The Effect of Rotator Cuff Repair on Natural History

A Systematic Review of Intermediate to Long-Term Outcomes

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Background: Rotator cuff disease can have a progressive natural history of increasing tear size and worsening function. It remains unknown whether rotator cuff repair alters this natural history.

Methods: A systematic review of the intermediate to long-term (minimum 5-year) results of operative rotator cuff repair and no repair of rotator cuff injuries was performed to compare (1) patient-based outcomes, (2) future surgical intervention, (3) future tear progression or recurrence, and (4) tear size. The no-repair group included both conservative treatment and surgical treatment without repair. After the application of selection criteria, 29 studies with 1,583 patients remained. Meta-regression was conducted to adjust for baseline age, sex, tear size, and duration of follow-up.

Results: Comparison of the repair and no-repair groups revealed no significant differences in terms of age (p = 0.36), sex (p = 0.88), study level of evidence (p = 0.86), or Coleman methodology score (p = 0.8). The duration of follow-up was significantly longer for the no-repair group (p = 0.004), whereas baseline tear size was significantly larger in the repair group (p = 0.014). The percentage of patients requiring additional surgery was significantly higher in the no-repair group after adjustment for age, sex, duration of follow-up, and tear size (9.5% higher in estimated means between groups [95% confidence interval, 2.1% to 17%]; p = 0.012). The likelihood of a recurrent defect (repair group) or extension of the prior tear (no-repair group) was not different between groups after adjustment for age, sex, duration of follow-up, and tear size (p = 0.4). There were no differences between the repair and no-repair groups in terms of the Constant score after adjustment for age, sex, duration of follow-up, and tear size (p = 0.31). The final tear size was significantly larger in the no-repair group than the repair group (967 mm² higher in estimated means between groups [95% confidence interval, 771 to 1,164 mm²]; p < 0.001).

Conclusions: At intermediate to long-term follow-up, rotator cuff repair was associated with decreased final tear size and decreased need for future surgery after adjusting for age, sex, duration of follow-up, and tear size. The likelihood of a recurrent defect after rotator cuff repair did not differ from that of tear extension after nonoperative treatment. Thus, rotator cuff repair may not alter natural history.

Level of Evidence: Therapeutic Level IV. See Instructions for Authors for a complete description of levels of evidence.
clinical trials with short-term results have suggested that rotator cuff repair does not provide either a clinically or statistically significant benefit over nonoperative treatment.\(^4,19,20\) Nonoperative treatment does not reduce tear size or alter the natural history of rotator cuff disease\(^1-5\). Rotator cuff repair can result in an intact bone-tendon interface\(^16,21,22\), and these results can be maintained in the long term\(^14,23-26\). However, it remains unknown whether rotator cuff repair alters the natural history of rotator cuff disease.

The purpose of the present study was to conduct a systematic review of all published clinical studies with a minimum duration of follow-up of 5 years after rotator cuff repair and/or nonoperative treatment of rotator cuff disease in order to compare (1) strength and range of motion, (2) functional and patient-based outcomes, (3) the need for future surgical intervention, (4) the likelihood of future tear progression or recurrence, and (5) tear size. We hypothesized that rotator cuff repair would lead to increased strength and motion, improved outcomes, decreased need for future surgical intervention, no change in the likelihood of future tear progression or recurrence, and decreased final tear size when compared with nonoperative therapy.

### Materials and Methods

The present study was a systematic review of the literature. A search was performed with use of PubMed, Cochrane, and Embase databases. The search terms included rotator cuff repair, rotator cuff tear, rotator cuff conservative, rotator cuff nonoperative, rotator cuff nonoperative, outcomes, long-term, and long term. The search was conducted in November 2016. The exclusion criteria were a minimum duration of follow-up of <5 years, lack of either physical examination findings or clinical data at the time of the latest follow-up, case reports, technique articles, review articles, a sample size of <10, reconstruction with a graft, tendon transfers, arthroplasty studies, and studies published in languages other than English. We manually screened the references of each included study to ensure that no studies were missed. The tables of contents of the last 2 years of The Journal of Bone & Joint Surgery, The American Journal of Sports Medicine, Clinical Orthopaedics and Related Research, Arthroscopy, and Knee Surgery, Sports Traumatology, Arthroscopy were manually searched as well. The librarian at our institution was consulted with regard to the search algorithm. Finally, authors and study data were cross-checked to prevent data duplication, and longer-term data were preferentially included.

