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PO Box 117
221 00 Lund
+46 46-222 00 00

Clinical improvement after 6 weeks of eccentric exercise in patients with mid-portion Achilles tendinopathy – a randomized trial with 1-year follow-up

Ewa M. Roos¹, Mikael Engström², Annika Lagerquist³, Bengt Söderberg²

¹Department of Orthopedics, Lund University Hospital, SE-221 85 Lund, Sweden, ²Scandinavian Orthopedic Laboratory, Helsingborg, Sweden, ³Sports Medicine Clinic, Helsingborg, Sweden
Corresponding author: Ewa Roos, PT PhD, Department of Orthopedics, Lund University Hospital, S-221 85 Lund, Sweden.
Tel: +46(708)133550, Fax: +46(46)130732, E-mail: Ewa.Roos@ort.lu.se

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Achilles tendinopathy is common and treatment with eccentric exercises seems promising. We designed a prospective randomized clinical trial to test the hypothesis that eccentric calf muscle exercises reduce pain and improve function in patients with Achilles tendinopathy. Forty-four patients were recruited from primary care (mean age: 45 years; 23 women; 65% active in sports) and randomized to three treatment groups for 12 weeks: eccentric exercises, a night splint or a combination of both treatments. Pain and function were evaluated at 6, 12, 26 and 52 weeks by the Foot and Ankle Outcome Score. At 6 weeks, the eccentric group reported a significant pain reduction (27% compared with baseline, $P = 0.007$) which lasted for 1 year (42%,

$P = 0.001$). The two groups treated with a night splint also reported significant but less pain reduction than the eccentric group. Differences between all the three groups were not significant. At 12 weeks, the eccentric group reported significantly less pain than the splint-only group ($P = 0.04$). More patients in the eccentric group than in the splint group returned to sport after 12 weeks. We conclude that eccentric exercises seem to reduce pain and improve function in patients with Achilles tendinopathy. Our results are in line with previous studies and strengthen the recommendation that patients should undergo an eccentric exercise program prior to considering other treatments such as surgery.

Achilles tendinopathy is common, especially in physically active people, and the incidence increases with age (Kvist, 1994). Suggested etiological factors include extrinsic factors such as training errors and inappropriate footwear and intrinsic factors such as inflexibility, weakness and malalignment. However, as stated previously, very few controlled studies on these issues are available (Almekinders & Temple, 1998; McCrory et al., 1999).

Treatment of Achilles tendinopathy is initially non-operative. Most commonly studied non-operative treatments include rest, equipment changes, strength and flexibility exercises, anti-inflammatory agents and corticosteroids. The results are not conclusive, and in a literature review from 1998 concerning overall tendonitis, Almekinders and Temple suggested that we have to consider the possibility that current treatment may not significantly alter the natural history (Almekinders & Temple, 1998). Alternative explanations to why the results were not conclusive include Achilles tendinopathy being of multi-factorial origin and thus one single treatment not being possible, and poor study design. In a critical analysis of studies of Achilles tendon surgery

because of tendinopathy, an inverse correlation between reported success rate and methodological score was found: the better the result the study reported the more methodological problems with the study, indicating the need for more carefully designed studies within this field (Tallon et al., 2001).

The concept of eccentric exercises as treatment for tendinopathy has been described by Stanish and coworkers and is based on the belief that tendon injuries often occur during the eccentric phase of muscle work (Stanish et al., 1986, 2000). The mechanisms behind the effects of eccentric exercise as treatment of tendinopathy are largely unknown. It has been suggested that eccentric exercises may either directly affect tendon pathology or prepare the muscle for better function (Cook et al., 2002; Khan et al., 2003). Eccentric exercises have been shown to have positive effects on Achilles tendinopathy (Alfredson et al., 1998; Mafi et al., 2001; Silbernagel et al., 2001). However, only two of these trials were randomized and controlled (Mafi et al., 2001; Silbernagel et al., 2001) and in one of them the eccentric exercises were part of a treatment package

(Silbernagel et al., 2001). To aid clinical decision making and to establish evidence of an intervention several randomized controlled trials with consistent results within different populations are needed.

Prolonged stretching with the use of a night splint is prescribed and believed to maintain passive dorsiflexion, reduce pain and morning stiffness because of Achilles tendinopathy (Schepesis et al., 2002). Night splints are also used as treatment of plantar fasciitis (Probe et al., 1999; Martin et al., 2001; Berlet et al., 2002). To our knowledge the effect of night splints on Achilles tendinopathy have not been studied.

