Arthroscopic Rotator Cuff Repair

Prospective Evaluation With Sequential Ultrasonography

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Background: Recent studies have demonstrated predictable healing after arthroscopic rotator cuff repair at a single time point, but few studies have evaluated tendon healing over time.

Hypothesis: Rotator cuff tears that are intact on ultrasound at 1 time point will remain intact, and clinical results will improve regardless of healing status.

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

Methods: The Arthroscopic Rotator Cuff Registry was established to determine the effectiveness of arthroscopic rotator cuff repair with clinical outcomes using the American Shoulder and Elbow Surgeons score and ultrasound at 1 and 2 years, postoperatively. Patients were assigned to 1 of 3 groups, based on ultrasound appearance: group 1, rotator cuff tendon intact at 1 and 2 years (n = 63); group 2, rotator cuff tendon defect at 1 and 2 years (n = 23); group 3, rotator cuff tendon defect at 1 year but no defect at 2 years (n = 7).

Results: The ultrasound appearance was consistent at 1 and 2 years for 86 of the 93 patients (92.5%). The patients in the group 1 had a significantly lower mean age (57.8 ± 9.8 years) compared with that of the patients of group 2 (63.6 ± 8.6 years; P = .04). Group 2 had a significantly greater rotator cuff tear size (4.36 ± 1.6 cm) than that of group 1 (2.84 ± 1.1 cm; P = .00025). Each group had a significant improvement in American Shoulder and Elbow Surgeons scores from baseline to 2-year follow-up.

Conclusion: All intact rotator cuff tendons at 1 year remained intact at 2 years. A small group of patients with postoperative imaging did not appear healed by ultrasound at 1 year but did so at 2 years. Patients demonstrated improvement in American Shoulder and Elbow Surgeons shoulder scores, range of motion, and strength, regardless of tendon healing status on ultrasound.

Keywords: arthroscopic rotator cuff repair; rotator cuff tear; tendon healing; single row; double row; ultrasound

Sequential ultrasound has been used to study the natural history of asymptomatic rotator cuff tears treated nonoperatively: Yamaguchi et al25 found that 60% of these tears remained unchanged in size, 40% increased in size, and none decreased in size or went on to heal. There is 1 study that used serial ultrasounds to evaluate vascular and anatomical response after rotator cuff repair at early time points: Of the 50 rotator cuff repairs studied by Fealy et al,7 only 8 were arthroscopic repairs, with the remainder being open or mini-open repairs. The study found persistent defects in 50% of the repairs at 6 weeks, 45% at 3 months, and 43% at 6 months postoperatively.

The purpose of the present study was (1) to evaluate rotator cuff integrity after ARCR at multiple time points using ultrasound and (2) to determine which patient and rotator cuff characteristics were associated with healed
rotator cuff repairs. Specifically, we sought to characterize any change in the shape of repaired rotator cuff tendons over a period and to correlate these results with clinical outcome. We postulated that rotator cuff tears healed on ultrasound at 1 time point would remain healed on subsequent ultrasounds and that clinical results would improve regardless of healing status.

MATERIALS AND METHODS

Between August 2003 and August 2005, the Arthroscopic Rotator Cuff Registry was established to determine the effectiveness of ARCR with clinical outcomes and ultrasound at 1 and 2 years after surgery at a single institution. The study was approved by the Institutional Review Board, and all patients underwent the informed consent process before participation. In sum, 127 patients with symptomatic rotator cuff tears who were treated with ARCR completed 2-year clinical follow-up. In a retrospective cohort study based on healing status after ARCR, patients who had postoperative ultrasound at 1- and 2-year time points met the inclusion criteria. Patients with only 1 ultrasound or no postoperative ultrasound were excluded from the study. After all ultrasound studies, patients were assigned to 1 of 3 groups based on the ultrasound appearance from 1 to 2 years: group 1, rotator cuff tendon intact at 1 and 2 years; group 2, rotator cuff tendon defect at 1 and 2 years; group 3, rotator cuff tendon defect at 1 year but no defect at 2 years (Figure 1).

