

Arthroscopic Bridging Repair Using Human Dermis Allografts for Irreparable Rotator Cuff Tears

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Background: The purpose of this study was to assess the results of arthroscopic bridging repair using a human dermis allograft in the treatment of massive irreparable rotator cuff tears.

Methods: From November 2009 to April 2011, 12 patients underwent arthroscopic bridging repair using a human dermis allograft in the treatment of massive irreparable rotator cuff tears. Patients were followed for an average of 33.9 months. Clinical outcome was evaluated preoperatively and postoperatively using the mean University of California, Los Angeles (UCLA) score and the Korean Shoulder Scoring System (KSS). Magnetic resonance imaging (MRI) was performed postoperatively at an average of 6.5 months.

Results: At a mean follow-up of 33.9 months (range, 25 to 42 months), 11 out of 12 patients were satisfied with their procedure. Patients showed significant improvement in their mean modified UCLA score from 15.9 preoperatively to 29.4 postoperatively ($p=0.001$). The mean KSS score improved from 45.6 preoperatively to 80.5 postoperatively ($p=0.002$). In MRI studies, 9 out of 12 patients had full incorporation of the graft into the native rotator cuff remnant. To date, there has been no intraoperative or postoperative complication from the graft procedure, such as infection or allograft rejection, in any patient.

Conclusions: Arthroscopic bridging repair using a human dermis allograft can be considered as an option in treatment of select cases of massive irreparable rotator cuff tears, resulting in high patient satisfaction.

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Key Words: Rotator cuff tear; Massive irreparable; Human dermis allograft; Arthroscopic bridging repair

Introduction

Surgical treatment of massive irreparable rotator cuff tears is challenging,¹ with failure rates ranging from 20% to 90%.²⁻⁴ Furthermore, a large defect may remain even after extensive release and mobilization of the retracted tendon stump.¹ In the older patient population, such tears, particularly when associated with glenohumeral joint osteoarthritis, can be treated effectively by reverse shoulder arthroplasty.⁵ However, this is not an ideal option in the younger, more functional age group, where the goal is to reattach the rotator cuff to the anatomic insertion on the greater tuberosity.⁵ Atrophy, fibrosis, fatty infiltration, and severe tendon retraction are the most common causes of irreparable massive rotator cuff tears.⁶ In some cases, poor quality tissue

cicatrix, coupled with a wide tear margin, make surgical mobilization difficult and anatomical tension free repair almost impossible.⁷

Despite remarkable advancements in the surgical technique of rotator cuff tears over the last 15 years, which has enabled the opportunity for effective repair most lesions, there are still a number of conditions where limitations of reparative surgery are evident,⁸ with an irreparability rate of up to 30%.⁹ For treatment of a massive irreparable tear, surgeons report that a decompression and debridement,^{10,11} partial repair,^{12,13} tendon transfer,^{14,15} and tendinous or fascial allograft materials inserted into the rotator cuff deficiency¹⁶⁻¹⁸ provide a significant decrease in pain and a greater improvement in function. Despite much clinical and experimental debate surrounding this condition, there is not an

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accepted treatment consensus.¹⁹⁾ Poor functional outcomes and pain relief have led to the need for new repair or reconstructive strategies.

A new reconstructive repair strategy is needed for the treatment of massive irreparable rotator cuff tears in the younger more active patient population, particularly those with no or minimal glenohumeral osteoarthritis. We have reported that clinical and radiological outcomes of arthroscopic bridging repair of massive irreparable rotator cuff tears, using a porcine dermis xenograft, were not satisfactory.²⁰⁾ On the contrary, we describe more promising results of arthroscopic bridging repair using a human dermis allograft in the treatment of massive irreparable rotator cuff tears.

Methods

Materials

From November 2009 to April 2011, 216 patients underwent arthroscopic repair of full thickness rotator cuff tears by one surgeon (I.B.K.). Of these patients, 12 patients (12 shoulders) who underwent arthroscopic bridging repair using a human dermis allograft in the treatment of massive irreparable rotator cuff tears were included in this study. A retrospective chart review was performed.

