Clinical and Radiographic Outcomes After Arthroscopic Lamina-Specific Double-Row Repair of Large Delaminated Rotator Cuff Tears in Active Patients

Daisuke Mori,*† MD, Kazuha Kizaki,† MD, Noboru Funakoshi,† MD, Fumiharu Yamashita,† MD, PhD, Yasuyuki Mizuno,† MD, Takaaki Shirai,† MD, PhD, and Masahiko Kobayashi,† MD, PhD

Investigation performed at the Department of Orthopaedic Surgery, Kyoto Shimogamo Hospital, Kyoto, Japan

Background: The presence of delamination and a larger rotator cuff tear (RCT) size have been associated with poorer outcomes in rotator cuff repair. Therefore, we developed a new surgical procedure, arthroscopic lamina-specific double-row fixation (ALSDR), for the repair of large delaminated RCTs.

Purpose: To investigate the clinical outcomes, magnetic resonance imaging findings, and satisfaction with several variables after ALSDR for large delaminated RCTs.

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

Methods: A total of 30 active patients (mean age, 59.1 years) undergoing ALSDR were assessed by a numeric rating scale (NRS; 0-10) for pain, surgery, work, and exercise as well as American Shoulder and Elbow Surgeons (ASES), Constant, and Simple Shoulder Test (SST) scores at a mean of 65.9 months postoperatively. Rotator cuff integrity was determined by magnetic resonance imaging. The Spearman correlation coefficient (ρ) was used to determine the correlation between clinical and NRS scores.

Results: Five patients (16.7%) had a retear. Each of the postoperative functional and NRS scores except the NRS work score was significantly better in the healed shoulders than in the shoulders with a retear ($P < .001$). The NRS pain score showed a significant negative correlation with ASES, Constant, and SST scores ($\rho = -0.775$, -0.668, and -0.742, respectively; $P < .001$ for all). The NRS surgery score had a positive correlation with Constant and SST scores ($\rho = 0.393$ [$P = .032$] and $\rho = 0.456$ [$P = .011$], respectively). The NRS work score had a positive correlation with ASES, Constant, and SST scores ($\rho = 0.382$ [$P = .037$], $\rho = 0.386$ [$P = .035$], and $\rho = 0.414$ [$P = .023$], respectively). The NRS exercise score had a positive correlation with ASES, Constant, and SST scores ($\rho = 0.567$ [$P = .001$], $\rho = 0.511$ [$P = .004$], and $\rho = 0.639$ [$P < .001$], respectively).

Conclusion: Our results showed that there was a significant correlation between clinical and NRS scores. The results indicate that ALSDR can provide a high degree of functionality and can be a useful alternative treatment for active patients with large delaminated RCTs.

Keywords: large rotator cuff tear; delamination; correlation; structural and clinical outcomes

Delamination is a commonly observed finding at the time of rotator cuff repair, and some clinical studies have reported it as a negative prognostic factor in rotator cuff healing.[3,5,9,10,18,19,31] However, the best operative treatment for delaminated rotator cuff tears (RCTs) remains controversial. Sugaya et al[33] described a double-row technique for delaminated RCTs that involved the repair of each layer separately, without reporting clinical and radiographic outcomes. Sakaguchi et al[29] reported a 50% retear rate after conventional en masse double-row repair for large to massive RCTs. Conversely, Sonnabend et al[31,32] and MacDougal and Todhunter[18] reported curetting delaminated components at the time of surgery and noted that their presence had no effect on the clinical outcomes of rotator cuff repair. These differences in outcomes may be caused by surgeon perception of tear configuration, tear location, and thickness of the inferior layer.[9,10]

In the repair of large-sized delaminated RCTs, which are anatomically more complex than nondelaminated RCTs, it may be expected that maintaining rotator cuff integrity will

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be difficult compared with the repair of small- to medium-sized delaminated RCTs.[9,10,19,21,34] One purpose of rotator cuff repair is to gain pain relief and functional recovery. However, it remains controversial whether maintaining rotator cuff integrity is crucial, as some studies have demonstrated that postoperative rotator cuff integrity does not always correlate with residual pain and shoulder dysfunction.[6,28] We believe that maintaining rotator cuff integrity is necessary in active patients who have large RCTs for muscle strength recovery to achieve desired outcomes.[11,13,25,35] Therefore, we developed a technique using a combination of a double row and an additional row, which we call arthroscopic lamina-specific double-row fixation (ALSDR), for the treatment of large-sized delaminated RCTs in active patients.[22]

The purpose of the present study was to evaluate the efficacy of ALSDR using clinical and structural outcomes. In addition, we correlated our numeric rating scale (NRS) for satisfaction with usefulness of the shoulder after the index surgery and activity level during work and exercise with clinical shoulder scores. We hypothesized that ALSDR would provide a high level of functionality, allowing active patients with large delaminated RCTs to meet desired activity levels.

METHODS

Patient Selection

The study protocol was approved by our institutional review board, and informed consent for inclusion in the study was preoperatively obtained from all patients. Data were prospectively collected in our database and retrospectively reviewed. The initial study sample consisted of 63 consecutive patients with delaminated RCTs who underwent arthroscopic separate double-layer double-row fixation for small- to medium-sized (1-3 cm) RCTs (31 patients) or arthroscopic lamina-specific double-row fixation (ALSDR) for large-sized (3-5 cm) RCTs (32 patients) by a single surgeon (D.M.) between June 2007 and November 2011.

The diagnosis of RCTs was based on magnetic resonance imaging (MRI). The final evaluation, however, was performed at the time of arthroscopic surgery. We defined delamination as a horizontal tear occurring between the layers of the rotator cuff and the presence of 2 distinct layers during the arthroscopic assessment. The indications for ALSDR were as follows: (1) the inferior layer (deep layer/articular side) in a delaminated RCT was retracted medially to the glenoid and could be advanced to the medial footprint of the greater tuberosity with a tendon grasper after tendon mobilization, (2) the superior layer (bursal side) was able to be advanced laterally to the edge of the greater tuberosity, and (3) a 3- to 5-cm tear size. We used this to define large delaminated RCTs.[22] We performed separate double-layer double-row fixation for small to medium delaminated RCTs.[33]

The inclusion criteria for this study were (1) an RCT with pain and functional disability refractory to conservative treatment for at least 6 months, (2) active patients with the hope of possible complete recovery of function and muscle strength and premorbid activity levels after the index surgery (see below), (3) an intact teres minor tendon, (4) availability of MRI to evaluate the integrity of the rotator cuff tendons before surgery and at 12 months and final follow-up after surgery, (5) a minimum follow-up period of 24 months after surgery, and (6) relatively higher education with a high level of literacy (ie, some high school, high school graduate, college graduate), as lower education level has been associated with poorer functional outcomes in rotator cuff surgery.[14] The exclusion criteria were (1) small- to medium-sized RCTs, (2) irreparable RCTs diagnosed during surgery as rotator cuff tendons that are so damaged as to be unable to mobilize the tendon to the insertion, (3) a bursal layer that was more retracted than the articular layer ($n = 0$), (4) grade 3 or 4 fatty infiltration in the affected rotator cuff muscle on MRI according to the classification of Goutallier et al,[8] (5) the development of symptoms after a motor vehicle accident because patients did not receive long-term follow-up (those with workers' compensation were included in this study), (6) a history of surgery, and (7) full-thickness subscapularis tendon tears. Of the 32 patients who underwent ALSDR, 1 who met the inclusion criteria was lost to follow-up, and 1 had sedentary activity. The remaining 30 shoulders in 30 active patients who underwent ALSDR were included in the study. None of the patients had a history of diabetes.

