Early Functional Treatment versus Early Immobilization in Tension of the Musculotendinous Unit after Achilles Rupture Repair: A Prospective, Randomized, Clinical Study

Jarmo Kangas, MD, Ari Pajala, MD, Pertti Siira, PT, Martti Hämäläinen, MD, PhD, and Juhana Leppilahti, MD, PhD

Background: **The aim of our prospective, randomized, clinical study was to compare two postoperative regimens after Achilles rupture repair and determine whether early functional treatment will give a better result than early immobilization in tension of the musculotendinous unit.**

Methods: **Fifty patients with acute Achilles tendon rupture were randomized postoperatively to receive either early movement of the ankle between neutral and plantar flexion in a brace for 6 weeks or Achilles tendon immobilization in tension using a below-knee cast with the ankle in a neutral position for 6 weeks. Full weight bearing was allowed after 3 weeks in both groups. The patients were assessed clinically at 1, 3, 6, 12, and 24 weeks, and the last control visit took place at a mean of 60 (SD 6.4) weeks postoperatively.**

Results: **The isokinetic calf muscle strength scores were excellent in 56%, good in 32%, fair in 8%, and poor in 4% of the patients in the early motion group at the last control checkup; whereas the scores in the cast group were excellent in 29%, good in 50%, and fair in 21% of the patients. The ankle performance scores were excellent or good in 88%, fair in 4%, and poor in 8% of the patients in the early motion group, whereas the scores in the cast group were excellent or good in 92% and fair in 8% of the patients. At 3 months and at the last control checkup, no significant differences were seen between the two groups with regard to pain, stiffness, subjective calf muscle weakness, footwear restrictions, range of ankle motion, isokinetic calf muscle strength, or overall outcome. The complications included one rerupture in the early motion group and one deep infection and two reruptures in the cast group. Deep infection and the rerupture in the cast group occurred in the same patient. The outcome of the complications was good in two cases and poor in one.**

Conclusion: **The isokinetic calf muscle strength results were somewhat better in the early motion group, whereas the other outcome results obtained in the two groups of patients were very similar. We recommend early functional postoperative treatment after Achilles rupture repair for athletes and well-motivated patients and for less-motivated patients and nonathletes.**

Key Words: **Achilles rupture surgery, Functional postoperative treatment, Immobilization in tension.**

J Trauma. 2003;54:1171–1181.

Until the 1980s, casting was the standard postoperative regimen after Achilles tendon rupture, regardless of the surgical technique used. The ankle was conventionally immobilized in an equinus position without weight bearing for 4 to 9 weeks. Experimental studies have shown that immobilization of a muscle in a shortened position is deleterious, whereas immobilization in a stretched position markedly delays the development of atrophy. One week of immobilization was already found to be detrimental for muscle tissue.[1] Maxwell and Enwemeka[2] showed that immobilization of rabbit hind-limb muscles in a shortened position resulted in serious atrophy within 4 weeks, which was not reversed by subsequent immobilization at normal length. Rantanen et al.[3] showed that postoperative immobilization of rat hind-limb muscles in tension led to significantly less extensive calf muscle atrophy than immobilization in a shortened position. The latter is deleterious because myofibers very rapidly adjust to their new length by reducing the number of consecutive sarcomeres.[4] This makes rehabilitation difficult, as the myofibers need to not only reassume their original diameter but also readjust to their normal length by neosynthesis of sarcomeres. The soleus muscle, which contains a high proportion of type I muscle fibers, is particularly susceptible to atrophy if immobilized in a shortened position,[5] whereas the gastrocnemius is able to move when a below-knee cast is used, and is thus less affected.

Rantanen et al.[6] reported good results obtained by Achilles rupture treatment using early postoperative immobilization of the ankle in a neutral position, but no controlled comparisons with other regimens have been reported. Since the late 1980s, there has been a trend toward functional postoperative treatment, which has been reported to be well-tolerated, safe, and effective in compliant, well-motivated patients.[7–12] These studies have not included control groups, however, which is why the advantages and risks associated with early functional treatment have not been documented in sufficient detail. Cetti et al.[13] showed in a controlled study

Submitted for publication May 20, 2002.
Accepted for publication September 20, 2002.

from the Departments of Surgery (J.K., A.P., M.H., J.L.) and Physical Medicine and Rehabilitation (P.S.), Oulu University Hospital, Oulu, Finland.
Address for reprints: Juhana Leppilahti, MD, PhD, Department of Surgery, Oulu University Hospital, PL Box 22, 90220 Oulu, Finland; email: juhana.leppilahti@oulu.fi.

DOI: 10.1097/01.TA.0000047945.20863.A2

Table 1 Demographic Data on the Achilles Rupture Patients in the Two Randomized Groups

	Group I (Early Motion, n = 25)	Group II (Cast, n = 25)	*p* Value
Men/women	22/3	24/1	0.609
Mean age (range)	35 (21–55)	37 (23–53)	0.318
Body mass index (range)	26 (20–31)	26 (20–38)	0.872
Activity level			
Competitive athlete	4	3	0.714
Recreational athlete	17	18	
Nonathlete	14	4	
Previous AT symptoms	2	2	>0.99

that patients treated postoperatively for 6 weeks with a mobile cast were able to resume sports activities sooner than those treated for 6 weeks with a below-knee cast with the ankle in a 20-degree equinus position. Recently, Mortensen et al.[14] have shown in a controlled study that early restricted motion shortens the time needed for rehabilitation. The aim of our prospective, randomized, clinical study was to compare two postoperative regimens after Achilles rupture repair and determine whether early functional treatment will give a better result than early Achilles immobilization in tension in a cast with the ankle in a neutral position.

PATIENTS AND METHODS

The trial was approved by the local research ethics committee. All patients received oral and written information, and freely given informed consent was obtained in writing. One hundred six patients were treated for an acute complete closed Achilles tendon rupture between July 1995 and July 1998. Fifty-six patients were excluded from the study before the operation. The exclusion criteria were age over 60 years (12 patients), treatment delayed by 1 week or more after the rupture (4 patients), systemic corticosteroid treatment (2 patients), local corticosteroid injection(s) around the Achilles tendon during the 6 months before the rupture (2 patients), a previous Achilles tendon rupture on the opposite side (1 patient), diabetes mellitus (1 patient), and living outside the county and unwillingness to participate in the protocol (35 patients). Thus, the present population consisted of 50 patients (47 men and 3 women; age range, 21–55 years).

