Outcomes After Double-Layer Repair Versus En Masse Repair for Delaminated Rotator Cuff Injury

A Systematic Review and Meta-analysis

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Background: Delamination of rotator cuff tears during arthroscopic shoulder surgery has an incidence of 38% to 92%. Double-layer (DL) repair and en masse (EM) repair are most commonly used in this situation.

Purpose: To compare the clinical results of the DL versus EM repair techniques for delaminated rotator cuff tears using a meta-analysis.

Study Design: Systematic review; level of evidence, 3.

Methods: We identified relevant studies comparing the clinical results of DL and EM repair for delaminated rotator cuff injuries in the PubMed, Embase, and Cochrane databases after the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines. The primary outcomes were the Constant score and retear rate. Additionally, we compared other postoperative shoulder functional scores, shoulder range of motion, and visual analog scale (VAS) pain scores between the 2 suture methods using a meta-analysis. The mean difference (MD) was compared for continuous outcomes, and the odds ratios (ORs) were compared for categorical outcomes.

Results: Of the 197 studies initially identified, 6 studies were included in this analysis. There were significant differences in the Constant score (MD, 8.64 [95% CI, 4.47 to 12.8]; $P < .05$) and external rotation (MD, 5.10 [95% CI, 2.63 to 7.56]; $P < .05$) between the 2 techniques, with DL repair having superior outcomes. No significant differences were observed between the 2 techniques in forward flexion (MD, 0.62 [95% CI, –1.18 to 2.43]; $P = .50$), VAS pain (MD, –0.03 [95% CI, –0.34 to 0.27]; $P = .84$), or retear rate (OR, 0.73 [95% CI, 0.37 to 1.41]; $P = .35$).

Conclusion: Results of this review and meta-analysis suggest that DL repair was more beneficial than EM repair in terms of the Constant score and shoulder external rotation in patients with delaminated rotator cuff injuries.

Keywords: arthroscopic; delaminated; double-layer repair; en masse repair; rotator cuff tear

One of the most frequent causes of shoulder discomfort and dysfunction is rotator cuff injury, which has an incidence of 20% to 34%, and the prevalence increases with age.[43] The main aim of treatment is to ease pain and improve shoulder function. One of the most frequent treatments with a successful outcome is arthroscopic rotator cuff repair. However, studies that concentrated on arthroscopic rotator cuff repair reported a retear rate of 11.4% to 94%, which would lead to a poor surgical outcome.[17] Many reasons contribute to this, and delaminated rotator cuff tears are considered one of these reasons.[31] The literature has reported that poor surgical outcomes are related to a low postoperative shoulder function score and a high retear rate.[2]

Because of the various definitions and different surgical techniques, the reported prevalence of delaminated rotator

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cuff tears varies[17] from 38% to 92%. Delaminated rotator cuff tears are often caused by the degeneration of the tendon, and they usually involve a tear that runs horizontally between the superior bursal layer and the inferior articular layer.[17] With the development of arthroscopic techniques and equipment, the observation of delamination has increased in recent years, especially in degenerative tears.[2,9] In addition, patients with large rotator cuff tears are more prone to delaminated rotator cuff tears. In a retrospective study, Iwashita et al[14] reviewed the characteristic features of delaminated rotator cuff injuries during arthroscopy. They found no significant difference in patient age, sex, symptom duration, or diabetes between patients with rotator cuff injuries and those without delamination. However, patients with >2 tendon tears and large tears and those who smoked were more prone to delaminated rotator cuff tears.[14]

Based on anatomic research at the histological level, there are 5 layers that make up the rotator cuff tear.[6] However, during arthroscopy, we often observe only 2 layers (the superior bursal and inferior articular layers). One possible reason that causes such delamination may be due to the existing shear force between the 2 layers.[8] Another histological study showed that delamination often occurs between 2 layers of collagen fibers in various directions.[38] In the same study, the authors pointed out that during arthroscopy, the articular layer is often observed to be further retracted than the bursal layer. Therefore, the stress of the 2 layers might not be equal during repair, which may contribute to retear. Therefore, surgical methods are important.[34] The ideal way to achieve good healing is to anatomically restore the tendon to the footprint, adhering the deep tendon layer to the medial aspect of the footprint while approximating the superior tendon layer to the more lateral aspect.[40] Both separate double-layer (DL) repair and conventional en masse (EM) repair are classic techniques for treating rotator cuff tears with delamination. EM repair by simultaneously passing the suture through both the inferior and superior layers can yield a good outcome.[31] DL repair is believed to have an anatomic restoration.[10] However, there is still no final conclusion regarding which technique can have a better clinical outcome. Some have reported that the DL technique can have a better clinical outcome, and others have reported that both techniques have equivalent outcomes.[4,16]

In this systematic review and meta-analysis, we identified observational studies and randomized controlled trials (RCTs) that compared the clinical outcomes between the 2 repair techniques for treating rotator cuff tears with delamination. We hypothesized that DL repair would be associated with better shoulder functional results than EM repair.

