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Patch Augmentation for Massive Rotator Cuff Tears

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Rotator cuff tears commonly affect the shoulder joints. Despite developments in surgical techniques and instrumentation, the treatment of massive rotator cuff tears remains challenging. The problems associated with rotator cuff repairs, such as inferior mechanical properties and high retear rates are yet to be solved. Recently, patch augmentation has been suggested as an alternative treatment because it can reinforce mechanical properties at the initial stage of healing and reduce gap formation. The purpose of this article was to comprehensively summarize the concepts and the consensus surrounding patch augmentation and evaluate the clinical and anatomical outcomes after patch augmentation for massive rotator cuff tears.
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Key Words: Rotator cuff; Tear; Tendon; Shoulder

Introduction

A rotator cuff tear is a common disease of the shoulder. These tears are often classified by their size as small, medium, large, or massive. The most severe, massive tears are defined as a complete separation of two or more tendons. And, although literature reports vary in terms of its prevalence, massive rotator cuff tears have been shown to account for around 10% to 30% of all cuff tears.[1] The first-line of treatment for rotator cuff tears should ideally be conservative, and failed conservative management or large tears should be treated surgically. Among the surgical treatments, the primary rotator cuff repair has been shown to give a functionally complete recovery and is also the recommended choice of treatment. However, for massive rotator cuff repairs, which often include the repair of the anatomical footprint, only a subset of studies has shown good outcomes.[2,3] This is thought to be because the stiffened and shortened cuff tendons in patients with massive cuff tears causes sufficient footprint coverage. Despite developments in surgical techniques and instrumentation, repairs of massive cuff tears remain a challenge to many orthopedic surgeons.

Furthermore, outcomes of massive rotator cuff repairs have often been shown to be either unsatisfactory or unpredictable. And the early-stage excessive tension that the cuff complex has to endure has been associated with the high failure rates of this procedure even when a successful restoration is initially observed.[4,5] The reported values of this failure rate differ depending on tear size, patient age, muscle atrophy, fatty degeneration, and chronicity, even reaching a rate of 94%.[6-10] Improving the success rates of rotator cuff repairs, thereby the clinical outcomes, involves two essential requirements: 1) the rotator cuff complex must be able to endure early tension during the early reparative stage (between the repair of mechanical properties and the formation of tendon) and 2) biological ability that maximizes the healing capacity of the bone-tendon junction must be obtained. As a solution to these milestones, an augmentation graft made up of patch material was introduced for large-to-massive rotator cuff tears, for irreparable tears, or for poor quality tendons (Fig. 1).

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Classification of Patch Grafts

Patch grafts can be classified broadly into xenografts, synthetic grafts, allografts, and autografts. The common harvest sources for xenografts are the porcine dermis and the porcine small intestinal submucosa; for synthetic grafts, the polyglycolic acid sheet, polypropylenes, the mersilene mesh, the gore-tex patch, and etc.; for allografts, the human dermal matrix and freeze-dried cadaveric rotator cuffs; and for autografts, the biceps tendon, the fascia lata, and the patellar tendon (Table 1).[11-13] In the past, xenografts had been the most widespread form of patch grafts, but they fell out of popularity because, compared to other grafts, they were associated with less favorable structural healing rates. Its superiority to primary repairs was never demonstrated and there were several reports of immunogenic complications that disfavored their use.[14] Further, compared to groups that had not use synthetic grafts or to groups that had used allografts, groups that had used synthetic grafts were associated with better structural and functional results. Theoretically, these synthetic composite materials can be engineered in a way that key biomechanical properties, such as strength are optimally manipulated. But the biological consequences of these synthetic materials, such as foreign body reaction, poor integration, and synovitis, upon insertion into the body may be inevitable. Well designed controlled studies that investigate the effectiveness of these synthetic grafts are still lacking.

Fig. 1. Insertion of the patch graft during an arthroscopic rotator cuff repair.

