# [ Orthopaedic Surgery ]

# Meta-analysis of Clinical and Radiographic Outcomes After Arthroscopic Single-Row Versus Double-Row Rotator Cuff Repair

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**Context**: Double-row rotator cuff repair methods have improved biomechanical performance when compared with single-row repairs.

**Objective**: To review clinical outcomes of single-row versus double-row rotator cuff repair with the hypothesis that double-row rotator cuff repair will result in better clinical and radiographic outcomes.

Data Sources: Published literature from January 1980 to April 2010. Key terms included *rotator cuff, prospective studies, outcomes,* and *suture techniques.* 

Study Selection: The literature was systematically searched, and 5 level I and II studies were found comparing clinical outcomes of single-row and double-row rotator cuff repair. Coleman methodology scores were calculated for each article.

Data Extraction: Meta-analysis was performed, with treatment effect between single row and double row for clinical outcomes and with odds ratios for radiographic results. The sample size necessary to detect a given difference in clinical outcome between the 2 methods was calculated.

**Results**: Three level I studies had Coleman scores of 80, 74, and 81, and two level II studies had scores of 78 and 73. There were 156 patients with single-row repairs and 147 patients with double-row repairs, both with an average follow-up of 23 months (range, 12-40 months). Double-row repairs resulted in a greater treatment effect for each validated outcome measure in 4 studies, but the differences were not clinically or statistically significant (range, 0.4-2.2 points; 95% confidence interval, -0.19, 4.68 points). Double-row repairs had better radiographic results, but the differences were also not statistically significant (P = 0.13). Two studies had adequate power to detect a 10-point difference between repair methods using the Constant score, and 1 study had power to detect a 5-point difference using the UCLA (University of California, Los Angeles) score.

**Conclusions:** Double-row rotator cuff repair does not show a statistically significant improvement in clinical outcome or radiographic healing with short-term follow-up.

Keywords: rotator cuff repair, outcomes, double row, prospective studies

Repair methods. <sup>1,6,13,14,16,17,24</sup> A recent systematic

review found lower retear rates in DR versus SR repairs when structural healing was assessed by clinical imaging.<sup>7</sup> Individual clinical studies show a trend toward improved healing of DR over SR repairs but are limited by small numbers and are often retrospective.<sup>11,25</sup>

The purpose of our study was to determine whether SR or DR rotator cuff repair was significantly better in terms of clinical outcomes (as measured by functional assessment scores) and structural healing (as assessed by postoperative imaging). The hypothesis was that DR rotator cuff repair would result in better clinical and radiographic outcomes.

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	Min-Max	Franceschi <sup>9</sup>	Grasso <sup>10</sup>	Burks <sup>2</sup>	Park <sup>20</sup>	Charousset <sup>3</sup>
Study size	0-10	7	10	10	10	10
Mean follow-up	0-5	2	5	2	5	5
No. procedures	0-15	0	0	0	0	0
Type of study	0-1	15	15	15	10	10
Diagnostic certainty	0-5	5	5	5	5	5
Surgical description	0-5	5	5	5	5	5
Rehab description	0-10	10	10	10	10	10
Outcome criteria	0-10	10	8	10	10	10
Outcome assessment	0-15	5	8	8	5	8
Patient selection	0-15	15	15	15	10	15
Total		74	81	80	73	78

Table 1. Coleman methodology scores for each study.



# **METHODS**

# Literature Search

A search was performed of Medline, Pubmed, Cochrane Database of Systematic Reviews, American College of Physicians Journal Club, Database of Abstracts of Reviews of Effects, and Cochrane Central Register of Controlled Trials (Figure 1) to find relevant articles on rotator cuff repair published from January 1980 to April 2010.<sup>8</sup> Studies were included if they assessed the results of repair according to repair method in a comparative fashion, contained a detailed description of the operative technique, allowed extraction of data on clinical outcomes (strength, range of motion, functional assessment scales) according to repair method, and used validated outcome scores (American Shoulder and Elbow Surgeons [ASES]; Disabilities of the Arm, Shoulder, and Hand [DASH]; University of California Los Angeles [UCLA]; Constant; and/or Western Ontario Rotator Cuff Index [WORC]) as a primary means of patient assessment at a minimum of 1 year following surgery. Because of a paucity of studies on DR rotator cuff repair with 2-year follow-up, studies were selected with 1-year outcomes. Retrospective or level III or IV studies were excluded. The references of included articles were reviewed for articles not identified by the literature search. The authors of the included studies were contacted to acquire primary data and clarify outcome measures. Results were analyzed according to repair method and grouped as SR or DR suture anchor.