Criteria for inclusion required the condition to be irreparable despite meticulous release of the remnant cuff during the operation, the use of a human dermis allograft as bridging material to fill the gap between the torn tendon and the anatomic insertion of the rotator cuff, and an inability to reduce the residual cuff to the anatomic footprint after full mobilization of the tendon. Exclusion criteria included severe glenohumeral osteoarthritis and/or rotator cuff arthropathy based on preoperative radiographs and magnetic resonance imaging (MRI) scans, and a rotator cuff that is reducible to the lateral footprint during arthroscopy (no longer requiring a bridging repair). None of the patients showed evidence of superior migration of humerus.

Follow-up data were collected retrospectively at an average of 33.9 months (range, 25–42 months). Twelve patients (8 men, 4 women) with a mean age of 58.3 years (range, 50–66 years) were included in this study. Operations were performed on 11 right and 1 left shoulders, all of which were the dominant side. Three out of 12 patients underwent revision bridging repair for a persistent or recurrent rotator cuff tear after primary repair surgery.

Clinical outcome was evaluated using the mean University of California, Los Angeles (UCLA) score and the Korean Shoulder Scoring System (KSS),²¹⁾ which included both subjective outcomes, including function (30 points), pain (20 points), and satisfaction (10 points), and objective outcomes, including active range of motion (20 points) and muscle power consisting of strength (10 points) and endurance (10 points). The active range

of motion was measured using a goniometer, examining forward flexion, external rotation from 0° of abduction, and internal rotation, described as the level of thumb reach to the back.

Four of 12 patients showed chronic pseudoparalysis of shoulder elevation (defined as 'an inability to actively elevate the arm in the presence of free passive range of motion, and in the absence of a neurologic lesion'). They were able to perform active forward elevation only to 30° to 45°. Goutallier stage of the supraspinatus muscle was present in 3 out of 6 cases and 2 out of 6 cases. Tangent sign was positive in 7 cases.

Intraoperative findings and complications were also recorded. All patients were examined preoperatively and postoperatively at 6 weeks; 3, 6, and 12 months; and every 6 months thereafter.

Imaging of the rotator cuff using MRI was performed at a mean 6.5-month follow-up (range, 6–8 months). Repairs were classified as either fully intact, partial re-tear, partially intact, or full re-tear, based on the appearance of the graft-tendon interface as well as the tendon at the anatomic footprint on the humeral head.

Operative Technique

All patients were positioned in the standard lateral decubitus position. After appropriate treatment of the pathology, the stump of the cuff was carefully mobilized with a shaver and a liberator elevator. When repair was considered irreparable, despite meticulous release of the remnant cuff, the defect size of the cuff was measured using a ruler probe. Two measurements were taken: anterior to posterior at the edge of the articular cartilage, and medial to lateral at the central portion (tear patterns in all cases were round U shaped with the largest defect located in the central portion).

The mean thickness of the human dermis allograft (Mega-derm®; L&C BIO, Seongnam, Korea) was 2.9 mm. It was hydrated in a sterile solution for approximately 20 minutes and then cut to size of the template according to the measurements attained, with an additional 1 cm at each edge. Eight points on the human dermis allograft were marked with a surgical pen at 5–10-mm intervals (4 medial, 2 anterior, and 2 posterior).

Viewing from the posterolateral portal, 8 corresponding points on the remnant cuff were sutured using a suture passer and shuttled with a braided composite suture to the 8 corresponding points on the patch graft. Eight thread ends underneath the cuff were retrieved via an anterolateral portal, leaving the other thread end on top of the cuff at the posterior and anterior cannulas. The anterolateral cannula was removed, and all retrieved threads were placed into the human dermis allograft on the back table, as previously marked.

The human dermis allograft was then folded and the end was clamped with a retriever. By pulling the free ends of the anterior 4 and posterior 4 Fiber Wires, the graft was guided into the subacromial space and unfolded. The 4 posterior and 4 anterior

ends of the threads were retrieved into their respective posterior and anterior portals.

