Comparing Clinical Outcomes After Subacromial Spacer Insertion Versus Other Reconstruction Methods in the Treatment of Irreparable Massive Rotator Cuff Tears

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Background: Previous studies on subacromial spacer (SAS) insertion have been limited to case series that did not compare the effectiveness of this technique with other techniques.

Hypothesis: Outcomes after SAS insertion for the treatment of irreparable massive rotator cuff tears (IMRCTs) will be similar to those of other techniques.

Study Design: Cohort study; Level of evidence, 3.

Methods: This retrospective study was based on data collected from patients who underwent correction of IMRCTs between January 2010 and October 2017. Group 1 patients (n = 17) received SAS insertion with or without partial repair; group 2 patients (n = 36) were treated with other techniques (isolated partial repairs or bridging grafts). Preoperative tear size and global fatty degeneration index values were evaluated. Range of motion, visual analog scale for pain, American Shoulder and Elbow Surgeons (ASES) score, Constant score, Simple Shoulder Test (SST), Disabilities of the Arm, Shoulder and Hand score, and acromiohumeral distance (AHD) were assessed preoperatively and at final follow-up at least 2 years after the surgery (range, 24-60 months). In both groups, ultrasonographic examination was performed at 3 and 6 months postoperatively, and magnetic resonance imaging (MRI) was performed at 1 year.

Results: Tear size and preoperative global fatty degeneration index were not significantly different between the groups (all $P > .05$). There were no differences in functional scores between the groups at final follow-up (all $P > .05$). AHD was maintained at final follow-up in group 1 (mean ± SD: 6.2 ± 2.1 mm [postoperatively] vs 6.7 ± 2.3 mm [final follow-up]; $P = .678$), and there was no difference compared with group 2 (7.2 ± 3.2 mm; $P = .244$). Patients with retears in group 2 (23 of 36, 63.9%) had lower ASES ($P = .041$) and SST ($P = .027$) scores at final follow-up when compared with patients in group 1. Six patients (35.3%) in group 1 had partial repairs; these patients had better external rotation at 90° ($P = .047$), better SST scores ($P = .036$), and higher AHDs at final follow-up ($P = .046$) than those in group 1 who had no repair. Three patients (50%) showed retears of partially repaired tendons on MRI. Of 13 patients (76.5%) in group 1 with postoperative MRI, 12 (92.3%) showed fibrotic tissue in the subacromial space not seen preoperatively.

Conclusion: There was no difference in outcomes between SAS and the other reconstruction methods for treating IMRCTs. However, given the high retear rate associated with other techniques and poor functional outcomes after retear, SAS insertion could be a viable option for treating IMRCTs.

Keywords: irreparable massive rotator cuff tears; subacromial spacer; partial repair; bridging graft; outcomes

Clinical outcomes after rotator cuff repairs have improved overall owing to the recent developments in surgical techniques and devices.[8,37] However, the postoperative retear rate is still approximately 40% for massive rotator cuff tears (MRCTs), which are defined as tears ≥5 cm or those that involve >2 tendons.[8,37] It has also been reported that the possibility of retear after rotator cuff tendon repair increases as the size of tear increases and that approximately 30% of rotator cuff tears are irreparable because they were severely retracted.[3]

Various surgical methods have been attempted to treat irreparable tears.[25] These methods include superior capsular reconstruction,[20] which has drawn attention recently, bridging grafts with the long head of the biceps tendon

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(LHBT) or biological tissues,[28,29] tendon transfer,[22] partial repair,[23] tuberoplasty,[26] or, as a last resort, reverse shoulder arthroplasty. However, only a few studies have evaluated clinical outcomes after superior capsular reconstruction.[4,20] Hu et al[16] reported that superior capsule plays a negligible role in preventing superior translation of the humeral head. Several studies have shown high failure rates and less satisfactory functional outcomes with the use of bridging grafts.[28,36] The results of other surgical techniques, such as tendon transfer, partial repair, and tuberoplasty, remain controversial and limited.[1,8,11,19,26] Therefore, it is challenging for shoulder surgeons to determine the appropriate surgical technique for patients who have irreparable rotator cuff tears and are too young to undergo reverse shoulder arthroplasty.

The insertion of biodegradable subacromial spacers (SASs; InSpace Balloon System, Orthospace) has drawn much attention recently. The spacer, fabricated from a copolymer substance (L-lactide-co-ε-caprolactone),[32] expands the acromiohumeral distance (AHD) by inserting a balloon that plays an auxiliary role in the force couple. This procedure has mainly been used in patients with irreparable MRCTs (IMRCTs).[33] Several recent studies have reported that SAS insertion led to satisfactory functional improvements.[5,33,38] Moon et al[21] did a systematic review of SAS insertion and concluded that patients who had SAS insertion for the treatment of IMRCTs had satisfactory outcomes at the 2- to 3-year follow-up, with a low rate of complication. However, 1 study showed unsatisfactory outcomes after SAS insertion.[30]

There are also some biomechanical studies on SAS insertion. Singh et al[35] showed that SAS restored the humeral head position from the superiorly migrated location. Chevalier et al[6] applied this technique on 6 cadaveric specimens and reported that it reduced peak and mean subacromial space pressures in abduction-adduction. Therefore, some surgeons use it as an internal splint to protect the repair site until the rotator cuff is fully healed.[38] However, there are no current standard protocols for SAS insertion, including whether concomitant partial repair or tuberoplasty is necessary, which size is better, and so on.

Because such controversy exists, the question arises: Which method is optimal for treating IMRCTs? However, most previous studies on SAS insertion have been limited to case series that did not analyze the effectiveness of this technique in comparison with other techniques. Therefore, the objective of the current study was to analyze clinical and radiographic results to compare the effectiveness of SAS insertion with that of other reconstruction methods in the treatment of IMRCTs. We hypothesized that the outcomes after SAS insertion would be similar to those of other techniques in the treatment of IMRCTs.

METHODS

Patient Enrollment

Between January 2010 and October 2017, a total of 3096 consecutive patients were surgically treated for rotator cuff tears at our institutions. Among 843 patients (27.2%) who had MRCTs, 68 (2.2%) had MRCTs that could not be mobilized and reattached to the greater tuberosity, owing to considerable retraction of the rotator cuff tendon. The medical records of these 68 patients were then evaluated in this retrospective cohort study, and patients were divided into 2 groups as noted below and in Figure 1. Data collection and all protocols were approved by the institutional review board of Seoul National University Bundang Hospital.

Group 1: SAS (InSpace). For 19 of the 68 patients with IMRCTs, biceps augmentation could not be performed because of concomitant complete biceps rupture or poor tendon quality. These patients underwent SAS insertion from May 2016 to October 2017. Of the patients with minimum 2-year follow-up, 17 (89.5%) were allocated to group 1.

Group 2: Other Reconstruction Methods. Among 35 patients with IMRCTs and intact biceps tendons, arthroscopic rotator cuff repair with the LHBT as the bridging graft was performed. Of those 35 patients, 9 were excluded from the analysis: 8 were lost to follow-up, and 1 had considerable pain in the contralateral shoulder, which would have affected postoperative rehabilitation, as it is highly dependent on the use of the opposite arm. For 10 patients with concomitant complete biceps rupture, rotator cuff repair with an allogenic dermal patch graft was performed. Among these 10 patients, 2 were lost to follow-up. For 5 patients who had complete biceps tendon tear and did not want an allogenic dermal patch graft, the senior author (J.H.O.) performed isolated partial repair without any graft. Two of these patients were lost to follow-up, and another patient was excluded after undergoing reverse total shoulder arthroplasty because of worsening pain and poor functional outcomes at 6 months after the surgery.

