

Superior Capsule Reconstruction for Irreparable Rotator Cuff Tear with a Porcine Dermal Graft: Preliminary Results at 2 Years Minimum Follow-up

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SUMMARY

Purpose. Currently, no consensus has been achieved regarding treatment of irreparable and massive rotator cuff tears. The purpose of this study was to evaluate clinical outcomes and acromiohumeral distance after superior capsular reconstruction, using a porcine dermal graft.

Methods. In this study, patients underwent arthroscopic superior capsule reconstruction were included. Grafts used a porcine dermal matrix. Main inclusion criterion was a symptomatic massive, irreparable supraspinatus tear. Patients were excluded for severe shoulder osteoarthritis or important fatty degeneration or shoulder stiffness. Constant score, VAS, ASES and complications were assessed preoperatively and at last follow-up. Acromiohumeral distance was measured using X-ray.

Results. Among the 23 patients enrolled, mean age was 60,5years (± 3). Mean follow-up was 29,3months ($\pm 3,7$). Mean Constant score improved from 34,7 ($\pm 7,8$) to 78,3 ($\pm 16,5$), $p=2.81E-13$. At last follow-up, mean forward flexion increased to 126° ($\pm 33^\circ$, $p=9.05E-12$), muscle strength (points/25) increased to 15.3 (± 5.6 , $p=0.56$). Mean ASES increased from 38,2 ± 4.3 to 81 $\pm 14,1$ at last follow-up ($p=6.48E-16$). VAS had decreased to 1.4 (± 1.9) from a mean of 4,8 (± 1.3), $p=1.68E-07$. Acromiohumeral distance increased from 6.6mm ± 1.2 to 8.7mm ± 1 , $p=3.11E-07$.

At last follow up, major complications included 5 revisions (21%), 2 latissimus dorsi transfer and 3 reversed shoulder arthroplasty. Neither rejection nor sepsis were observed.

Conclusions. In this preliminary study of superior capsule reconstruction with a porcine dermal matrix xenograft, improvements in shoulder outcomes were showed. Despite a high rate of revisions and potential confounding factors, superior capsule reconstruction with such porcine graft may be an effective treatment to re-centring the humeral head with respect to the glenoid on this selective population.

KEY WORDS

cuff; shoulder; arthroscopy; superior capsule reconstruction; knottless; tear

INTRODUCTION

Chronic and irreparable massive rotator cuff tears remain one of the most challenging shoulder surgery. Arthroscopic repair by an experimented surgeon is possible but long term healing, especially in younger subjects (< 65 years old), remain low (1) because of the chronic nature of these tears, limited excursion and fatty atrophy develop. Non repaired tear or failed arthroscopic repair cause eccentric shoulder osteoarthritis in more than 50% of cases, which then progress through the 5 grades described by Hamada and Fukuda (2) and cause pain and mobility loss.

Multiple alternative repairs exist in the literature. Good results have been reported with the reverse shoulder prosthesis, which lowers the centre of rotation and medializes the humeral head, resulting in optimised deltoid function (3). However, complication rates are very high among older subjects (up to 20%) and even higher among patients under 65 years of age (up to 40%) (4,5).

For younger subjects, it exists a range of therapeutic options with different degrees of invasiveness (i.e. including muscle flaps, fascia lata, partial repairs, tenotomy of the long head biceps...) and varying results (6-13). Treating the younger

population with porcine dermal superior capsule reconstruction seemed particularly interesting, as it allows for muscle mass preservation (latissimus dorsi) and retains the possibility of performing flap or shoulder prosthesis procedures at a later stage.

Principal advantage is control of humeral head's upward migrations by restoring balanced force couples and restoration of the shoulder function. To date, medium- and long-term comparative studies (14) are too scarce to establish a standard therapy for irreparable and massive cuff tears.

Aim of this study was to evaluate clinical outcomes and the acromiohumeral distance after superior capsular reconstruction, using a porcine dermal graft for massive and irreparable cuff tears. This study hypothesis superior capsule reconstruction using porcine dermal graft is a safe and effective option for irreparable and massive cuff tears.