METHODS

Search Strategy

This study was performed in accordance with the guidelines of the Cochrane Handbook for Systematic Reviews of Interventions and the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines.[26] The protocol for this systematic review was prospectively registered at the International Prospective Register of Systematic Reviews (PROSPERO; ID CRD42022348275). To find relevant studies, the PubMed, Medline, Embase, and Cochrane Library databases were searched from inception to July 2020. Electronic searches were performed using Medical Subject Headings (MeSH) terms and relevant keywords (MeSH, “Rotator Cuff Injuries” and all their entry terms; keywords, “delaminated,” “delamination,” “double layer,” “separate layer”).

Selection Criteria

The initial search was conducted separately by 2 reviewers (X.Q. and J.W.) who eliminated duplicate records, review articles, case reports, cadaveric studies, animal studies, studies without all necessary data, and studies not directly comparing delaminated rotator cuff tears. Both reviewers had previously participated in meta-analysis. We included observational studies and RCTs in this meta-analysis based on the following criteria: (1) studies on patients diagnosed with full-thickness delaminated rotator cuff tear using arthroscopy; (2) intervention with a different surgical technique; (3) comparator being EM or DL repair; and (4) with ≥1 of the following outcomes: shoulder range of motion; visual analog scale (VAS) for pain; Constant Shoulder Score; American Shoulder and Elbow Surgeons (ASES) score; University of California. Los Angeles (UCLA) score; Simple Shoulder Test (SST); and retear rate. The level of rotator cuff retear was evaluated by the magnetic resonance imaging (MRI) examination, with Sugaya grades 4 and 5 considered as retears.[39] Studies were excluded if they were not written in English or did not repair both the bursal and articular layers.

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Data Extraction

Using a standardized electronic form, 2 reviewers (X.Q. and J.W.) extracted the data, while a third reviewer (Z.L.) double-checked the form. Any disagreements were adjudicated by the third reviewer. The following items were extracted: first author, publication year, number of participants, age, sex, country, study type, level of evidence, follow-up, outcome, and outcome data. The primary outcomes were shoulder functional scores and retear rates. Secondary outcomes included VAS pain scores and shoulder range of motion.

Risk of Bias Assessment

The Cochrane risk of bias tool was applied to evaluate the risk of bias in the RCT studies.[7] Nonrandomized studies were graded using the Newcastle-Ottawa scale, including selection, comparability, and outcome. Assessment for nonrandomized studies is difficult because they are usually less clear in reporting their methodology. Different methodological appraisal tools may have particular emphasis. Therefore, we used another method—the methodological index for nonrandomized studies (MINORS)—to assess the risk of bias in the included nonrandomized studies.[37] The risk of bias assessment was accomplished independently by 2 reviewers (X.Q. and J.W.). If any disagreements emerged during the procedure, they were addressed and resolved by the 2 reviewers.

Statistical Analysis

We analyzed the correlated data using Review Manager (RevMan for Macintosh Version 5.3; Nordic Cochrane Centre, Cochrane Collaboration). For dichotomous outcome data, the odds ratios (ORs) using Mantel-Haenszel statistics with 95% CIs were estimated. We estimated mean differences (MDs) with 95% CIs for continuous outcome data. When we integrated the studies, we determined the P value and I^2 statistic as a measure of the heterogeneity of the studies that were included. If the I^2 statistic was >50% or the P value was $< .1$, the random-effects model was used in the analysis; otherwise, the fixed-effects model was used. For specific outcomes for which data were merged from the included studies, forest plots were constructed. All P values are 2-sided, and the results with $P < .05$ were deemed to be statistically significant. In addition, the minimal clinically important difference (MCID) of each result was taken into consideration.

RESULTS

Literature Search

During the search process, 197 studies were identified. After removing duplicate studies, 116 studies remained. After removal based on assessing the titles and abstracts of the studies, 11 potentially eligible studies remained.

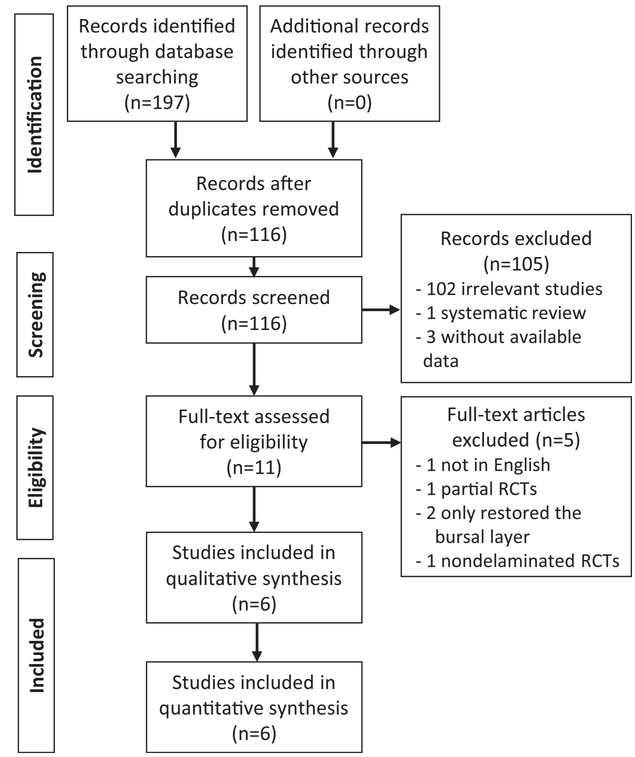

Figure 1. PRISMA flowchart of study inclusion. PRISMA, Preferred Reporting Items for Systematic Reviews and Meta-Analyses; RCT, randomized controlled trial.

