*Internal*Brace™ Ligament Augmentation Procedure in the Repair of Acute Deltoid Rupture Associated With Ankle Fracture

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Objective

Traditionally, acute deltoid rupture associated with ankle fracture was often left untreated surgically.[1,2] This treatment philosophy, which stemmed from low-power studies, is now being challenged with growing awareness of the benefits of primary repair.[1] The objective of this study was to compare results of primary repair with and without the *Internal*Brace ligament augmentation procedure in the surgical treatment of acute deltoid rupture associated with ankle fracture using matched-paired cadaveric specimens. Further, we performed tests to determine whether the *Internal*Brace ligament augmentation procedure affects ankle range of motion.

Materials and Methods

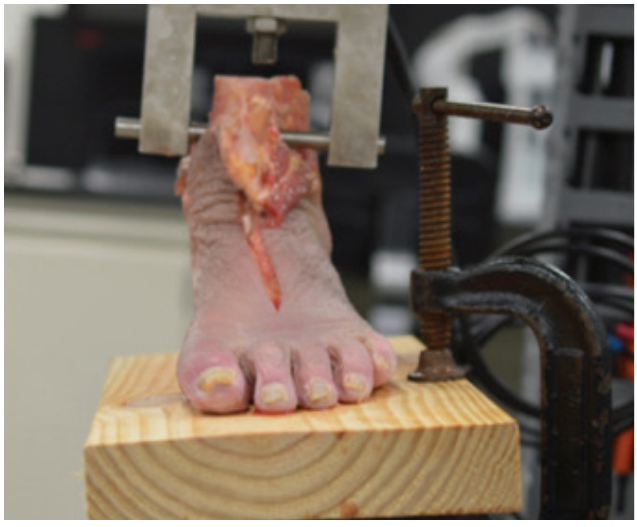
Human cadaveric specimens (mean age, 55 years; all males) were used. Specimens were prepared by transecting the medial deltoid ligament of the ankle to simulate an acute disruption, which was confirmed fluoroscopically. In addition, the ankle syndesmosis was disrupted to simulate a PER 4 injury. This allowed isolated strength evaluation of the medial soft-tissue repair. In initial bench tests, FiberTape® suture with one anchor in the tibia and one anchor in the talus was superior to other constructs; therefore, additional anchors in the talus or calcaneus were omitted from the construct. This study evaluates whether a single "deep-anterior" *Internal*Brace ligament augmentation procedure adequately augments a deltoid repair. For this reason, we compared the use of one 4.75 mm BioComposite SwiveLock® anchor in the tibia and one 3.5 mm BioComposite SwiveLock anchor in the talus with FiberTape suture, consistent with standard *Internal*Brace ligament augmentation techniques, to a control group. The contralateral matched limb was used as a control, which consisted of deltoid primary repair using two SutureTape FiberTak® anchors. For mechanical testing, the foot was oriented in 7° of valgus to simulate foot position during injury (Figure 1).

Compression force of 222N (50 lb) was applied to represent body weight, followed by internal tibial rotation torque with 400/s loading rate until failure. Mechanical data from both groups were compared. Range of motion was measured before and after the *Internal*Brace repair using fluoroscopy to compare the change in the long axis of the talus and tibia.

Results

Figure 2 shows pairwise comparison between *Internal*Brace ligament augmentation repair and contralateral control. Statistical analysis revealed a statistically significant difference in maximum torque between the *Internal*Brace ligament augmentation group and the control group ($P = .028$). Table 1 and Figure 3 show mean maximum torque values for both groups. The mode of failure for all samples was either suture pull-out or suture loosening (Figure 4). There was no decrease in range of motion in any of the specimens after the *Internal*Brace ligament augmentation procedure (dorsiflexion range before *Internal*Brace repair, 0-15°; after *Internal*Brace repair, 0-15°).

Figure 1. Test setup.



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.

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Conclusion

This cadaveric biomechanical analysis provides data on the use of *the Internal*Brace™ ligament augmentation procedure in the setting of acute deltoid disruption. For this configuration, the tibial anchor is placed in the intercollicular groove, while the talus anchor is positioned at the insertion of the deep deltoid on the medial wall of the talus. The stay suture is used to repair the disrupted deep deltoid fibers, with the FiberTape® suture positioned over the ligament fibers with the foot in a neutral position. DX FiberTak® anchors are then used to directly repair the superficial deltoid. Compared with primary repair as the control, the *Internal*Brace ligament augmentation repair provided statistically significant stability before pull-out occurred. There were no significant changes in sagittal plane range of motion in either group. As the *Internal*Brace ligament augmentation group was identified to be superior biomechanically, this procedure may be beneficial for the repair of an acute disrupted deltoid. Clinical studies are necessary to further validate these results.

Table 1. Mean maximum torque values for both groups

Groups	Mean Max. Torque (Nm) ± SD
*Internal*Brace Ligament Augmentation	24.98 ± 6.13
Control	19.78 ± 5.61

Figure 2. Pairwise comparison between *Internal*Brace (IB) ligament augmentation groups and their corresponding contralateral controls.

