

Management of Massive Rotator Cuff Tears in Active Patients with Minimal Glenohumeral Arthritis: A Prospective Observational Study with Clinical and Radiographic Analyses of Reconstruction using Dermal Tissue Matrix Xenograft

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ABSTRACT

Objectives: To evaluate the clinical and radiographic outcomes of patients undergoing interposition reconstruction of massive, otherwise irreparable rotator cuff tears through a mini-open approach with the use of a porcine dermal tissue matrix.

Materials and methods: We performed a prospective observational study of 26 patients (27 shoulders) who underwent reconstruction of massive rotator cuff tears using dermal tissue matrix xenograft. Pain level (scale 0-10, 10 = severe pain), active range of motion, and supraspinatus and external rotation strength were assessed. Additional outcome measures included modified American shoulder and elbow score (MASES) and short form-12 (SF-12) score. Clinical and radiographic analyses were performed at an average 32 months follow-up period (minimum 2-year follow-up). Ultrasound imaging (static and dynamic) of the operative shoulder was performed at final follow-up to assess the integrity of the reconstruction.

Results: Mean patient age was 60. Mean pain level decreased from 5.1 to 0.4 ($p = 0.002$). Mean active forward flexion, abduction, and external rotation motion improved from 138.8 to 167.3 ($p = 0.024$), 117.9 to 149.3 ($p = 0.001$) and 57.7 to 64.7° ($p = 0.31$), respectively. Supraspinatus and external rotation strength improved from 7.2 to 9.4 ($p = 0.001$) and 7.4 to 9.5 ($p = 0.001$), respectively. Mean MASES improved from 62.7 to 91.8 ($p = 0.0007$) and mean SF-12 scores improved from 48.4 to 56.6 ($p = 0.044$). Twenty-one patients (twenty-two shoulders) returned for a dynamic and static ultrasound of the operative shoulder at a minimum 2-year follow-up. Sixteen (73%) demonstrated a fully intact tendon/graft reconstruction. Five (22%) patients had partially intact reconstructions, and one (5%) had a complete tear at the graft-bone interface due to suture anchor pullout as a result of a fall. There were no cases of infection or tissue rejection.

Conclusion: We present a reproducible surgical technique for the management of massive irreparable rotator cuff tears. In our series, patients demonstrated a significant improvement in both subjective and objective clinical outcomes. Radiographic analysis demonstrated that the majority of patients had a fully intact reconstruction at a minimum 2-year follow-up.

Keywords: Massive rotator cuff tear, Xenograft, Augmentation, Repair.

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INTRODUCTION

The management of massive rotator cuff tears presents a treatment challenge. Multiple treatment options have been described, including debridement, debridement with partial repair (arthroscopic or open), latissimus dorsi transfer, extracellular tissue matrix augmentation, and arthroplasty (including hemiarthroplasty and reverse total shoulder arthroplasty).^{3,10,11,15} These options may not be the ideal choice for relatively healthy, active patients with minimal glenohumeral arthritis. The purpose of this study was to prospectively evaluate the clinical and radiographic outcomes of a novel technique using porcine dermal extracellular tissue matrix (ECM) for the management of massive irreparable rotator cuff tears.

MATERIALS AND METHODS

Institutional review board approval was obtained for this study. Informed consent was obtained from all patients. From October 2008 to November 2009, 26 patients (27 shoulders) underwent interposition reconstruction of massive, irreparable rotator cuff tears using Conexa™ xenograft. The use of this graft as an interposition to fill the void created by severe retraction of the native rotator cuff is 'off-label' according to US Food and Drug Administration (FDA) regulations (please refer to www.fda.gov for further details on regulations regarding the use of extracellular tissue matrices for rotator cuff repair). The study cohort was comprised of 14 females and 12 males with an average age of 60 years (range: 45-77).

Our hypothesis had two components: (1) Patients undergoing reconstruction of massive otherwise irreparable rotator cuff tears would demonstrate improvements in pain, range of motion, strength and subjective functional outcomes, (2) postoperative ultrasonography would demonstrate intact repairs at a minimum 2-year follow-up.