The objective of the present study was to prospectively study the short- and long-term effects of eccentric exercises and prolonged stretching with the use of a night splint on pain and function because of Achilles tendinopathy in subjects recruited from primary care.

Materials and methods

Patients

Patients 20–60 years of age seeking medical care within primary care in Helsingborg, Sweden because of insidious onset of Achilles tendinopathy were candidates for inclusion in the study. The activity level prior to the current problems should be at least equivalent to heavy household work, heavy yard work and walking on even ground. The patients should report at least moderate pain/problems when performing physical activities, and the duration of symptoms should be more than 4 weeks. Patients who fulfilled these written inclusion criteria were referred to one examiner who randomized the patients by pulling an envelope from a box holding 60 randomly ordered envelopes, 20 for each treatment group. The examiner also did a clinical examination and verified symptoms 2–6 cm proximally of the insertion. To ensure the diagnosis, patients with symptoms localized at the insertion of the tendon were excluded.

Study design

The design was a randomized study with three treatment groups for 12 weeks: eccentric exercises, night splint or a combination of both treatments. The combined group was

added because it was hypothesized that prolonged stretching possibly could reduce muscle soreness, a well-known side-effect of eccentric exercises, and thus result in a program better tolerated by patients.

The outcome was evaluated by a patient-administered questionnaire at baseline and at 6, 12, 26 and 52 weeks after initiation of treatment.

The study protocol was approved by the Ethics Committee at the Medical Faculty at Lund University.

Eccentric exercise program

Eccentric calf-muscle exercises (3×15 repetitions with straight and bent knee) were prescribed twice daily for 12 weeks as previously described by Alfredson et al. (1998). In the study by Alfredson et al., the patients experienced severe muscle soreness during the first weeks of exercise (H. Alfredson, 1998, personal communication). To possibly diminish this initial muscle soreness, the patients in the current study were instructed to gradually increase the number of repetitions:

Days 1–2	1 × 15 repetitions
Days 3–4	2 × 15 repetitions
Days 5–7	3 × 15 repetitions

During the first week, the patients only did their exercises with extended knee. During weeks 2–12, the patients were instructed to perform 3×15 repetitions with both extended and bent knees at each exercise occasion. This gradual onset was not used by Alfredson et al. (1998).

One physical therapist instructed the patients how to perform the exercises. The exercises were carried out in a standing position with full bodyweight on the forefoot and the ankle joint in plantar flexion. The patient lowered the heel beneath the forefoot. During the eccentric part, the patient had full weight on the injured foot, and during the concentric part only the non-injured foot was used (Figs 1 and 2). When the patients could perform their exercise without discomfort they were instructed to increase the load by adding books or other weight to a backpack. Patients also received a written manual how to progress the intensity of the exercise program including contact information for the therapist and instructions to call if they had any questions. After 1 week, the patients saw the physical therapist to discuss possible problems and to check-up how the program was performed. After 6 weeks, the therapist called the patients by phone to discuss possible problems with progression of the intensity of the program.



Fig. 1. Eccentric exercises with straight knee. The affected leg (right) is marked.

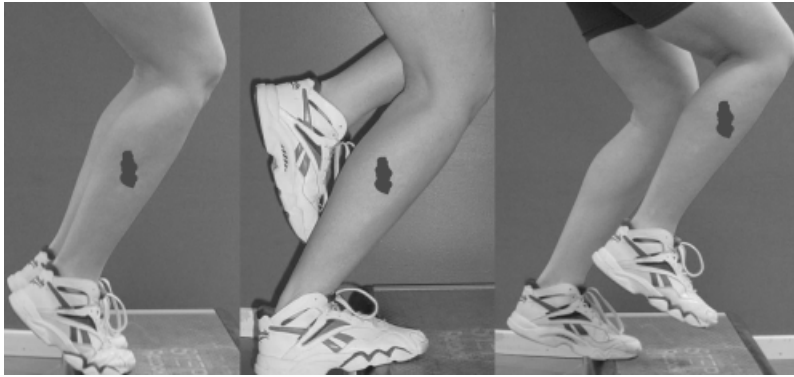


Fig. 2. Eccentric exercises with bent knee. The affected leg (right) is marked.

