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Radial shock wave treatment alone is less efficient than radial shock wave treatment combined with tissue-specific plantar fascia-stretching in patients with chronic plantar heel pain

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HIGHLIGHTS

- ESWT for chronic heel pain is an effective and evidence-based treatment modality.
- Stretching specific to the plantar fascia is highly effective as well.
- Combining ESWT and stretching lead to better results than ESWT alone.

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ABSTRACT

Background: Whether shock wave therapy or shock wave therapy combined with plantar fascia-specific stretching is more efficient in treating chronic plantar heel pain remains unclear. The aim of the study was to test the null hypothesis of no difference of these two forms of management for patients who had unilateral plantar fasciopathy for a minimum duration of twelve months and which had failed at least three other forms of treatment.

Methods: One hundred and fifty-two patients with chronic plantar fasciopathy were assigned to receive repetitive low-energy radial shock-wave therapy without local anesthesia, administered weekly for three weeks (Group 1, n = 73) or to receive the identical shock wave treatment and to perform an eight-week plantar fascia-specific stretching program (Group 2, n = 79). All patients completed the nine-item pain subscale of the validated Foot Function Index and a subject-relevant outcome questionnaire. Patients were evaluated at baseline, and at two, four, and twenty-four 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 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 shock-wave therapy plus plantar fascia-specific stretching than those managed with shock-wave therapy alone ($p < 0.001$), as well as individually for item 2 ($p < 0.001$). Twenty-four patients in Group 1 (32%) versus forty-seven patients in Group 2 (59%) were satisfied with the treatment ($p < 0.001$). Significant differences persisted at four months, but not at twenty-four months.

Conclusions: A program of manual stretching exercises specific to the plantar fascia in combination with repetitive low-energy radial shock-wave therapy is more efficient than repetitive low-energy radial shock-wave therapy alone for the treatment of chronic symptoms of proximal plantar fasciopathy.

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1. Introduction

Plantar heel pain, commonly referred to as insertional plantar fasciitis, is a common condition among orthopedic patients [1]. The characteristic complaints are knife-like pain at the calcaneal insertion of the medial part of the plantar fascia, typically worse on first arising in the morning, and often lasting months to years [2]. Typically, diagnosis can be made based on a detailed history and physical examination that allow the clinician to pinpoint the location of maximal tenderness. Weight-bearing plain radiographs should be obtained to assess alignment and degenerative changes and to exclude fracture and other skeletal abnormalities. Advanced imaging studies and electromyography (EMG) can be used to confirm or rule out certain diagnoses and to provide additional information when the diagnosis is uncertain [1].

Recommended treatment regimens consist of one or more nonsurgical modalities, including rest, shoe wear modification, NSAIDs, home stretching exercises, physical therapy, prefabricated shoe inserts, and custom orthoses [1,3]. Such measures are effective in most patients, especially when both the patient and physician allow adequate time for them to work.

Corticoid injection around the insertion of the plantar fascia show only short-term benefit and may be associated with severe side effects as rupture of the plantar fascia, and infection [4–7].

With surgery considered only for carefully selected patients with recalcitrant pain whose symptoms have persisted despite an appropriate course of nonsurgical measures, a new treatment modality came into focus, extracorporeal shock wave therapy (ESWT) [8–10].

There is still uncertainty around the use of ESWT and its clinical effectiveness remains controversial. Moreover, use of this modality is often limited by its low insurance coverage and resultant high patient cost. In a recent survey among U.S. foot and ankle surgeons, the number of physicians who chose ESWT as their preferred intervention for long-standing plantar fasciitis (10 months) increased from 33% to 42% in the absence of patient cost or insurance considerations [11].

Two recent meta-analyses [12,13] described ESWT as a safe and effective treatment of chronic plantar fasciitis refractory to non-operative treatments. And stretching specific to the plantar fascia has recently been shown to provide superior pain relief when compared with Achilles tendon stretching at 8 weeks; however, no significant difference was seen at 2-year follow-up [14,15].

