Calcaneal plating with small diameter screws: Mechanical performance and anatomical considerations

The *DePuy Synthes* 2.7 mm VA Locking Calcaneal Plate versus a comparable locking plate with 3.5 mm screws

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Background: Reconstruction of a fractured calcaneus is associated with a high incidence of complications. Understanding of the calcaneus bone structure and developing a standardized mechanical test model will help in adapting implant design to the individual patient and improve implant stability. The present study evaluates mechanical performance of a new calcaneal plating system and compares its design with published evidence on the calcaneal bone architecture.
Methods: The fatigue strength of the *DePuy Synthes* 2.7 mm Variable Angle (VA) Locking Calcaneal Plate was compared with that of a similarly designed construct using 3.5 mm locking screws. After an initial Finite Element Analysis (FEA), a validated mechanical three-point bend test model was applied to evaluate plate strength. A literature review was completed and bone measurements taken to obtain better insight into calcaneal bone morphology.
Results: Both the FEA-predicted plate fatigue strength and the actual measured mechanical construct fatigue limit were significantly higher in the *DePuy Synthes* 2.7 mm VA Locking Calcaneal Plate construct compared to the benchmark construct with 3.5 mm locking screws. Cadaveric bone measurements confirmed that the current design of the *DePuy Synthes* 2.7 mm VA Locking Calcaneal Plates is well suited to a wide variety of bone shapes.
Conclusion: The *DePuy Synthes* 2.7 mm VA Locking Calcaneal Plates have achieved greater construct strength than a comparable plate construct with 3.5 mm locking screws. The anatomical plate design seems well adapted to the calcaneal bone and capitalizes on VA locking technology for rafting of the subtalar joint surface, where the strongest bone is found.

INTRODUCTION

The calcaneus is the largest bone in the foot and able to withstand the daily forces generated by body weight.[1] Fractures most frequently result from an excessive axial load, such as a fall from a great height. They occur at high incidence rates (1–2% of all fractures in adults) and differ in levels of complexity.[2,3] Calcaneal fractures are at high risk for complications and present several technical challenges that may result in long-term disability with a potentially severe economic impact on the patient.[4,5]

A thorough understanding of the structural architecture of the calcaneus is important to better comprehend fracture patterns and improve treatment options. Cancellous bone, the predominant bone type in the calcaneus, derives much of its strength from its trabeculae, which are usually arranged along stress trajectories so the bone can support the areas experiencing the greatest force. Mechanical stress on the trabeculae causes them to adapt in shape, size, and direction in order to enhance bony support.[6] Thorough understanding of bone dimensions and internal bone structure may help to anticipate stress-sensitive areas that require additional material strength, reduce excessive plate material that could irritate soft tissues, and find the optimal angle and position for screws in a plate-and-screws construct.

OBJECTIVE

DePuy Synthes Companies of Johnson & Johnson has introduced a new anatomic, low-profile plating system indicated for intra- and extra-articular fractures of the calcaneus, as well as for deformities and malunions. The plates feature a variable-angle (VA) locking technology with 2.7 mm locking screws, which are smaller in diameter than the typical locking screws used in currently available calcaneal plates. This evaluation compared the dynamic bending properties of the *DePuy Synthes* 2.7 mm VA Locking Calcaneal Plate construct with those in a competitive benchmark plating system that uses 3.5 mm locking screws. The

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improved anatomic plate design and screw trajectories were also compared with published evidence on the internal bone architecture of the calcaneus.

MATERIALS & METHODS

All testing was performed at the *DePuy Synthes Companies* Mechanical Testing Laboratory (West Chester, PA, United States).

Implant selection

Two study groups were compared in a dynamic mechanical test model (Figure 1):

- Group A consisted of seven medium *DePuy Synthes* 2.7 mm VA Locking Calcaneal Plate constructs with matching 2.7 mm locking screws, both made of commercially pure titanium, grade 4 (TiCP4).
- Group B consisted of five medium Stryker Calcaneus Mesh Plates made of commercially pure titanium, grade 2 (TiCP2), with matching 3.5 mm locking screws made of Titanium – 6% Aluminum – 4% Vanadium (TAV).

