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ORIGINAL PAPER

Intramedullary fixation versus anatomically contoured plating of unstable ankle fractures: a randomized control trial

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Abstract

Aim This study compared functional outcomes between anatomical shaped fibular plates and intramedullary nail fixation of adult patients who sustained unstable ankle fractures.

Methods A prospective randomized control trial was conducted between November 2013 and December 2016 on patients that presented with an unstable ankle fractures. They were randomized into a plate-and-screw group and a fibula nail group. At each post-operative visit the wounds were reviewed, and specific outcome measures were recorded, which included (i) the patient reported outcome measure (PROM) Olerud and Molander functional score, (ii) the Grimby score, (iii) swelling around the malleoli, (iv) plantar flexion, (v) dorsiflexion, (vi) inversion, and (vi) eversion.

Results Significant differences were observed in scar size ($p < 0.001$) and screening time ($p < 0.001$) whilst no differences were observed in functional and PROM measures. Although not statistically significant, of clinical value is one deep infection that occurred in the plate group, whilst no infections occurred in the nail group.

Conclusion Both fixation methods yielded very similar functional results with differences only in scar size, screening time and swelling. Although none of these warrant a change in surgical decision-making processes, taken together, these factors potentially influence the decisions made in terms of surgical modalities used.

Keywords Unstable ankle fracture · Fibula plating · Fibula nail · Functional outcome · Internal fixation · Surgery

Introduction

Tygerberg Hospital is a tertiary level referral centre that treats approximately 1214 trauma cases per month, from a drainage area of 129,000 km^2 and ankle fractures form a substantial part of this trauma burden. The incidence of ankle fractures, internationally, is reported at 107 to 187 per 100,000 population [1, 2]. The high trauma burden in financially constrained healthcare systems has led to the exploration of treatment options that could potentially provide timely, cost effective, stable and soft tissue friendly surgical stabilization of these injuries.

Open reduction and internal fixation (ORIF) remains the gold standard for unstable ankle fracture management. Clinically and radiologically unstable ankle fractures are defined as those fractures that involve both columns of the ankle joint, but the associated iatrogenic soft tissue injury often poses a risk of wound breakdown and infection after open ankle approaches [2–4].

High wound complication rates and prominent hardware have resulted in the exploration of fixation options with less invasive implants [3, 5]. The development of intramedullary fibular nailing systems is one such option which allows stable bony fixation with minimal iatrogenic soft tissue injury [5, 6].

The aim of this study was to compare functional outcomes between anatomical shaped fibular plates and intramedullary nail fixation of adult patients who sustained unstable ankle fractures. Secondary aims were to compare clinical and surgical outcomes between treatment groups.

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Materials and methods

A randomized control trial was conducted between November 2013 and December 2016. Patients presenting with an unstable ankle fractures were considered and inclusion criteria included (i) isolated ankle fracture in (ii) skeletally mature patients with (iii) no previous ankle surgery and (iv) no congenital abnormalities. Patients were excluded if they (i) did not have complete baseline information, (ii) had multiple injuries, (iii) refused to participate in the study, (iv) were operated on by a surgeon not involved in this study or (v) had a fibular intramedullary canal that would not accommodate a nail. Preoperative planning in both treatment groups was the same except for specific reference to the medullary canal of the fibula for patients randomized into the fibula nail group. A canal that was measured to less than 3.1 mm, using the antero-posterior and lateral radiograph, was considered to not accommodate the nail and therefore excluded from the study. Ethical approval and institutional permission were obtained prior to commencement of the research. Research was conducted following the guidelines of the Declaration of Helsinki and the South African Guidelines for Good Clinical Practice [7].

Patient information was recorded, and patients were randomized into a plate group or a nail group using simple randomisation. An independent party drew the group allocation from a sealed, opaque container for each admission. The plate group was reviewed daily until the soft tissues were considered amenable to perform surgery, whilst the nail group received surgery on the next available theatre list. Time delays between injury, admission, surgery and discharge were recorded.

