Human Dermal Allograft Interposition for the Reconstruction of Massive Irreparable Rotator Cuff Tears

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Abstract

This retrospective study sought to determine the effectiveness of the acellular human dermal allograft as a bridging device for reconstruction of massive irreparable rotator cuff tears (RCTs).

Fourteen patients with an average age of 54.6 years underwent open reconstruction for massive irreparable RCTs. Significant improvement was found for pain and range of motion (ROM). Patient satisfaction was high. The mean American Shoulder and Elbow Surgeons (ASES) score improved from 23.8 points preoperatively to 72.3 postoperatively (P = .001). A significant correlation was found between the size of the tendon gap, which was bridged with the allograft, and the pain, ROM and ASES score. Patients with less than 2 cm tendon gap had a better outcome than those with greater tendon defects.

Open reconstruction of chronic massive irreparable RCTs with human dermal allograft interposition is an alternative technique with encouraging short-term results. Our study indicates that the dermal allograft can be used safely to bridge tendon gaps of up to 2 cm with great success.

Chronic massive rotator cuff tears (RCTs) represent a therapeutic challenge. In an older patient population such tears, especially when associated with glenohumeral joint osteoarthritis, can be treated effectively with reverse shoulder arthroplasty. 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. Massive RCTs most commonly are irreparable due to atrophy, fibrosis, fatty infiltration, and severe tendon retraction.[1] In some cases the poor-quality tissue and cicatrix coupled with wide-tear margin makes surgical mobilization difficult and anatomical tension free repair almost impossible.[2]

Open and arthroscopic anatomic repair of chronic massive RCTs have demonstrated high recurrence rate.[3-7] In order to avoid recurrence failure, numerous surgical techniques have been developed to address this issue. Partial repair of massive RCTs, arthroscopic debridement of such tears and tendon transfers, such as latissimus dorsi transfer, represent alternative option for the treating surgeon.[8-13]

Recently, the use of tissue-engineered biomaterials has been proposed as an alternative reconstructive procedure for the treatment of massive RCTs. Collagen patches derived from porcine small intestine submucosa have demonstrated low healing potential with high failure rate, poor functional outcomes, and aseptic drainage.[14,15] Cross-linked porcine dermis patches have also been used but the reports have demonstrated mixed results.[16,17] The acellular human dermis allograft has been used with great success for other orthopedic applications, without many of those reported complications.[18-21] Promising results were also noted after the use of this material for the reconstruction of chronic massive RCTs.[22-24]

We are not aware of any study reporting on the use of acellular dermis allograft as an interposition device for the open reconstruction of RCTs, which are severely retracted and not capable of being mobilized. For this reason, we conducted a retrospective study to evaluate the functional outcomes of open rotator cuff reconstruction interposed by human acellular dermis allograft.

Materials and Methods

An Institutional Review Board approval was available for this study (RC-5047). A retrospective chart review of patients who had rotator cuff repair with acellular dermis allograft (GraftJacket; Wright Medical Technology Inc, Arlington, Tennessee) in the practice of the senior author identified 20 such procedures. The criteria for inclusion were: 1) the presence of a massive RCT, which was minimally or not capable of mobilization to the anatomic insertion, 2) the use of GraftJacket (Wright Medical Technology Inc) as an interposition material to bridge the gap between the tendon and the anatomic insertion of the rotator cuff, and 3) a minimum follow up time of 18 months. Cuff tears were characterized as massive intraoperatively, when their size was over 5 cm and a tension free repair was not

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possible with less than 60° of abduction. Five patients had a massive rotator cuff repair with GraftJacket (Wright Medical Technology Inc) augmentation and one was lost from follow up. These patients were excluded from the study.

Fourteen patients (9 men, 5 women) with a mean age of 54.6 years (range, 33-64 years) were included in this study (**Table I**). Operations were done on 9 right and 5 left shoulders, of which nine were the dominant side. Nine out of 14 patients underwent revision repair for a persistent or recurrent RCT. The patients who needed revision surgery had undergone an average of 2.3 procedures prior to the GraftJacket (Wright Medical Technology Inc) interposition procedure. A total of 21 operative procedures had been performed in those patients, before the use of acellular dermis allograft. The average time from onset of symptoms to surgery was 10.1 months (range, 3-24 months). Among the 5 patients who had a primary rotator cuff repair with GraftJacket (Wright Medical Technology Inc) interposition, 4 had a traumatic tear, and 1 had the gradual onset of pain due to a degenerative cuff condition. Of the revision patients, 4 had a new injury and 5 had persistent symptoms after the initial procedure, with 3 of them having worker's compensation insurance.