Group B served as a benchmark. These plates were selected because their dimensions closely match those of group A.

Finite Element Analysis

A musculoskeletal Finite Element Analysis (FEA) was developed to predict the biomechanical performance of calcaneal plates based on musculoskeletal loads applied to the calcaneus during level walking. In accordance with previous biomechanical publications,[7,8] a Sanders type IIB fracture pattern[9] was created in a virtual bone model. ScanIP software (Simpleware, Exeter, United Kingdom) was used to process the calcaneal fracture model and generate a mesh in Abaqus/CAE (SIMULIA, 3DS, Providence, RI, United States). Using the AnyBody Modeling System™ (AnyBody Technology, Aalborg, Denmark), the musculoskeletal loads were applied to the calcaneus. The plates and screws were assembled to the fractured calcaneus with Abaqus/CAE and the model was solved with the Abacus Standard implicit solver. The model was then used to determine a novel, mechanical three-point bend test, such that the stress distribution in the plates matched the musculoskeletal model.[10] This three-point bend test model was used for mechanical fatigue-strength testing of the full construct, while the FEA was used for fatigue-strength prediction of the plates.

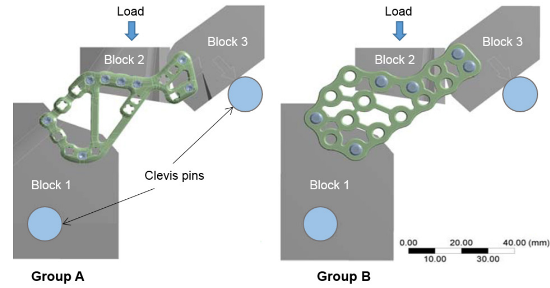

FIGURE 1. Mechanical three-point test model.
The schematic drawing shows the calcaneal plates attached to mechanical test blocks for group A (left) and group B (right).

Mechanical test setup

The mechanical three-point test model used in this study has been previously validated as a reliable measurement for construct fatigue strength.[10] The mechanical test setup was designed to mimic cyclic musculoskeletal loading on the calcaneus during level gait. The model represented the same fracture pattern used for our FEA, which allowed us to induce maximal stress on the plate.[10]

This novel test model included typical mechanical testing equipment. The calcaneal fracture model consisted of three polymer test blocks created with an Objet 3D printer (Stratasys, Eden Prairie, MN, United States). The test blocks were connected to the test frame using half-inch clevis pins. One pin was inserted into the lowermost, left segment of the construct (block 1), and a second pin was positioned underneath the center of the uppermost, right segment of the construct (block 3), as shown in Figure 1. The calcaneal plates were fixed to the test blocks with matching locking screws using a torque-limiting wrench.

Mechanical testing was performed using an ElectroPuls E1000 (Instron, Norwood, MA, United States) test frame. An initial load of 27.5 N was applied to the first plate of the test series. The constructs were cyclically loaded between 10% and 100% of the load at a rate of 5 Hz for 1 000 000 cycles or until construct failure. The loading parameters were adjusted using the stair-step method by modifying the load on any additional plate with a step of 2.5 N (minimum load 20.0 N, maximum load 30.0 N).[11] Construct failure was defined as either plate breakage, plate cracking, screw breakage, or contact of the test blocks. The load and number of cycles per sample were evaluated and the type of failure of each sample that did not achieve a run-out was reported. The median fatigue endurance limit was also calculated if applicable. Results of both groups were then compared statistically using a one-sample T-test with a 95% confidence level.