Inclusion criteria included: Failure of a minimum of 6 months of conservative management (including physical therapy, nonsteroidal anti-inflammatory medication, and corticosteroid injection), a full thickness rotator cuff tear

with tear retraction greater than 5 cm during arthroscopic evaluation, inability to reduce residual cuff to the anatomic footprint after full mobilization of the tendon, and the ability to fully participate in the postoperative rehabilitation protocol. Exclusion criteria included: Glenohumeral arthritis and/or rotator cuff tear arthropathy based on preoperative radiographs and/or MRI, greater than 50% fatty infiltration of the supraspinatus muscle based on the T1-weighted oblique sagittal magnetic resonance imaging (MRI),¹² a rotator cuff that is reducible to the lateral footprint during arthroscopy (no interposition needed), and an inability to participate in the postoperative rehabilitation protocol.

Clinical and radiographic data were collected prospectively at a minimum 2-year follow-up (average 32 months, range: 24-40 months). Objective outcome measures included active range of motion including forward flexion, abduction, external rotation at zero degrees of shoulder abduction, and strength of the shoulder in two planes: abduction in the plane of the scapula and external rotation at zero degrees of shoulder abduction (surrogates of supraspinatus and infraspinatus muscle strength). Strength assessment was assessed based on the modified medical research council scale for strength assessment. These values were then converted to a 10-point scale based on the strength scale defined by FP Kendall et al for statistical analysis purposes.¹⁴ If the patient had a pain-free shoulder on the contralateral side, then this was added as a reference for strength comparison as well. Subjective outcome measures included pain determined by visual analog scale (VAS, scale 0 to 10, 10 = severe pain), modified American shoulder and elbow score (MASES) and short-form 12 (SF-12) score.

Ultrasounds were performed and interpreted by one physician with more than 5 years of experience in musculoskeletal ultrasonography of the shoulder. He has performed greater than 2,000 shoulder sonograms, and is a continuing medical education (CME) instructor on musculoskeletal ultrasonography. Images were obtained using a GE Logic E (General Electric, Fairfield, CT, USA) gray scale ultrasound machine and a 12 MHz probe. Dynamic and static images were taken of the complete shoulder using standard shoulder imaging protocols. The ultrasonographer identified both the native rotator cuff tendon, graft and insertional footprint. The repairs were classified as 'fully intact', 'partially intact', and 'not intact' based on the appearance of the native rotator cuff tendon, tendon-graft interface, as well as the tendon at the anatomic footprint on the humeral head. A 'fully intact' repair indicated that there were no visible defects in the native rotator cuff, tendon-graft interface, or the graft-humeral interface. A 'partially intact' repair indicated that there was

a partial-thickness defect detected in either the native rotator cuff, tendon-graft interface, or the graft-humerus interface. 'Not intact' meant that there was a full-thickness defect appreciated anywhere in the repair. For 'fully intact' and 'partially intact' repairs, dynamic imaging was scrutinized to determine if the native rotator cuff-graft construct and the insertional footprint at the greater tuberosity moved as a complete unit.

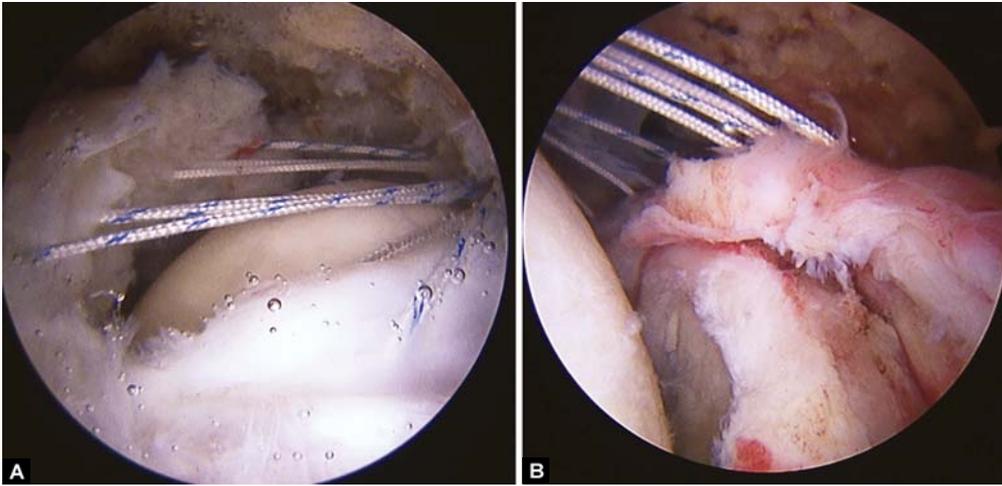
Statistical analysis was performed using a repeated measures analysis of variance (ANOVA) to compare three or more means since data was collected on all patients under repeated conditions. Standard deviation was calculated on all data sets. A p-value less than 0.05 indicated statistical significance.

