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The fate of hypoechoic cleft

Han Liu, MD, Lisa Hackett, AMS, Patrick H. Lam, MD, PhD, George A.C. Murrell, MD, DPhil *

Orthopaedic Research Institute, St George Hospital Campus, University of New South Wales, Sydney, NSW, Australia

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Background: Hypoechoic clefts are small defects found on ultrasonographs in the intact rotator cuff tendon after rotator cuff repair. Little is known about the fate of these hypoechoic clefts, as to whether they will heal, persist, or develop into a retear.

Methods: This prospective study involved 24 patients who underwent arthroscopic rotator cuff repair surgery and were found to have a hypoechoic cleft at the 6-month postoperative ultrasonograph. A subsequent ultrasonography follow-up was performed at 9 months or later by the same ultrasonographer and the repair re-examined.

Results: At an average postoperative follow-up of 21 months, 14 of the 25 hypoechoic clefts (56%) had healed; 5 (20%) had persistent clefts whereas 6 (24%) had progressed to a full-thickness rotator cuff retear. Patients with a hypoechoic cleft ≥ 36 mm² were 5 times more likely to have a retear than patients with hypoechoic cleft < 36 mm² (relative risk = 5.1; $P < .05$). Patients with hypoechoic clefts ≥ 36 mm² had a higher frequency of pain during activity and sleep and a lower level of satisfaction at the 21-month follow-up compared to those with small hypoechoic clefts ($P = .05$).

Conclusion: This is the first study to evaluate the natural history of a hypoechoic cleft found at ultrasonography following rotator cuff repair. The study showed that clefts less than 36 mm² are likely to heal, while those greater than 36 mm² are at high risk of progressing to full-thickness retears.

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Rotator cuff tear is a common cause for pain and loss of shoulder function. The majority of tears occurs at the supraspinatus; however, more than 1 tendon of the rotator cuff can be involved.¹⁷ The main treatment for symptomatic rotator cuff tears is rotator cuff repair.¹³ The most common complication after rotator cuff repair is retear, with the retear rate ranging from 11%–94%.¹⁵

Postoperative imaging is important in the assessment of postoperative rotator cuff tendon integrity. High-resolution ultrasonography in real time is a commonly used and effective imaging modality to demonstrate rotator cuff pathology and associated intratendinous changes.^{1,13} The rate of structural defects reported after open and arthroscopic rotator cuff repair surgery ranges from 13%–94%.³

When examining patients with ultrasonography at 6 months after their rotator cuff repair surgery, our senior sonographer (L.H.) has from time to time noted hypoechoic clefts within the repaired tendon. Hypoechoic clefts are defined by the sonographer as partial-thickness defects found in an intact rotator cuff tendon.

They are a small focal area of hypoechoic area (largest identified in this study was 110 mm²) with well-defined margins (Fig. 1). The well-defined margin of a hypoechoic cleft differs from the jagged margin found in rotator cuff tears and retears. Hypoechoic clefts also differ from postoperative heterogenous tendon, as the postoperative tendon are shades of grey whereas the cleft is black, similar to cyst lesions. There is no evidence of fibrillar structure or vascularity within the cleft. Hypoechoic clefts are usually located near the anchor site and extend mediolaterally along the tendon.

Little is known about the fate of these hypoechoic clefts. The primary aim of this study, therefore, was to determine the fate of these hypoechoic clefts, whether they heal, persist in the tendon, or further develop into retears. Secondary aims were to determine whether hypoechoic cleft size influences patient-ranked pain and functional outcomes, and examiner-assessed range of motion and strength.

Materials and methods

Study design

This study was a prospective evaluation of the morphologic outcomes of the rotator cuffs at the 9-month follow-up or later after

This study was approved by the Human Research Ethics Committee, Prince of Wales Hospital, Randwick, Sydney (HREC Ref 12/310).

* Corresponding author: George A.C. Murrell, MD, DPhil, Orthopaedic Research Institute, St George Hospital, 4-10 South Street, Kogarah, NSW 2217, Australia.

E-mail address: murrell.g@ori.org.au (G.A.C. Murrell).