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Calcaneal bone measurements

A wide range of calcaneal bones (n ≥ 30) provided by the University of Tennessee, Forensic Anthropology Center, Department of Anthropology, were analyzed. The study involved specimens of different gender, age, body size, and ethnicity. Measurements of overall dimensions, contour, and potential screw trajectory locations were taken.

RESULTS

Mechanical fatigue endurance

The median fatigue endurance limit for group A was 26.8 ± 2.9 N. The median fatigue endurance limit for group B could not be calculated because all specimens failed at the tested loads. Therefore, we have defined the lowest load (20.0 N) as an upper limit and chosen a one-sample T-test for the statistical analysis. A superiority T-test showed that group A was significantly stronger than group B ($p \leq 0.003$) (Figure 2).

The most frequent failure observed in group A was screw failure in block 2 (4 out of 10 plates), while in group B it was plate cracking in the web (4 out of 5 plates), followed by disengagement of the locking screw from the plate (1 out of 5 plates).

Finite Element Analysis

Since screw failure was the predominant failure observed in group A during mechanical testing, the finite element model was used to focus on the fatigue strength of the plates. Using the modified Goodman criteria, FEA results demonstrated that the predicted fatigue load was greater in group A than in group B. We predicted a fatigue load of 25.98 N for group A compared to 13.55 N for group B. We found the weakest areas, that is, the areas with the highest stress concentration, occurred around the screw holes (group A) and in the plate bridges towards the center of the web (group B) (Figure 3).

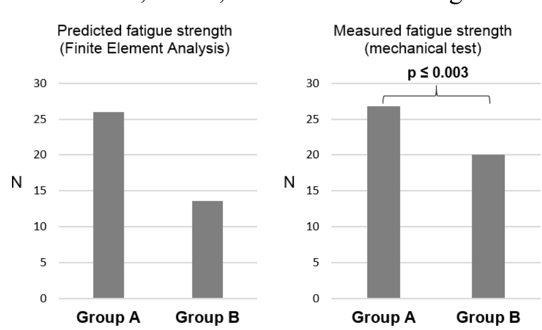

FIGURE 2. Median fatigue strength.
The predicted fatigue loads of groups A and B derived from the Finite Element Analysis (FEA) are shown on the left. The median fatigue strengths measured in the three-point mechanical test are shown on the right.

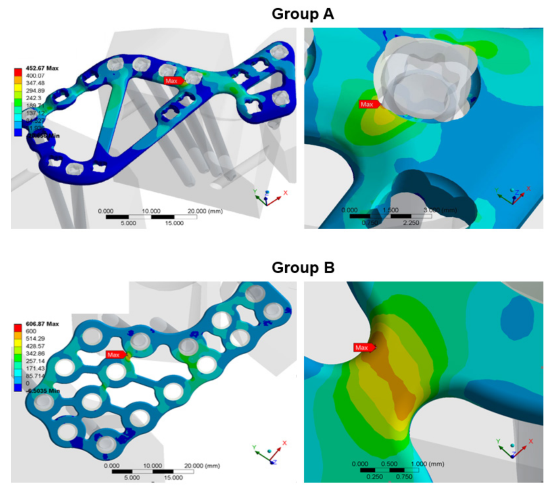

FIGURE 3. Finite Element Analysis.
Finite Element Analysis (FEA) was used to predict and compare plate fatigue performance for group A (top) and group B (bottom). The right panels show an enlarged view of the predicted weakest areas of the plate.

