*Internal*Brace™ Ligament Augmentation Procedure: Biomechanical Testing of an Anterior Talofibular Ligament Repair as a Function of SwiveLock® Anchor Size, Drill Bit Diameter and Bone Tap 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 using a talus-to-fibula *Internal*Brace ligament augmentation procedure as a function of SwiveLock anchor size, drill bit diameter and bone tap size.

Methods and Materials

Six matched pairs of fresh-frozen human cadaveric ankle specimens (average age = 49.7±13.3 years, 6 male) were used. The ATFL was isolated during specimen dissection. 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. Norman Waldrop, MD (Birmingham, AL) performed the ligament augmentation procedures and subsequent release of the ATFL. Following repair, each sample was secured to a 14" long section of 2" x 8" wood using drywall screws. Any remaining tissue proximal to the repair was released.

All of the repairs were performed using one 3.5 mm BioComposite™ SwiveLock and one 4.75 mm BioComposite SwiveLock (AR-2325BCC and AR-2324BCC, respectively). The talus anchor was loaded with FiberTape and inserted first with subsequent tensioning to the fibula for all samples. The repairs were categorized into one of the two groups presented in Table 1.

Table 1. Test Group Description

Test Group Summary						
	Group A			**Group B**		
	Drill Bit Diameter [mm]	Bone Tap [mm]	Anchor Size [mm]	Drill Bit Diameter [mm]	Bone Tap [mm]	Anchor Size [mm]
Talus	3.40	4.75	4.75	2.70	3.50	3.50
Fibula	3.40	No tap	3.50	4.00	4.75	4.75

Prepared samples were c-clamped to a custom-designed jig, which held the foot in 20º of inversion and 10º of plantar flexion to simulate worst-case mechanical loading.[1,2] 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.[1,2] A one-way ANOVA was performed to determine if the two repair groups differed significantly with respect to maximum load.

Results

The average maximum load for each group is presented in Table 2 and illustrated in Figure 2. The results of the one-way ANOVA indicated that the maximum load was not significantly different between the test groups (p=0.447).

Figure 1. Complete Testing Setup

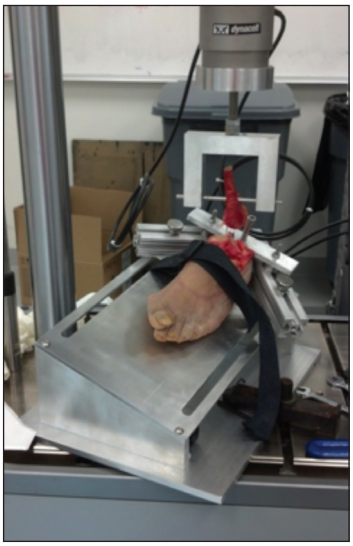


Table 2. Average Maximum Load Results to Failure

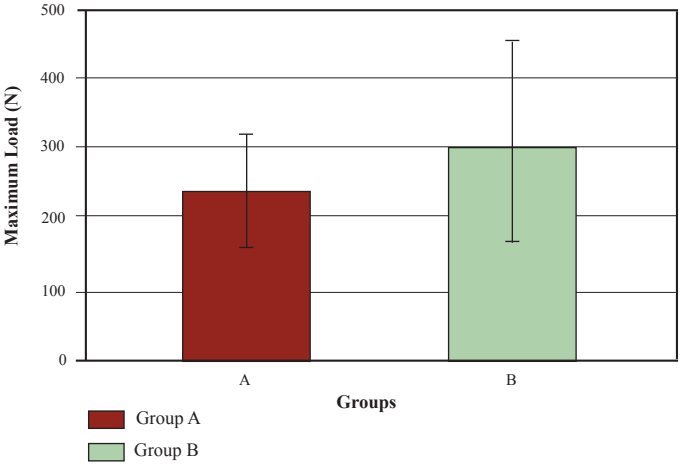
Test Results Summary		
Group	**Maximum Tensile Load [N] avg ± std dev**	**Mode of failure (# of occurrences)**
Group A Bone: Drill/Tap/Anchor T: 3.4/4.75/4.75 F: 3.4/NT/3.5	**244.40** ± 85.96	Anchor pullout at Fibula (1), Suture slip at Fibula (2), Suture pullout at Fibula (1), Eyelet pullout (1), Suture/slip anchor pullout (1) at Fibula
Group B Bone: Drill/Tap/Anchor T: 2.7/3.5/3.5 F: 4.0/4.75/4.75	**296.78** ± 137.34	Anchor pullout at Talus (2), Suture slip/anchor crack at Fibula (1), Anchor pullout at Fibula (1), Suture pullout at Talus (1), Suture slip at Fibula (1)

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.

Conclusion

Differences in anchor size, drill bit diameter and bone tap size did not significantly influence maximum load. Additionally, both of the currently tested constructs in which the FiberTape® suture was tensioned from talus to fibula demonstrate maximum load values higher with Brostrom plus InternalBrace ligament augmentation procedure versus Brostrom alone. Suture slip/pullout and anchor/eyelet pullout equally contributed to 42% of observed failures, respectively. A combination of suture/anchor failure was observed in 16% of the samples. Bone avulsion did not contribute to construct failure.

Figure 2. Average Maximum Load per Group



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

2. Viens NA, Wijdicks CA, Campbell KJ, LaPrade RF, Clanton TO. Anteror talofibular liagment ruptures, part 1: biomechanical comparison of augmented broström repair techniques with the intact anterior talofibular ligament, *Am J Sports Med*. 2014;42(2): 405-411.