Fifteen-Year Results of a Comparative Analysis of Tendon Repair Versus Physiotherapy for Small-to-Medium-Sized Rotator Cuff Tears

A Concise Follow-up of Previous Reports*

S. Moosmayer, MD, PhD, G. Lund, PT, U. Sire Seljom, PT, B. Haldorsen, PT, I.C. Svege, PT, T. Hennig, OT, A.H. Pripp, PhD, and H.J. Smith, MD, PhD

Investigation performed at Martina Hansen's Hospital, Gjettum, Norway

Abstract: The optimal treatment for small-to-medium-sized rotator cuff tears remains a topic of debate. While both tendon repair and physiotherapy have shown comparable short-term results, there are concerns about the long-term effectiveness of physiotherapy. In 2 previous reports presenting the 5 and 10-year results of this trial, significant and increasing differences were observed in favor of tendon repair. Further investigation of the unexplored time interval after 10 years is essential to fully understand the implications of our treatment approaches. A total of 103 patients with a full-thickness rotator cuff tear not exceeding 3 cm were randomly allocated to tendon repair or physiotherapy with optional secondary repair. Measurements of shoulder function were performed by a blinded assessor at 6 months and 1, 2, 5, 10, and 15 years. The outcome of primary interest was the 15-year result for the Constant score. Secondary outcome measures included the self-report section of the American Shoulder and Elbow Surgeons (ASES) score; the Short Form-36 (SF-36) Health Survey; assessments of pain, motion, and strength; and patient satisfaction. Tear-size increase in unrepaired tears was assessed by sonography. Statistical analysis was by mixed-model analysis for repeated measurements and by intention to treat. Eighty-three (81%) of 103 patients attended the 15-year follow-up. Fifteen of 51 patients in the physiotherapy group had crossed over to secondary surgery. Results from primary tendon repair were superior by a mean difference of 11.8 points for the Constant score ($p = 0.001$), 13.9 points for the ASES score ($p < 0.001$), 1.8 cm on a 10-cm visual analog scale for pain ($p < 0.001$), and 16.2° and 22.4°, respectively, for pain-free abduction and flexion ($p = 0.04$ and 0.001). On the SF-36, differences did not reach significance for any of the scoring scales. In 26 tears treated by physiotherapy only, the mean tear size had increased from 16.2 to 31.6 mm in the anterior-posterior direction. Long-term outcomes from primary tendon repair remained superior to physiotherapy up to 15 years of follow-up, supporting its use as the primary treatment for small-to-medium-sized rotator cuff tears.

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

The role of tendon repair versus physiotherapy in treating small-to-medium-sized full-thickness rotator cuff tears is still under debate. Over the last decade, considerable efforts have been made to define evidence-based guidelines for treatment selection for patients with tears mainly affecting the supraspinatus tendon[1-8]. Some randomized studies have reported

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TABLE I Inclusion and Exclusion Criteria

Inclusion Criteria
Pain, at rest or during exercise, laterally on the shoulder
A painful motion arc[38]
A positive impingement sign[39,40]
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[41]
Exclusion Criteria
Patient age of <18 yr
Tears involving >25% of the width of the subscapularis tendon
Presence of other local or systemic diseases affecting shoulder function
A history of surgical treatment of the involved shoulder
A medical contraindication for surgery or anesthesia
An inability to understand written and spoken Norwegian

comparable treatment effects from primary tendon repair and physiotherapy, and a primary nonoperative approach is now often recommended. An important inadequacy of the majority of existing studies, however, is their limited duration of follow-up of only 1 or 2 years[3,4,6,7]. Studies of the natural course of unrepaired tears have shown that these tears are at risk for anatomic and functional deterioration over time[9-14], and earlier published results of the present study showed an increase in outcome differences in favor of tendon repair from the 2 to 10-year follow-ups[2,5]. Further evidence from longer-term comparisons is necessary to better understand the full impact of our treatment decisions.

In the present study, we aimed to investigate the outcome differences between tendon repair and physiotherapy in the yet-unexplored interval from 10 to 15 years. We hypothesized that the results from tendon repair would remain stable while those from unrepaired tears would continue to worsen, and that this would lead to an increase in between-group differences at 15 years.

Materials and Methods

In the current report, we present the 15-year results of a single-center, randomized, 2-arm, parallel-group, single-blinded superiority trial performed at a secondary care institution in

