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Superior capsular reconstruction using a porcine dermal xenograft for irreparable rotator cuff tears: outcomes at minimum two-year follow-up

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Purpose: To evaluate midterm outcomes of arthroscopic superior capsular reconstruction (SCR) using a decellularized porcine dermal xenograft in patients with massive, irreparable rotator cuff tears and to determine the influence of concomitant, repairable subscapularis tears.

Methods: This is a retrospective study of 56 patients with a minimum 2-year follow-up. Preoperative and postoperative range of motion, American Shoulder and Elbow Surgeons score, Subjective Shoulder Value, and visual analog score for pain were measured. Postoperative data were collected at 3, 6, 12, 24, and 36 months.

Results: Of the 56 patients who underwent arthroscopic SCR, there were 39 men and 17 women. The mean age at operation was 65 ± 9 years, and the mean follow-up was 34 ± 8 months. The mean preoperative American Shoulder and Elbow Surgeons improved from 41 ± 19 to 78 ± 18 at 24 weeks, to 86± 16 at 12 months, and to 90±9 at 24 months, $P < .0001$. Similarly, the mean preoperative Subjective Shoulder Value improved from 39 ± 17 to 74 ± 18 at 24 weeks, to 80 ± 18 at 12 months, and to 80 ± 11 at 24 months, $P < .0001$. The mean preoperative visual analog score improved from 6.5 ± 2.1 to 1.4 ± 2.2 at 24 weeks, to 0.7± 1.1 at 12 months, and to 0.2 ± 0.4 at 24 months, $P < .0001$. There were no differences in outcome scores between patients with intact vs. repaired subscapularis. Similarly, no statistically significant differences were found in forward flexion or external rotation after SCR between patients with an intact vs. repaired subscapularis. Failure of the SCR graft was observed on magnetic resonance imaging in 14 patients, 4 of whom opted for revision to reverse shoulder arthroplasty. Eleven patients were truly pseudoparalytic before surgery; in 5 cases, pseudoparalysis was reversed after SCR.

Conclusions: SCR can alleviate pain and disability from irreparable rotator cuff tears and provide significant improvements in shoulder function; however, the xenograft technique resulted in inconsistent reversal of true pseudoparalysis. No difference was found between patients who required concomitant subscapularis repair vs. those who did not.

Level of evidence: Level IV; Case Series; Treatment Study

Keywords: Superior capsular reconstruction; dermal xenograft; massive rotator cuff tears; pseudoparalysis; subscapularis tears; arthroscopy

Massive rotator cuff tears, defined as complete tears of 2 or more tendons with retraction beyond the humeral head, result in altered shoulder kinematics and if left untreated may progress to superior translation of the humeral head and cuff tear arthropathy.[12,25,26] The definition of

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irreparability of rotator cuff tears varies, as it is determined by a combination of preoperative and intraoperative factors such as grade of fatty infiltration (Goutallier grade 3 or 4), acetabularization of the acromion, femoralization of the humeral head and/or failure of arthroscopic release techniques, interval slides, and rip-stop fixation.[17] In the elderly or low-demand patients, reverse shoulder arthroplasty (RSA) is a reliable option for massive irreparable rotator cuff tears. However, RSA may not be appropriate for younger individuals or patients requiring higher levels of shoulder activity due to the high reported complication rates and possible need for revision surgery in the future.[2,6,10] For these cases, in which glenohumeral arthritis is not present, tendon transfers have been used; nevertheless, pain relief and functional improvement reports have been variable in addition to the added difficulty of lengthy rehabilitation protocols.[1,13,24]

Superior capsular reconstruction (SCR) for the treatment of irreparable rotator cuff tears was first described in 2012 by Mihata et al.[21] In this study, the authors emphasized graft attachment medially to the superior glenoid and laterally to the greater tuberosity to restore superior stability of the humeral head.[21] The advantages of the SCR procedure include low complication rate, standardized rehabilitation protocol, and easy revisability in case of failure. In recent years, various types of grafts (autologous fascia lata and dermal decellularized allograft) have been proposed to recreate superior stability, therefore improving the overall function of the shoulder joint by restoring glenohumeral kinematics.[5,9,21]

In our country, the human dermal allograft, Arthroflex (LifeNet Health, Virginia Beach, VA, USA), was not available, for cost and regulatory reasons; therefore, the only non-autograft option available to use for SCR was the porcine xenograft dermal extracellular matrix, DX Reinforcement Matrix (Arthrex Inc., Naples, FL, USA).

