Title of the Study

Mid-term outcome of superior capsular reconstruction using doubled acellular human dermal allograft for irreparable rotator cuff tear

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Abstract

Purpose: Thicker (folded) facia lata autografts have been shown to be superior to thinner grafts and single-layered acellular human dermal (HD) allografts for superior capsular reconstruction (SCR) in biomechanical studies. The aim of this study was to evaluate the mid-term clinical outcomes following SCR for irreparable supraspinatus tears using doubled (folded) HD allograft.

Methods: Thirty-two patients who had undergone SCR using doubled HD allograft between February 2012 through January 2020 were recruited in a continuous manner in this retrospective study. The inclusion criteria were SCR performed for irreparable supraspinatus tear and a minimum of two years follow-up. The primary outcome measure was the American Shoulder and Elbow Surgeons (ASES) score. The secondary outcome measures were complications and revision surgery. A subgroup analysis was performed between patients who received a "Standard" graft of mean 3mm thickness or a "Thick" graft of mean 4.4mm thickness.

Results: One patient was lost to follow up. A total of 31 patients (31 shoulder joints) were analysed with mean follow up duration of 48 months (range, 25-96 months). Following surgery, there was significant improvement in ASES score from 18.1 ± 14.3 (preoperative) to 76.3 ± 25.1 (post-operative) ($P < 0.001$) with a satisfactory clinical outcome obtained in 83.8% of the patients. In a subset of eight patients completing five-years follow up, clinical improvements were sustained. The percentage of patients with a clinically successful outcome was higher with thick grafts compared to patients with standard grafts, although this failed to reach statistical significance (94.4% vs 69.2%, RR=1.36 (95%CI 0.93-1.99, $P = 0.13$). One patient within the standard group underwent revision surgery.

Conclusion: SCR for irreparable rotator cuff tears with doubled HD allograft results in improved clinical outcomes and low reoperation at mid-term follow up duration.

Level of evidence: Level IV, Retrospective case series

Key Terms: Dermal allograft; outcome; rotator cuff tear; superior capsular reconstruction.

Introduction

Superior capsular reconstruction (SCR) provides an alternate option for irreparable supraspinatus tears with promising early outcomes reported, demonstrating excellent pain relief and restoration of function in younger individuals with preserved glenohumeral cartilage.[3] SCR was originally proposed by Mihata et al[21] using fascia lata (FL) autograft to re-establish superior stability and restore glenohumeral biomechanics.[19] Mihata et al[17] has published five-year clinical results of SCR using 5mm thick FL grafts demonstrating excellent outcomes with an improvement in ASES score of 63.3 points. Graft tear occurred in 10% of patients who consequently developed severe rotator cuff arthropathy. Through a biomechanical study, they have subsequently recommended further folding the graft in order to achieve a graft thickness of 6-8 mm in order to achieve better restoration of glenohumeral biomechanics.[20] A 4 and 8mm thick (folded) FL graft reduced subacromial peak pressure after SCR, but only the thicker 8mm graft was able to decrease superior translation. However, this requires greater length of FL harvest and the potential for donor site morbidity. de Campos Azevedo et al[6] reported donor-site changes in 76.2% of their patients with 56.1% of patients being symptomatically bothered by their harvested thigh.

In 2015, Hirahara and Adams[10] first published the results of SCR using a single-layered acellular human dermal (HD) allograft of thickness between 2.5-3.5mm (Arthroflex, Lifenet Health, VA, USA). A recent systematic analysis of the available literature on the outcome following SCR has revealed that SCR using both FL and HD grafts results in significant improvement in short-term outcomes.[5] HD allograft offers a number of advantages over FL autograft including reduced donor-site morbidity, shorter operative time and easier preparation.[1,5,10] However, the disadvantages include higher cost along with concern over histological integration of the acellular graft and inferior biomechanics. In a cadaveric study, Mihata et al[15] has shown that compared to an 8mm FL graft, a single layer (2-5-3.5mm) dermal allograft only partially restored superior glenohumeral stability and was susceptible to 15% greater cyclical elongation, casting doubt over their long term suitability. More recently biomechanical studies have investigated the potential benefits of folding/doubling dermal allografts, demonstrating superior results for thicker grafts.[4,25] Currently no clinical results on the use of folded/doubled dermal allografts have been reported in the literature and the longest available mean follow-up using HD graft is up to two years.[3,11,13,23]