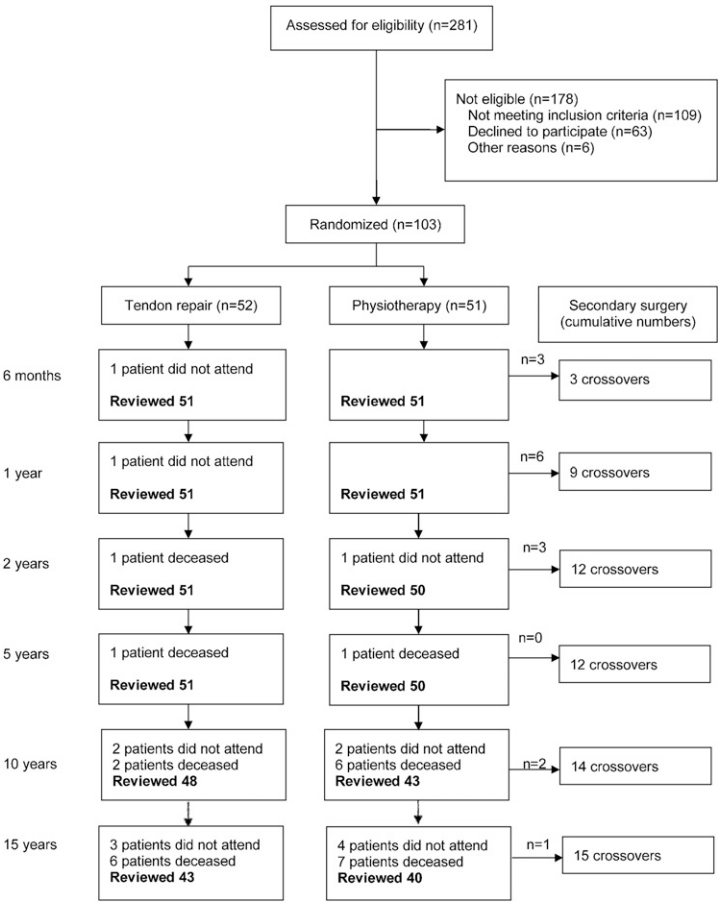

Fig. 1

Trial flowchart: screening, randomization, and primary outcome population. Patients who crossed over to secondary surgery remained in the physiotherapy group for analysis in accordance with the intention-to-treat principle.

Norway. The 1, 5, and 10-year results were previously published[1,2,5]. The study was approved by the Committee for Medical and Health Research Ethics in Norway and was registered at ClinicalTrials.gov (NCT00852657). Written informed consent was obtained from all participants after study information was given orally and in writing.

Patients and Procedures

Between September 2004 and October 2007, a total of 103 patients referred from primary care services for the treatment of a full-thickness rotator cuff tear of not more than 3 cm in diameter were included in the study. Inclusion and exclusion criteria are given in Table I, and the patient flow through the study is shown in Figure 1.

Outcome Measures

Measurements of shoulder function at the 15-year follow-up were performed by the same blinded assessor (T.H.) as at the previous follow-ups. The 15-year result for the Constant score was the outcome of primary interest[15]. Secondary outcome measures were the self-report section of the American Shoulder and Elbow Surgeons (ASES) score[16], the Short Form-36 (SF-36) Health Survey[17], and assessments of pain on a 10-cm visual analog scale (VAS), strength (with a handheld spring balance), pain-free mobility of the shoulder (with a goniometer), and patient satisfaction. To measure patient satisfaction, patients were asked to respond to the question, "How satisfied are you with the treatment result of your shoulder?" using a VAS ranging from 0 (very unsatisfied) to 10 (very satisfied). The clinical relevance of the results for the Constant and ASES score assessments was investigated by using the patient acceptable symptom state (PASS) and the percentage of maximal outcome improvement (%MOI) as cutoffs in a proportion analysis[18-20]. Sonographic follow-up included assessment of tear widening in unrepaired tears and of repair integrity in repaired tears, and was performed blinded to the patient's clinical data and the results of earlier ultrasound examinations. A Sonoline Antares (Siemens Medical; VFX13-5 linear transducer, 8.5 to 11.5 MHz) and Logiq S8 scanner (General Electric; ML6-15D linear transducer, 4 to 15 MHz) were used by an experienced sonographer whose accuracy in diagnosing rotator cuff tears has been documented[21,22]. The diagnostic criteria for rotator cuff tears and full- and partial-thickness retears that were used in the current study were previously described[23-26].

Randomization

The randomization list (block length of 20 and 1:1 ratio) was generated by an external statistician before the start of the study. The randomization sequence was concealed from the study's collaborators until interventions were assigned, and from the outcome assessor for the entire duration of the study.

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 direction	15.6 ± 6.7	14.3 ± 6.3
Medial-lateral direction	14.9 ± 5.7	14.7 ± 6.9
Type of injury†		
Acute-on-chronic‡	30	29
Chronic§	22	22
Occupational situation†		
On job	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 drug	7	9
None	12	11
Muscle atrophy on MRI[41]†		
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. ‡A tear in a shoulder with an acute onset of pain following minor trauma. §A tear in a shoulder with a gradual onset of pain in the absence of trauma.

Surgical Procedures and Postoperative Management

Tendon repair was performed using a mini-open or open approach, with the patient in the beach-chair position. Following diagnostic arthroscopy, the tear was exposed through a deltoid-splitting approach. An acromioplasty was performed as described by Neer[27]. The rotator cuff was mobilized

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

	Primary Tendon Repair	Physiotherapy with Optional Secondary Surgery
Site other than the index shoulder		
Medical event	Polymyalgia rheumatica (n = 1)* Cerebral apoplexy (n = 1)†, (n = 1)§ Chronic lymphocytic leukemia (n = 1)‡ Lymphoma (n = 1)§ Myocardial infarction (n = 1)§ Implantation of pacemaker (n = 1)§ Atrial fibrillation (n = 1)§ Renal failure (n = 1)§	Polymyalgia rheumatica (n = 1)* Herpes zoster (n = 1)* Lymphoma (n = 1)* Leukemia (n = 2)‡
Surgical event	Operation for abdominal aortic aneurysm (n = 1)† Hepatic transplantation (n = 1)‡ Lumbar discectomy (n = 1)‡ Operation for prostate cancer (n = 1)§ Tendon repair in the contralateral shoulder (n = 3)‡ Hip replacement (n = 1)§ Knee replacement (n = 1)§	Acromioplasty in the contralateral shoulder (n = 1)‡ Tendon repair in the contralateral shoulder (n = 1)‡ Operation for spinal stenosis (n = 2)§ Operation with artificial heart valve (n = 2)§ Hip replacement (n = 1)§ Knee replacement (n = 2)§
Musculoskeletal event	Lateral humeral epicondylitis (n = 1)* Low back pain (n = 1)† Cervical radiculopathy (n = 1)*, (n = 1)†, (n = 1)§	Cervical radiculopathy (n = 1)*
Index shoulder		
Need for additional therapeutic measures	Physiotherapy (n = 1)* Reoperation with acromioplasty and biceps tenotomy (n = 1)†	Physiotherapy (n = 3)†, (n = 1)‡ Glenohumeral arthrosis, conservatively treated (n = 1)‡
New shoulder trauma	Fracture of the humerus, conservatively treated (n = 1)* Contusion of the shoulder (n = 1)†, (n = 2)‡ Fracture of the humerus, conservatively treated (n = 1)‡ Traumatic retear of the rotator cuff, surgically treated (n = 2)§	Contusion of the shoulder (n = 2)*, (n = 1)†, (n = 2)‡, (n = 2)§ Shoulder dislocation (n = 1)§ Spontaneous tear of the long head of the biceps tendon (n = 1)§

