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Perspective Article

Efficacy and Outcomes of Soft Tissue Augmented Rotator Cuff Repairs

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Abstract

Introduction: Rotator cuff tears are very common, occurring in approximately 20% of the general population. One method used to increase the longevity and overall mechanical strength of the rotator cuff tendons is augmentation with biological matrices. The purpose of this study was to describe our tendon augmentation surgical technique and present outcomes on a series of patients who underwent rotator cuff repair (RCR) augmented with a biologic matrix.

Methods: We studied a series of patients who underwent RCR, augmented with Proformix® tissue matrix between January-July 2014. We included patients with medium/large rotator cuff tears, and were considered good candidates for tendon augmentation with a biologic matrix. Patients completed the Simple Shoulder Test (SST), Constant Murley Score and the DASH pre-operatively, and at 3 months, 6 months and approximately 24 months post-operatively.

Results: Twenty patients (12 females, 8 males) who had medium-to-large size cuff tears were included. Mean age was 70.3 (range, 55-83) with an average BMI of 27.8 (range, 21.6-36.4). Mean follow-up was 23.1 months (range, 17-29). Patients reported significant improvement from pre-operative to latest follow-up for SST (4.8 to 10.2, p<.001), Constant Score-ADL (13.8 to 32.4, p<.001), DASH (44.6 to 90.1, p<.001) and Quick DASH (41.2 to 88.3, p<.001).

Conclusion: The current soft tissue augmentation study using a biologic matrix shows excellent clinical results in an overall suboptimal (older) patient population. Our results help to reinforce the efficacy of rotator cuff augmentation surgery. Our patient series was nearly a decade older than similar studies, yet achieved /exceeded previously published results.

Keywords: Augmentation; Biologic Matrix; Rotator Cuff

Introduction

Rotator cuff tears are a very common problem in the USA, occurring in approximately 20% of the general population [1]. Over 75,000 rotator cuff repairs are performed annually nationwide, with approximately 20% of patients not experiencing long-term relief of pain and return of function [2]. In addition, the rate of long-term structural success with rotator cuff repairs has been lower than hoped for. Several factors increase the chances of structural failure such as age, size of tear, osteoporosis and other comorbidities [3]. The primary indication for rotator cuff repair/reconstruction is shoulder pain that has failed non-operative management with the diagnosis of a full thickness tear. Our goals are to decrease pain and increase function. Surgical intervention can reproducibly decrease pain. It is also expected to decrease the likelihood of tear progression and improve strength potential. Functional improvements can be obtained but rely on numerous variables. The eventual healing of the rotator cuff depends on the tear size, tissue quality, chronicity of the tear, smoking, co-morbidities, and fatty atrophy [4]. Relative contraindications for surgery would include proximal humeral migration, advanced glenohumeral arthritis, severe fatty atrophy, and significant neurologic injury, while an absolute contraindication would be active infection [5,6].

Preoperative Management

In the preoperative evaluation and discussions, it is stressed to the patient that they essentially have five categories of treatment choices:

- Activity modification
- Consumption of oral medication (NSAIDS, Acetaminophen, Narcotics)
- Physical therapy program

- Injections (Steroids, Platelet Rich Plasma, Stem Cell Therapy)
- Surgical management

All of the above choices have pluses and minuses. Only surgical intervention is expected to positively change the infrastructure. The surgeon has numerous options, once he/she decides to proceed with surgery. However, one can only work with what the patient brings to us. If the tear is chronic, large, retracted, and the patient is older with questionable tissue quality, one needs to consider advanced surgical techniques. In the past, some of the available xenograft augments were associated with high complication rates. This caused surgeons look for other treatment options. Arthroscopic debridement with acromioplasty and nonoperative management of "nonrepairable tears" has shown variable results with unpredictable longevity [6]. Partial rotator cuff repairs have been reported to improve pain and function [7]. On examination, the patient frequently has impingement signs, progressive pain, sleep interruption, and difficulty with above shoulder level activities [8]. There are numerous patients that are highly functional but have large tears. These patients frequently complain of low level pain at rest, but report that they have difficulty with activities requiring muscle endurance: for instance, the senior softball player who can no longer throw the ball overhand, but has insignificant pain.

