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Plantar Fascia-Specific Stretching Versus Radial Shock-Wave Therapy as Initial Treatment of Plantar Fasciopathy

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Background: Whether plantar fascia-specific stretching or shock-wave therapy is effective as an initial treatment for proximal plantar fasciopathy remains unclear. The aim of this study was to test the null hypothesis of no difference in the effectiveness of these two forms of treatment for patients who had unilateral plantar fasciopathy for a maximum duration of six weeks and which had not been treated previously.

Methods: One hundred and two patients with acute plantar fasciopathy were randomly assigned to perform an eight-week plantar fascia-specific stretching program (Group I, n = 54) or to receive repetitive low-energy radial shock-wave therapy without local anesthesia, administered weekly for three weeks (Group II, n = 48). All patients completed the seven-item pain subscale of the validated Foot Function Index and a patient-relevant outcome questionnaire. Patients were evaluated at baseline and at two, four, and fifteen months after baseline. The primary outcome measures were a mean change in the Foot Function Index sum score at two months after baseline, a mean change in item 2 (pain during the first few steps of walking in the morning) on this index, and satisfaction with treatment.

Results: No difference in mean age, sex, weight, or duration of symptoms was found between the groups at baseline. At two months after baseline, the Foot Function Index sum score showed significantly greater changes for the patients managed with plantar fascia-specific stretching than for those managed with shock-wave therapy ($p < 0.001$), as well as individually for item 2 ($p = 0.002$). Thirty-five patients (65%) in Group I versus fourteen patients (29%) in Group II were satisfied with the treatment ($p < 0.001$). These findings persisted at four months. At fifteen months after baseline, no significant between-group difference was measured.

Conclusions: A program of manual stretching exercises specific to the plantar fascia is superior to repetitive low-energy radial shock-wave therapy for the treatment of acute symptoms of proximal plantar fasciopathy.

Level of Evidence: Therapeutic Level I. See Instructions to Authors for a complete description of levels of evidence.

Histologic assessments of tissues from patients with chronically painful plantar fascia demonstrate findings more consistent with a failed healing response process, without histopathological evidence of inflammation. Instead of the more common term *plantar fasciitis,* which implies an inflammatory process, we prefer the term *plantar fasciopathy* in the same way that overuse tendon problems are better termed *tendinopathy*[1,2].

The cause of plantar fasciopathy, with or without a plantar heel spur, is poorly understood and is probably multifactorial[3]. In runners, it appears to be associated with overuse, training errors, and improper or excessively worn footwear.

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TABLE I Summary of Baseline Measures for Treatment Groups*

Characteristic	Group I, PFSS (N = 54)	Group II, SWT (N = 48)
Age: mean (range) *(yr)*	53.1 (27-70)	49.8 (29-68)
Number of women (%)	36 (66)	30 (63)
Weight: mean (range) *(kg)*	76.1 (51-121)	78.2 (49-115)
Body-mass index: mean (range) *(kg/m²)*	27.2 (20-32)	28.3 (22-33)
Number of hours standing: mean (range)	7 (3-12)	6 (2-11)
Duration of symptoms: mean (range) *(wk)*	3.9 (2-6)	3.6 (2-6)
Affected foot: number (%)		
Left	22 (41)	21 (44)
Foot Function Index Pain Subscale (0-10)†: mean (SD)		
Item 1: Pain at its worst	8.3 (0.8)	8.5 (0.8)
Item 2: Pain during first few steps of walking in the morning	7.8 (1.0)	7.9 (1.0)
Item 3: Pain at end of day	4.3 (1.0)	4.7 (1.3)
Item 4: Pain while walking barefoot	6.8 (1.0)	7.2 (1.2)
Item 5: Pain while standing barefoot	4.0 (0.9)	4.2 (1.1)
Item 6: Pain when walking with shoes	4.7 (1.1)	4.7 (1.2)
Item 7: Pain when standing with shoes	4.1 (0.9)	4.3 (1.1)

*Group I was managed with a plantar fascia-specific stretching (PFSS) program, and Group II was managed with radial shock-wave therapy (SWT).
†Subscale scores range from 0 to 10, with higher scores indicating greater impairment. SD = standard deviation.

