Benefits of Patch Augmentation on Rotator Cuff Repair

A Systematic Review and Meta-analysis

André Luís Lugnani de Andrade,*† MD, PhD, Thiago Alves Garcia,‡ MS, Henrique de Sancti Brandão,† MD, Amanda Veiga Sardeli,§ PhD, Guilherme Grisi Mouraria,† MD, PhD, and William Dias Belangero,‖ MD, PhD

Investigation performed at School of Medical Sciences, Campinas State University, Campinas, São Paulo, Brazil

Background: Despite technological advances, the overall retear rate on rotator cuff repair is still high. Patches have shown significant reduction in retear rate and pain scores; however, this is not a universal finding and conflicting results have been shown among functional shoulder scales.

Purpose: To analyze previous controlled trials of the literature to bring a consensus about the effectiveness of patch use on rotator cuff repair.

Study Design: Systematic review; Level of evidence, 1.

Methods: The search was conducted in PubMed, Web of Science, EMBASE, Scopus, and Cochrane in April 2020. The results of rotator cuff repair with patch augmentation versus without augmentation (control) were compared through odds ratio (OR), raw mean difference (RMD), and standardized mean difference (SMD) of retear rate; functional shoulder scales; strength; and range of motion (ROM).

Results: Of 733 initial studies, 7 of them met the criteria to be included in the analysis. Compared with the control group, the patch augmentation group had a significantly lower retear rate (OR, 0.32 [95% CI, 0.18 to 0.55]; $P < .001$), lower pain (SMD, –0.42 [–0.71 to –0.12]; $P < .01$), a higher University of California Los Angeles Shoulder Rating Scale (RMD, 0.87 [0.15 to 1.60], $P = .017$), and a trend toward higher strength (SMD, 0.95 [–0.03 to 1.94], $P = .05$) and lower forward elevation ROM (RMD, –10.50 [–21.86 to 0.67]; $P = .06$), while no changes were noted for other functional scales or for internal and external rotation ROM.

Conclusion: The results point to benefits of patch augmentation in rotator cuff repair, particularly a reduction in retear rate. More interventional studies with better methodological quality should be conducted to confirm the results of this initial review.

Keywords: rotator cuff; retear; surgery; shoulder injury; patch; patch augmentation; arthroscopy

Rotator cuff tear is the most common dysfunction of the upper limbs, reaching a prevalence of 1 in every 3 persons older than 60 years of age.[27] Usually after inefficient nonoperative treatment, patients undergo rotator cuff repair to reattach the injured tendon on the humeral head. According to the National Health Service, more than 17,000 rotator cuff repair surgical procedures are performed each year in the United Kingdom.[28] Despite technological advances and a high number of performed procedures, the overall retear rate can range from 3% to as high as 46% if the tear is massive or the patient is older.[17,24,31]

Patches can be made of biological material and are expected to facilitate the insertion of the tendon on bone as a mechanical or biological support that self-integrates tissues, favoring vascularization and local cellular growth.[1,12,35] An experimental study found effective healing with the use of biological patch compared with debridement in a canine model.[34]

The recommendation of patch use seems to increase over time.[4] A few studies have shown that patch augmentation significantly reduces retear rate[2,7] and pain scores[26]; however, other studies found contrary results for retear rate[16] and pain.[2,23] Regarding functionality, findings have differed according to subjective outcome scales. For example, in a 2019 randomized controlled trial, significantly higher Constant scores were seen in the patch augmentation group versus patients without augmention, while Simple

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Shoulder Test (SST) scores were not significantly different.[2] Patch augmentation also affects muscle strength and range of motion (ROM) in different ways,[33] depending on the specific movements tested, which suggests that these different outcomes, specific functional outcomes, and specific movements are all confounding factors that should be taken into account to better address the true benefits of a patch.

A meta-analysis by Bailey et al[3] compared the subjective and objective outcomes in retrospective studies of patients undergoing patch augmentation versus rotator cuff repair alone. This meta-analysis suggested a lower retear rate and improvement in one of the subjective functional scales (American Shoulder and Elbow Surgeons Shoulder Score [ASES]), while no change was seen on the other scale (University of California Los Angeles Shoulder Rating Scale [UCLA]) or on the visual analog scale (VAS) for pain.[3] Because that analysis considered the baseline condition (ie, repair without patch augmentation), an investigation of interventional studies is important to isolate the effects of patch augmentation independently of individual condition (such as the higher likelihood of massive tears in the patch groups). Furthermore, in an updated search we found more controlled trials than the 2 studies[5,26] included in the Bailey et al[3] meta-analysis; these additional studies would allow further understanding of the effects of patch augmentation on rotator cuff repair.

The purpose of the present study was to analyze interventional studies in the literature to bring a consensus about the effectiveness of patch augmentation on rotator cuff repair. We hypothesized that the summarized effects calculated for retear rate, muscle strength, pain, ROM, and subjective functional shoulder scales would be improved in patients undergoing rotator cuff repair with patch augmentation.

METHODS

This systematic review and meta-analysis was reported in accordance with the recommendations of the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) statement.[25]

Eligibility Criteria

To answer the research question, we needed (1) interventional studies (2) with no population restrictions (3) that compare the effects of rotator cuff repair using patch augmentation with those of rotator cuff surgical procedures without patch augmentation (controls), (4) report measures for at least 1 of the main outcomes—retear rate, outcome scores (VAS, UCLA, Constant, ASES, and SST), strength, and ROM—(5) with at least 12 months postoperative follow-up, and (6) are written in English.

Search Strategy

A systematic search was conducted in PubMed (Medline), Web of Science, EMBASE, Scopus, and Cochrane Central Register of Controlled Trials (CENTRAL) with the last update in April 2020. The search combined the synonyms of "rotator cuff surgery" and "patch" according to each database's descriptors and fields of search as detailed in Appendix Table A1.

Study Selection

After the duplicates were automatically removed with Mendeley reference manager, 2 independent researchers (T.A.G. and H.S.B.) screened the studies by title and abstract reading using Rayyan software.[29] Any conflicts were resolved by a third researcher (A.L.L.A.).

Risk-of-Bias Assessment

The Physiotherapy Evidence Database (PEDro) scale quantified the quality of the studies, and the scores on the PEDro scale ranged from 0 (very low methodological quality) to 10 (high methodological quality). The first of the 11 questions (eligibility criteria specified) was qualitatively described but not included in the sum, according to the scale's guidelines.[22] The quality of the studies was used only for qualitative purposes and was not an exclusion criterion.

