A commentary by Jay D. Keener, MD, is linked to the online version of this article at jbjs.org.

At a 10-Year Follow-up, Tendon Repair Is Superior to Physiotherapy in the Treatment of Small and Medium-Sized Rotator Cuff Tears

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Background: Tendon repair and physiotherapy are frequently used treatment methods for small and medium-sized rotator cuff tears. In 2 previous publications of the 1 and 5-year results of this study, we reported significant but small between-group differences in favor of tendon repair. Long-term results are needed to assess whether the results in both groups remain stable over time.

Methods: In this study, 103 patients with a rotator cuff tear not exceeding 3 cm were randomly assigned to primary tendon repair or physiotherapy with optional secondary repair. Blinded follow-up was performed after 6 months and 1, 2, 5, and 10 years. Outcome measures included the Constant score; the self-report section of the American Shoulder and Elbow Surgeons score; the measurement of shoulder pain, motion, and strength; and patient satisfaction. Magnetic resonance imaging (MRI) was performed on surgically treated shoulders after 1 year, and ultrasound was performed on all shoulders after 5 and 10 years. The main analysis was by 1-way analysis of covariance and by intention to treat.

Results: Ninety-one of 103 patients attended the last follow-up. After 10 years, the results were better for primary tendon repair, by 9.6 points on the Constant score ($p = 0.002$), 15.7 points on the American Shoulder and Elbow Surgeons score ($p < 0.001$), 1.8 cm on a 10-cm visual analog scale for pain ($p < 0.001$), 19.6° for pain-free abduction ($p = 0.007$), and 14.3° for pain-free flexion ($p = 0.01$). Fourteen patients had crossed over from physiotherapy to secondary surgery and had an outcome on the Constant score that was 10.0 points inferior compared with that of the primary tendon repair group ($p = 0.03$).

Conclusions: At 10 years, the differences in outcome between primary tendon repair and physiotherapy for small and medium-sized rotator cuff tears had increased, with better results for primary tendon repair.

Level of Evidence: Therapeutic Level I. See Instructions for Authors for a complete description of levels of evidence.

Tendon repair and physiotherapy have both been found to be effective in the treatment of small to medium-sized rotator cuff tears[1-8]. Comparison studies have rarely been performed and those that have been performed have short to intermediate-term follow-ups only. Two such studies found comparable results between treatment methods after 1 and 2 years[9-11]. In previous publications involving the present study[12,13], we reported significant but small and possibly clinically irrelevant differences in favor of tendon repair both at the 1-year follow-up[12] and for the main effect of treatment from 6 months to 5 years[12,13]. However, treatment decisions should not be based on short-term to intermediate-term results only. Different changes over time have been reported for repaired and unrepaired tears, with stable results for the former but anatomic and functional deterioration for the latter[7,14-18]. Consequently, differences that are small in the intermediate term may reach clinical importance in the long term. If larger differences in shoulder function are found after 10 years, this

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A **data-sharing statement** is provided with the online version of the article (http://links.lww.com/JBJS/F314).

TABLE I Inclusion and Exclusion Criteria

Inclusion criteria
Pain at rest or exercise laterally on the shoulder
A painful motion arc[39]
A positive impingement sign[40,41]
Passive shoulder motion of at least 140° for abduction and flexion
Demonstration of a full-thickness tear of the rotator cuff by both sonography and MRI, with a tear size not exceeding 3 cm on sonography
Muscle atrophy not exceeding Thomazeau stage 2 on MRI[42]
Exclusion criteria
Patient age of <18 years
Tears involving >25% of the width of the subscapularis tendon
Presence of other local or systemic diseases affecting shoulder function
History of surgical treatment of the involved shoulder
Medical contraindication for surgery or anesthesia
Inability to understand written and spoken Norwegian

may have an influence on surgical indications, especially in younger patients with painful rotator cuff tears.

The aim of this study was to compare 10-year results from physiotherapy and primary tendon repair for small to medium-sized rotator cuff tears. We hypothesized that the results from tendon repair would be more consistent than those from physiotherapy and that larger between-group differences would be seen after 10 years.

Materials and Methods

This study shows the 10-year results of a single-center, randomized clinical trial with parallel groups, of which the 1-year and 5-year results have been published[12,13]. The study was approved by our institution's ethics committee and was registered at ClinicalTrials.gov (NCT00852657). Written informed consent was obtained from all participants.

Patients and Procedures

Between September 2004 and October 2007, 103 patients with a symptomatic full-thickness rotator cuff tear not exceeding 3 cm in diameter were included in the trial. Inclusion and

