J Shoulder Elbow Surg (2019) 28, 1639–1646

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Journal of Shoulder and Elbow Surgery

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Does arthroscopic preemptive extensive rotator interval release reduce postoperative stiffness after arthroscopic rotator cuff repair?: a prospective randomized clinical trial

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Background: To investigate whether preemptive extensive rotator interval (RI) release during arthroscopic rotator cuff repair (ARCR) would reduce postoperative stiffness.
Methods: From July 2015 to September 2016, a total of 80 patients who were scheduled for ARCR were enrolled and randomly allocated into 2 groups: the preemptive extensive RI release group (group 1, n=40) and the RI nonrelease group (group 2, n=40). The American Shoulder and Elbow Surgeons scale, Constant score, Korean Shoulder Scale (KSS), visual analog scale (VAS) pain score, and range of motion (ROM) were evaluated before surgery; 3, 6, and 12 months after surgery; and at last follow-up. Magnetic resonance imaging was performed at postoperative 12 months.
Results: The mean follow-up period was 26.5 months. The functional and pain scores in both groups were significantly improved at the last follow-up ($P < .05$). Group 1 showed a significantly higher sum of ROM with a difference of 27° and 1.6 vertebral level of internal rotation compared to group 2 at postoperative 3 months ($P < .05$). Constant score and KSS were significantly higher in group 1 than in group 2 at this time point ($P < .05$). Functional scores and ROM were not significantly different between 2 groups at postoperative 6 or 12 months or at the last follow-up ($P > .05$). The retear rate and pathologic change of the long head of the biceps tendon during follow-up were not significantly different between the 2 groups ($P > .05$).
Conclusion: Arthroscopic preemptive extensive RI release can reduce early postoperative shoulder stiffness after ARCR but does not significantly change the overall clinical outcome after surgery.

This study was approved by the Institutional Review Board of Seoul St. Mary's Hospital, the Catholic University of Korea (study no. KC17OESI0118).

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1058-2746/$ - see front matter
https://doi.org/10.1016/j.jse.2019.05.021

Level of evidence: Level I; Randomized Controlled Trial; Treatment Study

Keywords: Rotator cuff repair; shoulder arthroscopy; rotator interval; rotator interval release; postoperative stiffness; shoulder stiffness

Postoperative stiffness is the most frequent and pain-causing complication after arthroscopic rotator cuff repair (ARCR).[3,5] The incidence of postoperative stiffness 3 months after ARCR is known to range from 4.9% to 32.7%.[3,11,31] Although ARCR is a minimally invasive procedure, postoperative stiffness may still develop and lead to inferior functional outcomes.[27] There have been numerous attempts to prevent postoperative stiffness after ARCR. But those remain controversial.[6,8,14] Furthermore, there is no definite method to prevent postoperative stiffness after ARCR. [28]

The main radiologic findings of adhesive capsulitis are thickening of the coracohumeral ligament (CHL) and the joint capsule in the rotator interval (RI) and reduction of the fat triangle between the CHL and the coracoid process.[4,17,20] In a cadaveric study, Harryman et al reported that sectioning of the RI increased the ROM of the shoulder, especially in flexion, extension, adduction, and external rotation (ER).[9] On the other hand, Jazrawi et al examined the effects of arthroscopic RI closure and found that imbrication of the RI resulted in a loss of about 11° of ER. These studies demonstrate that the RI is closely related to the ROM of shoulder.

To our knowledge, there have been no studies on intraoperative surgical procedures to reduce postoperative stiffness after ARCR in patients with no preoperative stiffness. The purpose of this study was to investigate whether preemptive extensive RI release as an intraoperative procedure would reduce postoperative stiffness after ARCR.

