# Comparative Effectiveness of Operative Versus Nonoperative Treatment for Rotator Cuff Tears

## A Propensity Score Analysis From the ROW Cohort

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**Background:** The evidence to support operative versus nonoperative treatment for rotator cuff tears is sparse and inconclusive.

**Purpose:** To assess pain and functional outcomes in patients undergoing operative and nonoperative treatments for rotator cuff tears.

**Study Design:** Cohort study; Level of evidence, 3.

**Methods:** From March 2011 to February 2015, a multicenter cohort of patients with rotator cuff tears undergoing operative and nonoperative treatments was recruited. Patients completed a detailed history questionnaire, the Shoulder Pain and Disability Index (SPADI), and the American Shoulder and Elbow Surgeons (ASES) standardized form and underwent magnetic resonance imaging. In addition to baseline assessments, patients received follow-up questionnaires at 3, 6, 12, and 18 months. Propensity score weighting was used to balance differences in characteristics of the operative and nonoperative groups.

**Results:** Adjusted for propensity scores, the operative (n = 50) and nonoperative (n = 77) groups had similar characteristics, as evidenced by the small standardized mean differences between the groups. Adjusted mean differences in the SPADI and ASES scores between the operative and nonoperative groups were –22.0 points (95% CI, –32.1 to –11.8) and –22.2 points (95% CI, –32.8 to –11.6) at 18 months, respectively. The operative group had a significantly higher proportion of patients who showed ≥30% ($P$ = .002) and ≥50% ($P < .0001$) improvement in SPADI and ASES scores as compared with the nonoperative group.

**Conclusion:** In this prospective cohort study, patients undergoing operative treatment had significantly better pain and functional outcomes as compared with patients undergoing nonoperative treatment for rotator cuff tears. Differences between the 2 groups in SPADI and ASES scores at the 6- to 18-month time points met the minimal clinically important difference (depending on the threshold used). A large randomized controlled trial is needed to answer this question more definitively.

**Keywords:** rotator cuff tears; arthroscopic surgery; nonoperative

Shoulder pain accounted for 12.6 million ambulatory care visits to physician offices in 2015 in the United States.[4] Rotator cuff tears are one of the leading causes of shoulder pain and disability and accounted for 272,148 surgical procedures in 2006.[12,25] Nonoperative treatment and surgery are offered to patients with rotator cuff tears with good outcomes for both.[4,5,8,16,17,21,28,51] However, the evidence base to support surgical versus nonsurgical treatment is quite small and conflicting.[29,30,33,39,40] This paucity of evidence is highlighted in the 2012 American Academy of Orthopaedic Surgeons clinical practice guidelines,[44] Cochrane reviews,[11,18] a report by the Agency for Healthcare Research and Quality,[1] and expert reviews.[2,9,36,37,42,49,56] Some experts also raise concerns about the potential for fatty degeneration and increase in the tear size of the rotator cuff over time in patients treated nonoperatively.

In a cohort of patients with rotator cuff tears followed longitudinally, we assessed the comparative effectiveness of operative versus nonoperative treatment as measured by shoulder pain and function. Such an analysis compared the outcomes of 2 treatments (operative and nonoperative) while adjusting for important confounders. We hypothesized that patients undergoing surgery would have better outcomes as compared with those treated nonoperatively.

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## METHODS

### Patient Population

We recruited a cohort of patients with symptomatic partial- and full-thickness rotator cuff tears in a multicenter longitudinal study named the Rotator Cuff Outcomes Workgroup (ROW). Patients aged ≥45 years were recruited from sports/shoulder clinics in 3 academic settings and 1 community setting between March 2011 and February 2015. Exclusion criteria were a current shoulder fracture, prior shoulder surgery (on the index shoulder), and active cervical radiculopathy (elicited as neck pain radiating to the shoulder/arm/hand). Additional details about this cohort have been provided previously.[22,23] Patients provided informed consent, and the study was approved by our institutional review board. Patients who met eligibility criteria, completed a baseline assessment, and were recommended either operative or nonoperative treatment for rotator cuff tears without crossing over from nonoperative treatment to surgery (n = 7) were included in this analysis (n = 127). Patients crossing over from the nonoperative arm to surgery were excluded to avoid contamination of treatment effects because these patients underwent nonoperative treatment before undergoing surgery.

### Structured History Questionnaire and Outcome Measures

Patients were asked to complete a structured shoulder and general health questionnaire at enrollment. An abbreviated version of this questionnaire was mailed to patients around each of the follow-up time points. Patients were asked about their demographics, comorbidities, symptoms, smoking/alcohol habits, and patient expectations from treatment in the questionnaires. Patients were asked about manual labor at their current job to obtain information on daily use of their shoulder at work. If patients were not working, they were instructed to provide information on manual labor at their previous job. Because psychosocial factors are associated with treatment outcomes in patients with rotator cuff tears,[14] patients completed the Fear-Avoidance Beliefs Questionnaire (FABQ)[53] to assess their fear-avoidance beliefs about physical activity and work in those with low back pain. The FABQ physical activity questionnaire (4 items that contribute toward scoring) was slightly modified for our study to state "shoulder" instead of "back." The scale has 24 possible points, with a higher score indicating worse fear-avoidance behavior. The Mental Health Inventory–5 (MHI-5),[7] a component of the 36-item Short Form Health Survey,[54] was used to obtain information on mental health. MHI-5 scores range from 0 to 100. A score of ≤68 on the MHI-5 is indicative of a probable mood disorder (including depression).[27,52]

Shoulder pain and function were measured using the Shoulder Pain and Disability Index (SPADI),[46] a standardized 13-item questionnaire, and the American Shoulder and Elbow Surgeons (ASES) standardized form,[45] an 11-item questionnaire with minor modifications as described elsewhere.[41] Score ranges for the ASES and SPADI are from 0 to 100, with higher scores reflecting worse pain and function.

