Fluoroscopically Guided Subacromial Spacer Implantation for Massive Rotator Cuff Tears

Two Years of Prospective Follow-up

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Background: Massive rotator cuff tears (MRCTs) are common and have been estimated to account for nearly 40% of all rotator cuff tears. An evolving strategy for management of MRCTs has been the implantation of a degradable subacromial spacer balloon that attempts to restore normal shoulder biomechanics.

Purpose: To assess the safety and efficacy of fluoroscopically guided balloon spacer implantation under local anesthesia in a cohort of patients with 2 years of postoperative follow-up.

Study Design: Case series; Level of evidence, 4.

Methods: The safety and efficacy of using fluoroscopically guided subacromial spacer implantation was assessed in 46 patients. Follow-up visits were scheduled according to routine clinical practice. Shoulder function was evaluated using Constant and American Shoulder and Elbow Society (ASES) scores.

Results: Overall, 87.5% (35/40) of patients saw clinically significant improvement in the total Constant and ASES scores from 6 weeks postoperatively, with improvement maintained up to 24 months postoperatively.

Conclusion: The data suggest that fluoroscopically guided subacromial spacer implantation under local anesthesia is a low-risk, clinically effective option, especially for the elderly population and those patients who have multiple comorbidities or a contraindication to general anesthesia. Patients undergoing subacromial spacer implantation for the treatment of MRCTs had satisfactory outcomes at 2-year follow-up, with a low rate of complications.

Keywords: massive rotator cuff tears; local anesthesia; biodegradable spacer balloon; fluoroscopically guided subacromial implantation

Massive, irreparable rotator cuff tears (MIRCTs) are common and have been estimated to account for nearly 40% of all rotator cuff tears (RCTs).[9] The identification and management of true MIRCTs present unique challenges for the orthopaedic surgeon in terms of cost containment as well as immediate versus long-term patient benefit. The up-to-date management of these tears is challenging, and no specific surgical procedure has demonstrated clinical superiority in the literature.[1] Patients who have MIRCT and no evidence of glenohumeral joint arthritis pose tremendous challenges in terms of the surgical decision. Among the numerous treatment options are retraining of the deltoid and residual rotator cuff,[2] subacromial decompression and a biceps procedure, partial tendon repairs, interposition of synthetic grafts, tendon transfers, subacromial spacer (balloon) superior capsular reconstruction, and reverse arthroplasty; however, no definitive guidelines for ideal surgical management have been acknowledged.[3]

The implantation of a biodegradable subacromial spacer attempts to restore normal shoulder biomechanics by preventing humeral head proximal migration, thus improving the ability of the deltoid to actively elevate the arm; this is a valuable treatment option for this patient population.[15,22] Patients who are not suitable candidates for traditional tendon transfer, who exhibit proximal humeral migration in the setting of a massive full-thickness RCT, and who have preserved passive range of motion (ROM) are considered the most suitable candidates for subacromial spacer implantation. Gervasi et al[7] demonstrated that the insertion of a subacromial spacer balloon (InSpace; OrthoSpace) can be carried out in an office or outpatient setting with the patient under local anesthesia and is not technically demanding.

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The initial cohort of this single-arm prospective study comprised 15 patients who were evaluated for a short-term period and demonstrated significant improvement in functional outcomes. Current extension of this study aimed at validating these preliminary results in a larger cohort of 45 patients treated using fluoroscopically guided balloon spacer implantation under local anesthesia and followed for 2 years postoperatively. It was hypothesized that patients with massive rotator cuff tears (MRCTs) treated using spacer implantation under local anesthesia would have improved outcomes of ROM, pain, and function.

METHODS

The study was reviewed and approved by a regional ethics committee, and each participating patient gave written consent before any study procedure, as required. Enrollment in the study started in May 2013 and was completed in August 2017, followed by 24 months of postoperative follow-up. The inclusion criteria included age >50 years, preoperative magnetic resonance imaging (MRI) confirming MRCTs involving at least 2 tendons with fatty infiltration of grade 3 or 4, and documented failure of previous operative or nonoperative treatment. Exclusion criteria were radiologic evidence of severe osteoarthritis or cartilage damage in the shoulder, significant glenohumeral instability, major joint trauma, infection, or necrosis in the shoulder.