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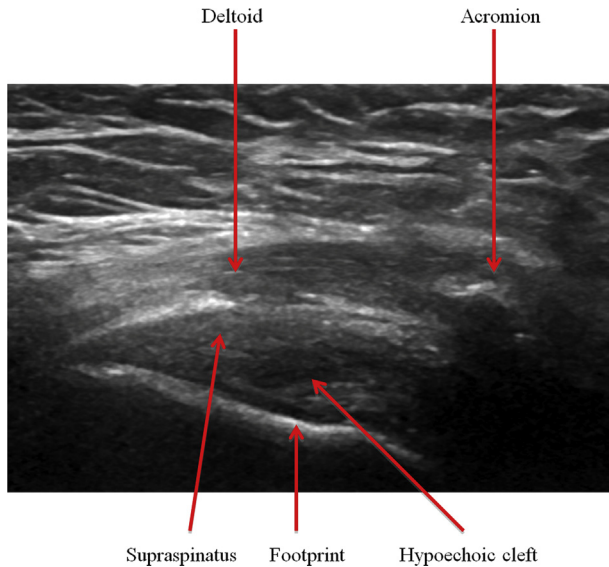


Figure 1 Long-axis ultrasonographic image of the supraspinatus tendon with hypoechoic cleft.

rotator repair surgery in patients who had an arthroscopic rotator cuff repair and were found to have a hypoechoic cleft on ultrasonography at the 6-month postoperative follow-up. The primary outcome of the study was to determine whether the hypoechoic cleft had resolved, persisted, or progressed to a full-thickness re-ear. Secondary outcomes were to investigate the relationship between hypoechoic cleft size and patient-assessed pain, function, and satisfaction scores and examiner-assessed passive range of motion and strength. Patients were included in this study if they had an arthroscopic rotator cuff repair and were found to have a hypoechoic cleft on the repaired tendon at 6-month follow-up ultrasonography. Patients were excluded from the study if they had a rotator cuff repair with an interpositional polytetrafluoroethylene (PTFE) patch, partial rotator cuff repair, osteoarthritis of the shoulder (\geq grade II), and concurrent fracture of the humerus. Patients who satisfied the inclusion/exclusion criteria were invited to attend a follow-up clinic to determine the status of rotator cuff tendon postsurgery.

Operative procedure and rehabilitation

All arthroscopic surgical procedures included in the study were performed by the senior author (G.A.C.M). Patients who underwent arthroscopic rotator cuff repair received an interscalene block and were placed in the beach-chair position. A posterior portal was created for insertion of an arthroscope into the glenohumeral joint to allow intra-articular assessment of the glenohumeral joint and the rotator cuff tendons. Following assessment and location of the torn rotator cuff tendon, an anterolateral portal was made under direct vision with the use of a spinal needle. Tears were débrided and partial-thickness tears were converted to full-thickness tears using an arthroscopic shaver ensuring unobstructed contact over the anatomic footprint. Repairs were approached either from within the glenohumeral joint (undersurface), from within the subacromial bursa (bursal), or both approaches. Rotator cuff repair was performed using sutures and knotless suture anchors (Opus SmartStitch and OPUS Magnum-2 knotless anchor; ArthroCare Corp, Sydney, Australia) in a single-row inverted mattress tension-band configuration securing the tendon to the greater tuberosity. Sutures were passed via the anterolateral portal through the débrided tendon edge using the Opus SmartStitch device. A T-handled punch was

used to create a hole on the footprint of the greater tuberosity, and the suture ends were passed through an Opus Magnum-2 (ArthroCare) suture anchor. The anchors were deployed into the hole and sutures tightened to obtain tendon-to-bone fixation. Tear size and tear thickness were determined on visualization and estimation of the torn area. Tissue quality, tendon mobility, and quality of the repair were ranked as fair, good, very good, or excellent and later converted to a numerical scale (fair = 1, good = 2, very good = 3, excellent = 4). Other documented items were operative time and the number of anchors used for the repair. After repair, the portals were closed with sutures and the shoulder was dressed.

Patients were placed into a sling immediately after the surgery with a small abduction pillow (Ultrasling II, DJO, Sydney, Australia) to be worn for 6 weeks. Patients were discharged on the day and were given an ice pack (DuraSoft Shoulder Wrap) to be used on the repaired shoulder for 20 minutes every 2 hours during waking hours for 2 days.

