Long-Term Results of Radial Extracorporeal Shock Wave Treatment for Chronic Plantar Fasciopathy: A Prospective, Randomized, Placebo-Controlled Trial With Two Years Follow-Up

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ABSTRACT: Numerous randomized controlled trials (RCTs) demonstrated efficacy and safety of extracorporeal shock wave therapy (ESWT) for chronic plantar fasciopathy (cPF). However, only two such RCTs investigated a follow-up period of more than 1 year, both applying focused ESWT. Corresponding data for radial ESWT (rESWT) have not yet been reported. We therefore tested the hypothesis that rESWT is effective and safe for the management of cPF with long-term follow-up of 2 years. To this end $n = 50$ patients with cPF were randomly allocated to either two sessions of rESWT (one session per week; 2,000 shock waves with energy flux density of 0.16 mJ/mm^2 per session) ($n = 25$) or to placebo treatment ($n = 25$). Evaluation was by change in Visual Analog Scale (VAS) score and Roles and Maudsley (RM) score. Mean pretreatment VAS scores for the rESWT and placebo groups were 8.5 and 8.9, respectively. 1, 3, 6, 12, and 24 months after treatment, the mean VAS scores for the rESWT and placebo groups were 0.6, 1.1, 0.5, 2.3, and 1.4 and 7.6, 7.7, 7.4, 6.9, and 5.6 ($p < 0.001$), respectively. Differences in mean RM scores were statistically significant between groups at 1, 3, 6, 12, and 24 months post treatment, but not at baseline. There were no significant complications. These data indicate that rESWT is effective and safe for the management of cPF with long-term follow-up of 2 years. © 2016 Orthopaedic Research Society. Published by Wiley Periodicals, Inc. J Orthop Res 35:1532–1538, 2017.

Keywords: extracorporeal shock wave therapy (ESWT); focused extracorporeal shock wave therapy (fESWT); painful heel; plantar fasciopathy; radial extracorporeal shock wave therapy (rESWT)

Plantar fasciopathy (PF) is a painful disorder of the plantar fascia.[1–3] It is the most common cause of plantar heel pain and accounts for approximately 11–15% of foot symptoms presenting to physicians.[2,4] Diagnosis is based on the clinical features of the disease.[1–3] Imaging studies, although usually not necessary, may be helpful when the diagnosis is in doubt.[5]

Most patients respond to conservative treatment modalities including rest, physiotherapy, stretching, exercises, shoe inserts/orthotics, night splints, non-steroidal anti-inflammatory drugs, and local corticosteroid injections.[6] Patients not responding to conservative treatment for 6 months (between 10 and 20% of all patients) are usually offered more extensive treatment such as extracorporeal shock wave therapy (ESWT) or surgery.[6]

Numerous studies demonstrated efficacy and safety of ESWT for chronic plantar fasciopathy (cPF). There are currently 37 high-quality randomized controlled trials (RCTs) regarding ESWT and PF listed in the PEDro database (www.pedro.org.au).[7] The PEDro database is a freely available database of over 31,000 RCTs, systematic reviews, and clinical practice guidelines in physical and rehabilitation medicine.[8] For PF, 37 out of all 82 RCTs listed in the PEDro database (45%) were RCTs on ESWT at the deadline, May 17, 2015.[7] Among these 37 RCTs, 9 were performed with radial ESWT (rESWT), 27 with focused ESWT (fESWT), and 1 with both rESWT and fESWT.[7] Furthermore, in 31 out of these 37 RCTs (84%), ESWT was found significantly better statistically than either placebo or alternative treatment modalities.[7] Among those six RCTs in which ESWT was not found significantly better statistically than either placebo or alternative treatment modalities, three[9–11] were performed on non-chronic patients with symptoms for less than 6 months, one[12] was performed under local anesthesia and with insufficient energy (both may adversely affect outcome of ESWT[13,14]), and another one was performed with insufficient energy.[15]

It is of note that among those RCTs listed in the PEDro database in which ESWT for cPF was found significantly better statistically than either placebo or alternative treatment modalities, only two[16,17] investigated a follow-up period of more than 1 year, both applying fESWT. According to some authors who defined long-term follow-up in studies on ESWT for

Conflicts of interest: John P. Furia is employed by SUN Orthopaedic Group (Lewisburg, PA) and paid for clinical work, not for any research activities. C. Schmitz serves as paid consultant for and receives benefits from Electro Medical Systems, the manufacturer and distributor of the radial extracorporeal shock wave device, Swiss DolorClast. However, Electro Medical Systems had no any role in study design, data collection and analysis, decision to publish, or preparation of the present manuscript. No other potential conflicts of interest relevant to this article were reported.

