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Title: Biomechanical Comparison of Modified Calcanail System with Plating Fixation in Intra-articular Calcaneal Fracture: A Finite Element Analysis

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Abstract

Calcanail system is a novel intramedullary approach for calcaneal fractures but is believed to be insufficient to treat complex fractures. We propose a modified Calcanail technique by adding a transfixation screw to improve stability. The aim of this study was to evaluate the biomechanical stability of the modified Calcanail system and compare it with the traditional Calcanail system and plate fixation. A Sanders type-IIIAB calcaneal fracture model was built and simulated fixation with the three implants. A vertical loading of 700 N was applied to the subtalar joint surfaces, and the posteroinferior calcaneal tuberosity was fixed. Construct stiffness, fracture migration, and von Mises stress were assessed. The results showed the modified Calcanail system demonstrated the highest construct stiffness, smallest migration, and lowest von Mises stress among three fixations. The study suggested that the modified Calcanail system can provide comparatively sufficient stability, that makes it preferable to treat complex calcaneal fractures.

Keywords: Calcaneal fracture; Fracture fixation; Intramedullary nail; Locking plate; Biomechanics; Finite element analysis

1. Introduction

Calcaneal fractures are the most common tarsal bone fractures, and more than two-thirds of them are displaced intra-articular calcaneal fractures (DIACFs) [1]. The DIACF is characterized by the sagittal and coronal fracture lines that divide the calcaneus into anterolateral and superolateral fragments. Patients with DIACFs often have a poor functional outcome, particularly after improper treatments. In extreme case, some of them were handicapped for three years and partially disabled for five years [2]. In fact, the management of a calcaneal fracture is highly complex, and there were debates on the ideal surgical methods [3, 4].

Open reduction and plate fixation could result in a complication rate over 30% [5]. The complications were mostly attributed to the large lateral incision. Surgeons thus switched to minimally invasive techniques in treating DIACFs. Both Kirschner pins and cannulated screws have been clinically used to fix DIACFs [6]. Good clinical results were shown for certain types of fractures, particularly when the reduction was monitored arthroscopically [7]. However, a large number of inadequate reductions and redisplacements occurred when this technique was applied to more comminuted DIACFs [2, 8]. Some cadaveric studies also criticized the biomechanical stability and reduction accuracy of minimally invasive techniques [9, 10].

Recently, a new implant, the Calcanail® system, which uses a novel intramedullary nail, was introduced to treat DIACFs using an intrafocal reduction approach [11]. This implant is composed of a hollow nail and two locking screws, as shown in **Figure 1**. The geometry of the implant was claimed to enhance angular stability, reduction precision, and fixation strength. The working channel of the implant can accommodate bone grafts and facilitate bone union. The preliminary clinical results of the Calcanail system were positive [12-14]. Biomechanical tests were also conducted to compare its primary stability with other techniques [15, 16].

While the design of the Calcanail system was appreciated, some physicians concerned about its indications and stability to accommodate complex fractures [17]. In this study, we proposed a modified Calcanail technique by combining Calcanial with lag screw fixation. Placing a transfixation screw into the Calcanail channel to hold the anterior process to the main part of calcaneus will help to improve its stability for complex fractures. The plan was inspired by an adjuvant fixation to treat calcaneal fractures using a longitudinal screw [18].

The objective of this study is to determine the biomechanical stability of the Calcanail system and the modified Calcanail system using a transfixation screw in treating complex calcaneal fractures, and to compare them with the traditional plating fixation using finite element analysis (FEA). FEA can provide a versatile platform to evaluate surgical interventions in a controlled environment and to simulate different adverse conditions [19]. It has been commonly used to evaluate the biomechanics of the foot and ankle clinically, such as understanding the mechanism of pathologies and trauma [20], evaluation of foot support [21], implant and fixators [22-23].

2. Materials and methods

2.1 Geometry Reconstruction

The right foot of a male cadaver was scanned by computed tomography (Brilliance 64, Philips Electronics, Netherlands) for the reconstruction of calcaneus geometry. The subject was 62 years old, 170 cm tall, and weighed 70 kg. Ethical approval was granted by the Ethnic Committee of Shanghai Pudong New Area Peoples' Hospital (No. 2017-21). The scan was taken in the transverse direction at 0.75 mm intervals and at 0.54-mm/pixel resolution. The calcaneus bone geometry was reconstructed based on the segmentation of the clinical images using Mimics 15.0 (Materialise, Leuven, Belgium) and a 2.68-mm thick cortical layer was segmented from the trabecular core [24].

The geometry of three implants (Calcanail system, modified Calcanail with transfixation screw, and plate fixation) were reconstructed according to manufacturers' specifications [13] using computer-aided design software Solidworks (Dassault Systèmes Solidworks Corp., MA, USA). The Calcanail implant (FH Orthopedics, Heimsbrunn, France) has a 10-mm diameter and 50-mm-long hollow nail, with slot on both sides and locking screws on both ends (**Figure 1**). The modified Calcanail system was realized by inserting a 3.5-mm diameter transfixation screw through the slot of the Calcanail implant. Plate fixation was carried out with a calcaneal locking plate (Synthes, Solothurn, Switzerland) and screws with simplified cylinders of 3.5-mm diameter.