Postoperatively, patients completed a rehabilitation exercise program through a progression of 3 phases, which was closely monitored by the physiotherapist over 6 months.¹²

Rotator cuff integrity

Two ultrasonographic examinations of the rotator cuff were performed by a single musculoskeletal ultrasonographer (L.H.). The first ultrasonographic examination was performed at 6 months postoperatively and the second ultrasonographic examination at 9 or more months postoperatively. Real-time ultrasonographic evaluation of the rotator cuff was performed using a General Logiq E9 machine (General Electric, Sydney, Australia) with a 12-MHz linear transducer, following a standardized protocol.¹ Hypoechoic cleft was defined as a small focal area of hypoechoicogenicity with well-defined margin and no evidence of fibrillar structure or vascularity within the cleft. The location and longitudinal and transverse diameter of hypoechoic cleft or any tear of the rotator cuff was recorded on a standardized form (Supplementary Appendix S1). The size of the hypoechoic cleft was calculated by multiplying the longitudinal and transverse diameter of the hypoechoic cleft.

Shoulder function

Patients were evaluated preoperatively and at the 1-week, 6-week, 12-week, 6-month, and \geq 9-month follow-ups postoperatively. At each visit, patients completed a standardized questionnaire (Supplementary Appendix S2) based on the L'Insa-lata Shoulder Questionnaire,⁹ which appraised pain, daily activities, recreational and sporting activities, work, and overall satisfaction, using Likert-type scales.

Range of motion

Examiners measured passive range of shoulder motion preoperatively and at the 6-week, 12-week, 6-month, and \geq 9-month follow-ups postoperatively. Range of forward flexion, abduction, external rotation, and internal rotation was determined visually with the use of a previously validated protocol (Supplementary Appendix S3).¹⁶

Strength

Examiners measured shoulder strength preoperatively and at the 6-week, 12-week, 6-month, and \geq 9-month follow-ups postoperatively. Strength of internal rotation, external rotation, supraspinatus, lift-off, and adduction was measured using a handheld dynamometer (Supplementary Appendix S3).¹⁶

Table I

Subgroup cohort demographics defined by ultrasonography-measured hypoechoic cleft size at 6 months post rotator cuff repair surgery

Demographics	Small-cleft group (hypoechoic cleft size < 36 mm ²)	Large-cleft group (hypoechoic cleft size ≥ 36 mm ²)
Age, yr, mean ± SEM (range)	54 ± 2.2 (34-73)	53 ± 2.9 (45-62)
Sex (male-female)	12:6	4:3
Duration of Symptoms, mo, mean ± SEM (range)	31 ± 10.4 (0.5-132)	69 ± 41.6 (1-301)
Affected side (right-left)	10:8	5:2
Tear thickness, %		
Full	44	71
Partial	56	29
Tear size, cm ² , mean ± SEM (range)	3.0 ± 0.5 (0.64-7.84)	2.9 ± 1.3 (0.72-10.5)
Repair approach, %		
Undersurface	50	57
Bursal	11	29
Both	39	14
Number of anchors, mean ± SEM (range)	2 ± 0.2 (1-3)	2 ± 0.2 (1-2)
Surgeon-ranked tissue quality, mean ± SEM	2 ± 0.2	2 ± 0.3
Surgeon-ranked tendon mobility, mean ± SEM	3 ± 0.2	3 ± 0.3
Surgeon-ranked repair quality, mean ± SEM	3 ± 0.1	3 ± 0.2
Operative time, min, mean ± SEM (range)	17 ± 2.2 (9-45)	18 ± 3.2 (8-35)

SEM, standard error of the mean

Statistical analysis

Comparisons were made within the group at each time point using paired Student *t*-tests, and those with categorical data were compared using Wilcoxon signed-rank tests. Comparisons between groups were made using unpaired Student *t* tests, and those with categorical data were compared using Mann-Whitney rank-sum tests. Fisher exact test was used to assess dichotomous data.

Results

Study group

From October 2005 to December 2013, a total of 2058 patients had arthroscopic rotator cuff repair surgery performed by the senior author. Of these, 33 patients were identified who met the inclusion criteria, that is, patients with a hypoechoic cleft present at 6 months following arthroscopic rotator cuff repair surgery. Of these, 11 already had a second follow-up ultrasonograph after discovery of hypoechoic cleft. Of the remaining 22 patients, 13 were able to come in for a second follow-up ultrasonograph to assess the integrity of the repaired rotator cuff tendon. This gave a sample of 25 patient shoulders, which formed the study cohort.