MATERIAL AND METHODS

This study was conducted from March 2015 till december 2016. Requirements for inclusion were the presence of an irreparable supra-spinatus tendon tear and, when relevant, an intact or reparable subscapularis and intact deltoid.

Further inclusion criteria were: minimum clinical follow-up of 2 years with radiographic control and below 65 years old. Surgery could be primary or secondary.

Patients were excluded for severe shoulder osteoarthritis (>4 according to the Hamada classification (2)), fatty degeneration (>2 of the subscapularis) according to the Goutallier classification (15) or shoulder stiffness.

Indications for superior capsule reconstruction was restricted active range of motion and severe pain caused by massive rotator cuff tear.

25 patients (25 shoulders) met the inclusion criteria. 2 patients were lost to follow-up or unable to undergo post-operative control imaging. Consequently, the study included 23 patients (33).

PRIMARY AND SECONDARY OUTCOME MEASURES

Primary outcome measures were mean Constant Score (CS) and acromio-humeral distance (in mm).

Secondary outcomes measures included pain severity on visual analogue scale (VAS) from 0 to 10, ASES score, and complications. Focus was placed on rejection-type reactions or sepsis because of the xenograft nature of the matrix.

Clinical outcomes were monitored at regular intervals by an independant observator, from the pre-operative period until last follow-up.

Patients were invited to perform a 24-month follow-up MRI to evaluate the evolution of xenograft.

PATIENT ASSESSMENT

True anteroposterior and lateral shoulder X-rays were taken to examine shoulder osteoarthritis. Acromiohumeral distance was measured on true AP shoulder radiograph and defined by Gruber and al. as the shortest distance measured from the cortical bone at the inferior aspect of the acromion to the humeral head (16). A value between 8 and 12 mm was considered normal. Diagnosis and indication for surgery were determined on MRI or arthro-CT scans, which allowed assessment of supraspinatus tendon tears, degree of retraction (Patte classification (17)), and associated fatty degeneration (Goutallier classification (15)).

Physician provided to the patient clear and appropriate information regarding aim of the therapy and porcine origin of the matrix. In all cases, surgeon will reassess the necessity and feasibility of the superior reconstruction capsule based on per-operative arthroscopic findings. Secondary outcome measures were assessed preoperatively.

Tear retraction and severity were confirmed during arthroscopic surgery.

SURGICAL TECHNIQUE

All procedures were performed, by the same senior surgeon, on patients in the beachchair position under general anaesthesia with loco-regional anesthesia (interscalene block).

A posterior portal was positioned in order to expose and assess the lesions.

Tear retraction was assessed with gripping forceps to confirm that the lesion was irreparable;

Biceps tenotomy or tenodeses was performed systematically. Acromioplasty was performed systematically (we do not performed another subacromial decompression if it was done during the first arthroscopic repair).

Glenoid and tuberosity anchorages

Two 3.0-mm PEEK (polyether ether ketone) SutureTak anchors were inserted into the supraglenoid tuberosity with 2 high Strength sutures (Arthrex, Naples, Florida).

On the tuberosity, the graft was fixed to the humerus using a knotless double bridging construct (Arthrex, Naples, Florida) in order to obtain better fixation and tuberosity maximum coverage. Two 4.75-mm BioComposite Swive-Lock anchors loaded with suture tapes (Arthrex, Naples, Florida) sutures were inserted into the articular margin firstly.

Porcine dermal capsule preparation and fixation

Capsule was cut and prepared simultaneously by an assistant. Capsule DX Matrix (Arthrex, Naples, Florida) was an acellular and sterile porcine dermic matrix, composed mostly of collagen. Growth factors (VEGF, TGF β) were present inside in order to stimulate incorporation of adjacent tendon cells. A sizing and sterile device (Arthrex, Naples, Florida) was used to measure the appropriate anteroposterior and medial-lateral dimensions of the defect. Graft dimensions were then drawn twice with a sterile, felt-tipped marker in order to double the thickness of the matrix, and cut. The two matrix layers were stitched together using Vicryl 2-0 in an edge-to-edge continuous suture (**figure 1**).

