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Doctor of Philosophy

Superior Capsular Reconstruction for the Treatment of Massive
Rotator Cuff Tears: Surgical Outcomes and Clinical Significances

The Graduate School
of the University of Ulsan

Department of Medicine

Hui Ben

Superior Capsular Reconstruction for the Treatment of Massive
Rotator Cuff Tears: Surgical Outcomes and Clinical Significances

Supervisor: In-Ho Jeon

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Hui Ben

Department of Orthopaedic Surgery

University of Ulsan, Korea

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Superior Capsular Reconstruction for the Treatment of Massive Rotator Cuff Tears: Surgical Outcomes and Clinical Significances

This certifies that the dissertation

of Ben Hui is approved.

Committee chair Dr. Kim, Jae-Kwang

Committee member Dr. Jeon, In-Ho

Committee member Dr. Koh, Kyoung-Hwan

Committee member Dr. Lee, Woo-Yong

Committee member Dr. Kwak, Jae-Man

Department of Orthopaedic Surgery

University of Ulsan, Korea

August 2024

ABSTRACT

Background and purpose: Superior capsule reconstruction (SCR) was introduced and developed for the management of massive rotator cuff tears. Although age, gender, body mass index (BMI), fatty infiltration (FI), stump classification, timeline of clinical benefits achievements, tendon maturation/healing, Patient Acceptable Symptom State (PASS), minimal clinically important difference (MCID), and substantial clinical benefit (SCB) have been demonstrated to be associated with clinical outcomes after rotator cuff repair, these factors have not been fully investigated in cases of SCR. This study aimed to investigate the effects of these factors on surgical outcomes and clinical benefits after SCR.

Methods: We retrospectively collected data from patients who underwent ASCR using a fascia lata autograft (FLA) between June 2013 and October 2022. Preoperative and postoperative surgical findings were thoroughly reviewed. Based on stump classification using the signal intensity ratio of the tendon rupture site to the deltoid muscle in the coronal view of preoperative T2-weighted, fat-suppressed MRI scans, the patients were classified into types 1, 2, and 3 with ratios of < 0.8 , $0.8-1.3$, and > 1.3 . Graft remodeling was evaluated by analyzing the signal-to-noise quotient (SNQ). Patient-reported outcome measures (PROMs), including the American Shoulder and Elbow Surgeons (ASES) score, single assessment numeric evaluation (SANE) score, Constant score, visual analog scale (VAS) score for pain, and range of motion were evaluated. Anchor questions for deriving PASS, MCID, and SCB values were applied postoperatively. PASS, MCID, and SCB were derived using sensitivity- and specificity-based approaches. The time in which patients achieved MCID, SCB, and PASS was calculated using Kaplan-Meier analysis.

Results: Significant improvements were found in ASES, Constant, SANE, and VAS for all groups based on gender and age. All scores had acceptable areas under the curve for PASS. Analysis of achieving MCID and

PASS showed no difference between the groups in the majority of outcome measures. However, female patients achieved the SANE thresholds for PASS at significantly higher rates than male patients. Patients ≥ 65 years old achieved ASES and Constant thresholds for MCID at significantly higher rates than patients < 65 years old. Significant improvements in VAS and ASES scores were observed in all three groups. Normal and overweight patients had significant improvements in the Constant score; however, no difference was observed in obese patients. No significant difference was observed in the probability distributions of CSOs between the BMI groups. Patients with type 1 stump had significantly higher ASES, constant scores, and forward flexion compared with the other 2 groups. Based on the preoperative FI of infraspinatus, clinical and radiological outcomes significantly improved after SCR. Graft failure was more frequent in patients with severe FI than in those with mild FI. For patients with severe FI of infraspinatus, SCR combined with lower trapezius tendon transfer showed significantly better ASES and lower VAS scores postoperatively compared with the SCR alone. The mean SNQ in the FLA + Mesh group was significantly lower than that in the FLA group at postoperative 3 months. Furthermore, significant differences were found between the 2 groups at the humeral and mid-substance sites. However, there was no difference between the 2 groups at the glenoid site. Furthermore, in the FLA group, there was a significant decrease in SNQ between 3- and 12-month postoperative MRI examination. However, there is no difference between the two time points in the FLA + Mesh group. The PASS, MCID, and SCB values were 1.5, 2.5, and 4.5 for pVAS; 81.0, 19.0, and 27.5 for the ASES score; 60.5, -0.5, and 5.5 for the Constant score; and 75.0, 27.5, and 32.5 for SANE, respectively. The time of mean achievement of MCID, substantial clinical benefit, and PASS for ASES was 13.2 ± 1.0 , 16.8 ± 1.0 , and 18.3 ± 0.9 months, respectively. The time of mean achievement of MCID, substantial clinical benefit, and PASS for the Constant score was 11.6 ± 0.9 , 15.1 ± 1.0 , and 14.7 ± 0.9 months, respectively. The time of mean achievement of MCID, substantial clinical benefit, and PASS for SANE was 14.4 ± 1.0 ,

16.1 ± 1.0, and 15.5 ± 0.8 months, respectively.

Conclusion: Female patients achieved PASS on SANE at significantly higher rates than male patients and older patients achieved MCID on ASES and Constant at higher rates than young patients. Thus, age is a stronger factor for achieving MCID than gender. However, no differences were observed in all PROMs and the likelihood of achieving CSOs among the different BMI groups. Stump classification may be useful for predicting postoperative clinical outcomes; however, the clinical importance of these differences may be limited. Severe FI of the infraspinatus muscle was a factor indicating a poor prognosis for graft integrity. SCR combined with lower trapezius tendon transfer contributed to significantly lower graft tear rates and better clinical outcomes for patients with severe FI of the infraspinatus muscle. At the 3-month follow-up, the FLA + Mesh group showed a lower MRI signal intensity than the FLA group. The healing and remodeling of an FLA may be enhanced when a mesh is used. The Mesh contributed to maintained graft remodeling until 1 year postoperatively. Reliable PASS, MCID, and SCB values were achieved for at least 1 year after SCR surgery. Most patients achieved MCIDs around 1 year after SCR.

Keywords: age; gender; body mass index; fatty infiltration; graft failure; infraspinatus; advanced glycation end-products; signal intensity of the stump; graft remodeling and healing; signal intensity; clinically significant outcomes; irreparable rotator cuff tear; rotator cuff; superior capsule reconstruction; minimal clinically important difference; patient acceptable symptomatic state; substantial clinical benefit; superior capsular reconstruction; time to achieve clinical significance

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LIST OF ABBREVIATIONS

MRCTs	Massive rotator cuff tears
RCR	Rotator cuff repair
SCR	Superior capsular reconstruction
CSOs	Clinically significant outcomes
NORM	Normal BMI group
OW	Overweight BMI group
OB	Obese BMI group
BMI	Body mass index
n.s.	Not significant
ROI	Region of interest
SNQ	Signal to noise quotient
SI	Signal intensity
ASES	American Shoulder and Elbow Surgeons
SANE	Single Assessment Numeric Evaluation
VAS	Visual analog scale for pain
AHD	Acromiohumeral Distance

GFDI	Global Fatty Degeneration Index
PASS	Patient Acceptable Symptom State
SCB	Substantial clinical benefit
AUC	Area under the curve
MCID	Minimal clinically important difference
PPV	Positive Predictive Value
NPV	Negative Predictive Value
FLA	Fascia lata autograft
PM/Mesh	Polypropylene mesh
SSP	Supraspinatus
FI	Fatty infiltration
LTT	Lower trapezius tendon
RSA	Reverse shoulder arthroplasty
ROM	Range of motion
PreOP	Preoperative
PostOP	Postoperative

Part I: Surgical outcomes after SCR

INTRODUCTION

Massive rotator cuff tears (MRCTs) are usually characterized by severe shoulder pain and functional impairments.⁷⁴ The treatment of MRCTs was challenging for orthopaedic surgeons. Galatz et al reported a poor healing rate after rotator cuff repair, which was always associated with following arthritic changes.³⁸ Reverse total shoulder arthroplasty is demonstrated to be a favorable option for the treatment of MRCTs; however, concerns remained because of its longevity in the young active population.¹⁰⁵ As a result, many joint-preserving surgeries were considered, including partial rotator cuff repair (RCR),³⁰ tendon transfers,³⁹ patch grafts,¹⁵ the Chinese way,¹⁷ and superior capsular reconstruction (SCR)¹⁰.

Recently, SCR using fascia lata autografts⁵² and allografts³⁴ has been introduced and developed for the treatment of MRCTs. The reconstructed capsule was proved to function as a static stabilizer to compress the humeral head migration.¹⁴ Many studies have reported the improved stability of the glenohumeral joint and clinical outcomes^{8,52,108}. Some factors have been demonstrated to be related to inferior outcomes. System reviews reported that the age of the pooled patients undergoing SCR ranged from 60-70 years.⁵⁵ Kholinne et al demonstrated that SCR resulted in a favorable surgical outcome for both younger and older adult patients based on a retirement age of 65 years as defined by the World Health Organization.⁵² Mihata et al demonstrated that the reparability of the subscapularis affects superior glenohumeral stability.⁸² Graft healing has been a well-known and critical factor in reaching favorable clinical outcomes after SCR.^{27,80} However, graft tear rates were reported to vary from 0% to 55%.⁵³ Mihata et al demonstrated that an 8-mm-thick fascia lata autograft (FLA) lead to greater stability of the glenohumeral joint than did a 4-mm-thick FLA.⁸⁴ Furthermore, Kholinne et al demonstrated that SCR using FLA with polypropylene mesh augmentation could reduce graft tear rate to restore superior shoulder joint stability.⁵³

Gender and age are reported to influence outcomes after arthroscopic surgery.^{6,25} Studies have found that female patients are associated with a greater chance of clinical failure after ASCR.⁴⁰ Fares et al. found that the patients with normal weight reached significantly higher clinical outcomes after rotator cuff repair.³⁵ Although use of a mesh has been reported to provide biomechanical advantages and excellent biocompatibility, it is also associated with several adverse effects, such as foreign body responses that aggravate inflammation.^{5,59,111} Previous studies reported that fatty infiltration (FI) of rotator cuff was a vital prognostic factor in rotator cuff repair and patch autograft surgery for massive rotator cuff tears.⁶⁶ Li et al demonstrated that SCR using fascia lata autograft sutured with torn supraspinatus (SSP) could lead to better outcomes than SCR alone.⁷⁰ Meshram et al demonstrated that patients who underwent revision RCR after failed RCR showed inferior clinical outcomes compared with primary RCR.⁷⁹ As a newly developed procedure for just 10 years from 2013,⁸³ knowledges about factors affecting surgical outcomes after SCR is still limited.

This study aimed to investigate the effect of these factors on the clinical and radiological outcomes after SCR, including older age, female, obesity, severe FI in the infraspinatus, lower trapezius tendon transfer, better tendon quality of remaining supraspinatus, mesh augmentation. It was hypothesized that: 1) older age, female, obesity, and severe FI in the infraspinatus were related to inferior surgical outcomes; 2) additional lower trapezius tendon transfer and better quality of remaining supraspinatus tendon were related to superior surgical outcomes.

METHODS

Patients Selection

Patients who underwent SCR at a tertiary referral hospital between January 2013 and January 2023 were retrospectively reviewed. The inclusion and exclusion criteria were shown in **Table 1**.

Table 1. Inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
Diagnosis of MRCT with (A) greatest dimension of the tear >5 cm, (B) complete tear of ≥ 2 tendons, medial retraction of at least (C) Patte grade 3 on a preoperative MRI scan according to their medical record ⁶¹	Rotator cuff tear arthropathy of Hamada grade 4 & 5
Autograft (tensor fascia lata graft)	Irreparable subscapularis tendon tear
MRCT after arthroscopic reduction trial	<1 year of minimum follow-up
Intact deltoid muscle on preoperative physical examination	Cervical nerve or axillary nerve palsy

MRCT; massive rotator cuff tear; MRI, magnetic resonance imaging.

SCR using folded fascia lata autograft (FLA) was performed between January 2013 and September 2016. Based on the operating surgeons' observation for the preliminary surgical outcomes of the earlier technique, the polypropylene mesh was inserted into the folded FLA for biomechanical augmentation. Based on the

operating surgeons' observation for the preliminary surgical outcomes, the surgical technique was changed from ASCR to ASCR + lower trapezius tendon (LTT) transfer for patients with severe FI of infraspinatus.

Surgical Technique

All patients underwent the surgery in a beach chair position after general anesthesia. First, a 5-cm horizontal incision approximately 1 cm inferior to the scapular spine and crossing over the medial 1/3 edge of the scapula was made to expose the lower trapezius tendon. The lower trapezius tendon was exposed and detached from the underlying infraspinatus fascia. A No.2 polyester suture (Ethibond) was used to tag the tendon (**Figure 1A**).

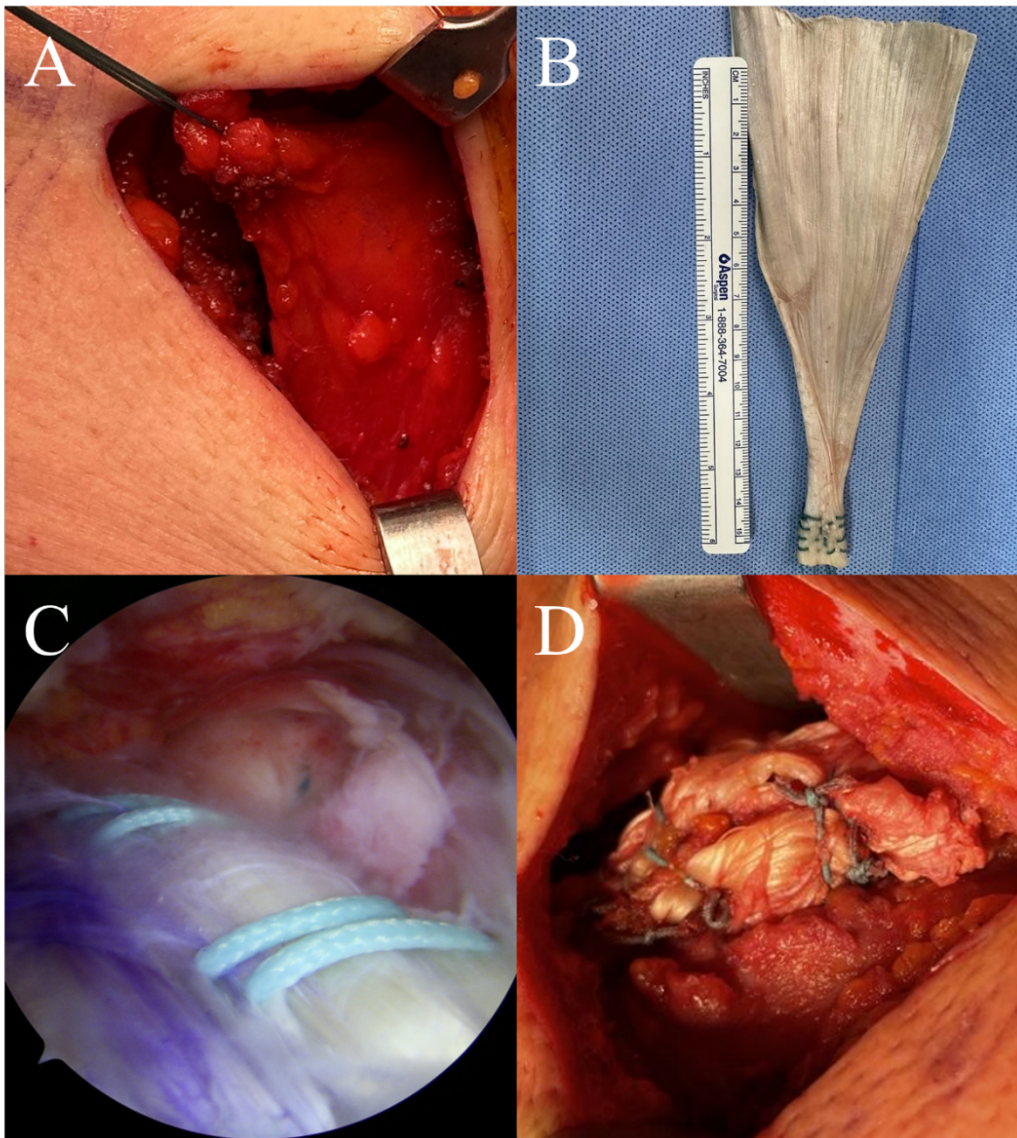


Figure 1. (A) Lower trapezius tendon; (B) Achilles tendon allograft; (C) Achilles tendon allograft on top of the graft; (D) Achilles tendon allograft sutured with lower trapezius tendon.

