Eccentric Loading, Shock-Wave Treatment, or a Wait-and-See Policy for Tendinopathy of the Main Body of Tendo Achillis

A Randomized Controlled Trial

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Background: Few randomized controlled trials compare different methods of management in chronic tendinopathy of the main body of tendo Achillis.

Purpose: To compare the effectiveness of 3 management strategies—group 1, eccentric loading; group 2, repetitive low-energy shock-wave therapy (SWT); and group 3, wait and see—in patients with chronic tendinopathy of the main body of tendo Achillis.

Study Design: Randomized controlled trial; Level of evidence, 1.

Methods: Seventy-five patients with a chronic recalcitrant (>6 months) noninsertional Achilles tendinopathy were enrolled in a randomized controlled study. All patients had received unsuccessful management for >3 months, including at least (1) peritendinous local injections, (2) nonsteroidal anti-inflammatory drugs, and (3) physiotherapy. A computerized random-number generator was used to draw up an allocation schedule. Analysis was on intention-to-treat basis.

Results: At 4 months from baseline, the Victorian Institute of Sport Assessment (VISA)-A score increased in all groups, from 51 to 76 points in group 1 (eccentric loading), from 50 to 70 points in group 2 (repetitive low-energy SWT), and from 48 to 55 points in group 3 (walt and see). Pain rating decreased in all groups, from 7 to 4 points in group 1, from 7 to 4 points in group 2, and from 8 to 6 points in group 3. Fifteen of 25 patients in group 1 (60%), 13 of 25 patients in group 2 (52%), and 6 of 25 patients in Group 3 (24%) reported a Likert scale of 1 or 2 points ("completely recovered" or "much improved"). For all outcome measures, groups 1 and 2 did not differ significantly. For all outcome measures, groups 1 and 2 showed significantly better results than group 3.

Conclusion: At 4-month follow-up, eccentric loading and low-energy SWT showed comparable results. The wait-and-see strategy was ineffective for the management of chronic recalcitrant tendinopathy of the main body of the Achilles tendon.

Keywords: Achilles pain; tendinopathy; eccentric loading; shock wave therapy

Although Achilles tendinopathy is common and extensively studied, there are remarkably few randomized and controlled studies to clarify the causes, pathologic changes, and the optimal management of tendinopathy of the main body of the Achilles tendon.

In a recent Cochrane review,[16] only 9 clinical trials for a total of 697 patients were of sufficient quality to be considered. The review showed weak evidence from 3 trials of a modest benefit of nonsteroidal anti-inflammatory drugs (NSAIDs) for the alleviation of acute symptoms. Low-dose heparin, heel pads, topical laser therapy, and peritendinous steroid injection produced no difference in outcome when compared with no treatment. The results of a comparison of glycosaminoglycan sulfate with an NSAID were inconclusive. Overall, there was insufficient evidence from the randomized controlled trials to determine which method is the most appropriate for managing Achilles tendinopathy.

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In contrast, several studies have demonstrated that painful eccentric calf-muscle training can be an effective treatment for noninsertional Achilles tendinopathy.[1,17,25] Fahlstrom et al[5] observed in an uncontrolled observational trial that a 12-week eccentric calf strength training led to a satisfactory outcome in 90 of the 101 Achilles tendons (89%) with chronic painful midportion Achilles tendinosis. In these patients, the amount of pain during activity, registered on the visual analog scale, decreased significantly from 6.7 to 1.0.[5]

A wait-and-see approach[27] and repetitive low-energy shock-wave therapy (SWT)[19,22-24,28] have both proven to be successful in the management of other tendinopathy conditions such as lateral epicondylopathy. A congress report of a randomized placebo-controlled pilot study investigating the use of shock waves of a high-energy flux density on Achilles tendinopathy has been promising.[2] Recently, one of us (J.P.F.) has shown that SWT with a high-energy flux density is effective for the management of chronic insertional Achilles tendinopathy.[6] To our knowledge, there have been no randomized placebo-controlled trials published until now assessing the efficiency of a wait-and-see approach or of eccentric stretching or of a repetitive low-energy shock-wave therapy protocol for midportion Achilles tendinopathy. Therefore, no references for an accepted treatment protocol for this modality and this condition can be given.

The purpose of this study was to compare the efficacy of 3 protocols—a "wait-and-see" approach, repetitive low-energy SWT, and eccentric calf strengthening—for the treatment of chronic tendinopathy of the main body of the Achilles tendon.