Surgical Technique

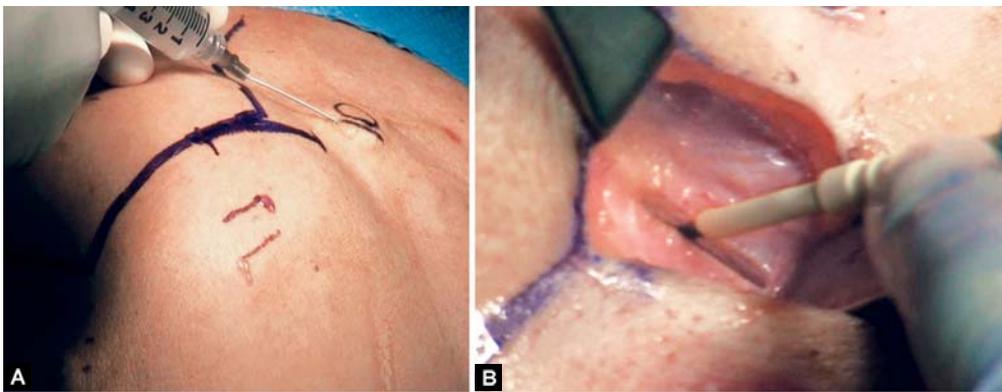
The patient is positioned in the standard sitting position. A diagnostic arthroscopy is performed through posterior and anterior portals, with a lateral instrumentation portal created under direct visualization. The long head of the biceps tendon is evaluated due to the high incidence of biceps pathology in the presence of massive rotator cuff tears.⁶ If the biceps tendonopathy is noted, a tenotomy or tenodesis is performed depending on the patient's physiologic age and quality of the tendon. The glenohumeral and acromioclavicular joints are evaluated for any arthritic changes and debrided as indicated.

Diagnostic arthroscopy allows for complete visualization of the rotator cuff tear pattern. Unhealthy rotator cuff tissue is debrided. A grasper is used to assess mobility of the native tendon. If it cannot be reduced to the native footprint, an extracellular matrix graft is used to fill this void. To begin the reconstruction, sutures are passed into the native rotator cuff tendon arthroscopically using the Opus SmartStitch™ device (ArthroCare® corporation, Sunnyvale, CA) in a horizontal mattress configuration (Figs 1A and B).

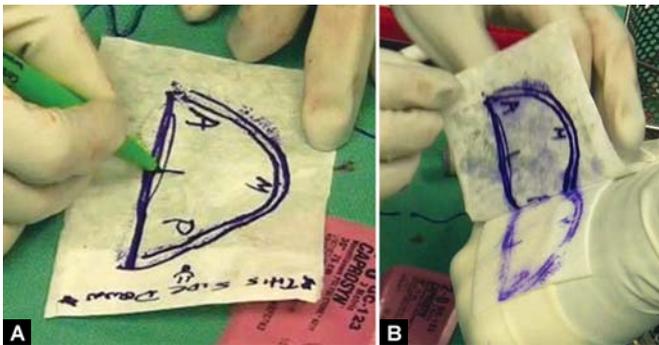
A mini-open approach to the rotator cuff is then performed via a 4 cm incision in-line with Langer's lines based off the anterolateral acromion (Fig. 2A). The superficial deltoid fascia is exposed. The raphe between the anterior and middle deltoid is incised longitudinally with electrocautery (Fig. 2B). It is critical to be in the raphe (not posterior to the raphe) to gain sufficient exposure. A Kolbel retractor (Innomed, Inc, Savannah, GA) is placed to expose the rotator cuff with minimal tissue trauma. The subacromial bursa is excised with Metzenbaum scissors. A Cobb elevator is placed under and over the tendon to release any adhesions to the underlying humeral head and subacromial space to ensure complete mobilization of the cuff. Mobilization is carried to the margin of the glenoid. Following maximum