All patients underwent preoperative radiographs including anteroposterior, axillary, acromioclavicular (AC) joint, and scapular outlet views of the affected shoulder. None of the patients had any evidence of arthritic changes at the glenohumeral joint. Regarding acromion morphology, based on Bigliani classification, 4 patients had type II acromion, 5 had type III, and 5 had a previously performed acromioplasty.[25] Twelve patients had evidence of AC joint arthritis and 2 patients with recurrent RCT had a distal clavicle resection from a previous surgery. The acromiohumeral interval (AHI) was measured on the anteroposterior (AP) shoulder view with the arm at the side in neutral rotation. A value of less than 6 mm was considered indicative of RCTs, as has been proposed by numerous authors.[26-29] The mean AHI was 6.8 mm (range, 4.2-10.2 mm).

Magnetic resonance imaging (MRI) of the affected shoulder was available for all but 1 patient, who had a cardiac pacemaker. All the patients have had a posterosuperior RCT. A severely retracted tendon at the level of the glenoid was identified in the coronal views in all patients. This was considered as a strong indication for interposition, particularly in the revision setting, although the final decision was made intraoperatively. The subscapularis tendon was intact in every case. MRI evaluation for rotator cuff atrophy revealed 6 patients with no evidence of muscle atrophy. The remaining 7 patients had muscle atrophy, with various degrees of fatty infiltration based on Goutallier's classification (**Table I**).[30]

Each patient underwent subjective and objective evaluations. The pain level was measured using a visual analog scale ranging from 0 to 10, with 0 being no pain and 10 representing maximal pain. The range of motion (ROM) was assessed with a goniometer. Muscle strength was evaluated by the British Medical Research Council Scale (BMRC) in a scale from 0 through 5, with 0 corresponding to no movement and 5 cor-

Table I. **Case Summaries**

Case	Age	Gender	Duration of symptoms (months)	Follow-up (months)	Primary/ revision	Number of operations	Acromion type	AC joint arthritis	AHI (mm)
1	59	M	7	22	primary	-	III	yes	9.20
2	47	F	24	20	revision	2	resected	yes	6.20
3	33	M	9	30	revision	2	resected	yes	7.30
4	49	M	5	40	primary	-	III	yes	10.20
5	51	M	15	19	revision	2	resected	resected	7.50
6	63	F	3	23	primary	-	II	yes	4.40
7	64	F	12	50	revision	3	resected	yes	8.30
8	54	M	9	21	revision	3	II	yes	4.60
9	55	M	13	18	revision	2	III	yes	8.10
10	61	M	24	34	revision	2	III	yes	6.80
11	54	M	6	52	revision	2	III	yes	4.20
12	50	M	3	22	primary	-	II	yes	7.60
13	61	F	6	42	revision	3	resected	resected	5.70
14	64	F	6	30	primary	-	II	yes	4.60

Abbreviations: AC joint, acromioclavicular joint; AHI, acromiohumeral interval; MRI, magnetic resonance imaging.

responding to normal muscle function against full resistance. Patients who were unable to abduct their arm to 90° received a strength score of 0 as described by Constant and Murley.[31] Those measurements were assessed by an independent physical therapist. In addition, patients were evaluated using the Shoulder Score of the American Shoulder and Elbow Surgeons (ASES).[32] All patients were asked to grade their general satisfaction according to the following scale: very satisfied, satisfied, or not satisfied. Intraoperative findings and complications were also recorded. The patients were examined preoperatively and postoperatively at 6 weeks, 3, 6 and 12 months, and every 6 months thereafter.