Materials and methods

Inclusion and exclusion criteria

From July 2015 to September 2016, we prospectively enrolled 87 patients who met the following inclusion criteria: (1) a small to medium (tear size <3 cm) full-thickness supraspinatus tear confirmed by preoperative magnetic resonance imaging (MRI) and intraoperative inspection at the time of ARCR, (2) no trauma history, (3) having undergone ARCR, (4) no preoperative shoulder stiffness and at least ROM of forward flexion ≥130° (maximal, 150°; without scapulohumeral rhythm[13]), ER at 90° abduction and at the side ≥80°, and internal rotation (IR) equal to or greater than the 10th thoracic level. Patients who had previously undergone shoulder surgery or who had concomitant glenohumeral arthritis, labral lesions, and rotator cuff tear >3 cm were excluded. Among the 87 enrolled patients, 7 were lost to follow-up; thus, 80 patients were evaluated in this study.

Baseline characteristics

Patients who were scheduled for ARCR were enrolled preoperatively and randomly allocated into 2 groups: the extensive RI release group (group 1) and the RI nonrelease group (group 2). Computer-generated block-randomization numbers were used to assign patients to each group. After selection of patients who satisfied both the inclusion and exclusion criteria, a random number was chosen from a sealed envelope to determine the method of treatment. All patients understood both treatment methods and were informed of the possible postoperative complications of the surgery. Patients were allocated to groups blindly. Ultimately, 40 patients from each group were evaluated until the time of last follow-up (Fig. 1). The demographic characteristics of these patients are described in Table I.

Operative techniques

All the procedures of arthroscopy were performed with the patients under general anesthesia in the lateral decubitus position. A single senior surgeon performed all the arthroscopic surgical procedures. A posterior portal was first made as a standard viewing portal for inspection of the glenohumeral joint, and a standard anterior portal was made as a working portal in the RI capsule. An electrocautery device (ArthroCare, Sunnyvale, CA, USA) was inserted through the anterior portal and used to release the RI tissue. First, the middle glenohumeral ligament was released. Then, the CHL was released until the base of the coracoid process and the coracoacromial ligament was exposed (Fig. 2). However, the most lateral portion of the RI tissue and the pulley of the long head of the biceps tendon (LHBT) was not released, which can affect the stability of the LHBT. After RI release in the glenohumeral joint, the arthroscope was inserted into the subacromial space. Following removal of the inflamed subacromial bursal tissue, acromioplasty was performed for type 2 and 3 acromions. The size and reducibility of the torn rotator cuff were determined, and then the rotator cuff was repaired with suture anchors. For rotator cuff tears of partial thickness and small size, single-row repair was performed. For medium-size and delaminated rotator cuff tears, double-row repair or transosseous equivalent repair was performed.

Rehabilitation

Both groups received the same postoperative rehabilitation. For 1 month postoperatively, an abduction brace was applied. After the brace was discarded, pendulum exercise was started. Two months

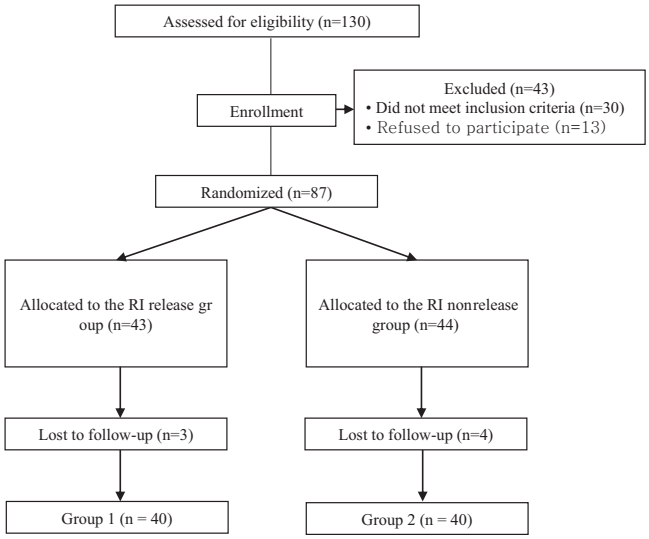

Figure 1 Flowchart displaying the study protocol according to the Consolidated Standards of Reporting Trials (CONSORT) criteria.

postoperatively, patients started sleeper-stretch and pulley exercises. Three months postoperatively, patients began isometric exercises using a yellow Thera-Band (Eugene Health Care, Seoul, Republic of Korea) to restore the power of ER and IR. All sports activities were permitted 6 months after the surgery, and the use of the shoulder was not limited within a tolerable loading.

