Achilles tendinopathy accounts for a substantial proportion of overuse injuries in sports and is prevalent in the workplace too. The essence of tendinopathy is a failed healing response, with haphazard proliferation of tenocytes, some evidence of degeneration in tendon cells, disruption of collagen fibers, and subsequent increase in noncollagenous matrix. Over the past few years, various new therapeutic options have been proposed for the management of tendinopathy. Despite the morbidity associated with tendinopathy in athletes, management is far from scientifically based, and many of the therapeutic options described and in common use lack hard scientific background. A recent Cochrane review showed that there was insufficient evidence from the randomized controlled trials to determine which of more than 20 methods was the most appropriate to manage Achilles tendinopathy. Despite this abundance of therapeutic options, very few randomized,
prospective placebo-controlled trials exist to assist in choosing the best evidence-based management.

In the hands of one group of authors, a program of eccentric exercise is effective in the symptomatic nonoperative management of tendinopathy, probably by promoting collagen fiber cross-linkage formation within the tendon, thereby facilitating tendon remodeling. Although evidence of actual histological adaptations after an adapted program of eccentric exercise is lacking, and the mechanisms by which a program of eccentric exercise may help to resolve the pain of tendinopathy remain unclear, clinical results after such an exercise program appear promising. Although effective in a Scandinavian population, the results of eccentric exercises observed from other study groups were less convincing, with only up to 60% of good and excellent outcome after a regimen of eccentric training both in athletic and sedentary patients. In general, the overall trend suggested a positive effect of an exercise program, with no study reporting adverse effects.

Low-energy shock-wave treatment (SWT) to address the failed healing response of a tendon is not widely known among the medical community. The rationale for its clinical use is stimulation of soft tissue healing and inhibition of pain receptors. There is no consensus on the use of repetitive low-energy SWT, which does not require local anesthesia, and on the use of high-energy SWT, which requires local or regional anesthesia.

We have tested low-energy SWT for chronic Achilles tendinopathy using a randomized controlled trial design. Low-energy SWT and eccentric training produced comparable results, and both management modalities showed outcomes superior to a wait-and-see policy. The likelihood of recovery after 4 months was comparable after both eccentric loading and SWT, but success rates were 50% to 60%. In this study, patients who had no treatment success with a wait-and-see regimen were offered eccentric training and/or SWT. Most opted for a combination of both, and after 4 months, more than 80% reported a success, defined as reporting themselves as “completely recovered” or “much improved.”

This observation was at the basis for the current trial to compare the efficacy of 2 protocols, a combined approach of painful eccentric loading plus SWT versus painful eccentric calf strengthening alone for the treatment of chronic midportion Achilles tendinopathy.

MATERIALS 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 (Table 1). In all patients, the diagnosis of midportion tendinopathy of the Achilles tendon was ensured by the senior investigator using the following definition: 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 as follows: an established diagnosis of chronic midportion Achilles tendinopathy for at least 6 months before treatment and failure of nonoperative management. Nonoperative management included at least one injection of a local anesthetic and/or corticosteroid, a trial of anti-inflammatory medications, orthotics and/or a heel lift, and physiotherapy. Patients were 18 to 70 years old and had to be able to complete questionnaires and to give informed consent.

We excluded from the study patients who were professional athletes, patients who had received peritendinous injections (local anesthetic and/or corticosteroids) within the last 4 weeks, patients with bilateral Achilles tendinopathy, patients in whom symptoms were present for less than 6 months, and patients with other conditions that could significantly contribute to posterior ankle pain (osteoarthrosis, inflammatory arthritides, radiculopathy, systemic neurological 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 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 68 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 was implemented. The assignment of patients to eccentric loading alone or to the combined approach of eccentric loading plus SWT 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. The patients were not blinded to their treatment assignment at any point of time during the study.

