Biomechanical Comparison of Three Augmented Rotator Cuff Repair Techniques

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Introduction: Rotator cuff tears affect forty percent of individuals older than sixty years of age and are a common cause of shoulder pain, dysfunction, weakness and a deteriorated quality of life[1]. The reported rates of failed repair of the rotator cuff range between 20% and 70%. There is a possibility of augmenting those rotator cuff tears with low potential for healing with mechanical reinforcement. One of the goals of the surgeon is 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.

The Artelon Tissue Reinforcement (ATR) is FDA approved through the 510(k) regulatory process to be used for reinforcing soft tissue insufficiency in the musculoskeletal system such as a suture or suture anchor repair during rotator cuff surgery or other soft tissue repairs of tendons, joint capsules etc. The ATR is a novel polycaprolactone-based polyurethane urea scaffold with slow degradation properties that comes in various sizes for implantation with a unique weave that facilitates cell attachment and growth. Once presoaked in normal saline the ATR will absorb blood from the bleeding bone in the greater tuberosity which contains essential mesenchymal stem cells from the endosteal blood supply of the humerus. The purpose of this study is to evaluate three methods of augmentation with the ATR for rotator cuff tear repair in a human cadaveric rotator cuff tear model using both cyclic and monostatic biomechanical testing.

Methods: Fifteen cadaveric shoulders were used for the comparison, with 5 shoulders in each group. Each shoulder was prepared by removing the extrinsic shoulder muscles and sharply dissecting the supraspinatus from the humeral insertion. A conventional rotator cuff tear repair (RCTR) was performed with two anchors in the lateral aspect of the supraspinatus foot print using alternating simple and Modified Mason-Allen technique. The three augmentation techniques compared were: 1) ATR independently anchored to the humerus with two anchors lateral to the medial row alternating two simple sutures with two Modified Mason-Allen sutures, 2) ATR anchored to humerus incorporating the rotator cuff and the ATR with two lateral anchors alternating simple and Mason Allen suture technique and 3) same as method 2 plus a third anchor was added lateral to the subscapularis which was incorporated into the repair. Each repaired humerus was clamped in the test machine at 30° to the vertical and the supraspinatus was clamped in a tissue clamp and attached to the actuator of an Instron E3000 (Instron Corp, Norwood MA). The mechanical test consisted of a sinusoidal tensile load from 10 to 100 N in load control at 0.5 Hz for 200 cycles. Final load to failure was then performed in displacement control at a rate of 1.0 mm/sec. The monitoring of the stretch across the repair was performed with two digital variable reluctance transducers (DVRT's) placed spanning the repair location, one side in the humerus and the other in the ATR. The voltages from the DVRT's were captured on an A/D converter and stored on computer and synchronized with the measures of load and displacement from the Instron.