Operative Technique

All operations were performed by the senior author (DGS), with the patients in the beach-chair position under general anesthesia. Diagnostic arthroscopy was performed initially to assess the glenohumeral joint for additional pathology and to evaluate the size, the configuration, and the location of the cuff tear. Chondral lesions of the glenohumeral joint were found in all cases. Five patients had grade 2 chondromalacia, 8 had grade 3, and 1 had grade 4 (early osteoarthritic changes). The long head of biceps (LHB) showed degenerative changes in 9 patients, 7 with moderate to severe fraying, and 2 with a partial rupture. In 1 case the LHB was intact. A chronic rupture of the LHB was found in 2 cases and 2 patients had undergone a biceps tenotomy in a previous surgery. Seven patients with degenerative changes of the LHB underwent biceps tenotomy and 2 biceps tenotomy and tenodesis.

After verifying the presence of a massive RCT the mobility of the rotator cuff was evaluated and if an arthroscopic repair was not amenable, because of extensive retraction (>5 cm) and inability to mobilize it, we proceeded then to an open cuff repair with allograft interposition. A deltoid splitting approach, with detachment of the deltoid from the anterior aspect of the acromion, was utilized to access the rotator cuff. Then, a primary acromioplasty was performed in 9 patients, according to the technique described by Neer.[33] The acromioplasty was revised in 5 patients, because it was considered inadequate. In addition, an open distal clavicle resection was executed in 12 patients with clinical and/or radiographic evidence of AC joint arthrosis. Of the revision patients, 2 had undergone a distal clavicle resection in a previous operation.

The edges of the RCT were identified and debrided and the bone insertion site of the tendon was lightly abrased to create a bleeding surface. Subsequently, the rotator cuff was mobilized utilizing capsular releases. Applying continuous traction to the rotator cuff we measured the distance between the anatomic insertion onto the great tuberosity and the torn tendon edge. This was defined as the tendon gap, which had to be bridged with the allograft. The mean tendon gap was found to be 1.82 cm (range, 1-2.5 cm). Next, the allograft was interposed in order to cover the defect. We attempted to cover as much defect as possible on the humeral head. The GraftJacket (Wright Medical Technology Inc) was tied down anteriorly, posteriorly, and medially to the cuff with FiberWire sutures (Arthrex Inc, Naples, Florida). Laterally, the graft was fixed to the bone with suture anchors. The 5.5 mm Bio-Corkscrew FT suture anchor (Arthrex Inc, Naples, Florida) containing two number-2 FiberWire sutures (Arthrex Inc) were used for tendon to bone reattachment. The number of suture anchors, used to reattach the tendon to bone, was based on the size and configuration of the tear (range, 2-5 anchors).

MRI findings					
Muscle atrophy	Fatty infiltration Grade	Chondral lesions Grade	Biceps status	Biceps management	Gap size (cm)
N/A	N/A	3	frayed	tenotomy	1.5
yes	3	2	frayed	tenotomy	2.5
no	0	3	frayed	tenotomy	2.5
yes	1	2	parial rupture	tenodesis	1.5
no	0	2	chronic rupture	tenotomy	1.0
no	0	3	frayed	tenotomy	1.5
yes	3	2	intact	tenotomy	2.5
no	0	3	chronic rupture	tenotomy	1.5
yes	1	3	tenotomized	tenotomized	2.5
no	0	2	parial rupture	tenotomy	2.0
yes	4	4	tenotomized	tenotomized	1.5
yes	1	3	frayed	tenodesis	1.0
no	0	3	frayed	tenotomy	2.5
yes	2	3	frayed	tenotomy	1.5

Postoperative Regimen

Postoperatively, all patients followed a standard protocol of rehabilitation. The arm was maintained in a sling with 30° of abduction and internal rotation for 6 weeks to protect the repair. Sutures were removed at 2 weeks. Passive ROM was initiated at 4 to 6 weeks and active ROM was started at 6 to 8 weeks. Strengthening was commenced at 12 weeks.

Statistical Analysis

The Wilcoxon signed-rank test was used to compare the pre- and post-operative numerical data. The means of variables between independent groups