During the enrollment period (August 2003 to August 2005), 193 patients were enrolled in the Arthroscopic Rotator Cuff Repair Registry, from whom 127 were available for follow-up. Of the 127 who had 2-year clinical follow-up, 2 had no postoperative ultrasound; 10 had ultrasound at 1 year only; 22 had ultrasound at 2 years only; and 93 patients had ultrasound at 1 and 2 years.

Of the 127 patients, 93 (73%) met the study criteria and were reviewed in the present study. At the time of surgery, there were 54 men (58.1%) and 39 women (41.9%), with an average age of 59.1 ± 9.8 years (range, 35.7-74.8). The right upper extremity was involved in 84.6% of cases and the left upper extremity in 15.4% of cases. The mean size of the rotator cuff tear was 3.3 ± 1.5 cm (range, 1.0-7.0), and rotator cuff tears involved a single tendon in 60 cases and multiple tendons in 33 cases. Additional procedures that were performed included subacromial decompression (n = 93), acromioclavicular joint coplane (n = 21) or distal clavicle resection (n = 7), and biceps tenotomy (n = 9) or biceps tenodesis (n = 5).

Surgical Technique

The patient was administered an interscalene block and placed in the beach chair position. A posterior portal was created approximately 3 cm inferior and in line with the posterolateral acromion. The 30° arthroscope was inserted, and diagnostic glenohumeral arthroscopy was performed. An initial anterior portal was created high in the rotator interval with an outside-in technique after localization with an 18-gauge spinal needle. The articular side of the rotator cuff tear was visualized, and the surgeon estimated the coronal and sagittal plane dimensions of the rotator cuff tear. After the completion of a diagnostic arthroscopy of the glenohumeral joint, the arthroscopic equipment was moved into the subacromial space. A lateral portal was established under direct visualization. Soft tissues were removed from the undersurface of the acromion, and the coracoacromial ligament was released and debrided back to a smooth and stable edge. A shaver, followed by a bur, was then used to remove the anterior inferior prominence of the acromion.

The greater tuberosity at the site of the rotator cuff tear was debrided from the lateral portal to ensure adequate decortication of the bony surface for the tendon to heal. A spinal needle was used to localize anchor placement,
and a 6.0-mm threaded cannula was used as an accessory portal for suture passage and knot tying. Once the rotator cuff tear size and pattern had been recognized, the surgeon determined the repair construct. The torn rotator cuff tendon was repaired using a suture-passing device (Expressweave, Flexible Suture Passer, Depuy Mitek Inc, Raynham, Massachusetts) with a simple or mattress stitch configuration tied with reversing half-hitches on alternating posts using hybrid suture filament (FiberWire, Arthrex Inc, Naples, Florida; Orthocord, Depuy Mitek Inc; Ultrabraid, Smith & Nephew Endoscopy, Andover, Massachusetts). For isolated supraspinatus tears, the repair generally involved 2 suture anchors placed at the articular margin in a single-row configuration. Two-tendon tears were repaired with 2 to 4 suture anchors, with the medial row at the articular margin tied with a horizontal mattress stitch and with the lateral edge of the greater tuberosity tied with a simple stitch in a double-row configuration, when the tissue quality allowed the tendon to be mobilized. A margin convergence stitch was placed between the supraspinatus and infraspinatus tendons, when appropriate.

The details of the ARCR were recorded and so included information on the number of suture anchors, the suture anchor row configuration (single or double), repair (anatomic or nonanatomic), margin convergence (yes or no), and tissue quality (normal or poor). Additional procedures were performed according to surgeon discretion and so recorded, including acromioplasty (yes or no), superior labrum anterior-posterior procedures (none, debridement, or repair), biceps procedures (none, debridement, tenotomy, or tenodesis), or acromioclavicular joint procedures (none, acromioclavicular joint coplaning, or distal clavicle excision).