Surgical technique

Patient positioning

Patients were positioned supine on the operating table with sandbag under the ipsilateral buttocks, tourniquet on the upper thigh and injured limb was elevated by a long narrow pillow below the calve to the heel. The image intensifier was positioned over the contralateral leg, perpendicular to the leg being operated. This ensured visualization of an anteroposterior (AP) view and lateral view without movement of the ankle.

Plate group

Plating was performed using AO technique for locking plate fixation (Fig. 1). The Acumed (Acumed, Oregon, USA) anatomical contoured plate was used. Syndesmosis integrity evaluated using the Burwell and Charnley criteria [8]. A tibiofibular clear space increased of ≥ 1 mm was deemed unstable, and a syndesmotic screw was inserted.

Fig. 1 Intra-operative incisions for plate fixation

Nail group

The surgeon was positioned at the foot end of the patient. Reduction of the fibula fracture was crucial and was achieved with percutaneous clamping of the fracture. The Acumed (Acumed, Oregon, USA) fibula nail was inserted using the surgical technique described by Bugler et al. [9]. Figure 2 illustrates the incisions required for nail insertion.

The proximal and distal screws were inserted to enable rotation of the fibula as it lies within the incisura of the tibia. The same criteria for syndesmotic instability used in the plate group, was applied to the nail group. With an unstable syndesmotic injury, the jig was used to "rock" the nail with one hand, whilst the other hand was used to palpate the fibula position in the tibial incisura. This technique enabled palpation of where the "sweet spot" was to insert the syndesmotic screw. A single or two fully treaded syndesmotic screws was inserted through the nail across three cortices.

Fig. 2 Intra-operative incisions for nail insertion and fixation

The posterior lateral approach was used for posterior malleolus fractures, and the nail was inserted with the standard surgical technique [9].

Outcome measures and follow-up

Total operating time and total screening time was recorded intra-operatively. Patients were reviewed postoperatively at six weeks, three months, six months and one year. At the six week follow-up visit, the cast was removed, and patients in both groups received standardized physiotherapy-assisted rehabilitation. The length of the incision was measured whilst, at each visit, the wounds were reviewed and specific outcome measures were recorded, which included (i) the patient reported outcome measure (PROM) Olerud and Molander functional score, (ii) the Grimby score to evaluate activity of the study population, (iii) swelling around the malleoli (circumference at the level of the medial malleolus) (iv) plantar flexion, (v) dorsiflexion, (vi) inversion and (vi) eversion. All measurements were recorded of both ankles at the first follow-up visit, and thereafter only of the injured ankle. As part of standard operating procedure, all patients received AP, mortise and lateral radiographs of both ankles at the first follow-up visit and thereafter only of the injured ankle. Loss to follow-up was defined as patients who failed to follow-up at the one year visit.

Statistical analysis

Data was analysed using Stata (v15 StataCorp LLC, TX, USA) and Statistica v13 (TIBCO software). The sample size of this study was calculated using a minimal clinically important difference of 15-point difference in the Olerud and Molander functional score with an expected standard deviation of 20 points, as previously described [10, 11]. A sample size of 58 participants was considered adequate to obtain a power of 80% at a significance level of $\alpha = 0.05$. Central tendency and dispersion of data was reported using the appropriate measures. Frequencies and counts were used to represent categorical data. Differences between groups were detected by means of an independent t test or a Mann–Whitney U test whilst a paired t test or Wilcoxson test was used to detect differences within groups. Differences in categorical data were detected by means of a chi-squared or Fisher's exact test, where appropriate. Patients who were lost to follow-up or had missing data points were excluded from the particular analysis.