Large tears are usually associated with progressive weakness and higher repair failure rates [8]. We specifically counsel patients with documented large tears that their recovery will take longer than small tears. In order to increase the healing response, longevity and overall mechanical strength of the rotator cuff tendons, several different methods have been employed, including growth factors, stem cells, plasma-rich platelets and various types of synthetic and biologic augmentation [9-14]. Biologic augmentation can be very advantageous for the long term outcome of rotator cuff repair as it seeks to enhance the natural healing response, recreate normal anatomy and structural support [1]. Due to its ability to add strength to the repair, tendon augmentation with biological matrixes has been repeatedly shown to be quite beneficial [15-18]. Because of this, biologic matrix augmentation has been used increasingly in chronic and complex injuries where reinforcement is required [17, 19,20]. The primary expectations for tendon augmentation materials are to give the repaired tendon an immediate increase in load sharing and to provide a framework for integration and eventual remodeling of host tissue [16,21]. Complicating factors can include trauma, tenosynovitis and the length of time prior to treatment [15,22]. Biological matrices can be comprised of various cell types (small intestine submucosa, dermis, pericardium or fascia lata), and are derived from mammalian sources including porcine, bovine and human [1]. Unlike human cadaver tissues, xenograft matrices are regulated by the FDA as medical devices. Differences in species of tissue origin, processing, whether cross-linked or not and integrity of the collagen matrix suggests that not all grafts will perform equally.

Some of these materials have displayed unfavorable properties after implantation and the search for a wholly satisfactory material has not been easy. Crosslinked biological matrices have been associated with encapsulation and minimal integration into host tissue [20]. While porcine small intestinal submucosal matrices were early to market, intact porcine dermis has been shown to be superior in tensile strength [23]. In fact, several rotator cuff studies have shown porcine small intestine submucosa matrices to result in unfavorable outcomes in terms of complication, muscle strength and inflammatory reactions [24-27]. The purpose of this study was to describe our tendon augmentation surgical technique and present outcomes on a series of patients who underwent rotator cuff repair augmented with a recently introduced biologic matrix.

Materials and Methods

Our study reports on a single surgeon series of patients who underwent rotator cuff repair, augmented with a Proformix biologic matrix. Patients were administered the Simple Shoulder Test (SST), Constant Morley Score and the DASH score prior to surgery, as well as at 3 months, 6 months and approximately 24 months after surgery. All patients were given an interscalene regional block, in addition to general anesthesia, and were placed in the beach chair position. Lower extremity sequential compression devices were used during the entire procedure. An arthroscopically aided mini-open rotator cuff reconstruction was employed for all patients in this study. The glenohumeral joint was arthroscopically assessed and all intra-articular pathology was addressed. An arthroscopic subacromial decompression and partial bursectomy were also performed. We then converted to a mini-open procedure. We used an incision approximately 3cm in length placed over the anterolateral edge of the acromion. The dissection is carried down to the deltoid fascia, with the aid of electrocautery. We then identify the raphe between the anterior and middle deltoid. The raphe is split and self retaining retractors were placed. High strength, #2 non-absorbable, polyester reinforced sutures were placed in an inverted horizontal mattress (Figure 1).

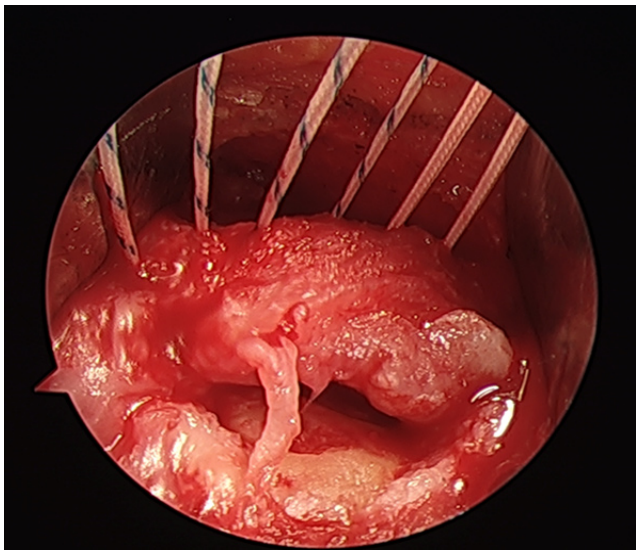

Figure 1: High strength, #2 non-absorbable sutures placed in an inverted horizontal mattress technique.

Each pass of the suture was approximately 10mm apart. After passing the sutures through the native cuff, the graft was addressed. Once the graft tissue is trimmed to size, sutures were passed through the graft approximately 4mm from its edge (Figure 2).

