J Shoulder Elbow Surg (2023) 32, 1432–1444

ELSEVIER

Journal of Shoulder and Elbow Surgery

www.elsevier.com/locate/ymse

Evaluation of survivorship of asymptomatic degenerative rotator cuff tears in patients 65 years and younger: a prospective analysis with long-term follow-up

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Background: The purpose of this prospective study is to describe the mid- to long-term natural history of untreated asymptomatic degenerative rotator cuff tears in patients 65 years and younger.

Methods: Subjects with an asymptomatic rotator cuff tear in one shoulder and a contralateral painful cuff tear aged 65 years or younger were enrolled in a previously described prospective longitudinal study. Annual physical and ultrasonographic evaluations and surveillance for pain development were performed using independent examiners for the asymptomatic shoulder.

Results: Two hundred twenty-nine participants (mean age 57.1 years) were followed for a median of 7.1 (range 0.3-13.1) years. Tear enlargement occurred in 138 (60%) shoulders. Full-thickness tears were at greater risk for enlargement compared with partial-thickness (hazard ratio [HR] 2.93, 95% confidence interval [CI] 1.71-5.03, $P < .0001$) and control shoulders (HR 18.8, 95% CI 4.63-76.1, $P < .0001$). Mean survival rates from Kaplan-Meier analyses indicate that full-thickness tears enlarged earlier (mean 4.7, 95% CI 4.1-5.2 years) than partial-thickness (mean 7.4, 95% CI 6.2-8.5 years) and control shoulders (mean 9.7, 95% CI 9.0-10.4 years). Tear presence in the dominant shoulder was associated with a greater enlargement risk (HR 1.70, 95% CI 1.21-1.39, $P = .002$). Patient age ($P = .37$) and gender ($P = .74$) were not associated with tear enlargement. The 2-, 5-, and 8-year survivorship free of tear enlargement for full-thickness tears was 74%, 42%, and 20%, respectively. Shoulder pain developed in 131 (57%) shoulders. Pain development was associated with tear enlargement (HR 1.79, 95% CI 1.24-2.58, $P = .002$) and was more common in full-thickness tears compared with controls ($P = .0003$) and partial tears ($P = .01$). An analysis of progression of muscle degeneration was performed in 138 shoulders with full-thickness tears. Tear enlargement was seen in 104 of 138 (75%) of these shoulders during follow-up (median 7.7 [interquartile range 6.0] years). Progression of muscle fatty degeneration was seen in the supraspinatus in 46 (33%) and the infraspinatus in 40 (29%) shoulders. Adjusting for age, both the presence of fatty muscle degeneration and the progression of muscle changes for both the supraspinatus ($P < .0001$) and infraspinatus ($P < .0001$) muscles were associated with tear size. For both the supraspinatus ($P = .03$) and infraspinatus ($P = .03$) muscles, tear enlargement was significantly associated with progression of muscle fatty degeneration. Anterior cable integrity was significantly associated with the risk of muscle degeneration progression for both the supraspinatus ($P < .0001$) and the infraspinatus ($P = .005$) muscles.

Washington University Institutional Review Board approved this study (no. 201103230).

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1058-2746/$ - see front matter
https://doi.org/10.1016/j.jse.2023.03.008

Conclusions: Asymptomatic degenerative rotator cuff tears progress in patient 65 years and younger. Full-thickness rotator cuff tears have a higher risk of continued tear enlargement, progression of fatty muscle degeneration, and pain development than partial-thickness tears.

Level of evidence: Level II; Prospective Cohort Design; Prognosis Study

Keywords: Natural history; rotator cuff tear; degenerative; tear progression; long-term follow-up

Rotator cuff disease remains a significant source of patient morbidity as the population ages,[28] and the volume of rotator cuff repair is increasing.[32] Despite the frequency with which this pathology is encountered in clinical practice, large variations in surgical practice are seen in the United States.[1,29] Specifically, indications for surgery for painful rotator cuff tears are often influenced by surgeon factors rather than tear anatomy or patient-specific factors.[6]

An improved understanding of the natural history of degenerative rotator cuff tears can help refine surgical indications and better predict which patients are at highest risk for progression of their tear. In turn, refined surgical indications can improve outcomes and decrease costs, an essential aspect of any surgical treatment in our current value-driven clinical environment.[20,23]

Several studies have contributed to an improved understanding of the natural history of rotator cuff disease.[9,10,13,14,18,24,31] In aggregate, this literature changed the fundamental understanding of degenerative rotator cuff pathology as primarily a biologic, rather than mechanical, issue and helped improve the surgical indications for rotator cuff repair. However, fundamental questions remain, particularly in the context of long-term follow-up of degenerative rotator cuff disease.

The clinical relevance of a prospective cohort study examining the natural history of rotator cuff disease is dependent on the age of the cohort at enrollment. Existing literature has clearly demonstrated patient age to be a major factor influencing the likelihood of successful healing of degenerative rotator cuff tears.[2,5,7,12,21] Decreased healing capacity following surgery for a given tear decreases beyond the age of 60-65 years, although the exact inflection point is debated. In general, the decision to operate on a degenerative cuff tear is influenced by the likelihood of successful tendon healing, especially given the growing popularity of reverse shoulder arthroplasty as an option for the treatment of painful rotator cuff disease in older patients. To fully understand the potential impact of surgery, there is value in determining the long-term natural history of degenerative cuff disease in a cohort possessing a favorable chance for tendon healing with surgery.

The purpose of this study is to analyze the natural history of asymptomatic degenerative rotator cuff tears in a targeted group of patients aged 65 years and younger at medium to long-term follow-up. Previous analyses have described progression of degenerative rotator cuff tears in a prospectively followed cohort at a shorter follow-up period with the inclusion of significant proportion of older patients that possess a decreased capacity to heal with surgical intervention. This study aims to provide data on the natural history of a more clinically relevant patient population at longer-term follow-up in order to better define higher risk patients with rotator cuff tears that may be considered optimal candidates for surgical intervention based on age.

