Primary stability of an intramedullary calcaneal nail and an angular stable calcaneal plate in a biomechanical testing model of intraarticular calcaneal fracture

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A R T I C L E   I N F O

Article history:
Accepted 19 September 2013

Keywords:
Calcaneal fracture
Reduction techniques
Minimum invasive approach
Fracture fixation
Intramedullary nail
Angular stable plate
Biomechanics
In vitro testing
Primary stability

A B S T R A C T

Background: Nowadays, open anatomic reduction and internal fixation can be considered as a valuable treatment for displaced intra-articular fractures of the calcaneus. However, the application of a calcaneal plate via an extensile lateral approach is at risk for a substantial rate of complications including delayed healing, skin necrosis, or infection. There is some evidence that a limited exposure might contribute to a decreased soft tissue complication rate bearing in mind that most minimally invasive techniques have to accept a reduced primary stability compared with the open application of an angular stable plate. Recently, an intrafocal minimal invasive reduction technique has been established employing an intramedullary nail for fracture stabilisation and support of the subtalar joint. The aim of this study was to compare the primary biomechanical performance of the new device versus lateral angular stable plating.

Material and methods: Biomechanical testing were performed on 14 human cadaveric feet (7 pairs). Dry calcaneal bones were fractured resulting in a Sanders type IIB fracture pattern and fixed by either a calcaneal locking plate or an intramedullary calcaneal nail. Compressive testing via the corresponding talus was employed at a constant loading velocity until failure with an universal testing machine and a specific mounting device to avoid any shear forces. Apart from the data of the load deformation diagram the relative motion of the fracture elements during loading was recorded by 8 extensometric transducers. After failure the specimens were carefully examined to check the failure patterns.

Results: The displacement of the subtalar joint fragment was substantially lower in specimens fixed with the nail. Stiffness and load to failure were significantly higher after fixation with the intramedullary nail than after application of the angular stable plate. Failure with both fixation modes generally occurred at the anterior calcaneal process fragment.

Conclusions: The primary stability of an intramedullary nail appeared to be superior to an angular stable plate representing the present standard technique in open reconstruction of the fractured calcaneus. The results from the experimental model speak in favour of the clinical use of the intramedullary calcaneal nail.

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0020–1383/$ – see front matter © 2013 Elsevier Ltd. All rights reserved.
http://dx.doi.org/10.1016/j.injury.2013.10.031

Introduction

Intra-articular calcaneal fractures comprise around 75% of all calcaneal fractures and are frequently associated with severe functional impairment [1,2], At present, there is not a single effective treatment option for intra-articular calcaneal fractures [2–9]. There is even not sufficient evidence that surgical treatment would be generally superior to non-operative treatment [1]. But, operative treatment seems to be beneficial for several subgroups of patients, e.g. women and younger males, patients with lighter workload, for those who are not receiving Workers’ Compensation and those with simple displaced fracture types [1,10–12]. Finally, the subtalar arthrodasis rate is significantly less with surgical treatment and, in addition, on a socio-economic basis, operative management appears to be less costly and more effective than nonsurgical treatment [1]. On the other hand, open reduction and
internal fixation via the lateral extended approach representing the most frequently recommended and applied approach nowadays exposes the patient to inherent risks as wound healing problems, skin necrosis and infection [2,13,14]. Despite that fact that this particular approach respects the vascular anatomy of the corresponding skin flap soft tissue complication rates are reported within the range from 1 to more than 25% [2,14,15]. These high complication rates again may limit a generous indication for surgery, in particular with patients at risk for delayed wound healing due to concomitant diseases [13,14]. Therefore, other operative procedures have been suggested including two-staged procedures, external fixators, medial approaches, percutaneous reduction and fixation via the limited lateral or sinus tarsi approach [13,16–21,9]. Due to the limited exposure most modifications of the latter procedure are technically demanding, make alternative tools for the verification of adequate reduction necessary (e.g. arthroscopy, 3-D fluoroscopy) and are currently reserved for experienced surgeons or simple fracture types, only [13,19,9]. Meanwhile, there exists sufficient evidence on the basis of studies comparing the outcome and risks of the sinus tarsi and the extended lateral approach that the minimised approach may allow for a comparable functional result at a reduced risk for soft tissue complications [6,22,23]. Due to the limited surgical exposure less stable implants as K-wires, multiple screws or special plates are used with less stability of fixation and the potential for a secondary loss of reduction within a range from 1 to 67% [9,13,20,21,24].