Rupture of Achilles tendon was diagnosed on the basis of a clinical examination, palpation of the defect, and a positive calf squeeze test.[15,16] Forty-seven patients (95%) had sustained the rupture during a sports-related activity, most frequently badminton (21 patients [42%]), volleyball (9 patients [18%]), soccer (5 patients [10%]), tennis (4 patients [8%]), and indoor hockey (3 patients [6%]).

Surgical Technique

All the patients were managed with the same operative technique. One author repaired 42 of the ruptures, and six other surgeons operated on the remaining 8. The operations were performed under spinal anesthesia in a prone position using a tourniquet. A posteromedial skin incision was made, and the fascia and paratenon were divided in the same line. The tendon was repaired by the two modified Kessler[17] suture technique with absorbable polydioxanone 2-0 sutures (Ethicon, Somerville, NJ) and smaller apposition sutures with Vicryl (polyglactin, Ethicon). A central gastrocnemius aponeurosis flap, as proposed by Silfverskiöld,[18] was turned down over the suture line and stitched to the Achilles tendon with Vicryl. After suturing, the ankle was easily placed in a neutral position. The fascia was carefully resutured with Vicryl, and the skin was closed with Ethilon (nylon) sutures (Ethicon). At the end of the operation, a below-knee rigid plaster splint was applied with the ankle in a neutral position. The postoperative randomization group was not known at the time of the operation.

Postoperative Management

The 50 patients were randomized postoperatively, using randomly mixed sealed envelopes, between postoperative regimens of either early mobilization (25 patients, group I) or immobilization in tension (25 patients, group II). The groups did not differ significantly with respect to gender, age, body mass index, activity level, and previous Achilles tendon symptoms (Table 1). The patients randomized into the early motion group had a below-knee dorsal cast (3M Soft cast) for 6 weeks, which allowed active free plantar flexion of the ankle and in which dorsiflexion was restricted to neutral (Fig. 1), whereas those randomized into the immobilization group were given a below-knee plaster cast (3M Scotchcast) with the ankle in a neutral position for 6 weeks. Full weight bearing was allowed after 3 weeks in both groups.

The patients in both groups were instructed to perform postoperative exercises according to a standard rehabilitation regimen (Table 2). The exercises started with early ankle motion exercises in group I; concentric contractions of the ankle flexors and extensors in group II; and toe, knee, and hip movement series in both groups. The number of series was increased at 3 weeks. Resisted ankle movements, ankle rotation exercises, standing on toes and heels, and movements with a rubber strip were added to the regimen at 6 weeks. Raising and lowering of the heels, ankle movements against a rubber strip, and stretching were included at 9 weeks. The program included 10 to 25 repetitions in three series for each exercise three times daily at home. None of the patients

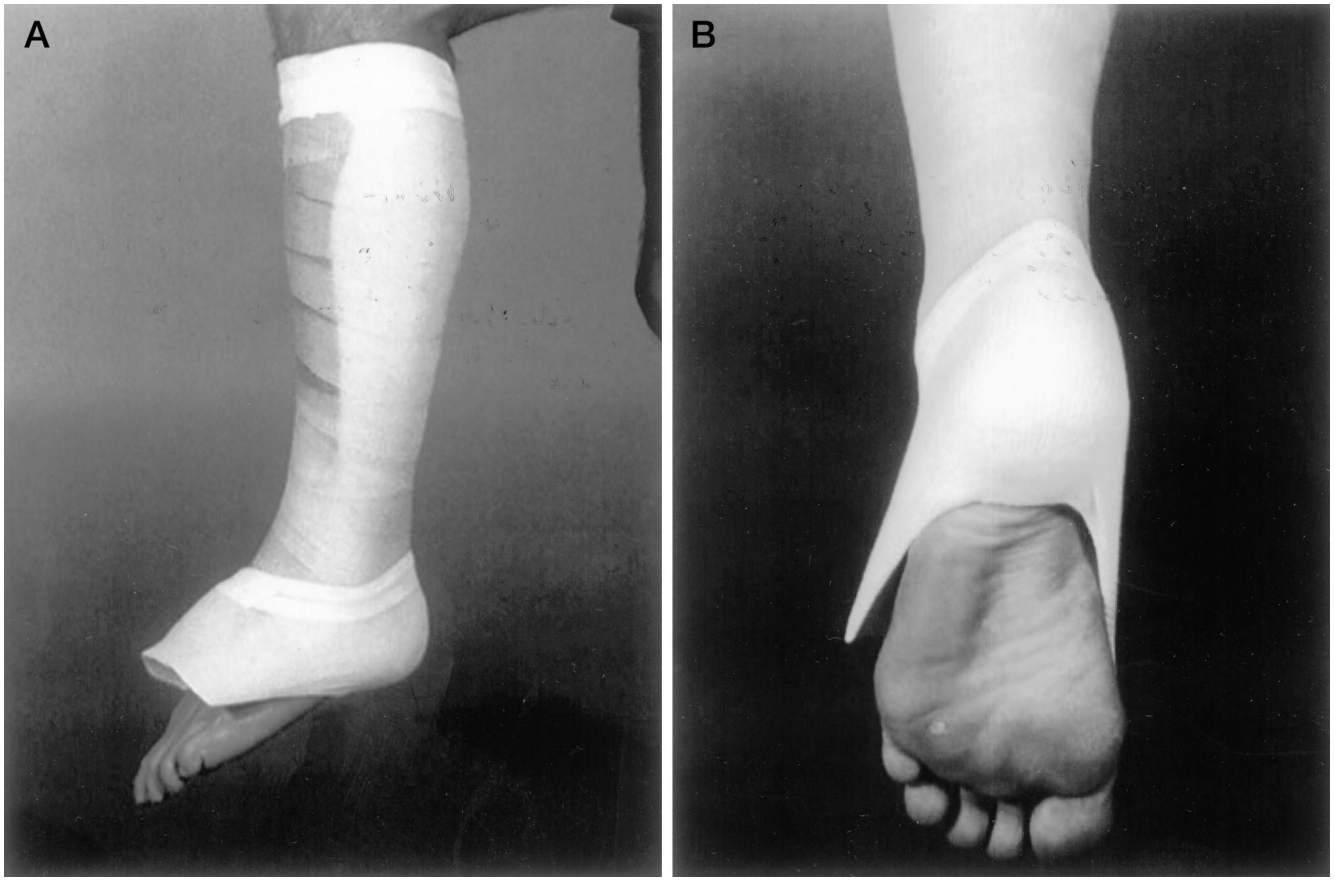

Fig. 1. *The early motion cast allowing active plantar flexion of the ankle.*

received professional physiotherapy. Jogging was increased at 12 weeks, and all types of sports were permitted at 6 months.