### Strength Testing

Strength testing was performed at the time of enrollment using a handheld dynamometer in abduction, external rotation, and internal rotation by trained research assistants. Our detailed protocol for standardized strength testing has been previously described.[26,38] Strength testing using a dynamometer has good intrarater and interrater reliability.[20] We used a ratio of affected shoulder strength versus contralateral shoulder strength in the analysis. There were 2 patients with a strength ratio above 3. These patients were given a value of 3 for the strength ratio to avoid outlying values in the analysis.

### Diagnostic Imaging

Shoulder magnetic resonance imaging (MRI) scans were read in a blinded fashion (reviewers were blinded to patient identifying information) by consensus by 2 shoulder experts (N.B.J. and L.D.H., or N.B.J. and J.E.K.) (shoulder fellowship trained). Our detailed protocol for imaging review and good interrater and intrarater reliability for these MRI readings as compared with a reading by a musculoskeletal radiologist have been previously described.[24]

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## Diagnosis of Rotator Cuff Tear

Our algorithm for the diagnosis of a rotator cuff tear has been previously described.[22,23] A diagnosis of a rotator cuff tear was made based on the clinical impression of a sports/shoulder fellowship–trained attending physician (N.B.J., J.E.K., J.J.P.W., K.M.B., E.M., or L.D.H.) and evidence of a structural deficit on MRI (when available). If MRI was unavailable (because it was not clinically indicated; n = 17), the diagnosis was based on the clinician's impression. It is important to include patients without MRI in the analysis to avoid a spectrum bias in patients undergoing nonoperative treatment, who in many cases do not need imaging unless surgery is indicated.

The biceps tendon is commonly affected in patients with rotator cuff tears. The diagnosis of a biceps tendon abnormality was based on the physician's indicating that the patient had clinical signs and symptoms corresponding to a biceps defect (a "yes/no" question).

## Nonoperative Treatment and Surgery

Patients underwent nonoperative treatment, including physical therapy, or rotator cuff surgery after their baseline visit. Treatment decisions were made based on shared decision making between the physician and the patient. Physical therapy included rotator cuff strengthening, scapular stabilization exercises, and capsular stretching. Surgery was performed by 1 of the study surgeons, and patients underwent postoperative rehabilitation after surgery. Patients typically wore a sling for about 3 to 6 weeks after surgery based on the surgeon's preference. Patients could receive additional interventions such as injections and medications as medically indicated in either arm.

## Longitudinal Follow-up

Patients were followed at approximately 3, 6, 12, and 18 months after the baseline visit. Follow-up was performed via mail, and patients received telephone or email reminders if they did not return the questionnaires.

## Statistical Analysis

Data for this study were entered twice to minimize inaccuracies during data entry. If there was a discrepancy between the 2 data sets, source documentation was reviewed to resolve them. Variables that were considered for our analysis include those presented in Table 1. Because there were missing values for some of the variables, we used multiple imputation using 20 data sets with the predictive mean matching method to impute missing data for covariates.[47] Propensity scores based on variables in Table 1 were used to adjust for inherent differences in patient characteristics between the operative and nonoperative groups because of the lack of randomization in our cohort study. A propensity score was estimated for each patient as the probability of undergoing surgery using multivariable logistic regression.[3,34] Weighting was performed for each patient such that imbalances in patient characteristics between the operative and nonoperative groups could be minimized. In addition to adjusting for propensity scores, our primary models also controlled for length of follow-up and interaction of treatment with length of follow-up. Adjusting for length of follow-up is important because outcomes in both groups will be expected to improve during follow-up just from the natural history of rotator cuff tears. An interaction allows for the assessment of differential improvement in outcomes between the operative and nonoperative groups over time. Inverse probability weighting was used to adjust estimates for the propensity of being in the operative versus nonoperative group. The primary model, adjusting for propensity scores, allowed us to estimate the average treatment effect at the population level. A 2-sided alpha level at .05 was considered statistically significant. Statistical analysis was performed using the computing environment R (R Core Team).

# RESULTS

There were 77 patients who underwent nonoperative treatment and 50 patients who underwent operative treatment in our cohort. This included 11 patients who were recommended surgery but did not undergo surgery. These patients were included in the nonoperative arm of our cohort. Adjusted for propensity scores, the operative and nonoperative groups had similar characteristics, as evidenced by the small standardized mean differences between the 2 groups (Table 1). The standardized mean differences also decreased after propensity score weighting, which is the desired result.

