Fatigue Loading of SutureTape for Use as an *Internal*Brace™ Ligament Augmentation Repair as Part of an Ulnar Collateral Ligament Repair

Arthrex Research and Development

Objective

The purpose of this testing is to evaluate the fatigue behavior of SutureTape for use as an *Internal*Brace ligament augmentation repair as part of an ulnar collateral ligament (UCL) repair.

Methods and Materials

Samples were prepared by fixating lengths of SutureTape into 20/40 lb foam blocks using 3.5 mm PEEK forked eyelet DX Swivelock® SL anchors (AR-8978P). The foam blocks had been predrilled using a 3.0 mm bit.

In order to define the fatigue cycling limits, preliminary anchor pull-out testing was performed to determine the maximum pull-out strength of the forked eyelet anchor/SutureTape construct (n=5). For fatigue loading, 50% maximum pullout strength, 150 N, was the maximum load applied to the samples.

Foam blocks were oriented and secured within a shear fixture so that the direction of anchor insertion was perpendicular to the direction of cyclic loading, simulating the direction of force applied in a UCL repair (Figure 1). Both tails of the SutureTape were secured in a pneumatic clamp attached to the piston of an INSTRON®* ElectroPuls™ Dynamic Testing System (Illinois Tool Works, Inc).

After preloading, samples were cycled 15 N to 150 N for 50,000 cycles at a rate of 2 Hz. Load and displacement data were recorded for each sample (n=3). Elongation and elastic displacement were calculated using the resulting load vs displacement curve of each sample. Elongation was defined as the total amount of unrecoverable movement experienced by each sample over the course of cycling. Elastic displacement was defined as the amount of recoverable displacement experienced by each sample over 1 cycle.

Results

Average elongation and elastic displacement for the forked anchor/SutureTape constructs are presented in Table 1. All 3 samples survived the 50,000 cycles of loading.

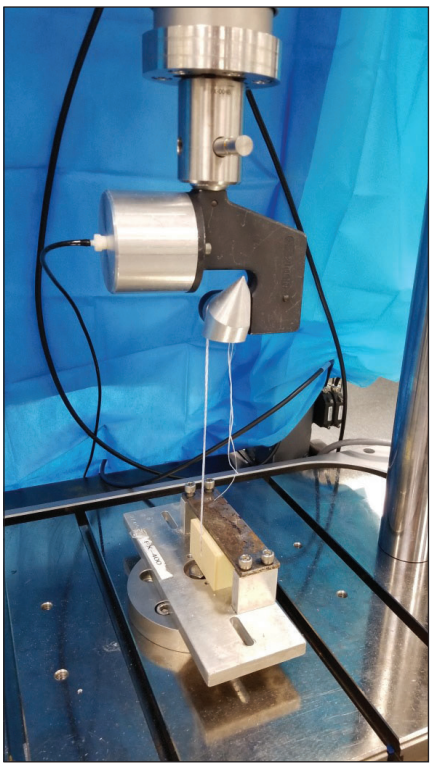
Table 1. **Test Results Summary**

Parameter	Mean ± SD
Elongation (mm) × 2	8.04 ± 0.22
Elastic displacement (mm)	0.687 ± 0.01

Conclusions

An anchor/SutureTape construct when used for an *Internal*Brace ligament augmentation procedure as part of a UCL repair is capable of successfully withstanding 50,000 cycles of loading. Previous studies have demonstrated a figure-of-8 or Bio-Tenodesis™ screw construct to have maximum loads of 23.5 N and 24.3 N, respectively.[1] With a maximum anchor pull-out strength of 300 N, a SutureTape *Internal*Brace augmentation procedure offers superior strength and stability over standard UCL repairs alone. It also demonstrates the ability to withstand significant repetitive loading.

Figure 1. ***Test results summary***



Reference

1. Baskies MA, Tuckman D, Paksima N, Posner MA. A new technique for reconstruction of the ulnar collateral ligament of the thumb. *Am J Sports Med*. 2007;35(8):1321-1325. doi:10.1177/0363546507303663.

The *Internal*Brace surgical technique is intended only to augment the primary repair/reconstruction by expanding the area of tissue approximation during the healing period and is not intended as a replacement for the native ligament. The *Internal*Brace technique is for use during soft tissue-to-bone fixation procedures and is not cleared for bone-to-bone fixation.