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What happens to patients in the long term when we do not repair their cuff tears? Ten-year rotator cuff quality of life index (RC-QOL) outcomes following nonoperative treatment of patients with full-thickness rotator cuff tears

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Background: The purpose of this study was to examine long-term, greater-than-ten-year outcomes of patients with full-thickness rotator cuff tears treated nonoperatively.
Methods: Patients with a chronic, full-thickness rotator cuff tear (demonstrated on imaging) who were referred by their physician for shoulder surgery were enrolled in this prospective study between October 2008 and September 2010. Patients then participated in a comprehensive nonoperative treatment program. After the three-month program, patients were defined as "successful" or "failed." "Successful" patients were essentially asymptomatic and did not require surgery. "Failed" patients were symptomatic and consented to surgical repair. All patients were followed-up at 1 year, two years, and five years using a validated, disease-specific rotator cuff quality of life score (the RC-QOL) and whether or not they eventually underwent surgery during these time intervals. All of the patients who participated at the five-year follow-up were contacted for this study between 10 and 12 years (mean 11.4 years) after treatment.
Results: Original results from this study showed that 75% of patients were treated successfully with the nonoperative program, while 25% failed and needed surgery. These numbers were maintained at the two-year follow-up and five-year follow-up (previously reported). At greater than ten years, 88 patients were contacted for follow-up. Only two patients crossed-over from "success" at 5 years to "failed" at 10 years. The nonoperative "success" group had a mean RC-QOL score of 80 (SD = 18) at the previously reported two-year follow-up and 82 (SD = 16) at five-year follow-up. Forty-one patients provided follow-up RC-QOL data at a mean of 11.4 years. The mean RC-QOL scores of the successfully treated nonoperative group were actually higher than those who required surgery during the course of the study (success group mean 86, SD = 12; "failed"/surgery group mean 78, SD = 24), although this was not statistically different ($P = .27$). Two patients had crossed over from the successful group to undergo surgery between 5 and 11 years (one had an acute traumatic injury and the other reported aggravation with activity).
Conclusion: Nonoperative treatment is an effective and lasting option for many patients with a chronic, full-thickness rotator cuff tear. While some may argue that nonoperative treatment delays inevitable surgical repair, this long-term study shows that patients can do very well over time.

Chronic rotator cuff tears have long posed a treatment dilemma for clinicians, and the existing literature is full of conflicting reports for optimal management. An abundance of literature supports surgical repair as a primary and long-lasting treatment option, while seemingly just as much literature supports conservative management.[3-5,7-9,11,12,14-16,18-22]

A meta-analysis from Khatri et al, published in 2019, concluded that patients with full-thickness rotator cuff tears improve whether treated operatively or nonoperatively, suggesting that the natural history of a cuff tear is to improve over time, no matter the treatment given.[10] Narvani et al's review of the literature in 2020 demonstrates similar findings: nonsurgical treatment has a role in the management

Ethics approval was granted by the Conjoint Health Research Ethics Board, University of Calgary Study #: REB15-2501.

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of degenerative rotator cuff tears; however, rotator cuff repair also has a good clinical outcome.[19] Chalmers showed that the likelihood of tear extension in a nonoperatively treated tear was no different than the chance of a recurrent defect following cuff repair.[4] In 2009, Maman et al published a study, which retrospectively assessed nonoperatively treated rotator cuff tears utilizing magnetic resonance imaging (MRI) at least 6 months following treatment. They showed that tear progression occurred more with longer duration follow-up (>18 months). It also suggested that patients greater than 60 years old and those who had fatty infiltration experienced greater tear progression.[17] However, it is also known that rotator cuff pathology on imaging does not directly correlate with patient symptoms.[6,20,21]

The authors have previously published the results of a prospective cohort of patients who underwent a structured and supervised course of nonoperative treatment for chronic, full-thickness rotator cuff tears. Follow-up at 2 years and 5 years has previously been reported.[1,2] The success rate for this nonoperative treatment program was 75%, and most of these patients continued to do well at the two- and five-year follow-ups.[1,2] The patients who failed the nonoperative treatment program underwent rotator cuff repair surgery, and these patients also had excellent outcomes at two- and five-year follow-up. Of concern, however, was that nonoperative management might not yield a long-lasting successful result and that it would only delay the inevitable need for surgery. Therefore, the purpose of the present study was to examine 10-plus-year outcomes of patients previously enrolled in our nonoperative rotator cuff study.