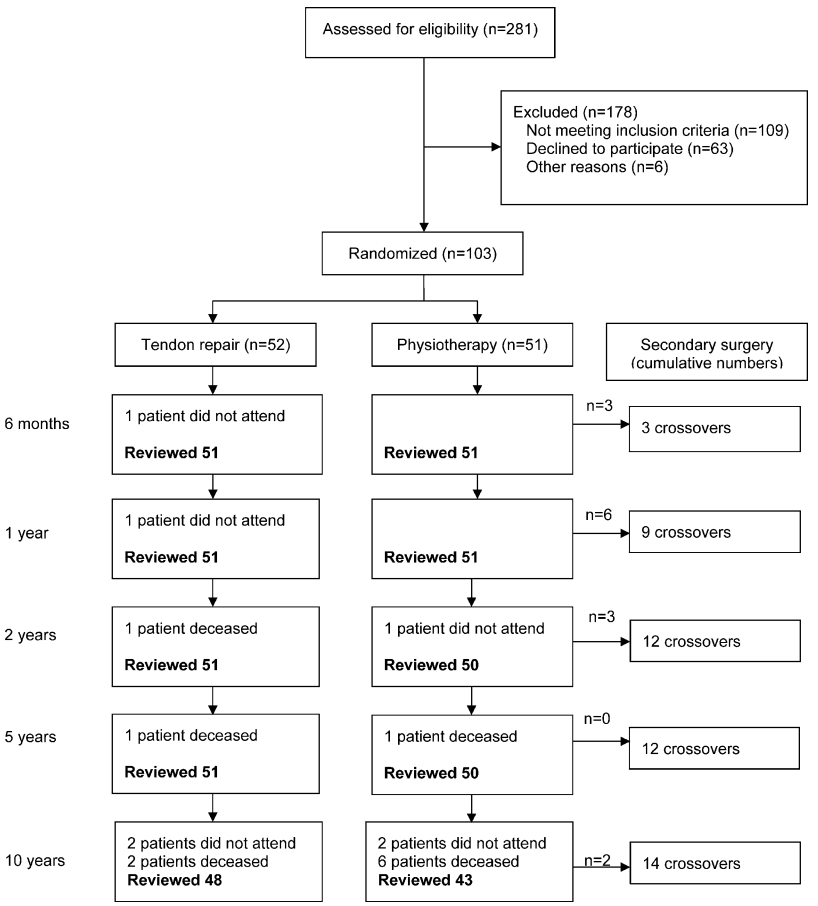

Fig. 1

Flowchart of the trial enrollment and analysis. Patients who crossed over to secondary surgery remained in the physiotherapy group for analysis according to intention to treat.

TABLE II Patient Characteristics at the Time of Enrollment

	Primary Tendon Repair (N = 52)	Physiotherapy with Optional Secondary Repair (N = 51)
Age* *(yr)*	59 ± 7.5	61 ± 7.6
Male sex†	37	36
Right side affected†	31	29
Tear on dominant side†	33	31
Shoulder-demanding activities†	26	28
Duration of symptoms* *(mo)*	12.3 ± 18.7	9.8 ± 9.8
Tear size on ultrasound* *(mm)*		
Anterior-posterior plane	15.6 ± 6.7	14.3 ± 6.3
Medial-lateral plane	14.9 ± 5.7	14.7 ± 6.9
Type of injury†		
Acute on chronic	30	29
Chronic	22	22
Occupational situation†		
Working	23	24
On sick leave	15	8
Retired	11	17
Receiving disability benefit	3	2
Earlier treatment†		
Physiotherapy	28	21
Cortisone injections	5	10
Nonsteroidal anti-inflammatory drugs	7	9
None	12	11
Muscle atrophy on MRI†		
Grade 0	26	23
Grade 1	12	18
Grade 2	13	10
MRI not available	1	0
Localization of tear on ultrasound†		
Supraspinatus only	37	40
Supraspinatus and infraspinatus	14	10
Supraspinatus and subscapularis	1	1
Current smoking status†		
Nonsmoker	37	44
≤10 cigarettes per day	10	3
>10 cigarettes per day	5	4

*The values are given as the mean and the standard deviation. †The values are given as the number of patients.

exclusion criteria are given in Table I. The patient flow through the study is shown in Figure 1.

Outcome Measures

Patient evaluation was performed at baseline, 6 months, and 1, 2, 5, and 10 years by an assessor who was blinded to treatment allocation. The primary outcome measure was the Constant score[19]. The secondary outcome measures included the self-report section of the American Shoulder and Elbow Surgeons (ASES) score[20], the Short Form-36 Health Survey (SF-36)[21], and the measurement of pain, strength, and pain-free mobility of the shoulder. After 1, 5, and 10 years, patients had to answer the question "How satisfied are you with the treatment result of your shoulder?" on a visual analog scale (VAS) ranging from 0 (very unsatisfied) to 10 (very satisfied). The clinical relevance of the result was explored by using the valuation scale of the Constant score (≥81 points indicates good to excellent; 71 to 80 points, satisfactory; ≤70 points, adequate to poor)[22,23]. We assumed that the achievement of a good-to-excellent result rather than a satisfactory or adequate-to-poor result would represent clinical importance. Surgically treated shoulders were reexamined by magnetic resonance imaging (MRI) after 1 year, and all shoulders were reexamined by ultrasound after 5 and 10 years. Ultrasound was performed by a sonographer with >15 years of experience whose accuracy in diagnosing tears of the rotator cuff has been well documented[24,25] and who was blinded to the patient's clinical data and shoulder function. A Sonoline Antares scanner (Siemens Medical Solutions) equipped with a linear array transducer of 8.5 to 11.5 MHz was used, and a standard examination protocol, as described earlier, was followed[24,25]. Diagnostic criteria for a rotator cuff tear and for full-thickness and partial-thickness retears were used as described in the literature[26-29].

Randomization

Patients were randomly assigned to primary tendon repair or physiotherapy with optional secondary repair. An external statistician generated the randomization list (block length of 20 and 1:1 ratio). The randomization sequence was concealed from the study's collaborators until interventions were assigned and from the outcome assessor throughout the whole study.