Patch grafts or isolated partial repairs were performed in the included patients for 2 possible reasons: (1) the biceps tendon could not be used for augmentation because of complete rupture; (2) the SASs were not available at that time in our country. Ultimately, 36 patients who underwent

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Ethical approval for this study was obtained from Seoul National University Bundang Hospital Institutional Review Board (No. B-1812/510-104).

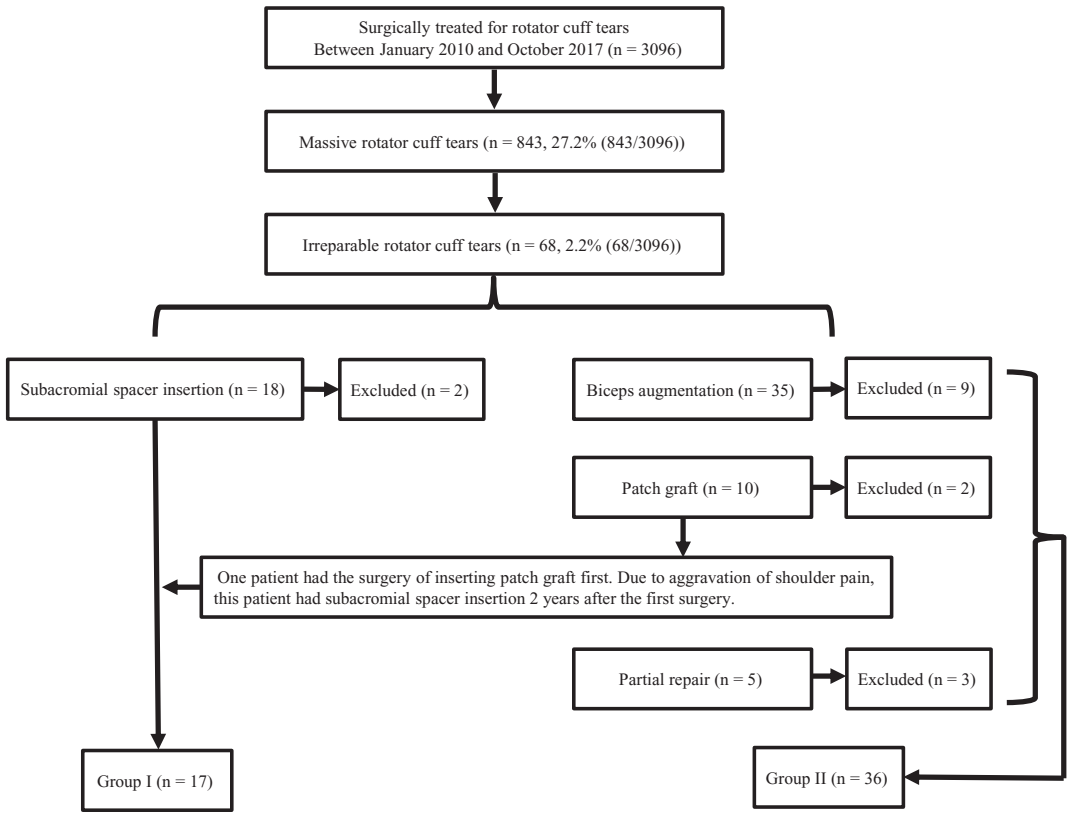

Figure 1. Flowchart depicting included and excluded patients.

surgery between January 2010 and January 2017 were enrolled and allocated to group 2.

Surgical Procedure

All surgical procedures were performed by the senior author. For surgery, each patient was placed in the lateral decubitus position with traction to the involved arm while under general anesthesia. With the posterior portal as the viewing portal, intra-articular pathologies, including biceps lesions, were evaluated. After a glenohumeral inspection, subacromial bursectomy was performed. The coracoacromial ligament was dissected if there was fraying or tearing of the ligament. Acromioplasty was performed if there was a subacromial spur and the thickness of acromion was >7 mm, according to a previous study in which patients with full-thickness rotator cuff tears had thicker acromions.[24] Then, the reparability of the torn rotator cuff was assessed. If the torn end of the rotator cuff could not be attached to the footprint, intra- and extra-articular releases were performed to allow for greater mobilization of the tendon. In cases where the torn tendon could not be attached even with sufficient release and medialization, an SAS insertion or other reconstruction method was performed (biceps augmentation, patch graft augmentation, or isolated partial repair). Before each procedure, the anterior-posterior dimension and medial retraction of the torn rotator cuff tears were measured with a probe with 5-mm markings (AR-10010; Arthrex) after the torn end was debrided.

In patients undergoing SAS insertion (Figure 2), bursectomy and acromioplasty were performed. Initially, the senior author did not perform partial repairs, to follow the manufacturer's instructions. After 2 episodes of postoperative new-onset pseudoparalysis (PNOP),[17] however, every effort was made to perform the partial repairs to regain the force couple. The spacer size (small, medium, or large) was selected per the distance from 1 cm medial to the glenoid apex to the lateral border of the greater tuberosity (Table 1).[31] If the distance between the glenoid rim and the lateral border of the greater tuberosity fell between 2 spacer sizes (eg, 45 mm), the larger spacer size was chosen. After satisfactory balloon inflation, the device was sealed, and the delivery system was removed. The shoulder was passively moved through its full range of motion (ROM) to confirm proper SAS placement.

For those who had bridging augmentation with autogenic LHBTs (Figure 3), tenotomy was performed from the anchor of the biceps tendon at the superior labrum. Next, the footprint was prepared by creating bleeding bony surfaces. After tendon mobilization, we selected the portion of the rotator cuff where the biceps graft would be needed. That portion corresponded to the most retracted and nonmobilized part of the rotator cuff tendon, which showed the largest gap between the torn rotator cuff tendon and the footprint. Anteriorly and posteriorly, the well-mobilized

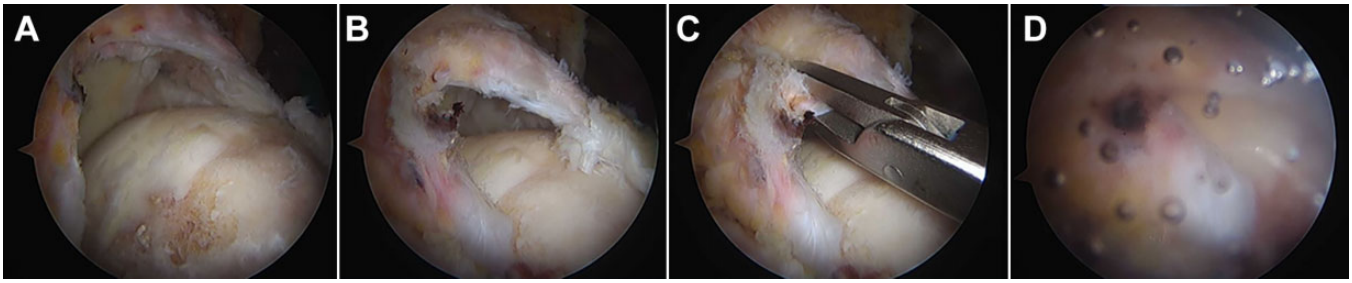

Figure 2. (A) After arthroscopic evaluation through the posterior viewing portal of this massive rotator cuff tear of the right shoulder, (B) a partial repair was performed (as in all similar cases, if possible). (C) After rechecking, the remaining rotator cuff tendon could not be reattached to the footprint, and therefore (D) a subacromial spacer was inserted.