Among the 11 studies, we removed 5, as 1 study[33] was written in Chinese, 1 study[29] included partial rotator cuff tears, 2 studies[12,18] restored only the bursal layer, and 1 study[3] included nondelaminated rotator cuff tears. In the end, 1 RCT[21] and 5 observational studies[11,15,16,28,30] were included in this meta-analysis. Figure 1 presents the flowchart for the study-inclusion process.

Study Characteristics

The included studies were all published between 2016 and 2022. With a total of 398 patients included in this meta-analysis, the sample sizes of the included studies ranged from 37 to 98—188 patients treated with DL repair and 210 patients treated with EM repair. The mean follow-up lasted between 15 and 32 months. Table 1 provides specific information about the included studies. The postoperative rehabilitation protocol of each study is presented in Table 2.

Risk of Bias Assessment

The methodological quality assessment of the 6 included studies was evaluated (Table 3, Table 4, and Figure 2). According to the Newcastle-Ottawa grading system, 3 studies[11,16,28] received a score of 9, 1 study[15] received a score of 7 for selecting the nonexposed cohort and comparability, and 1 study[30] received a score of 8 for comparability, representing a low risk of bias. According to the

TABLE 1
Characteristics of Included Studies[a]

Lead Author (Year)	Country	Patients, M/F, n EM	Patients, M/F, n DL	Mean Age, Y EM	Mean Age, Y DL	Study Type; LOE	Follow-Up, mo	Outcomes	Retear rate, % EM	Retear rate, % DL
Kim[21] (2016)	Republic of Korea	16/32	11/23	65.2	65.5	RCT; 2	26	CM, ROM, VAS, ASES, SST	17	18
Nakamizo[28] (2018)	Japan	28/24	20/26	65.8	64.1	RE; 3	28	ROM, VAS, UCLA	13.5	6.5
Kakoi[15] (2018)	Japan	28/11	26/9	62.9	66.1	RE; 3	15	JOA, ROM	7.9	5.9
Heuberer[11] (2019)	Austria	10/10	12/5	64.8	62.8	PRO; 2	24	CM, ROM, VAS, ASES, SST	5	5.8
Okubo[30] (2021)	Japan	12/6	11/12	69	69.6	RE; 3	32	CM, ROM	27.8	12.5
Kim[16] (2022)	Republic of Korea	13/20	14/19	64.7	63.9	RE; 3	27	CM, ROM, VAS, ASES, UCLA	3	3

[a]ASES, the American Shoulder and Elbow Surgeons score; CM, Constant-Murley score; DL, double-layer repair; EM, en masse repair; F, female; JOA, the Japanese Orthopedic Association score; LOE, level of evidence; M, male; RCT, randomized controlled trial; RE, retrospective study; PRO, prospective study; ROM, shoulder range of motion; UCLA, the University of California, Los Angeles score; SST, the Simple Shoulder Test score; VAS, the visual analog scale score.

TABLE 2
Postoperative Rehabilitation Protocol of the Included Studies[a]

Study, Lead Author (Year)	Sling Duration	Passive Motion Exercises: Start Date	Active Motion Exercises: Start Date	Strengthening Exercises: Start Date
Kim[21] (2016)	4 wk	Immediately	Wk 5	—
Nakamizo[28] (2018)	4-6 wk	Wk 2	Wk 5-7	Wk 12
Kakoi[15] (2018)	4-6 wk	Wk 3	Wk 6-8	—
Heuberer[11] (2019)	4 wk	Immediately	Wk 5	Wk 12
Okubo[30] (2021)	3-4 wk	Immediately	Wk 4-5	Wk 12
Kim[16] (2022)	6 wk	Wk 5	Wk 7	Wk 12

[a]Dashes indicate that the protocol was not used in that study.

TABLE 3
Newcastle-Ottawa Scores for the Included Nonrandomized Studies[a]

Study, Lead Author (Year)	Selection Criteria (1)	(2)	(3)	(4)	Comparability (5)	Outcome (6)	(7)	(8)	Total Score
Nakamizo[28] (2018)	1	1	1	1	2	1	1	1	9
Kakoi[15] (2018)	1	0	1	1	1	1	1	1	7
Heuberer[11] (2019)	1	1	1	1	2	1	1	1	9
Okubo[30] (2021)	1	1	1	1	1	1	1	1	8
Kim[16] (2022)	1	1	1	1	2	1	1	1	9

[a]Newcastle-Ottawa Scale items: (1) representativeness of the exposed cohort; (2) selection of the nonexposed cohort; (3) ascertainment of exposure; (4) demonstration that the outcome of interest was not present at the start of the study; (5) comparability of cohorts based on design or analysis; (6) assessment of outcome; (7) follow-up long enough for outcomes to occur; and (8) adequacy of follow-up of the cohorts.

