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# Acute Achilles Tendon Rupture

## Minimally Invasive Surgery Versus Nonoperative Treatment With Immediate Full Weightbearing— A Randomized Controlled Trial

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**Background:** Surgical repair of acute Achilles tendon ruptures is considered superior to nonoperative treatment, but complications other than rerupture range up to 34%. Nonoperative treatment by functional bracing seems a promising alternative.

**Hypothesis:** Nonoperative treatment of acute Achilles tendon rupture with functional bracing reduces the number of complications compared with surgical treatment with a minimally invasive technique.

**Study Design:** Randomized controlled clinical trial; Level of evidence, 2.

**Method:** Using concealed random allocation, 83 patients with acute Achilles tendon rupture were assigned to nonoperative treatment by functional bracing or minimally invasive surgical treatment followed by tape bandage. Patients were allowed full weightbearing, and follow-up was 1 year.

**Results:** Complications risk other than rerupture by intention-to-treat basis was 9 in 42 patients (21%) for surgical treatment and 15 in 41 patients (36%) for nonoperative treatment (risk ratio, 0.59; 95% confidence interval, 0.29-1.19). Reruptures risk was 5 in 41 patients after nonoperative treatment and 3 in 42 patients for surgical treatment (risk ratio, 0.59; 95% confidence interval, 0.15-2.29). The mean time to work was 59 days (SD, 82) after surgical treatment and 108 days (SD, 115) after nonoperative treatment (difference, 49 days; 95% confidence interval, 4-94;  $P < .05$ ). The difference between treatments for return to sports (risk ratio, 0.55; 95% confidence interval, 0.23-1.29), pain, and treatment satisfaction did not reach statistical significance.

**Conclusion:** There appears to be a clinically important difference in the risk of complications between minimally invasive surgical treatment and nonoperative treatment for acute Achilles tendon ruptures, but this was not statistically significant.

**Keywords:** Achilles tendon; rupture; treatment; complications

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Surgical repair of acute Achilles tendon (AT) ruptures is generally considered superior to nonoperative treatment as it reduces rerupture rates and allows functionality after treatment.<sup>4,9,20,22</sup> However, postoperative complications

other than rerupture (eg, wound infection, scar adhesion, surgery-related sural nerve injury) have been reported to range up to 34%.<sup>9</sup> Minimally invasive surgical techniques (using limited incisions or percutaneous techniques) are considered to reduce the risk of operative complications and appear successful in preventing rerupture in cohort studies.<sup>1-3,5,11,14,16,26,28</sup> But to date, evidence from randomized trials is very limited.<sup>9,13</sup> On the other hand, nonoperative treatment by cast immobilization eliminates the risk of wound complications and intraoperative sural nerve damage but has a considerable risk of rerupture.<sup>9,20</sup> A major disadvantage of cast immobilization is delayed recovery owing

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to calf muscle weakness.<sup>7,8,15,21,25</sup> Functional bracing allows exercise and training, therewith preventing calf muscle atrophy and enabling faster recovery. At the same time, a low risk for rerupture and a low overall complication rate have been reported for functional bracing.<sup>17,23,24,27</sup>

The goal of this randomized trial is to compare the results of minimally invasive surgical repair with those of nonoperative treatment by functional bracing for acute ruptures of the AT. The design of this trial has been published previously.<sup>18</sup>

**MATERIALS AND METHODS**

The study was conducted in 4 teaching hospitals in the Netherlands. Eligible were patients with an acute AT rupture who visited the accident and emergency departments of 1 of the 4 hospitals. Treatment was initiated (surgery or cast application) within 3 days from AT rupture. Inclusion and exclusion criteria are listed in Table 1.

The surgeon, surgical resident, or emergency department doctor allocated treatment to patients. This was done in a concealed manner via a specially designed Internet site for which treatment randomization was stratified by hospital in blocks of 4 to balance groups over hospitals. The treatment nature was open to patients, physicians, and physical therapists.