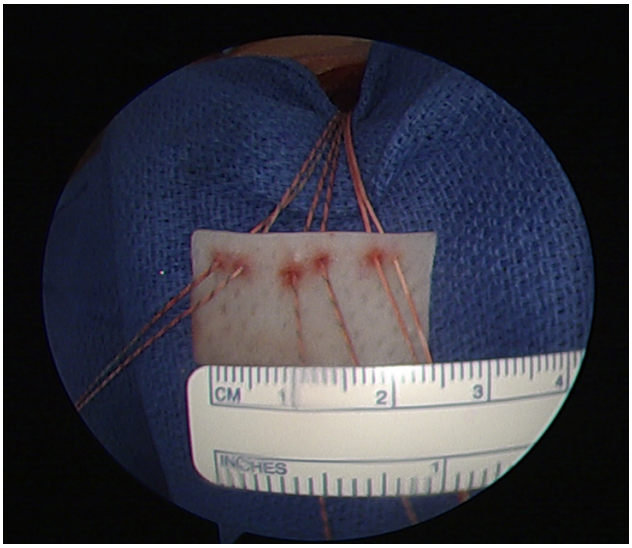

Figure 2: Sutures passed through the graft tissue approximately 4mm from the edge.

Each pass of the suture was approximately 10mm apart (Figure 3).

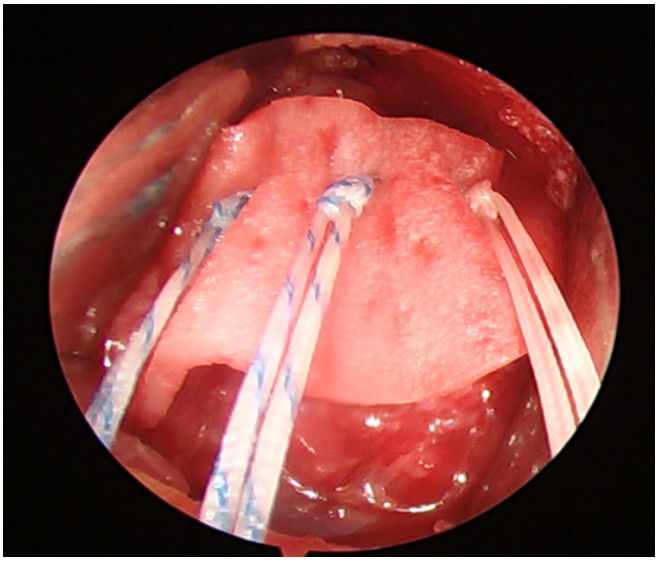

Figure 3: Securing the graft to the cuff remnant by placing multiple alternating half-hitch knots.

The graft was then secured by placing a sliding knot followed by multiple alternating, half-hitch knots. The entire construct was then pulled laterally to cover the footprint towards anatomic positioning (Figure 4). Care was taken to minimize excess traction. We employed a single-row, lateral construct with pre-loaded knotless anchors. The lateral row anchors were then placed, and the tendon/graft construct was secured.

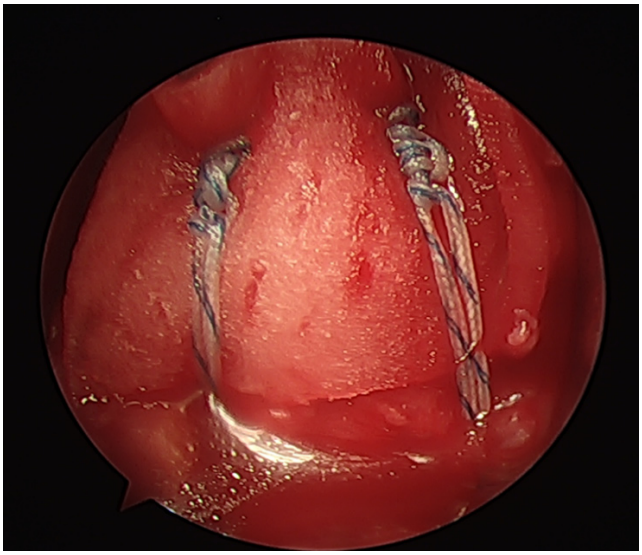

Figure 4: Anchors are placed approximately 10mm apart and are appropriately tightened.

The deltoid was closed with a #0 absorbable suture, the skin was closed with a #2-0 absorbable suture followed by a #4-0 absorbable monofilament subcuticular suture. The arm was placed in an abduction sling. A motorized, ice water cooling cuff is then used for post-operative pain control.