Materials and methods

This was a single-center, prospective study. Patients were enrolled in this study between October 2008 and September 2010. All patients were referred for surgical consult by their primary care physician to one of the two shoulder specialty trained surgeons. All patients demonstrated full-thickness rotator cuff tearing on advanced imaging (ultrasound and/or MRI).

Study criteria were as follows:

Inclusion criteria:

- Age 40-85 years
- Full-thickness tear of supraspinatus or infraspinatus, confirmed via ultrasound or MRI
- Symptomatic for a minimum of three months

Exclusion criteria:

- Already exhausted nonoperative treatment (minimum of three months of stretching and strengthening with the use of analgesics, anti-inflammatories, and/or modalities, with or without injections)
- Full-thickness tear of subscapularis and/or teres minor
- Concomitant pathology of the affected shoulder (eg, instability, cuff tear arthropathy, osteoarthritis)
- Substantial cervical spine pathology and/or radiculopathy
- Elite athlete
- Acute injury (symptoms <3 months)
- Substantial medical issues precluding surgery
- Secondary gain issues (eg, worker's compensation or litigation)
- Unable or unwilling to complete study outcomes
- Unable or unwilling to provide informed consent.

Patients who provided informed consent underwent a personalized home-based treatment program led by a sports medicine physician and physiotherapist. Treatment included stretching and strengthening exercises and anti-inflammatory and/or corticosteroid supplementation on an individualized basis. Weekly contact was maintained by the research coordinator to aid compliance and assist patients as needed.

After the three-month treatment program, patients were assessed by the surgeon, and their outcome was considered "successful" or "failed." A "successful" outcome was deemed if surgery was no longer an appropriate treatment option by both the patient and the surgeon because the patient had improved considerably and was predominantly asymptomatic. A "failed" outcome was determined by continued symptomatology and consent for surgical repair. All outcome determinations (successful or failed) were a joint decision by the patient and the surgeon.

All patients (successful and failed) were followed-up at 1 year, two years, and five years using a validated, disease-specific rotator cuff quality of life score (the RC-QOL) and whether or not they eventually underwent surgery during these time intervals (previously reported).[1,2] At each follow-up visit, the senior surgeon investigator measured the range of motion (ROM) (via goniometry) and strength (via manual muscle testing) and reported as full or less than full as compared to the opposite side. These measurements were done consistently by the same surgeon examiner at every timepoint throughout the study.

Ten-year follow-up

All of the patients who participated at the five-year follow-up were contacted for this study between 10 and 12 years postinitial treatment. The research team telephoned and emailed all enrolled patients. If no contact was made after four attempts, the surgeon then attempted to contact them. Any patient who did not respond was considered lost to follow-up. Patients who did respond were asked to attend an in-person follow-up visit for physical exam (ROM and strength measurements by the senior surgeon investigator) plus x-ray imaging, and those from the "success" group who were willing underwent a follow-up MRI. Patients who were not willing to attend in person were asked to complete the RC-QOL online and confirm whether or not they had undergone surgery since their last follow-up visit.

Patients were grouped according to "successful" or "failed" classifications, and mean RC-QOL scores and standard deviations were compared between groups using t-tests. Fisher's exact tests were utilized to compare strength (full vs. less than full compared to the opposite side). The significance level was set at $P = .05$. Patients who crossed over between groups (eg, were successful but became failures or were failures but became successful) were examined descriptively due to low numbers.