The prepared graft was then orientated and pushed to the glenoid. To avoid tangling, care should be taken to tension the passed sutures, and do not twist the graft.

When the graft was positioned over the SutureTak anchors firmly onto the glenoid, the sutures were tied over the graft with a static surgeon's knot.

Creation of the lateral bridging portion of the knotless bridging construct was then undertaken. In order to obtain the better coverage of the graft on the footprint and suffi-

cient compression, the limbs of the suture tape were then individually tensioned.

At the end of the procedure, the dermal matrix was then sutured edge-to-edge to the rest of the infraspinatus, and the anterior edge to the subscapularis (**figure 2**). The mechanical effectiveness of the superior capsule reconstruction in preventing the humeral head from raising during shoulder movements was verified during per-operative period.

Post-surgical follow up

After surgery, patients were immobilized for 4 weeks with a sling (Sober, Crolles, France). Shoulder rehabilitation consisted of free passive range of motion exercises starting from post-operative day 1. Active motion was initiated at 4 weeks. Rotator cuff-strengthening exercises began 10–12 weeks after surgery. Full return to sports and heavy labour were allowed after 6 months, according to individual functional recovery.

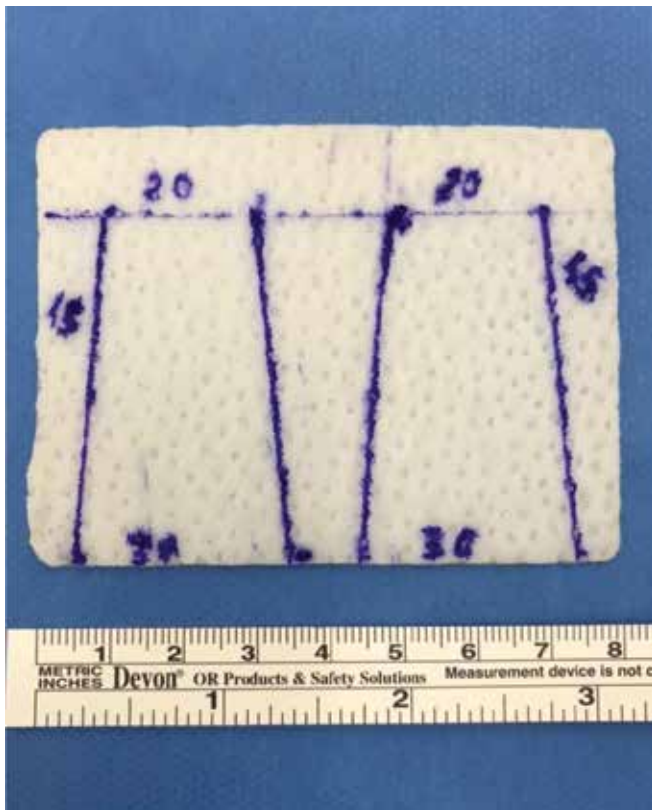


Figure 1. Porcine dermal graft sizing and preparation.