Postoperative Management

The postoperative management is via a moderately conservative protocol. It is modified based on the tissue quality, size of tear, and age of the patient. All of the cases in this series were augmented with a biologic matrix. The patients are advised that the recovery is expected to take 4-7 months. They are also told that it may take 12 months before they have full strength. The preoperative discussion is critical to formulate reasonable expectations. We also advise them that they may have a mild "weather ache" for 1 year. Some patients have very little pain and can potentially be their own worst enemy. We emphasize that our goal is not to work to failure. The post op regimen is not a "no pain no gain" situation. The patients continuously wear an abduction sling for 2 weeks. We then remove the sutures and the abduction portion of the sling. They continue with the sling for another 4 weeks. We ask them to remove the sling only for physical therapy and personal hygiene. When grafts are used, the home-based therapy program is limited to table slides and pendulum exercises. Our goal in this early stage is to limit shear at the reconstruction site and concurrently minimize stiffness. Patients are also encouraged to perform active finger, wrist and elbow range of motion. At week 6, we advance to active assist exercises like pulleys and supine cane bench press. It is important to progress within the limits of pain. At week 10, we advance to terminal range stretching and begin rubber band strengthening. It is important to progress the strengthening slowly. Weights are not used prior to 4 months. For patient who golf, chipping and putting starts at 4 months, with progression towards full golf at 6 months.

The following study was approved by Quorum Review IRB.

Statistical Analysis

Repeated Measures ANOVAs were used to determine differences in outcomes scores over time. Post-hoc t-test were utilized where appropriate, to determine significant differences between time points. Statistical Analyses were performed using SPSS v.23 (SPSS, Inc., Chicago, IL). Significance was set at $p<0.05$.

Results

We performed rotator cuff repair augmented with a biologic matrix on 20 patients (12 females and 8 males) who had medium-to-large size cuff tears. Medium tears were classified as being 1cm - 3cm, while large tears were 3cm - 5cm. Our study includes 5 medium and 15 large tears. Mean age was 70.0 (range, 55-83), and included 16 that were 65 years or older. The average BMI in our patients was 27.8 (range, 21.6-36.4). Patients reported their shoulder pain to have started 38.5 months before surgery on average (range 3 - 240). With the three outliers removed, mean pain duration becomes 14.2 months (range, 3 - 72). 10 rotator cuff tears (50%) were classified as traumatic injuries, while the remaining 50% were considered chronic nontraumatic. Comorbidities found within our study population included the following (there were several patients with multiple comorbidities): 70% with hypertension, 45% with hypercholesterolemia, 40% with hyperthyroidism, 15% with arrhythmia, 10% with depression, 10% with asthma, 5% with diabetes mellitus, 5% with chronic obstructive pulmonary disease, 5% with Gout, 5% with Hepatitis C, 5% with seizures and 5% with early dementia. Patient Reported Outcome Measures (PROMs) were recorded pre-operatively, and at 3 months, 6 months and approximately 2 years post-operatively. Mean follow-up was 23.1 months (range 17-29). Patients reported a significant improvement from pre-operative to latest follow-up for the Simple Shoulder Test (4.8 to 10.2, $p<.001$), Constant Score - Activities of Daily Living (13.8 to 32.4, $p<.001$), DASH (44.6 to 90.1, $p<.001$) and the QuickDASH (41.2 to 88.3, $p<.001$). For each PROM recorded, the same pattern of improvement was seen from pre-operative to 2 years post-operative. Significant improvements were seen from pre-operative to 3 months, and again from 3 months to 6 months. Although each score continued to improve from 6 months to 2 years, this improvement was not significant with the numbers available (Figure 5).

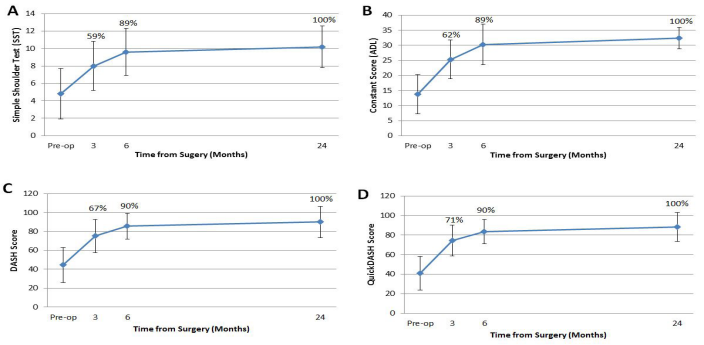

Figure 5: % represents proportion of overall improvement achieved at each time point.