### TABLE I Study Characteristics

| Variable                          | Repair Cohorts (N = 32) | No-Repair Cohorts (N = 13) | P Value | Test |
|-----------------------------------|-------------------------|----------------------------|---------|------|
| Level of evidence (no. of cohorts) |                         |                            | 0.86    | Fisher |
| I                                 | 3 (9%)                  | 2 (15%)                    |         |      |
| II                                | 2 (6%)                  | 1 (8%)                     |         |      |
| III                               | 9 (28%)                 | 2 (15%)                    |         |      |
| IV                                | 18 (56%)                | 8 (62%)                    |         |      |
| Approach (no. of cohorts)         |                         |                            |         |      |
| Arthroscopic                      | 16 (50%)                | —                          |         |      |
| Open                              | 16 (50%)                | —                          |         |      |
| Coleman methodology score* (points) | 62.5 ± 11.8             | 61.5 ± 11.3                | 0.80    | T    |

*The values are given as the mean and the standard deviation.

### TABLE II Demographics

| Variable                  | Repair | No Repair |
|---------------------------|--------|-----------|
| No. of Cohorts*           | 32     | 13        |
| No. of Studies*           | 30     | 13        |
| Total no. of patients/shoulders | 1,294 | 289       |
| Age                       | 58.6 yr (56.4 to 60.8 yr) | 56.5 yr (52.7 to 60.4 yr) |
| Male sex                  | 66.9% (61.2% to 72.3%)   | 67.6% (60% to 74.8%)     |
| Dominant side             | 70.3% (59.8% to 80.8%)   | 67% (49.1% to 85%)       |
| Duration of follow-up     | 9.6 yr (8.6 to 10.7 yr)   | 14.9 yr (11.5 to 18.3 yr) |