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cPF as measures taken close to 2 years after treatment,[18] this would imply that long-term success of rESWT for cPF has not yet been demonstrated.

Therefore it was the aim of the present study to determine whether rESWT is effective and safe for the management of cPF with long-term follow-up of 2 years. Because no preliminary data were available, the null hypothesis of the present study was that rESWT for cPF does not result in long-term success measured 2 years after treatment.

MATERIALS AND METHODS

A total of $n = 55$ patients with unilateral cPF were enrolled in this prospective, randomized, placebo controlled, double blind trial (level of evidence: I) between October 2007 and November 2008. The present study is a continuation of an earlier RCT on rESWT for cPF with follow-up examinations at 1, 3, and 6 months after treatment.[19] Patients were diagnosed by primary care physicians with cPF primarily based on the patient's history and physical examination, including heel pain and local tenderness over the plantar's medial aspect of the calcaneal tuberosity near the plantar fascia insertion. Radiographs showed the presence of a heel spur in 77% of the patients. All patients suffered from PF for at least 6 months and had undergone various conservative treatments, including medical treatment (pain and anti-inflammatory medications), at least two corticosteroid injections and 12 physical therapy sessions (comprising electrical muscles stimulation, pulsed ultrasound, and stretching exercises). Patients were then referred to the office of the principal investigator in Brooklyn (NY) and considered for participation in the present study according to the inclusion and exclusion criteria summarized in Table 1. Before randomization, $n = 2$ patients chose to withdraw their consent for participation in the study, and another $n = 3$ patients declined to sign the consent form. Patients of any gender, race, and ethnicity were eligible to participate in the present study. After having obtained written informed consent from each patient, they were randomly assigned by an independent treatment center affiliated with Rocky Mountain University of Health Professions (RMU) at Provo (UT) in blocks of two to receive either rESWT ($n = 25$) or placebo treatment ($n = 25$). Randomization was performed by a computerized random number generator created by an independent biostatistician to draw up groups' allocation. An administrative assistant distributed interventions via opaque, sealed envelopes, containing information about the individual allocation schedule. Both patients and the study investigators at RMU were blinded for the entire duration of the study. Specifically, the study investigators did not have access to the patients' treatment records, including patient allocation or the allocation sequence, until all patients had completed the 2-year follow-up re-evaluation. Ethical approval was obtained from the Institutional Review Board of RMU before starting the study (RMUoHP IRB Protocol # 070609-02). The study was carried out in accordance with the World Medical Association Declaration of Helsinki.[20] It has been registered with ClinicalTrials.gov (Identifier NCT02679521).

With the numbers available, the patients treated with rESWT were not significantly different statistically from the patients treated with placebo in respect of the mean age, mean body weight, sex distribution, affected side, types of job, mean Visual Analog Scale (VAS) score at baseline, and mean modified Roles and Maudsley (RM) score[21] at baseline (Table 2).

The flow of patients through the present RCT according to the CONSORT 2010 Statement[22] is shown in Figure 1.

Table 1. Inclusion and Exclusion Criteria of Patients With Chronic Plantar Fasciopathy Enrolled in the Present Study

Inclusion Criteria
Adults over the age of 18 years
Diagnosis of painful heel syndrome by clinical examination, with the following positive clinical signs: 1. Pain in the morning or after sitting a long time 2. Local pain where the fascia attaches to the heel 3. Increasing pain with extended walking or standing for more than 15 min
History of 6 months of unsuccessful conservative treatment
Therapy free period of at least 4 weeks before referral
Signed informed consent
Exclusion Criteria
Bilateral plantar fasciitis
Dysfunction of foot or ankle (e.g., instability)
Arthrosis or arthritis of the foot
Infections or tumors of the lower extremity
Neurological abnormalities, nerve entrapment (e.g., tarsal tunnel syndrome)
Vascular abnormality (e.g., severe varicosities, chronic ischemia)

(*Continued*)

Table 2. Summary of Baseline Measures for Treatment Groups ($n = 25$ Each)