TABLE 4
MINORS Scores for the Included Nonrandomized Studies[a]

Study, Lead Author (Year)	MINORS Item[b] (1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)	(12)	Score
Nakamizo[28] (2018)	2	2	2	2	2	2	2	0	2	0	2	2	20
Kakoi[15] (2018)	2	2	2	2	0	2	2	0	2	2	2	2	20
Heuberer[11] (2019)	2	2	2	2	2	2	0	0	2	2	2	2	20
Okubo[30] (2021)	2	2	2	2	0	2	2	0	2	2	2	2	20
Kim[16] (2022)	2	2	2	2	1	2	2	0	2	2	2	2	21

[a]MINORS, methodological index for nonrandomized studies.
[b]MINORS items: (1) clearly stated aim; (2) inclusion of consecutive patients; (3) prospective collection of data; (4) endpoints appropriate to the aim of the study; (5) unbiased assessment of the study endpoint; (6) follow-up period appropriate to the aim of the study; (7) loss to follow-up <5%; and (8) prospective calculation of the study size. Additional criteria for comparative studies: (9) adequate control group; (10) contemporary groups; (11) baseline equivalence of groups; and (12) adequate statistical analyses.

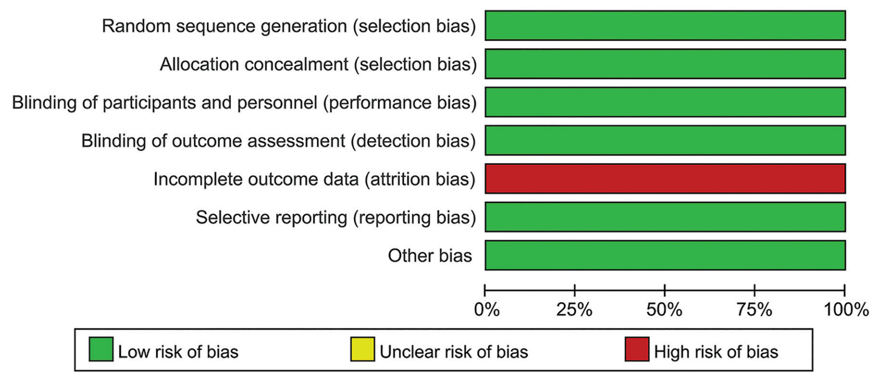

Figure 2. Risk of bias assessment for the included randomized controlled trial.[21] If every component is rated as low risk, the study is judged to be low risk. When >2 elements are rated as high risk, a study is rated as being high risk. Otherwise, the study is rated as being moderate risk.

MINORS system, all included studies had scores >20, indicating that including these nonrandomized studies was appropriate. All of the nonrandomized studies lacked prospective calculations of study size; 1 study[11] had a loss to follow-up rate of >5%, 3 studies did not blindly evaluate the outcome,[15,16,30] and 1 study[28] conducted a historical comparison. The included RCT[21] was found to have a low risk of bias.

Constant Score

Constant scores were reported in 3 studies,[11,16,30] comparing 144 patients, with 73 patients receiving DL repair and 71 patients receiving EM repair. With P = .78 and I^2 = 0%, no heterogeneity was observed among the studies; therefore, we used a fixed-effects model. The pooled analysis showed that DL repair was associated with better functional improvement than EM repair (MD, 8.64 [95% CI, 4.47-12.8]; $P < .01$) (Figure 3A).

Other Shoulder Function Assessments

ASES Score. Two studies[11,16] reported the comparison of postoperative ASES scores. No significant difference was observed in the studies by Kim et al[16] (EM [88.3 ± 17.4] vs DL [91.4 ± 6.8]; P = .75) and Heuberer et al[11] (EM [83.4 ± 16.5] vs DL [88.4 ± 11.2]) for ASES scores. A total of 2 studies[11,28] provided relevant data on the SST score. No significant difference was observed between the 2 methods of treatment in the study by Heuberer et al[11] (EM [9 ± 2.8] vs DL [9.4 ± 2.7]). However, in the study by Nakamizo et al,[28] the EM group had a postoperative SST score of 9.5 ± 1.2, and the DL repair group had a score of 10 ± 1(P = .014). DL repair obtained a better functional outcome in the study by Nakamizo et al.[28] Two studies[16,28] reported the comparison of postoperative UCLA scores. No significant difference was observed between the 2 groups in UCLA scores in the study by Kim et al[16] (EM [31.1 ± 6] vs DL [31.2 ± 3.3]; P = .51). However, in the study by Nakamizo et al,[28] the EM group had a postoperative UCLA score of 32 ± 3.3, while it was 33.2 ± 2.3 in the DL repair group. In their study, DL repair obtained a better functional outcome.