Outcome measurements

American Shoulder and Elbow Surgeons (ASES) scale,[24] Constant score, and Korean Shoulder Scale (KSS) were used to evaluate functional outcomes preoperatively; 3, 6, and 12 months postoperatively and at the last follow-up. A goniometer was used to evaluate the ROM of forward flexion (FF), ER at the side (ER_s), and ER at 90° of abduction (ER_{ab}). The ROM was evaluated by a blinded physician who had no information about the enrolled patients. IR was evaluated based on the highest vertebral level reached by the tip of the thumb in the sedentary position. The levels of the vertebra were numbered serially from the sacrum (level 0) to the seventh thoracic vertebra (level 12). A visual analog scale was used to evaluate the degree of pain (0-10). A physician who was completely blinded to the study collected all the assessment data prospectively, and all the patients were also blinded until the final checkup at last follow-up.

In patients who had an intact LHBT during ARCR, the presence of tenderness along the biceps groove was assessed at each follow-up period. MRI was used to evaluate the integrity of the repaired rotator cuff and the presence of subluxation or dislocation of LHBT from the biceps groove 12 months postoperatively, and the results were independently evaluated by 2 authors. The Sugaya classification[26] was used to evaluate the retear pattern of the repaired rotator cuff, with types 4 and 5 considered as retears.

Statistical methods

The sample sizes were calculated to detect significant differences in ASES score (mean difference, 8 points; standard deviation, 12 points), which has been validated and widely used to evaluate clinical outcomes after ARCR.[14] A sample size of 37 patients per group was required for 80% power at a type I error level of 0.05.

Table I Demographic data

	Group 1	Group 2	*P* value
Total no. of patients	40	40	
No. of patients according to tear size			.77
PT	6	7	
Small-sized FT	8	8	
Medium-sized FT	26	25	
No. of patients who underwent acromioplasty	25	26	1.00
No. of patients according to suture method			.78
Single-row repair	14	15	
Double-row repair	14	14	
Transosseous equivalent repair	12	11	
No. of patients with delaminated FT	15	13	.82
Age, yr, mean (range)	60.6 (52-71)	58.6 (49-72)	.30
Sex, men/women, n	19/21	17/23	.75
Average follow-up period, mo	25.4 ± 6.2	27.6 ± 9.2	.46
Average tear size of rotator cuff, cm			
Medial to lateral	1.3 ± 0.6	1.4 ± 0.8	.73
Anterior to posterior	1.3 ± 0.6	1.3 ± 0.7	.94
Initial ROM, degrees			
Forward flexion	146 ± 6	146 ± 9	.61
External rotation at 90° of abduction	87 ± 6	86 ± 7	.54
External rotation at the side	85 ± 9	86 ± 7	.90
Internal rotation	10 ± 3	10 ± 2	.53
Initial clinical score			
VAS for pain	3.8 ± 2.3	4.3 ± 2.1	.34
ASES	62.7 ± 18.7	58.0 ± 20.0	.26
Constant score	74.0 ± 12.5	69.3 ± 16.5	.19
KSS	68.7 ± 15.1	64.4 ± 13.6	.21

PT, partial-thickness tear; *FT*, full-thickness tear; *ROM*, range of motion; *VAS*, visual analog scale for pain; *ASES*, American Shoulder and Elbow Surgeons scale; *KSS*, Korean Shoulder Scale.