Patients were asked to avoid pain-provoking activities throughout the 12-week treatment period. Walking and bicycling were allowed if it could be performed with 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 regimen (group 1). The senior author demonstrated how to perform the eccentric exercises to each patient on an individual basis, following the suggestions from Alfredson and his colleagues, however with a more gradual introduction of the exercises. Patients were given practice instruction and a written manual on how to progress. In the beginning, the loading consisted of the body weight. The patients were standing with all their body weight on their injured leg. From an upright body
position and standing with all body weight on the forefoot, with the ankle joint in plantarflexion, the calf muscle was loaded by having the patient lower the affected limb down by dorsiflexing the ankle until the heel was well below the level of the step with the ankle in maximum dorsiflexion. The exercises were performed with the knee straight to eccentrically load the gastrocnemius and with the knee flexed to eccentrically load the soleus. Patients only loaded the calf muscle eccentrically; no concentric loading was performed, as the patients were instructed to use the non-injured leg and/or their arms to get back to the start position. Patients aimed to complete 3 sets of 15 repetitions with 1 minute of rest between the sets twice a day 7 days per week for 12 weeks. Patients started with one set of 10 repetitions on 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.

When these exercises could be completed with no pain or discomfort, the patients progressed to carry a rucksack containing 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. Patients were informed that calf muscle soreness and increased pain in the Achilles insertion could appear during the first 2 weeks of eccentric training. All patients were contacted by telephone after 6 weeks to check training compliance. All patients could contact the main investigator during working hours if they had questions about the training program. After 6 weeks, the patients were told to slowly return to their previous sports/recreational activity. If necessary, paracetamol (2000-4000 mg daily) or naproxen (1000 mg daily) as prescribed.

**Eccentric training regimen plus SWT (group 2).** In group 2, patients started with the training program described above. After 4 weeks, additionally to the ongoing eccentric loading exercises, all patients received 3 sessions of SWT, following the regimen described previously. A radial shock-wave device (EMS Swiss Dolorclast, Munich, Germany) was used. A projectile in a hand piece 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 bar (equals an energy flux density of 0.1 mJ/mm²). The treatment frequency was 8 pulses per second. According to the principle of clinical focusing, the area of maximal tenderness was treated in a circumferential pattern, starting at the point of maximum pain level. No local anesthesia was applied.

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 cointerventions during the 4-month follow-up period were discouraged, but prescription of pain medication if necessary was allowed.

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**TABLE 1**
Baseline Characteristics of Patients

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Group 1 Eccentric Loading (n = 34)</th>
<th>Group 2 Eccentric Loading + SWT (n = 34)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, mean (SD), y</td>
<td>46.2 (10.2)</td>
<td>53.1 (9.6)</td>
</tr>
<tr>
<td>Women, no. (%)</td>
<td>20 (59)</td>
<td>18 (53)</td>
</tr>
<tr>
<td>Duration of symptoms, mean (SD), mo</td>
<td>13 (7)</td>
<td>16 (5)</td>
</tr>
<tr>
<td>Affected foot, no. (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Left</td>
<td>17 (50)</td>
<td>14 (41)</td>
</tr>
<tr>
<td>Right</td>
<td>17 (50)</td>
<td>20 (59)</td>
</tr>
<tr>
<td>Previous treatment, no. (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>NSAIDs</td>
<td>34 (100)</td>
<td>34 (100)</td>
</tr>
<tr>
<td>Physical therapy</td>
<td>34 (100)</td>
<td>34 (100)</td>
</tr>
<tr>
<td>Orthotics</td>
<td>34 (100)</td>
<td>34 (100)</td>
</tr>
<tr>
<td>Conventional stretching exercises</td>
<td>34 (100)</td>
<td>34 (100)</td>
</tr>
<tr>
<td>Injections</td>
<td>34 (100)</td>
<td>34 (100)</td>
</tr>
<tr>
<td>≥2 cortisone injections</td>
<td>22 (65)</td>
<td>30 (88)</td>
</tr>
<tr>
<td>SWT</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Surgery</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>VISA-A score [0-100], mean (SD)</td>
<td>50.6 (10.3)</td>
<td>50.2 (11.1)</td>
</tr>
<tr>
<td>General assessment, Likert [1-6], mean (SD)</td>
<td>5.2 (0.9)</td>
<td>4.7 (0.9)</td>
</tr>
<tr>
<td>Load-induced pain, NRS [0-10], mean (SD)</td>
<td>7.0 (0.8)</td>
<td>6.8 (1.0)</td>
</tr>
<tr>
<td>AP diameter of AS tendon of affected leg, mean (SD), mm</td>
<td>10.2 (3.5)</td>
<td>11.1 (5.3)</td>
</tr>
<tr>
<td>AP diameter of AS tendon of unaffected leg, mean (SD), mm</td>
<td>4.9 (2.0)</td>
<td>5.0 (2.3)</td>
</tr>
</tbody>
</table>