Cohort demographics

The study cohort consisted of 16 male and 8 female patients with a mean age of 54 years ± 1.7 (mean ± standard error of the mean [SEM]) (range 34-73 years) and mean duration of symptoms of 42 months ± 13.7 (range 0.5-301 months). Arthroscopic rotator cuff repair was performed on 10 left shoulders and 15 right shoulders.

Intraoperatively, 15 shoulders (60%) had full-thickness tears, 10 shoulders (40%) had partial-thickness tears with a mean (±SEM) tear size area of 3 cm² (±0.5 cm²) (range 0.6-10.5 cm²). The number of anchors needed for repair was 2 ± 0.1 (range 1-3). Mean operative time was 17 ± 1.8 minutes (range 8-45 minutes). Concurrent

Table II

Retear rate: small cleft vs. large cleft

	Intact	Retear	Total
Small cleft (<36 mm ²)	16	2	18
Large cleft (≥36 mm ²)	3	4	7
Total	19	6	25

acromioplasty was performed on 2 patients. The senior author ranked tissue quality as very good to excellent, tendon mobility as very good to excellent, and repair quality as excellent (Table 1).

Six-month follow-up ultrasonography data

At 6-month follow-up ultrasonography, the mean (±SEM) hypoechoic cleft (Fig. 1) area was 31 ± 5.7 mm² (range 3-110 mm²). These hypoechoic clefts were often located near the anchor site and on the bursal side of the supraspinatus tendon.

Retear, healing, and hypoechoic cleft rate

At the 21 ± 3-month (range 9-54 months) follow-up of the patients with hypoechoic clefts, retears were found in 6 of the 25 shoulders, corresponding to a re-tear rate of 24%. The mean re-tear size was 1.5 cm² ± 0.4 cm² (range 0.7-3.2 cm²). Four of the 6 retears subsequently underwent revision rotator cuff repair surgery performed by the same surgeon, with no retears at the 6-month follow-up after the revision surgery.

Fourteen of the 25 shoulders that previously had a hypoechoic cleft at the 6-month ultrasonographic examination had an intact rotator cuff with no hypoechoic cleft at an average of 21-month follow-up, corresponding to a healing rate of 56%.

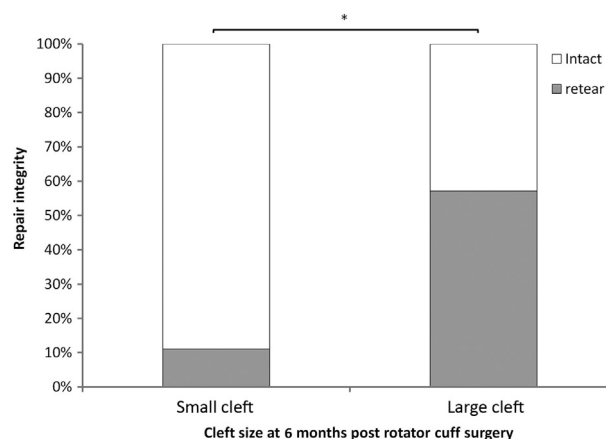


Figure 2 Intact and re-tear rates: comparison between the small- and large-cleft groups. **P* < .05 using chi-squared analysis.

Table III
Patient-ranked pain scores

Outcome	Small cleft	Large cleft	Small vs. large	P value
Pain frequency*				
Activity				
6 mo	2.2	2.7	NS	.39
21 mo	1.5	2.9	0.05	.05
Sleep				
6 mo	1.7	2.1	NS	.56
21 mo	1.2	2.6	0.05	.05
Extreme				
6 mo	0.5	1.7	NS	.12
21 mo	1	2.2	NS	.14
Pain severity†				
At rest				
6 mo	1.1	1	NS	.93
21 mo	0.8	1.5	NS	.33
Overhead				
6 mo	1.7	1.6	NS	.81
21 mo	1.3	2.4	NS	.09
When sleeping				
6 mo	1.2	1.4	NS	.69
21 mo	1.1	2	NS	.21
Shoulder stiffness‡				
6 mo	1.2	1.9	NS	.3
21 mo	1	1.4	NS	.51
Level of difficulty§				
With reaching behind the back				
6 mo	1.8	1.4	NS	.51
21 mo	1.4	2.1	NS	.21
With overhead activities				
6 mo	1.7	1.7	NS	.94
21 mo	1.4	2.1	NS	.21
Overall shoulder satisfaction 				
6 mo	2.9	2.4	NS	.4
21 mo	3	1.9	0.05	.05

NS, not significant.