Patient Assessment

Activity Level. Activity level was defined using the criteria of Galatz et al[7] and Kim et al.[14] Overall activity levels were rated as sedentary, light, moderate, or strenuous. The patient was considered to be sedentary when he or she did not participate in sports, and general lifting was limited to 15 lb (6.8 kg). Light activity was defined as participation in light recreational sports, such as golf, light gardening, water aerobics, walking, and stretching, or the ability to lift 25 to 30 lb (11.3-13.6 kg). Activity was considered moderate if the patient regularly participated in moderate-stress recreational sports such as racket sports excluding tennis, gardening, jogging, light swimming, recreational golf, and landscaping or could lift 50 to 75 lb (22.7-34.0 kg) on a regular basis. Strenuous activity meant that the

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*Address correspondence to Daisuke Mori, MD, Department of Orthopaedic Surgery, Kyoto Shimogamo Hospital, 17 Shimogamo Higashimorigamaecho, Sakyo-ku, Kyoto, 606-0866, Japan (email: altair.0421@gmail.com).

†Department of Orthopaedic Surgery, Kyoto Shimogamo Hospital, Kyoto, Japan.

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Ethical approval for this study was obtained from Kyoto Shimogamo Hospital (No. 2012-002).

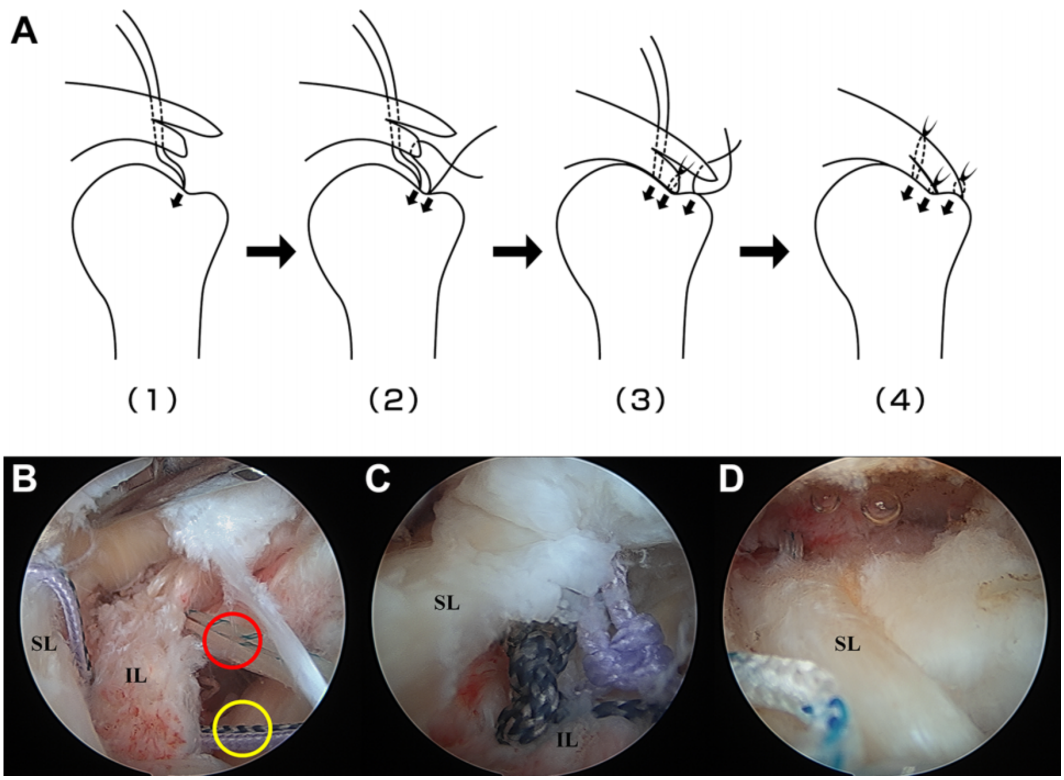

Figure 1. (A) Illustrations of arthroscopic lamina-specific double-row fixation. *1*, Sutures of the medial-row anchor are placed through the inferior and superficial layers in a mattress fashion. *2*, A lamina-specific lateral-row anchor is inserted between the typical medial and lateral rows. A suture limb of the lamina-specific lateral-row anchor is placed just through the inferior layer in a simple suture fashion. *3*, Sutures of the lamina-specific lateral-row anchor are tied. A suture limb of the lateral-row anchor is placed through the superficial layer. *4*, Knot tying for the lateral row of simple sutures is performed, and repair is then completed by knot tying for the medial row in a mattress fashion. (B-D) Arthroscopic images of the right shoulder as viewed from the posterolateral portal. Images B, C, and D correspond to illustrations *2*, *3*, and *4*, respectively. (B) The red circle indicates sutures of the medial-row anchor, and the yellow circle indicates sutures of the lamina-specific lateral-row anchor. (C) The inferior layer is fixed on the footprint. (D) Repair is completed. IL, inferior layer; SL, superficial layer.

patient regularly participated in contact sports or overhead-throwing sports at a competitive level, such as tennis, baseball, lap swimming, running, and weight lifting, or could lift >75 to 100 lb (34.0-45.4 kg) on a regular basis. Activity level was defined on the basis of the most strenuous work or leisure activities that the patient performed on a regular basis.

Outcome Assessment. Outcome scores were used to assess patients on the day before surgery, at 12 and 24 months postoperatively, and at a final functional evaluation performed a minimum of 24 months postoperatively. Measures used included the Constant score and the American Shoulder and Elbow Surgeons (ASES) score. The Simple Shoulder Test (SST) was used at final follow-up. Objective outcome measures, including range of motion and muscle strength, were performed by the treating surgeon (D.M.) and a clinical assistant who was not involved in the study to verify the results and avoid errors in the assessments. A goniometer was used to measure active shoulder range of motion to the point of pain, including forward flexion, external rotation with the arm at the side, and internal rotation at the back. To aid in statistical analysis, for internal rotation, we converted the vertebral level reached to a numeric value: levels T1-T12 converted to 1-12, levels L1-L5 to 13-17, the sacrum to 18, and the buttock to 19. An Isobex dynamometer (Cursor AG) was used to quantitatively assess isometric muscle strength in both the affected and the unaffected upper extremities. Abduction strength was tested with the arm abducted to 90° in the scapular plane with the elbow extended and the forearm pronated. The measurement was made 3 times, and the mean of these values was used for analysis to calculate the Constant score.

Pain, Satisfaction, and Activity Level Scoring. An 11-point (0-10) NRS was used to assess pain at strenuous activity, at rest, and while sleeping. Of the 3 domains, the highest pain level was chosen for the clinical assessment. In addition, an NRS for satisfaction with usefulness of the shoulder after the index surgery (NRS surgery) was utilized. Similarly, patient activity level was assessed with the use of an 11-point NRS in each of 2 domains: (1) activity at work and (2) activity during sports/recreation (NRS work and NRS exercise, respectively) (Appendix Table A1).