**Sample Size**

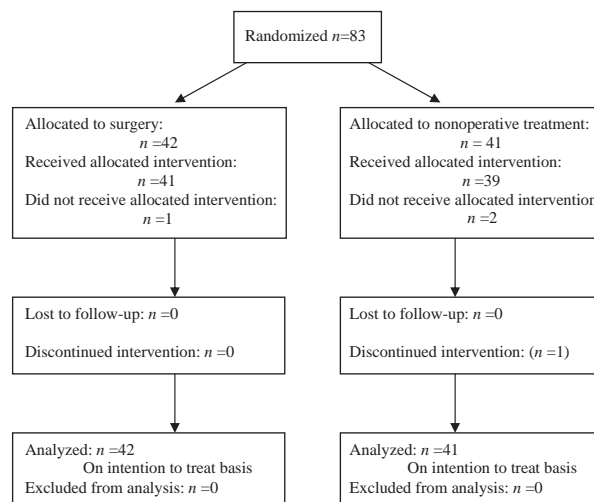
Prospective data on the risk of complications of minimally invasive repair are very scant. The systemic review by Khan et al<sup>9</sup> provides the best empirical estimate for the postsurgical risk of complication (excluding rerupture) for any surgical treatment. Based on this postsurgical risk of 34%, a statistical power (1 - β) of .80, and an attrition rate of 10%, at least 36 patients per treatment arm are needed for this balanced group trial to reach statistical significance (1-sided α = .05) for a risk difference of 30% (Figure 1).

**Treatment**

In all hospitals, physicians were familiar with the surgical technique before trial participation. Surgery was performed under the supervision of 1 of 4 surgeons (E. V., G. C., E. H., M. V.). Surgery was performed under regional or general anesthesia, with the patient in the prone position. No tourniquet was used. The minimally invasive surgical repair<sup>3</sup> started with a less than 5-cm longitudinal incision over the posteromedial aspect of the affected leg just proximal to the rupture area. A Bunnell-type suture was placed through the proximal end of the AT (atraumatic PDS 1.0). With a hollow mandarin, the suture was tunneled to the lateral aspect of the calcaneus and guided out through a 5-mm stab incision. A hole was drilled through the calcaneus 1 cm distal to the tendon insertion (exit through 5-mm stab incision medially). The PDS was guided through the hole and with the mandarin back proximally. Finally,

**TABLE 1**  
Inclusion and Exclusion Criteria

Inclusion Criteria	Exclusion Criteria
Primary Achilles tendon rupture (midzone tear)	Rerupture/bilateral rupture/open rupture
Treatment starts within 72 hours	Combination with fracture of foot or ankle
Diagnoses by physical examination: palpable gap and positive calf muscle squeeze test result	Former application (injection) of local corticosteroids in tendon area
Age: 18-65 years	Contraindications for surgery
Written informed consent	Physical or mental handicaps that do not allow functional treatment or otherwise interfere with the ability to follow up on the study protocol



**Figure 1.** Diagram of patient flow through the trial.

the suture was tied with the foot in relaxed equinus position (approximately 30° of plantar flexion) (Figure 2). After wound closure, a cast was applied with the foot in plantar flexion for 1 week. In the following 6 weeks, tape bandage was applied, supported by a 2-cm heel raise the first 2 weeks; thereafter, the height was reduced to 1 cm. During the last 2 weeks, the heel raise was removed.

Nonoperative therapy consisted of a cast in plantar flexion for 1 week; thereafter, a functional bracing system (Vacoped, OPED, Valley, Germany) was applied. The Vacoped bracing system is a multifunctional below-knee splint consisting of several components (Figure 3). The essential parts are the dorsal and ventral honeycomb-shaped plastic shell, the vacuum cushion with changeable terry cloth covers, the belts with security locks, and the removable sole.<sup>19</sup> Before the trial, the brace was successfully



**Figure 2.** Surgical repair technique. Taken with permission from Bijlsma and van der Werken. Operative treatment of Achilles tendon rupture: a minimally invasive technique allowing functional after-treatment. *Orthop Traumatol.* 2000; 8:285-290.<sup>3</sup>

used in a small pilot series to test feasibility of technical aspects of design and protocol. An instructional meeting on brace application was held in all participating hospitals. In the first 2 weeks, the brace was fixed in 30° of plantar flexion. In the following 2 weeks, bracing was in 15° of plantar flexion. In the last 2 weeks, the brace was applied in a dynamic status enabling movement from neutral position to 30° of plantar flexion. The braces were sealed to reveal illicit removal outside of protocol.

In both treatment groups, crutches were advised in the first week of casting; thereafter, the use of crutches was left at the discretion of the treating physician. Full weight-bearing when walking on flat surface was allowed.

### Follow-Up and End Points

The primary end point was all complications other than reruptures. Rerupture rates were expected to be equal for both treatments. Secondary end points were time to work resumption, participation in sports, and patient satisfaction with treatment and pain, both measured on a 0 to 10 visual analog scale. Follow-up visits were planned at 1, 3, 5, and 7 weeks and at 3, 6, and 12 months.