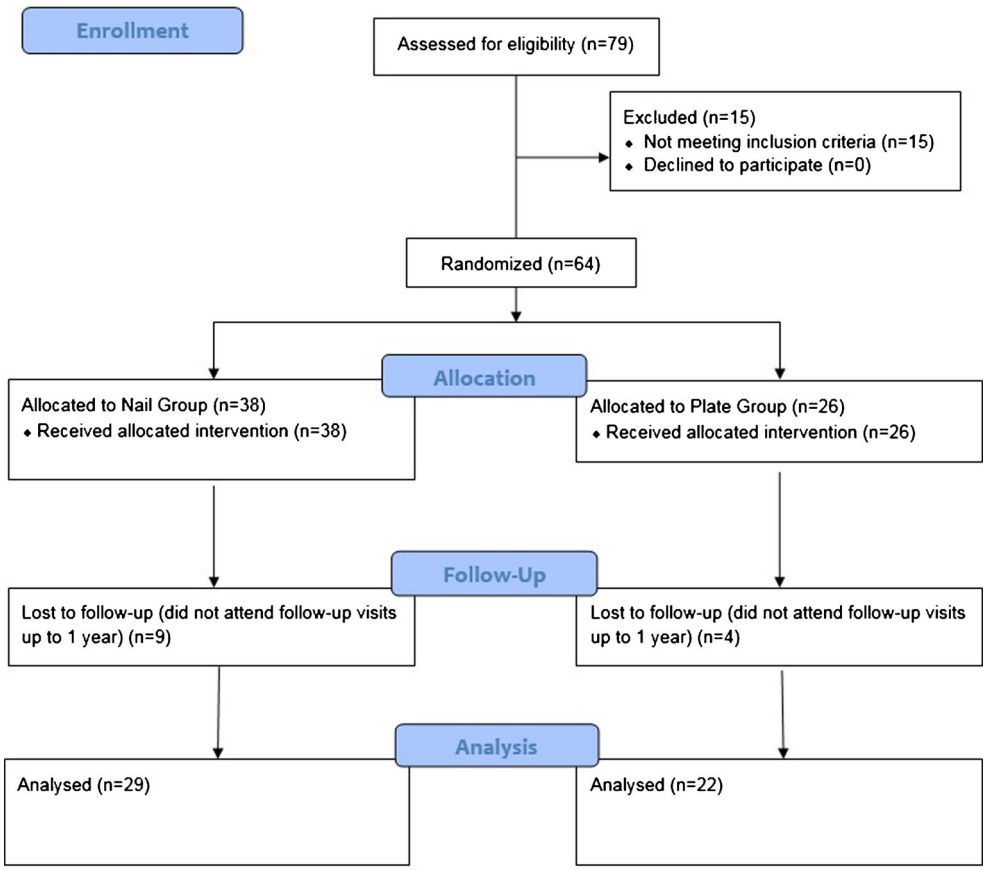

Fig. 3 CONSORT diagram of all patients assessed for eligibility, allocated, followed-up and analysed

Table 1 General characteristics between plating and nailing groups

	Group		*p* value
	Plate	Nail	
Age (years)	42.9 ± 13.9 (22)	42.8 ± 13.8 (29)	0.986
Gender (% female)	72.7 (16 of 22)	55.2 (16 of 29)	0.199
Height (cm)	162.9 ± 8.1 (22)	165.2 ± 8.5 (29)	0.338
Weight (kg)	78.9 ± 19.1 (22)	78.2 ± 16.3 (29)	0.894
BMI (kg.m^2)	29.7 ± 7.0 (22)	28.7 ± 5.8 (29)	0.590
Smoker (% yes)	36.4 (8 of 22)	42.9 (12 of 28)	0.642
Comorbid conditions (% yes)	18.2 (4 of 22)	32.1 (9 of 28)	0.264
HIV status (pos/neg/unknown)	4.5 (1)/54.5 (12)/40.9 (9)	3.4 (1)/82.8 (24)/13.8 (4)	0.080
Affected side (% right)	72.7 (16 of 22)	44.8 (13 of 29)	0.072

Data is expressed as mean ± standard deviation or frequencies with the total number of participants with non-missing data indicated in parentheses

Results

A total of 79 participants were considered for inclusion of which 15 patients were excluded because no baseline information had been collected. The final cohort therefore consisted of 64 patients (24 men; 32 women) of which 38 participants were treated in the nail group (15 men; 23 women) and 26 were treated in the plate group (9 men; 17 women). Nine patients in the nail group and four patients in the plate group were lost to follow-up over the one year period of the study, which resulted in a total of 51 participants ($n = 29$ nail group, $n = 22$ plate group) being analysed (Fig. 3).

