Presurgical tear characteristics and estimated shear modulus as predictors of repair integrity and shoulder function one year after rotator cuff repair

Matthew C. Ruder, MSa, Rebekah L. Lawrence, PT, PhDa, Steven B. Soliman, DO, RMSKb, Michael J. Bey, PhDab

aBone & Joint Center, Henry Ford Health System, Detroit, MI, USA
bDepartment of Radiology, Henry Ford Health System, Detroit, MI, USA

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B a c k g r o u n d : Rotator cuff repair provides pain relief for many patients; however, retears are relatively common and affect approximately 20%-70% of patients after repair. Although magnetic resonance imaging (MRI) offers the ability to assess tissue characteristics such as tear size, retraction, and fatty infiltration, it provides little insight into the quality of the musculotendinous tissues the surgeon will encounter during surgery. However, shear wave elastography (SWE) could provide an indirect assessment of quality (ie, stiffness) by measuring the speed of shear waves propagating through tissue. The objective of this study was to determine the extent to which estimated shear modulus predicts repair integrity and functional outcomes 1 year after rotator cuff repair.

M e t h o d s : Thirty-three individuals scheduled to undergo arthroscopic rotator cuff repair were enrolled in this study. Before surgery, shear modulus of the supraspinatus tendon and muscle was estimated using ultrasound SWE. MRIs were obtained before and 1 year after surgery to assess tear characteristics and repair integrity, respectively. Shoulder strength, range of motion, and patient-reported pain and function were assessed before and after surgery. Functional outcomes were compared between groups and across time using a two-factor mixed model analysis of variance. Stepwise regression with model comparison was used to investigate the extent to which MRI and shear modulus predicted repair integrity and function at 1 year after surgery.

R e s u l t s : At 1 year after surgery, 56.5% of patients had an intact repair. No significant differences were found in any demographic variable, presurgical tear characteristic, or shear modulus between patients with an intact repair and those with a recurrent tear. Compared with presurgical measures, patients in both groups demonstrated significant improvements at 1 year after surgery in pain (P < .01), self-reported function (P < .01), range of motion (P < .01), and shoulder strength (P < .01). In addition, neither presurgical MRI variables (P > .16) nor shear modulus (P > .52) was significantly different between groups at 1 year after surgery. Finally, presurgical shear modulus generally did not improve the prediction of functional outcomes above and beyond that provided by MRI variables alone (P > .22).

C o n c l u s i o n : Although SWE remains a promising modality for many clinical applications, this study found that SWE-estimated shear modulus did not predict repair integrity or functional outcomes at 1 year after surgery, nor did it add to the prediction of outcomes above and beyond that provided by traditional presurgical MRI measures of tear characteristics. Therefore, it appears that further research is needed to fully understand the clinical utility of SWE for musculoskeletal tissue and its potential use for predicting outcomes after surgical rotator cuff repair.

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and postsurgical shoulder function is often unpredictable. Previous clinical studies have suggested that age, tear size, and tear retraction may be risk factors for recurrent tearing and poor clinical outcomes. Unfortunately, these imaging and clinical descriptors provide little insight into the quality of the musculotendinous tissues the surgeon will encounter during surgery. This limitation is clinically important because without a reliable measure of tear quality, it is difficult for surgeons to assess the potential for repair healing before surgery and how best to counsel patients on postsurgical activities and expected outcomes.

Shear wave elastography (SWE) is an ultrasound-based technology that provides an indirect assessment of quality (ie, stiffness) by measuring the speed of shear waves propagating through tissue. Clinical applications of this technology initially focused on diagnosing breast and liver pathology. However, the technology has been used increasingly to assess musculoskeletal tissues including the rotator cuff. Although recent evidence suggests that SWE is not associated with individual rotator cuff tear characteristics, it may provide a more global assessment of tissue quality. Furthermore, it is possible that SWE, either alone or in conjunction with existing magnetic resonance imaging (MRI)-based measures, could be a stronger predictor of healing and functional outcomes than conventional parameters such as patient age, rotator cuff tear size, and muscle fatty degeneration or atrophy.