## Methodology Scoring

A Coleman methodology score was independently calculated for each eligible study by 2 researchers, who resolved conflicting assessments (Table 1).<sup>4</sup>

## Meta-analysis

The treatment effect between the SR and DR rotator cuff repair methods for each clinical variable was the postoperative mean difference. For imaging results, the odds ratio was used to compare the probability of anatomic and watertight healing. The overall treatment effect for each variable was estimated

lable 2. Population data and clinical assessments used in the included studies. <sup>a</sup>								
	Constant <sup>2,3,20</sup>	DASH <sup>10</sup>	ASES <sup>2,20</sup>	UCLA <sup>2,9</sup>	WORC <sup>2</sup>			
Studies, n	3	1	2	2	1			
Repairs, n								
SR	93	37	60	46	20			
DR	86	35	58	46	20			
SR								
Age, y	57.1	58.3	56.7	60.2	56			
Follow-up, mon	23.2	24.8	20.7	17.9	12			
Tear size	N/A	244.7 mm <sup>2</sup>	< 3 cm, n = 43	1-3 cm, n = 18	1-3 cm, n = 18			
			> 3 cm, n = 17	> 3 cm, n = 28	> 3 cm, n = 2			
DR								
Age, y	56.8	55.2	55.3	58.5	57			
Follow-up, mon	23.2	24.8	20.6	17.9	12			
Tear size	N/A	261.9 mm <sup>2</sup>	< 3 cm, n = 36	1-3 cm, n = 15	1-3 cm, n = 15			
			> 3 cm, n = 22	> 3 cm, n = 31	> 3 cm, n = 5			

"SR, single row: DR, double row: Constant, Constant-Murley; DASH, Disabilities of the Arm, Shoulder, and Hand; ASES, American Shoulder and Elbow Surgeons; UCLA, University of California, Los Angeles; WORC, Western Ontario Rotator Cuff Index.

with the minimum-variance estimator, commonly used in the context of meta-analyses and defined as the linear combination of the study-specific treatment effects inversely weighted by their corresponding estimated sampling variances. Estimates of the sampling variance for each study-specific treatment effect were obtained directly from the individual study reports or extracted using the available statistical quantities.<sup>15</sup> For each overall treatment effect, a corresponding 95% confidence interval was computed on the basis of asymptotic normality of the sampling distributions. The log odds ratio was used instead of the odds ratio when results were combined, because the sampling distribution is better approximated in this case. All analyses were performed using SAS 9.2.

#### Sample Size Calculation

A clinically significant difference between repair methods was defined as a postoperative improvement of 2 and 5 points (UCLA score) or 5 and 10 points (all other scoring scales). Published standard deviations of these scores were used to calculate the sample size necessary to detect these differences for each clinical outcome score. The clinically significant difference for the postoperative improvement was based on

previously published studies.<sup>5,14,24</sup> There is no validated clinical difference for the Constant score.<sup>22</sup> Five points was chosen for a clinically important difference in the Constant score on the basis of noninjured individuals according to age.<sup>5,12</sup> An effect size (or clinical difference) of 2 and 5 points for the UCLA score was used; a difference of 2 at the upper end of the scale separates good and excellent, whereas > 5-point differences are found between poor and fair, fair and good.8 Sample sizes were calculated for a 5-point effect because the minimal clinically important difference for the ASES score is close to 5, at 6.4.<sup>18,21</sup> Ten points was also used for a sample size calculation; the minimal clinically important difference for the DASH score was 10.2 (DASH correlates well with ASES and Constant).18,21,23

# RESULTS

# Literature Search

Of the 128 abstracts reviewed, 5 articles met the inclusion criteria and were the foundation of this study (Figure 1)specifically, 3 level I randomized controlled trials<sup>2,9,10</sup> and 2 prospective cohort studies,<sup>3,20</sup> yielding 156 patients with SR repairs and 147 with DR repairs. These studies were

