Optimizing Long-Term Outcomes and Avoiding Failure With the Fibula Intramedullary Nail

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OPTIMISING THE SURGICAL TECHNIQUE IN THE MANAGEMENT OF UNSTABLE ANKLE FRACTURES USING THE FIBULAR INTRAMEDULLARY NAIL

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CONFLICTS STATEMENT

One of the senior authors (TOW) has been involved in the design of the 2nd generation of the fibular nail manufactured by the company Acumed (Hillsboro, Oregon, USA). TOW 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.

ABSTRACT

Objectives: To identify risk factors for fixation failure, report patient outcomes and advise on modifications to the surgical technique for fibula nail stabilisation of unstable ankle fractures.

Design: Retrospective review.

Setting: Orthopaedic trauma unit serving a capital city.

Patients: All 342 patients were identified retrospectively from a prospectively collected single-centre trauma database over a nine-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 due to an inadequate mechanical construct. The mid-term outcomes included the Olerud-Molander Ankle Score (OMAS) and the Manchester-Oxford Foot Questionnaire (MOXFQ).

Results: Twenty failures occurred (6%), of which seven (2%) were due to device failure and 13 (4%) due to surgeon error. Of the surgeon errors, eight consisted of inappropriate weight bearing after syndesmotic diastasis and five 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 >20mm 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 OMAS and MOXFQ 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.

Conclusion: The fibula nail offers secure fixation and good patient reported outcomes for unstable ankle fractures. Appropriate post-operative management and surgical technique, including careful placement of the PLS is essential to minimise construct failure risk.

Level of Evidence: III – Retrospective cohort study.

INTRODUCTION

Open reduction and internal fixation (ORIF) is the most common method employed in the management of unstable ankle fractures. The incidence and severity of ankle fractures in the elderly is steadily rising. [1, 2] In this multi-comorbid patient group, high rates of post-operative 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 **(Fig. 1)** is supported by prospective randomised 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 post-operative management is essential. The evolution of the fibula nail technique was described by Bugler et al (2012) [10] and emphasises the importance of correct nail placement and the insertion of at least two locking screws; an anteroposterior distal locking screw (DLS), and a proximal locking screw (PLS) that traverses the fibula and syndesmosis to engage the tibia **(Fig. 2)**. The reporting of patient outcome and the assessment of fixation failures is essential to allow a greater understanding of this method and allow further refinement of the surgical technique.

This study aims to investigate the short and mid-term outcome 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 paper by Bugler et al (2012). 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 digitalised radiographs was performed using the Picture Archiving and Communication System (PACs, Rochester, NY, USA: Carestream Health, Inc). Pre-operative radiographs were classified according to Orthopaedic Trauma Association (OTA) Classification and Lauge-Hansen systems, [11, 12] and the presence of distal tibiofibula diastasis was noted. Intra-operative 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 (1965). [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 **(Fig. 2)**. Post-operative radiographs were assessed for talar mal-reduction and fixation failure requiring revision surgery. Failures were divided into two 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 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 failure of the nail, DLS(s), or PLS(s).

Correlation was sought between device failure, injury characteristics and intra-operative 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 1st generation Acumed fibula nail (Hillsboro, Oregon, USA) was used in all cases. This solid titanium implant is available in two diameters (3mm and 3.6mm) and three lengths (110mm, 145mm and 180mm). Where possible, the wider nail is employed with a length that allows passage of the nail at least 20mm beyond the fracture. Treatment of a bony medial malleolar component was at the discretion of the operating surgeon and included non-operative management, 3.5mm partially threaded cancellous screws, or tension band wire construct. Posterior malleolus fractures were predominantly manged operatively only if they contributed to posterior subluxation of the talus when assessed intra-operatively, using percutaneously inserted anteroposterior 3.5mm partially threaded cancellous screws or application of a posterior tibial buttress plate. Post-operatively, patients were placed in a removable orthosis or cast and allowed to mobilise 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 was failure defined as any case that required revision surgery due to an inadequate mechanical construct. Patients underwent short-term follow-up assessment at our centre, which is the single provider of orthopaedic trauma care in the region. All patients underwent at minimum of two post-operative clinical and radiographic reviews, the first at two weeks and the second between six and eight 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 (PROMs), 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 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. A Student's unpaired t-test was employed to analyse parametric continuous data. The Mann-Whitney U test was used to compare nonparametric continuous 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