*SWT, shock-wave treatment; SD, standard deviation; NSAIDs, nonsteroidal anti-inflammatory drugs; NRS, numerical rating scale; AP, anteroposterior.*
Outcome Assessment

Acknowledging that midportion Achilles pain has a non-inflammatory origin and embracing the tendinopathy paradigm propagated by Khan et al., the need to allow time for collagen turnover and remodeling inherent in this tendinosis was accepted. The main follow-up was therefore chosen no sooner than at 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). The VISA-A questionnaire contains 8 questions that cover the 3 domains of pain (questions 1-3), function (questions 4-6), and activity (questions 7 and 8). Questions 1 to 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

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Figure 1. Flow chart of the trial until main follow-up at 4 months from baseline.
undertaking a 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 from 1 to 6. For the computation of success rates, patients who rated themselves 1 or 2 (ie, completely recovered or much improved) were counted as successes; patients who rated themselves 3 (somewhat improved), 4 (hardly improved), 5 (not improved), or 6 (worse) were rated as failures.

**Pain Assessment**

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

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.

**Power of the Study**

From preliminary data, the number of subjects to treat was calculated to be 34 for each group. This sample size accounted for a 10% loss to follow-up, a type I error rate of .05, and a power of .8. The assumption was a Δ of 15 points in the VISA-A score and a standard deviation of 20 points.

**Statistical Analysis**

The primary aim of this study was to compare the clinical outcome after eccentric training, and after eccentric training plus repetitive low-energy SWT without local anesthesia. The primary efficacy endpoint was prospectively defined as improvement of the VISA-A score from baseline to month 4. With 2 time points available for the main outcome criteria, a difference of difference model was applied.

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 treatment group. Descriptive statistics are reported. Continuous variables were summarized within management groups using mean, standard deviation, median, and range. Categorical variables were summarized within treatment groups using mean and percentage.

For the comparison of mean improvement of the VISA-A score and the NRS assessed at 4 months from baseline, analyses used the Wilcoxon test. Missing responses (3 of 34 in group 1, 4 of 34 in group 2) were imputed as the last observation carried forward. Here, last observation was defined as the last observed value before the initial treatment. For comparison of the number of patients who reached at least 50% improvement in pain, the Wilcoxon test was performed. Analysis was based on intention-to-treat. Differences in improvement between the groups for continuous outcomes were analyzed by 1-way analysis of variance.

**RESULTS**

**Follow-up**

By the end of the study (4-month follow-up), 7 patients were lost to clinical follow-up; that is, 61 patients were re-examined. One patient from group 1 (eccentric loading) and 3 patients from group 2 (eccentric loading plus SWT) reported that pain completely disappeared after the intervention, and they refused to attend for further review. Three patients (2 from group 1, 1 from group 2) discontinued the intervention because of persisting pain after the 6-week evaluation. For these 7 patients, outcome analysis was completed using the last set of data provided by each patient, that is, the original data when enrolled to the study.