*The values are given as the number of studies in which the value was reported. †The values are reported as the estimated mean, with the 95% CI in parentheses.
| Study                  | Level of Evidence | Treatment  | Sample Size (no. of patients/shoulders) | Tear Size                      |
|------------------------|-------------------|------------|----------------------------------------|--------------------------------|
| Bell et al. 58 (2013)  | IV                | Repair     | 49                                     | Large                          |
| Bidwai et al. 59 (2016)| I                 | No repair  | 15                                     | Medium                         |
| Bidwai et al. 59 (2016)| I                 | Repair     | 18                                     | Medium                         |
| Björmsson et al. 60 (2010)| III              | No repair  | 10                                     | Partial                        |
| Björmsson et al. 60 (2010)| III              | No repair  | 3                                      | Full                           |
| Cuff et al. 61 (2016)  | III               | Repair     | 28                                     | Massive                        |
| Denard et al. 62 (2012)| III               | Repair     | 62                                     | Massive                        |
| Denard et al. 62 (2012)| III               | Repair     | 45                                     | Massive                        |
| Dodson et al. 63 (2010)| IV                | Repair     | 15                                     | Large                          |
| Galtat et al. 64 (2001)| IV                | Repair     | 33                                     | Large                          |
| Goutallier et al. 25 (2009)| III             | Repair     | 30                                     | Large                          |
| Gulotta et al. 24 (2011)| II               | Repair     | 106                                    | Large                          |
| Inderhaug et al. 65 (2017)| IV              | Repair     | 147                                    | Massive                        |
| Jaeger et al. 66 (2016)| IV                | No repair  | 22                                     | Partial                        |
| Jaeger et al. 66 (2016)| IV                | No repair  | 17                                     | Full                           |
| Jaeger et al. 66 (2016)| IV                | No repair  | 17                                     | Rotator cuff tear arthropathy  |
| Kartus et al. 41 (2006)| IV                | No repair  | 26                                     | Partial                        |
| Kijima et al. 67 (2012)| II                | No repair  | 43                                     | Full                           |
| Kluger et al. 51 (2011)| III               | Repair     | 72                                     | Large                          |
| Kluger et al. 51 (2011)| III               | Repair     | 35                                     | Large                          |
| Lucena et al. 68 (2015)| III               | Repair     | 25                                     | Medium                         |
| Lucena et al. 68 (2015)| III               | Repair     | 25                                     | Medium                         |
| Marrero et al. 69 (2011)| IV                | Repair     | 24                                     | Medium                         |
| Miyazaki et al. 23 (2015)| III             | Repair     | 35                                     | Massive                        |
| Moosmayer et al. 4 (2014)| I                | No repair  | 39                                     | Small                          |
| Moosmayer et al. 4 (2014)| I                | Repair     | 52                                     | Medium                         |
| Nich et al. 70 (2009)  | IV                | Repair     | 33                                     | Medium                         |
| Nich et al. 70 (2009)  | IV                | Repair     | 4                                      | Medium                         |
| Norlin et al. 71 (2008)| IV                | Repair     | 89                                     | Tendinosis                     |
| Norlin et al. 71 (2008)| IV                | Repair     | 45                                     | Partial                        |
| Norlin et al. 71 (2008)| IV                | Repair     | 5                                      | Partial                        |
| Norlin et al. 71 (2008)| IV                | Repair     | 12                                     | Medium                         |
| Norlin et al. 71 (2008)| IV                | Repair     | 11                                     | Medium                         |
| Paxton et al. 72 (2013)| IV                | Repair     | 15                                     | Massive                        |
| Porcellini et al. 73 (2011)| IV             | Repair     | 67                                     | Massive                        |
| Ranebo et al. 42 (2017)| IV                | No repair  | 24                                     | Full                           |
| Ranebo et al. 42 (2017)| IV                | No repair  | 45                                     | Partial                        |
| Saraswat et al. 14 (2015)| II               | Repair     | 59                                     | Medium                         |
| Sperling et al. 74 (2004)| IV                | Repair     | 29                                     | Large                          |
| Stephens et al. 75 (1998)| IV                | No repair  | 11                                     | Partial                        |
| Stephens et al. 75 (1998)| IV                | No repair  | 17                                     | Complete                       |
| Stuart et al. 76 (2013)| IV                | Repair     | 15                                     | Partial                        |
| Zandi et al. 77 (2006)  | IV                | Repair     | 74                                     | Medium                         |
| Zumstein et al. 26 (2008)| IV               | Repair     | 23                                     | Massive                        |
We adhered to the Preferred Reporting Items for Systematic reviews and Meta-analyses (PRISMA) guidelines\(^1\). Studies with levels of evidence ranging from I to IV were included. Studies were divided into those in which a repair of the rotator cuff was performed and those in which no repair was performed. The no-repair group included nonoperative treatments such as physical therapy and steroid injections, surgical subacromial decompression without repair, and surgical debridement with repair. These no-repair treatments were combined as the purpose of the study was to determine whether repair alters natural history. Repair techniques, including open and arthroscopic approaches and single-row and double-row techniques, were combined to allow comparison. Two authors were involved in the decision process regarding the inclusion and exclusion of studies.

### Data Collection
The study-related data that were collected included first author, year of publication, journal, level of evidence, number of

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### TABLE IV Distribution of Pre-Treatment Tear Types in No-Repair and Repair Cohorts