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, 3) per patient. Sixty-one patients (18%) had diabetes mellitus, of which 25 (7% of total cohort, 41% of diabetic group) were insulin dependent and 20 patients (6% of total cohort, 33% of diabetic group) had peripheral neuropathy. Forty-five patients (13%) were obese with a body-mass index >30 kg/m^2, 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 OTA classification, there were 280 (82%) 44-B2/44-B3 fractures, 45 (13%) 44-C2 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 (PER) type fractures and seven (2%) supination-adduction (SAD) 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 seven (2%) due to device failure. Patient comorbidity was comparable to the total cohort with a median number of comorbidities of 3 (interquartile range, 4) per patient. Three patients (15%) had diabetes mellitus, of which two were insulin dependent (10%) and one (5%) had peripheral neuropathy. Two patients (10%) were obese, one (5%) had chronic renal impairment and one patient (5%) was taking long-term steroid medication. A summary of failed cases and revision procedures are 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). The majority of 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. 3)**. Five cases failed due to poor intra-operative technique or talar reduction **(Fig. 4)**. An 'anatomical' or 'fair' reduction quality was achieved with the fibula nail 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. Out of the 12 cases of 'poor' quality reduction, two required revision and are included in the failures cohort.

All seven device failures occurred in relation to the PLS, in patients aged 60 years or older, with a mean age of 74 years (range, 60 – 93 years), ten years older than the mean total study cohort **(Fig. 5)**. Three of these patients had an established radiological diagnosis of osteoporosis, on pharmacological treatment.

Over 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 **(Fig. 1)**. There were no cases of nail breakage or DLS failure. Independent risk factors for device failure are presented in **Table 2**. Constructs were more likely to fail if the PLS was inserted >20mm above the level of the plafond (p=0.003).

Soft tissue complications

Thirteen patients (4%) required further surgery due to non-infected symptomatic implant, including removal of the fibula nail and all locking screw in five cases, the PLS in five cases and the DLS in three cases. Lateral side infection occurred in nine (3%) patients, six of whom required oral antibiotics, two required intravenous antibiotics and three required removal of nail, supplemented by intravenous antibiotics. The overall re-operation 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, three 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 (interquartile range, 45) and MOXFQ of 10.94 (interquartile range, 44.00). Median patient satisfaction was 90 (interquartile range, 20). Patients requiring revision surgery presented a poorer outcome across all domains, but their outcome did not differ significantly compared with non-failed cases, apart from in one score (OMAS). Pain and overall health scores were comparable between groups. Only four patients in the failures group were working and engaged in sport before their injury, of whom two returned to work at a mean of 14 weeks. The same two patients returned to sport at six months and 18 months respectively. Outcome scores for the total group, failures (n=12) and non-failures (n=217) are summarised in **Table 3**.

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 intra- and post-operative surgeon errors. However, for those patients with adequate talar reduction, appropriate nail insertion and correct post-operative weight-bearing instruction, the failure rate was 2%. Both figures compare favourably with previous work reporting a failure rate of up to 14% for traditional ORIF in patients aged over 50 years. [17]

The present study supports and develops the findings of Bugler et al (2012) that demonstrated a failure rate of 7% in an earlier cohort of 105 fibula nails implanted with various screw configurations. [10] This previous paper demonstrated the importance of the PLS to the fibula nail construct, a concept that is further reinforced in this study. All seven 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 (HR-pQCT) of cadaveric tibiae. [18] Similarly, PLS pull-out was related to screw position: a construct with a PLS sited more than 20mm above the plafond **(Fig. 2)**, and therefore in less dense tibial bone, had a significantly increased risk of failure.