Results

Original results from this study showed that 75% of the patients were treated successfully with the nonoperative program, while 25% failed and needed surgery. These numbers were maintained at the two-year follow-up and five-year follow-up (previously reported).[1,2]

All of the patients who participated at the five-year follow-up were contacted between 10 and 12 years (mean 11.4 years) post-treatment. At greater than ten years, 88 patients were contacted for follow-up (Fig. 1). Two patients were confirmed deceased since the five-year follow-up. Of the 86 remaining patients, 41 followed up for in-person visits. Two were subsequently excluded from the study at this timepoint: 1 had severe neurologic issues and one had polymyalgia rheumatica. Thus, RC-QOL and additional surgery data were collected on 39 patients (22 "successes" and 17 "failures"; 22 males and 17 females). 31 of these 39 patients attended in-person

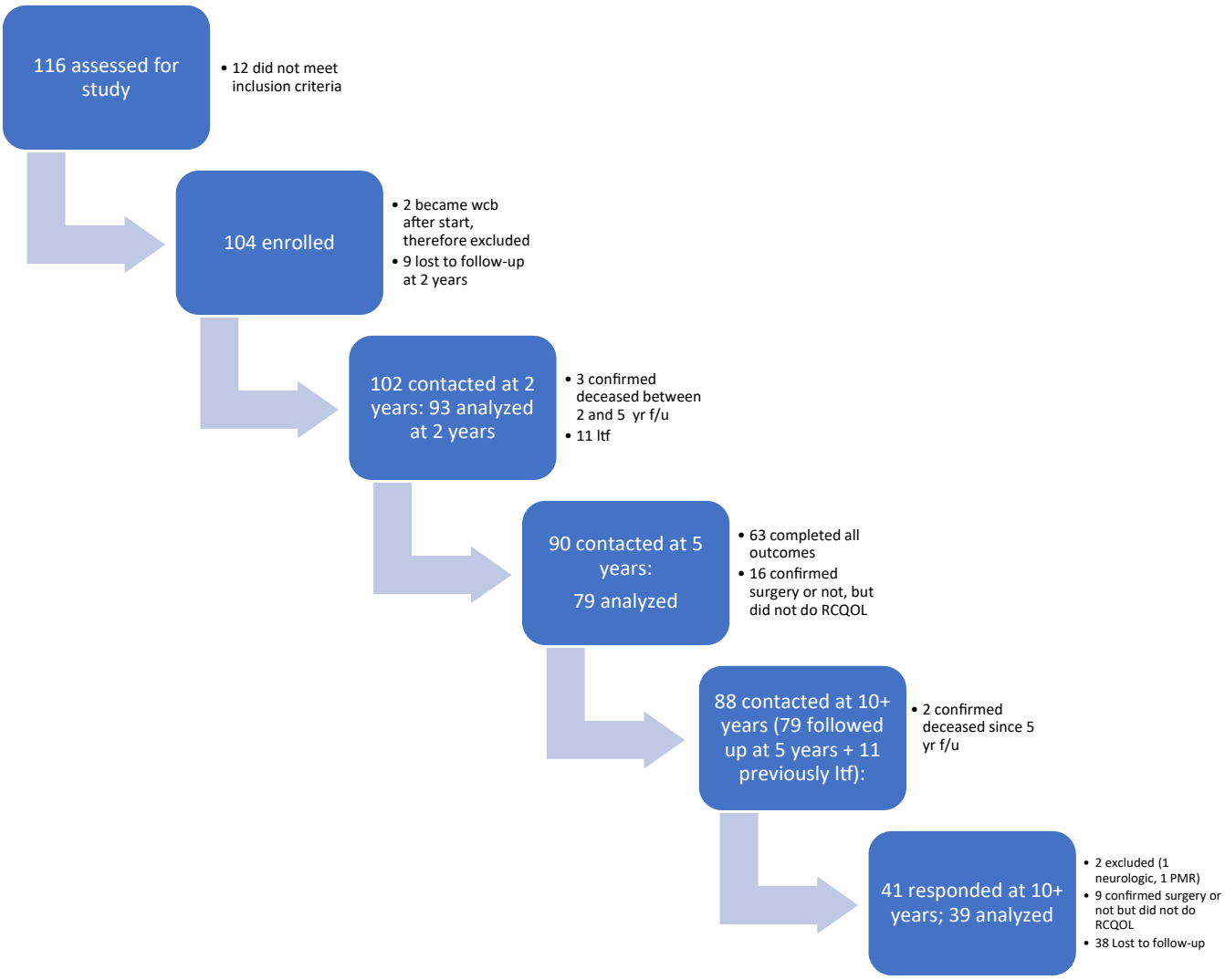

Figure 1 "CONSORT" diagram of study participation over time.

visits at 10+ years for ROM and strength measures in addition to RC-QOL and additional surgery data. The mean age of the group followed up was 70 years (SD = 7.9 years). Further 9 patients declined in-person follow-up but confirmed additional surgery or not at the 10+ year time point. This group had a mean age of 68 years (SD = 9.1 years) and consisted of 4 males and 5 females. Baseline characteristics of those who responded vs. those who did not were not different and are presented in Table I.

The nonoperative "success" group had a mean RC-QOL score of 80 (SD = 18) at the previously reported two-year follow-up and 82 (SD 16) at the five-year follow-up. 10+-year follow-up mean RC-QOL score of the "success" group was 86 (SD 12). The "failure" group (those who underwent surgery) had a mean RC-QOL score of 78 (SD 23) at two years, 89 (SD 11) at 5 years, and 78 (SD 24) at 10+ years (Table II).

The mean RC-QOL scores of the successfully treated nonoperative group were actually higher than those who required surgery during the course of the study (success group mean 86, SD = 12; surgery group mean 78, SD = 24), although this was not statistically different ($P = .27$).