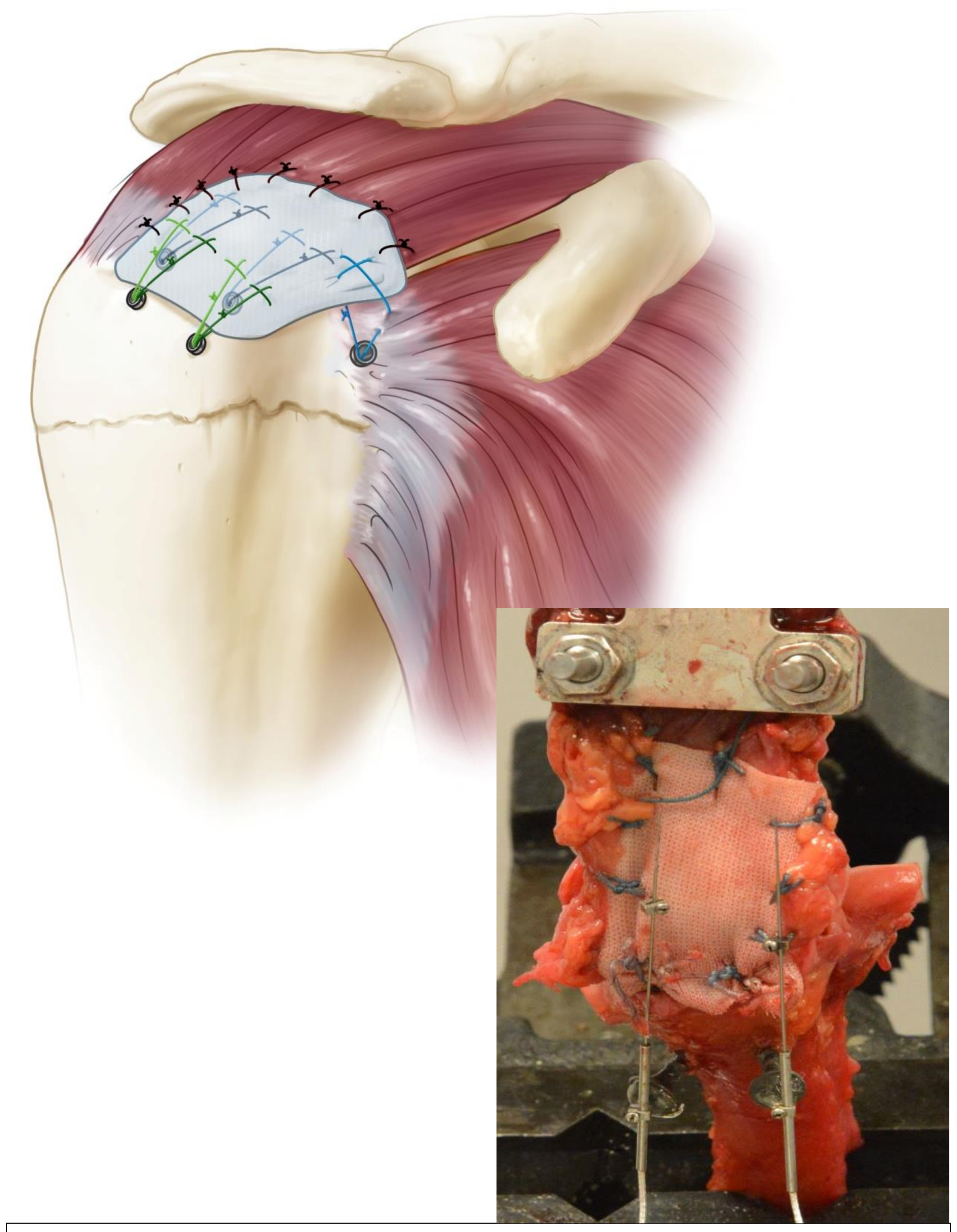

Figure 1 – ATR repair with cuff and subscapularis anchor, left. DVRT placement on specimen ready to test, right.

Results: A preexisting tear in one cadaver reduced the second group to 4 specimens. After cycling there was no evidence of residual stretch or gap formation in any of the groups. The subsequent measuring of the 5 mm "gap" employing the DVRT's[1] was actually a measure of the stretching of the soft tissues in the area. Also no statistically significant difference between the repair methods regarding the load reached after a 5 mm stretch was measured.

The final load to failure revealed that the technique with the subscapularis incorporated in the repair (41.7 ± 10.4 N/mm) was significantly stiffer ($p = 0.046$ N/mm) than the identical repair without the subscapularis incorporated (28.0 ± 3.6 N/mm), see Fig. 1. Repair 2 was less stiff than the first method (35.6 ± 10.4 N/mm) but not significantly so ($p = 0.24$). The third technique (856.8 ± 81.4 N) also was statistically significantly stronger ($p = 0.046$) than the first method (538.0 ± 156.1 N) that didn't suture the ATR with the rotator cuff but not statistically stronger ($p = 0.051$) than the second method (687.0 ± 86.8 N) that did.