The RCT was diagnosed and classified preoperatively using shoulder MRI. The involved tendons were detected, tear size was noted, and the vitality of the muscle (fatty infiltration) was recorded according to the classification of Goutallier et al.[8] Patients identified as having involvement of the supraspinatus and at least 1 additional tendon with grade 3 (50%-75%) or 4 (75%-100%) fatty infiltration of the muscle were included in the study.

Radiographic classification of arthritis as described by Hamada et al[10] was used to follow changes of osteoarthritis in the shoulder from preoperative radiographs. Patients were classified into 4 groups: (1) no arthritis; (2) mild arthritis (Hamada 1); (3) moderate arthritis (Hamada 2); and (4) severe arthritis (Hamada 3). In addition, patient characteristics, nonorthopaedic comorbidities, medication intake, type and severity of shoulder injury, pain level, and baseline physical function were recorded.

Surgical Procedure

All procedures were performed by 2 fellowship-trained shoulder surgeons (E.G. and E.C.). In brief, implantations were performed using fluoroscopy with the patient seated in either a beach-chair position or lateral decubitus position and under local anesthesia, as previously described.[6,7]

A standard lateral arthroscopic portal was created to introduce the arthroscope at the level of the subacromial space and verify the irreparability of the rotator cuff and the absence of signs of severe osteoarthritis. The same portal was used to introduce the InSpace spacer under fluoroscopic control. Synovitis was assessed macroscopically during the surgical procedure and graded using a subjective scale (ie, mild, moderate, and severe). Macroscopic assessment of synovitis included the following parameters: synovial villi, hyperemia, and density.[13]

If degeneration of the long head of the biceps tendon (LHBT) was detected, a tenotomy of the intra-articular portion was performed using an accessory portal created through the rotator triangle, or rotator interval, after local anesthesia was applied. No debridement was performed before device implantation. Ease of use of the InSpace device was assessed by the surgeon using a score between 1 and 10, where 1 is very difficult and 10 is very easy to deploy and operate.

Functional Outcome Measures

A single orthopaedic surgeon (E.C.) assessed pre- and postoperative shoulder function at each follow-up visit. Shoulder function was assessed postoperatively using the Constant and the American Shoulder and Elbow Surgeons (ASES) scores[19] at the following time points: 2 weeks, 6 weeks, 3 months, 6 months, 12 months, and 24 months. Primary outcomes were defined as final total functional scores (Constant and ASES scores). Overall patient satisfaction with the surgical outcome was verified at 6, 12, and 24 months postoperatively using a satisfaction scale of 0 to 10 points, where 10 is very satisfied. Ultrasonography was performed in all patients up to 3 months after implantation to verify device positioning.

Rehabilitation

The rehabilitation program was similar for all patients. The shoulder was immobilized in a sling for the first 2 weeks after surgery with recommendation for passive and active assisted

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exercises to avoid stiffness and minimize edema at the elbow and hand. Forward flexion and abduction were limited to 60° or less, if painful. Active physical therapy was initiated at approximately 3 weeks after surgery and continued for 6 to 10 weeks. Strengthening began with light resistance and increased over time, with limited power activity for the first 2 months after the operation. Approximately 6 weeks after the operation, patients were expected to have regained at least their preoperative ROM and to continue with steady gains on weekly until painless full ROM was achieved.

Statistical Analysis

Study data were analyzed using SAS Version 9.4 (SAS Institute). Study measures were summarized using descriptive statistics, where continuous variables are represented by mean and SD, and categorical variables are represented by count and percentage.

Baseline characteristics, together with safety analyses, were assessed for all patients enrolled. A baseline value was defined as the last valid value before the study procedure. We assessed the changes from baseline in Constant scores (total score and all subscale scores) and the ASES shoulder outcome questionnaire using repeated-measures analysis of variance, where the change in scores from baseline was modeled as a function of visit (categorical) adjusted for baseline values. This model assesses whether the change is significantly different from zero (whether there is any change or no change). The model-estimated mean (least-squares mean) changes from baseline are presented as the *P* value and the 95% CI of the changes.

To assess differences in efficacy between patients who underwent tenotomy and those who did not, the models were repeated using an indicator as to whether the patient underwent tenotomy along with the interaction between tenotomy and visit entered into the model as fixed factors. *P* values <.05 were considered statistically significant, and no adjustment for multiple testing was performed; nominal *P* values are presented.