Evidence Quality

The quality of evidence was assessed by the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach, by giving 1 point for each of the 5 evaluation items for clinical studies: risk of bias, imprecision, inconsistency, indirectness, and publication bias.[15] The quality of evidence can range from very low ($\leq$1) to high (4).

Data Collection Process

Means, standard deviations, and sample sizes for the patch augmentation and control groups were collected for analysis of VAS pain, UCLA, Constant, ASES, SST, ROM, and

*Address correspondence to André Luís Lugnani de Andrade, MD, PhD, Campinas State University, Clinics' Hospital, Rua Tessália Vieira de Camargo, 126 - Cidade Universitária Zeferino, Campinas, SP, 13083-887, Brazil (email: drandre@unicamp.br).
†Clinical Hospital, State University of Campinas, Campinas, São Paulo, Brazil.
‡Orthopaedic Biomaterials Laboratory (LABIMO), School of Medical Sciences, State University of Campinas, Campinas, São Paulo, Brazil.
§Exercise Physiology Laboratory, School of Medical Sciences, State University of Campinas, Campinas, São Paulo, Brazil.
‖School of Medical Sciences, State University of Campinas, Campinas, São Paulo, Brazil.
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strength. One study[5] presented just one value of SD for pre- and postoperative values, and we used this same standard deviation for each time point, considering it could be a mean of pre- and postoperative standard deviations, even though it was not described. To analyze the odds ratios (ORs) of retear rate for the patch versus control groups, we collected data from the patients who experienced retear in each group. The number of retears was assessed by magnetic resonance imaging in all studies. When studies reported the number of healed patients, we calculated the number of patients with retears by the following equation: *retear = total – healed*. In general, the rotator cuff repair was considered healed when there was no communication through the intra-articular and subacromial environment, even when the tendon had a partial-thickness tear. A rotator cuff was not considered to be healed when it had a full-thickness tear, even when injuries were reduced compared with the preoperative condition.

Outcomes were assessed at different postoperative time points, including 3, 6, 12, 24, and 35 months, and the inclusion of more than 1 time point from each study in the meta-analyses could lead to sample overlap (ie, the results of the same individuals could be included more than once), which in turn would erroneously estimate the population effects. As most of the included studies reported their outcomes at 12 months, and considering that at 12 months most of the retears and improvements in functional outcomes had already occurred,[9,20,37] we selected this time point when it was available and chose the closest time point to 12 months when not available. We extracted the data reported at other time points for complementary analysis. We also extracted the type of movement (ie, external rotation, internal rotation, and forward elevation) for ROM assessments. For strength analysis, the abduction measurements were chosen, because all studies with strength measurements tested this movement.

Statistical Analysis

The meta-analyses were performed using Comprehensive Meta-Analysis software (Version 3.3.070; Biostat Inc). We performed 10 meta-analyses: 1 for each outcome measure (retear rate, VAS pain, UCLA, Constant, ASES, SST, and strength) and the 3 different ROM movements (external rotation, internal rotation, and forward elevation). The effect size was calculated based on either the pre- versus postoperative difference in outcomes between the patch augmentation and control groups (VAS, UCLA, Constant, ASES, SST, ROM, and strength) or the difference in the number of individuals with retears between the patch and control groups. When the variables were presented in the same unit in all studies, we used the raw mean difference (RMD), which is the own absolute effect score of each outcome variable (eg, UCLA, Constant, ASES, ROM). VAS, SST, and strength assessments were not presented with the same units in all studies; thus, we calculated the standardized mean difference (SMD). The retear rate was presented as an OR since the studies offered the number of events in the patch and control groups. When there was significant heterogeneity ($P \leq .05$), we calculated the randomized effect (ie, retear rate, Constant, strength, and external rotation ROM), and when there was no significant heterogeneity ($P > .05$), we used fixed effects (ie, VAS, UCLA, ASES, SST, and internal rotation and forward elevation ROM). Publication bias was analyzed by the Egger test in each meta-analysis, and $P \leq .05$ was considered significant.[13]

The percentage of heterogeneity between studies was presented as the I^2 statistic. We tested the effects of patch augmentation at different time points when there were enough studies to be compared (at least 3 for each subgroup), and thus, different time points were presented for VAS and Constant scores. The effects of patch augmentation were compared between randomized and nonrandomized studies for the Constant score since there was significant heterogeneity in this analysis.

RESULTS

Study Selection

From 733 studies, 187 were removed as duplicates, and among the studies excluded by reading the titles and abstracts (n = 539), there were studies that did not use patch, studies that used patch in other locations, nonoriginal studies, nonhuman studies, other study designs, and cadaveric studies (Figure 1). Only 1 study that matched our study criteria had to be removed since it used xenograft tissue that had been recalled from the market owing to failure.[16] Ultimately, 7 studies[2,5-7,23,26,32] were included in the systematic review, and 10 meta-analyses were constructed from their data (1 for each outcome).

Some studies presented different classifications. For example, Cai et al[7] classified the levels of healing from 1 to 5, with levels 4 and 5 considered retears. Mori et al[26] presented 2 tendon retears apart from the 3 patch retears in the patch group, and they were summed for analysis. In Avanzi et al,[2] the partially healed and not healed individuals were combined in the retear group for analysis.

Study Characteristics

Most studies included both sexes among the patients; the patients' age varied between 34 and 80 years. Regarding surgical technique, there was some variation on how the patch was attached, but in general, 2 anchors with sutures was the method used in most of the studies for the repair of the rotator cuff tear (Table 1). The rehabilitation protocols were similar among the studies (Appendix Table A2); they included approximately 6 weeks of immobilization with a sling, and active contractions were introduced after this time. Although Maillot et al[23] and Rosales-Varo et al[32] were nonrandomized studies and Mori et al[26] was a retrospective comparative study, the variance within these studies was not different from the other studies.