When plantar fasciopathy occurs in sedentary adults, it is often attributable to obesity, a contracted gastrocnemius[4,5], poor intrinsic muscle strength, and poor force attenuation, secondary to acquired pes planus and compounded by a decrease in the body's healing capacity[6,7].

Nonsurgical therapy is the mainstay in managing plantar heel pain[1,8,9]. A systematic review in 2003[10] evaluated twenty-six different conservative management modalities recommended for the treatment of plantar fasciopathy. Of these, only heel pads, orthoses, corticosteroid injections, night splints, and shock-wave therapy had been evaluated in randomized studies.

Since then, additional randomized controlled studies have been published[1]. In a randomized, placebo-controlled double-blind study on the efficacy of oral nonsteroidal anti-inflammatory drugs in the treatment of plantar fasciopathy, there was no difference between the placebo group and the nonsteroidal anti-inflammatory drug group at one, two, or six months[11]. Two randomized controlled investigations described a clinically relevant effect of an eight-week manual plantar fascia-specific stretching program on chronic recalcitrant plantar heel pain[12,13]. No data for the management of acute heel pain were provided. Two randomized controlled trials have described a clinically relevant effect of repetitive low-energy shock-wave therapy on chronic recalcitrant plantar heel pain[14,15]. No data for the management of acute heel pain were provided.

We therefore performed a randomized controlled study to evaluate the effectiveness of repetitive plantar fascia-specific stretching or repetitive low-energy shock-wave therapy as initial treatment for plantar fasciopathy. As the initiation of conservative treatment soon after the onset of symptoms is assumed to provide a cure in most patients within six weeks, regardless of management[16], the null hypothesis was that plantar fascia-specific stretching and shock-wave therapy would produce equivalent outcomes at two months after baseline.

Materials and Methods

The study was designed as a randomized, parallel treatment study with a blinded independent observer to evaluate the effectiveness of repetitive plantar fascia-specific stretching or of repetitive low-energy radial shock-wave therapy for patients with a previously untreated unilateral plantar fasciopathy of up to six weeks in duration. Demographic data are summarized in Table I. Inclusion and exclusion criteria are given in Table II.

The study was conducted in three outpatient clinics. The study design and the information documents were approved by the Internal Study Board of the senior author's (J.D.R.) institution, and the study is registered at Current Controlled Trials (http://www.controlled-trials.com/ISRCTN03438342). Patients received oral and written information about the two treatments and gave informed consent to participate in the study. All patients were informed that anonymized data concerning the study could be submitted for publication, and they consented. Patient confidentiality was protected.

Following the suggestions from DiGiovanni et al.[12], the patients initially completed a self-administered questionnaire that provided background information and a history profile of the heel pain. The background information included age, sex, height, weight, hours spent standing during the day, duration

TABLE II Inclusion and Exclusion Criteria

Inclusion criteria
History of plantar fasciitis for <6 weeks
Numeric Rating Scale (NRS) score ≥6 points for pain during the first few steps of walking in the morning
Localized pain on palpation of the proximal plantar fascia
Willingness to abstain from any other treatments or medications during the treatment and follow-up period
Exclusion criteria
<18 years of age
Receiving local injections prior to the randomization visit
Receiving physical therapy prior to the randomization visit
Receiving NSAIDs* for any chronic conditions whether or not related to plantar fasciitis prior to the randomization visit
Prior self-treatment with any kind of stretching
Receiving systemic therapeutic anticoagulants
Bilateral plantar fasciitis
History and/or physical findings of lower-extremity dysfunction, local arthritis, generalized polyarthritis, rheumatoid arthritis, ankylosing spondylitis, or local arthrosis
Neurologic abnormality (changes of deep tendon reflexes, or motor or sensory deficit)
Arthrosis of the foot or ankle, as confirmed by radiographic diagnosis (anteroposterior and lateral views)
Previous surgery of the foot
Participation in a Workers' Compensation program or plans to apply for the program
Thrombopathy, infection, tumor, diabetes mellitus, systemic lupus erythematosus, severe cardiac disease, or other severe systemic diseases
Pregnancy

*NSAIDs = nonsteroidal anti-inflammatory drugs.

of symptoms, and types of prior treatments. One hundred and fifty-three patients were checked for selection criteria; four patients did not meet the inclusion criteria (Table II) and forty-seven refused consent (Fig. 1).