Materials and methods

This study was approved by our institutional review board (IRB 201103230). The defined cohort in this study were patients with an asymptomatic rotator cuff tear who presented for evaluation of shoulder pain secondary to rotator cuff disease in the contralateral shoulder. This cohort has been described in previous publications and consists of participants recruited in 2 distinct recruitment cycles.[9,13] In this analysis, inclusion criteria were (1) bilateral shoulder ultrasonography performed to investigate unilateral shoulder pain, (2) painful rotator cuff disease in the symptomatic shoulder, (3) a rotator cuff tear in the asymptomatic shoulder at the time of study enrollment, (4) no history of trauma to either shoulder and no traumatic episode throughout the study period, and (5) age $\leq$65 years at enrollment. Control participants were enrolled during the study period as well, which were defined as patients with no ultrasonographic evidence of a rotator cuff tear in one shoulder and painful rotator cuff disease in the contralateral shoulder. The control shoulders served as a comparison group to examine the risk of tear progression compared to shoulders with known tears at baseline. Exclusion criteria were (1) any past or current pain in the ''asymptomatic'' shoulder, (2) continuous use of narcotic or nonsteroidal anti-inflammatory drugs in the 3 months prior to enrollment, (3) a traumatic episode affecting the asymptomatic shoulder, (4) inflammatory arthritis, (5) radiographic evidence of glenohumeral osteoarthritis in the asymptomatic shoulder, (6) upper extremity weightbearing demands, (7) an isolated subscapularis tendon tear in the asymptomatic shoulder, and (8) a very small (<5-mm) partial-thickness tear in the asymptomatic shoulder. This value was chosen to cover the inherent variability in ultrasonography accuracy when used to diagnose rotator cuff disease.[27]

The study protocol has previously been described.[9] For this present study, we focused analysis and continued follow-up on participants aged $\leq$65 years at enrollment. Attempts were made to follow participants actively enrolled at the time of a previous publication until a minimum 8 years' follow-up. Subjects were followed annually until either (1) minimum 8-year follow-up, (2) surgical intervention, or (3) participant was lost to follow-up. Data

for all participants were used regardless of length of follow-up. Patients returned annually for assessment of potential shoulder pain, physical examination, and repeat shoulder ultrasonography. The physical examination of the asymptomatic shoulder was performed by a trained research nurse. Range of motion was measured with a goniometer; isometric shoulder elevation and external rotation strength (in adduction and neutral rotation) were measured with an IsoBex dynamometer (Medical Device Solutions, Oberburg, Switzerland). Pain and functional scores were captured using the visual analog scale (VAS [0-10]), American Shoulder and Elbow Surgeons Standardized Shoulder Assessment Form score, and the Simple Shoulder Test. Shoulder pain was assessed in the patient at study enrollment and during follow-up visits, and pain was defined as meeting any of the following conditions: (1) shoulder pain $\geq$3 on a 10-point scale lasting 6 weeks or longer, (2) pain greater than that experienced as part of daily living, (3) pain requiring narcotic or nonsteroidal anti-inflammatory drugs, (4) pain prompting evaluation by a physician, and (5) night pain affecting sleep.

Shoulder ultrasonography and tear enlargement criteria

Each participant underwent a standardized shoulder ultrasonographic study at baseline and subsequent annual visits.[26,27] The method of shoulder ultrasonography used has previously been validated for accuracy to detect the presence and dimensions of a rotator cuff tear and assessment of muscle degenerative changes.[27,30] The details of how tears were measured and classified have previously been described.[9] In brief, a full-thickness tear was considered to have enlarged if its size had increased by $\geq$ 5 mm in any dimension compared to baseline. A partial-thickness tear was considered to have enlarged when it became a full-thickness one. In control shoulders, enlargement was defined as the development of a partial-tear or full-thickness tear of at least 5 mm in any dimension. Tear enlargement was defined as a change in the tear type or an increase in the size from baseline values. Once a tear progressed, the tear was then included in the more advanced tear type category and analyzed as such with regard to pain development. Fatty degeneration of the rotator cuff musculature was evaluated using the echogenicity and architecture of the supraspinatus and infraspinatus muscles and each was graded with a previously validated, modified 3-point scale.[25,30] For the purpose of muscle fatty degeneration analysis, attention was focused on muscle changes that occur to full-thickness tears, as previous research has demonstrated that muscle degeneration is rare in shoulders with partial-thickness tears. Similar to prior publications,[8,19] the anterior cable attachment of the supraspinatus tendon was considered torn when the anterior margin of the rotator cuff tear was less than 3 mm of the lateral aspect of the long head of the biceps or the lateral aspect of the biceps groove.

Statistical analysis

A priori power calculations were performed to determine the sample size needed for acceptably precise estimated rates of tear enlargement in shoulders with asymptomatic tears at 8 years' follow-up based on enlargement rates seen at the previous follow-up period. At the previous follow-up, there were 65 patients who were aged $\leq$65 years with a minimum 8-year follow-up whose tear enlargement and progression to pain rates estimated from Kaplan-Meier curves yield standard errors (SEs) of approximately 5.2% at year 8. As previously described, with additional follow-up and assuming a constant attrition rate of 4.4% of participants per year, we expect to have at least 104 participants who provide 8-year follow-up. The additional data from this proposal will significantly improve precision with an approximate reduction in standard errors to only 3.6% at year 8, and greater reductions at earlier years. Conservatively assuming a constant hazard rate across years, the proposed study will have 80% power to detect a minimum hazard ratio (HR) of 1.7 at year 8 for the association between muscle degeneration and enlargement. Power will increase if the observed HRs are not constant and increase substantially during longer follow-up as expected.

