Determining the rotational strength of Lateral Malleolus Locking Plate versus Fibula Intramedullary nail in Supination External Rotation type IV injuries: Cadaveric study

by

GIDEON FRANCOIS VAN STADEN

Registrar Department Orthopedic Surgery

University of the Free State, Bloemfontein, South Africa

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SUPERVISOR :Dr.Johan van der Merwe

Senior Consultant Department Orthopedic Surgery

University of the Free State, Bloemfontein, South Africa

DECLARATION

I, Gideon Francois van Staden, declare that the coursework Master's Degree mini-dissertation that I herewith submit in a publishable article format for the Master's Degree qualification MMed(Orth) at the University of the Free State is my independent work, and that I have not previously submitted it for a qualification at another institution of higher education. All sources used and/or quoted have been indicated and acknowledged by means of complete references.

The author declares that he has no conflict of interest.

Ethics approval was obtained from the Ethics Committees of the University of the Free State (ECUFS NR 190/2014). The study was executed in accordance with the World Medical Association Declaration of Helsinki (2013).

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GF van Staden[1], JF van der Merwe[2]

ABSTRACT

Introduction: Open reduction and internal fixation (ORIF) with anatomical reduction of displaced ankle fractures have been the standard of care since the 1960, but are associated with increased risk of complication, especially wound dehiscence and infections. Studies showed that minimal invasive ankle fracture fixation with a fibula intramedullary nail can reduce these complications with good clinical results after fracture fixation. Biomechanical evidence of its strength compared with locking plates and screws, is currently limited.

Aims: We examined the biomechanical properties of a distal fibular locking plate with the fibula intramedullary nail for fixation of ankle fractures induced in cadaveric models. Methods: 14 cadavers (28 limbs) were used and supination external rotation (SER) IV injury was surgically created. Right limbs was allocated to the locking plate group and left limbs to the intramedullary fibula nail group. Biomechanical testing was performed simulating an external rotation force.

Results: There was no statistical difference between the mean force needed for loss of anatomical reduction in the locking plate group and fibula nail group. There was, however, a statistical difference between the mean forces for total implant failure between the locking plate group and fibula nail group.

Conclusion: This cadaver study supports previous biomechanical research findings of comparable stability between the two surgical techniques when looking at the force needed to cause loss of anatomical reduction. The locking plates, was however superior to the fibula nail with regards to the amount of force needed to cause implant failure. From a biomechanical perspective, this showed that the fibula nail is be a viable option when treating unstable fibula fractures.

KEYWORDS

Ankle fracture; biomechanical stability; lateral malleolus; fibular nail; intramedullary nail, locking plate, supination external rotation IV injury, cadaver study

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LIST OF ABBREVIATIONS

ORIF	open reduction internal fixation
SER IV	supination external rotation type 4
MIS	minimal invasive surgery
CRIF	closed reduction internal fixation
AO	ArbeitsgemeinschaftfürOsteosynthesefragen
OTA	Orthopaedic Trauma Association

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GF van Staden[1], JF van der Merwe[2]

1. MBChB. Registrar, Orthopedic Surgery, University of the Free State (UFS), Bloemfontein, South Africa. Logeman str, Universitas Hospital, Bloemfontein, 9301 Email: gideonvanstaden@gmail.com

2. MBChB, MMed (Orth). Senior Consultant Orthopedic Surgery, UFS, Bloemfontein, South Africa. PO Box 339, Bloemfontein, 9300 Email: orthodocjohan@gmail.com

1. Introduction

Ankle fractures are very common and accounts for approximately 9% of all bone injuries[1]. There is a an annual increase of 0.2%, especially in the elderly population[2]. The preferred method of treating unstable fibula fractures is open reduction and internal fixation (ORIF) to achieve anatomical reduction and stability[3].

Little has change over the past 50 years in terms of the methods of internal fixation with conventional plate and screws, or lag screw and neutralization plate being the most commonly used techniques[4]. This, however, is associated with increased complications, of which wound dehiscence and painful prominent hardware is the most devastating, affecting up to 26-50% of patients[5,6]. These complications are particularly problematic in the elderly population, diabetics, smokers and patients that sustained a high-energy injury such as tibial plafond fracture with compromised soft-tissue[7,8]. Conventional lag screw and neutralization plate technique can be difficult in the elderly population due to their soft osteoporotic bone[9]. In these cases a locking plate can be used to help with the fixation of unstable fractures[10].