VAS Pain Score. VAS pain scores were reported in 3 studies,[11,16,28] comparing 201 patients, of whom 96 underwent DL repair and 105 patients underwent EM repair. With P = .18 and I^2 = 42%, no heterogeneity was observed among the studies; therefore, we used a fixed-effects model. The pooled analysis showed no significant difference in VAS scores between the 2 suture methods (MD, –0.03 [95% CI, –0.34 to 0.27]; P = .84) (Figure 3B).

Forward Flexion. A comparison of postoperative forward flexion was conducted among 5 included studies,[11,15,16,28,30] which included 316 patients—154 patients underwent DL repair and 162 patients underwent EM repair. Testing for heterogeneity revealed that none of the studies had any heterogeneity (P = .49; I^2 = 0%); therefore, to combine the data from the 5 trials, we utilized a fixed-effects model. The findings demonstrated no significant difference in shoulder flexion between the 2 surgical procedures (MD, 0.62 [95% CI, –1.18 to 2.43]; P = .50) (Figure 3C).

External Rotation. External rotation was reported in 5 included studies,[11,15,16,28,30] comparing 316 patients, of whom 154 underwent DL repair and 162 underwent EM repair. High heterogeneity was found across the included studies; then, a sensitivity analysis was conducted. We found heterogeneity in 1 of the studies[15] and removed it from the analysis. The remaining studies compared 305 patients—119 patients who underwent DL repair and 123 patients who underwent EM repair—with no heterogeneity (P = .27; I^2 = 24%). The findings demonstrated a significant difference between the 2 surgical procedures (MD, 5.10 [95% CI, 2.63-7.56]; $P < .05$) (Figure 4A) and that the DL repair was a better surgical option.

Retear Rate. A comparison of the postoperative retear rate was conducted among the 6 included studies,[11,15,16,21,28,30] which included 398 patients, of whom 188 patients received DL repair and 210 patients received EM repair. Testing for heterogeneity revealed no heterogeneity in the included studies (P = .95; I^2 = 0%). Therefore,

A

Study or Subgroup	DL Mean	DL SD	DL Total	EM Mean	EM SD	EM Total	Weight	Mean Difference IV, Fixed, 95% CI
Heuberer 2019	78.8	11.2	17	68.8	15.8	20	22.7%	10.00 [1.27, 18.73]
Kim 2022	91.4	6	33	84.3	16.4	33	48.9%	7.10 [1.14, 13.06]
Okubo 2021	87.6	11.4	23	77.4	13.6	18	28.4%	10.20 [2.38, 18.02]
Total (95% CI)			**73**			**71**	**100.0%**	**8.64 [4.47, 12.80]**

Heterogeneity: Chi² = 0.50, df = 2 (P = 0.78); I² = 0%
Test for overall effect: Z = 4.06 (P < 0.0001)

B

Study or Subgroup	DL Mean	DL SD	DL Total	EM Mean	EM SD	EM Total	Weight	Mean Difference IV, Fixed, 95% CI
Heuberer 2019	1.32	1.1	17	0.74	1.3	20	15.6%	0.58 [-0.19, 1.35]
Kim 2022	1.1	0.9	33	1.1	1.1	33	39.6%	0.00 [-0.48, 0.48]
Nakamizo 2018	1.07	1.19	46	1.34	1.1	52	44.8%	-0.27 [-0.73, 0.19]
Total (95% CI)			**96**			**105**	**100.0%**	**-0.03 [-0.34, 0.27]**

Heterogeneity: Chi² = 3.47, df = 2 (P = 0.18); I² = 42%
Test for overall effect: Z = 0.20 (P = 0.84)

C

Study or Subgroup	DL Mean	DL SD	DL Total	EM Mean	EM SD	EM Total	Weight	Mean Difference IV, Fixed, 95% CI
Heuberer 2019	152	18.7	17	158.7	25.1	20	1.6%	-6.70 [-20.84, 7.44]
Kakoi 2018	142.3	15.2	35	142.7	15.1	39	6.8%	-0.40 [-7.31, 6.51]
Kim 2022	164.7	7.5	33	165.9	5.9	33	30.8%	-1.20 [-4.46, 2.06]
Nakamizo 2018	165.8	5.9	46	163.9	6	52	58.6%	1.90 [-0.46, 4.26]
Okubo 2021	159.6	19.7	23	158.9	20.5	18	2.1%	0.70 [-11.73, 13.13]
Total (95% CI)			**154**			**162**	**100.0%**	**0.62 [-1.18, 2.43]**

Heterogeneity: Chi² = 3.44, df = 4 (P = 0.49); I² = 0%
Test for overall effect: Z = 0.68 (P = 0.50)