So far, to the best of our knowledge, there was no controlled testing of the usefulness of combining both modalities in chronic plantar fasciitis. The aim of the study was to test the null hypothesis of no difference of these two forms of management for patients who had unilateral plantar fasciopathy for a minimum duration of twelve months and which had failed at least three other forms of treatment.

2. Materials and methods

The study was designed as a randomized, parallel treatment study with a blinded independent observer to evaluate the effectiveness of repetitive low-energy radial shock wave therapy without local anesthesia, administered weekly for three weeks or this exact shock wave treatment in combination with an eight-week plantar fascia-specific stretching program.

2.1. Inclusion criteria

Patients had to report start-up pain, that is, plantar medial heel pain that culminates either with their first steps in the morning or subsequent to prolonged periods of rest for at least twelve months. Physical examination revealed tenderness at the site of the plantar fascial insertion on the medial calcaneal tuberosity. Tenderness extended along the plantar fascia, and it increased with maneuvers that stretch the plantar fascia, including passive toe dorsiflexion [1,2]. All patients were referred for orthopedic diagnosis and treatment. All of the patients enrolled had at least three of the previous non-operative treatments: nonsteroidal anti-inflammatory medications, orthoses, heel cups, calf stretching exercises, massages, night splints, injections, and/or activity modifications. None had undergone surgery of the plantar fascia.

2.2. Exclusion criteria

Patients were excluded if they were <18 years of age; if they had bilateral plantar fasciitis; if there was a history and/or physical findings of lower-extremity dysfunction, local arthritis, generalized polyarthritis, rheumatoid arthritis, ankylosing spondylitis, or local arthrosis; if there were signs of neurologic abnormality (changes of deep tendon reflexes, or motor or sensory deficit); if there was arthrosis of the foot or ankle, as confirmed by radiographic diagnosis (anteroposterior and lateral views); if it patients participated in a Workers' Compensation program or planned to apply for the program; if there was thrombopathy, infection, tumor, diabetes mellitus, systemic lupus erythematosus, severe cardiac disease, or other severe systemic diseases; if patients were pregnant; if there was restricted ankle dorsiflexion due to contracture of the Achilles tendon or the gastrocnemius muscle itself: the Silfverskjöld test was performed to differentiate between primary contracture of the gastrocnemius muscle itself and of the gastrocnemius–soleus complex [16]; if they had prior heel surgery; if heel pain was not consistent with proximal plantar fasciitis; if patients were unwilling to accept either of the interventions in this study.

2.3. Enrollment

The prospective, randomized controlled study was conducted in a single center. The study design and the information documents were approved by the Internal Study Board of the author's institution, and the study is registered at Current Controlled Trials (http://www.controlled-trials.com/ISRCTN11644582). Patients received oral and written information about the two treatments and gave informed consent to participate in the study.

Patients were informed that they were free to leave the study, without explanation and without any negative consequences on their future treatment. Every precaution was taken to protect the privacy of research subjects and the confidentiality of their personal information. All personal patient details were rendered anonymous before data entry, by referring to all patient records and data only by their assigned research number. There are no known additional risks associated with patient participation in the study, other than the normal risks associated with these common treatments.

Recruitment strategies included: informational brochures at the office, information articles about our study in publications, and informational lectures given at community centers of the Rhein-Main area.

Following the suggestions from DiGiovanni et al. [14], 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 of symptoms, and types of prior treatments.

One hundred and ninety-five patients were checked for selection criteria; six patients did not meet the inclusion criteria and thirty-three refused consent (Fig. 1). Thus, a total of one-hundred

and fifty-two patients who had painful plantar fasciopathy for a minimum of twelve months were enrolled in the study over a four-year period.

Demographic data are summarized in Table 1.

All of the patients who were enrolled had undergone previous treatments. 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 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, 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, as was a neurology or rheumatology assessment. An orthopedic surgeon who specialized in foot and ankle disorders conducted a physical examination and confirmed the clinical diagnosis of proximal plantar fasciopathy of at least twelve-month duration.