General and clinical characteristics

The distribution between the plate group and nail group showed no significant difference in any demographic variables (Table 1). The fracture classification was significantly different between the plate and nail groups ($p = 0.007$) (Supplementary Table 1).

No significant difference between the plate and nail groups was observed in the median number of days that passed between the injury occurring, admission to hospital and receiving surgery (Supplementary Table 2). The high trauma burden in our facility did not allow for all patients to receive early surgery when the soft tissue was deemed ready, due to other higher prioritized emergencies.

Surgical outcomes

A significant difference was observed in scar size ($p < 0.001$) with the nail group having a smaller total scar length with a median of 1.5 cm (interquartile range, IQR 1.0–1.5) for three incisions compared with the plate group which had a median scar size of 10 cm (IQR 10.0–11.0). (Table 2) There was also a statistically significant difference ($p < 0.001$) in screening time with the nail group having a median of 0.6 min (IQR 0.4–1.3) compared with the plate group, median of 0.3 min (IQR 0.2–0.5). Although not statistically significant, of clinical value is one deep infection that occurred in the plate group ($p = 0.431$), whilst no infections occurred in the nail group (Table 2). Figures 4 and 5 illustrate Weber B fractures stabilized with anatomical locked plate and fibula nail.

Table 2 Surgical variables between the plating and nailing groups

	Group		p value
	Plate	Nail	
Scar size (cm)	10.0 (10.0–11.0) (22)	1.5 (1.0–1.5) (29)	**<0.001**
Total operating time (min)	55.0 (45.0–60.0) (19)	50.0 (40.0–60.0) (27)	0.192
Total screening time (min)	0.3 (0.2–0.5) (19)	0.6 (0.4–1.3) (27)	**<0.001**
Infection (% yes @ 6 weeks)	4.5 (1 of 22)	0.0 (0 of 29)	0.426

Data is expressed as median with interquartile ranges or frequencies with the total number of participants with non-missing data indicated in parentheses; *cm* centimetre, *min* minutes

Fig. 4 Weber B fracture pattern (**a**) stabilized with anatomical locked plate (**b**)

A return to baseline soft tissue circumference was observed at the 12-month follow-up in the nail group (Fig. 6) with a mean soft tissue malleolus circumference of 26.3 ± 2.6 cm in the affected leg versus 25.6 ± 2.1 cm in the unaffected leg (a mean difference of 0.7 cm) compared with 26.8 ± 1.7 cm in the affected leg versus 25.1 ± 2.3 cm in the unaffected leg (a mean difference of 1.7 cm) in the plate group. No differences were however observed in soft tissue malleolus circumference between the two groups at the 6-week, 3-, 6- and 12-month follow-up visits ($p = 0.774$, $p = 0.214$, $p = 0.546$ and $p = 0.421$, respectively) (Supplementary Table 3). No significant differences in functional scores, as measured by die Olerud and Molander scoring system or in the Grimby score at 3-, 6- and 12-months were observed (Table 3). Figures 7 and 8 illustrate Weber C fractures stabilized with a fibula nail and anatomical contoured lock plate.

There was no difference between plantar- and dorsiflexion between the groups in the unaffected leg and similarly, no differences between plantar- and dorsiflexion between the plate group and nail group were observed at any of the follow-up visits (Supplementary Figs. 1 & and 2). There were however significant differences at various time points between the unaffected and affected leg within each group, as can be expected (Supplementary Figs. 1 and 2). Similarly, there were no differences between inversion and eversion ranges between the plate group and nail group in the unaffected leg, and no differences between the groups were observed at any of the follow-up visits in inversion and eversion (Supplementary Figs. 3 and 4). Significant differences during the healing phase were observed between the unaffected and affected leg, throughout the study period. Both groups had 100% union rates with no loss of initial reduction.

Discussion

The aim of the study was to compare functional outcomes between anatomical shaped fibular plates and intramedullary nail fixation of adult patients who sustained unstable ankle fractures. This study demonstrated no differences in functional score or in physical activity between patients treated with an anatomically contoured plate versus those treated with an intramedullary nail. This is in contrast with previously reported findings where patients treated with intramedullary nails had significantly higher functional scores compared with those treated with plates at one year following surgery, when used in the internal fixation of the fibula in ankle fractures [12] or in acute ankle syndesmosis ruptures [10]. Asloum et al. further reported a significant difference in functional outcome, measured with the Kitaoka score with the nail outperforming the plate [12].

