SILVERBACK™

ANKLE FUSION PLATING SYSTEM

DEMONSTRATING PERFORMANCE IMPROVEMENTS USING SUPPLEMENTAL PLATE FIXATION WHEN COMPARED TO A THREE-SCREW ANKLE FUSION STRATEGY

Paragon 28® Research & Development

Exclusively foot & ankle

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Introduction

Ankle arthrodesis is used to treat thousands of patients every year, with procedural volumes increasing by 146% between 1994 and 2006[1]. Complications of ankle arthrodesis are primarily linked to infection or non-union of the joint, which occurs in approximately 12% (range 3-23%) of fusions[2]. Proper bony integration is required to achieve a successful ankle fusion, and for proper integration to occur joint motion must be minimized. Previous studies have demonstrated improved union rates when using a three-screw versus a two-screw fusion strategy[3] suggesting improved union with increased construct stability. However, additional crossing screws at the joint decrease the amount of joint surface area able to be fused. The use of supplemental plate fixation has been shown to increase construct rigidity in a cadaveric model[4] and may provide a path for increased rigidity during fusion, while also preserving surface area at the joint.

The Paragon 28 Silverback™ Ankle Fusion Plating System is comprised of relatively thinner plates that help to evenly distribute force across the construct and help guard against stress shielding during healing, when used with a crossing screw. Thus, the plate design allows for increased joint rigidity, maintaining joint surface area, and minimal soft tissue disruption when compared to traditional ankle arthrodesis treatment options.

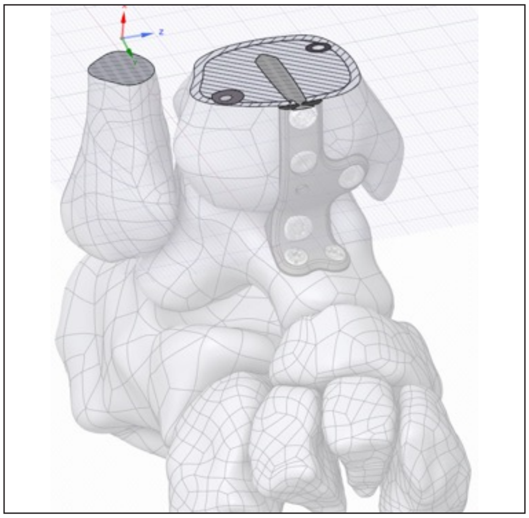

Figure 1 Silverback Mini-Open model in Ansys SpaceClaim with view plane tohighlight cortical shell and implant geometry.

The Silverback™ Anterior Mini-Open Plate provides surgeons an alternative to a three-screw construct for ankle arthrodesis. The Anterior Mini-Open Plate allows for a smaller incision when compared to traditional ankle arthrodesis plates to allow for preservation of the soft tissue envelope. In using fewer screws across the TT joint as compared to a three-screw construct, the Anterior Mini-Open Plate can preserve bony surface area necessary for healing at the tibiotalar joint.

This study will demonstrate improved construct rigidity of the Silverback Mini-Open Ankle Fusion plating system when compared to a standard three-screw construct in a finite element analysis.

Methods

Finite Element Model

A finite element model of the foot was developed in ANSYS Mechanical Workbench. The tibia and talus were segmented from computed tomography (CT) using 3D Slicer (www.slicer.org)[5] and their geometries were extracted as stereolithography CAD files (STL). The models of the talus and tibia were split into two distinct regions to improve model fidelity: trabecular and cortical. The cortical region was built in ANSYS SpaceClaim using the shell feature with a 2 mm thickness which falls between reported thickness magnitudes for talar and tibial bones[6,7]. The trabecular body was then created using the inverse of the region enclosed by the cortical region.

The Silverback Anterior Mini-Open Plate and the three-screw arthrodesis models were assembled in SolidWorks. All screws were placed along screw trajectories defined by Precision Guides in the Silverback Anterior Mini-Open Plating System (Figure 1). The three-screw model was assembled using the two tibiotalar crossing trajectories as defined by the Anterior Mini-Open Plating System. The third Ø7.0 mm screw was aligned from the posterolateral tibia to the talar head. Screw threading and fluting were removed to improve mesh characteristics and simulation performance.

Simulation Setup

The experimental setup described by Tarkin et al.[4] was reproduced in a finite element environment. The distal talus was fixed to mimic the experimental potting in Methymethacrylate, and pure moments were applied to the tibia in dorsiflexion (7 Nm), internal tibial rotation (5 Nm), and eversion (5 Nm) across three separate simulations. Contact was modeled between bones, screws, and plates using an augmented Lagrange contact formulation.