The aim of this study is to establish the results of patients with massive, irreparable rotator cuff tears treated with an arthroscopic SCR using this decellularized porcine dermal xenograft. In addition, this study evaluates the influence on outcomes of concomitant, repairable subscapularis tears: the rate of graft survival and the reversal of pseudoparalysis with this technique.

Materials and methods

This is a multicenter retrospective review of prospectively collected data of a continuous series of patients with massive irreparable cuff tears who were treated with an arthroscopic SCR technique using a doubled-over DX Matrix graft. All patients included had massive irreparable posterosuperior cuff tears with an intact or repairable subscapularis and no or minimal (grade 1 Outerbridge cartilage wear at arthroscopy) glenohumeral arthritis. The exclusion criteria were as follows: irreparable rotator cuff tears involving the subscapularis and/or teres minor, glenohumeral joint changes with Hamada classification 4 or 5, history of fractures involving the glenohumeral joint, and inability to comply with postoperative rehabilitation.[14]

A total of 56 patients were included for review at a mean duration of 34 months postoperatively. Informed consent was obtained from all participating patients.

All patients completed a physiotherapy rehabilitation protocol developed specifically for the SCR procedure (Supplementary Appendix S1) and completed the American Shoulder and Elbow Surgeons (ASES) score, Subjective Shoulder Value (SSV), and visual analog score (VAS) preoperatively, and at 3 months, 6 months, 1 year, 2 years, and 3 years postoperatively. Active range of motion was also measured. In addition, the following data were collected: age, gender, laterality, Hamada grade, acromiohumeral distance, presence of subscapularis tear, and number of patients with ''true'' pseudoparalysis before surgical intervention. Pseudoparalysis was predefined as the inability to actively elevate the arm above 90° with anterosuperior escape, despite full passive range of motion, and a positive drop-arm sign. We applied this strict definition of pseudoparalysis as we felt that other definitions may relate to simple weakness or pain-related inability to elevate the arm.

Surgical technique

The arthroscopic capsular reconstruction technique was performed either in the beach chair or lateral decubitus position, depending on surgeon preference.

Principles of rotator cuff repair were followed including tear pattern recognition, footprint preparation, and identification of the direction of mobilization. If tenosynovitis of the biceps was present, a tenotomy or tenodesis was performed, depending on the patient's age and activity level. If the subscapularis tendon was torn, we began by repairing this tendon first. Depending on the type of tear, a single- or double-row repair was used. If the supraspinatus and/or infraspinatus were found to be truly irreparable, the subscapularis was repaired or intact, and the patient displayed minimal or no glenohumeral arthritis, an SCR was performed.

Two cortical anchors were placed in the glenoid superiorly, with care not to penetrate the glenoid cartilage. Two medial row humeral anchors were placed, and the distances between the 4 anchors were measured in order to size the graft.

The 6 × 8 cm DX Matrix graft (Arthrex Inc.), which is on average 1.5 mm thick, was folded on itself to give a double layer, equating to approximately 3 mm thickness. A topical skin adhesive (Dermabond; Ethicon, Somerville, NJ, USA) was used to attach the 2 layers together (Fig. 1).

Subsequently, the sutures from the glenoid anchors were passed through the graft. The graft was passed into the shoulder joint using the glenoid sutures, a traction suture passed through the Neviaser portal, and an arthroscopic grasper (Fig. 2). Then, the glenoid sutures were tied down. Any remaining native rotator cuff tissue medially was repaired to the graft via these glenoid sutures also. A transosseous equivalent double-row repair was performed on the lateral aspect of the graft to secure it to the humerus. The graft was then repaired with 2 to 3 side-to-side sutures to the remaining infraspinatus/teres minor posteriorly (Fig. 3). After the conclusion of the procedure, the patient was placed in a 15° abduction shoulder immobilizer in neutral rotation for 6 weeks and followed a specific rehabilitation protocol designed at our institution (Supplementary Appendix S1).