Figs 1A and B: Incline mattress sutures are passed arthroscopically into the residual cuff tissue. Subacromial (A) and anterior (B) portal views



Figs 2A and B: A 4 cm longitudinal incision is marked in-line with the anterolateral acromion (A). The raphe between the anterior and lateral deltoid is split in-line with its fibers using electrocautery (B)



Figs 3A and B: The defect is drawn to size on a glove paper template (A), this template is imprinted onto the graft (B)

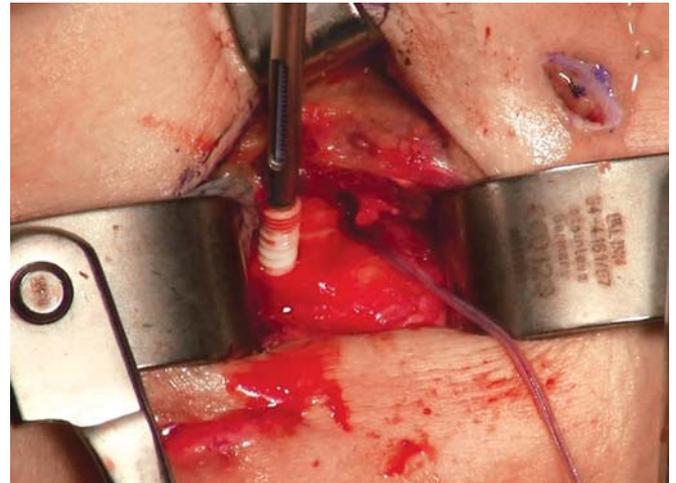


Fig. 4: A 4.5 mm PEEK suture anchor is placed at the articular margin for medial row fixation. Two or three are often required for stable fixation

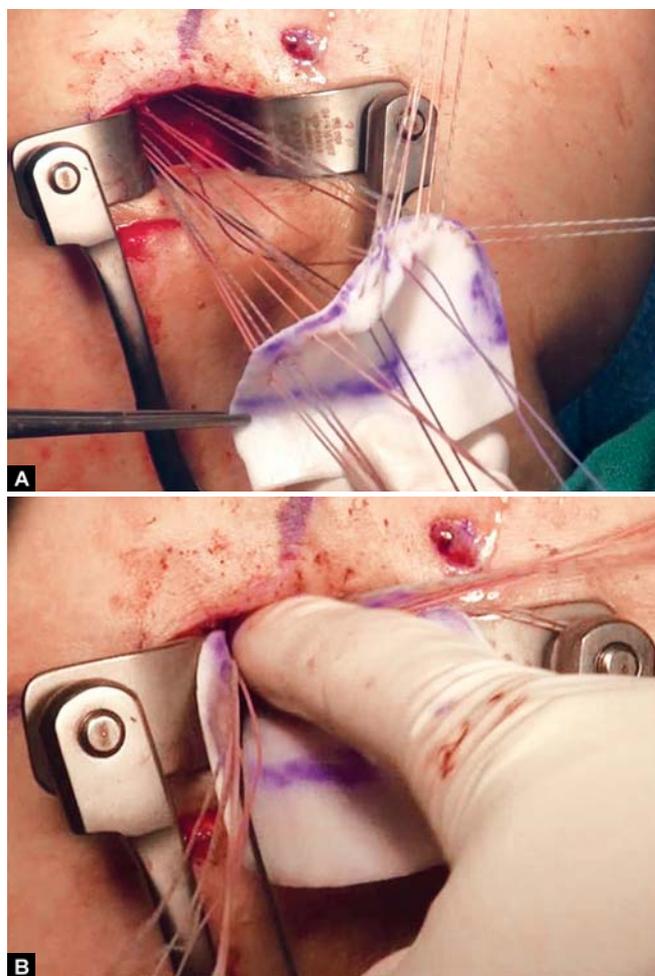
mobilization, another attempt is made to reduce the native rotator cuff tendon to the greater tuberosity by pulling tension on the previously placed sutures. If reduction to the anatomic footprint cannot be achieved, then a bridging reconstruction is performed.