TABLE 1
Subacromial Spacer Size and Instructed Inflation Volumes

Size	Width, mm	Length, mm	Maximal Volume, mL	Instructed Volume, mL
Small	40	50	15-17	9-11
Medium	50	60	22-24	15-16
Large	60	70	40	22-24

tendon was repaired in a single-row manner first. Usually, the middle-retracted tendon was impossible to mobilize to the footprint, and 1 limb of the suture was penetrated through the posterior part of the irreparable tendon, while the other matching limb of sutures was passed through the most distal part of the tenotomized biceps tendon. Similarly, the biceps tendon was interposed between the retracted tendon and footprint in a matrix suture pattern. Rotator cuff repair with biceps bridging augmentation was usually performed with 2 or 3 anchor sutures.

In patients undergoing bridging augmentation with an allogenic dermal patch graft (Figure 4), the same procedure was performed as for biceps augmentation to prepare the bone bed at the greater tuberosity. The graft (MegaDerm, L&C Bio Co; CGDerm, CGBio Co, Dae-woong Pharm) was cut 1 cm larger than the footprint defect. After partial repair of the well-mobilized tendon, we measured the size of the irreparable rotator cuff defect. Then, 4 to 6 different-colored FiberWires (Arthrex) were used to penetrate the retracted rotator cuff tendon for corner stitches. The threads that were located at the articular side were pulled out through the lateral cannula. Then, the allogenic dermal patch was penetrated with the threads at the matching site of the torn rotator cuff. Next, the graft was introduced into the subacromial space. One thread from the rotator cuff and the other from the allogenic patch graft were retrieved and tied sequentially. Finally, suture anchors were inserted to the footprint, and a single-row repair of the patch graft was performed under minimal tension with $>60^\circ$ of shoulder abduction. Sometimes further side-to-side sutures were placed between the rotator cuff and the patch for additional fixation.

In patients undergoing an isolated partial repair (Figure 5), coracoacromial ligament release, subacromial bursectomy, acromioplasty, and footprint preparation were performed as in other methods. The less retracted anterior-to-posterior margins of the torn rotator cuff tendons were repaired. Marginal convergence of the far-retracted tendon was performed, but it was impossible to attach to the footprint.

Rehabilitation

Patients who had SAS insertion without partial repairs had their shoulders supported in neutral rotation in a sling, and active assistive exercises were encouraged immediately after surgery. In patients with partial repairs, braces (Acro Assist 50A1; Ottobock) with abduction pillows were prescribed for 4 weeks. These patients could remove the brace intermittently for passive shoulder exercises (forward flexion [FF], abduction, and external rotation [ER]) in the supine position starting on postoperative day 2. Active shoulder exercises were initiated after 4 weeks in these patients. Muscle strengthening exercises were allowed after 2 months with TheraBands (The Hygienic Corp). Sporting activities were allowed at 5 to 6 months postoperatively.

Among patients who had biceps augmentation, patch augmentation, or isolated partial repair, no passive shoulder motions were allowed during the first 6 postoperative weeks. Active-assisted ROM was initiated at 6 weeks after surgery. Muscle strengthening exercises were initiated at 3 months after surgery.

Outcome Assessment

Regarding functional outcomes, preoperative and final visual analog scale (VAS) scores for pain were assessed. VAS scores for patient satisfaction were also assessed at the final follow-up at least 2 years after the surgery (range, 24–60 months). The American Shoulder and Elbow Surgeons (ASES) score, Constant score, Simple Shoulder Test (SST), and Disabilities of the Arm, Shoulder and Hand (QuickDASH) score were evaluated preoperatively and at the final follow-up. In terms of ROM of the shoulder, active FF, ER at the side, ER at 90°, and internal rotation (IR) were evaluated preoperatively and at the final follow-up.

For the anatomic evaluations, fatty degeneration was evaluated preoperatively by a blinded musculoskeletal

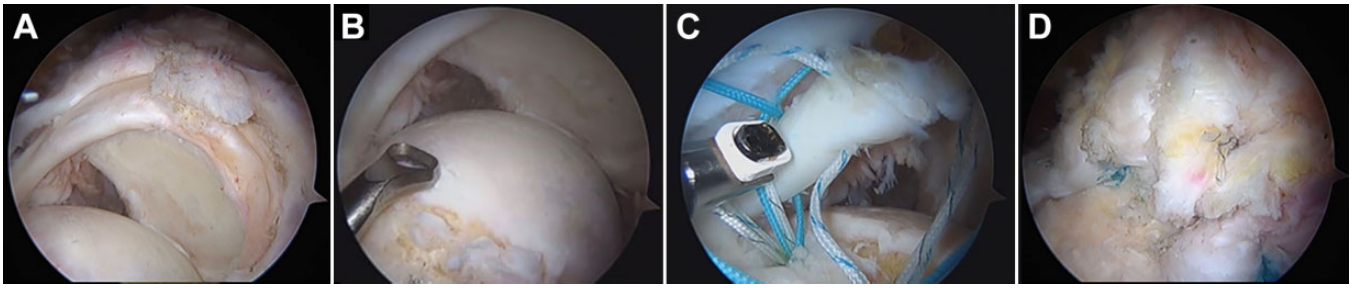

Figure 3. (A) After arthroscopic evaluation through the posterior viewing portal of this massive rotator cuff tear of the left shoulder, (B) the bone bed was prepared to promote bone-to-cuff healing with medialization. (C) After anchor insertion, the threads were inserted through the retracted rotator cuff tendon, and matching sutures penetrated the biceps tendon. (D) Knots were tied for biceps tenodesis, and then simple sutures were placed for the rotator cuff repair.

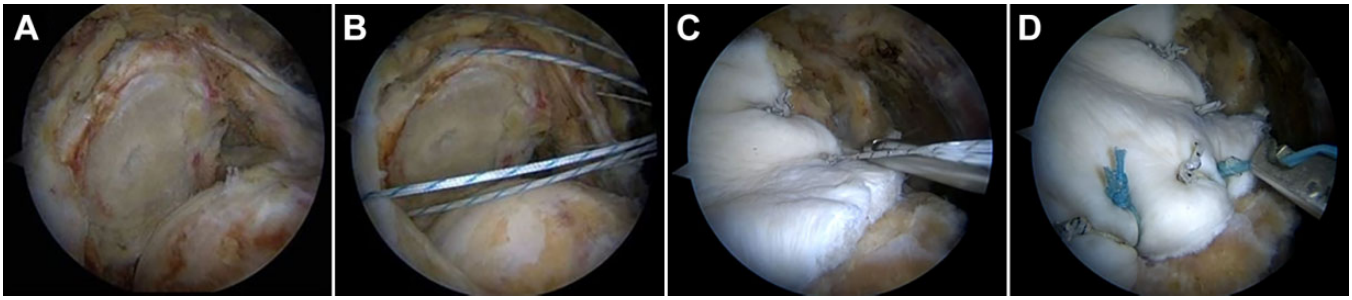

Figure 4. (A) After arthroscopic evaluation through the posterior viewing portal of this massive rotator cuff tear of the right shoulder, (B) FiberWires were used to suture the corner of the torn end of the remaining cuff, and an articular-side suture was retrieved through the lateral arthroscopic portal. (C) The sutured allogenic dermal patch graft was inserted into the subacromial space through a lateral portal, and a simple suture was placed onto the rotator cuff. (D) The lateral end of the patch was then sutured to the footprint with an anchor suture.