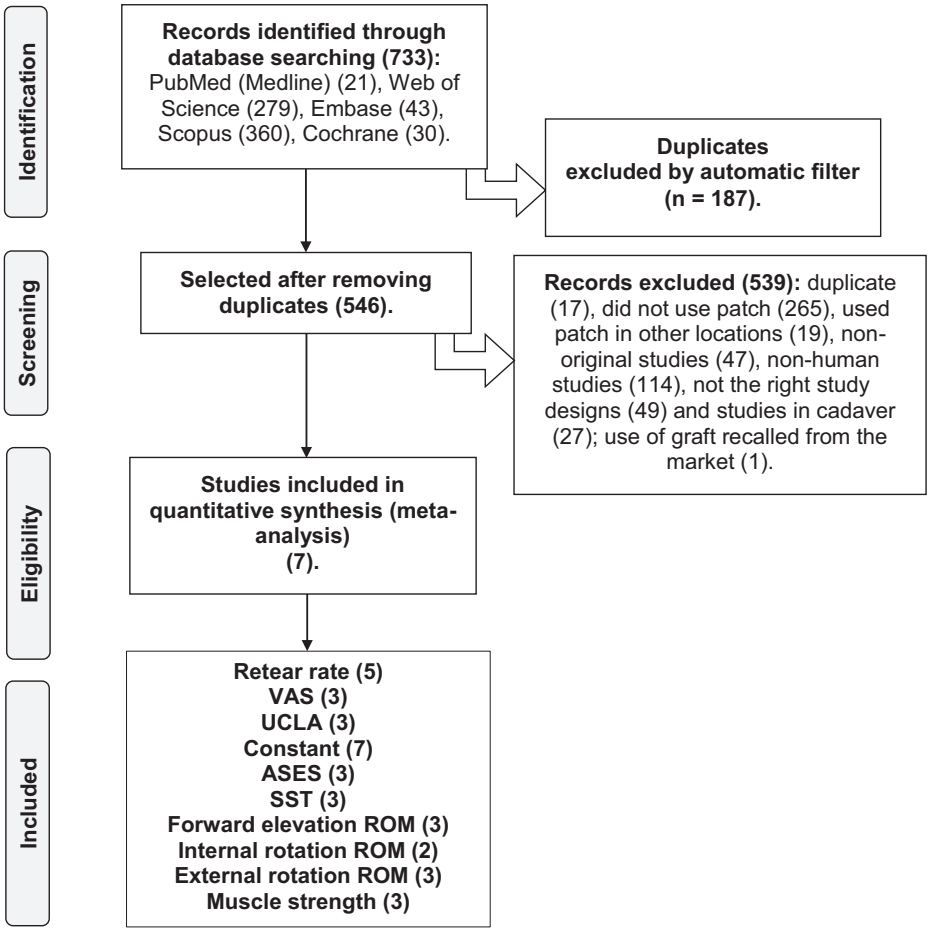

Figure 1. Flow diagram of study selection. ASES, American Shoulder and Elbow Surgeons Shoulder Score; ROM, range of motion; SST, Simple Shoulder Test; UCLA, University of California Los Angeles Shoulder Rating Scale; VAS, visual analog scale.

TABLE 1
Characteristics of Surgical Technique[a]

First Author (Year)	Associated Procedures (Patch/No Patch)	Tear Size[b]	Technique	Tendon Fixation	Implant	Patch Augmentation; Medial Fixation; Lateral Fixation	Follow-up Time
Avanzi (2019)[2]	Biceps tenotomy and decompression	Small and medium	Arthroscopy	Medial single row	2 double-loaded PEEK anchors	Onlay porcine dermal patch; 2 simple stitches at myotendinous junction; 2 metal knotless anchors lateral to the footprint	3, 6, 12, and 24 mo
Barber (2012)[5]	Subacromial decompression (20/18); Mumford (0/6); biceps tenodesis (4/5); biceps debridement (1/2); biceps tenotomy (1/1); labral debridement (3/3); SLAP repair (1/0)	Large (>3 and <5 cm)	Arthroscopy	Medial single row; Mason Allen or simple stitches	2 double- or triple-loaded anchors	Onlay acellular human dermal matrix; 2 stitches at myotendinous junction; 2 anchors lateral to the footprint	24 (mean) mo
Bryant (2016)[6]	Acromioplasty; rotator cuff release; medialization if necessary. Biceps debrided (3/2); tenodesis (10/5); removed osteophytes (3/1); excised distal clavicle joint (6/6)	Moderate to large tear	Open	At the base of tuberosity, up to 1 cm of medialization	Transosseous or absorbable anchors	Onlay porcine small intestine submucosa; baseball stitches at bursal surface; transosseous suture lateral to the tuberosity[c]	12 and 24 mo

(continued)

Table 1 (continued)

First Author (Year)	Associated Procedures (Patch/No Patch)	Tear Size[b]	Technique	Tendon Fixation	Implant	Patch Augmentation; Medial Fixation; Lateral Fixation	Follow-up Time
Cai (2018)[7]	None	Moderate to large tear	Arthroscopy	Double row	Suture anchors medial and lateral	3D type 1 collagen matrix between the rotator cuff and footprint; no medial or lateral fixation	6, 12, and 28 (mean) mo
Maillot (2018)[23]	Biceps tenotomy and decompression	Large and massive tears (>3 cm)	• Patch: open • Control: arthroscopy	• Patch: single row placed laterally to the bony trough	• Patch: 2 nonabsorbable suture anchors • Control: ≥2 suture anchors placed laterally to the bony trough	Onlay acellular porcine dermis; 4-10 anterior, posterior, and medial No. 2 Ethibond sutures; fixed to 2 single-row sutures	3,6, 12, and 24 mo
Mori (2013)[26]	Biceps tenodesis (<70 y) if partially torn or severely degenerated and tenotomy (>70 y); subacromial decompression; coracohumeral ligament and capsular release	Large and massive tear (>3 cm)	Arthroscopy	• Patch: posterior double row and anterior single row • Control: mostly double row	Double-loaded suture anchor	Onlay fascia lata autograft; mattress suture of medial row; single row	12 and 35 (mean) mo
Rosales-Varo (2018)[32]	1 case of acromioplasty	100-340 mm^2	Open	Double row	Metal anchor	Onlay fascia lata autograft; 2-0 Vicryl suture; 2-0 Vicryl suture	12 mo

[a]3D, 3-dimensional; PEEK, polyetheretherketone; SLAP, superior labrum anterior to posterior.
[b]Tear size was taken from each included study but was not specifically defined.
[c]Some patients had mattress sutures at the central bursal surface.