The graft is rehydrated in saline for 30 seconds according to the manufacturer's instructions. If a margin convergence of the native tendon is needed, this is performed with direct suture repair prior to sizing the graft. The residual defect is

drawn to size on a glove paper template after directly measuring the defect size in the anterior-posterior and medial-lateral directions. The glove paper is then used as transfer paper to imprint the size of the defect onto the graft (Figs 3A and B). The order of suture passage through the

graft is marked on the template to guide in suture management. The graft is cut slightly larger than the defect to allow for some overlap at the reconstruction site. Any sclerotic bone or osteophytes on the greater tuberosity are removed with a shaver on bur mode to create a flat, bleeding, bony bed with minimal decortication. Two or three Biocryl Rapide (BR) or Polyether ether-ketone (PEEK) 4.5 mm suture anchors are placed at the articular margin for medial row fixation (Fig. 4). We choose these anchors due to their high biomechanical failure strength.⁵ BR anchors are preferred for use in osteoporotic bone due to its brittleness and potential risk of fracture in young healthy bone. The sutures emanating from these anchors are passed through the native rotator cuff lateral tendon if it can be reduced to the medial articular margin. If the cuff cannot be reduced to the articular margin, the sutures are passed through the medial edge of the graft. The horizontal mattress sutures already passed through the native rotator cuff tendon, including the articular margin suture row (if necessary), are then passed in a horizontal mattress fashion through the graft using a suture passing device such as the MultiFire Scorpion™ (Arthrex, Inc, Naples, FL). We prefer this device as it reduces the risk of graft tearing which can be encountered with free-hand suture passage. Suture passage is performed outside the shoulder on a padded stand. It is important to mark the graft based on the template for suture passage to ensure adequate suture spacing to avoid bunching of the graft when it is placed into the wound. The graft is then 'zip-lined' down to the native rotator cuff (Figs 5A and B). The medial sutures (native cuff secured to the graft) are tied. This often requires an arthroscopic knot pusher given the degree of medial retraction of the native rotator cuff. The graft is then placed over the rotator cuff footprint and gently tensioned laterally. Depending on the size of the graft necessary, three to four sutures in a horizontal mattress configuration are passed into the lateral aspect of the graft using the Opus SmartStitch™ device. Alternatively, a suture passer with a small needle, such as the Scorpion (Arthrex, Inc, Naples, FL) can be used to pass Mason-Allen sutures in the lateral aspect of the graft. The free suture limbs in the lateral graft are then anchored to the greater tuberosity with knotless anchors (Fig. 6) and manually tensioned until the graft is fully reduced to the lateral footprint. We prefer anchors that allow manual tensioning of the suture because overtensioning the construct laterally can lead to suture cutting through the tendon at the medial and/or lateral margins. This provides a double-row fixation.

The graft is then secured anterior and posterior to the surrounding infraspinatus and subscapularis tendons (if torn) with #2 Ethibond figure-of-eight sutures. The integrity of



Figs 5A and B: The prior horizontal mattress sutures already passed through the native cuff, including the articular margin suture row, are then passed in a horizontal mattress fashion through the graft (A). The patch is then 'kite stringed' down to fill the defect (B)

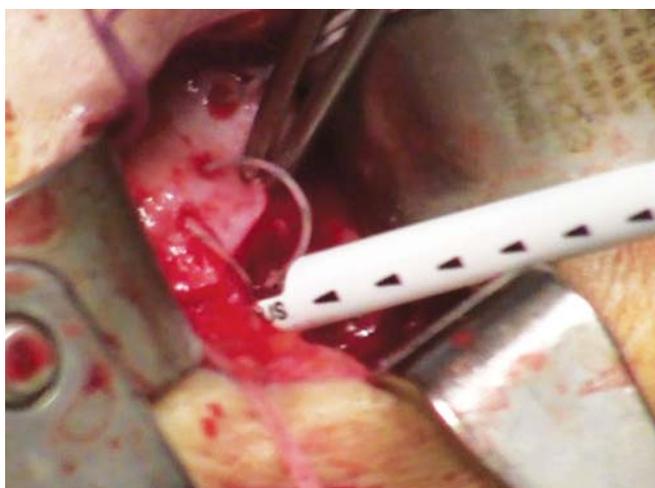


Fig. 6: Three to four horizontal mattress sutures are passed into the lateral aspect of the graft. The free suture limbs laterally are then anchored to the greater tuberosity

the reconstruction is assessed by passively ranging the shoulder in all planes (Fig. 7). We try to achieve a watertight seal between the glenohumeral joint and subacromial space with the graft in order to mimic normal anatomy.

