

High-load strength training improves outcome in patients with plantar fasciitis: A randomized controlled trial with 12-month follow-up

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The aim of this study was to investigate the effectiveness of shoe inserts and plantar fascia-specific stretching vs shoe inserts and high-load strength training in patients with plantar fasciitis. Forty-eight patients with ultrasonography-verified plantar fasciitis were randomized to shoe inserts and daily plantar-specific stretching (the stretch group) or shoe inserts and high-load progressive strength training (the strength group) performed every second day. High-load strength training consisted of unilateral heel raises with a towel inserted under the toes. Primary outcome was the foot function index (FFI) at 3 months. Additional follow-ups were performed at 1, 6, and 12 months. At the primary endpoint, at 3 months,

the strength group had a FFI that was 29 points lower [95% confidence interval (CI): 6–52, $P = 0.016$] compared with the stretch group. At 1, 6, and 12 months, there were no differences between groups ($P > 0.34$). At 12 months, the FFI was 22 points (95% CI: 9–36) in the strength group and 16 points (95% CI: 0–32) in the stretch group. There were no differences in any of the secondary outcomes. A simple progressive exercise protocol, performed every second day, resulted in superior self-reported outcome after 3 months compared with plantar-specific stretching. High-load strength training may aid in a quicker reduction in pain and improvements in function.

Plantar fasciitis (PF) is the most commonly reported cause of inferior heel pain (Singh et al., 1997; Buchbinder, 2004). It is characterized by pain at the calcaneal origin of the plantar fascia and increased thickness of the plantar fascia (Buchbinder, 2004). The condition is prevalent in both sports active and sedentary populations. The prevalence in the general population is estimated to range from 3.6% to 7% (Dunn et al., 2004; Hill et al., 2008), whereas plantar fasciitis may account for as much as 8% of all running-related injuries (Lysholm & Wiklander, 1987; Taunton et al., 2002). The histology of plantar fasciitis is poorly understood, but studies show degenerative changes at the plantar fascia entheses, including a deterioration of collagen fibers, increased secretion of ground substance proteins, focal areas of fibroblast proliferation, and increased vascularity (Jarde et al., 2003; Lemont et al., 2003).

Results from randomized controlled trials suggest that plantar fascia-specific stretching and shoe inserts are effective in the treatment of PF (DiGiovanni et al., 2003;

DiGiovanni et al., 2006; McPoil et al., 2008). However, approximately 40% of patients continue to have symptoms and pain 2 years after diagnosis (DiGiovanni et al., 2006). Therefore, new and effective treatments are warranted. High-load strength training that causes high tensile loads across the tendon has shown promising results on degenerative tendon disorders such as Achilles and patellar tendinopathy and may yield a higher treatment effect compared with plantar-specific stretching (Malliaras et al., 2013). However, the clinical effect from high-load strength training seems to take time before it manifests and therefore studies often use 3 months as the primary endpoint (Malliaras et al., 2013).

One option to induce controlled high-load tensile forces across the plantar fascia is by the combined use of Achilles tendon loading and the windlass mechanism. The windlass mechanism causes tightening of the plantar fascia during dorsal flexion of the metatarsophalangeal joints. Additionally, the close anatomical connection between the Achilles tendon, paratendon, and the plantar

fascia suggests that high loading of the Achilles tendon is transferred to the plantar fascia (Cheung et al., 2006; Stecco et al., 2013). Collectively, this might suggest that high loading of the Achilles tendon combined with activation of the windlass mechanism is likely to cause high tensile loads across the plantar fascia (Carlson et al., 2000). This may be achieved by performing unilateral heel raises combined with dorsiflexion of the metatarsophalangeal joints (Carlson et al., 2000). The purpose of this study was to investigate the effectiveness of shoe inserts and plantar fascia-specific stretching vs shoe inserts and high-load strength training consisting of unilateral heel raises and dorsal flexion of the metatarsophalangeal joints in patients with plantar fasciitis. We hypothesized that patients randomized to shoe inserts and high-load strength training would have a larger improvement in foot function index (FFI) from baseline to primary endpoint at 3 months compared with patients randomized to shoe inserts and plantar-specific stretching.