Night splint

An anterior night splint, thought to reduce morning pain and stiffness, holding the foot in 90° of dorsiflexion was used. Maintaining a foot position of neutral plantigrade, a 3.2 mm thickness of Omega Plus (Northcoast Medical Inc., CA, USA), a low-temperature thermoplastic, was draped directly onto the anterior lower leg and foot of each patient. Each template of material was 70 mm wide and of length equal to the measure from the tibial tuberosity to the metatarsal heads. Reinforcement was applied at the level of the anterior ankle crease prior to heating. Skin protection was afforded by stockinette (Fig. 3). Once cooled, a liner of 3 mm low-density polyethylene was added, along with four Velcro straps (Homecraft Ability One, Nottinghamshire, UK) for securing the night splint. These were placed immediately inferior to the tibial tuberosity, at the proximal malleoli, the level of the mid-tarsal joint and across the metatarsal heads (Fig. 4).



Fig. 3. The anterior night splint.

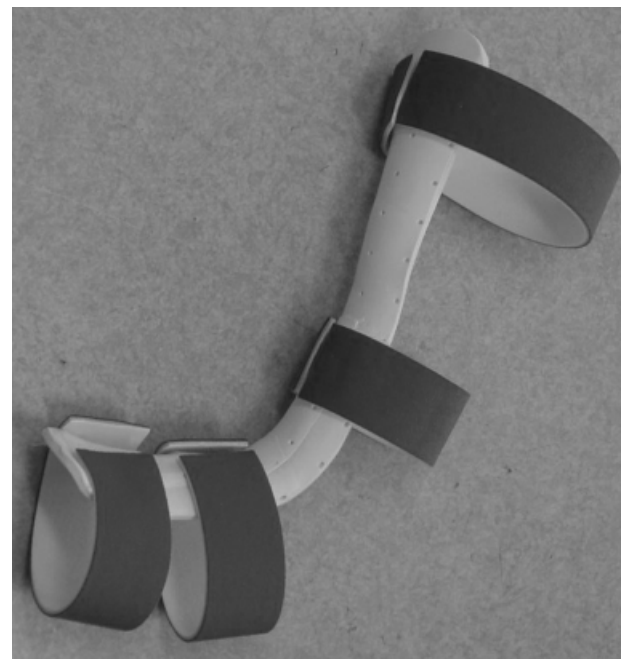


Fig. 4. The anterior night splint.

Each patient was directed on proper application of the orthosis and on its nighttime use only. Possible problems which might be encountered were also discussed.

Anterior night splints are advantageous over posterior ones, should the patient wish to get out of bed during the night, they are able to walk without first removing the orthosis. Also as a smaller surface area of the leg is covered better heat dissipation is experienced and thus led to comfort.

Daily logs

To determine compliance with the treatments and possible side-effects, the patients kept daily logs that were returned at 6 and 12 weeks, respectively. *Compliance* was assessed on a weekly basis. The eccentric exercise group was prescribed exercise 14 times a week. Good compliance was defined as reporting at least 75%, e.g., 10 exercise times a week. Recommended use of the night splint was seven nights a week. Similarly, good compliance was defined as using the night splint at least 75%, e.g., five nights a week. *Side-effects* (examples given included muscle soreness, bruising, sleep disturbances) were also evaluated on a weekly basis.

Outcome measures

Foot and ankle outcome score

Symptoms, function and foot and ankle-related quality of life were evaluated by a mailed survey, the Foot and Ankle Outcome Score (FAOS) (www.koos.nu). A formal validation has been carried out in subjects with lateral ankle ligament injury (Roos et al., 2001). The test–retest reliability was high, indicating the FAOS being an accurate measure with high ability to measure also small changes over time. The FAOS is an adaptation of the Knee Injury and Osteoarthritis Outcome Score (KOOS) (Roos et al., 1998a, b) and assesses patient-relevant outcomes in five separate subscales: Pain, Other Symptoms, Activities of Daily Living (ADL), Sport and Recreation Function, and Foot and Ankle-related Quality of Life. Pain was considered the primary outcome. A percentage score from 0 to 100 is calculated for each subscale, 100 representing the best possible score. For the KOOS, a 10% score change is considered to indicate a clinical change (Roos & Lohmander, 2003). As the subjects of the current study are of similar age and activity level to the subjects evaluated by the KOOS, we decided to apply a 10% change to indicate a clinical improvement also in the present study.