Diagnostic arthroscopy was performed to confirm the size and configuration of the torn cuff. After subacromial decompression and tenotomy of biceps (if present), a probe was used to measure the distance for graft sizing. An ipsilateral fascia lata graft was harvested and folded with a single layer of polypropylene mesh (Prolene Mesh; Ethicon Inc) inserted between the folded graft. A running stitch No. 2-0 polyester suture (Ethibond) was applied to seal the graft margin. At last, a graft with a ≥ 6 mm thickness was prepared

(Figure 2). No. 2 polyester sutures were used to seal the end of Achilles tendon allografts using the Krackow method (Figure 1B). Three all-soft anchors (1.7-mm SUTUREFIX Suture Anchor; Smith & Nephew) were used at the glenoid site to fix the graft. In the medial row of the footprint, two PEEK threaded anchors (4.5-mm HEALICOIL Suture Anchor; Smith & Nephew) were used for graft fixation. After graft fixation, the Achilles tendon was passed through an interval between the infraspinatus muscle and deltoid muscle. Four threads of the posterior anchor in the medial row and Achilles tendon were taken out from the anterior portal. An empty needle was used to pass the limbs through the Achilles tendon for fixation at the posterior footprint of the humeral head. The four threads of the Achilles tendon were fixed by using a knotless anchor (Footprint Ultra 4.5 mm; Smith & Nephew). After fixation of the Achilles tendon, the shoulder was put in the position of abduction and external rotation and No. 2 polyester sutures were used to suture the Achilles tendon and the lower trapezius tendon using the Fish-Mouth method (Figure 1D).

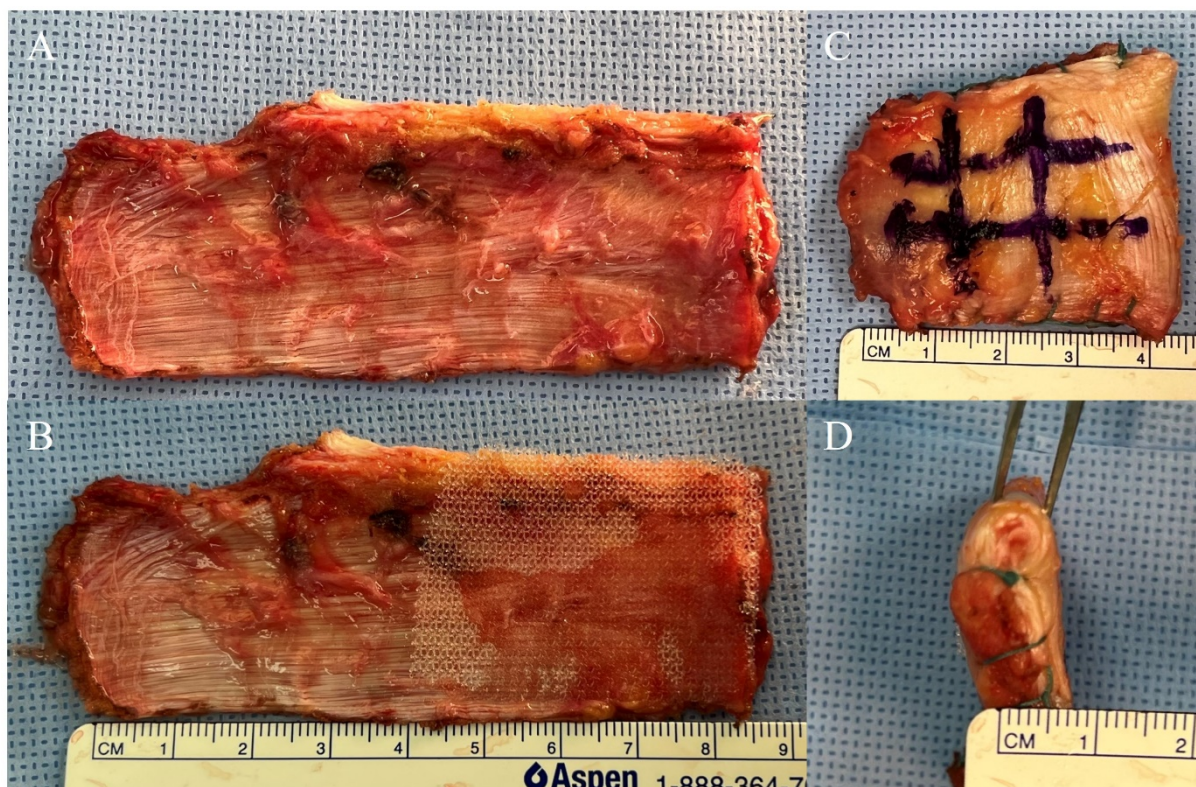


Figure 2. Graft preparation using mesh augmentation. (A) Fascia lata autograft. (B) One additional layer of polypropylene mesh on the graft. (C–D) Mesh fashioned inside the folded fascia lata.

Postoperative rehabilitation

After the surgery, a 30° of shoulder abduction was applied for postoperative immobilization for 6 weeks. At 3 weeks postoperatively, patients were instructed to perform pendulum exercises. Once full range of motion (ROM) was gained, strengthening exercises were performed under the instruction of experienced physical therapists.

Assessment of Clinical Outcomes

Demographic and intraoperative variables, including age, sex, affected side, hypertension, diabetes, smoking and subscapularis repair/not, were collected from the medical record. The range of motion (ROM), including forward elevation and external rotation, was assessed using a goniometer. The internal rotation was assessed and recorded using a numbering method.⁷ Clinical outcomes were assessed using a VAS, ASES SANE, and Constant scores.

Questionnaire

Patient Acceptable Symptom State (PASS), minimal clinically important difference (MCID), and substantial clinical benefit (SCB) were investigated through anchor-based or distribution-based methods. As shown in

Table 2, the anchor questions were asked for determining PASS, MCID, and SCB using the anchor-based method.¹¹⁶ MCID was derived as the value equal to one-half of standard deviation of the change in postoperative and the preoperative outcomes.³⁶

Table 2 Anchor Questions

Variable	Description	Group
PASS	Are you satisfied with your superior capsular reconstruction surgery?	Yes: Satisfied No: Unsatisfied
MCID and SCB		
A: None	No improvement and pain persists compared with before surgery	Unchanged
B: Poor	Mild improvement but with persistent pain and discomfort	Unchanged
C: Good	Considerable improvement but a little pain and discomfort remained	Changed (MCID)
D: Excellent	Sufficient improvement and satisfaction with the present state	Improved (SCB)

PASS: Patient Acceptable Symptom State; MCID: Minimal Clinically Important Difference; SCB:

Substantial Clinical Benefit

Assessment of Radiological Outcomes

The anteroposterior plain radiographs were used to assess the acromiohumeral distance (AHD) and Hamada classification.¹¹⁶ Preoperative MRI was used to assess the patte classification⁹⁵ and FI.⁶⁶ The global fatty degeneration index was used to indicate the FI of rotator cuff tendon.⁴² Stump classification was measured

based on Ishitani et al's study.⁴⁷ The signal intensity of the RC tendon stump (C) and deltoid muscle (D) was calculated on preoperative MRIs. The C/D ratio was measured to classify the patients into type 1 ($C/D < 0.8$), type 2 ($0.8 \leq C/D \leq 1.3$), and type 3 ($C/D > 1.3$) groups.

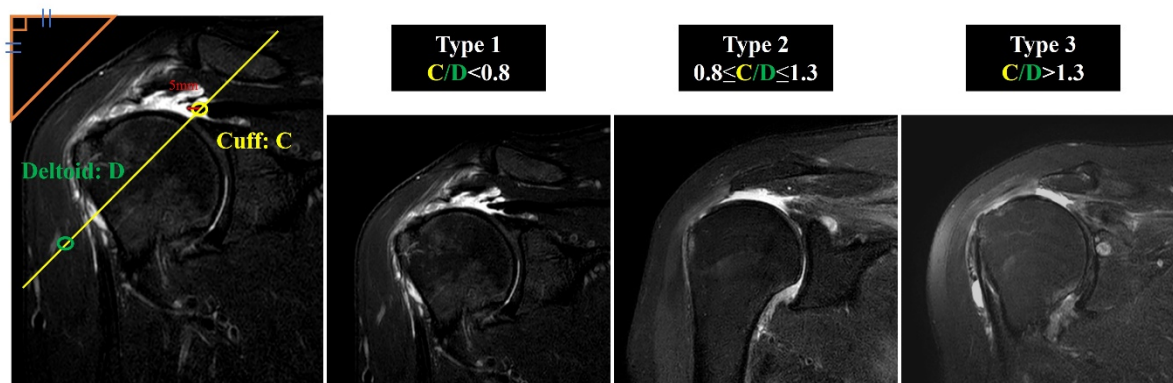


Figure 3. D, deltoid signal intensity; C, rotator cuff stump signal intensity.

Postoperative MRI was used to assess the graft integrity and progression of FI. Any sign of graft discontinuity was recorded as a graft failure.¹¹⁶ For patients with intact grafts, the signal intensity (SI) of grafts were measured according to Pfalzer et al's study.⁹⁶ T2 images were selected and the regions of interest (ROIs) were used to measure the SI and generate the signal to noise quotient (SNQ) at the humeral side region (SNQh), the mid-substance region (SNQm), glenoid side region (SNQg) and the background site (approximately 2 cm lateral to the shoulder) (**Figure 4**).⁷² The SNQ was equal to SI of graft/signal of background.⁶⁹ At last, the average of the three SNQ values was generated.

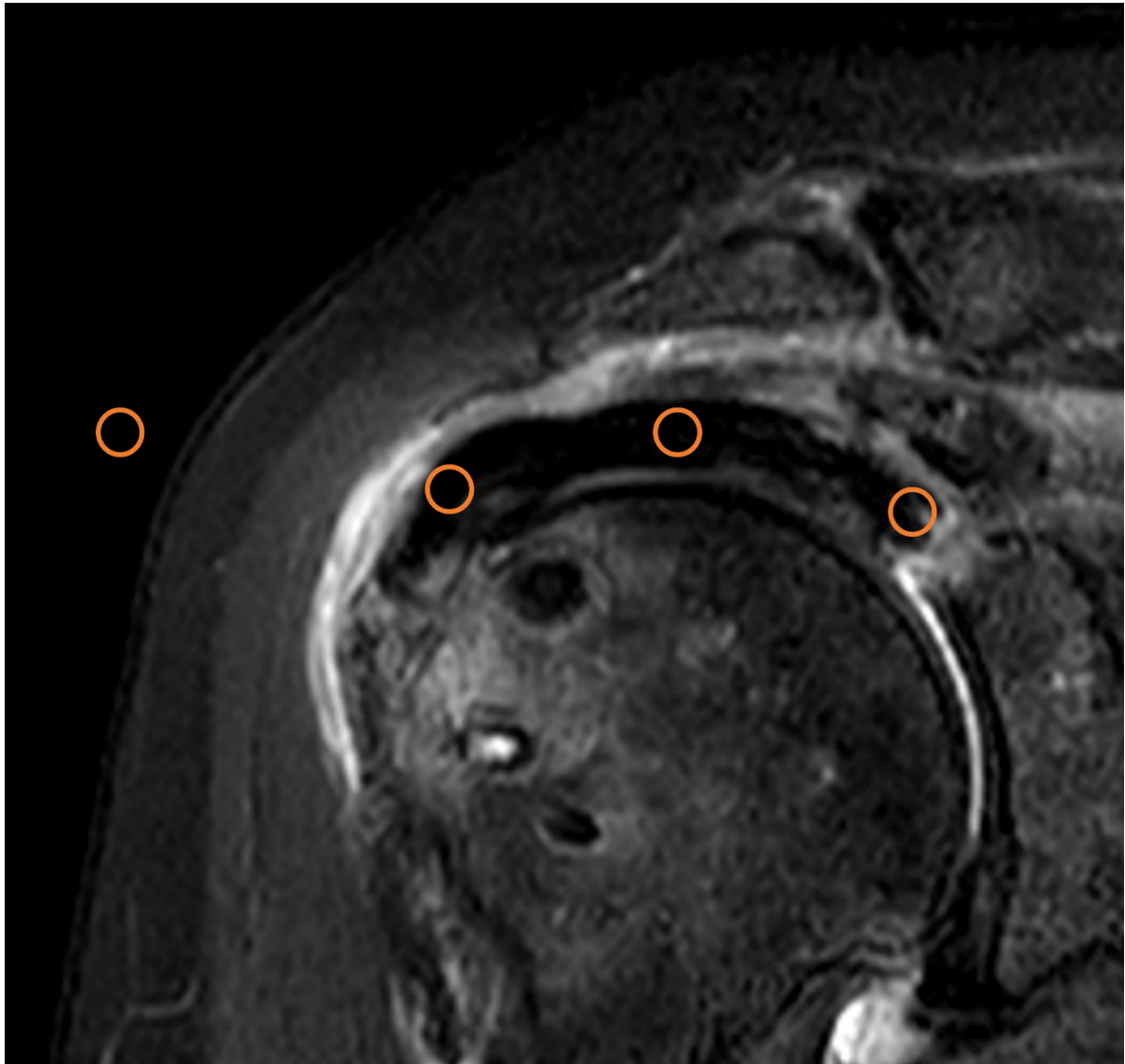


Figure 4. Coronal view of a MRI image. Region of interest (ROI) circles were placed at three locations (1, humeral site; 2, mid-substance site; 3, glenoid site; and 4, background).

Statistical analysis

Continuous data was compared using the Student t test, Wilcoxon signed-rank test, Mann-Whitney U test or Kruskal–Wallis test, and categorical data was compared using the Chi-square test or Fisher test. The time required to achieve each CSO was analyzed using the Kaplan–Meier survivorship curve and the generalized log-rank test. Statistical analysis was performed using SPSS 27.0 software (IBM, NY, USA) with the statistical significance level set at $P < 0.05$.

RESULTS

The effect of age & gender on outcomes

As shown in **Table 3**, there were no differences in sex, BMI, preoperative AHD, graft failure, and follow-up time between the 2 groups. Older patients had better ASES and Constant scores than younger patients ($P = 0.003$, and $P = 0.008$, respectively).

Age	≥65 Years	<65 Years	<i>P</i> Value
Gender			n.s.
Male	14	22	
Female	27	20	
Body mass index	25.8 ± 3.5	26.3 ± 4.0	n.s.
Side, n (%)			n.s.
Left	11	13	
Right	30	29	
Dominant side affected, n	30	30	n.s.
Diabetes mellitus	6	7	n.s.
Graft, FLA /PM (n)	17/24	12/28	n.s.
Graft failure (n)	14	11	n.s.
AHD, mm	4.9 ± 1.7	5.1 ± 2.6	n.s.
VAS score	5.7 ± 1.8	5.6 ± 1.8	n.s.
ASES score	44.6 ± 17.1	55.9 ± 16.6	0.003
Constant score	49.1 ± 13.7	56.4 ± 10.8	0.008
SANE score	42.4 ± 19.5	41.7 ± 20.7	n.s.
Follow-up time, years	3.7 ± 1.5	3.4 ± 1.2	n.s.

Table 3. Patient Demographics by Age 65 Years Old

FLA, fascia lata autograft; PM, polypropylene mesh; AHD, acromiohumeral distance; VAS, visual analog scale; ASES, American Shoulder and Elbow Surgeons; SANE, single assessment numeric evaluation; n.s., not significant.

There were no differences between the female and male patients in demographics, functional outcomes, and preoperative radiological outcomes (**Table 4**). Females showed a significantly higher VAS score than males preoperatively ($P = 0.026$).

Table 4. Patient Demographics by Gender

FLA, fascia lata autograft; PM, polypropylene mesh; AHD, acromiohumeral distance; VAS, visual analog scale; ASES, American Shoulder and Elbow Surgeons; SANE, single assessment numeric evaluation; n.s., not significant.

Based on the gender and age of the 65-year-old patients, all 4 groups achieved significant improvement in

Gender	Female	Male	<i>P</i> Value
Age in Years	66.3 ± 6.8	63.4 ± 6.4	n.s.
≥65 Years	20	22	n.s.
<65 Years	27	14	
Body mass index	26.4 ± 4.4	25.6 ± 2.6	n.s.
Side, n			n.s.
Left	12	12	
Right	35	24	
Dominant side affected, n	36	24	n.s.
Diabetes mellitus	6	8	n.s.
Graft, FL: FLA/PM (n)	20/27	11/25	n.s.
Graft failure (n)	12	13	n.s.
AHD, mm	4.7 ± 2.0	5.1 ± 2.5	n.s.
VAS score	6.0 ± 1.9	5.2 ± 1.6	0.026
ASES score	48.6 ± 17.7	52.6 ± 17.6	n.s.
Constant score	50.8 ± 13.9	55.4 ± 10.7	n.s.
SANE score	41.1 ± 20.6	43.2 ± 19.3	n.s.
Follow-up time, years	3.4 ± 1.4	3.8 ± 1.3	n.s.

