/j.injury.2006.04.130 2006/07/04.
2. Donken CC, Al-Khateeb H, Verhofstad MH, et al. Surgical versus conservative interventions for treating ankle fractures in adults. Cochrane Database Syst Rev. 2012:CD008470. https://doi.org/10.1002/14651858.CD008470.pub2 2012/08/17.
3. Barbosa P. Malleoli: infrasyndesmotic, medial fracture with lateral fracture/avulsion. 2015. https://www2.aofoundation.org/wps/portal/surgery?showPage=diagnosis&bone=Tibia&segment=Malleoli. Accessed 1 Sept 2018.
4. Ricci WM, Tornetta P, Borrelli J Jr. Lag screw fixation of medial malleolar fractures: a biomechanical, radiographic, and clinical comparison of

Appendix

unicortical partially threaded lag screws and bicortical fully threaded lag screws. J Orthop Trauma. 2012;26:602–6. https://doi.org/10.1097/BOT.0b013e3182404512 2012/03/23.
5. Parada SA, Krieg JC, Benirschke SK, et al. Bicortical fixation of medial malleolar fractures. Am J Orthop (Belle Mead NJ). 2013;42:90–2 2013/02/23.
6. King CM, Cobb M, Collman DR, et al. Bicortical fixation of medial malleolar fractures: a review of 23 cases at risk for complicated bone healing. J Foot Ankle Surg. 2012;51:39–44. https://doi.org/10.1053/j.jfas.2011.09.007 2011/12/27.
7. Parker L, Garlick N, McCarthy I, et al. Screw fixation of medial malleolar fractures: a cadaveric biomechanical study challenging the current AO philosophy. Bone Joint J. 2013;95-B:1662–6. https://doi.org/10.1302/0301-620X.95B12.30498 2013/12/03.
8. Wera JC, Seligson D, Riehl JT. Medial malleolus screws: out in one view and out. Eur J Orthop Surg Traumatol. 2015;25:1189–93. https://doi.org/10.1007/s00590-015-1673-7 2015/07/23.
9. Buckley R, Kwek E, Duffy P, et al. Single-screw fixation compared with double screw fixation for treatment of medial malleolar fractures: a prospective randomized trial. J Orthop Trauma. 2018;32:548–53. https://doi.org/10.1097/BOT.0000000000001311 2018/09/14.
10. Ostrum RF, Litsky AS. Tension band fixation of medial malleolus fractures. J Orthop Trauma. 1992;6:464–8 1992/01/01.
11. Georgiadis GM, White DB. Modified tension band wiring of medial malleolar ankle fractures. Foot Ankle Int. 1995;16:64–8. https://doi.org/10.1177/107110079501600202 1995/02/01.
12. Johnson BA, Fallat LM. Comparison of tension band wire and cancellous bone screw fixation for medial malleolar fractures. J Foot Ankle Surg. 1997;36:284–9 1997/07/01.
13. Barnes H, Cannada LK, Watson JT. A clinical evaluation of alternative fixation techniques for medial malleolus fractures. Injury. 2014;45:1365–7. https://doi.org/10.1016/j.injury.2014.05.031 2014/07/22.
14. Cheng RZ, Wegner AM, Behn AW, et al. Headless compression screw for horizontal medial malleolus fractures. Clin Biomech (Bristol, Avon). 2018;55:1–6. https://doi.org/10.1016/j.clinbiomech.2018.03.023 2018/04/01.
15. Tekin AC, Cabuk H, Dedeoglu SS, et al. Anterograde headless cannulated screw fixation in the treatment of medial malleolar fractures: evaluation of a new technique and its outcomes. Med Princ Pract. 2016;25:429–34. https://doi.org/10.1159/000447426 2016/06/12.
16. Li ZH, Yu AX, Guo XP, et al. Absorbable implants versus metal implants for the treatment of ankle fractures: a meta-analysis. Exp Ther Med. 2013;5:1531–7. https://doi.org/10.3892/etm.2013.1017 2013/06/06.
17. Clyde J, Kosmopoulos V, Carpenter B. A biomechanical investigation of a knotless tension band in medial malleolar fracture models in composite Sawbones. J Foot Ankle Surg. 2013;52:192–4. https://doi.org/10.1053/j.jfas.2012.11.001 2012/12/21.
18. Downey MW, Duncan K, Kosmopoulos V, et al. Comparing the knotless tension band and the traditional stainless steel wire tension band fixation for medial malleolus fractures: a retrospective clinical study. Scientifica (Cairo). 2016;2016:3201678. https://doi.org/10.1155/2016/3201678 2016/06/14.
19. Herscovici D Jr, Scaduto JM, Infante A. Conservative treatment of isolated fractures of the medial malleolus. J Bone Joint Surg Br. 2007;89:89–93. https://doi.org/10.1302/0301-620X.89B1.18349 2007/01/30.
20. Hanhisuanto S, Kortekangas T, Pakarinen H, et al. The functional outcome and quality of life after treatment of isolated medial malleolar fractures. Foot Ankle Surg. 2017;23:225–9. https://doi.org/10.1016/j.fas.2016.06.004 2017/12/06.