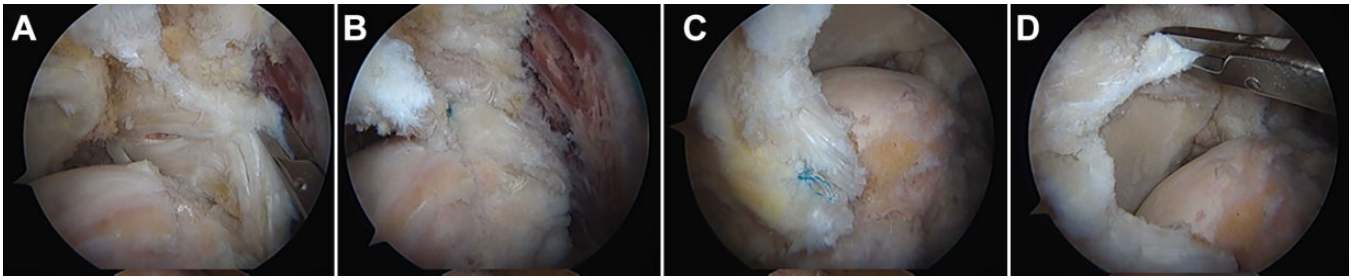

Figure 5. (A) After arthroscopic evaluation through the posterior viewing portal of this massive rotator cuff tear of the right shoulder, an isolated partial repair was performed to attach the (B) subscapularis and (C) infraspinatus, if possible. (D) After repair, the remaining rotator cuff tendon could not be reattached to the footprint.

radiologist (not involved in the current study) using the Goutallier classification system.[13] The interpretations were provided by a senior radiologist who had >14 years of experience. The mean global fatty degeneration index (GFDI) of the supraspinatus, infraspinatus, subscapularis, and teres minor tendons was calculated. The status of the SAS was assessed at 3 and 6 months postoperatively with ultrasonography (USG). The healing status of tendons that were partially repaired with SAS and the status of the SAS itself were evaluated at 1 year postoperatively on magnetic resonance imaging (MRI). The retear rates of the other reconstruction methods were evaluated at 3 and 6 months postoperatively with USG and 1 year postoperatively via USG or MRI by a blinded musculoskeletal radiologist not involved in this study. Rotator cuff integrity was evaluated on USG in patients who could not afford the cost of MRI or who were unable to undergo MRI because of implanted magnetic devices, such as pacemakers. The AHD was calculated to determine whether it increased or remained the same from preoperatively to final follow-up. To assess the

efficiency of the SAS insertion in group 1, we compared the results to those of group 2 both with and without retear. To evaluate the effect of SAS insertion with partial repair, these patients were compared with patients who underwent SAS insertion without partial repair.

Statistical Analysis

According to a previous study on postoperative improvements in ASES scores among patients who had biceps augmentation for IMRCT,[28] a power analysis showed that the minimum sample size was 14 to show an equivalent improvement in ASES score with statistical power of 0.90 ($\alpha = 5\%$). Based on an assumed 20% dropout rate, 18 patients were needed in each group. All statistical analyses were performed with SPSS software (v 21.0; SPSS Inc). The Mann-Whitney *U* test was used to compare the difference between the groups' continuous variables. The patient demographics were analyzed with a chi-square test for categorical variables to assess the difference between the groups. The Wilcoxon signed-rank test was used to evaluate differences between the pre- and postoperative variables in a group.

RESULTS

Demographic data are shown in Table 2. The only statistical difference was found in operative times (mean ± SD: group 1, 80.3 ± 23.5 minutes; group 2, 134.6 ± 35.0 minutes; $P < .001$).

Perioperative Details in Group 1 Cases

Regarding LHBT lesions, 5 patients had complete rupture, and 1 had a tenotomy in a previous surgical procedure. Among 8 patients who had partial tears of the LHBT, 3 had soft tissue tenodesis to the rotator interval, and 5 had tenotomy at the time of surgery. Three patients had intact biceps tendons, and no procedures were performed, as there were no biceps-related symptoms. Partial repair was performed in 6 patients; it was impossible in the others.

Large-sized spacers were inserted in 10 patients, medium-sized in 6, and small-sized in 1. In 14 patients, the balloons were located centrally above the greater tuberosity, as confirmed by USG at 1 day after the surgery. In 1 patient, the balloon was located slightly anteriorly, and in 2 patients, it was located slightly posteriorly. At 6 months postoperatively, the balloons were collapsed and mostly absorbed in all patients. PNOP was diagnosed in 2 patients in group 1, both of whom recovered at 6 months after surgery. In both patients, the torn subscapularis was not repaired during the SAS insertion; no PNOP was observed in patients with an intact or repaired subscapularis. One patient complained of pain secondary to synovitis for the first 6 postoperative weeks but recovered afterward.

Functional Assessments

In group 1, the preoperative VAS score for pain was 6.5 ± 1.8 and decreased after surgery to 1.8 ± 2.5 ($P < .001$). The satisfaction VAS score was 7.3 ± 2.5 at the final follow-up. The ASES score increased from 44.7 ± 12.5 to 80.2 ± 18.6 ($P = .001$), the Constant score increased from 52.6 ± 10.5 to 60.3 ± 7.0 ($P = .011$), the SST improved from 2.9 ± 2.2 to 8.3 ± 4.0 ($P = .002$), and the QuickDASH score improved from 40.4 ± 16.1 to 10.7 ± 9.9 ($P = .019$) after surgery. In group 2, the preoperative VAS score for pain was 6.2 ± 2.6 and decreased postoperatively to 2.2 ± 2.8 ($P < .001$). The satisfaction VAS was 7.3 ± 2.4 at the final follow-up. The ASES

TABLE 2
Demographic Data of Patients[a]

Variable	Group 1 (n = 17)	Group 2 (n = 36)	*P*
Age, y	61.7 ± 8.1	65.4 ± 5.7	.069
Male:female	12:5	18:18	.138
Pseudoparalysis	2	4	.533
Positive ER lag sign	3	5	.846
Previous rotator cuff repair history	6	2	.213
Dominant hand (right:left:both)	16:1:0	30:5:1	.711
Surgical side (right:left)	11:6	24:12	.899
Fatty degeneration			
Supraspinatus	3.5 ± 0.5	3.7 ± 0.6	.076
Infraspinatus	2.7 ± 1.3	2.8 ± 1.2	.888
Subscapularis	1.8 ± 1.3	2.0 ± 1.8	.868
Teres minor	0.5 ± 0.6	0.8 ± 0.6	.082
GFDI	2.0 ± 0.8	2.3 ± 0.7	.372
Operation time, min	80.3 ± 23.5	134.6 ± 35.0	**<.001**
Mean follow-up period, mo	24.4	30.1	.451
Intraoperative tear size, cm			
AP	3.9 ± 0.8	3.7 ± 0.9	.707
Retraction	4.0 ± 0.6	3.9 ± 0.8	.720
Torn tendons			.788
SSP + SSC	1	2	
SSP + ISP	3	10	
SSP + ISP + SSC	13	24	
Subscapularis full-thickness tear	9 (52.9%)	15 (41.7%)	.718
Preoperative clinical scores			
Pain VAS	6.5 ± 1.8	6.2 ± 2.6	.318
ASES score	44.7 ± 12.5	56.8 ± 19.9	.155
Constant score	52.6 ± 10.5	51.6 ± 20.2	.537
Simple Shoulder Test	2.9 ± 2.2	3.8 ± 2.7	.438
QuickDASH	40.4 ± 16.1	46.1 ± 16.2	.211
Preoperative ROM			
Forward flexion, deg	134.1 ± 40.0	129.3 ± 48.0	.711
External rotation at side, deg	39.1 ± 22.2	37.2 ± 19.3	.634
External rotation at 90°, deg	59.4 ± 18.0	66.8 ± 23.8	.097
Internal rotation[b]	T10.7 ± 2.8	T10.2 ± 3.1	.787