Two patients had crossed over from the successful group to undergo surgery between 5 and 10+ years (one had an acute traumatic injury, and the other reported aggravation with activity). One patient was classified as a cross-over from failure to success after originally consenting for surgery but never actually undergoing it and reporting an RC-QOL score of 80/100 at 11 years.

At 10+ years of follow-up, 11 patients reported continued conservative treatment, including ongoing home exercises, physiotherapy, acupuncture, chiropractic, and/or cortisone injections. 7 of the 11 patients were "success" patients, while 4/11 were "failed" patients who had undergone surgery.

ROM was not statistically different between the successful and failed groups in forward elevation or external rotation at the side (Table III). The strength measured via manual muscle testing was also not statistically different between "success" and "failed" groups at 10+ years of follow-up (Table IV).

Imaging outcomes

X-ray

Four patients out of 21 (19%) in the "success" group demonstrated superior humeral migration on radiologic follow-up at 10+ years, with one (4.7%) of those demonstrating cuff tear arthropathy. In the "failed" group, two patients out of 9 (22%) demonstrated superior humeral migration, with one (11%) of those demonstrating cuff tear arthropathy. Comparison of RC-QOL scores between those

Table I
Loss to follow-up comparison (Baseline data of patients grouped by 10+ y of follow-up response).

Baseline data	RC-QOL completed at 10+ y (n = 39)	Confirmed surgery at 10+ y but no data collected (n = 9)	Not able to contact at 10+ y (n = 38)
Age at enrolment	Mean: 59 y SD: 7.9	Mean: 57 y SD: 9.1	Mean: 62 y SD: 10.2
Gender	M: 21 F: 18	M: 4 F: 5	M: 20 F: 18
Size tear (mm)	Mean: 16.6 mm SD: 7.3	Mean: 17.1 mm SD: 10.7	Mean: 15.0 mm SD: 7.6
Smoker			
N = non smoker	N: 34	N: 7	N: 30
Y = smoker	Y: 5	Y: 2	Y:8
FE ROM	Mean: 156 SD: 18.9	Mean: 158 SD: 22.2	Mean: 151 SD: 24.6
Full ER strength			
Y = yes	Y: 14	Y: 4	Y: 11
N = no	N: 25	N: 5	N: 27
Dominant side			
N = not involved	N: 12	N: 2	N: 11
Y = involved	Y: 27	Y:7	Y: 27
Onset			
I = insidious	I: 20	I: 4	I: 21
A = acute	A: 19	A: 5	A:17
Baseline RC-QOL (/100)	Mean: 48.9 SD: 19.6	Mean: 27.3 SD: 12.3	Mean: 45.4 SD: 22.9

