

Biomechanical Testing of an Ulnar Collateral Ligament Repair: SwiveLock® Anchor with *InternalBrace*™ Ligament Augmentation Procedure vs SwiveLock Anchor Alone

Arthrex Research and Development

Objective

The purpose of this study is to compare the maximum load and load at clinical failure of an ulnar collateral ligament (UCL) suture anchor repair using 1 SwiveLock suture anchor vs an *InternalBrace* ligament augmentation repair with 2 SwiveLock suture anchors.

Methods and Materials

Six matched pairs of fresh-frozen human cadaveric thumb specimens (average age=49.6±14.6 years) were used in this study. Prior to repair, the proximal first metacarpal was potted in a section of PVC pipe using fiberglass resin to facilitate loading in the material testing setup. The thumb was disarticulated from the hand at the carpometacarpal joint during specimen dissection and a repair using either a SwiveLock anchor or SwiveLock anchors with *InternalBrace* ligament augmentation procedure was performed by Steven Shin, MD (Los Angeles, CA). The repairs were then isolated by releasing the UCL and any remaining proximal tissue.

All repairs were performed using 3.5 mm Forked Eyelet DX SwiveLock SL anchors (AR-8978P) and the appropriate drills and taps found in the DX SwiveLock SL Anchor Disposable Kit (AR-8978DS). LabralTape™ suture (AR-7276T) was used for the repair with *InternalBrace* ligament augmentation. The repairs were categorized into 1 of 2 groups previously mentioned (Table 1).

Table 1: Test Group Description

Test Group Summary	
Group	Construct Description
Repair A	SwiveLock Anchor
Repair B	SwiveLock Anchor With <i>InternalBrace</i> Ligament Augmentation Repair

The *InternalBrace* 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 *InternalBrace* technique is for use during soft tissue-to-bone fixation procedures and is not cleared for bone-to-bone fixation.

Figure 1:
Complete
Testing Setup



*Instron is a registered trademark of Illinois Tool Works Inc

Following repair, each sample was secured within a custom-designed vise and centered below a concave plunger centered 20 mm distal from the metacarpophalangeal joint. A cantilever-style load was applied to the sample using an INSTRON® ElectroPuls Dynamic Testing System (INSTRON, Canton, MA), Figure 1.

After preloading, a valgus load was applied to each sample at a rate of 0.1 mm/sec until failure occurred. A t-test was performed to identify any statistically significant differences in maximum load and load at clinical failure between the groups, ($\alpha=0.05$). Clinical failure was defined as the load corresponding to a valgus deflection of 30° or approximately 12.81 mm of vertical displacement.

Figure 2: SwiveLock anchor repair without *InternalBrace* ligament augmentation, a) drawing, b) image

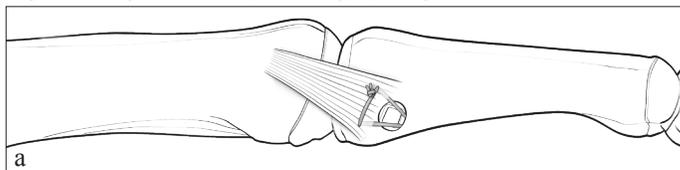


Figure 3: SwiveLock anchor with *Internal/Brace* ligament augmentation procedure, a) drawing, b) image

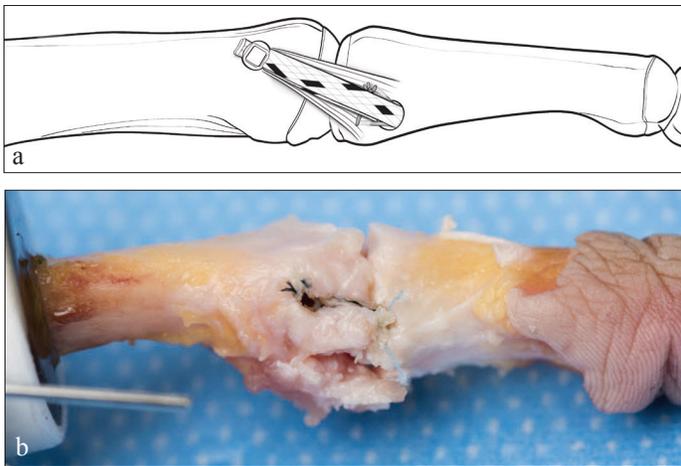


Table 2: Test Results Summary

Test Group Summary		
Parameter	A. SwiveLock® Anchor	B. SwiveLock Anchors With <i>Internal/Brace</i> ™ Ligament Augmentation
Load @ Clinical Failure (N) avg ± std dev	6.0 ± 2.39	25.31 ± 18.34
Maximum Load (N) avg ± std dev	8.02 ± 2.24	46.56 ± 25.56

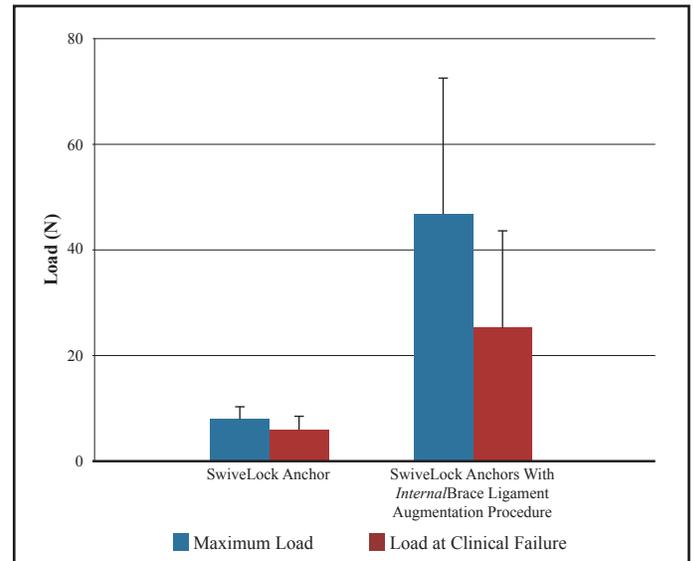
Results

The average maximum load and load at clinical failure for each group are presented in Table 2 and illustrated in Figure 4. Five (5) of the 6 repairs incorporating the *Internal/Brace* ligament augmentation procedure failed due to some degree of suture slippage, with 1 sample failing due to anchor pull-out. Repairs using a SwiveLock anchor only experienced a combination of different failure modes; the most prominent being suture/knot slippage and tissue tearing with 1 sample surviving to clinical failure. The results of the t-tests indicated that the maximum load and load at clinical failure were both significantly higher for the *Internal/Brace* ligament augmentation repairs ($p=0.002$, for both comparisons).

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.

Figure 4: Average Maximum Load and Load at Clinical Failure per Group



Conclusion

The UCL repair performed using SwiveLock anchors with *Internal/Brace* ligament augmentation procedure significantly increased the maximum load as well as load observed at clinical failure compared to the repair with only a SwiveLock suture anchor. Additionally, repairs that included the *Internal/Brace* ligament augmentation procedure demonstrated superior maximum loads to previously studied repairs involving either a figure-of-8 tendon weave or Bio-Tenodesis™ screw construct (23.5N and 24.3N, respectively).¹