Thus, a total of 102 patients who had painful plantar fasciopathy for a maximum of six weeks were enrolled in the study over a three-year period. None of the patients who were enrolled had undergone any previous treatment. All patients had maximum pain on palpation of the origin of the plantar fascia on the medial calcaneal tubercle, consistent with a diagnosis of plantar fasciopathy. All patients had worsening of symptoms with weight-bearing activities, and all had been referred to us for diagnosis and treatment. For all patients, conventional radiographs of the heel were made in two planes to rule out fracture, tumor, and infection. Because there is no evidence of a correlation between the presence or absence of a plantar heel spur and treatment outcome[5-7], the presence of a plantar heel spur on radiographs played no role in establishing the diagnosis of plantar fasciopathy. Depending on the individual case, supplementary magnetic resonance imaging and/or bone scintigraphy were performed[16-18], as was a neurology or rheumatology assessment. An orthopaedic surgeon who specialized in foot and ankle disorders conducted a physical examination and confirmed the clinical diagnosis of proximal plantar fasciopathy of less than six-week duration.

A computerized random-number generator was used to formulate an allocation schedule. Patients were allocated to treatment groups in blocks of six. A medical assistant allocated interventions according to the allocation schedule. The medical assistant was unaware of the size of the blocks. It was not possible to blind the individual patient to his or her treatment assignment at any point during the study.

Interventions

All patients enrolled were counseled to pursue daily activities as tolerated. A pair of heel pads (ViscoHeel; Bauerfeind, Zeulenroda-Triebes, Germany) was dispensed at the time of the first office visit.

Patients randomized to treatment Group I received instructions regarding our slightly modified version of a plantar fascia-specific stretching program[12,13]. Stretching exercises were to be done three times daily, for eight weeks. Patients were instructed to perform this exercise while sitting and by first crossing the affected leg over the contralateral leg. Then, while using the hand of the affected side, they were to place the fingers across the base of the toes on the sole 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. They were to confirm that the stretching was correct by palpating the tension in the plantar fascia with the opposite hand while performing the stretching. As a modification to the original protocol, patients were then taught to take the heel with the opposite hand and impose an additional longitudinal stretch on the plantar fascia. Patients were instructed to hold each stretch for a count of ten and to repeat the exercise ten times. They were asked to perform the stretching program three times per day. The first stretch was to be done before taking the first step in the morning. An examiner evaluated each patient to ensure that he or she was performing the exercises correctly. Patients were given a written protocol of the stretching program and asked to keep a daily log of exercise completion, and they were asked to refrain from other forms of physical therapy intervention. They were also informed that increased pain in the plantar fascia could appear during the first two weeks of the stretching program. All patients were contacted by telephone every two weeks to check on training compliance. Patients could contact the main investigator during working hours if they had questions about the training program. After four weeks, the patients were told to slowly return to their previous sport and/or recreational activity.

Patients who were randomized into treatment Group II received three sessions of radial shock-wave therapy, following a regimen described previously by Rompe et al.[14] and Gerdesmeyer et al.[15]. A radial shock-wave device (EMS Electro Medical Systems, Nyon, Switzerland) was used. The treatment took place in three sessions at weekly intervals. At each session, 2000