PATIENTS AND METHODS

We performed a randomized trial in a primary care setting, enrolling patients who had consulted one of 3 participating orthopaedic physicians for Achilles tendon complaints.

The patients were then referred to the clinic of the senior author (J.D.R.) (Table 1). In all patients, the diagnosis of tendinopathy of the main body of tendo Achillis[11] (synonymous with noninsertional or midportion Achilles tendinopathy) was confirmed by the senior author. For the purposes of this study, noninsertional Achilles tendinopathy was defined as pain over the main body of the Achilles tendon 2 to 6 cm proximal to its insertion, swelling, and impaired function. All patients enrolled had an ultrasound study that revealed local thickening of the tendon and/or irregular tendon structure with hypoechoic areas and/or irregular fiber orientation.

Inclusion criteria for the study were an established diagnosis of chronic midportion Achilles tendinopathy for at least 6 months before treatment and failure of nonoperative management. A "wash-out" period of 12 weeks was required between any nonoperative therapy and inclusion in the study. All patients included had undergone a combination of at least one peritendinous injection of a local anesthetic and/or corticosteroid, a trial of anti-inflammatory medications, use of orthotics and/or a heel lift, and physiotherapy. Patients were to be 18 to 70 years old, able to complete questionnaires, and able to give informed consent.

We excluded from the study patients who had received peritendinous injections of a local anesthetic and/or corticosteroid within the last 4 weeks, patients with bilateral Achilles tendinopathy, patients in whom symptoms were present for <6 months, and patients with other conditions that could significantly contribute to posterior ankle pain (osteoarthrosis, inflammatory arthritides, radiculopathy, systemic neurologic conditions, etc). Patients were also excluded if they had congenital or acquired deformities of the knee and ankle, prior surgery to the ankle or the Achilles tendon, prior Achilles tendon rupture; and/or if they had prior dislocations or fractures in the area in the preceding 12 months.

Study Protocol

An assistant who was not directly involved in the management of the patients checked all selection criteria and enrolled 75 patients. Informed consent was obtained. The local medical ethics committee had approved the protocol.

A computerized random-number generator was used to formulate an allocation schedule. Block randomization (permuted blocks of 3) was implemented. The assignment of patients to eccentric loading, shock-wave therapy, or a wait-and-see policy took place after final selection and baseline assessment by the senior author. A medical assistant allocated interventions via opaque sealed envelopes marked according to the allocation schedule (Figure 1). The medical assistant was unaware of the size of the blocks.

Patients were asked to avoid pain-provoking activities throughout the 12-week treatment period. Walking and bicycling was allowed if it could be performed with only mild discomfort or pain. Light jogging on flat ground and at a slow pace was allowed after 4 to 6 weeks, but only if it could be undertaken without pain. Thereafter, activities could be gradually increased if no severe tendon pain occurred.

Methods of Treatment

Eccentric training. Our eccentric loading exercise program is based on previous work,[5,26] and is outlined below.

Patients were instructed on how to perform the eccentric training. The senior author demonstrated how to perform the eccentric exercises to each patient on an individual basis. Patients were given practice instruction and a written manual on how to progress. Proper form and technique were assessed by a medical assistant after 6 weeks. In the beginning, the loading consisted of the body weight. The patients were standing with all their body weight on the injured leg. From an upright body position and standing with all body weight on the forefoot, with the ankle joint in plantar flexion, the calf muscle was loaded by having the patient lower the affected limb down by dorsiflexing the ankle until the plantar aspect of the heel lay below the level of the step, and the ankle was in maximum dorsiflexion. The exercises were performed with the knee straight to eccentrically load the gastrocnemius, and flexed to eccentrically load the soleus. Patients were only loading the calf muscle eccentrically; no following concentric loading was performed, as the patients

TABLE 1
Baseline Characteristics of Patients[a]