The objective of this study was to determine the extent to which pre-surgical estimated rotator cuff shear modulus predicts repair integrity and functional outcomes 1 year after rotator cuff repair. We hypothesized that presurgical shear modulus of the rotator cuff would be associated with repair tissue healing, shoulder function, and pain after rotator cuff repair. Furthermore, we hypothesized that presurgical shear modulus would provide a significant improvement when added to the prediction of these outcomes provided by MRI-based measures alone.

Materials and methods

Participants

After institutional review board approval and informed consent, 33 participants enrolled in this study. Participants were eligible to participate in the study if they were 50-80 years old and were scheduled for surgical repair of a small- or medium-sized full-thickness tear of the supraspinatus tendon, as determined via presurgical MRI. The exclusion criteria included a traumatic tear, prior shoulder surgery, more than one steroid injection, body mass index greater than 30 kg/m², current smoker, uncontrolled diabetes, or an outstanding worker’s compensation claim.

Presurgical shear wave elastography

Approximately 1-2 weeks before surgery, ultrasound SWE images of each participant’s supraspinatus muscle and intramuscular tendon were acquired by one operator using a Siemens ACUSON S3000 with a 9L4 linear transducer (Siemens; Erlangen, Germany). Images were acquired with the participant’s shoulder supported in 30° of scapular-plane abduction in neutral rotation. The intramuscular tendon was imaged by placing the transducer in the supraspinatus fossa, in the long axis relative to the intramuscular tendon, and visually aligning with the tendon fibers (Fig. 1, A and B). The muscle was imaged by placing the transducer in the supraspinatus fossa, in the long axis relative to the supraspinatus muscle belly, and visually aligning with the muscle fibers. Five trials were acquired for each tissue region of interest (ie, intramuscular tendon, muscle) using the system’s built-in elastography module and a transmit frequency of 8 MHz. Each trial acquired a B-mode image and a corresponding SWE image (Fig. 1, B and C). Reliability of this protocol was established previously by Baumer et al (intraclass correlation coefficients: intrarater >0.87, inter-rater >0.72).

For each trial, the region of interest (ie, muscle or intramuscular tendon) was isolated from surrounding tissues on the B-mode image using ImageJ interfaced with custom software (MATLAB, The MathWorks, Inc.; Natick, MA, USA). As per manufacturer recommendations, data within the region of interest in the corresponding SWE image were retained for pixels whose proprietary quality metric was greater than 0.87 (Fig. 1, D). For each pixel, the shear wave speed data were then converted to an estimate of shear modulus as previously described, and then, a single estimated shear modulus was determined as the median value of all retained pixels. Finally, the mean shear modulus was calculated across all five trials for each tissue region.

Presurgical functional assessment

Patient-reported measures of pain and function were assessed using the visual analog scale for pain and the Western Ontario Rotator Cuff Index. Active range of motion (AROM) was manually measured with a goniometer for sagittal-plane flexion and frontal-plane abduction. Isometric shoulder strength was measured during coronal-plane abduction at 30° of abduction, sagittal-plane elevation at 30° elevation, internal rotation at 15° of frontal plane elevation and 0° of humeral rotation, and external rotation at 15° of frontal-plane elevation and 0° of humeral rotation with an isokinetic dynamometer (Biodex System 2, Biodex Medical Systems, Shirley, NY, USA). The order of strength testing was randomized, and three trials were performed at each testing position. Average strength was calculated across the three trials and normalized based on the research of Hughes et al.

Presurgical MRI assessment

Presurgical MRI scans were obtained for each participant. These examinations were typically acquired on a 1.5T scanner, with the scan protocol including axial and sagittal-oblique fat-suppressed proton density sequences, coronal-oblique and sagittal-oblique T1-weighted sequences, and a coronal-oblique fat-suppressed T2-weighted sequence. A fellowship-trained, board-certified musculoskeletal radiologist (SBS) with 12 years of clinical experience evaluated each presurgical MRI examination in terms of the full-thickness rotator cuff anteroposterior tear size, amount of tendon retraction, supraspinatus occupation ratio, supraspinatus atrophy using the “tangent sign” and amount of fatty degeneration as per the Goutallier classification system.