[a]Values are presented as mean ± SD or n (%). Bolded *P* value indicates statistically significant between-group difference ($P < .05$). AP, anterior to posterior; ASES, American Shoulder and Elbow Surgeons; ER, external rotation; GFDI, global fatty degeneration index; ISP, infraspinatus; QuickDASH, Disabilities of the Arm, Shoulder and Hand; ROM, range of motion; SSC, subscapularis; SSP, supraspinatus; VAS, visual analog scale.

[b]Internal rotation as measured by the level of vertebral spinous process that could be reached with the patient's thumb.

TABLE 3
Comparison of Final Outcomes Between the Groups[a]

Variable	Group 1	Group 2	P
Functional outcomes			
Pain VAS	1.8 ± 2.5	2.2 ± 2.8	.479
Satisfaction VAS	7.3 ± 2.5	7.3 ± 2.4	.539
ASES score	80.2 ± 18.6	72.0 ± 25.6	.672
Constant score	60.3 ± 7.0	63.0 ± 17.4	.281
Simple Shoulder Test	8.3 ± 4.0	6.7 ± 4.1	.342
QuickDASH	10.7 ± 9.9	17.4 ± 21.5	.548
Range of motion			
Forward flexion, deg	143.4 ± 27.5	140.7 ± 16.4	.245
External rotation at side, deg	51.3 ± 21.3	54.0 ± 24.3	.869
External rotation at 90°, deg	81.9 ± 25.1	83.0 ± 23.0	.827
Internal rotation[b]	T9.0 ± 1.7	T9.3 ± 2.5	.847
AHD at final follow-up, mm	6.7 ± 2.3	7.2 ± 3.2	.244

[a]Values are presented as mean ± SD. AHD, acromiohumeral distance; ASES, American Shoulder and Elbow Surgeons; QuickDASH, Disabilities of the Arm, Shoulder and Hand; VAS, visual analog scale.
[b]Internal rotation as measured by the level of vertebral spinous process that could be reached with the patient's thumb.

score increased from 56.8 ± 19.9 to 72.0 ± 25.6 ($P = .047$), the Constant score increased from 51.6 ± 20.2 to 63.0 ± 17.4 ($P = .021$), and the QuickDASH score improved from 46.1 ± 16.2 to 17.4 ± 21.5 ($P = .003$) after surgery. The SST improved from 3.8 ± 2.7 to 6.7 ± 4.1, but the difference was not significant ($P = .115$). At the final follow-up, there were no significant differences in scores between the groups (Table 3).

Range of Motion

In group 1, all ROM improved pre- to postoperatively except FF (FF: 134.1° ± 40.0° to 143.4° ± 27.5°, ER at side: 39.1° ± 22.2° to 51.3° ± 21.3°, ER at 90°: 59.4° ± 20.1° to 81.9° ± 25.1°, and IR: T10.7 ± 2.8 to T9.0 ± 1.7: $P = .505$, .008, .004, and .005, respectively). Pseudoparalysis resolved in 1 patient, and the ER lag sign disappeared in 2. In group 2, all ROM increased except FF and IR (FF: 129.3° ± 48.0° to 140.7° ± 16.4°, ER at side: 37.2° ± 19.3° to 54.0° ± 24.3°, ER at 90°: 66.8° ± 23.8° to 83.0° ± 23.0°, and IR: T10.2 ± 3.1 to T9.3 ± 2.5; $P = .563$, $<.001$, .006, and .925). Pseudoparalysis resolved in 4 patients, and the ER lag sign disappeared in 3. At the final follow-up, ROM was not significantly different between the groups (Table 3).

Radiological Assessments

Overall, 13 of the 17 patients (76.5%) in group 1, including all 6 patients who had partial repair, had MRI evaluations at 1 year postoperatively. Among the 6 partial repair patients, 3 (50%) showed retears of the partially repaired tendons on postoperative MRI. Twelve patients (92.3%) showed fibrotic tissue in the superior subacromial space that was not seen on the preoperative MRI (Figure 6).

In group 2, retears were identified in 23 of the 36 patients (63.9%) at 1 year after surgery. Fifteen of 26 patients (57.7%) who had bridging grafts with autogenous biceps tendons developed retears, and 6 of 8 patients (75%) who had bridging grafts with allogenic dermal patches developed retears. Two patients had isolated partial repairs, and both developed retears.

Regarding the AHD (Table 3), the mean distance in group 1 was maintained (6.2 ± 2.1 mm preoperatively to 6.7 ± 2.3 at final follow-up; $P = .678$). The patient who did not recover from pseudoparalysis by the time of final follow-up had a preoperative AHD of 4.9 mm that decreased to 3.0 mm by final follow-up. In group 2, the AHD decreased nonsignificantly from 7.7 ± 2.4 mm to 7.2 ± 3.2 mm at final follow-up ($P = .224$). There was no difference in AHD between groups 1 and 2 at final follow-up ($P = .244$).

Group 1 vs Group 2 With Retears

Patients in group 2 who had retears (23 of 36 patients) had a higher level of fatty degeneration of the teres minor ($P = .035$) than those in group 1. Patients in group 1 showed significantly better ASES ($P = .041$) and SST ($P = .027$) scores than these group 2 patients, although ROM and AHD values were not significantly different between the groups (Table 4).

Among patients in group 2 with retears, the preoperative VAS score for pain was 5.8 ± 2.2, which decreased to 2.4 ± 2.7 postoperatively ($P = .006$). The satisfaction VAS score was 6.7 ± 2.8 at the final follow-up. There were no improvements in the functional scores at the final follow-up (ASES: from 66.1 ± 14.7 to 66.1 ± 25.3, Constant: from 61.6 ± 9.0 to 60.4 ± 18.8, SST: from 4.4 ± 3.2 to 5.4 ± 4.2, and QuickDASH: from 46.2 ± 16.1 to 21.2 ± 25.5; $P = .859$, .859, .805, and .161, respectively). Only ER at side improved significantly (FF: 126.2° ± 53.8° to 135.9° ± 45.4°, ER at side: 30.6° ± 21.0° to 49.4° ± 25.9°, ER at 90°: 66.4° ± 19.6° to 77.3° ± 29.4°, and IR: T10.7 ± 3.3 to T9.8 ± 2.6; $P = .775$, .003, .150, and .161). The AHD decreased nonsignificantly from 8.2 ± 2.5 mm preoperatively to 7.1 ± 3.4 mm at final follow-up among those in group 2 with retears ($P = .496$).

Group 1 vs Group 2 Without Retears

At the final follow-up, there was no difference in functional scores or ROM between patients in group 1 and those in group 2 without retears. The AHD was not significantly different between the groups (Table 5).

