Biomechanical Comparison of a Conventional and Augmented Rotator Cuff Tear Repair

Higgs G[1], Collon K[2], Kaimrajh D[3], Milne E[3], Peterson L[4], Madrid J[5], Smith M[6], Latta L[3]
[1]Lumin Health OrthoCare, Plano, TX; [2]Univ. of Miami, Sch. of Med., Miami, FL; [3]Max Biedermann Instit. for Biomech., Miami Beach FL; [4] Gothenburg Univ., Sweden; [5]Clinica Integral, Rancagua, Chile; [6]Old Dominion Univ., Norfolk, VA

Introduction: Healing of a repaired rotator cuff tear remains a challenge to the Orthopaedic Surgeon and the patient. The reported rates of failed repair of the rotator cuff range between 20% and 70%. The goal of rotator cuff tear repair is to restore normal biomechanics to the glenohumeral joint by obtaining secure fixation of the ruptured rotator cuff tendon at its anatomic footprint on the humeral tuberosities to allow healing of the tendon to bone interface. A repair must have enough fixation strength under minimal tensile stress of the rotator cuff tendon to withstand cyclic loading without gap formation during the entire rehabilitation period. Burkhart et al have conjectured that if a 5 mm or greater gap forms between the tendon and the bone at any time during the critical healing process of a rotator cuff tear repair, then the repair will fail.[1] Gap formation results from low level muscle contraction during the rehabilitation process and possibly even during sling immobilization. It is a goal of the surgeon to minimize the gap formation at the tendon to bone interface during the healing phase of the repair in an effort to ensure a healthy tendon to bone construct.

A recent comprehensive systematic review by Ferguson[2] concluded that augmentation of large to massive rotator cuff tears using human dermal allografts is superior to conventional repair; conversely, the authors concluded that xenograft use does not provide the same benefits; finally this review deems current available data on the use of synthetic patches for rotator cuff repair augmentation to be promising, however limited. Our study aims to substantiate this latter conclusion, and add to the existing data on the efficacy of synthetic patch augmentation for rotator cuff repair. Further, we introduce a synthetic material – the Artelon Tissue Reinforcement device (ATR) – that, while shown clinically to be beneficial in the repair of various ligamentous injuries including the rotator cuff, has not been investigated in depth for its biomechanical properties in the setting of tissue reinforcement. In rotator cuff tear repair the ATR provides a mechanical augmentation by off-loading the repair immediately and during a period of postoperative healing and rehabilitation. Further, the device allows for reparative revascularization and tissue ingrowth in the repaired area over time.

Methods: Eight pairs of cadaver shoulders were identically prepared by removing the extrinsic shoulder muscles. The rotator cuff and underlying capsule were left intact. The supraspinatus tendon was sharply dissected from the footprint at the greater tuberosity to simulate the lesion. The most lateral 5 mm of tendon were removed to simulate a chronic situation and then one-half of the rotator cuff thickness from the most lateral 5 mm of the remaining tendon were resected to simulate a delaminated rotator cuff condition. The right and left sides were randomly selected for one of 2 procedures.

One side of each matched pair was randomly assigned for a conventional rotator cuff repair (CRCR). Two anchors containing #2 non-absorbable sutures were placed 2 cm apart at 45˚ in the mid-lateral supraspinatus footprint on the humeral head. The sutures were placed through the supraspinatus tendon 1 to 1½ cm from the lateral edge and secured to the humerus alternating simple and modified Mason-Allen suture technique. Two additional anchors were placed to create a lateral row and the sutures were passed using the same technique.

The opposite side was repaired with an Artelon

Methods … continued …

Graft augmentation after performing the CRCR repair as described above. The longitudinal axis of the ATR was placed so that it was oriented approximately 30 to 40 degrees to the orientation of the supraspinatus tendon so that the lateral anterior edge of the ATR could reach far enough to cover the anterior superior subscapularis. Non-absorbable sutures were used to secure the ATR to the rotator cuff. The most medial apical stitch was placed first (Fig. 1). A simple stitch was used throughout the implantation. The sutures were placed at approximately 1 cm intervals. The second suture was placed adjacent to the first stitch on the posterior aspect of the ATR. The third suture was placed anteriorly adjacent to the apical stitch. Then alternate posterior and anterior stitches were placed migrating laterally until the ATR was secured adequately to the rotator cuff all the way out to the rotator cuff attachment to bone. Simultaneously, the ATR was overstretched with each stitch by pulling the edge and taking advantage of the elasticity of the ATR to unload the tendon repair. Alternating from posterior to anterior prevented over pulling the ATR too much in one direction or another, which could potentiate inadequate coverage of the rotator cuff.

The tension on the sutures was progressed so that each suture securely pulled the ATR down onto the rotator cuff to maximize contact between the ATR and the rotator cuff. The ATR should actually press down on the bursal side of the rotator cuff throughout the extent of coverage. The ATR was then sutured to the rotator cuff laterally after placing two lateral row anchors and passing the sutures through both the ATR and the rotator cuff using alternating Modified Mason-Allen and simple suture technique.