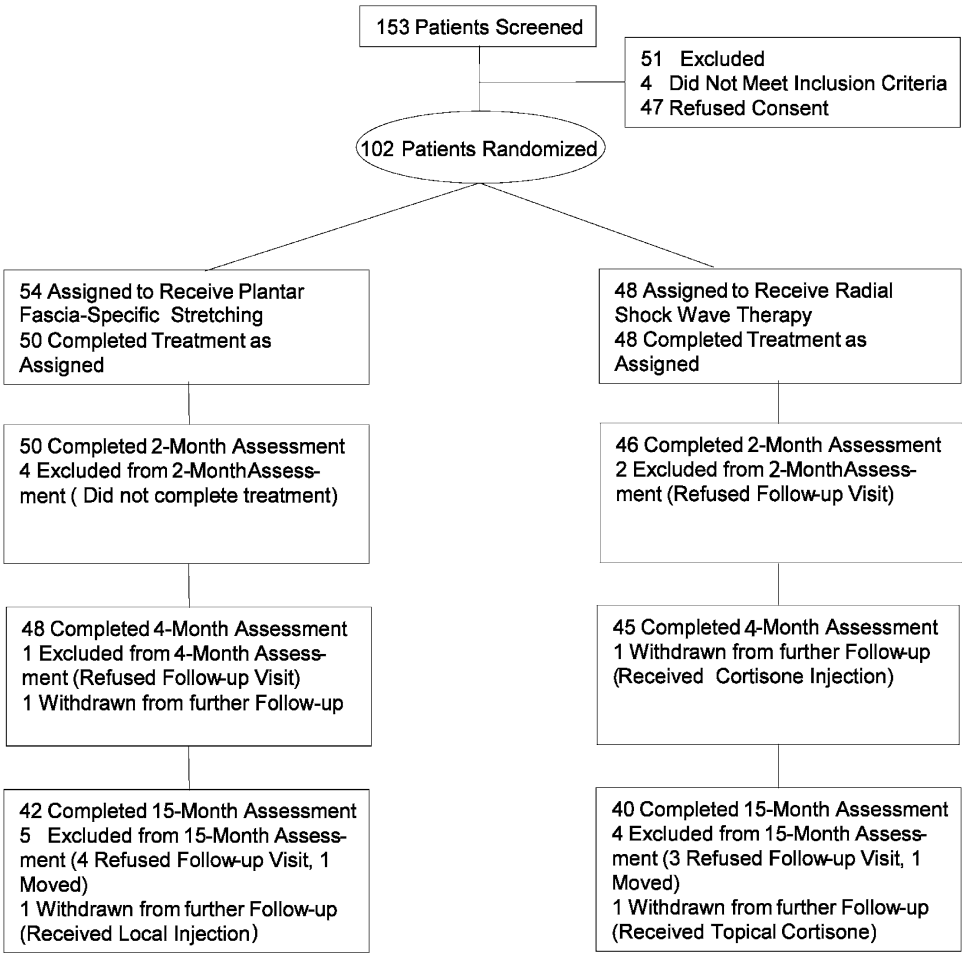

Fig. 1

Flowchart of the study.

pulses were applied with a pressure of 4 bar (equal to an energy flux density of 0.16 mJ/mm^2).The total energy flux density per treatment was 320 mJ/mm^2. The treatment frequency was 8 pulses/sec. With use of 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. Patients were asked to refrain from other forms of physical therapy intervention. Patients were informed that increased pain in the plantar fascia could appear during the first two weeks of the radial shock-wave therapy.

If needed, a nonsteroidal anti-inflammatory medication (75 mg diclofenac, twice per day) could be taken. When individuals could not tolerate the diclofenac, they were instructed to change to ibuprofen (600 mg, twice per day). If unable to tolerate ibuprofen, the patient was instructed to discontinue the nonsteroidal anti-inflammatory medication completely. Subjects were asked to note in a diary the intake of the rescue medication, the number of tablets taken, and the day on which the tablets were taken, as well as any other kind of medication taken during the study.

Outcome Measures

At two months, four months, and fifteen months after baseline, patients from both groups were invited to return for a follow-up examination and completion of the following: (1) the pain subscale of the validated Foot Function Index (PS-FFI)[19-22], and (2) a patient-relevant outcome measures (SROM) questionnaire that included generic and condition-specific outcome measures related to pain, function, and satisfaction with treatment outcome (see Appendix).