A cannula was inserted into the anterolateral portal. Two free ends of the same thread were retrieved and tied to the post on the graft and the graft mounting on the cuff. This process was repeated for the other threads sequentially.

The lateral portion of the graft was fixed onto the footprint using a standard suture-bridge technique. Acromioplasty was performed as necessary.

Postoperatively, the arm was supported in an abduction brace for 6 weeks. Patients removed the sling 3 to 4 times a day for scapular mobilization, as well as elbow, wrist, and hand exercises. Pendulum exercises were initiated on day 1 and transitioned to active-assisted elevation at 6 weeks. The graft was evaluated via MRI at 6.5 months postoperatively. Progressive resistance exercises were allowed at 4 months, and patients were permitted to return to unlimited activity at 6 months, if tolerable.

Statistical Analysis

Preoperative and postoperative scores were compared using the Wilcoxon Signed rank test. Analysis of data was performed using the statistical software package IBM SPSS ver. 20.0 (IBM CO., Armonk, NY, USA). Values of $p < 0.05$ were considered

statically significant.

Results

Eleven of 12 patients were satisfied with their procedure. Patients also showed significant improvement in their mean modified UCLA score from 15.9 preoperatively to 29.4 postoperatively ($p=0.001$). Overall, the mean KSS score improved from 45.6 preoperatively to 80.5 postoperatively ($p=0.002$). All components of the KSS score showed functional improvement. Mean scores increased from preoperatively to postoperatively as follows: function increased from 15.2 to 23.5 ($p=0.002$), pain improved from 5.8 to 15.4 ($p=0.004$), satisfaction increased from 3.3 to 7.5 ($p=0.003$), and range of motion improved from 9.5 to 15.8 points ($p=0.005$). Forward flexion increased on average from 104.2 to 159.6 ($p=0.003$). During external rotation, the range of motion improved from 32.5 to 61.3 ($p=0.003$). During internal rotation, the range of motion improved from L5 level to L3 level ($p=0.003$). Strength increased on average from 6.7 points preoperatively to 8.5 points postoperatively ($p=0.009$) and endurance improved on average from 5.1 to 9.8 ($p=0.005$).

In particular, preoperative chronic pseudoparalysis in 4 patients was resolved postoperatively. Forward elevation showed