TABLE 1
Baseline Demographics and Characteristics[a]

	Total Cohort (N = 30)	Intact (n = 25)	Retear (n = 5)	*P* Value
Sex, n (%)				.119[b]
Male	26 (86.7)	23 (92.0)	3 (60.0)	
Female	4 (13.3)	2 (8.0)	2 (40.0)	
Age, y	59.1 ± 7.5 (43-72)	59.2 ± 7.9 (43-72)	58.4 ± 5.3 (51-64)	.824[c]
Follow-up period, mo	65.9 ± 11.1 (32-88)	66.7 ± 11.5 (32-88)	66.2 ± 8.6 (52-71)	.420[c]
Affected side, n (%)				>.999[b]
Right	18 (60.0)	15 (60.0)	3 (40.0)	
Left	12 (40.0)	10 (60.0)	2 (40.0)	
Dominant side affected, n (%)	21 (83.3)	17 (68.0)	4 (80.0)	>.999[b]
Workers' compensation, n (%)	4 (13.3)	3 (12.0)	1 (20.0)	.538[b]
Smoking, n (%)	1 (3.3)	0 (0.0)	1 (20.0)	.167[b]
Partial subscapularis tear, n (%)	7 (23.3)	6 (24.0)	1 (20.0)	>.999[b]
Biceps tenodesis, n (%)	3 (10.0)	2 (8.0)	1 (20.0)	.433[b]
Tear size, cm				
Medial to lateral	3.5 ± 0.5 (3-5)	3.5 ± 0.5 (3-5)	3.4 ± 0.4 (3-4)	.680[c]
Anterior to posterior	2.9 ± 0.5 (2-4)	2.8 ± 0.5 (2-4)	2.9 ± 0.5 (2-4)	.821[c]
No. of anchors				
Greater tuberosity	5.5 ± 0.5 (5-6)	5.5 ± 0.5 (5-6)	5.2 ± 0.4 (5-6)	.203[c]
Humeral head	5.9 ± 1.0 (5-9)	5.9 ± 0.9 (5-9)	5.8 ± 1.3 (5-8)	.870[c]
Fatty degeneration[d]				
Subscapularis	0.9 ± 0.6 (0-2)	1.0 ± 0.5 (0-2)	0.6 ± 0.9 (0-2)	.184[c]
Supraspinatus	2.1 ± 0.3 (2-3)	2.1 ± 0.3 (2-3)	2.0 ± 0.0 (2-2)	.432[c]
Infraspinatus	1.8 ± 0.4 (1-2)	1.8 ± 0.4 (1-2)	2.0 ± 0.0 (2-2)	.289[c]

[a]Data are reported as mean ± SD (range) unless otherwise indicated.
[b]Fisher exact test.
[c]Unpaired *t* test.
[d]According to the classification of Goutallier et al.[8]

MRI Examination

MRI was performed with a 1.5-T closed-type scanner (EXCELART Vantage powered by Atlas or VISART/EX; Toshiba). Oblique coronal, oblique sagittal, and axial T2-weighted scans were acquired for structural and qualitative assessments of the rotator cuff tendons, and repair integrity was evaluated. The slice thickness was 4 mm, and the interslice gap was 0.5 mm in the former scanner and 0.8 mm in the latter scanner. Repair integrity was evaluated using the classification of Sugaya et al,[33] in which types III to V are considered a retear. The MRI scans showing tendon healing were evaluated by 3 observers including the treating surgeon (D.M., K.K., N.F.). The intraclass correlation coefficient revealed good intraobserver reliability (0.771 [95% CI, 0.628-0.874]).[17] The final assessment was determined by the majority rating. However, in cases of a discrepancy among the 3 observers, the assessment was discussed to reach a consensus.

Surgical Procedure

Patients were placed in the beach-chair position under general anesthesia. The operative technique of ALSDR has been described in detail previously (Figure 1).[22] The operative indication of ALSDR was as follows: The treating surgeon evaluated delamination by pulling the torn superior and inferior layers laterally to the footprint using a tendon grasper with a 7-mm bite. If the edge of the inferior layer could be grasped and pulled laterally to the footprint with the grasper, we regarded this inferior layer as thick and tough tissue. We performed ALSDR for delaminated RCTs with such inferior layers. If the inferior layer tissue was torn and fragile at the time of the evaluation, standard double-row fixation (separate double-layer double-row fixation) was performed.

The ALSDR was performed using an additional row (lamina-specific lateral row) of suture anchors placed between the typical medial and lateral rows of suture anchors. Medial-row sutures were passed through the inferior (articular side) and superior (bursal side) layers in a mattress fashion. Next, lamina-specific lateral-row simple sutures were passed through the inferior layer. Last, lateral-row simple sutures were passed through the superior layer.

Postoperative Rehabilitation

Shoulders were immobilized postoperatively for 6 weeks using a sling immobilizer or an abduction pillow. In all patients, relaxation of the shoulder girdle muscles was started on the first postoperative day with a physical therapist. After 2 weeks, patients were instructed to commence isometric exercises and active-assisted exercises. After 6 weeks, patients started strengthening exercises of the rotator cuff and the scapular stabilizers. Patients were allowed

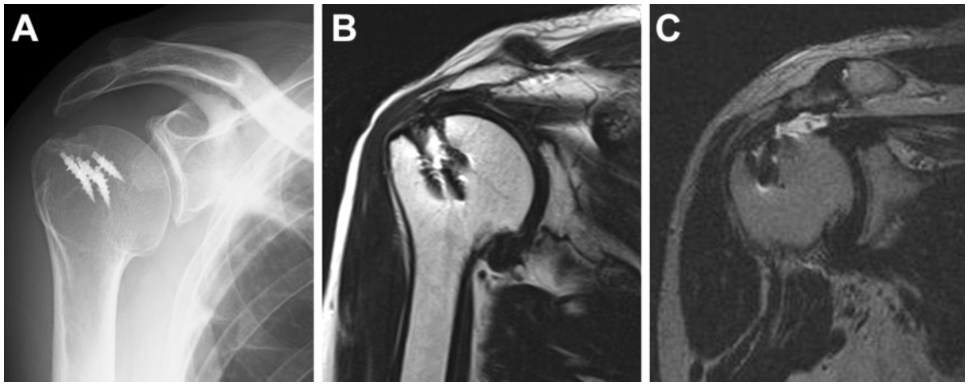

Figure 2. (A) Postoperative radiograph. (B) Repair integrity shown on postoperative oblique coronal T2-weighted magnetic resonance imaging (MRI) of the right shoulder. Sugaya type II tendon showing sufficient thickness with partial high intensity as in an intact shoulder. (C) Repair integrity shown on postoperative oblique coronal T2-weighted MRI of the right shoulder. Sugaya type V tendon showing the presence of discontinuity as in a shoulder with a retear.

TABLE 2
Functional Outcomes[a]

	Total Cohort (N = 30)	Intact (n = 25)	Retear (n = 5)	*P* Value
ASES score				
Preoperative	42.8 ± 10.9 (11.7 to 59.9)	43.6 ± 10.7 (11.7 to 59.9)	38.7 ± 12.4 (26.7 to 56.7)	.368[b]
Postoperative	93.6 ± 11.0 (60.0 to 100.0)	97.9 ± 3.5 (85.0 to 100.0)	71.7 ± 9.1 (60.0 to 81.7)	<.001[b]
Change (95% CI)	50.8 ± 13.9 (45.6 to 55.9)	54.3 ± 10.7 (49.9 to 58.7)	33.0 ± 15.3 (14.0 to 51.9)	.001[b]
P value	<.001[c]	<.001[c]	.008[c]	
Constant score				
Preoperative	45.5 ± 9.1 (20.0 to 58.0)	46.6 ± 7.6 (25.0 to 58.0)	40.0 ± 14.7 (20.0 to 58.0)	.146[b]
Postoperative	86.2 ± 10.5 (60.0 to 100.0)	90.1 ± 5.8 (81.0 to 100.0)	66.8 ± 5.8 (60.0 to 73.0)	<.001[b]
Change (95% CI)	40.7 ± 11.6 (36.4 to 45.1)	43.5 ± 9.1 (39.8 to 47.3)	26.8 ± 13.5 (10.0 to 43.6)	.002[b]
P value	<.001[c]	<.001[c]	.011[c]	
Constant strength score				
Preoperative	7.5 ± 2.5 (2.0 to 11.0)	7.8 ± 2.3 (2.0 to 11.0)	6.2 ± 3.4 (2.0 to 11.0)	.209[b]
Postoperative	16.8 ± 6.2 (5.0 to 25.0)	18.4 ± 5.4 (8.0 to 25.0)	9.2 ± 3.4 (5.0 to 14.0)	.001[b]
Change (95% CI)	9.3 ± 6.1 (7.1 to 11.6)	10.6 ± 5.8 (8.2 to 13.0)	3.0 ± 2.1 (0.4 to 5.6)	.008[b]
P value	<.001[c]	<.001[c]	.034[c]	
SST				
Postoperative	11.4 ± 1.1 (8.0 to 12.0)	11.8 ± 0.5 (10.0 to 12.0)	9.4 ± 1.1 (8.0 to 11.0)	<.001[b]
NRS pain				
Preoperative	6.5 ± 1.2 (4.0 to 9.0)	6.4 ± 1.2 (4.0 to 9.0)	7.0 ± 1.2 (5.0 to 8.0)	.294[b]
Postoperative	0.7 ± 1.4 (0.0 to 5.0)	0.1 ± 0.4 (0.0 to 2.0)	3.6 ± 0.9 (4.0 to 9.0)	<.001[b]
Change (95% CI)	–5.8 ± 1.6 (–6.6 to –5.2)	–6.2 ± 1.2 (–6.6 to –5.8)	–3.4 ± 1.3 (–5.1 to –1.7)	<.001[b]
P value	<.001[c]	<.001[c]	<.001[c]	