Table 3. Meta-analysis of clinical outcomes: double-row versus single-row rotator cuff repair. <sup>a</sup>									
		Single Rov	Double Row						
Endpoint	n <sup>b</sup>	Mean	SD	n <sup>b</sup>	Mean	SD	Point Estimate	SE of Estimate	95% CI
Constant									
Burks <sup>2</sup>	20	77.8	9	20	74.4	18.4	-3.40	4.58	–12.79, 5.99
Charousset <sup>3</sup>	35	80.7	9.6	31	82.7	9.6	2.00	2.37	-2.73, 6.73
Park <sup>20</sup>	40	76.68	8.56	38	79.66	4.52	2.98	1.54	-0.1, 6.06
Overall							2.24	1.24	-0.19, 4.68
ASES									
Burks <sup>2</sup>	20	85.9	14	20	85.5	20	-0.40	5.46	-11.49, 10.69
Park <sup>20</sup>	40	91.6	4.48	38	92.97	2.27	1.37	0.80	0.23, 2.97
Overall							1.33	0.79	-0.22, 2.88
UCLA									
Burks <sup>2</sup>	20	28.6	3.6	20	29.5	5.6	0.90	1.49	-2.13, 3.93
Franceschi <sup>9</sup>	26	32.9	1.17	26	33.3	0.97	0.40	0.30	-0.2, 1.0
Overall							0.42	0.29	-0.15, 0.99

<sup>a</sup>Meta-analysis of mean diff (double row minus single row). ASES, American Shoulder and Elbow Surgeons; UCLA, University of California, Los Angeles; CI, confidence interval.

<sup>b</sup>Sample size.

arthroscopic repairs with suture anchors. Transosseous suture bridge or combined techniques were not included. The studies did not include individual patient data, only averages for the patients with SR versus DR repair. The average Coleman score for all studies was 77.2; for level I studies, 78.3; for level II, 75.5 (Table 1).

#### **Clinical Outcomes**

The average age for SR repairs was 58.5 years and for DR repairs, 56.9 years. The average follow-up was 23.4 months for SR repairs and 23.5 months for DR. Only 1 study required a minimum of 24 months' follow-up3; 3 studies29,20 included patients with less than 24 months' follow-up (Table 2). Patientoriented outcome measures varied among studies (Table 3).

We were unable to analyze repair results according to tear size or number of anchors, owing to lack of detail in the studies. Strength was recorded as an individual variable in 3 studies<sup>2,3,20</sup> but was measured differently among them, thus not allowing direct comparison. Range of motion was recorded independently in 1 study9; pain, activity, and subjective satisfaction were also recorded independently in only 1 study.<sup>3</sup>

## Radiographic Outcomes

Radiographic assessment of structural healing (odds ratios of anatomic and watertight healing) was performed for 81 SR and 77 DR rotator cuff repair in 3 studies (Table 4).

#### Sample Size Calculations

Ten patients were needed per repair method for detection of a 5-point difference in UCLA score with a standard deviation of 4 points (Table 5). Furthermore, 250 patients per repair method were needed for detection of a 5-point difference in Constant, ASES, or Western Ontario Rotator Cuff Index scores with a standard deviation of 20 points. Based on these calculations, the Grasso study<sup>10</sup> was adequately powered to detect a 10-point difference on the Constant and DASH scores. The Park<sup>20</sup> study was adequately powered to detect a 10-point difference on the Constant score. The Franceschi<sup>9</sup> study was adequately powered to detect a 5-point difference on the UCLA scale. Burks<sup>2</sup> and Charousset<sup>3</sup> were both underpowered to detect a 10-point difference on the Constant scale. No study was adequately powered to detect a 5-point difference on the Constant, ASES,

lable 4. Imaging results for single-row and double-row rotator cuff repairs.								
	Burks <sup>2</sup>	Charousset <sup>3</sup>	Franceschi <sup>9</sup>	Combined				
Method	Nonarthrographic MRI	Arthrographic CT	Arthrographic MRI					
Timing	6 wk, 3 mo, 12 mo <sup>a</sup>	6 mo	22.5 mo	13 mo (average)				
Single row <sup>b</sup>								
n	20	35	26	81				
Full-thickness tears	2 (10)	14 (40)	2 (7.7)	18 (22.2)				
Partial-thickness tears	0	7 (20)	10 (38.5)	17 (21)				
Intact tendons	18 (90)	14 (40)	14 (53.8)	46 (56.8)				
Double row <sup>b</sup>								
n	20	31	26	77				
Full-thickness tears	2 (10)	7 (22.6)	1 (3.9)	10 (13)				
Partial-thickness tears	2 (10)	5 (16.1)	7 (26.9)	14 (18.2)				
Intact tendons	16 (80)	19 (61.3)	18 (69.2)	53 (68.8)				
Log of odds ratio								
Anatomic healing <sup>c</sup>	-0.81 (-2.64, 1.02)	0.86 (-0.12, 1.85)	0.66 (-0.48, 1.79)	0.55 (-0.14, 1.24)				
Watertight healing <sup>d</sup>	0.00 (-2.07, 2.07)	0.83 (-0.25, 1.91)	0.73 (-1.73, 3.20)	0.66 (-0.23, 1.55)				

"Burks performed MRI at multiple points; the published data were from the final follow-up, at 12 months. CT, computed tomography. <sup>b</sup>n (%).

cIntact tendon on postoperative imaging study.