| Tear Type                  | No-Repair Cohort (N = 289) | Repair Cohort (N = 1,294) |
|----------------------------|-----------------------------|----------------------------|
| Partial                    | 114 (39%)                   | 154 (12%)                  |
| Small                      | 39 (13%)                    | 12 (1%)                    |
| Medium                     | 15 (5%)                     | 337 (26%)                  |
| Large                      | 0 (0%)                      | 369 (29%)                  |
| Massive                    | 0 (0%)                      | 422 (33%)                  |
| Full                       | 104 (36%)                   | 0 (0%)                     |
| Rotator cuff tear arthropathy | 17 (6%)                    | 0 (0%)                     |
patients, minimum duration of follow-up, mean duration of follow-up, and treatment technique used (Table I). The demographic data that were collected included the number of patients in whom the dominant side was affected and the duration of symptoms before treatment (Table II). The clinical data that were collected (both preoperatively and at the time of the latest follow-up) included the number of patients who required further surgery, the number of patients with a documented increase in tear size, abduction strength, range of motion; absolute Constant score\(^2\), American Shoulder and Elbow Surgeons (ASES) score\(^2\), Disabilities of the Arm, Shoulder and Hand (DASH) and QuickDASH (an abbreviated version of the DASH) scores\(^3\), visual analogue scale (VAS) score for pain, University of California Los Angeles (UCLA) score\(^4\), Simple Shoulder Test (SST) scores\(^5\), and Western Ontario Rotator Cuff score\(^6\). The radiographic data that were collected included the number of patients at each radiographic Hamada stage\(^7\), the number of patients with each Goutallier fatty infiltration stage\(^8\), and acromiohumeral distance\(^9\). All strength measurements were converted to kilograms from pounds and newtons. The tear sizes before treatment and at the time of the latest follow-up were also collected as reported in each study on the basis of either magnetic resonance imaging (MRI) or ultrasound. All tear sizes were converted to square millimeters. When the length and width rather than the area were stated, these two 1-dimensional measurements were combined to calculate tear size, with the assumption being that the tears were rectangular, and when only a single dimension was stated, it was assumed to represent both the length and the width of a square tear; such calculations were necessary only in 3 of the 23 included repair cohorts. In addition, each cohort was classified as including partial, small, medium, large, or massive tendon tears (according to the authors’ description of the cohorts or the measurements included in the studies) with use of the Cofield system\(^10\). Studies that did not describe tear size are classified as “full” and “rotator cuff tear arthropathy” as described by the authors of these studies. When possible, cohorts were split into multiple parts to allow for finer definitions of preoperative tear size; i.e., a study with both small and medium tear cohorts in which outcomes were reported for both cohorts would be split into 2 cohorts (1 containing small tears and 1 containing medium tears) for the purposes of our analysis (Table III). Studies that included patients with tendinosis with no discrete tear at the time of inclusion were excluded. Study quality was graded with use of the Coleman methodology score\(^11\).

**Statistical Analysis**

Study characteristics, including level of evidence, surgical approach (arthroscopic or open), and Coleman methodology score were summarized as the count (and percentage) or the mean and the standard deviation and were compared between repair and no-repair cohorts with use of the Fisher exact test or \(t\) test as appropriate. Age, male percentage, dominant-side percentage, and number of years of follow-up were pooled across studies with use of a random-effects model with inverse variance weighting. A chi-square Q test for heterogeneity was used to test for differences between repair and no-repair groups. Mixed-effects meta-regression models were used to compare the repair and no-repair groups in terms of the

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**TABLE V Effect of Repair (Versus No Repair) on Primary Outcomes with Adjustment for Covariates**

| Outcome                                      | No. of Cohorts | Coefficient (95% CI)† | P Value |
|----------------------------------------------|----------------|-----------------------|---------|
| Percent requiring additional surgery         | 34             | \(-0.095 \(-0.17\) to \(-0.021\)\) | 0.012   |
| Percent with subsequent increase in tear size| 22             | 0.529 (\(-0.693\) to 1.751) | 0.4     |
| Constant score at latest follow-up           | 14             | 21.197 (\(-20.01\) to 62.403) | 0.31    |

*Age, sex, duration of follow-up, and pre-treatment tear size. †Coefficients can be interpreted as estimated mean differences between groups after adjustment for covariates.

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**TABLE VI Effect of Repair (Versus No Repair) on Secondary Outcomes**

| Outcome at Latest Follow-up | No. of Cohorts | Coefficient* (95% CI) | P Value |
|----------------------------|----------------|-----------------------|---------|
| ASES score                 | 10             | 1.67 (\(-17.21\) to 20.55) | 0.86   |
| VAS pain score             | 8              | 1 (\(-25.23\) to 27.23) | 0.94   |
| Elevation                  | 9              | \(-14.87\) (\(-49.31\) to 19.57\) | 0.4     |
| Elevation strength         | 6              | 1.13 kg (\(-5.17\) to 7.43 kg) | 0.72   |
| Tear size                  | 6              | \(-967.37\) mm\(^2\) (\(-1,163.89\) to \(-770.84\) mm\(^2\)) | <0.001 |

*Coefficients can be interpreted as estimated mean differences between groups after adjustment for covariates.
percentage of patients or shoulders requiring further surgery, the percentage with an increase in tear size or recurrence of a defect, and the post-treatment operative Constant score, with adjustment for age, male percentage, number of years of follow-up, and preoperative tear size. Mixed-effects meta-regression also was used to compare the repair and no-repair groups with regard to postoperative ASES, VAS pain score, elevation, elevation strength, and tear size (while controlling for preoperative measures). Meta-analysis and meta-regression were conducted with use of the R package version 3.4 for meta-analysis. Studies in which results were presented as summaries for different subgroups such as repair status or treatment type were included in the analysis as separate studies. If variance or standard deviation was not given, standard deviation was calculated from the standard error, 95% confidence interval (CI), or range, as available. The level of significance was set at $p < 0.05$, and all tests were 2-tailed.