Characteristic	rESWT Group	Placebo Group	Comparison
Age, mean, SEM, range (yr)	56.6, 2.7, 26–87	49.1, 2.6, 28–78	$p = 0.053$ (T-test)
Body weight, mean, SEM, range (kg)	90.3, 3.7, 57.5–125	84.2, 2.8, 60–110	$p = 0.192$ (T-test)
Number of women (%)	18 (72)	14 (56)	$p = 0.239$ (Chi-Square test)
Affected side: number (%) left	11 (44)	12 (48)	$p = 0.777$ (Chi-Sqare test)
Types of jobs: sedentary, light, medium-heavy, heavy	0, 6, 14, 5	3, 3, 15, 4	$p = 0.777$ (Chi-Sqare test)
VAS score, mean, SEM, range (points)	8.5, 0.34, 5–10	8.9, 0.19, 7–10	$p = 0.312$ (T-test)
RM score, mean, SEM, range (points)	3.8, 0.1, 2–4	3.8, 0.1, 3–4	$p = 0.955$ (U-test)

RM, modified Roles & Maudsley score.

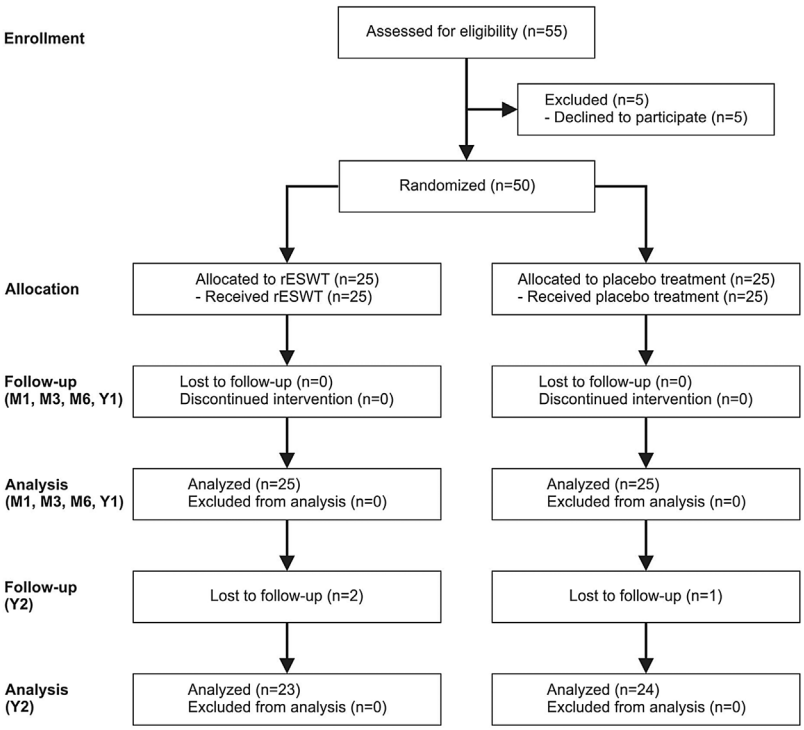

Figure 1. Flow of patients through the present study according to the CONSORT 2010 Statement.[22]

Treatment

Radial extracorporeal shock wave therapy (rESWT) was performed by the principal investigator with a Swiss DolorClast device (EMS Electro Medical Systems Corporation; Dallas, TX). Each patient received two sessions of rESWT 1 week apart, with 2,000 impulses per session (air pressure of the device set at 3.5 bar; impulses applied with the 15 mm applicator at frequency of 8 Hz). Placebo treatment was performed identically but with a clasp on the heel that prevented transmission of the impulses from the applicator to the skin at the treatment site. The patients were not made aware as to whether they received rESWT or placebo treatment. The principal investigator who applied the treatments was not blinded (as was the case in all 37 studies on ESWT for PF listed in the PEDro database[7]). Therefore, the principal investigator interacted with study participants strictly in a standardized way irrespective of treatment allocation, preventing any behavior that could have indicated to the patients whether they received rESWT or placebo treatment. Specifically, (i) no patient knew how placebo treatment was actually achieved; (ii) the sound, look, and handling of the rESWT device were identical in both rESWT and placebo treatments; and (iii) all rESWT or placebo treatment sessions took approximately 10 min. Local anesthesia was not applied because it may have adversely affected outcome of ESWT.[13,14] No other treatments were allowed during the first 6 months after rESWT or placebo treatment. Afterwards, patients were allowed to chose any possible treatment modality, but would have been excluded in case they would have undergone any treatment considered 2nd tier (corticosteroid injection, custom orthotics, night splint, immobilization, Rx physical therapy) or 3rd tier (ESWT, fasciotomy with or without nerve release) by the American College of Foot and Ankle Surgeons (ACFAS) heel pain committee.[6] In fact, most of the patients in the placebo group continued to use pain medication, and most of the patients in both groups said they continue doing home care exercises. However, no patient underwent any treatment considered 2nd or 3rd tier by the ACFAS heel pain committee.[6] Accordingly, no patient was excluded at the 1- and 2-year follow-up examinations.