[a]Data are reported as mean ± SD (range) unless otherwise indicated. ASES, American Shoulder and Elbow Surgeons; NRS, numeric rating scale; SST, Simple Shoulder Test.
[b]Unpaired *t* test (intact vs retear).
[c]Paired *t* test (preoperative vs postoperative).

to return to sports and heavy labor after 6 months depending on each person's functional recovery.

Assessing ALSDR Efficacy

The expected healing rate after arthroscopic rotator cuff repair has yet to be defined.[1] Moreover, we did not know how many shoulders were needed for assessing ALSDR efficacy. Hence, we created the following process. First, we looked for differences in the retear rate between our groups and previous studies with inclusion and exclusion criteria similar to ours. A study by Sakaguchi et al[29] reported the retear rate as 50% after en masse repair for 18 shoulders with large or massive delaminated RCTs. In addition, Barber at al[2] performed arthroscopic dermal matrix augmentation for patients with arthroscopically

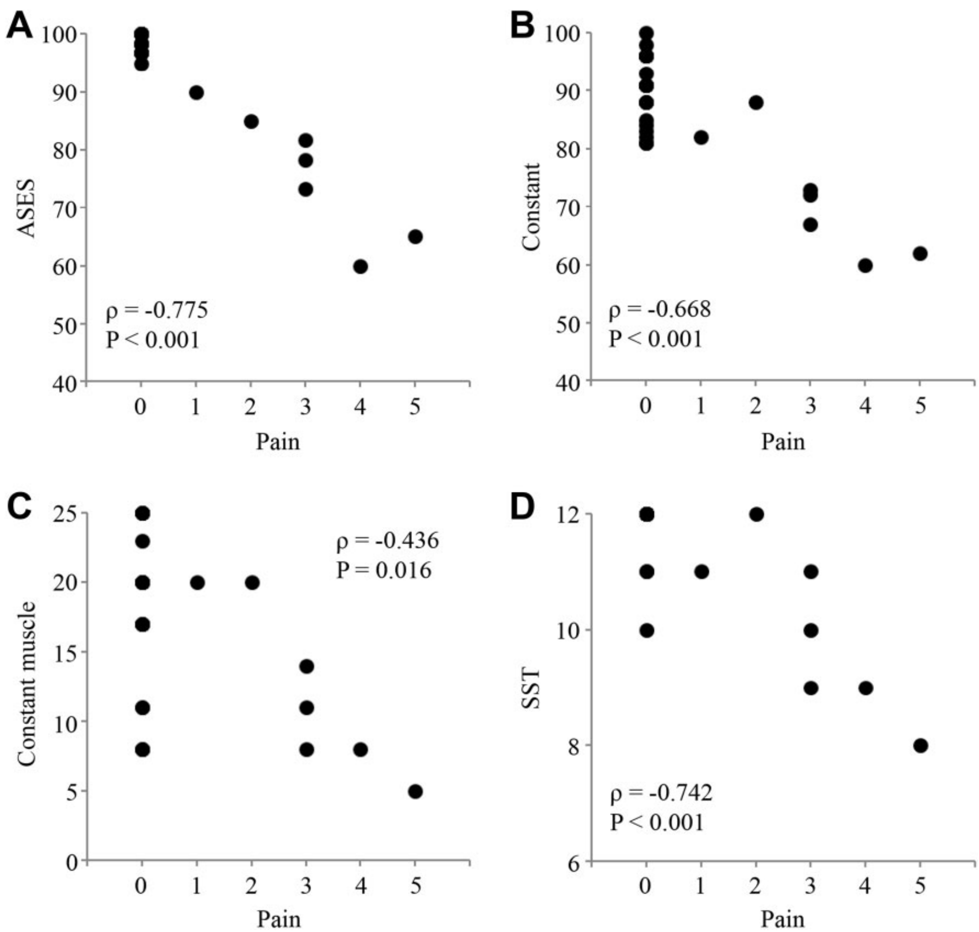

Figure 3. Scatter plot showing the correlation between the (A) American Shoulder and Elbow Surgeons (ASES), (B) Constant, (C) Constant strength, and (D) Simple Shoulder Test (SST) scores and the numeric rating scale pain score. ρ, Spearman correlation coefficient.

repairable large RCTs that were 3 to 5 cm in size and found more intact repair sites, as detected by MRI, in such patients compared with the control group (rotator cuff repair without augmentation). In that study, Barber at al[2] hypothesized that reducing the retear rate by half would be clinically meaningful when comparing the augmented and nonaugmented groups. Based on their work, we hypothesized that reducing the retear rate in our groups to less than half the retear rate of 50% reported by Sakaguchi et al[29] was clinically meaningful.

Second, we know that this technique has higher medical costs, such as requiring more suture anchors and a longer operative time, compared with other operative techniques, such as conventional en masse repair or separate double-layer double-row fixation. The principle of ALSDR is to maintain rotator cuff integrity, resulting in the restoration of shoulder function and individual premorbid activity levels. Therefore, we created the following 2 criteria to assess the efficacy of ALSDR for large delaminated RCTs. First, we looked for clinical differences in patients with and without a retear after ALSDR by using the ASES and Constant scores, the Constant strength score, and the SST. Second, we correlated the above clinical outcome scores with the aforementioned NRS scores for pain, index surgery success, and activity level.

Statistical Analysis

As previously mentioned, the sample sizes were calculated with a significant difference set at a retear rate less than 25% in our groups compared with the study by Sakaguchi et al[29] using a binomial test. A sample size of 30 patients was required for the present study to achieve a statistical power of 80% at a type I error level of .05. A paired *t* test was used to compare the preoperative and postoperative clinical scores, range of motion, and NRS pain score. The baseline patient characteristics and clinical scores between the intact and retear groups were compared using the Fisher exact test and unpaired *t* test. In addition, we used the Spearman correlation coefficient (ρ) to determine the correlation between clinical scores, such as ASES, Constant, Constant strength, and SST scores, and NRS scores for pain, surgery, work, and exercise. The level of significance for statistical tests was set at $P = .05$, and 95% CIs were