FE ROM, forward elevation range of motion; *ER*, external rotation; *RC-QOL*, Rotator Cuff Quality of Life Index.

Table II
RC-QOL scores (/100) of successful vs. failed patients at each reported study time point.

Time point	Success group	Failed group*
Baseline	RC-QOL: 49 SD: 22	RC-QOL: 33 SD: 15
3 mo	n = 70 RC-QOL: 82 SD: 12	n = 23 RC-QOL: 38 SD: 21
2 y	n = 68 RC-QOL: 80 SD: 18	n = 25 RC-QOL: 78 SD: 23
5+ y	n = 55 RC-QOL: 83 SD: 16	n = 24 RC-QOL: 89 SD: 11
11+ y	n = 22 RC-QOL: 86 SD: 12	n = 26 RC-QOL: 78 SD: 24

RC-QOL, Rotator Cuff Quality of Life Index.
*Failed 3-mo nonoperative treatment program and went on to surgery.

demonstrating superior humeral migration vs. not was not significant ($P = .32$), likewise with those demonstrating cuff tear arthropathy vs. not ($P = .33$).

MRI

Nineteen patients underwent MRI imaging at the 10+-year follow-up. 17 of these were in the "success" group, while the other two were the crossovers originally defined as "successful" who underwent surgery after 10+ years.

The MRIs were read by a musculoskeletal-specialized radiologist. Progression was defined a priori as an extension of the tear by 1 centimeter or greater from the original imaging at the outset of the study. 8 of 17 (47%) of the "successful" patients showed increased tearing or retraction; however, the mean RC-QOL score of these 8 patients at 10+ years was 84.1/100 (SD = 7.6, range 70-92). Both crossover patients demonstrated retraction or worsening of the tear.

Discussion

The results show that nonoperative management of chronic, full-thickness rotator cuff tears is a reasonable treatment option that can provide lasting relief over the long term. It would be our inference that successfully treated patients are relatively asymptomatic and most often remain that way over time. The results demonstrate durability over time. It should be emphasized that those patients who failed nonsurgical treatment independent of the timeline ended up with a similar outcome to those who failed early. Therefore, the authors would recommend following nonsurgically treated patients regularly (annually) to ensure that patients who deteriorate are identified and operated on if symptoms and structural progression indicate. The fear that many tears may generally become more symptomatic over time is not founded based on this study.

Extensive work has been published by the Multicenter Orthopaedic Outcomes Network group showing results extremely similar to the current study.[13] The 10-year follow-up of the MOON group's large cohort indicated durable 10-year outcomes of nonoperative treatment with minimal decrease in patient-reported outcome measures over time. The MOON group study did not report structural integrity via imaging at any long-term time points.

The results also show that at 10+ years, operative and nonoperative outcomes are still not significantly different from each other. Indeed, the nonoperative group had a higher RC-QOL score than the operated group, although this difference was not statistically significant.

The long-term diagnostic imaging results were not statistically different between the groups in this study either. Both groups had a small percentage of patients that progressed in this regard, although it did not correlate with their clinical condition, as measured by the RC-QOL. If patients continue to do well clinically, we don't believe this information is important to patient management. However, if patients did become symptomatic in the long term, there would still be surgical treatment options for them, including possible reverse arthroplasty for cuff tear arthropathy if necessary.