Evaluation of Treatment Success

Patients were requested to assess pain and quality of life before (i.e., at baseline) as well as 1 month (M1), 3 months (M3), 6 months (M6), 1 year (Y1), and 2 years (Y2) after rESWT or placebo treatment, respectively. To this end, both the VAS score and the modified RM score were used. The clinical outcome was assessed face to face by observers blinded to treatment allocation during visits of the patients to the clinic of the principal investigator at baseline and at M1, M3, M6, Y1, and Y2. During each visit a questionnaire was filled in that addressed the VAS score and the modified RM score. A separate form attached to the questionnaire was used to document that the patients had not undergone any treatment considered 2nd or 3rd tier by the ACFAS heel pain committee[6] since the last visit to the clinic.

The VAS is a horizontal, 10-cm-long line with the phrase "no pain" on the left side (score: 0) and the phrase "pain as bad as it could be" on the right side of the line (score: 10). Patients were asked to place a hatch mark on the line that corresponded to their current level of pain. The distance between the phrase "no pain" and the hatch mark was used as linear measure of the VAS score. All patients scored substantial pain of at least five or greater on the VAS at baseline.

The modified RM score[21] was used to evaluate the patients' pain in relation to normal life's activities. RM score 1 represented "excellent" quality of life (i.e., no symptoms; unlimited walking ability without pain; patient satisfied with the treatment outcome [when assessed after rESWT or placebo]), RM score 2 represented "good" quality of life (i.e., ability to walk more than 1 h without pain; symptoms substantially decreased after treatment; patient satisfied

with the treatment outcome), RM score 3 "acceptable" quality of life (i.e., inability to walk more than 1 h without pain; symptoms somewhat better and pain more tolerable than before treatment; patient slightly satisfied with the treatment outcome), and RM score 4 "poor" quality of life (i.e., inability to walk without severe pain; symptoms not better or even worse after treatment; patient not satisfied with the treatment outcome). Only 2% (1/50) of all patients reported a RM score of 2 at baseline, 18% (9/50) a RM score of 3 at baseline, and 80% of the patients a RM score of 4 at baseline. Accordingly, 98% of the patients were not able to walk more than 1 h without pain at baseline, and 80% of the patients could not walk at all without severe pain at baseline.

Dropout Rate

Two patients treated with rESWT dropped out from the study between Y1 and Y2, as well as one patient who received placebo treatment. Accordingly, 100% of the patients either treated with rESWT or who received placebo treatment were analyzed at M1, M3, M6, and Y1, as well as 92% (23/25) of patients treated with rESWT and 96% of patients who received placebo treatment.

Statistical Analysis

Statistical analysis was performed on the basis of a strict intention-to-treat-analysis (sITT)[23] applying the Last Observation Carried Forward (LOCF) method[24] (note that this applied only for Y2 because all patients that were allocated to either rESWT or placebo treatment were analyzed at M1, M3, M6, and Y1).

For the patients who were treated with rESWT as well as for those who received placebo treatment, mean and SEM of VAS scores and RM scores were calculated for each investigated time point (i.e., at baseline as well as at M1, M3, M6, Y1, and Y2). Comparisons between rESWT and placebo treatment were performed using two-way Repeated Measured (RM) analysis of variance (ANOVA), followed by Bonferroni post tests to compare replicate means by the investigated time points. In all analyses, an effect was considered statistically significant if its associated p value was smaller than 0.05. Calculations were performed using GraphPad Prism (Version 5.01 for Windows; GraphPad Software, San Diego, CA).

Furthermore, the treatment (rESWT or placebo) was considered successful when a patient reported a percentage decrease in the VAS score larger than 60% from baseline at any of the follow-up examinations. On this basis the power of the present RCT was calculated using the free, web-based, open-source software, OpenEpi (www.openepi.com).