Physical activity level

Physical activity level was evaluated on a seven-grade scale from 0 to 6, 0 representing no household work, TV and reading and six representing competitive sports (Table 1). This scale has previously been used to evaluate the physical activity level of young and middle-aged patients with post-traumatic knee osteoarthritis. The reliability has been found good (Roos et al., 1999). Difficulty during sporting activities was assessed on a five-point Likert scale (no, mild, moderate, severe, extreme). For comparisons of difficulty between treatment groups, the answers were categorized into no or mild difficulty and moderate-to-extreme difficulty.

Statistics

To safely deal with protocol violations such as non-compliance and cross-over between treatments, the analyses were based on the groups as randomized, e.g., intention-to-treat analysis was used. Non-parametric statistics were used. Post-treatment change across all times was assessed by Friedman's test. When this test was significant, post-treatment change at 6, 12, 26 and 52 weeks compared with baseline was assessed by Wilcoxon's signed rank test. The Kruskal–Wallis test was used when comparing three groups and the Mann–Whitney *U*-test was used when comparing two groups. The χ^2 test was used for comparison of proportions.

Table 1. Self-reported recreational activities

Which description describes your recreational activities the best? Please mark <i>one</i> alternative.	
6	Competitive sports: soccer, racquet sports, track and field, skiing, etc.
5	Recreational sports: jogging, skiing, racquet sports, etc.
4	Golf, dancing, hiking, water aerobics
3	Heavy yard work, heavy household work, walking on even ground
2	Light yard work, light household work, shopping
1	Minimal household work, card games, sewing
0	No household work, TV, reading

A power analysis was carried out prior to the study. It was determined that totally 60 patients were needed to detect a clinically significant mean score difference of 10 points in the FAOS subscale pain between groups with 80% power and at $P = 0.05$.

Results

Patients

From September 1998 to July 2001, 44 patients (23 women) were recruited by 23 primary-care physicians and referred to one examiner. Their mean age was 46 (range, 26–60 years), 65% were active in sports prior to the current symptoms, 86% reported pain daily or always, while 14% reported having weekly pain. The median symptom duration was 5.5 months (range, 1–180 months) and 86% reported having had symptoms for more than 3 months. Eighty-four percent reported an insidious onset. The patients reporting a sudden onset had a median symptom duration of 5 months. Sixty percent reported having tried other treatments previously, often in combinations. The most common previous treatments were oral NSAIDs ($n = 12$), topical NSAIDs ($n = 10$), shoe modifications ($n = 10$), rest ($n = 9$) and physical therapy ($n = 8$). One patient, randomized to the eccentric exercise group, was operated on twice because of Achilles tendinopathy. There were no significant differences in sex, age, activity level, symptom duration or baseline status between the groups with one exception, patients randomized to the splint group reported a significantly better foot and ankle-related quality of life at baseline (Table 2). Pain and swelling 2–6 cm proximally of the Achilles tendon insertion was confirmed for all patients.

The patients were randomized to either eccentric exercises ($N = 16$), eccentric exercises and night splint ($N = 15$) or night splint only ($N = 13$). Data were available for 33 (75%) patients after treatment (12 weeks), and for 35 (80%) patients at the 1-year follow-up (Fig. 5).

Change over time within the groups

All groups improved significantly across all times ($P < 0.05$). The eccentric group reported a significant pain reduction (27% compared with baseline, $P = 0.007$) already at 6 weeks which lasted for 1 year (42% compared with baseline, $P = 0.001$). The group treated with eccentric exercises *and* night splint reported less pain reduction (18% at 6 weeks, $P = 0.14$; 22% at 12 weeks, $P = 0.008$; and 22% at 26 weeks, $P = 0.08$ compared with baseline). The group treated with night splint *only* reported the least pain reduction of the three groups (19% at 6 weeks,

Table 2. Foot and Ankle Outcome Score (FAOS) subscores (mean ± SD) on a 0–100 worst–best scale