TABLE 2
PEDro Assessment of Study Quality[a]

	PEDro Scale Item[b]										
Study	1	2	3	4	5	6	7	8	9	10	11	Sum
Avanzi (2019)[2]	N	Y	Y	Y	Y	N	N	N	N	Y	Y	6
Barber (2012)[5]	N	Y	Y	N	N	N	Y	N	N	Y	Y	5
Bryant (2016)[6]	N	Y	Y	Y	Y	N	Y	Y	N	Y	Y	8
Cai (2018)[7]	N	Y	N	Y	N	N	Y	Y	N	Y	Y	6
Maillot (2018)[23]	N	N	N	N	N	N	N	N	Y	Y	Y	3
Mori (2013)[26]	N	N	N	Y	N	N	Y	N	N	Y	Y	4
Rosales-Varo (2018)[32]	N	N	N	Y	N	N	N	Y	Y	Y	Y	5

[a]N, no; Y, yes. PEDro, Physiotherapy Evidence Database.
[b]1 = eligibility criteria specified; 2 = random allocation; 3 = concealed allocation; 4 = groups similar at baseline; 5 = patient blinding; 6 = surgeon blinding; 7 = assessor blinding; 8 = <15% drop-outs; 9 = intention-to-treat analysis; 10 = between-group statistical comparisons; 11 = point measures and variability data.

Risk of Bias Within Studies

The quality of the included studies varied from 3 to 8 on the PEDro scale (Table 2), with all studies lacking specification of clear eligibility criteria and the ability to achieve surgeon blinding, which was expected. Fundamental methodological rigor, such as random and concealed allocation, patient and assessor blinding, and similar groups at baseline, were also lacking in many studies.

Quality of Evidence

We considered the 5 items suggested by GRADE. Since there was important risk of bias in the primary studies (Table 2), 1 point was removed for the first item. Most analyses were homogeneous, but a few showed considerable inconsistency (I^2 = 75%-100%); thus, we removed 1 point from the following analyses: Constant, external rotation ROM, and strength. We did not remove any points for indirect evidence, since all studies tested intervention effects and also included a control group for comparisons. We did not remove any points for publication bias, as the Egger test P values (>.05) confirmed this was not significant. Regarding imprecision, 1 point from each analysis was removed because the sample size in most analyses was lower than 100, with the exception of retear rate (sample sizes of 180 [patch] and 165 [control]). Thus, the quality of evidence (ie, GRADE score) varied from very low (1) to moderate (3), as follows: retear rate (3), VAS (3), UCLA (2), Constant (1), ASES (2), SST (2), forward elevation ROM (2), internal rotation ROM (2), external rotation ROM (1), and muscle strength (1).

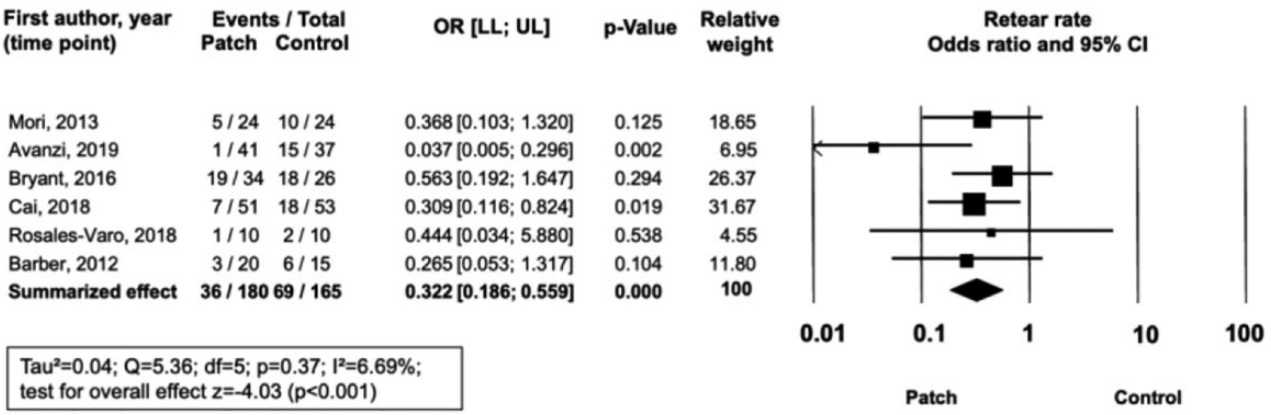

Figure 2. Forest plot of retear rate between patch augmentation and control groups. LL, 95% CI lower limit; OR, odds ratio; UL, 95% CI upper limit.

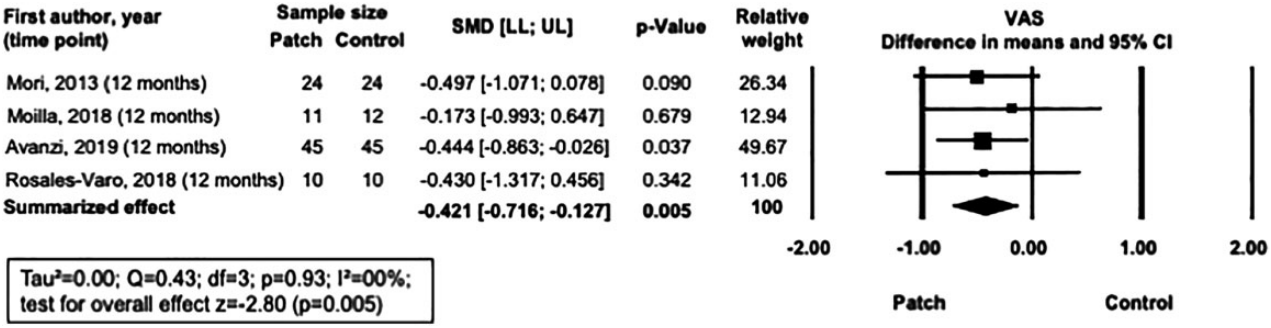

Figure 3. Forest plot of visual analog scale's (VAS) standardized mean difference (SMD) between patch augmentation and control groups. LL, 95% CI lower limit; UL, 95% CI upper limit.

Evidence Synthesis

Patch augmentation led to beneficial effects, such as a lower retear rate (Figure 2), lower VAS (Figure 3), a higher UCLA score (Figure 4A), a trend toward lower forward elevation ROM (Figure 5A), and higher strength (Figure 6).

There was a significantly lower retear rate for patch augmentation compared with control (OR, 0.322 [95% CI, 0.186 to 0.559]; $P < .001$), and the analysis was very homogeneous ($I^2 = 6.69$; $P = .37$).

Sensitivity analyses were performed for 6 and 12 months within the VAS and for 6, 12, and 24 months within the Constant meta-analyses. Results indicated that patch augmentation improved VAS scores at 12 months but not at 6 months; Constant scores improved at 6 months but not at 12 or 24 months (Table 3).