ASES, Constant, SANE, and VAS scores at the latest follow-up compared with preoperative levels ($P < 0.05$

for all) (**Table 5**).

	Preoperative	Postoperative	<i>P</i> Value
ASES			
Female			
All	48.6 ± 17.7	79.9 ± 15.8	< 0.001
≥65 Years	42.5 ± 16.3	78.9 ± 15.1	< 0.001
< 65 Years	56.9 ± 16.5	81.2 ± 17.0	< 0.001
Male			
All	52.6 ± 17.6	81.8 ± 12.6	< 0.001
≥65 Years	48.7 ± 18.5	83.9 ± 11.6	< 0.001
< 65 Years	55.0 ± 16.9	80.5 ± 13.4	< 0.001
Constant			
Female			
All	50.8 ± 13.9	60.8 ± 10.6	< 0.001
≥65 Years	46.4 ± 14.0	59.4 ± 10.9	< 0.001
< 65 Years	56.6 ± 11.8	62.8 ± 10.2	0.025
Male			
All	55.4 ± 10.7	65.3 ± 9.6	< 0.001
≥65 Years	54.1 ± 11.9	68.3 ± 9.5	< 0.001
< 65 Years	56.2 ± 10.1	63.3 ± 9.4	0.010
SANE			
Female			
All	42.0 ± 19.9	77.7 ± 16.4	< 0.001
≥65 Years	40.1 ± 20.4	77.6 ± 15.8	< 0.001
< 65 Years	44.7 ± 19.5	77.9 ± 17.6	< 0.001
Male			
All	43.2 ± 19.3	75.9 ± 17.1	< 0.001
≥65 Years	46.9 ± 17.5	78.6 ± 16.8	< 0.001
< 65 Years	40.9 ± 20.4	74.1 ± 17.4	< 0.001
VAS			
Female			
All	6.0 ± 1.9	1.3 ± 1.4	< 0.001
≥65 Years	6.2 ± 1.9	1.4 ± 1.4	< 0.001
< 65 Years	5.9 ± 1.9	1.2 ± 1.4	< 0.001
Male			
All	5.2 ± 1.6	1.3 ± 1.6	< 0.001
≥65 Years	4.8 ± 1.4	0.6 ± 0.9	< 0.001
< 65 Years	5.4 ± 1.7	1.7 ± 1.8	< 0.001

Table 5. Comparison of Baseline and 2-year Functional Score Averages by Gender and Age of 65 Years

VAS, visual analog scale; ASES, American Shoulder and Elbow Surgeons; SANE, single assessment numeric evaluation; n.s., not significant.

A comparison of change for each score at the final follow-up based on age and gender is shown in **Figure 5**.

Significant differences in ASES and Constant score changes were detected between patients ≥ 65 years old and < 65 years old ($P = 0.003$ and 0.008 , respectively, **Figure 5A**). Similarly, a significant difference was found in VAS scores between female and male patients ($P = 0.026$, **Figure 5B**).

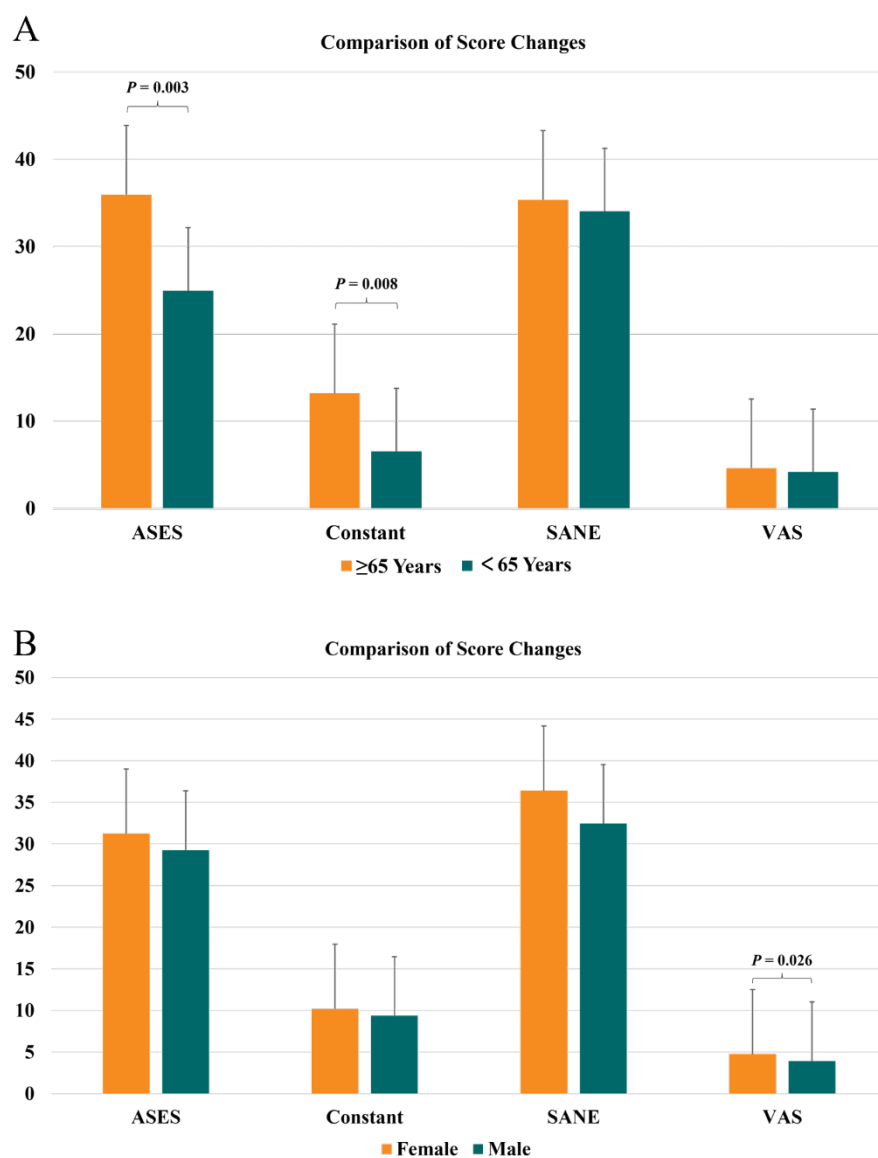


Figure 5. (A) Comparison of score changes between ≥ 65 - and < 65 -year-old groups. (B) Comparison of score changes between female and male patients. ASES, American Shoulder and Elbow Surgeons; SANE, single

assessment numeric evaluation; VAS, visual analog scale for pain.

MCID and PASS determination

Statistically significant improvements were found in ASES, Constant, SANE, and VAS scores at the latest follow-up compared with baseline ($P < 0.001$ for all) (**Table 6**). Changes in ASES, Constant, SANE, and VAS scores over the 2 years required to achieve MCID were 10.3, 6.2, 11.5, and 1.1, respectively, whereas

	Preoperative	Postoperative	<i>P</i> Value
ASES	50.3 ± 17.7	80.7 ± 14.4	< 0.001
Constant	52.8 ± 12.8	62.7 ± 10.4	< 0.001
SANE	42.5 ± 19.6	76.9 ± 16.6	< 0.001
VAS	5.7 ± 1.8	1.3 ± 1.5	< 0.001

the 2-year threshold scores for achieving PASS were 81.5, 61.5, 82.5, and 1.5, respectively.

Table 6. Comparison of Preoperative and Postoperative Functional Score Averages for the Cohort

VAS, visual analog scale; ASES, American Shoulder and Elbow Surgeons; SANE, single assessment numeric evaluation; n.s., not significant.

The rates of achieving both in the entire cohort are summarized in **Table 7**.

Table 7. MCID and PASS Threshold Scores and Frequency of Achievement

	Score Threshold	Frequency
MCID		
ASES	10.3	67 (80.7%)
Constant	6.2	52 (62.7%)
SANE	11.5	64 (77.1%)
VAS	1.1	79 (95.2%)
Any MCID	-	82 (98.8%)
PASS		
ASES	81.5	47 (56.6%)
Constant	61.5	56 (67.5%)
SANE	82.5	45 (54.2%)
VAS	1.5	52 (62.7%)
Any PASS	-	68 (81.9%)

Statistical significance is indicated in bold. VAS, visual analog scale; ASES, American Shoulder and Elbow

Surgeons; SANE, single assessment numeric evaluation; MCID, minimal clinically important difference;

PASS, Patient-Acceptable Symptom State; n.s., not significant.

Analysis of MCID and PASS according to gender

A comparison of achieving PASS between the 2 groups showed that a significantly greater proportion of females achieved SANE thresholds for PASS than male patients ($P = 0.045$) (Table 8).

Table 8. Rates of Achieving MCID and PASS by Gender

	Female	Male	<i>P</i> Value
MCID			
ASES	37 (78.7%)	30 (83.3%)	n.s.
Constant	29 (61.7%)	23 (63.9%)	n.s.
SANE	37 (78.7%)	27 (75.0%)	n.s.
VAS	45 (95.7%)	34 (94.4%)	n.s.
Any MCID	46 (97.9%)	36 (100.0%)	n.s.
PASS			
ASES	25 (53.2%)	22 (61.1%)	n.s.
Constant	30 (63.8%)	26 (72.2%)	n.s.
SANE	30 (63.8%)	15 (41.7%)	0.045
VAS	28 (59.6%)	24 (66.7%)	n.s.
Any MCID	36 (76.6%)	31 (86.1%)	n.s.

Statistical significance is indicated in bold. VAS, visual analog scale; ASES, American Shoulder and Elbow Surgeons; SANE, single assessment numeric evaluation; MCID, minimal clinically important difference; PASS, Patient-Acceptable Symptom State; n.s., not significant.

Analysis of MCID and PASS based on Age of 65 Years

A comparison of achieving MCID between the 2 groups showed that patients ≥ 65 years old achieved ASES and Constant thresholds for MCID at significantly higher rates than patients < 65 years old ($P = 0.030$ and $P = 0.004$, respectively) (**Table 9**).

Table 9. Rates of Achieving MCID and PASS based Age of 65 Years

	≥ 65 Years	< 65 Years	<i>P</i> Value
MCID			
ASES	37 (90.2%)	30 (71.4%)	0.030
Constant	32 (78.0%)	20 (47.6%)	0.004
SANE	32 (78.0%)	32 (76.2%)	n.s.
VAS	40 (97.6%)	39 (92.9%)	n.s.
Any MCID	40 (97.6%)	42 (100.0%)	n.s.
PASS			
ASES	23 (56.1%)	24 (57.1%)	n.s.
Constant	28 (68.3%)	26 (61.9%)	n.s.
SANE	18 (43.9%)	17 (40.5%)	n.s.
VAS	27 (65.9%)	25 (59.5%)	n.s.
Any PASS	33 (80.5%)	32 (76.2%)	n.s.

Statistical significance is indicated in bold. VAS, visual analog scale; ASES, American Shoulder and Elbow Surgeons; SANE, single assessment numeric evaluation; MCID, minimal clinically important difference; PASS, Patient-Acceptable Symptom State; n.s., not significant.

The effect of BMI on outcomes

The baseline variables were described in **Table 10**. When stratified by BMI category, 47.6% of patients were observed to have normal weight ($23.2 \pm 1.3 \text{ kg/m}^2$), 39.7% were overweight ($27.2 \pm 1.2 \text{ kg/m}^2$), and 11.1% were obese ($33.4 \pm 3.0 \text{ kg/m}^2$).

No differences were observed regarding age, sex distribution, diabetes, hypertension, as well as the preoperative VAS, ASES, Constant scores, and active ROMs (all $P > 0.05$) among the three groups (**Table 10**).

Table 10. Patients Demographics

Variable	Normal	Overweight	Obese	<i>P</i> Value
Age	64.9 ± 7.7	65.8 ± 7.4	60.7 ± 14.8	0.792
Sex				0.443
Male	12	6	3	
Female	19	19	4	
BMI	23.2 ± 1.3	27.2 ± 1.2	33.4 ± 3.0	< 0.001
Diabetes	4	4	1	> 0.999
Hypertension	13	11	2	0.872
Preoperative VAS	5.5 ± 1.8	5.9 ± 2.0	5.7 ± 1.4	0.654
Preoperative ASES	50.6 ± 17.7	49.2 ± 16.4	46.9 ± 17.6	0.892
Preoperative Constant	54.7 ± 9.9	52.6 ± 13.7	53.7 ± 13.2	0.906
Preoperative forward elevation	144.2 ± 26.8	135.0 ± 33.3	150.7 ± 15.9	0.561
Preoperative external rotation	48.2 ± 22.1	35.4 ± 21.5	36.4 ± 11.8	0.053
Preoperative internal rotation	12.4 ± 3.1	11.4 ± 2.5	14.0 ± 2.7	0.091

Data expressed as mean ± standard deviation. BMI, body mass index; VAS, visual acuity scale; ASES, American Shoulder and Elbow Surgeons.

Patient-reported Outcomes

As shown in **Figure. 6**, VAS scores significantly decreased after surgery at all three time points compared with the preoperative baseline in all three groups (all $P < 0.05$).

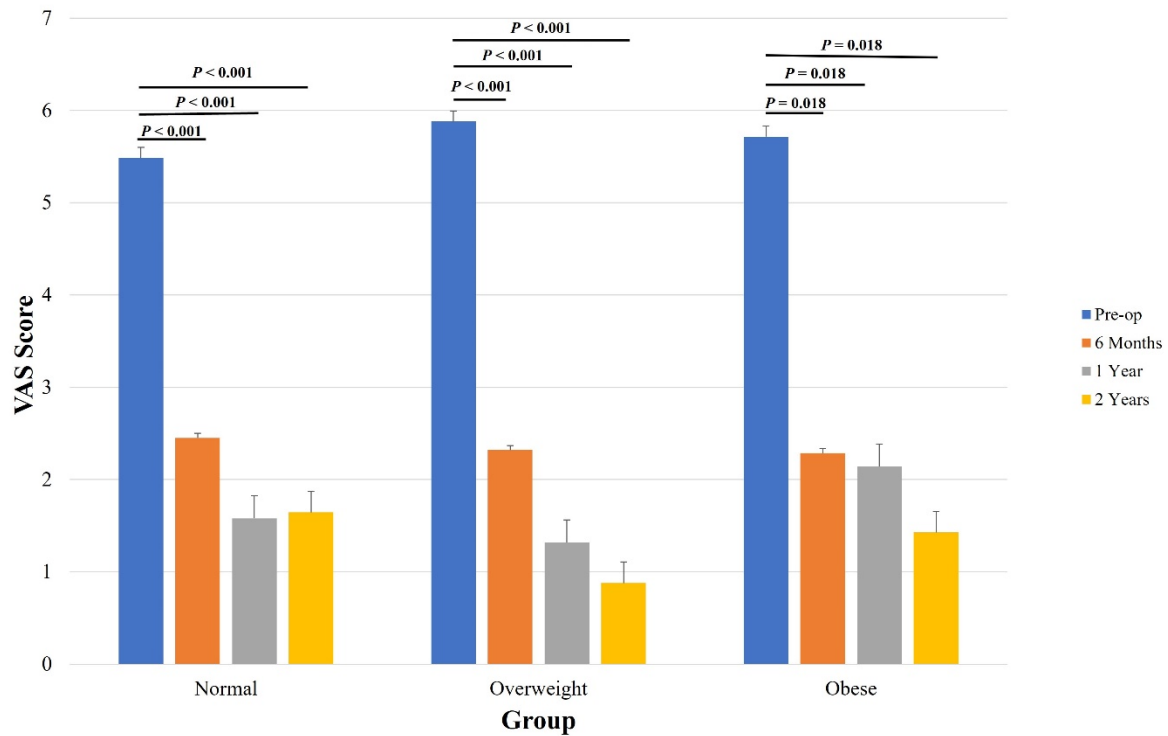


Figure. 6 Comparison of postoperative 6-month, 1-year, and 2-year follow-up VAS score among the three BMI categories. VAS, visual analog scale for pain; BMI, body mass index.

As depicted in **Figure 7**, ASES scores exhibited significant improvement after surgery at all three time points compared to the preoperative baseline in both the normal and overweight groups (all $P < 0.05$). However, in the obese group, ASES scores significantly improved only from the preoperative baseline to the 6-month and 1-year follow-up time points, with no discernible difference observed between the preoperative baseline and the 2-year follow-up.

