

# Biomechanical Performance of FastForward™ PEEK Screws for Hallux Valgus Correction

MedShape Research and Development

## Objective

Tethering suture material between the 1<sup>st</sup> and 2<sup>nd</sup> metatarsals has been described as a viable approach to reduce hallux valgus deformities. The FastForward™ Bunion Correction System is one tethering approach that involves looping suture tape around the 2<sup>nd</sup> metatarsal and then fixating it in the 1<sup>st</sup> metatarsal using PEEK screws. The purpose of this study was to compare the performance of the FastForward 1<sup>st</sup> metatarsal fixation approach with a suture button device by measuring the load-to-failure when the suture material is pulled in tension.

## Materials & Methods

- 4.75 x 17.5mm FastForward™ PEEK Interference Screws (MedShape, Inc.)
- FastForward™ insertion driver
- 3.5mm QuikCord™ Suture Tape (MedShape, Inc.)
- Mini-TightRope AS-8914DS (Arthrex, Inc.)
- Electromechanical testing system, Model 5567 (Instron)
- Custom pullout fixture and S-hook assembly (MedShape, Inc.)
- Polyurethane foam blocks 10x30PCF (Pacific Research Laboratories, Ltd.)

Testing was performed using either 37(L) x 30(W)mm or 53(L) x 30(W)mm polyurethane foam blocks.<sup>1</sup> A 9mm thick piece of 10 PCF foam block was sandwiched in between two 30 PCF “cortices” of 3mm thickness to replicate the bi-cortical anatomy and average bone density of the 1<sup>st</sup> metatarsal.<sup>1,2</sup> The following groups were tested:

1. QuikCord tape fixated by 1 FastForward PEEK Screw
2. QuikCord tape fixated by 2 FastForward PEEK Screws
3. Mini-TightRope® suture button with #2 Fiberwire®

For groups 1 and 2, one or two 4mm holes, respectively, were drilled through the bone blocks. The QuickCord was doubled over such that two strands were placed inside the drill holes, and each screw was inserted per the FastForward technique. For group 3, the button was fixated on the far cortex by tying three knots, per the manufacturer’s recommendation. Each construct was loaded into a custom pullout fixture at the bottom of the Instron, and the suture free ends were looped over the S-hook assembly at the top of the Instron. The suture was pulled in tension at 50mm/min and the maximum load and failure mode were recorded (n=5). A Tukey’s Multiple Comparison Test was performed to make any statistical comparisons.

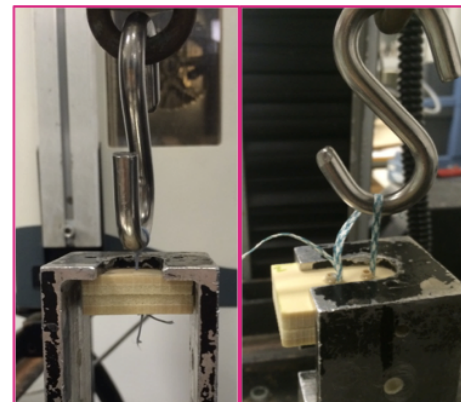


Figure 1. Testing Setups for the (Left) Mini-Tightrope and (Right) 2 screw configuration

## Results

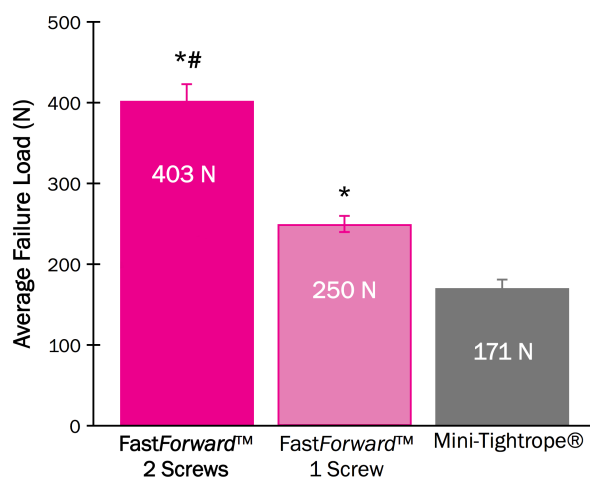


Figure 2. Comparison of failure loads for the three test groups. Values represent average ± standard deviation. \*p-value<0.05 vs. Mini-TightRope. #p-value<0.05 vs. 1 FastForward screw.

## Conclusions

- The failure mode for both the 1-screw and 2-screw constructs was suture slippage. The failure mode for the Mini-Tightrope was knot slippage for all tests.
- Fixating with 2 PEEK screws produced the highest failure load, 60% higher than using 1 screw and more than 2X higher than the failure load of the Mini-Tightrope.
- These results suggest that using 2 PEEK screws with suture tape provides the best fixation in the 1<sup>st</sup> metatarsal when reducing hallux valgus deformities.

### References:

- <sup>1</sup>ASTM F 1839-01: 2007, “Rigid Polyurethane Foam for Use as a Standard Material for Testing Orthopedic Devices and Instruments.”
- <sup>2</sup>Commean et al, Tarsal and Metatarsal Bone Mineral Density Measurement Using Volumetric Quantitative Computed Tomography. Journal of Digital Imaging 2009; 22(5): 492-502.22(5): 492-502.