For the Constant score, it was also possible to test the effects of the randomized studies[2,5-7] on patch augmentation effects. Isolating the randomized studies for analysis led to no significant patch effects and maintained the high heterogeneity in this analysis ($I^2 = 88.44\%$). In addition, there was no difference ($P = .65$) between RMD of the nonrandomized studies[23,26,32] (0.08 [95% CI, –4.52 to 4.69]; $P = .97$) versus the randomized studies (2.12 [–5.23 to 9.46]; $P = .57$).

DISCUSSION

The present meta-analyses showed that the addition of patch on rotator cuff repair led to a significantly reduced retear rate (OR, 0.32 [95% CI, 0.186 to 0.559]; $P < .001$) (Figure 2) and pain score (SMD, –0.421 [–0.716 to –0.127]; $P = .005$) (Figure 3) as well as improvement in shoulder functionality as assessed by UCLA (RMD, 0.879 [0.155 to 1.602]; $P = .017$) (Figure 4A). However, there was no improvement in the other functional scales (Constant: RMD, 1.471 [95% CI, −3.434 to 6.377], $P = .557$; ASES: RMD, 1.463 [–2.868 to 5.793], $P = .508$); and SST: SMD, –0.248 [–0.569 to 0.074]; $P = .131$) (Figure 4B–D) or objective criteria, such as ROM ($P > .05$ for the 3 types of movements) (Figure 5) and strength (SMD, 0.955 [–0.038 to 1.948]; $P = .059$) (Figure 6).

Rotator cuff repair aims to restore the normal anatomy and reestablish the envelope. Included in the range of techniques to achieve this goal, musculotendon repair, where the ruptured tendon is reinserted in the humeral head, is the most common. Although the surgery provides the required conditions to tendon reintegration, the complete process can take a few months. In this study, we considered 12 months as the standard time point for the analysis, since the majority of retear or functionality gains have already occurred at this point[8,20,37] and

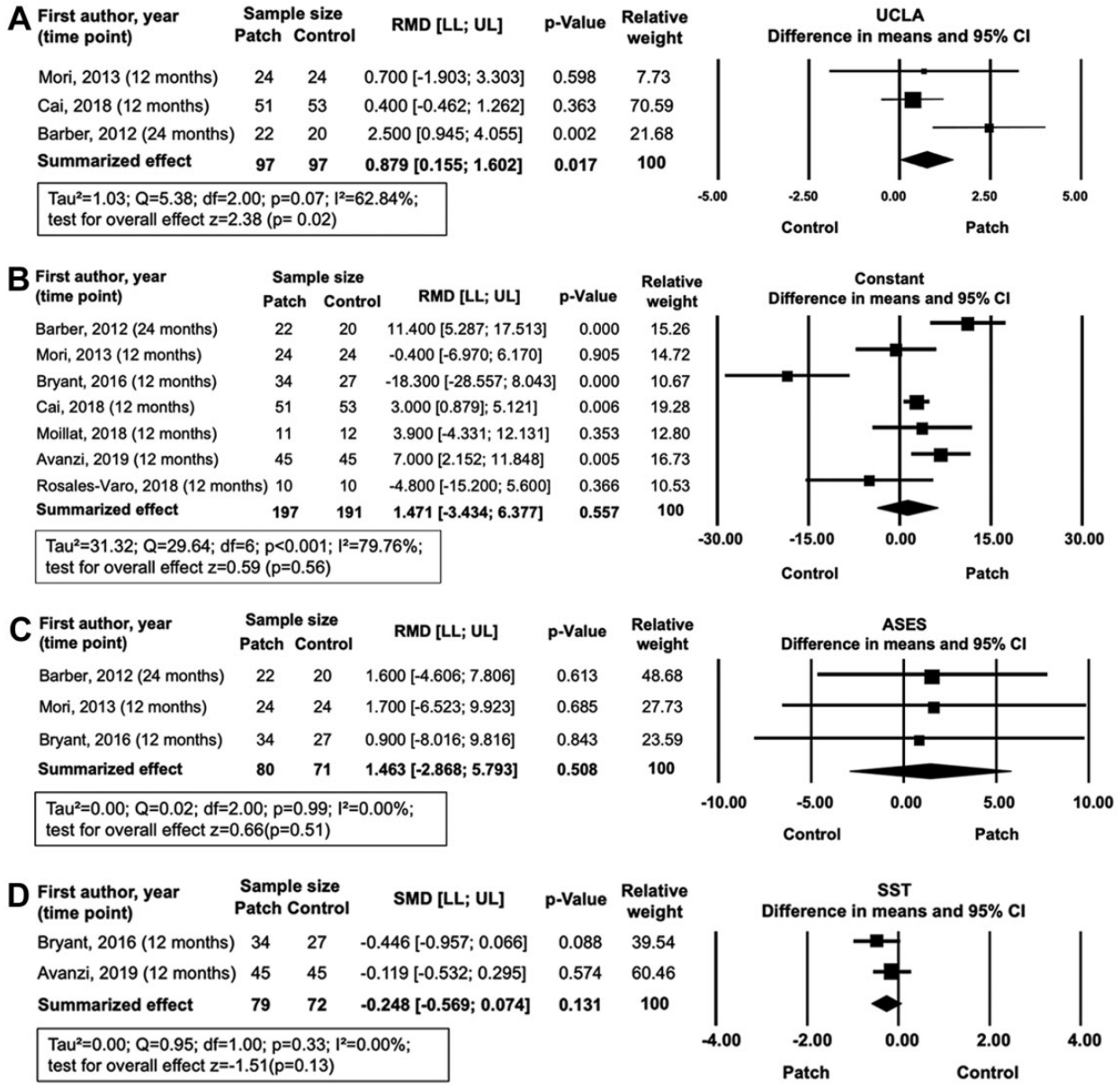

Figure 4. Forest plot of functional shoulder scales using the (A) University of California Los Angeles Shoulder Rating Scale (UCLA), (B) Constant, (C) American Shoulder and Elbow Surgeons Shoulder Score (ASES), and (D) Simple Shoulder Test (SST) between patch augmentation and control groups. LL, 95% CI lower limit; RMD, raw mean difference; SMD, standardized mean difference; UL, 95% CI upper limit.

because most studies assessed this specific time point. The sensitivity analyses on other time points as analyzed for VAS and Constant scores did not lead to very conclusive information, since patch augmentation improved VAS at 12 months but not at 6 months, and Constant scores improved at 6 months but not at 12 or 24 months,

Considering the retear rate can reach 44% of rotator cuff repair cases and even 73% in massive tears,[31] our finding of significantly reduced retear rates with the use of patch augmentation is important. This specific analysis of retear rate had a moderate quality of evidence (GRADE score 3), which strengthened the relevance of our findings. The literature has conflicting information regarding the impact of retear rate on shoulder function.[8,11,14,19,21,37] For example, while a few studies showed improved function with healing,[11,14,37] others did not verify any differences between healed and retear groups in functional outcomes.[8,19,21] We were unable to test the direct correlation between retear rate and the functional shoulder scales in this study, and the effective reduction in retear rate was not accompanied by considerable improvements in functional scales.