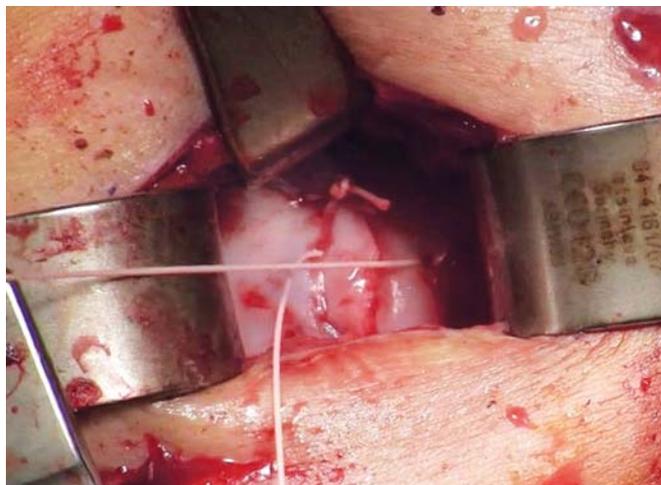


Fig. 7: The construct is then oversewn circumferentially to surrounding infraspinatus and subscapularis tendons with #2 Ethibond figure-of-eight sutures

The wound is irrigated and the deltoid raphe is reapproximated with a running 0-braided absorbable suture. The subcutaneous tissue is closed with 2-0 monofilament inverted mattress sutures followed by a 3-0 monofilament running subcuticular suture. The arm is placed in a shoulder sling with abduction pillow.

Postoperative Rehabilitation

A massive rotator cuff tear rehabilitative protocol is initiated on postoperative day three. Phase I comprises the first 8 weeks and allows unrestricted passive range of motion exercises with scapular stabilization. Weeks 8 to 12 focus on progressive active range of motion with the goal of full active range of motion in all planes by week 12. Phase II is comprised of progressive isometric strengthening exercises and begins at 12 weeks postoperatively. Phase III is initiated at 4 months with goals of progression to full activities of daily living and recreational activity by 6 months. This protocol is used as a framework; however, each patient's postoperative course is individualized based on their preoperative functional status and quality of intraoperative reconstruction.

RESULTS

Twenty-five of 26 patients were satisfied with their outcome and would undergo surgery again. There were no infections, inflammatory reactions, or tissue rejections. In all 26 cases, porcine dermal xenograft was utilized to bridge the void between the irreducible, retracted cuff and its native anatomic footprint. All 26 patients returned for clinical follow-up. Please refer to Table 1 for a summary of clinical results. Mean pain level decreased from 5.1 to 0.4 ($p = 0.002$). Mean active forward flexion, abduction and external

rotation motion improved from 138.8° to 167.3° ($p = 0.024$), 117.9° to 149.3° ($p = 0.001$) and 57.7° to 64.7° ($p = 0.31$), respectively. Supraspinatus and external rotation strength improved from 7.2 to 9.4 ($p = 0.001$) and 7.4 to 9.5 ($p = 0.001$), respectively. Mean MASES improved from 62.7 to 91.8 ($p = 0.0007$). Mean SF-12 scores improved from 48.4 to 56.6 ($p = 0.044$). Twenty-one patients (22 shoulders – 81%) returned for a dynamic and static ultrasound of the operative shoulder at a minimum 2-year follow-up. Sixteen (73%) demonstrated a fully intact tendon/graft reconstruction. Five (22%) patients had partially intact reconstructions, and one (5%) had a complete tear at the graft-bone interface. All 'fully intact' and 'partially intact' repairs moved as a complete unit with the greater tuberosity on dynamic imaging. Please refer to Table 2 for a summary of ultrasound findings.