Calcaneal bone measurements and plate design

The calcaneus consists of a cortical shell with variable thickness and a complex internal trabecular structure that reflect its static and dynamic loads. The visible stress trajectories correspond closely to a number of distinct trabecular systems.[12-15] Compressive trajectories, suited for transmitting the compressive forces exerted by the talus, extend anteriorly and posteriorly along the cranial half of the calcaneus, while tensile trajectories extend along the inferior part of the bone.[13-15] In correspondence with the expected high loads transferred across the subtalar joint, strong cortical bone condensation is found between the anterior and posterior articular facet, including a part of the medial wall.[12,14] This condensation is most pronounced at the anterior site of the posterior talar facet, spreading to the angle of Gissane.[12,14] Strong cortical condensations are also seen in the inferior portion of the posterior tuberosity.[14,15] The weakest area, sparse in trabecular bone, is called the 'neutral triangle' and is found in the anterolateral cortex, just posterior to the calcaneocuboid joint. Together with the antero-inferior part of the lateral wall, the neutral triangle represents an area prone to fracture.[2,12,15,16]

In-depth understanding of the internal calcaneal structure may help in the interpretation of fracture patterns and improve implant design. Measurements of human bone samples from a collection of calcaneal bones at the University of Tennessee, Forensic

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Anthropology Center, Department of Anthropology, provided a useful basis to develop an optimized plate design. The resulting *DePuy Synthes* 2.7 mm VA Locking Calcaneal Plate design matched the outer shapes of the bones well and the available size range covered a wide selection of bones.

The *DePuy Synthes* 2.7 mm VA Locking Calcaneal Plates are anatomically pre-contoured to the anterior process, posterior facet, and calcaneal tuberosity. The plate material and design allow for additional contouring in the tuberosity and anterior process portion of the plate, if required. There are no screw holes in the neutral triangle area of the calcaneus. This may provide greater plate strength and avoid screw placement in a frequently fractured area.

The new plates feature a row of several small diameter screws just below the subtalar joint, potentially acting as a 'raft' to support subtalar joint fragments (Figure 4). A similar rafting technique with small diameter screws has been gaining popularity in other articular fracture indications, such as those for proximal tibial fractures.[17-21] The tibial plateau is also a load-bearing lower-leg joint surface, similar to the cranial portion of the calcaneus just below the subtalar joint. Recently, Wang et al. suggested that implant screws be placed in the condensed area under the calcaneocuboid articular surface.[22] We believe that this biomechanical concept of small diameter screw rafting may have some benefits in the calcaneus as well.

DISCUSSION

In this study, we compared the *DePuy Synthes* 2.7 mm VA Locking Calcaneal Plate construct with a benchmark product with comparable plate dimensions using 3.5 mm locking screws. For this purpose, we used a previously validated FEA model, and then a recently developed mechanical three-point test model to conduct a comparative analysis. Notably, the predictions for plate fatigue strength found in the FEA corresponded with the construct strengths measured in the mechanical test. Moreover, the areas of high stress predicted in the FEA were revealed to be the plates' weakest points in the mechanical test. Therefore, the FEA may indeed be a reliable prediction method for determining plate strength. The current FEA may potentially be even further improved by combining research results on force distribution with information on the internal trabecular architecture of the bone. Combining different computational approaches may eventually lead to an effective biomechanical analysis for characterizing critical factors in the functional adaptation of the foot.[13,14]

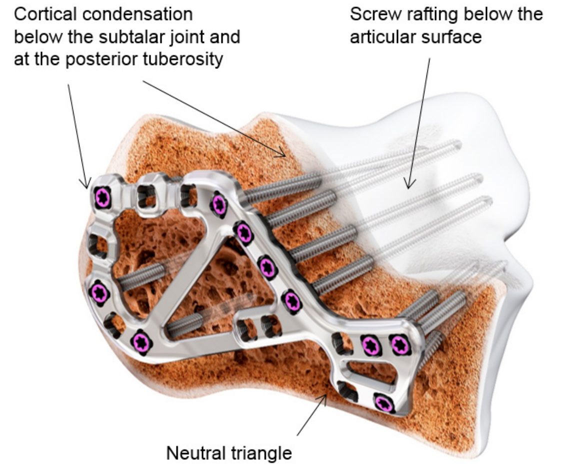

FIGURE 4. *DePuy Synthes* 2.7 mm VA Locking Calcaneal Plate modelled on an average calcaneus.
This figure shows the optimal position and the anatomic contour of the *DePuy Synthes* 2.7 mm VA Locking Calcaneal Plate. A row of screws in the superior plate rim may allow for rafting the subtalar joint surface. The regions with stronger cortical condensation are indicated.

