ORIGINAL ARTICLE

Nonoperative or Surgical Treatment of Acute Achilles' Tendon Rupture

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ABSTRACT

BACKGROUND

Whether surgical repair of an acute Achilles' tendon rupture by an open-repair or minimally invasive approach is associated with better outcomes than nonsurgical treatment is not clear.

METHODS

We performed a multicenter, randomized, controlled trial that compared nonoperative treatment, open repair, and minimally invasive surgery in adults with acute Achilles' tendon rupture who presented to four trial centers. The primary outcome was the change from baseline in the Achilles' tendon Total Rupture Score (scores range from 0 to 100, with higher scores indicating better health status) at 12 months. Secondary outcomes included the incidence of tendon rerupture.

RESULTS

A total of 554 patients underwent randomization, and 526 patients were included in the final analysis. The mean changes in the Achilles' tendon Total Rupture Score were –17.0 points in the nonoperative group, –16.0 points in the open-repair group, and –14.7 points in the minimally invasive surgery group (P=0.57). Pairwise comparisons provided no evidence of differences between the groups. The changes from baseline in physical performance and patient-reported physical function were similar in the three groups. The number of tendon reruptures was higher in the nonoperative group (6.2%) than in the open-repair or minimally invasive surgery group (0.6% in each). There were 9 nerve injuries in the minimally invasive surgery group (in 5.2% of the patients) as compared with 5 in the open-repair group (in 2.8%) and 1 in the nonoperative group (in 0.6%).

CONCLUSIONS

In patients with Achilles' tendon rupture, surgery (open repair or minimally invasive surgery) was not associated with better outcomes than nonoperative treatment at 12 months. (Funded by the South-Eastern Norway Regional Health Authority and Akershus University Hospital; ClinicalTrials.gov number, NCT01785264.)

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An acute Achilles' tendon rupture is one of the most common musculoskeletal injuries, with an annual incidence of 5 to 50 events per 100,000 persons, and may result in severe disability.[1-3] This injury is more common with older age, more active lifestyles, and male sex,[4] and has been increasing in incidence over the past few decades.[5]

Randomized, controlled trials that have compared nonoperative treatment with open repair of acute Achilles' tendon rupture have shown similar patient-reported outcomes and physical performance with both approaches.[6,7] A recent systematic review of 10 randomized, controlled trials (involving 944 patients) and 19 observational studies (involving 14,918 patients) showed a higher risk of rerupture after nonoperative treatment, whereas surgical treatment was associated with the risks of postoperative complications such as infections and nerve injuries.[8] However, the trials that were reviewed were generally small, and treatment and rehabilitation protocols varied or, in some cases, were incompletely described. Several studies have suggested that accelerated functional rehabilitation protocols that emphasize early mobilization and weight-bearing may lessen the risk of rerupture after nonoperative treatment,[9,10] but these findings are inconsistent.[11,12] Minimally invasive surgical techniques have been developed to reduce the risk of complications associated with open surgical repair,[13] but randomized, controlled trials that have compared nonoperative treatment, open repair, and minimally invasive surgery are few in number and involved limited sample sizes.[14-17] To better inform clinical decision making with regard to acute Achilles' tendon rupture, we conducted a multicenter, randomized trial to compare nonoperative treatment, open repair, and minimally invasive surgery.

Methods

Trial Design and Oversight

We conducted this three-group, randomized, controlled trial at four centers. Full details of the trial design, conduct, oversight, and analyses are provided in the protocol and statistical analysis plan, available with the full text of this article at NEJM.org. The trial was approved by the institutional review board at each center and the Regional Committee for Medical and Health Research Ethics South East Norway. The first, last, and two other authors vouch for the accuracy and completeness of the data and for the fidelity of the trial to the protocol.