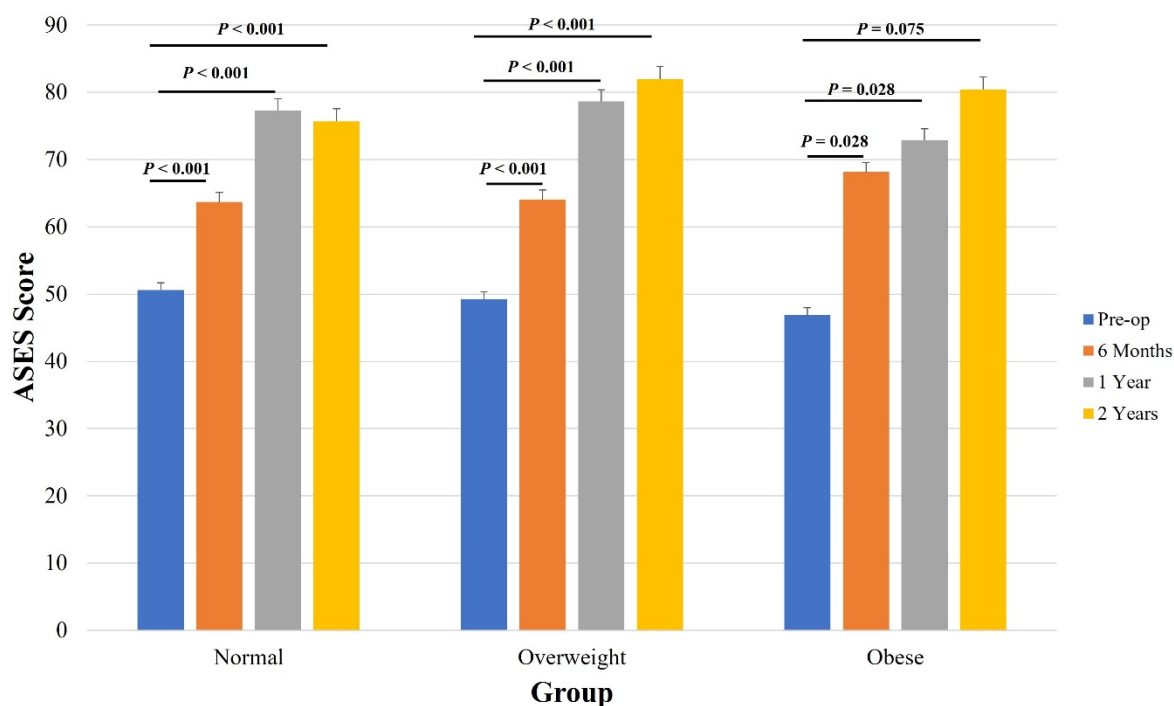


Figure. 7 Comparison of postoperative 6-month, 1-year, and 2-year follow-up ASES score among the three BMI categories. ASES, American Shoulder and Elbow Surgeons; BMI, body mass index.

As illustrated in **Figure 8**, the Constant score demonstrated significant improvement from the preoperative baseline to the 2-year follow-up (all $P < 0.05$) for all patients. Conversely, no improvements were noted at the 6-month follow-up (all $P > 0.05$). By the 1-year follow-up, patients in the normal and overweight groups displayed significant enhancements in the Constant scores (all $P < 0.05$), while no difference was observed

in the obese group.

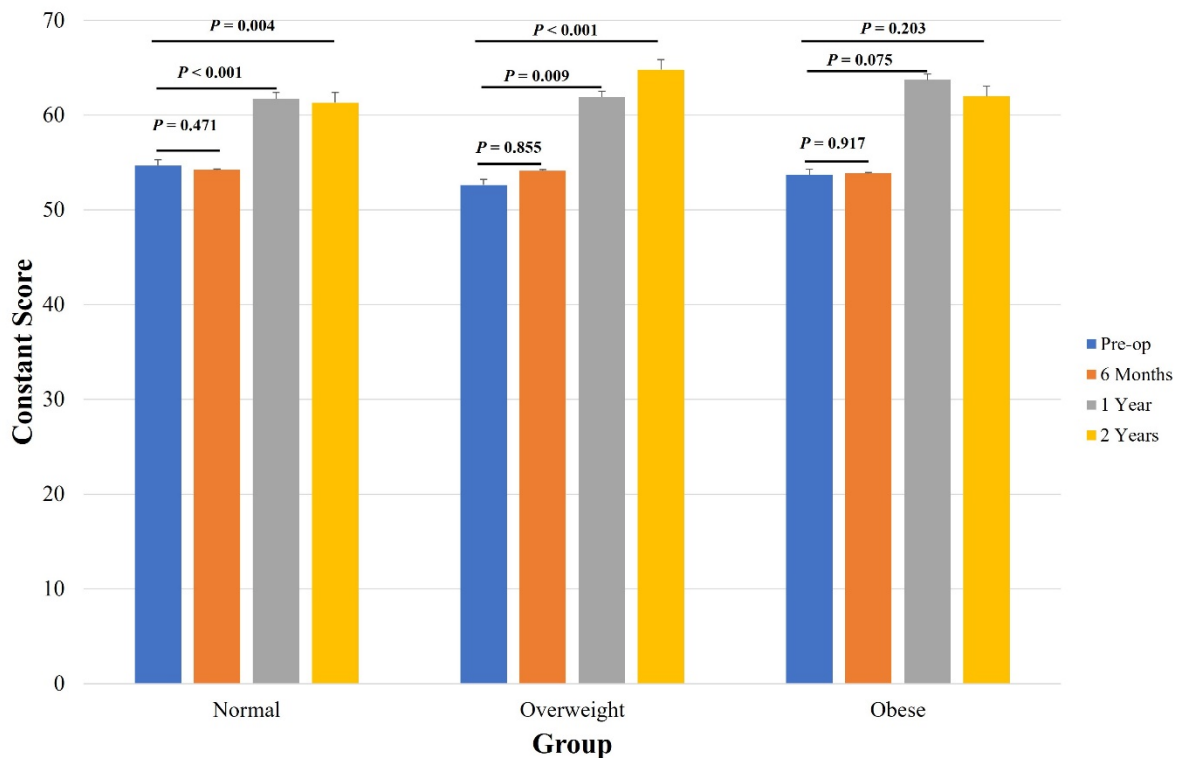


Figure. 8 Comparison of postoperative 6-month, 1-year, and 2-year follow-up Constant score among the three BMI categories. ASES, American Shoulder and Elbow Surgeons; BMI, body mass index.

ROM

As presented in **Table 11**, only patients in the obese group exhibited significantly inferior internal rotation compared to those in the normal group ($P = 0.010$). However, no differences were observed in forward elevation and external rotation among the three groups ($P = 0.132$ and 0.276 , respectively).

The rates for MCID, SCB, and PASS achievements at the 2-year postoperative mark are detailed in **Table 11**. Across all three groups, at least 70% of patients achieved MCID, with no significant differences observed in the MCID achievement rates (all $P > 0.05$). While the rates of SCB achievement were lower across all groups compared to the MCID rates, no significant differences were noted in the SCB achievement rates (all

$P > 0.05$). Moreover, in all three groups, at least 50% of patients achieved PASS, with no differences detected in the rates of PASS achievement between the groups (all $P > 0.05$).

Table 11. Patient-reported Outcomes, ROM, and Survivorship at 2-year Follow-up

Variable	Normal	Overweight	Obese	<i>P</i> Value
VAS at 2-year follow-up	1.7 ± 1.7	0.9 ± 1.0	1.4 ± 1.3	0.259
ASES at 2-year follow-up	75.7 ± 18.3	82.0 ± 16.7	80.4 ± 12.3	0.419
Constant at 2-year follow-up	61.3 ± 11.1	64.8 ± 8.0	62.0 ± 7.6	0.324
Forward elevation at 2-year follow-up	151.3 ± 14.4	154.2 ± 11.0	161.4 ± 10.7	0.132
External rotation at 2-year follow-up	42.4 ± 13.9	44.8 ± 18.3	35.0 ± 6.5	0.276
Internal rotation at 2-year follow-up	11.2 ± 3.3	12.3 ± 2.8	14.9 ± 2.2	0.013
Achieved MCID within 2 years				
VAS	29 (93.5%)	23 (92.0%)	7 (100%)	> 0.99
ASES	22 (71.0%)	20 (80.0%)	6 (85.7%)	0.695
Constant	26 (83.9%)	22 (88.0%)	5 (71.4%)	0.489
Achieved SCB within 2 years				
VAS	17 (54.8%)	17 (68.0%)	3 (42.9%)	0.436
ASES	17 (54.8%)	18 (72.0%)	4 (57.1%)	0.406
Constant	22 (71.0%)	17 (68.0%)	5 (71.4%)	> 0.999
Achieved PASS within 2 years				
VAS	24 (77.4%)	21 (84.0%)	5 (71.4%)	0.741
ASES	20 (64.5%)	22 (88.0%)	4 (57.1%)	0.069
Constant	24 (77.4%)	21 (84.0%)	5 (71.4%)	0.716

Data expressed as mean ± standard deviation or percentages. ROM, range of motion; VAS, visual acuity scale; ASES, American Shoulder and Elbow Surgeons;

MCID, minimum clinically important difference; SCB, substantial clinical benefit; PASS, patient-acceptable symptom state.

Time Required to Achieve MCID, SCB, and PASS

The likelihood of reaching MCID, SCB, and PASS for VAS scores is outlined in **Table 12**. Remarkably, there were no notable differences observed in the probability of achieving MCID (log-rank: all $P > 0.05$), SCB (log-rank: all $P > 0.05$), or PASS (log-rank: all $P > 0.05$) among these groups. This suggests that the timelines for attaining these Clinically Significant Outcomes (CSOs) were similar across the three groups.

Similarly, regarding the probability of achieving MCID, SCB, and PASS for the ASES scores (**Table 13**) and Constant scores (**Table 14**) at each time point, no significant differences were observed in the probability distributions between the BMI groups ($P > 0.05$).

Table 12 Probability of Achieving MCID, SCB, and PASS for VAS at Each Follow-up Time Point

CSOs and Follow-up Time For VAS	Normal	Overweight	Obese	<i>P</i> Value
Achieving MCID				
6 months	54.8	68.0	57.1	NORM vs OW, 0.446
1 year	77.4	84.0	57.1	NORM vs OB, 0.805
2 years	74.2	84.0	85.7	OW vs OB, 0.845
Achieving SCB				
6 months	22.6	40.0	28.6	NORM vs OW, 0.261
1 year	48.4	52.0	28.6	NORM vs OB, 0.628
2 years	48.4	68.0	42.9	OW vs OB, 0.249
Achieving PASS				
6 months	12.9	24.0	28.6	NORM vs OW, 0.472
1 year	58.1	56.0	28.6	NORM vs OB, 0.989
2 years	54.8	72.0	57.1	OW vs OB, 0.619

CSOs, clinically significant outcomes; VAS, visual acuity scale; MCID, minimum clinically important difference; SCB, substantial clinical benefit; PASS, patient-acceptable symptom state; NORM, normal BMI group; OW, overweight BMI group; OB, obese BMI group.

Table 13. Probability of Achieving MCID, SCB, and PASS for ASES at Each Follow-up Time Point

CSOs and Follow-up Time For ASES	Normal	Overweight	Obese	<i>P</i> Value
Achieving MCID				
6 months	35.5	36.0	57.1	NORM vs OW, <i>P</i> = 0.575
1 year	67.8	72.0	71.4	NORM vs OB, <i>P</i> = 0.336
2 years	54.8	72.0	85.7	OW vs OB, <i>P</i> = 0.558
Achieving SCB				
6 months	19.4	24.0	42.9	NORM vs OW, <i>P</i> = 0.275
1 year	48.4	48.0	28.6	NORM vs OB, <i>P</i> = 0.739
2 years	38.7	64.0	57.1	OW vs OB, <i>P</i> = 0.672
Achieving PASS				
6 months	16.1	12.0	14.3	NORM vs OW, <i>P</i> = 0.326
1 year	54.8	44.0	28.6	NORM vs OB, <i>P</i> = 0.697
2 years	51.6	76.0	57.1	OW vs OB, <i>P</i> = 0.252

CSOs, clinically significant outcomes; ASES, American Shoulder and Elbow Surgeons; MCID, minimum clinically important difference; SCB, substantial clinical benefit; PASS, patient-acceptable symptom state; NORM, normal BMI group; OW, overweight BMI group; OB, obese BMI group.

Table 14. Probability of Achieving MCID, SCB, and PASS for the Constant score at Each Follow-up Time Point

CSOs and Follow-up Time For Constant	Normal	Overweight	Obese	<i>P</i> Value
Achieving MCID				
6 months	48.4	56.0	71.4	NORM vs OW, <i>P</i> = 0.570
1 year	71.0	72.0	71.4	NORM vs OB, <i>P</i> = 0.975
2 years	74.2	88.0	71.4	OW vs OB, <i>P</i> = 0.731
Achieving SCB				
6 months	19.4	28.0	28.6	NORM vs OW, <i>P</i> = 0.986
1 year	58.1	56.0	71.4	NORM vs OB, <i>P</i> = 0.779
2 years	54.8	64.0	71.4	OW vs OB, <i>P</i> = 0.801
Achieving PASS				
6 months	9.7	32.0	71.4	NORM vs OW, <i>P</i> = 0.175
1 year	61.3	60.0	57.1	NORM vs OB, <i>P</i> = 0.990
2 years	64.5	76.0	71.4	OW vs OB, <i>P</i> = 0.428

CSOs, clinically significant outcomes; MCID, minimum clinically important difference; SCB, substantial clinical benefit; PASS, patient-acceptable symptom state;

NORM, normal BMI group; OW, overweight BMI group; OB, obese BMI group.

Effect of the quality of remnant supraspinatus

As shown in **Table 15**, no differences were found in demographic characteristics and preoperative findings.

Table 15. Baseline Characteristics for Different Types

Variables	Type 1	Type 2	Type 3	P value
Sex, male: female (n)	16:28	4:13	6:8	0.496
Age, years	66.1 ± 6.2	63.5 ± 11.3	65.1 ± 7.6	0.701
Body mass index, kg/m ²	25.4 ± 3.3	26.5 ± 4.0	26.0 ± 2.5	0.439
Affected side, right: left (n)	37:7	14:3	5:9	0.353
Diabetes mellitus, n (%)	10 (22.7)	3 (17.6)	2 (16.7)	0.760
Graft, FL: FL/M (n)	13:31	5:12	6:8	0.603
Follow-up time, months	20.2 ± 7.3	17.4 ± 6.4	24.3 ± 10.2	0.093
Tear size (the Patte classification), n				0.455
I: Greater tuberosity	0	0	0	
II: humeral head exposed	1	0	0	
III: Glenoid	22	5	6	
IV: Medial to glenoid	21	12	11	
GFDI	2.1 ± 1.0	2.2 ± 0.9	2.1 ± 1.3	0.682
Hamada classification, n				0.624
Grade 1	18	9	6	
Grade 2	24	8	7	
Grade 3	1	0	0	
Grade 4	1	0	0	
Grade 5	0	0	0	
AHD, mm	5.4 ± 2.5	6.2 ± 3.8	5.6 ± 2.8	0.954

FL, fascia lata; M, mesh augmentation; PreOP, preoperative; VAS, visual analog scale; ASES, American Shoulder and Elbow Surgeons; ROM, range of motion; GFDI, global fatty degeneration index; AHD, acromiohumeral distance.

Clinical Outcomes

Preoperative VAS, ASES, and Constant scores were similar across the three groups (all $P > 0.05$; **Table 15**). Following SCR, VAS scores significantly decreased in all groups (all $P < 0.05$; **Table 16**), with no significant difference observed among the groups ($P = 0.078$). Preoperative ASES and Constant scores did not differ among the three groups (**Table 15**). ASES scores showed significant improvement post-surgery in all three groups (all $P < 0.05$; **Table 16**). The improvements in Type 1, 2, and 3 all surpassed the MCID threshold (15.2) for the ASES score after SCR.⁷³ Nevertheless, a notable contrast in the Constant score was solely observed within the type 1 group ($P < 0.001$), with the disparity falling below the MCID threshold (10.4) for the Constant score after rotator cuff repair.⁶⁰ Following surgery, individuals in the type 1 group exhibited notably elevated ASES and Constant scores compared to those in the type 2 and 3 groups ($P = 0.014$ and 0.005 , respectively). Nevertheless, no significant disparity was observed between the type 2 and 3 groups. Regarding the postoperative ASES score, the discrepancy between type 1 and 2 was 9, and between type 1 and 3 was 8, both of which fell below the MCID for the ASES score (15.2).⁷³ Regarding the postoperative Constant score, the variances between type 1 and 2, as well as between type 1 and 3, were both beneath the MCID threshold (10.4) for the Constant score.⁶⁰

ROM

Preoperatively, there were no distinctions in the ROMs among the three groups. Postoperatively, type 1 and 2 patients exhibited notably superior forward flexion in comparison to type 3 patients ($P = 0.022$ and 0.023 , respectively). Nonetheless, there was no discernible difference between type 2 and 3 patients (**Table 16**).