2.4. Randomization

A computerized random-number generator (www.randomization.com) 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.

2.5. 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 who were randomized into treatment Group 1 received three sessions of radial shock-wave therapy, for no charge, following a regimen described previously [2,17,18]. A radial shock wave device (EMS ElectroMedical Systems, Nyon, Switzerland) was used. The device generates radial shock waves by accelerating a projectile within a guiding tube with the aid of compressed air. When the projectile strikes a metal applicator at the end of the guiding tube a pressure wave is generated in the applicator. This pressure wave is then transmitted as a radial shock wave into to the underlying tissue.

The treatment took place in three sessions at weekly intervals. Before the intervention, the point of maximum tenderness in the region of the median calcaneal tubercle was clinically located by the treating clinician, and the hand-piece was coupled to the identified area by using specific ultrasound coupling gel (EMS Electro Medical Systems). At each session, 2000 pulses were applied with an air pressure of 4 bar (equal to a positive energy flux density of 0.16 mJ/mm^2). The total positive energy flux density per

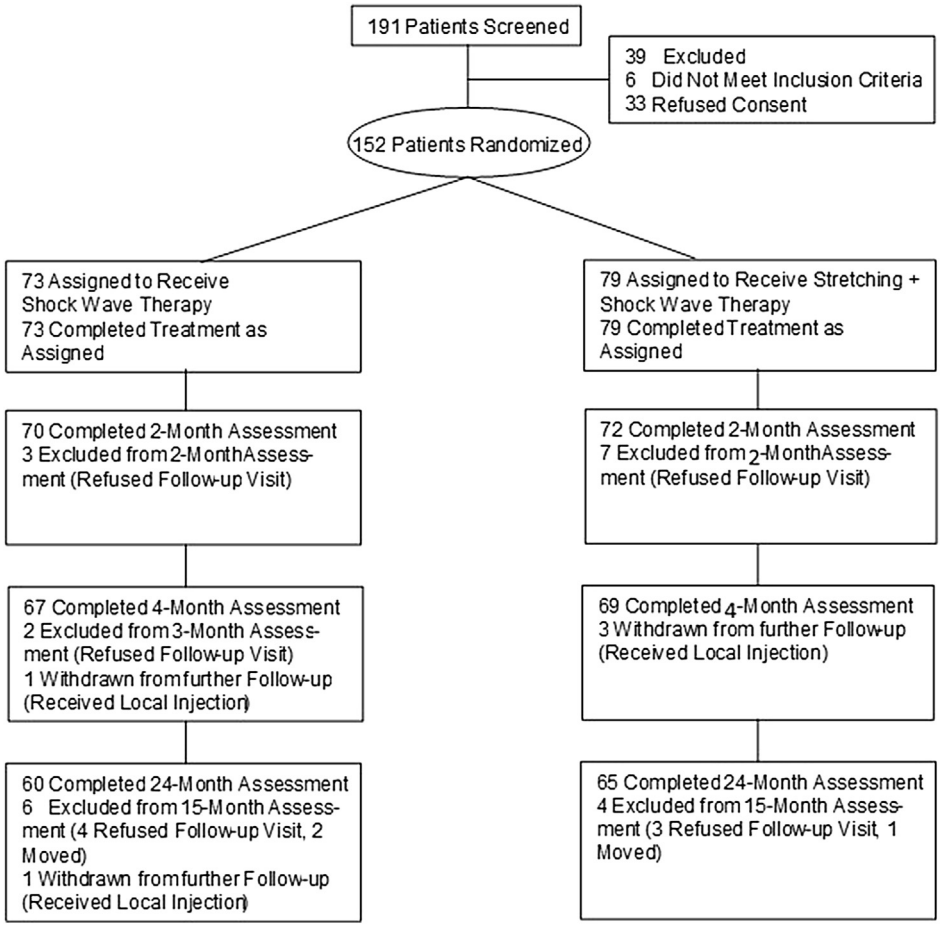

Fig. 1. Flow diagram showing recruitment and handling of the study population during the course of the study.