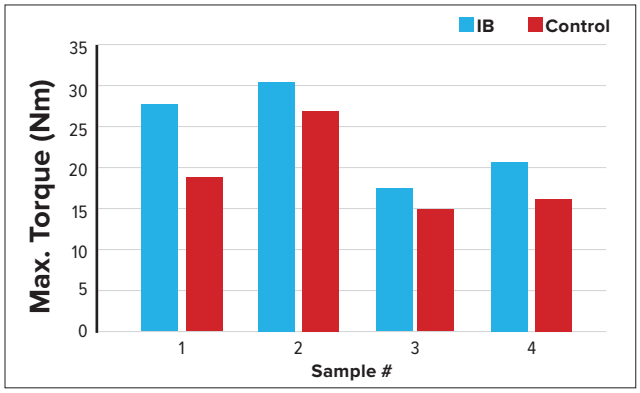
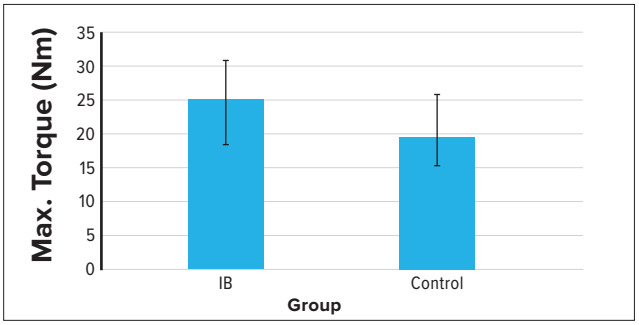


Figure 3. Direct comparison between the two groups.



Acute Deltoid *Internal*Brace Ligament Augmentation

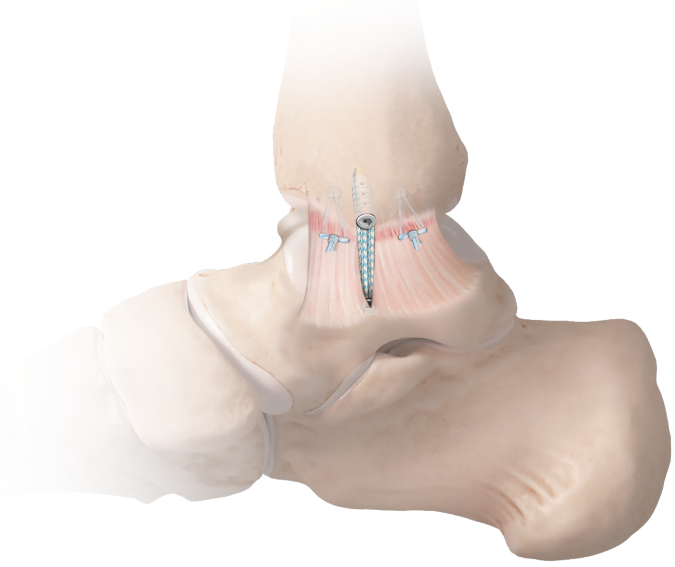
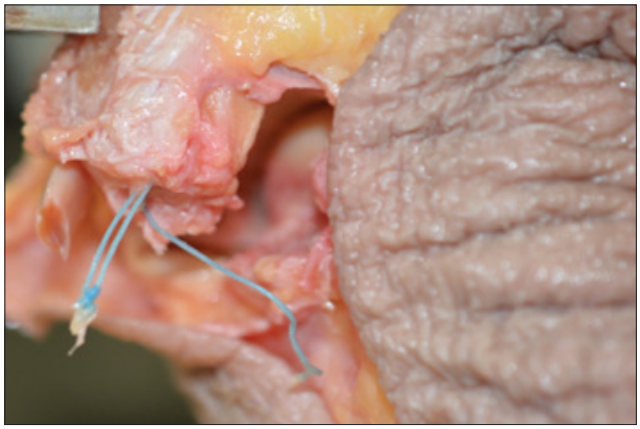
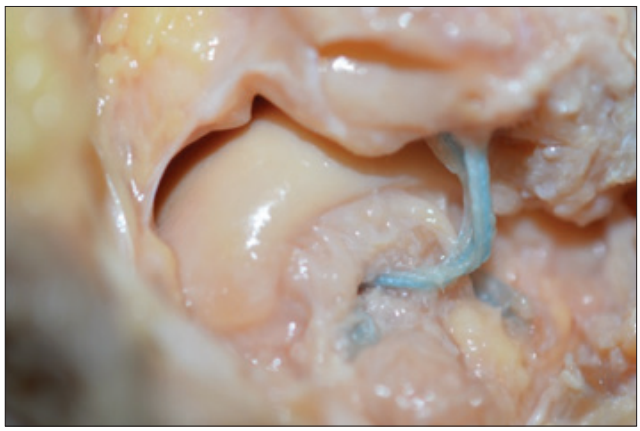


Figure 4. Typical mode of failure in all samples.



Suture pull-out



Suture loosening

References

1. Zeegers AV, van der Werken C. Rupture of the deltoid ligament in ankle fractures: should it be repaired? *Injury*. 1989;20(1):39-41.
2. Hintermann B, Knupp M. Pagenstert GI. Deltoid ligament injuries: diagnosis and management. *Foot Ankle Clin*. 2006;11(3):625-637. doi:10.1016/j.fcl.2006.08.001.

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