In 2012, when the senior author commenced SCR using dermal allograft, the thickest available graft was 1.27-1.78mm. Consequently, the dermal allograft was folded to create a graft

between 2.5-3.5mm in an attempt to obtain a thicker graft and replicate more closely the biomechanics of the original 5mm FL graft. Subsequently, a thicker HD graft (1.80-2.51mm) became available in 2016 and was used in similar folded fashion. The aim of this study was to evaluate the mid-term clinical outcome and complications following SCR using a doubled HD allograft and investigate the potential influence of graft thickness on clinical outcome.

We hypothesized that SCR using a doubled HD allograft results in successful clinical outcome at mid-term follow-up, with success defined as achieving the minimal clinically important difference in American Shoulder and Elbow Surgeons (ASES) Score (17 points).

Materials and Methods

A total of 43 patients who underwent SCR between 2012 and 2022 at a single centre were retrospectively identified utilising the hospital database and medical records. The inclusion criteria were SCR performed for irreparable posterosuperior rotator cuff tear involving supraspinatus with or without infraspinatus with a minimum of two years follow up at the time of review and planned followup outcome measurement. The indication for SCR included failed non-operative treatment for a symptomatic irreparable supraspinatus tear (when the retracted tendon could not be advanced to the footprint after complete mobilization) or a supraspinatus tear with grade IV Goutallier fatty infiltration in patients who felt too young or active for reverse shoulder arthroplasty. Patients with evidence of acetabularization (Hamada 3 or above) on x-ray or MRI were also not considered suitable. Intra-operative exclusion criteria were an irreparable tear of subscapularis or infraspinatus and/or evidence of significant arthropathy. Following screening, 32 patients satisfied the inclusion criteria. One patient was lost to follow up, hence was excluded from the study, leaving a final study population of 31 patients. Ethical approval for the study was obtained from the regional ethics committee. A power analysis was undertaken to estimate the required sample size for the main research hypothesis using dedicated software (G*Power vs. 3.1.9.7, University of Dusseldorf, Germany). Assuming a mean improvement in ASES Score of 17 points, a baseline and postop standard deviation (SD) of 20 and 16 points, respectively[17] and a correlation coefficient of 0.5 between baseline and followup score, the study would need 12 patients to achieve 80% power at the two-tailed p=0.05 significance level.

All surgeries were performed by a single surgeon (senior author) in the beach-chair position. After initial diagnostic arthroscopy to assess the suitability for the procedure, the subscapularis and infraspinatus were repaired when torn, using knotted suture anchors (4.5mm Healicoil,

Smith & Nephew, Andover, MA). Additional procedures such as biceps tenotomy/tenodesis, acromioplasty, inferior capsular release (for loss of passive range of motion) and suprascapular nerve decompression (when Goutallier[9] grade 1 or 2 fatty atrophy of infraspinatus was present) were undertaken as deemed necessary. After preparation of the glenoid and humeral footprint, two glenoid anchors (2.8 Q-Fix, Smith & Nephew, Austin, TX) and two medial row anchors (4.5mm Healicoil, Smith & Nephew, Andover, MA) were inserted.

The graft used was an acellular human dermal allograft (Graftjacket, Wright Medical Technology, Memphis, TN) which was doubled (folded) in all patients and sewn across three edges using a 2.0 vicryl running suture (Fig 1.). From 2012 to mid 2016 a graft of mean 1.5mm thickness (tolerances 1.27-1.78mm, Graftjacket, maxforce) was used which, when folded had a overall mean thickness of 3mm. These patients will hereby be referred to as the 'Standard' graft group. From mid 2016 onwards, a graft with mean thickness of 2.2mm (tolerances 1.80-2.51mm, Graftjacket, maxforce extreme) was used which, when folded had a overall mean thickness of 4.4mm . These patients will be hereby referred as the 'Thick' graft group. All grafts were pre-tensioned to remove any initial creep, which resulted in a consistent minor reduction in thickness which was not quantified.