Findings from a recent systemic review of animal and clinical experiments suggest that the effectiveness of xenografts are questionable, whereas those for synthetic grafts and allografts indicated they were associated with good clinical outcomes.[15] A study that estimated re-tear rates according to patch graft type reported that xenografts showed the worst re-tear rate (xenografts [44%] vs. synthetic graft [15%] vs. allografts [23%]).[16] These negative findings of xenografts have been succeeded with a corresponding decrease in the use of xenografts in the clinic. As an alternative to xenografts, patch grafts—a type of allografts consisting of human dermal matrix—are increasingly coming under light because of their low incidence of complications, such as disease transmission and graft rejection, and their relatively safety.[11,17] Patch grafts are de-cellularized freeze-dried human cadaveric material consisting of collagen type I, II, IV, and VII, elastin, chondroitin sulfate, proteoglycans, and fibroblast growth factors and has in it preserved basement membrane and vascular channels, two constituents which have been shown to help host incorporation.[18,19] However, well-designed and long-term studies that investigate the mechanism of patch grafts and their effects are limited. And the possibility of remnant allogenic proteins within the scaffolds means that inflammatory responses may occur and cause tissue degeneration. Furthermore, bony in-growth formation, which is fundamental for functional restoration of the tendon, is nonexistent in allografts, restricting their use.[12,20-22]

Common harvest sources of autografts include the tensor fascia lata, the biceps long head tendon, the hamstring tendon, the patellar tendon, and the Achilles tendon. Because these grafts originate from the person's own body, they are regarded as the gold-standard choice of graft. Studies on autografts have shown favorable clinical outcomes,[23-25] and the successful outcomes have been shown to be dependent on cells within scaffolds that activate collagen synthesis and, thereby, start the process of tendon re-formation. Accordingly, autografts with viable donor cells are preferred over frozen allografts with unviable donor cells.[26] Biomechanically, autografts have been reported to be stronger than allografts.[12] However, using allografts has disadvantages of causing donor site morbidity and of limited availability; normally, finding an appropriate graft is difficult because a graft must be both sufficiently thick and sufficiently sturdy to withstand the

Table 1. Classification of Patch Grafts

Xenografts	Porcine dermal graft, porcine small intestine submucosa, fetal bovine dermis
Allografts	Human dermal matrix, freeze-dried cadaveric rotator cuffs, freeze-dried cadaveric Achilles tendon
Synthetic grafts	Polyglycolic acid sheet, poly-L-lactide polymer, polyurethane polymer, polyethylene terephthalate, mersilene mesh, Gore-Tex patch, carbon fiber tow, polytetrafluoroethylene
Autografts	Biceps tendon, fascia lata, patellar tendon, Achilles tendon, quadriceps tendon

early postoperative mechanical loading. Thus, choosing the right graft material is also very important for a successful treatment.

Clinical Results

The research on the clinical outcomes of rotator cuff repairs using various types of patch augmentation is abundant.[16,27-32] Most of these studies have investigated large-to-massive tears while only a few have investigated smaller tears.[29,30] However, studies on the effectiveness of collagen patch grafts and polypropylene patch grafts are extremely limited.[28] And the fact that many studies do not include control groups makes it difficult to conduct comparative analyses (Table 2).[17,19,29-31,33-47] Studies that compare outcomes of graft augmentation with those of other control surgical techniques, such as the conventional repair technique, are summarized in Table 3.[27,28,32,46,48-50]

