InternalBrace™ Ligament Augmentation Procedure: Biomechanical Testing of an Anterior Talofibular Ligament Repair, Insertion Order vs. SwiveLock® Anchor Size

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**Objective**

The purpose of this study is to compare the maximum load and mode of failure of Broström anterior talofibular ligament (ATFL) repairs with InternalBrace ligament augmentation procedure as a function of SwiveLock anchor size and insertion order in the fibula and talus.

**Methods and Materials**

Twelve matched pairs of fresh-frozen human cadaveric ankle specimens (average age=51±13 years) were used. The ATFL was isolated during specimen dissection and the InternalBrace ligament augmentation procedure was performed by Nicholas T. Gates, MD (Edgewood, KY). A medial to lateral hole was drilled through the distal fibula, proximal to the lateral malleolus and the fibula was shortened to facilitate loading in the material testing machine. The repairs were then isolated by releasing the ATFL.

All repairs were performed using one 3.5 mm BioComposite SwiveLock and one 4.75 mm BioComposite SwiveLock (AR-2325BCC and AR-2324BCC, respectively) and the appropriate drills and taps found in the InternalBrace ligament augmentation repair kit (AR-1678-CP). The repairs were categorized into one of four groups as presented in Table 1.

**Results**

The average maximum load for each group is presented in Table 2 and illustrated in Figure 2. The results of the two-way ANOVA indicated that the order in which anchors were implanted did not significantly influence maximum load (p=0.722). Additionally, a significant difference was noted in anchor size. Constructs with 4.75 mm anchors in the fibula had significantly higher maximum loads than those implanted with the 3.5 mm anchors (p=0.001). No significant interaction existed between anchor size and insertion order (p=0.156). Each of these four test groups provide maximum load values above that of native ligament (154N) and studied Broström repairs (68N & 79N). [1,2]

**Conclusion**

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.
Insertion order did not significantly influence maximum load. Additionally, each of the constructs and insertion protocols tested in the current study demonstrated maximum load values comparable or higher than those found for native ligament (154N) and previously studied Broström repairs (68N & 79N). Suture slip/pull-out contributed to 87.5% of the observed failures as compared to eyelet/anchor pull-out, 33%. Bone avulsion did not contribute to construct failure.

References


Figure 2: Average Maximum Load per Group