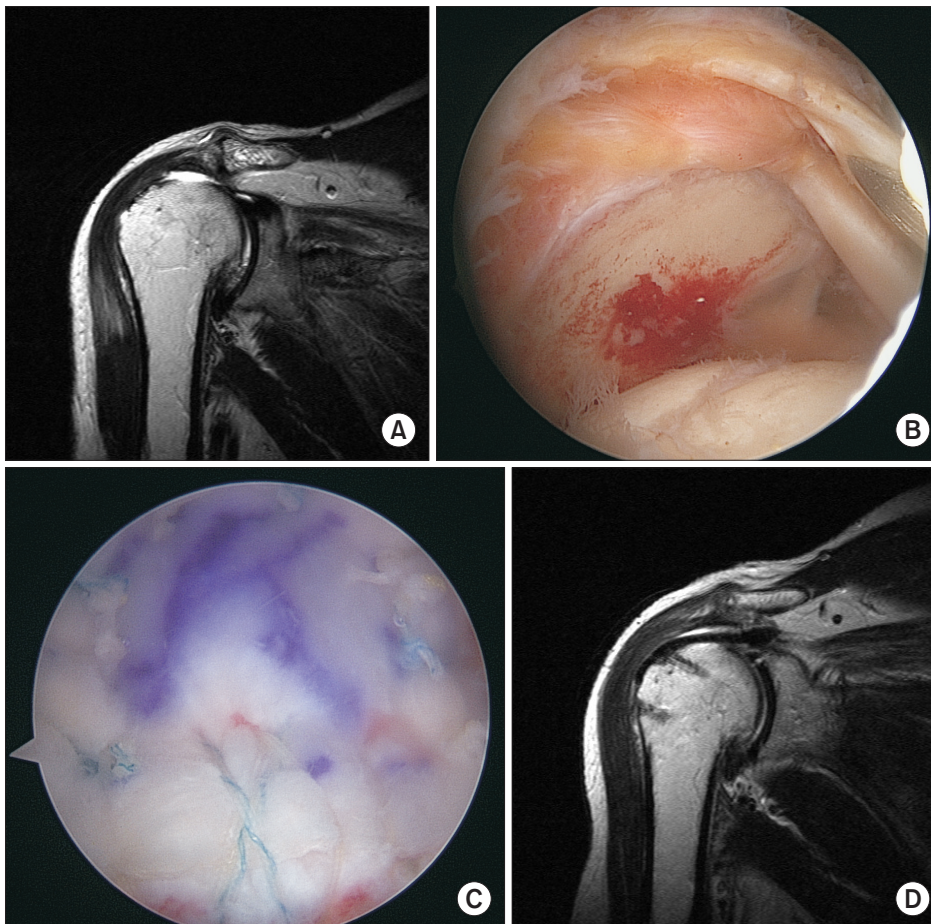


Fig. 1. (A) A 57-year-old female underwent arthroscopic bridging repair using a human dermis allograft for an irreparable rotator cuff tear. Preoperative magnetic resonance paracoronal image, T2-weighted fast spin-echo proton density: supraspinatus tendon was torn with retraction. (B) Arthroscopic view shows an irreparable rotator cuff tear with retraction. (C) Final view shows arthroscopic bridging repair using a human dermis allograft in the treatment of the massive irreparable rotator cuff tear. (D) A 6.5-month follow-up magnetic resonance paracoronal image, T2-weighted fast spin-echo proton density: integrity of the reparation with integration between tendon and human dermal allograft that can no longer be distinguished.

improvement from a mean 34° to 151° ($p=0.001$).

To date, there has been no occurrence of an intraoperative or postoperative complication from the graft procedure, as well as no infections and no allograft rejections in any patients.

All patients agreed to undergo an MRI at 6.5 months (range, 6–8 months) postoperatively to evaluate the structural integrity of the graft. Nine of 12 patients had full incorporation of the graft into the native rotator cuff remnant (Fig. 1). To date, 3 patients have had a radiographic failure of the allograft material. One patient also had a full thickness re-tear of the subscapularis tendon. The other 2 patients, with a partial graft tear, exhibited allograft failure along the medial and posterior borders of the graft. Nevertheless, 11 patients, including the patient with a radiographic partial tear of the graft, were satisfied at their last clinical follow-up due to significant relief of their preoperative pain.

Discussion

Despite the recent conspicuous development in understanding rotator cuff tear pathology, suture materials, the arthroscopic technique and equipment, management of massive irreparable rotator cuff tears still represents a therapeutic challenge, particularly in relatively younger patients, with no evidence of glenohumeral joint arthritis.⁵⁾

Several efforts have been made to treat these types of massive irreparable rotator cuff tears. Arthroscopic debridement with or without subacromial decompression has been reported to have satisfactory short-term outcomes.^{11,22,23)} Rockwood et al.¹¹⁾ reported satisfactory results in 83% of shoulders at a mean of 6.5 years of follow-up. Other investigators, however, contend that in patients treated with debridement alone, deterioration typically occurs over time, and they therefore recommend rotator cuff repairs, particularly in younger patients.^{3,4,10,22,24)} Positive outcomes of partial repair of irreparable rotator cuff tears have been reported.^{12,13)} However, this procedure should be considered as an option only when good tissue quality is available and when an isolated repair of the infraspinatus or margin convergence rotator cuff repair can be performed safely.⁵⁾ In addition, the re-tear rate for partial repair was 52% based on ultrasonography.²⁵⁾ Tendon transfer represents another alternative procedure for this complex pathology.^{9,26)} Although favorable results have been published with the transfer of the latissimus dorsi tendon for irreparable posterosuperior rotator cuff tears, patient selection plays a major role in achievement of a successful outcome.⁵⁾ It seems that the tendon transfer of latissimus dorsi is a viable surgical option only for young patients with an adequate preoperative active motion range of at least 90° arm elevation, who require strength to perform occupational tasks and are willing to participate in a long and rigorous rehabilitation program.⁵⁾

