Long-term successful arthroscopic repair of large and massive rotator cuff tears with a functional and degradable reinforcement device

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Background: Rotator cuff repair is a procedure with varying outcomes, and there has been subsequent interest in devices that reinforce the repair and enhance structural and functional outcomes. The objective of this study was to determine these outcomes for arthroscopic repair of large and massive rotator cuff tears augmented with a synthetic absorbable mesh designed specifically for reinforcement of tendon repair by imaging and clinical assessments.

Materials and methods: Consecutive arthroscopic repairs were performed on 18 patients with large to massive rotator cuff tears by use of a poly-l-lactic acid synthetic patch as a reinforcement device and fixation with 4 sutures. Patients were assessed preoperatively and at 6 months, 12 months, and a mean of 42 months after surgery by the American Shoulder and Elbow Surgeons (ASES) shoulder score to evaluate clinical performance and at 12 months by ultrasound to assess structural repair.

Results: Ultrasound showed that 15 of 18 patients had intact rotator cuff repair at 12 months; at 42 months, an additional patient had a failed repair. Patients showed improvement in the ASES shoulder score from 25 preoperatively to 71 at 12 months and 70 at 42 months after surgery. Patients with intact rotator cuff (n = 14) at 42 months had an ASES shoulder score of 82.

Discussion: The poly-l-lactic acid bioabsorbable patch designed specifically to reinforce the surgical repair of tendons supported successful repair of large to massive rotator cuff tears in 83% of patients at 12 months after surgery and 78% of patients at 42 months after surgery, with substantial functional improvement.

Level of evidence: Level IV, Case Series, Treatment Study.

Keywords: Rotator cuff tear; arthroscopic reconstruction; augmentation; reinforcement; graft; bioabsorbable; synthetic

Rotator cuff repair can produce widely varying outcomes, particularly apparent when imaging (magnetic resonance imaging [MRI] or computed tomography) is used to assess failure of the repair. Primary surgical repair in patients with small to medium-sized tears has a reported success rate of 60% to 89% when it is measured by imaging. However, the success rate is lower when ultrasound and MRI studies are employed to assess anatomic repair of large tears (range, 5%-90%) and massive rotator cuff tears (range, 24%-63%). There has been subsequent interest in using devices that can reinforce the surgical repair and enhance the structural and functional outcomes.

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Devices that enhance stability of the tendon-bone repair have the potential to substantially improve surgical outcomes of rotator cuff repair. A variety of reinforcement patches fabricated from extracellular matrix or polymer have been used, including allograft rotator cuff, human cadaveric skin, pig and bovine skin, equine pericardium, and porcine intestinal submucosa. Synthetic patches have been both degradable and nondegradable, such as polyglcolide, polyurethane-urea, Gore-Tex, and polytetrafluoroethylene. However, biomechanical analyses of commercially available patches indicate that tensile properties (stiffness and strength) are substantially inferior to tendon, suggesting they would be unlikely to provide significant mechanical reinforcement.

Despite the availability of a number of devices, assessment of the structural outcome when devices are used for reinforcement of rotator cuff repair is limited and yields mixed results. Arthroscopic deployment of these devices is particularly desirable; however, reports on this surgical approach are even more limited. Synthetic absorbable reinforcement devices have some significant potential advantages, including uniformity of product and perceived safety. However, there are no reports of clinical outcomes of such a device for rotator cuff repair.

Recent studies have evaluated a woven mesh of absorbable poly-L-lactic acid (X-Repair; Synthesome Inc, San Diego, CA, USA), designed specifically to reinforce tendon repair, containing mechanical properties similar to human tendon, high suture pullout strength, and slow absorption. In a preclinical study, the device effectively supported repair of surgically induced acute rotator cuff injury in a canine model. In a human cadaveric shoulder study, the device was able to significantly enhance the mechanical properties of a surgically induced acute repair of rotator cuff. In vitro and in vivo studies showed that the device supported cell infiltration and matrix deposition throughout the mesh and integrated with adjacent host tendon. These preclinical studies indicated that the product could potentially provide a functional reinforcement of rotator cuff tendon repair. The objective of this study was to determine the functional and structural outcomes for arthroscopic repair of large to massive (2 or 3 tendons) rotator cuff tears augmented with this synthetic absorbable mesh by imaging and clinical assessments.