### Functional Outcome Evaluation

Per the Arthroscopic Rotator Cuff Registry protocol, an independent observer collected the data before surgery and at 1 and 2 years after surgery. The clinical assessment included a physical examination by an orthopaedic surgeon that included range of motion with a goniometer and manual muscle strength testing. Strength testing was performed with a handheld dynamometer (Lafayette Manual Muscle Test System, Lafayette Instrument Co, Lafayette, Indiana). The American Shoulder and Elbow Surgeons (ASES) shoulder score, a validated shoulder-specific outcome instrument, was used at baseline and after ARCR at 1 and 2 years.

### Ultrasonography

Shoulder ultrasounds were performed and interpreted by a musculoskeletal radiologist with 19 years of experience performing musculoskeletal ultrasound. Scans were performed using a broadband linear L12-5-MHz transducer employing tissue compound imaging to reduce speckle and an IU22 scanner (Philips Medical, Bothell, Washington) or a 7.5-MHz linear transducer operating in tissue harmonic mode on a Siemens Elegra scanner (Siemens-Acusion, Mountainview, California). The arm was maintained in internal rotation with minimal hyperextension to maximize comfort. The rotator cuff repair was examined in long (coronal) and short (sagittal) axes, and the images were stored in a digital format in the ultrasound scanner hard drive. The images were transferred to a Philips PACS (Philips Medical) workstation for review. A musculoskeletal radiologist, without knowledge of the clinical examination or prior ultrasound scans, performed and interpreted all the ultrasounds. The repaired rotator cuff tendon was scored according to a previously described rotator cuff tendon repair criteria. An intact tendon was defined as a continuous band of tissue extending to the suture anchor. A tendon was determined to have a defect (1) in the presence of a discretely marginated hypoechoic area in the tendon up to the suture anchor, (2) in the absence of cuff tissue over the humeral head with interposed fluid, or (3) by direct apposition of the peribursal fat. The defect size was measured; the extent of the defect was indicated (intrasubstance, partial thickness, or full thickness); and the location was noted for partial-thickness defects (bursal or articular surface). The defect area was determined by multiplying the size of the defect measured in long and short axes. The defect composition was characterized as fluid or soft tissue, whenever possible.

To assess the interobserver reliability of the criteria used to define a tendon defect, 2 independent musculoskeletal radiologists (blinded) interpreted the ultrasound images in a subcohort of patients. Thirty-two ultrasounds were required to detect a significant kappa statistic (chance-corrected agreement) between intact tendons and defect tendons and single- versus multiple-tendon involvement, to provide 80% power. The kappa value was .894 to detect intact versus defect tendons and .925 to detect single- versus multiple-tendon involvement. These ultrasounds were also used to provide sufficient power to calculate intraclass correlation coefficients for defect area measurements in 2 planes. The intraclass correlation coefficient for defect area was .906.

### Statistical Analysis

Intragroup comparison before and after ARCR was tested with paired t tests (SPSS Inc, Chicago, Illinois). Intergroup comparisons were performed using analysis of variance and post hoc analysis, with the Tukey test for continuous variables and the Kruskal-Wallis test for proportions. A P value of less than .05 was considered to be significant.

### RESULTS

Between August 2003 and August 2005, 127 patients completed the 2-year follow-up and 93 patients met the study criteria. There were no statistically significant differences in terms of age, defect size, proportion or tendon involvement, and proportion of row configuration between the patients who met the study criteria and those who did not. At 1 year after ARCR, 63 patients (67.7%) had an intact tendon and 30 (32.3%) had a full-thickness defect. All the tendons that were intact at 1 year remained intact at 2 years (group 1). Of the 30 tendons with full-thickness defects, 23 (74%) had residual defects at 2 years after...
ARCR (group 2); the remaining 7 (7.5%) had a full-thickness defect at 1 year but demonstrated a change in the imaging characteristics at the 2-year time point such that there was no defect (group 3) (Figure 2).

