Biomechanical Evaluation of FiberTag® TightRope® Implant

Arthrex Research and Development

Objective

To biomechanically evaluate the FiberTag TightRope product (AR-1588RTT) and technique compared to a locking #2 FiberLoop® stitch and the first generation FiberLoop with FiberTag construct.

Materials and Methods

Constructs were made by trained technicians familiar with techniques (see references for detailed techniques for preparing grafts with the FiberLoop suture, FiberLoop with FiberTag construct, and FiberTag TightRope implant).[1-3] The FiberTag TightRope technique uses 4 needle passes through the FiberTag suture (2 up, over the TightRope implant, and 2 more passes down) in order to reinforce the prepared graft. Ultimate load (N) values were determined for each group.

Figure 1. Control A (FiberLoop suture)

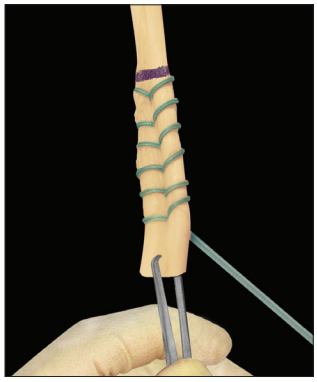


Figure 2. Control B (FiberLoop with FiberTag construct)

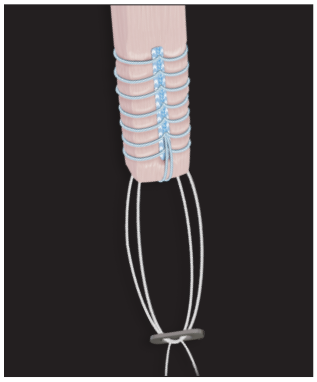
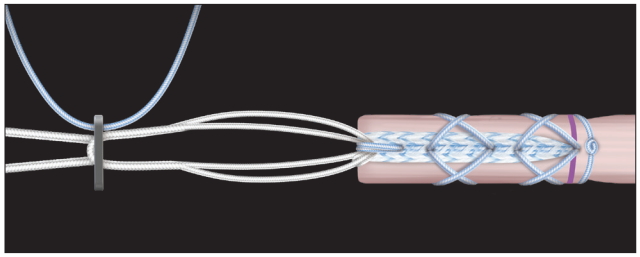


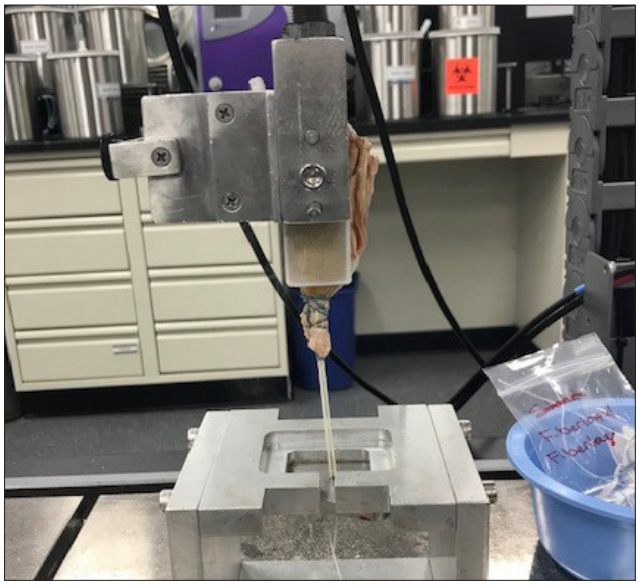
Figure 3. New Technique (FiberTag TightRope implant)



Biomechanical testing was performed using an ElectroPuls Instron with a 10kN load cell attached to the crosshead. The tendons were attached to a custom inter-digitizing freeze clamp with dry ice. The buttons were held to the testing surface by a metal plate with a 4.0 mm hole drilled through it. An example image of the testing setup can be found in Figure 1 below. The sample was precycled from 10N to 50N at 1 Hz for 10 cycles. At this point, the system paused, allowing time for the button to be retensioned.

A six-throw surgeon's knot was tied under the button. The system then continued cycling from 50N to 250N at 1 Hz for 500 cycles. Post cycling, pull-to-failure was conducted at 20 mm/min. Load and displacement data were collected at 500 Hz. The ultimate load (N), cyclic displacement (mm), and modes of failure were recorded for each sample.

Figure 4. Test Setup



Results and Conclusions

Table 1 shows a direct comparison between a FiberLoop® technique and the FiberTag® TightRope® technique. The FiberTag TightRope device performs similarly to the FiberLoop with FiberTag construct with an added TightRope implant. Although the differences are significant, the FiberTag TightRope implant's ultimate load and displacement values are improved compared to the FiberLoop with FiberTag construct. A student's T-test indicated there was no statistical difference found between predicate FiberLoop with FiberTag construct cyclic displacement data and the FiberTag TightRope implant (AR-1588RTT) tested in this report (*P= .059,* Power=0.486).

Table 1: Direct Comparison Between 2 Techniques

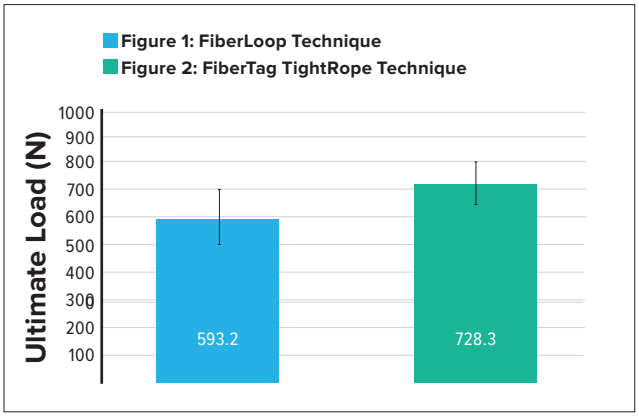
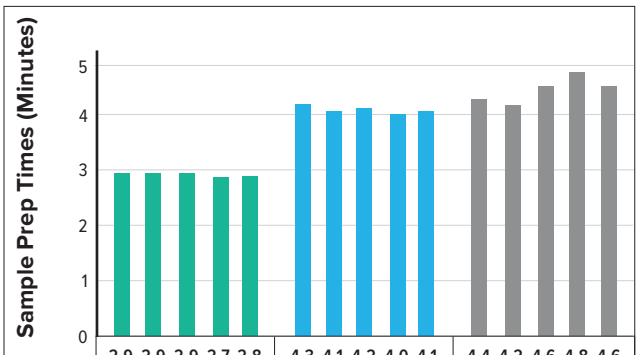


Table 2: Preparation Time for Each Suturing Device (Samples of 5) Measured in Minutes



Grafts	FiberTag TightRope Technique	FiberLoop Technique	FiberLoop w/ FiberTag Technique
Average	2.9 min	4.1 min	4.5 min

The sample preparation time in seconds for each sample is shown in Table 2. The amount of time required to prepare a graft with the FiberTag TightRope technique was significantly less than that of the other two techniques ($P < .001$ for each comparison): 31% less time than FiberLoop technique and 37% less time than FiberLoop with FiberTag technique.

References

1. Arthrex, Inc. LT1-000010-en-US. Naples, FL; 2019
2. Arthrex, Inc. LT0135D. Naples, FL; 2011.
3. Arthrex, Inc. LT1-0134-EN. Naples, FL; 2017.

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