



Subacromial Spacer Implantation During Arthroscopic Partial Repair in Patients With Massive Irreparable Rotator Cuff Tears Provides Satisfactory Clinical and Radiographic Outcomes: A Retrospective Comparative Study

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Purpose: To compare the clinical and radiographic outcomes of partial rotator cuff repair (RCR) with and without implantation of a biodegradable subacromial spacer in the treatment of symptomatic irreparable massive rotator cuff tears (MRCTs). **Methods:** Patients with MRCT who underwent arthroscopic partial repair alone (PR) or combined with subacromial spacer augmentation (PRS) were included. Patient-reported outcomes, including visual analog scale (VAS), American Shoulder and Elbow Surgeons (ASES), and Constant scores in addition to range of motion (ROM) were collected preoperatively and at the final follow-up. Additionally, we determined the percentages of all of the patients in groups that achieved the minimal clinical important difference (MCID), substantial clinical benefit (SCB), and patient-acceptable symptomatic state (PASS) for the VAS, ASES, and Constant scores. Acromiohumeral distance (AHD) was determined as well. **Results:** A total of 32 patients were included. Group PR included 20 patients with a median age of 68 years (range: 64-73) and median follow-up 28.0 months (14.0-60.0). Group PRS included 12 patients with a median age of 68.5 years (range: 63-74) and median follow-up of 17.0 months (12.0-32.0). At the final follow-up, the ASES, VAS, and Constant scores were significantly higher in the PRS group (75.5 [55-88.3], 1.0 [0-3], and 70.0 [43-79], respectively, compared to the PR group (55.0 [37.5-65], 2.0 [0-4], and 55.0 [31-79], respectively; $P < .05$). The only statistically significant differences were found between the PR and PRS groups in terms of the proportions of the patients who achieved MCID for the ASES (70% vs. 100%; $P = .04$) and in terms of the proportions of the patients who achieved SCB for the ASES (60% vs 100%; $P = .01$) There was also statistically significant difference between the PR and PRS groups, in terms of the proportions of the patients who achieved PASS for the VAS and ASES ([30 % vs 66.7 %; $P = .04$] and [0 % vs 50 %; $P = .001$], respectively). AHD was also improved in the PRS group (8.4 [7-9.5] vs 7.85 [5.5-9]; $P < .05$). ROM was greater in the PRS group at final follow-up with median forward flexion degree, 140.0° (90°-150°) versus 120.0° (80°-153°) ($P < .001$) and median abduction degree, 100.0° (70°-130°) versus 90.0° (70°-110°). There was no difference in terms of external rotation between groups (3° [2°-5°] vs 3.0° (2°-4°); $P = .4$). **Conclusions:** Arthroscopic partial RCR with implantation of a subacromial spacer leads to satisfactory clinical and radiographic outcomes in patients with symptomatic irreparable MRCT compared with patients treated with partial repair alone. **Level of Evidence:** Level III, retrospective comparative study.

Introduction

Symptomatic irreparable massive rotator cuff tears (MRCT) represent not only a debilitating condition for the patient but also a difficult challenge for the treating orthopedic surgeon. Numerous treatment

options are available starting with nonoperative treatment. If this fails or a higher level of function is desired, surgical therapy options range from less invasive methods, such as debridement, subacromial decompression, and biceps tenotomy/tenodesis to latissimus