Table 1
Summary of baseline measures for treatments groups.[a]

Characteristic	Group 1 shock wave therapy (SWT) (n = 73)	Group 2 SWT + PFSS (n = 79)
Age, range, yr	51.2 (27–71)	52.0 (30–73)
Number of women (%)	40 (55)	41 (52)
Weight: mean (range) kg	78.2 (49–128)	76.8 (54–131)
Body-mass index: mean (range) (kg/m^2)	29.3 (19–35)	28.0 (20–35)
Number of hours standing: mean (range)	7 (3–14)	6 (3–12)
Duration of symptoms: mean (range) (mo)	18 (12–34)	16 (12–30)
Affected foot: number (%)		
Left	43 (59)	40 (51)
Previous treatment: number (%)		
NSAIDs	73 (100)	79(100)
Physical therapy	73 (100)	79 (100)
Orthotics	73 (100)	79 (100)
Stretching exercises	73 (100)	79 (100)
Casting/night splints	15 (21)	20 (25)
Cortisone injections	53 (73)	49 (62)
Radiotherapy	70 (96)	71 (89)
Surgery	0 (0)	0 (0)
Pain during first steps [0–10], mean (SD)	7.0 (4.4)	7.4 (4.7)
Foot function index pain subscale [0–10][b]: mean (SD)		
Item 1: Pain at its worst	9.4 (13.7)	9.2 (14.6)
Item 2: Pain during first steps	6.8 (4.1)	6.0 (5.3)
Item 3: Pain at end of day	5.1 (3.7)	4.9 (3.4)
Item 4: Pain while walking barefoot	6.2 (5.2)	6.7 (8.8)
Item 5: Pain while standing barefoot	3.4 (1.5)	3.9 (2.7)
Item 6: Pain when walking with shoes	4.0 (3.7)	4.3 (3.9)
Item 7: Pain when standing with shoes	5.2 (6.6)	5.0 (7.1)
Item 8: Pain when walking with orthotics	3.8 (2.3)	3.6 (2.1)
Item 9: Pain when standing with orthotics	3.5 (3.0)	3.4 (2.7)

[a] Group 1 was managed with radial shock wave therapy (SWT), and Group 2 was managed with radial shock wave therapy (SWT) in combination with a plantar fascia-specific stretching (PFSS) program.
[b] Subscale scores range from 0 to 10, with higher scores indicating greater impairment.

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.

Patients randomized to treatment Group 2 received instructions regarding a plantar fascia-specific stretching program [14,15]. Stretching exercises were to be done from baseline, three times daily, for eight weeks. Radial shock wave therapy, as described above, was initiated for no charge one week from baseline.

Patients were instructed to perform the plantar fascia-specific stretching program 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 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.

2.6. Outcome measures

At two months, four months, and twenty-four 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) [19–21], and (2) a patient-relevant outcome measures (SROM) questionnaire.

The PS-FFI consists of 9 items and measures foot pain in different conditions. Due to the versatility of the FFI questionnaire, the PS-FFI is frequently chosen by clinicians as a measurement

outcome in the assessment of acute and chronic foot and ankle conditions [22]. The questions are scored on a scale from 0 (no pain) to 10 (worst pain imaginable). The PS-FFI showed an high validity (Cronbach's alpha, 0.93) and reliability (Person reliability, 0.89) [22]. 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 the validated PS-FFI. In the current trial, the smallest relevant clinical change was determined to be two points in item "2" of the PS-FFI. The change in the PS-FFI score (i.e., the score after two months or four months or twenty-four months minus the baseline score) was used for subsequent analysis. A negative change in the PS-FFI signified patient improvement.