Surgical repair and postsurgical rehabilitation

Within two weeks of acquiring the SWE images, each patient underwent arthroscopic rotator cuff repair by one of three orthopedic surgeons fellowship-trained in sports medicine or orthopedic surgery (median postfellowship experience: 9 years). The repair technique (ie, number of rows and anchors) was determined based on surgeon discretion. A double-row repair technique was used in 71% of cases with a median of 2 anchors (min – 1, max – 5). After surgery, patients were discharged with a shoulder abduction sling and standard postoperative medications and precautions. A continuous passive motion device was used by 90% of patients.
during the first month after surgery. Although postsurgical rehabilitation was not standardized, general guidelines were as follows: (1) postop weeks 0-5: passive range of motion only, (2) postop week 6: progression to active-assisted range of motion, (3) postop week 8: progression to AROM, (4) postop weeks 6-8: isometric strengthening, and (5) postop weeks 10-12: progression to resisted exercises. All rehabilitation progressions were guided by patient tolerance and the avoidance of compensatory movement patterns (eg, shoulder shrugging).

**Postsurgical assessments**

At 1 year after surgery, participants were contacted in regard to returning for reevaluation. Of the 33 participants who completed presurgical testing, 23 completed the postsurgical testing. Demographic data of these participants are presented in Table I. The suboptimal follow-up rate was predominantly due to the COVID-19 public health crisis and the associated health system restrictions which precluded human subjects’ data collection for several months. Patient-reported measures of pain and function were reassessed as previously described. Finally, a postsurgical MRI was obtained for each participant and evaluated by the same radiologist (SBS) in terms of rotator cuff repair integrity (ie, intact repair or recurrent tear) and muscle quality.

**Statistical analysis**

Demographics, presurgical tear characteristics, and postsurgical function were described using summary statistics and compared between groups using two-sample t-tests and Fisher’s exact tests, as appropriate. Functional outcomes were compared between groups and across time (ie, preop and postop) using a two-factor mixed model analysis of variance. Main effects were only interpreted in the absence of a significant group-by-time interaction. Stepwise regression with model comparison was used to investigate the extent to which MRI and shear modulus predicted repair integrity at 1 year after surgery as follows. First, variable distribution was assessed using skewness and kurtosis. Second, a logistic regression model was calculated with the MRI variable (tear size, retraction, occupation ratio) that was the strongest predictor of repair integrity at 1 year after surgery (MRI model). Third, the mean shear modulus was added to the logistic regression (MRI + SWE model). Finally, the two models (MRI and MRI + SWE) were compared via analysis of variance model comparison to determine whether the addition of the shear modulus significantly improved the prediction of repair integrity above and beyond the MRI variable alone. Separate models were fit using the estimated shear moduli of the supraspinatus muscle and intramuscular tendon. A similar approach was used with linear
regression to investigate the extent to which MRI and SWE variables predicted shoulder function at 1 year after surgery. All statistical analyses were performed using R (R Core Team, 2018). Statistical significance was defined as \( P < .05 \).

**Results**

As a result of disruptions in human subjects’ data collection due to the COVID-19 pandemic, only 23 patients completed the study with an average 1-year follow-up time of 1.2 ± 0.2 years (range: 1.0-1.6 years). Of the patients who completed the study, the average age was 60 ± 7 years old, 8 (34.8%) were female, 12 (52.2%) had the surgical repair on their dominant shoulder, and 13 (56.5%) had an intact repair at 1 year after surgery. No significant differences were found in any demographic variable, MRI-based presurgical tear characteristic, or shear modulus measure between individuals with an intact repair and those with a recurrent tear (Table I). Compared with presurgical measures, patients in both groups demonstrated significant improvements at 1 year after surgery in pain (ie, visual analog scale) \((P < .01)\), self-reported function (ie, Western Ontario Rotator Cuff Index) \((P < .01)\), abduction and flexion AROM \((P < .01)\), and all measures of shoulder strength \((P < .01)\) (Fig. 2). Abduction strength improved in both groups, but patients with an intact repair experienced significantly greater improvement in abduction strength than those with a recurrent tear \((P = .047, \text{Fig. 2})\).

**Predicting postsurgical repair integrity**

Although not significantly different between patient groups, the occupation ratio was the presurgical MRI measure with the highest potential to distinguish between groups (ie, lowest \( P \) value, Table I) and therefore was used as the MRI predictor in the regression models. On its own, the occupation ratio was not a significant predictor of repair integrity at 1 year after surgery \((P = .22, r^2 = 0.06)\). Furthermore, the prediction of repair integrity at 1 year after surgery was not significantly improved by the addition of shear modulus of the supraspinatus muscle \((P = .22, \text{change in } r^2 = 0.05)\) or intramuscular tendon \((P = .35, \text{change in } r^2 = 0.03)\).