Patients

Patients were assessed for eligibility if they were 18 to 60 years of age and had presented with an Achilles' tendon rupture at a participating center. Patients had to be fluent in Norwegian to complete the questionnaires. Exclusion criteria were a previous Achilles' tendon rupture, the American Society of Anesthesiologists physical status classification higher than II (on a scale of I to VI, with higher classes indicating more severe systemic disease), the receipt of quinolones or local glucocorticoid injections (in the area of the Achilles' tendon) in the 6 months before the injury, dependence on walking aids, and other disabilities related to walking.[18-21]

Trial Procedures

Eligible patients were randomly assigned, in a 1:1:1 ratio, to receive nonoperative treatment or to undergo open repair or minimally invasive surgery. Randomization was stratified according to trial center, with random block sizes of 6, 9, and 12. We used Random Allocation Software, version 1.0 (Microsoft), to perform randomization[22]; the investigators were unaware of the group assignments.

The two surgical procedures are described in detail in Section S2.1 of the Supplementary Appendix (available at NEJM.org).[23,24] Participating surgeons were required to have performed at least one open repair and one minimally invasive surgical procedure before participating in the trial. Patients did not receive antibiotic prophylaxis.[25] A below-the-knee equinus cast (with plantar flexion) was applied within 72 hours after the injury regardless of the treatment group assignment (Fig. S1). The cast was maintained for 2 weeks after application in the nonoperative group; in the surgical groups, a new cast was applied after surgery and maintained for 2 weeks. For 6 weeks after the cast was removed, patients were allowed to bear weight on the injured foot as tolerated using an ankle–foot orthosis with heel wedges. The number of heel wedges was gradually reduced from three in the first week of orthosis treatment to none in the last week. All the participants followed a stan-

dardized rehabilitation protocol (Section S2.2). Participants wore knee-high socks to mask potential surgical scars at the 6- and 12-month physical assessments. Additional information pertaining to the interventions, rehabilitation, follow-ups, and testing procedures is provided in Sections S2.1 through S2.4.

OUTCOMES

The primary outcome was the change from baseline in the Achilles' tendon Total Rupture Score at the 12-month follow-up. The Achilles' tendon Total Rupture Score is a patient-reported assessment designed to measure outcomes in patients treated for acute Achilles' tendon rupture. The questionnaire consists of 10 questions to assess symptoms and the level of physical activity; answers are assessed on an 11-point Likert scale (scores range from 0 to 10, with a maximum possible score of 100; higher scores represent better health status). The minimal clinically important difference in the score has previously been defined as 8 to 10 points,[12,26,27] and the minimal detectable change, which represents the smallest change detectable beyond measurement error, has been reported to be 7 points.[32,33]

Secondary outcomes included the change from baseline in the Achilles' tendon Total Rupture Score at the 3- and 6-month follow-ups; the change from baseline in the subscore for physical functioning, the physical component summary, and the mental component summary on the 36-Item Short Form Health Survey (SF-36) at the 6- and 12-month follow-ups; physical performance at the 6- and 12-month follow-ups; and the incidence of tendon rerupture at the 12-month follow-up. The SF-36 evaluates general health-related quality of life on the basis of patients' responses to 36 questions sorted into eight multi-item subscales. Scores on each subscale range from 0 to 100, with higher scores indicating better health status.[28] The eight subscales all contribute to the physical component summary and the mental component summary. The physical component summary emphasizes physical function, pain, and general health, and the mental component summary focuses on social functioning, mental health, and emotional well-being. We generated baseline scores for the Achilles' tendon Total Rupture Score and SF-36 retrospectively by instructing the patients to answer the questionnaires at the time of enrollment (after the application of the equinus cast but before randomization) according to their preinjury status. The validity and reliability of the Norwegian translations of the Achilles' tendon Total Rupture Score and SF-36 have previously been assessed, and construct validity for both questionnaires is supported by Spearman's correlation coefficients of more than 0.7.[29,30]

We tested physical performance using the MuscleLab measurement system (Ergotest Innovation), which consists of two different jump tests, two different strength tests, and one muscular endurance test.[31] Six different measurements were derived from the five physical performance tests (supplementary section S2.4) and presented as a limb-symmetry index representing the ratio of the test result for the injured foot to the result for the uninjured foot, multiplied by 100 (with a score of 100 indicating that the physical performance of the injured foot is equal to that of the uninjured foot).