	Pain	Symptoms	ADL	Sport/rec	QOL
<i>Baseline</i>					
Exc	60 ± 19	61 ± 12	73 ± 20	42 ± 23	33 ± 17
Exc+splint	60 ± 13	60 ± 16	70 ± 18	43 ± 20	32 ± 16
Splint	61 ± 13	58 ± 13	69 ± 18	45 ± 20	48 ± 15
<i>6 weeks</i>					
Exc	77 ± 14	70 ± 19	85 ± 14	58 ± 24	46 ± 19
Exc+splint	71 ± 14	69 ± 15	81 ± 15	54 ± 19	40 ± 16
Splint	73 ± 16	72 ± 15	78 ± 20	59 ± 26	46 ± 17
<i>12 weeks</i>					
Exc	82 ± 18	79 ± 19	90 ± 14	74 ± 20	55 ± 28
Exc+splint	74 ± 16	71 ± 18	81 ± 18	58 ± 26	48 ± 23
Splint	69 ± 20	73 ± 15	79 ± 24	57 ± 26	48 ± 19
<i>26 weeks</i>					
Exc	84 ± 18	78 ± 22	88 ± 16	70 ± 28	61 ± 32
Exc+splint	74 ± 22	68 ± 20	80 ± 21	61 ± 31	46 ± 24
Splint	72 ± 29	74 ± 23	77 ± 26	61 ± 30	54 ± 30
<i>52 weeks</i>					
Exc	86 ± 17	83 ± 20	88 ± 16	74 ± 24	65 ± 27
Exc+splint	82 ± 19	77 ± 17	86 ± 21	65 ± 32	59 ± 21
Splint	83 ± 16	79 ± 17	87 ± 17	69 ± 26	62 ± 28

ADL = activities of daily living, Sport/rec = sport and recreation function, QOL = foot and ankle-related quality of life, Exc = exercise.

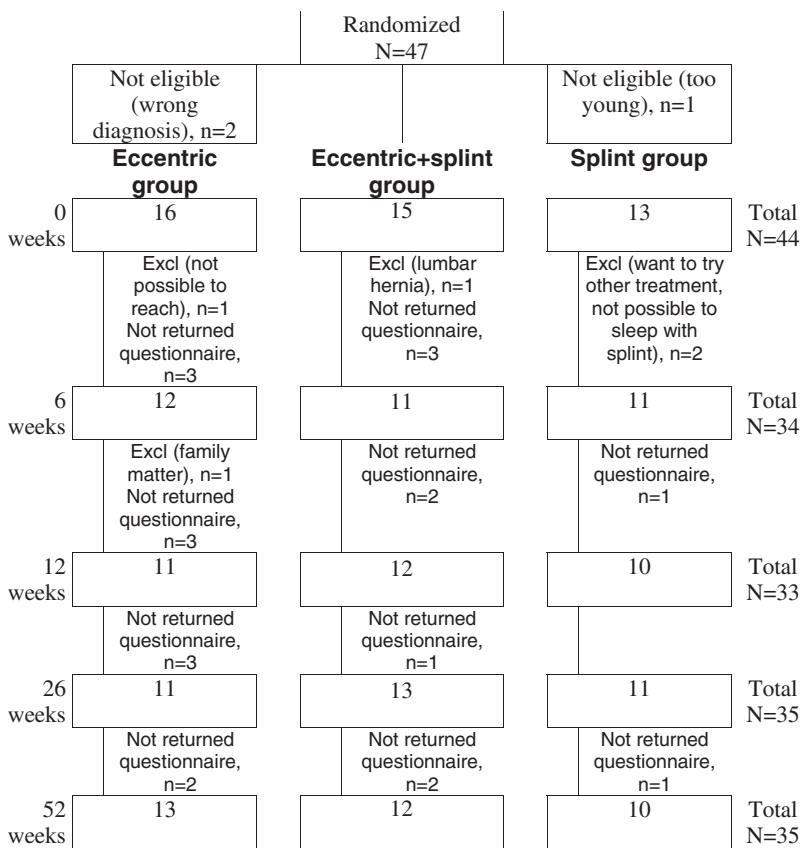


Fig. 5. Flow chart of patients in the study.

$P = 0.005$; 13% at 12 weeks, $P = 0.14$ and 17% at 26 weeks, $P = 0.14$ compared with baseline). From 26 to 52 weeks, significant improvement occurred in both groups, treated with a night splint, and at 52 weeks, all three groups reported pain reduction of 35–42%

($P < 0.001$) compared with baseline (Fig. 6). Similar results were seen for improvement in the other FAOS subscales covering other symptoms, function in daily life, sport and recreation function, and foot and ankle-related quality of life (Table 2).