Methods

Design and recruitment

The design was a randomized controlled trial. The study was approved by the local ethics committee of North Denmark Region (N-20090020). Patients were included at three sites: Aalborg University Hospital, Kaalunds Clinic (private clinic), and at Silkeborg Regional Hospital with inclusion between 2009 and 2012. Patients eligible for inclusion were told that we were investigating two effective treatments and we were investigating which treatment was the best. The same medical doctor at each site included patients. To the best of our ability, the patients were included consecutively. The manuscript complies with the CONSORT statement for reporting of randomized trials and all analyses was defined *a priori* (Schulz et al., 2010).

Inclusion and exclusion criteria

The inclusion criteria are as follows:

1. History of inferior heel pain for at least 3 months before enrollment.
2. Pain on palpation of the medial calcaneal tubercle or the proximal plantar fascia.
3. Thickness of the plantar fascia of 4.0 mm or greater (McMillan et al., 2009).

The exclusion criteria are as follows:

1. Below 18 years of age.
2. History of systemic diseases.
3. Prior heel surgery.
4. Pregnant.
5. Corticosteroid injection for plantar fasciitis within the previous 6 months.

Randomization

Forty-eight patients with ultrasonography-verified PF were block randomized to shoe inserts and daily plantar-specific stretching (the stretch group) or shoe inserts and high-load strength training

every second day (the strength group) using a computer-generated sequence created by the main investigator (M. S. R.) in blocks of 6.

Interventions

Before the trial started, the principal investigator (M. S. R.) arranged two meetings with the physiotherapists and medical doctors involved in the trial. This was carried out to ensure uniform diagnosis; interventions and information were delivered to all patients across the three centers.

Patient education and heel inserts

Both groups received a short patient information sheet and gel heel inserts. The patient information sheet covered information on plantar fasciitis, advice on pain management; information on how to modify physical activity; how to return slowly to sports; and information on how to use the gel heel inserts. Patients also received this information in a one-page leaflet (attached as Appendix S1). The heel inserts were Tuli's polar bear gel heel cups (Medi-Dyne Healthcare Products, Colleyville, Texas, USA).

Plantar-specific stretching

The plantar-specific stretching protocol was identical to that of DiGiovanni et al. (2003). Patients were instructed to perform this exercise while sitting by crossing the affected leg over the contralateral leg. Then, while using the hand on the affected side, they were instructed to place the fingers across the base of the toes on the bottom of the foot (distal to the metatarsophalangeal joints) and pull the toes back toward the shin until they felt a stretch in the arch of the foot (Fig. 1). They were instructed to palpate the plantar fascia during stretching to ensure tension in the plantar fascia. As in the study of DiGiovanni et al. (2003), patients were instructed to perform the stretch 10 times, for 10 s, three times per day. In the case of bilateral pain, they were instructed to perform the plantar-specific stretching on both feet.

High-load strength training

High-load strength training consisted of unilateral heel raises with a towel inserted under the toes to further activate the windlass mechanism (Fig. 2). The patients were instructed to do the exercise on a stairway or similar location. The towel was individualized, ensuring that the patients had their toes maximally dorsal flexed at the top of the heel rise. The patients were instructed to perform the exercises every second day for 3 months. Every heel rise consisted of a 3-s concentric phase (going up) and a 3-s eccentric phase (coming down) with a 2-s isometric phase (pause at the top of the exercise). The high-load strength training was slowly progressed throughout the trial, as previously reported by Kongsgaard et al. (2009). They started at a 12 repetition maximum (RM) for three sets. 12RM is defined as the maximal amount of weight that the patient can lift 12 times through the full range of motion while maintaining proper form. After 2 weeks, they increased the load by using a backpack with books and reduced the number of repetitions to 10RM, simultaneously increasing the number of sets to four. After 4 weeks, they were instructed to perform 8RM and perform five sets. If they could not perform the required number of repetitions, they were instructed to start the exercises using both legs until they were strong enough to perform unilateral heel raises. They were instructed to keep adding books to the backpack as they became stronger. This information was given to patients as a one-page manual including pictures of the exercises together with a description of progression. In the case of



Fig. 1. Plantar-specific stretching was performed with the patient crossing the affected leg over the contra lateral leg. While placing the fingers across the base of the toes, the patient pulled the toes back toward the shin until they felt a stretch in the arch or plantar fascia. The patients were instructed to use their other hand to palpate the tension in the plantar fascia to confirm the stretch.



Fig. 2. Unilateral heel raises were performed with a towel under the toes to increase dorsal flexion of the toes during heel raises.

bilateral pain, they were instructed to perform the high-load strength training with both limbs.