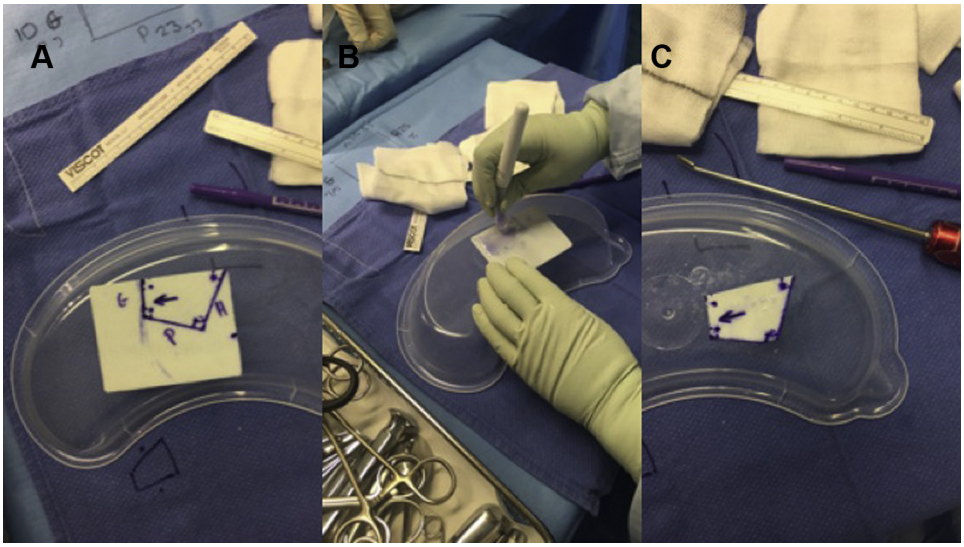

Figure 1 (**A**) Drawing of the arthroscopic measures on the porcine dermal xenograft. (**B**) Application of the dermal adhesive. (**C**) Final folded-over graft.

Statistical analysis

Continuous data with normal distribution are presented as mean ± standard deviation. Categorical variables are represented by frequencies. Patients were then analyzed in 2 comparison groups: those with a repairable subscapularis (group 1) and those with an intact subscapularis (group 2). Differences in continuous variables between categories of patients were studied by the unpaired Student *t*-test, the Mann-Whitney *U*-test (in case of non-normal distribution), or the analysis of variance *t*-test, where applicable. The Bonferroni post hoc test was used to determine where the difference was between groups. Differences in proportions were analyzed by the χ^2 test or the Fisher exact test, where applicable. Pearson coefficient of correlation was used to estimate an association between the Hamada grade and outcome scores. All statistical tests were performed with SPSS software (version 20.0; IBM, Armonk, NY, USA). A 2-tailed P value $< .05$ was considered statistically significant.

Results

Of the 56 patients who underwent arthroscopic SCR, there were 39 men and 17 women (Table I). The mean age at operation was 65 ± 9 years, and the mean follow-up was 34 ± 8 months. This was a continuous series, and no patients were lost to follow-up. Of the 46 patients with available preoperative imaging studies for review, 18 patients (39.1%) were Hamada grade 1, 23 (50.0%) were Hamada grade 2, and 5 patients (10.9%) were Hamada grade 3. The mean acromiohumeral distance preoperatively was 5.4 ± 2 mm and was measured in the sagittal plane of the magnetic resonance imaging (MRI) as the shortest distance between the apex of the head and the acromion.[23]

The 52 patients who did not undergo revision to RSA were included in the statistical analysis. In these patients, the mean preoperative ASES improved from 41 ± 19 to 78 ± 18 at 24 weeks, to 86 ± 16 at 12 months, and to 90 ± 9 at 24 months, $P < .0001$ (Table II). Similarly, the mean preoperative SSV improved from 39 ± 17 to 74 ± 18 at 24 weeks, to 80 ± 18 at 12 months, and to 80 ± 11 at 24 months, $P < .0001$. There was a significant decrease in pain levels as evidenced by the mean VAS values at the 24-week follow-up (Fig. 4). The mean preoperative VAS improved from 6.5 ± 2.1 to 1.4 ± 2.2 at 24 weeks, to 0.7 ± 1.1 at 12 months, and to 0.2 ± 0.4 at 24 months, $P < .0001$. At each time point, the preoperative value was compared with the most recent value and assessed for significance. Patients revised to RSA were excluded from the analysis. In addition, we performed a correlation analysis between preoperative Hamada grade and postoperative outcome scores of patients with available preoperative imaging and found no significant association in any of the follow-ups, bearing in mind that no Hamada grade 4 or 5 patients were offered SCR.