Characteristic	Group 1 Eccentric Training (n 25)	Group 2 SWT (n 25)	Group 3 Wait and See (n 25)
Age, mean (SD), y	48.1 (9.9)	51.2 (10.3)	46.4 (11.4)
Women, no. (%)	16 (64)	14 (56)	16 (64)
Duration of symptoms, mean (SD), mo	10.9 (7.7)	12.5 (6.8)	9.2 (10.5)
Nonathletic patients, no. (%)	16 (64)	18 (72)	18 (72)
Athletic patients, no. (%)	9 (36)	7 (28)	7 (28)
Affected foot, no. (%)			
Left	12 (48)	10 (40)	14 (56)
Right	13 (52)	15 (60)	11 (44)
Previous treatment, no. (%)			
NSAIDs	25 (100)	25 (100)	25 (100)
Physical therapy	25 (100)	25 (100)	25 (100)
Orthotics	25 (100)	25 (100)	25 (100)
Stretching exercises	25 (100)	25 (100)	25 (100)
Injections	25 (100)	25 (100)	25 (100)
≥2 cortisone injections	16 (64)	12 (48)	10 (40)
SWT	4 (16)	1 (4)	1 (4)
Surgery	0 (0)	0 (0)	0 (0)
VISA-A score [0-100], mean (SD)	50.6 (11.5)	50.3 (11.7)	48.2 (9.0)
General assessment, Likert [1-6], mean (SD)	5.3 (0.8)	4.8 (0.9)	4.8 (0.8)
Load-induced pain, NRS [0-10], mean (SD)	7.0 (0.8)	6.8 (0.9)	7.9 (0.6)
Pain threshold, kg, mean (SD)	1.5 (0.6)	1.4 (0.8)	1.6 (0.8)
Tenderness at 3 kg, NRS [0-10], mean (SD)	7.1 (3.6)	6.4 (4.4)	6.8 (3.1)
AP diameter of Achilles tendon of affected leg [mm], mean (SD)	12.8 (4.1)	11.8 (4.7)	11.3 (3.8)
AP diameter of Achilles tendon of unaffected leg [mm], mean (SD)	5.3 (2.1)	5.5 (1.7)	5.9 (2.0)

[a]AP, anteroposterior, NSAIDs, nonsteroidal anti-inflammatory drugs; NRS, numeric rating scale; SD, standard deviation; SWT, shock-wave therapy.

were instructed to use the noninjured leg and/or the arms to get back to the start position. Patients aimed to complete 3 sets of 15 repetitions with 1 minute rest between the sets twice a day, 7 days per week for 12 weeks. Patients started with 1 set of 10 repetitions in the first day of exercises and gradually progressed to 3 sets of 15 repetitions by the seventh day, aiming to complete 3 sets of 15 repetitions twice a day by the second week of treatment. Patients were advised to continue the exercises through mild or moderate pain, stopping only if the pain became unbearable. Patients started to load the calf muscles with their body weight. When the exercise could be completed with no pain or discomfort, they progressed to using a rucksack with 5 kg of books. They were invited to continue to add weight in multiples of 5 kg if they did not experience pain in the Achilles tendon by the end of the third set of the eccentric exercises. Patients were asked to refrain from other forms of physical therapy intervention, not to use insoles, and not to take NSAIDs.

Shock-wave therapy. Patients received SWT from the senior author. A radial shock-wave device (EMS Swiss DolorClast, EMS Electro Medical Systems, Munich, Germany) was used (Figure 2). A projectile in a handpiece is accelerated by a pressurized air source and strikes the 15-mm-diameter metal applicator. The energy generated is transmitted to the patient's skin as a shock wave through a standard commercially available ultrasound gel. The wave then disperses radially from the application site into the tissue to be treated. The energy generated depends considerably on the working pressure to which the device has been set. The treatment took place in 3 sessions at weekly intervals. At each session, 2000 pulses were applied with a pressure of 3 bars (equals an energy flux density of 0.1 mJ/mm^2). The treatment frequency was 8 pulses/sec. Using the principle of clinical focusing, we treated the area of maximal tenderness in a circumferential pattern, starting at the point of maximum pain level. No local anesthesia was applied.

Wait-and-see policy. Patients allocated to the wait-and-see group visited their orthopaedic physician once again during the intervention period of 12 weeks. Training modifications, implementation of stretching exercises, and ergonomic advice were discussed with the patient. If necessary, paracetamol (2000 to 4000 mg daily) or NSAIDs (naproxen 1000 mg daily) were prescribed. Patients were encouraged to await further spontaneous improvement.

Details of the content of each treatment session and of any adverse effects were reported on standardized forms and given to the medical assistant. All co-interventions during the 4-month follow-up period were discouraged, but prescription of pain medication if necessary was allowed.

Figure 1. Flow chart of the trial through the main follow-up at 16 weeks from baseline.