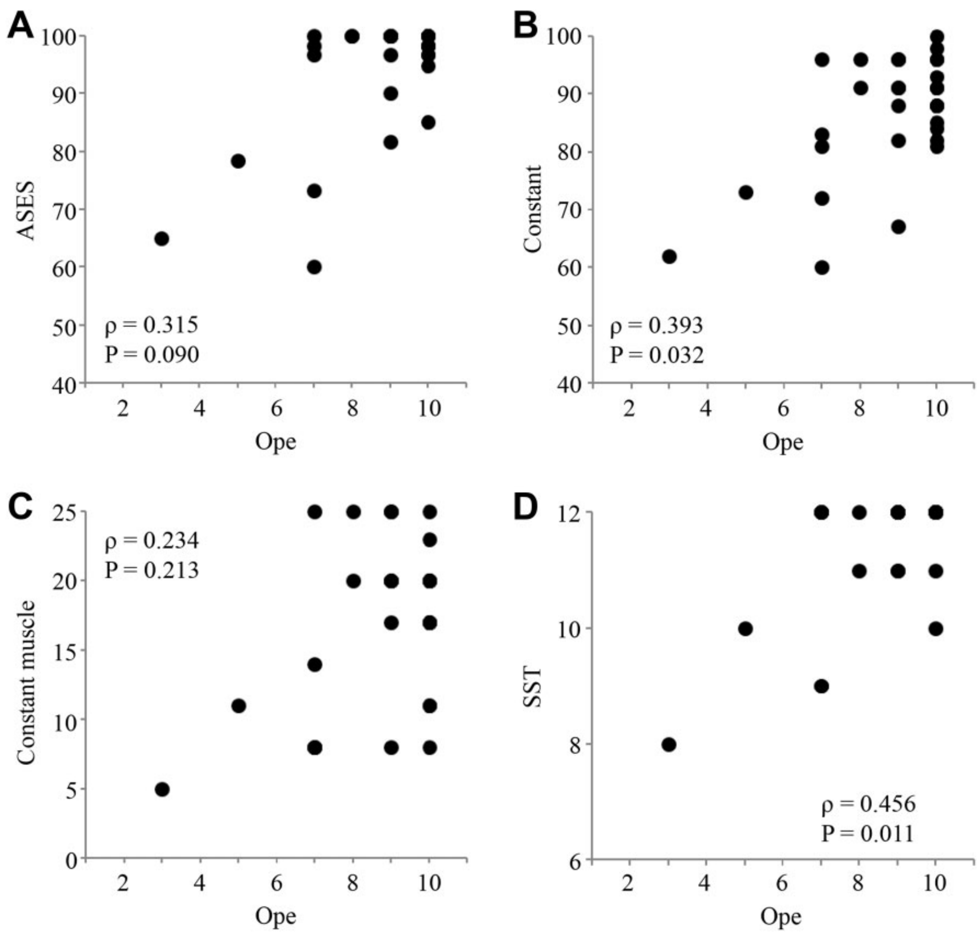

Figure 4. Scatter plot showing the correlation between the (A) American Shoulder and Elbow Surgeons (ASES), (B) Constant, (C) Constant strength, and (D) Simple Shoulder Test (SST) scores and the numeric rating scale surgery score. Ope, satisfaction for the operated shoulder. ρ, Spearman correlation coefficient.

calculated. All statistical analyses were performed using SAS version 9.2 (SAS Institute).

RESULTS

Preoperative Patient Demographics

Detailed information for the 30 patients is shown in Table 1 and Appendix Table A2.

Structural Outcomes

Postoperative MRI at final follow-up showed 5 tendons with Sugaya type I (16.7%), 20 tendons with Sugaya type II (66.6%), and 5 tendons with Sugaya type V (16.7%). The retear rate was 16.7% (Figure 2 and Appendix Table A3).

Total Functional Outcomes and NRS Pain

The mean outcome scores significantly improved from preoperatively to final follow-up for the ASES (from 42.8 ± 10.9 to 93.6 ± 11.0), Constant score (from 45.5 ± 9.1 to 86.2 ± 10.5), and Constant strength score (from 7.5 ± 2.5 to 16.8 ± 6.2) ($P < .001$ for all). The mean NRS pain score significantly improved from 6.5 ± 1.2 preoperatively to 0.7 ± 1.4 at final follow-up ($P < .001$) (Table 2 and Appendix Table A3).

Range of Motion

Mean shoulder range of motion significantly improved from preoperatively to final follow-up for active forward flexion (from 127.2° ± 25.2° to 164.5° ± 7.9°), external rotation at the side (from 32.8° ± 14.8° to 52.5° ± 11.4°), and internal rotation at the back (from 15.7° ± 2.7° to 12.1° ± 1.9°) ($P < .001$ for all) (Appendix Table A4).

Comparison of Shoulders With and Without Retears

Each of the postoperative functional and NRS scores except the NRS work score was significantly better in the healed shoulders (ASES: 97.9 ± 3.5; Constant: 90.1 ± 5.8; Constant strength: 18.4 ± 5.4; SST: 11.8 ± 0.5; NRS pain: 0.1 ± 0.4;

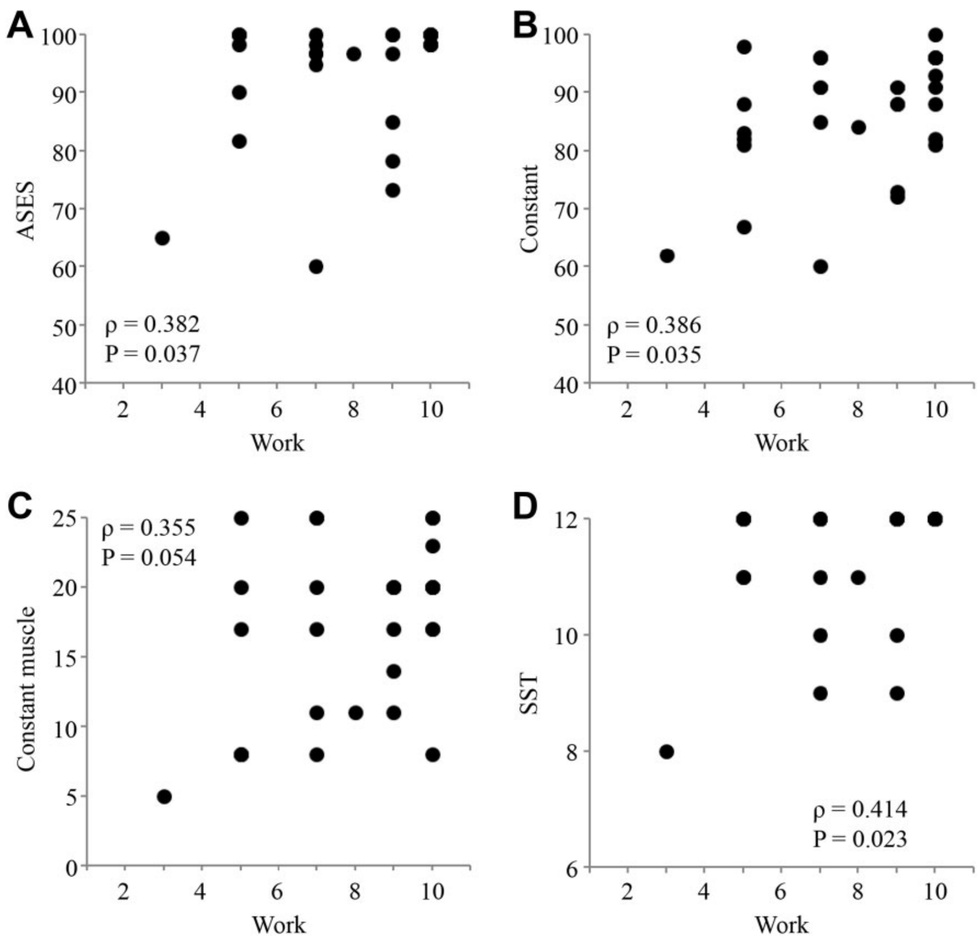

Figure 5. Scatter plot showing the correlation between the (A) American Shoulder and Elbow Surgeons (ASES), (B) Constant, (C) Constant strength, and (D) Simple Shoulder Test (SST) scores and the numeric rating scale work score. ρ, Spearman correlation coefficient.