Follow-Up Assessments

The patients were examined clinically at 1, 3, 6, 12, 24 and, finally, a mean of 60 (SD 6.4) weeks postoperatively. The outcome was assessed at the 3-month and final checkups by the clinical scoring method described by Leppilahti et al.[19] (Table 3). The scoring included subjective factors such as pain, stiffness, muscle weakness, footwear restrictions, and subjective outcome, and objective factors such as the range of active ankle motion and isokinetic calf muscle strength. The patients were asked to complete a written questionnaire independently. The clinical observers were not blinded to the treatment groups.

Muscle Strength

The isokinetic and isometric muscle function parameters were assessed for the two groups at the 3-month and final checkups using the computer-based Lido Multi-Joint II isokinetic dynamometer (Loredan Biomedical, Inc., West Sacramento, CA). One physiotherapist performed all the isokinetic tests. All the patients were informed of the procedure, and a 10-minute warm-up period of ergometer cycling was included before the test. The testing position was supine, and the patient was fixed to the testing apparatus with straps round the foot and the pelvis with the knee supported in extension. The extent of ankle motion was from 40 degrees of plantar flexion to 20 degrees of dorsiflexion. Before testing, the patient performed some submaximal and maximal repetitions of the ankle flexion and extension movements at the isokinetic test velocity. The isokinetic dorsiflexion and plantar flexion strengths were measured, first at a speed of 60 deg/s, then at 120 deg/s, and finally at 180 deg/s after 2 minutes of rest. Five maximal voluntary muscular torque contractions were required. After the isokinetic tests, the maximal isometric plantar flexion strength was measured with the ankle in the neutral position. The isokinetic t speed was used to analyze the strength results (Table 4).

Statistical Analysis

The statistical analysis was performed with the Statistical Package for Social Sciences (SPSS version 6.1, SPSS, Inc., Chicago, IL). The summary statistics for continuous variables are expressed as means with SD. Student's *t* test was used to

Table 2 Postoperative Exercise Program

Group I (Early Mobilization)	Group II (Early Immobilization in Tension)
At 0–3 wk	At 0–3 wk
1. Flexion and extension of the toes in a supine posititon. 25 × 3 series, 3 times daily.	1. Flexion and extension of the toes in a supine position. 25 × 3 series, 3 times daily.
2. Plantar flexion of the ankle and dorsiflexion to neutral in a supine position. 30 × 3 series, 3 times daily.	2. Concentric contractions of the plantar flexors and extensors of the ankle (hold 5 s) 30 × 3 series, 3 times daily.
3. Extension of the knee in a sitting position (hold 2 s). 10 × 3 series, 3 times daily.	3. Extension of the knee in a sitting position (hold 2 s). 10 × 3 series, 3 times daily.
4. Flexion of the knee in a prone position. 10 × 3 series, 3 times daily.	4. Flexion of the knee in a prone position. 10 × 3 series, 3 times daily.
5. Extension of the hip in a prone position (hold 2 s) 10 × 3 series, 3 times daily.	5. Extension of the hip in a prone position (hold 2 s) 10 × 3 series, 3 times daily.
At 3–6 wk	At 3–6 wk
As above	As above.
At 6–9 wk	At 6–9 wk
1. Ankle flexion and extension exercises with manual help. 30 × 3 series, 3 times daily.	As in group I.
2. Rotation of the ankles in both directions. 30 × 3 series, 3 times daily.	
3. Standing on the toes and heels alternately. 30 × 3 series, 3 times daily.	
4. Ankle extension exercises against a rubber strip. 20 × 3 series, 3 times daily.	
5. Ankle stretching exercises to flexion with the help of a rubber strip. 30 seconds × 5 series, 3 times daily.	
6. Stretching of the calf muscle by standing with the leg to be stretched straight behind and the other leg bent in front and learning the body forward, with support from a wall or chair. 30 s × 5 series, 3 times daily.	
7. Stretching exercises for the toes and ankle against the hand in a sitting position. 30 s × 5 series, 3 times daily.	
At 9 wk	At 9 wk
1. Raising and lowering of the heel. First with both feet at the same time, later with one foot. 20 × 5 series, 3 times daily.	As in group I.
Exercises against a rubber strip for:	
2. Ankle extension 20 × 5 series, 3 times daily.	
3. Ankle flexion 20 × 5 series, 3 times daily.	
4. Ankle abduction 20 × 5 series, 3 times daily.	
5. Ankle adduction 20 × 5 series, 3 times daily	
6. Stretching of the calf muscle against the wall. 30 seconds × 5 series, 3 times daily.	
7. Standing with the knee somewhat flexed. 30 s × 5 series, 3 times daily.	

calculate the differences between the means, and Fisher's exact test was used to calculate the differences between frequencies. Two-tailed p values were reported, and $p < 0.05$ was considered statistically significant.

RESULTS

Isokinetic and Isometric Calf Muscle Strength

Peak Torque

The mean relative peak torque (PT) deficits for plantar flexion in the injured limb at 3 months were 20.8%, 17.9%, and 5.9% at 60, 120, and 180 deg/s, respectively, for group I; and 26.6%, 24.9%, and 12.4% for group II. The mean difference in PT was significantly greater at the low test speed (60 deg/s) than at the high speed (180 deg/s). At the last follow-up, the mean relative peak torque deficit for plantar flexion was 3.5%, 5.3%, and 1.4% at 60, 120, and 180 deg/s, respectively, for group I; and 6.6%, 7.8%, and 3.6% for group II (Table 5).

The average PT values for dorsiflexion were three to four times smaller than those for plantar flexion at the control visits. There was no dorsiflexion weakness detectable on the injured side on comparison between the legs or between the two groups at the 3-month or final checkup (Table 5).