* Pain frequency: 0 = never, 1 = monthly, 2 = weekly, 3 = daily, 4 = always.

† Pain severity: 0 = none, 1 = mild, 2 = moderate, 3 = severe, 4 = very severe.

‡ Shoulder stiffness: 0 = none, 1 = a little, 2 = moderately, 3 = quite, 4 = very.

§ Level of difficulty: 0 = none, 1 = mild, 2 = moderate, 3 = severe, 4 = very severe.

|| Overall shoulder satisfaction: 0 = very bad, 1 = bad, 2 = poor, 3 = fair, 4 = good.

A hypochoic cleft was still present in 5 of the 25 shoulders, corresponding to 20%. The mean persistent hypochoic cleft size was $42 \pm 14.7 \text{ mm}^2$ (range 14-63 mm^2).

Subgroup analysis

To assess the effect of cleft size on shoulder function in patients with a hypochoic cleft at 6 months after rotator cuff repair surgery, the group was divided according to ultrasonography-measured hypochoic cleft size at 6-month follow-up post rotator cuff repair surgery. The frequency distribution of retear rate and cleft size of the entire cohort showed fewer retears with cleft size smaller than 36 mm^2 in contrast to cleft size larger than 36 mm^2 . Patients were allocated to the “small cleft” group if their hypochoic cleft size was $<36 \text{ mm}^2$ ($n = 18$) or to the “large cleft” group if their hypochoic cleft size was $\geq 36 \text{ mm}^2$ ($n = 7$).

Cohort demographics

The mean hypochoic cleft size was $18 \pm 2.6 \text{ mm}^2$ (range 3-35 mm^2) in the small-cleft group, and $66 \pm 11.7 \text{ mm}^2$ (range 36-110 mm^2) in the large-cleft group.

There were no statistically significant differences between the demographic characteristics of patients of the small-cleft group and the large-cleft group in the subgroup analysis ($P > .05$), for example, age, sex, preoperative tear size, operative factors, etc.

Retear rate

At an average of 21 months' follow-up, the small-cleft group had significantly fewer retears, 2 retears (11%, 2 of 18) compared to the large-cleft group, 4 retears (57%, 4 of 7) ($P = .032$) (Table II, Fig. 2). Retear was 5 times more likely to occur in the large cleft group than in the small cleft group (relative risk = 5.1).

Patient-ranked pain scores

At the 6-month follow-up after their initial surgery, both groups had significantly decreased pain frequency during sleep compared to

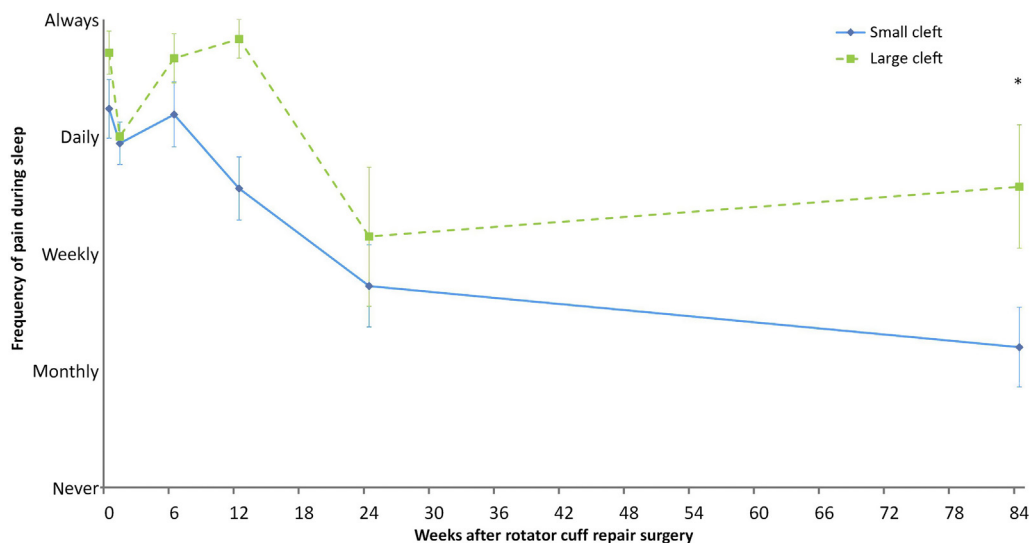


Figure 3 Frequency of pain during sleep: comparison between the small- and large-cleft groups. * $P < .05$ using unpaired two tailed Student's *t*-tests.