<sup>d</sup>Intact tendon or partial thickness tear on postoperative imaging study.

or Western Ontario Rotator Cuff Index scores or a 2-point difference on the UCLA scale.

# DISCUSSION

We were unable to support our hypothesis that DR rotator cuff repair would lead to better clinical and radiographic results compared with SR. For the 3 clinical scoring systems with adequate data, the 95% confidence intervals of the postoperative mean difference for each analyzed score contained zero. Although the majority of treatment effect favored DR repair, no study or score absolutely favored it.

We did not find a statistically significant difference among radiographic outcomes. This may be due to the inclusion of various sized tears (< 1 cm to > 3 cm), which have different rates of healing.<sup>8,12,13</sup> Despite randomization, all 3 studies that reported tear size had larger tears in the DR group (Table 2).

In an effort to objectively analyze the quality of the studies reviewed, Coleman methodology scores were independently assigned to each study (Table 1).<sup>4</sup> All studies specifically included other procedures or did not clearly specify their

exclusion-particularly, biceps tenotomy/tenodesis or distal clavicle excision. Thus, it is hard to ascribe the results solely to rotator cuff repair. Studies also lost points in assessing outcomes: Investigators were not independent of the surgeon; written assessments were not completed; or assessments were not completed by the patients themselves.

The meta-analysis was limited by the clinical assessment used in each study. Grasso et al<sup>10</sup> used the "total Constant score normalized for age and gender" and compared outcomes "with adjustment for baseline values." Whereas normalization or adjustment of the Constant score allows comparison of a specific patient population to a matched standard, without the primary individual patient data, it is difficult to understand how a patient could have a score greater than the maximum of 100.10 Comparison of normalized Constant scores may be erroneous if adjustment is not performed using the same calculation reference table.<sup>12</sup> The Grasso Constant score data were not included in the meta-analysis.

Use of different scoring scales, even within the same patient samples, may yield varying results because functional assessment assigns different weights to the various domains.

		Effect Size				
Scoring System	Standard Deviations <sup>b</sup>	2 Points	5 Points	10 Points		
ASES <sup>2,20</sup>	15-20		148-250	35-64		
Constant <sup>2,3,20</sup>	10-20		40-250	17-64		
DASH <sup>10</sup>	10-18		40-200	17-52		
UCLA <sup>9,10</sup>	4-6	60-128	10-22			
WORC <sup>2</sup>	15-20		148-250	35-64		

Table 5. Number of patients needed per group for varying effect size and standard deviation.<sup>a</sup>

<sup>a</sup>Calculated for  $\alpha = 0.05$  and power = 0.80. The range shows the number of patients needed, as calculated from the lower standard deviation to the higher standard deviation.

<sup>b</sup>The standard deviations are taken from the published results of the studies composing the foundation of our study: Constant, Constant-Murley; DASH, Disabilities of the Arm, Shoulder, and Hand; ASES, American Shoulder and Elbow Surgeons; UCLA, University of California, Los Angeles; WORC, Western Ontario Rotator Cuff Index.

The magnitude of a clinically important difference varies among scores and is necessary to appropriately power a study (Table 5).

There have been 2 recent systematic reviews published comparing clinical outcomes of DR versus SR rotator cuff repair.<sup>19,26</sup> This study differs in that the results from each level I and II study were combined and analyzed to detect differences in clinical outcomes between SR and DR rotator cuff repairs with larger numbers. In addition, rather than highlight biases, the methodology was analyzed using Coleman scores.

Strengths of this study are the predefined inclusion and exclusion criteria for level I and II studies. In addition, the studies were ranked according to Coleman criteria to assess the quality of the studies. Weaknesses include the small number of extractable cases and the inability to obtain primary data on tear size from the majority of authors.

# CONCLUSIONS

Compared with SR, DR rotator cuff repair methods are more time-consuming, use more implants, and are more expensive.<sup>9</sup> Their use should be justified by well-designed level I studies. The 5 studies analyzed present the highest level evidence available. Even these studies were limited by low Coleman scores (n = 5), short-term follow-up (n = 5), lack of radiographic assessment of healing (n = 2), inconsistent use of scoring systems (n = 2), and small sample size (n = 4).

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