**Materials and methods**

**Patient enrollment**

Consecutive arthroscopic repairs (n = 18) of massive rotator cuff tears were performed by one surgeon (C.S.P.) using a woven absorbable mesh (X-Repair) to reinforce the surgical repair. Indications for surgery included MRI consistent with rotator cuff tear and failure of a nonoperative treatment involving physical therapy. Adhesive capsulitis was regarded as a contraindication to surgery. Massive rotator cuff tears were initially diagnosed by presurgery MRI, followed by identification during surgery of 2 or 3 tendon tears that included the supraspinatus and retraction of 3 cm or more. Age (>65 years), smoking, osteoarthritis of the glenohumeral joint, rheumatoid arthritis, diabetes, workers' compensation claims, and previous rotator cuff repair were regarded as risk factors but not exclusion criteria.

**Clinical assessment**

On preoperative MRI, 13 patients (76%) had atrophy of the supraspinatus muscle, the infraspinatus muscle, or both. Patients underwent preoperative evaluation; postoperative evaluation at 6 weeks and 3, 6, and 12 months; and final examination. Functional assessment was performed by the American Shoulder and Elbow Surgeons (ASES) shoulder score, a validated shoulder-specific assessment that considers pain and functional parameters of the patient; physical examination included range of motion and strength assessment. Anatomic assessment was performed with ultrasound and, if necessary, MRI. The ultrasound examination targeted the supraspinatus, infraspinatus, and subscapularis to detect the presence of the tendons and their attachment to the bone. The shoulder was observed while the patient moved the arm to determine attachment and functionality of the graft.

**Arthroscopic rotator cuff repair with X-Repair**

All procedures were performed with the patient in the lateral decubitus position under regional and general anesthesia. Standard posterior, lateral, and anterior portals were developed along with accessory lateral portals needed to insert the suture anchors. After any glenohumeral disease was addressed, the arthroscope was positioned in the subacromial space and a bursectomy and débridement were performed, allowing visualization of the rotator cuff tear. A conservative acromioplasty was performed as necessary, removing only prominences causing impingement; the coracocromial ligament was not released. The size of the cuff tear was measured, and the tendons were mobilized on the articular and bursal side with release of the coracohumeral ligament if indicated. No interval slide between the infraspinatus and supraspinatus was performed. The greater tuberosity was débrided with the rotary shaver.

A suture passer was then used to pass two No. 2 polyester braided sutures at the medial aspect of the rotator cuff, close to the muscle-tendon junction, in a reverse mattress configuration, such that one suture was positioned at the anteromedial aspect of the cuff and the other at the posterosmedial aspect with the ends of the suture brought out through the anterior and posterior portals, respectively. The rotator cuff was then repaired with 5.5-mm PEEK suture anchors with triple-loaded, nonabsorbable sutures, attached with a simple stitch technique (Fig. 1, A, B). The suture anchors were placed near the articular margin to minimize repair tension.

After completion of the arthroscopic rotator cuff repair, one end of each medial suture was passed out of the subacromial space, through the lateral cannula, and through one end of the mesh, approximately 6 mm from each side. The device was then passed through the cannula into the subacromial space over the sutures in a retrograde fashion, and the medial sutures were tied arthroscopically with simple sutures over the medial end of the device. The lateral end of the device was fixed to the greater
tuberosity with 2 simple sutures. This was accomplished by either attaching sutures to the suture anchors used for the rotator cuff repair or placing 2 additional single-loaded suture anchors more laterally to the cuff repair. Finally, care was taken to suture the device with a small amount of medial to lateral tension to ensure that load was imposed on the device and load sharing with the tendon occurred (Fig. 1, C).