RESULTS

A total of 46 patients who met study eligibility criteria were enrolled. One patient was excluded intraoperatively because of anatomic constraints related to previous shoulder surgery that did not allow proper placement of the spacer in situ.

Of the 45 eligible patients, 40 (89%) were available for the 2-year postoperative follow-up; the mean follow-up time of the entire study population was 23.13 months (range, 3-26 months). A total of 5 patients (11%) prematurely discontinued participation because of death of malignancy not related to the device or procedure (n = 1; 2.2%), loss to follow-up (n = 1; 2.2%), or investigator decision to discontinue owing to failed improvement (n = 3; 6.7%). These latter 3 patients were evaluated for 6 months after device placement and underwent conversion to reverse shoulder arthroplasty. They were included in the safety and efficacy data analysis until the time they discontinued their participation in the study.

TABLE 1
Patient Characteristics and Rotator Cuff History (N = 46)[a]

	n	%
Sex		
Male	17	36.96
Female	29	63.04
Dominant side affected		
No	12	26.09
Yes	34	73.91
Previous treatment for rotator cuff syndrome		
Steroid injection	29	63.04
Pain medication (NSAIDs, COX-2 inhibitors, opioids, acetaminophen, etc)	6	13.04
Other (physical therapy, activity modification)	11	23.91
Previous surgery to the treated shoulder	16	34.78
LHBT tenotomy (with acromioplasty, with capsular release, tenotomy only)	5	10.87
Debridement	2	4.35
Cuff repair	4	8.70
Open cuff repair	4	8.70
Not known	1	2.17
Had both previous surgery and steroid injection(s)	10	21.74

[a]Total of 46 patients including the patient that was excluded intraoperatively and followed for safety only. COX, cyclooxygenase; LHBT, long head of the biceps tendon; NSAID, nonsteroidal anti-inflammatory drug.

Patient Characteristics and Rotator Cuff History

The recruited patients included 29 (63%) female and 17 male (37%) patients with a mean ± SD age of 73 ± 65 years (range, 58-84 years). The treated tears were nonacute and were considered degenerative, with a mean duration of 22.5 months (range, 5.5-264.4 months) from the onset of symptoms to the time of balloon placement (Table 1).

All patients had at least 1 failed treatment of their rotator cuff symptoms. These treatments included nonoperative treatment such as steroid injections (29/46; 63%), analgesic agents (6/46; 13%), and physiotherapy (11/46; 24%). In addition to these various nonoperative treatments, 16 of 46 (34.8%) patients had previous surgical interventions, such as cuff repair, debridement, or biceps tenotomy (Table 1).

A total of 10 of 46 (21.7%) patients had undergone previous surgical interventions followed by treatment using steroid injection before inclusion in the study because of insufficient improvement or shoulder pain recurrence after the surgery.

The mean preoperative visual analog scale (VAS) score for pain was 7.1 ± 1.46. The mean total Constant and ASES scores were 28.5 ± 11.6 and 24.3 ± 11.8, respectively.

Preoperative Shoulder Imaging and Intraoperative Findings

In all 46 (100%) operatively treated patients, RCTs involved the supraspinatus tendon. Additionally, 44 of the 46 (95.65%) patients had a torn infraspinatus tendon, and 12 (26.09%) had a torn subscapularis tendon. The fatty

TABLE 2
Preoperative Shoulder Imaging and Intraoperative Findings (N = 46)[a]

	n	%
Involved tendons		
Torn SSP	46	100.00
Torn ISP	44	95.65
Torn SSP	12	26.09
Torn LHB	22	47.83
Intact LHB	24	52.17
Fatty infiltration grade		
3	19	41.30
4	27	58.70
Arthritis grade		
None	3	6.52
Mild	38	82.61
Moderate	5	10.87
Biceps tenotomy/tenodesis performed		
Yes	22	47.83
No	24	52.17
Surgeon's ease of use of device[b]		
No answer	2	4.35
2	1	2.17
4	2	4.35
7	4	8.70
8	4	8.70
9	10	21.74
10	23	50.00

[a]ISP, infraspinatus; LHB, long head of the biceps; SSP, supraspinatus.
[b]On a scale of 1 (very difficult) to 10 (extremely easy).

infiltration grade was assessed preoperatively using shoulder MRI and was found to be grade 4 in 27 (58.70%) of the 46 operatatively treated patients. Furthermore, 43 (93.47%) of the patients had mild to moderate osteoarthritis (Table 2). The LHBT was found to be intact in nearly half of the patients (22/46; 47.83%); in 22 patients, tenotomy was performed.