Procedure

After patients had signed informed consent and were included by an experienced rheumatologist or orthopedic surgeon, they were referred to a physiotherapist. The physiotherapist delivered patient information, heel inserts, and instructed the patients on either plantar-specific stretching or high-load strength training. At 1-month follow-up, the patients were seen by the same medical doctor and the same physiotherapist. The medical doctor performed ultrasonographic measurement of the thickness of the plantar fascia. Afterward, the physiotherapist assessed how the plantar-specific stretching or high-load strength training was per-

formed. If necessary, the physiotherapist corrected the plantar-specific stretching or high-load strength training.

Primary outcome

The primary outcome was defined *a priori* and consisted of the change in total FFI from baseline to the 3-month follow-up. The FFI is a self-report questionnaire that assesses multiple dimensions of foot function (Budiman-Mak et al., 1991). The FFI consists of 23 items divided into three subscales that quantify the impact of foot pathology on pain, disability, and activity limitation. The scores range from 0 to 230, with 0 reflecting no pain, disability, or activity limitations (Budiman-Mak et al., 1991). The minimal important change is 7 points for the total scale (Landorf & Radford, 2008). Self-report questionnaires were filled in by

Rathleff et al.

patients at baseline and at 1, 3, 6, and 12 months after inclusion in the study.

Secondary outcome

Secondary outcomes included the thickness of the plantar fascia, item 1 in the FFI (foot pain at worst) and item 2 (foot pain during first step in the morning), satisfaction with the result of the treatment, physical activity level measured as sports participation, and average leisure time sports participation per week. Ultrasonographic measurements were made at baseline and at 1, 3, and 6 months. The same rater performed all measurements in the patient. Ultrasonographic measurements were carried out using a previously described method with substantial reliability (Skovdal Rathleff et al., 2011). In brief, subjects were positioned in a prone position. The toes were dorsally flexed, and the talocrural joint was positioned in 0 degree flexion. The transducer was placed over the plantar aspect of the hindfoot to examine the plantar fascia at the insertion onto the calcaneus. Long-axis scans were obtained approximately 0.5 cm medial to the midline of the plantar surface of the foot where the border of the plantar fascia is well defined by ultrasonography. Three successive scans were made and the average was used for data analysis.

Sample size

The sample size was defined *a priori*. The study was powered to detect a 15-point larger change in FFI (40 points vs 25 points on the FFI) from baseline to follow-up at 3 months in the group randomized to high-load strength training compared with those randomized to plantar-specific stretching (Landorf & Radford, 2008). Based on a previous trial, we used a common standard deviation of 18, which showed that 23 patients were needed in each group to detect a statistical difference (power 0.80, alpha 0.05) (DiGiovanni et al., 2003).

Statistical analyses

All analyses took place after the 12-month follow-up and no intermediate analyses were performed. Between-group comparison was analyzed on an intention-to-treat basis. The primary outcome was analyzed using linear regression with adjustment for baseline scores. This was carried out using the outcome (FFI) as the dependent variable with group and baseline data as the independent variables. Secondary outcomes were also analyzed using linear regression with adjustment for baseline values, except leisure physical activity, which was analyzed using Poisson regression with adjustment for baseline leisure time physical activity.

Results

Forty-eight patients were included and 24 were randomized to plantar-specific stretching and 24 patients to high-load strength training (Fig. 3, Table 1). Follow-up ranged from 77% to 94%, with an 81% follow-up at primary endpoint at 3 months.

Primary outcome

At primary endpoint at 3 months, the strength group had a FFI that was significant and 29 points lower [95% confidence interval (CI): 6–52, $P = 0.016$] compared with the stretch group, corresponding to an effect size of

0.81 (Fig. 4). At 1, 6, and 12 months, there was a non-significant 5–7 point difference in FFI between groups ($P > 0.34$). At 12 months, the total FFI score was 22 points (95% CI: 9–36) in the strength group and 16 points (95% CI: 0–32) in the stretch group.

Secondary outcomes and satisfaction

The secondary outcomes showed that patients randomized to high-load strength training reported significantly less worse foot pain at the primary endpoint at 3 months (item 1 in the FFI). Otherwise, there were no significant differences between groups, but patients randomized to high-load strength training tended to be more satisfied with the result of the treatment at 3 and 12 months (Table 2). There were no adverse events besides minor delayed onset of muscle soreness in the group received high-load strength training.