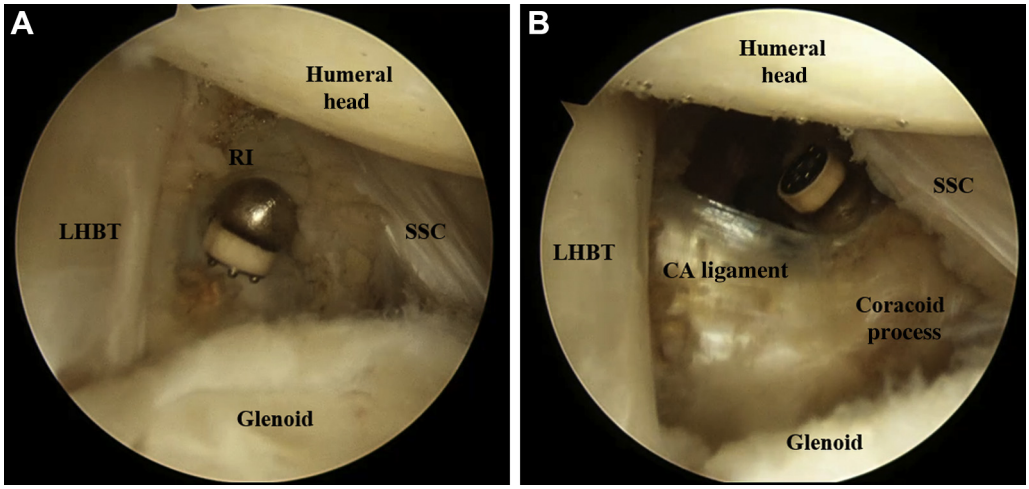

Figure 2 Extensive RI release in the glenohumeral joint of the right shoulder. Viewed from the posterior portal. (**A**) The electrocautery device (ArthroCare, Sunnyvale, CA, USA) was inserted through the anterior portal into the glenohumeral joint. (**B**) The RI capsule (including the coracohumeral ligament) was released until the base of the coracoid process and the CA ligament was exposed. *RI*, rotator interval; *LHBT*, long head of the biceps tendon; *SSC*, subscapularis; *CA*, coracoacromial.

Expected follow-up loss was about 20%. All statistical analyses were performed with SPSS, version 21.0 (IBM, Armonk, NY, USA). An independent *t* test was used to compare the differences in demographic and clinical variables between the 2 groups, and a paired *t* test was used to compare the differences in ROM and functional scores before and after surgery for each group. Fisher exact test was used to compare the new-onset LHBT symptoms of the 2 groups. The χ^2 test was used to compare the retear rates of the 2 groups. Significance was set at a *P* value less than .05.

Results

Demographic characteristics did not differ significantly between the 2 groups ($P > .05$) (Table I). The mean follow-up period was 26.5 months (25.4 months for group 1 and 27.6 months for group 2). There were no differences between the preoperative and postoperative ROM measurements in either group ($P > .05$) (Table II). In both groups, the functional scores at last follow-up were significantly better than those recorded preoperatively ($P < .05$) (Table III). Three months postoperatively, the mean ROM (including FF, ER_{ab}, ER_s, and IR) of group 1 was significantly better than that of group 2 ($P < .05$) (Fig. 3 and Table IV). The average differences in ROM between the 2 groups 3 months postoperatively were 8° of FF, 11° of ER_{ab}, 9° of ER_s, and 1.6 spinal levels of IR. Functional scores (the Constant score and the KSS) were also better in group 1 than in group 2 at this time point (Fig. 4 and Table V). However, there were no significant differences in the ROM values, visual analog scale pain scores, or functional scores between the 2 groups at any time point except 3 months postoperatively ($P > .05$) (Figs. 3 and 4; Tables IV and V). The retear rate, which were assessed 12 months postoperatively by MRI, did not differ significantly between the 2 groups ($P = .50$). Six patients (15%) in group 1 and 4 patients (10%) in group 2 experienced retear of the repaired rotator cuff.

Table II Comparison of preoperative and postoperative range of motion

Measure	Range of motion		*P* value
	Preoperative	Last follow-up	
Forward flexion			
Group 1	146 ± 6	149 ± 3	.46
Group 2	146 ± 9	149 ± 2	.12
External rotation at 90° of abduction			
Group 1	87 ± 6	89 ± 3	.59
Group 2	86 ± 7	89 ± 3	.21
External rotation at the side			
Group 1	85 ± 9	88 ± 4	.50
Group 2	86 ± 7	89 ± 2	.34
Internal rotation			
Group 1	10 ± 3	11 ± 2	.52
Group 2	10 ± 3	11 ± 0	.15

Values are in degrees, mean ± standard deviation.

