Clinically Relevant Effectiveness of Focused Extracorporeal Shock Wave Therapy in the Treatment of Chronic Plantar Fasciitis: A Randomized, Controlled Multicenter Study

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Clinically Relevant Effectiveness of Focused Extracorporeal Shock Wave Therapy in the Treatment of Chronic Plantar Fasciitis

A Randomized, Controlled Multicenter Study

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Background: The effectiveness of extracorporeal shock wave therapy in the treatment of plantar fasciitis is controversial. The objective of the present study was to test whether focused extracorporeal shock wave therapy is effective in relieving chronic heel pain diagnosed as plantar fasciitis.

Methods: Two hundred and fifty subjects were enrolled in a prospective, multicenter, double-blind, randomized, and placebo-controlled U.S. Food and Drug Administration trial. Subjects were randomized to focused extracorporeal shock wave therapy (0.25 mJ/mm^2) or placebo intervention, with three sessions of 2000 impulses in weekly intervals. Primary outcomes were both the percentage change of heel pain on the visual analog scale composite score (pain during first steps in the morning, pain with daily activities, and pain with a force meter) and the Roles and Maudsley score at twelve weeks after the last intervention compared with the scores at baseline.

Results: Two hundred and forty-six patients (98.4%) were available for intention-to-treat analysis at the twelve-week follow-up. With regard to the first primary end point, the visual analog scale composite score, there was a significant difference ($p = 0.0027$, one-sided) in the reduction of heel pain in the extracorporeal shock wave therapy group (69.2%) compared with the placebo therapy group (34.5%). Extracorporeal shock wave therapy was also significantly superior to the placebo therapy for the Roles and Maudsley score ($p = 0.0006$, one-sided). Temporary pain and swelling during and after treatment were the only device-related adverse events observed.

Conclusions: The results of the present study provide proof of the clinically relevant effect size of focused extracorporeal shock wave therapy without local anesthesia in the treatment of recalcitrant plantar fasciitis, with success rates between 50% and 65%.

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

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Plantar fasciitis is the most common cause of heel pain[1-3], and nonsurgical treatment is successful in about 90% of patients[1,2,4]. A relevant proportion of patients who fail nonoperative care are treated with surgery[1,2,4,5].

Extracorporeal shock wave therapy has been introduced for the treatment of chronic inflammatory and degenerative processes of bone-tendon junctions since the induction of hyperemia, neovascularization, and regeneration of tendon tissue have

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TABLE I Demographic and Baseline Characteristics of the Intention-to-Treat Population

Characteristic	Intention-to-Treat Population: Extracorporeal Shock Wave Therapy Group (N = 125)	Intention-to-Treat Population: Placebo Group (N = 121)
Age* *(yr)*	50.0 ± 11.2	47.4 ± 10.6
Male sex	32.0%	27.3%
Body mass index* *(kg/m²)*	28.6 ± 6.18	29.5 ± 7.19
Activity†		
Sedentary	7 (5.6%)	14 (11.6%)
Active	101 (80.8%)	87 (71.9%)
Athletic	17 (13.6%)	20 (16.5%)
Heel pain duration†		
Six to twelve months	40 (32.0%)	37 (30.6%)
More than twelve to twenty-four months	38 (30.4%)	37 (30.6%)
More than twenty-four months	47 (37.6%)	47 (38.8%)
VAS* *(points)*		
Heel pain while taking first steps in the morning	7.9 ± 1.55	8.0 ± 1.61
Heel pain while doing daily activities	7.9 ± 1.55	7.9 ± 1.51
Heel pain after application of the F-Meter	9.3 ± 1.25	9.3 ± 1.28
Roles and Maudsley score* *(points)*	3.6 ± 0.49	3.7 ± 0.48

*The values are given as the mean and the standard deviation. †The values are given as the number of patients, with the percentage in parentheses.

been demonstrated. Established indications are calcifying tendinitis of the shoulder, Achilles tendinopathy, and chronic painful heel syndrome[6-9]. However, the effectiveness of extracorporeal shock wave therapy in plantar fasciitis is controversial[2,5,7,10-14], and the superiority of extracorporeal shock wave therapy compared with a placebo was summarized in systematic reviews as being significant but not clinically relevant[2,15]. Specific treatment parameters of extracorporeal shock wave therapy are of importance for treatment success but have been neglected in systematic reviews[3,7,11,12,16]. First, local anesthesia has been shown to reduce efficacy[17,18]. Second, higher total shock wave energies have been associated with greater pain reduction[7,19,20]. Third, focused shock waves have demonstrated clinical superiority compared with radial shock waves[21]. Consequently, pooling data of more and less effective treatment protocols in systematic reviews underestimates the real effectiveness of optimized extracorporeal shock wave therapy protocols.