21. Carter TH, Mackenzie SP, Bell KR, et al. Selective fixation of the medial malleolus in unstable ankle fractures. Injury. 2019;50(4):983–9. https://doi.org/10.1016/j.injury.2019.03.010. Epub 2019 Mar 11.
22. Hoelsbrekken SE, Kaul-Jensen K, Morch T, et al. Nonoperative treatment of the medial malleolus in bimalleolar and trimalleolar ankle fractures: a randomized controlled trial. J Orthop Trauma. 2013;27:633–7. https://doi.org/10.1097/BOT.0b013e31828e1bb7 2013/03/05.
23. Schulz KF, Altman DG, Moher D, et al. CONSORT 2010 statement: updated guidelines for reporting parallel group randomised trials. Int J Surg. 2011;9:672–7. https://doi.org/10.1016/j.ijsu.2011.09.004 2011/10/25.
24. Weil NL, Termaat MF, Rubinstein SM, et al. WARRIOR-trial—is routine radiography following the 2-week initial follow-up in trauma patients with wrist and ankle fractures necessary: study protocol for a randomized controlled trial. Trials. 2015;16:66. https://doi.org/10.1186/s13063-015-0600-x 2015/04/16.
25. White TO, Bugler KE, Appleton P, et al. A prospective randomised controlled trial of the fibular nail versus standard open reduction and internal fixation for fixation of ankle fractures in elderly patients. Bone Joint J. 2016;98-B:1248–52. https://doi.org/10.1302/0301-620X.98B9.35837 2016/09/03.
26. Makwana NK, Bhowal B, Harper WM, et al. Conservative versus operative treatment for displaced ankle fractures in patients over 55 years of age. A prospective, randomised study. J Bone Joint Surg Br. 2001;83:525–9 2001/05/31.
27. Willett K, Keene DJ, Mistry D, et al. Close contact casting vs surgery for initial treatment of unstable ankle fractures in older adults: a randomized clinical trial. JAMA. 2016;316:1455–63. https://doi.org/10.1001/jama.2016.14719 2016/10/12.
28. Olerud C, Molander H. A scoring scale for symptom evaluation after ankle fracture. Arch Orthop Trauma Surg. 1984;103:190–4 1984/01/01.
29. Garratt AM, Naumann MG, Sigurdsen U, et al. Evaluation of three patient reported outcome measures following operative fixation of closed ankle fractures. BMC Musculoskelet Disord. 2018;19:134. https://doi.org/10.1186/s12891-018-2051-5 2018/05/04.
30. Dawson J, Coffey J, Doll H, et al. A patient-based questionnaire to assess outcomes of foot surgery: validation in the context of surgery for hallux valgus. Qual Life Res. 2006;15:1211–22. https://doi.org/10.1007/s11136-006-0061-5 2006/09/27.
31. Rabin R, de Charro F. EQ-5D: a measure of health status from the EuroQol Group. Ann Med. 2001;33:337–43 2001/08/09.
32. Pott P. Some few general remarks on fractures and dislocations. 1758. Clin Orthop Relat Res. 2007;458:40–1. https://doi.org/10.1097/BLO.0b013e31803dd063 2007/05/03.
33. Yablon IG, Heller FG, Shouse L. The key role of the lateral malleolus in displaced fractures of the ankle. J Bone Joint Surg Am. 1977;59:169–73 1977/03/01.
34. Hughes J. The medial malleolus in ankle fractures. Orthop Clin North Am. 1980;11:649–60 1980/07/01.
35. Kimizuka M, Kurosawa H, Fukubayashi T. Load-bearing pattern of the ankle joint. Contact area and pressure distribution. Arch Orthop Trauma Surg. 1980;96:45–9 1980/01/01.
36. Pagliaro AJ, Michelson JD, Mizel MS. Results of operative fixation of unstable ankle fractures in geriatric patients. Foot Ankle Int. 2001;22:399–402. https://doi.org/10.1177/107110070102200507 2001/06/29.
37. Zaghloul A, Haddad B, Barksfield R, et al. Early complications of surgery in operative treatment of ankle fractures in those over 60: a review of 186 cases. Injury. 2014;45:780–3. https://doi.org/10.1016/j.injury.2013.11.008 2014/01/07.
38. Costa ML, Achten J, Parsons NR, et al. Percutaneous fixation with Kirschner wires versus volar locking plate fixation in adults with dorsally displaced fracture of distal radius: randomised controlled trial. BMJ. 2014;349:g4807. https://doi.org/10.1136/bmj.g4807 2014/08/07.
39. Schwartz D, Lellouch J. Explanatory and pragmatic attitudes in therapeutical trials. J Clin Epidemiol. 2009;62:499–505. https://doi.org/10.1016/j.jclinepi.2009.01.012 2009/04/08.

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