Table 2. Uncontrolled Clinical Studies on Patch Grafts for Rotator Cuff Tears

Author	Type	Graft	Year	No. of patient	Technique	Tear size	Mean F/U (mo)	Main clinical finding
Ozaki et al.[36]	Synthetic	Polytetrafluoroethylene	1986	25	Open	Massive	25	ROM: abduction 44.16→133.2, strength: abduction 3+→4*, ER 3+→4+*
Visuri et al.[31]	Synthetic	Carbon fiber tow	1991	14	Open	> 3 cm	48.9	ROM: abduction 72.9→157.1
Metcalf et al.[37]	Xenograft	Porcine small intestine submucosa	2002	12	Open	Massive	24	ROM: FE 30→90, abduction 27→86, ER 0→40, IR 3→40, strength: abduction 0.8→3.1*, UCLA score 9.3→19.9
Hirooka et al.[30]	Synthetic	Gore-Tex patch	2002	28	Open	All size	44	-
Audenaert et al.[35]	Synthetic	Mersilene mesh	2006	39	Open	Massive	43	ROM: FE 69.2→136, abduction 68.4→133.7, ER 32.4→38.3, IR 3.4→7.5 of 10 points, strength: abduction 0→7.9†, Constant score 25.7→72.1
Burkhead et al.[38]	Allograft	Human dermal matrix	2007	17	Open	Massive	14.4	UCLA score 9.06→26.12
Badhe et al.[33]	Xenograft	Porcine dermal collagen	2008	10	Open	Massive	52	Strength: abduction 6.3→9.8, Constant score 41.5→62.2
Phipatanakul and Petersen[39]	Xenograft	Porcine small intestine submucosa	2009	11	Open	Massive	26	ROM: FE 109→126, ER 37→28, ASES score 36.3→71.8, UCLA score 13.9→25.7
Wong et al.[17]	Allograft	Human dermal matrix	2010	45	Arthroscopic	Large to massive	48	UCLA score 18.4→27.5
Nada et al.[40]	Synthetic	Polyethylene terephthalate	2010	21	Mini open	Massive	36	ROM: FE 65→120, abduction 60→120, ER 39→57, IR 4.2→8.4, strength: abduction 3.9→5*, Constant score 46.7→84.5
Rotini et al.[19]	Allograft	Human dermal matrix	2011	5	Open/Arthroscopic	Large to massive	13.6	Constant score 64→88
Encalada-Diaz et al.[29]	Synthetic	Polyurethane polymer	2011	10	Mini open	All size	12	ROM: FE 90→160, abduction 70→155, ER 15→30, IR sacrum→T12, ASES score 44→73.3
Gupta et al.[41]	Allograft	Human dermal matrix	2012	24	Mini open	Massive	36	ROM: FE 111.7→157.3, abduction 105→151.7, ER 46.2→65.1, strength: abduction 7.2→9.4§, ER 7.8→9.3§, ASES score 66.6→88.7
Venouziou et al.[34]	Allograft	Human dermal matrix	2013	14	Open	Massive	30.2	ROM: FE 73.6→129.3, abduction 67.5→117.9, ER 7.9→43.2, ASES score 23.8→72.3
Petrie and Ismaiel[42]	Synthetic	Ligament augmentation Reconstruction system	2013	29	Open	Massive	40	-
Proctor[43]	Synthetic	Poly-L-lactide polymer	2014	18	Arthroscopic	Large to massive	42	ASES score 25→70
Giannotti et al.[45]	Xenograft	Porcine dermal collagen patch	2014	9	Open	Massive	36	ASES score 38→79, Constant score 42→73
Cho et al.[46]	Xenograft	Porcine dermal collagen	2014	5	Mini open	Massive	20.6	ASES score 39.4→86.4, UCLA score 15.4→31.2
Lenart et al.[44]	Synthetic	Poly-L-lactide polymer	2015	13	Open	Massive or retear	18	ROM: FE 145→160, ASES score 32.8→74.2
Petri et al.[47]	Allograft	Human dermal matrix	2016	13	Open	Large to massive	30	ASES score 64.5→86.0

Numeric data reflect improvement from preoperative baseline data.
F/U: follow-up, ROM: range of motion, ER: external rotation, FE: forward elevation, IR: internal rotation, UCLA: University of California-Los Angeles, ASES: American Shoulder and Elbow Surgeons Evaluation Form.
*Based on the 5-point Medical Research Council Scale. †Power assessed as part of Constant-Murley score. §Based on the 10-point Modified Medical Research Council Scale.