**VISA-A Score**

The VISA-A score showed no significant difference before interventions in either group (group 1: 51 ± 10; group 2: 50 ± 11). At the 4-month follow-up, both groups showed better results than premanagement (group 1: 73 ± 19; group

### TABLE 2

<table>
<thead>
<tr>
<th>Outcome Measure</th>
<th>4 Months Mean (SD; range)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Group 1 Eccentric Loading Mean (SD; 90% CI)</td>
</tr>
<tr>
<td>Visa-A score [0-100]</td>
<td>73.0 (19.0; 28-100)</td>
</tr>
<tr>
<td>Likert scale [1-6]</td>
<td>2.9 (1.8; 1-8)</td>
</tr>
<tr>
<td>Load-induced pain, NRS [0-10]</td>
<td>3.9 (2.0; 0-8)</td>
</tr>
</tbody>
</table>

aSD, standard deviation; CI, confidence interval; SWT, shock-wave treatment; NRS, numerical rating scale.
2: 87 ± 16). Patients from group 1 and from group 2 differed significantly ($P = .0016$; post hoc power: .96).

**General Assessment**

Nineteen of 34 (56%) patients in group 1 and 28 of 34 patients (82%) in group 2 reported a 1 (completely recovered) or 2 (much improved) on the Likert scale. Patients from group 2 achieved significantly better results than patients from group 1 ($P = .001$). 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). At the 4-month follow-up, both groups showed better results than premanagement, and patients from group 2 achieved significantly better results than patients from group 1 (group 1: 3.9 ± 2.0; group 2: 2.4 ± 2.2) ($P = .0045$).

**Cointerventions**

All cointerventions during the 4-month follow-up period were discouraged, but prescription of pain medication if necessary was allowed. Taking naproxen or paracetamol was closely related to failure of patients. Fourteen of 15 failed patients in group 1 and 6 of 6 failed patients in group 2 requested taking the named analgesic drugs, but no other patients.

**Side Effects**

There were no serious complications. In all patients, transient reddening of the skin occurred after low-energy SWT, but no bruising. 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. During the study period, no patient sustained a rupture of the Achilles tendon.

**Further Follow-up**

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

Fulfilling this criterion, all 15 failed patients from group 1 received the combined treatment approach. Six failed patients of group 2 opted for surgical intervention. At 12 months from baseline, 43 patients were examined clinically, 17 were contacted on the telephone, and 8 patients were lost to follow-up. The 12-month follow-up Likert scores are shown on intention-to-treat in Figure 2.

**DISCUSSION**

Although there are several possible explanations for the effectiveness of eccentric exercise, none has been fully investigated, including affecting type I collagen production, increasing the tendon volume over the longer term, “lengthening” of the muscle-tendon unit having an effect on capacity of the musculotendinous unit to effectively absorb load, and alteration of neovascularization and accompanying nerves.

The modern model of eccentric training involves no concentration loading and emphasizes the need for patients to complete the exercise protocol despite pain in the tendon. If patients experience no tendon pain doing this program, the load should be increased until the exercises provoke pain. Good short- and long-term clinical results have been reported. In a Scandinavian athletic population, this 12-week program claimed to be effective when other conventional treatments had failed and was successful in approximately 90% of patients with midtendon pain. These excellent results could not be reproduced by other groups despite compliance with the same regimen.

Although the working mechanisms of low-energy SWT are still not understood completely, in animal experiments, SWT stimulated bone healing, triggered the endogenous pain control system, decreased the number of sensory free nerve endings with repetitive application exerting a cumulative effect regarding delay of reinnervation, and enhanced angiogenesis.

Costa et al. 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 used a management protocol previously shown to be ineffective.

Various level I therapeutic studies have provided evidence for a distinct management effect of SWT for tendinopathies such as lateral elbow pain and plantar heel pain under the following circumstances: (1) application of 1500 to 2000 shocks of low-energy flux density (0.08-0.15 mJ/mm²), (2) application to the site of maximal discomfort (patient guidance), (3) no local anesthesia, (4) weekly intervals (3-4 applications), and (5) at least 3 months’ follow-up after the last application (for detailed analysis, see Rompe et al). Following those recommendations, the management protocol proved to be effective also for both noninsertional and insertional Achilles tendinopathy, with success rates of 52% and 64%, respectively. Most recently, Rasmussen et al. found similar results when investigating the effects of supplementary radial SWT in enhancing recovery of Achilles tendinopathy.

