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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.[6,7,9,14,19,22-24,31] However, the success rate is lower when ultrasound and MRI studies are employed to assess anatomic repair of large tears (range, 5%-90%)[6,17-19,22,23,38] and massive rotator cuff tears (range, 24%-63%).[10,11,18,19,22,31,35,38] 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.[1,2] 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.[33] Synthetic patches have been both degradable and nondegradable, such as polyglycolide, polyurethane-urea, Gore-Tex, and polytetrafluoroethylene.[33] However, biomechanical analyses of commercially available patches indicate that tensile properties (stiffness and strength) are substantially inferior to tendon,[5,15] suggesting they would be unlikely to provide significant mechanical reinforcement.[1,2]

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[3,4,8,16,22,37] and yields mixed results. Arthroscopic deployment of these devices is particularly desirable; however, reports on this surgical approach are even more limited.[5,8] 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; Synthasome 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.[15] 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.[28] 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.[14,36] 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),[7,11,13] smoking,[26,30] osteoarthritis of the glenohumeral joint, rheumatoid arthritis,[34] diabetes,[11,12] workers' compensation claims,[21] and previous rotator cuff repair[20,32] 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,[29] 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 coracoacromial 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 posteromedial 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