

InternalBrace™ Ligament Augmentation Repair for the MCL

Arthrex Research and Development

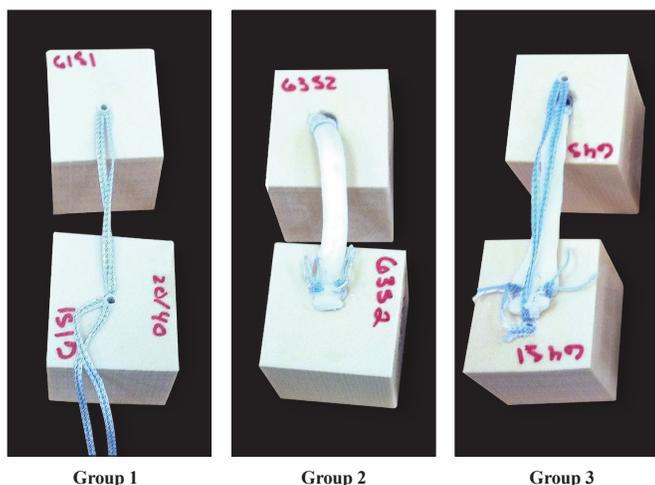
Objective

The objective of this study was to determine the yield and maximum load, mode of failure, and stiffness of a primary MCL repair and compare with a primary MCL repair with *InternalBrace* ligament augmentation repair.

Methods and Materials

Samples (n=3 per group) were prepared using a 20-lbf laminate layer and were grouped into the following constructs: Group 1 - FiberTape® suture fixated with (x2) 4.75 mm BioComposite SwiveLock® anchors (FiberTape suture/SwiveLock anchor); Group 2 - Bovine tendon graft repair using 5.5 mm BioComposite Corkscrew® suture anchor and interference screw (MCL repair); and Group 3 - Bovine tendon graft with 5.5 mm BioComposite Corkscrew suture anchors and interference screw (MCL repair), and FiberTape suture fixated with (x2) 4.75 mm BioComposite SwiveLock anchors (FiberTape suture/SwiveLock anchor). Each pair of blocks was spaced 30 mm apart, with 20 mm from the edge of each block to the point of insertion for each end of the repair. Load to failure was conducted at 20 mm/min. Load and displacement were recorded at 500 Hz in order to determine maximum load, yield load, and stiffness of each construct.

Figure 1. Constructs tested from left to right: Group 1 - *InternalBrace* ligament augmentation repair; Group 2 - Primary MCL repair; and Group 3 - Primary MCL repair with *InternalBrace* ligament augmentation repair.



Results

Figure 2. Tensile test results for MCL *InternalBrace* ligament augmentation repair techniques.

MCL <i>InternalBrace</i> Ligament Augmentation Tensile Test Results			
	Yield Load (Mean±SD N)	Maximum Load (Mean±SD N)	Stiffness (Mean±SD N/mm)
FiberTape suture and SwiveLock anchor	294±25	298±21	84.9±34.2
MCL repair	182±71	182±71	22.9±4.2
FiberTape suture augmentation	414±107	414±107	58.3±3.7

A 1-way ANOVA was run to determine if any significant difference existed in yield load, maximum load, or stiffness with respect to each construct group. A significant difference was found between 3 of the comparison groups: yield load of FiberTape suture augmentation compared to the MCL repair ($P=.021$), maximum load of FiberTape suture augmentation compared to MCL repair ($P=.004$).

Conclusions

Arthrex's FiberTape suture and SwiveLock anchor combination provides a viable method to augment a primary MCL repair. The *InternalBrace* ligament augmentation repair provides a significant difference in maximum load ($P=.017$) and yield load ($P=.022$) when compared to the primary MCL repair alone.

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.