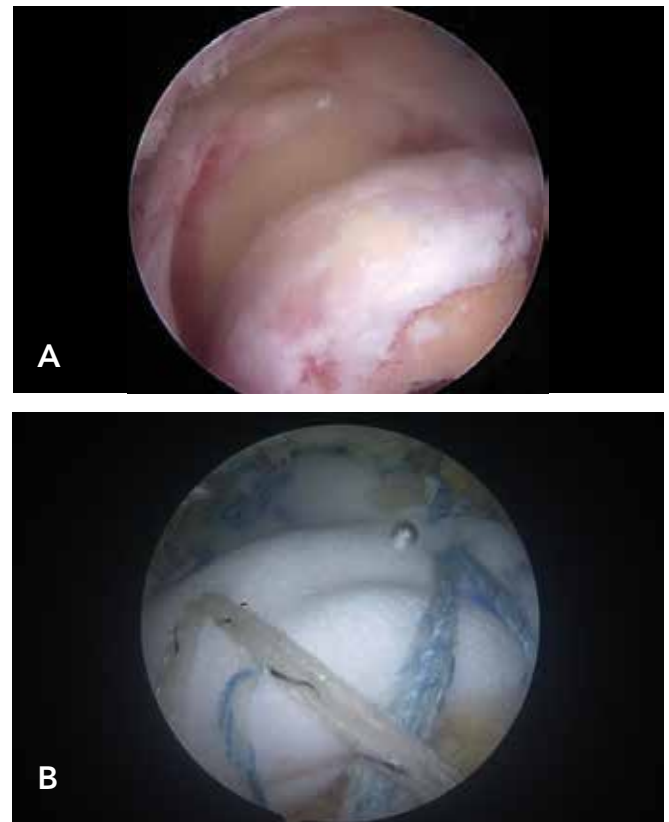


Figure 2. Operative views.

2a. Arthroscopic view with a massive postero-superior rotator cuff tear (man; 58 y.o.; primary surgery). **2b.** Final arthroscopic views with the superior capsule reconstruction.

Patients were examined at 3 months, 6 months, 12 months post-surgery and after, ones each year. During these follow-up visits, true anteroposterior (in neutral rotation) and lateral shoulder X-rays were taken, and primary and secondary outcome measures were assessed. Radio-clinical exam was done systematically if patient presented pain or restricted motion.

Statistical analysis

Means and 95% confidence intervals were calculated using the software R (<http://www.R-project.org>). Differences between pre- and postoperative mean Constant, VAS and ASES scores were analyzed with the Student's t-test. Significance was set at $p < 0,001$ (Bonferroni correction).

RESULTS

A total of 23 patients were enrolled in our study with irreparable rotator cuff tears involving supra-spinatus tendon. Mean age was 60,5 years (± 3) and median follow-up was 29,3 months ($\pm 3,7$). Surgery was primary in 17 cases. 16 tenotomy and 7 tenodesis of the long biceps were performed. Among those undergoing revision surgeries, 5 had previous arthroscopic rotator cuff repair and one had undergone latissimus dorsi flap reconstruction. Demographic data are summarized in **table I**.

The shoulders were grade 1 in 14 cases (62%), grade 2 in 5 (23%) and grade 3 in 4 (15%), according to the Hamada classification (2). Fatty degeneration was grade 2 in 4 cases and 19 supra-spinatus were grade 3 (80%). According to Patte's classification, all patient had a type 3 tear (tendon lesion reached the level of the glenoid).

Mean Constant score showed a significant improvement in shoulder function, as it increased from 34,7 ($\pm 7,8$) preoperatively to 78,3 ($\pm 16,5$) ($p=2.81E-13$) at last follow-up. Improvement in Constant score is clinically significant. Difference between the pre- and post-operative scores is greater than the MCID (minimal clinically important difference) for 22 shoulders (96,7%). Pain severity decreased to 1.4 (± 1.9) at last follow-up ($p=1.68E-07$).

Table I. Demographic data.

	Population (n=23)
Age (year) (mean \pm SD)	60,5 \pm 3
Men/Women	16/7
Professional Activity (manual labor)	18
Dominant Side	19
Primary surgery	17

Mean ASES Score increased from 38.2 (± 4.3) to 81 ($\pm 14,1$) at last follow-up ($p=6.48E-16$). ASES improvement is clinically relevant. Difference between pre and post-operative ASES is greater than the MCID for all subjects. Shoulder mobility improved with a mean forward flexion of 126° ($\pm 33^\circ$) vs 77° ($\pm 18^\circ$) in preoperative period ($p=9.05E-12$), and a mean abduction of 117° ($\pm 28,5^\circ$) vs 61° ($\pm 19,5^\circ$) at baseline ($p=3.36E-12$). Mean muscle strength (points/25) increased from 5.1 (± 4.5) preoperatively to 15.3 (± 5.6) at last follow-up, but this improvement was not statistically significant. All these results are summarized in **table II**.

Similarly, the mean acromiohumeral distance started below the normal range at baseline (6.6 mm \pm 1.2) and increased to 8.7 mm \pm 1 at last follow-up ($p=3.11E-07$) (**figure 3**).