The observed SPADI (5.6 [95% CI, 2.6-8.7] for operative and 25.7 [95% CI, 19.4-32.0] for nonoperative) (Figure 1A) and ASES (10.4 [95% CI, 5.5-15.2] for operative and 27.1 [95% CI, 21.4-32.8] for nonoperative) (Figure 1B) scores plateaued by 12 months of follow-up in our cohort.

Adjusted for propensity scores, the estimated difference in SPADI scores between the operative and nonoperative groups (operative – nonoperative) was –22.0 points (95% CI, –32.1 to –11.8) (Table 2) at 18 months. Similarly, the estimated difference in ASES scores between the operative and nonoperative groups was –22.2 points (95% CI, –32.8 to –11.6) (Table 3) at 18 months. In a sensitivity analysis with a single model adjusting for smoking, age, alcohol use, baseline SPADI or ASES score, external rotation strength ratio, daily shoulder use at work, trauma, fatty infiltration, number of tendons torn, MHI-5 score, patient expectations, and thickness of tear, undergoing operative treatment versus nonoperative treatment showed a differential effect over time, with visits at 6, 12, and 18 months for the operative group having lower SPADI and ASES scores than at the 3-month visit ($P < .01$).

In an analysis of $\geq$30% improvement from baseline in SPADI and ASES scores, a significantly higher proportion of patients undergoing operative treatment improved versus those undergoing nonoperative treatment (SPADI: 90% vs 57%, respectively [chi-square $P$ = .002]; ASES: 88% vs 61%, respectively [chi-square $P$ = .002]) (Tables 4 and 5). Similarly, when $\geq$50% improvement from baseline in SPADI and ASES scores was used, a significantly higher

TABLE 1
Baseline Characteristics of Patients Undergoing Operative and Nonoperative Treatments Before and After Propensity Score Weighting[a]

| | Before Weighting | | | After Weighting | | |
|---|---|---|---|---|---|---|
| | Operative (n = 50) | Nonoperative (n = 77) | SMD | Operative (n = 50) | Nonoperative (n = 77) | SMD |
| Sex, % | | | 0.257 | | | 0.017 |
| Female | 38.0 | 50.6 | | 45.6 | 44.7 | |
| Male | 62.0 | 49.4 | | 54.4 | 55.3 | |
| Age,[b] y | 59.3 ± 8.9 | 63.8 ± 8.3 | 0.534 | 61.5 ± 8.3 | 61.1 ± 8.5 | 0.038 |
| Highest level of education, % | | | 0.019 | | | 0.101 |
| Less than college | 33.3 | 34.2 | | 31.6 | 36.4 | |
| College or above | 66.7 | 65.8 | | 68.4 | 63.6 | |
| Marital status, % | | | 0.139 | | | 0.032 |
| Single/divorced/widowed | 22.0 | 28.0 | | 27.5 | 26.1 | |
| Married | 78.0 | 72.0 | | 72.5 | 73.9 | |
| Shoulder symptoms and strength | | | | | | |
| Symptom duration, mo | 22.6 ± 40.6 | 23.9 ± 54.3 | 0.048 | 25.3 ± 46.3 | 27.2 ± 57.7 | 0.035 |
| Dominant shoulder affected, % | | | 0.041 | | | 0.023 |
| No | 22.9 | 24.7 | | 29.0 | 30.1 | |
| Yes | 77.1 | 75.3 | | 71.0 | 69.9 | |
| Daily shoulder use at work, % | | | 0.154 | | | 0.008 |
| Light/no manual labor | 75.5 | 81.8 | | 79.9 | 79.6 | |
| Heavy/moderate manual labor | 24.5 | 18.2 | | 20.1 | 20.4 | |
| Traumatic tear,[b] % | | | 0.266 | | | 0.055 |
| No | 46.0 | 59.2 | | 47.9 | 45.2 | |
| Yes | 54.0 | 40.8 | | 52.1 | 54.8 | |
| SPADI score at baseline | 55.0 ± 20.5 | 44.2 ± 23.1 | 0.493 | 49.1 ± 20.7 | 49.6 ± 21.6 | 0.025 |
| External rotation strength ratio[b,c] | 0.5 ± 0.3 | 0.8 ± 0.5 | 0.768 | 0.7 ± 0.3 | 0.7 ± 0.3 | 0.105 |
| Isolated abduction strength ratio[c] | 0.9 ± 0.2 | 0.9 ± 0.2 | 0.110 | 0.9 ± 0.2 | 0.9 ± 0.2 | 0.041 |
| Comorbidities and social history | | | | | | |
| No. of comorbidities, % | | | 0.280 | | | 0.048 |
| ≤1 | 58.0 | 44.2 | | 48.9 | 51.3 | |
| >1 | 42.0 | 55.8 | | 51.1 | 48.7 | |
| Smoking status, % | | | 0.026 | | | 0.002 |
| Never | 50.0 | 48.7 | | 47.2 | 47.3 | |
| Past/current | 50.0 | 51.3 | | 52.8 | 52.7 | |
| Alcohol use, % | | | 0.389 | | | 0.015 |
| ≤2-3 times per month | 37.5 | 56.6 | | 50.8 | 51.6 | |
| ≥1-2 times per week | 62.5 | 43.4 | | 49.2 | 48.4 | |
| FABQ physical activity score[b] | 19.0 ± 4.3 | 16.4 ± 6.1 | 0.495 | 17.9 ± 4.8 | 17.6 ± 4.8 | 0.050 |
| MHI-5 score | 80.5 ± 16.9 | 80.3 ± 14.9 | 0.013 | 82.1 ± 14.8 | 81.6 ± 16.0 | 0.035 |
| Patient expectations after treatment,[b] % | | | 0.762 | | | 0.067 |
| Great improvement | 94.0 | 65.3 | | 87.4 | 85.2 | |
| Moderate/little/no improvement or worse | 6.0 | 34.7 | | 12.6 | 14.8 | |
| Biceps tendinitis/tenosynovitis, % | | | 0.003 | | | 0.060 |
| No | 70.0 | 70.1 | | 72.1 | 74.7 | |
| Yes | 30.0 | 29.9 | | 27.9 | 25.3 | |
| Tear characteristics on MRI[d] | | | | | | |
| Cross-sectional area of tear,[b,e] mm$^2$ | 14.5 ± 19.3 | 7.9 ± 15.3 | 0.376 | 16.3 ± 22.5 | 17.2 ± 21.7 | 0.039 |
| Thickness of tear,[b,f] % | | | 0.841 | | | 0.005 |
| Partial-thickness | 10.4 | 45.2 | | 15.2 | 15.4 | |
| Full-thickness | 89.6 | 54.8 | | 84.8 | 84.6 | |
| Presence of fatty infiltration,[g] % | | | 0.362 | | | 0.147 |
| No | 54.8 | 71.9 | | 51.6 | 58.9 | |
| Yes | 45.2 | 28.1 | | 48.4 | 41.1 | |
| No. of torn tendons,[b] % | | | 0.224 | | | 0.083 |
| 1 | 60.4 | 71.0 | | 53.0 | 57.1 | |
| 2 or 3 | 39.6 | 29.0 | | 47.0 | 42.9 | |
| Tendon retraction,[b] % | | | 0.414 | | | 0.032 |
| Stage I or not applicable[h] | 60.4 | 79.0 | | 60.5 | 58.9 | |
| Stage II or more | 39.6 | 21.0 | | 39.5 | 41.1 | |