Table 16. Clinical Outcomes

	Type 1	<i>P</i> Value	Type 2	<i>P</i> Value	Type 3	<i>P</i> Value	<i>P</i> Value Between 3 Types
ASES score							
PreOP	49.3 ± 17.7		49.7 ± 16.2		45.8 ± 13.8		0.639
PostOP	83.8 ± 10.0	<0.001	74.9 ± 14.7	0.002	75.5 ± 14.2	0.001	0.014 (1>2=3)
Constant score							
PreOP	54.4 ± 11.2		56.4 ± 7.4		48.0 ± 13.1		0.113
PostOP	65.4 ± 5.1	<0.001	61.1 ± 9.5	0.083	56.1 ± 12.5	0.133	0.005 (1>2=3)
VAS score							
PreOP	5.5 ± 1.9		5.6 ± 2.3		5.5 ± 1.6		0.870
PostOP	1.0 ± 1.3	<0.001	1.9 ± 1.7	0.001	1.4 ± 1.3	0.001	0.078
Active ROM							
Forward flexion							
PreOP	145.7 ± 28.2		142.4 ± 19.5		142.9 ± 30.7		0.309
PostOP	155.5 ± 10.2	0.180	154.1 ± 15.4	0.062	144.6 ± 12.5	0.751	0.013 (1=2>3)
External rotation							
PreOP	43.1 ± 18.7		42.1 ± 25.6		40.7 ± 29.2		0.933
PostOP	46.1 ± 16.3	0.430	42.1 ± 14.3	0.977	35.7 ± 16.6	0.609	0.108
Internal rotation							
PreOP	12.5 ± 2.9		12.1 ± 2.5		12.1 ± 2.9		0.553
PostOP	11.8 ± 3.1	0.347	12.2 ± 2.7	0.856	12.1 ± 3.1	0.798	0.928

ASES, American Shoulder and Elbow Surgeons; VAS, visual analog scale; ROM, range of motion; PreOP, preoperative; PostOP, postoperative

Radiological Outcomes

As illustrated in **Table 17**, only the acromiohumeral distance (AHD) exhibited a significant increase between pre- and postoperative measurements in the type 1 group ($P < 0.001$). There were no disparities observed in pre- and postoperative AHD or in the Hamada classification across the groups. Additionally, no variance was noted in the graft failure rate following surgery ($P = 0.749$). Seven patients were identified with graft tears before the 12-month postoperative mark. However, patients treated with fascia lata autograft displayed a significantly higher graft failure rate (12/24) compared to those treated with fascia lata autograft with mesh augmentation (11/51) ($P = 0.017$). Moreover, a notable difference was observed in the integrity of the connection between the stump and graft among the groups ($P = 0.003$).

Table 17. Radiological Outcomes

Variables	Type 1	Type 2	Type 3	<i>P</i> Value Between 3 Types
Hamada classification				0.085
Grade 1	32	10	6	
Grade 2	8	6	7	
Grade 3	0	0	0	
Grade 4a	1	0	0	
Grade 4b	0	1	0	
Grade 5	0	0	1	
AHD, mm				
PreOP	5.4 ± 2.5	6.2 ± 3.8	5.5 ± 2.4	0.954
PostOP	8.0 ± 2.4	7.0 ± 3.3	7.0 ± 2.6	0.248
<i>P</i> value	<0.001	0.298	0.221	
Graft integrity, n (%)				0.749
Success	32 (72.7)	11 (64.7)	9 (64.3)	
Failure	12 (27.3)	6 (35.3)	5 (35.7)	
Time of failure				0.849
<12 months	3	2	2	
≥12 months	9	4	3	
Integrity of the connection between the stump and graft				0.003
Intact	36	7	7	
Torn	8	10	7	

Data are presented as numbers or the mean ± SD. Statistical significance is indicated in bold.

PreOP, preoperative; PostOP, postoperative; AHD, acromiohumeral distance; SD, standard deviation.

The effect of FI of infraspinatus on outcomes

Among the cohort, 20 individuals (36.4%) were identified preoperatively as having severe fatty infiltration (FI) of the infraspinatus muscle (Goutallier grade 3-4). As per **Table 18**, no significant differences were observed in demographic characteristics and preoperative clinical data between the two groups. Concurrent severe FI of the supraspinatus was more prevalent in the Goutallier 3-4 group compared to the Goutallier 0-2 group ($P = 0.008$). However, the patte classification, AHD, and Hamada classification did not exhibit statistically significant differences between the two groups.

Table 18 Demographics and Preoperative Findings

	Goutallier 0-2	Goutallier 3-4	P Value
Age, y	62.83 ± 8.00	66.90 ± 6.69	0.061
Sex, male:female, n	16:19	4:16	0.062
Affected shoulder, right:left, n	25:10	12:8	0.391
Hypertension, n	17	6	0.185
Diabetes mellitus, n	9	2	0.291
Previous shoulder surgery, n	3	0	0.292
Graft, FL:FL/M, n	14:21	12:8	0.150
Follow-up period, mo	34.36 ± 17.48	42.60 ± 22.92	0.141
ASES score	52.38 ± 17.91	52.80 ± 14.89	0.930
Constant score	52.41 ± 12.39	53.40 ± 12.87	0.781
VAS score	5.66 ± 1.96	5.35 ± 1.79	0.575
Active shoulder ROM, deg			
Forward flexion	144.55 ± 33.57	142.11 ± 32.89	0.801
External rotation	35.16 ± 20.89	31.58 ± 14.44	0.513
Goutallier classification, grades 0:1:2:3:4, n			
Supraspinatus	0:6:24:5:0	0:0:10:7:3	0.008
Infraspinatus	0:9:26:0:0	0:0:0:15:5	<0.001
Teres minor	13:22:0:0:0	11:9:0:0:0	0.190
Subscapularis	3:31:1:0:0	1:17:2:0:0	0.495
Patte classification, n			0.716
Grade 1	0	0	
Grade 2	0	0	
Grade 3	30	16	
Grade 4	5	4	
Hamada classification, n			0.462
Grade 1	13	4	
Grade 2	14	11	
Grade 3	6	2	
Grade 4a	1	2	
Grade 4b	1	1	
Grade 5	0	0	
Acromiohumeral distance	5.19 ± 2.53	4.90 ± 1.85	0.641

ASES, American Shoulder and Elbow Surgeons; FL, fascia lata; FL/M, fascia lata with mesh interposed;

ROM, range of motion; VAS, visual analog scale.

Table 19 presents a comparison of clinical outcomes between the two groups and within each group. The ASES score demonstrated significant improvement in both groups (both $P < 0.001$). Likewise, the VAS score exhibited a significant decrease after SCR (both $P < 0.001$). However, postoperative ASES, Constant, and VAS scores did not show any statistically significant differences (all $P > 0.05$). Additionally, postoperative active ROMs were comparable between the two groups ($P > 0.05$).

Table 19 Clinical Outcomes

	Goutallier 0-2	Goutallier 3-4	P Value
ASES score			
Preoperative	52.38 ± 17.91	52.80 ± 14.89	0.931
Postoperative	76.67 ± 26.56	77.22 ± 11.23	0.920
<i>P</i> value	<0.001	<0.001	
Constant score			
Preoperative	52.41 ± 12.39	53.40 ± 12.87	0.781
Postoperative	54.50 ± 23.50	54.56 ± 18.95	0.993
<i>P</i> value	0.190	0.730	
VAS score			
Preoperative	5.66 ± 1.96	5.35 ± 1.79	0.572
Postoperative	1.00 ± 1.29	1.60 ± 1.64	0.211
<i>P</i> value	<0.001	<0.001	
Active shoulder ROM, deg			
Forward flexion			
Preoperative	144.55 ± 33.57	142.11 ± 32.89	0.801
Postoperative	149.00 ± 25.37	147.22 ± 36.11	0.842
<i>P</i> value	0.541	0.272	
External rotation			
Preoperative	35.16 ± 20.89	31.58 ± 14.44	0.511
Postoperative	40.54 ± 21.27	34.71 ± 12.81	0.313
<i>P</i> value	0.083	0.442	

ASES, American Shoulder and Elbow Surgeons; ROM, range of motion; VAS, visual analog scale.

Following surgery, the AHD significantly increased in the 2 groups ($P < 0.001$ and $P = 0.006$, respectively) and did not exhibit significant differences between them ($P = 0.580$). Postoperative plain radiography revealed no significant disparities in Hamada grades between the two groups ($P = 0.220$) (**Table 20**). However, the rate of graft failure after SCR detected by MRI was notably higher in the patients with Goutallier 3-4 compared with the counterparts. ($P = 0.004$).

Table 20 Radiological Outcomes

	Goutallier 0-2	Goutallier 3-4	P Value
Hamada classification, n			0.220
Grade 1	25	10	
Grade 2	7	7	
Grade 3	3	3	
Grade 4a	0	0	
Grade 5	0	0	
Rotator cuff tear arthropathy, n (%)			0.760
Improved	16 (45.7)	8 (40.0)	
No change	16 (45.7)	11 (55.0)	
Worse	3 (8.6)	1 (5.0)	
Acromiohumeral distance			
Preoperative	5.19 ± 2.53	4.90 ± 1.85	0.640
Postoperative	7.19 ± 2.61	6.73 ± 3.50	0.580
P value	<0.001	0.006	
Graft integrity, n (%)			0.004
Success	30 (85.7)	10 (50.0)	
Failure	5 (14.3)	10 (50.0)	

The effect of LTT on outcomes

Table 21 indicates that the 2 groups of patients showed no significant differences in terms of their demographics. The SCR group had a longer follow-up time compared with the SCR +LTTT group ($P = 0.01$).

There was no difference between the 2 groups before surgery in other demographics.

Table 21 Demographics and Preoperative Findings

	SCR (n = 21)	SCR + LTTT (n = 15)	P Value
Age, y	65.7 ± 5.8	65.5 ± 5.9	.800
Sex, male:female, n	8:13	10:5	.091
Body mass index, kg/m ²	25.7 ± 2.8	27.1 ± 1.8	.053
Affected shoulder, right:left, n	15:6	12:3	.705
Hypertension, n	12	8	.392
Diabetes mellitus, n	3	3	.677
Smoking, n	4	4	.694
Follow-up period, y	3.0 ± 1.5	1.7 ± 0.5	0.01
Goutallier classification, grades 0:1:2:3:4, n			
Supraspinatus	0:2:13:4:2	0:4:7:2:2	0.601
Infraspinatus	0:0:0:9:12	0:0:0:8:7	0.535
Teres minor	13:6:1:0:1	11:9:0:0:0	0.470
Subscapularis	8:11:1:1:0	9:3:3:0:0	0.095
Patte classification, n			0.151
Grade 1	0	0	
Grade 2	0	0	
Grade 3	12	12	
Grade 4	9	3	
Hamada classification, n			0.104
Grade 1	7	1	
Grade 2	13	14	
Grade 3	1	0	

SCR, superior capsular reconstruction; LTTT, lower trapezius tendon transfer.

As shown in **Table 22**, The ASES, Constant, and SANE scores improved significantly at the final follow-up in both groups ($P < 0.05$ for both). The VAS score decreased significantly after surgery in both groups ($P < 0.05$ for both). The SCR + LTT group showed significantly better ASES, ER, and lower VAS scores at 6 months postoperatively compared with the SCR group ($P = 0.036, 0.036$ and <0.001 , respectively). The SCR + LTT group showed significantly better ASES, Constant, ER, and lower VAS scores at the final follow-up ($P < 0.05$ for all).

Table 22 Clinical Outcomes

	SCR (n = 21)	SCR + LTT (n = 15)	P Value
ASES score			
Preop	45.1 ± 18.0	54.5 ± 20.5	0.117
Postop (6M)	56.4 ± 13.6	65.8 ± 13.7	0.036
Postop (Final)	73.1 ± 16.4	83.7 ± 10.7	0.049
P value ^b	<0.001	0.001	
Constant score			
Preop	55.8 ± 7.6	61.1 ± 8.1	0.062
Postop (6M)	52.0 ± 9.8	55.6 ± 7.7	0.170
Postop (Final)	67.7 ± 15.2	76.7 ± 9.0	0.007
P value ^b	0.681	0.030	
VAS score			
Preop	5.3 ± 2.2	4.1 ± 2.6	0.160
Postop (6M)	3.5 ± 2.0	1.0 ± 0.9	<0.001
Postop (Final)	1.8 ± 1.7	0.7 ± 0.7	0.046
P value ^b	<0.001	0.001	
Active shoulder ROM, deg			
Forward flexion			
Preop	143.1 ± 22.2	145.3 ± 18.5	0.825
Postop (6M)	128.6 ± 29.6	127.7 ± 19.9	0.465
Postop (Final)	136.0 ± 29.5	149.0 ± 16.5	0.238
P value ^b	0.209	0.273	
External rotation			
Preop	26.9 ± 16.7	26.0 ± 17.5	0.975
Postop (6M)	24.8 ± 17.9	37.3 ± 15.3	0.036
Postop (Final)	34.8 ± 13.5	45.7 ± 16.2	0.049
P value ^b	0.074	0.009	

SCR, superior capsular reconstruction; LTT, lower trapezius tendon transfer; ASES, American Shoulder and Elbow Surgeons; SANE, Single Assessment Numeric Evaluation; ROM, range of motion; VAS, visual analog scale; Preop, preoperative; Postop, postoperative; Final, final follow up.

^bP value of the differences between the preoperative and final follow-up values.

Postoperatively, the AHD significantly increased in the 2 groups ($P = 0.033$ and 0.003 , respectively) and the SCR + LTT group showed significantly bigger AHD than the SCR groups ($P = 0.018$). Two patients had both tears at fascia lata autografts and Achilles tendon allografts on the humeral site during follow up. The fascia lata autograft tear rate in SCR group was significantly higher than that in the SCR + LTT group (47.6% vs 13.3%, respectively; $P = 0.040$) (Table 23).

Table 23. Radiological Outcomes

	SCR (n = 21)	SCR + LTT (n = 15)	P Value
Acromiohumeral distance			
Preoperative	5.0 ± 1.3	4.9 ± 1.1	0.427
Postoperative	6.3 ± 2.3	8.1 ± 2.5	0.018
P value	0.033	0.003	
Hamada classification, n			0.509
Grade 1	12	12	
Grade 2	6	2	
Grade 3	3	1	
Fascia lata autograft integrity, n (%)			0.040
Success	11 (52.4)	13 (86.7)	
Failure	10 (47.6)	2 (13.3)	
Achilles tendon allograft integrity, n (%)			-
Success	-	13 (86.7)	
Failure	-	2 (13.3)	

SCR, superior capsular reconstruction; LTT, lower trapezius tendon transfer

Effect of mesh on early graft maturation

Detailed demographic data are shown in **Table 24**. No statistically significant difference was found between the two groups.

Table 24. Patient demographics

Variables	FLA	FLA + Mesh	P-value
Age, yr	64.9±9.3	65.7±7.9	0.715
Body mass index, kg/m ²	25.6±3.7	25.4±2.8	0.884
Sex, male:female	7:17	25:29	0.156
Rotator-cuff retraction: Patte			0.928
I: Great tuberosity	0	0	
II: Humeral-head exposure	1	2	
III: Glenoid	19	41	
IV: Medial to glenoid	4	11	
Goutallier classification			
Grades 0:1:2:3:4			
Supraspinatus	0:1:13:8:2	1:10:18:22:3	0.275
Infraspinatus	2:2:12:5:3	2:10:15:24:3	0.102
Subscapularis	1:21:0:1:1	12:31:3:6:2	0.101

FLA, fascia lata autograft; Mesh, polypropylene mesh.

A summary of the SNQs is provided in **Table 25**. The mean SNQ was 30.603 in the FLA group and 18.367 in the FLA + Mesh group ($P < 0.001$). Furthermore, significant differences were observed between the two groups at the humeral and mid-substance sites ($P < 0.001$ and $P = 0.003$, respectively). However, there was no significant difference between the two groups at the glenoid site ($P = 0.057$). In terms of intragroup comparison of the SNQ among the three sites, no significant difference was detected in either group, with relatively higher values observed in the FLA group and lower values in the FLA + Mesh group at the humeral site.