NRS surgery: 9.2 ± 1.1; NRS exercise: 8.3 ± 2.1) than in the shoulders with a retear (ASES: 71.7 ± 9.1 [$P < .001$]; Constant: 66.8 ± 5.8 [$P < .001$]; Constant strength: 9.2 ± 3.4 [$P = .001$]; SST: 9.4 ± 1.1 [$P < .001$]; NRS pain: 3.6 ± 0.9 [$P < .001$]; NRS surgery: 6.2 ± 2.3 [$P < .001$]; NRS exercise: 2.8 ± 0.4 [$P < .001$]) at final follow-up. There was no significant difference between the shoulders with and without retears for the NRS work score (8.2 ± 2.0 vs 6.6 ± 2.6, respectively; $P = .136$).

Correlation Between Multiple Clinical Scores and NRS Scores

The NRS pain score showed a significant negative correlation with ASES, Constant, Constant strength, and SST scores ($\rho = -0.775$, -0.668, -0.436, and -0.742, respectively; $P = .016$ for Constant strength score and $P < .001$ for the remaining 3 scores). The NRS surgery score showed a significant positive correlation with Constant and SST scores ($\rho = 0.393$ [$P = .032$] and $\rho = 0.456$ [$P = .011$], respectively). The NRS work score showed a significant positive correlation with ASES, Constant, and SST scores ($\rho = 0.382$ [$P = .037$], $\rho = 0.386$ [$P = .035$], and $\rho = 0.414$ [$P = .023$], respectively). The NRS exercise score showed a significant positive correlation with ASES, Constant, Constant strength, and SST scores ($\rho = 0.567$ [$P = .001$], $\rho = 0.511$ [$P = .004$], $\rho = 0.511$ [$P = .004$], and $\rho = 0.639$ [$P < .001$], respectively) (Figures 3-6).

Complications

No patients had neural injuries, wound infections, or suture anchor problems at the final visit. In 1 patient, we experienced difficulty with the anchor during knot tying of middle-row sutures because of the anchor pulling out. However, we reinserted a larger anchor at the time of surgery.

DISCUSSION

The uniqueness of this study is that, to find the value of performing ALSDR on active patients with large delaminated RCTs, we investigated not only the improvement in clinical scores and the retear rate but also the

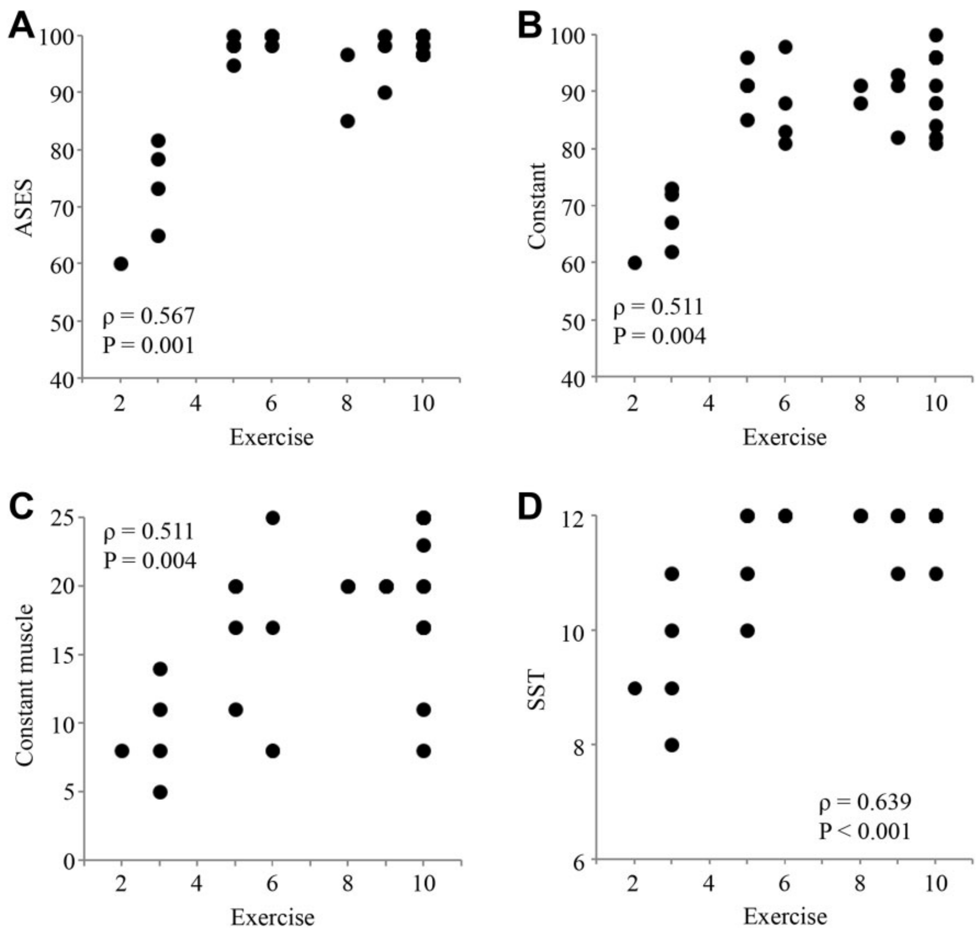

Figure 6. Scatter plot showing the correlation between the (A) American Shoulder and Elbow Surgeons (ASES), (B) Constant, (C) Constant strength, and (D) Simple Shoulder Test (SST) scores and the numeric rating scale exercise score. ρ, Spearman correlation coefficient.

correlation between clinical scores and NRS scores for pain and activity level (surgery, work, and exercise). The most important finding of this study was the high healing rate and good improvement in outcome scores in patients with this difficult tear pattern. Note that there was only 1 patient (3.3%) who was a smoker, which might have played a role in the high healing rate that we found (83.3%). Additionally, the present study demonstrated 2 findings: (1) patients with healed rotator cuff tendons had significantly higher clinical scores than patients with retears at final follow-up, and (2) multiple outcome scores (ASES, Constant, Constant strength, and SST) significantly correlated with NRS pain, surgery, work, and exercise scores. These findings support our hypothesis that ALSDR can provide good functional results in active patients with large delaminated RCTs.

Some previous studies have reported that rotator cuff tendon healing at the repair site correlated with clinical improvement, particularly in the recovery of muscle strength, although structural failure (rotator cuff tendon retear) did not always imply clinical failure.[3,6,12,14,25,28] Indeed, in this study, shoulders with intact rotator cuff tendons had significantly higher Constant and Constant strength scores than the improved scores in shoulders with a retear (rotator cuff tendon failure). However, the Constant score is a self- and examiner-based tool.[16] For the ASES and SST, healed shoulders also had significantly higher scores than unhealed shoulders. However, these 2 outcome measures are based solely on patient self-assessment, which is a subjective tool. Hence, we used the Constant score as an objective assessment and the ASES and SST as subjective assessments to assess the efficacy of ALSDR. Therefore, in our active patients, greater pain relief and muscle strength restoration were associated with greater patient satisfaction with their clinical results and individual activity level recovery.

For active patients with RCTs, an anatomically intact repair site may be necessary for satisfaction and functional recovery because these patients usually engage in more physically active recovery.[6,12,23,35] Several previous studies have shown a correlation between retears and satisfaction with surgery or between retears and unsuccessful outcomes after rotator cuff repair. Kim et al[14] demonstrated that patients with a full-thickness rotator cuff retear had significantly lower subjective shoulder function compared with those without a retear, especially for younger patients. Namdari et al[25] described an association between a labor-intensive occupation and outcomes after structural failure of rotator cuff repair. These studies support the use of ALSDR to ensure structural integrity for a satisfactory outcome in physically active patients.