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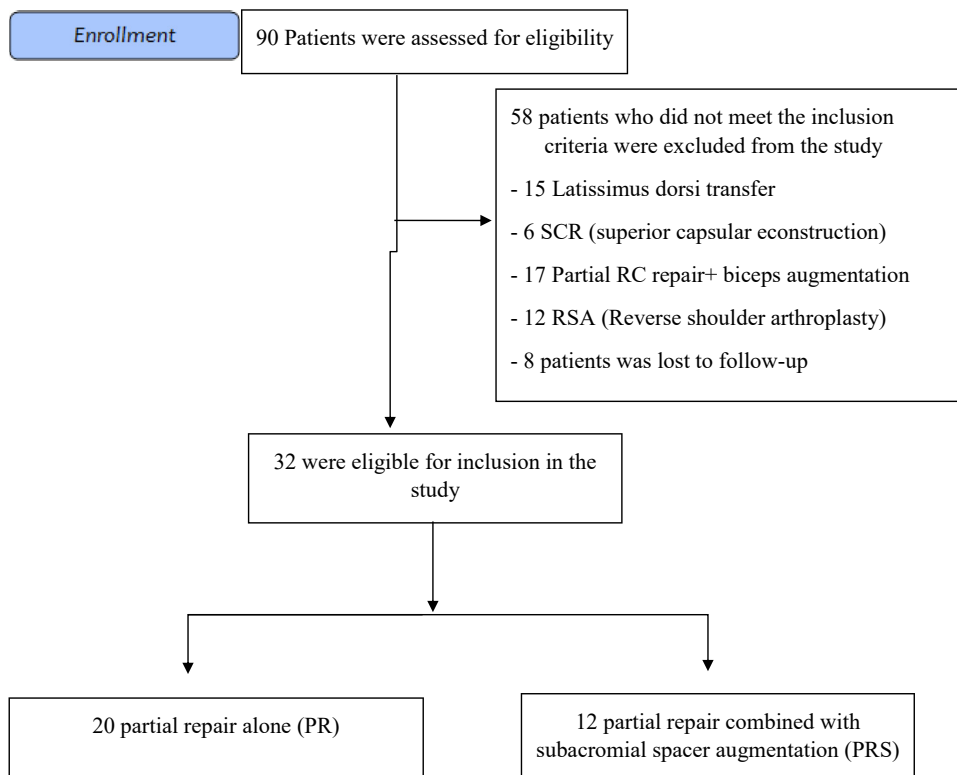


Fig 1. Flowchart showing the diagram of the flow of participants through the study.

tendon or lower trapezius transfers, superior capsular reconstruction, or reverse shoulder arthroplasty.¹ Partial repair is a viable option as an intermediate solution. However, results without additional therapy are variable.²⁻⁹

The introduction of the subacromial balloon implantation less than a decade ago provided a novel treatment option since the spacer provides a barrier for the humeral head to migrate superiorly and thus keeps it centered.¹⁰ However, there is limited literature on the

outcomes of this technique. Despite questions regarding the resorption of the spacer after approximately 1 year following implantation, early clinical studies show promising results.¹¹⁻¹⁴ On the other hand, the balloon can be deflated after 10-12 weeks, and this may affect clinical outcomes.

The purpose of this study was to compare the clinical and radiographic outcomes of partial RCR with and without implantation of a biodegradable subacromial spacer in the treatment of symptomatic irreparable

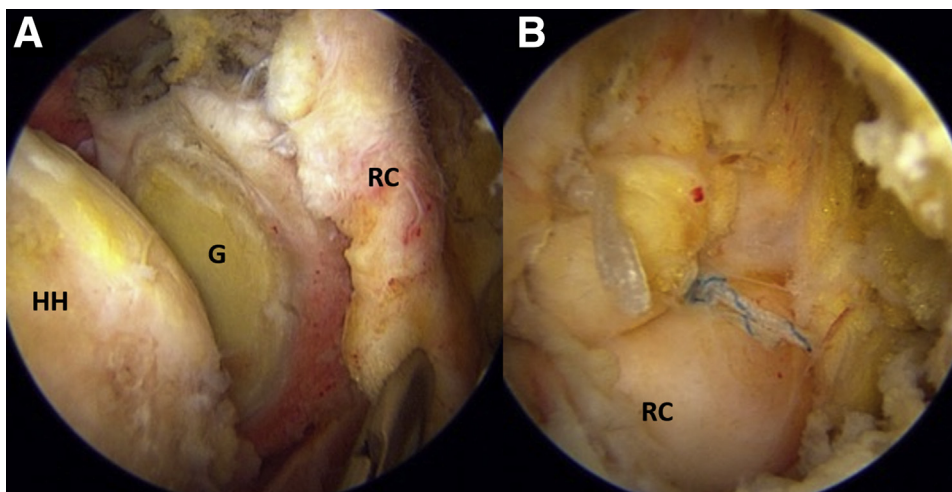


Fig 2. Left partial rotator cuff repair. View from lateral portal. Before (A) and after (B) partial repair. Note the torn rotator cuff retracted to the level of the glenoid. G, glenoid, HH, humeral head; RC, rotator cuff.