Categorical characteristics were compared across tear type groups using chi-square test or Fisher exact test (when the number of observations within category was small). Continuous variables were compared across tear types using analysis of variance. When the overall model was significant ($P < .05$), Sidak-adjusted (for categorical variables) or Tukey-adjusted (for continuous variables) pairwise comparisons were performed. Without regard for the temporal relationship of events, the Cochran-Armitage trend test was used to determine if advancing category of tear type was associated with tear enlargement and new pain development.

The annual rate at which tear enlargement occurred by tear type is described using Kaplan-Meier survival curves and survival rates are reported for the time between study entry and enlargement at 2, 5, and 8 years of follow-up. Mean survival time and associated 95% confidence interval (CI) are reported by tear type.

Cox proportional hazard regression was used to determine if risk factors were associated with the time between study entry and the occurrence of tear enlargement. Participants who underwent surgery were censored at the time of surgery. Participants who were lost to follow-up were censored at the final visit. HRs with 95% CI for the HR are reported. The reference group for the HR for categorical characteristics was patients without the risk factor. HRs for continuous risk factors are expressed for a 1-unit increase in the factor.

After adjusting for age at baseline, tear measurements were compared for tears with and without muscle fatty degeneration using analysis covariance where age was the covariate and fatty degeneration (presence/absence) was the independent variable.

Without regard for the temporal association of events, the association of muscle fatty degeneration with tear enlargement and rotator cable integrity was assessed with chi-square tests.

Summary data for continuous variables that are normally distributed are expressed as mean (standard deviation) or median (interquartile range) for variables not normally distributed.

Results

Demographics

Three hundred ninety-five participants were initially enrolled in the study over 2 recruitment periods. One hundred sixty-six participants were excluded. Of the excluded participants, 135 had a self-reported age >65

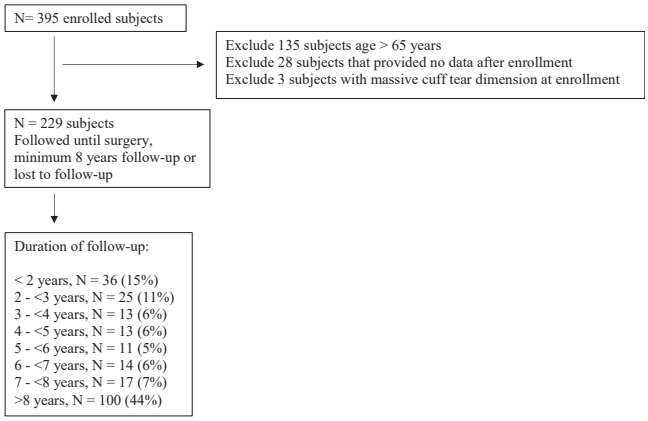

Figure 1 Strobe flowchart of enrolled participants.

years at the time of enrollment, 28 provided no data after enrollment, and 3 participants had a massive tear dimension at the time of enrollment (Fig. 1). This left 229 participants who were aged ≤65 years at enrollment without a massive tear and who provided data for at least 1 annual follow-up visit (Table I). The mean age of participants was 57.1 years (SD 6.5) at enrollment. Increasing age was associated with more severe tear type ($P = .02$); however, there were no differences in gender ($P = .81$) or occupational demand ($P = .19$) between tear types.

Baseline tear characteristics

Of the 229 participants in the analyzed cohort, 105 (46%) had a full-thickness tear, 77 (34%) had a partial-thickness tear, and 47 (20%) were controls at the time of enrollment (Table I). At baseline, the full-thickness tears were significantly larger than the partial-thickness tears in both tear length (median, 12.0 mm vs. 6.0 mm, $P < .0001$) and width (median, 10.0 mm vs. 8.0 mm, $P < .0001$). Full-thickness tears had a higher association with muscle fatty infiltration of both the supraspinatus ($P = .0009$) and infraspinatus ($P = .0004$) at baseline. Despite the presence of high shoulder function scores in all tear categories, there were worse baseline American Shoulder and Elbow Surgeons Standardized Shoulder Assessment Form and Simple Shoulder Test scores among participants based on tear type ($P < .0001$) but no significant difference in baseline strength.

Tear progression and survivorship analysis

The median duration of follow-up was 7.1 years (range 0.3-13.1 years). Tear enlargement was observed in 138 (60%) of shoulders, with a median time to enlargement of 3.4 years (IQR 3.4; range 0.3-11.9 years). Mean with 95% CI survival rates from Kaplan-Meier analyses indicate that full-thickness tears enlarged at an earlier time point in surveillance (4.7 years, 95% CI 4.1-5.2) than partial-thickness (7.4 years, 95% CI 6.2-8.5) and control shoulders (9.7 years, 95% CI 9.0-10.4). Tear progression was significantly associated with the severity of the tear type at enrollment, with enlargement occurring in 69% of full-thickness, 60% of partial thickness, and 40% of control shoulders ($P = .002$; Table II). When considering the association of final tear classification with enlargement, there were even stronger associations. At the last recorded time point for a given tear within the cohort, there were 30 control shoulders, and 44 shoulders with partial-thickness and 155 shoulders with full-thickness tears.

Using tear enlargement of at least 5 mm or progression to a more severe type as the end points the 2-, 5-, and 8-year survivorship of partial-thickness tears was 92%, 73%, and 61% compared to 74%, 42%, and 20% for full-thickness tears (Fig. 2). The presence of the tear in the dominant hand was associated with a higher risk of tear enlargement (HR 1.70, 95% CI 1.21-1.39, $P = .002$) (Table III). Multiple tear enlargement events occurred in 26% (59 of 229) of the entire cohort, including 37% (57 of 155) of full-thickness tears.