Table 1 presents group characteristics and comparisons: average age, intraoperative defect size, single- versus multiple-tendon involvement, biceps procedures, acromioclavicular joint procedures, and single- versus double-row configuration. Group 1 patients had a significantly lower mean age than that of group 2 patients \( (P = .04) \). Compared with group 1, group 2 had a significantly greater mean rotator cuff tear size \( (P = .00025) \). The proportion of single- and multiple-tendon tears differed significantly between groups 1 and 2 \( (P < .0001) \) and between groups 2 and 3 \( (P < .0001) \). Compared with groups 1 and 3, group 2 had a higher proportion of cases that underwent biceps and acromioclavicular joint procedures. Group 2 had 47.6% of cases with concomitant biceps tenodesis or tenotomy compared with 5.7% in group 1 and 33.3% in group 3 \( (P < .0001) \). Group 2 also had a significantly greater proportion of cases that required acromioclavicular joint coplaning or distal clavicle excision (73.7%) in contrast to group 1 (26.4%) and group 3 (0%; \( P = .001 \)). The proportion of single- and double-row configuration did not significantly differ between groups \( (P = .513) \). There were no statistically significant differences between groups 1 and 3 in terms of age, defect size, single- and multiple-tendon involvement, biceps procedures, acromioclavicular joint procedures, and row configuration.

Clinically, each group had a statistically significant improvement in ASES scores from preoperative to 1-year follow-up and from preoperative to 2-year follow-up \( (P < .05) \). Group 1 had an ASES score of 93.5 ± 11.9, which was significantly greater than the group 2 ASES score of 85.5 ± 17.0 at 2 years \( (P = .028) \) (Figure 3). With regard to active range of motion, all groups demonstrated improvement from baseline to 2-year follow-up, but there were no statistical differences between groups for forward elevation \( (P = .471) \) and external rotation \( (P = .657) \) (Figures 4A and 4B). There were no differences observed between groups in terms of strength in the plane of forward elevation \( (P = .987) \) (Figure 4C). The baseline strength in external rotation of group 2 was 3.72 ± 1.0, compared with 5.0 ± 0.0 for group 3 \( (P = .035) \), and the 2-year postoperative strength for group 1 \( (4.79 ± 0.80) \) was significantly greater than that of group 2 \( (4.17 ± 1.3; P = .0323) \) (Figure 4D).

**DISCUSSION**

The present study is the one of the largest to evaluate rotator cuff healing at multiple time points after ARCR, involving multiple surgeons at a single institution. Ours is also the first to report that all patients with an intact rotator cuff tendon remained healed until at least the 2 years after surgery. In addition, ultrasound appearance
remained consistent at 1 and 2 years for 86 of the 93 patients (92.5%). The remaining 7 (7.5%) improved in ultrasound appearance, and the full-thickness defect observed at 1 year was no longer present and, at 2 years, shared the ultrasound criteria and dynamic properties of an intact tendon.

Galatz et al.9 published the first study to evaluate the efficacy of ARCR with postoperative ultrasound and so demonstrated that 17 of 18 patients had a persistent defect 1 year after surgery. In Galatz’s study, 15 patients had a rotator cuff tear size greater than 3 cm, as compared with the present study, in which 39 of 113 patients (34.5%) had multiple-tendon involvement. More recent studies, however, have reported tendon healing after single-row fixation, with ranges of 53% to 88%,3,4,6,9,15,24 which is consistent with the 75% intact rotator cuff tendon (groups 1 and 3) after ARCR observed in the present study (Figure 5A). The similar rates of healing are likely related to a larger proportion of single-tendon involvement reported in the more recent studies. Case series of ARCR with double-row fixation have demonstrated tendon defects from 11% to 22% (Figure 5B).1,10,19,21 Three studies compared single- and double-row fixation with postoperative imaging analysis,5,8,20 2 of which reported a statistically significant difference in the proportion of healed tendons between the 2 techniques (Figure 5C).
Sugaya and colleagues\textsuperscript{20} and Charousset and colleagues\textsuperscript{5} determined that double-row repairs, compared with single-row repairs, demonstrated an improved structural appearance. In the present study, there were no statistically significant differences observed in proportion of row configuration between any groups.