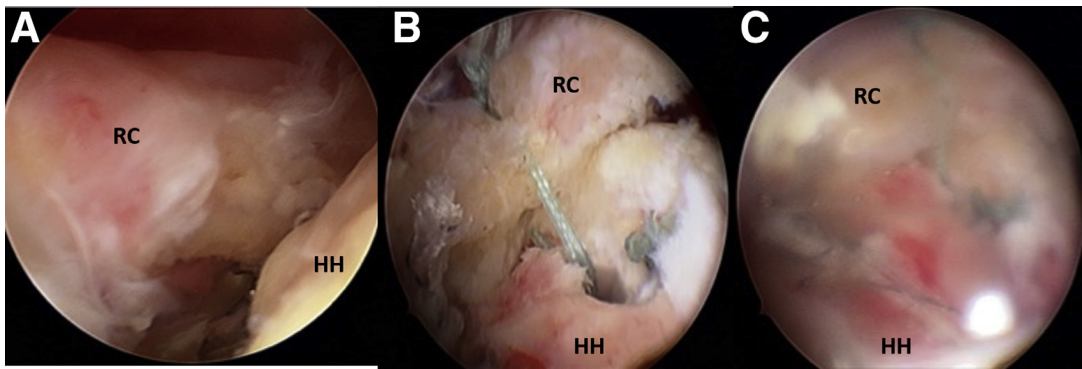


Fig 3. Left partial rotator cuff repair with subacromial balloon spacer implantation. View from lateral portal. Before (A) and after (B) partial repair and after subacromial balloon spacer implantation (C). HH, humeral head; RC, rotator cuff.

MRCTs. Our hypothesis was that the addition of the biodegradable subacromial spacer would lead to superior clinical and radiological outcomes due to supporting the cuff as an internal brace and maintaining the acromiohumeral distance (AHD).

Methods

Study Population

Institutional Review Board approval (59/1211/2018) was obtained prior to the start of the study. Between March 2012 and February 2017, all patients who had undergone arthroscopic partial RCR with or without implantation of a biodegradable subacromial spacer were identified (Fig. 1). The exclusion criteria included a rotator cuff arthropathy >2 according to the Hamada classification,¹⁵ subscapularis repairs, and patients with pseudoparalysis.

The indications for arthroscopic therapy were as follows: all patients presenting to our institution with a symptomatic and irreparable MRCT with tendon retraction > stage 2, according to the Patte classification,¹⁶ without significant osteoarthritis and with a minimum 1-year follow-up. All patients were operated by a single surgeon, and the irreparability of the tear was confirmed after failure to reattach the torn tendon despite adequate lysis of adhesions and mobilization.

After identification of the included patients, they were divided into two groups. Group PR comprised patients who underwent arthroscopic partial cuff repair only while group PRS consisted of patients who had additional implantation of a subacromial spacer.

Surgical Technique

All patients were placed in the beach chair position after general anesthesia and interscalene block. All surgeries were performed by the senior author. Standard diagnostic arthroscopy was performed using the posterior viewing and anterosuperior working portals. After verification of the subscapularis tendon integrity, the long head of the biceps tendon was assessed, and a tenotomy was performed routinely in all patients. Following subacromial bursectomy and decompression, the reparability of the rotator cuff tear was assessed after extensive release and proper mobilization of the tendon (Fig 2A). After confirmation of the irreparability, a partial repair of the infraspinatus tendon was performed to provide the force couple. This was performed in a margin-convergence fashion and/or medialized single-row fashion, with the use of suture anchors (DePuy Mitek, Raynham, MA) (Fig 2B). Next, a probe was inserted to measure the appropriate size of the spacer. The subacromial spacer, made of polylactic acid and epsilon-caprolactone (InSpace Balloon System, Orthospace, Caesarea, Israel), was introduced through the lateral portal and was inflated with saline solution, as recommended by the manufacturer. After removal of the delivery system, the accurate and stable position of the spacer was assessed with passive shoulder mobilization (Fig 3, A-C).

