*Internal*Brace™ Ligament Augmentation: Biomechanical Testing of an Anterior Talofibular Ligament Repair, Insertion Order vs. SwiveLock Anchor Size

Arthrex Research and Development

Objective

The purpose of this study is to compare the maximum load and mode of failure of Broström anterior talofibular ligament (ATFL) repairs with *Interna*lBrace Ligament Augmentation 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 *Internal*Brace Ligament Augmentation construct 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 Implant System, *Internal*Brace Ligament Augmentation Repair (AR-1678-CP). The repairs were categorized into one of four groups as presented in Table 1.

Table 1: Test Group Description

Testing Group Summary			
Group	**Talus Anchor Size (mm)**	**Fibular Anchor Size (mm)**	**Inserted First**
Group 1a	4.75	3.5	Fibula
Group 1b	4.75	3.5	Talus
Group 2a	3.5	4.75	Fibula
Group 2b	3.5	4.75	Talus

Following repair, each sample was strapped to a custom designed jig which held the foot in 20º of inversion and 10º of plantar flexion to simulate worst-case mechanical loading. A set screw was turned into the superior portion of the heel to prevent lift during testing and the fibula was secured to an INSTRON ElectroPuls Dynamic Testing System (INSTRON, Canton, MA) via the fibula drill hole using a clevis/pin fixture, Figure 1.

After preloading, each sample was pulled to failure at a rate of 20 mm/min. A two-way ANOVA was performed to identify any statistically significant differences in maximum load with respect to insertion order and anchor size, (α=0.05).

Figure 1: Complete testing setup

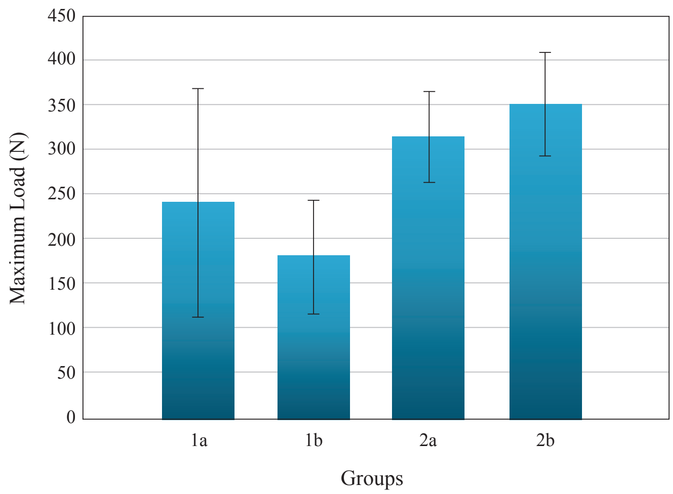
Results

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]

Table 2: Average Maximum Load Results to Failure

Tensile Testing Results Summary		
Group	**Maximum Load [N] avg ± std dev**	**Mode of failure (# of occurences)**
Group 1a: 3.5FA, 4.75TA, FF	241.57 ± 127.15	Eyelet pull-out from fibula (1), anchor pullout/suture slip from fibula (2), suture pull-out from fibula (3)
Group 1b: 3.5FA, 4.75TA, TF	181.13 ± 63.14	Anchor pull-out/suture slip from fibula (1), suture slip from fibula (5)
Group 2a: 4.75FA, 3.5TA, FF	314.67 ± 50.56	Anchor pull-out/suture slip from talus (2), suture slip from talus (2), suture slip from fibula (1), suture slip from both (1)
Group 2b: 4.75FA, 3.5TA, TF	352.31 ± 57.61	Suture slip from fibula (3), suture pull-out from talus (1), eyelet pull-out from talus (1), anchor slip from fibula (1)

Figure 2: Average Maximum Load per Group



Conclusion

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). [1,2] 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

1. Waldrop III NE, Wijdicks CA, Jansson KS, LaPrade RF, Clanton TO. Anatomic suture anchor versus the broström technique for anterior talofibular ligament repair. *Amer. J. Sports Med.* 2012;40(11):2590 – 6.

2. Viens NA, Wijdicks CA, Campbell KJ, LaPrade RF, Clanton TO. Anterior talofibular ligament ruptures, part 1: biomechanical comparison of augmented broström repair techniques with the intact anterior talofibular ligament. *Amer. J. Sports Med.* 42(2):405 – 411.