At the last control checkup, the isokinetic calf muscle scores were excellent in 56%, good in 32%, fair in 8%, and poor in 4% of the patients in group I; whereas the scores in

Table 3 Achilles Rupture Performance Score*

	No. of Points†
Pain (15 points)	
None	15
Mild, no limitations on recreational activities	10
Moderate, limitations on recreational but not daily activities	5
Severe, limitations on recreational and daily activities	0
Stiffness (15 points)	
None	15
Mild, occasional, no limitations on recreational activities	10
Moderate, limitations on recreational but not daily activities	5
Severe, limitations on recreational and daily activities	0
Subjective calf muscle weakness (15 points)	
None	15
Mild, no limitations on recreational activities	10
Moderate, limitations on recreational but not daily activities	5
Severe, limitations on recreational and daily activities	0
Footwear restrictions (10 points)	
None	10
Mild, most shoes tolerated	5
Moderate, unable to tolerate fashionable shoes, modified shoes tolerated	0
Active range-of-motion difference between ankles (15 points)	
Normal (≤ 5 deg)	15
Mild (6–10 deg)	10
Moderate (11–15 deg)	5
Severe (≥ 16 deg)	0
Subjective result (15 points)	
Very satisfied	15
Satisfied with minor reservations	10
Satisfied with major reservations	5
Dissatisfied	0
Isokinetic muscle strength score (15 points)	
Excellent	15
Good	10
Fair	5
Poor	0
Maximum possible total	100

* From Leppilahti et al. 1998.[19]

† At least 90 points = excellent, 75–89 points = good, 60–74 points = fair, and <60 points = poor.

the early motion group were excellent in 29%, good in 50%, and fair in 21% of the patients ($p = 0.17$) (Table 6).

Average Work

The mean relative average work differences between the normal and injured legs in plantar flexion were 3.5%, 5.2%, and 1.4% at 60, 120, and 180 deg/s, respectively, for group I; and 32.0%, 26.6%, and 19.2% for group II at the 3-month checkup. At the last checkup, the mean relative average work deficit was 8.8%, 8.2%, and 10.4% at 60, 120, and 180 deg/s, respectively, for group I; and 7.9%, 9.0%, and 7.5% for group II (Table 5).

Table 4 Isokinetic Ankle Strength Scale for Scoring Plantar Flexion and Dorsiflexion Peak Torques of the Ankle at Three Test Speeds (60, 120, and 180 deg/s)*

	No. of Points†
Plantar flexion peak torque 60 deg/s percentage difference (uninjured-injured) (17 points)	
≤ 2%	17
>2 ≤ 5%	15
>5 ≤10%	13
>10 ≤ 25%	9
>25 ≤ 50%	5
>50%	0
Dorsiflexion peak torque 60 deg/s percentage difference (17 points)	
≤ 2%	17
>2 ≤ 5%	15
>5 ≤ 10%	13
>10 ≤ 25%	9
>25 ≤ 50%	5
>50%	0
Plantar flexion peak torque 120 deg/s percentage difference (17 points)	
≤ 2%	17
>2 ≤ 5%	15
>5 ≤ 10%	13
>10 ≤ 25%	9
>25 ≤50%	5
>50%	0
Dorsiflexion peak torque 120 deg/s percentage difference (17 points)	
≤ 2%	17
>2 ≤ 5%	15
>5 ≤10%	13
>10 ≤ 25%	9
>25 ≤ 50%	5
>50%	0
Plantar flexion peak torque 180 deg/s percentage difference (17 points)	
≤ 2%	17
>2 ≤ 5%	15
>5 ≤ 10%	13
>10 ≤ 25%	9
>25 ≤ 50%	5
>50%	0
Dorsiflexion peak torque 180 deg/s percentage difference (17 points)	
≤ 2%	17
>2 ≤ 5%	15
>5 ≤ 10%	13
>10 ≤ 25%	9
>25 ≤ 50%	5
>50%	0
Maximum possible total	102

* From Leppilahti et al., 1998.[19]

† At least 87 points = excellent, 72–86 points = good, 57–71 points = fair, and <56 points = poor.

Isometric Strength

The mean relative isometric strength deficit in the injured limb in plantar flexion at the 3-month checkup was 25.2% for group I and 24.1% for group II, the differences

Table 5 Mean Peak Torques (Nm) of Plantar Flexion and Dorsiflexion of the Ankles at Velocities of 60, 120, and 180 deg/s, Mean Average Work (J) of the Plantar Flexion of the Ankles at the Same Velocities, and Mean Isometric Strength of Plantar Flexion in Patient Groups I and II at the Last Follow-Up

Test Speed	Group I (Early Motion, n = 25)					Group II (Cast, n = 24)				
	Injured, Mean (SD)	Uninjured, Mean (SD)	% Difference, Mean (SD)	p Value	95% CI	Injured, Mean (SD)	Uninjured, Mean (SD)	% Difference, Mean (SD)	p Value	95% CI
Peak torque										
Plantar flexion										
60 deg/s	109.2 (33.2)	115.2 (28.4)	3.5 (15.6)	0.129	–3.1–10.1	103.0 (21.6)	110.9 (22.7)	6.6 (11.6)	0.006	1.7–11.5
120 deg/s	80.2 (23.1)	86.6 (22.5)	5.3 (16.2)	0.040	–1.6–12.1	76.0 (14.6)	84.2 (19.6)	7.8 (13.4)	0.001	2.2–13.5
180 deg/s	64.5 (15.0)	66.8 (15.7)	1.4 (13.9)	0.229	–4.5–7.2	62.2 (11.1)	65.1 (12.6)	3.6 (11.2)	0.049	–1.1–8.4
Dorsiflexion										
60 deg/s	32.6 (6.9)	30.3 (7.3)	–9.8 (23.5)	0.030	–19.7–0.2	28.3 (5.9)	27.2 (5.4)	–5.7 (22.9)	0.347	–15.3–4.0
120 deg/s	25.5 (5.1)	23.6 (1.1)	–9.9 (26.8)	0.047	–21.2–1.5	22.4 (4.3)	22.0 (3.7)	–2.8 (16.9)	0.616	–9.9–4.3
180 deg/s	23.9 (4.3)	22.6 (5.0)	–7.3 (20.8)	0.054	–16.2–1.4	21.9 (3.9)	21.4 (3.6)	–2.8 (12.8)	0.417	–8.2–2.6
Average work										
Plantar flexion										
60 deg/s	63.6 (21.9)	70.7 (18.7)	8.8 (16.1)	0.008	2.0–15.6	61.8 (12.8)	68.4 (15.9)	7.9 (14.9)	0.006	1.6–14.2
120 deg/s	48.0 (15.8)	53.5 (14.8)	8.2 (16.4)	0.007	1.3–15.1	45.6 (7.8)	51.9 (12.9)	9.0 (16.6)	0.002	1.9–16.0
180 deg/s	37.3 (11.2)	42.4 (10.9)	10.4 (15.9)	0.001	3.7–17.1	37.5 (7.7)	41.3 (9.8)	7.5 (14.4)	0.005	1.5–13.6
Isometric strength										
Plantar flexion	119.5 (45.8)	144.6 (41.4)	14.4 (19.5)	0.001	6.2–22.6	123.7 (33.0)	133.0 (34.4)	5.6 (17.3)	0.057	–1.7–12.9