Surgical Procedure and Postoperative Management

Operative treatment was open or mini-open tendon repair. Following a diagnostic arthroscopy of the glenohumeral joint, the tear was exposed through a deltoid-splitting approach, and an anterior acromioplasty was performed[30]. Tendons were mobilized and repaired by transosseous sutures. Tenodesis of the long head of the biceps was performed in patients with a partial tear of the tendon.

Postoperatively, the arm was immobilized in a sling, and passive range-of-motion exercises were started and were continued for 6 weeks. Active range-of-motion exercises were started 6 weeks after the surgical procedure and were supplemented by strengthening exercises after 12 weeks.

Physiotherapy

Treatment was given by 1 of 4 study physiotherapists. The study's rehabilitation program was previously reported[12,13]. Treatment sessions of 40 minutes were given twice weekly for 12 weeks and with decreasing frequency during the following 6 to 12 weeks. No additional treatment measures such as anti-inflammatory or analgesic medication were given.

TABLE III Adverse Events and Need for Additional Therapeutic Measures During Follow-up

	Primary Tendon Repair	Physiotherapy with Optional Secondary Repair
Site other than the index shoulder		
Medical event	Polymyalgia rheumatica (n = 1)*	Polymyalgia rheumatica (n = 1)*
	Cerebral apoplexy (n = 1)†	Herpes zoster (n = 1)*
	Chronic lymphocytic leukemia (n = 1)‡	Lymphoma (n = 1)*
		Leukemia (n = 2)‡
Surgical event	Operation for abdominal aortic aneurysm (n = 1)†	Tendon repair in the contralateral shoulder (n = 1)‡
	Hepatic transplantation (n = 1)‡	Acromioplasty in the contralateral shoulder (n = 1)‡
	Lumbar discectomy (n = 1)‡	
	Tendon repair in the contralateral shoulder (n = 3)‡	
Musculoskeletal event	Lateral humeral epicondylitis (n = 1)*	Cervical radiculopathy (n = 1)*
	Low back pain (n = 1)†	
	Cervical radiculopathy (n = 1)*	
	Cervical radiculopathy (n = 1)†	
Index shoulder		
Need for additional therapeutic measures	Physiotherapy (n = 1)*	Physiotherapy (n = 3)†
	Reoperation with acromioplasty and biceps tenotomy (n = 1)†	Physiotherapy (n = 1)‡
		Glenohumeral arthrosis, conservatively treated (n = 1)‡
New shoulder trauma	Fracture of the humerus (n = 1)*	Contusion of the shoulder (n = 2)*
	Contusion of the shoulder (n = 1)†	Contusion of the shoulder (n = 1)†
	Contusion of the shoulder (n = 2)‡	Contusion of the shoulder (n = 2)‡
	Fracture of the humerus, conservatively treated (n = 1)‡	

*Occurred prior to the 2-year follow-up. †Occurred between the 2 and 5-year follow-ups. ‡Occurred after the 5-year follow-up.

Secondary Surgery

Patients who were unsatisfied with their results after a minimum of 15 physiotherapy sessions and who had persistent clinical findings were offered a secondary surgical treatment.

Statistical Analysis

According to the original sample size calculation, reported in our earlier publication[12], a group size of 45 patients was needed to detect a 12-point difference in the Constant score. To compensate for an expected loss to follow-up, 103 patients were included in the study.

One-way analyses of covariance (ANCOVAs) were performed separately for each time of follow-up on our primary and secondary outcome scores and on data from subgroups based on the anatomic outcome (tear size increase, retear) and on the treatment that was given (post hoc as-treated analysis). The choice of treatment was used as the explanatory factor, and all analyses were performed with adjustment for baseline differences in the respective dependent variable and age. Analyses of primary and secondary outcomes were by intention to treat. No adjustment for multiple comparisons was considered to be necessary. To assess if missing outcome data during follow-up had affected our results, a supplementary linear mixed model repeated-measurement analysis was performed. The linear mixed model had a random intercept and fixed effects consisting of the follow-up time, the treatment group, and an interaction term between the follow-up time and the treatment group. Analyses were performed with adjustment for the baseline differences of the respective dependent variable and for age. The results did not differ from the ANCOVAs (see Appendix). The change from 2 to 10 years in the difference between the treatment groups was assessed by a linear mixed model analysis by estimation of the respective linear combination.

The clinical importance of the results was explored in a proportion analysis by assessing the distribution of individual responses across the valuation scale of the Constant score[22,23]. The number needed to treat for the achievement of a good-to-excellent result was calculated as the inverse of the difference between the proportions. Normalized (age and sex-adjusted) Constant scores were calculated and are given in the Appendix[31].