*Time of occurrence before 2-year follow-up. †Time of occurrence between 2 and 5-year follow-ups. ‡Time of occurrence between 5 and 10-year follow-ups. §Time of occurrence between 10 and 15-year follow-ups.

until coverage of the footprint was achieved. The footprint was prepared to bleeding bone, and a tendon-to-bone repair was performed with transosseous sutures using a Mason-Allen technique. Tenodesis of the long head of the biceps to the intertubercular sulcus was performed when the tendon was found to be degenerated or partially torn. A detailed description of the surgical method was previously reported[1,2].

Postoperatively, the arm was immobilized in a sling for 5 to 6 weeks, and passive range-of-motion exercises were started immediately. Active range-of-motion exercises were initiated 6 weeks after surgery, and were supplemented by strengthening exercises after 12 weeks.

Physiotherapy

The physiotherapy group received outpatient treatment at our hospital from 4 physiotherapists experienced in shoulder rehabilitation. A previously reported rehabilitation program, which was individually adapted, was followed[2,28]. During the first 12 weeks, treatment sessions of 40 minutes were given twice weekly, with decreasing frequency during the following 6 to 12 weeks. No supplementary treatment measures, such as anti-inflammatory or analgesic medication, were given.

Secondary Surgery

Patients with insufficient progress after at least 15 physiotherapy sessions could ask for reexamination at any point during the study. In cases of persistent clinical findings, secondary surgical treatment was offered.

Statistical Analysis

The original sample-size calculation was previously presented and was performed on the basis of a t test of the primary outcome[1]. It showed that a group size of 45 patients was needed to detect a 12-point difference in the Constant score with a power of 80% and a 2-sided significance level of 0.05.

We present categorical baseline data as the number of patients and continuous data as the mean and standard deviation. To handle missing data, we analyzed our primary and secondary outcome data by using a linear mixed model for repeated measurements under a "missing at random" assumption. All available data were used in the analysis. Analyses were adjusted for baseline

TABLE IV Summary of Primary and Secondary Outcomes by Treatment Group

	Primary Tendon Repair (N = 52/ 51/51/51/51/48/43)*	Physiotherapy with Optional Secondary Repair (N = 51/51/51/50/50/43/40)*	Between-Group Difference	
			Mean (95% CI)†	P Value‡
Primary				
Constant score *(points)*				
Baseline	35.3 ± 13.2	38.4 ± 14.2		
6 mo	65.6 ± 16.3	63.9 ± 20.2	2.7 (−3.6 to 9.0)	
1 yr	77.7 ± 13.4	70.3 ± 19.1	8.3 (2.0 to 14.5)	
2 yr	79.3 ± 13.6	77.7 ± 14.9	3.0 (−3.3 to 9.3)	
5 yr	79.8 ± 15.0	74.2 ± 20.3	6.8 (0.5 to 13.1)	
10 yr	80.5 ± 9.8	71.8 ± 17.8	10.0 (3.5 to 16.5)	
15 yr	79.9 ± 9.7	68.5 ± 22.2	11.8 (5.1 to 18.5)	0.001
Secondary				
ASES score§ *(points)*				
Baseline	45.5 ± 14.5	48.2 ± 14.4		
6 mo	85.3 ± 13.7	75.4 ± 20.2	10.7 (4.2 to 17.2)	
1 yr	93.6 ± 12.5	83.6 ± 18.3	10.8 (4.3 to 17.2)	
2 yr	93.1 ± 13.9	88.0 ± 14.9	6.4 (0.1 to 12.9)	
5 yr	92.8 ± 13.3	85.4 ± 21.0	8.4 (1.9 to 14.9)	
10 yr	94.0 ± 9.5	80.0 ± 20.2	15.2 (8.4 to 22.0)	
15 yr	92.0 ± 10.9	78.7 ± 27.8	13.9 (6.9 to 20.9)	<0.001
VAS pain *(cm)*				
Baseline	5.6 ± 2.0	5.3 ± 1.9		
6 mo	1.1 ± 1.3	2.7 ± 2.2	1.6 (0.9 to 2.3)	
1 yr	0.5 ± 1.2	1.6 ± 1.6	1.1 (0.4 to 1.8)	
2 yr	0.7 ± 1.5	1.4 ± 1.4	0.8 (0.1 to 1.5)	
5 yr	0.6 ± 1.4	1.6 ± 1.6	1.1 (0.4 to 1.8)	
10 yr	0.6 ± 1.3	2.3 ± 2.4	1.8 (1.1 to 2.5)	
15 yr	0.6 ± 1.1	2.4 ± 3.0	1.8 (1.1 to 2.6)	<0.001
Pain-free abduction *(deg)*				
Baseline	73.7 ± 28.0	81.9 ± 29.8		
6 mo	135.4 ± 41.7	135.4 ± 47.9	2.4 (−12.1 to 16.9)	
1 yr	158.4 ± 33.7	143.8 ± 43.9	17.1 (2.6 to 31.6)	
2 yr	161.7 ± 30.8	163.6 ± 32.6	1.2 (−13.3 to 15.8)	
5 yr	167.3 ± 30.6	155.1 ± 41.2	15.2 (0.7 to 29.8)	
10 yr	169.1 ± 23.8	151.7 ± 40.9	19.9 (4.8 to 35.1)	
15 yr	168.1 ± 30.4	152.4 ± 48.4	16.2 (0.6 to 31.8)	0.04
Pain-free flexion *(deg)*				
Baseline	86.8 ± 41.3	88.6 ± 32.1		
6 mo	147.3 ± 34.5	146.6 ± 46.3	1.3 (−11.1 to 13.7)	
1 yr	166.1 ± 27.5	155.6 ± 38.4	11.1 (−1.3 to 23.5)	
2 yr	168.5 ± 26.1	170.5 ± 23.0	−0.6 (−13.1 to 11.9)	
5 yr	170.6 ± 27.9	163.5 ± 35.4	8.3 (−4.2 to 20.8)	
10 yr	175.8 ± 12.0	162.0 ± 35.5	15.1 (2.2 to 28.1)	
15 yr	176.4 ± 16.2	153.8 ± 45.3	22.4 (9.0 to 35.9)	0.001
Strength *(kg)*				
Baseline	7.5 ± 5.5	8.1 ± 5.8		
6 mo	8.0 ± 4.6	10.6 ± 5.4	−2.6 (−4.3 to −0.8)	
1 yr	11.1 ± 4.0	11.9 ± 5.1	−0.7 (−2.5 to 1.0)	