Our analysis showed that both predicted and measured fatigue values of the *DePuy Synthes* 2.7 mm VA Locking Calcaneal Plate were higher than those of a comparable benchmark plate with 3.5 mm locking screws ($p \leq 0.003$). This suggests that reducing the screw diameter may have no negative effect on overall fatigue strength. Previous mechanical testing comparing the *DePuy Synthes* 2.7 mm TiCP4 VA Locking Calcaneal Plate with the *DePuy Synthes* 3.5 mm Stainless Steel Locking Calcaneal Plate supports these findings, showing that no statistically significant difference exists between the median fatigue endurance limits of these constructs ($p > 0.05$). Even though different materials were compared with each other, these findings further support that reducing the screw diameter from 3.5 mm to 2.7 mm may have no negative effect on plate strength.

Measurements of a selection of human calcaneal bones have provided additional detail on individual bone sizes and dimensions. This data, along with available evidence on the inner calcaneal architecture, can be used to further adapt the plate system. A better understanding of bone dimensions also provides more detailed information about the optimal angle and position for the screws. The VA technology of the *DePuy Synthes* 2.7 mm VA Locking Calcaneal Plates allows for adjustment of the screw trajectory at different angles in order to match individual variations. It may also enhance rafting of the articular surface

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without penetrating the joint surface—a technique frequently used in other load-bearing indications like those for the proximal tibia.[17-21]

In an osteoporotic foam simulation of a proximal tibial fracture, Patil et al. have demonstrated that a raft of four 3.5 mm cortical screws is significantly stronger in resisting axial compression than two 6.5 mm cancellous screws ($p = 0.009$).[23] In non-osteoporotic foam, however, the team did not find a significant difference between the two groups ($p = 0.42$), but they observed less bone fragmentation in the group with small diameter screws.[23] In a biomechanical study with human cadaveric proximal tibiae, fixation constructs with a subcortical screw raft were more resistant to local depression loads than constructs without a screw raft ($p = 0.0314$).[18]

The small diameter screws of the *DePuy Synthes* 2.7 mm VA Locking Calcaneal Plate may therefore be beneficial for articular rafting of the calcaneocuboid articular surface. Together with the VA technology, the surgeon has the means to place locked screws precisely below the articular surface, creating a fixed-angle construct. However, this hypothesis regarding the rafting technique in the calcaneus requires further biomechanical and clinical substantiation.

Our analysis also inherits some limitations. First, the mechanical model is a standardized test based on an individual healthy person's gait. It, therefore, does not account for individual variations in a patient's foot anatomy or gait pattern. Second, the mechanical test is designed to examine a cranio-caudal force on the calcaneus as observed during normal gait and does not include unexpected lateral forces that might occur from accidental missteps or falling. Third, even though the mechanical test involved the maximum gait force, the constructs are not considered to be fully load bearing during fracture healing. Last, the model was based on a Sanders type IIB intra-articular fracture, which is a clinically relevant and frequently occurring fracture type that is often used for biomechanical testing.[9,24-26] However, the implications for other fracture types should still be carefully evaluated.

CONCLUSIONS

This study has demonstrated that the median fatigue strength of the *DePuy Synthes* 2.7 mm VA Locking Calcaneal Plate is statistically significantly higher than a comparable benchmark construct with 3.5 mm locking screws. Therefore, reducing the screw diameter may not necessarily affect overall strength of the full construct. Additionally, the study suggests that the anatomical plate design seems well adapted to the calcaneal bone and capitalizes on VA locking technology for rafting of the subtalar joint surface, where the strongest bone is found. Future clinical studies yet have to confirm that our findings can be fully applied to a larger patient collective.

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