A previous meta-analysis comparing postoperative outcomes between cuff repair alone versus with patch augmentation showed nonsignificant improvement in UCLA and

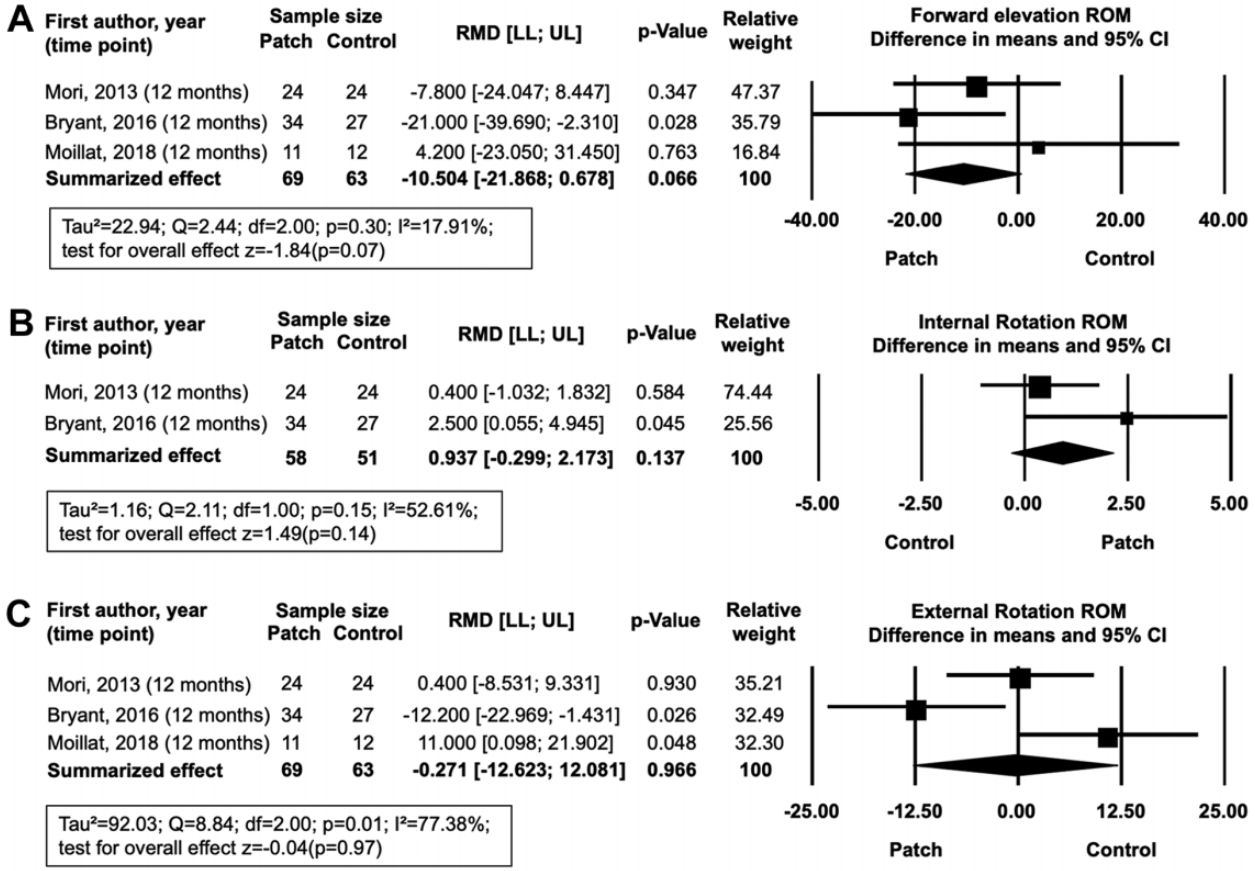

Figure 5. Forest plot of range of motion (ROM) for (A) forward elevation, (B) internal rotation, and (C) external rotation between patch augmentation and control groups. LL, 95% CI lower limit; RMD, raw mean difference; UL, 95% CI upper limit.

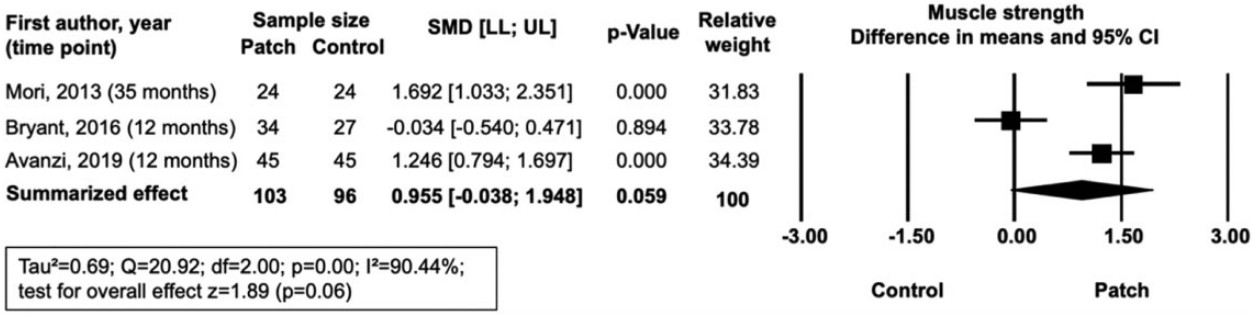

Figure 6. Forest plot of the standardized mean difference (SMD) for muscle strength between patch augmentation and control groups. LL, 95% CI lower limit; UL, 95% CI upper limit.