The SROM questionnaire included generic and condition-specific outcome measures related to feeling (SROM 1; better of/same/worse), description of heel pain (SROM 2; no/less/same/more), percent improvement in heel pain (SROM 3; none/1–25%/26–50%/51–75%/76–99%/100%), rating of heel pain (SROM 4; all better/much better/slightly better/unchanged/worse), and percent improvement in overall daily function (SROM 5; totally satisfied/satisfied with minor reservations/satisfied with major reservations/dissatisfied).

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. The analysts were blinded to the allocated intervention.

2.7. Statistics

The primary goal of this study was to compare the clinical outcome of chronic, previously multiply treated plantar fasciopathy after either shock wave therapy alone or after shock wave therapy in combination with plantar fascia-specific stretching. 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 a ($p < 0.025$).

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

Power estimates based on the change in the end point for the PS-FFI and a standard error estimate obtained from recent studies with a similar design [1,14,24,25] revealed that a sample size of sixty 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. [14,15] 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. For analysis, the level of significance was set at $p < 0.025$.

Statistical analysis was performed using GraphPad InStat version 3.10 for Windows (GraphPad Software, San Diego California USA, www.graphpad.com).

All analyses were performed on an intention-to-treat basis. When there were missing responses, the last observation was carried forward (LOCF) (with last observation defined as the last recorded value), as the current "Guideline on Missing Data in Confirmatory Clinical Trials" of the European Medicines Agency had elaborated that LOCF may be a good technique particularly for studies on chronic pain where the condition is expected to improve spontaneously over time.

Differences (with 95% confidence interval) in change between the groups were computed.

2.8. Source of funding

There was no external funding source for this study. Electro Medical Systems did not fund the actual trial, either by providing a device or financially in any way.

3. Results

Of the one hundred fifty-two patients randomized into the study, one hundred forty-two returned for a follow-up evaluation two months after baseline, one hundred thirty-six patients returned four months after baseline, and one hundred twenty-five returned twenty-four months after baseline. Details are given in Fig. 1.

Table 1 summarizes the baseline characteristics of the patients who were enrolled in the study. With the numbers available, the patients treated with shock wave therapy alone were not statistically different from the patients treated with shock wave therapy in combination with a plantar fascia-specific stretching program (Chi-square test; unpaired two-tailed Student's t test). 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.

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 statistically significant effect of treatment ($p < 0.01$) and a statistically significant treatment-time interaction ($p < 0.01$) at two months after baseline in favor of shock wave therapy in combination with plantar fascia-specific stretching (Group 2) compared with shock wave therapy alone (Group 1). Statistically significant differences, but not clinically important differences, persisted at four months after baseline, and at twenty-

four months after baseline. Details are given in Table 2.

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. At two months after baseline, twenty-four patients (32%) of Group 1 versus forty-seven patients (59%) of Group 2 were totally satisfied or satisfied with minor reservations with the treatment ($p < 0.001$); at four months after baseline, thirty-three patients (49%) of Group 1 versus forty-nine patients (71%) of Group 2 were totally satisfied or satisfied with minor reservations with the treatment ($p = 0.01$); at twenty-four months after baseline, forty patients (66%) of Group 1 versus forty-five patients (69%) of Group 2 were totally satisfied or satisfied with minor reservations with the treatment (N.S.).

The null hypothesis was rejected.

The percentage of positive responses to question 1–5 of the SROM questionnaire with regard to pain, activity limitations, was less in the shock wave therapy group (Group 1) than in the shockwave therapy plus plantar fascia-specific stretching group (Group 2) (p value between <0.001 and 0.01) at two months, and a similar greater percentage persisted at four months after baseline. No statistically significant between group differences were detected at twenty-four months after baseline.

Until two months after baseline, twenty-eight patients in the shock wave therapy group and thirty-four patients in the shock wave therapy plus plantar fascia-specific stretching group took diclofenac (or ibuprofen) as rescue medication. The difference was not statistically significant.