Discussion

This is the first randomized trial to compare high-load strength training with plantar-specific stretching among patients with ultrasonography-verified plantar fasciitis. The primary endpoint at 3 months showed that high-load strength training was associated with a larger improvement in FFI and that patients tended to be more satisfied with the results of the treatment. This study adds new knowledge on the positive effect of a new, simple, progressive exercise protocol for a severe and debilitating condition.

Explanation of results

The results showed a 29-point greater improvement in FFI in patients randomized to high-load strength training at the primary endpoint of 3 months. This difference exceeded the 7 points, which is considered the minimally relevant difference in FFI and suggests clinical relevance. The question is why was high-load strength training associated with a larger improvement compared with plantar-specific stretching after 3 months? Before commencing the trial, we were interested in exercises that caused controlled high-load tensile forces across the plantar fascia. Large tensile forces have been associated with improvements in symptoms in other conditions involving degenerative changes, as seen in plantar fasciitis. From a theoretical perspective, this was achieved using the windlass mechanism in combination with loading of the Achilles tendon. The plantar fascia is made up of collagen type 1 fibers (Stecco et al., 2013). It appears that this type of collagen responds to high-load through increased collagen synthesis (Langberg et al., 2007). As patients with plantar fasciitis show degenerative changes at the plantar fascia entheses (Jarde et al., 2003; Lemont et al., 2003), increased collagen synthesis may help normalize tendon structure and improve