continued

TABLE IV (*continued*)

	Primary Tendon Repair (N = 52/ 51/51/51/51/48/43)*	Physiotherapy with Optional Secondary Repair (N = 51/51/51/50/50/43/40)*	Between-Group Difference	
			Mean (95% CI)†	P Value‡
2 yr	11.9 ± 4.3	12.8 ± 5.3	−0.8 (−2.6 to 1.0)	
5 yr	12.1 ± 4.7	11.4 ± 5.4	0.9 (−0.9 to 2.6)	
10 yr	11.7 ± 4.5	10.2 ± 5.6	1.7 (0.1 to 3.5)	
15 yr	10.2 ± 5.4	8.4 ± 5.8	1.8 (0.0 to 3.6)	0.05

*The values are the raw measurement data, given as the mean and the standard deviation. N = number of patients at the 7 measurement points. †The values were adjusted for baseline measurements of the variable and patient age; positive values indicate a better result for primary tendon repair. ‡A p value of <0.05 indicates a significant between-group difference at the 15-year follow-up. §Self-report section of the ASES score.

differences in the respective dependent variable and patient age and were performed according to the intention-to-treat principle. We estimated the linear mixed model by using linear maximum likelihood and included a random intercept, the baseline value of the dependent variable, and patient age as covariates, and observation time after the intervention and the type of intervention as well as their interaction term as factors. We used mean differences between groups at the 15-year follow-up from the linear mixed model to assess differences between interventions. We considered a 2-sided p value of <0.05 to be significant. The same statistical method was used for a supplementary as-treated analysis comparing the 15-year results for the Constant score between patients treated by primary surgery, physiotherapy only, or physiotherapy followed by secondary surgery.

The change in the between-group difference in the Constant score from the 2-year to the 15-year follow-up was assessed by a linear mixed-model analysis by estimation of the linear combination of change between follow-up times.

We explored the clinical importance of the results by a between-group comparison of the proportions of patients meeting or exceeding the PASS value and the %MOI predicting treatment satisfaction for the Constant and the ASES scores[18-20].

A paired samples t test was used to compare the increase in tear size from baseline to follow-up in the physiotherapy-only group, and an independent samples t test was used to compare results between intact repairs and retears and to investigate differences in patient satisfaction between the tendon repair group and the physiotherapy group. Normalized Constant scores were also calculated and are given in Appendix 1[29].

Results

At 15 years, 83 (81%) of the original 103 patients were available for follow-up (43 randomized to primary tendon repair and 40 randomized to physiotherapy with optional secondary repair). Patients with missing values were, on average, 5 years older than those with a complete data set but did not differ with respect to any of the other data registered at baseline. Over the 15-year follow-up period, 15 (29%) of the patients had crossed over from physiotherapy to secondary surgical repair. Patient characteristics at the time of enrollment are given in Table II. Adverse events and the need for additional therapeutic measures during follow-up are presented in Table III.

Treatment Effects

Primary Outcome

At 15 years, the mean Constant score was 79.9 points in the primary tendon repair group and 68.5 points in the physiotherapy with optional secondary repair group. The between-group difference of 11.8 points (95% confidence interval [CI], 5.1 to 18.5 points) was significant (p = 0.001) (Table IV, Fig. 2-A). The difference between the treatment groups increased significantly from 2 to 15 years (by 8.8 points [95% CI, 2.0 to 15.7 points]; p = 0.01). The clinical relevance of the result was supported by a significantly higher percentage of patients in the tendon repair group who met or exceeded the reported values for the PASS (70% versus 43%; p = 0.02) and %MOI for treatment satisfaction (86% versus 53%; p = 0.002) (see Appendices 2a and 2b)[18,20].