For these reasons a posterior approach had been developed to perform both an intrafocal reduction of the subtalar joint and the tuber calcanei fragment and an internal fixation with a novel intramedullary interlocking implant having in mind the high degree of stability and the favourable outcomes of epi-metaphyseal locking nails in various locations [17,25]. It was the aim of the study to compare the primary stability of the intramedullary calcaneal nail with an angular stable calcaneal plate during compressive loading in an experimental model of a standardised calcaneal fracture.

Materials and methods

Cadaver specimens and test set-up

7 pairs of enzymatically corroded human calcaneal and talar bones (“dry bones”) were recruited for biomechanical testing. A 3-fragment intra-articular calcaneal fracture (Sanders type 2B, Utheza horizontal, vertical and mixed) was generated using a motorised oscillating saw according to the protocol of Bardet al. [26,27]. The fractures of the corresponding calcaneal bone pairs were fixed either by an uniaxially angular stable AO locking plate (Synthes Inc., Paoli, PA 19301-1222, USA) according to the recommendation of Sanders and Gregory or with a calcaneal interlocking nail with 2 locking screws (Calcanaill™, FH ORTHOPEDICS, 68990 Heimsbrunn, France) according the original implantation technique [25,28] (Fig. 1). A hydraulic testing machine (monaxial MTS® machine with 25 kN of maximum load, MTS® headquarters, Eden Prairie, MN, USA) was employed for compressive loading, force and motion analysis. The talus, the anterior calcaneal process and the calcaneal tuberosity were fixed each with epoxy power glue (Pattex®, Henkel AG & Co. KGaA Headquarters, D-44058 Düsseldorf, Germany) to the fixation devices providing a 15° calcaneal inclination angle and a hindfoot angle of 0° to simulate the anatomic position of the heel. The calcaneal tuberosity was positioned onto a sliding platform to avoid any additional shear forces during vertical loading (Fig. 2a and b). Progressive loads were applied through the corresponding talus. As pretests had shown that corroded bones were far not able to carry load levels of 1000 N and more as applied by Bardet et al. in fresh-frozen cadaveric bones the original testing protocol was modified [26]. A preload of 18 N was applied at a constant loading velocity (0.5 mm/min) via the traverse of the testing machine carrying the embedded talus. The calcaneus was instrumented with a total of 8 extensometric sensors to record the displacement of each fracture element during loading. Sensors 2 and 3 registered...
the deformation of the subtalar joint fragment (Fig. 3). The resolution of the sensors corresponded to 0.02 mm. Load-deformation diagrams and sensor displacements were registered at a frequency of 1 Hz via Catman® AP data software (HBM Deutschland, D-64293 Darmstadt, Germany) (Fig. 3). All data were exported and stored for further statistical analysis.

First fracture was determined from the load-deformation diagram as the first “step” or levelling within the corresponding curve while the specimen could further carry increased loading. Failure (end-point) was defined as a simultaneous further deformation of the specimen and a decrease of the load level [29,30]. The stiffness was determined via the slope of the load-deformation diagram before the first fracture occurred. All specimens were examined after failure to check for the failure pattern and maintenance of Boehler’s angle (Fig. 4).

**Statistical analysis**

Data were analysed for normal distribution first. In case of missing normal distribution a Mann–Whitney rank sum test was applied then, otherwise a paired t-test. The null hypothesis at the level of $p < 0.05$ was that there was no difference regarding the fixation strength with the two different implants.

**Results**

No failure of any implant or implant component occurred during all test runs.