RESULTS

The mean VAS score of the patients treated with rESWT decreased from 8.52 ± 0.34 (mean $\pm$ SEM) at BL to 0.64 ± 0.31 at M1, 1.08 ± 0.28 at M3, 0.52 ± 0.14 at M6, 2.32 ± 0.43 at Y1, and 1.44 ± 0.32 at Y2, and of the patients who received placebo treatment from 8.92 ± 0.19 at BL to 7.56 ± 0.42 at M1, 7.72 ± 0.24 at M3, 7.40 ± 0.49 at M6, 6.88 ± 0.64 at Y1, and 5.64 ± 0.70 at Y2. Differences in mean VAS score were statistically significant between patients treated with rESWT and patients who received placebo treatment at M1, M3, M6, Y1, and Y2 but not at BL (RM ANOVA: $p_{\text{Treatment}} < 0.001$, $p_{\text{Time}} < 0.001$, and $p_{\text{Interaction}} < 0.001$; "post hoc" Bonferroni tests: $p > 0.05$ at BL and $p < 0.001$ at M1, M3, M6, Y1, and Y2) (Fig. 2A).

The number of patients treated with rESWT with individual improvement of VAS score by more than 60% was 23 at M1, 24 at M3, 25 at M6, 18 at Y1, and 22 at Y2. In contrast, the number of patients who received placebo treatment with individual improvement of VAS score by more than 60% was 1 at M1, 0 at M3, 4 at M6, 5 at Y1, and 6 at Y2. Accordingly, the present RCT had a power based on normal approximation (or normal approximation with continuity correction, respectively) of 100% (100%) at M1, M3, and M6, 97.86% (95.35%) at Y1, and 99.97% (99.87%) at Y2 to detect a difference between rESWT and placebo treatment for cPF with a two sided-confidence interval of 95%. On this basis, the null hypothesis was rejected.

The mean RM score of the patients treated with rESWT decreased from 3.76 ± 0.11 (mean $\pm$ SEM) at BL to 1.20 ± 0.10 at M1, 1.44 ± 0.15 at M3, 1.32 ± 0.10 at M6, 1.88 ± 0.15 at Y1, and 1.52 ± 0.13 at Y2, and of the patients who received placebo treatment from 3.80 ± 0.08 at BL to 3.56 ± 0.14 at M1, $3.20 + 0.23$ at M3, 3.16 ± 0.19 at M6, 2.80 ± 0.24 at Y1, and 3.12 ± 0.20 at Y2. Differences in mean RM score were statistically significant between patients treated

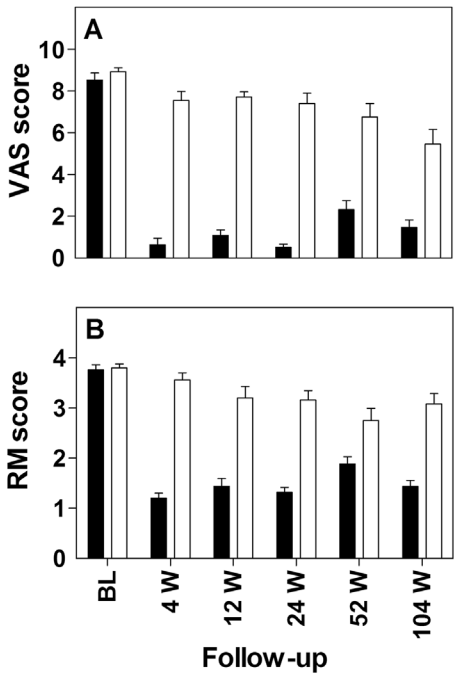

Figure 2. Mean and standard error of the mean of VAS scores (A) and RM scores (B) of patients suffering from chronic plantar fasciopathy treated with rESWT (closed bars) or placebo treatment (open bars) at baseline (BL) and at 1 month (M1), 3 months (M3), 6 months (M6), 1 year (Y1), and 2 years (Y2) follow-up. At M1, M3, M6, Y1, and Y2, differences between patients treated with rESWT and patients who received placebo treatment were statistically significant ($p < 0.001$; post hoc Bonferroni tests). Data for M1, M3, and M6 were taken from ref.[19]

with rESWT and patients who received placebo treatment at M1, M3, M6, Y1, and Y2 but not at BL (RM ANOVA: $p_{\text{Treatment}} < 0.001$, $p_{\text{Time}} < 0.001$, and $p_{\text{Interaction}} < 0.001$; "post hoc" Bonferroni tests: $p > 0.05$ at BL and $p < 0.001$ at M1, M3, M6, Y1, and Y2) (Fig. 2B).