Table II. **Preoperative and Postoperative Data**

	Preoperative					Postoperative					
Case	Pain	FF	Abd	ER	ASES Score	Pain	FF	Abd	ER	ASES Score	Satisfaction
1	6	125°	100°	20°	25	1	170°	170°	80°	92	very satisfied
2	8	20°	20°	0°	15	2	60°	60°	20°	54	not satisfied
3	4	30°	30°	0°	18	2	80°	80°	30°	56	not satisfied
4	7	120°	100°	0°	28	0	180°	180°	50°	92	very satisfied
5	6	130°	100°	30°	32	0	180°	180°	50°	92	very satisfied
6	8	60°	60°	15°	28	2	120°	100°	25°	68	satisfied
7	8	30°	30°	0°	16	3	100°	100°	30°	52	satisfied
8	8	90°	70°	0°	30	3	90°	90°	30°	62	satisfied
9	8	80°	90°	10°	28	1	160°	90°	45°	86	very satisfied
10	8	80°	80°	0°	18	1	180°	180°	75°	68	very satisfied
11	8	60°	60°	0°	28	3	90°	90°	30°	56	satisfied
12	9	80°	80°	0°	15	0	180°	180°	75°	94	very satisfied
13	7	80°	80°	35°	34	5	60°	60°	20°	62	not satisfied
14	8	45°	45°	10°	18	1	160°	90°	45°	78	very satisfied

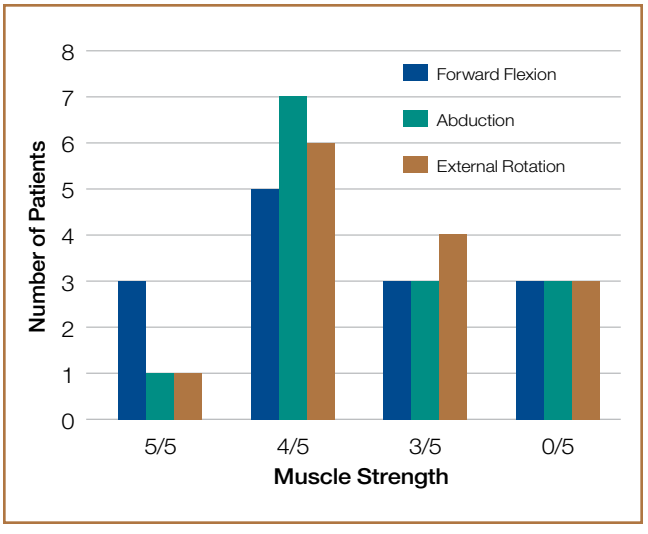
Abbreviations: Abd, abduction; ASES, American Shoulder and Elbow Surgeons; ER, external rotation; FF, forward flexion.

(primary vs. revision repair) were tested by the Mann-Whitney test. Spearman's rank correlation coefficient (r_s) was used to test the statistical association between variables. All reported P-values are two-tailed with P<.05 being considered significant. The analysis of the data was carried out using the statistical software package SPSS version 17.0 (SPSS Inc, Chicago, Illinois).

Results

The mean follow-up time was 30.2 months (range, 18-52 months). **Table II** demonstrates the preoperative and postoperative data for each case.

Figure. Diagram showing the distribution of the patients according to the postoperative muscle strength measurements.



All patients experienced significant pain relief. The mean preoperative pain score improved from 7.4 points (range, 4-9 points) to 1.7 points (range, 0-5 points) at 18 months follow up ($P = .001$). The improvement of pain was maintained in patients with longer follow up time. ROM significantly improved postoperatively. The average forward flexion improved from 73.6° preoperatively to 129.3° postoperatively ($P = .002$). Preoperatively active forward flexion was 90° or less in 11 patients (78.5%). At the final follow-up, 7 patients had greater than 150° of forward flexion and only 5 patients demonstrated forward elevation under 90°. The mean abduction improved from 67.5° preoperative to 117.9° postoperatively ($P = .002$). The average external rotation increased from 7.9° preoperatively to 43.2° postoperatively ($P = .001$). The mean pre- and post-operative values are summarized in **Table III**.

Muscle strength measurements according to BMRC are shown in the **Figure**. Three patients were unable to abduct the shoulder up to 90° and were considered to have 0/5 muscle strength, whereas another 3 patients with only 90° of abduction did have 3/5 strength. The muscle strength in the remaining 8 patients was at least 4/5 (**Figure**).

The mean ASES Score improved from 23.8 points (range, 15-34 points) preoperatively to 72.3 points (range, 52-94 points) postoperatively at the final follow-up ($P = .001$). Of 14 patients, 11 were satisfied or very satisfied and 3 patients were not satisfied with the outcome of the surgical procedure.