Outcome Assessment

Acknowledging that midportion Achilles pain has a noninflammatory characteristic, and embracing the tendinopathy paradigm propagated by Khan et al,[10] we accepted the need to allow time for collagen turnover and remodeling. The main follow-up was accordingly chosen no sooner than 4 months from baseline. Observer-blinded outcome assessments therefore were performed before randomization and at 16 weeks after baseline assessment (Table 2).

VISA-A score. At each visit, every patient completed a pain score validated for Achilles tendon problems (VISA-A).[14,20] The VISA-A questionnaire contains 8 questions that cover the 3 domains of pain (questions 1 through 3), function (questions 4 through 6), and activity (questions 7 and 8). Questions 1 through 7 are scored out of 10, and question 8 carries a maximum of 30. Scores are summed to give a total out of 100. An asymptomatic person would score 100. For question 8, participants must answer only part A, B, or C. If the participant has pain when undertaking

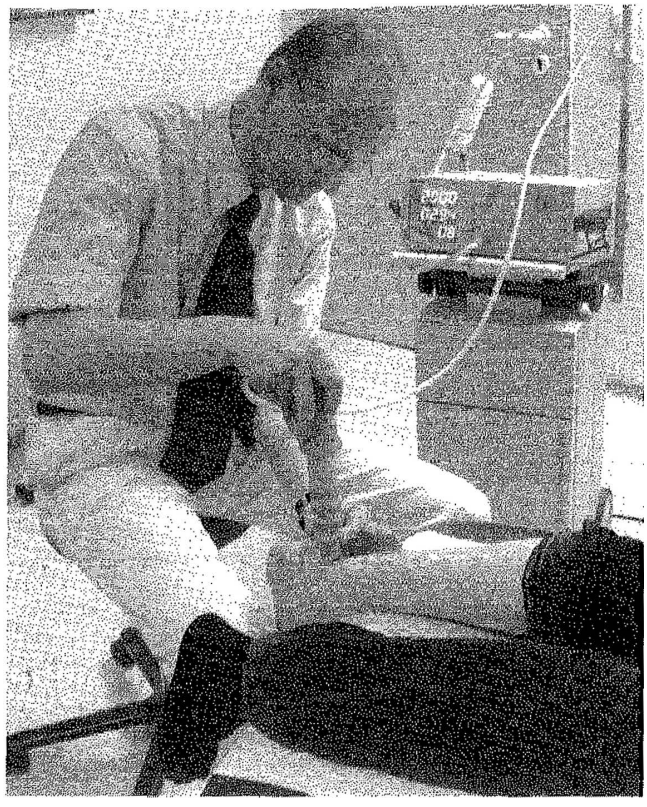

Figure 2. Application of shock-wave treatment.

sport, he or she automatically loses at least 10, and possibly 20, points.

General assessment. General assessment was scored by the patient on a 6-point Likert scale, which measures the extent to which a person agrees or disagrees with a statement. The scale used was 1 to 6, with 1 being completely recovered; 2, much improved; 3, little improved; 4, unchanged; 5, a little worse; and 6, much worse compared with baseline.[27,32] For the computation of success rates, patients who rated themselves 1 (completely recovered) or 2 (much improved) were counted as successes.

Pain assessment. Patients also scored the severity of their main complaint, pain during the day, and inconvenience on an 11-point numeric rating scale (NRS; 0 = no pain to 10 = very severe pain).

An algometer (Pain Test Model FPK, Wagner Instruments, Greenwich, Conn) was used as a measuring device that allows subjective assessment of pressure pain threshold and tenderness using a 1-cm^2 tip. Pain threshold was defined as the minimum pressure that induced pain in the most tender area of the thickened Achilles tendon. Tenderness was defined as the pain rating on the NRS at a pressure of 3 kg applied to the most tender area of the thickened Achilles tendon.

Finally, the use of analgesics and all consultations with family doctors, physiotherapists, and other health-care providers were reported every week in a diary kept by the patient. The diaries were collected and checked by the administrative assistant during the subsequent visit to the research center. The assistant was unaware of the allocated intervention. Before assessment, patients were asked by the assistant not to reveal any information about their treatment.