The graft was fixed medially on the glenoid using the double loaded anchors via two simple sutures and a double pulley technique. The lateral fixation was achieved with a double pulley and a knotless suture bridge (with 1 tape from each anchor) using two knotless lateral row anchors (Multi-Fix S, Smith& Nephew, Austin, TX) with the shoulder in 20-30 degree of abduction and 20 degree of forward flexion (Fig 2). A posterior margin convergence between the graft and infraspinatus was undertaken in all patients and an anterior margin convergence was undertaken with the interval tissue when possible.

Post-operative rehabilitation included six weeks of immobilization in an abduction sling, with passive external rotation allowed. Active assisted range of motion was commenced at 6 week and strengthening exercises at 3 months. A return to full activity, including sporting activity was resumed at 9-12 months.

The American Shoulder and Elbow Surgeons (ASES) score was the primary outcome measure, and was recorded pre-operatively and repeated following recruitment into the study. A "clinical success" or satisfactory outcome was defined as a 17 point improvement in the ASES, which corresponds to the validated minimal clinically important difference (MCID) in rotator cuff repair.[3,7,26] An improvement in ASES score of less than 17 points was considered an

unsatisfactory outcome or 'clinical failure'. Secondary outcome measure were complications and or revision surgeries.

All surgeries were performed in a public health system and so routine post-operative evaluation using Magnetic Resonance Imaging (MRI) was not performed unless there was concern regarding the patient's recovery or following injury. All scans were assessed for graft healing by a fellowship trained musculoskeletal radiologist. Failure of the graft-bone interface at the glenoid or humerus or mid-substance discontinuity of the graft was considered a radiological graft failure.

Statistical analysis

The statistical analysis was performed using SPSS 22.0 (IBM Corp, Armonk, NY, USA). The descriptive data was presented as absolute number or percentages for categorical variables such as demographics and operative parameters and mean ± SD for continuous variables such as ASES scores. The pre and post-operative outcomes were compared with a paired t-test to assess the improvement in ASES score. Further comparison was performed in the two groups of patients based on the thickness of graft. The outcome between the patients with thin and thick graft was compared with an unpaired t-test for continuous variables and Fisher exact test for categorical variables. The P value of less than 0.05 was considered as statistically significant.

Results

A total of 31 patients (31 shoulders) formed the final study group for analysis. The patient's demographic and intra-operative variables are presented in table 1. The mean follow up was 48 months (range, 25-96 months) (Fig 3).

Table 2 describes the clinical outcome and complications in the study population. There was significant improvement in mean ASES score for the whole cohort of patients. Twenty six (83.8%) patients were defined as having a satisfactory outcome (>17 point improvement in ASES score), with a mean ASES score of 85.6 ± 12.3 points. Five (16.1%) patients failed to achieve the MCID in ASES and were defined as having an unsatisfactory outcome. The two groups were wide apart, with the 26 defined as satisfactory doing very well (mean improvement 69 points) and the five whose outcome was unsatisfactory having essential no change in outcome (mean change 3 points; Table 2). Two of these five patients experienced a deterioration in the ASES score, one of which (3.2%) underwent revision to reverse shoulder arthroplasty.

Eight patients had completed a minimum of five-years follow up (mean, 71.3 months; range, 61-96 months), with an overall significant improvement in ASES score. A satisfactory outcome was maintained in five (62.5%) patients with a mean ASES score of 90 ± 5.8 points. Three (37.5%) patients failed to achieve the MCID and were classified as clinical failures, however none required revision surgery.