The final tear dimensions for the tears classified as full-thickness tears at final follow-up are as follows: for the 105 shoulders designated as full-thickness at baseline, the median length and width were 16 mm (IQR 9.5 mm) and 14 mm (IQR 11 mm), and 9 shoulders had progressed to massive (unmeasurable) classification. For the 50 shoulders designated as partial-thickness (n = 40) or control (n = 10) at baseline, the median length and width were 9 mm (IQR 5 mm) and 9 mm (IQR 7 mm).

Symptom progression

Shoulder pain development occurred in 131 (57%) shoulders at a median of 3.0 years (IQR 3.6). The median visual analog scale pain score changed from 0 (IQR 2) at baseline to 5 (IQR 3) at pain onset ($P < .0001$) for the shoulders that became symptomatic. The median American Shoulder and Elbow Surgeons Standardized Shoulder Assessment Form score decreased from 93.1 ± 8.3 at baseline to 61.6 ± 17.2 ($P < .0001$). A higher proportion of shoulders that had a more severe tear type either at baseline or based on final tear type developed pain. Among final tear types, 27% of control patients, 43% of patients with a partial tear, and 67% of patients with a full-thickness tear developed pain ($P < .0001$; Table IV).

Tear enlargement was associated with a higher risk of pain development compared to tears that remained stable (HR 1.79, 95% CI 1.24-2.58, $P = .002$) (Table V). Without regard to the temporal relationship of events, a larger proportion of tears that enlarged developed pain during follow-up compared to the proportion of tears that developed pain but did not enlarge (70% vs. 37%, $P < .0001$). Sixty-three percent of stable tears remained painless compared with 30% of tears that enlarged. However, the length of included

Table I Sample characteristics overall and by baseline tear type

Variable	Entire cohort	Baseline tear type			*P* value
	n = 229	Control (n = 47)	Partial (n = 77)	Full (n = 105)	
Age at baseline, yr, mean (SD)	57.1 (6.5)	55.6 (6.7)	56.2 (7.2)	58.3 (5.6)	.02[*] control vs. full = .045
Sex, female, n (%)	92 (40)	19 (40)	33 (43)	40 (38)	.81[†]
Retired, n (%)	60/227 (26)	9 (19)	22/76 (29)	29/104 (28)	.44[†]
Work demand, 1 = sedentary, 5 = very heavy work, median (IQR)	2 (2), n = 217	2 (2), n = 45	2 (2), n = 72	2 (1), n = 100	.19[*,‡]
Study side is dominant shoulder, n (%)	86 (38)	12 (26)	24 (31)	50 (48)	.01[†] control vs. full = .03
Presence of SS muscle degeneration at BL[§], n (%)	13/197 (7)	1/43 (2)	0/64 (0)	12/90 (13)	.0009[‖] partial vs. full = .004
Presence of IS muscle degeneration at BL[§], n (%)	14/197 (7)	1/43 (2)	0/64 (0)	13/90 (14)	.0004[‖] partial vs. full = .002
Numeric pain score at BL (0-10), median (IQR)	0 (0)	0 (0)	0 (0)	0 (2)	.01[*,‡] control vs. full = .01 control vs. partial = .04
SST score at BL, median (IQR)	100 (17), n = 226	100 (0), n = 46	100 (17)	91.7 (17), n = 103	<.0001[*,‡] control vs. full < .0001 control vs. partial = .0007
ASES score at BL, median (IQR)	98.3 (10)	100 (0)	98.3 (10)	96.3 (13)	<.0001[*,‡] control vs. full < .0001 control vs. partial = .006
External rotation strength, N[¶], mean (SD)	71.8 (31), n = 224	75.5 (26)	74.0 (32), n = 75	68.5 (32), n = 102	.33[*]
Elevation strength, N[¶], mean (SD)	49.7 (29), n = 167	55.5 (27), n = 44	50.1 (31), n = 59	45.3 (28), n = 64	.19[*]
Forward elevation AROM, degrees, mean (SD)	157 (13), n = 228	155 (12)	159 (11), n = 76	156 (15)	.20[*]
External rotation AROM at the side, degrees, mean (SD)	70.0 (15), n = 228	65.1 (15)	70.1 (14), n = 76	72.0 (16)	.04[*] control vs. full = .03
External rotation AROM in abduction, degrees, mean (SD)	92.8 (12), n = 228	92.1 (11)	95.9 (13), n = 76	90.8 (11)	.01[*] control vs. partial = .01
Internal rotation AROM behind back, degrees, n (%)					.14[‖]
T5	25/227 (11)	6 (13)	10/76 (13)	9/104 (9)	
T7	93/227 (41)	22 (47)	38/76 (50)	33/104 (32)	
TL	86/227 (38)	15 (32)	22/76 (29)	49/104 (47)	
Belt	22/227 (10)	4 (9)	6/76 (8)	12/104 (12)	
Buttock	1/227 (<1)	0 (0)	0/76 (0)	1/104 (<1)	
Side	0/227 (0)	0 (0)	0/76 (0)	0/104 (0)	

Tear characteristics at baseline					
Tear length at BL, mm, median (IQR)		n/a	6.0 (3.0)	12.0 (11.0), n = 102	<.0001[*,‡]
Tear width at BL, mm, median (IQR)		n/a	8.0 (5.0), n = 76	10.0 (10.0)	<.0001[*,‡]
Tear area at BL, mm^2, median (IQR)		n/a	51.5 (41.5), n = 76	130 (187), n = 102	<.0001[*,‡]
Follow-up in the study period, yr, median (IQR)	7.1 (6.4), range 0.3-13.1	8.1 (6.8), range 0.5-10.4	8.0 (6.9), range 0.8-12.0	6.1 (6.6), range 0.3-13.1	.11[*,‡]
Time to first enlargement[#], yr, median (IQR)	3.8 (4.9), range 0.3-11.9	4.9 (6.6), range 0.5-10.2	4.9 (6.0), range 0.8-11.8	2.9 (3.3), range 0.3-11.9	.04[*,‡]

n, sample size; *SD*, standard deviation; *IQR*, interquartile range; *SS*, supraspinatus; *IS*, infraspinatus; *BL*, baseline; *SST*, Simple Shoulder Test; *ASES*, American Shoulder and Elbow Surgeons Standardized Shoulder Assessment Form; *AROM*, assisted range of motion; *TL*, thoracolumbar joint; *n/a*, not applicable.