In order to reduce soft-tissue and hardware complications, other techniques such as minimal invasive surgery (MIS) and intramedullary hardware have been used. MIS aim to decrease surgical trauma, lessen soft tissue stripping with smaller skin incisions and potentially decreasing wound problems[11]. Techniques such as the use of Rush rods, Knowles pins or 4,2mm fully treaded intramedullary screws have been used in the past. These techniques combined the advantages of MIS and intramedullary hardware with small skin incision and no bulky hardware under the skin. This was done in an attempt to reduce the risk of developing soft-tissue complications due to superficial hardware[12–14].

Pins and rods were, however, associated with other complications such as loss of anatomical reduction, especially shorting of the fibula during insertion[15], and hardware migration leading to concurrent soft-tissue problems. The loss of reduction and rotational instability is a big concern because this can result in a widened ankle mortis[15]. Recent studies have shown the potential benefit of using an intramedullary nail device in the treatment of ankle fractures deferring from bulky plates[16,17].

Recently more anatomical devices such as the Biomet nail (Biomet Inc, Swansea, United Kingdom) and Acumed fibula nail (Hillboro,Oregan, USA) have been used with satisfactory result, especially in elderly patients[18,19]. Newly designed fibula nails have anteroposterior and lateral cancellous screws that go through the nail, aiming to prevent rotation and shortening. Biomechanical studies have shown that these nails provide adequate immobilization and stability for fractures to heal while preventing shortening or displacement[20].

White et al in a biomechanical cadaver study demonstrated greater fixation strength and fracture stability when comparing the fibula intramedullary nail to standard lag-screw and neutralizing plate technique[20]. Data comparing the biomechanical strength of locking plate and screw fixation with that of a fibula intramedullary nail is still limited[21].

The primary aim of this study was to evaluate and compare the biomechanical properties of a distal fibular locking plate (Acumed Low-profile Locking Lateral Fibula Plate, Hillboro, Oregan) and the Acumed fibula nail. This comparison was done in cadaveric models simulating Arbeitsgemeinschaft für Osteosynthesefragen/Orthopaedic Trauma Association (AO/OTA) 44B-type, supination external rotation (SER) IV fracture pattern. This is one of the most common ankle fracture patterns seen in elderly patients[22,23].

2. <u>Materials and methods</u>

Specimen preparation and surgical technique

Our objective was to measure the force needed to cause loss of anatomical reduction and implant failure. Twenty-eight limbs from fourteen intravenous embalmed cadavers were obtained from the Department of Anatomy, Faculty of Health Sciences, University of the Free State (Bloemfontein, South Africa). Nine male and five female cadavers were used. The ages of the cadavers were unknown. The limbs were all examined for signs of any previous injuries, including a previous fibula and medial malleolus fracture or deltoid ligament injury, of which was considered an exclusion criterion. The skin and muscle were removed in order to expose the fibula and syndesmosis. We simulated a (AO/OTA) 44B-type, supination external rotation (SER) IV fracture pattern. Release of the anterior inferior tibiofibular ligament, posterior inferior tibiofibular ligament and transverse ligament was done using sharp dissection. Oblique osteotomy was performed from proximal-posterior to distal-anterior at a 45 degrees angle on a level approximately 1cm above the tibial plafond.

The matched specimens were placed into two groups: a left limb group and a right limb group. All the left limb specimens were allocated to the locking plate group and all right limb specimens to the fibula intramedullary nail group.

The plating technique involved anatomical reduction of the osteotomy with bone reduction forceps and application of a 9-hole pre-contoured locking plate (Acumed, Hillsboro, Oregan) on the lateral aspect of the fibula with 3 appropriate size bicortical locking screws proximal and 3 unicortical locking screws distal to the osteotomy. (Figure 1a)

The same technique was used to get an anatomical reduction of the osteotomy in the fibula nail group. A smooth k-wire was passed through the tip of the lateral malleolus. The wire was over-drilled up to the laser marking on the cannulated drill bit. An appropriate size hand reamer was used to ream the rest of the fibula medullary canal. Depending on the hand reamer and size of the medullary canal, either a size 3.0mm or 3.6mm diameter 145mm long fibula nail was inserted. The nails were locked in place with x 2 anteroposterior 3.5mm bicortical screws and x 2 lateral bicortical cross screws. Fluoroscopy was not used to assess reduction. Adequate anatomical reduction and fixation was assessed visually. (Figure1b)

Biomechanical testing

There was no biomechanical facility available at the University of the Free State to assist with equipment for this biomechanical study. A baseplate was custom designed by the author to stabilize the limb specimen in order to perform rotational testing. The tibias of the specimens were stabilized by insertion of two Swann pins, anterior to posterior in the proximal tibia. The two Swann pins were connected to an external frame, which was connected to a base plate and table (Figure 2).