At 6 months, patient outcome was evaluated by the Leppilahti scoring method, a clinical scoring system, including subjective assessment of symptoms and evaluation



**Figure 3.** Vacoped bracing system.

by independent physical therapists of the range of motion and isokinetic muscle strength of plantar flexion and dorsiflexion of the ankle.<sup>12</sup>

### Data Analysis

Both study groups were compared for their baseline characteristics. The number of complications was calculated for the primary end point. Distribution measures were calculated for the secondary end points at the different follow-up periods. Differences between groups for the number of complications and distribution of other end points were calculated for each outcome measure with a 95% confidence interval (CI). The study groups were compared with the  $\chi^2$  test for categorical outcome variables and the independent-sample Student *t* test for continuous outcome variables. During the analysis, the intention-to-treat principle was adhered; that is, all patients were analyzed according to their randomized treatments. A listing of dropouts and withdrawals, including date and reason, was summarized by treatment group. Because the intervention was standardized, no important differences between centers was anticipated. The Mantel-Haenszel procedure was used to explore the effect of possible between-center differences.

### RESULTS

Between January 2004 and September 2005, 83 patients with an acute AT rupture participated: 42 were allocated

to minimally invasive surgical treatment and 41 to nonoperative treatment by functional bracing. Both groups were comparable at baseline (Table 2). The AT rupture occurred mainly during sports, notably ball sports such as tennis, squash, and volleyball. Most patients were in their third or fourth decade of life.

For all patients, follow-up data on treatment complications were obtained (Table 3). Reruptures occurred in 5 of 41 (12%) patients after nonoperative treatment and 3 of 42 (7%) patients after surgical treatment. Consequently, the reduction in absolute risk of rerupture in favor of surgical treatment was 5%, whereas the relative risk reduction was 41% (risk ratio, 0.59; 95% CI, 0.15-2.29). One of the reruptures in the surgical treatment group occurred in a patient who, after refusing allocated surgical treatment, received nonoperative treatment. In addition, 2 patients consenting to trial participation refused allocated nonoperative treatment and subsequently received surgery. Consequently, according to treatments as received, rerupture occurred in 6 of 40 patients (15%) with nonoperative treatment and 2 of 43 patients (5%) with surgery, resulting in a risk ratio of 0.31 (95% CI, 0.07-1.45; *P* = .11). Reruptures were diagnosed clinically and by ultrasound examination in the AT midzone, approximately 2 to 5 cm from the calcaneus. For 6 reruptures (1 after primary surgical and 5 after primary nonoperative treatment), patients underwent surgery. Both remaining patients (1 after primary surgical and 1 after primary nonoperative treatment) were treated nonoperatively. The rerupture in the nonoperative treatment group occurred in a patient suffering severe dermatitis during bracing. It was treated nonoperatively by cast as the skin had not yet completely healed. One rerupture in the surgical treatment group was a partial rerupture on clinical and ultrasound examination and was treated nonoperatively by tape bandage.

Of all complications, many were skin related: 5 of 12 (42%) for surgical treatment and 13 of 20 (62%) for nonoperative treatment. Most skin-related complications (eg, fungal infections, pressure sores, and blisters) resolved quickly when brace or tape bandage was removed 7 weeks after treatment initiation. All postoperative wound adhesions documented by surgeons at follow-up were reported

TABLE 2  
Baseline Characteristics

Baseline Characteristic	Surgery No.	Nonoperative No.	Total No. (%)
No. of patients	42	41	83
Age, y	40 (range, 23-63)	41 (range, 25-62)	
Gender: male	31	35	66 (79.5)
Body mass index, mean	25.9	26.3	
Smoking	8	10	18
Diabetes mellitus	0	2	2
Cause: sports	37	33	70 (84)
Side: left	28	21	49 (59)

as asymptomatic. One of the 2 patients who were operated on after refusing nonoperative treatment had short-term postoperative sensibility loss in the sural nerve area. Three other patients suffering sural nerve injury still had partial sensibility loss at 1-year follow-up. One surgically treated patient developed a complex regional pain syndrome 3 months after surgery. Although improving, this patient was not fully recovered at 1-year follow-up.