Plate fixation is the gold standard for unstable ankle fracture management, but the associated soft tissue injury poses a risk of wound breakdown and infection after open ankle approaches [2–4] whilst intramedullary nailing has been reported to afford minimal iatrogenic soft tissue injury with stable fixation in patients with vascular insufficiency and diabetic ankle fractures [5, 6, 13]. In the current study, we report no difference in infection rates between the two groups with only one case of infection in a patient treated with plate and screws and no infections occurring in the group treated with nails. The latter being in keeping with a previous study by White et al. who compared fibular nails to ORIF in elderly patients, and also reported a zero infection rate in the nail group [5].

Another factor to consider for surgical decision-making is time delays due to soft tissue swelling which need to decrease

Fig. 5 Weber B fracture pattern (**a**) stabilized with fibula nail (**b**)

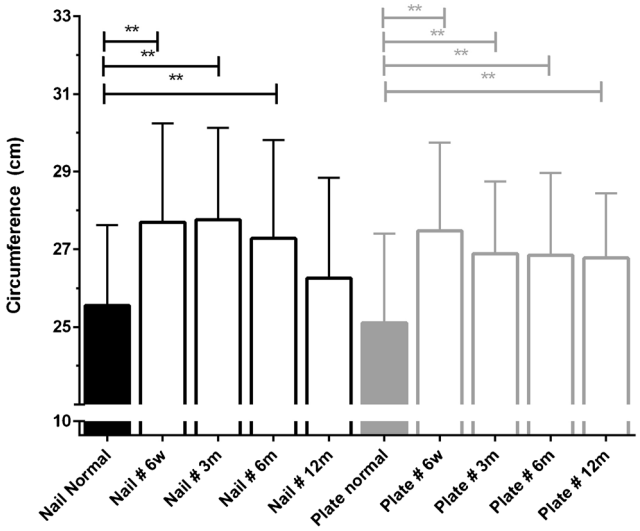

Fig. 6 Ankle malleolus circumference for the nail- (black bars) and plate (grey bars) groups for the normal (unaffected) leg (solid bar) versus each follow-up visit (clear bars) for each follow-up timepoint. **, $p < 0.001$

before surgery can performed, if plates are used. This is not the case when treating patients with intramedullary nails and patients in the nail group received surgery, despite clear blisters or soft tissue swelling when a theatre became available. Despite an expected earlier surgical readiness in the nail group, the system and burden of patients awaiting surgery at our institution does not allow for non-life-threatening surgery to be performed immediately, which is evident from the delay between admission and surgery in the nail group. All patients in this study therefore received surgery from day three onwards. Delays due to soft tissue swelling have an effect on associated costs and burden of patients awaiting surgery, especially in busy trauma centres and resource limited settings. Additionally, the risk of infection has been reported to potentially be higher between three and seven days post injury [4], and longer hospital stays are associated with increased risk of infection [4]. Therefore, ideally, patients should be operated as soon as possible.

A previous study, investigating the same treatment modalities, investigated the cost implications of the two methods in elderly patients and concluded that fibular nailing is more cost effective than delayed-staged ORIF techniques often used in elderly patients [5, 14]. Investigation of the economic implications as a result of delays to surgical readiness of the two different treatment modalities in our setting is warranted. Not only does an increased hospital stay carry significant financial implications, but length of hospital stay has been reported to also influence patient satisfaction [15].