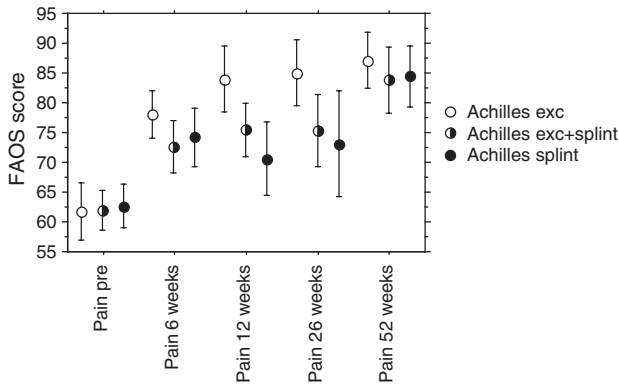


Fig. 6. Mean (± 1 SE) FAOS pain score for the different treatment groups at all different times.

Comparison between groups

No significant differences were found in pain between the three groups at any point in time ($P = 0.14-0.98$). However, clinically significant differences of more than 10 points in mean pain score in favor of the eccentric-only group compared with the splint-only group were present at 12 and 26 weeks (Table 2). When comparing the eccentric-only group and the splint-only group, the difference in pain after 12 weeks of treatment was significant (82 vs. 69, $P = 0.04$).

Physical activity level

In the eccentric group, five of eight patients active in sports prior to the onset of symptoms returned to their pre-injury activity level after 12 weeks. In the eccentric+splint group, three of eight patients returned, and in the splint group one of 10 patients had returned to sports after 12 weeks.

Difficulty during sporting activities

At baseline, more than 80% of the patients in all treatment groups reported moderate-to-extreme difficulty during sporting activities. At 12 weeks, 27% in the eccentric group compared with 58% in the splint+eccentric group and 50% in the splint group reported moderate-to-extreme difficulty during sporting activities. The numbers were similar at 26 weeks. At 52 weeks, 15% in the eccentric group compared with 54% in the splint+eccentric group and 56% in the splint group reported moderate-to-extreme difficulty during sporting activities ($P = 0.07$).

Compliance

Compliance was good (at least 75% of recommendation) for the eccentric exercises for the first weeks but

declined over time and at 12 weeks only 50% reported good compliance. The compliance with the night splint increased over the first weeks and was good for most of the study period (Fig. 7). The numbers were too small in each group to calculate the association between compliance and outcome.

Side-effects

During the first week of treatment, 33% of patients reported muscle soreness as a result of the eccentric exercises. No differences were seen between the eccentric group and the eccentric+splint group. Four patients reported pressure-related problems and two patients reported sleep disturbances because of the night splint. During week 3, one patient stopped using the night splint because of sleep disturbances. The number of patients reporting side-effects decreased over time and after week 6, no patient reported muscle soreness. One patient in the eccentric group however continued to report calf muscle stiffness throughout the study and two patients using night splints continued to have problems with pressure-related pain now and then.

Cross-over between treatments

At 12 months, 50% of the patients from the splint-only group reported having tried other treatments as compared with 15% from the groups performing eccentric exercises ($P = 0.04$). One patient from the splint group reported having tried eccentric exercises with no effect. One patient from the eccentric group reported having tried night splint with no effect. Other treatments included corticosteroids, acupuncture, ultrasound, laser, massage, new shoes, topical agents, orthotics, operation, stretching and concentric exercises. The median reported effect of these treatments was poor on a five-point scale (no effect, poor, fair, good, very good effect). Thirteen of the 33

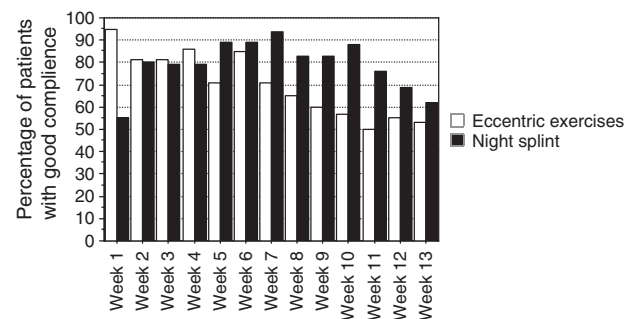


Fig. 7. Percentage of patients reporting good compliance (at least 75% of recommendation) with the eccentric exercises (unfilled bars) and the use of night splint (filled bars) during the treatment period.

patients reported continuation of the allocated treatment.