Several authors have carried out a histological assessment of delaminated RCTs.[18,19,32] Clark and Harryman[4] demonstrated that rotator cuff tendons are composed of 5 layers, with layers 2 and 3 containing the fibers of the supraspinatus and infraspinatus tendons and layer 5 being the true joint capsule of the shoulder. Matsuki et al[19] and MacDougal and Todhunter[18] stated that delamination appears to be a separation of layers 2 and 3 (as described by Clark and Harryman[4]) in rotator cuff tendons, while Sonnabend et al[32] reported that a synovium-like lining was often present in delaminated layers. In contrast to these opinions, we regard the thick inferior layer as a complex structure including at least layer 5 (capsule), which stabilizes the glenohumeral joint.[20] A recent study by Nimura et al[26] showed that the attachment of the shoulder joint articular capsule occupied a substantial area of the greater tuberosity. The articular side of the rotator cuff insertion is under greater stress during shoulder movements.[30,36] These reports support the rationale for using ALSDR.[20,26,30,36]

Park et al[27] reported a retear rate for en masse suture bridge repair of large to massive delaminated RCTs of 19% (4/21 shoulders), which was comparable with our retear rate (16.7%) in patients with similarly sized tears. In other words, ALSDR may not significantly reduce the retear rate compared with en masse suture bridge repair. Indeed, there were no significant differences between intact shoulders and shoulders with a retear in terms of baseline variables such as tear size, number of suture anchors, and fatty degeneration in each rotator cuff muscle (see Table 2). ALSDR is a combination of separate double-row repair with suturing of the superior and inferior layers in a mattress fashion, which may avoid tendon mismatch and ensure articular-side fixation.[22] However, there is a disadvantage to ALSDR in that the knots for articular-side lamina repair have to be buried within the repaired tendons, which may lead to an inflammatory foreign-body response and negatively produce strangulation and necrosis of the repaired tendon, possibly resulting in poor tendon healing.[11] Kim et al[15] compared en masse repair and separate double-layer double-row fixation for the treatment of delaminated RCTs, finding lower pain scores in patients undergoing separate double-layer double-row fixation. Nakamizo and Horie[24] compared en masse repair and double-layer suture bridge repair for the treatment of delaminated RCTs, finding better range of motion in patients undergoing double-layer suture bridge repair. However, these studies did not investigate the reason for such differences in their results.[15,24] We also could not clarify the cause of retears based on our results. Therefore, further trials with a reduced number of anchors should be considered.[11]

This study has several limitations. First, the data were prospectively collected but retrospectively reviewed. Second, the mean follow-up period was in the short-term to midterm range. Third, although the objective outcome measures were assessed by the treating surgeon and a clinical assistant not involved in the study for verification and to avoid assessment errors, the possibility of observer bias remains. The structural outcomes assessment included the same weakness, despite good intraobserver reliability in the 3 observers. Fourth, we did not have a control group to compare ALSDR with other conventionally used techniques, such as en masse suture bridge repair or separate double-layer double-row fixation for large delaminated RCTs. However, based on the data from the present study, we believe that, to assess a new shoulder treatment method in clinical practice, a combination of reliable and previously tested shoulder outcome instruments and subjective patient assessments of satisfaction with the treatment and recovery of quality of life during work and/or sports is helpful.

CONCLUSION

Our results showed that there was a significant correlation between clinical and NRS scores. The results indicate that ALSDR can provide high functionality, allowing active patients with large delaminated RCTs the ability to meet desired activity levels.

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APPENDIX

TABLE A1
11-Point Numeric Rating Scales

A **I would like to know when the intensity of your shoulder pain occurs**

	↓ Mark Your Pain Intensity Here ↓										
	← Least					Pain				Worst →	
Symptoms	0	1	2	3	4	5	6	7	8	9	10
Strenuous activity											
When resting											
While sleeping											

B **I would like to know how useful you find your shoulder to be. Please check 0 if the body part is useless. Please check 10 if the body is completely normal**

Please ✓ check your satisfaction rating											
of the usefulness of:	← **Dissatisfied**								**Satisfied** →		
	0	1	2	3	4	5	6	7	8	9	10
Operated shoulder											

C **"How would you describe the level of physical demand at your work?" Please ✓ check your working rating of the usefulness**

0	1	2	3	4	5	6	7	8	9	10

- 0: Absolutely sedentary
- 2: Mostly desk work with a little physical work
- 5: 50% desk work 50% manual labor
- 7: Mostly manual labor combined with some desk work
- 10: Absolutely hard manual labor

D **"How would you describe the level of physical demand with your sports/recreational activities?" Please ✓ check your working rating of the usefulness**

0	1	2	3	4	5	6	7	8	9	10

- 0: No exercise
- 2: 1-4 times/month of light exercise
- 5: 1-3 times/week of moderate exercise
- 7: 1-3 times/week of vigorous exercise
- 10: > 3 times/week of vigorous exercise

Light exercise: walking, water aerobics, stretching, etc
Moderate exercise: jogging, light swimming, recreational golfing, etc
Vigorous exercise: tennis, baseball, basketball, lap swimming, running, long distance bicycling weight lifting, fitness dancing, competitive golfing, etc

TABLE A2
Demographics

Patient No.	Sex	Age at Surgery, y	Side	Follow-up, mo	Occupation	Sport
1	Male	50	Right	61	Farmer	Recreational golf
2	Male	54	Right	73	Farmer	Jogging
3	Male	61	Right	71	Farmer	Recreational golf
4	Male	55	Left	83	Manual worker	Running
5	Male	64	Right	73	Landscaping	Weight lifting
6	Male	62	Right	58	Carpenter	Light swimming
7	Male	62	Right	61	Waste collector	Weight lifting
8	Male	59	Right	73	Pharmacy clerk	Jogging
9	Male	57	Left	74	Manual worker	Tennis
10	Male	71	Right	64	Landscaping	Tennis
11	Male	66	Left	65	Carpenter	Weight lifting
12	Male	58	Right	60	Carpenter	Tennis
13	Female	64	Right	56	Housewife	Classical dance
14	Female	68	Right	63	Housewife	Tennis
15	Male	51	Left	52	Landscaping	Weight lifting
16	Male	58	Left	61	Waste collector	Jogging
17	Male	46	Right	71	Manual worker	Recreational golf
18	Female	61	Right	71	Cook	Recreational golf
19	Male	72	Right	68	Landscaping	Jogging
20	Male	53	Left	88	Truck driver	Swimming
21	Male	72	Right	72	Farmer	Recreational golf
22	Male	52	Right	78	Therapist	Weight lifting
23	Male	68	Left	65	Carrier	Mountain biking
24	Male	55	Left	61	Forklift driver	Weight lifting
25	Male	43	Right	68	Carpenter	Weight lifting
26	Male	62	Left	85	Manual worker	Recreational golf
27	Male	52	Left	54	Manual worker	Recreational baseball
28	Male	66	Left	54	Carpenter	Recreational golf
29	Female	53	Right	63	Farmer	Swimming
30	Male	58	Left	32	Cook	Swimming
Mean ± SD		59.1 ± 7.5		65.9 ± 11.1		

TABLE A3
Rotator Cuff Integrity and Functional Outcomes[a]