Limitations

The response rate at five-year follow-up was 84%. Not unexpectedly, the response rate at 10+ years was not as good. The actual mean follow-up time was 11.4 years. This was largely because the 10-year follow-up window occurred during the COVID pandemic.

Table III
Range of motion at 10+-y follow-up of successful vs. failed patients.

	Success group (n = 21)	Failed group* (n = 10)	Comparison *P*
FE: affected side	169 (SD 12)	167 (SD 9)	.58
FE: opposite side	162 (SD 23)	156 (SD 27)	.48
ER: affected side	58 (SD 20)	61 (SD 20)	.74
ER: opposite side	57 (SD 21)	62 (SD 17)	.55

FE, forward elevation; *ER*, external rotation.
n = 31 (21 success and 10 failed) attended in-person follow-up at 10+ y.
*Failed 3-mo nonoperative treatment program and went on to surgery.

Table IV
Strength (measured via manual muscle testing) at 10+-y follow-up of successful vs. failed patients.

	Success group (n = 21)	Failed group* (n = 10)	Comparison: fisher's exact
Abduction: affected side	Full strength: 14/21 Less than full: 7/21	Full Strength: 5/10 Less than full: 5/10	0.447
Abduction: opposite side	Full strength: 16/21 Less than full: 5/21	Full strength: 4/10 Less than full: 6/10	0.106
ER: affected side	Full Strength: 17/21 Less than full: 4/21	Full strength: 6/10 Less than full: 4/10	0.381
ER: opposite side	Full Strength: 17/21 Less than full: 4/21	Full strength: 5/10 Less than full: 5/10	0.105
Belly press: affected Side	Full strength: 15/21 Less than full: 6/21	Full strength: 8/10 Less than full: 2/10	1.00
Belly press: opposite Side	Full strength: 14/21 Less than full: 7/21	Full strength: 8/10 Less than full: 2/10	0.677

ER, external rotation.
n = 31 (21 success and 10 failed) attended in-person follow-up at 10+ y.
*Failed 3-mo nonoperative treatment program and went on to surgery.

With an older, potentially vulnerable (health-wise) population, we did not feel it was appropriate to bring patients in for in-person follow-up during social distancing restrictions and stay-at-home mandates. It can reasonably be assumed that this resulted in additional loss to follow-up. Further, our local health authority would not allow us to search the regional clinical database to determine if "lost" patients had died or suffered severe medical conditions or if they had shoulder surgery in a different center in the 5-10-year follow-up window, which would have provided a more complete picture of those that did not follow-up.

In order to determine if the patients who fully responded differed in any way from the partial responders and those lost to follow-up, we compared their baseline characteristics. Patients were classified into the three following groups: 1) completed RC-QOL at 10+ years; 2) confirmed surgery or no surgery but did not complete RC-QOL at 10+ years; or 3) patients lost to follow-up. The baseline data showed no differences between the three groups (Table I). Therefore, we feel confident that those who responded were representative of the whole group, and those who were lost to follow-up likely did not differ significantly from the rest of the cohort.

An additional limitation of this study is the terminology originally used to classify patients into the groups "successful" and "failed." This terminology was selected at the outset of the study to classify patient response to the nonoperative treatment program. However, as the study progressed into longer term follow-up with distinct groups undergoing continued conservative treatment or surgery, the terms "success" and "failed" may cause some confusion. Many "failed" patient (ie, those who went on to surgery) had an eventual successful outcome, and some who had "successful" outcomes initially (ie, did not undergo surgery) required ongoing conservative treatment. The original terminology selected could have been clearer with respect to longer-term outcomes. However, we feel that the intent behind the grouping labels was specific to the original objective of the study and is not a major limitation.

Conclusion

Nonoperative treatment is an effective and lasting option for many patients with a chronic, full-thickness rotator cuff tear. While some may argue that nonoperative treatment just delays inevitable surgical repair, this long-term study shows that patients can do very well over time.

Disclaimers:

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Conflicts of interest: The authors, their immediate families, and any research foundations with which they are 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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