[a]Data are presented as mean ± SD unless otherwise specified. Data are presented after multiple imputation for missing values was performed. Missing before imputation: daily shoulder use at work, n = 1; alcohol use, n = 3; highest level of education, n = 3; smoking status, n = 3; traumatic tear, n = 6; patient expectations after treatment, n = 2; symptom duration, n = 5; dominant shoulder affected, n = 6; marital status, n = 2; external rotation strength ratio, n = 8; isolated abduction strength ratio, n = 10; MHI-5 score, n = 2; FABQ physical activity score, n = 5; SPADI score at baseline, n = 7; and cross-sectional area of tear, n = 27. FABQ, Fear-Avoidance Beliefs Questionnaire; MHI-5, Mental Health Inventory–5; MRI, magnetic resonance imaging; SMD, standardized mean difference; SPADI, Shoulder Pain and Disability Index.

[b]Variable was significantly different between the 2 groups before weighting.

[c]Strength ratio was measured as affected shoulder versus unaffected shoulder.

[d]MRI information was available for 110 patients; fatty infiltration and muscle atrophy were determined from computed tomography in 2 patients, who were included in the analysis but not in the table.

[e]Tear size was determined by the sum of supraspinatus and infraspinatus tears in longitudinal or transverse planes for full-thickness tears only.

[f]If any of the tendons had a full-thickness tear, the tear was classified as full-thickness.

[g]Fatty infiltration was reported for muscles most severely affected.

[h]It was not applicable because the tear was partial-thickness.

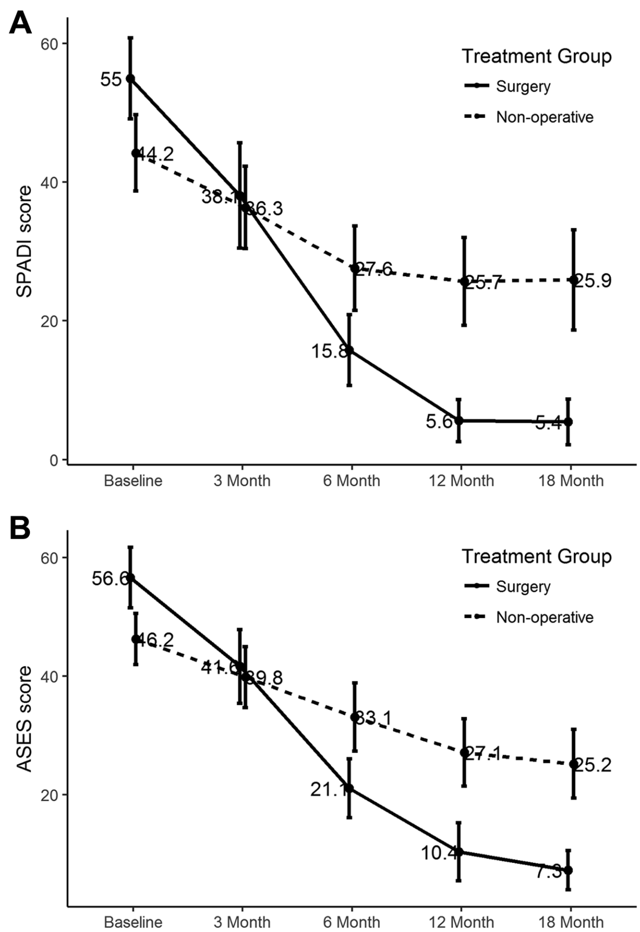


**Figure 1.** (A) Observed Shoulder Pain and Disability Index (SPADI) scores with 95% CIs of operative and nonoperative treatments over 18 months of follow-up. (B) Observed American Shoulder and Elbow Surgeons (ASES) scores with 95% CIs of operative and nonoperative treatments over 18 months of follow-up.