With regard to the validated PS-FFI, to our knowledge no effort has been made so far to define what is the smallest meaningful change in score (minimal clinically important difference). For us, the smallest relevant clinical change was determined to be 2 points in item 2 of the PS-FFI. An assistant who was unaware of the allocated intervention collected the forms *before* contact with the treating physician and entered the responses into a database. The outcomes of the study were analyzed by a different group of researchers from those who had provided treatment.

Questions from the PS-FFI were used to produce the primary numeric outcome scores. The questions could be scored on a scale from 0 (no pain) to 10 (worst pain imaginable). Similar to

what was done in a previous heel pain study that had comparable outcome measures[10,11], only the first seven items were used to produce an overall score, as the remaining two items on the pain subscale are related to orthotic use. The change in the PS-FFI score (i.e., the score after two months or four months or fifteen months minus the baseline score) was used for subsequent analysis. A negative change in the PS-FFI signified patient improvement.

Statistics

The primary goal of this study was to compare the clinical outcome of acute, previously untreated plantar fasciopathy after either plantar fascia-specific stretching or shock-wave therapy.

The primary efficacy end point was prospectively defined as a change of the summed score of the PS-FFI from baseline to month two. Further criteria regarding the primary efficacy were the change of item 2 on the PS-FFI from baseline to month two, and the response rate to question number 6 of the SROM questionnaire at two months compared with baseline. A value of $p < 0.025$ (two-sided) was considered significant. To keep the full level of α, the three efficacy criteria were tested in the a priori ordered sequence of Maurer et al.[23]. According to this sequence, if the first test (change of PS-FFI sum score) is significant ($p < 0.025$), the second test (change of item 2 on the PS-FFI) can be performed with the full level of α ($p < 0.025$). If the second test (change of item 2 on the PS-FFI) is also significant, the third test (response rate to question 6 of the SROM questionnaire) can be performed with the full level of α ($p < 0.025$).

Secondary outcomes were a change in the summed score of the PS-FFI from baseline to month four, and to month fifteen; a change in the score of item 2 on the PS-FFI from baseline to month four, and to month fifteen; and the association of treatment with response rates of the SROM questionnaire at month two, at month four, and at month fifteen.

Power estimates based on the change in the end point for the PS-FFI and a standard error estimate obtained from a recent study with a similar design[10] revealed that a sample size of fifty patients per group would result in a test power of approximately 80% in detecting differences of 20% or more between the groups with respect to the change in the PS-FFI summed score. A dropout rate of 10% was taken into account before the start of the study.

A two-way analysis of variance, with group as the between-patients factor and time as the within-patients factor, was used to assess the presence of significant differences between the groups and within each group before treatment and at the scheduled follow-up periods. A Tukey post hoc comparison was used to assess significant differences between mean values when a significant main effect and interaction were found. For all analyses, the level of significance was set at $p < 0.025$. Significance levels for multiple comparisons were adjusted with the Bonferroni procedure.

With respect to the ratings in the PS-FFI, changes in ratings over time for every patient were calculated by subtracting the results at baseline from those at the time of follow-up.

With respect to the SROM questionnaire, the responses to the corresponding questions on the patient-relevant outcome measures were collapsed into dichotomized data indicating a positive response or a negative response. A negative response represented little or no improvement. Acknowledging that dichotomization may lead to a loss of possibly important information, we chose this method of analysis following the example from DiGiovanni et al.[12,13] to allow direct comparison of the studies. The association of treatment with response rates was analyzed with use of the Fisher exact test in two-way contingency tables.

All analyses were performed on an intention-to-treat basis. When there were missing responses, the last observation was carried forward (with last observation defined as the last recorded value). Differences (with 95% confidence interval) in change between the groups were computed.

Source of Funding

There was no external funding source for this study. Furthermore, although Dr. Schmitz is a paid consultant for Electro Medical Systems and his expertise in medical writing was useful in getting this paper under way, Electro Medical Systems did not fund the actual trial itself, either by providing a device or financially in any way.