STATISTICAL ANALYSIS

We calculated that a sample of 480 patients (160 in each group) would be needed to provide the trial with 80% power, at a two-sided test with a 5% significance level, to detect a difference of 7 points in the Achilles' tendon Total Rupture Score.[32,33] To compensate for patients who were prematurely withdrawn from the trial or lost to follow-up, we targeted an enrollment of 530 patients. Questionnaires for the Achilles' tendon Total Rupture Score and the SF-36 that were completed up to 2.2 years postinjury were included in the analysis to increase the number of responses. The late responses were accepted because improvements in the Achilles' tendon Total Rupture Score and physical performance after 1 year postinjury are minimal[34]; thus, long-term scores would not substantially differ from the primary outcome at 12 months.

We assessed the change from baseline in the Achilles' tendon Total Rupture Score using a mixed-model analysis. The treatment group, interaction of the treatment group and trial visit, the trial center (as a stratification factor), and the score at baseline were included as fixed factors. To account for dependent variables in the repeated measures, we included a patient-specific random intercept, and an unstructured correlation structure was assumed for the repeated

measures. Using this model, we estimated marginal means for each trial visit and treatment group.

We used hierarchical testing to control the overall type I error. A primary omnibus test was conducted with the primary null hypothesis defined as no differences among the three treatment groups at the 12-month follow-up. If there were no significant differences among the three treatment groups, additional pairwise testing was conducted without significance testing. The absolute between-group differences and 95% confidence intervals are presented for these analyses; the 95% confidence intervals were not adjusted for multiplicity, and definitive treatment effects cannot be inferred from these data.

The primary efficacy analyses were performed according to the intention-to-treat principle and included the full analysis population, which included all the patients who underwent randomization, received treatment, and had at least one complete follow-up questionnaire for the Achilles' tendon Total Rupture Score. If one or more responses were missing on a questionnaire, the score was considered to be missing for that visit.[35] Missing questionnaires at baseline for patients were imputed with the use of median imputation. The remaining missingness of data was handled with the use of mixed modeling.

Sensitivity analyses were performed according to the intervention that was received (per-protocol population) and in the population of patients who completed all questionnaires. We also performed analyses to assess the sensitivity of the imputation of data for any Achilles' tendon Total Rupture Score questionnaires missing at baseline and scores that were reinverted owing to indications that patients may have inverted the scale when answering the questionnaires. Details of the analyses are provided in the statistical analysis plan. We conducted a post hoc sensitivity analysis by excluding the 12-month questionnaires for the Achilles' tendon Total Rupture Score that were answered before 11 months or after 13 months.

We analyzed data from the SF-36 questionnaire according to the intention-to-treat principle for all patients who had at least one nonmissing follow-up assessment that included both the Achilles' tendon Total Rupture Score and SF-36 questionnaires. SF-36 values that were missing at baseline were imputed with the use of mean imputation. The change in SF-36 score from baseline was analyzed similarly to the primary outcome with the use of a linear mixed model. SF-36 scores were treated as missing as specified in the SF-36 scoring instructions. Missing SF-36 scores at the two follow-up visits were handled with the use of mixed modeling.

At the 6- and 12-month follow-ups, we analyzed the physical test results using linear regression models, with adjustment for the treatment variable according to the trial center. Missing data were handled with a combination of threshold and multiple imputation; details are provided in the statistical analysis plan.

Adverse events were registered until trial closure for all participants. For reruptures, the pairwise risk difference between the treatment groups and their 95% confidence intervals (unadjusted for multiplicity) were calculated with the use of the Newcombe hybrid score.

Figure 1 (facing page). Screening, Randomization, Treatment, and Follow-up.

Patients who received treatment and had at least one follow-up Achilles' tendon Total Rupture Score (ATRS) were included in the full analysis population. The data were analyzed according to the treatment groups that the patients were originally assigned to. One patient who had been assigned to undergo a minimally invasive procedure instead underwent open repair owing to intraoperative technical difficulties.