proportion of patients undergoing operative treatment improved versus those undergoing nonoperative treatment (SPADI: 86% vs 44%, respectively [chi-square $P < .0001$]; ASES: 84% vs 45%, respectively [chi-square $P < .0001$]) (Tables 4 and 5).

Sensitivity analyses were performed by excluding 17 patients missing MRI information to make the diagnosis of a rotator cuff tear. Results from these sensitivity analyses showed similar results to our primary analyses for the SPADI and ASES.

## DISCUSSION

We assessed the comparative effectiveness of operative versus nonoperative treatment for rotator cuff tears in a well-characterized cohort of patients recruited from academic and community settings. Our results show that over an 18-month follow-up period, patients undergoing surgery had significantly improved pain and functional outcomes, as measured by the SPADI and ASES, compared with those undergoing nonoperative treatment. The difference between the groups was sustained over the duration of the study after the first 3 months. When assessed as a 30% or 50% change in SPADI or ASES scores from baseline, patients undergoing surgery had a significantly higher proportion meeting these outcome improvement benchmarks.

Our study was designed to be a cohort study. Given the nonrandomized nature of a cohort study, it has inherent bias in patients who undergo operative versus nonoperative treatment.[31] We used propensity score methodology, as has been previously described,[19,31] to control for confounding by indication. This method accounts for differences in the likelihood of patients with certain characteristics to undergo operative versus nonoperative treatment and weights each patient in the cohort to balance the 2 groups. The gold-standard study design for minimizing bias is a randomized controlled trial. Thus, even though we have used advanced methodology in this comparative effectiveness study to adjust for indication bias, our results should be interpreted with caution.

There is substantial literature on pain and functional improvements after operative and nonoperative treatments.[††] Surgical studies generally report favorable outcomes but do not have a nonoperative comparison group.[††] Similarly, studies on nonoperative treatment show improved symptoms and function over 12 to 24 weeks but do not have a surgical comparison group. There are 3

TABLE 2
Propensity Score–Adjusted Differences in SPADI Score Between Operative and Nonoperative Treatments at Follow-up Time Points[a]

| | Estimated Difference (95% CI) |
|---|---|
| 3 mo | 13.0 (3.4 to 22.1) |
| 6 mo | –17.0 (−26.6 to −7.2) |
| 12 mo | –27.0 (−36.4 to −17.2) |
| 18 mo | –22.0 (−32.1 to −11.8) |

[a]SPADI, Shoulder Pain and Disability Index.

TABLE 3
Propensity Score–Adjusted Differences in ASES Score Between Operative and Nonoperative Treatments at Follow-up Time Points[a]

| | Estimated Difference (95% CI) |
|---|---|
| 3 mo | 9.9 (–0.1 to 19.9) |
| 6 mo | –14.8 (−25.5 to −4.2) |
| 12 mo | –19.0 (−29.6 to −8.5) |
| 18 mo | –22.2 (−32.8 to −11.6) |

[a]ASES, American Shoulder and Elbow Surgeons.

[††]References 4-6, 10, 16, 17, 21, 28, 35, 43, 51.

TABLE 4
Improvement in SPADI Score Between Operative and Nonoperative Treatments During 18 Months of Follow-up[a]

| Improvement From Baseline | Operative, n (%) | Nonoperative, n (%) | *P* Value (Operative vs Nonoperative) |
|---|---|---|---|
| <30% | 5 (10) | 26 (34) | .002 |
| ≥30% | 45 (90) | 44 (57) | |
| <50% | 7 (14) | 36 (47) | <.0001 |
| ≥50% | 43 (86) | 34 (44) | |

[a]Missing for nonoperative: n = 7 (9%). SPADI, Shoulder Pain and Disability Index.

TABLE 5
Improvement in ASES Score Between Operative and Nonoperative Treatments During 18 Months of Follow-up[a]

| Improvement From Baseline | Operative, n (%) | Nonoperative, n (%) | *P* Value (Operative vs Nonoperative) |
|---|---|---|---|
| <30% | 5 (10) | 27 (35) | .002 |
| ≥30% | 44 (88) | 47 (61) | |
| <50% | 7 (14) | 39 (51) | <.0001 |
| ≥50% | 42 (84) | 35 (45) | |

[a]Missing for operative: n = 1 (2%); missing for nonoperative: n = 3 (4%). ASES, American Shoulder and Elbow Surgeons.

published small randomized trials on operative versus nonoperative treatment for rotator cuff tears.[29,33,39] Moosmayer et al[39] had clinically relevant study entry criteria such as the exclusion of subscapularis tendon tears and prior shoulder tendon surgery and the inclusion of only full-thickness tears. Their trial showed a statistically significant improvement in the operative versus nonoperative group, as measured by the Constant score[13] (13-point difference) and the visual analog scale for pain (1.7-cm difference). Recently, results from 2- and 5-year follow-up of this cohort were presented.[40] The difference in Constant scores between the operative and nonoperative groups in an intention-to-treat analysis was 2.6 (95% CI, –3.1 to 8.3) at 2 years and 5.3 points (95% CI, –0.1 to 10.7) at 5 years of follow-up. Thus, differences between the 2 groups were not statistically significant.