Group 1 With vs Without Partial Repair

Results of the comparison between group 1 patients with versus without partial repair are shown in Table 6. In terms of functional outcomes, patients who had partial repairs had higher SST scores at the final follow-up ($P = .036$). Other functional outcomes were not significantly different. ER at side was better among patients with partial repairs (partial repair vs no repair: 68.0 ± 11.0 vs 46.4 ± 23.4; $P = .047$), but the other ROM values were not significantly different. The AHD was higher in the patients who had partial repairs (partial repair vs no repair: 7.1 ± 1.7 vs 6.0 ± 4.1 mm; $P = .046$).

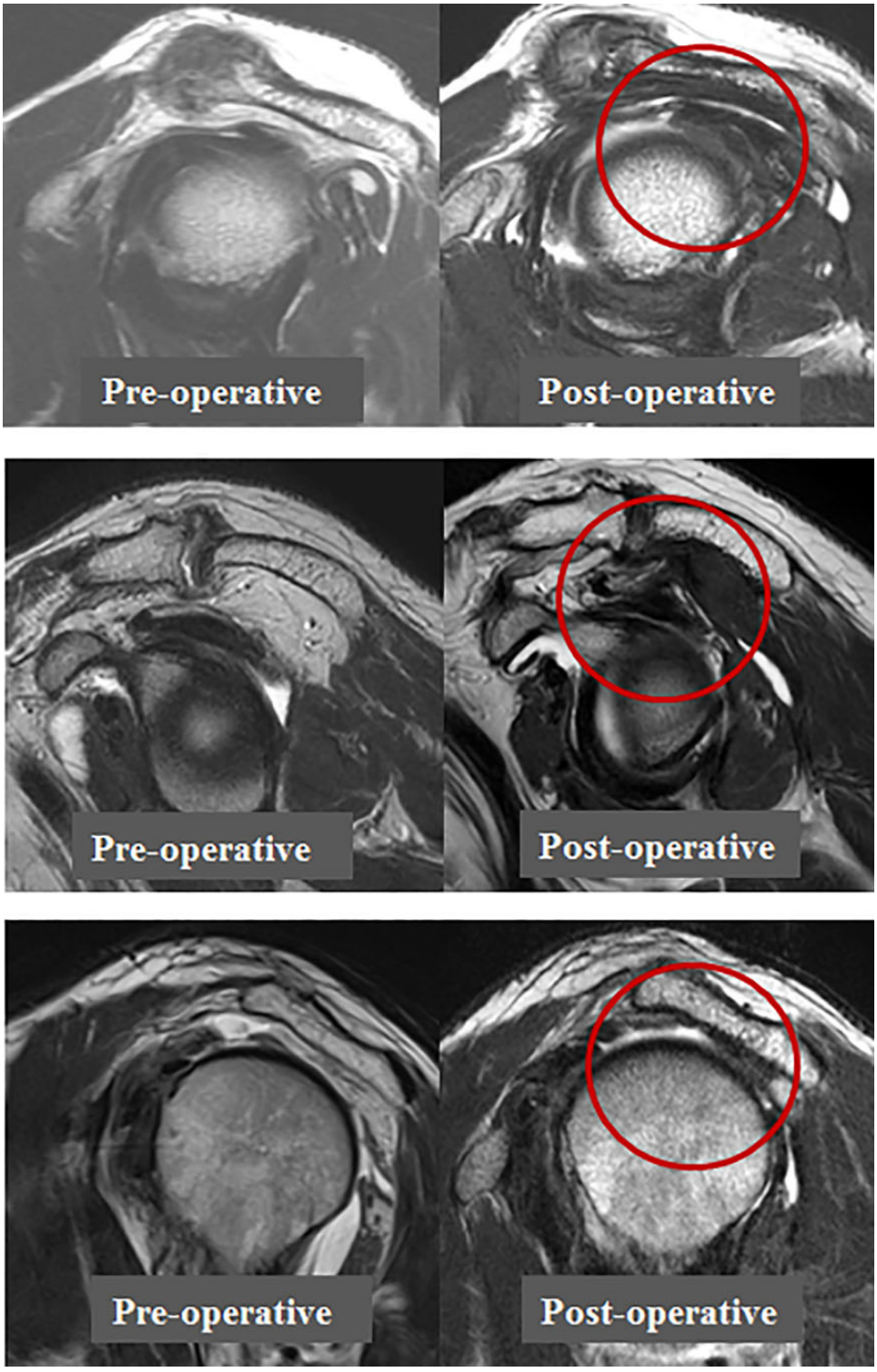

Figure 6. Twelve of 13 patients (92.3%) in group 1 who had magnetic resonance imaging at 1 year after the surgery showed low signal intensity fibrous filling in the subacromial space (red circle).

DISCUSSION

The current study showed that SAS insertion and other reconstruction methods were not significantly different with respect to functional outcomes, ROM, and AHD at final follow-up after surgery for IMRCTs. However, the ASES and SST scores of patients who received SASs were significantly higher than those of patients who had retears

TABLE 4
Comparison of Final Outcomes Between Group 1 and Group 2 With Retear[a]

Variable	Group 1 (n = 17)	Group 2 With Retear (n = 23)	*P*
Preoperative tear size, cm			
AP	3.9 ± 0.8	3.9 ± 1.0	.255
Retraction	4.0 ± 0.6	4.2 ± 0.9	.685
Preoperative fatty degeneration			
Supraspinatus	3.5 ± 0.5	3.8 ± 0.4	.061
Infraspinatus	2.7 ± 1.3	2.8 ± 1.1	.900
Subscapularis	1.8 ± 1.3	1.4 ± 1.2	.452
Teres minor	0.5 ± 0.6	0.9 ± 0.7	**.035**
GFDI	2.0 ± 0.8	2.3 ± 0.6	.121
Final functional outcomes			
Pain VAS	1.8 ± 2.5	2.4 ± 2.7	.433
Satisfaction VAS	7.3 ± 2.5	6.7 ± 2.8	.496
ASES score	80.2 ± 18.6	66.1 ± 25.3	**.041**
Constant score	60.3 ± 7.0	60.4 ± 18.8	.767
Simple Shoulder Test	8.3 ± 4.0	5.4 ± 4.2	**.027**
QuickDASH	10.7 ± 9.9	21.2 ± 25.5	.591
Final range of motions			
Forward flexion, deg	143.4 ± 27.5	135.9 ± 45.4	.202
External rotation at side, deg	51.3 ± 21.3	49.4 ± 25.9	.737
External rotation at 90°, deg	81.9 ± 25.1	77.3 ± 29.4	.566
Internal rotation[b]	T9.0 ± 1.7	T9.8 ± 2.6	.411
AHD at final follow-up, mm	6.7 ± 2.3	7.1 ± 3.4	.978

[a]Values are presented as mean ± SD. Bolded *P* values indicate statistically significant between-group difference ($P < .05$). AHD, acromiohumeral distance; AP, anterior to posterior; ASES, American Shoulder and Elbow Surgeons; GFDI, global fatty degeneration index; QuickDASH, Disabilities of the Arm, Shoulder and Hand; VAS, visual analog scale.

[b]Internal rotation as measured by the level of vertebral spinous process that could be reached with the patient's thumb.