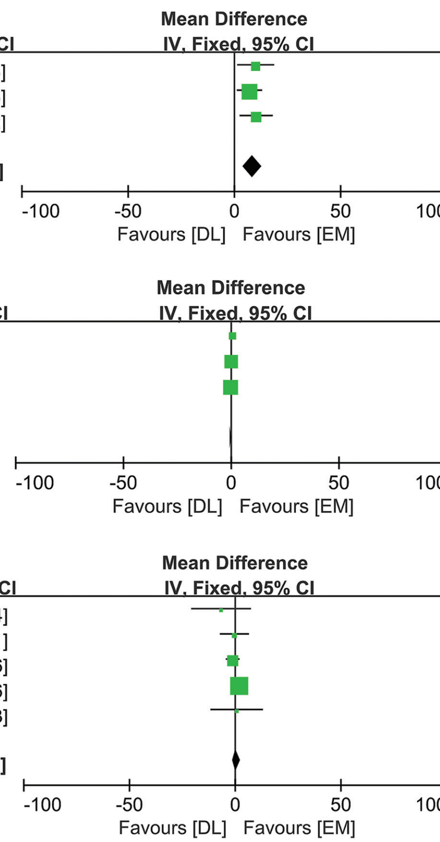

Figure 3. Forest plots for (A) Constant scores, (B) VAS scores, and (C) forward flexion. DL, double-layer repair; EM, en masse repair; IV, inverse variance; VAS, visual analog scale.

A

Study or Subgroup	DL Mean	DL SD	DL Total	EM Mean	EM SD	EM Total	Weight	Mean Difference IV, Fixed, 95% CI
Heuberer 2019	71.6	8.4	17	68.5	8	20	21.5%	3.10 [-2.21, 8.41]
Kakoi 2018	44.9	21.5	35	53.1	16.3	39	0.0%	-8.20 [-16.97, 0.57]
Kim 2022	71.1	10.7	33	69.2	11	33	22.2%	1.90 [-3.34, 7.14]
Nakamizo 2018	53.7	8.5	46	46.1	9.4	52	48.4%	7.60 [4.06, 11.14]
Okubo 2021	71.4	14.9	23	67.2	13.7	18	7.9%	4.20 [-4.58, 12.98]
Total (95% CI)			**119**			**123**	**100.0%**	**5.10 [2.63, 7.56]**

Heterogeneity: Chi² = 3.93, df = 3 (P = 0.27); I² = 24%
Test for overall effect: Z = 4.05 (P < 0.0001)

B

Study or Subgroup	DL Events	DL Total	EM Events	EM Total	Weight	Odds Ratio M-H, Fixed, 95% CI
Heuberer 2019	1	17	1	20	4.2%	1.19 [0.07, 20.54]
Kakoi 2018	2	35	3	39	12.9%	0.73 [0.11, 4.63]
Kim 2016	6	34	8	48	26.3%	1.07 [0.33, 3.43]
Kim 2022	1	33	1	33	4.7%	1.00 [0.06, 16.69]
Nakamizo 2018	3	46	7	52	29.6%	0.45 [0.11, 1.85]
Okubo 2021	4	23	5	18	22.3%	0.55 [0.12, 2.43]
Total (95% CI)		**188**		**210**	**100.0%**	**0.73 [0.37, 1.41]**
Total events	17		25			

Heterogeneity: Chi² = 1.18, df = 5 (P = 0.95); I² = 0%
Test for overall effect: Z = 0.94 (P = 0.35)

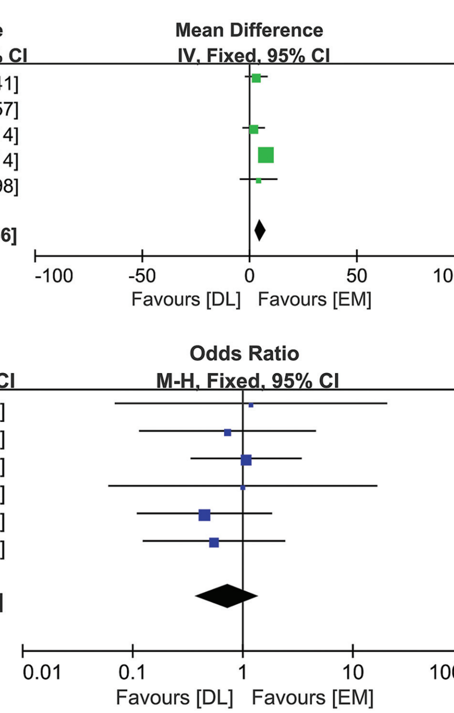

Figure 4. Forest plots for (A) external rotation and (B) retear rate. DL, double-layer repair; EM, en masse repair; IV, inverse variance; M-H, Mantel-Haenszel.