The mean ± SD duration of surgery was 33.1 ± 11.3 minutes (range, 15-60 minutes), whereas the mean ± SD time for device implantation was 9.49 ± 5.2 minutes (range, 2-30 minutes). The surgeons found the device easy to use in 80.4% of the surgeries, with a mean score of 8.8 (range, 2-10).

Postoperative Results: Functional Outcomes

Of the eligible patients who completed the study follow-up, 87.5% (35/40) had a clinically significant improvement of at least 10 points from their baseline total Constant score with no device-related adverse events at 2 years after the operation; these patients were considered responders. The total Constant score improved significantly from a preoperative (baseline) mean ± SE of 28.6 ± 11.6 points to 67.9 ± 16.7 points ($P < .0001$) at 24 months after the operation (Figure 1).

The ASES score improved significantly from a preoperative (baseline) mean ± SE score of 24.37 ± 11.8 points to 84.21 ± 21.01 points at 24 months ($P < .0001$). The pain score (using VAS) improved from 7.16 ± 1.46 to 0.93 ± 2.26 ($P < .0001$), and the activities of daily living (ADL)

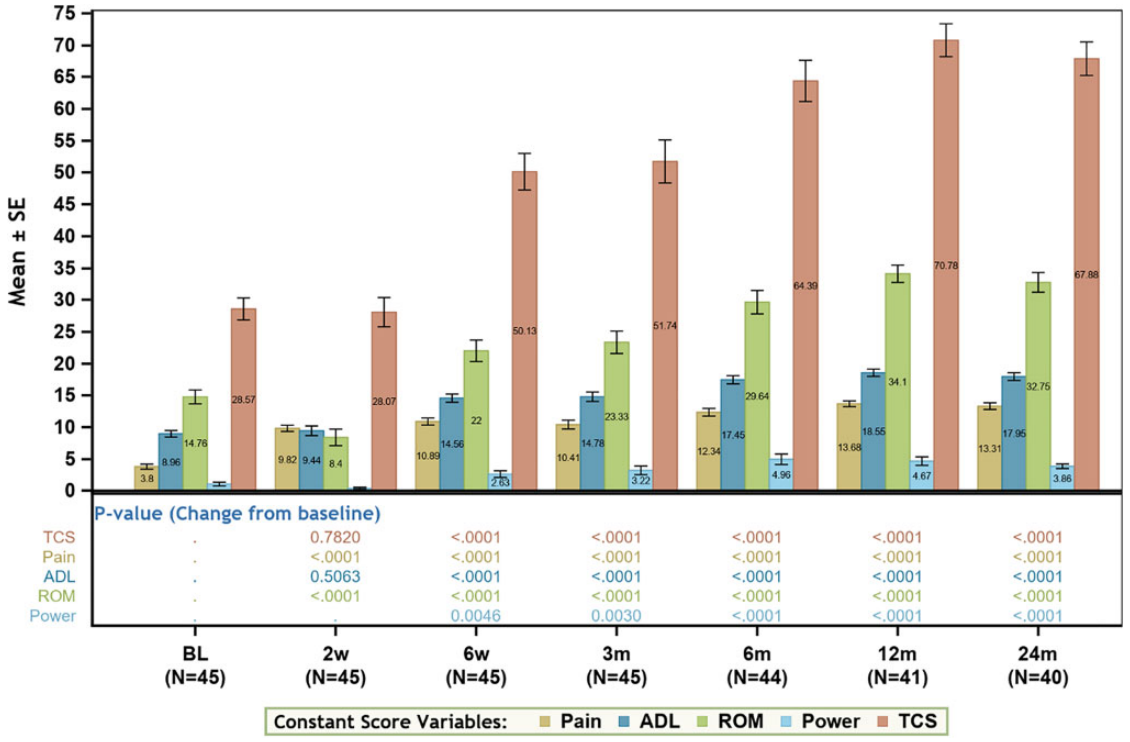

Figure 1. Change in Constant score over time. Values are presented as mean ± SE. ADL, activities of daily living; BL, baseline; ROM, range of motion; TCS, total Constant score.