Patient No.	Rotator Cuff Integrity[b]	NRS Pain		ASES Score		Constant Score		Constant Strength Score		SST
		Preoperative	Postoperative	Preoperative	Postoperative	Preoperative	Postoperative	Preoperative	Postoperative	Postoperative
1	Type II	7.0	0.0	33.3	96.7	25.0	91.0	5.0	20.0	10.0
2	Type II	7.0	0.0	43.3	96.7	48.0	96.0	8.0	25.0	12.0
3	Type V	5.0	3.0	56.7	73.3	58.0	72.0	11.0	14.0	9.0
4	Type II	8.0	0.0	44.5	100.0	51.0	91.0	8.0	20.0	12.0
5	Type II	7.0	0.0	53.3	98.3	42.0	91.0	8.0	17.0	12.0
6	Type II	7.0	1.0	31.7	90.0	41.0	82.0	5.0	20.0	11.0
7	Type II	7.0	0.0	33.3	100.0	35.0	91.0	5.0	20.0	11.0
8	Type II	7.0	0.0	35.0	96.7	47.0	96.0	8.0	25.0	12.0
9	Type II	7.0	0.0	44.3	100.0	52.0	98.0	8.0	25.0	12.0
10	Type II	4.0	0.0	59.9	100.0	58.0	81.0	11.0	8.0	12.0
11	Type II	6.0	0.0	38.3	100.0	42.0	88.0	5.0	17.0	12.0
12	Type I	5.0	0.0	54.9	100.0	51.0	96.0	8.0	25.0	12.0
13	Type V	7.0	5.0	45.0	65.0	49.0	62.0	5.0	5.0	8.0
14	Type II	6.0	0.0	49.9	100.0	55.0	83.0	8.0	8.0	12.0
15	Type V	7.0	3.0	36.7	81.7	41.0	67.0	5.0	8.0	11.0
16	Type I	8.0	2.0	41.7	85.0	48.0	88.0	8.0	20.0	12.0
17	Type II	6.0	0.0	56.6	98.3	52.0	96.0	5.0	20.0	12.0
18	Type V	8.0	4.0	28.3	60.0	20.0	60.0	2.0	8.0	9.0
19	Type II	5.0	0.0	56.7	94.9	50.0	85.0	11.0	11.0	10.0
20	Type II	7.0	0.0	45.0	100.0	48.0	100.0	11.0	20.0	12.0

(continued)

TABLE A3 (continued)

Patient No.	Rotator Cuff Integrity[b]	NRS Pain		ASES Score		Constant Score		Constant Strength Score		SST
		Preoperative	Postoperative	Preoperative	Postoperative	Preoperative	Postoperative	Preoperative	Postoperative	Postoperative
21	Type I	6.0	0.0	43.3	98.3	39.0	81.0	2.0	8.0	12.0
22	Type II	5.0	0.0	46.7	100.0	56.0	96.0	11.0	23.0	12.0
23	Type II	6.0	0.0	51.7	100.0	49.0	88.0	8.0	17.0	12.0
24	Type V	8.0	3.0	27.7	78.3	32.0	73.0	8.0	11.0	10.0
25	Type I	6.0	0.0	43.3	98.3	51.0	93.0	8.0	20.0	12.0
26	Type I	9.0	0.0	11.7	100.0	38.0	91.0	8.0	20.0	12.0
27	Type II	5.0	0.0	51.6	100.0	54.0	88.0	11.0	17.0	12.0
28	Type II	8.0	0.0	28.3	96.7	38.0	84.0	8.0	11.0	11.0
29	Type II	5.0	0.0	48.3	98.3	49.0	82.0	8.0	17.0	12.0
30	Type II	5.0	0.0	43.3	100.0	45.0	96.0	8.0	25.0	12.0
Mean ± SD		6.5 ± 1.2	0.7 ± 1.4	42.8 ± 10.9	93.6 ± 11.0	45.5 ± 9.1	86.2 ± 10.5	7.5 ± 2.5	16.8 ± 6.2	11.4 ± 1.1

[a]ASES, American Shoulder and Elbow Surgeons; NRS, numeric rating scale; SST, Simple Shoulder Test.
[b]Retear represents any repair integrity that was rated type III to V according to the classification of Sugaya et al.[33]

TABLE A4
Shoulder Range of Motion and NRS Scores[a]

Patient No.	Forward Flexion, deg		External Rotation, deg		Internal Rotation[b]		Postoperative NRS Score		
	Preoperative	Postoperative	Preoperative	Postoperative	Preoperative	Postoperative	Surgery	Work	Exercise
1	90.0	140.0	30.0	40.0	L1 (13)	L1 (13)	10.0	9.0	8.0
2	160.0	160.0	60.0	45.0	L1 (13)	L1 (13)	7.0	7.0	10.0
3	145.0	160.0	60.0	20.0	L1 (13)	T12 (12)	7.0	9.0	3.0
4	120.0	170.0	30.0	60.0	L3 (15)	L1 (13)	9.0	10.0	10.0
5	120.0	170.0	30.0	45.0	L3 (15)	L1 (13)	10.0	7.0	5.0
6	110.0	170.0	40.0	45.0	Buttock (19)	L3 (15)	9.0	5.0	9.0
7	90.0	150.0	30.0	50.0	L3 (15)	L1 (13)	8.0	7.0	5.0
8	110.0	170.0	40.0	70.0	L3 (15)	T12 (12)	9.0	7.0	10.0
9	170.0	150.0	50.0	50.0	L1 (13)	T10 (10)	10.0	5.0	6.0
10	140.0	170.0	40.0	45.0	L1 (13)	L2 (14)	10.0	10.0	10.0
11	130.0	170.0	15.0	65.0	Buttock (19)	L1 (13)	10.0	5.0	10.0
12	120.0	170.0	40.0	70.0	L3 (15)	L3 (15)	9.0	10.0	10.0
13	160.0	160.0	40.0	60.0	L1 (13)	L1 (13)	3.0	3.0	3.0
14	140.0	170.0	40.0	55.0	L1 (13)	T7 (7)	7.0	5.0	6.0
15	140.0	165.0	40.0	45.0	Buttock (19)	L1 (13)	9.0	5.0	3.0
16	140.0	165.0	40.0	50.0	L1 (13)	T8 (8)	10.0	9.0	8.0
17	160.0	165.0	60.0	55.0	L1 (13)	L1 (13)	10.0	10.0	5.0
18	60.0	160.0	–10.0	50.0	Buttock (19)	T12 (12)	7.0	7.0	2.0
19	130.0	155.0	40.0	35.0	Buttock (19)	L1 (13)	10.0	7.0	5.0
20	140.0	170.0	20.0	50.0	Buttock (19)	T9 (9)	10.0	10.0	10.0
21	120.0	170.0	30.0	55.0	L1 (13)	T9 (9)	7.0	5.0	6.0
22	150.0	170.0	30.0	60.0	L2 (14)	T9 (9)	10.0	10.0	10.0
23	140.0	170.0	20.0	65.0	L5 (18)	L1 (13)	10.0	10.0	10.0
24	90.0	155.0	20.0	30.0	Buttock (19)	L1 (13)	5.0	9.0	3.0
25	130.0	170.0	30.0	60.0	L5 (18)	T12 (12)	10.0	10.0	9.0
26	100.0	170.0	20.0	60.0	Buttock (19)	L1 (13)	9.0	9.0	9.0
27	150.0	170.0	40.0	60.0	L1 (13)	T12 (12)	9.0	9.0	6.0
28	110.0	160.0	20.0	60.0	L1 (13)	L1 (13)	10.0	8.0	10.0
29	140.0	170.0	20.0	60.0	L5 (18)	L1 (13)	10.0	10.0	10.0
30	110.0	170.0	20.0	60.0	Buttock (19)	L1 (13)	8.0	10.0	10.0
Mean ± SD	127.2 ± 25.2	164.5 ± 7.9	32.8 ± 14.8	52.5 ± 11.4	15.7 ± 2.7	12.1 ± 1.9	8.7 ± 1.7	7.9 ± 2.1	7.4 ± 2.8

[a]NRS, numeric rating scale.
[b]For internal rotation, we converted values into contiguously numbered groups: levels T1-T12 to 1-12, levels L1-L5 to 13-17, the sacrum to 18, and the buttock to 19.