Between patients who had primary rotator cuff repair and those with revision repair there was no statistical significant difference in pre- and post-operative pain, ROM, and ASES score. The only significant difference between those groups

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Table III. Mean Pre- and Post-operative Values for Range of Motion, Pain, and ASES score

	Preoperative	Postoperative	*P* value†
Pain (Visual Analog Scale)	7.4 (4-9)	1.7 (0-5)	.001
Forward flexion	73.6° (20°-130°)	129.3 (60-180)	.002
Abduction	67.5° (20°-100°)	117.9° (60°-180°)	.002
External rotation	7.9° (0°-35°)	43.2° (20°-75°)	.001
American Shoulder and Elbow Score (ASES)	23.8 (15-34)	72.3 (52-94)	.001

†Wilcoxon's signed ranks test

Table IV. Correlation of Tendon Gap to Postoperative Variables

	Postoperative Pain	Postoperative FF	Postoperative Abd	Postoperative ER	Postoperative ASES Score
Spearman's ρ	.553	-.633°	-.656°	-.534°	-.685
P value	.04	.015°	.011°	.049°	.007

Abbreviations: Abd, abduction; ASES, American Shoulder and Elbow Surgeons; ER, external rotation; FF, forward flexion.

was the size of the tendon defect. The mean tendon gap was 1.4 cm in the patients with no previous surgery and 2.056 cm in the revision group ($P = .046$).

We have also found a statistically significant correlation between the size of the tendon gap and the postoperative pain, ROM, and ASES score. The statistical correlation of the tendon gap with each parameter is summarized in **Table IV**. Of the 5 patients with active forward flexion below 90°, 3 patients had a tendon gap of 2.5 cm.

The AHI was found to have significant correlation only with the final postoperative pain ($r_s = -.54$, $P = .046$). There was no significant correlation between the age, sex, duration of symptoms, type of acromion, presence of AC joint arthritis, muscle atrophy, fatty infiltration and the pain, ROM or ASES score. No foreign body reaction or complication relating to rejection of the acellular dermal allograft was observed in this study.

Discussion

Management of massive irreparable RCTs represents a therapeutic challenge, especially in patients younger than 70 years, with no evidence of glenohumeral joint arthritis. In such cases, tissue engineered biomaterials can be used as an alternative reconstructive procedure. Currently, there are several tissue-engineered biomaterials for the reinforcement of a rotator cuff repair but the outcomes of the clinical studies have been mixed. In this study, the GraftJacket allograft (Wright Medical Technology Inc) was utilized as a bridging patch for reconstruction of chronic massive irreparable RCTs, through a deltoid split approach. The purpose of this study was to report the outcome of this technique.

All the patients of the present series demonstrated significant pain reduction postoperatively and this may explain the high satisfaction rate among them. We believe that the combination of acromioplasty, distal clavicle excision and biceps tenotomy or tenodesis plays a fundamental role in pain reduction. Regarding the long head of the biceps tendon, there is no reason to preserve it, as its function as a humeral head depressor is minimal to absent.[34] In addition, biceps pathology is known to be responsible for continued pain in cases of irreparable RCTs.[35,36] Biceps tenodesis was performed in 2 men, with an age under 60 years, to avoid "Popeye" sign.

The ROM of the affected shoulder improved significantly, with greater than 100° postoperative active forward flexion in the majority of the patients (9/14). The mean ASES score increased from 23.8 points preoperatively to 72.3 points at the final follow-up ($P = .001$). The pain, ROM, and functional outcome was found to have significant correlation with the size of the tendon gap, which had to be bridged by the allograft. Patients with more than 2 cm tendon gaps had worse pain, ROM, and ASES score, compared with tendons with smaller gaps.

The GraftJacket allograft (Wright Medical Technology Inc) has been used successfully by other authors for the reconstruction of irreparable cuff tears.[22-24] Burkhead and colleagues[24] reported on a series of 17 patients after open reconstruction with dermal allograft. After a mean follow-up of 1.2 years 64% of the patients reported no or occasional slight pain and 70% had normal function or slight restriction, with 10 patients having greater than 150° active forward elevation. The University of California, Los Angeles (UCLA) score improved significantly from a mean 9.06 preoperatively to 26.12 postoperatively.[24] The authors were able to achieve an anatomic repair of the rotator cuff, utilizing side-to-side margin convergence sutures. The dermal allograft was used to augment the repair, as there was no tendon defect, and for this reason, their results cannot be compared to ours.