Clinically relevant effectiveness of extracorporeal shock wave therapy has been shown in previous studies applying high but tolerable shock wave energies to the point of maximum tenderness without local anesthesia[7,8,12,22]. The present study was performed to evaluate the effectiveness of an optimized treatment protocol of extracorporeal shock wave therapy in chronic plantar fasciitis.

Materials and Methods

Study Design and Follow-up

This double-blind, randomized, placebo-controlled trial with parallel group design was conducted at five study centers in the United States. A total of 250 patients were randomly assigned to receive either focused extracorporeal shock wave therapy or placebo intervention. Randomization was performed with concealed allocation in permuted blocks of four to eight, stratified by treatment center, with the use of a computer-generated random list and nontransparent envelopes. Whereas the treating physician (A.S., L.A.D., L.G., R.T.B., and D.S.C.) was nonblinded, both participants and evaluating physicians were blinded to randomization. The trial was registered and was conducted as a U.S. Food and Drug Administration (FDA) approval study (Investigational Device Exemption number IDE G050236). Standardized guidelines of good clinical practices from the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) were respected.

After three interventions of shock waves or a placebo in weekly intervals, patients were followed for twelve weeks after the last intervention (follow-up 1). At this visit, the participants' response to treatment was rated. Individuals who met the predefined criteria for treatment success at the time of follow-up 1 continued until twelve months after the last intervention (follow-up 2) to assess intermediate-term stability of treatment success. Subjects who did not show sufficient improvement discontinued the study after follow-up 1 and were not included in follow-up 2. Treatment was considered successful if there was at least 60% reduction in pain on two of three visual analog scale (VAS) scores or, alternatively, if all three of the following criteria were fulfilled: the study participant was able to work, the participant was satisfied with the treatment outcome, and no concomitant therapy to control heel pain was required.

Subjects

The study was approved by the FDA and the responsible independent institutional review boards. Written informed consent was obtained from all participants. Patients were recruited from the participating study sites and from community-based referring physicians (primary care physicians, podiatrists, and orthopaedic surgeons). A total of 250 patients were randomized. The Consolidated Standards of Reporting Trials (CONSORT) diagram for the study is displayed in Figure 1.