RESULTS

PATIENTS

Patients were enrolled from February 2013 through May 2018, and the 12-month follow-up was concluded in May 2019. A total of 1084 patients were excluded before undergoing randomization for reasons listed in Figure 1 and Table S7. Of the 554 patients who underwent randomization, 22 patients were excluded before receiving treatment or before analysis (Fig. 1). Of the remaining 532 patients, 526 (98.9%) had at least one follow-up Achilles' tendon Total Rupture Score and hence constituted the full analysis population, and 492 patients (92.5%) completed the questionnaire for the 12-month Achilles' tendon Total Rupture Score. Table S8 shows the distribution of patients among the trial sites.

The characteristics of the three groups at baseline were similar across the trial groups

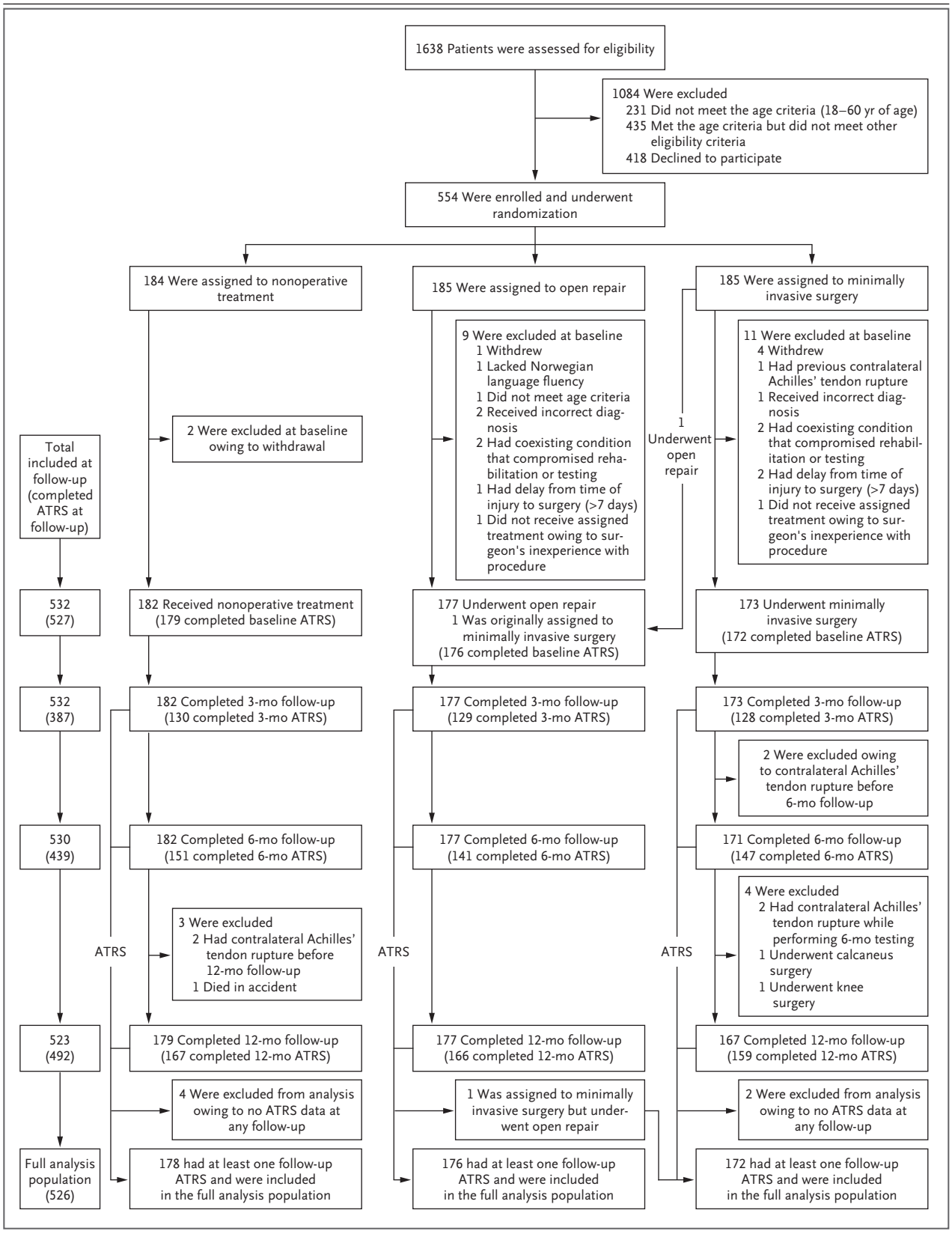

Table 1. Characteristics of the Patients at Baseline.*

Characteristic	Nonoperative Treatment (N=178)	Open Repair (N=176)	Minimally Invasive Surgery (N=172)
Age — yr	39.9±8.1	39.9±8.9	39.1±8.4
Male sex — no. (%)	136 (76.4)	132 (75.0)	123 (71.5)
Body-mass index†	27.0±3.6	26.5±3.6	26.7±3.6
Injury to right Achilles' tendon — no. (%)	91 (51.1)	83 (47.2)	91 (52.9)
Highest education level — no. (%)			
Middle school	4 (2.2)	7 (4.0)	9 (5.2)
High school	58 (32.6)	53 (30.1)	49 (28.5)
Higher education ≤4 yr	63 (35.4)	70 (39.8)	66 (38.4)
Higher education >4 yr	48 (27.0)	43 (24.4)	47 (27.3)
Missing data	5 (2.8)	3 (1.7)	1 (0.6)
ASA physical status — no. (%)‡			
I	113 (63.5)	103 (58.5)	113 (65.7)
II	63 (35.4)	73 (41.5)	57 (33.1)
III	0	0	2 (1.2)
Missing data	2 (1.1)	0	0
Baseline ATRS§	92.7±16.2	93.9±15.1	94.2±12.9

* Plus–minus values are means ±SD. The trial population included all the patients who underwent randomization and had at least one follow-up score on the Achilles' tendon Total Rupture Score (ATRS; scores range from 0 to 100, with higher scores indicating better health status).
† The body-mass index is the weight in kilograms divided by the square of the height in meters.
‡ The American Society of Anesthesiologists (ASA) physical status classification is assessed on a scale of I to VI, with higher classes indicating more severe systemic disease.