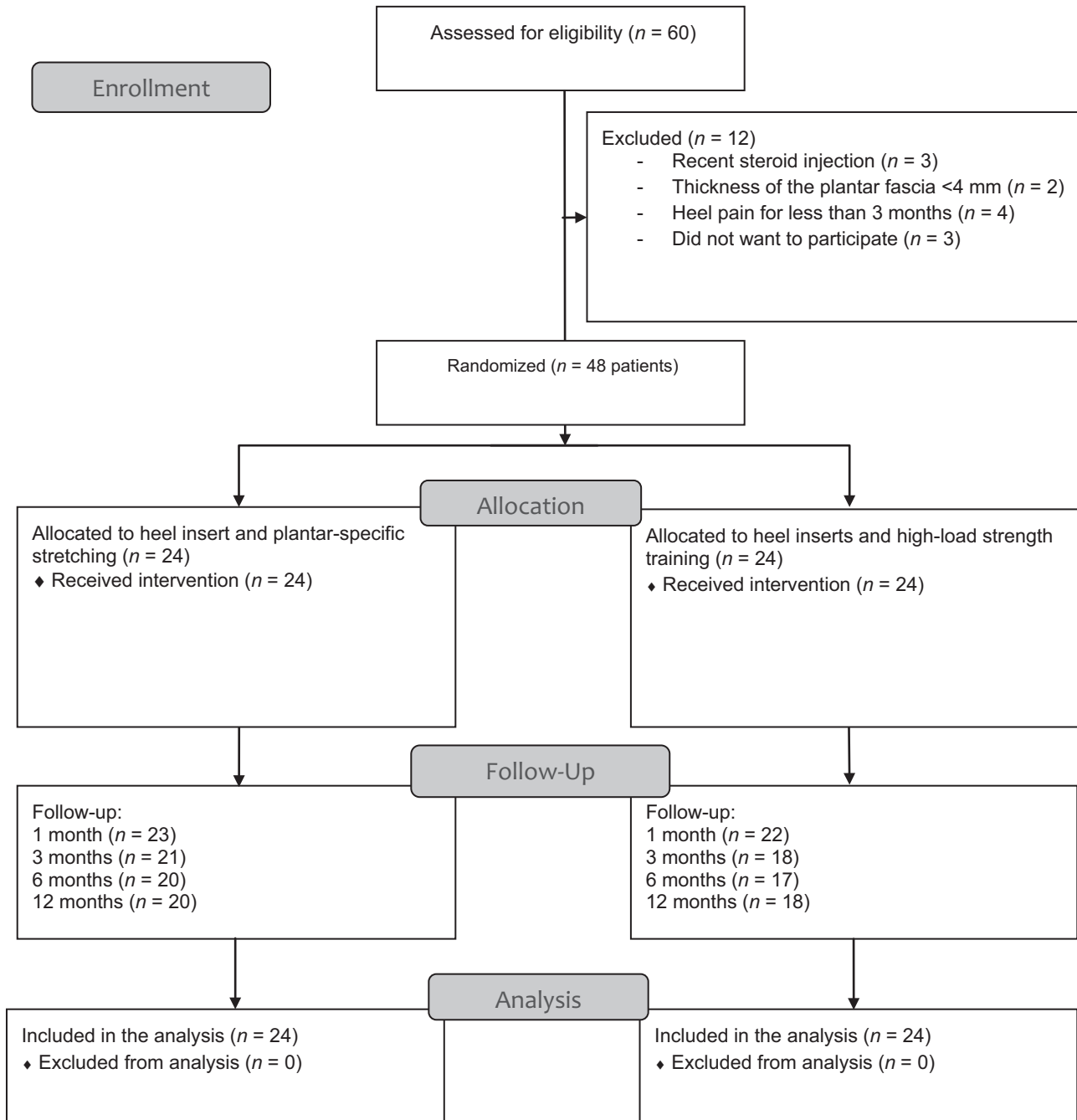


Fig. 3. Flow chart showing patient recruitment.

patient outcomes. However, it is important to highlight that the high-load strength training was not associated with larger reduction in the thickness of the plantar fascia and at follow-up compared with those allocated to plantar-specific stretching. Both groups had a significant reduction in the thickness of the plantar fascia, but the majority of patients still had significant thickening of the plantar fascia compared with the level of approximately 2.2–4.0 mm observed in pain-free individuals (McMillan et al., 2009). This may point toward that some abnormalities within the fascia may still persist

even though symptoms have decreased. This is similar to the “iceberg theory,” with pain being just the tip of the iceberg (Fredberg & Stengaard-Pedersen, 2008).

An additional benefit of the high-load strength training exercise could also be increased ankle dorsiflexion strength. Decreased ankle dorsiflexion strength has previously been identified among patients with plantar fasciitis (Kibler et al., 1991). Previous studies indicate that patients with plantar fasciitis have lower dorsal flexion of the ankle joint (Riddle et al., 2003; Patel & DiGiovanni, 2011). Even though this was not

Table 1. Baseline characteristics

	Plantar-specific stretching (<i>n</i> = 24)	High-load strength training (<i>n</i> = 24)	All (<i>n</i> = 48)
Age	45 (± 8)	47 (± 7)	46 (± 8)
Gender (% females)	67	65	66
Weight (kg)	80.2 (± 13.5)	79.0 (± 15.5)	79.6 (± 14.4)
Height (cm)	169.9 (± 8.1)	173.3 (± 9.4)	172 (± 8.9)
BMI (kg/m ²)*	27.1 (24.3–31.0)	26.4 (23.4–28.8)	27.1 (23.5–30.2)
Bilateral (% who reported bilateral symptoms)	13	25	19
Duration of symptoms* (months)	8 (5.5–11)	7 (5.5–12)	7 (5.5–11)
Previous treatment for heel pain (% who replied yes)	29	43	36
Sports participation (% participation in leisure time sports)	54	67	60
Average time spent doing leisure time sports (h)	3 (1.25–3.5)	2.75 (1.5–4)	3 (1.5–4)
Pain medication for heel pain (% who replied yes)	29	43	36%
FFI (points)	73 (± 26)	84 (± 34)	78 (± 30)
Item 1 in FFI, foot pain at worst (points)	7.5 (± 1.6)	7.9 (± 1.7)	7.7 (± 1.7)
Item 2 in FFI, foot pain during first step in the morning (points)	6.9 (± 2.4)	6.0 (± 3.2)	6.4 (± 2.8)
Thickness of the plantar fascia (mm)	6.0 (± 1.2)	6.7 (± 1.7)	6.4 (± 1.5)

*Median and interquartile range.

BMI, body mass index; FFI, foot function index.