TABLE IV Results for Primary and Secondary Outcome Measures from a 1-Way ANCOVA

Outcomes	Primary Tendon Repair*†	Physiotherapy with Optional Secondary Repair*†	Between-Group Difference‡§	P Value#
Primary				
Constant score *(points)*				
Baseline	35.3 ± 13.2	38.4 ± 14.2		
6 months	65.6 ± 16.3	63.9 ± 20.2	2.8 (−4.5 to 10.1)	
1 year	77.7 ± 13.4	70.3 ± 19.1	8.5 (1.9 to 15.0)	
2 years	79.3 ± 13.6	77.7 ± 14.9	2.6 (−3.1 to 8.3)	
5 years	79.8 ± 15.0	74.2 ± 20.3	6.5 (−0.7 to 13.6)	
10 years	80.5 ± 9.8	71.8 ± 17.8	9.6 (3.6 to 15.7)	0.002
Secondary				
ASES score** *(points)*				
Baseline	45.5 ± 14.5	48.2 ± 14.4		
6 months	85.3 ± 13.7	75.4 ± 20.2	10.6 (3.8 to 17.5)	
1 year	93.6 ± 12.5	83.6 ± 18.3	10.8 (4.6 to 17.0)	
2 years	93.1 ± 13.9	88.0 ± 14.9	5.5 (−0.3 to 11.4)	
5 years	92.8 ± 13.3	85.4 ± 21.0	8.3 (1.2 to 15.3)	
10 years	94.0 ± 9.5	80.0 ± 20.2	15.7 (9.3 to 22.1)	<0.001
VAS pain *(cm)*				
Baseline	5.6 ± 2.0	5.3 ± 1.9		
6 months	1.1 ± 1.3	2.7 ± 2.2	1.6 (0.9 to 2.3)	
1 year	0.5 ± 1.2	1.6 ± 1.6	1.2 (0.6 to 1.8)	
2 years	0.7 ± 1.5	1.4 ± 1.4	0.7 (0.1 to 1.4)	
5 years	0.6 ± 1.4	1.6 ± 1.6	1.0 (0.2 to 1.8)	
10 years	0.6 ± 1.3	2.3 ± 2.4	1.8 (1.1 to 2.6)	<0.001
Pain-free abduction *(deg)*				
Baseline	73.7 ± 28.0	81.9 ± 29.8		
6 months	135.4 ± 41.7	135.4 ± 47.9	2.2 (−15.8 to 20.3)	
1 year	158.4 ± 33.7	143.8 ± 43.9	16.8 (1.2 to 32.4)	
2 years	161.7 ± 30.8	163.6 ± 32.6	−0.5 (−13.3 to 12.2)	
5 years	167.3 ± 30.6	155.1 ± 41.2	14.7 (0.1 to 29.4)	
10 years	169.1 ± 23.8	151.7 ± 40.9	19.6 (5.6 to 33.6)	0.007
Pain-free flexion *(deg)*				
Baseline	86.8 ± 41.3	88.6 ± 32.1		
6 months	147.3 ± 34.5	146.6 ± 46.3	2.1 (−13.9 to 18.1)	
1 year	166.1 ± 27.5	155.6 ± 38.4	10.3 (−3.1 to 23.6)	
2 years	168.5 ± 26.1	170.5 ± 23.0	−1.0 (−10.8 to 8.7)	
5 years	170.6 ± 27.9	163.5 ± 35.4	8.3 (−4.4 to 21.0)	
10 years	175.8 ± 12.0	162.0 ± 35.5	14.3 (3.3 to 25.3)	0.01
Strength *(kg)*				
Baseline	7.5 ± 5.5	8.1 ± 5.8		
6 months	8.0 ± 4.6	10.6 ± 5.4	−2.5 (−4.2 to −0.7)	
1 year	11.1 ± 4.0	11.9 ± 5.1	−0.8 (−2.4 to 0.9)	
2 years	11.9 ± 4.3	12.8 ± 5.3	−0.8 (−2.5 to 1.0)	
5 years	12.1 ± 4.7	11.4 ± 5.4	0.8 (−1.1 to 2.7)	
10 years	11.7 ± 4.5	10.2 ± 5.6	1.8 (−0.2 to 3.8)	0.08

*The values are raw measurement data. In the analysis of the 2 groups, there were 52 patients in the primary tendon repair group and 51 patients in the physiotherapy with optional secondary repair group analyzed at baseline, 51 patients in each group analyzed at 6 months and 1 year, 51 patients in the primary tendon repair group and 50 patients in the physiotherapy with optional secondary repair group analyzed at 2 and 5 years, and 48 patients in the primary tendon repair group and 43 patients in the physiotherapy with optional secondary repair group analyzed at 10 years. †The values are given as the mean and the standard deviation. ‡The values were adjusted for baseline measurements of the variable and for patient age; positive values indicate a better result for primary tendon repair. §The values are given as the mean, with the 95% CI in parentheses. #A p value of <0.05 indicates a significant between-group difference at the 10-year follow-up. **This is the self-report section of the ASES score.

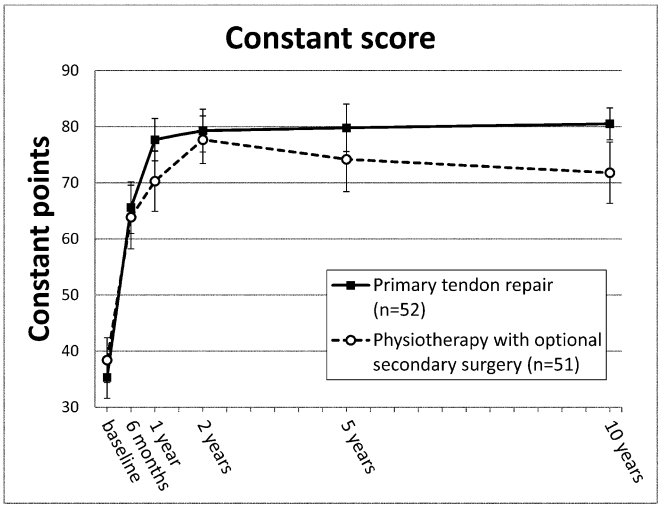

Fig. 2

Plot showing the mean Constant scores at baseline and all follow-ups for the primary tendon repair group and the physiotherapy with optional secondary surgery group. The cumulative number of patients who were treated by secondary tendon repair was 3 patients at 6 months, 9 patients at 1 year, 12 patients at 2 and 5 years, and 14 patients at 10 years. Analysis is by intention to treat, with the results from secondary surgery included in the physiotherapy group. The error bars indicate 95% CIs.

