Mechanical and computational evaluation of minimally invasive plate osteosynthesis in calcaneal fractures

DePuy Synthes 2.7 mm VA Locking Anterolateral Calcaneal Plate versus DePuy Synthes 3.5 mm Locking Calcaneal Plate

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Background: Open reduction and internal plate fixation through the extensile lateral approach is considered the gold standard for the treatment of complex displaced intra-articular calcaneal fractures. However, wound healing problems occur in 14% to 27% of patients who undergo this type of fixation. New fixation techniques such as minimally invasive plate osteosynthesis (MIPO) report lower rates of wound healing problems and shorter operative times. To date, it remains unclear whether the MIPO technique is capable of maintaining reduction during cyclic loading compared to a standard lateral plating technique.
Methods: A 2.7 mm variable-angle MIPO plate and a standard 3.5 mm lateral fixed-angle locking plate were both tested in a validated mechanical three-point bend test model. A sinusoidal load pattern with increasing loads was applied to determine fatigue strength.
Results: The median fatigue limit was significantly higher in the MIPO group compared to the standard lateral plating group ($p < 0.05$).
Conclusion: Fixation with a 2.7 mm variable-angle MIPO plate technique revealed superior results compared to a standard 3.5 mm lateral fixed-angle locking plate technique. These results need to be confirmed by clinical evidence with long-term follow-up.

INTRODUCTION

Calcaneal fractures represent 2% of all adult fractures, with intra-articular fractures accounting for around 70%.[1] Open reduction and internal fixation (ORIF) is considered the gold standard, especially for complex displaced intra-articular fractures that cannot be reduced by less invasive methods.[2] For ORIF, most surgeons prefer the extended lateral approach,[3] which involves a L-shaped incision and a full-thickness flap created by subperiotsteal dissection of the lateral calcaneus.[4] This approach allows access to the lateral calcaneus, the anterior process, and the middle articular surface,[4] and is ideal for lateral plate fixation. However, soft-tissue complications have been shown to be proportionally related to how invasive the surgical approach is.[2] Wound healing problems occur in 14% to 27% of patients after ORIF of calcaneal fractures,[3,5,6] which is the main reason why ORIF is not recommended in every case.[2]

Closed reduction and percutaneous fixation, i.e. independent screw fixation or pinning, boasts a lower risk of wound complications, shorter operative time, and faster healing because soft tissues are preserved.[1] Percutaneous fixation may be particularly useful in patients with significant comorbidities, soft tissue compromise or impaired healing, or true tongue-type fracture patterns,[1] where the use of ORIF is not ideal. Good results are achieved by percutaneous screw fixation or pinning in selected cases.[7-11] However, the aforementioned techniques carry an inherent risk of inadequate reduction especially in complex fractures.[1,9,10]

In an attempt to lower the incidence of wound healing problems while still achieving stable fixation, new fixation devices have evolved combining the advantages of small angular-stable plate fixation with independent percutaneous screw fixation. Minimally invasive plate osteosynthesis (MIPO) is typically performed through a small, 3 to 5 cm subtalar incision over the sinus tarsi.[12-15] Usually, MIPO techniques involve anterolateral plate fixation with 2.4 to 2.7 mm screws in combination with two to three independent screws inserted posteriorly for fixation of the tuberosity fragment to the anterior and/or subtalar fragments.[12,13] Clinical results with this new type of osteosynthesis are promising. First clinical series report a low rate of wound complications[12,13] with mainly good to excellent postoperative reduction and functional results.[12]

Some authors advocate the use of minimally invasive techniques for all calcaneal fractures,[7,13,14] while others consider it difficult to achieve and maintain anatomical reduction percutaneously. They therefore recommend limiting minimally invasive techniques to patients with significant comorbidities, soft tissue compromise or impaired healing, and less severe fracture patterns.[1,2,10,16,17] The question remains open whether the MIPO technique with 2.7 mm screws is capable of maintaining reduction during cyclic loading in a clinically relevant fracture model compared to a standard 3.5 mm lateral plating system.

OBJECTIVE

DePuy Synthes has introduced a new anatomical plating system for MIPO. This system is based on variable-angle (VA) locking technology with 2.7 mm locking screws. The present study compares the 2.7 mm MIPO plating technique to a standard 3.5 mm lateral fixed-angle locking plate for determining the overall strength of the osteosynthesis.

MATERIALS & METHODS

Development and validation of a feasible mechanical test model

To establish an adequate mechanical test model, we performed a qualitative computational comparison between a musculoskeletal model and the planned mechanical test model.