**Predicting postsurgical functional outcomes**

Across all presurgical variables, only tear size and tear retraction were significantly correlated with postsurgical functional outcomes (Table II). Specifically, smaller presurgical tear size and tear retraction were found to be moderately but significantly associated with higher postsurgical abduction, flexion, and internal rotation strength (Table II). Presurgical shear modulus of the supraspinatus muscle and intramuscular tendon was not found to be significantly associated with any postsurgical functional outcome measure \((P > .12, r^2 ≤ 0.12, \text{Table II})\). In general, presurgical shear modulus did not improve the prediction of postsurgical functional outcomes (Table III). The only exception was that the combination of tear size and shear modulus for the supraspinatus intramuscular tendon significantly improved the prediction of postsurgical flexion AROM above and beyond tear size alone \((P = .01, \text{change in } r^2 = 0.22, \text{Table III})\).

**Discussion**

The objective of this study was to determine the extent to which presurgical shear modulus predicts repair tissue healing and functional outcomes at one year after surgical rotator cuff repair. We hypothesized that presurgical shear modulus would be associated with repair tissue healing, shoulder function, and pain after rotator cuff repair. However, presurgical shear modulus was not
found to be associated with repair tissue healing or any postsurgical functional outcome measure. Furthermore, with only one exception, the addition of presurgical shear modulus to presurgical MRI-based tear characteristics was not found to improve the prediction of postsurgical repair integrity or functional outcomes. Predicting structural outcomes—that is, whether a rotator cuff repair is likely to remain intact after surgery—remains a challenging endeavor. It is therefore not surprising this study failed to identify any presurgical factors that were significantly different between the intact repair and recurrent tear patient groups. However, this outcome is consistent with previous research as there are conflicting reports regarding the ability of conventional clinical data to predict postsurgical repair integrity. For example, some previous studies have reported that tear size is associated with repair integrity after surgical repair, whereas other studies have reported no such association exists. These conflicting findings likely reflect the implicit heterogeneity of patient populations and large number of factors including genetics, biological factors, and postsurgical activity levels that are difficult to control in clinical studies. Thus, identifying factors that discriminate between intact repair and recurrent tear patient groups requires substantial differences between groups or large sample sizes. For example, Le et al measured 18 presurgical and surgical variables in 1000 patients after rotator cuff repair and reported that only presurgical tear dimensions (specifically, anteroposterior tear size, mediolateral tear length, tear size area, and tear thickness), patient age, and surgical time were independent predictors of repair integrity. In a follow-up study with an even larger patient cohort (n = 1662), this same research team determined that patient age, tear size, hospital type (private vs. public), and case number (ie, surgeon experience) were the only significant predictors of repair integrity. Taken together, these comprehensive studies suggest that patient age and tear size may be the most reliable presurgical predictors of postsurgical repair integrity.

Similar to the challenges in predicting postsurgical repair integrity, predicting postsurgical functional outcomes (ie, strength, ROM, pain) after rotator cuff repair is equally difficult. In the present study, presurgical tear size and tear retraction were significantly associated with measures of postsurgical abduction strength, flexion strength, and external rotation strength. These findings are consistent with previous research indicating that presurgical tear dimensions significantly impact postsurgical shoulder strength. In contrast, neither muscle nor tendon presurgical shear modulus values were significantly associated with any postsurgical functional outcomes. Furthermore, the addition of shear modulus to MRI-based outcomes did not result in widespread improvements in the prediction of any postsurgical functional outcomes over MRI-based outcomes alone (Table III). The notable exception was that the addition of tendon shear modulus to the occupation ratio improved the prediction of flexion ROM over the occupation ratio alone (P = .01, Table III). However, this outcome should be interpreted with caution because it is difficult to understand mechanistically as to how the combination of tendon material properties (ie, tendon modulus) and muscle volume (ie, occupation ratio) would significantly influence ROM but not shoulder strength.