§ Baseline ATRS data were missing for three patients in the nonoperative group, for one patient in the open-repair group, and for one patient in the minimally invasive surgery group.

(Table 1), and the ethnic composition of the trial participants was representative of the Norwegian population (Table S9). Details regarding the number of participating surgeons, their experience, and the types of anesthesia that were used are provided in Tables S10 through S12. The median time from injury to completion of the final questionnaire was 1.1 years, and the mean was 1.2 years (range, 0.9 to 2.2) (Fig. S2).

PRIMARY AND SECONDARY OUTCOMES

The change in the Achilles' tendon Total Rupture Score from baseline to the 12-month follow-up was –17.0 points (95% confidence interval [CI], –20.0 to –14.0) in the nonoperative group, –16.0 points (95% CI, –19.0 to –12.9) in the open-repair group, and –14.7 points (95% CI, –17.9 to –11.6) in the minimally invasive surgery group (P=0.57) (Table 2 and Fig. S3). Pairwise differences in the mean change in scores were 1.0 point (95% CI, –5.2 to 3.1) for nonoperative treatment as compared with open repair, –2.6 points (95% CI, –6.5 to 2.0) for nonoperative treatment as compared with minimally invasive surgery, and –1.2 points (95% CI, –5.5 to 3.0) for open repair as compared with minimally invasive surgery (Tables S13 and S14). Results were similar in the various sensitivity analyses in which missing data were handled by different imputation techniques and questionnaire scores were reinverted (owing to the likelihood that patients inverted the scale when completing the questionnaires). A post hoc analysis that excluded the Achilles' tendon Total Rupture Score questionnaires that were answered before 11 months postinjury or after 13 months postinjury also yielded results similar to those of the primary analysis (Tables S1 through S6). Likewise, there were no apparent differences among the groups in the changes in the Achilles' tendon Total Rupture Score at 3 months and 6 months or in the SF-36 physical functioning score or in

Table 2. Changes in Patient-Reported Outcome Measures from Baseline (Preinjury) to Follow-up.*