Table 3. Controlled Clinical Studies on Patch Grafts for Rotator Cuff Tearss

Authors	Type	Graft	Year	No. of patient	Technique	Tear size	Mean F/U (mo)	Control group	Clinical outcomes		Radiologic outcomes	
									Outcome	Comparison	Outcome	Comparison
Iannotti et al.[49]	Xenograft	Porcine small intestine submucosa	2006	15	Open	Large to massive	14	Conventional	Penn: 83 (patch), 91 (control)	Significant (control>patch)	MRI at 1 year 4/15 (patch) vs. 9/19 (control)	Not significant
Walton et al.[32]	Xenograft	Porcine small intestine submucosa	2007	16	Open	Large to massive	24	Conventional	Less strength (lift-off, IR, adduction), slower rate of resolution of pain, less sports participation in xenograft	Significant (control>patch)	MRI mean tendon thickness 1.50 mm (patch) vs. 1.58 mm (control)	Not significant
Barber et al.[27]	Allograft	Human dermal matrix	2012	22	Arthroscopic	Large to massive	24	Conventional	ASES (p=0.035), Constant (p=0.008), UCLA (p=0.43)	Significant	MRI intact cuffs in 85% of repairs in patch group vs 40% in control (p<0.001)	Significant
Modi et al.[48]	Allograft	Human dermal matrix	2013	61	Open	> 3 cm	43.2	Partial repair	Constant (p=0.001), ASES (p=0.021), VAS (p=0.028)	Significant	MRI Graft: 8.3% retear, control: 41.7% retear (p=0.015)	Significant
Ciampi et al. (synthetic)[28]	Synthetic	Polypropylene	2014	52	Open	Massive	36	Conventional	UCLA score at 36 months was significantly higher (p<0.001)	Significant	USG after 12 months 41% (21/51) for the control group vs. 17% (9/52) for the polypropylene group	Significant
Ciampi et al. (collagen)[28]	Xenograft	Bovine pericardium derived collagen	2014	49	Open	Massive	36	Conventional	UCLA score at 36 months was not significantly higher	Not significant	USG after 12 months 41% (21/51) for the control group vs. 51% (25/49) for the collagen group,	Not significant
Yoon et al.[50]	Allograft	Human dermal matrix	2016	21	Arthroscopic	Massive	23	Conventional	1 year and final follow-up: not significant (VAS, SST, UCLA, Constant, ASES)	Not significant	MRI at 12 months retear: 19.0% (patch) vs. 46.3% (control)	Significant

F/U: follow-up, IR: internal rotation, ASES: American Shoulder and Elbow Surgeons Evaluation Form, UCLA: University of California-Los Angeles, VAS: visual analog scale, SST: simple shoulder test, MRI: magnetic resonance imaging, USG: ultrasonography.

In almost all studies, whichever graft was used, clinical parameters, such as range of motion, the American Shoulder and Elbow Surgeons Evaluation Form (ASES) score, the University of California-Los Angeles (UCLA) score, and the Constant score significantly improved with patch augmentation. However, many of these studies do not have a control group; thus, we cannot be certain that these improved results are attributable to patch augmentation. In terms of graft type, we found that compared to other patch grafts, the synthetic grafts had significantly larger improvements in forward flexion and in abduction, whilst allografts showed the highest improvement in external rotation.[16] The anatomical results obtained using postoperative follow-up imaging were compared by study (Table 3);[27,28,32,46,48-50] interestingly, we found that most of the studies that had reported no significant difference between grafting and the conventional repair had used xenografts.

Studies generally showed improved muscle strength after patch augmentation, in particular a significant improvement in abduction strength.[28,33] A few studies also showed that external rotation strength is improved after grafting.[34-36,48] However, Walton et al.[32] presented anomalous data wherein patients without patch augmentation compared to those with had better abduction strength. Similarly, a different study reported that patients who had not received augmentation had greater external rotation strength than those who had received augmentation. Interestingly, the patients who had not received patch augmentation in this study had been treated using xenografts (restore orthobiologic implant).[32]

Almost all studies on patch augmentation report improvements in clinical parameters, specifically the ASES, the UCLA, the Constant, the Penn, and the Oxford scores. These improvements appeared irrespectively of graft type, but when comparing xenografts to synthetic grafts and allografts, we found that their improvement was relatively smaller. Other clinical parameters such as pain, satisfaction, ADL performance, and return to sports or to daily activities showed significant improvements in various papers.

In the literature, the rates of retear measured through postoperative evaluation of anatomical outcomes show a substantial variation ranging from 8.3% to 73.4%, depending on the surgical indication, the treatment method, and the mode of assessment.[50] A recent systemic review on 22 studies calculating retear rates showed that the overall retear rate was 22% for complete tears and 2.7% for partial tears.[16] Among complete tears, the overall retear rates by graft type were 15.0% for synthetic grafts, 42.0% for xenograft, and 9.9% for allografts. Among partial tears, the corresponding percent values were 0%, 1.7%, and 12.7%, respectively.[16]

A few explanations are given in the literature for how patch augmentation may reduce the occurrence of retears.[50] For example, it has been suggested to reduce the tension applied to the torn tendon by pulling the edges of torn tendons in massive cuff tears toward the lateral footprint (Fig. 2). Taking the same action (that is, pulling the torn tendons as laterally as possible to cover the rotator cuff footprint) in medial row repairs would exacerbate tension overloading because massive rotator cuff tears usually have much retracted and stiffened tendons. Thus, patch graft repairs in contrast would allow less lateralization of the torn tendon ends, resulting in less tension.