It was somewhat surprising that presurgical shear modulus values had negligible value for predicting postsurgical repair integrity given that SWE has been shown to be correlated with tissue mechanical properties, which are generally believed to affect postsurgical outcomes. Evidence supporting this premise comes from previous studies that have focused on the role of fatty degeneration (an issue shown to affect mechanical properties) as an important factor in a patient’s potential outcome from rotator cuff repair, as well as studies with small animal models demonstrating that muscle/tendon degeneration negatively affects rotator

Table II
Correlations between presurgical tear/tissue characteristics and functional outcome measures at approximately 1 year after surgery.

| Post surgical functional outcome | Presurgical tear/tissue characteristics (predictor variables) |
|---------------------------------|---------------------------------------------------------------|
|                                 | Tear size (MRI) | Tear retraction (MRI) | Occupation ratio (MRI) | Muscle shear modulus (SWE) | Tendon shear modulus (SWE) |
| Pain (VAS)                      | –0.13 (0.57)     | –0.07 (0.78)           | –0.23 (0.32)           | –0.18 (0.44)             | –0.20 (0.40)             |
| Function (WORC)                | –0.14 (0.57)     | –0.26 (0.27)           | 0.08 (0.74)            | 0.10 (0.67)             | 0.20 (0.38)             |
| AROM: ABD                      | –0.16 (0.51)     | –0.03 (0.90)           | –0.08 (0.73)           | 0.17 (0.47)             | –0.35 (0.12)             |
| AROM: FLX                      | –0.22 (0.35)     | –0.08 (0.73)           | –0.23 (0.31)           | 0.05 (0.84)             | –0.21 (0.35)             |
| Strength: ABD                  | –0.53 (0.02)     | –0.52 (0.02)           | 0.00 (0.98)            | 0.04 (0.85)             | –0.06 (0.81)             |
| Strength: FLX                  | –0.52 (0.02)     | –0.44 (0.05)           | 0.25 (0.27)            | 0.14 (0.55)             | –0.05 (0.82)             |
| Strength: ER                   | –0.56 (0.01)     | –0.55 (0.01)           | 0.00 (0.99)            | –0.18 (0.45)            | –0.04 (0.86)             |
| Strength: IR                   | –0.12 (0.61)     | –0.03 (0.92)           | 0.01 (0.96)            | 0.06 (0.79)             | 0.04 (0.85)              |

Table III
Comparison of predictive utility of two linear regression models: (1) a model predicting the functional outcome at 1 year after surgery using a single MRI predictor and (2) a model predicting the combined effect of the MRI predictor and shear modulus.

| Post surgical functional outcome | Best MRI predictor | MRI + muscle shear modulus | MRI + tendon shear modulus |
|---------------------------------|-------------------|---------------------------|---------------------------|
| Pain (VAS)                      | Occupation ratio  | 0.56 (0.73)               | 0.73 (0.73)               |
| Function (WORC)                | Tear retraction   | 0.15 (0.67)               | 0.19 (0.67)               |
| AROM: ABD                      | Tear size         | 0.29 (0.19)               | 0.31 (0.19)               |
| AROM: FLX                      | Occupation ratio  | 0.20 (0.01)               | 0.01 (0.01)               |
| Strength: ABD                  | Tear size         | 0.52 (0.80)               | 0.93 (0.80)               |
| Strength: FLX                  | Tear size         | 0.83 (0.93)               | 0.31 (0.93)               |
| Strength: ER                   | Tear size         | 0.48 (0.16)               | 0.76 (0.16)               |
| Strength: IR                   | Tear size         | 0.06 (0.76)               | 0.04 (0.76)               |

Results are presented as P values testing whether the two linear regression models are significantly different (ie, P < .05 suggests that SWE adds to the prediction of the functional outcome above and beyond that provided by the MRI measure alone). Statistically significant differences (ie, P < .05) are indicated in bold.
cuff repair tissue healing.4,24,35,38,40,55 One potential explanation for this discrepancy is that tissue changes associated with a rotator cuff tear likely have opposing influences on SWE measurements.41 For example, fatty degeneration is expected to reduce the estimated shear modulus because fat presumably reduces a tissue’s stiffness. Conversely, other tissue changes found in degenerative rotator cuff tears (eg, tendon retraction and fibrosis) have been shown to increase tissue stiffness41,24,35,42,54,55 and are therefore expected to increase SWE measurements. Given that these tissue changes occur to various degrees simultaneously within an individual patient, the global nature of the SWE measure may have hindered the predictive value of SWE-estimated shear modulus for estimating the clinical construct of “tissue quality” in this patient population.