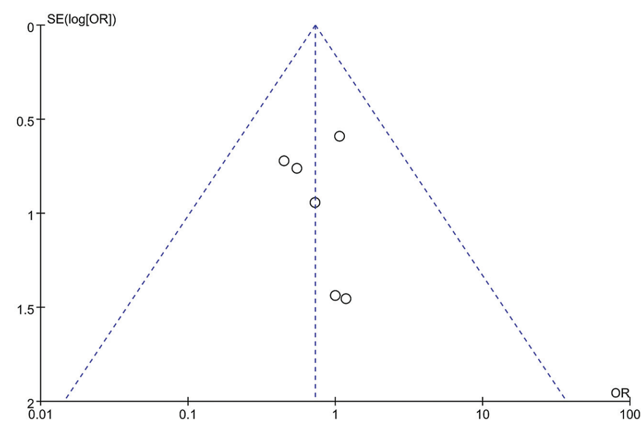

Figure 5. Funnel plot for publication bias. Each point represents a separate study for the indicated association. The vertical line represents the mean effect size; diagonal lines represent the 95% CI. OR, odds ratio.

we employed a fixed-effects model to combine the data from the 6 included studies. Although the outcomes demonstrated that the pooled OR was 0.73 (95% CI, 0.37-1.41; P = .35), there was no significant difference between the 2 methods (Figure 4B).

Publication Bias

We conducted a sensitivity analysis to assess the stability of the findings in this meta-analysis. For most outcomes, after sequentially removing each trial, the heterogeneity results did not appear to have altered, suggesting that our findings were statistically accurate. The funnel plot of the included studies in this meta-analysis is shown in Figure 5. The fairly symmetrical distribution of the points in the funnel plot suggests that publication bias was not significant.

DISCUSSION

The principal findings of this study showed that compared with EM repair, DL repair had better shoulder functional outcomes, with superior Constant score and shoulder external rotation. The Constant score of the DL group was significantly superior to that of the EM group, with an MD of 8.64 ($P < .05$). Lie et al[42] investigated the MCID in the Constant shoulder score for arthroscopic rotator cuff repair and found that the MCID ranged from 3.6 to 9.1, with a mean of 6.3. For shoulder external rotation, DL repair showed a better postoperative recovery than EM repair, with an MD of 5.1 ($P < .05$). Simovitch et al[36] reported that the MCID of active external rotation is 3°.

For the other shoulder functional scores, findings were not sufficient to make an analysis. We reported only the outcomes in some existing studies. No significant difference was observed in the VAS pain score, forward flexion, or retear rate between the 2 groups. The results of the mean VAS pain score in the reported studies were all <1.5. The MCID of the VAS[36] was 1.6; thus, the difference was not clinically significant, which means that the 2 methods relieve shoulder pain equivalently. For the retear rate, none of the included studies found any significant difference between the 2 methods. However, in the study by Kim et al,[16] they found a thicker tendon after DL repair, and T2-weighted MRI showed better results than EM repair. This finding needs further investigation.

In a previous meta-analysis of 5 studies by Chen et al,[4] both techniques were similarly successful and had a similar retear rate. However, they included a study[3] that compared single-layer repair and DL repair and included nondelaminated patients, which could have affected their outcome. After a strict selection process, we included only 2 of the 5 studies.[21,28] In recent years, more studies have concentrated on delaminated rotator cuff tears. Therefore, we conducted this meta-analysis to update our knowledge on this matter. In contrast to previous meta-analyses, we included 4 new studies and excluded non-English articles. We found that DL repair was associated with better Constant score and shoulder external rotation.

It is difficult to ignore the delamination of rotator cuff tears during arthroscopic surgery because of its prevalence of 38% to 92%. In the cohort study by Kim et al,[19] it was concluded that delamination of rotator cuff tears was detrimental to the surgical repair of the structural integrity of the rotator cuff and could affect the functional outcome. Therefore, it is advisable to address delamination.

In histologic research, Schwarz et al[35] found that the articular layer was composed of the rotator cable or the rotator-crescent complex, the capsule of the shoulder joint, and the fibers of the supraspinatus muscle in the posterior part. The bursal side was a composition of parallel tendons originating from parts of the supraspinatus and infraspinatus muscles.[35] Sonnabend et al[38] reported the histologic characteristics of delaminated rotator cuff tears, and they found 5 characteristics, the most important of which was the existence of a lining with synovial tissue between the delaminated layers because it was believed to prevent the layers from healing together. Therefore, it is important to clear the lining between the 2 layers during surgery. In a biomechanical studyies, shear force between the 2 layers has been found, suggesting that this could be one of the reasons contributing to delamination.[27] In another biomechanical study, Huang et al[13] reported that during the process of rotator cuff tears, the deep layer of the posterosuperior rotator cuff disrupts first, followed by the superficial layer of the posterosuperior rotator cuff and then the infraspinatus. There have been reports of different degrees of retraction between the 2 layers, with the deep layer being more retracted than the superior layer.[8,9] This may lead to tension mismatch between the 2 layers when repairing a rotator cuff tear with delamination.

To repair such tears, different methods have been reported. The conventional EM repair can reunite the separated layers and prevent the shear force between the 2 layers. In a retrospective study, Park et al[31] enrolled 36 patients treated with arthroscopic EM repair, with a mean follow-up of 37 months. They concluded that the delamination of a torn rotator cuff tear can be solved using this suture technique. Mochizuki et al[25] proposed that the 2 layers should be repaired separately because they found that the articular layer originated differently from the bursal layer and was more retracted and thicker. Heuberer et al[11] reported the results of patients' clinical examinations and MRI findings for those who were diagnosed with delaminated rotator cuff tears and treated with DL repair, suggesting a considerably improved shoulder function and a low retear rate. The MRI results showed satisfactory tendon integrity as well.