TABLE V Results from Repeated Sonographic Tear-Size Measurements and Constant Scores in 26 Unrepaired Rotator Cuff Tears*

	Baseline	5 Yr	10 Yr	15 Yr
Tear size in the anterior-posterior direction *(mm)*	16.2 ± 5.8	20.8 ± 10.2	28.0 ± 13.9	31.6 ± 14.0
Tear size in the medial-lateral direction *(mm)*	16.0 ± 7.0	19.4 ± 8.9	23.1 ± 11.0	26.9 ± 11.1
Constant score *(points)*	37.9 ± 13.0	73.2 ± 21.3	69.5 ± 17.1	62.5 ± 25.3

*The values are given as the mean and the standard deviation.

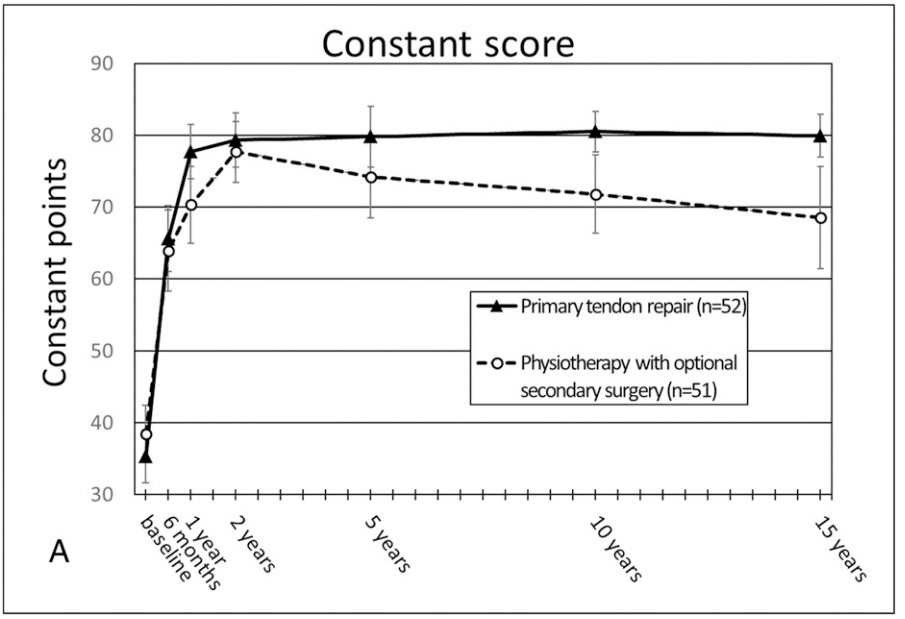

Fig. 2-A

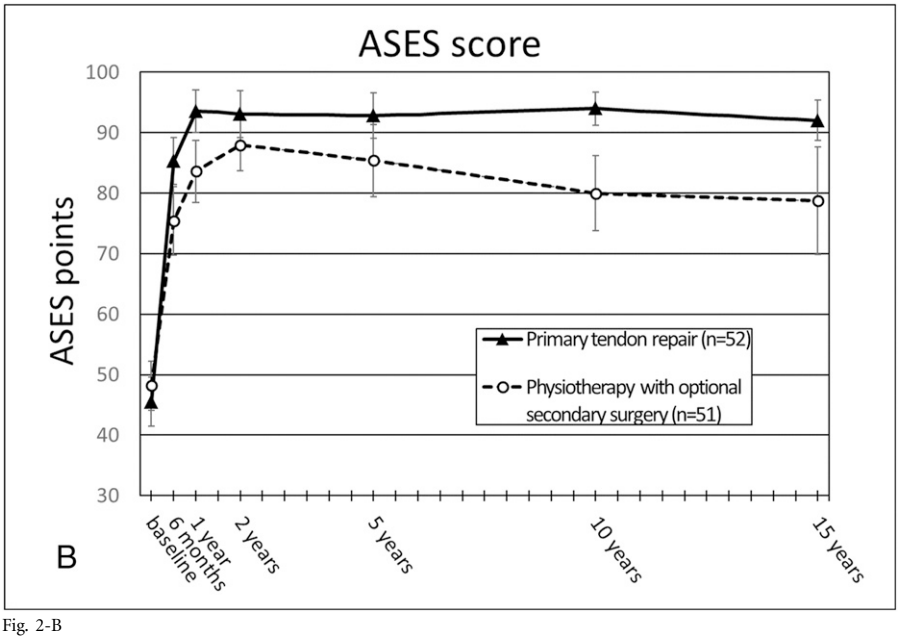

Fig. 2-B

Figs. 2-A through 2-F Graphs showing mean results at baseline and all follow-up times for the Constant score (**Fig. 2-A**); ASES score (**Fig. 2-B**); VAS score for pain (**Fig. 2-C**); active, pain-free abduction and flexion (**Figs. 2-D and 2-E**); and strength (**Fig. 2-F**) in the 2 study groups. The cumulative number of patients who had crossed over from physiotherapy to secondary surgical treatment was 3 patients at 6 months, 9 at 1 year, 12 at 2 and 5 years, 14 at 10 years, and 15 at 15 years. Analysis is by intention to treat, with the results from secondary surgery included in the physiotherapy group. Whiskers represent the 95% confidence interval. Higher values on the y axis represent better results, except for the VAS for pain, for which lower values represent a better result.