Results

After 10 years, 48 of 52 patients from the primary tendon repair group and 43 of 51 patients from the physiotherapy group were available for follow-up. The overall 10-year follow-up rate was 97%. Demographic data at baseline are presented in Table II. Adverse events and the need for additional therapeutic measures during follow-up are reported in Table III.

Treatment Effects

At the 10-year follow-up, the Constant score was 80.5 points in the primary tendon repair group compared with 71.8 points in the physiotherapy group, with a significant age and baseline-corrected between-group difference of 9.6 points (95% confidence interval [CI], 3.6 to 15.7 points; p = 0.002) (Table IV). The change in the difference between treatment groups from 2 to 10 years was significant at 6.8 points (95% CI, 0.4 to 13.2 points; p = 0.04) (Fig. 2).

A good-to-excellent result of ≥81 points on the Constant score was achieved by a significantly larger proportion of patients treated by primary tendon repair (71% compared with 42%; p = 0.006). The calculation of the number needed to treat showed that 3.5 patients (95% CI, 2.1 to 10.7 patients) would have to be treated by tendon repair instead of by physiotherapy for 1 additional patient to achieve a good-to-excellent result on the Constant score.

Significant differences in favor of primary tendon repair were found for the ASES score (difference, 15.7 points [95% CI, 9.3 to 22.1 points]; p < 0.001), for a 10-cm VAS for pain (difference, 1.8 cm [95% CI, 1.1 to 2.6 cm]; p < 0.001), for active, pain-free shoulder abduction (difference, 19.6° [95% CI, 5.6° to 33.6°]; p = 0.007) and flexion (difference, 14.3° [95% CI, 3.3° to 25.3°]; p = 0.01), and for a VAS for patient satisfaction (9.2 compared with 8.2 cm, with a difference of 0.97 cm [95% CI, 0.13 to 1.82 cm]; p = 0.03). For shoulder strength, the difference of 1.8 kg was not significant (p = 0.08) (Table IV). The change in shoulder scores and subscores from baseline to the 10-year follow-up is shown in Figures 2, 3, and 4. On the SF-36 score for quality of life, between-group differences were small and not significant (p > 0.05) (Table V).

Secondary Tendon Repair

Fourteen patients (27%) in the physiotherapy group reported an insufficient treatment result from physiotherapy and crossed over to secondary surgery (9 patients during the first year, 3 patients between 1 and 2 years, and 2 patients between 5 and 10 years). Treatment was by secondary tendon repair in 12 cases and, because of patient preference, by acromioplasty in 2 cases. Patient characteristics at baseline (Table II) were comparable between the physiotherapy-only group and the crossover group.

In a supplementary, post hoc, as-treated analysis, results are given separately for the primary tendon repair group, the physiotherapy-only group, and the crossover group (Fig. 5). After 10 years, with the primary tendon repair group as the reference, we found significantly inferior results for the

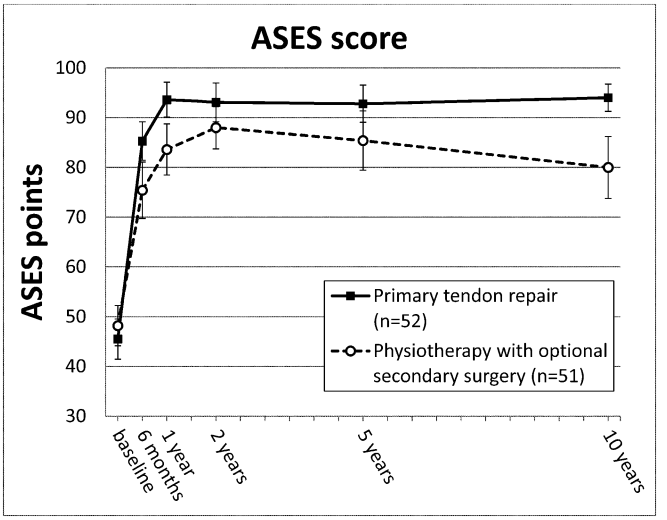

Fig. 3

Plot showing the mean ASES scores at baseline and at follow-ups of 6 months and 1, 2, 5, and 10 years for the primary tendon repair group and the physiotherapy with optional secondary surgery group. The cumulative number of patients who were treated by secondary tendon repair was 3 patients at 6 months, 9 patients at 1 year, 12 patients at 2 and 5 years, and 14 patients at 10 years. Analysis is by intention to treat, with the results from secondary surgery included in the physiotherapy group. The error bars indicate the 95% CIs.