Among the patients who had intact LHBT when ARCR was performed (16 patients in group 1, 21 patients in group 2), there was no subluxation or dislocation of LHBT from the biceps groove in both groups on 12-month postoperative MRI. Only 1 patient in each group had new-onset clinical tenderness along the biceps groove during the follow-up period (1 patient in group 1 at 15

Table III Comparison of preoperative and postoperative functional scores

Measure	Preoperative score	Score at last follow-up	*P* value
VAS			
Group 1	5.6	2.1	<.001
Group 2	4.3	1.5	<.001
ASES			
Group 1	57.6	82.5	<.001
Group 2	57.9	86.5	<.001
Constant score			
Group 1	72.8	85.3	<.001
Group 2	68.7	80.5	.01
KSS			
Group 1	69.3	86.8	<.001
Group 2	64.1	80.6	<.001

VAS, visual analog scale for pain; *ASES*, American Shoulder and Elbow Surgeons scale; *KSS*, Korean Shoulder Scale.

months postoperation; 1 patient in group 2 at 9 months postoperation), and their symptoms were resolved by steroid injection on the biceps groove. In both groups, there were no other complications (including instability) through the last follow-up visit.

Discussion

Our study revealed that better ROM values and functional scores were achieved 3 months after ARCR in the RI release group than in the RI nonrelease group. However, the functional scores and ROM were not significantly different between the 2 groups at 6 or 12 months postoperation or at the final follow-up. Historically, postoperative stiffness after ARCR has been an important issue for shoulder surgeons, because even though ARCR is a minimally invasive procedure, postoperative stiffness may develop and lead to inferior functional outcomes.[27] Kim et al[14] compared the clinical outcomes of an early passive motion exercise group and a no passive motion exercise group after ARCR in a randomized controlled study. They reported that early passive motion exercise after ARCR did not guarantee early ROM gain or pain relief, but also did not negatively affect cuff healing. Many surgeons have argued about the potency of healing versus the importance of early rehabilitation to reduce postoperative stiffness, and there are still many controversies.[5,6,8,11,14,16,18,22] Although many trials have been conducted on this topic, no study has described an intraoperative procedure to reduce postoperative stiffness after ARCR.