Results

Of the 102 patients randomized into the study, ninety-six returned for a follow-up evaluation two months after baseline, ninety-three patients returned four months after baseline, and eighty-two returned fifteen months after baseline (Fig. 1).

Table I summarizes the baseline characteristics of the patients who completed the study.

Both groups reported an overall reduction in pain. For the change in the pain subscale scores of the PS-FFI, the analysis of variance demonstrated a significant effect of treatment ($p < 0.01$) and a significant treatment-time interaction ($p < 0.01$) at two months after baseline in favor of plantar fascia-specific stretching (Group I) compared with shock-wave therapy (Group II). Details are given in Table III. Similar significant differences persisted at four months after baseline. No significant differences were detected between the groups at fifteen months after baseline.

A summary of the responses to the SROM questionnaire (dichotomized data) is presented in the Appendix. Statistical analysis of the response rates to the SROM questionnaire demonstrated a significant difference between the groups at two months with regard to question 6, which addressed patient satisfaction ($p < 0.001$). The null hypothesis was rejected. The percentage of positive responses with regard to pain, activity limitations, and patient satisfaction was greater in the plantar fascia-specific stretching group (Group I) than in the shock-wave therapy group (Group II) (p value between <0.001 and 0.006) at two months, and a similar greater percentage persisted at four months after baseline. No significant between-group differences were detected at fifteen months after baseline (see Appendix).

TABLE III Change Between Pain Subscale Scores of the Foot Function Index from Baseline to the Two-Month, Four-Month, and Fifteen-Month Follow-up Evaluations*

	Mean Change from Baseline to 2 Mo†	P Value	Mean Change from Baseline to 4 Mo†	P Value	Mean Change from Baseline to 15 Mo†	P Value
Item 1, Group I (PFSS)	–4.4 ± 2.7 (–5.8 to –3.7)	<0.001	–5.5 ± 2.6 (–6.2 to –4.8)	0.007	–6.1 ± 2.6 (–6.8 to –5.4)	0.516
Item 1, Group II (SWT)	–2.0 ± 2.3 (–2.6 to –1.3)		–3.9 ± 3.1 (–4.8 to –3.0)		–6.4 ± 2.5 (–7.2 to –5.7)	
Item 2, Group I (PFSS)	–4.5 ± 2.4 (–5.1 to –3.8)	<0.001	–5.2 ± 2.5 (–5.8 to –4.5)	0.002	–5.8 ± 2.3 (–6.4 to –5.1)	0.756
Item 2, Group II (SWT)	–1.8 ± 2.0 (–2.4 to –1.2)		–3.5 ± 2.8 (–4.3 to –2.7)		–5.9 ± 2.6 (–6.7 to –5.1)	
Items 1-7, Group I (PFSS)	–21.4 ± 10.6 (–24.3 to –18.5)	<0.001	–24.9 ± 13.0 (–28.5 to –21.4)	<0.001	–29.1 ± 12.8 (–32.6 to –25.6)	0.950
Items 1-7, Group II (SWT)	–6.6 ± 1.2 (–9.1 to –4.1)		–15.5 ± 10.1 (–18.4 to –12.6)		–28.9 ± 12.3 (–32.5 to –25.3)	

*Group I was managed with a plantar fascia-specific stretching (PFSS) program, and Group II was managed with radial shock-wave therapy (SWT). †Data are given as the mean change and the standard deviation, with the 95% confidence interval in parentheses.

Until two months after baseline, fifteen patients in the plantar fascia-specific stretching group and thirty-eight patients in the shock-wave group took diclofenac (or ibuprofen) as rescue medication; the mean number of tablets taken was eleven and thirty-two, respectively ($p < 0.001$).