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 shock wave therapy plus plantar fascia-specific stretching group (Group 2) 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 twenty-four-month follow-up periods, patients in the shock wave therapy plus plantar fascia-specific stretching group (Group 2) 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, twenty of forty-nine patients who had answered positively 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 twenty-four months, only four of forty-five 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 patients reported that they would start stretching again on their own when and if symptoms returned.

3.1. Side effects

All patients showed transient reddening of the skin after shock wave therapy. One hundred and one of one hundred fifty-two patients receiving shock wave therapy in both groups reported treatment related pain of >5 on the Pain Numeric Rating Scale (0 = no pain; 10 = worst pain imaginable). Apart from these minor findings, no clinically relevant side effect was observed. No device-related complications occurred.

4. Discussion

Randomized controlled studies have shown that stretching exercises improve recalcitrant plantar fasciopathy symptoms within a reasonable time frame [14,15,25]. 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.

The mechanism of shock wave therapy is not fully understood either. The most important physical parameters of shock wave therapy for the treatment of orthopedic disorders include the pressure distribution, energy flux density and the total acoustic energy. In contrast to lithotripsy in which shock waves disintegrate renal stones, orthopedic shock waves are not being used to disintegrate tissue, but rather to microscopically cause interstitial and extracellular responses leading to tissue regeneration [17,26], whereby radial extracorporeal shock waves, as were applied in the current trial, differ from focused extracorporeal shock waves by penetration depth and certain physical properties. Specifically, the maximum flux energy of radial extracorporeal shock waves is reached at the tip of the applicator – on the surface of the skin – whereas the maximum flux energy of focused extracorporeal shock waves is in reached in a focal zone with the treated tissue. Both forms of shock waves are characterized by an initial high positive peak pressure between 10 and 100 Megapascal reached in less than 1 μs, a low tensile amplitude (negative pressure) following the positive pressure amplitude, a short life cycle of 10–20 μs, and a broad frequency spectrum. During the tensile phase cavitation, i.e. the formation of vapor bubbles of a liquid in the region where the pressure falls below its vapor pressure, has been observed for both radial and focused extracorporeal shock waves, resulting in local shear forces when collapsing at the end of the phase of negative pressure.

Multiple *in vitro* and *in vivo* studies investigated the effect of shock wave therapy on tendinopathies [27–30]. The majority of the studies have shown a dose-dependent destructive effect of shock wave therapy, but they provided also evidence that an optimal dosage of shock wave therapy determines a stimulatory effect on cell proliferation, as well as the activation and enhancement of healing process. In fact, taken together, the morphological changes,

Table 2
Change between pain subscale scores of the foot function index from baseline to the two-month, four-month, and twenty-four-month follow-up evaluations. SWT: Shock Wave Therapy. PFSS: Plantar Fascia-Specific Stretching.

	Mean change from baseline to 2 Mo	P Value	Mean change from baseline to 4 Mo	P value	Mean change from baseline to 24 Mo	P value
Item 1, Group 1 (SWT)	−2.4 ± 2.1 (−2.9 to −1.9)		−4.0 ± 2.0 (−4.5 to −3.5)		−5.7 ± 1.6 (−6.1 to −5.4)	
Item 1, Group 2 (SWT + PFSS)	−4.7 ± 1.5 (−5.0 to −4.3)	<0.001	−5.1 ± 1.6 (−5.4 to −4.7)	<0.001	−6.4 ± 2.1 (−6.9 to −6.0)	<0.01
Item 2, Group 1 (SWT)	−1.8 ± 2.0 (−2.3 to −1.3)		−3.7 ± 2.2 (−4.2 to −3.1)		−4.2 ± 2.5 (−4.8 to −3.6)	
Item 2, Group 2 (SWT + PFSS)	−4.0 ± 1.5 (−4.3 to −3.7)	<0.001	−5.0 ± 2.1 (−5.5 to −4.5)	=0.001	−5.1 ± 2.5 (−5.7 to −4.5)	<0.05, N.S.
Items 1–9, Group 1 (SWT)	−12.2 ± 6.3 (−13.7 to −10.7)		−20.1 ± 10.2 (−22.5 to −17.6)		−27.6 ± 13.8 (−30.9 to −24.3)	
Items 1–9, Group 2 (SWT + PFSS)	−20.1 ± 7.8 (−21.9 to −18.3)	<0.001	−27.1 ± 8.0 (−29.0 to −25.2)	<0.001	−35.8 ± 11.0 (−38.4 to −33.3)	<0.01