The AnyBody Modeling System™ (AnyBody Technology, Aalborg, Denmark) Foot Model was used to estimate the loads applied on the calcaneus bone during the stance phase of a healthy person's gait (body weight 76 kg, foot length 235 mm). The foot model contained all the individual foot bones, muscles, and major ligaments. The calcaneus bone received loads from the subtalar and calcaneocuboid joint, muscles, ligaments, and the plantar pressure distribution. Figure 1 shows the load inputs and muscles activated during gait.

The information gathered pertaining to the musculoskeletal loads was used as input for an Abaqus (SIMULIA, 3DS, Providence, RI, United States) Finite Element Analysis (FEA) model of the calcaneus. The calcaneus bone model used in Abaqus was processed from the AnyBody Technology .stl file using ScanIP (Simpleware, Exeter, United Kingdom) to define a complete smooth volume. In accordance with previous biomechanical publications,[18,19] a Sanders type IIB fracture pattern[20] was created in the virtual bone model (Figure 2). This fracture model resulted in a separation between the anteromedial articular portion and the posterior facet, maximizing the stress on the plate. The calcaneus model was virtually fixed with a small Stainless Steel DePuy Synthes Locking Calcaneal Plate and 3.5 mm locking screws. To simulate a typical surgical procedure, the plate was slightly bent to match the anatomy of the

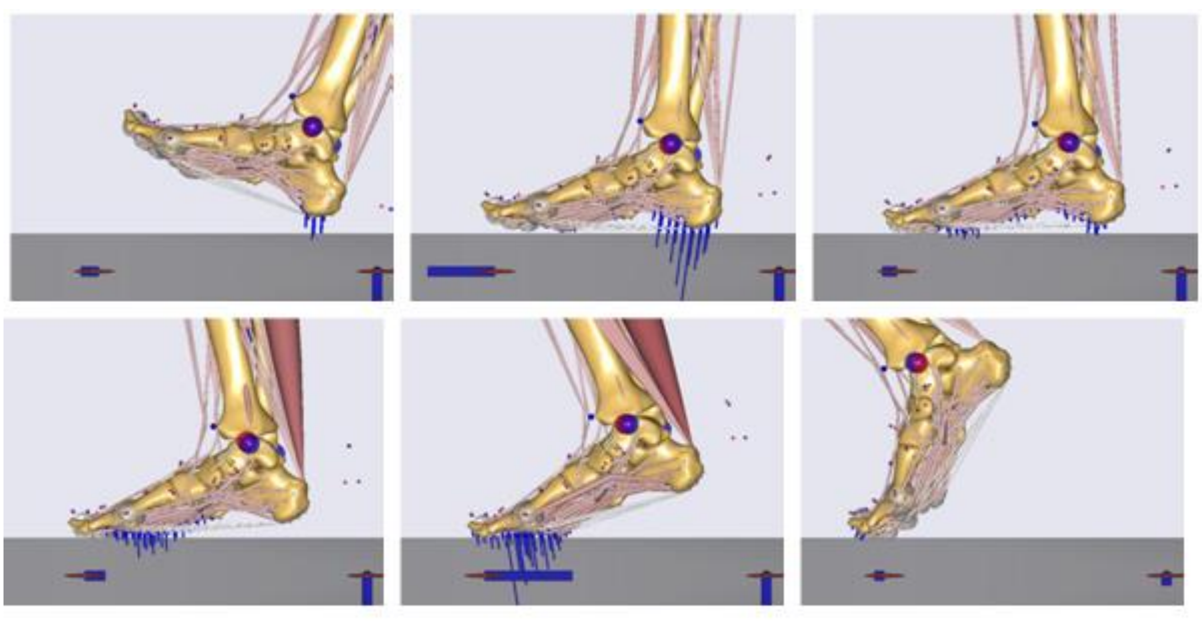

FIGURE 1. Musculoskeletal model used for load estimation.

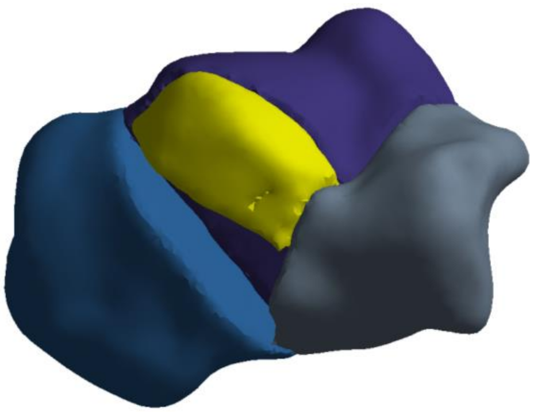

FIGURE 2. Sanders type IIB fracture model used for computational model.