CI, Confidence interval.

being statistically significant within the two groups ($p < 0.001$), whereas the mean percentage strength difference between the groups was not significant. At the last checkup, the mean relative strength deficit was 14.4% for group I ($p = 0.057$) and 5.6% for group II ($p < 0.001$).

Pain Relief

The mean visual analogue scale score was 2.17 ± 2.7 in group I and 2.02 ± 1.7 in group II at 1 week postoperatively ($p = 0.08$), 0.83 ± 1.2 in group I and 0.82 ± 1.3 in group II at 3 weeks postoperatively ($p = 0.797$), and 0.65 ± 1.4 and 0.60 ± 0.9 at 6 weeks postoperatively ($p = 0.346$). Twenty-four Achilles tendons were painless at the 3-month checkup, whereas 12 were mildly painful, 7 moderately so, and 6 severely so ($p = 0.578$ between groups). One patient was excluded because of Achilles tendon rerupture at 3 months. At the last checkup, 21 Achilles tendons (84%) were painless in groups I and II, whereas in both groups 3 tendons (12%) were mildly painful and 1 (4%) was moderately painful.

Stiffness

At the last control visit, 11 patients (44%) reported no Achilles stiffness and 14 (56%) reported mild stiffness in group I, whereas in group II 17 patients (68%) reported no stiffness and 8 (32%) reported mild stiffness ($p = 0.087$ between groups) (Table 6).

Subjective Calf Muscle Weakness

Nineteen patients (76%) had no subjective calf muscle weakness at the last checkup, 4 (16%) had mild weakness, 1 (4%) had moderate weakness, and 1 (4%) had severe weakness in group I; whereas in group II, 19 patients (76%) had no subjective calf muscle weakness, 5 (20%) had mild weakness, and 1 (4%) had moderate weakness ($p = 0.77$ between groups) (Table 6).

Footwear Restrictions

Seventeen patients (68%) had no footwear restrictions at the last follow-up, 7 (28%) had mild restrictions, and 1 (4%) had moderate restrictions in group I; whereas in group II, 23 patients (92%) had no footwear restrictions and 2 (8%) had mild restrictions ($p = 0.096$ between groups) (Table 6).

Range of Motion

Range of motion was normal in 18 (72%) at the last control visit, mildly limited in 5 (20%), moderately limited in 1 (4%), and severely limited in 1 (4%) of the patients in group I; whereas in group II, range of motion was normal in 19 (79%), mildly limited in 4 (17%), and moderately limited in 1 (4%) of the patients ($p = 0.77$) (Table 6).

Subjective Result

Thirteen patients (52%) were very satisfied at the last follow-up, 11 (44%) were satisfied with minor reservations, and 1 (4%) was dissatisfied in group I; whereas in group II, 19 patients (76%) were very satisfied, 4 (16%) were satisfied with minor reservations, and 2 (8%) were satisfied with major reservations ($p = 0.06$) (Table 6).

Overall Result

The ankle performance scores were excellent or good in 88%, fair in 4%, and poor in 8% of the patients in group I at the last control visit, whereas the scores in group II were excellent or good in 92% and fair in 8% of the patients ($p =$

Table 6 Results at the Last Follow-Up Evaluation

Clinical Factor	Group I (Early Motion, n = 25)	Group II (Cast, n = 25)	Overall Series (n = 50) (%)	*p* Value
Pain				>0.99
None	21	21	42 (84)	
Mild, no limitations on recreational activities	3	3	6 (12)	
Moderate, limitations on recreational but not daily activities	1	1	2 (4)	
Severe, limitations on recreational and daily activities	0	0	0	
Stiffness				0.087
None	11	17	28 (56)	
Mild, occasional, no limitations on recreational activities	14	8	22 (44)	
Moderate, limitations on recreational but not daily activities	0	0	0	
Severe, limitations on recreational and daily activities	0	0	0	
Calf muscle weakness (subjective)				0.774
None	19	19	38 (76)	
Mild, no limitations on recreational activities	4	5	9 (18)	
Moderate, limitations on recreational but not daily activities	1	1	2 (4)	
Severe, limitations on recreational and daily activities	1	0	1 (2)	
Footwear restrictions				0.096
None	17	23	40 (80)	
Mild, most shoes tolerated	7	2	9 (18)	
Moderate, unable to tolerate fashionable shoes, modified shoes tolerated	1	0	1 (2)	
Active range-of-motion difference between ankles				0.773
Normal (≤ 5 deg)	18	19	37 (74)	
Mild (6–10 deg)	5	4	9 (18)	
Moderate (11–15 deg)	1	1	2 (4)	
Severe (≥16 deg)	1	0	1 (2)	
Missing data*		1	1 (2)	
Subjective result				0.060
Very satisfied	13	19	32 (64)	
Satisfied, with minor reservations	11	4	15 (30)	
Satisfied, with major reservations	0	2	2 (4)	
Dissatisfied	1	0	1 (2)	
Isokinetic muscle strength (score)				0.170
Excellent	14	7	21 (42)	
Good	8	12	20 (40)	
Fair	2	5	7 (14)	
Poor	1	0	1 (2)	
Missing data*		1	1 (2)	
Ankle performance score				0.846
Excellent	15	15	30 (60)	
Good	7	7	14 (28)	
Fair	1	2	3 (6)	
Poor	2	0	2 (4)	
Missing data*		1	1 (2)	

* Missing data = one patient living abroad.

