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# Biomechanical evaluation of a new treatment for distal tibia fractures

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The first two authors JRF and SK share equal contribution to this paper.

## 1. Introduction

Distal tibial fractures are often the result of high-energy impacts combined with excessive soft-tissue injury. Treatment options include either open reduction and internal fixation usually as a minimally invasive plate osteosynthesis (MIPO) or the insertion of an antegrade intramedullary (IM) nail. The MIPO method is reported to achieve a better fragment alignment however it may result in delayed union and a higher risk of post-operative failure (Iqbal and Pidikiti, 2013). The strong advantage of the IM nail is the preservation of connective tissues and vascularity surrounding the fracture site. However, this technique is challenging and carries with it the risk of primary and secondary misalignment (Vallier et al., 2011).

The current antegrade IM nail is inserted at the proximal tibia before descending to reach a distal fracture site. The result is a high occurrence of knee pain and a risk for fat emboli. As a consequence, a retrograde tibial nail prototype (RTN) has been developed by the Mainz research group (Kuhn et al., 2014<sup>a</sup>). Biomechanical testing of prototypes has shown favourable results. Thereafter design modifications have been made and a new prototype is currently under preclinical evaluation.

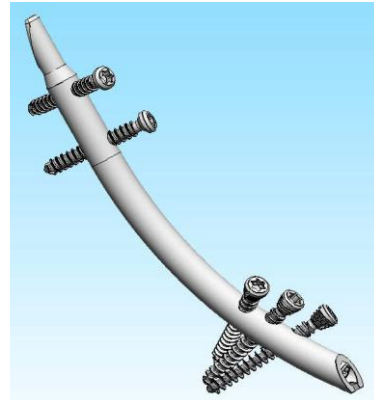
The present study aimed to assess a new RTN prototype against the currently clinically used antegrade IM nail (ETN®, Synthes). Results of the ETN were taken from formerly published papers by some of the same authors (Kuhn et al., 2014<sup>a</sup>; Kuhn et al., 2014<sup>b</sup>).

## 2. Methods

### 2.1 Samples

Seven fourth generation medium sized composite tibiae (Sawbones Europe, Malmö, Sweden) were inserted with the new RTN prototypes. The RTN (Figure 1) was 116.5 mm in length and 8 mm in diameter with a curvature of radius 110 mm. Its locking system consists of three distal screw holes,

Figure 1. The new RTN with a total of five screws, two proximal and three distal.



each at a divergence of 25° and placed at 13, 19.5 and 26 mm from the distal end. The 4.0 mm distal locking screws feature a dual core design and a screw head with

a self-tapping cortical thread which purchases in the cis cortex. The proximal locking screws consist of a single core design, also with the threaded screw head. Proximal screw holes were situated at 80 and 90 mm from the distal end, with a divergence of 30°.

### 2.2 RTN Protocol

Kirschner wire (K-wire) was centrally placed into the medial malleolus and in a true lateral position. Its position was verified using periodic x-rays. An 8.0 mm trepan drill was guided over the K-wire, and extra reaming to 8.5 mm for easier implant insertion was standard procedure. The RTN was attached to an aiming device and inserted into the created canal using slow twisting movements. The aiming device allows for the precise hole-drilling and insertion of all screws. Bicortical drilling was performed for all screws except for the second most distal screw to exclude irritation of the distal tibiofibular joint. Additionally, an end cap is placed, which leads to an angle-stable distal screw to nail construct. Finally, an AO/OTA 43 A3 fracture was simulated by removing a 10mm section of bone between 40 and 50mm proximal from the distal articular surface using a hand saw without damaging the nail.

**2.3 Mechanical testing** The samples were tested one by one in a servopneumatic simulator (SincoTec, Bauteil-Prüftechnik GmbH, Clausthal-Zellerfeld, Germany; Figure 2). Axial compression tests included subjecting the samples to one pre-cycle and three

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recorded cycles at 350 N and 600 N at a frequency of 0.05 Hz. Bidirectional torsional testing was performed at 8 Nm. A test to failure was conducted by gradually applying an extra-axial compression force up to 1200 N. Preloads of 18 N were applied in all cases. Fragment movements were recorded using a high speed camera, as well as by an actuator integrated into the testing machine.

**2.4 Data analysis and statistics** The stiffness construct of the implants was calculated from force-displacement data (compression: N.mm<sup>-1</sup>; torsion:



Nm/°). A Mann-Whitney U test was used to compare the implants' mechanical properties. IBM SPSS Statistics for Windows, Version 22.0 was used.

Figure 2. Test set-up for axial testing.

### 3. Results and discussion

The results in Table 1 show that the new RTN prototype has a greater resistance to torsion by approximately two-fold than the ETN as more torque is required to produce fragment movement (1.30 > 0.63; 1.18 > 0.65;  $p < .001$ ). However, there is significantly less resistance to axial compression with the greatest difference occurring at 350 N (538.0 < 862.5;  $p = .04$ ).

Table 1. Stiffness construct values (mean ± SD) for all prototypes in the four test conditions.

Load applied	ETN	RTN new	<i>p</i> -value
Axial 350 N	862.5 ± 322.2	538.0 ± 106.0	.040
Axial 600 N	795.6 ± 202.4	583.4 ± 140.0	.072
Torsion +8 Nm	0.63 ± 0.10	1.30 ± 0.05	<.001
Torsion -8 Nm	0.65 ± 0.08	1.18 ± 0.05	<.001
Extra-axial 1200 N	524.9 ± 153.3	385.0 ± 94.2	.094

Nonetheless, the axial compression is not considered to be harmful to the patient as some axial compression is important for promoting bone regrowth through callous formation.

Unwanted torsional movement is the most detrimental to patients with respect to delayed and non-union.

Hence the increased torsional stability of the RTN over the standard antegrade nail can be considered as an advantage.

The new retrograde tibial nail is not only biomechanically advantageous over the antegrade nail, but also with respect to its design, it is more apt for the treatment of distal fractures. The antegrade nail requires a 40 mm distal fragment for its locking system, whereas the RTN requires only 25 mm, allowing it to address far distal fractures (Kuhn et al., 2014<sup>b</sup>). Future implications for this nail include the treatment of distal tibial shaft fractures (AO/OTA 42 A-C) and extra-articular metaphyseal fractures (AO/OTA 43 A). With the aid of a primary lag screw fixation, fractures with simple intraarticular involvement (AO/OTA 43 C1, and C2) can also be addressed by this implant.

### 4. Conclusions

The RTN offers a minimally invasive technique which promotes load sharing and spares soft tissues as well as the knee joint. Its biomechanical evaluation tests show promising results in comparison to the current standard antegrade IM nail. The concept of retrograde tibial nailing is currently under preclinical evaluation and offers the potential of a biomechanical stable and soft tissue sparing surgical treatment.

### Acknowledgements

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