proliferation and motility of treated cells, functional outcome on neovascularization and collagen synthesis, as well as the expression of differentiation critical genes suggest that shock wave therapy may be able to increase tendon healing. Nevertheless, it is not possible to define how, *in vivo*, extracorporeal shock wave therapy acts on exposed tissues. They may provide mechanical and biological stimuli determining the activation of a complex network of molecules, including a large panel of cytokines and metalloproteinases [31].

Clinically, five randomized controlled studies have shown that low-energy radial 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 [12,17]. All five trials concluded that radial shock wave therapy was efficient in the treatment for chronic plantar fasciopathy [18,32–35].

The current study supports those results. Once more, it demonstrated the usefulness of shock wave therapy in patients with chronic recalcitrant plantar fasciopathy. However, when combined with an eight-week plantar fascia-specific stretching program, significantly quicker pain relief was achieved within two months after baseline compared to shock wave therapy as a stand-alone form of treatment. While 59% of patients receiving shock wave therapy and performing the plantar fascia-specific stretching program reported total satisfaction with treatment or satisfaction with treatment with minor reservations (item 5 of the SROM questionnaire) at two months after baseline, only 32% did so after shock wave therapy alone. 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.

For further assessment the pain subscale of the Foot Function Index (PS-FFI) was used. This is not only a validated instrument [19–21], but it has already been used in a similar study. DiGiovanni et al. [14] 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 nine items of the PS-FFI as well as when the scores were analyzed individually, significant differences were detected in favor of the combined treatment Group 2 at both two months and four months after baseline. With regard to item 2 “pain during first steps” both groups improved, Group 1 by 1.8 points, Group 2 by 4.0 points ($p < 0.001$). According to our definition, that was a clinically important difference between the groups. Four months after baseline, both groups had improved further (Group 1: by 3.7 points; Group 2: by 5.0 points; $p = 0.001$). By definition, this difference between the groups did no longer fulfil the criterion of a clinically important difference between the groups. Twenty-four months after baseline, both groups had a difference of less than one point, being statistically not significant, and clinically not relevant.

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 chronic classic proximal plantar fasciopathy.

In contrast with the study by DiGiovanni et al. [14], 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 of two years after baseline.

Our data show a superiority of the combination of shock wave therapy with a specific stretching program for at least four months after baseline, whereas both groups had improved comparably by twenty-four months after baseline.

The results of the current study cannot be generalized. Patients enrolled in the current study clearly formed a well-selected cohort. As such they are representative for this group only, and not, for example, for athletes or for very old, obese women.

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 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 shock wave therapy alone and shock wave therapy combined with plantar fascia-specific stretching. Keeping in mind the rigid inclusion criterion of a twelve-month recalcitrant plantar heel pain it is reasonable to assume that the spontaneous healing rates in such patients are at least very low.

The results of sham treatment of the current protocol, however, had already been reported in the FDA confirmatory study from Gerdesmeyer et al. [18].

The slow recovery rate in the shock wave therapy group indicates that quick resolution of symptoms is by no means ensured after this form of management.

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 twenty-four months, it appears that stretching was helpful to resolve pain more quickly.

In conclusion, recovery of chronic plantar fasciopathy is frequently slow. A program of manual stretching exercises specific to the plantar fascia in combination with repetitive low-energy radial shock wave was found to be superior to shock wave therapy alone for the management of chronically presenting plantar fasciopathy.

Conflicts of interest

None.

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