Secondary Outcomes

Significant differences in favor of primary tendon repair were found for the ASES score (difference, 13.9 points [95% CI, 6.9 to 20.9 points]; $p < 0.001$), the 10-cm VAS for pain (difference, 1.8 cm [95% CI, 1.1 to 2.6 cm]; $p < 0.001$), and active pain-free shoulder abduction (difference, 16.2° [95% CI, 0.6° to 31.8°]; $p = 0.04$) and flexion (difference, 22.4° [95% CI, 9.0° to 35.9°]; $p = 0.001$). For shoulder strength, the difference of 1.8 kg in favor of tendon repair was just below the level of significance (95% CI, 0.0 to 3.6 kg; $p = 0.05$) (Table IV, Figs. 2-B through 2-F). Patient satisfaction as

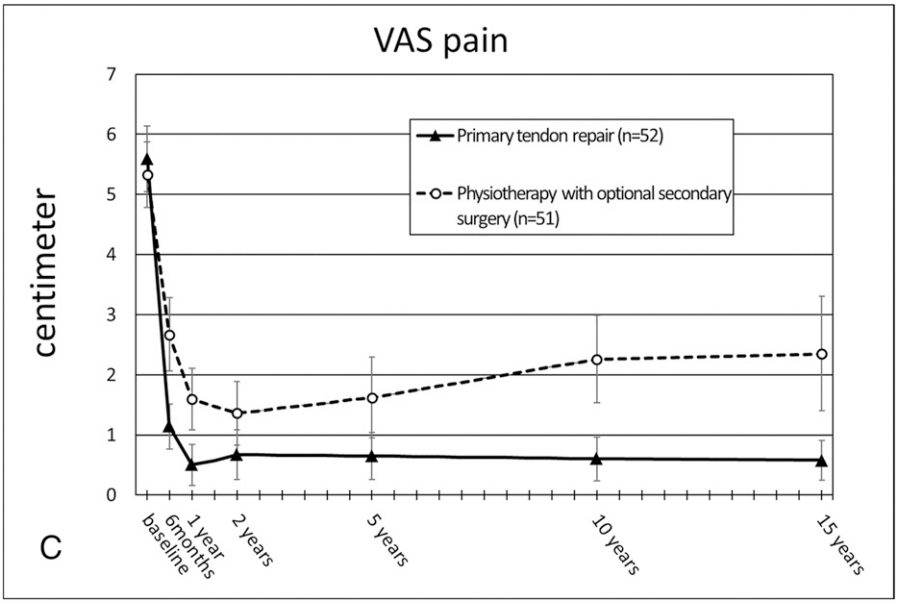

Fig. 2-C

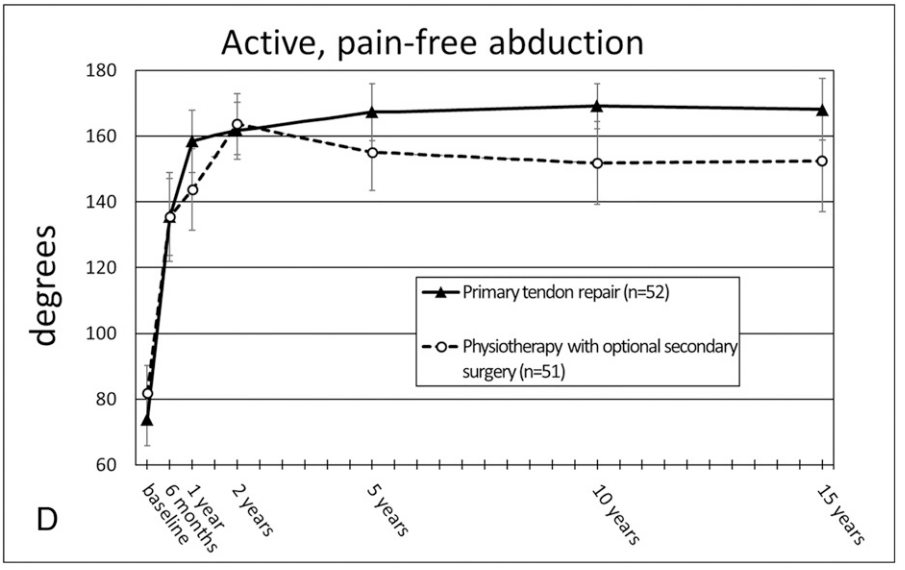

Fig. 2-D

measured on a 10-cm VAS was superior in the tendon repair group compared with the physiotherapy group (mean, 9.2 compared with 7.9 cm; difference, 1.3 cm [95% CI, 0.3 to 2.3 cm]; p = 0.02). Regarding the SF-36 score for quality of life, the between-group differences for the 8 component scales and the 2 summary scales for physical and mental health did not reach significance (see Appendix 3). The clinical relevance of the results for the ASES score was supported by the larger number of patients in the tendon repair group who met or exceeded the corresponding values for the PASS and %MOI for treatment satisfaction (see Appendices 4a and 4b).

Secondary Surgical Treatment

Fifteen (29%) of the 51 patients in the physiotherapy group did not achieve a satisfactory result and crossed over to secondary tendon repair (13 patients) or acromioplasty (2 patients): 9 during the first year, 3 during the second year, 2 between 5 and 10 years, and 1 between 10 and 15 years. Twelve patients with a secondary repair attended the 15-year follow-up, and they had a mean Constant score that did not differ from that of the primary tendon repair group but was 16.5 points superior to that of patients with physiotherapy only (95% CI, 9.4 to 23.6 points; p < 0.001) (Fig. 3).