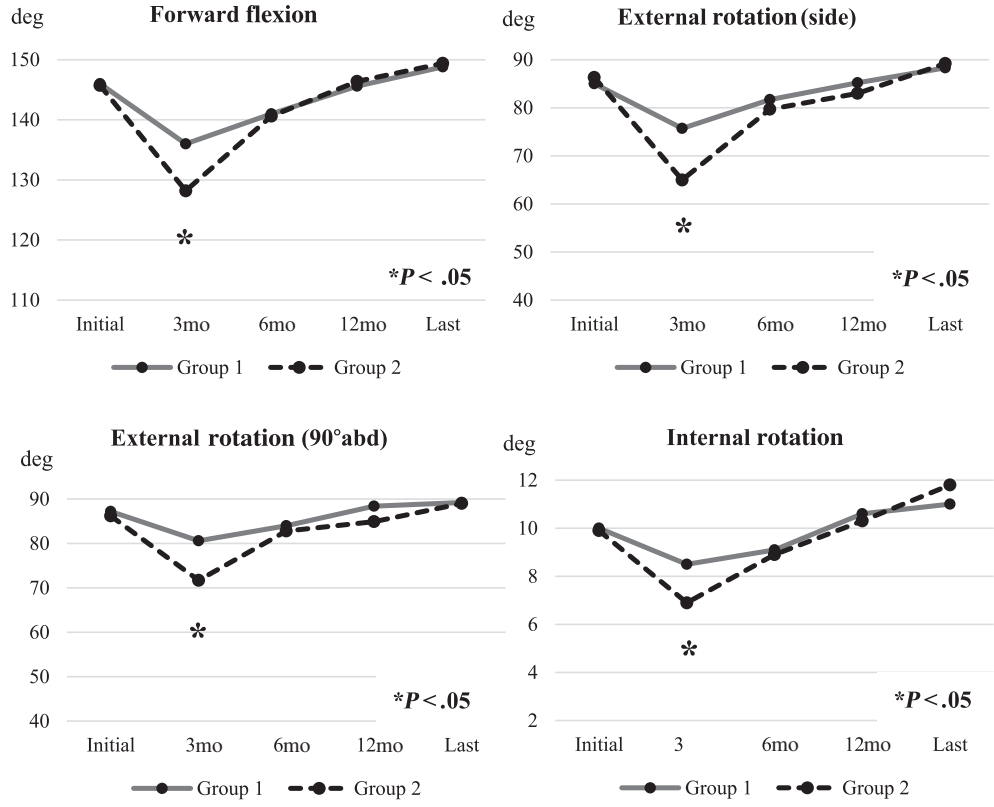

Figure 3 The range of motion (forward flexion, external rotation at 90° abduction and at the side, internal rotation) did not differ significantly between the initial measurement and the last follow-up measurement in either group. Three months after the surgery, group 1 had a better ROM than group 2. Otherwise, there were no significant differences between the 2 groups at any time point. *deg*, degree; *abd*, abduction.

Table IV Comparison of range of motion

Measure	Group 1	Group 2	*P* value
Forward flexion			
Initial	146 ± 6	146 ± 8	.46
3 mo	136 ± 15	128 ± 15	.03*
6 mo	141 ± 11	141 ± 8	.85
Last	149 ± 3	149 ± 2	.41
External rotation at 90° of abduction			
Initial	85 ± 9	86 ± 9	.74
3 mo	76 ± 18	65 ± 21	.02*
6 mo	82 ± 10	80 ± 11	.43
Last	88 ± 4	89 ± 3	.44
External rotation at the side			
Initial	87 ± 6	86 ± 7	.51
3 mo	80 ± 16	72 ± 20	.04*
6 mo	84 ± 8	83 ± 8	.51
Last	89 ± 3	89 ± 2	.34
Internal rotation			
Initial	10 ± 3	10 ± 2	.60
3 mo	9 ± 3	7 ± 3	.02*
6 mo	9 ± 2	9 ± 3	.63
Last	11 ± 2	12 ± 0	.15

Values are in degrees, mean ± standard deviation.
* $P < .05$.

The CHL and RI capsule are known to be the major areas affected by shoulder stiffness.[2,9,21] In a cadaveric study, Harryman et al[9] found that sectioning of the RI increased the ROM of the shoulder, especially in flexion, extension, adduction, and ER. Mologne et al[19] revealed that arthroscopic RI closure significantly reduced ER in both neutral and abducted arm positions in a cadaveric study. Tsai et al[29] reported that arthroscopic extended RI release for patients with refractory adhesive capsulitis improved the ROM of the shoulder joint. At last follow-up, the ROM of the affected shoulder (including FF, ER_s, ER_{ab}, and IR) was almost identical to that of the unaffected contralateral shoulder. For patients with preoperative stiffness, capsulectomy including RI release is considered to be an effective procedure.[7,10,15,23,25,29] Thus, we hypothesized that preemptive removal of the RI capsular tissue could prevent immediate postoperative stiffness after ARCR.

The RI is known to have 2 main functions.[1,9,12,30] First, it helps to stabilize the shoulder joint. The SGHL and the CHL provide resistance to inferior and posterior translation of the humeral head. The RI also provides check-rein restraint against an excessive ROM in terms of flexion, extension, adduction, and ER. The other main function of the RI is to stabilize the LHBT. Thus, we had concerns about these natural functions of the RI and assessed

