

In Vitro Biomechanical Performance of MedShape Eclipse Soft Tissue Anchor for Tendon Transfer Procedures

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Study Objectives

To evaluate the biomechanical performance of the Eclipse Soft Tissue Anchor when used to fixate soft tissue to bone for tendon transfers in the foot and ankle.

Materials and Methods

Mature bovine flexor tendons were obtained from Animal Technologies, Inc (Tyler, TX). Specimen preparation and testing protocol were adapted from previous work by Kousa et al¹ and Donley et al². Tendons were closely dissected down to a 5 mm wide graft. Two types of synthetic bone (Pacific Research Laboratories) were used: (1) 10/20 (2 mm 20 PCF cortical layer with 10PCF underlying cancellous layer) representing the density of the calcaneus; (2) 20/40 PCF modeling healthy, dense bone such as in the navicular bone. A hole of specified diameter (Table 1) was drilled into the bone blocks. The following fixation devices were tested:

1. Eclipse Soft Tissue Anchor, 5x12mm (MedShape, Inc)
2. Bio-Tenodesis™ Screw, 5.5x15mm (Arthrex, Inc)

Each device was inserted adjacent to the flexor tendon in the drilled hole. The Eclipse Deployment Gun was used to insert the compressed sheath into the bone hole. Tendon fixation was achieved by pulling the trigger on the Deployment Gun to facilitate sheath expansion. The Bio-Tenodesis screw was inserted per the manufacturer's instructions for use. Each device-tendon-bone construct was mounted on a universal test machine (Instron electromechanical testing system 5567) using custom-designed fixtures (Figure 1). The tendon was then pulled at 50 mm/minute until failure. Load versus extension was recorded, and the pullout load was defined as the maximum load measured on the initial load versus extension curve (n=6 per device).

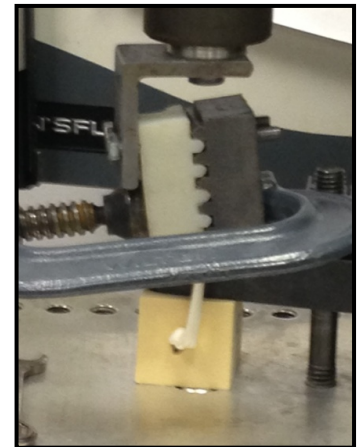


Figure 1. Test setup

Table 1.

Bone Model	Implant	Implant Size (mm)	Hole Diameter (mm)
10/20 PCF	Eclipse	5	5.5
	Bio-Tenodesis	5.5	5.5
20/40 PCF	Eclipse	5	6
	Bio-Tenodesis	5.5	6.5

Results

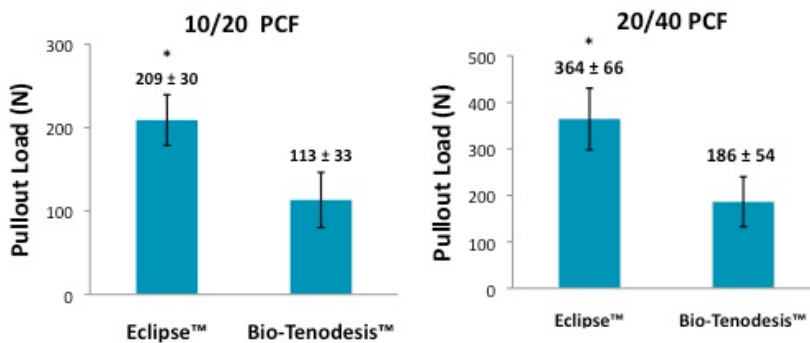


Figure 2. Comparison of pullout loads between Eclipse and Bio-Tenodesis screw using the sizing schemes in Table 1. Values represent mean +/- standard deviation. *p value < 0.05.

Conclusions

The Eclipse device exhibits significantly superior pullout strength compared with the Bio-Tenodesis screw in both bone models under the sizing conditions utilized in this study. The pullout load of the Bio-Tenodesis screw obtained in this study is consistent with values reported in the literature¹ demonstrating the utility of this biomechanical model to assess fixation strength of interference devices using flexor tendon grafts.

¹Louden et al. *Foot and Ankle International*, 2003; 24(1):67-72.

²Donley et al.. *Foot and Ankle International*, 2007; 28(10): 1078-1081.