pain scores and a small improvement in ASESs in patients who underwent repair with augmentation.[3] The main difference between the previous meta-analysis and the present one was that here we only considered interventional studies (ie, those that analyzed changes through time within the same participant), which allowed us to remove the confounding factor of different baseline levels among groups. In our meta-analysis, the Constant score was the most frequent functional assessment among the studies (all 7 studies included this assessment[2,5-7,23,26,32]), followed by UCLA (3 studies[5,7,26]) and ASES (3 studies[5,6,26]). Significant patch benefits were seen for UCLA in this meta-analysis; however, it was based on just 3 studies with low quality of evidence. The 95% CI improvement in UCLA score (0.879 points [95% CI, 0.155 to 1.602 points]) fell within a much lower range than the minimum clinically important difference (MCID) of 3 points.[38] Regarding pain scores, although there was a significant reduction with patch augmentation (4 studies[2,23,26,32] in the analysis), this effect was also not clinically relevant (MCID).[18]

TABLE 3
Summarized Effects Between Patch Augmentation and Control Groups[a]

	k	Studies	Effect Size (95% CI)	P[b]
VAS: 6 mo	3	Avanzi,[2] Maillot,[23] Rosales-Varo[32]	0.05 (–0.74 to 0.84)	.90
VAS: 12 mo	4	Avanzi,[2] Maillot,[23] Mori,[26] Rosales-Varo[32]	–0.42 (–0.72 to –0.13)	**.005**
Constant: 6 mo	3	Avanzi,[2] Cai,[7] Maillot[23]	3.85 (1.83 to 5.87)	**<.001**
Constant: 12 mo	6	Avanzi,[2] Bryant,[6] Cai,[7] Maillot,[23] Mori,[26] Rosales-Varo[32]	–0.22 (–5.33 to 4.89)	.93
Constant: 24 mo	4	Avanzi,[2] Barber,[5] Maillot[23]	–1.25 (–9.08 to 11.58)	.81

[a] k, number of trials in each analysis; VAS, visual analog scale.
[b] P value for the differences between patch augmentation and control. Bolded P values indicate statistically significant differences between patch and control groups ($P \leq .05$).

Thus, considering these 4 study findings together (small improvements for ASES in previous meta-analyses that did not include baseline values in the analysis; absence of significance on previous meta-analyses for UCLA and pain; significant improvement in UCLA and pain scores not reaching MCID; and no significant effect for Constant score and SST), we concluded that there were no important effects from patch augmentation on any of these subjective criteria.

We found a trend in the patch group toward a reduction in forward elevation ROM ($P = .066$) and increase in strength ($P = .059$). Of note, there was a very high effect[10] of patch on muscle strength (SMD, 0.955 [95% CI, –0.038 to 1.948]),[10] and since these findings were not significant, futures studies will be fundamental to confirm or deny these trends. On the other hand, forward elevation ROM tended to be lower with patch augmentation, which was an unexpected result. Other reviews[3,36] have reported contrary results, finding increased forward elevation ROM with patch augmentation. It is important to highlight that these reviews based their findings on retrospective studies without controlling for patch augmentation and with generally poorer study designs than the studies included here.

Limitations

The first limitation of this study is the variety of patches included in the same analysis (porcine small intestine submucosa; acellular porcine dermis patch; fascia lata autograft patch; 3-dimensional type 1 collagen matrix; scaffold derived from submucosal and basilar mucosal layers of small intestine submucosa; acellular human dermal matrix; and porcine dermal patch), which causes methodological inconsistency and hinders the understanding about the effects of each of the patches. However, considering the analyses of most outcomes were homogeneous, it seems they were not affected by the different patches applied.

There are other confounding factors worthy of mention. For example, the included study by Bryant et al[6] showed a large amount of third-party compensation in the patch group (almost 2 times than that in the control group). Maillot et al[23] used open surgery for the patch group, while the control group was operated by arthroscopy, which hinders the isolation of patch effects. Other relevant factors such as the size of the tears (some described only as "small," "medium," or "large"), time from diagnosis to surgery, and duration of surgery were not pointed out by the articles included in our study. Even though those biases were relevant, we opted to keep those studies in the analysis, considering their results agreed with the other studies and did not seem to be an important source of heterogeneity.

CONCLUSION

The study results point to benefits with the use of patch augmentation in rotator cuff repair, particularly a reduction in retear rate, in an analysis of homogeneous studies that included a control group without patch augmentation. The patch improved pain and shoulder functionality as assessed by UCLA score; however, these effects were not clinically meaningful and the analyses had low quality. The other functional scales did not show improvement with patch, with a trend toward improvement in muscle strength. More controlled trials with better methodological quality should be conducted to confirm the benefits of patch augmentation for rotator cuff repair.

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TABLE A1
Complete Search Strategy

	PubMed (Medline)
1	((“Rotator cuff”[mh] AND “surgery”[sh]) OR(“rotator Cuff Injuries”[mh] AND “surgery”[sh]) OR(“Rotator Cuff” [mh] AND “ultrastructure”[sh]) OR((“Rotator cuff”[mh]) AND (“Reconstructive Surgical Procedures”[mh] AND “instrumentation”[sh])) OR((“Rotator cuff”[mh]) AND (“Reconstructive Surgical Procedures”[mh] AND “methods”[sh]))OR((“Rotator cuff”[mh]) AND (“Arthroscopy”[mh] AND “methods”[sh])) OR((“Rotator cuff”[mh]) AND (“Arthroplasty”[mh] AND “methods”[sh])))

(continued)

Table A1 (continued)