A third pin (foot pin) was inserted into the foot through the third toe and metatarsal bone into the calcaneus, creating a leaver arm by which the ankle could be externally rotated (Figure 1). The foot pin was connected to a mechanical testing apparatus (traction scale) used to measure the external rotation force exerted on the ankle syndesmosis during testing.

With the aid of the traction scale, the foot pin was used to externally rotate the foot of the specimen while the proximal tibia was stabilized. During each test we firstly assessed the force needed to cause loss of anatomical reduction and secondly the force needed for total implant failure. Loss of anatomical reduction was defined as clear visual displacement of the osteotomy. Total implant failure was defined as the point at which the screws pulled out the bone or caused the fibula to fracture. We recorded the force needed (kilogram converted to newton) for both the loss of anatomical reduction and total implant failure. All specimens were inspected visually after the test was done to assess the mode of implant failure.

Data collection and Statistics

Data was reviewed and processed by the researcher and study leader using the *Data Analysis* ad-in of Microsoft Excel®. The data of both methods were described using basic descriptive statistics with ranges, medians, means, CVs and SDs. To demonstrate statistical differences between the two methods, the paired two tail T-test was utilized to obtain a *p*-value. A *p*-value of less than 0.05 was considered statistically significant.

3. Results

The test results are summarized in Table 1. There was no statistically significant difference between the mean force needed for loss of anatomical reduction in the locking plate group and fibula intramedullary nail group (mean 223N vs 166N respectively, p-value=0,064) when using the paired two tail T-test. This did not change when comparing the male (p=0,256) and female cadavers separately (p=0,169).

There was a remarkable difference between the mean force for total implant failure between the locking plate group and fibula nail group (mean 396N vs 266N respectively, p=0,016). The same was also true for the female cadavers (p=0,033) but not in the male group (p=0,191).

There could be a clinical significant difference since our results showed that the locking plate was 34% stronger than the intramedullary nail (223N vs 166N) when looking at the force needed for loss of anatomical reduction although this was not statistically significant. The same was observed looking at total implant failure results (396N vs 266N) with the locking deeming to be 48% stronger than the fibula intramedullary nail. This could have clinical implications, but further studies are needed before any real conclusion can be made.

Looking at the male and female cadaver separately the female cadavers deemed stronger, especially in the locking plate group with 39% higher force needed for loss of anatomical reduction (347N vs 484N) but because the data was skewed, five male cadavers versus nine female cadavers, this will not be discussed further.

4. Discussion

There is limited literature available which compare the rotational torsional forces and biomechanical stability of various fixation techniques of the distal fibula. Locking plate fixation is the most commonly tested ankle fracture fixation technique[24]. The large number of variables, different techniques and parameters used hampers comparisons of the different meta-analysis studies. Various studies previously failed to prove that locking plates were superior to conventional lag-screw and neutralization plate when treating lateral malleolus fractures[24].

A recent study by White et al compared the fibula intramedullary nail with a lag-screw and neutralization technique[19]. We, however, decided because locking plate fixation of the lateral malleolus was the most often tested technique, to compare locking plate fixation with intramedullary nail fixation. We found that biomechanically the fibula intramedullary nail was comparable to the locking plate when looking at the force needed for loss of reduction. This would indicate that a fractured ankle, treated with a fibula nail, wound loss its anatomical reduction with the same amount of force needed for a locking plate to fail. Since we are aiming for an anatomical reduction in these unstable fractures any loss of reduction would be catastrophic leading to early onset degenerative joint disease[25].

When comparing total implant failure (screw tear-out, periprostetic fracture, hardware break), the locking plate group is deemed stronger and can withstand more force than the fibula nail group. This can be attribute to the fact that the screws are locked into the plate and the whole construct failed as a unit when the screws tear out. This is one of the main reasons why we would use locking plates in osteoporotic patients with soft bone. The most common mode of failure in our study for the locking plate group was screw tear-out. The distal screws were more likely to tear-out of the softer distal fibular bone. In practice this is also a big problem, especially in the elderly more osteoporotic patients with fragility type fractures. The fibula nail group failed due to distal screw tear-out, but also rotation of the nail in the proximal part of the osteotomy. We suspect it's because the fibula nail rely on frictional forces in the intramedullary cavity to provide stability. There are no screws locking into the proximal part of the fracture. The force needed to overcome the frictional force in the intramedullary cavity is less than the force needed to cause the screw to tear out of the bone.