calcaneus, the tabs were removed, and one plate hole was cut off. The maximum value of stress in the plate was determined to occur in the late stance phase during a normal gait cycle. This is the time when the maximum loads occur in the talocalcaneal and calcaneocuboid joint as well as the Achilles tendon.[21]

In addition, a mechanical three-point bend test model was created to simulate the main fracture fragments (Figure 3). This model included a block for the tuberosity fragment (block 1), one for the subtalar joint fragments (block 2), and one for the anterior fragment (block 3). The location of the supporting pins and the location and orientation of the applied load was calculated to produce similar internal shear moments on the plate compared to the FEA model of the calcaneus. Again, this mechanical test model was simulated in Abaqus using the same fracture fixation method described above.

Qualitatively, the maximum principal stress distribution of the musculoskeletal model was similar to the mechanical test model (Figure 4). This indicates that

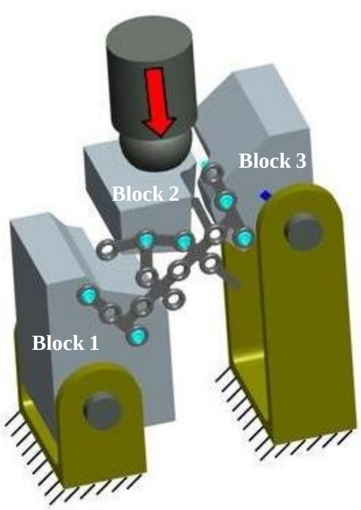

FIGURE 3. Mechanical three-point bend test model.

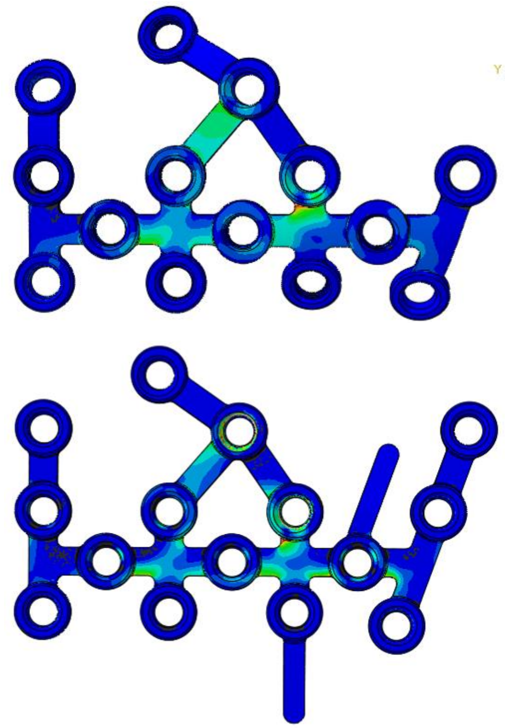

FIGURE 4. Qualitative FEA comparison of musculoskeletal (top) and mechanical test model (bottom).

the use of a simplified mechanical three-point bend test model may be sufficient for a qualitative comparison of different implants used for the fixation of calcaneal fractures.

Mechanical test setup and implant selection

Mechanical testing was performed with the three-point bend test model described above. Test blocks were created using an Objet 3D printer with VeroWhitePlus material (Stratasys, Eden Prairie, MN, United States). The parts contained pre-tapped pilot holes in the desired screw locations at the nominal axes of the screw holes. Constructs were assembled with the respective plate and screws leaving a gap of 1 mm between the plate and the stereolithography parts, in order to represent a worst-case scenario. Screws were inserted with the recommended torque limiting attachment at nominal angle. Test block 1 was fixed with a pin allowing for rotation in the sagittal plane. Test block 3 resided on a roller allowing translation in the sagittal plane. The load was introduced through the test machine in a craniocaudal direction onto test block 2. Mechanical testing was performed using an ElectroPuls E1000 (Instron, Norwood, MA, United States) test frame. A photograph of the test construct and setup is shown in Fig. 5.

The new MIPO plating system was compared to the predicate lateral plating system. Mechanical testing was performed with two study groups (Figure 6):

- Group A (MIPO) – DePuy Synthes 2.7 mm VA Locking Anterolateral Calcaneal Plate, short, Stainless Steel, with five 2.7 mm VA locking screws in combination with two 2.7 mm cortex screws used as independent screws
- Group B (lateral plating) – DePuy Synthes 3.5 mm Locking Calcaneal Plate, small, Stainless Steel, with six 3.5 mm locking screws

Worst-case constructs were selected from both groups. The 2.7 mm VA Locking Anterolateral Calcaneal Plate is offered in two sizes, small and large. The small size plate was determined to be worst case for this test, because it features an identical basic geometry except for being shorter in its posterocranial portion compared to the large plate. The 3.5 mm Locking Calcaneal Plate is offered in four sizes, extra-small, small, large and extra-large. The small size was chosen because it most closely aligns with the plates of group A.