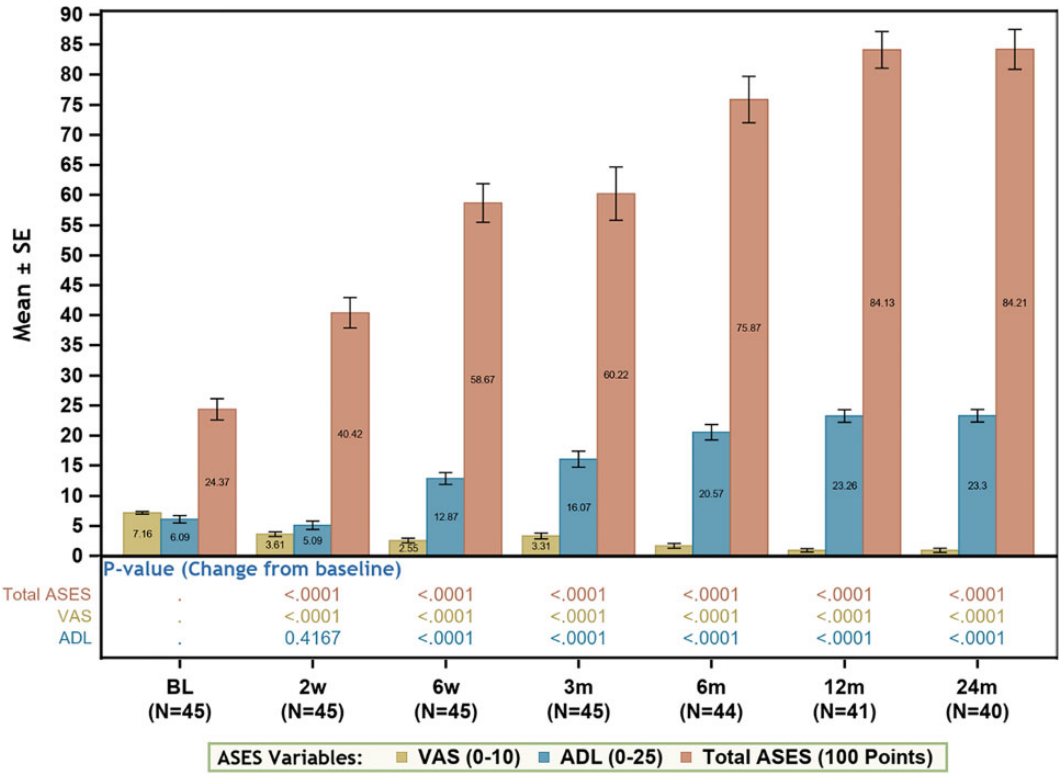

Figure 2. Change in ASES score over time. Values are presented as mean ± SE. ADL, activities of daily living; ASES, American Shoulder and Elbow Society; BL, baseline; VAS, visual analog scale.

score improved from 6.09 ± 4.14 to 23.30 ± 6.55 ($P < .0001$) (Figure 2).

The pain variable for both total Constant and ASES scores improved significantly ($P \leq .005$) from 2 weeks after implantation onward (Figures 1 and 2), whereas other shoulder variables (ADL, ROM, and power/strength) improved from 6 weeks after implantation onward (Figure 2). Statistically significant increases in active forward elevation (maximum arm-trunk angle), active and passive external rotation (arm comfortably at side), and active and passive external rotation (arm at 90° of abduction) were observed from the 6-week visit until the end of the follow-up (24 months). The median time to discontinuation of physical therapy was 35 days (95% CI, 32-38 days).

Subgroup analysis by sex and age revealed that the improvement from baseline in total Constant score was higher in male patients at 6 weeks ($P = .0391$) and 3 months ($P = .0222$) postoperatively. At other time points, as well as in the ASES scores, there were no statistically significant differences between male and female patients. The improvement from baseline in total Constant score in younger patients (age <70 years) was higher at the 1- and 2-year visits ($P = .0164$ and .0360, respectively). At other time points, as well as in the ASES scores, there were no statistically significant differences between age groups. In 3 patients (6.5%), the clinical improvement in shoulder pain and function was insufficient, and these patients were referred to undergo a reverse shoulder arthroplasty procedure.