0.85) (Table 6). One of the patients with poor performance scores was a woman who had moderate exertion pain and mild stiffness in the Achilles region and moderate subjective calf muscle weakness. She was unable to use fashionable shoes. Her range of ankle motion was normal, but isokinetic strength scores were poor. The other patient with poor outcome had a rerupture and a deep infection postoperatively, which led to loss of the Achilles tendon. Two microvascular operations failed and the functional outcome was poor. Previous Achilles tendon symptoms did not predispose her to a poor isokinetic calf muscle strength result or poor outcome. The subjectively satisfied patients were the ones with the best range of ankle motion and the best calf muscle strength results, whereas the dissatisfied patients had the poorest performance scores.

Complications

The major complications included one deep infection and three reruptures, affecting three patients. The reruptures occurred a mean of 5 months (range, 3–7 months) after the primary operation, one in group I and two in group II. One rerupture was operated on with Lynn's plasty, and the isokinetic strength score and overall outcome were good at the last control visit. The deep infection plus rerupture in another patient required two microvascular reconstructions, which failed, and the Achilles tendon was lost. The isokinetic calf

muscle score at the last checkup was fair and the overall outcome poor. The third rerupture was resutured, but the patient was lost from the follow-up because he moved abroad. According to the questionnaire sent to him, the musculotendinous unit was painless and not stiff and the subjective end result was good. There was still some moderate subjective calf muscle weakness in recreational activities but not in everyday movement.

DISCUSSION

The major finding was that the isokinetic calf muscle strength results were somewhat better in the early motion group, whereas the other outcome results obtained in the two groups of patients were very similar. The present study was the first to compare these two postoperative regimens.

The strengths of the study were its prospective, randomized study design and the homogeneous groups of patients. A limitation of the study was the small number of patients, which reduced the statistical power. Exclusion criteria included age over 60 years, delayed treatment, systemic or local corticosteroid treatment, previous Achilles tendon rupture, diabetes mellitus, living outside the county, and unwillingness to participate in the study. Fifty-six patients did not meet the inclusion criteria. In contrast, only one randomized patient was lost from the clinical control and the isokinetic calf muscle strength measurements, because of moving abroad, and even he returned the completed questionnaire. The groups did not differ significantly with respect to gender, age, body mass index, activity level, or previous Achilles tendon symptoms. This was a single-center study, and one of the authors repaired most of the ruptures (42 of 50). The surgeon was not aware of the randomization at the time of the operation, because the allocation was made postoperatively. The outcome criteria included a previously published functional scoring system designed to measure isokinetic calf muscle strength and a questionnaire sent to the patients to be completed independently.

The outcome results show that it is not necessary to use complicated suture techniques that rely on mechanically strong stitches, because the tendons were successfully repaired with the two modified Kessler suture technique using absorbable 2-0 polydioxanone sutures and smaller apposition Vicryl sutures, and a central gastrocnemius aponeurosis flap, as proposed by Silfverskiöld,[18] was turned down over the suture line and stitched to the Achilles tendon with Vicryl. Suture techniques show differences from continent to continent. In Europe, many authorities use strong monofilament or braided absorbable sutures, whereas in North America the tendency is to use mechanically strong stitches extending well above and below the site of rupture (the Krackow technique) with braided nonabsorbable material. The augmentation technique involves a more extensive operation than the simple suture technique. Central gastrocnemius aponeurosis flap repair is superior to standard Kessler repair by virtue of its strength, Gerdes el al.[20] having shown in a series of 18 paired fresh anatomic Achilles tendons that one flap augmentation repair with No. 1 Ticron had an average strength of 217 N, whereas conventional repair with two interrupted Kessler sutures (No. 1 Ticron) failed at an average of 154 N.

The present ankle performance scores at the last control visit were excellent or good in 88% of the cases in the early motion group, fair in 4%, and poor in 8%, whereas the scores in the cast group were excellent or good in 92% and fair in 8%. Thus, no significant differences were detected between the groups at either the 3-month or the final checkup. The performance scores in both groups were better than in the series of Leppilahti et al.,[19] in which the postoperative treatment consisted of 6 weeks of below-knee cast immobilization with the ankle in an equinus position for 3 weeks and in a neutral position for 3 weeks, allowing gradual weight bearing after 3 weeks, for which the scores were excellent or good in 79% of the 101 cases, fair in 17%, and poor in 4% at a mean of 3 years postoperatively. Part of the reason that our results were better might be the homogenous patient groups, because patients over 60 years, patients with systemic diseases, and patients with late Achilles tendon ruptures were excluded in the present study.

The isokinetic calf muscle strength results in the present study were somewhat better in the early motion group, being excellent or good in 88% at the last checkup, fair in 8%, and poor in 4%, whereas the scores after immobilization in tension were excellent or good in 79% of cases and fair in 21%. Again, the results in both groups were better than those reported by Leppilahti et al.,[19] in which the isokinetic strength scores were excellent or good in 71% of cases, fair in 18%, and poor in 11%.

Previous reports on operatively treated Achilles tendon ruptures followed by 6 to 8 weeks of cast immobilization of the ankle in an equinus position have shown a mean isokinetic plantar flexion peak torque deficit of over 10%,[19,21,22] whereas recent accounts of early functional postoperative treatment have quoted plantar flexion peak torque deficits of only 1% to 8% (Table 7).[7–10,12] The present average peak torque deficit values were under 8% in both groups and comparable to previous results of early motion postoperative treatment.

The rate of major complications was 8%: there was one deep infection (2%) and three reruptures (6%), affecting three patients. The rerupture rate is higher than the figures of 21 of 742 (2.8%), for surgical treatment, reported in the review by Lo et al.[23] Rerupture was preceded in each case by a new trauma. As the reruptures occurred a mean of 5 months (range, 3–7 months) after the primary operation, it cannot be said that more substantial or more prolonged protection would have been necessary. It is not known whether these reruptures could have been avoided by the primary use of strong nonabsorbable sutures. In any case, the outcomes consisted of one excellent result, one subjectively good result (the patient who moved abroad), and one poor outcome because of a deep infection and loss of the Achilles tendon.