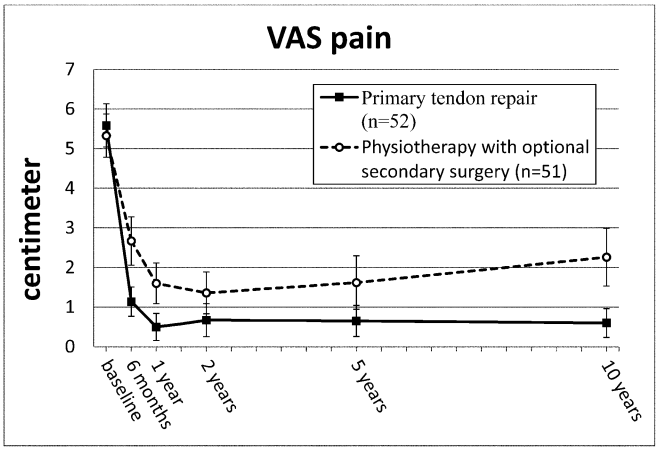

Fig. 4-A

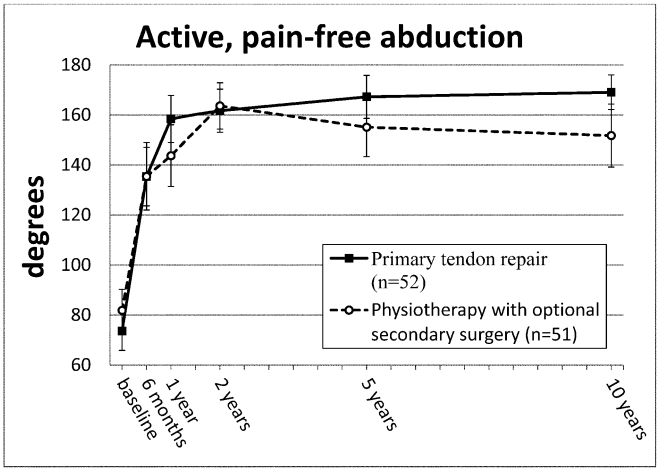

Fig. 4-B

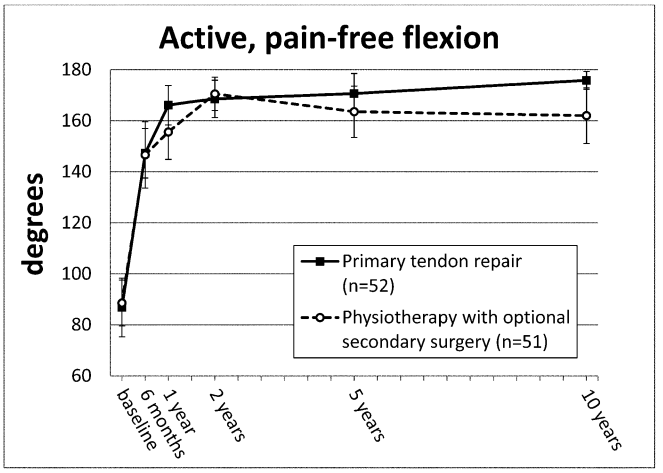

Fig. 4-C

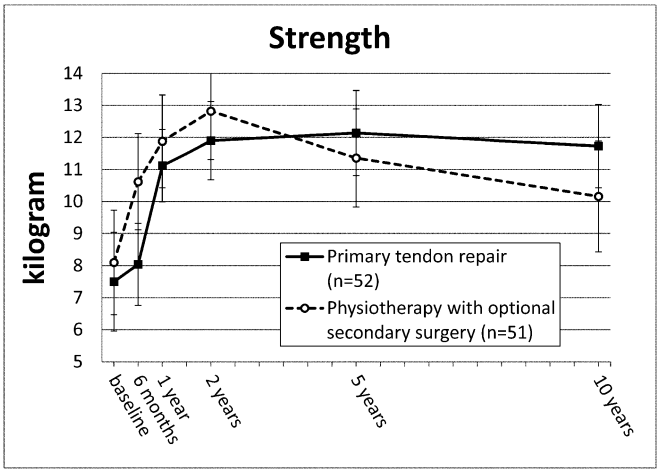

Fig. 4-D

Plots showing results for pain (**Fig. 4-A**); active, pain-free abduction (**Fig. 4-B**); active, pain-free flexion (**Fig. 4-C**); and strength (**Fig. 4-D**) at baseline and all follow-ups for the primary tendon repair group and the physiotherapy with optional secondary surgery group. The cumulative number of patients who were treated by secondary tendon repair was 3 patients at 6 months, 9 patients at 1 year, 12 patients at 2 and 5 years, and 14 patients at 10 years. Analysis is by intention to treat, with the results from secondary surgery included in the physiotherapy group. The error bars indicate 95% CIs.

Constant score in the secondary surgery group, by 10.0 points (95% CI, 0.9 to 19.2 points; p = 0.03).

Structural Results and Functional Outcome

Results from sonographic tear size measurement at baseline and at 5-year and 10-year follow-ups were available for 32 patients treated by physiotherapy only. Tear size increased with time in both measurement planes (Table VI). From baseline to the 10-year follow-up, the mean tear widening was 10.1 mm (95% CI, 5.7 to 14.4 mm; p < 0.001) in the anterior-posterior plane and 6.3 mm (95% CI, 2.9 to 9.8 mm; p = 0.001) in the medial-lateral plane. The increase in tear size exceeded 5 mm in 19 patients (59%) and 10 mm (range, 10.8 to 37.0 mm) in 13 patients (41%). Patients with tears with widening of ≥10 mm had a Constant score of 63.9 points, an outcome that was inferior by 14.0 points (95% CI, 4.1 to 24.0 points; p = 0.007) compared with the score of 78 points in patients with tears with widening of <10 mm.