Discussion

Our randomized controlled study, including patients from primary care and using validated outcomes, confirmed previous studies showing that a home program of eccentric calf muscle exercises seem to reduce pain and improve function because of Achilles tendinopathy. This study adds information on that eccentric exercise is effective treatment of Achilles tendinopathy also in patients seeking care within the primary-care system and that the improvement seen after treatment lasts for 1 year. The patients in the present study represented a heterogeneous group with regard to age, sex, activity level and symptom duration. Previous studies have recruited patients referred to surgical treatment (Alfredson et al., 1998; Mafi et al., 2001) and by mailings to clinics and sports clubs (Silbernagel et al., 2001) yielding patients more frequently involved in sports and with a longer symptom duration. Repeated studies yielding similar results in different populations strengthen the evidence of eccentric exercises as a good treatment for most subjects with Achilles tendinopathy.

Pain reduction was seen already at 6 weeks as compared with 12 weeks in previous studies (Alfredson et al., 1998; Mafi et al., 2001; Silbernagel et al., 2001). The results lasted for 1 year. Other evaluated parameters supporting eccentric exercises being superior to treatment with a night splint indicated that more patients in the eccentric groups than splint-only group returned to sport after treatment, and that fewer patients in the eccentric groups compared with the splint-only group reported having tried other treatments during the 1-year follow-up.

Also the night splint group reported a significant, yet smaller, initial reduction in pain. The effect was highest at 6 weeks and less at 12 and 26 weeks (Fig. 6). We suggest interpreting this initial pain reduction as a placebo effect. Improvement was seen between 6 and 12 months which could be interpreted as the benign natural course of tendinopathy. The long-term prognosis on subjective outcomes of Achilles tendinopathy is favorable (Paavola et al., 2000).

Power of the study

We were, despite a close to 3-year recruitment period involving more than 20 primary-care physicians, not able to recruit the 60 patients needed to show statistical significance when clinically significant

differences between the groups were present. We found mean score differences of at least 10 points, considered clinically relevant, in favor of the eccentric group for pain and ADL function at 12 and 26 weeks, and for Sport and Recreation function at 12 weeks. Only the difference in pain at 12 weeks was statistically significant. Previous studies on eccentric exercise in Achilles tendinopathy have recruited a similar number of patients (Mafi et al., 2001; Silbernagel et al., 2001), possibly indicating a general difficulty in recruiting patients with Achilles tendinopathy. To increase power with a set number of patients, in theory, we could have chosen a control treatment with less expected effect, used more responsive outcome measures, or used only two treatment groups. It was regarded important to choose a control treatment with the same amount of attention for two reasons: to measure the effect of the exercise program as opposed to attention, and to minimize the drop-out rate. At the study center, night splints were increasingly prescribed and thought useful for reduction of pain and morning stiffness as a result of Achilles tendinopathy.

The questionnaire used for assessment of patient-relevant outcomes in this study has been found sensitive enough to detect treatment differences between small groups undergoing non-surgical treatment because of knee complaints (Colker et al., 2002; Braham et al., 2003). Recently, the reliability and validity of a new outcome measure specific to Achilles tendinopathy has been published (Robinson et al., 2001). This instrument was, however, not available when our study started.

Future studies should recognize the difficulty in recruiting patients with chronic Achilles tendinopathy and consider a multi-center design.

Muscle soreness

The reason for combining eccentric exercises with the use of a night splint in a third group was to decrease muscle soreness, a commonly reported side-effect of eccentric exercises (Lee et al., 2002). Muscle soreness was thought to be reduced by stretching. This belief was however not supported by either the results of our study or the recent literature. In our study, the same number of patients in both groups performing eccentric exercise, with and without prolonged stretching by the use of a night splint, reported muscle soreness. In a recent systematic review of the literature it was concluded that stretching before or after exercising does not confer protection from muscle soreness (Herbert & Gabriel, 2002). To improve compliance with the treatment, it is important to inform the patients that muscle

soreness is to be expected when initiating the program. However, by inclusion of the combined treatment group, we found that the use of a night splint (prolonged stretching) seems to weaken (modulate) the effect of eccentric exercises. This finding leads to speculations about the underlying mechanisms behind the positive effects of eccentric exercises on tendinopathy.