Assessment	Nonoperative Treatment (N = 178)		Open Repair (N = 176)		Minimally Invasive Surgery (N = 172)	
	No. of Completed Questionnaires	Mean Change from Baseline (95% CI)	No. of Completed Questionnaires	Mean Change from Baseline (95% CI)	No. of Completed Questionnaires	Mean Change from Baseline (95% CI)
ATRS†						
At 12 mo	167	−17.0 (−20.0 to −14.0)	165	−16.0 (−19.0 to −12.9)	160	−14.7 (−17.9 to −11.6)
At 3 mo	130	−45.9 (−49.2 to −42.6)	128	−43.1 (−46.4 to −39.8)	129	−49.8 (−53.2 to −46.5)
At 6 mo	151	−28.8 (−32.0 to −25.7)	140	−28.0 (−31.2 to −24.8)	148	−31.2 (−34.4 to −28.0)
SF-36 physical-functioning score						
At 6 mo	156	−3.73 (−4.56 to −2.91)	147	−3.78 (−4.63 to −2.94)	149	−3.87 (−4.72 to −3.02)
At 12 mo	172	−1.03 (−1.83 to −0.23)	170	−1.46 (−2.27 to −0.65)	163	−1.04 (−1.86 to −0.21)
SF-36 physical component summary score						
At 6 mo	156	−4.77 (−5.77 to −3.77)	146	−4.56 (−5.59 to −3.53)	149	−4.83 (−5.86 to −3.80)
At 12 mo	171	−2.04 (−3.02 to −1.07)	170	−2.09 (−3.08 to −1.11)	163	−2.00 (−3.00 to −1.00)
SF-36 mental component summary score						
At 6 mo	156	−0.43 (−1.47 to 0.61)	146	−0.25 (−1.32 to 0.83)	149	0.33 (−0.75 to 1.34)
At 12 mo	172	−0.71 (−1.72 to 0.30)	170	−0.96 (−1.98 to 0.06)	165	−0.38 (−1.42 to 0.65)

* Values represent mean changes in scores from baseline (preinjury) to the indicated follow-up. Missing baseline data on ATRS and 36-Item Short Form Health Survey (SF-36) were imputed by median and mean imputation, respectively, and missing follow-up data on ATRS and SF-36 were handled with the use of mixed modeling. All scores range from 0 to 100, with higher scores indicating better health status. P=0.57 for the test of differing effect of treatment.

† The change from baseline in the ATRS at 12 months was the primary outcome.

The New England Journal of Medicine

the physical- or mental-component summaries at 6 months and 12 months (Table 2 and Fig. S3) or when mean scores (instead of the changes from baseline) from any of the follow-up assessments were used (Table S15).

At least one valid test that assessed physical performance was available at the 6-month follow-up for 424 patients and at the 12-month follow-up for 363 patients. There were no material differences among the groups in any of the six limb-symmetry–index measurements (Tables 3, S16, and S17 and Fig. S4).

SAFETY

Serious adverse events occurred in similar percentages of patients in the three groups (Tables 4 and S18). There were 11 reruptures in the nonoperative group (in 6.2% of the patients), 1 in the open-repair group (in 0.6%), and 1 in the minimally invasive surgery group (in 0.6%); no patient had more than 1 rerupture. The risk of rerupture was 5.6 percentage points higher in the nonoperative group than in the open-repair group (95% CI, 1.9 to 10.2) and the minimally invasive surgery group (95% CI, 1.8 to 10.2). The risk of rerupture was similar in the two surgical groups (difference in risk, −0.01 percentage points; 95% CI, −2.7 to 2.6). Half the reruptures occurred within the first 10 weeks (range, 2 to 28) after injury (Fig. S6). There were 9 nerve injuries in the minimally invasive surgery group (in 5.2% of the patients) as compared with 5 in the open-repair group (in 2.8%) and 1 in the nonoperative group (in 0.6%). The incidence of other adverse events was similar among the groups.

DISCUSSION

In a multicenter trial involving patients with acute Achilles' tendon rupture, we found no significant differences in changes in the Achilles' tendon Total Rupture Score among patients who had been randomly assigned to receive nonoperative treatment or undergo open repair or minimally invasive surgery. There were also no appreciable differences among the groups in the secondary outcomes. The risk of rerupture was higher with nonoperative treatment than with either of the operative treatments.