LHB Tenotomy

Subgroup analysis of patients who underwent tenotomy (22/46; 47.8%) compared with patients without tenotomy (24/46; 52.2%) showed similar changes in total Constant score and ASES score, except at 2 weeks after implantation, when the results of the patients who had only balloon spacer implantation (without tenotomy) showed greater improvement from baseline (by 9.29 points; $P = .0379$) compared with the subgroup without tenotomy. At all other time points, there were no statistically or clinically significant differences between the groups (Figure 3).

Patient Satisfaction

The mean ± SD satisfaction level at 2 years after the operation was 8.88 ± 2.62, with the majority of patients (33/40; 82.5%) scoring their satisfaction with the surgical outcome as 8 to 10 on a 10-point scale.

Postoperative Safety Results

A majority of the patients (37/46; 80.4%) were able to leave the hospital on the same day as surgery, whereas the remainder (9/46; 19.6%) stayed overnight. Patients who

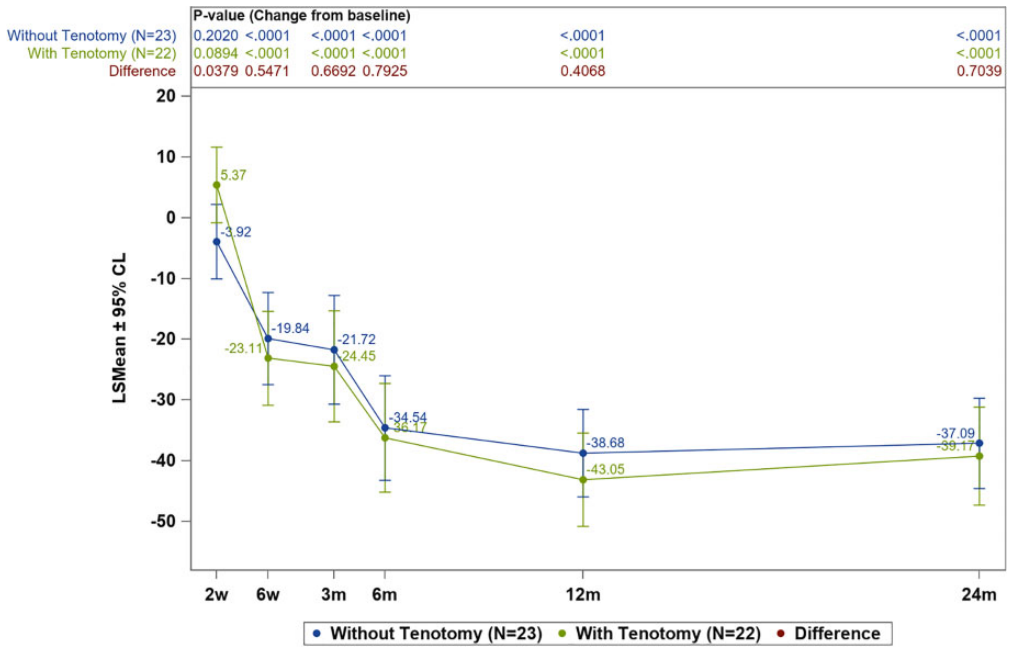

Figure 3. Least Squares Means (LSMean) change from baseline in Constant score for patients with and without tenotomy.

stayed overnight were of advanced age or had a long distance to travel from the hospital to home. None of the overnight stays were related to device- or surgery-related adverse effects.

During the postoperative period, no serious or clinically significant device-related adverse effects were observed. One patient reported increased shoulder pain after spacer implantation, which was successfully treated using a single steroid injection. A further 3 patients (6.5%) had insufficient improvement of shoulder symptoms and were referred for shoulder arthroplasty.

DISCUSSION

The principal results of the current study were that the vast majority of eligible patients that completed study follow-up (35/40; 87.5%) had an overall clinically significant improvement in the total Constant and ASES scores from 6 weeks, which was maintained up to 24 months postoperatively ($P < .0001$) (Figures 1 and 2).