The total number of complications on the intention-to-treat basis was 12 of 42 (29%) for surgical treatment and 20 of 41 (49%) for nonoperative treatment. Consequently, the absolute risk reduction in favor of surgical treatment was 20%, whereas the relative risk reduction was 41% (risk ratio, 0.59; 95% CI, 0.33-1.04). The total number of complications other than rerupture on the intention-to-treat basis was 9 of 42 (21%) for surgical treatment and 15 of 41 (36%) for nonoperative treatment. Consequently, the absolute risk reduction in favor of surgical treatment was 15%, whereas the relative risk reduction was 41% (risk ratio, 0.59; 95% CI, 0.29-1.19).

For all patients, follow-up data were obtained for time to resumption of work and participation in sports. Five of the 83 patients had no paid work, and 14 of the 83 patients did not participate in any sport at randomization. In Table 4, the

TABLE 3  
Complications of Treatment: Intention to Treat<sup>a</sup>

Complication	Surgery (n = 42)		Nonoperative (n = 41)		Risk Data		
	No.	%	No.	%	Risk Ratio	<i>P</i>	RD
Rerupture	3	7.1	5	12.2	0.59 (0.15 to 2.29)	.44	0.05 (95% CI, -0.08 to 0.18)
Sural nerve injury	3		1				
Deep vein thrombosis lower leg	0		1				
Complex regional pain syndrome	1		0				
Skin-related complications <sup>b</sup>	2		13				
Deep wound infection	0		0				
Scar adhesion	3		0				
Total complications other than rerupture	9	21.4	15	36.6	0.59 (0.29 to 1.19)	.13	0.15 (95% CI, -0.04 to 0.34)
Total (0.41)	12	28.6	20	48.8	0.59 (0.33 to 1.04)	.06	0.20 (95% CI, -0.003 to 0.41)

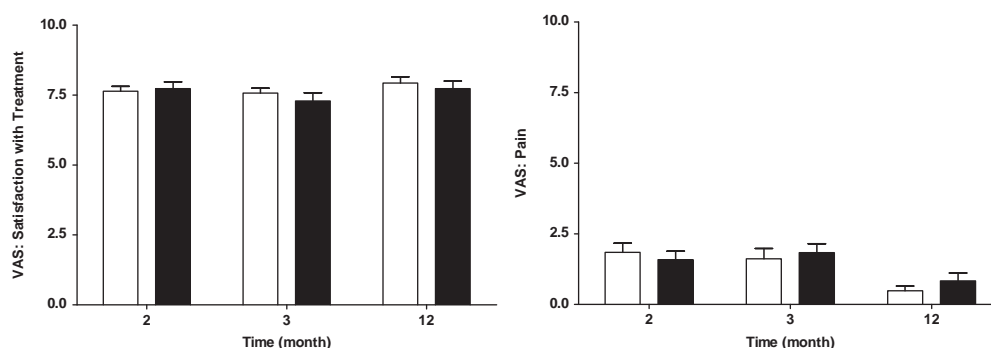
<sup>a</sup>CI, confidence interval; RD, risk difference.

<sup>b</sup>Skin-related complications include fungal infection, pressure sores, blisters, and superficial wound infection.

TABLE 4  
Return to Work and Sports<sup>a</sup>

Recovery to Work and Sports	Surgery	Nonoperative	Statistics
Return to work			Difference, 49 days; 95% CI, 4-94; $P < .05$
Mean days (SD)	59 (82)	108 (115)	
Median, d	39	63	
Have not returned to work, n	1	0	
No job, n	2	3	
Sports prerupture			
Active in sports, n	36/42	33/41	
Sports postrupture, n			RR, 0.82 (95% CI, 0.62 to 1.08); $P = .16$ ; RD, 0.15 (95% CI, -0.35 to 0.05)
Returned to sports	24/36	27/33	
Changed sport	4	4	
Stopped sports	8	2	

<sup>a</sup>CI, confidence interval; RD, risk difference; RR, risk ratio.



**Figure 4.** Visual analog scale (VAS) scores for patient satisfaction and pain at 2, 3, and 12 months. □, surgical treatment group; ■, nonoperative treatment group.

numbers of data available per group are presented for each variable. All but 1 patient returned to their former jobs. The 1 patient who did not was still suffering from a complex regional pain syndrome. The mean time off work was 59 days (SD, 82) for the surgically treated patients and 108 days (SD, 115) for the nonoperatively treated patients (difference, 49 days; 95% CI, 4-94;  $P < .05$ ).