In addition to differences between patients in presurgical muscle/tendon properties, it is highly likely that many other factors played important roles in the patient’s postsurgical functional and structural outcomes. For example, factors such as the patient’s postsurgical activity levels, adherence to postsurgical management prescription, the tendon’s microvascular supply, and intrinsic healing capacity are difficult to assess or control in a clinical study. Therefore, it is possible that these and other more rudimentary factors (eg, patient age, tear size) may have overwhelmed the effect of presurgical tissue quality. Further efforts of repair “failure” may occur due to distinct mechanisms that were not assessed in the present study. For example, the ability of the repaired tendon to resist suture pull-out and its biological capacity for healing may define distinct clinical subgroups. More research is needed to better understand these mechanisms of structural repair failure and to develop assessment tools to predict their occurrence and inform presurgical clinical decision-making.

Despite the associations detected in the present study between tear dimensions and shoulder strength, a perplexing issue that continues to confound the prediction of functional outcomes is the disconnect between functional and structural outcomes after rotator cuff repair. Specifically, patients can have acceptable strength despite a recurrent tear or limited strength with an intact repair. For example, some studies have reported differences in shoulder strength between intact and failed repairs,7,11,18,31,43 whereas other studies have reported no difference.4,29,40,51 Similarly, some studies have reported a difference in patient-reported outcome scores between intact and failed repairs,7,8,18,31,43 whereas other studies have failed to detect a difference in these outcomes.1,11,13,48,50 McElvany et al reviewed 77 studies that compared the clinical results for intact and failed repairs and concluded that patient-reported outcomes generally improve regardless of whether or not the repair remains intact.40 Furthermore, they concluded that there was no consistent relationship between the integrity of the repair and the clinical outcome.40

Although the results of this study suggest that SWE provides little additional predictive value compared with MRI alone, it is important to remember that MRI and SWE provide very different, but potentially complementary, information as recently described.31 Clinical MRIs typically provide information regarding rotator cuff structure (eg, tear dimensions, tear thickness, muscle atrophy), integrity, and tissue composition or degeneration, whereas SWE provides an estimate of tissue mechanical properties. This discrepancy may help explain the poor relationship between presurgical shear modulus and postsurgical tear integrity observed in the present study and the lack of strong associations between SWE measures and rotator cuff tear characteristics previously reported.41,51 Although the clinical utility of SWE may still hold promise, it appears that more research is needed to fully understand its clinical utility for musculoskeletal tissues and, in particular, its potential for predicting outcomes after surgical rotator cuff repair.

This study has several limitations to consider when interpreting the results. First, only 23 of 33 participants returned for the postsurgical follow-up visit because of the ongoing COVID-19 public health crisis. Second, the small sample size likely affected the study’s statistical power. An a priori power analysis suggested a sample size of 40 patients was required to detect an increase in $r^2$ of 0.18 with 80% power. However, the generally weak associations between predictors and outcomes suggest that meaningful predictions were not likely ignored despite the small sample size. Third, only patients scheduled to undergo arthroscopic repair of a small- or medium-sized rotator cuff tear were included in the study. As a result, the between-subject variability in measures of tear chronicity was limited, which may have impacted our ability to identify potentially meaningful relationships. Fourth, patients with acute tears were excluded from the study to increase the likelihood that chronic changes would be seen within the muscle–tendon unit. However, doing so may have increased the observed rate of recurrent tear. Fifth, although the reliability of the methods used in this study has been established,2 SWE measurements are often challenging to standardize both within and across individuals. Consequently, the present study used a standardized patient position, the same SWE operator for all subjects, and custom software run by a single operator in an attempt to improve reliability and to quantitatively calculate SWE measures.

Conclusion

Although SWE remains a promising modality for many clinical applications, this study found that SWE-estimated shear modulus did not predict repair integrity or functional outcomes at 1 year after surgery, nor did it add to the prediction of outcomes above and beyond that provided by traditional presurgical MRI measures of tear characteristics. Therefore, it appears that further studies are necessary to fully understand the clinical utility of SWE for musculoskeletal tissue and, in particular, its potential use for predicting outcomes after surgical rotator cuff repair.

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