A Biodegradable Button to Augment Suture Attachment in Rotator Cuff Repair

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Abstract

Recent experimental studies suggest that the use of suture anchors for rotator cuff tear (RCT) repair transfers the “weak link” to the suture-tendon interface where failure occurs as the sutures cut through the tendon. The purpose of this study was to evaluate the effect of using a suture augmentation button on the fixation strength of rotator cuff tendon repair.

A 1.5 cm by 2 cm defect was created in the supraspinatus tendon of seven cadaveric shoulder pairs and two suture anchors inserted in each humerus for suture attachment. For one of each pair, the defect was repaired with sutures placed in a horizontal mattress configuration. The other side was repaired with the sutures being passed through low profile, bioabsorbable buttons placed on the bursal tendon surface prior to knot tying.

The supraspinatus tendon was cyclically loaded at a physiologic rate and load (33 mm/sec and 180 N, respectively). The number of loading cycles was recorded when the specimens developed 0.75 cm and 1.5 cm gaps at the repair site. The specimens were then tested to failure. Specimens in the unaugmented group developed 0.75 cm and 1.5 cm gaps at an average of 135 cycles and 362 cycles, respectively. The button augmented group developed these gaps at average of 420 cycles and 708 cycles, respectively. These differences were statistically significant (p < 0.05). The gaps progressively increased in all specimens, which eventually failed by suture cutting through tendon in all specimens.

This study demonstrates that in vitro, suture augmentation with a low profile, bioabsorbable button provides significantly enhanced fixation when using suture anchors to repair torn rotator cuff tendon. This device may be a useful adjunct to current methods of rotator cuff repair.

The arthroscopic repair of rotator cuff tears (RCTs) by suture anchors has effectively transferred the “weak link” in this repair to the suture-tendon interface. A clinical study by Cummins and colleagues demonstrated that in 19 of 22 failed rotator cuff repairs, the mode of failure was suture pulling through tendon. Techniques to improve tendon fixation have included using different suture stitch configurations, the use of reinforcing meshes or grafts, and the use of screws and washers. Devices such as the Endo-button (S&N Arthroscopy, Memphis, TN) the PLLA Suture Button (Arthrex, Naples, FL) have been useful for improving ACL fixation in the knee and experimental buttons have been used in the hand and shoulder to improve soft tissue suture fixation. They theoretically can distribute the stress of fixation more evenly over a larger surface area, effectively reducing the potential for cutout of the suture through tendon.

The purpose of this study was to compare a PLLA suture button augmented repair with that of an unaugmented repair in a human cadaveric model of RCT repair.

Methods

Fourteen (seven matched pairs) fresh-frozen human cadaveric shoulders (average age: 65; range: 47 to 75 years) were thawed, dissected, and examined for evidence of rotator cuff pathology for which none were excluded. Specimens were then prepared by disarticulating the humerus while preserving only the rotator cuff muscles and their tendinous attachments.

The supraspinatus tendon was isolated and followed to its distal attachment at the greater tuberosity. At the distal
tendon, a 1.5 cm x 2 cm (1.5 cm in medial to lateral dimension; 2 cm in anteroposterior direction) defect was created. This closely simulates the in vivo scenario, where most rotator cuff tears observed involve tendon degeneration with some element of visible tendon loss.

For one of each pair, the rotator cuff was repaired using two 5.0 mm Corkscrew Suture Anchors (Arthrex, Naples, FL) preloaded with No. 2 Ethibond suture. Anchors were inserted with a Corkscrew handled inserter (Arthrex, Naples, FL) at a 45° angle to the bone surface, 5 mm from the articular margin, and were spaced 1.5 cm apart from each other. Suture limbs were then passed through the rotator cuff tendon 1 cm from its free margin and were secured in a horizontal mattress configuration. For the other shoulder of each pair, a low profile PLLA Suture Button (Arthrex, Naples, FL) was passed over each of the sutures and thus interposed between a simple knot fixation and the bursal tendon substance. This button is 0.75 cm in diameter and 1.5 mm thick with four holes. All knots were tied by one surgeon and were tensioned with only enough force to oppose the tissues of the repair site. The proximal end of the supraspinatus tendons were prepared by attaching a looped Dacron strap with multiple mattress sutures to provide a means to apply load to the repair.

Humeri were then cut at the mid-diaphysis, potted with acrylic in a holder, and were secured in an angled vise to the actuator of the servohydraulic testing machine (Instron Model 1331, Instron Corp., Canton, MA), (Fig. 1).

The specimens were mounted in an orientation simulating 45° of abduction, which corresponds to the angle at which the greatest force is placed across the tendon in vivo. The Dacron strap was secured to an eyebolt on the load cell of the testing machine.

Each specimen was cyclically loaded to 180 N at a rate of 33 mm/sec. The duration of each cycle was 5 seconds. This load of 180 N represents approximately two-thirds the load that could be delivered by maximum cuff contraction, thus being considered within the physiologic range for this tendon. The loading rate of 33 mm/sec has been previously reported as a loading rate that simulates the rate occurring in normal daily activities. Two data values were recorded corresponding to the number of cycles required to produce gaps of 7.5 and 10 mm at the simulated repair. Gaps of similar sizes have been used as reference points in other cyclic loading studies of RCT fixation. Gaps were determined during testing using Vernier calipers.

Cycling was continued until failure where the load could not be sustained by the repair. Statistical analysis was preformed using a paired Student t-test to compare the number of cycles required to reach gap size for both groups. Statistical significance was set at p < 0.05.

Results
Progressive gap formation at the repair site was noted in every specimen tested. For the unaugmented specimens, the 7.5 mm gap occurred at an average of 135 cycles (range: 95 to 182 cycles) and the 15 mm gap at an average of 362 cycles (range: 240 to 564 cycles). The button augmented specimens reached a 7.5 mm gap at a significantly higher average of 420 cycles (range: 100 to 540 cycles) (p = 0.003) and a 15 mm gap at a significantly higher average of 708 cycles (range: 550 to 864 cycles) (p < 0.001).

The mode of failure was noted to be suture pullout through tendon in all specimens. No specimens demonstrated signs of suture anchor failure or loosening, suture breakage or knot failure.

Discussion
The results of this study clearly demonstrate that, in vitro, suture augmentation with a PLLA button provides significantly enhanced fixation of RCT repair under cyclic loading conditions compared to unaugmented mattress suture tendon fixation. The PLLA button was observed to establish a secure buttress at the tissue-bone interface as has been observed for repairs made by screw and washer fixation.

One limitation of the current study was that specimens were prepared in an open manner. Thus, the difficulty of passing the PLLA button into the surgical field arthroscopically and introducing the sutures remains to be determined. Also, the effects of movement of a rigid button and any possible fragments as it degrades in the bursa are not known.

This study supports the hypothesis that suture augmentation in rotator cuff repair is superior to sutures alone. Whether this will lead to higher healing rates and improve-
ments in patient outcomes still remains to be determined. Still, we feel this method of suture augmentation for rotator cuff repair is an encouraging step in the right direction toward improving our methods of fixation for this common procedure.

References