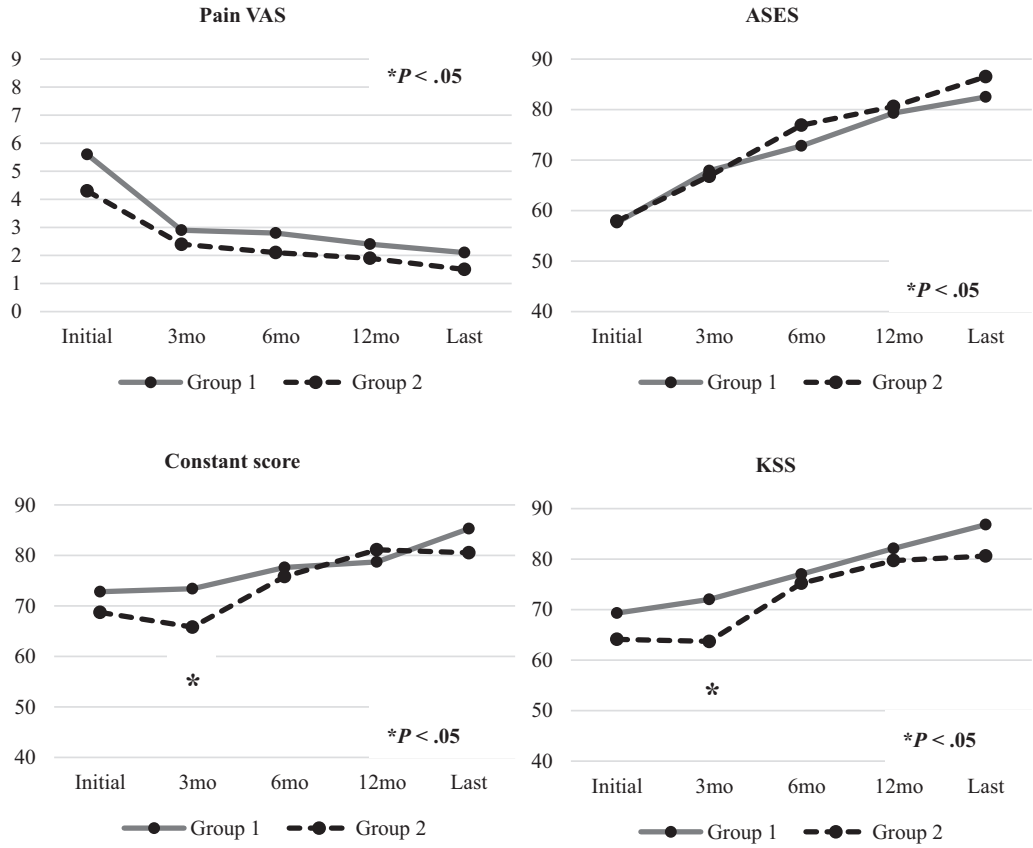

Figure 4 Functional scores (Pain VAS, ASES, Constant score, and KSS) were significantly better after surgery in both groups. Three months after the surgery, group 1 had better functional scores (Constant score, KSS) than group 2. Otherwise, there were no significant differences between the 2 groups at any time point. *VAS*, visual analog scale; *ASES*, American Shoulder and Elbow Surgeons scale; *KSS*, Korean Shoulder Scale.

Table V Comparison of functional scores

Measure	Group 1	Group 2	*P* value
VAS			
Initial	5.6 ± 2.3	4.3 ± 2.1	.10
3 mo	2.9 ± 2.1	2.4 ± 1.7	.30
6 mo	2.8 ± 2.1	2.1 ± 1.7	.14
Last	2.1 ± 2.3	1.5 ± 1.5	.31
ASES			
Initial	57.6 ± 18.2	57.9 ± 19.6	.81
3 mo	67.9 ± 18.0	66.8 ± 15.9	.79
6 mo	72.8 ± 16.7	76.9 ± 15.7	.30
Last	82.5 ± 12.5	86.5 ± 13.4	.39
Constant score			
Initial	72.8 ± 12.3	68.7 ± 17.0	.25
3 mo	73.4 ± 14.5	65.8 ± 16.4	.04*
6 mo	77.6 ± 14.5	75.8 ± 13.3	.57
Last	85.3 ± 8.9	80.5 ± 17.9	.27
KSS			
Initial	69.3 ± 14.8	64.1 ± 13.5	.11
3 mo	72.0 ± 13.7	63.7 ± 18.0	.03*
6 mo	77.0 ± 14.9	75.2 ± 13.8	.61
Last	86.8 ± 6.6	80.6 ± 20.8	.16