Sonography

Ultrasound was performed with a linear transducer (Sonoline Prima, Siemens, Erlangen, Germany) at 7.5-MHz frequency at inclusion and 4 months later. The examinations were performed with the patient in a prone position with both feet free from the examination table to enable movement of the feet. The Achilles tendons were examined in longitudinal and transverse planes. It was important to examine the tendons parallel with the fibers in the longitudinal plane and perpendicular in the transversal plane to minimize artefacts. Both tendons were always examined in the same manner. The pathologic changes in the painful thickened Achilles tendon were registered. The maximum anteroposterior diameter of the thickened tendon was recorded.

Crossover

The ethical committee involved insisted on giving patients the possibility to cross over to the other groups or to choose any other therapy they wished when not reporting a Likert scale rating of 1 or 2 after 4 months. Patients were informed accordingly and gave consent. When not fulfilling the success criterion, they were informed about the 2 other treatment regimens. They could choose to have one therapy or a combination of both therapies. Of course, if the patient wanted, other treatments were offered as well, such as injections or surgery.

Power of the Study

We calculated that the number of subjects to treat was 25 for each group. This sample size accounted for a 10% loss to follow-up, a type I error rate of 0.05, and a power of 0.8. The assumptions of a delta of 3.0 points in pain rating on the NRS and a standard deviation of 2.0 were conservatively based on the data of previous studies.[5,19,27]

Statistical Analysis

The primary aim of this study was to compare the clinical outcome after eccentric training, after repetitive low-energy SWT without local anesthesia, and after a wait-and-see policy. The primary efficacy end point was prospectively defined as improvement of the VISA-A score from baseline to month 4.

Changes in scores over time for every patient were calculated by subtracting the results at baseline from those at follow-up. The main analysis was performed on an intention-to-treat basis.

Summarizations were performed separately for each management group. Descriptive statistics are reported. Continuous variables were summarized within management groups using mean, standard deviation, median, and range. Categorical variables were summarized within management groups using mean and percent.

TABLE 2
Outcome Assessment at 4-Month Follow-up[a]

Outcome Measure	4 Months Mean (SD; Range)			Between-Group Difference Mean (95% CI)		
	Group 1 Eccentric Stretching	Group 2 SWT	Group 3 Wait and See	Group 1 vs Group 2	Group 1 vs Group 3	Group 2 vs Group 3
VISA-A score [0-100]	75.6 (18.7; 28-100)	70.4 (16.3; 34-100)	55.0 (12.9; 35-82)	5.2 (–3.9-14.3) $P = .259$	20.6 (12.3-28.9) $P < .001$	15.4 (7.8-23.0) $P < .001$
Likert scale [1-6]	2.7 (1.5; 1-6)	2.9 (1.5; 1-6)	4.3 (1.6; 1-6)	–0.2 (–1.0-0.5) $P = .557$	–1.6 (–0.8-2.4) $P < .001$	–1.4 (–2.2—0.6) $P = .001$
Load-induced pain, NRS [0-10]	3.6 (2.3; 0-8)	4.0 (2.2; 0-8)	5.9 (1.8; 3-9)	0.5 (–0.8-1.6) $P = .494$	2.4 (1.3-3 5) $P < .001$	2.0 (1.0-3.0) $P < .001$
Pain threshold [kg]	3.1 (1.1; 1.4-4.2)	2.8 (0.9; 1.5-4.0)	2.1 (1.0; 0.8-3.4)	0.4 (-0.1-0.9) $P = .181$	1.0 (0.5-1.5) $P < .001$	0.7 (0.2-1.2) $P = .008$
Tenderness	1.7 (3.9; 0-5)	2.6 (4.2; 0-5)	4.3 (7.0; 0-9)	–0.9 (–2.9-1.2) $P = .393$	–2.6 (–5.5-0.3) $P = .076$	–1.7 (–4.7-1.3) $P = .260$

[a]CI, confidence interval; NRS, numeric rating scale; SD, standard deviation; SWT, shock-wave therapy.

For comparison of mean improvement of the VISA-A score and the NRS assessed at 4 months from baseline, analyses used the Wilcoxon test (Graphstat, Graphpad Inc, San Diego, Calif). For comparison of the number of patients who reached at least 50% improvement in pain, the Wilcoxon test was performed. Differences in improvement between the groups for continuous outcomes were analyzed by one-way analysis of variance.

In accordance with the CONSORT statement for reporting randomized trials, all statistical analyses were done on an "intention-to-treat" basis to avoid overestimation of clinical effectiveness. All patients were included for statistical calculations, regardless of the treatment actually received and regardless of subsequent withdrawal or deviation from the protocol, ie, loss to follow-up. Missing responses (2 of 25 in group 1, 1 of 25 in group 2, 2 of 25 in group 3) were imputed as the last observation carried forward. The last observation was defined as the last observed value before the initial management, ie, in cases lost to follow-up. It was supposed that there was no improvement from the basic evaluation.