Subgroup analysis was performed between group 1 (subscapularis repair) and group 2 (subscapularis intact). In

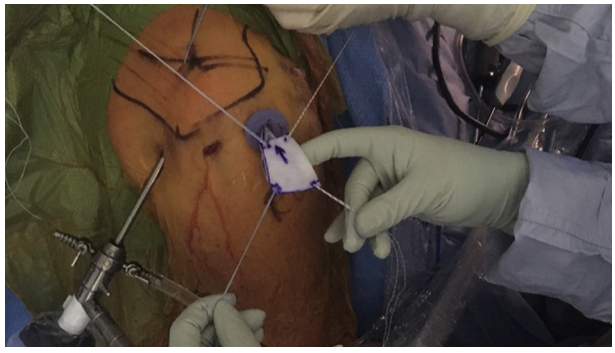

Figure 2 Passage of the graft into the shoulder joint.

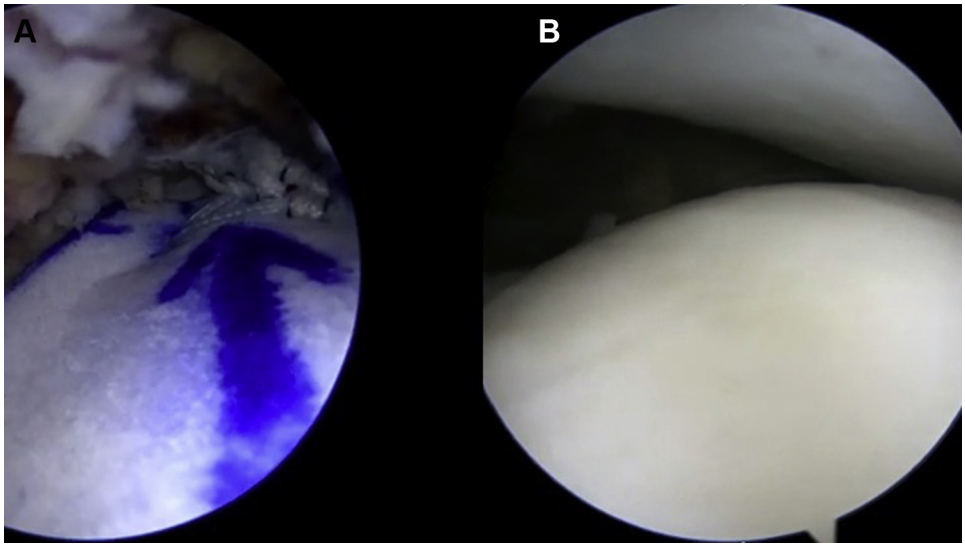

Figure 3 (**A**) Subacromial view of the attached graft at the glenoid level. (**B**) Glenohumeral view from the posterior portal of the attached graft at the humeral level.

Table I Patient characteristics

	N = 56
Age (yr), mean ± SD	65 ± 9
Sex, male:female	39:17
Follow-up (mo), mean ± SD	34 ± 8
Previous rotator cuff repair surgery	n = 16 (29%)
Hamada grade (1:2:3:4:5) (n = 46)	18:23:5:0:0
AHD (mm), mean ± SD (n = 46)	5.43 ± 2

SD, standard deviation; *AHD*, acromiohumeral distance.

terms of patient-reported outcomes at 24 weeks, there were no differences between patients with an intact or repaired subscapularis in mean ASES ($P = .36$), SSV ($P = .63$), or VAS pain score ($P = .89$). In addition, there were no differences between the 2 groups in terms of active forward flexion (129° ± 46° group 1 vs. 139° ± 31° group 2, $P = .60$) or active external rotation (45° ± 11° group 1 vs. 43° ± 9° group 2, $P = .68$) (Table III).

With our definition of ''true'' pseudoparalysis, a total of 11 patients were classified as pseudoparalytic before surgery (Table IV). After the SCR procedure, 5 patients (45%) had complete reversal of their pseudoparalysis at 1-year follow-up (Table IV).

Failure of the surgical technique was defined as graft detachment (either humeral or glenoid side) confirmed by MRI. There were a total of 14 graft failures. Of these, 4 patients opted for revision to RSA (Table IV).