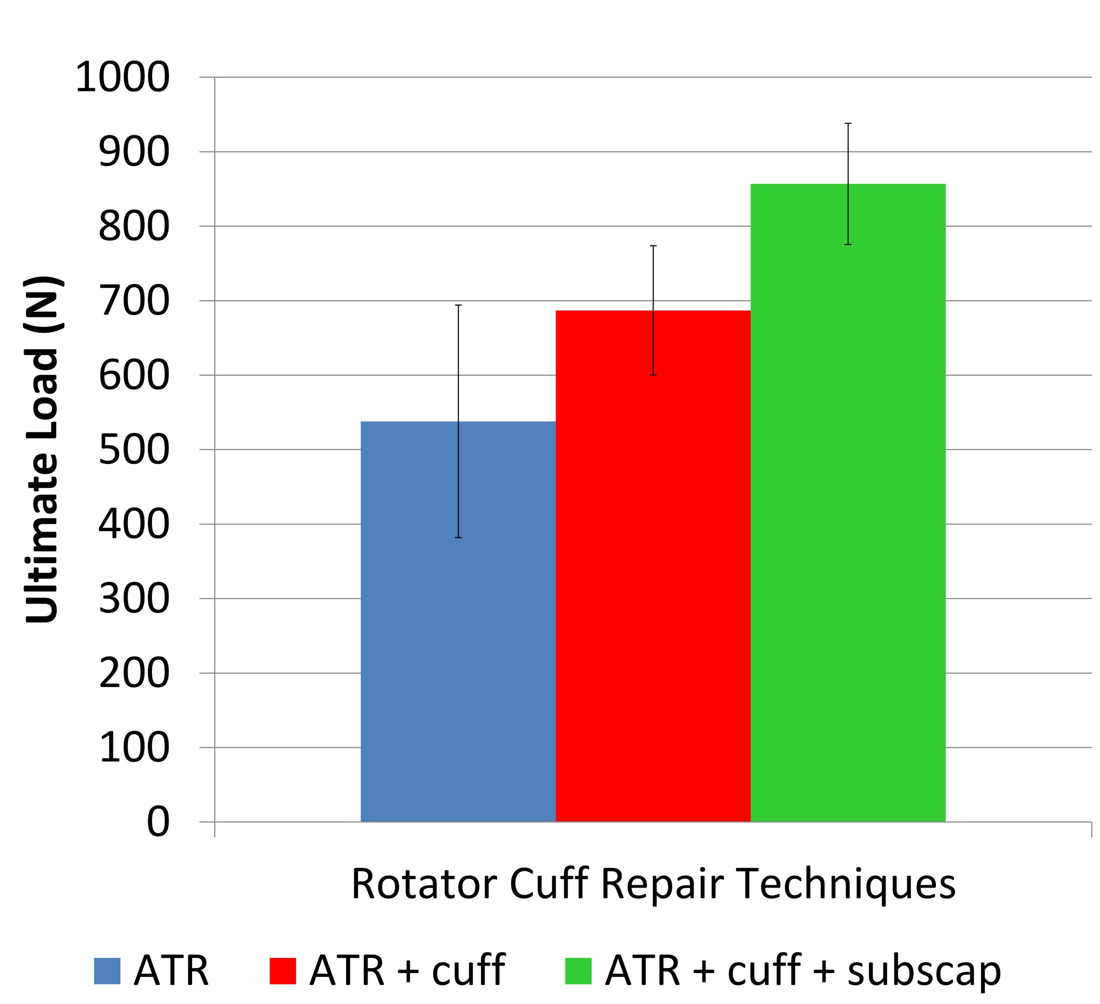

Fig. 2 – Ultimate load to failure

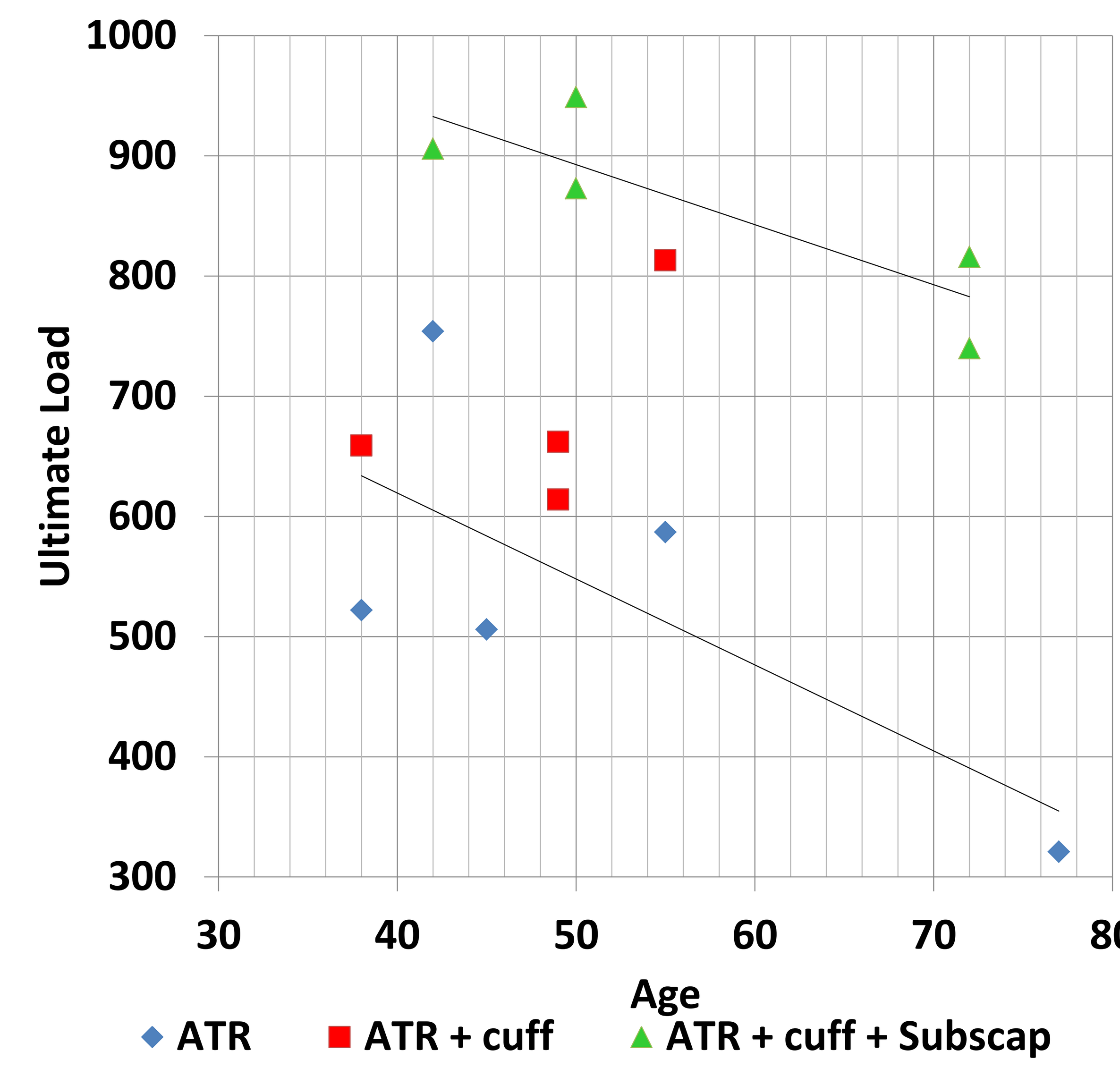

Fig. 3 – Ultimate load to failure vs Age

Discussion: Caution has to be used for the interpretation of the data produced by the DVRT's. What was originally assumed was a measurement of the gap opening was subsequently determined, upon video analysis, to be mostly stretching of the tissues. One interesting statistic that was not anticipated was the influence of hand dominance. The right limbs consistently were stronger than the left limbs regardless of the repair technique. Caution has to be employed when using paired limbs in upper limb studies. Though Repair 3 requires more surgery and implants than Repair 1, and Repair 1 seems adequate for most patients, it may be wise to consider the extra strength of Repair 3 for more elderly patients with poor bone stock, see Fig. 3. Age seems to have a strong trend to weaken the repair and the extra anchor may provide strength closer to that of the ATR repair in the younger patients, and may be worth the extra effort and cost.

Conclusion: The cyclic testing of the repairs did not result in any gap formation for the three repair methods. As a result of this the conclusions from the study are based on the final test to failure that took place after 200 cycles of tensile loading. The incorporation of the subscapularis in the rotator cuff repair enhanced the stiffness of the repair as well as significantly increasing the force required to disrupt the repair.

References: 1) Shea KP, Obopilwe E, Sperling JW, Iannotti JP: "A biomechanical analysis of gap formation and failure mechanics of a xenograft-reinforced rotator cuff repair in a cadaveric model", J Shoulder Elbow Surg 2012 21 1072-1079

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