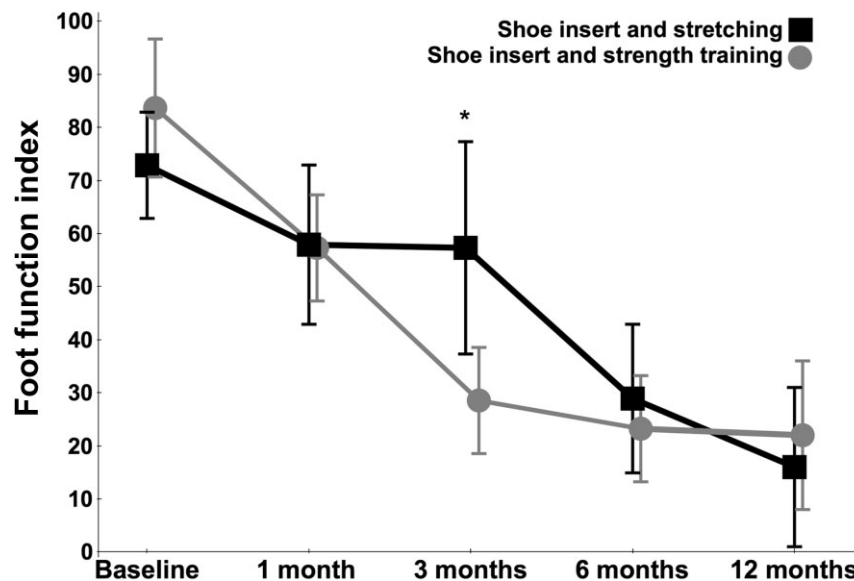


Fig. 4. Primary outcome (foot function index) at baseline and at 1, 3, 6, and 12 months.

investigated, it seems plausible that the exercise may also increase the joint range of motion as patients continuously reach maximal dorsal flexion of the metatarsophalangeal joints and the ankle joint (O'Sullivan et al., 2012), which may contribute to the observed improvements.

Comparison to previous studies

The outcome at the primary endpoints at 3 months showed that the controlled loading of the plantar fascia was associated with a greater improvement in FFI. Although this is the first trial among patients with plantar fasciitis, it is similar to the body of knowledge in Achilles and patella tendinopathy showing that high loading is

important in degenerative tendon disorders (Cook & Purdam, 2009; Malliaras et al., 2013). Despite the efficacy of high-load strength training, a significant proportion of patients continue to have symptoms and pain after treatment; this is similar to previous randomized trials and a common finding (DiGiovanni et al., 2006; Roos et al., 2006; McMillan et al., 2012; Ball et al., 2013). This highlights the need for future trials to investigate the optimal treatment of plantar fasciitis.

The sample recruited is similar to previous studies on the treatment of plantar fasciitis, as it shows body mass index above the normal range and a long symptom duration (DiGiovanni et al., 2003; McMillan et al., 2012; Ball et al., 2013). Likewise, the thicknesses of the plantar fascia at baseline (6.0 and 6.7 mm) are almost

Table 2. Secondary outcomes including thickness of the plantar fascia, sports participation, and satisfaction with the results of treatment

Outcome	Plantar-specific stretching, <i>n</i> = 24 (95% CI)	High-load strength training, <i>n</i> = 24 (95% CI)	Adjusted mean difference between groups (95% CI)
Thickness of the plantar fascia (mm)			
1 month	5.7 (5.1; 6.3)	6.3 (5.7; 6.8)	0.4 (-0.2; 1.0)
3 months	5.8 (5.1; 6.6)	5.8 (5.1; 6.5)	-0.2 (-1.2; 0.8)
6 months	5.1 (4.4; 5.7)	5.7 (5.1; 6.3)	0.3 (-0.3; 0.9)
Item 1 in FFI, foot pain at worst (points)			
1 month	6.1 (5.2; 7.1)	6.1 (5.1; 7.2)	-0.2 (-1.5; 1.2)
3 months	6.1 (4.4; 7.7)	3.5 (2.3; 4.7)	-2.6 (-4.6; -0.6) [‡]
6 months	3.4 (2.0; 4.7)	2.5 (1.4; 3.6)	-0.9 (-2.7; 0.9)
12 months	1.8 (0.7; 3.0)	2.9 (1.7; 4.0)	0.9 (-0.8; 2.6)
Item 2 in FFI, foot pain during first step in the morning (points)			
1 month	5.4 (4.5; 6.4)	4.0 (2.8; 5.3)	-0.9 (-2.1; 0.4)
3 months	4.8 (3.2; 6.4)	3.1 (1.8; 4.4)	-1.5 (-3.6; 0.6)
6 months	3.3 (1.9; 4.7)	2.2 (1.0; 3.3)	-1.3 (-3.1; 0.6)
12 months	1.4 (0.2; 2.7)	1.7 (0.5; 2.8)	0.3 (-1.4; 2.1)
Proportion involved in leisure time sports			
			Odds ratio > 1, favors high-load strength training
1 months	86%	65%	0.3 (0.1; 1.3)
3 months	67%	70%	1.2 (0.3; 4.6)
6 months	71%	68%	0.9 (0.2; 3.9)
12 months	88%	89%	1.2 (0.2; 9.8)
Leisure time sports per week among those who participate in leisure time sports (h)[*]			
			Coefficients (Poisson regression) [†]
1 month	2 (1.25–4.0)	2 (1.5–3.0)	-0.1 (-0.58; 0.40)
3 months	2 (1.5–4.5)	2 (1.5–4.0)	-0.2 (-0.67; 0.35)
6 months	1 (0–1.0)	1 (0–1.0)	0.0 (-0.17; 0.18)
12 months	1 (1.0–1.0)	1 (1.0–1.0)	0.1 (-0.37; 0.53)
Satisfaction with the result of the treatment (% who replied yes)			
			Odds ratio > 1, favors high-load strength training
1 month	77%	65%	0.5 (0.1; 2.2)
3 months	56%	75%	2.3 (0.5; 10.5)
6 months	77%	74%	0.8 (0.2; 4.4)
12 months	65%	85%	3.1 (0.6; 15.0)