TABLE 5
Comparison of Final Outcomes Between Group 1 and Group 2 Without Retear[a]

Variable	Group 1 (n = 17)	Group 2 Without Retear (n = 13)	*P*
Preoperative tear size, cm			
AP	3.9 ± 0.8	3.5 ± 0.7	.394
Retraction	4.0 ± 0.6	3.8 ± 0.9	.394
Preoperative fatty degeneration			
Supraspinatus	3.5 ± 0.5	3.5 ± 0.8	.404
Infraspinatus	2.7 ± 1.3	2.7 ± 1.3	.781
Subscapularis	1.8 ± 1.3	1.4 ± 0.7	.746
Teres minor	0.5 ± 0.6	0.5 ± 0.5	.394
GFDI	2.0 ± 0.8	2.2 ± 1.0	.109
Final functional outcomes			
Pain VAS	1.8 ± 2.5	1.9 ± 3.0	.853
Satisfaction VAS	7.3 ± 2.5	8.0 ± 1.0	.792
ASES score	80.2 ± 18.6	78.5 ± 23.7	.856
Constant score	60.3 ± 7.0	63.8 ± 16.7	.238
Simple Shoulder Test	8.3 ± 4.0	7.6 ± 3.6	.643
QuickDASH	10.7 ± 9.9	17.6 ± 13.7	.212
Final range of motions			
Forward flexion, deg	143.4 ± 27.5	141.0 ± 47.5	.201
External rotation at side, deg	51.3 ± 21.3	57.6 ± 21.8	.978
External rotation at 90°, deg	81.9 ± 25.1	90.0 ± 8.2	.871
Internal rotation[b]	T9.0 ± 1.7	T8.8 ± 1.9	.856
AHD at final follow-up, mm	6.7 ± 2.3	7.8 ± 3.3	.629

[a]Values are presented as mean ± SD. AHD, acromiohumeral distance; AP, anterior to posterior; ASES, American Shoulder and Elbow Surgeons; GFDI, global fatty degeneration index; QuickDASH, Disabilities of the Arm, Shoulder and Hand; VAS, visual analog scale.

[b]Internal rotation as measured by the level of vertebral spinous process that could be reached with the patient's thumb.

after other reconstruction methods. Interestingly, the AHD was maintained at final follow-up in patients who had SAS insertion, even though the spacer collapsed and was absorbed at 6 months after surgery. Furthermore, we found that patients who had SAS insertion with partial repairs experienced better functional outcomes and greater AHDs than those who had no repair. Taken together, SAS insertion with partial repair seems to be advantageous for patients with IMRCTs.

Many studies have reported satisfactory outcomes after SAS insertion.[9,12,27,31-33,38] However, studies related to SAS insertion to this point have been single case reports or case series studies, and no studies have compared this method with other surgical techniques. Senekovic et al[33] conducted a prospective study of biodegradable spacer insertion in 24 patients (20 patients with IMRCTs and 4 with reparable rotator cuff tears). They reported that functional improvement was maintained during at least 5 years of follow-up and that 84.6% of patients were satisfied with their results. The authors also reported that muscle strength significantly increased for 6 months postoperatively and was maintained until the final follow-up assessment. Deranlot et al[9] carried out a prospective study of biodegradable spacer insertion in 39 patients with IMRCTs and reported that the ROM and functional outcomes were improved at least 1 year after surgery. In this regard, only 1 study has reported unsatisfactory results[30]; in that prospective study, only 6 patients showed improvement >10 points on the Constant score, whereas 5 patients required reconversion to a reverse total shoulder arthroplasty (at a median 9.8 months postoperatively) because of a lack of improvement or worsening of symptoms. Moreover, the authors in that study followed the manufacturer's instructions and did not perform subacromial bursectomy or acromioplasty with partial repair.

Regarding complications, Senekovic et al[33] reported that synovitis occurred in 2 of their 24 patients after SAS insertion. However, most studies indicated that the postoperative results were generally good, with no complications.[9,32] In our study, 17 patients who were evaluated for a minimum of 2 years showed postoperative improvements in function and ROM. Although we observed PNOP in 2 patients and synovitis in 1, all of them recovered, showing that SAS insertion seems to have minimal risk of complications.

TABLE 6
Comparison of Final Outcomes Between Group 1 With and Without Partial Repair[a]

Variable	Partial Repair (n = 6)	No Repair (n = 11)	*P*
Preoperative tear size, cm			
AP	3.8 ± 0.8	3.6 ± 1.4	.808
Retraction	4.1 ± 0.4	3.7 ± 1.4	.525
Preoperative fatty degeneration			
Supraspinatus	3.3 ± 0.5	3.1 ± 1.1	.961
Infraspinatus	2.2 ± 1.3	2.7 ± 1.4	.462
Subscapularis	2.0 ± 1.3	1.6 ± 1.4	.525
Teres minor	0.8 ± 0.8	0.2 ± 0.4	.098
GFDI	2.8 ± 0.9	2.6 ± 1.0	.808
Final functional outcomes			
Pain VAS	1.3 ± 2.4	1.8 ± 2.6	.884
Satisfaction VAS	8.5 ± 0.5	6.9 ± 3.0	.256
ASES score	76.4 ± 37.8	74.5 ± 20.3	.492
Constant score	62.5 ± 6.4	53.8 ± 20.1	.606
Simple Shoulder Test	11.5 ± 0.6	7.0 ± 4.0	**.036**
QuickDASH	2.9 ± 1.2	13.9 ± 10.1	.106
Final range of motions			
Forward flexion, deg	152.0 ± 13.0	135.9 ± 30.2	.267
External rotation at side, deg	68.0 ± 11.0	46.4 ± 23.4	**.047**
External rotation at 90°, deg	97.0 ± 8.4	75.5 ± 27.7	.115
Internal rotation[b]	T7.8 ± 0.4	T9.2 ± 1.7	.180
AHD at final follow-up, mm	7.1 ± 1.7	6.0 ± 4.1	**.046**

[a]Values are presented as mean ± SD. Bolded *P* values indicate statistically significant between-group difference ($P < .05$). AHD, acromiohumeral distance; AP, anterior to posterior; ASES, American Shoulder and Elbow Surgeons; GFDI, global fatty degeneration index; QuickDASH, Disabilities of the Arm, Shoulder and Hand; VAS, visual analog scale.

[b]Internal rotation as measured by the level of vertebral spinous process that could be reached with the patient's thumb.

Several studies have reported favorable clinical outcomes after bridging grafts and partial repairs for IMRCTs.[2,7,18,29] However, when confined to patients with a GFDI exceeding 2, the results seem to be unsatisfactory. Cho et al[7] reported that open or arthroscopic rotator cuff repair with autologous LHBT resulted in healing in 64.3% of patients; thus, autologous LHBT graft could be used for repairing rotator cuff tears that could not be easily pulled into their original footprint. However, the same research group showed that the retear rate was 75% when the GFDI exceeded 2.[7] For bridging grafts with allogenic or xenogenic patches, some studies have reported overall favorable outcomes, improvement of functional outcomes, and satisfactory retear rates (8.3%-27%).[14,23] However, Soler et al[36] showed unsatisfactory results, including a 100% retear rate; thus, the controversy remains. Likewise, our previous study showed a 54.2% retear rate for bridging grafts with the LHBT and a 75% retear rate for bridging grafts with allodermal patches for IMRCTs with GFDIs >2.[28]

Large rotator cuff tears have a high rate of LHBT pathology.[10] The high retear rate of bridging grafts with LHBTs could be due to discordance between the macroscopic appearance of the LHBT and the severity of the tendinopathy.[40] In terms of the high retear rate with allogenic dermal patches, there are concerns regarding the lower mechanical properties of allogenic grafts and the possibility of inflammation caused by DNA from an allogenic source.[41] Regarding partial repairs, Shon et al[34] reported that about half of the patients in their study were dissatisfied with their outcomes at 2 years after surgery, which deteriorated over time. Therefore, the effectiveness and use of partial repair remain controversial. In our study, the GFDI was 2.3 in the patients who were treated with other reconstruction methods for IMRCTs, and the retear rate was 63.9% (23 of 36 patients). Moreover, the ASES and SST scores at the final follow-up were lower in patients who had retears as compared with those who underwent SAS insertion. The loss of the repaired tendon's integrity and the higher degree of fatty degeneration of the teres minor could have resulted in the lower functional outcomes in these patients.[39] Given the high retear rate and reduced functional outcomes associated with retears after the other reconstruction methods, SAS insertion, which does not carry the same risk of retear, can be considered a favorable option for IMRCTs.