On the contrary, use of biologic patches as bridging devices appears to be a good alternative for the anatomic reconstruction

of irreparable rotator cuff tears when the indications are against a palliative (debridement, non-anatomic repair) or a salvaging (tendon transfer) procedure.⁵⁾ Several tissue-engineered biomaterials have recently emerged for the reinforcement of an irreparable massive rotator cuff repair, however the outcomes of the clinical studies have been mixed.^{3,27)}

The in vivo behavior of human dermal allografts used in human rotator cuff tear repairs is not known but animal studies have shown promising results. In a canine model, full-thickness infraspinatus tears were created, and either a human dermal allograft or the autologous tendon was used to bridge the defect. At time 0, similar strength was observed in control and experimental repair subjects. At 6 weeks, the strength of the allograft repair was half that of the autologous repair, but by 12 weeks, the strength of the two groups was equivalent. Histologically, cells infiltrated both groups by 6 weeks. At 6 months, both groups had normal tendon structure, both grossly and histologically. This study suggests that a human dermal allograft has the potential to behave like a native tendon, both biomechanically and histologically, in the early postoperative period.²⁷⁾ In a recent biopsy specimen obtained from a 62-year-old patient with a massive rotator cuff tear augmented with a human dermal allograft, there was evidence of incorporation of the allograft demonstrated by cellular infiltration, alignment of collagen fibers, and blood vessel ingrowth.²⁸⁾ These findings suggest that this type of allograft can play an important role in rotator cuff healing at the cellular level.²⁹⁾

Promising clinical results of human dermal allograft bridging or interposition repair of massive irreparable rotator cuff tears have also been reported.^{14,19,24,30)} The Snyder group reported results of arthroscopic replacement of massive, irreparable rotator cuff tears using a human dermal allograft, which demonstrated improved overall functional outcomes at a mean 26-month follow-up. Thirteen of 16 patients demonstrated full incorporation of the graft into the native tissue as shown by MRI.²⁴⁾ In addition, they reported good clinical results in 45 patients after a minimum follow-up period of 2 years.³⁰⁾ This group performed staged arthroscopic reconstruction, whereas we performed just one-stage arthroscopic reconstruction. We do not believe a staged approach involving two surgeries is necessary because one-stage arthroscopic reconstruction does not cause subacromial adhesion of the graft even after thorough subacromial decompression and 6–8 weeks is not enough time to estimate the pure effect of the debridement procedure.

In this study, a human dermal allograft was used as a bridging patch for repair of irreparable massive cuff tears, via an arthroscopic approach.

We have experienced 3 cases of re-tear. A radiographic failure of the allograft material was thought to occur due to patient noncompliance with postoperative rehabilitation. One patient was a hard laborer and returned to work just 2 weeks

after surgery. Despite the re-tear, this patient showed overall improvement in function, pain, satisfaction, range of motion, and strength at the final follow-up. His only complaint was a little weakness after working overhead for an extended period of time. The other two patients with partial graft tears showed allograft failure along the medial and posterior border of the graft. However, they exhibited an improved mean modified UCLA score from 13 preoperatively to 28 postoperatively. The mean KSS score also improved from 39 preoperatively to 75.5 postoperatively.

This study has several limitations. First, follow-up MRIs were taken on average only at 6.5 months. The full outcome course of the allograft cannot be determined within this limited time-frame. Second, there is no control group as this was not possible in practice. And, finally, the number of cases is too small and the follow-up period too short.

Conclusion

We have shown significant clinical success with arthroscopic rotator cuff reconstruction using human dermis allografts. We think that the procedure is safe and effective, yielding high patient satisfaction and without morbidity of tendon transfers or arthroplasty. Arthroscopic rotator cuff reconstruction using human dermis allografts can be considered as an option in the treatment of selected cases with massive irreparable rotator cuff tears.

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