There were only a few adverse events associated with rESWT or placebo treatment in the present study such as pain and/or discomfort during treatment. This was noted by $n = 3$ patients who received rESWT and $n = 2$ patients who received placebo treatment. However, all patients were able to complete their treatments without any anesthesia. Besides this, one patient reported minor skin reddening for a brief period following treatment. No other adverse events were observed.

DISCUSSION

To our knowledge, the present study is the first one demonstrating that rESWT is effective and safe for the management of cPF with long-term follow-up of 2 years. It is a continuation of an earlier RCT[19] on rESWT for cPF with follow-up of 6 months.

It is commonly believed that PF is a self-limiting condition, a syndrome that usually improves within 1 year[25] regardless of treatment,[26] and that more than 80% of patients experience resolution within 12 months, regardless of management.[5,27] Our data suggests otherwise. The mean VAS score of 8.92 ± 0.19 (mean $\pm$ SEM) for the placebo group at baseline and 5.64 ± 0.70 at the 2-year follow-up examination indicated an improvement by only 37% on average, compared to an improvement by 83% on average in case of those patients who were treated with rESWT. To our knowledge, no cohort study has been published that would support the aforementioned claims about the self-limiting nature of PF. Indeed, numerous authors have claimed that, regardless of treatment, 20–30% of patients with PF treated with nonsurgical measures will progress to a chronic condition (i.e., symptoms for more than 6 months).[28] The present trial considers only such patients.

Evaluation of long-term treatment success of ESWT for cPF (i.e., with follow-up examinations more than 1 year after the last treatment) was performed in only two RCTs.[16,17] Wang et al.[16] treated $n = 76$ patients (81 heels) suffering from PF for 9.8 ± 9.6 months (mean $\pm$ SD) with a single session of fESWT using an electrohydraulic Ossatron fESWT device (HMT, Kreuzlingen, Switzerland) (1,500 shock waves, EFD $= 0.32\,\text{mJ/mm}^2$; local anesthesia with 2% xylocaine) and another $n = 65$ patients (78 heels) suffering from PF for 9.4 ± 12.9 months (range, 6–38) with nonsurgical measures. On a 10-point VAS for pain intensity (with 0 = no pain and 10 = severe pain) patients treated with fESWT improved from 4.0 ± 1.3 (mean $\pm$ SD) at BL to 0.2 ± 0.7 at follow-up examinations performed at 64.1 ± 4.3 months (mean $\pm$ SD) after the treatment. In contrast, the patients treated with nonsurgical measures had a mean VAS score of 4.1 ± 1.1 at BL and 4.2 ± 1.7 at follow-up examinations performed at 39.8 ± 9.9 months after enrollment. The improvement of the mean VAS score of the patients treated with fESWT between baseline and follow-up was statistically significant ($p < 0.001$), as well as the difference in mean VAS score at follow-up between the patients treated with fESWT and the patients treated with nonsurgical measures ($p < 0.001$).

Hammer et al.[17] treated $n = 24$ patients (25 heels) suffering from PF for averaged 8.6 months with three sessions of fESWT at weekly intervals using a piezoelectric Piezoson 300 fESWT device (Richard Wolf, Knittlingen, Germany; 3,000 shock waves per session; EFD $= 0.20\,\text{mJ/mm}^2$; no local anesthesia) and examinated treatment success at W6, M3, M6, and Y2 after ESWT (Group 1). Another $n = 23$ patients (24 heels) suffering from PF for averaged 10.2 months were treated with iontophoresis with diclofenac and oral NSAID, and after 12 weeks with ESWT as described above (Group 2). On a VAS for pain intensity both groups showed improvement over time, with no statistically significant differences ($p > 0.05$) between Group 1 and Group 2 at any investigated follow-up time. However, because of a fundamentally different study design this study by Hammer et al.[17] can neither be compared to the study by Wang et al.[16] discussed above nor to the present study. Specifically, a control group with patients who were not treated with ESWT was investigated only for 12 weeks by Hammer et al.[17]

Considering the outcome of the present study, future research on treatment opportunities for PF should focus on the explicit recommendations of the ACFAS heel pain committee[6] that (i) initial treatment alternatives should be simple and cost-effective, whereas more resistant cases require more "aggressive treatment" (quoted from [6]); (ii) patients should possess chronic symptoms and undergo treatment for at least 6 months prior to consideration for ESWT or surgery; and (iii) patients should receive corticosteroid injections before ESWT.