RESULTS

By the end of the study (4-month follow-up), 5 patients were lost to follow-up. One patient from each group (group 1, eccentric loading; group 2, SWT; Group 3, wait and see) reported that pain completely disappeared after the intervention and they refused to attend for further review. Two patients (1 from group 1 and 1 from group 3) discontinued the intervention because of persisting pain after the 6-week evaluation. For these 5 patients, outcome analysis was completed using the last set of data provided by each patient.

Of 25 patients in the wait-and-see group, 19 reported to have used paracetamol or naproxen.

VISA-A Score

The VISA-A showed no significant difference before interventions in all groups (group 1, 50.6% ± 11.5%; group 2, 50.3% ± 11.7%; group 3, 48.2% ± 9.0%). At the 4-month follow-up, group 1 and group 2 showed significantly better results (all $P < .01$) than before management (group 1, 75.6% ± 18.7%; group 2, 70.4% ± 16.3%; group 3, 55.0% ± 12.9%). Patients from group 1 and group 2 achieved significantly better results than patients from group 3 (all $P < .001$; power = 0.99). There was no statistically significant difference between the results of group 1 patients and group 2 patients (P .259; power = 0.13) (Table 2).

General Assessment

Fifteen of 25 patients (60%) in group 1, 13 of 25 patients (53%) in group 2, and 6 of 25 patients (24%) in group 3 reported a 1 (completely recovered) or 2 (much improved) on the Likert scale. Patients from group 1 and from group 2 achieved significantly better results than patients from group 3 ($P < .001$; $P = .001$). The remaining patients could not return to their normal levels of activity, as pain significantly interfered with daily activities at 4-month follow-up.

Pain

The results of load-induced pain assessment showed no significant difference before interventions in all groups (group 1, 7.0 ± 0.8; group 2, 6.8 ± 0.9; group 3, 7.9 ± 0.6). At the 4-month follow-up, all groups showed better results than before management (group 1, 3.6 ± 2.3; group 2, 4.0 ± 2.2; group 3, 5.9 ± 1.8). Patients from groups 1 and 2 achieved significantly better results than patients from group 3 (all $P < .001$) (Table 2). Improvements from the pretreatment level were statistically significant in all groups (all $P < .001$).

Pain Threshold

At the beginning of the study, pain threshold values were not significantly different in all groups (group 1, 1.5 ± 0.6 kg; group 2, 1.4 ± 0.8 kg; group 3, 1.6 ± 0.8 kg). At the 4-month follow-up, all groups showed a higher mean pain threshold than before management (group 1, 3.1 ± 1.1 kg; group 2, 2.8 ± 0.9 kg; group 3, 2.1 ± 1.0 kg) (Table 2). Patients from groups 1 and 2 achieved significantly better results than patients from group 3 ($P < .001$; $P = .008$). Improvements from the pretreatment level were statistically significant in groups 1 and 2 (all $P < .001$).

Tenderness

Assessment of tenderness on the NRS showed no significant difference before interventions in all groups (group 1, 7.1 ± 3.6; group 2, 6.4 ± 4.4; group 3, 6.8 ± 3.1). At the 4-month follow-up, all groups showed better results than before management (group 1, 1.7 ± 3.9; group 2, 2.6 ± 4.2; group 3, 4.3 ± 7.0). Improvements from the pretreatment level were statistically significant in all groups (all $P < .001$) (Table 2). Intergroup differences were not statistically significant.

Tendon Diameter

At the 4-month follow-up, no group showed significant changes of the dimensions of the Achilles tendon of the affected leg compared with baseline ultrasound measurement.

Side Effects

There were no serious complications. In all patients, transient reddening of the skin occurred after low-energy SWT, but no bruising was seen. No device-related complications occurred. Patients reported ache in the calf after eccentric loading, but none had to interrupt the eccentric load training regimen because of this. There were no drug-related complications in group 3. During the study period, no patient sustained a rupture of the Achilles tendon.