Some dry bones failed far below a load threshold of 200 N leaving four complete pairs of calcaneal bones for comparison, only. First fracture of bone occurred at similar load levels in both groups (Fig. 5). Stiffness in the calcaneal nail specimens was around three times and significantly higher than in the angular stable plate group (Fig. 6). In accordance, load to failure was significantly higher in the specimens fixed with the nail (Fig. 7). First fracture frequently interfered with the calibration and measurements of the extensometers so that the corresponding values had to be discarded which did not allow a systematic analysis. The remaining measurements showed that the vertical displacement of the subtalar joint level at a load level of 200 N was substantially less in the nail than in the plate group (sensor position 2: 0.2 versus 0.4 mm, sensor position 3: 0.1 versus 1.4 mm).

Failure predominantly occurred at the anterior process level independent from the mode of fixation (Fig. 8). Boehler’s angle was
Discussion

It was the aim of this study to compare the primary stability of a recently developed intramedullary nail versus a standard angular stable plate via an introduced experimental model referring to a frequent type of intra-articular calcaneal fracture [26,27]. To the knowledge of the authors this has been the first report about the biomechanical performance of the intramedullary calcaneal nail in comparison to a standard angular stable plate. Load to failure and stiffness were significantly higher within the nail group compared with the plated specimens. The integrity of Boehler’s angle as a rough measure of hindfoot geometry had better been preserved in the specimens fixed with the nail than with the locking plate. Thus, the null hypothesis could not be confirmed. Relative motion of the subtalar joint fragment appeared to be substantially reduced comparing the specimens fixed with the nail versus those fixed with the plate. These observations support the notion that primary stabilisation with an intramedullary calcaneal implant may provide a similar or even superior primary stability as with the angular stable plate. There have been several reports on the results of in vitro testing of different implant types based on different calcaneal fracture types, specimens and loading protocols [26,28–30,32]. The typical failure mechanism at the anterior calcaneal process has been reported by others [29,30]. Apart from the fact that a majority of the examiners could not find a superiority of the various types of locking plates versus nonlocking plates regarding primary fixation strength and stiffness, plates were generally more stable as single screws which are frequently used during minimum-invasive procedures [17–21,29,31,33]. The high mechanical competence of the intramedullary nail offers an enhanced reduction stability and allows to realise minimum invasive reduction techniques, as well. The need for special and more stable implants than single screws in minimum invasive calcaneal fracture surgery has been identified, recently [20]. The corresponding authors were able to show that more stable implants employed in conjunction with a minimum invasive approach could allow physiological forces during bone healing [20].

There were some limitations to this study. The use of dry enzymatically corroded cadaver bones certainly reduced the inherent biohazard, but the resultant brittleness of material led to a substantially increased rate of early material failure and a reduced number of valid test specimens. Repetitive testing and cyclic loading could not be performed under these circumstances. Fresh frozen cadaver specimens are compatible with a cyclic loading protocol at loads up to more than 2500 N and better suited for biomechanical tests than artificial calcaneal specimens [29]. Therefore, the comparative testing including the calcaneal nail and the angular stable plate will be repeated with fresh frozen calcaneal specimens and an extended repetitive loading protocol.

Conclusion

Our results showed that the primary stability at the chosen experimental set-up of a standardised calcaneal fracture was better with the intramedullary calcaneal nail than with the standard calcaneal locking plate. These observations support the assumption that the clinical application of the intramedullary calcaneal nail in conjunction with the intrafocal posterior minimum invasive reduction technique may be beneficial in terms of a reduced risk of secondary loss of reduction under partial weight-bearing. Thus, the intramedullary calcaneal nail appears to comprise a novel fixation principle for minimum invasive calcaneal fracture treatment with enhanced primary fixation stability.

Conflict of interest

No funds were received in support of this study.

Mario Goldzak, Patrick Simon and Thomas Mittelmeier are co-inventors of the Calcanaill® implant.

Acknowledgment

The authors want to thank Lise Trousselier, Institut Clément Ader, Professor Michel Lorrain, INSA Toulouse, Professor Dominique Saraggaglia, Professor Jean Philippe Cahuzauc for their advice and contribution. Further, the authors are grateful to Thomas Wodetzki, Rostock for his support with the graphic material.

References

and postural control after intra-articular calcaneal fracture correlate with clinical and radiological outcome? Injury 2011;42(October (10)):1135–43.