In 47 patients who were treated by primary repair, tendon integrity was assessed by MRI after 1 year and by sonography after 5 and 10 years. We found an increasing number of full or partial-thickness retears, with 10 (21%) after 1 year, 13 (28%) after 5 years, and 16 (34%) after 10 years. Five of the retears after 10 years were classified as partial-thickness only. A comparison of the Constant score after 10 years between the 16 patients with a retear at the last follow-up (76.9 points) and the 31 patients with an intact repair (82.9 points) showed a better result for intact repairs, with a between-group difference of 6.0 points (95% CI, 0.2 to 11.8 points; p = 0.04). A longitudinal follow-up of 10 retears that were diagnosed on MRI at the 1-year follow-up showed a stable Constant score, with 76.7 points at the time of diagnosis and 77.7 points 9 years later (p = 0.8).

TABLE V Results for the SF-36 Score for Quality of Life from a 1-Way ANCOVA

SF-36 Score	Primary Tendon Repair*†	Physiotherapy with Optional Secondary Repair*†	Between-Group Difference†§	P Value#
Physical functioning				
Baseline	73.5 ± 10.6	72.7 ± 16.0		
10 years	84.8 ± 16.6	84.2 ± 21.8	0.02 (−6.7 to 6.7)	1.00
Role physical				
Baseline	20.2 ± 30.5	27.9 ± 37.6		
10 years	70.3 ± 39.5	77.3 ± 36.5	−6.1 (−22.0 to 9.8)	0.45
Bodily pain				
Baseline	41.2 ± 15.6	42.8 ± 20.7		
10 years	75.2 ± 19.9	73.5 ± 22.7	2.4 (−6.4 to 11.1)	0.60
General health				
Baseline	74.6 ± 17.9	72.6 ± 19.1		
10 years	76.2 ± 17.0	79.4 ± 19.6	−2.1 (−8.5 to 4.3)	0.51
Vitality				
Baseline	58.2 ± 25.1	61.4 ± 24.0		
10 years	69.4 ± 23.6	75.9 ± 17.9	−5.3 (−13.6 to 2.9)	0.20
Social functioning				
Baseline	84.1 ± 21.5	83.1 ± 25.5		
10 years	92.7 ± 14.1	94.8 ± 12.9	−2.1 (−7.4 to 3.3)	0.44
Role emotional				
Baseline	65.4 ± 42.8	86.3 ± 29.9		
10 years	81.3 ± 34.3	92.2 ± 26.1	−2.6 (−15.7 to 10.5)	0.69
Mental health				
Baseline	83.2 ± 16.7	84.5 ± 15.0		
10 years	86.3 ± 15.0	90.4 ± 9.2	−3.1 (−8.0 to 1.7)	0.18
Physical component summary score				
Baseline	38.2 ± 6.0	38.6 ± 8.7		
10 years	49.7 ± 9.2	50.0 ± 10.8	0.07 (−3.8 to 4.0)	0.97
Mental component summary score				
Baseline	54.1 ± 11.5	57.3 ± 9.4		
10 years	55.1 ± 10.0	58.6 ± 4.9	−2.1 (−5.4 to 1.2)	0.20

*The values are raw measurement data. In the analysis of the 2 groups, there were 52 patients in the primary tendon repair group and 51 patients in the physiotherapy with optional secondary repair group analyzed at baseline, and 48 patients in the primary tendon repair group and 43 patients in the physiotherapy with optional secondary repair group analyzed at 10 years. †The values are given as the mean and the standard deviation, in points. ‡The values were adjusted for baseline measurements of the variable and for patient age; positive values indicate a better result for primary tendon repair. §The values are given as the mean, with the 95% CI in parentheses. #A p value of <0.05 indicates a significant between-group difference at the 10-year follow-up.

Discussion

A comparison of treatment efficacy between the 2 study groups over 10 years showed better results for primary tendon repair at all follow-ups. Both groups improved during the first 1 to 2 years. Thereafter, shoulder function remained stable in the surgical group but declined in the physiotherapy group, leading to increasing between-group differences. A possible explanation for this functional decline is the deterioration of tear anatomy that has been reported to develop in unrepaired tears over time. Studies of the natural course of unrepaired tears have found that tear size increases exceed 10 mm in about 20% in the short term and in 30% in the long term and that tear enlargement is associated with inferior outcomes[15,32,33]. In our study, 41% of tears that were still unrepaired after 10 years showed a tear enlargement of ≥10 mm and a low Constant score of 63.9 points. This subgroup is an important factor for the inferior result in the physiotherapy group, and identification of risk factors leading to tear progression would be important but was not possible in our study.