While wound complications are commonly in the range of 10%, outcome after surgical intervention is far more difficult to interpret, as success rates vary between series. In a recent study from our group involving 48 nonathletic patients with chronic Achilles tendinopathy, only 25 (52%) reported an excellent or good result. As pointed out above, results after eccentric loading or SWT had been comparatively satisfying, yet without the need of reduced weightbearing and time off from work.

In the current trial, the combined approach of painful eccentric loading plus repetitively low-energy SWT produced significantly better results than eccentric calf muscle training alone. The demonstrated success rate of 82% of the combined regimen of eccentric loading plus SWT has never been observed before by the senior author in any
randomized trial assessing the effectiveness of a stand-alone SWT for any soft tissue lesion. There were no complications associated with SWT or eccentric strengthening, and the outcomes achieved were considerably better than those reported from our group in the most recent surgical trial in nonathletic patients suffering from chronic midportion Achilles tendinopathy.

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

Another potential weakness is the relatively small number of patients included. Nevertheless, power was even higher in the post hoc analysis than estimated before the study began, and the results are univocal.

Of 68 patients enrolled for this study, only 21 (9 in group 1, 12 in group 2) performed some sort of sports activity on a regular schedule, at least once a week. So the results from our study cannot be necessarily extrapolated to an athletic community.

From an economic standpoint, eccentric training was inexpensive. It is however somewhat technique dependent, which might explain why the results observed from our group were less convincing than those previously reported. Nevertheless, the senior author took great care to demonstrate the exercises in a correct fashion and to make sure that the patients were able to perform them correctly.

Also, the attention effect may play a role. The authors, however, are not aware of any controlled trial comparing the effectiveness of eccentric training in relation to the number of follow-up observations and supervisions of the patients. The effectiveness of eccentric training alone may increase with such intensive care taking as Stergioulas et al. showed recently when having patients perform eccentric exercises with supervision 4 times per week for 8 weeks.

There is, however, little consensus regarding which variables might influence the outcome of eccentric training, including whether training should be painful, home- versus clinic-based training, the speed of the exercise, the duration of eccentric training, and the method of progression. Large randomized controlled trials that consider these parameters and include blinded assessors and extended follow-up periods are required.

In the present study, the eccentric exercises were performed with the patients bearing weight fully on the affected

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**Figure 2.** Breakdown of the 12-month follow-up regarding success criteria on the Likert scale. Success, Likert scores “1” or “2.” Failure, Likert scores “3” to “6.” EL, eccentric loading; SWT, shock-wave therapy; Surg, surgery; C, examined clinically; T, contacted on telephone; FU, follow-up; F, failure.
limb. For a sedentary patient with reduced calf strength, and possibly increased weight/calf strength ratio, full weight-bearing eccentric exercises may well impose a relatively greater load on the Achilles tendon than the same exercise would in a well-conditioned athlete. Although there is some evidence that, to be effective, the eccentric load should impose pain, some individuals in our study population may have experienced loads too painful for their Achilles tendons.

Recent improvements in technology have helped make SWT a less expensive and quicker procedure. Radial shock-wave generating devices are much less expensive to purchase and operate than focused shock-wave devices depending on fluoroscopic or sonographic guidance. 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 not that of competing management options. Following the present study, the 2 regimens can be used in concert and together lead to results superior to treatment with either eccentric loading or repetitive low-energy SWT alone.

In an environment where cost containment is considered mandatory, primary implementation of an SWT regimen instead of eccentric exercise alone may be considered an inappropriate allocation of resources. For patients who are striving for as quick and reliable a relief of chronic symptoms as possible and return to full activity, it clearly is appropriate to combine both managements.

CONCLUSION

The likelihood of recovery after 4 months was higher after a combined approach of both eccentric loading and SWT compared to eccentric loading alone. Eccentric training plus SWT should be offered to patients with chronic recalcitrant midportion tendinopathy of the Achilles tendon.

REFERENCES