Most of the published data are in line with the current study results. Senekovic et al[22] reported 5-year follow-up of a series of 20 patients with a mean age of 69 years who underwent this procedure without rotator cuff repair. The rate of follow-up was low (63%); the investigators reported that 1 patient underwent reverse shoulder arthroplasty at 4 years postoperatively, 2 patients died of unrelated causes, and 6 patients were lost to follow-up. The investigators found that >50% of patients exceeded the minimal clinically significant improvement of 10 points on the total Constant score, with >40% showing 25-point improvement. Deranlot et al[4] reported that balloon spacer implantation for MIRCTs led to significant improvement in shoulder function when assessed at 2 years after surgery. One patient underwent revision for spacer migration, and Hamada progression was observed in 19% of patients.

Piekaar et al[17] found that arthroscopic implantation of a spacer significantly reduced pain and improved the well-being of patients with MRCTs. The investigators reported that significant pain reduction and functional improvement were noticed postoperatively and were maintained at approximately 3 years after device implantation.

The current study further confirmed findings presented by Maman et al[14] that postoperative outcomes after spacer implantation were not significantly influenced by whether an additional LHB tenotomy was performed. Moreover, in the current study, during the first 2 weeks after implantation, the patients without LHB tenotomy had a significantly greater improvement of total Constant score (by 9.4 points) than patients who underwent LHB tenotomy in addition to spacer implantation.

Patient satisfaction has been reported in 3 previous studies.[7,11,17] Holschen et al[11] compared patients who underwent debridement with partial repair versus another group treated using debridement, partial repair, and implantation of the subacromial spacer. Although there were no differences in satisfaction between the 2 groups, those with spacer implantation had greater improvement in Constant and ASES scores. In the remaining 2 studies (59 patients, 61 shoulders), 81.4% (48/59) of patients were reportedly satisfied with their treatment.[7,17] These findings are consistent with the current study results showing that 82.5% of the treated patients were satisfied with the postoperative outcomes.

In contrast, 2 studies reported less favorable outcomes.[18,20] Ruiz Iban et al[20] reported a higher rate of patient dissatisfaction with the subacromial balloon spacer in a

study that included 16 patients. One-third of the patients required conversion to reverse shoulder arthroplasty, and only 60% of the remaining patients experienced an improvement in Constant score >10 points. The authors determined that only 40% of patients in the study seemed to benefit from the subacromial spacer implantation. Another study that included 24 shoulders described less satisfactory outcomes, with a 46% satisfaction rate and a 16.7% complication rate (anterior migration of the balloon, transient deficit of the lateral cutaneous nerve of the forearm, and infection).[18]

One of the most remarkable findings of the current study and previous studies is the safety profile of the device and the ease of the surgical technique. The incidence rate of device-related adverse effects or complications was very low. Within the published articles, 3 cases of implant displacement have been described.[18,21,23] In 2 of these cases, the displaced device was surgically removed with the patient under local anesthesia.[21]

Studies in many orthopaedic fields, such as hip and spine surgery, have shown that advanced age, lower American Society of Anesthesiologists physical status score,[5] concomitant cardiovascular disease, pulmonary disease, and diabetes are associated with higher risks of death and postoperative complications.[12,16] The vast majority of patients with MIRCTs belong to the advanced age group and might have similar diseases; thus, one could assume that the relative risk of postoperative complication would be as high as that in the aforementioned fields. The current study results suggest using a less invasive surgical procedure, such as spacer implantation, that can be performed in an outpatient clinic setting using local anesthesia.

The main limitation of this study is the lack of a control group; however, common surgical and nonoperative treatments for rotator cuff syndrome failed in the patients who participated in the study. Hence, we believe that for this specific indication, there is no suitable comparative arm and it is appropriate to use each patient as his or her own control at preoperative baseline. Another limitation of this study is the mid-term follow-up.

CONCLUSION

The data collected in this study suggest that fluoroscopically guided spacer implantation under local anesthesia is a low-risk, clinically effective option, especially for the elderly population and those patients who have multiple comorbidities or a contraindication to general anesthesia. Fluoroscopically guided spacer implantation can be an alternative to tendon transfers or superior capsular reconstruction in patients with full-thickness MRCTs with mild to moderate osteoarthritis. Improvement in function and symptoms after this procedure may prevent or delay the need for a more substantial procedure, such as a reverse geometry shoulder replacement.

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