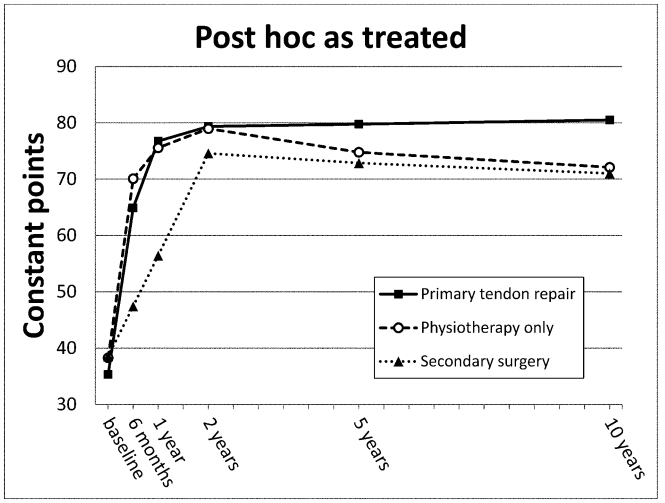

Fig. 5

Post hoc, as-treated analysis showing mean Constant scores at baseline and at follow-ups of 6 months and 1, 2, 5, and 10 years for the primary tendon repair group, the physiotherapy-only group, and the secondary surgery group. In the analysis of the 3 groups, there were 52 patients in the primary tendon repair group, 37 patients in the physiotherapy-only group, and 14 patients in the secondary surgery group analyzed at baseline; 51 patients in the primary tendon repair group, 37 patients in the physiotherapy-only group, and 14 patients in the secondary surgery group analyzed at 6 months and 1 year; 51 patients in the primary tendon repair group, 36 patients in the physiotherapy-only group, and 14 patients in the secondary surgery group analyzed at 2 and 5 years; and 48 patients in the primary tendon repair group, 31 patients in the physiotherapy-only group, and 12 patients in the secondary surgery group analyzed at 10 years.

Statistically, the 10-year between-group differences were significant for the majority of our outcome scores, but their clinical importance was difficult to determine. We assumed that achievement of a good-to-excellent result compared with a satisfactory or adequate-to-poor result on the Constant score would be important for the patients and found a significantly larger proportion of good-to-excellent outcomes in the tendon repair group. The clinical importance of the differences was further supported by our analysis of the number needed to treat, which showed that 3.5 patients would have to be treated by tendon repair instead of physiotherapy to achieve 1 additional good-to-excellent result after 10 years. The value must be interpreted in the context of treatment characteristics such as tolerability, risk of complications, and costs, but a number needed to treat of 3.5 for a surgical procedure with a low complication risk that resolves an important problem with life quality seems attractive. However, the time factor of 10 years may limit its importance to the group of younger and active patients.

Anatomic and functional deterioration may also be a concern in repaired tears that develop a retear. For small to medium-sized rotator cuff tears, retear rates of between 19% and 36% have been reported, and clinical results have been found to be better after a successful repair[5,34,35]. Our results showing a retear rate of 34% after 10 years and a better result in healed tendons are in accordance with these earlier reports. However, in contrast to unrepaired tears, retears seem to be functionally stable over time. Two longitudinal studies showed constant functional results over 4 and 7.6 years[36,37]. In our study, we found stable results in 10 retears that were diagnosed early and were followed over 9 years.

The following limitations warrant discussion. Twelve patients were unable to attend the last follow-up. However, a loss of patients over 10 years was anticipated, and with 91 attendees at the last follow-up, the study is still sufficiently powered for the main analyses. We also found that baseline characteristics were comparable between the attendees and the non-attendees.

Cuff tear arthropathy and muscle degeneration may have developed in unrepaired tears over 10 years and may have influenced the results[16], but were not assessed by radiographs or MRI in our study.

Surgical and physiotherapeutic techniques have been refined since our study was started, and we cannot exclude the possibility that today's procedures would give different outcomes. Outcomes may also have been influenced by the experience and the degree of specialization of our care providers and may differ from outcomes that are achieved under different treatment settings.

The achievement of a good-to-excellent result as an indicator for clinical importance may seem arbitrary. However, even if the limit for a clinically important result is moved down by 1 category (including satisfactory results), the analysis still shows a significant difference in favor of tendon repair. Other possible threshold values in a proportion analysis for clinical importance, such as the minimal clinically important difference (MCID) or the patient acceptable symptomatic state (PASS), could not be used. The MCID could not be used because it only has been reported for a 3-month follow-up for a group with a much higher Constant score at baseline[38], and the PASS could not be used because it has not yet been defined for the Constant score in the treatment of rotator cuff tears.

In summary, in this 10-year follow-up of treatment effects from tendon repair and from physiotherapy for small to medium-sized rotator cuff tears, we found outcome differences in favor of tendon repair that are small during the first years but increase over time and can be considered to have attained clinical relevance after 10 years. Our findings support a primary surgical approach for this type of rotator cuff tear in younger and active patients.

TABLE VI Sonographic Tear Size Change in 32 Unrepaired Rotator Cuff Tears from Baseline to the 10-Year Follow-up

	Baseline*	5 Years*	10 Years*
Anterior-posterior plane	14.8 ± 6.0	19.3 ± 10.5	24.9 ± 14.2
Medial-lateral plane (retraction)	14.3 ± 7.0	17.4 ± 9.2	20.6 ± 11.3

*The values are given as the mean tear size and the standard deviation, in millimeters.

Appendix

eA Supporting material provided by the authors is posted with the online version of this article as a data supplement at jbjs.org (http://links.lww.com/JBJS/F267). ■

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