When less than the entire cohort provided data, sample size (n) or the denominator is also reported. IQR is defined as the 75th minus the 25th percentile.

[*] *P* value compares tear type groups by analysis of variance. When the overall model is significant ($P < .05$), Tukey-adjusted pairwise comparisons were performed with significant comparisons reported.

[†] *P* value compares tear type groups by chi-square test. When the overall model is significant ($P < .05$), Sidak-adjusted pairwise comparisons were performed with significant comparisons reported.

[‡] Analysis performed using rank-transformed data.

[§] Fatty infiltration collected on 0-2 scale for architecture and echogenicity where there 2 scores are summed and values > 0 are considered presence.

[‖] *P* value compares tear type groups by Fisher exact test. When the overall model is significant ($P < .05$), Sidak-adjusted pairwise comparisons were performed with significant comparisons reported.

[¶] Isobex data are the mean of up to three trials.

[#] For nonenlargers, this is the final presurgical follow-up.

Table II Association of tear enlargement and tear type

Variable	Control	Partial-thickness tear	Full-thickness tear	*P* value
Baseline tear type, n	47	77	105	
Enlargement occurred, n (%)	20 (43)	46 (60)	72 (69)	.002 by Cochrane Armitage trend test, 1-sided
Final tear type, n	30	44	155	
Enlargement occurred, n (%)	2 (7)	15 (34)	121 (78)	<.0001 by Cochrane Armitage trend test, 1-sided

follow-up was significantly longer for the patients that enlarged (median 8.0 [IQR 5.1] vs. 4.0 [IQR 6.1] years, $P < .0001$), allowing more time to become symptomatic. After including the length of follow-up as a covariate in the Cox regression, the association between pain and enlargement remained (HR 1.73, 95% CI 1.20-2.50, $P < .004$).

Muscle degenerative changes

Of the 229 participants analyzed for tear progression, muscle fatty degeneration data were available in 152 shoulders. Seventy-seven shoulders were excluded either because they were never a full-thickness tear or all potential muscle degeneration data were missing (early study protocol). Fourteen shoulders without analysis of muscle degeneration at a minimum of 2 visits were excluded, leaving 138 shoulders available for muscle fatty degeneration analysis.

Of the 138 shoulders, 102 tears were designated as full-thickness at baseline. Muscle fatty degeneration was noted in the supraspinatus muscle in 12 (12%) and in the infraspinatus in 13 (13%) of shoulders at baseline (all classified as full-thickness tears). Tear enlargement was seen in 104 of the 138 shoulders (75%) analyzed for muscle changes during follow-up (median 7.7 [IQR 6.0] years). Progression of muscle fatty degeneration of at least 1 grade was seen in the supraspinatus muscle in 46 (33%) and in the infraspinatus in 40 (29%) of the 138 shoulders. Progression of muscle degeneration in either muscle was associated with older age at baseline (mean 56.1 [6.6] years for no progression vs. 60.1 [4.3] years for progression, $P < .0001$). Adjusting for age, both the presence of fatty muscle degeneration and the progression of muscle changes for both the supraspinatus and the infraspinatus muscles were associated with tear size (Table VI). The difference in tear dimensions was between 8 and 11 mm for both width and length between shoulders that developed muscle generative changes and those that did not. For both the supraspinatus ($P = .03$) and infraspinatus ($P = .03$) muscles, tear enlargement was a significant risk factor for progression of muscle degeneration (Table VII).

Data regarding assessment of anterior rotator cuff cable integrity and the risk for progression of muscle fatty degeneration was available for 117 shoulders. During follow-up, the anterior cable attachment was classified as disrupted in 49 (42%) of the 117 shoulders (Table VIII). The integrity of the anterior cable was significantly associated with progression of muscle degeneration for both the supraspinatus ($P < .0001$) and the infraspinatus ($P = .005$) muscles.

Discussion

The purpose of this article was to prospectively evaluate the risk of progression of asymptomatic degenerative rotator cuff tears in a cohort of participants aged 65 years and younger at enrollment. The age of this select cohort (mean 57 years) is especially clinically relevant given the potential beneficial influence of age on healing capacity following cuff repair surgery, as most clinicians would consider these patients ideal surgical candidates because of their potential healing capacity. Understanding the natural history of these shoulders without treatment provides a baseline to compare the potential benefits of surgical intervention and helps to provide a framework for refining surgical indications by identifying shoulders with higher-risk tears. The findings of this study demonstrate the progressive nature of degenerative cuff disease and highlights that full-thickness rotator cuff tears are at higher risk of tear enlargement over time compared with partial-thickness tears. Despite the relatively small mean size of the tears in this cohort, progression of muscle fatty degenerative changes was seen in fully one-third of full-thickness tears, which reinforces tear enlargement and anterior cable integrity as important predictors of these changes. It is important to recognize that not all tears will enlarge and that stable tears often do not develop worsening muscle changes. These findings combined with the fact that the median time to enlargement was 3.4 years emphasizes the fact that there is little risk for conservative treatment for painful rotator cuff tears of similar morphology in the short term.