Another factor which could potentially influence patient satisfaction is the time taken to "return to normal/baseline" function [16, 17]. As expected, significant differences in range of motion was observed between the affected and unaffected ankles of patients in both treatment groups. Dorsiflexion in the affected ankle returned to baseline in both groups after one year, whilst slightly decreased range of motion was present in all other measurements after a year. Although the fibula nail

Table 3 Functional and Grimby score at 3, 6 and 12 months between the plating and nailing groups

	Group		
	Plate	Nail	*p* value
Functional score (3 months)	70.0 (45.0–90.0) (18)	85.0 (65.0–95.0) (23)	0.386
Functional score (6 months)	100.0 (75.0–100.0) (19)	90.0 (85.0–100.0) (25)	0.767
Functional score (12 months)	100.0 (90.0–100.0) (22)	100.0 (90.0–100.0) (29)	0.717
Grimby (3 months)	2.0 (2.0–2.0) (18)	2.0 (2.0–2.5) (24)	1.000
Grimby (6 months)	2.0 (2.0–3.0) (19)	2.0 (2.0–2.0) (25)	0.758
Grimby (12 months)	2.0 (2.0–2.0) (22)	2.0 (2.0–2.0) (29)	0.924

Data is expressed as median and interquartile ranges, with the total number of participants with non-missing data indicated in parentheses

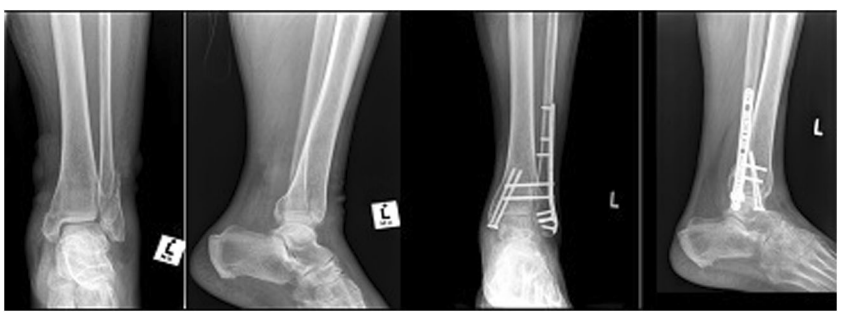

Fig. 7 Weber C fracture pattern (**a**) stabilized with anatomical lock plate (**b**)

Fig. 8 Weber C fracture (**a**) stabilized with fibula nail (**b**)

has been alluded to having superior biomechanical properties and therefore increased stability [6, 13], no differences were observed between the plate and nail groups in the current study.

Significant differences in the ankle circumference between affected and unaffected ankles were observed in both groups. However, at the 12-month follow-up visit, the ankle circumference of the affected ankle in the nail group had returned to its baseline whilst the swelling in the plate group's affected ankle was still significantly different to the unaffected ankle. The observed difference is probably due to the less iatrogenic soft tissue manipulation in the nail group. Similarly, a significant difference in screening time between the two groups was observed, but the clinical importance of this finding is limited, since both groups were still well within the allowable safe limits of radiation exposure [18].

Cosmetic appearance of large scars could potentially influence patient satisfaction and the thin soft tissue cover around the ankle region, which renders the plate fixation method prone to prominent hardware that might require a second surgery for removal [19]. Only two plates had to be removed in the current study, (data not shown) but recent designs of low profile plates minimize the need for hardware removal.

Limitations of the study includes the small sample size due to lost to follow-up, a notorious problem in our setting, and some missing data points in the follow-up periods which limits the conclusions which can be made of smaller observed differences [20]. Additionally, the nail group had more Weber C injuries than the plate group. This might have influenced the functional outcome but if compared with themselves as a control, there were no significant differences and therefore is not considered to be a confounding factor. An expected difference in total hospital stay, from admission to discharge, between patients treated with plates versus nails was not observed even though patients treated with nails can theoretically be operated immediately whilst those treated with plates need to wait until soft tissue swelling has decreased. Unfortunately our institutional protocol prioritizes certain injuries above others, and therefore, this potential difference could not be illustrated. This is however potentially an important outcome and should be investigated in future studies. Finally, considering the low infection rate reported in this study, it was not possible to determine whether any associations between comorbidities in the different treatment groups and risk of infection exist.

In conclusion, the plate and nail fixation methods yield similar functional results with differences in scar size, screening time and swelling reduction. Although none of these warrant a change in surgical decision-making processes, taken together, these factors potentially influence the decisions made in terms of surgical modalities used.

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Compliance with ethical standards

Conflict of interest The authors declare no conflict of interest.

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