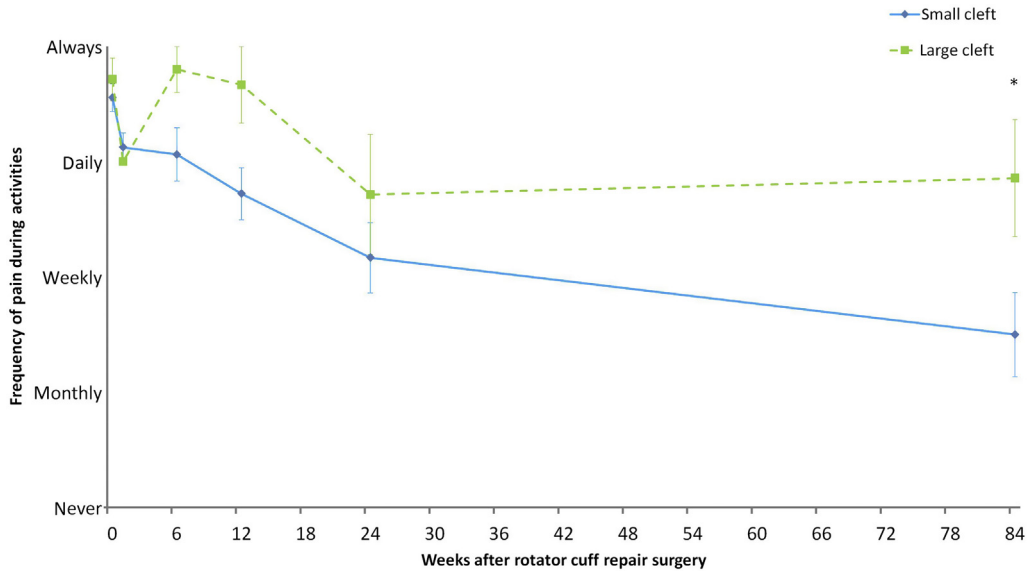


Figure 4 Frequency of pain during activities: comparison between the small- and large-cleft groups. * $P < .05$ using unpaired two tailed Student's t -tests.

before surgery. The 2 groups had similar pain frequency during sleep at the 6-month follow-up. The small-cleft group continued to improve between the 6- and 21-month follow-ups, whereas there was no improvement in pain frequency during sleep at 6 and 21 months for the large-cleft group. At the 21-month follow-up, patients in the small-cleft group had significantly less frequent shoulder pain during sleep than the large-cleft group (Table III, Fig. 3).

At the 21-month follow-up, the small-cleft group reported less frequent pain during activity and were more satisfied with their shoulders compared with the large-cleft group (Table III, Figs. 4 and 5).

Examiner-assessed range of shoulder motion and strength

At the 6- and 21-month follow-ups, there was no significant difference between the small- and large-cleft groups in abduction, forward flexion, and external rotation range of motion (Table IV).

At the 6- and 21-month follow-ups, there was no significant difference between the small- and large-cleft groups in supraspinatus and external rotation strength (Table IV, Fig 6).

Discussion

The study examined the fate of patients who had a hypoechoic cleft at 6-month follow-up ultrasonography after arthroscopic rotator cuff repair surgery. Among the study cohort, approximately half healed, one-quarter had a persistent hypoechoic cleft, and one-quarter progressed to a full-thickness retear. In the healed hypoechoic cleft group, there was evidence of scar tissue filling the previous hypoechoic cleft. Smaller hypoechoic clefts (<36 mm²) were 5 times more likely to heal than those greater than 36 mm².

Both ultrasonography and magnetic resonance imaging (MRI) have been used in previous studies to assess rotator cuff integrity postoperatively. This study used ultrasonography to assess the integrity of repaired rotator cuff tendons. Previous studies have shown that the sensitivity and specificity of ultrasonography for postoperative assessment of rotator cuff tendon integrity ranges between 85%-100% and 86%-100%, respectively.^{2,10,14} Ultrasonography also allows demonstration of intratendinous changes that occur in rotator cuff pathology.¹ On ultrasonographic scans, normal