Thirteen patients underwent SCR using a standard graft, while a thick graft was used in 18 patients (Table 3). Both groups had significant improvement in the ASES score following surgery. The patients with thick grafts had a higher improvement but the difference was not statistically significant (p=0.18). There was greater proportion of patients achieving the MCID in the thick graft group compared to the standard graft, however the difference failed to reach statistical significance (94.4% versus 69.2%, RR=1.36 (95%CI 0.93 to 1.99, P = 0.13). There were four clinical failures with the standard graft, one which occurred at 12 months, one at 30 months and two after 5 years post-surgery. The three patients with confirmed radiological graft failure noted on MRI, had SCR using the standard graft. The single revision surgery was performed in a patient with a standard graft who failed at 12 months.

An MRI scan was performed in eight patients where graft failure was noted in three patients at a mean follow up at 30 months, two on the humeral side and one on the glenoid side. Clinically two had an unsatisfactory outcome, whereas, one patient had a clinically satisfactory outcome despite radiological graft failure. The patient who underwent revision to reverse shoulder arthroplasty at 1.5 years post-SCR had a clinical and graft failure noted on MRI at 12 months. There were no further complications in the study cohort. On MRI, the two folds of the graft were found integrated into one layer in six patients. In two patients the graft remained as 2 separate folds, however both grafts were intact and were deemed a clinical success based on ASES (Fig 4). The graft thickness remained comparable to the intra-operative thickness with no appreciable thinning.

Discussion

The main finding of this study was that SCR using a doubled HD allograft leads to significant improvements in pain and function at mid-term follow-up with a low reoperation rate. At a mean follow-up of 48 months, 83.8% of patients were defined as having a clinically successful outcome. There was no evidence for improved ASES scores in patients receiving thick grafts or a greater proportion achieving the MCID when compared to standard grafts.

188 The superior capsule, reinforced by the rotator cuff tendons, serves as a static stabilizer of the
189 shoulder preventing superior translation of humeral head, the loss of this restraint results in
190 superior glenohumeral translation, secondary subacromial impingement and potential
191 pseudoparalysis.[8,10,12,14]

192 Clinically, SCR in rotator cuff deficient shoulders has been shown to result in significant
193 improvements in patient reported outcome measures, range of movement, strength, return to
194 sports and reversal of pseudoparalysis regardless of the type of graft used.[1,2,13,14,16,18,23] The
195 reported two-year results of SCR using single-layered HD allografts (1-3.5mm thick) have
196 been encouraging.[7,11,23,24] In a case series of 38 patients, Pennington et al[23] showed a success
197 rate of 94.8% with a significant improvement in ASES score of 35.8 points (from 49.5 to 85.3)
198 at two years post-surgery. Burkhart et al[3] published a single-surgeon series of 41 patients with
199 mean follow up of 34 months where ASES score improved 37 points (from 52 ± 3 to 89 ± 2)
200 at final follow up, with satisfactory outcome in 81% of patients. Similarly, Lacheta et al[13], at
201 mean follow up of 2.1 years, demonstrated satisfactory outcome in 85% of their patients with
202 a significant improvement in ASES of 29.9 points (from 54.0 to 83.9) at final follow up.
203 However, the mid-term results of SCR using HD allograft have not previously been reported.
204 The current study revealed a significant improvement in ASES score of 58.2 points (from 18.1
205 ± 14.3 to 76.3 ± 25.1) with 83.8% achieving clinical success at a mean follow-up of 4 years in
206 the entire cohort. Within the group with follow-up beyond 5 years (mean 5.9 years) the
207 proportion considered a clinical success was smaller (5/8 or 63%). However, just like in the
208 full cohort, these five patients had a very large mean improvement (76 ASES points),
209 demonstrating sustained clinical improvement. All patients with follow-up beyond 5 years
210 received the standard graft and so it is unknown if the results when using a thicker graft are
211 more durable. The finding of one clinical failure in the thick group at mean follow-up of 34.7
212 is encouraging.