Despite significant differences in age, tear size, and tendon involvement between groups 1 and 2, there were no differences between groups 1 and 3 for any variable. Groups 1 and 3 had an average age that was less than 60 years and a defect size less than or equal to 3 cm, whereas group 2 had an average age greater than 60 years and a defect size greater than 4 cm (Table 1). Group 3 still constituted a relatively small cohort, which seems to be a weakness. Perhaps at 5 years, we will see a greater number of patients fall into this category.

All groups demonstrated a significant improvement in ASES score from baseline to 2-year follow-up, and there was a statistically significant difference observed between groups 1 and 2 at 2 years. Groups 1 and 3 had ASES scores of 93.5 and 96.5, respectively, whereas group 2 had a score of 85.5. There were no observed differences between groups in terms of forward elevation and external rotation. Of interest, the baseline forward elevation for group 2 was 157.7°, compared with 148.7° for group 1, and there were no statistically significant differences in postoperative forward elevation (group 1, 173.3°; group 2, 169.7°) and strength in forward elevation (group 1, 4.9; group 2, 4.3) between these 2 groups despite the persistent defect on ultrasound detected in group 2. The patients in group 2 had an age greater than 60 years, a tear size greater than 4 cm, and about 75% multiple-tendon involvement, yet these patients still had a significant improvement in shoulder function. Compared with group 2, group 1 also demonstrated significantly greater strength in external rotation. The association of an intact tendon with improved functional outcome has been reported by several other studies.\textsuperscript{8,9,11,23,25} Other studies have also concluded that patients with a tendon defect still report excellent pain relief and high satisfaction.\textsuperscript{12,14} Despite persistent defects in group 2, ARCR may have restored the force couples in the rotator cuff, in combination with a structured postoperative rehabilitation program, to improve anterior deltoid strength to produce an improvement in overall shoulder functional outcome.\textsuperscript{14} Intermediate- and long-term studies are necessary.
to determine whether the clinical outcome deteriorates with persistent tendon defects.

Group 3 comprised 7 patients for whom a previously determined tendon defect at 1 year became less conspicuous at 2 years, and these findings were corroborated by 2 independent musculoskeletal radiologists without knowledge of the 1-year report. At 1 year, these tendons met the criteria for full-thickness defect, but the 2-year ultrasound appearance demonstrated a continuous band of tissue extending to the suture anchor without any evidence of fluid on either plane. The ultrasound can determine that there is intervening soft tissue in the previous defect, but the precise architecture of the tissue cannot be determined without a histological specimen. The nature of the tissue may be resorption of fluid, causing effacement of the defect margins and tissue granulation or adhesions. These cases suggest that an ongoing maturation of the repaired rotator cuff tendon that occurs up to 2 years after the index surgery. Serial imaging studies of the patellar tendon after harvesting the central third also show that ongoing morphologic changes occur beyond 1 year and even 2 years. \(^2,22\)

The present study highlights the remodeling potential of repaired rotator cuff tendons over time; thus, in patients with favorable rotator cuff characteristics (eg, age < 60 years, tears size < 3 cm, single-tendon involvement, absence of biceps or acromioclavicular joint injury), there is a high likelihood that the repaired tendon will meet the ultrasound criteria of an intact tendon by 1 year—even as late as 2 years. Only 2 of 23 patients (8.7%) in group 2 were younger than 60 years with tear sizes less than 3 cm, compared to 3 of 7 patients (42.9%) in group 3. There were no demographic or clinical differences between group 1 and group 3; otherwise, these 2 groups would have been combined if single ultrasound was performed at 2 years. These findings demonstrate the significance of serial imaging to facilitate a better understanding of changes in tendon morphologic characteristics after surgical repair.