Natural history studies are important to define the risk of disease progression without medical intervention. This allows establishment of a baseline in which to compare the effectiveness of treatment, such as rotator cuff repair surgery. To this point, asymptomatic tears provide an excellent model as painless tears require no treatment. The majority

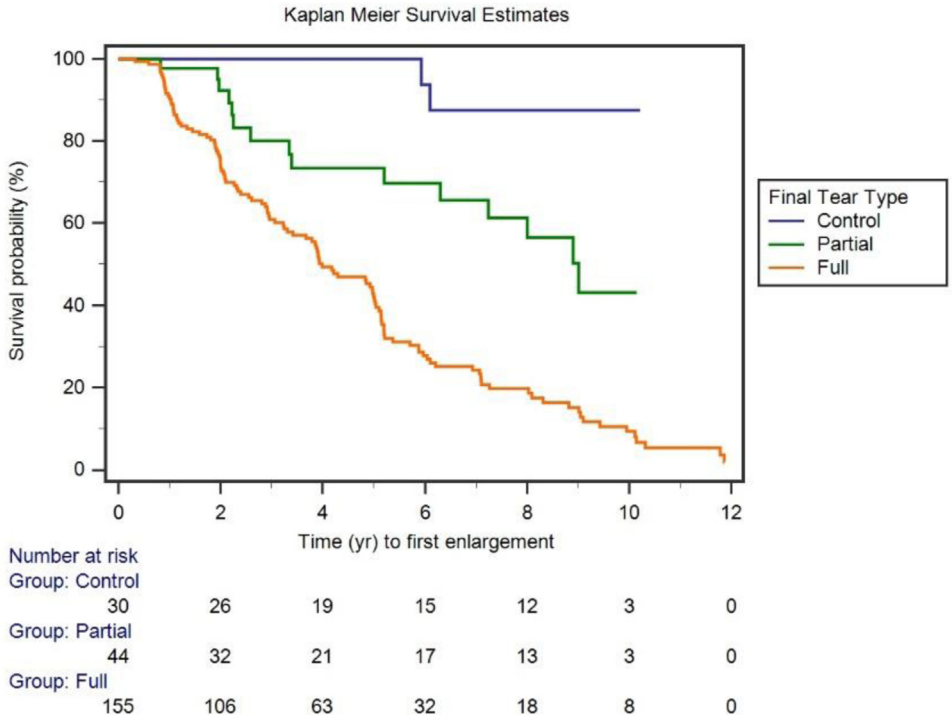

Figure 2 Survivorship curve with tear enlargement as the end point based on final tear type. Survivorship curves tear enlargement of a minimum of 5 mm from previous size or conversion to a more severe tear type as an endpoint. Number at risk refers to number of participants whose tears have not enlarged at that time point in each tear category.

of studies examining rotator cuff disease progression focus on painful rotator cuff tears, are retrospective in nature, and provide mostly short-term follow-up.[14,18,24] Prospective, longitudinal studies provide a more precise timeline for defining the risks of tear enlargement and progression of muscle fatty degeneration, thus allowing for identification of higher-risk tears where intervention should be considered. Given the strong association of age with the prevalence of degenerative rotator cuff tears and the known negative effect of advanced age on healing capacity following surgery, we chose to focus this study on a more clinically relevant group of younger patients where surgery for the treatment of a painful rotator cuff tear may alter the natural history of the tear.

In terms of tear enlargement, the current study expands on our previous findings but provides longer-term follow-up.[9] At a median follow-up of 7.1 years, 60% of the cohort demonstrated either tear enlargement or conversion to a more severe tear type. As a rotator cuff tear progresses from a partial- to full-thickness defect, the risks of further enlargement increases. The risks of tear enlargement for full-thickness rotator cuff tears at the 2-, 5-, and 8-year follow-up was 26%, 58%, and 80%, respectively, which were more than twice the risk of partial-thickness tears at similar time points. Although the median time to enlargement for the cohort was 3.4 years, there was a wide time range noted, highlighting the fact that these tears were enrolled at various stages of disease. An analysis of patient- and tear-related factors that predict a higher risk of tear enlargement showed only tear type and hand dominance to be significant. The median tear size of the full-thickness tears in this cohort increased only 4 mm from baseline; however, this datum is misleading when viewed in aggregate. It should be noted that there was a wide range of tear enlargement seen in this cohort and 37% of full-thickness tears, when followed prospectively, showed multiple tear enlargement events. In addition, close to 10% of the baseline full-thickness tears progressed to an unmeasurable ‘‘massive’’ classification, thus diluting the effect of enlargement on the final tear dimensions. A previous study of 49 full-thickness cuff tears retrospectively reviewed at a mean of 8.8 years showed a similar magnitude of tear enlargement.[17] When these authors defined enlargement by groups, progression of 20 mm or more was seen in 20% of shoulders. At this point, it is difficult to predict which tears will show a greater magnitude of enlargement, which would be valuable information for counseling patients with painful rotator cuff tears.