Discussion

In this study, we provide insight into midterm results obtained in 2 high volume centers using a specific technique of SCR with a decellularized porcine dermal xenograft. This type of procedure has only been reported in 1 study to date, with a smaller sample size and shorter follow-up. In addition, we provide a detailed description of the technique to confer reproducibility.[16]

With this technique, patients experienced a significant, progressive improvement in range of motion, ASES scores,

Table II Patient-reported outcome measures

Outcome questionnaires	Preoperative	24 weeks (n = 51)	12 mo (n = 49)	24 mo (n = 42)	*P* value
ASES	41 ± 19	78 ± 18	86 ± 16	90 ± 9	<.0001*
VAS	6.5 ± 2.1	1.4 ± 2.2	0.7 ± 1.1	0.2 ± 0.4	<.0001*
SSV	39 ± 17	74 ± 18	80 ± 18	80 ± 11	<.0001*

ASES, American Shoulder and Elbow Surgeons; *VAS*, visual analog score; *SSV*, Subjective Shoulder Value.
* Preoperative vs. 24 weeks/12 mo/24 mo.

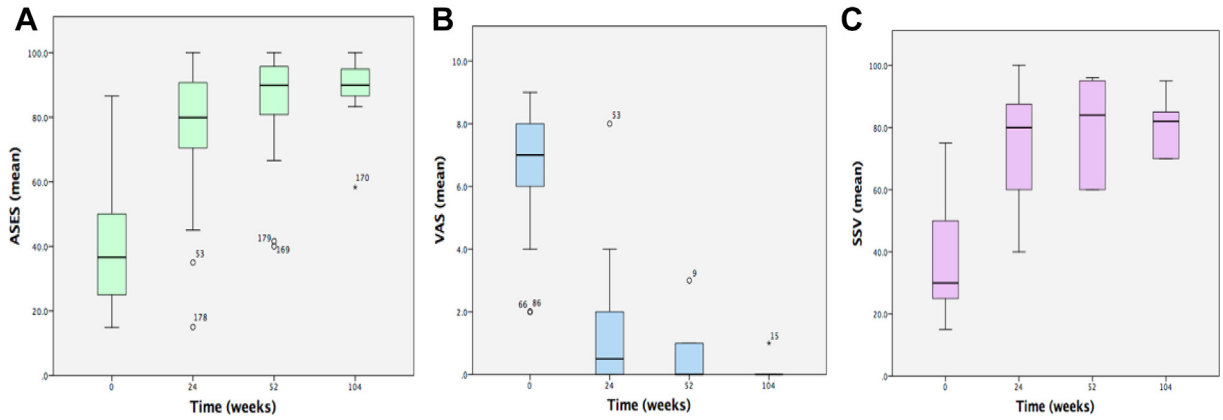

Figure 4 Patient-reported outcome scores. (**A**) Mean ASES scores vs. time (weeks). (**B**) Mean VAS scores vs. time (weeks). (**C**) Mean SSV vs. time (weeks). *ASES*, American Shoulder and Elbow Surgeons; *VAS*, visual analog score; *SSV*, Subjective Shoulder Value.

Table III Influence of concomitant subscapularis repair on patient-reported outcome measures at 24 weeks

	Subscapularis repair (n = 24)	Subscapularis intact (n = 32)	*P* value
ASES	81 ± 10	76 ± 21	.35
SSV	75 ± 19	71 ± 19	.63
VAS	1 ± 2	1 ± 3	.89
aFF	129 ± 46	139 ± 31	.60
aER	45 ± 11	43 ± 9	.68

ASES, American Shoulder and Elbow Surgeons; *SSV*, Subjective Shoulder Value; *VAS*, visual analog score; *aFF*, active forward flexion; *aER*, active external rotation.

SSV, and a decrease in pain levels.[3,15,18] This suggests that the SCR with dermal xenograft, in appropriately selected patients, provides a viable solution to irreparable rotator cuff tears. The most notable aspect of this technique is the rapid improvement in the visual analog pain scale reported by the patients as early as 3 months postoperatively, reaching nearly zero at the 1-year follow-up. This decrease in pain levels may be attributed to the spacer effect of the SCR, which prevents proximal migration of the humeral head and restores a more normal glenohumeral joint position during shoulder movement.[28] In addition, low VAS scores could also be explained due to the fact that patients with graft failure who required revision to RSA were not included in the statistical analysis.

We then decided to further evaluate our results by dividing the patients into 2 groups: those who required a subscapularis repair and those in whom the subscapularis was intact. There were no differences in terms of ASES, SSV, VAS, and range of motion in patients who required an additional subscapularis repair compared with those in whom the subscapularis was intact. This finding is important, as it reinforces the potential mechanism of action of the SCR as a force coupler, with the repair of a torn subscapularis being paramount.[29]

With our definition of pseudoparalysis, only 45% of the patients were able to reverse pseudoparalysis with the SCR dermal xenograft. Our results differ from other authors who have higher rates of pseudoparalysis reversal.[3,19] There are several reasons for this discrepancy such as difference in the definition of pseudoparalysis, graft type, graft thickness, and fixation technique.[30] In our experience, pseudoparalysis defined as inability to actively elevate the arm above 90° with anterosuperior escape despite full passive range of motion, and a positive drop-arm sign, is not reliably reversed by the SCR procedure. Even though SCR has the advantage of being a joint preserving option with a low rate of complications, it is in this subgroup of patients that further biomechanical and clinical studies would be beneficial.