The 3.5 mm Locking Calcaneal Plate is offered in 316L Stainless Steel and commercially pure titanium (TiCP Grade 2). The 2.7 mm VA Locking Anterolateral Calcaneal Plate is available in 316L Stainless Steel and titanium alloy (Titanium – 6% Aluminium – 7% Niobium [TAN]). The worst-case material was determined to be 316L Stainless Steel for both plates, because it represents the strongest 3.5 mm Locking Calcaneal Plate and the weakest 2.7 mm VA Locking Anterolateral Calcaneal Plate based on the 0.2% yield strengths of 316L Stainless Steel, TiCP Grade 2, and TAN (690 MPa, 275 MPa and 800 MPa, respectively).

In group A, the following screw configuration was considered worst case: three 2.7 mm VA locking screws were used to fix the subtalar fragment and provide minimal rafting (block 2), two 2.7 mm VA locking screws were used for minimal fixation of the anterior fragment (block 3), and two independent 2.7 mm cortex screws were used as a minimal fixation for the tuberosity fragment (block 1).

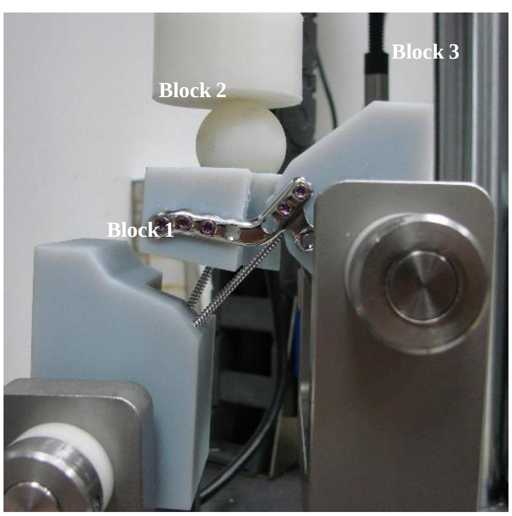

FIGURE 5. Photograph of the mechanical test setup used for both groups (group A shown).

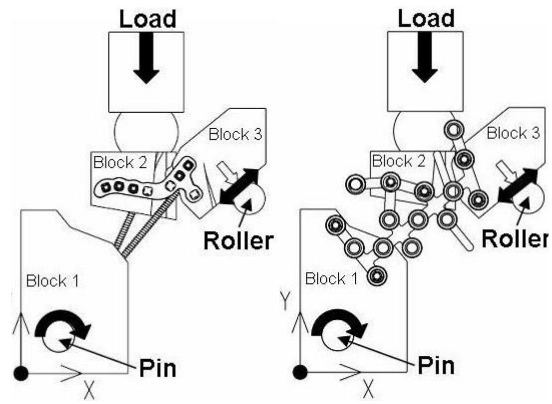

FIGURE 6. Mechanical test setup for group A (left) and group B (right).

In group B, the fewest number of screws was selected to provide minimal fixation of the construct: two 3.5 mm locking screws were used to secure each of the three fragments, thus maximizing force transmission across the screws.

The test protocol comprised a sinusoidal load pattern to determine fatigue strength. Construct failure was defined as plate breakage, plate cracking, screw breakage, or contact of the blocks. The constructs were loaded between 10% and 100% of the maximum load at a frequency of 5 Hz until 1 000 000 cycles or construct failure, starting at an initial maximum load of 27.5 N for the first construct. Subsequent tests were performed using an up and down method with a step load of 2.5 N. The fatigue limit was determined by the median fatigue limits method calculation.[22] The results of both groups were compared using an unpaired t-test with a 95% confidence level.

RESULTS

The median fatigue limit was 87.4 ± 13.1 N for the 2.7 mm VA Locking Anterolateral Calcaneal Plate and 30.9 ± 3.0 N for the 3.5 mm Locking Calcaneal Plate (Figure 7). Statistical analysis with an unpaired t-test showed a significant difference between both groups ($p < 0.05$).