Postoperative care

The shoulder was immobilized in a sling for 6 weeks, with limited passive motion exercises performed by a physiotherapist. From weeks 6 to 12, the patient performed home passive motion exercises. Active forward elevation and cuff strengthening started at 12 weeks after surgery.

Statistical analysis

ASES scores were compared by Kruskal-Wallis analysis of variance followed by Mann-Whitney post hoc test. \( P \leq .05 \) was considered significant. ASES scores of those with successful or failed repair and with and without workers’ compensation were compared by \( t \) test (workers’ compensation). The association of ASES score with age was assessed by determining the correlation coefficient.

Results

Patients (average age, 66 years; range, 52-89 years) with large to massive (>3 cm, 2-3 tendons, full thickness) rotator cuff tears underwent arthroscopic repair reinforced with this woven mesh and were assessed at 3 and 6 months after surgery, at an average of 14 (range, 10-19) months, and at an average of 42 (range, 35-47) months. Thirteen of the patients had chronic primary cuff tears, and 5 had 1 to 3 prior failed rotator repairs. All tears involved the supraspinatus and infraspinatus tendons. One also included the subscapularis tendon. The size of the tear, measured from medial to lateral at surgery, ranged from 30 to 49 mm (average, 37 mm). Two patients were smokers, 4 had diabetes, 6 were workers’ compensation patients, and 5 had had previous rotator cuff repair surgery.

After surgery, ultrasound was able to identify the patch in the subacromial space, and motion of the arm showed motion of the patch, suggesting attachment to the bone and tendon (Fig. 2). The patch was not visible by ultrasound more than 12 months after surgery. Two repairs failed at 2 months and 1 failed at 6 months as identified by clinical examination and confirmed by ultrasound and MRI. All others had intact repairs as identified by ultrasound at 12 months after surgery, indicating an 83% success rate in anatomic repair of the rotator cuff at that time. At 42 months, one additional failure occurred, reducing the long-term success rate to 78%. One patient in whom repair failed at 2 months was a smoker and had workers’ compensation insurance. The other patient in whom repair failed had diabetes and workers’ compensation insurance. The patient who had failed repair at 6 months was 89 years old at the time of surgery. The patient who had failed repair between 12 and 42 months had grade IV osteoarthritis of the glenohumeral joint.

The 18 patients had an average preoperative ASES shoulder score of 26, which rose to 57 at 3 months after surgery, 68 at 6 months after surgery, 71 at 12 months after surgery, and 70 at 42 months after surgery (Fig. 3). Compared with the preoperative score, all postoperative times showed significant \( (P < .05) \) improvement of ASES scores. There was significant improvement of scores at each consecutive time point \( (P < .05) \), except between 12 and 42 months \( (P > .05) \). In considering only those patients with intact rotator cuff, as shown by ultrasound, the ASES shoulder score was 68 at 6 months, 77 at 12 months, and 82 at 42 months (Fig. 4). Compared with preoperative scores, there was a significant improvement at all time points \( (P < .001) \), and there was also a significant improvement from 6 to 12 months \( (P = .03) \). However, there was no statistically significant difference in the ASES scores between 12 and 42 months or between 6 and 42 months \( (P > .1) \).

The ASES shoulder score at 6, 12, and 42 months for patients with intact rotator cuff by imaging was significantly higher than that for those with failed repair \( (P = .001) \) (Fig. 4). There was no correlation between ASES score and age \( (r = 0.2) \).
Discussion

Surgical repair of rotator cuff tears can often result in failure. To improve the success rate of rotator cuff repair, devices have been used in attempts to reinforce the repair to mitigate the problems of tear size, reduced cuff tissue quality, and high stress at the repair site. This study assessed the outcome after arthroscopic repair of large to massive rotator cuff tears when they were reinforced with a resorbable synthetic device designed to mimic the structural properties of rotator cuff tendon.