In our study there were no infections. There was one clear failure. One patient returned to clinic post-operatively with dissatisfaction in their outcome, and after viewing radiographs and performing a physical examination, the findings were consistent with a rotator cuff re-tear. No further treatment was performed at patient request.

Discussion

Augmentation of rotator cuff repairs with a biological matrix is becoming more prevalent. As interest in the use of augmentation

mounts, continued evidence of the failure of classic suture repairs remains a fact of life for orthopedists and their patients. Our experience with this new biological matrix proved highly successful to date. Ninety-five percent of our patients treated with it are doing quite well. One of the primary concerns with biologic matrix augmentations has been variability in long-term results, both functionally and structurally. With the superior outcomes that our patients achieved at 2 years post-operatively, we feel that both of these concerns have been alleviated, even with a relatively small sample size. Traditionally, several key factors have been predictive of long-term durability of rotator cuff repairs. These include factors such as age, onset of injury and smoking history, among many others [28]. Chung et al. showed that patients who were 65 years of age and older experienced an increase chance of having structural failure or poor clinical outcomes [3]. Further, a 2014 systematic review by Mall et al, looked at 1924 shoulders and found an average age of 65 in those shoulders that experienced a re-tear, while those healed shoulders with no re-tear had an average age of 58 years [29]. Of all of the studies referenced in this paper, the mean reported age at time of surgery ranged from 50.5 to 66.5, with the majority having a mean age of under 60 years old.

Our patient population is significantly older. The average age is 70 years old, which is clearly in the high-risk category. However, our study demonstrated excellent results that compare favorably with published results on younger patients. Historically, the older population with large rotator cuff tears has been relegated to the highly invasive reverse total shoulder replacement. These results support using a biological matrix rather than a more invasive alternative in the treatment of rotator cuff tears. While access to the biologic matrix and using appropriate patient selection criteria have been instrumental in achieving clinical success, not all matrixes are created equal and some will produce better results for the patient than others. When choosing a biologic augmentation scaffold, the knowledge of the biophysical properties of these materials is fundamental to making an educated decision about whether a given matrix might provide mechanical augmentation and/or enhance the biology of the tendon-to-bone healing [30]. We believe the matrix is successful in its role as an implantable scaffold, soft tissue reinforcement due to its acellular, non-crosslinked, natural porcine collagen material. It already has many years of successful clinical history as an implantable material in surgical procedures [31-33]. The limitations of our study include a relatively small sample size as well as the lack of a control group, yet, it should be noted that most published studies report on patients nearly a decade younger. Future studies are certainly needed with greater numbers of patients, in addition to randomized, control studies looking at multiple graft types.

Conclusion

Historically, the durability of rotator cuff repairs has been shown to be negatively affected by a number of factors out of the surgeon's control. Specifically: age over 65, insidious atraumatic onset, large size, and weakness over 6 months. In our study, while 80% (16) of the patients were 65 years or older, 50% (10) had atraumatic insidious tears, 75% (15) had large tears, and 60% (12) had pain and weakness for more than 6 months, we were still able to achieve a 95% success rate in terms of pain, function and satisfaction. It has been shown that patient satisfaction can remain good after repair failure. However, strength invariably suffers. All surgeons strive for creating the strongest construct possible with the goal of eventual repair longevity. Our study group contains primarily patients with significant poor prognostic factors. The reason for using the soft tissue augment was to attempt to level the playing field and add extrinsic strength to the repair site. As we move forward in our quest to treat patients, we must keep in mind the expense of medical devices. Soft tissue augments can be expensive. However, so are revision repairs and conversions to a reverse total shoulder replacement. The current success of reverse total shoulder replacements combined with the increased failure of many cuff repairs has tilted the scales toward more aggressive use of arthroplasties. Thirty percent (six) of our patients who were 70 years or older and had large tears, all of which are doing quite well.

Our ultimate goal is to help reinforce the literature with studies that show the true clinical benefit of biological matrix augmentation. The current study shows superior clinical results in an overall suboptimal patient population. Our results rival or exceed the clinical success of rotator cuff repairs reported in the orthopedic literature based upon younger patients. All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. For this type of study, retrospective analysis of standard of care data, formal consent is not required.

Conflicts of Interest and Sources of Funding

There are no conflicts of interests or sources of funding to disclose.

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