With regard to initial treatments for PF results of a RCT by Rompe et al.[9] showed that rESWT alone may not serve as the perfect treatment modality for newly diagnosed PF. Rather, a program of manual stretching exercises specific to the plantar fascia (developed by DiGiovanni et al.[29,30]) was superior to repetitive rESWT for the treatment of acute symptoms of proximal PF in this study by Rompe et al.[9]

Following the argument of the ACFAS heel pain committee[6] that initial treatment alternatives should be simple and cost-effective, whereas more resistant cases require more "aggressive treatment", corticosteroid injections into the plantar fascia would be considered more cost-effective and less aggressive than ESWT in the treatment of PF. In this regard Yucel et al.[31] randomly assigned a total of $n = 60$ patients with cPF to either local corticosteroid injections

($n = 33$; mean duration of symptoms before enrollment 39.4 ± 10.2 weeks; mean $\pm$ SD) or fESWT ($n = 27$; mean duration of symptoms before enrollment 37.7 ± 8.6 weeks; use of a Stonelith-V5 Lithotripter device [PCK, Ankara, Turkey]; one treatment session; 3,000 shock waves; EFD not provided; fivefold nerve block [posterior tibial, superficial and deep peroneal, sural, and saphenous nerves]). Both groups showed a statistically significant improvement of mean VAS score at M3 compared to baseline, with no statistically significant differences between groups. These data indicate that ESWT could serve as alternative to local corticosteroid injections in the treatment of cPF.

With regard to the "aggressiveness" of nonsurgical measures for cPF Lee et al.[32] addressed risk factors affecting chronic rupture of the plantar fascia. To this end the authors performed a retrospective comparative study (evidence based medicine Level III) and found that local corticosteroid injection was the only assessed risk factor (including ESWT) that was associated with the occurrence of a plantar fascia rupture, with an odds ratio of 18.8 when performing a single local corticosteroid injection, 34.6 when performing two local corticosteroid injections, and 125.8 when performing three and more local corticosteroid injections.[32] Lee et al.[32] concluded that local corticosteroid injections for PF should be cautiously administered because of the higher risk for plantar fascia rupture.

Finally, it should be mentioned that although most clinical trials of rESWT on cPF and other chronic tendinopathies have yielded positive results,[7] there remains uncertainty regarding the precise mechanism of action of rESWT on treated tissues. In this regard, a recent in vivo study on humans has shed some light as to the effects rESWT has on diseased tendons.[33] In this study, microdialysis was used to examine the real-time biological response of healthy and pathological tendons to rESWT. To this end, Waugh et al.[33] administered a single session of rESWT to the mid-portion of the Achilles tendon in thirteen healthy individuals and patellar or Achilles tendon of six patients with tendinopathies. In very brief, the microdialysis results obtained in this study suggested that the mechanical stimulus provided by the radial shock waves might aid tendon remodeling in tendinopathy by promoting the inflammatory and catabolic processes that are associated with removing damaged matrix constituents.[33]

CONCLUSION

The results of the present study suggest that the use of rESWT in patients with cPF is effective and safe, leading to a significant, long-term reduction in pain, without adverse effects. For this reason, clinicians should consider rESWT prior to surgical intervention in the management of cPF. Considering the recently documented risk of local corticosteroid injections for chronic rupture of the plantar fascia, clinicians should also consider rESWT as alternative to local corticosteroid injections in the management of cPF. Finally, acknowledging the poor response at final follow-up for those patients in the placebo group, the current recommendations in the "Plantar Heel Pain Treatment Ladder" as set forth by the American College of Foot and Ankle Surgeons (ACFAS) heel pain committee[6] should be reviewed and perhaps revised to reflect these findings.

AUTHORS' CONTRIBUTIONS

M. I. I. had major contribution in study design and writing, and treated all patients. R. D., M. H., and F. B. had major contribution in study design and carried out parts of manuscript revision. A. Z. H. and J. F. carried out parts of manuscript revision. C. S. carried out the statistical analysis and wrote the paper. All authors approved the final manuscript and submission.

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