This study used a woven mesh of poly-L-lactic acid to reinforce the rotator cuff repair. The device was developed to mimic the mechanical properties (tensile strength and tensile stiffness) of human tendons with high suture retention strength so that it can be used to effectively reinforce tendon repair. It does this by providing an independent reinforcement of the repair, successfully acting in tandem with the usual surgical repair. The device has previously been shown to be effective in supporting rotator cuff repairs in a canine model and improving the mechanical properties of rotator cuff repair in a human cadaveric study. In addition, in vitro and in vivo studies demonstrated cell infiltration and matrix deposition throughout the mesh, integrating the mesh with the adjacent tendon. Furthermore, an experimental and theoretical study showed that this scaffold had the capacity to carry up to 45% of the repair load for repair of tears with poor tendon quality or osteoporotic bone. Similarly, a cadaveric study administering a reinforced fascia showed reduced gapping at the rotator cuff–bone interface after cyclic loading.

This mesh was used to reinforce the repair of large to massive rotator cuff tears, rather than small to large tears, to best demonstrate the effectiveness of the mesh in improving anatomic repair success rate. This study had an 83% success rate at 12 months and 78% at 42 months after surgery for anatomically healed rotator cuff repairs, with significant clinical improvement based on ASES scoring at 3, 6, 12, and 42 months.

This is the first study of a synthetic absorbable mesh used to augment rotator cuff repairs and the first study to evaluate the use of a synthetic mesh (absorbable or nonabsorbable) to augment repair of large and massive rotator cuff tears.
rotator cuff tears. Previously, a synthetic nonabsorbable patch was used to augment surgical repair of small and medium-sized tears; objective clinical assessments including ASES score improved from 44 to 73, and MRI showed that the repairs were intact at 12 months after surgery in 90% of cases.

Biologic grafts have been used in surgical repair of rotator cuff tears. In a study on repair of rotator cuff tears, the ASES score improved from 48 to 99 with dermal graft augmentation, similar to the nonaugmented group. Whereas MRI showed that the augmented group was 85% intact, the nonaugmented group was intact in only 40% of cases.

The technique presented, using a resorbable mesh device to reinforce repair of large to massive rotator cuff tears, addresses the problem of increasing the mechanical stability of the repair. However, for successful long-term repair, complex events involving tendon-to-bone repair and integration must also occur. Additional improvement may be obtained with enhancement of the biology as well as mechanical reinforcement. At this time, it is not obvious how to distinguish patients with a propensity for poor biologic healing.

In this study, no particular exclusion criteria were imposed for the patients included, and so this patient group included smokers, diabetics, patients with retears after previous rotator cuff repair, a patient with grade IV osteoarthritis, and patients with workers’ compensation. Each of these conditions puts a patient having rotator cuff repair at greater risk of failure. Some studies that implement augmentation patches have used one or more of these conditions as exclusion criteria, although others have not had extensive exclusion criteria. In an effort to reflect a realistic patient population, that was not done. Therefore, the patient group in this study represents a challenging one. There was no obvious difference in outcome for patients with workers’ compensation or who were smokers, and there was no association with age. The results showed that even with this challenging group of patients with negative risk factors, successful repair was possible when this reinforcement patch was used.

This study has limitations that include a relatively modest sample size and no control group. Despite these limitations, this study demonstrates that use of this device can result in a high rate of success for anatomic repair of large to massive rotator cuff tears.

Conclusion

Recent advances have been made in rotator cuff repair techniques; however, the retear rates, especially in large and massive tears, remain unacceptably high. A synthetic mesh was designed with mechanical properties similar to human tendon. Preclinical in vitro and in vivo studies showed it to reinforce rotator cuff repair, to carry a substantial proportion of the repair load, to prevent gapping at the bone-tendon junction, and to integrate with the surrounding tissues. This clinical study assessed the postoperative outcome after rotator cuff augmentation of large and massive tears at an average of 42 months after surgery. ASES shoulder score increased from 25 to an average of 71, and ultrasound showed an intact repair in 78% of cases. Those patients with intact rotator cuff had an ASES score of 82 at 42 months.

Despite the limitations, this is the first study to report significant clinical and structural improvement of large and massive rotator cuff repairs augmented with a synthetic scaffold.

Disclaimer

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References