Postoperative Rehabilitation

The postoperative rehabilitation did not differ between groups. Immediately after surgery, patients were

Table 1. Patient Demographics and Surgical Information

	PR	PRS	P Value
Gender			.5
Female	16 (80%)	8 (66.6%)	
Male	4 (20%)	4 (33.3%)	
Median age in years (range)	68.0 (64-73)	68.5 (63-74)	.8
Median duration of nonoperative treatment in months	8.0 (4-16)	6.0 (3-12)	.2
Median number of corticosteroid injections	2 (0-4)	2 (0-3)	.4

Table 2. Preoperative and Postoperative Patient-Reported Outcome Scores

	PR	PRS	P Value
Preoperative median ASES (range)	30.0 (20-37.5)	30.8 (20-42)	.4
Postoperative median ASES (range)	55.0 (37.5-65)	75.5 (55-88.3)	<.001
Δ median ASES (range)	28.0 (7-40)	40.2(26.7-63.3)	<.001
Preoperative median Constant score (range)	26.0 (20-38)	28.5 (20-40)	.6
Postoperative median Constant score (range)	55.0 (31-79)	70.0 (43-79)	.01
Δ median Constant score (range)	29.0 (8-53)	39.0 (23-53)	.01
Preoperative median VAS (range)	8.0 (7-9)	7.5 (6-9)	.6
Postoperative median VAS (range)	2.0 (0-4)	1.0 (0-3)	.04
Δ median VAS (range)	5.5 (3-8)	6 (5-8)	.1

Bolded values indicate significant difference. ASES, American Shoulder and Elbow Surgeons score; VAS, visual analogue scale; Δ - improvement between pre-and postoperative scores.

placed in a sling with an abduction pillow. All patients started wrist and elbow passive isometric motion exercises on the first postoperative day. Active assisting range of motion exercises and deltoid strengthening exercises were started after the shoulder was rested in the arm sling for 4 weeks postoperatively. Active exercises to increase range of motion were allowed starting in the sixth postoperative week. Rotator cuff strengthening exercises were started after 3 months.

The senior surgeon examined all patients preoperatively and postoperatively. The range of motion (abduction, forward flexion, internal rotation, and external rotation) was recorded in degrees. Patient-reported outcomes measures, consisting of the American Shoulder and Elbow Surgeons (ASES) shoulder score and Constant score were obtained preoperatively and at the final follow-up. Visual analog scale (VAS) was used for the assessment of pain level. According to the thresholds reported in the literature, we determined the percentages of all of the patients in groups that achieved the minimal clinical important difference (MCID), substantial clinical benefit (SCB), and patient

acceptable symptomatic state (PASS) for the VAS, ASES, and Constant scores.¹⁷⁻²² Clinical failure was defined as the need for revision surgery or failed improvement in VAS at the latest follow-up. True anteroposterior, axillary lateral, and supraspinatus outlet radiographs of the shoulders were taken for all patients preoperatively and at the final follow-up. The acromion morphology was determined preoperatively, according to the Bigliani classification.²³ AHD and arthropathy according to Hamada¹⁵ were assessed radiographically both preoperatively and postoperatively.

Statistical Analysis

Kolmogorov-Smirnov and Shapiro-Wilk tests showed that the data were not normally distributed ($P < .001$). Data were analyzed using nonparametric univariate analysis performed with the Mann-Whitney U -test for two group comparisons. A Wilcoxon signed rank test was performed to compare within-group differences. Chi-square tests were run for coded binomial data comparisons. Statistical analysis was done with SPSS 19.0 (SPSS Inc., Chicago, IL). All reported P values were two-tailed with a level of .05, indicating statistical significance.