VAS, visual analog scale for pain; *ASES*, American Shoulder and Elbow Surgeons scale; *KSS*, Korean Shoulder Scale.
Values are mean ± standard deviation.
* $P < .05$.

patients for complications that could have been induced by disruption of the RI tissue. However, there was no case of instability after surgery in the RI release group. The retear rates 12 months postoperatively also did not differ significantly between the 2 groups ($P = .50$). And technically we performed RI release mainly with release of CHL from the base of the coracoid process. The most lateral portion of the RI tissue and the pulley of LHBT were not released to save the stability of LHBT. The retear rates, which were assessed 12 months postoperatively by MRI, also did not differ significantly between the 2 groups ($P = .50$). Six patients (15%) in group 1 and 4 patients (10%) in group 2 experienced retear of the repaired rotator cuff. This means that additional RI release during rotator cuff repair did not affect the integrity of the repaired rotator cuff. Among the patients who had intact LHBT when ARCR was performed (16 patients in group 1 and 21 patients in group 2), there was no subluxation or dislocation of LHBT from the biceps groove in both groups on the 12-month postoperative MRI. Because the RI stabilizes the LHBT, the position change of the LHBT after RI release can be expected. But, we did not release the most lateral portion of the RI tissue and the pulley of the LHBT, which can affect the stability of LHBT. As a result, the 12-month postoperative MRI revealed no new occurrences of LHBT subluxation or dislocation in both groups. Also, among those in the RI release group who had intact LHBT when they underwent ARCR, only 1 patient (6%) had new-onset LHBT symptoms 15 months after surgery. In the RI nonrelease group, 1 patient (5%) had pain in the LHBT 9 months postoperatively. From these results, we concluded that the RI release procedure during ARCR did not lead to clinically significant pathologic changes in the LHBT compared to the RI-saving operation.

Our study demonstrated that there were no significant differences in the ROM and functional scores between the 2 groups at any time point after 3 months postoperatively. Usually, if patients have undergone proper postoperative rehabilitation after ARCR, their ROM and functional outcomes ultimately improve appropriately. Because the enrolled patients in both groups in this study had proper rehabilitation management at each follow-up point, the functional outcomes did not differ significantly between the 2 groups after 3 months postoperatively. The difference in each plane of ROM at 3 months after surgery can be considered small. But the difference in the sum of total ROM between the RI release group and the non–RI release group was 27°. Additionally, the difference of IR degree was 1.6 vertebral level and the difference of ER at 90° abduction was 11°. This rotation motion of the shoulder joint has a great effect on daily activities, such as changing clothes or self-hygiene, in the early postoperative period. In conclusion, the reduction in early postoperative stiffness in the RI release group resulted in better ROM values and functional scores 3 months postoperatively, which could lead to higher patient satisfaction after the surgery.

There were several limitations to this study. First, the number of enrolled patients was relatively small. However, we satisfied the minimum number of patients calculated in the power analysis; thus statistical power was achieved. Another limitation was the relatively short mean follow-up period of 26.5 months. This follow-up period may have been too short to reveal long-term changes after RI release. However, the clinical outcomes only differed significantly between the 2 groups 3 months after the surgery, and there were no significant differences in the ROM and functional scores between the 2 groups from 6 months postoperatively till the last follow-up. Thus, we considered this follow-up period sufficient to investigate the ability of our procedure to enhance clinical outcomes in the early postoperative period after ARCR. Lastly, the shoulder ROM was checked once with a goniometer by a skilled physician who was blinded to the study. So we could not evaluate the intra- and interindividual variability. This could be another limitation of our study.

Conclusion

The extensive RI release group had better ROM values and functional scores than the RI nonrelease group 3 months after ARCR. Arthroscopic preemptive extensive

RI release can reduce early postoperative shoulder stiffness after ARCR but does not significantly change the overall clinical outcome after surgery.

Disclaimer

The authors, their immediate families, and any research foundations with which they are affiliated have not received any financial payments or other benefits from any commercial entity related to the subject of this article.

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