The daily exercise logs were not collected for analysis; however, at each point of follow-up, patients were questioned about their compliance with the frequency of the exercise program, and this method of questioning revealed that four patients in the plantar fascia-specific stretching group (Group I) had stopped the stretching exercises before the two-month follow-up. These patients left the trial, and their baseline data were carried forward and used for further analysis. Furthermore, at the four-month and fifteen-month follow-up periods, patients in the plantar fascia-specific stretching group were asked whether they had started stretching on their own when and if symptoms returned after conclusion of the initial eight-week home stretching program. At four months, thirteen of thirty-nine patients who had answered positively to SROM question 6 (satisfaction with treatment) said that they were still continuing with the stretching program on a daily basis, and nineteen patients reported that they would start stretching again on their own when and if symptoms returned. At fifteen months, only four of forty patients who had answered positively to SROM question 6 said that they were still continuing with the stretching program on a daily basis, and thirty-one patients reported that they would start stretching again on their own when and if symptoms returned.

Side Effects

For all patients in the shock-wave therapy group (Group II), transient reddening occurred after shock-wave therapy. Forty-one of forty-eight patients in Group II reported treatment-related pain of ≥5 on the Pain Numeric Rating Scale (0 = no pain; 10 = worst pain imaginable), as did eight of fifty-four patients in the plantar fascia-specific stretching group (Group I). Among those eight were the four patients who had stopped the stretching exercises before the two-month follow-up. Apart from these minor findings, no clinically relevant side effect was observed. No device-related complications occurred.

Discussion

While the initiation of conservative treatment soon after the onset of plantar fasciopathy symptoms[1] is assumed to afford a cure in most patients within six weeks[16], recovery from acute plantar fasciopathy is frequently slow and recurrent symptoms are not uncommon[8]. Neither of these assumptions has been tested in randomized controlled studies[2,9,10].

Randomized controlled studies have shown that stretching exercises improve recalcitrant plantar fasciopathy symptoms within a reasonable time frame[6,24,25]. The therapeutic mechanism involved in any stretching exercise is speculative, and there has been no clear explanation of why such treatment works. The optimal stretching intensity, speed, load, and frequency remain unclear[26].

Randomized controlled studies have shown that low-energy shock-wave therapy, when applied repetitively, directed to the most tender point at the medial calcaneal tubercle, and performed without local anesthesia, leads to significant and persistent improvement of recalcitrant plantar fasciopathy symptoms within a reasonable time frame[4,12,13,27-29].

The therapeutic mechanism involved in shock-wave therapy has been well described. In terms of pain relief, the biological basis for the analgesic effect of shock-wave therapy is interaction with sensory neuropeptides such as substance P or calcitonin gene-related peptide. Release of substance P and calcitonin gene-related peptide in the dorsal aspect of the spinal cord is associated with nociceptive transmission, and release from perivascular nerve endings has been shown to initiate neurogenic inflammation[30]. Neurogenic inflammation contributes to musculoskeletal

pain[31]. Application of shock-wave therapy to skin or tendon depletes sensory nerve fibers of substance P and calcitonin gene-related peptide in the area of application, and also reduces their expression in dorsal root ganglia. This phenomenon, more evident when shock-wave therapy is applied repetitively, is linked to the desensitization of the exposure area and provides an explanation for the analgesic effects of shock-wave therapy[30].

Shock-wave therapy also triggers physiological healing when there is a failed healing response, such as in cases of fracture nonunion or delayed union, bone necrosis, tendinopathy, or fasciopathy[32-34]. Shock-wave therapy, when applied to fibroblasts, enhances cell proliferation and induces changes in mRNA expression for transforming growth factor-beta 1 (TGF-β1), collagen I, and collagen III, which results in activation and acceleration of the healing process[35]. When applied to tenocytes, shock-wave therapy stimulates tenocyte proliferation, mediated by early upregulation of proliferating cell nuclear antigen and TGF-β1 gene expression, endogenous nitric oxide release, and, finally, TGF-β1 protein and collagen synthesis[36].