Results

The initial search revealed 938 abstracts. After the application of our study-selection algorithm, 29 studies remained (Fig. 1); of those, 8 evaluated the outcomes of treatment without repair and 23 evaluated the outcomes of repair. The studies included 2 randomized clinical trials, 3 prospective cohort series, 7 retrospective cohort series, and 17 retrospective case series. There were no significant differences in Coleman methodology score between the individual repair cohorts ($p = 0.8$). The overall repair group that was assessed in the present study included a total of 1,294 patients with a mean duration of follow-up of 9.6 years (95% CI, 8.6 to 10.7 years) (Table II). Of the patients in the repair group, 722 (56%) underwent an arthroscopic repair and 572 (44%) underwent open repair. Of the patients in the repair group, 45 (3.5%) were managed with a double-row technique, 461 (35.6%) were managed with a single-row technique, 505 (39.0%) were
managed with a transosseous technique, and 283 (21.9%) were managed with an unspecified technique. The no-repair group included a total of 289 patients with a mean duration of follow-up of 14.9 years (95% CI, 11.5 to 18.3 years). After the studies were split into tear-size and treatment cohorts, there were 32 individual cohorts within the overall repair group and 13 individual cohorts within the overall no-repair group. The repair and no-repair cohorts did not differ with respect to age...
The duration of follow-up was significantly longer in the no-repair group ($p = 0.004$). The baseline tear size was significantly larger in the repair group ($p = 0.014$) (Table IV). Fewer than 3 repair studies and fewer than 3 no-repair studies evaluated pre-treatment strength, pre-treatment active forward elevation, pre-treatment Constant score, pre-treatment ASES score, pre-treatment VAS score, and radiographic outcomes, and thus no analyses were conducted on these variables.

There were no differences between the groups in terms of physical examination findings or strength at the time of the latest follow-up. Specifically, there were no differences in terms of elevation range of motion ($p = 0.4$) or elevation strength ($p = 0.72$) (Table V). There also were no differences between the groups in terms of functional and patient-based outcomes, including the ASES score ($p = 0.86$) or VAS pain score ($p = 0.94$) at the time of the latest follow up (Table VI). In addition, the final Constant score did not differ between the groups after adjusting for age, sex, duration of follow-up, and tear size ($p = 0.31$) (Fig. 2 and Table VI).

The percentage of patients requiring additional surgery was significantly higher in the no-repair group after adjustment for age, sex, duration of follow-up, and tear size (9.5% higher in estimated means between groups [95% CI, 2.1% to 17%]; $p = 0.012$) (Fig. 3 and Table VI). The percentage of patients with a recurrent defect in the repair group did not differ from the percentage of patients with an increase in tear size in the no-repair group after adjusting for age, sex, duration of follow-up, and tear size ($p = 0.4$) (Fig. 4 and Table V). The final tear size was significantly larger in the no-repair group than the repair group (967 mm$^2$ greater [95% CI, 771 to 1,164 mm$^2$ greater], $p < 0.001$) (Table VI).
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Discussion

Rotator cuff tears may increase in size and can lead to pain, disability, and ultimately pseudoparalysis and rotator cuff tear arthropathy. Because rotator cuff repair can result in a continuous bone-tendon interface in the long term, rotator cuff repair may be able to forestall this natural history. The purpose of the present study was to conduct a systematic review of all published clinical studies with a minimum duration of follow-up of 5 years after rotator cuff repair and/or nonoperative treatment of rotator cuff disease in order to evaluate (1) strength and range of motion on physical examination, (2) functional and patient-based outcomes, (3) the need for future surgical intervention, (4) the likelihood of future tear progression or recurrence, and (5) final tear size.