Favorable outcomes after SAS insertion could be mainly due to postoperative maintenance of the AHD. Chung et al[8] conducted a multivariate analysis of 108 patients who underwent arthroscopic repair for MRCTs and reported that an AHD ≤4.1 mm could be a factor leading to postoperative functional deterioration. Therefore, we believe that it is important to maintain the AHD in all operative cases. In this study, although it was not significant, the AHD at final follow-up was higher after SAS insertions and was reduced after bridging grafts or isolated partial repairs. As Gervasi et al[12] noted, it was possible to confirm with real-time imaging that the gap between the acromion and humerus increased after balloon insertion. Therefore, the SASs might have caused a lowering of the humeral head and maintenance of the AHD in the present study.

Interestingly, among the 13 patients who had MRI evaluations at 1 year after surgery, 12 (92.3%) showed new formation of fibrotic tissue in the superior subacromial space that was not seen in the preoperative MRI. One study addressed the possibilities of fibrotic tissue affecting the maintenance of AHD after insertion of an SAS.[15] This could be another reason for suppressing the humeral head to maintain the AHD by the newly formed "scar-like superior capsule." However, another study on SASs showed that the AHD was reduced by 2.1 mm as compared with the preoperative value, indicating that imaging results were not satisfactory even if the rotator cuff function may have improved.[9] However, in that study, the authors did not perform acromioplasty or partial repair. Another study showed unfavorable outcomes after SAS insertion[30]; however, those authors also did not perform acromioplasty or partial repairs. In the present study, we made every effort to perform bursectomy and acromioplasty, and we tried to repair the mobilizing tendon as much as possible under minimal tension. Performing these procedures probably resulted in the maintenance of AHD and regained the force couple to a certain degree, which could have positively affected the improvement in pain and function.

There is still debate regarding the indications or surgical techniques for SAS insertion. The manufacturer's guidelines

suggest performing minimal subacromial bursectomy and avoiding the incision of the coracoacromial ligament to maintain the postoperative location of the balloon. Moreover, the manufacturer recommends not performing acromioplasty. Regarding subacromial bursectomy and acromioplasty, Gervasi et al[12] agreed with the manufacturer and reported that subacromial bursectomy was not necessary. Piekaar et al[27] reported satisfactory outcomes after inserting SASs without performing acromioplasty. However, the majority of studies recommend maximal subacromial bursectomy for several reasons: to eliminate a cause of pain, to determine the appropriate size of the balloon, and to insert the balloon in the proper position.[3,31] Furthermore, previous studies have indicated that when there is a subacromial spur, it is necessary to trim the spur to eliminate the cause of pain and prevent balloon damage from the spur.[3] In our study, we performed subacromial bursectomies with acromioplasties but did not observe excessive displacement of the balloons.

In terms of balloon size, some studies have reported that choosing the smaller size between 2 options could reduce the stimulation in the subacromial space.[3,38] Moreover, there is a concern that insertion of a larger balloon could adversely affect healing because the insertion can exert excess pressure on the repair site.[3,38] However, Savarese and Romeo[31] suggested that when there are 2 possible balloon sizes, it is preferable to choose the larger size to fix the balloon in an appropriate location. In this study, we also selected the larger size so that the balloon could be placed appropriately as much as possible. Furthermore, the senior author utilized larger sizes to maintain the AHD to regain the force couple.

Although clear indications have not been suggested, several studies have indicated that balloons should not be used in patients with torn subscapularis tendons, because the balloon can move forward if the torn subscapularis is not repaired.[9,33] However, Savarese and Romeo[31] recommended repair of the torn subscapularis to maintain the force couple to obtain better results. In this study, we did not initially repair the torn subscapularis, following to the manufacturer's guidelines. However, the senior author experienced 2 episodes of PNOP by just insertion of a balloon without partial repair. Since then, the senior author decided to perform partial repairs as much as possible, including the upper subscapularis. We also attempted partial repairs of the infraspinatus when possible.

After the procedure was changed, there was no PNOP, and this would be due to regaining the force couple. However, we can not further conclude that the risk of PNOP was reduced by partial repair. We do not think that SAS insertion without partial repair poses a high risk of PNOP. However, repair of the upper leading edge of the subscapularis as well as the posterior rotator cuff is important to elevate the arm. Therefore, to reduce PNOP, the senior surgeon did make every effort to maintain force coupling by partial repair of the remaining rotator cuff. As the AHD was maintained at final follow-up, the SAS insertion with partial repair had some effect on maintaining the force couple. Moreover, fibrotic tissue that formed in the subacromial space as seen on MRI after 1 year of surgery might have depressed the humeral head and affected the AHD.

Limitations

There are several limitations in this study. First, it was a retrospective study and thus had all the inherent drawbacks associated with retrospective models, including selection bias. Second, different types of reconstruction methods were used in group 2. Such heterogeneity could have affected the results. Furthermore, the results of biceps augmentation for IMRCT, which consisted of $>70\%$ of group 2, are less known than the results of partial repair or superior capsular reconstruction. Unfortunately, the senior author did not perform superior capsular reconstruction, and only 2 patients who had isolated partial repair were enrolled in this study. Therefore, it was better to compare these 2 procedures with SAS insertion. Third, there could be possible confounders, including biceps tenotomy/tenodesis and/or partial repair, that might have affected the outcomes after SAS insertion. We can not conclude that the satisfactory outcomes resulted solely from SAS insertion.

A fourth limitation was that SAS with and without partial repair was not separately analyzed with other reconstruction methods, owing to the small number of patients. Furthermore, comparing outcomes of SAS insertion with partial repair in group 1 with those of isolated partial repair in group 2 would help to clarify the necessity of SAS insertion with partial repair. However, as there were only 2 patients who had isolated partial repair in group 2, these data would not give any meaning to the necessity of SAS insertion with partial repair. Fifth, in this study, only anatomic failures were considered, and clinical failures were not assessed. The result could have been different if we had evaluated the clinical failures of patients who had SAS insertion, such as the patient who had reverse total shoulder arthroplasty after 6 months of SAS insertion. Finally, the short follow-up period could be another limitation. Further research is needed to investigate the long-term outcomes of SAS insertion and compare the results with those of the other treatment options.

CONCLUSION

In this study, there were no differences in outcomes between SAS and other reconstruction methods for treating IMRCTs. However, given the high retear rate associated with other techniques and the poor functional outcomes of other techniques after retears, the current findings suggest that SAS insertion is a viable option for treating IMRCTs.

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