DISCUSSION

ORIF lateral plating of calcaneal fractures through the extended lateral approach is offset by a high rate of wound healing problems occurring in 14% to 27% of cases.[3,5,6] MIPO plate and screw fixation has gained popularity due to a lower rate of such complications.[12,13] Because MIPO techniques are a recent development, clinical evidence with long-term results is still rare.

In a series of 50 displaced intraarticular fractures, Weber et al. compared the MIPO technique using a 2.7 mm recon plate and screw fixation or standalone percutaneous screws to ORIF through a standard lateral approach using a lateral plate.[13] The authors found a significantly shorter operative time in the MIPO group ($p < 0.001$) and lower wound complication rates of 4.2% versus 15.4%.[13] Although they consider the learning curve to be steep, the group has adopted the new procedure for all of their calcaneal fractures.

In a case series including 22 calcaneal fractures treated by MIPO with a straight 2.4 mm Locking Compression Plate (LCP) and independent screws, Nosewicz et al. found good or excellent posterior facet reduction in 64% of cases.[12] At follow-up, no loss of reduction at the posterior facet and calcaneocuboid joint was noted, and the functional results were considered excellent or good in 84% of cases.[12] The wound infection rate was found to be 14%, which is at the lower end of the range reported for standard ORIF using the extended lateral approach.[3,5,6] The authors concluded that even complex calcaneal fractures can be sufficiently exposed by a minimally invasive sinus tarsi approach for anatomic reduction and stable fixation.[12]

Even percutaneous screw-only techniques show promising results. In a randomized clinical trial involving 120 consecutive patients with 125 intraarticular calcaneal fractures, DeWall et al. compared standard ORIF using a lateral plate to a percutaneous screw-only technique.[7] While the radiological results were comparable, the ORIF group showed a significantly higher incidence of deep infections ($p = 0.002$) and minor wound complications ($p = 0.03$).[7] However, Benirsrchke and Rammelt both criticized this study because they consider it difficult to achieve and maintain anatomical reduction for all calcaneal fractures with a percutaneous screw-only technique.[16,17]

As outlined by several authors, the learning curve for the MIPO technique is steep and must be considered when starting with this procedure.[13,14] Many authors confirm that although it can sometimes be technically challenging, the MIPO technique is learnable, and can be used for all

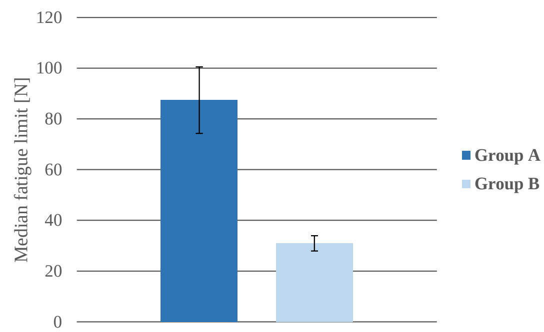

FIGURE 7. Median fatigue limit and standard deviation shown for both groups. The difference between group A and B was found to be statistically significant ($p < 0.05$).

fractures as surgical experience is increasing.[12-14] However, it is clearly recommended to start on fresh fractures with simpler fracture patterns and progress to older or more comminuted fracture patterns as the experience increases.[14]

Our investigations have a number of limitations. In the present study, we have developed a simplified mechanical three-point bend test model for the comparison of different fixation devices for calcaneal fractures. In a qualitative comparison to a musculoskeletal model, the mechanical test model matches well and is thus of great value for implant development. Furthermore, the location of the fatigue cracks during failure of the 3.5 mm Locking Calcaneal Plate was consistent with the location of the greatest maximum principal stress identified in the FEA model for test setup. However, as with every mechanical test model, the clinical significance of the test results has certain limitations and need to be interpreted carefully. Moreover, the loads used for mechanical testing are based on a healthy person's gait pattern. Despite the loads being beyond the expected loads during typical postoperative management, the loads reflected the relative magnitudes, locations, and orientations of the expected loads in vivo.

A further limitation includes the fact that our computational model is based on a single fracture type. Although the Sanders IIB fracture represents a clinically relevant and frequently used fracture model for biomechanical testing,[18,23,24] the implications of our results on other fracture types may be limited.

CONCLUSIONS

Our study indicates that a simplified three-point bend test may be sufficient to simulate mechanical loading in a clinically relevant fracture situation. This model can be used for qualitative comparison of different implants. In cyclic loading to failure of worst-case constructs, the 2.7 mm VA Locking Anterolateral Calcaneal Plate significantly outperforms the 3.5 mm Locking Calcaneal Plate. These promising mechanical test results need to be confirmed by clinical evidence with long-term follow-up.

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