Two studies have compared the 2 techniques.[5,32] In a rabbit model, Cheon et al[5] compared EM repair with layer-by-layer repair. They found that compared with the separate layer repair, the whole layer repair had a smaller gap between the 2 layers 3 weeks after the surgery, and the separate layer repair showed that the tendon healed more slowly between the 2 layers. They suggested that this may be the case because the whole layer repair could reunite the separated layers and balance the shear force between the 2 layers. In their biomechanical comparison, in the first 3 weeks, they found that the separate layer repair had a greater ultimate failure load and yield load. However, at 3 weeks, no significant difference was observed between the 2 suture methods in this biomechanical research. In a cadaveric study, Pauzenberger et al[32] compared different repair configurations. They suggested that DL repair yielded better footprint coverage and tendon compression while increasing shoulder abduction; however, the peak load at failure was equal between these methods. However, EM repair reduced footprint coverage as the glenohumeral abduction angle increased. They suggested that DL repair can provide better anatomic repair of the shoulder rotator cuff footprint.

In the study by Kim et al,[21] patients who underwent separate DL repair had lower VAS pain scores than those who underwent EM rotator cuff repair. Nakamizo et al[28] reported that DL repair could help patients achieve a better range of motion of the shoulder and higher UCLA and SST scores after surgery than EM repair. Heuberer et al[11] reported that patients who underwent DL repair showed higher shoulder function scores and better forward flexion and abduction angles than those who underwent EM repair. Similar results were reported by Kim et al[16] and Okubo et al.[30] In contrast, Ren et al,[33] in a 2017 study, reported no statistically significant differences in postoperative functional improvement and retear rates between the 2 groups, whereas DL repair increased the operation time. Kakoi et al[15] reported the same outcome as well. This may be due to the small sample size and differences in patient characteristics.

To achieve a better outcome, it is important to secure the articular layer. In a retrospective study, Kim et al[20] enrolled 99 patients with delaminated rotator cuff tears treated with EM repair. They classified these patients into 2 groups—a healing group and retear group—and compared the morphologic features between the 2 groups. They found that the retraction length of the superior layer and the gap between layers were similar between the 2 groups, indicating that these 2 features were not attributable to the retear. The type of delaminated tear was similar as well. However, the retraction length of the articular layer was significantly greater in the retear group than in the healing group. Therefore, during surgery, more attention should be paid to restoring the articular layer, as the articular layer of the rotator cuff experiences considerably more stress with loading than the bursal layer. As already proposed, identification, reduction, and anatomic restoration of the articular side are crucial when dealing with delaminated tears, especially to bring the articular layer to a tension-free state.[22]

Whether delamination affects tendon healing and shoulder function after arthroscopic rotator cuff repair is still unknown. A cohort study with 1043 patients suggested that delamination was a complicating factor rather than an independent prognostic factor that affected rotator cuff recovery.[23] In another cohort study, delaminated rotator cuff showed lower chances of full tendon recovery after arthroscopic repair.[1] Despite the possibility that the delamination of a torn rotator cuff would indicate a poor prognosis, it can be solved with the current arthroscopic technique.

Limitations

There are some limitations in our study that should be mentioned. First, the studies included were mostly observational that relied on retrospectively collected data and may affect the outcomes. In this meta-analysis, because of the lack of prospective randomized studies in this field, we included studies that met our criteria regardless of the type of study—including 1 RCT and 5 cohort studies. However, the evaluation of risk of bias shows that these studies have an acceptable risk. The outcome of our meta-analysis demonstrates this as well. All of our outcomes were tested for heterogeneity, and none of our results showed heterogeneity. Nevertheless, further research is needed to verify this result. Future studies should be prospective, calculate study size during the design stage, and perform a double-blind evaluation of subjective endpoints. Second, a few studies presented their outcomes as medians, and we recalculated their data to present mean values according to statistical methods, and this may have influenced the outcome.[24,41] Third, in this study, attention was not paid to the tear size and course of the rotator cuff injury. Boileau et al[1] mentioned that tear size may affect tendon healing. Fourth, we did not assess the difference in tendon healing according to the Sugaya classification. In a clinical study by Gwak et al,[8] there were chances (74.3%) that intrasubstance clefts remained between the 2 layers after arthroscopic repair, and in the study by Zilber et al,[44] the chances were 38%. As Cheon et al[5] reported, a greater gap between layers was observed in DL repair. Some believe that the suture and knots left between the 2 layers may prevent healing as well. This observation may need further investigation.

CONCLUSION

The results of this meta-analysis suggest that compared with the EM repair method, the DL repair method is more beneficial in terms of Constant score and shoulder external rotation in patients with delaminated rotator cuff injury treated with arthroscopic repair.

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