213 The pre-operative scores in this study are considerably lower than those previously reported,
214 consequently the final overall score is lower in comparison, particularly when the patients with
215 unsatisfactory outcome are included in the analysis. It is difficult to ascertain why the pre-op
216 scores are so much lower and may relate to the time to surgery within a public health system.
217 However, the improvement in ASES score in the patients with a satisfactory outcome are
218 comparable to the previous results and are maintained beyond 5 years. These results
219 demonstrate that SCR using doubled HD allograft can be durable in the mid-term.

The thickness of the graft is the main determinant of its biomechanical function when used for superior capsule reconstruction. Nimura et al[22] determined that the native superior capsule varied in thickness at its insertion on the humerus between 4-9mm, being thicker posteriorly. The final thickness of the FL autografts currently recommended is 6-8mm, which is obtained by folding the graft multiple times.[19] The maximal thickness of HD allografts is generally up to 3.5mm[7,23] and consequently all prior clinical results have been reported using grafts which at best correspond to the "standard" grafts in this study. Cline et al[4] in a biomechanical study compared 7.3mm thick FL allograft, with 6.4mm doubled and 2.5mm single layered HD allograft. At 0° abduction, all SCR conditions significantly decreased superior translation compared with the massive tear but did not restore translation ($P < .05$) to intact. Fascia lata and double-layer dermis SCR restored superior translation to intact at 30° and 60° of abduction, but single-layer dermis did not. In addition, single-layer dermis graft thickness significantly decreased more than fascia lata during testing ($P = 0.02$). Whilst the doubled HD allograft used was thinner that the thick grafts used in this study (6.4mm vs 4.4mm) it confirms the potential advantages of folding in order to increase graft thickness. The trend towards improved results in the thick group (94.4% versus 69% satisfactory results) may reflect this greater potential to resist superior translatory forces more effectively and consequently reduce the cyclical elongation seen with thinner grafts. A thicker graft may also have a greater interposition effect. One final potential advantage of a doubled HD allograft compared to a single layer, is that the graft can be implanted with the two porous surfaces on the superior and inferior aspect. This may provide greater surface area and porosity with consequent increased biological integration and vascular ingrowth from the adjacent bone and the subacromial bursa.

This study has a number of limitations. Firstly, this was a retrospective case series with a relatively small sample size. The small number of patients in our study cohort is probably one reason for lack of significance in statistical comparison between the standard and thick graft groups despite the trend towards improvements in the thick group. Likewise, small sample size could also explain the high percentage of clinical failures in patients over five years follow up in preliminary results, because they may represent our learning curve with this technique. A future randomized trial of thick versus thin allograft would need 70 patients (35 per group) based on a difference in ASES Score of 17 points, the overall SD of 25 points in this study, and assuming 80% power at the two-tailed p=0.05 level. Nevertheless, considering the first description of the superior capsule was in 2012, the 2-8 year results presented in this study is the first to provide potential valuable information as to the mid-term outcome of SCR with HD

allograft. Secondly, MRI scans and x-rays were not performed in all patients post-surgery, therefore, the true graft failure rate and subsequent Hamada grade in this study is unknown. The study was undertaken in a public health system where postoperative imaging is not routine. Ultimately, however, the most important outcome with any treatment, is the level and length of any clinical improvement. Thirdly, the functional outcome was measured in all patients at a single time point, on recruitment to the study. Hence, it was difficult to assess the change in ASES score over time in the patients with longer follow up. Moreover, the length of followup differed between the two groups which could introduce a bias. Fourth, this study is a single-surgeon series, which may affect the generalisability of our result. Fifth, there was a minor reduction in graft thickness with the pre-tension applied to remove creep. However, the reduction in thickness was experienced by all grafts in the study to a similar degree and so is unlikely to have affected the clinical outcome between groups. Sixth, almost half of our study cohort required infraspinatus and or subscapularis repair in addition to SCR which might have contributed to the improved ASES scores. The positive impact of balancing anterior and posterior force couples is well established and is a pre-requisite for SCR, but this does not account for the similar gains in ASES in those patients where repair was not required. Lastly, the standard grafts were used for the first half of the study and so the mean follow-up is longer in this group. This has likely contributed to an anticipated increase in clinical failures (37.5%) which was observed in these patients . Whilst comparative follow-up is needed to confirm this observation, thicker HD grafts have the potential to provide a more durable outcome.