Our findings are similar to those reported in randomized trials that showed no significant differences between nonoperative and surgical treatment of acute Achilles' tendon rupture.[6,7] However, previous trials were smaller than our trial and were not powered to detect differences as small as the minimal detectable change in the Achilles' tendon Total Rupture Score. Also, unlike previous trials, the present trial compared nonoperative treatment with minimally invasive surgery and open repair with the use of validated patient-reported outcome measures.[8,14-17]

Unlike some other trials,[9,36,37] this trial showed a lower risk of rerupture in the surgical groups than in the nonoperative group. The inconsistent results could be explained by the larger sample size in the present trial, since a meta-analysis that pooled data from 10 randomized, controlled trials and 19 observational studies yielded results similar to those in the present trial.[8] Studies have suggested that early, controlled weight-bearing carries less risk of rerupture than deferred weight-bearing among patients who undergo nonoperative treatment.[9,10,36] However, two randomized trials that compared early, controlled weight-bearing with immobilization for the first 6 to 8 weeks did not show significant differences in the risk of rerupture.[12,38] Nevertheless, the incidence of rerupture was low regardless of treatment strategy, and absolute differences were small.

The risk of rerupture in the surgical groups was lower than the risks reported in some other trials.[8] One possible explanation is the use of a modified Krackow suture technique in the open-repair group in this trial, which may have provided a stronger repair.[24] Surgeons also used three sutures instead of two sutures in the minimally invasive surgery group, although there is no direct evidence indicating that this technique increases biomechanical strength.[23,39]

Our trial has some limitations. For feasibility reasons, patients were not unaware of their assigned intervention. We collected baseline measures of health status retrospectively, after patients underwent casting but before they underwent randomization to treatment. However, because patients were unaware of treatment-group assignment at the time of health data collection, the misclassification of baseline status would be expected to be random with respect to treatment group.[40] In addition, some patients completed the 12-month questionnaires more than 12 months after the injury; however,

Table 3. Physical Test Results at 6 Months and 12 Months of Follow-Up.*

Completed Physical Test	Nonoperative Treatment		Open Repair		Minimally Invasive Surgery	
	No. of Completed Tests	Mean Result (95% CI)	No. of Completed Tests	Mean Result (95% CI)	No. of Completed Tests	Mean Result (95% CI)
Total at 6-mo follow-up	143		140		141	
Countermovement drop jump	131	75.8 (71.4–80.3)	130	75.6 (70.9–80.3)	131	75.2 (70.2–80.2)
Hopping	123	86.0 (80.7–91.3)	121	88.0 (82.9–93.1)	125	88.9 (83.6–94.3)
Concentric power	95	67.3 (60.6–74.1)	93	71.0 (63.7–78.3)	92	70.8 (63.1–78.4)
Eccentric power	68	62.2 (55.3–69.0)	61	58.2 (51.4–65.1)	63	57.9 (51.3–64.4)
Heel rise height	124	69.2 (65.1–73.3)	126	73.0 (69.1–76.8)	123	72.7 (68.4–77.0)
Heel rise work	122	51.0 (43.6–58.3)	124	52.2 (45.4–59.0)	119	55.1 (45.5–64.7)
Total at 12-mo follow-up	130		117		116	
Countermovement drop jump	118	88.0 (80.6–95.5)	113	82.4 (76.6–88.2)	112	86.8 (80.2–93.3)
Hopping	116	99.3 (91.7–107.0)	109	93.5 (86.4–100.6)	112	103.5 (93.6–113.3)
Concentric power	107	86.1 (71.8–100.5)	88	86.1 (68.2–95.7)	102	82.0 (68.2–95.7)
Eccentric power	99	81.7 (70.9–92.5)	84	73.5 (62.8–84.1)	89	88.6 (71.5–105.6)
Heel rise height	119	83.0 (77.7–88.3)	109	86.9 (80.6–93.3)	111	84.5 (78.6–90.4)
Heel rise work	119	68.0 (60.3–75.7)	108	71.3 (63.1–79.4)	111	74.4 (65.2–83.7)