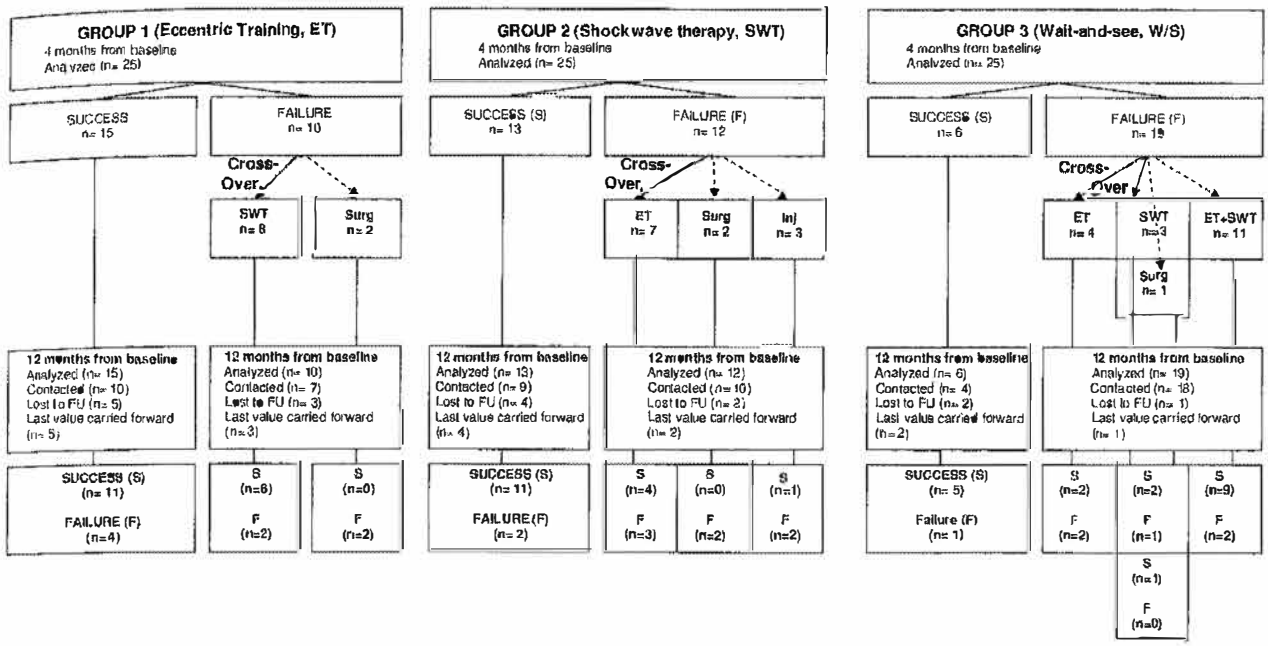

Figure 3. Breakdown of the 12-month follow-up by Likert scale success criterion. Surg, surgery; FU, follow-up; Inj, injection. S, success (Likert scores 1 or 2); F, failure (Likert scores 3 to 6).

Further Follow-up

The ethical committee involved insisted on giving patients the possibility to cross over to the other groups or to choose any other therapy they wished when not reporting a Likert scale rating of 1 or 2 after 4 months.

Fulfilling this criterion, 8 of 10 patients (group 1), 7 of 12 patients (group 2), and 7 of 19 patients (group 3) decided to cross over as planned after 4 months. Eight patients from group 1 then received SWT, 7 patients of group 2 then performed eccentric training, 4 patients from group 3 performed eccentric training, and 3 patients from group 3 received SWT. From the other patients, 5 decided for open surgery (2 from group 1, 2 from group 2, and 1 from group 3). Three patients from group 2 preferred another injection therapy with corticosteroids; 11 patients from group 3 favored SWT while performing eccentric training.

At 12 months from baseline, 38 patients were examined clinically, 18 were contacted on the telephone, and 19 patients were lost to follow-up. The 12-month follow-up Likert scores are shown on-intention-to-treat in Figure 3.