With continuing advancement in ARCRs, accurate postoperative imaging is important in assessing the quality of the repair and in guiding treatment for patients who remain symptomatic. Accuracy of MRI to determine whether a surgically repaired rotator cuff tendon is intact ranges from 70% to 90%, \(^6,10,15,19\) Sutures and suture anchors are used in most arthroscopic repairs and, as such, can introduce artifacts in the MRI that can be misinterpreted as a rotator cuff tear. In addition, the metallic debris from the arthroscopic instrumentation (shaver, bur, awls, drill, etc) may cause significant scatter on MRI, thereby compromising the quality of the study. Ultrasound is not affected by such artifacts; that is, there is nothing comparable to susceptibility artifact in magnetic resonance. With advancement in technology, ultrasound has become highly accurate in evaluating the integrity of the rotator cuff after surgical repair. Teefey et al\(^{25}\) showed a sensitivity of 100%, a specificity of 85%, and an overall accuracy of 96% in identifying full-thickness tears preoperatively in 65 torn rotator cuffs confirmed with arthroscopy. Prickett et al\(^{15}\) reported an accuracy of 89% in detecting rotator cuff integrity in 44 patients who had undergone shoulder surgery, 34 of whom had had a rotator cuff repair. In the present study, the interobserver reliability for ultrasound interpretation of postsurgical rotator cuff tendons demonstrated a high kappa (.894) for intact versus defect, as well as high interclass correlation scores (.906) for defect area. The musculoskeletal radiologists at our institution perform a high volume of shoulder ultrasounds with a high degree of proficiency. A number of studies have reported a high operator dependence in ultrasonography, \(^1,12,19\) and the accuracy of ultrasound as a diagnostic modality may vary from institution to institution, depending on the level of expertise from the musculoskeletal radiologist. Furthermore, ultrasound is less expensive, less time-consuming, and better tolerated, and the images are not distorted by the suture anchors. Patients with shoulder pain prefer ultrasound over MRI and are more willing to undergo a repeat ultrasound examination. \(^17\) In the current study, the average time per ultrasound examination was less than 10 minutes.

Ultrasound has been used to evaluate rotator cuff integrity at single time points postoperatively, and it has been correlated with clinical outcomes. Verma et al\(^{24}\) reported a 27.3% recurrent defect rate in 38 shoulders at a minimum of 2 years of follow-up. Galatz et al\(^{19}\) reported defects in 17 of 18 (94%) patients at a minimum of 12 months postoperatively, with large and massive tears. Anderson et al\(^{1}\) found defects in 9 of 52 (17%) shoulders at an average of 30 months postoperatively. Functional outcome did not correlate with defects in any of these studies. None of these studies, however, looked at serial postoperative ultrasounds to see what occurs to the cuff integrity over time once it is repaired. The only study that we know of that looked at consecutive ultrasounds did so to evaluate vascular and anatomical response after rotator cuff repair in 50 patients. Fealy et al\(^{7}\) found persistent defects in 50% at 6 weeks, 45% at 3 months, and 43% at 6 months postoperatively. Only 8 of the 50 repairs, however, were arthroscopic repairs, with the remainder being open or mini-open repairs. \(^7\)

The current study design was a retrospective cohort analysis based on the healing status after ARCR. Because of the nature of the question, the study could not be designed as a prospective cohort analysis or as a randomized clinical trial. Advantages of the study include its multiple time points for objective and subjective outcomes; furthermore, a musculoskeletal radiologist (blinded) performed and provided initial interpretation for all ultrasound examinations. Limitations in the study include percentage of patient follow-up and the short-term nature of the study. In addition, a number of other potential factors were not analyzed that might differentiate groups, such as size of anchors, type of anchor, anchor material (bio versus metal), tendon stitch configuration, arthroscopic knot, suture bridge. Seventy-three percent of patients in the registry met the study criteria; however, variables such as age, defect size, proportion of tendon involvement, and proportion of row configuration did not differ significantly between the patients who met the study criteria and those who did not. The patients in the registry will continue to be followed, and they will be reanalyzed at the 5-year time point with ultrasound and functional outcome scores.
CONCLUSION

The present study is the largest study to report on ARCR with serial objective and subjective outcome instruments. All groups demonstrated significant improvement in shoulder function, regardless of tendon healing. All arthroscopically repaired rotator cuff tendons that were healed at 1 year remained healed at 2 years. Evidence suggests that repaired tendons may remodel over a period of at least 2 years. Age less than 60 years, defect size less than or equal to 3 cm, and single-tendon involvement are positive prognostic factors associated with tendon healing after ARCR.

REFERENCES