The only reports using the GraftJacket (Wright Medical Technology Inc) as a bridging device to reconstruct rotator cuff defects are from Snyder's group.[22,23,37] With their novel technique, they demonstrated good results in 45 patients. The mean UCLA score increased from 18.4 preoperatively to 27.5 postoperatively ($P < .001$). The average Western Ontario Rotator Cuff score was 75.2, and the ASES score was 84.1 at the final follow-up. They concluded that the procedure is safe with a high patient satisfaction rate and without the morbidity of tendon transfer or arthroplasty.[23] However, this is an all-arthroscopic technique, which requires significant technical experience and time, and we are concerned about the reproducibility of the results.

Acellular dermal allograft has shown excellent biocompatibility in soft tissue surgery, including Achilles' tendon recon-

struction, rotator cuff repair, and thumb carpometacarpal joint arthroplasty.[18-20,22-24] In our study, there was no foreign body reaction or complication relating to rejection of the dermal allograft. Regarding the biocompatibility, the porcine dermal xenograft has demonstrated no adverse events.[16,17] In contrast, sterile inflammatory reactions and aseptic drainage have been reported after using collagen-based material derived from porcine small intestine submucosa.[14,38]

Xenografts have been used for rotator cuff reconstruction but the reported results are unfavorable. Collagen patches derived from porcine small intestine submucosa have demonstrated low healing potential with high failure rate and poor functional outcomes.[14,15,38] Cross-linked porcine dermis has been recently used by Soler and colleagues[16] as a bridging device to reconstruct massive rotator cuff defects in four patients. All procedures failed 3 to 6 months postoperatively, and the authors concluded that porcine dermis graft should not be used to bridge massive irreparable RCTs.[16] The only favorable outcome of xenografts as augmentation patches is from Badhe and colleagues.[17] Their study showed significant improvement in the mean Constant score, pain, and ROM in 10 patients who were treated with porcine dermis xenograft. They also found that 8 patients had an intact repair, proven by MRI, at an average of 4.5 years postoperatively.[17]

Comparable to our study, results have been published with other alternative techniques, in the case of chronic massive irreparable RCTs. Arthroscopic debridement with or without subacromial decompression has been reported to have satisfactory short-term outcomes.[10,39,40] In our practice this procedure is primarily indicated for elderly, low-demand patients with pain, but good preservation of preoperative active motion. Partial repair of irreparable RCTs has been shown good outcomes.[8,9] This procedure should be considered as an option only in the setting of good tissue quality, when an isolated repair of the infraspinatus or margin convergence rotator cuff repair can be performed safely. Tendon transfer represents another alternative procedure for this complex entity.[7,11,13,41] Although favorable results have been published with the transfer of latissimus dorsi, tendon for irreparable posterosuperior RCTs, patient selection plays a major role for a successful outcome.

In our opinion, the tendon transfer of latissimus dorsi is a viable surgical option for young patients with an adequate preoperative active motion with at least 90° of arm elevation, who require strength to perform occupational tasks and they are willing to participate in a long and rigorous rehabilitation program. The use of biologic patches as bridging devices appears to be a good alternative for the anatomic reconstruction of irreparable RCTs, whenever the indications are against a palliative (debridement, nonanatomic repair) or a salvaging (tendon transfer) procedure.

This study showed that acellular dermal allograft can be used safely and with good results for the treatment of chronic massive irreparable RCTs as an interposition graft. However, the study has some inherent limitations such as the retrospective nature and the lack of a control group. Hence, additional prospective, randomized studies will be necessary to assess the definitive validity of this method.

Conclusion

The treatment of chronic massive irreparable RCTs can be problematic due to severe retraction and poor quality of tissues. This challenge can be addressed, alternatively, using tissue engineered biomaterials as bridging devices. The acellular human dermis allograft has demonstrated the most favorable outcomes among all available off the shelf grafts. In our series the GraftJacket allograft (Wright Medical Technology Inc) has been used successfully to bridge up to 2 cm tendon gaps of the rotator cuff. The ROM and the functional outcome were all improved in the patients with less than 2 cm tendon gap. In the case of larger tendon defects the outcome is unpredictable.

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