About the 23 patients with satisfactory follow-up, 14 performed a control MRI at 24 months and 4 performed a shoulder ultrasound echography (claustrophobia). A complete healing was observed in 50% (9/18) and persistence of the xenograft was reported in 9 cases without phenomenon of recolonization or deterioration (**figure 4**).

COMPLICATIONS

Three intraoperative complications were recorded: two partial glenoid fractures diagnosed during surgery without major functional repercussions and a dehydrated porcine dermal matrix upon packaging opening.

Five revisions (21%) were needed due to persistent pain and loss of mobility. We performed two latissimus dorsal flap, 14 and 18 months after surgery. In two other cases, 8th and 16th month follow up, reversed shoulder prosthesis was performed due to poor clinical results. In one case, patch was pulled out at 23 months follow up after a trauma shoulder (car accident). Material removal and reversed shoulder prosthesis were done in the same time. Successful outcomes were noticed for these patients.

Table II. Pre-operative and post-operative Constant score, VAS, ROM, Strength and ASES (mean \pm SD).

	Pre-operative	Last follow-up	p
Constant score	34.7 \pm 7.8	78.3 \pm 16.5	2.81E-13
VAS	4.8 \pm 1.3	1.4 \pm 1.9	1.68E-07
Anteflexion (°)	77 \pm 18	126 \pm 33	9.05E-12
Abduction (°)	61 \pm 19.5	117 \pm 28.5	3.36E-12
Strength (points/25)	5.1 \pm 4.5	15.3 \pm 5.6	0.56
ASES	38.2 \pm 4.3	81 \pm 14.1	6.48E-16



Figure 3. Verifying radiologically humeral head re-centering after superior capsule reconstruction.

3a. Face and lateral X-ray before surgery (man, 62 y.o., primary surgery).

3b. 12 months after surgery.

One case of algodystrophy was diagnosed at the 6th month clinical exam and was healed with active re-education and adapted medics.

Neither rejection-type reactions nor sepsis were observed.

DISCUSSION

This series showed superior capsule reconstruction with a porcine dermal matrix resulted in safety, significant functional improvement and effective pain relief. According Harris et al. (18), our results were clinically relevant. Differ-

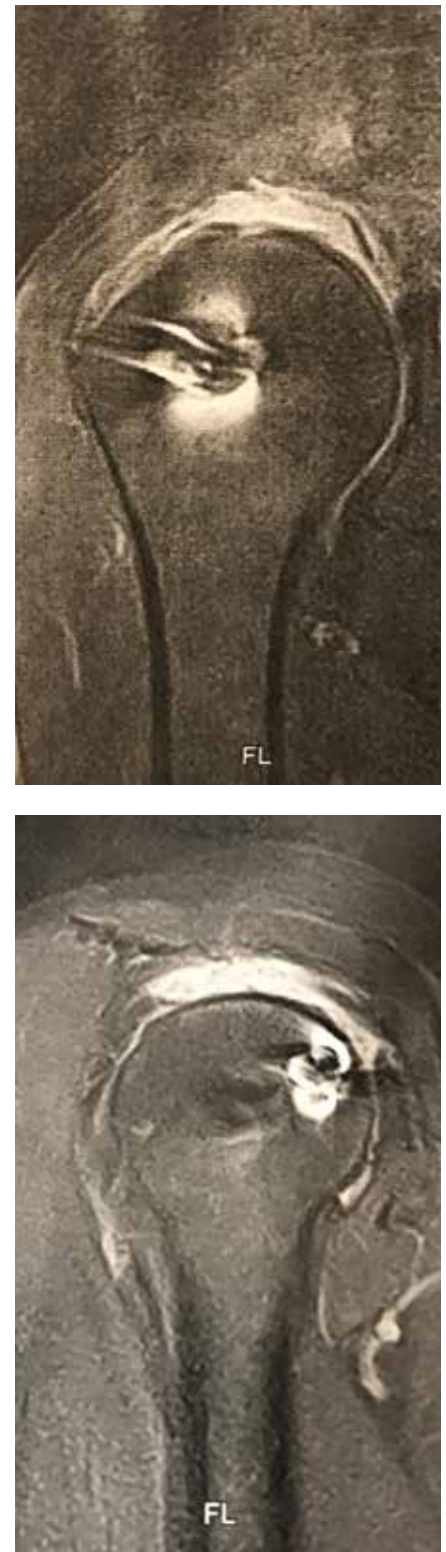


Figure 4. MRI assessment of the SCR (woman, 64 y.o., 24 months follow up).