The present study demonstrated no differences between rotator cuff repair and no repair with respect to strength and range of motion. This finding is in concordance with the 3 randomized clinical trials that have been performed to date, each of which demonstrated no differences between rotator cuff repair and no repair with respect to strength and range of motion. Following rotator cuff repair, shoulders in which an intact tendon is achieved have greater strength than those in which an intact tendon is not achieved. In addition, strength has been correlated with tear size. Given our finding that final tear size was larger in the no-repair group as compared with the repair group, improved strength would be expected in the repair group, but this effect may have been obscured by heterogeneity in strength measurement between studies.

We found that, compared with no repair, rotator cuff repair did not improve outcomes as measured with the Constant score even after adjustment for age, sex, duration of follow-up, and tear size. These findings are roughly congruent with those of the 3 randomized clinical trials that have been conducted to date. One of those studies demonstrated no clinically or statistically significant differences between groups, 1 demonstrated a statistically but not clinically significantly better outcome in terms of the Constant score for rotator cuff repair resulting in an intact tendon, and 1 demonstrated both a clinically and statistically significantly better outcome in terms of the Constant score for rotator cuff repair resulting in an intact tendon.

Our study demonstrated that rotator cuff repair appears to protect the shoulder from the need for future operative intervention after adjusting for age, sex, duration of follow-up, and tear size. As tear size increases following nonoperative treatment, some patients may become increasingly symptomatic and may be considered for arthroscopic debridement, subacromial decompression, biceps tenotomy or tenodesis, rotator cuff repair, tendon transfer, or ultimately reverse total shoulder arthroplasty. In addition, tear size, age, and muscular atrophy all continue to increase following nonoperative treatment, thereby decreasing the likelihood of achieving an intact tendon. As a result, nonoperative treatment both increases the likelihood of future surgery and may decrease the likelihood of success if that surgery is a repair.

The present study indicates that rotator cuff repair does not decrease the likelihood of sustaining a future tear after adjusting for age, sex, duration of follow-up, and tear size but does decrease final tear size. Rotator cuff repair does not alter the underlying tendon biology that causes rotator cuff tearing, and therefore the likelihood of a recurrent defect after rotator cuff repair may be similar to the likelihood of tear progression with nonoperative treatment. A “recurrent defect” after rotator cuff repair thus may be understood not as a surgical failure but instead as a continuation of the underlying, unaltered, biological degeneration that leads to rotator cuff pathology. However, our study demonstrated that final tear size was significantly smaller after rotator cuff repair than after treatment without repair.

Our study has several limitations. First, the data were drawn from studies with different designs, and thus heterogeneity between studies limits the conclusions that can be drawn. In addition, surgical repairs and postoperative rehabilitation have changed between the publication of the first study in 2001 and that of the most recent study in 2017. Second, as with any meta-analysis, the quality of the conclusions that can be drawn is limited by the quality of the original data, which are drawn from studies of varying levels of evidence. Third, the included studies were limited to those published in English, which may introduce bias. However, each of these limitations affect both the repair and no-repair cohorts, which may mitigate their influence on our results. Fourth, a variety of repair and no-repair treatment methods were included. There is continuing debate as to whether single-row or double-row repair provides superior outcomes or a higher likelihood of an intact tendon. Fifth, there are certainly other variables that would have been valuable to compare, such as radiographic progression toward rotator cuff tear arthropathy as indicated by Hamada stage, muscular atrophy or tendon quality at baseline and at the latest follow-up, and which specific subsequent procedures were necessary. Unfortunately, these details were not available in the included studies and thus we could not analyze them. Sixth, tear size was measured on both MRI and ultrasound scans. Finally, although no difference existed in baseline demographic data between the repair and no-repair cohorts, unmeasured residual bias likely existed between the cohorts. For instance, the baseline tear size was larger in the repair group. To mitigate this effect, we controlled for tear size in our analyses of the primary outcomes. However, for many other variables (strength, motion, Constant score, etc.), insufficient evidence existed within the pre-treatment data to allow comparison. We were able to control for age, sex, and tear size, which are the 3 variables that have been shown to most strongly correlate with outcome. Only a randomized controlled trial will be able to overcome this limitation.

In conclusion, at intermediate to long-term follow-up, rotator cuff repair was associated with decreased final tear size and decreased need for future surgery but was not associated with higher final standardized outcomes after adjusting for age, sex, duration of follow-up, and tear size. The likelihood of a recurrent defect after rotator cuff repair did not differ from the
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