Linear differential variable reluctance transducers (DVRT) (Microstrain, Burlington, VT, USA) were mounted anterior and posterior on the tendon across the repair gap and secured to the humeral head lateral to the anchor insertions (Fig. 1). The humeral shaft was held securely in an angle vice and the angle of the shaft was set to 30° from vertical. The supraspinatus muscle was gripped proximal to the repair site with a soft tissue grip and attached to the Instron E3000 (Instron, Canton, MA) for loading in tension vertically. A sinusoidal vertical cyclic load from 10 N to 100 N tension in load control at 0.5 Hz was applied for 200 cycles. After cyclic loading a final load to failure was performed in tension as a ramp displacement in stroke control at 33 mm/min.

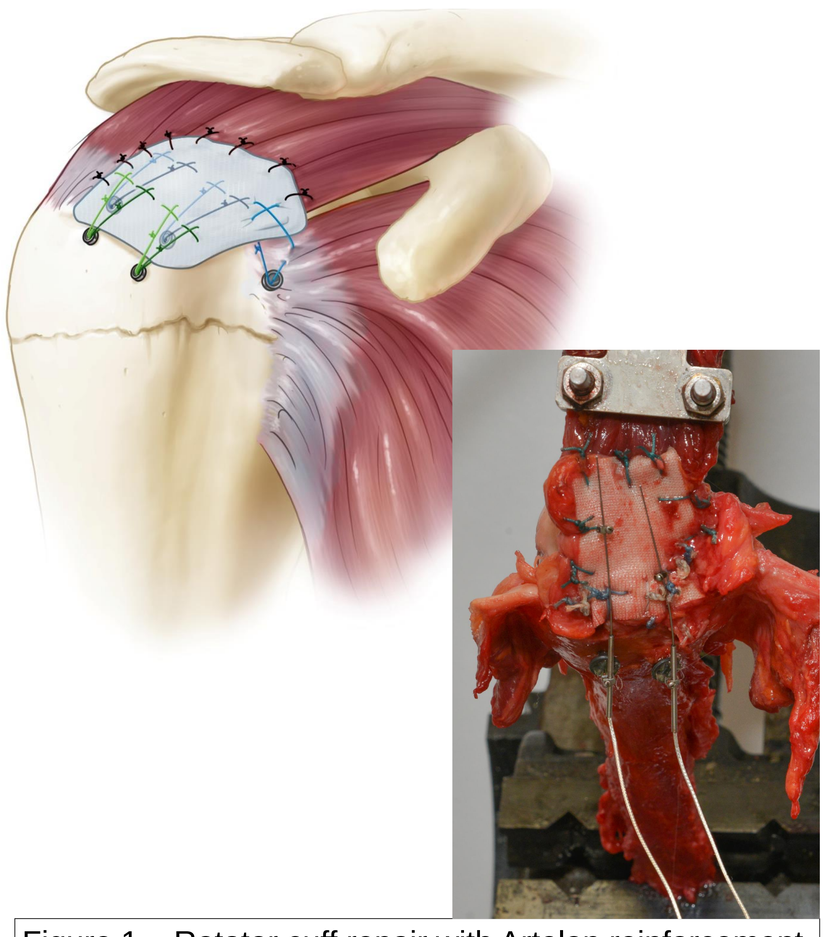

Figure 1 – Rotator cuff repair with Artelon reinforcement device, left, testing with DVRT's, right.

Results: There was a significant difference between the residual gaps which developed over the 200 cycles of loading for the CRS vs. ATR: 0.88 ± 0.53 mm for ATR vs. 4.05 ± 1.93 mm for the CSR, with paired sampling this was significant, $P < 0.0001$.

The difference in load to 5 mm gap between the augmented and suture repaired specimens was not as dramatically different as the ultimate load comparison. But this was a measure of gap increase from the starting point of the failure test until it reached 5 additional mm of movement between the bone and soft tissue markers on the fluoroscopic images. But, since the sutured repairs had already experienced 4.05 ± 1.93 mm residual gap after cyclic loading, their starting point at the beginning of the failure test was already close to 5 mm. So this load was what was recorded after 5 additional mm of gap opening. And the augmented grafts had only experienced 0.88 ± 0.53 mm residual gap after cycling, so this load to reach 5 mm of additional gap is much closer to a load value needed to create a 5 mm gap.

Stiffness was measured as the slope of a linear regression of the most linear portion of the load-displacement graph from the Instron measures. There was no significant difference in stiffness between the augmented and suture repaired specimens. However, there was a significant difference between right and left specimens hinting that hand dominance could be an important factor in upper limb pairs. This also points to the importance of mixing the variables randomly between right and left limbs when using paired sampling. We had 4 right and 3 left shoulders in the augmented group vs. 3 right and 4 left in the sutured group.

Conclusions: Augmentation of a repair to the supraspinatus with Artelon graft supplement did not allow the cut in the tendon to open more than one mm over 200 cycles of load from 10 to 100 N. The standard suture repair allowed about 4 mm of gap opening with the same cyclic loading regimen. The Artelon augmentation significantly increased the strength of the repair with tensile loading on the supraspinatus.

References: 1) Burkhart SS, et al. Arthroscopy. 1997; 13: 172–176. 2) Ferguson DP, et al. Am J Sports Med. 2016. 3) Shea KP, et al. J Shoulder Elbow Surg 21 8 Aug 2012 1072-1079

Acknowledgements: This project was supported by Artelon, Inc. and MBI for Biomechanics, at Mount Sinai Medical Center, Miami Beach, FL