	PubMed (Medline)
2	("Patch augmentation" [tiab] OR"dermal matrix augmentation"[tiab] OR"matrix augmentation"[tiab] OR"augmentation"[tiab]OR"biomaterial"[tiab]OR"dermal patch"[tiab] OR"Skin Transplantation"[mh]OR"Skin Graftings"[tiab] OR"Tissue Scaffolds"[mh] OR"Absorbable Implants"[mh])
3	("Controlled Clinical Trial" [Publication Type] OR"Controlled Clinical Trials as Topic"[mh])
Combination	1 AND 2 AND 3
	Web of Science
1	(TS=(Rotator cuff) AND TS=(surgery)) OR (TS=(rotator Cuff Injuries) AND TS=(surgery)) OR (TS=(Rotator cuff) AND (TS=(Reconstructive Surgical Procedures) AND TS=(instrumentation))) OR (TS=(Rotator cuff) AND (TS=(Reconstructive Surgical Procedures) AND TS=(methods))) OR (TS=(Rotator cuff) AND (TS=(Arthroscopy) AND TS=(methods))) OR (TS=(Rotator cuff) AND (TS=(Arthroplasty) AND TS=(methods)))
2	TS=(Patch augmentation) OR TS=(dermal matrix augmentation) OR TS=(matrix augmentation) OR TS=(augmentation) OR TS=(biomaterial) OR TS=(dermal patch) OR TS=(Skin Transplantation) OR TS=(Skin Graftings) OR TS=(Tissue Scaffolds) OR TS=(Absorbable Implants)
Combination	1 AND 2
	EMBASE
1	('rotator cuff injury'/exp AND ('orthopedic surgery'/exp OR 'reconstructive surgery'/exp OR 'shoulder arthroscopy'/exp OR 'shoulder arthroplasty'/exp))
2	('patch augmentation'/exp OR 'biomaterial'/exp OR 'skin transplantation'/exp OR 'tissue scaffold'/exp OR 'biodegradable implant'/exp)
Combination	1 AND 2
	Scopus
1	(TITLE-ABS-KEY ("Rotator cuff") AND TITLE-ABS-KEY ("surgery")) OR (TITLE-ABS-KEY ("rotator Cuff Injuries") AND TITLE-ABS-KEY ("surgery")) OR (TITLE-ABS-KEY ("Rotator Cuff") AND TITLE-ABS-KEY ("ultrastructure")) OR (TITLE-ABS-KEY ("Rotator cuff") AND (TITLE-ABS-KEY ("Reconstructive Surgical Procedures") AND TITLE-ABS-KEY ("instrumentation"))) OR (TITLE-ABS-KEY ("Rotator cuff") AND (TITLE-ABS-KEY ("Reconstructive Surgical Procedures") AND TITLE-ABS-KEY ("methods"))) OR (TITLE-ABS-KEY ("Rotator cuff") AND (TITLE-ABS-KEY ("Arthroscopy") AND TITLE-ABS-KEY ("methods"))) OR (TITLE-ABS-KEY ("Rotator cuff") AND (TITLE-ABS-KEY ("Arthroplasty") AND TITLE-ABS-KEY ("methods")))
2	(TITLE-ABS-KEY("Patch augmentation") OR TITLE-ABS-KEY("dermal matrix augmentation") OR TITLE-ABS-KEY("matrix augmentation") OR TITLE-ABS-KEY("augmentation") OR TITLE-ABS-KEY("biomaterial") OR TITLE-ABS-KEY("dermal patch") OR TITLE-ABS-KEY("Skin Transplantation") OR TITLE-ABS-KEY("Skin Graftings") OR TITLE-ABS-KEY("Tissue Scaffolds") OR TITLE-ABS-KEY("Absorbable Implants"))
Combination	1 AND 2
	Cochrane Central Register of Controlled Trials (CENTRAL)
1	(("Rotator cuff"): ti, ab, kw AND ("surgery"): ti, ab, kw) OR (("rotator Cuff Injuries"): ti, ab, kw AND ("surgery"): ti, ab, kw) OR (("Rotator Cuff"): ti, ab, kw AND ("ultrastructure"): ti, ab, kw) OR((("Rotator cuff"): ti, ab, kw) AND (("Reconstructive Surgical Procedures"): ti, ab, kw AND ("instrumentation"): ti, ab, kw)) OR((("Rotator cuff"): ti, ab, kw) AND (("Reconstructive Surgical Procedures"): ti, ab, kw AND ("methods"): ti, ab, kw))OR((("Rotator cuff"): ti, ab, kw) AND (("Arthroscopy"): ti, ab, kw AND ("methods"): ti, ab, kw)) OR((("Rotator cuff"): ti, ab, kw) AND (("Arthroplasty"): ti, ab, kw AND ("methods"): ti, ab, kw)))
2	("Patch augmentation"): ti, ab, kw OR ("dermal matrix augmentation"): ti, ab, kw OR ("matrix augmentation"): ti, ab, kw OR ("augmentation"): ti, ab, kw OR ("biomaterial"): ti, ab, kw OR ("dermal patch"): ti, ab, kw OR ("Skin Transplantation"): ti, ab, kw OR ("Skin Graftings"): ti, ab, kw OR ("Tissue Scaffolds"): ti, ab, kw OR ("Absorbable Implants"): ti, ab, kw
Combination	1 AND 2

TABLE A2
Rehabilitation Protocols in the Included Studies

First Author (Year)	Rehabilitation Protocol
Avanzi (2019)[2]	A rehabilitation of 4 months was standardized for both groups. The first phase focused on suture protection; the second phase aimed for gains in passive range of motion; the third phase focused on strength and reconditioning.
Barber (2012)[5]	The operated arm was placed in a sling in abduction for 4-6 weeks; pendulum exercises were allowed during this time. Physical therapy started after 4 weeks and strength exercises were initiated within 12 weeks.

(continued)

Table A2 (continued)

First Author (Year)	Rehabilitation Protocol
Bryant (2016)[6]	The operated arm was immobilized in a sling until 6 weeks; passive and active assisted exercises were allowed with avoidance of internal rotation. After the 6 weeks, active exercises and stretching were initiated. After 12 weeks, resisted exercises were started.
Cai (2018)[7]	During the first week, the operated arm was maintained in a standard abduction pillow; pendulum exercises and passive forward flexion were started for all patients. After 6 weeks, active assisted range of motion exercises were started, and after 8 weeks, active resistance muscle strengthening began. Since the first days after the operation until 3 months, light daily activities were permitted; heavy manual work and sports were permitted 6 months postoperation.
Maillot (2018)[23]	For both groups, the operated arm was immobilized in a sling for 3 weeks. Wrist and elbow rehabilitation started immediately. All patients received a written program where the patient could perform passive stretching for range of motion and pendulum exercises without limits if there was assistance from a physical therapist. After 3 months, strength exercises started and self-rehabilitation was encouraged. Heavy lifting was prohibited until 6 months postoperation.
Mori (2013)[26]	The operated arm was immobilized in a sling or an abduction pillow for 8 weeks in the patch group and 6 weeks in the control group. A relaxation of the shoulder girdle muscles started after the first day postoperation by a physical therapist. Isometric and active assisted exercises were introduced after 2 and strength exercises after 6 weeks, respectively; strength exercises focused on the scapular stabilizers and rotator cuff were initiated.
Rosales-Varo (2018)[32]	The protocol used was a personalized plan for shoulder problems and a modification of Rockwood Orthotherapy based on suggestions by the GANCHO research group.[30]

APPENDIX