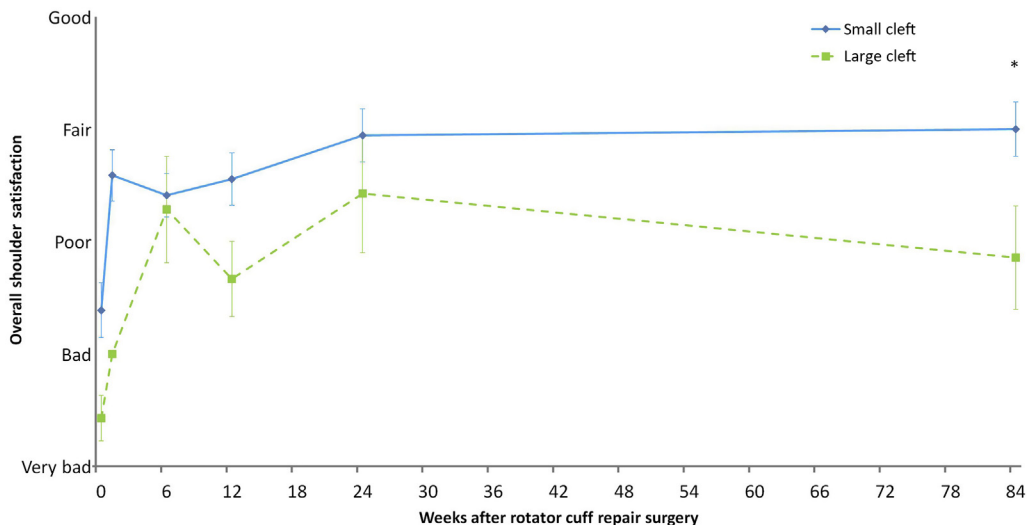


Figure 5 Overall shoulder satisfaction: comparison between the small- and large-cleft groups. * $P < .05$ using unpaired two tailed Student's t -tests.

Table IV
Examiner-assessed strength and range of motion

Variable	Small cleft	Large cleft	Small vs. large	P value
Range of motion, degrees				
Abduction				
6 mo	139	133	NS	.69
21 mo	153	133	NS	.36
Forward flexion				
6 mo	155	153	NS	.86
21 mo	161	147	NS	.47
External rotation				
6 mo	45	54	NS	.49
21 mo	69	44	NS	.06
Strength, N				
Supraspinatus				
6 mo	54	45	NS	.5
21 mo	47	41	NS	.66
External rotation				
6 mo	60	55	NS	.67
21 mo	56	56	NS	.99

rotator cuff tendon appears as a homogenous network of fine parallel and linear echogenic fibrillar structure, which is termed echotexture. A hypoechoic cleft found at 6-month follow-up ultrasonography after rotator cuff repair represents a disruption to the normal echotexture.¹¹

Our study showed that there is a potential for these small defects found in postoperative rotator cuff tendons to develop healing and scarring. The finding of healing is consistent with findings from previous studies.⁶ Fealy et al evaluated consecutive ultrasonographs at 6 weeks, 3 months, and 6 months after open or arthroscopic rotator cuff repairs, and found the defect rate decreased from 50% to 43%.⁴ In studies by Gulotta et al, 14 of 30 patients with a rotator cuff tendon defect found at 1-year follow-up ultrasonography after arthroscopic rotator cuff repair had spontaneous resolution of the defect at the 2- and 5-year follow-ups. Ultrasonography identified intervening soft tissue filling in the previous defect.⁶ An MRI study by Jost et al also reported 8 of the 20 reruptures seen in repaired tendon at 3.2 years after open rotator cuff repair were no longer identified at the 7.6-year follow-up. The tissue bridging the previous defect satisfied all of the MRI

criteria of scar tissue.⁸ There was no documentation of hypoechoic clefts in previous studies; however, a hypoechoic cleft may have been included in the defects reported.

Although the aforementioned studies reported postoperative defects and retears, there was no documentation of the size of the defects and whether defect size affected their ability to heal. No study thus far has specifically examined the relationship between hypoechoic cleft size and retear. Previous studies have identified younger age and single tendon involvement as predictive factors for spontaneous healing of a tendon defect after rotator cuff repair surgery.⁷ The MRI study by Jost et al suggested that defects of the supraspinatus after open rotator cuff repair surgery with size <400 mm² have the potential to heal in the long term.⁸ Our study found that a bigger hypoechoic cleft was associated with higher postoperative retear rates. Retears were 5 times more likely to develop in patients with hypoechoic cleft size ≥ 36 mm² measured at 6 months after surgery than those with hypoechoic cleft size <36mm². To our knowledge, this is the first study with sequential follow-up ultrasonographs of patients with postoperative hypoechoic clefts to determine healing of the defect and to evaluate the relationship between hypoechoic cleft size and retear rate. The data from this study is consistent with advice that sonographic assessment of postoperative tendon should include specifying the size of the defect.⁵