^{*}Presented as median and interquartile range.

[†]Coefficients from Poisson regression. The value is the expected increase in log count for the group randomized to high-load strength training compared with the group randomized to plantar-specific stretching. As 0 is included in the confidence interval, there is no significant difference between groups.

[‡]Comparisons with a significant difference (*P* < 0.05).

identical to those reported by McMillan et al. (6.3–6.7 mm), Tsai et al. (5.7–6.5 mm), and Ball et al. (5.8–6.2) (Tsai et al., 2006; McMillan et al., 2012; Ball et al., 2013). This indicates that the sample is comparable to previous trials. The within-group changes in the thickness of the plantar fascia are similar to those of McMillan et al., who used a steroid injection and also observed changes in plantar fascia thickness of around 0.4–1.0 mm after 12 weeks (McMillan et al., 2012). However, the changes in thickness are lower than seen by Ball et al. (1.4–1.5 mm after 6 weeks) and Tsai et al. (0.6–2.3 mm after 1 year), who both investigated the effect of a steroid injection (Tsai et al., 2006; Ball et al., 2013). Differences in interventions may account for these variations.

Strengths and weaknesses of the study

A significant strength is that all patients were recruited from the normal patient flow at the three sites. This

ensures that the patients were representative of those routinely seen at the three recruitment sites in Denmark. The addition of high-load strength training to heel insert and patient education are easy to implement as it only requires standard equipment such as a towel and a backpack.

One limitation of the study is that no data were obtained on adherence to exercises or the quality of the home-based exercises. Therefore, we do not know how often or for how long patients performed their exercises in either group. In addition, the exercise frequency is very different in the two groups and it is unknown if this will affect compliance and thereby outcome. High-load strength training was not associated with better long-term outcome at 12 months, but only with a better short-term effect after 3 months. This might be attributed to compliance with the intervention. We suspect that patients at some point will stop performing their exercises when they reach a pain level that is satisfactory to them. Valid data on long-term compliance would answer this question.

Perspectives

Plantar fasciitis is debilitating for patients as weight-bearing activities provoke symptoms. Therefore, this simple high-load strength training intervention is relevant as it enables the quicker reduction of pain and symptoms at 3 months compared with plantar-specific stretching. Furthermore, it only takes a short time to complete and, in comparison to plantar-specific stretching, it only needs to be performed every second day. However, this is the first trial performed among patients with long-standing plantar fasciitis and more trials are needed to confirm these findings, specifically regarding whether the effect can be maintained after 12 months.

In conclusion, a simple progressive exercise protocol consisting of high-load strength training, performed every second day, resulted in a superior outcome at 3 months compared with plantar-specific stretching and may aid in a quicker reduction in pain and improvements in function. However, there were no significant

benefits of high-load strength training at the secondary endpoints at 1, 6, and 12 months. This study adds new evidence for the positive effect of a simple, progressive exercise protocol for a severe and debilitating condition.

Key words: plantar fasciitis, progressive strength training, plantar heel pain.

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Supporting information

Additional Supporting Information may be found in the online version of this article at the publisher's web-site:

Appendix S1. Advice on your heel pain.

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