Average surgical time for this procedure was approximately 120 minutes. Of note, this operative time includes the time required to address additional intra-articular pathology (i.e. biceps tenotomy or tenodesis, distal clavicle excision, and subacromial decompression) if warranted. Please refer to Table 3 for a summary of associated intraoperative procedures.

One partial graft retear occurred due to patient non-compliance with postoperative rehabilitation. The patient began strengthening his operative extremity 2 weeks postoperatively against medical advice and developed acute shoulder pain. He failed conservative management and second-look arthroscopy demonstrated a tear at the supraspinatus-graft junction. The posterior infraspinatus-graft junction was intact, as well as the lateral graft insertion on the greater tuberosity. The tear was not amenable to repair and therefore debridement was performed. Despite the tear this patient demonstrated an overall improvement in pain, range of motion, and subjective outcomes at final follow-up compared to his preoperative status, with his only complaint being an occasional mechanical clicking sensation deep in the shoulder.

The patient with a complete tear experienced an acute 'pop' followed by severe pain after suffering a fall 2 weeks postoperatively. She was initially managed conservatively with oral anti-inflammatory medications and physical therapy. Her pain persisted despite conservative management. Second-look arthroscopy demonstrated suture-anchor pullout from the greater tuberosity at the lateral footprint. The graft was free floating and debrided. The medial row fixation was intact with partial tearing and debrided due to poor tissue quality. Postoperatively her pain was improved from her preoperative status, but subjective outcomes, strength, and range of motion were decreased.

	<i>Preoperative</i>	<i>Final follow-up</i>	<i>Std. dev</i>	<i>p-value*</i>
Pain	5.1	0.4	0.96	0.002
Active FF (degrees)	138.8	167.3	12.1	0.024
Active abduction (degrees)	117.9	149.3	24.0	0.001
Active ER (degrees)	57.7	64.7	16.8	0.31
SS strength**	7.2	9.4	0.76	0.001
ER strength**	7.4	9.5	0.90	0.001
MASES	62.7	91.8	13.3	0.0007
SF-12	48.4	56.6	6.1	0.04

*Repeated measures analysis of variance (ANOVA), where $p < 0.05$ indicates statistical significance

** Based on muscle strength conversion scale adapted from FP Kendall et al

	<i>n = 22 shoulders</i>	<i>Construct moves as unit</i>
Fully intact	16/22 (73%)	16/16 (100%)
Partially intact	5/22 (22%)	5/5 (100%)
Not intact*	1/22 (5%)	0/1 (0%)

*Patient suffered a fall with an acute tear of the construct 2 weeks postoperatively

DISCUSSION

Management of massive irreparable rotator cuff tears in the young, active patient with minimal arthritis continues to challenge surgeons. Many treatment strategies have been utilized and have been shown to improve shoulder pain, range of motion and function. Rockwood et al reported 83% satisfactory results with debridement, subacromial decompression, and acromioplasty of massive degenerative irreparable rotator cuff tears.¹⁸ Burkhart et al reported significant functional improvement with arthroscopic repair of massive rotator cuff tears with stage three and four fatty degeneration.⁵ Nove-Josserand et al reported improved pain, range of motion and strength with latissimus dorsi transfer for irreparable tears with loss of external rotation.¹⁶

Overall outcomes and the ability of the rotator cuff to heal, however, can be inversely correlated to the size and amount of retraction of tears as well as the amount of tension applied to the repair.^{2,4,8,13} In a recent prospective, randomized trial evaluating the effectiveness of debridement or partial repair of massive rotator cuff tears, patients demonstrated improvements in pain, Constant scores and disabilities of the arm, shoulder and hand (DASH) scores. The partial repair group demonstrated improved outcomes vs the debridement group. The retear rate for partial repair, however, was 52% based on ultrasonography.² Galatz et al reported a 94% retear rate at 2-year follow-up on patients undergoing all-arthroscopic repair of large rotator cuff tears.⁹ Sugaya et al reported a 5% retear rate for small to medium-sized tears and a 40% retear rate for large and massive tears following arthroscopic double-row repair. The