Results

Arthroscopic partial RCR was applied to 90 patients, and a total of 32 patients met the inclusion criteria (Fig 1). Group PR included 20 patients (16 women and 4 men) with a median age of 68 years (range: 64 - 73) and median follow-up 28.0 months (14.0-60.0). Group PRS included 12 patients (9 women and 3 men) with a median age of 68.5 years (range: 63-74) and median follow-up 17.0 months (12.0-32.0). There was no significant difference between the groups in terms of age (Table 1). The median duration of preoperative nonoperative treatment was also similar between groups: 8.0 months (range: 4-16) for group PR and 6.0 months (range: 3-12) for group PRS (not statistically significant). Further patient demographics are demonstrated in Table 1.

Table 3. Proportions of Patients Achieving MCID, SCB, and PASS Scores

Values	PR	PRS	P
VAS			
MCID	100	100	n.a.
SCB	100	100	n.a.
PASS	30	66.7	.04
ASES			
MCID	70	100	.04
SCB	60	100	.01
PASS	0	50	.001
Constant score			
MCID	95	100	.6
SCB	75	100	.08
PASS	75	91.7	.3

All values are given as percentages. ASES, American Shoulder and Elbow Surgeons score; MCID, minimal clinical important difference; n.a., not applicable; PASS, patient acceptable symptomatic state; SCB, substantial clinical benefit; VAS, visual analog scale.

Table 4. Preoperative and Postoperative Range of Motion

	PR	PRS	P Value
Preoperative median FF (range)	100.0° (75°-120°)	105.0° (75°-120°)	.5
Postoperative FF	120.0° (80°-153°)	140.0° (90°-150°)	.01
Δ median FF (range)	17.5° (-10°-33°)	30.0° (15°-40°)	<.001
Preoperative ABD (range)	80.0° (60°-100°)	85.0° (60°-100°)	.5
Postoperative ABD (range)	90.0° (70°-110°)	100.0° (70°-130°)	.03
Δ median ABD (range)	10.0° (-10°-30°)	20.0° (0°-40°)	.05
Preoperative ER (range)	3.0° (2°-3°)	3.0° (2°-3°)	.9
Postoperative ER (range)	3.0° (2°-4°)	3.0° (2°-5°)	.4
Δ median ER (range)	0.0° (-1°-2°)	1.0° (-1°-2°)	.5

(°) Data are presented as degrees. ABD, abduction; ER, external rotation; FF, forward flexion; Δ, improvement between preoperative and postoperative angles.

There was no statistically significant difference in preoperative median VAS, ASES, or Constant scores between groups (Table 2). There were statistically significant differences between groups in all postoperative outcome scores: VAS ($P = .04$), ASES ($P < .001$), and Constant ($P = .01$). The median improved ASES ($P < .001$) and Constant ($P = .01$) scores were also significantly different between groups (Table 2). Table 3 demonstrates the proportions of the patients who achieved MCID, SCB, and PASS for the VAS, ASES, and Constant scores. There were statistical differences between the PR and PRS groups in terms of the proportions of the patients who achieved MCID for the ASES (70% vs 100%; $P = .04$) and in terms of the proportions of the patients who achieved SCB for the ASES (60 % vs 100 %; $P = .01$) There were also statistically significant differences between the PR and PRS groups in terms of the proportions of the patients who achieved PASS for the VAS and ASES ([30 % vs 66.7 %; $P = .04$] and [0 % vs 50 %; $P = .001$], respectively). There was also no statistically significant difference between groups in terms of preoperative median ROM (Table 4). There were also statistically significant differences between groups in terms of postoperative forward flexion ($P = .01$) and abduction ($P = .03$) angles and the median improved forward flexion angle ($P < .001$) (Table 4).

The groups did not differ in terms of preoperative AHD and grade of fatty degeneration (Table 5). There was statistically significant difference between groups in

terms of postoperative median AHD ($P = .04$) (Table 5). The median improved AHD was also significantly different between groups ($P = .01$) (Table 5).