Kukkonen et al[29] randomized 173 patients with supraspinatus tears into 3 groups: physical therapy; physical therapy and acromioplasty; and rotator cuff repair, acromioplasty, and physical therapy. They reported no statistically significant differences in Constant scores at 12 months of follow-up across the 3 groups. After 2 years of follow-up, results again showed no difference in clinical outcomes between the 3 groups.[30]

Lambers Heerspink et al[33] randomized 56 patients with degenerative full-thickness tears and at 12 months of follow-up reported no significant difference in Constant-Murley scores between the surgery group and conservative care group. Although differences in visual analog scale for pain and disability scores between the 2 groups were statistically significant, these differences were small and unlikely to meet clinical significance. In our study, surgery had significantly superior outcomes as compared with nonoperative treatment at all follow-up time points except for 3 months. At the 3-month time point, patients who underwent surgery were still recovering from the operative procedure, and hence, it is not surprising that they had not improved. The differences in SPADI scores at the time points from 6 to 18 months between the operative and nonoperative groups were greater than the reported minimal clinically important difference (MCID) of 8 to 13.2 points for the SPADI.[32,48,57] A range of MCID values including 6.2-13.9, 12-17, 17.9, 21.9, and 26.9 points have been reported for the ASES.[15,50,55] Depending on the MCID threshold used for the ASES, some of the differences between the 2 groups cross the threshold between 6 and 18 months.

The limitations of our study include a relatively small sample size given the complexity of modeling, lack of a priori sample size calculation, missing MRI information in 17 patients, and unavailability of complete data at all of the time points. We were also limited by a cohort study design as opposed to a randomized controlled trial. We did not exclude patients with a history of arthritis (osteoarthritis or inflammatory), isolated subscapularis tears, adhesive capsulitis, or infections from our study, although the patient's primary diagnosis had to be a rotator cuff tear to be included in the study. We are unaware of the reliability of the FABQ for rotator cuff tears. The shared decision-making process for treatment and a surgical protocol was not standardized for the study.

In our prospective cohort study, surgery had significantly better pain and functional outcomes as compared with nonoperative treatment for rotator cuff tears. Differences between the 2 groups in SPADI and ASES scores (depending on the MCID threshold used) at the 6- to 18-month time points met the MCID. Thus, the pain and functional differences observed between the 2 groups in our study meet statistical significance and are clinically meaningful. An analysis with ≥30% and ≥50% improvement in SPADI and ASES scores from baseline also yielded similar results, with surgery significantly superior to nonoperative treatment. Although we present data from a well-designed cohort study and use advanced methodology, a large randomized controlled trial is needed to answer this question more definitively.