In our study, we had a total of 14 graft failures (25% failure rate) at a mean follow-up of 34 months, 4 of whom elected to undergo revision to an RSA. Our failure rate is higher than that reported by other studies and may be due to our longer follow-up, type of technique used, or to positive publication bias.[4,16] When we analyzed our results at 1 year, our failure rate was only 10% (n = 6), which is similar to that published in the literature. Thus, we believe that longer follow-up may lead to an increase in failure rates.

Symptomatic patients with low scores in patient-reported outcome measures were sent for MRI to assess for graft failure. Similar to other studies, all of the graft failures in our series were at the lateral graft-bone interface at the rotator cuff footprint on the greater tuberosity of the humerus.[7,8] Patients with graft failure had no history of further trauma, and thus the cause of graft failure in the humeral side remains unclear. Some authors suggest that failure of the graft such as suture cutout might be related to graft thickness, indicating that a 3-mm-thick dermal xenograft is not equivalent to the 6- to 8-mm-thick autologous fascia lata initially described by Mihata.[20,27] Future studies are required to evaluate optimal graft material and thickness.

Table IV Postoperative characteristics

	Number of patients (n = 56)
Pseudoparalysis reversed (yes:no) (total n = 11)	5:6
Graft failure	14
Need for further surgery (reverse shoulder arthroplasty)	4

Currently, we do not know the exact number of graft failures in our series because it has not been possible to routinely MRI asymptomatic patients. Thus, there is the possibility that graft failure might be actually higher than reported in the literature.[9,11,18,29] If the decision to order imaging studies is based on patient-reported outcome measures, in particular SSV, it does lead to the question of whether SCR graft integrity is needed to maintain acceptable patient satisfaction, or if in fact the SCR graft is merely acting as a temporary spacer that decreases pain levels to perform a deltoid-modified rehabilitation protocol.

There are several limitations to this study. First, this is a retrospective study with prospectively collected data on a continuous series of 56 patients. However, this sample size is comparable to other studies and is the largest in size and follow-up reported thus far with this specific technique.[3-5,7,16]

Another limitation is related to the method of radiographic measurements. The Hamada classification and measurement of the acromiohumeral distance were first described from plain radiographs. In our study, because of health insurance issues in our country, not all patients had radiographs for analysis, but all had an MRI. We therefore measured the acromiohumeral distance from the available MRIs and established the Hamada grade based on that distance. In this study, the acromiohumeral distance (AHD) on MRI was obtained as the shortest distance between the apex of the head and the acromion on the sagittal MRI. However, latest research suggests that AHD measurements between radiograph and MRI of the same shoulder with massive rotator cuff tears should not be used interchangeably in early Hamada grades to assess outcomes of superior capsule reconstruction.[22] Nevertheless, in our study, MRI was used as a preoperative classification of patients to confirm Hamada grade <3 and not for evaluation of the efficacy of the SCR.

A further limitation relates to the fact that patients with graft failure confirmed by MRI and requiring revision to RSA were excluded from the statistical analysis. This could explain the high mean patient-reported outcome scores.

Lastly, because patients were treated in 2 different centers, there was some potential variability in surgeon preference in terms of the classification system used to grade the type of subscapularis tears. This meant that subscapularis subanalysis was only performed between the presence of tear vs. the absence of tear and not by tear type. Perhaps analysis by tear type would have helped further understand the importance of subscapularis repair in combination with SCR reconstruction.

Conclusions

Despite the 25% failure rate, SCR alleviates pain and disability from irreparable rotator cuff tears in the majority of patients and provides significant improvements in shoulder function. No differences in outcomes were found between patients who required an additional subscapularis repair vs. those who had an intact subscapularis. In our experience, SCR using a doubled porcine dermal xenograft results in inconsistent reversal of pseudoparalysis when a strict definition of pseudoparalysis is applied. We prefer to consider RSA for these patients at the present time.

Disclaimer

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Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.jse.2020.08.020.

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