Tear-Size Increase and Shoulder Function

Repeated ultrasound measurements of tear size were performed in 26 of 28 patients who were treated by physiotherapy only. The mean tear-size increase from baseline to 15 years was from 16.2 to 31.6 mm in the anterior-posterior direction (difference, 15.4 mm

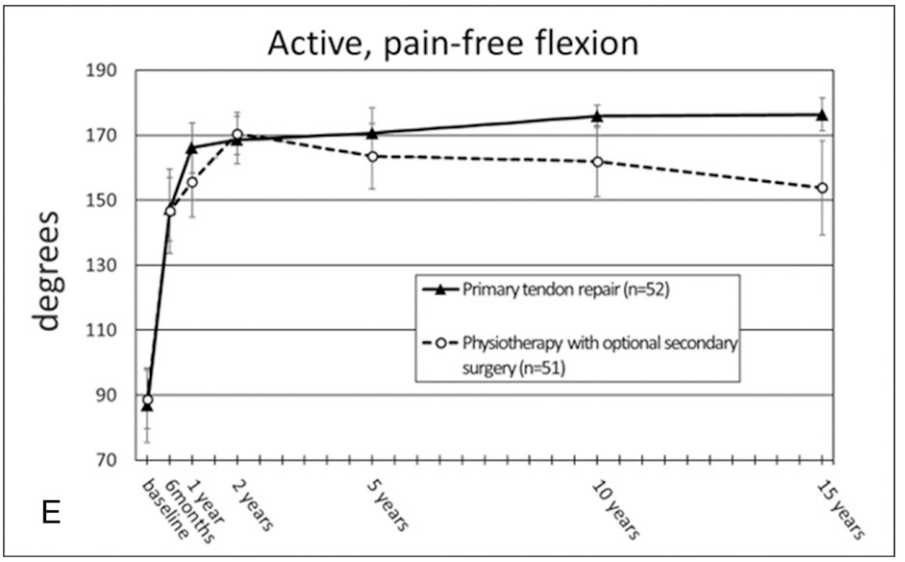

Fig. 2-E

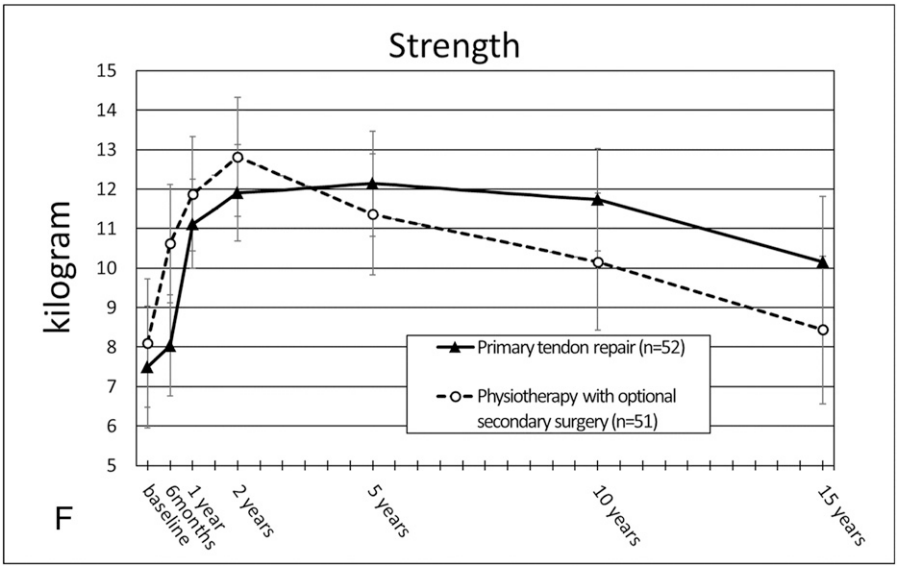

Fig. 2-F

[95% CI, 10.2 to 20.6 mm]; $p < 0.001$) and from 16.0 to 26.9 mm in the medial-lateral direction (difference, 11.0 mm [95% CI, 6.7 to 15.2 mm]; $p < 0.001$) (Table V). This was associated with a drop in the Constant score in the physiotherapy-only group from 78.8 points at 2 years to 63.7 points at 15 years, which was 16.5 points below the result for primary tendon repair at the last follow-up (95% CI, 9.4 to 23.6 points; $p < 0.001$) (Fig. 3; see also Appendix 5).

Among the 43 patients in the primary tendon repair group who attended the 15-year follow-up, 10 had been diagnosed with a recurrent tear (4 full-thickness and 6 partial-thickness) on magnetic resonance imaging (MRI) at 1 year after surgery, and an additional 6 were diagnosed with a later retear on ultrasound (2 after an adequate traumatic event). Only the 2 traumatic retears were treated by repeat surgery, but tendon healing was not achieved in either case. At 15 years, results for those with intact repairs were superior, with a mean Constant score of 82.2 points compared with 76.1 points for those with a retear (difference, 6.1 points [95% CI, 0.1 to 12.0 points]; $p = 0.05$).

Discussion

This study found significant and clinically relevant between-group differences in favor of primary tendon repair at 15-year follow-up. The findings are consistent with previous reports from the same study, which showed better outcomes for tendon repair compared with physiotherapy at 5 and 10-year follow-ups. The study implies that while both treatment options may yield comparable results in the short term, the differences between the groups increase over time in favor of tendon repair, mainly because of a gradual deterioration in physiotherapy outcomes.