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## REFERENCES

1. Agency for Healthcare Research and Quality. *Comparative Effectiveness of Nonoperative and Operative Treatments for Rotator Cuff Tears*. Rockville, Maryland: AHRQ; 2008.
2. Ainsworth R, Lewis JS. Exercise therapy for the conservative management of full thickness tears of the rotator cuff: a systematic review. *Br J Sports Med*. 2007;41(4):200-210.
3. Austin PC. An introduction to propensity score methods for reducing the effects of confounding in observational studies. *Multivariate Behav Res*. 2011;46(3):399-424.
4. Bartolozzi A, Andreychik D, Ahmad S. Determinants of outcome in the treatment of rotator cuff disease. *Clin Orthop Relat Res*. 1994;308:90-97.
5. Baysal D, Balyk R, Otto D, Luciak-Corea C, Beaupre L. Functional outcome and health-related quality of life after surgical repair of full-thickness rotator cuff tear using a mini-open technique. *Am J Sports Med*. 2005;33(9):1346-1355.
6. Bennett WF. Arthroscopic repair of massive rotator cuff tears: a prospective cohort with 2- to 4-year follow-up. *Arthroscopy*. 2003; 19(4):380-390.
7. Berwick DM, Murphy JM, Goldman PA, Ware JE Jr, Barsky AJ, Weinstein MC. Performance of a five-item mental health screening test. *Med Care*. 1991;29(2):169-176.
8. Bokor DJ, Hawkins RJ, Huckell GH, Angelo RL, Schickendantz MS. Results of nonoperative management of full-thickness tears of the rotator cuff. *Clin Orthop Relat Res*. 1993;294:103-110.
9. Clement ND, Nie YX, McBirnie JM. Management of degenerative rotator cuff tears: a review and treatment strategy. *Sports Med Arthrosc Rehabil Ther Technol*. 2012;4(1):48.
10. Cofield RH, Parvizi J, Hoffmeyer PJ, Lanzer WL, Ilstrup DM, Rowland CM. Surgical repair of chronic rotator cuff tears: a prospective long-term study. *J Bone Joint Surg Am*. 2001;83(1):71-77.
11. Coghlan JA, Buchbinder R, Green S, Johnston RV, Bell SN. Surgery for rotator cuff disease. *Cochrane Database Syst Rev*. 2008;1: CD005619.
12. Colvin AC, Egorova N, Harrison AK, Moskowitz A, Flatow EL. National trends in rotator cuff repair. *J Bone Joint Surg Am*. 2012; 94(3):227-233.
13. Constant CR, Murley AH. A clinical method of functional assessment of the shoulder. *Clin Orthop Relat Res*. 1987;214:160-164.
14. Coronado RA, Seitz AL, Pelote E, Archer KR, Jain NB. Are psychosocial factors associated with patient-reported outcome measures in patients with rotator cuff tears? A systematic review. *Clin Orthop Relat Res*. 2018;476(4):810-829.
15. Gagnier JJ, Robbins C, Bedi A, Carpenter JE, Miller BS. Establishing minimally important differences for the American Shoulder and Elbow Surgeons score and the Western Ontario Rotator Cuff Index in patients with full-thickness rotator cuff tears. *J Shoulder Elbow Surg*. 2018;27(5):e160-e166.
16. Galatz LM, Ball CM, Teefey SA, Middleton WD, Yamaguchi K. The outcome and repair integrity of completely arthroscopically repaired large and massive rotator cuff tears. *J Bone Joint Surg Am*. 2004;86(2):219-224.
17. Goldberg BA, Nowinski RJ, Matsen FA 3rd. Outcome of nonoperative management of full-thickness rotator cuff tears. *Clin Orthop Relat Res*. 2001;382:99-107.
18. Green S, Buchbinder R, Hetrick S. Physiotherapy interventions for shoulder pain. *Cochrane Database Syst Rev*. 2003;2:CD004258.
19. Haukoos JS, Lewis RJ. The propensity score. *JAMA*. 2015;314(15): 1637-1638.
20. Hayes K, Walton JR, Szomor ZL, Murrell GA. Reliability of 3 methods for assessing shoulder strength. *J Shoulder Elbow Surg*. 2002; 11(1):33-39.
21. Itoi E, Tabata S. Conservative treatment of rotator cuff tears. *Clin Orthop Relat Res*. 1992;275:165-173.
22. Jain NB, Ayers GD, Fan R, et al. Predictors of pain and functional outcomes after the nonoperative treatment of rotator cuff tears. *Orthop J Sports Med*. 2018;6(8):2325967118788531.
23. Jain NB, Ayers GD, Fan R, et al. Predictors of pain and functional outcomes after operative treatment for rotator cuff tears. *J Shoulder Elbow Surg*. 2018;27(8):1393-1400.
24. Jain NB, Collins J, Newman JS, Katz JN, Losina E, Higgins LD. Reliability of magnetic resonance imaging assessment of rotator cuff: the ROW study. *PM R*. 2015;7(3):245-254.e3.
25. Jain NB, Higgins LD, Losina E, Collins J, Blazar PE, Katz JN. Epidemiology of musculoskeletal upper extremity ambulatory surgery in the United States. *BMC Musculoskelet Disord*. 2014;15(1):4.
26. Jain NB, Wilcox RB 3rd, Katz JN, Higgins LD. Clinical examination of the rotator cuff. *PM R*. 2013;5(1):45-56.
27. Kelly MJ, Dunstan FD, Lloyd K, Fone DL. Evaluating cutpoints for the MHI-5 and MCS using the GHQ-12: a comparison of five different methods. *BMC Psychiatry*. 2008;8:10.
28. Kuhn JE, Dunn WR, Sanders R, et al. Effectiveness of physical therapy in treating atraumatic full-thickness rotator cuff tears: a multicenter prospective cohort study. *J Shoulder Elbow Surg*. 2013; 22(10):1371-1379.
29. Kukkonen J, Joukainen A, Lehtinen J, et al. Treatment of non-traumatic rotator cuff tears: a randomised controlled trial with one-year clinical results. *Bone Joint J*. 2014;96(1):75-81.
30. Kukkonen J, Joukainen A, Lehtinen J, et al. Treatment of nontraumatic rotator cuff tears: a randomized controlled trial with two years of clinical and imaging follow-up. *J Bone Joint Surg Am*. 2015; 97(21):1729-1737.
31. Kyriacou DN, Lewis RJ. Confounding by indication in clinical research. *JAMA*. 2016;316(17):1818-1819.
32. L'Insalata JC, Warren RF, Cohen SB, Altchek DW, Peterson MG. A self-administered questionnaire for assessment of symptoms and function of the shoulder. *J Bone Joint Surg Am*. 1997;79(5):738-748.
33. Lambers Heerspink FO, van Raay JJ, Koorevaar RC, et al. Comparing surgical repair with conservative treatment for degenerative rotator cuff tears: a randomized controlled trial. *J Shoulder Elbow Surg*. 2015;24(8):1274-1281.
34. Li L, Greene T. A weighting analogue to pair matching in propensity score analysis. *Int J Biostat*. 2013;9(2):215-234.
35. MacDonald P, McRae S, Leiter J, Mascarenhas R, Lapner P. Arthroscopic rotator cuff repair with and without acromioplasty in the treatment of full-thickness rotator cuff tears: a multicenter, randomized controlled trial. *J Bone Joint Surg Am*. 2011;93(21):1953-1960.
36. Marx RG, Koulouvaris P, Chu SK, Levy BA. Indications for surgery in clinical outcome studies of rotator cuff repair. *Clin Orthop Relat Res*. 2009;467(2):450-456.
37. Matsen FA 3rd. Clinical practice: rotator-cuff failure. *N Engl J Med*. 2008;358(20):2138-2147.
38. Miller JE, Higgins LD, Dong Y, et al. Association of strength measurement with rotator cuff tear in patients with shoulder pain: the Rotator Cuff Outcomes Workgroup study. *Am J Phys Med Rehabil*. 2016; 95(1):47-56.
39. Moosmayer S, Lund G, Seljom U, et al. Comparison between surgery and physiotherapy in the treatment of small and medium-sized tears