Postoperative complications differentially appear by graft type; for instance, xenografts are often associated with infection-induced immune responses. The more recent types—allografts and autografts—are commonly associated with bursitis, deep infection, skin rash, severe inflammatory reaction, humeral fracture, and cystic changes of the humeral head. Besides these, complications that generally occur with rotator cuff repairs have all been reported with grafting.

Consensus for Patch Grafts

For the treatment of massive or irreparable cuff tears, treatment modalities other than patch augmentation may be indi-

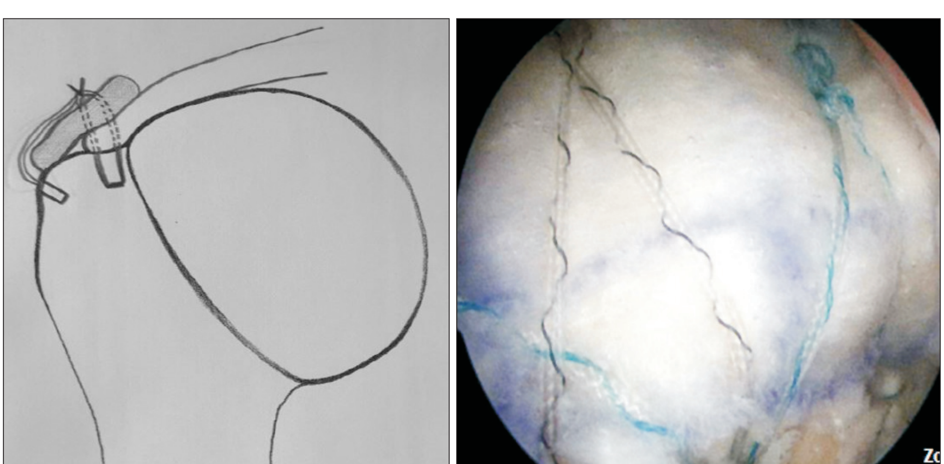

Fig. 2. Patch augmentations can decrease the initial high tension applied to repair sites in massive rotator cuff tears.

cated; a few examples are conservative treatment, subacromial debridement and decompression, partial repair, muscle transfer, superior capsular reconstruction, subacromial spacer, and reverse shoulder arthroplasty. Each treatment modality has been reported with favorable clinical outcomes.[51-56]

Controversy as to whether patch augmentation is the most ideal treatment for massive or irreparable cuff arthopathies remains, and some studies have attempted to answer this. In the American Academy of Orthopaedic Surgeons (AAOS)'s guidelines,[57] xenografts are not recommended, while partial repairs, debridement, and muscle transfer are weakly recommended. And whilst allografts are not recommended, the guidelines states there is not sufficient evidence to back their claim. In a survey that asked ASES members whether they agreed to the AAOS guidelines,[58] 86.5% of respondents agreed that partial repairs are appropriate for irreparable cuff tears and 64.6% agreed that debridement is appropriate. Only 11.2% and 45.4% of respondents said that allografts should be used for primary treatment and for revision treatment, respectively. Taking these findings into account, it seems that there is yet insufficient evidence, both empirically and consensually, that justifies the use of patch grafts.

Conclusions

No gold standard of treatment exists for massive rotator cuff tears, especially for irreparable cuff tears. These tears have been shown to be challenging to treat in young and active patients. The antecedent xenografts for cuff tear arthropathies were associated with unfavorable clinical outcomes and postoperative complications. For these reasons xenografts are no longer used in the clinic. The more current patch augmentation such as through human dermal allografts has been reported to have favorable outcomes, but well-designed, long-term randomized control studies are required to evaluate the cost-effectiveness of this treatment. Because there is a wide range of options for irreparable rotator cuff tears besides patch augmentation, such as debridement, partial repair, superior capsular reconstruction, and reverse arthroplasty, the choice of treatment should be carefully selected on the basis of the relative benefits and limitations of each method.

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