DISCUSSION

The causes and pathogenesis of chronic Achilles tendon pain are unknown. Even though tendon biopsies show an absence of inflammatory cell infiltration, anti-inflammatory agents (NSAIDs, corticosteroidal injections) are commonly used.[12,16] Management remains difficult. Evidence for the effectiveness of any available drug management regimen is at best controversial when tested in randomized controlled trials.[16]

Scandinavian researchers demonstrated that painful eccentric calf muscle training gives excellent short-term results in up to 89% of patients with chronic painful tendinopathy of the main body of tendo Achillis,[1,5,17,25] although these results have recently been challenged.[26] Good clinical results were associated with decreased tendon thickness and a structurally more normal tendon with no remaining neovessels.[1]

Experimentally, low-energy SWT stimulates soft tissue healing and inhibits pain receptors.[7-9,18,31] Effects after repetitive application were significantly greater than after single application. Low-energy SWT also enhances angiogenesis.[3,33,34] Clinically, SWT has rarely been tested for chronic Achilles tendinopathy in a randomized controlled setting. Astore et al[2] performed a prospective, randomized, double-blind, placebo-controlled clinical trial to test the efficacy of repetitive high-energy SWT at weekly intervals for 3 weeks in a total of 102 patients. At 6 months of follow-up, the authors reported a good or fair result in 38 of 51 (75%) of patients in the SWT group. In the placebo group, there were 21 of 51 (41%) good or fair results. Costa et al[4] performed a double-blind, randomized, placebo-controlled trial in 49 patients with insertional and noninsertional Achilles tendinopathy and found no difference in pain relief between the high-energy SWT and the control group. The study design was criticized[21] for using a management protocol previously shown to be ineffective.[29,30]

In the current study, both eccentric loading and repetitive low-energy SWT led to a successful outcome in 50% to 60% of patients. This is absolutely within the range of results of surgery, as recently reported from our group on 48 nonathletic patients with chronic Achilles tendinopathy.[13] Only

25 patients (52%) reported an excellent or good result. Nine patients underwent further surgery, and the remaining patients could not return to their normal levels of activity.

In the current trial, SWT and eccentric calf muscle training produced comparable results, and both management modalities showed outcomes superior to the wait-and-see policy applied. There were no significant complications associated with SWT or eccentric strengthening, and the outcomes achieved were comparable with those reported from our group in the most recent surgical trial.[13]

This trial has some limitations. Having been designed pragmatically in a primary-care setting, implementation of a blinded and unbiased assessment of outcome was difficult. The independent observer may have become aware of the treatment being received by patients in some instances. However, as the assistant was not directly involved in the management of patients, it is unlikely that this would have biased the results.

Another potential weakness is the relatively small number of patients included. Nevertheless, as estimated before, power was excellent for comparison of eccentric loading or SWT with a wait-and-see policy. A posteriori, we found that power was weak for comparison between eccentric loading and SWT. To reach a power greater than 80%, a sample size of 140 patients per group would be required to allow an adequate statistical analysis. For logistical and practical reasons, we doubt that this would be feasible.

Practically, the wait-and-see policy in the present study was the most convenient procedure, as it was uncomplicated to implement. However, it turned out to be the least effective.

Eccentric training was inexpensive, but is somewhat technique-dependent. The results observed from our group were less convincing than those reported from Scandinavia,[1,5,17,25] which may be a result of a selection of mostly athletic patients in those trials.

Recent improvements in technology have helped make SWT a less expensive and quicker procedure than in the past. Radial shock-wave generating devices, in particular, are now much less expensive to purchase and operate. A single SWT session takes only about 10 minutes and is now an affordable option for most patients.

Overall, the roles of eccentric loading and of SWT in the management pathway of tendinopathy of the main body of the Achilles tendon are yet to be defined. After the present study, we leave the choice of the modality up to our patients. We acknowledge that, in an environment where cost containment is considered, primary implementation of an SWT regimen instead of eccentric exercise may be considered an inappropriate allocation of resources. From an economic standpoint, consideration should be given to a sequential approach to the problem, whereby SWT is used in patients who have failed an eccentric exercise loading program. For patients who are striving for as quick and reliable a relief of chronic symptoms and return to full activity as possible, it might be wise to combine both management strategies. The patients start with the eccentric loading program and after 6 weeks, if progress is limited, SWT is applied as described. Patients then go on to complete the remainder of the eccentric loading program.

CONCLUSION

Spontaneous recovery after more than 6 months of symptoms of tendinopathy of the main body of the Achilles tendon is unlikely in the vast majority of patients. Our results show that the likelihood of recovery after 4 months was comparable after both eccentric loading and SWT, as applied. Success rates were 50%-60%.

Eccentric training or SWT should be offered to patients with chronic recalcitrant tendinopathy of the main body of tendo Achillis as an alternative to surgery. Further studies are needed to ascertain whether combined management strategies (eccentric training and SWT) will result in even higher success rates.

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