Tarkin et al. tested six osteopenic specimens in a 6 degree of freedom (DOF) joint simulator. They reported mean response to load in rotational DOFs of the ankle with a three-screw fusion construct. The bony material properties of the finite element model were calibrated within physiological bounds[8] in the simulated three-screw fusion model to best match the expected response measured experimentally *(Figure 2)*. Final material properties for calibrated bone material and implant hardware (Ti6-Al4-V ELI) can be found in *Table 1*. Loading was repeated on the Silverback Anterior Mini-Open Plate fusion model using the calibrated bony material properties and results were compared across the different fusion models.

Results

The amount of rotation and micromotion at the joint recorded by the Anterior Mini-Open Plate model for each DOF is reported in *Table 2*. Smaller values correspond to less motion and more stability when compared to three-screw fusion model results. The Anterior Mini-Open Plate model resulted in decreased motion in the sagittal (74.7%) and coronal (79.0%) planes, with similar response recorded in the frontal plane when compared to the three-screw fusion model. The Anterior Mini-Open Plate model resulted in decreased micromotion at the joint in all DOF when compared to the three-screw fusion model. Surface area on the tibial plafond was measured in the three-screw fusion model and the Anterior Mini-Open Plate model, which saw a 5.8% increase in surface area compared to standard three-screw fusion model.

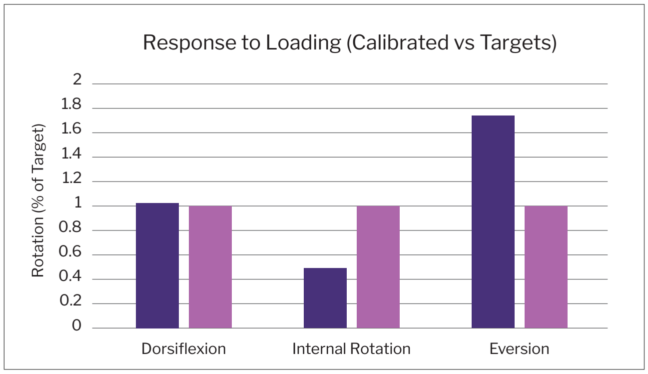

Figure 2 Simulated response to loading of the three-screw ankle fusion model (dark purple) compared against mean response described by Tarkin et al.[4]

Mini-Open System	
Young's Modulus	110 GPa
Tensile Strength (Yield)	860 MPa
Poisson's Ratio	0.32
Cortical Bone	
Young's Modulus	800 MPa
Poisson's Ratio	0.3
Trabecular Bone	
Young's Modulus	70 MPa
Poisson's Ratio	0.12

Table 1 Material properties (Ti6Al4V ELI) used for Mini-Open Plating System and final calibrated material properties used for cortical and cancellous regions in the foot model.

	Micromotion	Rotation
Dorsiflexion	61.4%	74.7%
Internal Rotation	74.7%	79.0%
Eversion	96.2%	100.0%

Table 2 Average micromotion across the tibial plafond and response to moments applied to the tibia in the Mini-Open plating simulations. All values are normalized relative to results seen in three-screw simulations.

Discussion

Tibiotalar arthrodesis is a solution for many pathologies including osteoarthritis, Charcot arthropathy, avascular necrosis of the talus, trauma, congenital deformities, and rheumatoid arthritis. With complex deformity and the presence of the co-morbidities presented above, allowing for optimal healing conditions to achieve bony union is vital.[9]

Many factors influence the ability to fuse arthrodesis sites including joint surface compression, rotational construct stiffness, bending stiffness, blood supply and bone apposition.[9] This study sought to evaluate construct bending and rotational stiffness, while evaluating the effect on the joint surface micromotion and available surface area for fusion.

Using the FEM to simulate static loading, the Silverback Anterior Mini-Open Plating System provided increased overall construct rigidity and fusible surface area at the joint when compared to a three-screw arthrodesis construct.

Limitations associated with this study are concerning the calibrated material properties of the bones and simplified screw geometry. Describing accurate bony material properties across complex geometric differences in cortical thickness is challenging. Calibrating the FEM to reported arthrodesis response to loading provided an avenue for comparison across different fusion strategies. Assumptions were made to simplify the cortical geometry and screw complexity however these assumptions were applied to all models allowing for valuable comparisons to be made in a finite element framework.

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