Table 7 Isokinetic Calf Muscle Strength after Achilles Rupture Repair

Reference	Study Design	No. of Patients	Mean Follow-Up (mo)	Surgical Technique	Postoperative Regimen	Isokinetic Dynamometer and Test Speeds	Mean Plantar Flexion Peak Torque Deficit at Follow-Up*
Shiels et al., 1978[22]	Retrospective	32	35	Augmentation with 1–2 flaps	Cast immobilization for 8 wk (4 wk long cast, 4 wk short cast, equinus 8 wk)	Cybex (30 deg/s)	14.2 (early repair) 17.6 (late repair)
Inglis and Sculco, 1981[21]	Retrospective	50	Not given	Augmentation with 2 flaps	Cast immobilization for 6 wk (3 wk long cast, 3 wk short cast, equinus 6 wk)	Cybex deg/s	12.1 (early repair) 14.8 (late repair)
Saw et al., 1983[9]	Retrospective	19	14	Modified Kessler	Early motion (cast for 2 wk, ankle in equine position, walker for 2–8 wk, ankle in neutral position)	Akron (60 deg/s)	3
Carter et al., 1992[7]	Retrospective	21	31	Bunnell or modified Kessler	Early motion (orthosis for 6–8 wk, unlimited plantar flexion, dorsiflexion limited to neutral)	Not given (30 deg/s)	1
Mandelbaum et al., 1995[8]	Prospective	29	6	Krackow	Early motion (splint for 2 wk, hinged orthosis up to 6 wk)	Cybex (60 deg/s) (120 deg/s)	2.9 2.3
Troop et al., 1995[12]	Prospective	13	27	Modified Kessler	Early motion (splint for 10 days, walking boots for 7 wk)	Cybex (60 deg/s)	8
Leppilahti et al., 1998[19]	Retrospective	101	37	Augmentation with 1–2 flaps in 95 cases	Cast immobilization for 6 wk (3 wk in plantar flexion, 3 wk in neutral position)	Lido (30 deg/s) (90 deg/s)	11 10
Speck and Klaue, 1998[10]	Prospective	20	12	Kessler	Early motion (walker for 6 wk, early full weight bearing)	Cybex (60 deg/s) (120 deg/s)	1.8 1.7

* Percent of uninjured side.

In this study, the isokinetic calf muscle strength results were somewhat better in the early motion group, whereas the other outcome results obtained in the two groups of patients were quite similar. We recommend early functional postoperative treatment after Achilles rupture repair for athletes and well-motivated patients and for less-motivated patients and nonathletes. Further prospective, randomized trials are nevertheless evidently needed with regard to augmentation and nonaugmentation techniques and the role of early full weight bearing in functional postoperative treatment.

REFERENCES

1. Hurme T, Lehto M, Kalimo H, Kannus P, Järvinen M. Sequence of changes in fibre size and type in muscle immobilized at various lengths. *J Sports Traumatol Rel Res.* 1990;2:77–85.
2. Maxwell LC, Enwemeka CS. Immobilization-induced muscle atrophy is not reserved by lengthening the muscle. *Anat Rec.* 1992; 234:55–61.
3. Rantanen J, Hurme T, Kalimo H. Calf muscle atrophy and Achilles tendon healing following experimental tendon division and surgery in rats: comparison of postoperative immobilization of the muscle-tendon complex in relaxed and tensioned positions. *Scand J Med Sci Sports.* 1999;9:57–61.
4. Baker JH, Matsumoto DE. Adaptation of skeletal muscle to immobilization in a shortened position. *Muscle Nerve.* 1988;11:231–244.
5. Häggmark T, Eriksson E. Hypotrophy of the soleus muscle in man after Achilles tendon rupture: discussion of findings obtained by computed tomography and morphologic studies. *Am J Sports Med.* 1979;7:121–126.
6. Rantanen J, Hurme T, Paananen M. Immobilization in neutral versus equinus position after Achilles tendon repair. *Acta Orthop Scand.* 1993;64:333–335.
7. Carter TR, Fowler PJ, Blokker C. Functional postoperative treatment of Achilles tendon repair. *Am J Sports Med.* 1992;20:459–462.
8. Mandelbaum BR, Myerson MS, Forster R. Achilles tendon ruptures: a new method of repair, early range of motion, and functional rehabilitation. *Am J Sports Med.* 1995;23:392–395.
9. Saw Y, Baltzopoulos V, Lim A, Rostron PKM, Bolton-Magg BG, Calver RF. Early mobilization after operative repair of ruptured Achilles tendon. *Injury.* 1993;24:479–484.
10. Speck M, Klaue K. Early full weightbearing and functional treatment after surgical repair of acute Achilles tendon rupture. *Am J Sports Med.* 1998;26:789–793.

11. Sölveborn S-A, Moberg A. Immediate free ankle motion after surgical repair of acute Achilles tendon ruptures. *Am J Sports Med.* 1994;22:607–610.
12. Troop RL, Losse GM, Lane JG, Robertson DB, Hastings PS, Howard ME. Early motion after repair of Achilles tendon ruptures. *Foot Ankle Int.* 1995;16:705–709.
13. Cetti R, Henriksen LO, Jacobsen KS. A new treatment of ruptured Achilles tendons. *Clin Orthop.* 1994;308:155–165.
14. Mortensen NHM, Skov O, Jensen PE. Early motion of the ankle after operative treatment of a rupture of the Achilles tendon: a prospective, randomized clinical and radiographic study. *J Bone Joint Surg Am.* 1999;81:983–990.
15. Simmonds FA. The diagnosis of the ruptured Achilles tendon. *Practitioner.* 1957;179:56–58.
16. Thompson TC, Doherty JH. Spontaneous rupture of tendon of Achilles: a new clinical diagnostic test. *J Trauma.* 1962;2:126–129.
17. Kessler I. The grasping technique for tendon repair. *Hand.* 1973; 5:253–255.
18. Silfverskiöld N. Über die subkutane totale Achillessehnenruptur und deren Behandlung. *Acta Chir Scand.* 1941;84:393–413.
19. Leppilahti J, Forsman K, Puranen J, Orava S. Outcome and prognostic factors of Achilles rupture repair using a new scoring method. *Clin Orthop.* 1998;346:152–161.
20. Gerdes MH, Brown TD, Bell AL, Baker JA, Levson M, Layer S. A flap augmentation technique for Achilles tendon repair: postoperative strength and functional outcome. *Clin Orthop.* 1992;280:241–246.
21. Inglis AE, Sculco TP. Surgical repair of ruptures of the tendo Achillis. *Clin Orthop.* 1981;156:160–169.
22. Shields CL, Kerlan RK, Jobe FW, Carter VS, Lombardo SJ. The Cybex II evaluation of surgically repaired Achilles tendon ruptures. *Am J Sports Med.* 1978;6:369–372.
23. Lo IKY, Kirkley A, Nonweiler B, Kumbhare D. Operative versus nonoperative treatment of acute Achilles tendon ruptures: a quantitative review. *Clin J Sports Med.* 1997;7:207–211.