Conclusions

Superior capsular reconstruction for irreparable supraspinatus tears with doubled human dermal allograft results in an 83.8% clinical success rate at mean follow-up of 48 months. There was no evidence to suggest that thicker dermal allograft may provide improved results and a larger sample size would be needed for such a study.

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371 **Figure Legends**

372 **Figure 1:** Doubled HD allograft prepared by folding the graft and running sutures across the
373 edges

374 **Figure 2:** Arthroscopic image showing the doubled HD allograft over the glenohumeral joint
375 to reconstruct the superior capsule

376 **Figure 3:** Chart showing the number of patients in relation to follow up duration

377 **Figure 4:** MR images at 1 year post-surgery showing (a) biologic integration of two layers of
378 allograft into one layer and (b) the graft remaining as two distinct layers

Table Legends

Table 1: Demographics of the 31 patients comprising the study population

Table 2: ASES scores and complications following surgery

Table 3: Clinical outcome score and complications with regards to graft thickness.

Figure 1

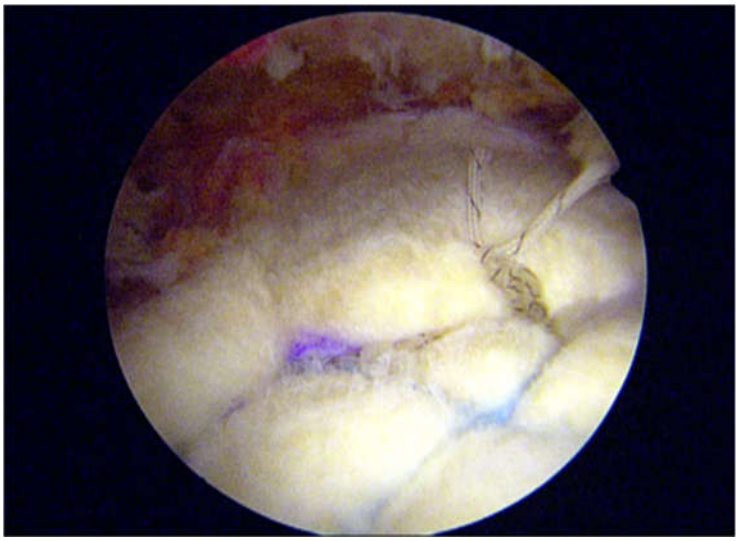

Figure 2

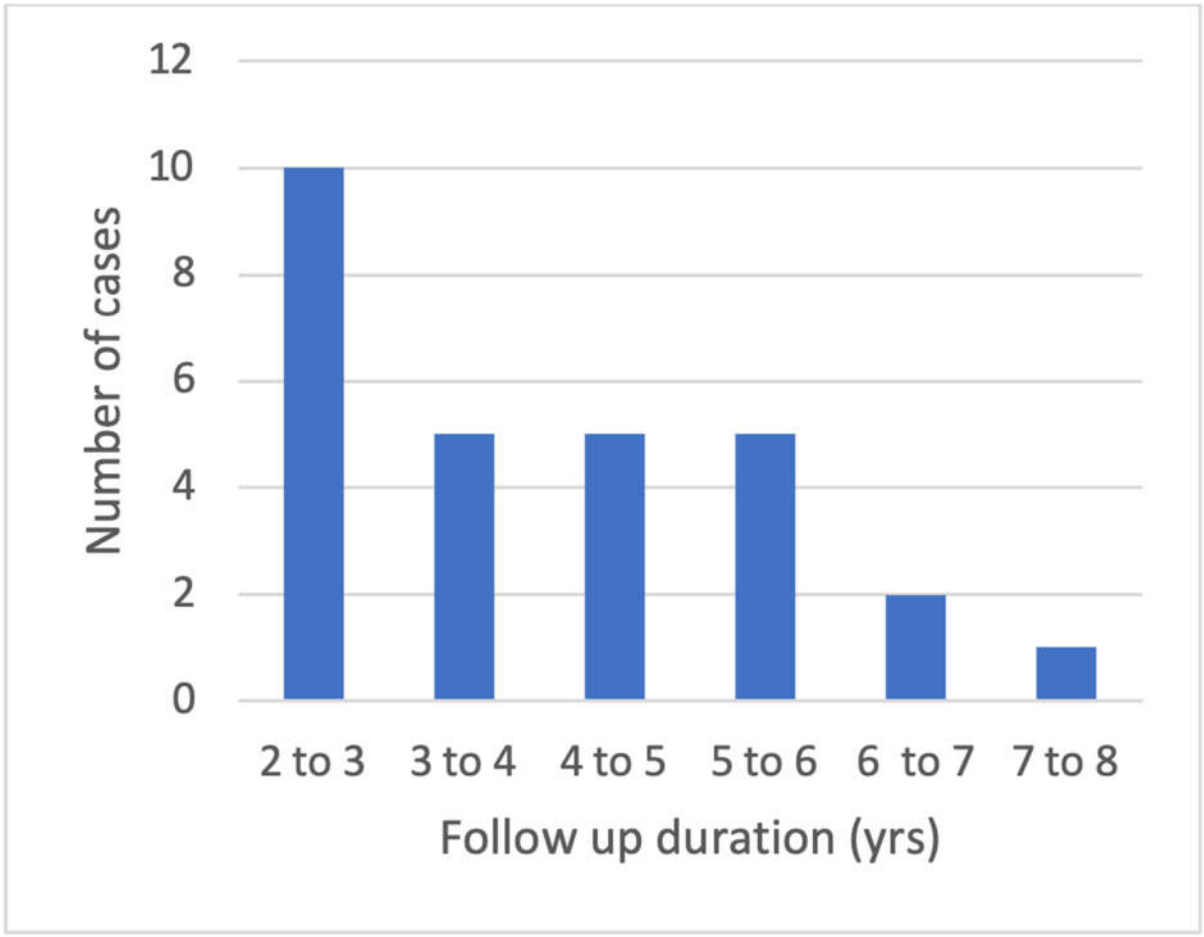

Figure 3

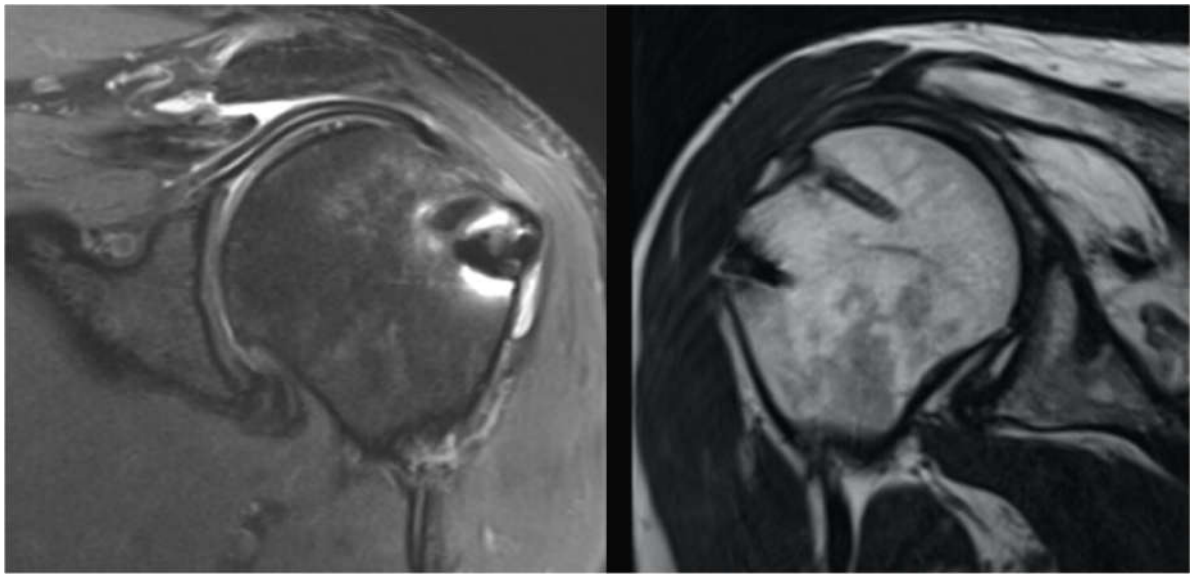

Figure 4

Table 1

Parameters	Result, n (%)
Mean age, yrs (range)	64 (47-81)
Male, %	14 (45.1%)
Right:Left*	22:9
Prior shoulder surgeries, %	5 (16.1%)
Infraspinatus repair, %	15 (48.3%)
Subscapularis repair, %	13 (41.9%)
Biceps tenotomy, %	16 (51.6%)
Biceps tenodesis, %	2 (6.4%)
Anterior side-to-side suturing, %	8 (25.8%)
Posterior side-to-side suturing, %	31 (100%)
Suprascapular nerve release, %	6 (19.3%)

* side of surgery

Table 2

Outcomes		> 2 years f/u*	> 5 years f/u#
Mean f/u (mths)		48 (range, 25-96)	71.3 (range, 61-96)
Overall outcome		n = 31	n = 8
	Pre-operative	18.1 ± 14.3	21.2 ± 17.4
	Post-operative	76.3 ± 25.1	69.9 ± 29.2
	Change	58.2 ± 30.4	48.8 ± 38.4
	P value	*< 0.001*	*0.008*
Clinical success		n = 26	n = 5
	Pre-operative	16.7 ± 12.8	14.3 ± 10.8
	Post-operative	85.6 ± 12.3	90 ± 5.8
	Change	68.9 ± 18.4	75.7 ± 8.9