of the rotator cuff: a randomised controlled study of 103 patients with one-year follow-up. *J Bone Joint Surg Br*. 2010;92(1):83-91.
40. Moosmayer S, Lund G, Seljom US, et al. Tendon repair compared with physiotherapy in the treatment of rotator cuff tears: a randomized controlled study in 103 cases with a five-year follow-up. *J Bone Joint Surg Am*. 2014;96(18):1504-1514.
41. Nho SJ, Brown BS, Lyman S, Adler RS, Altchek DW, MacGillivray JD. Prospective analysis of arthroscopic rotator cuff repair: prognostic factors affecting clinical and ultrasound outcome. *J Shoulder Elbow Surg*. 2009;18(1):13-20.
42. Oh LS, Wolf BR, Hall MP, Levy BA, Marx RG. Indications for rotator cuff repair: a systematic review. *Clin Orthop Relat Res*. 2007;455:52-63.
43. Park JY, Chung KT, Yoo MJ. A serial comparison of arthroscopic repairs for partial- and full-thickness rotator cuff tears. *Arthroscopy*. 2004;20(7):705-711.
44. Pedowitz RA, Yamaguchi K, Ahmad CS, et al. American Academy of Orthopaedic Surgeons clinical practice guideline on: optimizing the management of rotator cuff problems. *J Bone Joint Surg Am*. 2012;94(2):163-167.
45. Richards RR, An KN, Bigliani LU, et al. A standardized method for the assessment of shoulder function. *J Shoulder Elbow Surg*. 1994; 3(6):347-352.
46. Roach KE, Budiman-Mak E, Songsiridej N, Lertratanakul Y. Development of a Shoulder Pain and Disability Index. *Arthritis Care Res*. 1991;4(4):143-149.
47. Rubin DB. *Multiple Imputation for Nonresponse in Surveys*. New York: John Wiley and Sons; 2004.
48. Schmitt JS, Di Fabio RP. Reliable change and minimum important difference (MID) proportions facilitated group responsiveness comparisons using individual threshold criteria. *J Clin Epidemiol*. 2004;57(10):1008-1018.
49. Seida JC, LeBlanc C, Schouten JR, et al. Systematic review: nonoperative and operative treatments for rotator cuff tears. *Ann Intern Med*. 2010;153(4):246-255.
50. Tashjian RZ, Deloach J, Green A, Porucznik CA, Powell AP. Minimal clinically important differences in ASES and Simple Shoulder Test scores after nonoperative treatment of rotator cuff disease. *J Bone Joint Surg Am*. 2010;92(2):296-303.
51. Tashjian RZ, Henn RF, Kang L, Green A. Effect of medical comorbidity on self-assessed pain, function, and general health status after rotator cuff repair. *J Bone Joint Surg Am*. 2006;88(3):536-540.
52. Thorsen SV, Rugulies R, Hjarsbech PU, Bjorner JB. The predictive value of mental health for long-term sickness absence: the Major Depression Inventory (MDI) and the Mental Health Inventory (MHI-5) compared. *BMC Med Res Methodol*. 2013;13:115.
53. Waddell G, Newton M, Henderson I, Somerville D, Main CJ. A Fear-Avoidance Beliefs Questionnaire (FABQ) and the role of fear-avoidance beliefs in chronic low back pain and disability. *Pain*. 1993;52(2):157-168.
54. Ware JE Jr, Sherbourne CD. The MOS 36-item Short-Form Health Survey (SF-36), I: conceptual framework and item selection. *Med Care*. 1992;30(6):473-483.
55. Werner BC, Chang B, Nguyen JT, Dines DM, Gulotta LV. What change in American Shoulder and Elbow Surgeons score represents a clinically important change after shoulder arthroplasty? *Clin Orthop Relat Res*. 2016;474(12):2672-2681.
56. Williams GR Jr, Rockwood CA Jr, Bigliani LU, Iannotti JP, Stanwood W. Rotator cuff tears: why do we repair them? *J Bone Joint Surg Am*. 2004;86(12):2764-2776.
57. Williams JW Jr, Holleman DR Jr, Simel DL. Measuring shoulder function with the Shoulder Pain and Disability Index. *J Rheumatol*. 1995;22(4):727-732.