ence between pre and last follow-up Constant was higher than MCID for 96,7% of subjects and for all subjects about ASES score. Muscle strength was the only outcome measure in our study that did not show statistically significant improvement. However, it is likely that significance could be reached in a larger cohort with longer follow-up.

In comparison about dermal allograft in the literature (7, 14, 19), dermal xenograft presents satisfying results. Denard et al (14) in 2018 reported significant clinical improvement except external rotation. Large cohort (59 patients) but short term follow-up (17,7 months) and partial radiological evaluation were done. 11 patients needed revisions (7 reverse shoulder arthroplasties, 2 reinforcement of the reconstruction, 1 infection) and 1 subpectoral tenodesis was performed for chronic pain.

Clinical results of muscle transfers (latissimus dorsi, trapezius...) remain controversial with increasing risk of complications such as neurapraxy due to nerve procedure tension (table III).

Repairs by latissimus dorsi transfer are reported after more than 10 years follow-up. Gerber et al (20), reported significant improvement about forward flexion (118° vs 132.4°) and external rotation (18° vs 32.5°). Successive X-rays control showed a significative worsening Hamada ²¹Hamada et al. radiographically classified massive rotator cuff tears into five grades. Walch et al. subsequently subdivided Grade 4 to reflect the presence/absence of subacromial arthritis and emphasize glenohumeral arthritis as a characteristic of Grade 4. Questions/purposes We therefore deter-

mined (1 score. However, revisions were required principally for avulsion of the muscle transfer. These avulsions are well described by Grimberg et al (22), in 2015, which performed arthroscopic assisted latissimus dorsi: per-operative complication as great tuberosity fracture or post-operative fracture as screws pull-out and endo fixation button failures.

El Hassan et al (10), evaluated recently trapezius transfer in 2016. Vector of its muscle fibres would be identical to that of the infraspinatus fibres (23). 33 patients (53 y.o.) with 22 previous repair were included. Author performed this technique specifically for those who have pre-operative anterior flexion of more than 60°. Range of motion was improved and SSV was 78 at 53 months follow up.

About using fascia lata, Dimitrios et al (24), reported significant results as improvement of Constant score and decrease of pain at 43 months follow-up. Range of motion is also improved. 3 re-tears were diagnosed at 12 months with US. No case of infection was reported.

Advantages of these porcine matrices include a tear resistance 3–4 times greater than the fascia lata graft described by Mihata et al (550 Newton vs 180 Newton) (25). This graft contains growth factors, VEGF and TGF-beta, that are capable of optimizing the formation of fibrovascular scar tissue while maintaining structural integrity. It also limits donor-site morbidity. Acevedo et al (26), evaluated ethical questions they raise, and Snyder and al (27) shown the minimal immunologic and rejection risk of these xenografts.

D'ambrosi et al. (13) described in 2019, a meta analysis about the use of scaffolds in arthroscopic repairs of massive

Table III. Functional and structural results after massive rotator cuff tear repair in the literature.

Studies	Technique	Patients number	Mean age (years)	Mean follow up (months)	Mean functional results at last follow up	Re-tear rate (%)	Type of control imaging
Our Study	Dermal Xenograft	23	60,5	29.3	Constant : 78.3 ASES : 81	21	MRI/US
Denard et al. ¹⁴	Dermal Allograft	59	62	17.7	ASES : 77,5	32	MRI
Barber et al. ⁷	Dermal Allograft	22	56	24	Constant : 91.9 ASES : 98.9	15	MRI
Gerber et al. ²⁰	Latissimus Dorsi Transfer	46	68.4	146.6	Constant : 63.8 SSV : 70.1	-	-
Grimberg et al. ²²	Latissimus Dorsi Transfer	55	62	29.4	Constant : 65.4 SSV : 71.1	16.3	-
El Hassan et al. ¹⁰ 31-66 years	Trapezius Transfer	33	53	47	SSV : 78	-	-
Mihata et al. ³²	Fascia Lata	23	65.1	34.1	ASES : 92.9	16.7	MRI