The development of rotator cuff muscle degeneration has long been associated with increasing rotator cuff tear size and patient age.[8,15,16] Rotator cuff muscle degeneration or fatty infiltration is clinically relevant given its known influence on healing capacity following surgery.[3,11,22] In our previous longitudinal study, we were not able to

Table III Risk factors for tear progression

Variable	No enlargement, n = 91	Enlargement, n = 138	*P* value
Final tear type, n (%)			
Control	28 (31)	2 (1)	<.0001 by Cox
Partial	29 (32)	15 (11)	Partial vs. control, $P = .01$
Full	34 (37)	121 (88)	HR 6.40 (95% CI 1.46, 28.01) full vs. control, $P < .0001$: HR 18.77 (95% CI 4.63, 76.07) full vs. partial , $P < .0001$: HR 2.93 (95% CI 1.71, 5.03)
Smoking status at BL, n (%)			
No	79/90 (88)	124/136 (91)	.75 by Cox
Yes	11/90 (12)	12/135 (9)	HR 1.10 (95% CI 0.61, 2.00)
Dominant shoulder, n (%)			
No	66 (73)	77 (56)	.002 by Cox
Yes	25 (27)	61 (44)	HR 1.70 (95% CI 1.21, 2.39)
Sex			
Male	49 (54)	88 (64)	.74 by Cox
Female	42 (46)	50 (36)	HR 0.94 (95% CI 0.66, 1.34)
Work demands at BL*, median (IQR)	2 (2), n = 84	2 (2), n = 133	.87 by Cox HR 0.99 (95% CI 0.84, 1.16)
Age at BL, yr, mean (SD)	56.5 (7)	57.5 (6)	.37 by Cox HR 1.14 (95% CI 0.86, 1.51)
Length of included study period, yr, median (IQR)	4.0 (6.1), range 0.5 to 11.9	8.0 (5.1), range 0.3 to 13.1	<.0001 by Wilcoxon test

BL, baseline; *IQR*, interquartile range; *SD*, standard deviation; *HR*, hazard ratio; *CI*, confidence interval.
IQR is defined as the 75th minus the 25th percentile.
* 1 = sedentary and 5 = very heavy work.

Table IV Association between tear type and pain development

Variable	Control	Partial-thickness tear	Full-thickness tear	*P* value
Baseline tear type, n	47	77	105	
Pain developed, n (%)	17 (36)	46 (60)	68 (65)	.001 by Cochrane Armitage trend test, 1-sided
Final tear type, n	30	44	155	
Pain developed, n (%)	8 (27)	19 (43)	104 (67)	<.0001 by Cochrane Armitage trend test, 1-sided

n, sample size

adequately assess progression of degenerative muscle changes because of the limited duration of follow-up. The present study demonstrates that degenerative cuff tears possess a higher risk for tear enlargement than for progression of muscle degeneration over time. Despite the small size of most full-thickness tears in this cohort, progression of fatty muscle change occurred in the supraspinatus in 33% and the infraspinatus in 29% of full-thickness tears. When controlling for the effects of age, final tear size was strongly linked to the progression of muscle degeneration. It is apparent that full-thickness tears that are stable in size are at a much lower risk for progression of degenerative muscle changes at longer periods of prospective follow-up. Previous research has shown that tear size influences the presence of muscle degeneration, but most studies are a single time point assessment.[4,15,16] The current study prospectively demonstrates that there is an 8- to 11-mm difference in both tear width and length for full-thickness tears that show progression in muscle degeneration for both the supraspinatus and infraspinatus muscles compared with those that do not. Similar to a previous report, the association of anterior rotator cable integrity and the progression of muscle degeneration was noted in the current study, the effects of which are likely confounded by larger tear size in the cable disrupted group.[8]

Although the current study offers further insight into the factors responsible for pain development in patients with

Table V Pain development as a risk factor for tear enlargement

Variable	No enlargement, n = 91	Enlargement, n = 138	*P* value
Pain developed during study period			
Remained asymptomatic	57 (63)	41 (30)	<.0001 by χ^2
Became painful	34 (37)	97 (70)	.002 by Cox
		(66 before and 31 after first enlargement)	HR 1.79
			(95% CI 1.24, 2.58)

HR, hazard ratio; *CI*, confidence interval.

Table VI Rotator cuff tear size compared to the presence and progression of muscle fatty degeneration

Maximum tear size in follow-up	Presence and progression of muscle FD in follow-up		*P* value by ANCOVA (adjusted for age)
	No	Yes	
Supraspinatus FD presence, n	82	56	
Tear length, mm, median (IQR)	13.5 (9)	26.5 (28)	<.0001
Tear width, mm, median (IQR)	11.5 (10)	20.5 (20)	<.0001
Infraspinatus FD presence, n	87	51	
Tear length, mm, median (IQR)	15 (11)	24 (34)	<.0001
Tear width, mm, median (IQR)	12 (10)	23 (23)	<.0001
Supraspinatus FD progression	92	46	
Tear length, mm, median (IQR)	15 (10)	26.5 (34)	<.0001
Tear width, mm, median (IQR)	12 (11)	20.5 (20)	<.0001
Infraspinatus FD progression	98	40	
Tear length, mm, median (IQR)	15 (10)	26.5 (33)	<.0001
Tear width, mm, median (IQR)	12.5 (10)	23 (22.5)	<.0001

IQR, interquartile range; *FD*, fatty muscle degeneration; *ANCOVA*, analysis of covariance.
IQR is defined as the 75th minus the 25th percentile. In the ANCOVA, age is the covariate and fatty degeneration is the dependent variable.

asymptomatic tears, the findings are not novel. Fifty-seven percent of shoulders developed pain during this extended period of follow-up compared to 46% of shoulders at the previous follow-up. From an anatomy standpoint, tear severity and tear enlargement are the greatest risk factors for an asymptomatic tear to become painful. After controlling for the variable length of follow-up, tears that enlarge are 79% more likely to develop pain. However, 37% of tears that were stable developed pain and 30% of tears that enlarged remained asymptomatic. Clearly there are factors related to pain development that cannot be explained by tear enlargement analysis or perhaps there are tear thresholds for enlargement that the current study was not able to identify. Pain is known to be multifactorial and the factors that are responsible for the conversion of a painless to a painful tear have remained elusive over time. In addition, this cohort has a history of a painful cuff tear on the opposite shoulder that could affect the perception of pain and symptom development in an unknown manner. We do feel the findings of this study suggest that symptom progression should be evaluated as a clinical sign of tear progression.