Table 25. Summary of SNQs

SNQ	FLA	FLA + Mesh	<i>P</i> value
Humeral (H)	37.863 (5.092–81.187)	15.512 (1.814–80.869)	0.000
Mid-substance (M)	29.168 (6.103–73.900)	16.878 (2.454–92.416)	0.003
Glenoid (G)	25.346 (7.565–86.353)	20.354 (3.732–88.468)	0.057
Mean	30.603 (11.790–72.710)	18.367 (4.464–69.500)	0.000
<i>P</i> value			
All	0.563	0.099	
H vs M	0.447		
M vs G	0.787		
G vs H	0.303		

SNQ, signal to noise quotient; FLA, fascia lata autograft; Mesh, polypropylene mesh. H, humeral site; M, mid-substance site; G, glenoid site.

Serial changes of the SNQ

The 3-month postoperative MRI scan showed a statistically significant higher SNQ value in the FLA group compared to the FLA + Mesh group ($P = 0.000$). Furthermore, in the FLA group, there was a significant decrease in SNQ between 3- and 12-month postoperative MRI examination ($P = 0.041$). However, there is no difference between the two time points in the FLA + Mesh group ($P = 0.163$, **Figure 9**). An example of this difference is shown in **Figure 10**.

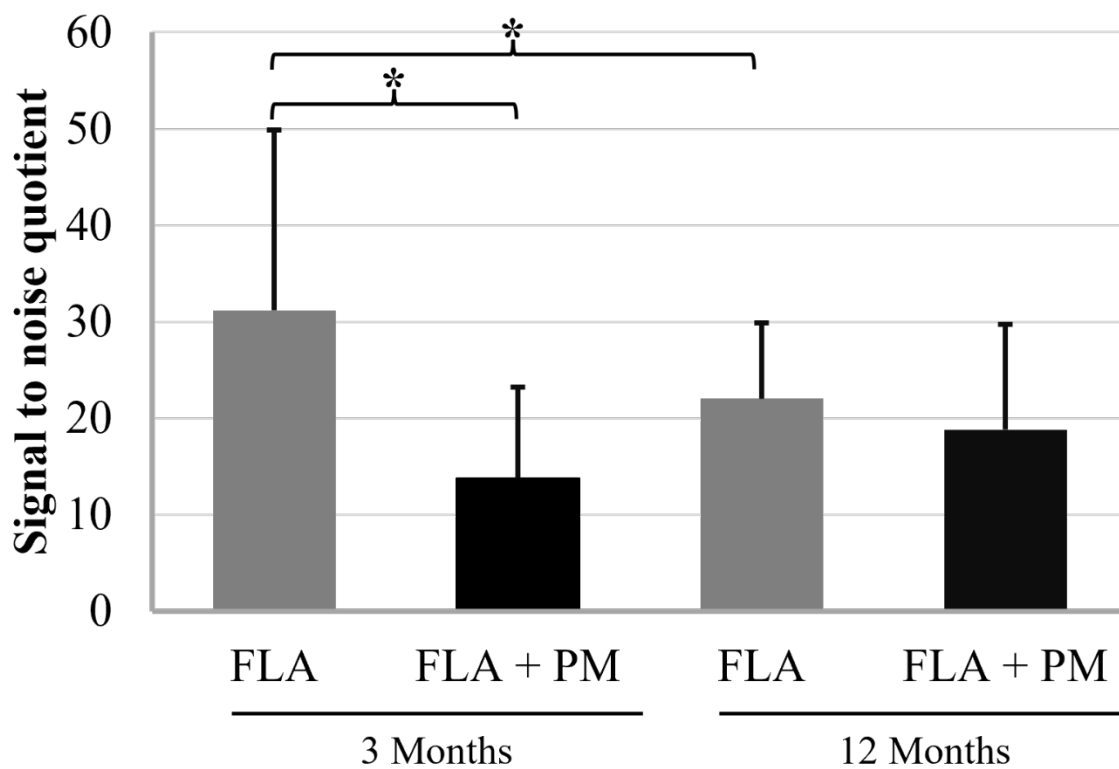


Figure. 9 Graph with data points representing SNQ of the FLA and FLA + PM groups at the 3-month and 12-month time points at 3 different regions. * $P < 0.05$. FLA, fascia lata autograft; PM, polypropylene mesh; SNQ, signal to noise quotient.

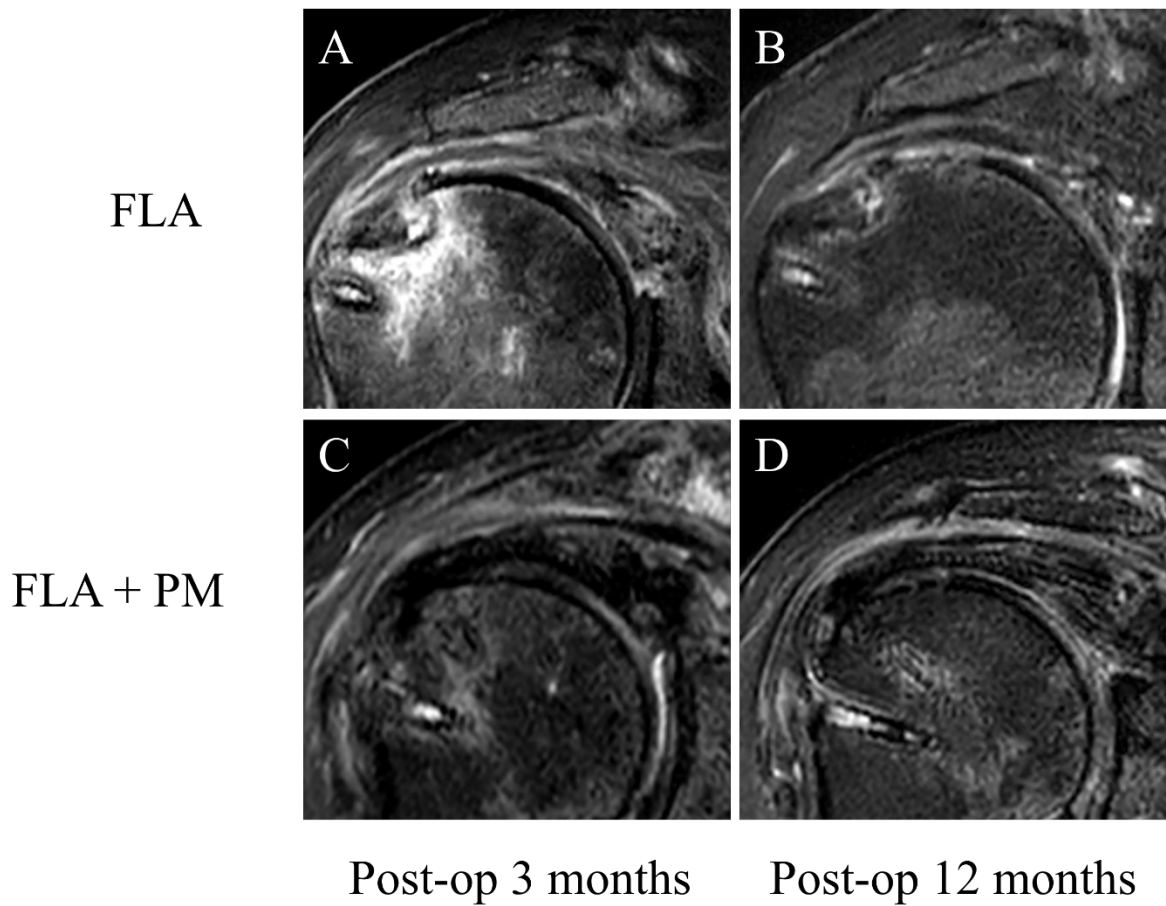


Figure. 10 (A) Coronal 3 months after SCR with FLA. (B) Coronal 12 months after SCR with FLA (same patient as in plane A). (C) Coronal 3 months after SCR with FLA + PM. (D) Coronal 12 months after SCR with FLA + PM (same patient as in plane C). SCR, superior capsular reconstruction; FLA, fascia lata autograft; PM, polypropylene mesh.

DISCUSSION

This study observed a tendency for female and older patients to achieve PASS and MCID for functional scores more frequently compared to male and younger patients. These findings appear to diverge from several studies where female and older patients were associated with poorer outcomes following ASCR and rotator cuff repair. For instance, Robinson et al. found that female patients aged 70 years and above exhibited significantly inferior functional scores after rotator cuff repair, suggesting that gender and age merit consideration in treatment planning.⁹⁹ Older patients typically experience inferior clinical outcomes compared to younger counterparts in cases of healing failure.⁹⁸ Orthopedic studies have increasingly emphasized establishing patient-centered benchmarks for success post-intervention.¹¹⁶ PROMs serve as a primary focus for evaluating surgical outcomes.⁷⁶ However, statistically significant differences between pre- and postoperative PROMs may not necessarily correlate with clinical relevance.¹² Consequently, PROMs may not universally apply to every patient, whereas PASS and MCID offer better parameters by indicating the minimum improvement threshold and satisfactory outcome threshold, respectively. In this study, patients aged 65 years and above demonstrated significantly greater improvements in ASES and Constant scores, elucidating why this age group achieved ASES and Constant thresholds for MCID at notably higher rates than those under 65 years old. Notably, the mean ages of female and male patients did not significantly differ. To further assess the relationship between age, gender, MCID, and PASS, an analysis was conducted using a four-group classification based on age (≥ 65 years vs. < 65 years) and patient gender. Both female and male patients aged 65 years and above achieved the Constant thresholds for MCID at higher rates compared to their younger counterparts. However, there were comparable rates of MCID achievement between female and male patients aged 65 years and above. This suggests that age may exert a more significant influence on

MCID achievement than gender. These results further support the notion that patients aged 65 years and above attain MCID following SCR.

Our findings align with other research indicating that obesity does not significantly impact clinical outcomes following rotator cuff repair,^{89,97} which may be attributed to the non-weight-bearing nature of the shoulder. Consequently, although obesity may potentially impede healing, favorable clinical outcomes are still observed.⁴⁹ Another possible explanation is that individuals with higher BMI exert less demand on their shoulders. Similar results have been reported that obese patients tend to have smaller ROM compared to non-obese patients.⁹¹ In addition to assessing functional scores, we found similar probabilities of achieving MCID, PASS, and SCB in the 3 groups. Consistent with existing literature, our study shows that obese patients can still achieve significant improvements after surgeries and exhibit similar compared to normal weight patients.

Rotator cuff (RC) changes detected via MRI have been shown to correlate with arthroscopic findings¹⁰⁴ and histological assessments.⁵⁸ Kjellin et al. reported that increased MRI SI of the SSP tendon corresponded to eosinophilic degeneration using a cadaver model.⁵⁸ Severe degeneration of the SSP tendon was found to correlate with areas of increased SI on MRI T2-weighted images.⁵⁸ Additionally, Gagey et al.³⁷ and Williams et al.¹¹⁴ also reported that MRI abnormalities of the RC correlated with tendon degeneration. Kijowski et al. demonstrated that the tendon stump with a smaller T2 signal could predict superior clinical outcomes.⁵⁴ Li et al reported that superior healing of the fascia-to-bone interface and better outcomes were associated with the strain from the SSP muscle.⁷¹ As per the results, type 1 stumps showed a better healing with the grafts compared to type 2 and 3 stumps, which may contribute to better clinical outcomes. However, there was no discernible difference among the three stump types in terms of fatty degeneration of the rotator cuff (RC)

muscles, as indicated by Goutallier fatty degeneration indices (GFDIs). These findings are in line with previous research that also found no discrepancy in GFDIs among the stump types. During surgery, suturing the remnant SSP tendon to the FLA has been noted to facilitate the transmission of contractile force of the remaining SSP to the graft and the humerus. This mechanism contributes to the enhanced healing and maturity of the fascia-to-bone interface.⁷⁰ Effective muscle contracture force has been found to promote the healing of the fascia lata autograft to bone.⁷⁰ However, it's worth noting that elevated levels of advanced glycation end products (AGEs) have been shown to hinder tendon healing,⁹⁴ bone regeneration,⁶⁸ and wound healing.²⁰ Additionally, severe inflammation has been associated with impaired tendon-bone healing and correlates strongly with poorer outcomes following RC repair.²² As part of surgical intervention, the remnant tendon and bursa tissue are fixed onto the graft during surgery to provide biological augmentation.⁵¹ However, it's important to consider that higher classifications have been associated with increased levels of AGEs and inflammation at the RC site.¹⁰⁷ Consequently, the impact of this biological augmentation on graft healing may vary among the three types of stumps.

A balanced transverse force couple contributes to the normal kinematics of shoulder joint.⁹⁰ However, severe FI of the rotator cuff impair balanced force couple owing to the progression of muscle deterioration.⁴¹ A balanced force couple is reported to maintain graft integrity.⁸² according to the results of this study, severe FI of the infraspinatus leads to graft failures after SCR. Similarly, FI of Goutallier grade ≥ 2 in the infraspinatus contributed to graft failures using allografts.¹¹⁵ SCR has been proved to be effective for treating MRCTs.^{9-11,66,116} Mihata demonstrated that SCR completely restored superior stability of the glenohumeral joint⁸⁶ and SCR with side-to-side suturing completely restored the superior stability by establishing posterior continuity between the graft and residual infraspinatus tendon.⁸⁵ However, Lee et al reported that high-grade

fatty infiltration (Goutallier grades 3-4) of the infraspinatus contributed to higher risk of graft tear after SCR.⁶⁶ Lee and Min et al found that poorer quality of infraspinatus muscle was related with increasing graft failure rate.⁶⁷ Severe FI also contributed to retears of the repaired infraspinatus tendon after SCR.⁸³ Hence, caution is advised when severe FI of the infraspinatus is detected on preoperative MRI scans. Our study indicated that FI of the supraspinatus had only a marginal effect on graft integrity after SCR. The results highlight the significance of the infraspinatus muscle, which constitutes the primary posterior force vector as described by force couple theory, being more crucial than the supraspinatus muscle in the context of SCR.

Several studies have been performed to compare the difference between SCR and LTT. Baek et al reported that poor quality of remnant infraspinatus muscle led to failure of restoration of normal glenohumeral kinematics and force coupling.⁴ Recently, LTT has been introduced for the treatment of IRCTs and it achieved the best restoration of the insufficient anteroposterior muscular force couple because similar line of pull as the native infraspinatus muscle.⁸⁷ Elhassan et al demonstrated that patients achieved good clinical outcomes after LTT using an Achilles tendon allograft at short-term follow-up.³² Chopra et al reported that LTT showed a high rate of healing of the transferred tendon and contributed to significant improvements in clinical outcomes at short-term follow-up.²¹ Baek et al demonstrated that LTT provided support for the mid-term safety and effectiveness for the treatment of posterosuperior IRCTs.² Recently, comparative studies of SCR and LTT for posterosuperior IRCTs were performed to investigate the difference in surgical outcomes. Baek et al reported that LTT was better than SCR in terms of functional improvement, patient satisfaction, progression of arthritis, and graft integrity.⁴ Marigi et al found that SCR led to better pain relief and restoration of forward elevation whereas LTT provided more reliable improvement in external rotation.⁷⁷ Difference was also found in biomechanical results, whereas Mihata reported SCR completely restored

superior stability of the glenohumeral joint⁸⁶ and Muench et al reported LTT did not completely restore native glenohumeral kinematics⁸⁷. Lee et al demonstrated that SCR combined with LTT showed improved shoulder kinematics and contact pressures in the posterosuperior MRCT model compared with SCR or LTT alone in the cadaveric model.⁶³ According to our results, patients with SCR + LTT showed significantly better outcomes and lower tear rates than those with SCR. As a result, combination of SCR and LTT could seemed to be a better option for the treatment of posterosuperior IRCTs with severe fatty infiltration (Goutallier grades 3-4) of the infraspinatus muscle.