EDITORIAL COMMENT

How good should medical research be to be good enough to change clinical care? The current generally accepted "gold standard" is a randomized controlled trial. In this issue of the *Journal of Trauma*, authors Kangas et al. report a randomized controlled trial comparing two postoperative regimens after surgical repair of an Achilles tendon rupture.[1] The research team is well qualified and multidisciplinary. The intent of the study is clear: to compare whether early functional treatment will give a better result than early immobilization in a cast. The methods are described with clarity and results are reported in detail. Seven outcomes are listed (pain, stiffness, muscle weakness, footwear restriction, range of motion, isometric calf strength, and subjective outcome), including 10 subscales of strength measurement. The analysis of results lists 28 *p* values and 20 confidence intervals. The discussion includes a succinct tabular summary of relevant prior studies. From a checklist of study quality perspective, this study should provide an excellent basis for clinical selection of postoperative regimens after Achilles tendon repair. The authors conclude that isokinetic calf strength results were better with early motion, and other outcomes in the two groups were similar.

The study has two fundamental limitations, and both of them severely restrict interpretation of the results. First, the authors do not specify which of their seven reported outcomes is the primary outcome. Second, the authors do not specify what level of similarity in results they considered acceptable when designing the study and stopping enrollment at 50 subjects.

The authors report isometric calf strength in great detail. Perhaps this is their primary outcome of interest. If so, the choice to measure this outcome at 3 months after surgery may not be meaningful, because one group has been in a cast for half of that interval. Table 5 actually does not clarify what the authors mean by "at last follow-up"; the text seems to suggest 3 months. Strength assessment at 6 months or 1 year may be more reflective of final results. Also, the data as presented in Table 2 show similar findings in the two groups: the injured side generates less plantar flexion torque and less work compared with the uninjured side within each group. Comparison of the two groups to each other is not presented, but plantar flexion torque numbers are slightly higher for the injured limb in the cast group.

The authors conclude that outcomes in the two groups are very similar. They acknowledge that the small sample size reduced power but do not elaborate further on what this may imply for interpretation of results. When comparing two treatments, lack of statistical significance does not necessarily mean that the two treatments are equal.[2] Frieman et al. in 1978 warned of the importance of beta/type II error, noting that 67 of 71 "negative" trials reported in a leading journal may have missed important clinical differences. The problem of inadequate sample size, though not new, remains common. Twenty-three years after the important publication of Frieman et al., Lochner et al. report that the type II error rate in orthopedic trauma trials is 90.52%.[3]

To illustrate the sample size problem in the study by Kangas et al., we can examine the comparison of a single proportion in the two study groups. Casts are generally applied after surgery to protect the repair. From this perspective, the primary outcome of interest to orthopedic surgeons and patients may be the rerupture rate for each treatment in a defined postoperative time interval. The authors report rerupture in 1 of 25 patients in the no-cast group and in 2 of 24 patients in the cast group. The study had a power of 2.5% to detect a difference of this magnitude.[4] The sample size needed to recognize these two proportions (4% vs. 8%) as statistically different with power = 80% would require 602 subjects in each group.[4] Stated another way, to detect different rerupture rates with adequate power in a study with only 25 subjects in each group, the magnitude of the difference in rerupture rates between the two groups would have to be greater than 10-fold (e.g., 4% in one group and greater than 40% in the other group).[4]

Randomized clinical trials are experiments on human beings. Experiments on living things should have reasonable justification.[5] Before asking patients to subject themselves to our experiments, we have to assure them and assure ourselves that the study plan at the outset at least has the capacity to answer the question it seeks to study. This assurance has several components: the answer to the primary study question must have value; a real uncertainty must exist between the options being compared (equipoise is a beautiful word,[6] but it should be described

in real and concrete terms); the study team must be qualified to perform the work; the study plan must be clear; the funding must be sufficient; the duration of the study (the number of enrolled patients followed to the endpoint) must be adequate to answer the primary question; and the context of the study and its results must be shared with physicians and patients.

So how good should clinical research be? It must be good enough for our patients. That is our highest standard, and that is also our minimal standard. Before establishing no difference between treatments, we must make sure that we looked carefully enough to recognize any real difference.

Sohail K. Mirza, MD
Department of Orthopaedics and Sports Medicine
University of Washington
Harborview Medical Center
325 Ninth Avenue, Box 359798
Seattle, WA 98104-2499

REFERENCES

1. Kangas J, Pajala A, Siira P, Hamalainen M, Leppitlahti J. Early functional treatment vs. early immobilization in tension of the musculotendinous unit after Achilles rupture repair: a prospective, randomized clinical study. *J Trauma.* (in press).
2. Freiman JA, Chalmers TC, Smith H Jr, Kuebler RR . The importance of beta, the type II error and sample size in the design and interpretation of the randomized control trial: survey of 71 "negative" trials. *N Engl J Med.* 1978;299:690–694.
3. Lochner HV, Bhandari M, Tornetta P III. Type-II error rates (beta errors) of randomized trials in orthopaedic trauma. *J Bone Joint Surg Am.* 2001;83:1650–1655.
4. Stata Press. *Stata Reference Manual, Release 7*. Vol 3. College Station, TX: Stata Press; 2001:166–175.
5. Horng S, Miller FG. Is placebo surgery unethical? *N Engl J Med.* 2002;347:137–139.
6. Katz J. Multidisciplinary Clinical Research Center for Spine and Upper Extremity Disorders Scientific Advisory Board Meeting, Seattle, Washington, 2002.