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 centre 14 years ago, and the fact 52 different surgeons of varying experience performed the procedures reported here, only five of the failures in the current study cohort were a direct result of technical error. We feel that this figure attests to the generalisability of the technique. Eight patients sustained a construct failure due to 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 five 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. We could not include 81 patients because they did not have adequate digitalised radiographs to perform a detailed evaluation. However, these earlier patients from 2002 onwards have been reviewed in the paper by Bugler et al (2012) [10] and comprise a group with comparable demographics to the current study cohort with a mean age at surgery of 65.0 years (range, 22 – 95 years). Within this excluded group of patients there were three documented failures (4%), but as previously discussed, it was not possible to perform a detailed radiographic assessment to characterise the modes. Furthermore, time to follow-up was variable with 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 post-operatively and therefore discharged from the service. As our region, with a patient population of approximately 850,000 is served by a single Orthopaedic centre 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 employ 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 centre. [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 two cases the nail was positioned so poorly in the distal fragment that it failed to grip it **(Fig. 4)**, and in the remaining three 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 following the lateral malleolus, results in residual displacement. Conversely, an overly lateral entry point results in medialisation of the fibula, loss of talar reduction, and displacement of an associated medial malleolar fracture **(Fig. 6)**. Revision of this error, as with other long bone nailing procedures, involves opening out the entry point to facilitate correct nail trajectory.
2. The base of the nail should be left flush with the cortex at the tip of the fibula, where it achieves optimal grip. Over-insertion leaves the base in the weaker cancellous bone of the fibula metaphysis where the grip is less satisfactory **(Fig. 7)**. 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 due to the DLS, only one of which was used in each case. Following 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. Additionally, 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 two PLS is advised in patients with a demonstrable syndesmotic injury or markedly poor bone density. Intra-operative 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 two 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 optimise the surgical technique.

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FIGURE LEGENDS

Fig. 1: Clinical picture demonstrating the three lateral wounds required to insert the fibula intramedullary nail. The swollen and blistered 'high risk' skin has been left undisturbed.

Fig. 2: Anteroposterior radiograph demonstrating the radiological outcome of the current 'gold standard' technique, in this instance with one anteroposterior distal locking screw (DLS) and one proximal locking screw (PLS) crossing the syndesmosis. The distance from the tibial plafond to the centre of the PLS has been highlighted (12mm).

Fig. 3: Anteroposterior radiograph from a 56-year-old patient who was allowed to fully weight bear following surgery, despite recognised syndesmotic injury, demonstrating loosening of the PLS and a diastasis seen four weeks post-operatively **(a)**. Final radiograph two years following revision surgery with deeper nail implantation, an additional PLS and non-weight bearing restrictions for eight weeks post-operatively **(b)**.

Fig. 4: Intra-operative lateral radiograph demonstrating inadequate fracture reduction and stabilisation, with the nail completely missing the distal fragment, highlighted in orange **(a)**. The construct failed rapidly 10 days after surgery, with the talus following the un-fixed lateral malleolar fragment posteriorly **(b),** eventually requiring a salvage arthrodesis.

Fig. 5: Intra-operative 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)**.

Fig. 6: Intra-operative radiographs from a 72-year-old woman showing an overly lateral guide wire entry point **(a)**. When the nail is inserted the fibula displaces the talus medially, mal-reducing the mortice **(b)**. The revised entry point opened up with fine nibblers **(c)** allowing medialisation of the entry reamer **(d)** and finally the nail **(e)**. Post-operative radiograph seven weeks following surgery **(f)**. The well-reduced medial malleolus has been treated conservatively as the fibula nail provides adequate lateral buttress to talar displacement.

Fig. 7: Post-operative anteroposterior radiographs from a 61-year-old male demonstrating nail over-insertion, with subsequent talar malreduction.

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 two PLS
Surgeon error: post-operative 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	1. Addition of second PLS to construct 2. Further failure with conversion to DC plate and screws

SER: supination-external rotation, PAB: pronation-abduction, PER: pronation-external rotation, PLS: proximal locking screw, DCP: dynamic compression plate

Table I: Fibular nail failures and details of revision procedures.

Risk Factor for failure	p-value
Age at surgery	0.627‡
Gender	0.718†
PLS sited >20mm above the plafond	**0.003**† *
Syndesmosis injury	**0.006**† *
Pronation-Abduction (PAB) configuration	**0.035**† *
Weber-C fracture classification	**0.047**† *
Fibular nail length	0.141†
Fibular nail width	0.476†
Number of PLS	0.831†
Length of PLS	0.337†
Absence of associated medial malleolus fixation	0.197†
Absence of associated posterior malleolus fixation	0.262†

‡ Unpaired t-test, † Chi Square test, * p-value <0.05

Table II: Risk factors for construct failure

Outcome Measure	Total Group (median, IQR)	Failure (median, IQR)	Non-failure (median, IQR)	p-value †
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

IQR: Interquartile range, EQ-5D: EuroQol-5D, OMAS: Olerud-Molander Ankle Score, MOXFQ: Manchester-Oxford Foot Questionnaire, VAS: visual analogue scale

† Mann-Whitney U test, * p-value <0.05

Table III: Patient reported outcome measures comparing failure and non-failure groups.