Excessive graft tension has been associated with diminished biomechanical properties and compromised revascularization,^{24,31} potentially leading to biological failure.⁷⁸ As a result, grafts are at a heightened risk of tear, particularly in the early postoperative period.^{16,46,110} In our study, FLA showed significantly smaller SNQs if mesh was inserted for augmentation postoperatively. The incorporation of a mesh has been proposed to optimize tension on FLA during the early postoperative phase. Therefore, these findings may support the utilization of a mesh to facilitate improved graft healing during the remodeling phase. Whether the mesh affects the SNQ measurements of FLA remains unknown owing to the lack of literature on how mesh appears on SNQ. However, the mesh will increase SNQ because of its hyperintensity even if it has some effects on the measurement. In this study, we compared SNQs between FLAs with and without mesh augmentation. We found that SNQ of an FLA with a mesh is lower than that of an FLA without a mesh. Thus, even if the mesh increased the SI measurement of the FLA, it did not affect the final outcomes of this study. Interestingly, the change of SNQ of the grafts in FLA + PM group had a different trend, which maintained relatively low and unchanged SNQ after mesh was embedded in the graft. The consistent tensions provided by the PM was suggested to contribute to a stable remodeling of the graft¹. Furthermore, Engebretsen et al³³ found that the

addition of lateral extra-articular tenodesis could significantly decrease loads on the ACL graft and Cavaignac et al¹⁹ found that ACL graft with lateral extra-articular tenodesis augmentation showed lower SNQ when compared with that of isolated ACL graft at 1 year postoperatively. For this reason, we postulated that the mesh could act as an “internal fixation” that provides strong stiffness to optimize the stable tension on the graft during the maturation process. Based on the results of this study, the FLA with mesh augmentation could maintain a lower and stable SNQ during the maturation process when compared with the isolated FLA, and the main difference mostly occurs in the early time after surgery.

There are several limitations to this study. First, the number of patients enrolled was relatively small because SCR has only been described recently with limited indications. Second, the follow-up time was short, and the long-term clinical and radiological outcomes could not be investigated. Future studies with long-term follow-up results need to be performed.

CONCLUSIONS

Female patients achieved PASS on SANE at significantly higher rates than male patients and older patients achieved MCID on ASES and Constant at higher rates than young patients. Thus, age is a stronger factor for achieving MCID than gender. However, no differences were observed in all PROMs and the likelihood of achieving CSOs among the different BMI groups. Stump classification may be useful for predicting postoperative clinical outcomes; however, the clinical importance of these differences may be limited. Severe FI of the infraspinatus muscle was a factor indicating a poor prognosis for graft integrity. SCR combined with lower trapezius tendon transfer contributed to significantly lower graft tear rates and better clinical

outcomes for patients with severe FI of the infraspinatus muscle. At the 3-month follow-up, the FLA + Mesh group showed a lower MRI signal intensity than the FLA group. The healing and remodeling of an FLA may be enhanced when a mesh is used. The Mesh contributed to maintained graft remodeling until 1 year postoperatively.

Part II: Clinical significances of SCR

INTRODUCTION

Most patients achieve reliable pain relief and functional improvement in the short- to mid-term follow-up after SCR.^{3,64,109} Consistently, studies have reported improvements in mean patient-reported outcome scores, including American Shoulder and Elbow Surgeons (ASES), single assessment numeric evaluation (SANE), visual analog scale (VAS), and Constant scores.^{52,65,81,116} However, a statistically significant outcome may not be clinically relevant.⁴³

Recently, there has been a shift toward establishing patient-centered evaluation to evaluate the result of the surgery based on the clinical significance to the patient.¹¹⁶ Evaluation of clinically significant outcomes (CSOs) by calculating minimally clinically important difference (MCID) and patient-acceptable symptoms state (PASS) thresholds following surgery is becoming more popular because these parameters can offer a more objective measure of patient satisfaction to optimize patient outcomes.³⁴ Manderle et al. investigated the timeline of the CSOs achievements after rotator cuff repair.⁷⁶ Although CSOs after SCR have been previously conducted,^{34,116} there was still a lack of information about the time-dependent nature of CSOs after SCR.

This study aimed (1) to investigate the CSO values after SCR; (2) to establish the timeline of CSOs achievements; and (3) to investigate the association between achieving MCID and PASS.

METHODS

Seen in METHODS of **Part I**.

Statistical analysis

Baseline data were compared using the independent Student *t*-test or Mann-Whitney U test for continuous data and the chi-square test or Fisher exact test for categorical data. ROC curves and the AUC was performed to check the reliability of derived PASS, MCID, and SCB values. Reliability and predictivity for determining MCID, SCB, and PASS were assessed using the receiver operating characteristic (ROC) curve and the area under the ROC curve (AUC). AUCs of ≥ 0.7 and ≥ 0.8 were considered acceptable and excellent, respectively.¹³ MCID was determined using sensitivity- and specificity-based approaches. The cut-off value of the ROC analysis between the unsatisfied and satisfied groups, unchanged and changed groups, and unchanged and improved groups were derived as the PASS, MCID, and SCB values.¹¹⁶ Chi-square or Fisher exact test was applied to investigate whether those who achieve the MCID have a higher chance of reporting satisfaction. The association between achieving MCID threshold and patient-reported satisfaction was evaluated and reported as sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), Likelihood Positive Ratio, and Likelihood Negative Ratio. A time-to-event analysis was used to investigate the timeline of CSOs achievements.

All statistics was analyzed by using SPSS 27.0 software (IBM, USA). The statistical significance was set as $P < 0.05$.

RESULTS

Baseline Data and Prevalidation Analysis

As shown in **Table 1**, 25 patients had a subscapularis tear and 17 patients underwent repair. Based on the result of anchor questions, 18 patients were divided in the unsatisfied group and 70 patients were divided in the satisfied group. Furthermore, 18 patients were in the unchanged, changed, and improved groups consisted of 18, 50, and 20 patients, respectively.

Table 1. Demographics and Preoperative Findings

	Value
Age, year	64.2 ± 8.1
Sex	
Male	35 (39.8)
Female	53 (60.2)
Follow-up Time, y	31.4 ± 18.6
Body mass Index	26.1 ± 3.8
Dominant side affected	67 (76.1)
Diabetes Mellitus	16 (18.2)
Mesh used	56 (63.7)
AHD, mm	5.0 ± 2.2
Patte Classification	
1 (Greater Tuberosity)	0
2 (Humeral Head Exposed)	0
3 (Glenoid)	52 (59.1%)
4 (Medial to Glenoid)	36 (40.9%)
GFDI	2.8 ± 0.6
Subscapularis Tear	25 (28.4)
Subscapularis Repair	17 (19.3)
Graft Failure	25 (28.4)

AHD: Acromiohumeral Distance; GFDI: Global Fatty Degeneration Index.

As shown in **Figure 1A**, the unsatisfied group showed significantly better outcomes compared with the unsatisfied group. **Figure 1B** shows that there are significant differences in score changes between the unchanged and changed groups and between the unchanged and improved groups. The ROC curves of 4 scores all showed acceptable AUCs (>0.7). The results showed reliable PASS, MCID, and SCB values.

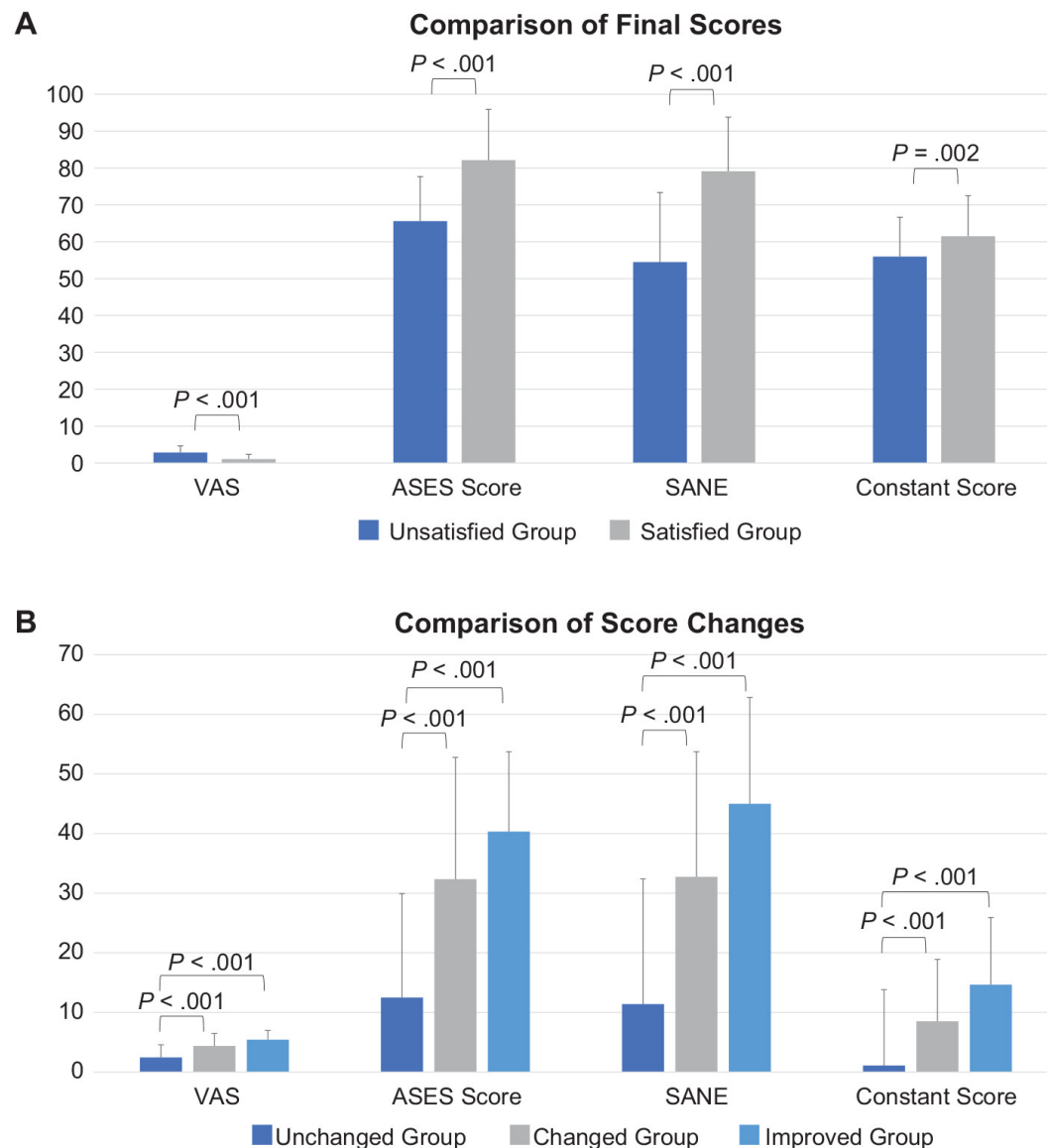


Figure 1. (A) Comparison of clinical outcomes between the unsatisfied and satisfied groups. (B) Comparison of score changes among unchanged, changed, and improved groups. ASES, American Shoulder and Elbow Surgeons; SANE, Single Assessment Numeric Evaluation; VAS, visual analog scale for pain.

Determination of PASS, MCID, and SCB Values

As shown in **Table 2**, The PASS values for pVAS, ASES, Constant, and SANE scores were 1.5, 81.0, 60.5, and 75.0, respectively. Similarly, the MCID values for pVAS, ASES, Constant, and SANE scores were 2.5, 19.0, -0.5, and 27.5, whereas the SCB values were 4.5, 27.5, 5.5, and 32.5, respectively.

Table 2 PASS, MCID, and SCB Values for Functional Outcomes After SCR

	Sensitivity- and Specificity-Based Approach			AUC
	Value	Sensitivity	Specificity	
PASS value				
Final pVAS	1.5	0.700	0.833	0.786
Final ASES	81.0	0.628	0.944	0.832
Final Constant	60.5	0.700	0.750	0.772
Final SANE	75.0	0.676	0.889	0.877
MCID value				
Final pVAS	2.5	0.860	0.579	0.788
Final ASES	19.0	0.700	0.789	0.791
Final Constant	-0.5	0.837	0.563	0.707
Final SANE	27.5	0.700	0.737	0.744
SCB value				
Final pVAS	4.5	0.850	0.842	0.896
Final ASES	27.5	0.900	0.842	0.918
Final Constant	5.5	0.900	0.733	0.827
Final SANE	32.5	0.800	0.842	0.868

SCR, superior capsular reconstruction; ASES, American Shoulder and Elbow Surgeons; AUC, area under the curve; MCID, minimal clinically important difference; PASS, Patient Acceptable Symptom State; pVAS, pain visual analog scale; SANE, Single Assessment Numeric Evaluation; SCB, substantial clinical benefit.

Mean time required to achieve PASS, MCID, SCB values

The percentage of MCID, SCB, and PASS achievements for VAS, ASES, Constant, and SANE are detailed in **Table 3**. The time required to achieve these values varied across different outcome measures (**Table 4**).

Table 3 Patients Achieving MCID, SCB, and PASS for VAS, ASES, Constant, and SANE

	MCID			SCB			PASS		
	6 M	1 Y	2 Y	6 M	1 Y	2 Y	6 M	1 Y	2 Y
VAS	59.3	78.0	81.4	30.5	47.5	55.9	13.6	50.8	64.4
ASES	37.3	71.2	66.1	22.0	47.5	50.8	10.2	45.8	61.0
Constant	54.2	74.6	81.4	23.7	61.0	62.7	18.6	64.4	69.5
SANE	27.1	62.7	69.5	23.7	50.8	57.6	10.2	62.7	67.8

VAS, visual analog scale; ASES, American Shoulder and Elbow Surgeons; SANE, Single Assessment Numeric Evaluation; MCID, minimal clinically important difference; SCB, substantial clinical benefit; PASS, Patient Acceptable Symptomatic State; M, month; Y, year.

Table 4 Mean Time Required (in Months) to Achieve MCID, SCB, and PASS for VAS, ASES, Constant, and SANE Score

	MCID	SCB	PASS
VAS	11.2 ± 0.9 (5.8 ± 1.8 ^β)	16.3 ± 1.1 (6.2 ± 2.9 ^β)	16.6 ± 0.9 (7.2 ± 3.8 ^β)
ASES	13.2 ± 1.0 (6.3 ± 2.4 ^β)	16.8 ± 1.0 (7.1 ± 4.1 ^β)	18.3 ± 0.9 (9.3 ± 5.9 ^β)
CONSTANT	11.6 ± 0.9 (6.9 ± 3.9 ^β)	15.1 ± 1.0 (7.1 ± 4.1 ^β)	14.7 ± 0.9 (8.7 ± 5.5 ^β)
SANE	14.4 ± 1.0 (-)	16.1 ± 1.0 (-)	15.5 ± 0.8 (-)

^βData in the brackets were derived from a published paper on rotator cuff repair.⁷⁶ VAS, visual analog scale; ASES, American Shoulder and Elbow Surgeons; SANE, Single Assessment Numeric Evaluation; MCID, minimal clinically important difference; PASS, Patient Acceptable Symptomatic State; SANE, Single Assessment Numeric Evaluation; SCB, substantial clinical benefit.

Relationship between MCID and PASS

Patients achieving MCIDs for VAS, ASES, and SANE scores had significantly greater improvement levels in clinical outcomes than their counterparts (*P* value <0.05, **Table 5**), except for the VAS score that demonstrated no difference between patients achieving and not achieving this MCID for SANE (*P* value = 0.069, **Table 5** and **6**).

Table 5. Association between Achieving MCID Thresholds on PROMs and PROMs Improvement

	Exceeded MCID (VAS)	Did Not Exceed MCID (VAS)	<i>P</i> -Value
Δ pVAS	5.8 ± 0.9	2.4 ± 1.5	<0.001
Δ ASES	39.1 ± 22.4	15.8 ± 14.9	<0.001
Δ SANE	37.7 ± 24.5	25.1 ± 21.3	0.035
Baseline pVAS	6.8 ± 1.2	4.6 ± 1.6	<0.001
	Exceeded MCID (ASES)	Did Not Exceed MCID (ASES)	<i>P</i> -Value
Δ pVAS	4.8 ± 2.1	3.1 ± 1.8	0.002
Δ ASES	40.4 ± 16.9	5.0 ± 8.2	<0.001
Δ SANE	41.3 ± 20.4	14.1 ± 18.9	<0.001
Baseline ASES	41.8 ± 17.4	63.2 ± 14.1	<0.001
	Exceeded MCID (SANE)	Did Not Exceed MCID (SANE)	<i>P</i> -Value
Δ pVAS	4.5 ± 2.0	3.5 ± 2.2	0.069
Δ ASES	34.8 ± 21.1	15.1 ± 18.9	<0.001
Δ SANE	45.6 ± 15.1	6.1 ± 12.3	<0.001
Baseline SANE	33.1 ± 16.4	56.8 ± 16.4	<0.001

MCID: minimal clinically important difference; PROMs: patient-reported outcome measures; pVAS: pain visual analog scale; ASES: American Shoulder and Elbow Surgeons; SANE: Single Assessment Numeric Evaluation.