A Sanders type-IIIAB calcaneal fracture was mimicked according to the model described by Smerek et al [11], with a V-shaped fracture line near the angle of Gissane and two 0.1-mm gaps on the posterior facet fragment. The implants were positioned and aligned according to the product guidelines [14] and clinical experience **(Figure 2)**, which was conducted by an orthopedic surgeon. The bone region which overlapped with the implant was removed using the Boolean operation with the implant.

2.2 Material Properties and Mesh Creation

The material properties were assigned according to previous reports [25-27] and are listed in **Table 1**. Linear tetrahedral elements (C3D4) were created by Abaqus 6.14 (Dassault Systèmes, Paris, France) on the calcaneus bone and implants. The intact calcaneus bone was meshed with 135489 elements. There were 17945, 1170 and 46775 elements in the Calcanail implant, transfixation screw and the plate respectively.

2.3 Boundary and Loading Conditions

The coefficient of friction of the bone-implant interface was assigned 0.3 [26], except for the bone-screw interaction that was fully bonded. A vertical loading of 700N force was applied to the surface of the posterior subtalar joint to simulate single stance standing. The posteroinferior portion of the calcaneal tuberosity was bonded to a polymethylmethacrylate (PMMA) holder to maintain the bone in position [23].

2.4 Data Analysis

The FE analysis was conducted using Abaqus 16.4 (Dassault Systèmes, Waltham, USA). The biomechanical stability was represented the construct stiffness and fracture gap enlargement (migration). The construct stiffness was defined by the ratio of the maximum vertical displacement of the calcaneus to the applied load. The fracture migration was calculated by measuring the distances of 16 pairs of points, which located at the midpoints and junctions along the fracture line. The average distance change of 16 pairs of points before and after loading was regarded as the fracture migration [28]. In addition, the von Mises stress distribution of the implant would be examined to speculate sites of stress concentration.

2.5 Model Validation

To validate the model, a cadaveric experiment was conducted using the same specimen of the FEA and the vertical stiffness of the experiment was compared with that of the FE prediction. The cadaveric experiment followed the same configurations as that of the simulation, including the creation of the fracture and fixation. The calcaneal posteroinferior tuberosity was bonded to a PMMA holder and 700N vertical loading was applied to the surface of the posterior subtalar joint, which were as same as the simulation.

3. Results

3.1 Construct Stiffness and Validation

Table 2 shows the construct stiffness predicted from the simulations of the three implants. The modified Calcanail system fixation provided the highest stiffness (552 N/mm), followed by the Calcanail system (522 N/mm), and that of the plate fixation was the weakest (454 N/mm). The modified system was 5% and 18% better than the Calcanail system and traditional plate fixation respectively.

With respect to the validation, computer simulations in this study showed good agreement with the cadaveric study. The construct stiffness of the cadaveric model was 450 N/mm, which was comparable to the FE model (454 N/mm). The small differences may be due to the simplification of locking screws in FE analysis.

3.2 Fracture Migration

The migration distances of the three models are also shown in **Table 2**. The inclusion of the lag screw in the modified Calcanail system can provide a higher fracture-stabilizing ability compared with the Calcanail implant alone.

Based on observation, both the Calcanail fixation and its modified technique had a larger mediolateral gap enlargement at the subtalar posterior facet (**Figure 3 (a))**. Conversely, the plate fixation had a larger anteroposterior gap enlargement between the fragments (**Figure 3(b))**. The results demonstrated that the Calcanail system had better stability in the sagittal plane, whereas the plate fixation was more stable in the coronary plane.

3.3 von Mises Stress

The stress distributions of the three implant conditions are illustrated in **Figure 4**. In both the Calcanail and modified Calcanail fixations, the peak stresses were concentrated at the slot of the implant, which was adjacent to the primary fracture line of the calcaneus. On the other hand, stress concentrations for the plate fixation were found at the posterosuperior and anterior parts of the implant, particularly at the plate-screw junction. The stress distribution on calcaneus was similar under three fixations. The stress was concentrated at the medial side, especially in the posterior fracture line of V-shaped angle, as shown in **Figure 5.**

The peak von Mises stresses of the implant and calcaneus cortical/trabecular are plotted in **Figure 6**. The maximum stresses of the Calcanail, modified Calcanail and plate construct were 98.12 MPa, 84.78 MPa, and 102.68 MPa, respectively. Generally, the modified Calcanail system had the lowest peak stress on the implant among the three implant conditions. The peak stress was approximately 17.4% less than that of the plate. Conversely, the plate fixation increased the cortical stress drastically and reduced the trabecular stress slightly. The stress of the cortical bone with the plate fixation was approximately 45% higher than that of the Calcanail system and the modified Calcanail system.