Discussion

The most important finding of this study was the statistically significant difference between with and without subacromial spacer implantation in partial RCR. There are various treatment options for the irreparable symptomatic MRCT. However, there is not a widely accepted treatment strategy on how to treat these patients. While latissimus dorsi transfer shows promising results, it is a relatively more invasive surgery with a long postoperative rehabilitation period.^{24,25} Alternative treatment options, such as the superior capsular reconstruction, have limited long-term outcome reporting.

In 36 patients with irreparable MRCT, Lee et al. showed achievement of satisfactory results with arthroscopic tuberopectomy with concomitant acromioplasty, as well as treatment of the biceps tendon when indicated, with good preservation of the preoperative and postoperative acromiohumeral interval and continuity in the inferior scapulohumeral line. Diminished pain and improvement of active forward elevation were noted on follow-up for at least 3 years after intervention.²⁶ When biologic reconstructive options fail, reverse total shoulder arthroplasty may be considered, especially in the case of pseudoparalysis, with or without antero-superior escape.²⁷

Arthroscopic partial RCR is a viable option for the treatment of MRCT. Kim et al. studied 27 patients with irreparable MRCT who underwent partial RCR and demonstrated an improvement of Constant score from 43.6 preoperatively to 74.1 postoperatively, although the strength of the affected side was not restored to the same level as the contralateral side.⁹ Concerning the functional outcome, the results of the present study are in agreement with the previous literature on subacromial spacer implantation. Senekovic et al. showed significant improvement of Constant score following subacromial spacer implantation, with 61.5% of the

Table 5. Preoperative and Postoperative Radiographic Data

	PR	PRS	P Value
Preoperative median AHD in mm (range)	7.5 (6-8)	8.0 (6.5-9.2)	.4
Postoperative median AHD in mm (range)	7.85 (5.5-9)	8.4 (7-9.5)	.04
Δ median AHD in mm (range)	0.0 (-0.8-1.8)	0.4 (0.2-1.8)	.01

AHD, acromiohumeral distance (in mm); Δ, improvement between preoperative and postoperative AHD.

patients having improvement of at least 25 points.¹² Deranlot et al. demonstrated a significant increase in the median Constant score from 44.8 preoperatively to 76 at the last follow-up.¹¹ In the present study, the median preoperative Constant score increased from 29 preoperatively to 67.7 at final follow-up. While the preoperative score was lower, similar improvements were achieved. This may be secondary to the subacromial spacer protecting the healing of the partial repair. In other hand, the proportions of the patients who achieved MCID, SCB, and PASS scores were higher in patients with subacromial spacer. Especially, we found statistical differences between the PR and PRS groups in terms of the proportions of the patients who achieved MCID, SCB, and PASS for the ASES. According to these results, subacromial spacer implantation for the partial RCR of irreparable symptomatic MRCT without significant glenohumeral osteoarthritis seems to be more successful in terms of patient satisfaction. However, longer-term follow-up with dedicated radiographic evaluation for the repair integrity is needed to prove this hypothesis.

Limitations

This study has some limitations in addition to those inherent to the retrospective design. First, there was no treatment group with subacromial spacer implantation alone, which could demonstrate the effect of partial RCR. This was due to the treating surgeon's clinical preference for partial repair. However, the study provides sufficient information as to the effect of subacromial spacer on the outcome after partial RCR. Second, the follow-up for the PRS group is shorter than the PR group. Longer follow-up is required to confirm the stability of difference in clinical and radiographic outcomes over time. However, the median follow-up of 1.5 years is sufficient to assess early outcome, given that Deranlot et al. could not show a decrease in Constant score after one and three years of follow-up.¹¹ Finally, a larger cohort with postoperative MRI to show healing integrity and fatty degeneration is needed to fully validate our results.

Conclusions

Arthroscopic partial RCR with implantation of a subacromial spacer leads to satisfactory clinical and radiographic outcomes in patients with symptomatic irreparable MRCT compared with patients treated with partial repair alone.

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