Our data showed that the fibula nail is comparable to other more conventional treatment methods (locking plates/conventional plate and screw) when looking at the amount of force needed to cause loss of anatomical reduction.

Ankle fractures are one of the most commonly treated orthopedic injuries and the burden is increasing due to an increasing elderly population[1]. The reason why surgeons previously looked at the option of using intramedullary devices to fixate these fractures is because of the devastating consequence of prominent hardware, wound dehiscence and infections. The poor soft-tissue coverage and muscle bulk of the lateral malleolus predispose this area to wound complications. With the peroneus longus and brevis tendon running in the posterior fibula groove, placing the plate and screw construct more posterolateral on the fibula could lead to hardware pain and the need to remove hardware after the fracture has healed[26].

There were some limitations to this study. A proper biomechanical testing facility could have helped with more accurate simulation of external rotation force and axial loading of the ankle joint during the stress test. We would, however, argue that all limbs were stressed in the same manner without any axial load and therefore the two groups are still comparable. Secondly the bone mineral density and ages of the cadavers used were not known. For this reason we decided to test the locking plate and fibula nail on the same cadaver right and left leg. We believe the bone mineral density of the limbs of the same cadaver would be comparable. Thirdly the cadavers used were embalmed using an intravenous technique, which do not have an effect on the bone quality of the cadaver[27].Topp et al showed that embalmed bones and fresh frozen bones had similar characteristics by mechanical testing.

Thus embalmed human cadaveric bone is a good option for mechanical testing of orthopedic and trauma devices[27]. In our study we showed the relationship between the biomechanical stability that both construct provide when used to stabilize a SER IV type ankle fracture. Because this was a cadaver study and no axial load was applied with all ankle syndesmosis ligaments surgically dissected, no conclusions can be made as to the amount of rotational force needed to cause loss of anatomical reduction in our patient population. Most other biomechanical studies looked at the torque needed to cause loss of anatomical reduction and implant failure. Torque is measured in newton-meter (Nm) and is a rotational force. We would have liked to compare our results directly with similar research done but we looked at linear force, measured in newton (N). Due to biomechanical apparatus limitations we could not measure the rotational displacement.

5. Conclusion

In this cadaver study the fibula intramedullary nails showed comparable stability to locking plates with regards to the force needed to cause loss of anatomical reduction. The latter was however superior to the fibula nail group with regards to force needed to cause implant failure. From a biomechanical perspective this study supports previous research done that showed the fibula nail to be a viable option when treating unstable fibula fractures. This could provide a potential benefit in patients that are at risk of wound complications, but further larger randomized control trails are needed.

6. Declaration of Conflict of Interest

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article. The author did not receive any royalties and has no connections with Acumed.

7. Ethics approval

Ethics approval was obtained from the Ethics Committees of the University of the Free State (ECUFS NR 190/2014). The study was executed in accordance with the World Medical Association Declaration of Helsinki (2013).

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10. Appendices

Figure 1a: Left ankle group Acumed pre-contoured fibula locking plate

Figure 1b: Right ankle group Acumed fibula intramedullary nail (Fibula Rod)

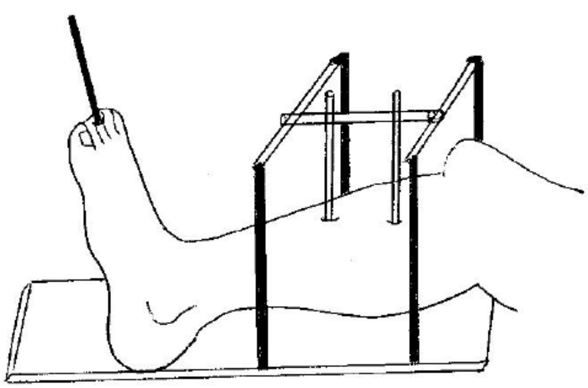

Figure 2: Illustrates the method of stabilization of the tibia.

Tabel 1:

Summary of Data

	Locking Plate	Intramedullary Nail	p-value
Loss of Anatomical Reduction:mean (range) in Newton (n=14)	223 (120-400)	166 (50-300)	0,064
Males (n=9)	214 (150-400)	170(50-300)	0,256
Females (n=5)	238 (180-400)	158(120-180)	0,169
Implant Failure: mean (range) in Newton	396 (190-700)	266 (150-450)	0,016
Males (n=9)	347(190-700)	258 (150-450)	0,191
Females (n=5)	484(300-700)	282(200-350)	0,033