4. Discussion

The use of the Calcanail fixation for calcaneal fractures is a novel surgical option. This approach can maintain the calcaneal height and width to facilitate early rehabilitation and reduce the risk of complications induced by the large incision. Clinical studies revealed favorable outcomes using the Calcanail system [12-14]. However, its capability to accommodate complex fractures, especially those involved anterior process and calcaneocuboid joint fragment was still been challenged. C-Nail was another intramedullary nail system, but up to nine screws would increase the operative complexity [16]. Transfixation screw fixation was a simple and effective tool to improve the fixation stability. For this reason, a modified technique using a lag screw with the Calcanail system was proposed, and its biomechanical performances were assessed and compared with the locking plate and the Calcanail system alone. The results of this study showed that the modified Calcanail system greatly improved the calcaneal fracture fixation stability, and potentially promote fracture union.

From the biomechanical point of view, the structural design of the Calcanail system contributes to better axial stability, whereas that of the calcaneal plate provides better lateral support. This perspective was supported by our findings regarding the fracture migration. In this study, the modified Calcanail technique demonstrated the smallest migration, representing better construct stability. This result was advocated by Wang's studies [18], where adding a transfixing screw can significantly enhance the fixation strength for calcaneal fractures. For the Calcanail system alone, the nail was designed to provide the fixation in one plane and maybe insufficient for comminuted fractures. This would limit the application of the Calcanail system in clinical practice. In this study, the higher stability and stiffness demonstrated by the modified technique can supplement the insufficiency of the Calcanail alone, and would allow a wider usage including displaced and depressed calcaneal fractures or patients with severe osteoporosis. The modified Calcanail fixation also allows earlier rehabilitation of injured foot, with a lower risk of secondary loss of reduction under partial weight-bearing. In addition, rapid and better fracture union is anticipated with more stable fixation techniques [18].

Construct stiffness is a major determinant to fracture site motion that affects the progression of fracture healing [29]. It was used in cadaveric studies to evaluate the fixation methods for calcaneal fractures [30]. Despite, the reported stiffness values could vary depending on the experimental configurations [29], and thus the interpretation of construct stiffness remains challenging and inconclusive. Smerek et al commented that plate and percutaneous fixation had comparable construct stiffness though there were significant difference with a deviation of 45 N/mm [9]. On the other hand, Rausch et al. found that the augmented screw osteosynthesis was superior to that of the fixed angle locking plate osteosynthesis with about 83 N/mm increase in construct stiffness [31].

Stress distribution is an important indicator representing risk of implant failure. The modified Calcanail fixation experienced the lowest stress compared with the other models. Some stresses may be shared by the transfixation screw, and thus less stress was born by the Calcanail. The plate fixation condition demonstrated the highest stress and was concentrated at the posterosuperior part of the plate and the plate-screw junction. The stress concentration at the plate-screw junction represented a potential risk for hardware failure. Customized stiffness in different portions of the implant could be an alternative to alleviate stress concentration and prevent implant fatigue. Nevertheless, it is worth noting that the magnitude of the stresses did not exceed the ultimate strength of the implant material, titanium (750–900 MPa), thus suggesting that the construct for all fixations could be primarily safe [32].

Adequate fracture migration at the fracture site could assist in the bone-healing process. Claes et al [33] demonstrated that fracture migration between 0.15 mm and 0.40 mm can assist in the healing of a fracture gap less than 3 mm. In this study, we simulated a joint depressed calcaneal fracture with three fragments and two gaps of 0.1 mm in the posterior subtalar fragment. The relative micro-movement under the normal standing of these bone fragments was less than 0.1 mm (Calcanail and modified Calcanail) and 0.1 mm (plate). Our predicted migration distance was within a range in which in vivo bone regeneration can be expected.

There are some limitations in this study. First, only axial loads were applied to the calcaneus for finite element analysis. The calcaneus, in reality, is exposed to complex forces and moments during walking [34, 35]. Second, soft tissues and other adjacent structures were not included in the models. Finally, the material properties of the calcaneal bone were assumed to be isotropic and linearly elastic. Despite this, the computational model in this study was comparable to those in previous in vitro studies. We believed that the finite element model should be adequately reliable to evaluate the effects of the three fixations. We recommend further biomechanical and clinical studies to validate the findings and explore novel protocols.

5. Conclusions

The present study demonstrated that the Calcanail system provided better biomechanical stability than the locking plate for a Sanders type-IIIAB calcaneal fracture fixation. Our proposed modification by adding a transfixation screw to the existing Calcanail system can further enhance the fixation strength/stability and decrease stress concentration. The modified Calcanial system should be routinely recommended for calcaneal fractures.

Conflict of Interests

The authors declare that there are no competing interests

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Ethical approval

This study was granted by the Ethnic Committee of Shanghai Pudong New Area Peoples' Hospital (No. 2017-21)

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