	<i>Total cases: n = 27</i>
Distal clavicle excision	7/27
Acromial spur removal	7/27
Biceps tenotomy	13/27
Biceps tenodesis	3/27

shoulders with larger repair defects also demonstrated inferior functional outcomes.²⁰ Repair under excess tension can also lead to inferior clinical outcomes compared to repair under normal physiologic tension. Davidson et al demonstrated that repairs with excessive tension led to inferior Constant scores, decreased isokinetic strength, and increased pain.⁸ With the advent of extracellular matrix scaffolds, new treatment strategies have evolved to address both the technical, mechanical and biological healing difficulties associated with primary repair of massive rotator cuff tears.^{1,17,21}

Prior studies evaluating the efficacy of porcine xenografts to augment rotator cuff tears have had varied results. Badhe et al evaluated the clinical outcome of the ZCRTM patch porcine dermal scaffold (Zimmer Inc, Warsaw, IN) used as an augmentation in 10 patients with massive rotator cuff tears. Pain, range of motion and abduction power significantly improved. Imaging studies demonstrated intact grafts in eight of the 10 patients.¹ Walton et al evaluated the RestoreTM subintestinal mucosa (SIS) patch (DePuy Orthopaedics, Warsaw, IN) for rotator cuff augmentation in a prospective, randomized controlled trial. The RestoreTM group had a higher failure rate and lower

clinical outcome scores at 2 years postoperatively. A sterile inflammatory reaction was seen in 20% of the patients in the Restore™ group, with pain, swelling, and increased skin temperature at the surgical site. They therefore did not recommend its use in augmentation of two-tendon rotator cuff tears.²³ Zheng et al reported that this reaction may be due to residual porcine cellular elements in the Restore™ patch.²⁴

Biological scaffolds have been engineered in an attempt to improve regenerative healing. The means by which biologic scaffolds undergo degradation or regeneration is not fully understood. Scaffolds that undergo degradation demonstrate decreased biomechanical strength vs those that undergo remodeling via host matrix incorporation. Therefore, the ideal graft is one that behaves like native tissue and allows for native regeneration, cellular integration, and the capacity to heal without inducing an inflammatory response that may lead to early failure.

Animal studies have shed light on the possible mechanisms that lead to degradation and failure of porcine SIS patches. Scaffolds composed of damaged or denatured collagen or those containing antigenic materials, such as cell debris or α -gal antigen provoke a vigorous inflammatory response that quickly replaces the matrix tissue with scar tissue. Scaffolds that are crosslinked in an attempt to slow their degradation demonstrate a chronic inflammatory response and do not integrate with host tissue well. When scaffolds are processed to remove all cellular DNA and minimize the presence of α -gal antigen, there is a lower grade transient immune response. This has been shown to result in improvements in overall tissue integration with little to no clinical evidence of inflammation or failure.^{7,19,22}

Conexa 200™, unlike the Restore™ patch is not cross-linked and it is sterilized to 10^{-6} SAL. SAL is a measure of sterility, or the probability of microorganism survival following sterilization. This renders it acellular without retained porcine elements that can lead to early degradation, such as α -gal antigen. We prefer this matrix to other grafts because of its firmness and pliability with ease of suture passage without concern for graft tearing which we have experienced with the use of other grafts.

It is important to recognize that our patient population had good preoperative active range of motion, minimal glenohumeral arthritis, and lacked high grade fatty infiltration based on oblique sagittal T1-weighted MRI imaging. These factors facilitate reconstruction. Performing this procedure in patients with glenohumeral arthritis, pseudoparalysis, or high-grade fatty infiltration may lead to inferior results. In a prospective evaluation of chronic rotator cuff tears repaired primarily, Thomazeau et al

demonstrated that the grade of supraspinatus atrophy on oblique sagittal T1-weighted MRI views directly correlated with the sagittal and coronal extent of the tear and represented a strong predictor of postoperative re-tearing.²¹

CONCLUSION

Porcine dermal xenograft interposition reconstruction of massive rotator cuff tears through a mini-open approach is a reproducible technique that leads to significant improvement in pain, range of motion, strength and subjective outcome measures. Ultrasound imaging at a minimum 2-year follow-up demonstrated fully intact repairs in the majority of patients. In addition, it has proven to be safe in our patient cohort, with no incidence of infection or tissue rejection.

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