* Data are presented according to the limb-symmetry index (the ratio of the test score for the injured foot to the test score for the uninjured foot, multiplied by 100). Missing data were handled with the use of threshold imputation and multiple imputation by chained equation. The countermovement drop jump measured the maximum number of vertical, 20-cm drop jumps on one leg; hopping score was the average air flight time divided by the floor contact time after 25 continuous jumps; the concentric power score was height and time of heel displacement, expressed as watts, during a series of continuous heel rises performed with increasing external weight; eccentric power scores were measurements, expressed as watts, obtained when the patient stood on one leg with the ankle plantar-flexed and performed an eccentric–concentric movement of the ankle with increasing external weights; heel rise height was the maximum heel rise height measured during the heel rise work test; and heel rise work measured muscle endurance, expressed as Joules, while the patient performed continuous heel rises until fatigue occurred.

The New England Journal of Medicine

Table 4. Serious and Minor Adverse Events.*

Event	Nonoperative Treatment (N=178)	Open Repair (N=176)	Minimally Invasive Surgery (N=172)
		number of patients (percent)	
Serious adverse event	16 (9.0)	11 (6.3)	15 (8.7)
Sensory-nerve injury†	1 (0.6)	5 (2.8)	9 (5.2)
Deep infection‡	2 (1.1)	2 (1.1)	3 (1.7)
Deep venous thrombosis	1 (0.6)	2 (1.1)	1 (0.6)
Pulmonary embolism§	0	1 (0.6)	1 (0.6)
Rerupture	11 (6.2)	1 (0.6)	1 (0.6)
Tendon elongation resulting in surgery	1 (0.6)	0	0
≥1 Serious adverse event	13 (7.3)	9 (5.1)	14 (8.1)
Minor adverse event	3 (1.7)	11 (6.3)	9 (5.2)
Superficial infection	0	3 (1.7)	1 (0.6)
Numbness of the heel	1 (0.6)	2 (1.1)	7 (4.1)
Wound-healing complication¶	2 (1.1)	4 (2.3)	0
Suture granuloma‖	0	2 (1.1)	1 (0.6)

* Shown are all the adverse events that occurred in the 526 patients who underwent randomization and were included in the full analysis population. A patient could have had more than one adverse event, but no patient had the same adverse event more than once.
† Sensory-nerve injury refers to sensory loss in both the heel and lateral aspect of the foot (sural nerve) or sensory loss between the first and second toes (deep peroneal nerve, which occurred in one patient in the open-repair group).
‡ The two deep infections that were observed in the nonoperative group were complications of subsequent open repairs performed after reruptures.
§ The patient in the open-repair group who had a pulmonary embolism did not have documented deep venous thrombosis.
¶ Wound-healing complications included delayed wound closure or secretion more than 2 weeks after surgery.
‖ The suture granuloma that occurred in the patient in the minimally invasive surgery group led to excision.

changes in the Achilles' tendon Total Rupture Score and in the physical performance more than 1 year after the time of tendon rupture have been reported to be minor,[34] and results of a post hoc sensitivity analysis that involved only patients who responded to questionnaires at 12 months yielded results similar to those of the primary analysis. Although physiotherapists who performed physical tests were unaware of treatment-group assignments, patients were not unaware of their assignments, nor were the physicians who conducted follow-up visits or the physiotherapists involved in rehabilitation; thus, bias is possible in patient self-reporting of outcomes or in the implementation of accelerated functional rehabilitation. A careful physical examination was performed preoperatively in the surgical groups and resulted in the exclusion of two patients in the open-repair group and one patient in the minimally invasive surgery group owing to identification of gastrocnemius muscle rupture (rather than Achilles' tendon rupture). Since patients in the nonoperative group did not undergo a similar evaluation before their treatment, it is possible that some patients with a muscle rupture (and not an Achilles' tendon rupture) were included in the nonoperative group; however, the number of such patients, if any, would be expected to be small and unlikely to affect the overall results.

Open repair or minimally invasive surgery in patients with acute Achilles' tendon rupture did not improve Achilles' tendon Total Rupture Scores at 12 months as compared with nonoperative treatment. Nonoperative treatment was associated with a higher risk of rerupture than surgical treatment but resulted in fewer nerve injuries than with minimally invasive surgery.

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