In the surgery group, 24 of 36 patients (67%) returned to their former levels of sport within 1 year versus 27 of 33 patients (82%) in the nonoperative treatment group (risk ratio, 0.82; 95% CI, 0.62-1.08). Seven patients (4 in the surgery group and 3 in the nonoperative group) had reasons other than their AT ruptures for not returning to or changing type of sports (eg, job or family reasons).

Follow-up data were complete for posttreatment visual analog scale scores for pain and patient satisfaction. In Figure 4, the 2 variables are given per patient group at 3 follow-up moments. At 7 weeks, surgically treated patients had more pain and were less satisfied than were nonoperatively treated patients. At 3 months and at 1 year, it was the reverse scenario.

Because 30% of all patients did not wish to participate in measurement of isokinetic strength and range of motion, the

Leppilahti scores could be calculated for 59 (70%) patients. There were fewer patients assigned to surgery and more smokers among patients with incomplete Leppilahti scores (Table 5). There were neither clinically important nor statistically significant differences between the treatment groups regarding isokinetic strength or range of motion (data not shown). In the surgery group, 26 of 32 of patients (81%) had good or excellent Leppilahti outcome scores; in the nonoperative treatment group, 24 of 27 patients (89%) had good or excellent Leppilahti outcome scores (Table 6). This difference did not reach statistical significance.

## DISCUSSION

We observed a 15% lower risk of complications other than rerupture after minimally invasive surgical treatment of acute AT rupture with an absolute risk reduction favoring surgery of 41% compared with nonoperative treatment, but this difference did not reach statistical significance. For our sample size calculation, we anticipated an absolute risk reduction of 30% favoring nonoperative treatment with a 34% risk of complications other than rerupture

TABLE 5  
Baseline Characteristics of Patients With Complete or Incomplete Results on Leppilahti Score

Baseline Characteristics	Complete N (%)	Incomplete N (%)
No. of patients	59	24
Age, y	40	42
Gender: male	47 (80)	19 (79)
Body mass index	25.9	26.3
Smoking	11 (19)	7 (29)
Diabetes mellitus	0	2 (8)
Surgical treatment	32 (54)	10 (42)
Side		
Left	36 (61)	13 (54)
Right	23	11

TABLE 6  
Leppilahti Score

Leppilahti Score	Surgery	Nonoperative
No. of patients	32 (76%)	27 (66%)
Excellent/good	26	24
Fair	6	2
Poor	0	1
Complications in tested patients		
Rerupture	1	2
Sural nerve injury	3	0
Skin complication	3	10

after surgical treatment.<sup>9</sup> The lower risk after surgical treatment might be explained by the applied less invasive operative technique, as the anticipated 34% risk of complications other than rerupture was derived from data on conventional open repair techniques.<sup>9</sup>

Most complications other than rerupture in the nonoperative treatment group were skin related, notably fungal infections, pressure sores, or blisters. This bracing system is generally used in postoperative fracture treatment and not continuously worn. In this trial, patients were not allowed to remove the brace between follow-up appointments. This might have contributed to the high incidence of skin-related complications.

In contrast to previous studies, we experienced a higher (not statistically significant) number of reruptures after nonoperative treatment using functional bracing.<sup>17,23,24,27</sup> But comparison with the other studies is difficult because we used a different type of bracing system. In all patients, treatment was started within 72 hours, as concerns have been expressed over initiating nonoperative treatment beyond this period. In some series on nonoperative AT rupture, treatment measuring tendon gap adaptation in plantar flexion by ultrasound is claimed to reduce rerupture risk; only patients without tendon gap in plantar flexion are considered for nonoperative therapy.<sup>6,10</sup> But there is no proper randomized trial on surgical versus nonoperative treatment in patients with AT rupture with no tendon gap at ultrasound investigation. For those without rerupture,

functional bracing appears to produce good results according to Leppilahti outcome scores.

All but 1 of the trial participants returned to their former professions. Therefore, we conclude that AT rupture does not influence patients' professional lives substantially. The higher number of complications might explain the longer sick leave from work in the nonoperative treatment group. In contrast, almost a quarter of all participants (18/69 patients) did not return to their preinjury levels of sport. Some patients claimed their AT ruptures were not the actual reason for changing or quitting sport; therefore, comparison between treatment groups is difficult. We can confirm conclusions from previous studies that AT rupture is an injury greatly influencing postrupture recreational sporting activity.

## CONCLUSION

Our data show that minimally invasive surgical treatment of acute AT rupture appears to have a lower risk of complications than does nonoperative treatment using functional bracing, although this difference is not statistically significant. Surgery does result in earlier return to work.

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