Underlying mechanisms of eccentric exercise

The mechanisms behind the positive effects of eccentric exercises as treatment for tendinopathy are largely unexplained. Previously, inflammation was assumed to produce tendon pain. This assumption is, however, contradicted by many (Puddu et al., 1976; Astrom & Rausing, 1995; Movin et al., 1997). More recently, mechanical and biochemical models have been suggested to explain tendon pain. Pain is suggested to originate from either mechanical discontinuity of collagen fibers or biochemical irritation that results from damaged tendon tissue activating nociceptors (Khan & Cook, 2000). In the present study, eccentric exercises alone were associated with larger pain reduction than eccentric exercises combined with prolonged stretching by a night splint. This finding suggests a modulating effect of prolonged stretching on the positive effects on pain of eccentric exercises. One parameter suggested to change in different directions when the muscle-tendon complex is subjected to eccentric exercises as opposed to stretching is stiffness of the muscle-tendon system. When moving a joint to a position that lengthens the muscle-tendon complex, the tissues resist the change in length. The ratio of the change in resistance to the change in length refers to the stiffness of the system (McNeil-Alexander, 1983). It is suggested that eccentric exercises improve muscle-tendon stiffness (Porter et al., 2002) and that stretching reduces muscle-tendon stiffness (Kubo et al., 2001; McNair et al., 2001; Cornwell et al., 2002). Moreover, muscle-tendon stiffness decreases with age (Kubo et al., 2003) as the incidence of Achilles tendinopathy increases (Kvist, 1994). We suggest exploring the possibility that stiffness in the muscle-tendon complex may play a part in Achilles tendinopathy and the positive effects seen of eccentric exercise.

Suggested methodology for clinical studies on Achilles tendinopathy

Poor methodology is one suggested reason for the weak evidence for treatment of tendinopathy (Almeinders & Temple, 1998). In a critical review on the outcome of surgery for chronic Achilles tendino-

pathy, the following seven methodological suggestions were given (Tallon et al., 2001): (1) Ideally, studies should be randomized controlled trials. (2) Patient selection criteria should be clearly documented, giving the number of patients in the original study cohort, the number of patients who were lost to follow-up, and stating the reasons why it was not possible to follow them up. (3) The investigators responsible for outcome assessment should be independent of the therapist and surgeon. Ideally, the outcome assessment should be in a written form with minimal investigator assistance. (4) Ultrasonography or magnetic resonance imaging (MRI) may be performed to assist in the diagnosis. The role of imaging in follow-up, however, is dubious. (5) In assessing clinical outcome, there are two forms of benefit to the patient: relief of pain and return to sporting activities. These points should possibly be incorporated into the patients' records. (6) Researchers should use a reliable and sensitive outcome measure. (7) The treatment period should be documented in detail, giving a full description of the protocol and the patient adherence and compliance to the protocol.

Most of these suggestions, when applicable for non-operative interventions, were met in the present study. The patients were randomized to the different treatment groups and monitored four times during the 1-year follow-up. The number of dropouts and the reasons given were recorded (Fig. 5). We used a rigorously developed and tested patient-relevant outcome measure assessing symptoms, functional limitations and the result of these on patients' quality of life (Roos et al., 1998a, b, 1999, 2001). For assessment of physical activity level, a reliable scale was used (Roos et al., 1999). To minimize investigator bias, the questionnaire was mailed to the patients and returned by mail (Roos, 2001). We assessed compliance with the protocols by having the patients record the number of daily repetitions of eccentric exercises and the use of the splint. The records were returned by mail after 6 and 12 weeks, respectively.

We did not ensure the diagnosis by the use of objective measures such as ultrasound or MRI. Thus, it was possible that patients with clinical symptoms, but without structural signs of tendinopathy, were included. Instead we aimed at including only patients having pain and swelling 2–6 cm from the Achilles tendon insertion. Symptoms from the Achilles tendon are frequently categorized into mid-tendon symptoms and symptoms from the insertion. Different etiologies and prognoses for these different pain localizations have been suggested (Schepsis & Leach, 1987). To include only patients with mid-tendon Achilles tendinopathy, patients with pain from the Achilles tendon insertion, or pain from

2–6 cm proximal of the Achilles tendon insertion and pain from the insertion, were excluded.

Perspectives

We conclude that eccentric exercises seem to improve function and reduce pain because of Achilles tendinopathy in patients recruited from primary care. The effects were apparent already after 6 weeks of treatment and lasted for 1 year. Our results are in line with previous studies and strengthens the recommendation that patients, regardless of the duration or the

severity of the problems, should undergo an eccentric exercise program prior to consideration of other treatments such as Achilles tendon surgery.

Key words: Foot and Ankle Outcome Score (FAOS), tendinopathy, tendinitis.

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