Table 6. Association between Achieving MCID Thresholds and Patient-reported Satisfaction

	Satisfied	Not Satisfied	
VAS			
Score improved by MCID (4.5 points)			<i>P</i> Value
Yes	29 (60.4%)	3 (21.4%)	0.015
No	19 (39.6%)	11 (78.6%)	
Δ VAS	4.6 \pm 1.9	2.6 \pm 2.2	0.001
ASES			
Score improved by MCID (14.5 points)			<i>P</i> Value
Yes	36 (75.0%)	4 (28.6%)	0.003
No	12 (25.0%)	10 (71.4%)	
Δ ASES	32.9 \pm 20.9	10.4 \pm 18.1	<0.001
SANE			
Score improved by MCID (25.0 points)			<i>P</i> Value
Yes	35 (72.9%)	5 (35.7%)	0.023
No	13 (27.1%)	9 (64.3%)	
Δ SANE	36.0 \pm 22.2	16.4 \pm 23.1	0.005

^aMCID: Minimal Clinically Important Difference; pVAS: Pain Visual Analog Scale; ASES: American

Shoulder and Elbow Surgeons; SANE: Single Assessment Numeric Evaluation.

Achieving MCIDs for VAS, ASES, and SANE scores was associated with a significantly higher proportion of patients reporting satisfaction than the group who failed to achieve the MCID (P value = 0.015) (**Table V**). Furthermore, 63.3% (19/30) of patients who fail to achieve the MCID for VAS score feel satisfied after ASCR. Patients achieving MCIDs for ASES and SANE scores demonstrated similar results (P value = 0.003 and 0.023, respectively). However, patients who fail to achieve MCIDs for ASES and SANE scores feel satisfied accounting for 54.5% (12/22) and 59.1% (13/22), respectively.

MCID achievement demonstrated a sensitivity, specificity, PPV, and NPV of 0.604, 0.786, 0.906, and 0.367 for the VAS score, 0.750, 0.714, 0.900, and 0.455 for the ASES score, and 0.729, 0.643, 0.875, and 0.409 for the SANE score, respectively, for predicting patient-reported satisfaction (**Table 7**).

Table 7. Association between Achieving MCID Thresholds to Predict Patient-reported Satisfaction

	Satisfied	Not Satisfied
VAS score improving by the MCID (4.5 points)	29 (60.4%)	3 (21.4%)
VAS score not improving by the MCID (4.5 points)	19 (39.6%)	11 (78.6%)
Test Characteristics		
Parameter	Point Estimate	95% CI
Sensitivity	0.604	0.463–0.734
Specificity	0.786	0.534–0.942
PPV	0.906	0.775–0.976
NPV	0.367	0.210–0.545
ASES score improving by the MCID (14.5 points)	36 (75.0%)	4 (28.6%)
ASES score not improving by the MCID (14.5 points)	12 (25.0%)	10 (71.4%)
Test Characteristics		
Parameter		
Sensitivity	0.750	0.617–0.857
Specificity	0.714	0.455–0.901
PPV	0.900	0.783–0.968
NPV	0.455	0.260–0.659
SANE score improving by the MCID (25.0 points)	35 (72.9%)	5 (35.7%)
SANE score not improving by the MCID (25.0 points)	13 (27.1%)	9 (64.3%)
Test Characteristics		
Parameter		
Sensitivity	0.729	0.594–0.841
Specificity	0.643	0.383–0.854
PPV	0.875	0.750–0.953
NPV	0.409	0.222–0.616

MCID: Minimal Clinically Important Difference; pVAS: Pain Visual Analog Scale; ASES: American Shoulder and Elbow Surgeons; SANE: Single Assessment Numeric Evaluation; PPV: Positive Predictive Value; NPV: Negative Predictive Value.

DISCUSSION

Recently, Evuarherhe et al³⁴ conducted a study using dermal allograft on the MCID, SCB, and PASS of scoring systems, including pVAS, ASES, Constant, and SANE scores. They reported MCID, SCB, and PASS values which differed from those observed in our study. Notably, their study indicated slightly higher PASS, MCID, and SCB values for ASES and SANE scores compared to previous studies. In a systematic review comparing allografts and autografts for ASCR, it was noted that postoperative ASES scores tended to be higher for autografts, although statistical comparison between the groups was not feasible.⁵⁵ This disparity in clinical scores might be attributed to differences in patient populations receiving autografts versus allografts, warranting further investigation for precise interpretation. Additionally, subscapularis tear emerged as a common factor hindering clinically significant outcomes following ASCR in these studies. In relation to the Constant score, despite noting a notable contrast among unchanged, changed, and improved groups, the reported Minimum Clinically Important Difference (MCID) and Substantial Clinical Benefit (SCB) values were -0.5 and 5.5 , respectively. It's intriguing that the Constant score didn't manifest significant enhancement for MCID when compared to preoperative scores, whereas SCB demonstrated marginal variance compared to other functional scores. This observation highlights the Constant score's inclination towards assessing strength. Individuals in the improved group exhibited a modest augmentation in Constant score strength without substantial deviation, while the remaining groups showcased similar preoperative and postoperative scores. This suggests a patient inclination towards prioritizing pain alleviation and functional restoration over pure muscle strength improvement to achieve MCID and SCB. Essentially, those who perceive themselves as "better" or "sufficiently better" post-ASCR seem to prioritize pain relief and functional rehabilitation over mere muscle strength enhancement.

These findings indicate that patients typically reach the MCID for clinical outcomes within 11–15 months following arthroscopic superior capsular reconstruction. Moreover, patients achieve SCB and PASS between 14 to 19 months post-surgery. Previous studies have shown significant improvements in pain and functional outcomes from one year^{26,57,106} to two years^{48,93} after SCR, which may explain why most patients attain clinically significant outcomes by one year, with further increases observed up to two years post-operation. Additionally, patients tend to sustain these improvements in clinically significant outcomes from one to two years postoperatively, suggesting stable benefits during this period. Evuarherhe *et al.*³⁴ observed that patients achieved MCID, SCB, and PASS for functional outcomes after SCR using a dermal allograft. In contrast, patients receiving a FLA achieved MCID, SCB, and PASS for functional outcomes at two years postoperatively, indicating potential superiority over dermal allografts. Understanding the two-year follow-up timeline for achieving clinically significant outcomes aids in patient education by providing insight into the estimated time for satisfactory recovery. Moreover, it underscores the importance of evidence-based recovery pathways as patient expectations can influence perceived outcomes after surgery.^{23,50} This understanding enables more efficient utilization of limited resources such as clinic follow-ups and physical therapy sessions to facilitate postoperative recovery. Additionally, setting realistic patient expectations regarding postoperative improvement can help alleviate frustration and enhance overall satisfaction following SCR. Comparing the time to achieve CSOs after SCR with that after arthroscopic rotator cuff repair indicates that patients undergoing the former procedure require a longer duration to reach MCID, SCB, and PASS compared to those undergoing the latter.⁷⁶

MCID is reported to be affected by many factors, including illness severity, patients' concepts of health and improvement, and biopsychosocial status.²⁹ Further, a significant limitation of MCID is the possibility of a

ceiling effect of achieving MCID in patients with high preoperative scores, even after achieving an excellent result.²⁸ Furthermore, previous studies revealed that patients with higher preoperative outcomes are more likely to fail to achieve the MCID postoperatively.^{88,100,103} Yoem et al. revealed that patients with higher preoperative scores have significantly lower odds ratios in achieving MCID following ASCR using fascia lata autograft.¹¹⁶ Evuarherhe et al. reported similar results using dermal allograft.³⁴ Hence, MCID was proposed to not precisely measure patient-reported satisfaction for individual patients. Patient satisfaction is associated with many factors, including increased compliance, improved outcomes⁴³, decreased risk of litigation,⁴⁵ patient understanding of their health,⁴³ and meeting preoperative expectation.⁴⁴ Decreased satisfaction is associated with poor patient health, slow recovery, and demographics.^{56,92,113} Acknowledging that patient satisfaction also varies from the surgery^{18,101,102} and is not always well understood by the treating surgeon is crucial.^{62,75,112} The results of this study revealed that PROMs cannot be used in isolation to predict patient satisfaction because many patients who failed to achieve MCID still expressed satisfaction following ASCR.

This study has some limitations. Despite the small number of included patients, the study demonstrated AUC values >0.7 for PASS, MCID, and SCB, which were comparable to findings in other studies. Bias was mitigated by having a single surgeon perform all surgical procedures. Secondly, the anchor question was collected at varying follow-up times of at least 1 year. While patients with different follow-up times may exhibit diverse clinical outcomes, no difference was found in postoperative 1-year and final outcomes. Future studies are expected to delve into long-term follow-up of SCR and derive consensus from the findings.

CONCLUSIONS: Reliable PASS, MCID, and SCB values were achieved for at least 1 year after SCR surgery. Most patients achieved MCIDs around 1 year after SCR. Achieving MCID thresholds on the VAS, ASES, SANE, and Constant scores, was predictive of patient-reported satisfaction after surgery. However, half of the patients failing to achieve MCID were still satisfied, regardless of improvements of clinical outcomes.

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ABSTRACT IN KOREAN

배경 및 목적 : 상부 관절낭 재건술(SCR)은 광범위 회전 근개 파열의 치료를 위해 도입되고 개발되었습니다. 연령, 성별, 체질량지수(BMI), 지방 침윤(FI), 잔여 힘줄 분류, 임상적 혜택 달성 기간, 힘줄 성숙/치유, 환자 수용 가능한 증상 상태(PASS), 최소 임상적으로 중요한 차이(MCID), 그리고 상당한 임상적 혜택(SCB) 등이 회전근개 봉합술 후 임상 결과와 관련이 있는 것으로 알려져 있으나, 이러한 요인들이 SCR 의 경우에 대해서는 충분히 조사되지 않았습니다. 본 연구는 SCR 후 수술 결과와 임상적 혜택에 대한 이러한 요인들의 영향을 조사하는 것을 목표로 합니다.

방법 : 본 연구는 2013 년 6 월부터 2022 년 10 월 사이에 넓다리 근막 자가 이식(FLA)을 사용하여 관절경적 상부 관절낭 재건술(ASCR)을 받은 환자들의 데이터를 후향적으로 수집했습니다. 수술 후의 수술 소견을 철저히 검토했습니다. 수술 전 T2 강조, 지방 억제 MRI 스캔의 관상면에서 힘줄 파열 부위와 삼각근의 신호 강도 비율을 사용한 잔여 힘줄 분류에 따라 환자들은 비율이 <0.8 , $0.8-1.3$, >1.3 인 유형 1, 2, 3 으로 분류되었습니다. 이식편 재형성은 신호 대 잡음 비율(SNQ)을 분석하여 평가되었습니다. 미국 어깨 및 팔꿈치 외과 학회(ASES) 점수, 단일 평가 숫자 평가(SANE) 점수, Constant 점수, 통증에 대한 시각적 아날로그 척도(VAS) 점수, 그리고 운동 범위를 포함한 환자가 보고한 결과 측정값(PROMs)이 평가되었습니다. 수술 후 PASS, MCID, SCB 값을 도출하기 위한 앵커 질문이 적용되었습니다. PASS, MCID, SCB 는 민감도 및 특이도 기반 접근법을 사용하여 도출되었습니다. 환자들이 MCID, SCB, PASS 에 도달하는 시간을 Kaplan-Meier 분석을 사용하여 계산했습니다.

결과 : 성별과 연령을 기준으로 모든 그룹에서 ASES, Constant, SANE, VAS 점수가 유의미하게 개선되었습니다. 모든 점수는 PASS에 대해 수용 가능한 곡선 아래 면적을 보였습니다. MCID 및 PASS 달성 분석 결과, 대부분의 결과 측정에서 그룹 간 차이는 없었습니다. 그러나 여성 환자는 남성 환자보다 SANE 기준에 대해 PASS를 유의미하게 더 높은 비율로 달성했습니다. 65세 이상의 환자는 65세 미만의 환자보다 ASES 및 Constant 기준에 대해 MCID를 유의미하게 더 높은 비율로 달성했습니다. 모든 세

그룹에서 VAS 및 ASES 점수가 유의미하게 개선되었습니다. 정상 체중 및 과체중 환자는 Constant 점수가 유의미하게 개선되었으나, 비만 환자에서는 차이가 관찰되지 않았습니다. BMI 그룹 간 CSO의 확률 분포에는 유의미한 차이가 없었습니다. 유형 1 잔여 힘줄을 가진 환자는 다른 두 그룹에 비해 ASES, Constant 점수 및 전방 굴곡에서 유의미하게 더 높은 점수를 기록했습니다. 극하근의 수술 전 FI에 기반하여, SCR 후 임상적 및 방사선학적 결과가 유의미하게 개선되었습니다. 중증 FI를 가진 환자에서는 경증 FI를 가진 환자보다 이식 실패율이 더 높았습니다. 극하근의 중증 FI를 가진 환자에 대해, SCR 단독 시행보다 SCR과 하부 승모근 힘줄 이식술을 병행한 경우 ASES 점수는 유의미하게 더 좋고, VAS 점수는 더 낮았습니다. FLA + Mesh 그룹의 평균 SNQ는 수술 후 3개월 시점에서 FLA 그룹보다 유의미하게 낮았습니다. 또한, 상완골 및 중간 부위에서 두 그룹 간 유의미한 차이가 발견되었으나, 견갑골 부위에서는 차이가 없었습니다. 또한, FLA 그룹에서는 수술 후 3개월과 12개월 사이에 SNQ가 유의미하게 감소하였으나, FLA + Mesh 그룹에서는 두 시점 간 차이가 없었습니다. PASS, MCID 및 SCB 값은 pVAS에서 각각 1.5, 2.5, 4.5; ASES 점수에서 각각 81.0, 19.0, 27.5; Constant 점수에서 각각 60.5, -0.5, 5.5; SANE에서 각각 75.0, 27.5, 32.5였습니다. ASES의 MCID, 상당한 임상적 이익 및 PASS의 평균 달성 시간은 각각 13.2 ± 1.0 개월, 16.8 ± 1.0 개월, 18.3 ± 0.9 개월이었습니다. Constant 점수의 MCID, 상당한 임상적 이익 및 PASS의 평균 달성 시간은 각각 11.6 ± 0.9 개월, 15.1 ± 1.0 개월, 14.7 ± 0.9 개월이었습니다. SANE의 MCID, 상당한 임상적 이익 및 PASS의 평균 달성 시간은 각각 14.4 ± 1.0 개월, 16.1 ± 1.0 개월, 15.5 ± 0.8 개월이었습니다.

결론 : 여성 환자는 남성 환자보다 SANE의 PASS를 유의미하게 높은 비율로 달성하였고, 고령 환자는 젊은 환자보다 ASES 및 Constant에서 MCID를 더 높은 비율로 달성하였습니다. 따라서 연령은 성별보다 MCID 달성에 더 강한 요인입니다. 그러나 BMI 그룹 간 모든 PROMs 및 CSO 달성 가능성에는 차이가 관찰되지 않았습니다. 잔여 힘줄 분류는 수술 후 임상 결과를 예측하는 데 유용할 수 있으나, 이러한 차이의 임상적 중요성은 제한적일 수 있습니다. 극하근의 중증 FI는 이식편의 예후가 좋지 않음을 나타내는 요인입니다. 하부 승모근 힘줄 이식술을 병행한 SCR은 극하근의 중증 FI를 가진 환자에게 유의미하게 낮은 이식편 과열률과 더 나은 임상 결과를 제공했습니다. 3개월 추적 관찰 시 FLA + Mesh 그룹은 FLA 그룹보다 MRI 신호 강도가 낮았습니다.

메쉬를 사용할 경우 FLA의 치유와 재형성이 촉진될 수 있습니다. 메쉬는 수술 후 1년 동안 이식편 재형성을 유지하는 데 기여했습니다. 신뢰할 수 있는 PASS, MCID 및 SCB 값은 SCR 수술 후 최소 1년 동안 달성되었습니다. 대부분의 환자는 SCR 후 1년 내에 MCID를 달성했습니다.

키워드 : 연령; 성별; 체질량지수(BMI); 지방 침윤(FI); 이식 실패; 극하근; 고급 당화 최종산물(AGE); 잔여 힘줄의 신호 강도; 이식편 재형성 및 치유; 신호 강도; 임상적으로 중요한 결과; 회복 불가능한 회전근개 파열; 회전근개; 상부 관절낭 재건술(SCR); 최소 임상적으로 중요한 차이(MCID); 환자 허용 증상 상태(PASS); 상당한 임상적 혜택(SCB); 상부 관절낭 재건술(SCR); 임상적 유의미성 달성 시간