rotator cuff tears. Cohorts of 10 articles were combined, resulting in a cohort of 178 repaired shoulders. In 32 cases, authors reported a retear. The complications are variable but the rate is lower than our series (10%). This meta-analysis confirms the efficiency and safety of scaffolds in superior capsular reconstructions. However, a prospective study needed to assess this type of repair more accurately.

The biomechanical objective of this repair, to avoid the ascension of the humeral head and the early evolution of osteoarthritis, was assessed by measurements of acromio humeral distance. At a mean of 29,3 months follow-up, the mean acromiohumeral distance had increased significantly from its baseline value. Superior capsular reconstructions allowed a reestablishment of forces vector, a lowering of the humeral head and thus an increase in the acromio-humeral interval. This result may confirm that superior capsule reconstruction with porcine graft acts as a long term spacer and is effective in re-centring the humeral head. In recent literature, Denard *et al.* (14), using a superior capsule reconstruction with dermal allograft, an improvement at 2 weeks postoperatively but a decrease to its baseline value at final follow-up.

Other treatments for irreparable cuff tears such as the latissimus dorsi transfer and deltoid transfer, are unable to prevent, superior migration of the humeral head. Acromiohumeral interval tended to remain low and decreased. Gerhardt *et al.* (28) and Nové-Josserand *et al.* (29), who performed latissimus dorsi transfer, despite they measured a significantly increase of the acromiohumeral interval, it remained under 8mm and did not prevent the ineluctable evolution of the osteoarthritis (3,8mm and 5,5mm respectively).

Excepted, superior reconstruction with fascia lata allograft presents similar results than our study. Mihata *et al.* (25) reported a significant height increase, $8.7 \text{ mm} \pm 2.6$ at last follow-up.

However, we are aware that the accuracy and reproducibility of this measurement is not ideal because of the challenges in recording X-rays of every patient using identical angle of incidence and magnification. For future studies, it may be wise to assess humeral head re-centring by radiographically measuring the restitution of a proper glenohumeral alignment.

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This study presents multiple limits. Potential pitfalls of the technique were identified and included mismeasurements, insufficient filing of the greater tuberosity, incorrect anchor placement and glenoid anchorage. Similar challenges were identified in the few technical notes (3, 14, 30, 31). There was no power analysis or comparative group such as a graft with single row arthroscopic repair. We can think that arthroscopic repair with knotless tape bridging improved our results. Graft persistence was not assessed systematically by MRI. Complete healing was observed 50% of patients and in 50% of patients, MRI did not reveal changes in the porcine dermal matrix (i.e., neither recolonization nor deterioration). Using a dermal allograft, Denard *et al.* reported on postoperative magnetic resonance imaging, 45% of the grafts demonstrated complete healing (14).

There are many potential confounding factors in this series (acromioplasty, tenotomy/tenodesis of the biceps) that can explain our positive results. Our small series does not allow us to carry out multivariate analyses in order to avoid these biases. Finally, SCRs have a high failure rate (21%), we believe that it is necessary for the patient to be informed of this particularly high risk. The patient will also be informed of the benefits of this technique, which we will describe as minimally invasive, and of the possibility of performing a muscle flap or reverse shoulder prosthesis without difficulty in case of failure.

CONCLUSIONS

In this preliminary study of superior capsule reconstruction with a porcine dermal matrix xenograft, improvements in shoulder outcomes were showed. Despite a high rate of revisions and potential confounding factors, superior capsule reconstruction with such porcine graft may be an effective treatment to re-centring the humeral head with respect to the glenoid on this selective population. A larger cohort and longer follow-up is needed to confirm these results.

CONFLICT OF INTERESTS

The authors declare that they have no conflicts of interests

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