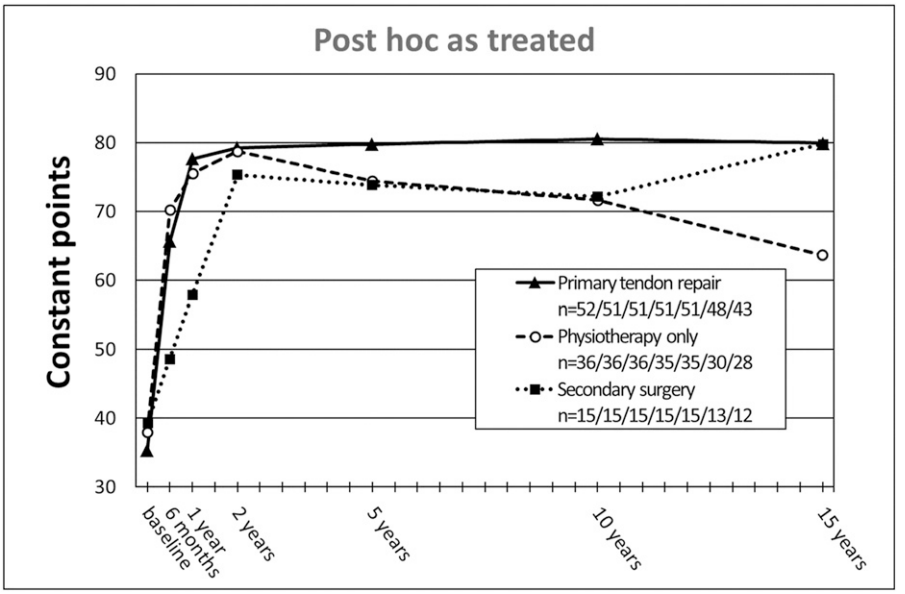

Fig. 3

Results from a post-hoc, as-treated analysis for the Constant score at baseline and all follow-up times for the primary tendon repair group, the physiotherapy-only group, and the secondary surgery group. Mean scores are shown; n = number of patients in each group at the 7 measurement points.

Clinical decision-making regarding nonoperative or operative treatment for small-to-medium-sized rotator cuff tears is challenging. Better long-term results in the present study may support a primary operative approach. However, physiotherapy together with optional secondary repair also resulted in improvement compared with baseline, and most physiotherapy patients did not require surgery. Both treatment options should be discussed during counseling, but patients should be informed that while physiotherapy can be effective, long-term results from primary tendon repair are superior.

Our finding of a time-dependent decrease in the results from physiotherapy is supported by reports from studies of the natural course of unrepaired tears showing that they are at risk for anatomic and functional deterioration[10,11,30-35]. According to the literature, tear widening is likely to occur in approximately 50% of unrepaired rotator cuff tears and may progress over many years, highlighting the need for long-term monitoring[36]. In the present study, tears in the physiotherapy group that remained unrepaired for 15 years had progressively increased in size, and this was associated with a decrease in the Constant score. The observation that these patients had little interest in supplementary treatment measures at their last follow-up indicates that they may have developed effective coping strategies that enabled them to live well despite restrictions in shoulder function.

Over the 15-year follow-up period, 29% of the patients initially assigned to physiotherapy had crossed over to secondary surgical treatment but, in accordance with the intention-to-treat principle, they remained in the physiotherapy group for analysis. This led to a more favorable outcome in the physiotherapy group, since unsatisfactory results from physiotherapy were replaced by better results from secondary surgery, thereby reducing the difference between the groups. However, this reflects current clinical practice, where crossover is an option after an unsuccessful trial of physiotherapy. It is noteworthy that the crossover group's results at 15 years for the first time equaled those of the primary surgery group, which is in contrast to the 5 and 10-year results. However, since only 12 crossover patients attended the final follow-up, this finding should be interpreted with caution.

Strengths and Limitations

The strengths of the study are its long observation time and high follow-up rate of 81% at 15 years. The study provides new insights into the previously unexplored period from 10 to 15 years after operative and nonoperative treatment of small-to-medium-sized rotator cuff tears.

The following limitations need to be considered. First, loss to follow-up is inevitable in long-term studies and may have affected our study outcomes. However, the study's follow-up rate of 81% exceeds the reported cutoff of 80% for an acceptable follow-up in randomized trials[37], and with 83 attendees at the most recent follow-up, the study retained sufficient statistical power for the main analyses.

Second, over 15 years, external factors other than the treatment selection may have affected the results. However, we regularly monitored the study patients and urged them to contact us immediately in the event of any shoulder-related incident. Additionally, we recorded all other medical and surgical events during routine follow-ups and found them evenly distributed between the 2 groups.

Third, the non-inclusion of 63% of the patients assessed for eligibility who did not match the study's eligibility criteria or declined to participate may have weakened the study's external validity.

Conclusions

This 15-year follow-up report, which compared the effects of tendon repair and physiotherapy for small-to-medium-sized rotator cuff tears, showed that initially small between-group differences increased over time in favor of tendon repair and reached statistical significance and clinical relevance. The results provide a better understanding of the long-term impact of our treatment decisions and will help to select the treatment that best meets patients' present and future shoulder demands.

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/I155). ■

S. Moosmayer, MD, PhD[1]
G. Lund, PT[2]
U. Sire Seljom, PT[2]
B. Haldorsen, PT[2]
I.C. Svege, PT[2]
T. Hennig, OT[3]
A.H. Pripp, PhD[4]
H.J. Smith, MD, PhD[5]

[1]Department of Orthopaedic Surgery, Martina Hansen's Hospital, Gjettum, Norway

[2]Department of Physiotherapy, Martina Hansen's Hospital, Gjettum, Norway

[3]Department of Occupational Therapy, Martina Hansen's Hospital, Gjettum, Norway

[4]Centre of Biostatistics and Epidemiology, Oslo University Hospital, Oslo, Norway

[5]Division of Radiology and Nuclear Medicine, Institute of Clinical Medicine, University of Oslo, Oslo, Norway

Email for corresponding author: st.moos@online.no

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