The current study contradicts the assumption that, if treatment is started soon after the onset of symptoms, most patients will be pain-free within six weeks, regardless of treatment method[16]. In our study, an intention-to-treat analysis, with both groups having been given soft heel pads and with both groups having been counseled to pursue daily activities as tolerated, there was a significant difference in outcome. While 65% of patients performing the plantar fascia-specific stretching program reported total satisfaction with treatment or satisfaction with treatment with minor reservations (item 6 of the SROM questionnaire) at two months after baseline, only 29% did so after shock-wave therapy. It was not possible to distinguish from this questionnaire whether patients related their satisfaction to the outcome or to the process of treatment that led to the outcome.

As a hypothesis, we suggest that, at acute presentation, the features of a failed healing response are not yet present. Therefore, tissue-healing, which has been shown to be initiated by shock-wave therapy, may not play a role in acute plantar fasciopathy. As there is not (to our knowledge) a single experimental report claiming that low-energy shock-wave therapy might impede a healing response, we consider it more likely that the observed lack of effectiveness of shock-wave therapy at two months after baseline results from the amount of time needed to trigger a healing response. A follow-up period of two months may just be too short to allow shock-wave therapy to work.

Strengths of the current study are the prospective, randomized design and the stringent method of patient selection. To minimize confounding variables, specific attention was paid to the inclusion of only patients who clearly had classic proximal plantar fasciopathy.

We used the pain subscale of the Foot Function Index (PS-FFI). This is not only a validated instrument[19-22], but it has already been used in a similar study. DiGiovanni et al.[12] only used the first seven items of the PS-FFI as their primary numeric outcome measure. An independent analysis of item 1 (pain at its worst) and item 2 (pain during the first few steps of walking in the morning) was performed, since these two were thought to be most clinically relevant to the patients' complaints. In the current study, when the scores were combined for all seven items of the PS-FFI as well as when the scores were analyzed individually, significant differences were detected in favor of the plantar fascia-specific stretching group at both two months and four months after baseline.

In contrast with the study by DiGiovanni et al.[12], our loss-to-follow-up rate was comparable in both groups, thus eliminating a bias in clinical outcomes through dissimilarity in the attrition rates between the two groups. In the current study, the baseline characteristics of the patients who dropped out of the study did not vary significantly from those of the patients who returned for follow-up visits.

Another strength of the current investigation is that the duration of follow-up was not limited to eight weeks. Our data show a superiority of the stretching program for at least four months after baseline, whereas both groups had improved comparably by fifteen months after baseline.

We acknowledge concerns that the varying intake of a nonsteroidal rescue medication might have influenced the results of either treatment group. The main weakness of the current investigation, however, is that it did not involve a sham treatment group. Enrolling patients without offering them any kind of treatment—a "wait and see" group—was deemed not feasible as only patients with severe pain ratings (≥6 of 10 points for pain during the first few steps of walking in the morning) were enrolled. Therefore, the spontaneous healing rate cannot be distinguished from the measured outcomes of both plantar fascia-specific stretching and shock-wave therapy. The low recovery rate in the shock-wave therapy group indicates that quick resolution of symptoms is by no means ensured.

Patients were not encouraged to continue stretching for longer than eight weeks; thus, because of the difference seen at two months and at four months but not at fifteen months, it appears that stretching was helpful to resolve pain more quickly. However, over time, the pain will resolve on its own, reflecting the self-healing nature of plantar fasciopathy.

The results of the current study cannot be generalized. Patients enrolled in the current study clearly formed a well-selected cohort. When informing patients about the study, a yet untreated individual with plantar heel pain of a maximum duration of six weeks was relatively rare in the participating orthopaedic outpatient clinics.

In conclusion, recovery of acute plantar fasciopathy is frequently slow and recurrences are not uncommon. A program of manual stretching exercises specific to the plantar fascia was found to be superior to repetitive low-energy radial shock-wave therapy for the initial management of acutely presenting plantar fasciopathy.

Appendix

eA The SROM outcome questionnaire and detailed data tables for the pain subscale scores of the FFI and the SROM

outcome scale are available with the electronic version of this article on our web site at jbjs.org (go to the article citation and click on "Supporting Data"). ■

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