	P value	*< 0.001*	*< 0.001*
Unsatisfactory outcome		n = 5	n = 3
	Pre-operative	25.3 ± 20.5	32.7 ± 22.7
	Post-operative	27.9 ± 16.6	36.7 ± 15.9
	Change	2.6 ± 13.5	3.9 ± 12.7
	P value	0.687	0.409
Radiological graft failure		3	2
Reoperation		1	0

* > 2 years f/u indicates the entire study population,
# > 5 years f/u indicates subset of patients who had completed 5 years follow up duration.

Table 3

Outcomes		Standard graft	Thick graft	*P* value
Mean f/u (mths)		63.8 (range, 51-96)	34.7 (range, 25-46)	*< 0.001*
Overall outcome		n = 13	n = 18	
	ASES Pre-op	21.2 ± 19.3	15.8 ± 9.1	0.313
	ASES Post-op	70.7 ± 24.6	80.3 ± 21.8	0.299
	ASES change	49.5 ± 33.1	64.5 ± 27.5	0.180
	P value	*< 0.001*	*< 0.001*	
Successful outcome		n = 9	n = 17	0.13
	ASES Pre-op	19.3 ± 18.4	15.2 ± 9.1	0.463
	ASES Post-op	87.9 ± 8.6	84.3 ± 14.1	0.497
	ASES change	68.6 ± 16.2	69.1 ± 20.1	0.955
	P value	*< 0.001*	*< 0.001*	
Unsatisfactory outcome		n = 4	n = 1	
	ASES Pre-op	25.4 ± 23.6	25	0.494
	ASES Post-op	31.9 ± 14.2	11.7	0.169
	ASES change	8.3 ± 13.7	-13.3	0.112
	P value	0.342	-	
Graft failure		3	0	
Reoperation		1	0	0.274