This study also examined the relationship between hypoechoic cleft size and postoperative outcomes of arthroscopic rotator cuff repair surgery. The results from this study showed that the large cleft group had slightly inferior long-term pain and patient satisfaction outcomes compared to the small cleft group, including higher pain frequency during sleep and activity, and lower level of shoulder satisfaction at the 21-month follow-up. This may be due to the higher retear rate in the large cleft group compared to the small cleft group at the 21-month follow-up.

Strengths of this study were the precise inclusion and exclusion criteria and regular collection of data. In this study, a single surgeon with extensive experience performed all arthroscopic rotator cuff repairs using the same repair technique, and a single experienced sonographer performed all ultrasonographic examinations and interpretations.

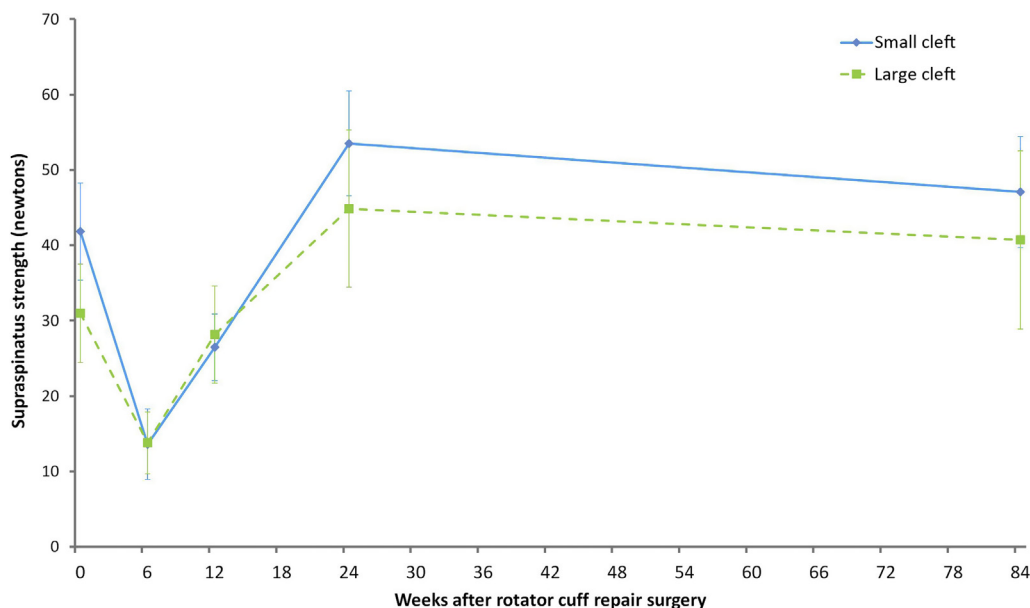


Figure 6 Supraspinatus strength: comparison between the small- and large-cleft groups.

Limitations of this study included a relatively small cohort and short-term follow-up. A longer duration of follow-up would allow for better understanding of the natural history of the patients with persistent hypoechoic clefts. Retears may continue to occur beyond the final follow-up time point, and outcome measures, including patient-ranked pain, examiner-assessed range of motion, and strength, may continue to change beyond this time point. Having a single surgeon and sonographer may limit the applicability of these findings to other practices.

Conclusions

In conclusion, our study showed that there was a healing capacity in tendons with hypoechoic clefts after arthroscopic rotator cuff repair surgery. Smaller hypoechoic clefts ($<36 \text{ mm}^2$) found at the 6-month follow-up after arthroscopic rotator cuff repair were more likely to heal compared to larger hypoechoic clefts ($\geq 36 \text{ mm}^2$). Likewise, large hypoechoic clefts were 5 times more likely to re-tear compared to small hypoechoic clefts. Patients with large hypoechoic clefts had a higher frequency of pain during activity and sleep, and lower level of satisfaction at an average 21 months' postoperative follow-up compared to those with small hypoechoic clefts.

Disclaimer

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Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.jses.2019.07.006>.

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