The strengths of this study are related to the study design. This was a prospective cohort followed with a standardized annual protocol performed by trained research staff and independent radiologists, thus minimizing examiner bias. Strict definitions of tear enlargement and pain development were defined at the outset of the study. However, the findings of this study must be interpreted in the context of its limitations. The participants of this study had painful cuff disease on the contralateral shoulder; therefore, our findings may differ from patients with unilateral disease. Given the known risk of degenerative cuff tears in bilateral shoulders, we feel that our cohort represents the patients commonly seen in clinical practice when presenting with an atraumatic cuff tear. Additionally, it is not known if the natural history of painless cuff disease is the same as untreated painful tears. We believe the asymptomatic tear is an ideal cohort to study tear progression as there is no need for treatment interventions, which may alter the natural history of the disease. A further limitation relates to the assessment of pain development, which can be biased by the fact that patients are aware that they possess a tear and are being monitored. Active participation in a pain surveillance study could potentially influence their perception of future symptoms. Another limitation relates to the evaluation of muscle degeneration and anterior cable integrity, which was not performed early in the study protocol, potentially limiting muscle analysis findings. We did not routinely assess muscle status until we

Table VII Tear size enlargement and progression of muscle fatty degeneration

Cuff muscle versus enlargement	Muscle FD progression		Total	*P* value
	No	Yes		
Supraspinatus muscle				
Tear enlargement, n (%)				
No	28 (30)	6 (13)	34 (25)	
Yes	64 (70)	40 (87)	104 (75)	
Total	92 (67)	46 (33)	138	.03 by χ^2
Infraspinatus muscle				
Tear enlargement, n (%)				
No	29 (30)	5 (12)	34 (25)	
Yes	69 (70)	35 (88)	104 (75)	
Total	98 (71)	40 (29)	138	.03 by χ^2

FD, muscle fatty degeneration.

Table VIII Rotator cuff cable integrity compared to development of fatty muscle degeneration

Cuff muscle versus enlargement	Rotator cable integrity		Total	*P* value
	Disrupted	Intact		
Supraspinatus FD progression, n (%)				
No	19 (39)	56 (82)	75 (64)	
Yes	30 (61)	12 (18)	42 (36)	
Total	49 (42)	68 (58)	117	<.0001 by χ^2
Infraspinatus FD progression, n (%)				
No	27 (55)	54 (79)	81 (69)	
Yes	22 (45)	14 (21)	36 (31)	
Total	49 (42)	68 (58)	117	.005 by χ^2

FD, muscle fatty degeneration.

were able to validate ultrasonographic accuracy compared with magnetic resonance imaging. Despite this limitation, we were able to clearly identify tear-related risk factors for muscle degeneration. Another limitation of this study relates to assessment of final tear size dimensions. When a rotator cuff tear reaches a massive designation, shoulder ultrasonography has limitations in measuring tear dimensions because of retraction of the tendon edge medially under the acromion. The authors believe that magnetic resonance imaging may provide a more accurate tool to track tear size changes once reaching a massive tear size designation, which may provide a more accurate description of tear size changes from baseline. Another limitation relates to participant selection. Unlike our previous publication of this cohort, we chose those aged 65 years or younger as the focus of this current study. We do not believe this to be a significant limitation as our previous study did not demonstrate age to be a risk factor for tear enlargement[9]; however, advancing age has been shown to be a risk factor for muscle degeneration. Given the known effect of tear enlargement on healing after cuff repair surgery, we chose to focus analysis on participants who would most likely benefit from surgical intervention (if symptomatic). Analysis of this younger cohort provides a more clinically relevant comparison group in which to examine the potential benefits of surgery on altering the natural history of degenerative cuff disease. Finally, we recognize that attrition of participants over time and the addition of small number of shoulders with short follow-up weakens our findings. We chose to include all patients regardless of follow-up length as their data can contribute important information regarding tear survivorship over time. The majority of participants we lost related to the development of pain and the choice for surgical intervention. We feel inclusion of this shorter-term data is necessary as it describes the clinical evolution of cuff disease given that these patients were enrolled at various stages of disease.

Conclusion

In conclusion, this prospective longitudinal study demonstrates the progressive nature of degenerative rotator

cuff tears in patients aged 65 years or younger. The risk of tear enlargement is greater for full-thickness than partial-thickness tears. With prospective evaluation, tear enlargement is observed more frequently than progression of muscle degeneration. The development of muscle degeneration is directly related to enlargement, overall tear size, and tear location (anterior cable integrity). When considering surgical indications, full-thickness rotator cuff tears with either a recent enlargement event, with disruption of the anterior rotator cable, or that are >20-25 mm in size possess a different natural history than stable, smaller degenerative tears.

Acknowledgment

The authors acknowledge Ken Yamaguchi for research design support and Jinli Wang for statistical analysis consultation.

Disclaimers:

Funding: This study was funded by the National Institute of Health (NIH R01-AR051026).
Conflicts of interest: Julianne A. Sefko, Karen Steger-May, Sharlene Teefey, and William Middleton received funding for data collection and salary support from the National Institutes of Health (AR-051026). Jay Keener received funding for salary support from the National Institutes of Health (AR-051026). He also reports conflicts not related to the current paper: consultancy fees from Stryker; royalties from Stryker and Shoulder Innovations; stock in Genesis, LLC; and is an Associate Editor of *Seminars in Shoulder Arthroplasty.* Mike T. Torchia, his immediate family, and any research foundation with which he is affiliated have not received any financial payments or other benefits from any commercial entity related to the subject of this article.

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