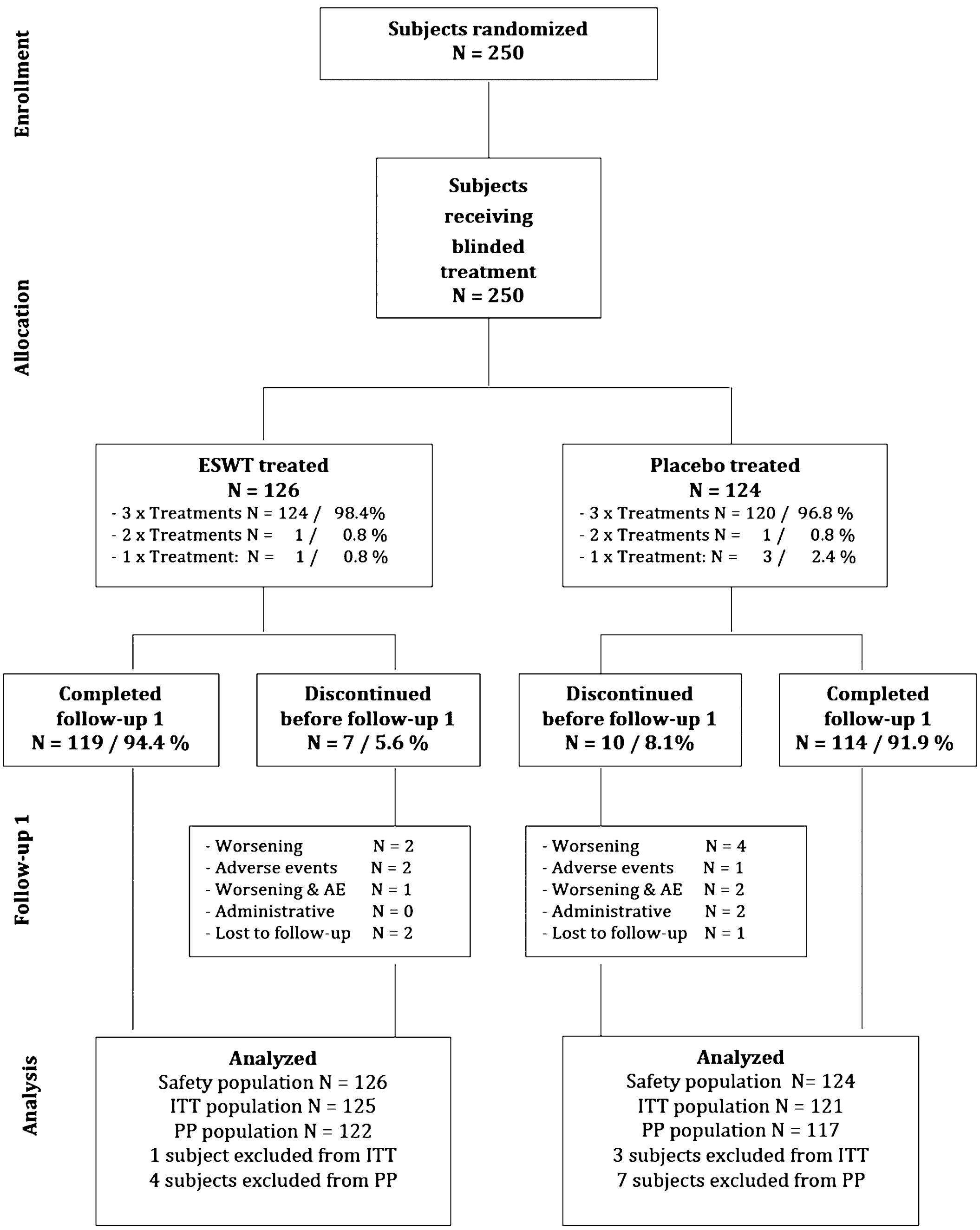

Fig. 1

A CONSORT diagram showing the flow of participants through the study. The safety analysis population included all patients receiving at least one treatment session. The intention-to-treat (ITT) population included all subjects who had had at least one treatment session and also at least one evaluation following the first treatment without severe deviation of entry criteria (i.e., the ITT population was the full analysis set as defined in the ICH guideline E9 [biostatistics][25]). The per-protocol (PP) population also included the patients excluded from the intention-to-treat population because of protocol violations (inclusion and exclusion criteria, incomplete study treatment, or premature discontinuation). ESWT = extracorporeal shock wave therapy, and AE = adverse event.

Inclusion Criteria

Inclusion required a history of plantar fasciitis resistant to nonsurgical treatment for at least six months. All participants had failed at least four nonsurgical treatment modalities, including at least two nonpharmacological and at least two pharmacological treatments. Diagnosis of plantar fasciitis was made by experienced foot and ankle specialists with more than ten years of professional experience according to the clinical practice guideline of the American College of Foot and Ankle Surgeons[1]. Magnetic resonance imaging (MRI), nerve conduction velocity/electromyography, or other diagnostic testing was performed if appropriate to confirm plantar fasciitis or to rule out other diagnoses.

TABLE II Primary Efficacy Criteria at Twelve Weeks (Follow-up 1)

	Intention-to-Treat Groups			
Primary Efficacy Criteria*	Extracorporeal Shock Wave Therapy Group (N = 124)	Placebo Group (N = 121)	P Value†	Mann-Whitney Effect Size‡
Composite score for heel pain (VAS)§			0.0027	0.6026 (0.5306)
Median change from baseline#	−69.2%	−34.5%		
Mean change from baseline**	−54.5% (−61.4% to −47.7%)	−40.3% (−47.5% to −33.1%)		
Roles and Maudsley score** *(points)*	2.5 (2.3 to 2.7)	2.9 (2.7 to 3.1)	0.0006	0.6135 (0.5466)

*All results have the last value carried forward to replace missing values and score correction for interfering concomitant therapy. †The p values were determined by a one-sided test for superiority with use of the Wilcoxon-Mann-Whitney test. ‡The values are given as the effect size, with the lower bound of the one-sided 97.5% confidence interval in parentheses. §The values are the sum of scores of heel pain (VAS) while taking the first steps of the day, heel pain (VAS) while doing daily activities, and heel pain (VAS) after application of the F-Meter. #The values are given as the median. **The values are given as the mean, with the 95% confidence interval in parentheses.

Participants had to self-rate ≥5 points on all three VAS scores (heel pain while taking the first steps in the morning, heel pain while doing daily activities, and heel pain while applying a standardized local pressure with the Force-Meter [F-Meter; Storz Medical, Tägerwilen, Switzerland]). Pain was measured on a 10-cm VAS in which 0 points indicated no pain and 10 points indicated excruciating pain. To be eligible, subjects must also have had a Roles and Maudsley score of fair or poor[23]. A minimum washout phase after preceding nonsurgical treatments was required prior to enrollment (a time gap of at least six weeks since the last corticosteroid injection; four weeks since the last local anesthetic injection, iontophoresis, ultrasound, or electromyostimulation; one week since the last nonsteroidal anti-inflammatory drugs; and two days since the last analgesics, heat, ice, massage, stretching, modification of night splinting, and orthosis). The complete list of inclusion criteria is summarized in the Appendix.

Exclusion Criteria

The main reasons for exclusion were active infection or history of chronic infection in the treatment area, systemic inflammatory disease, neurological or vascular insufficiencies, nerve entrapment, disturbance of coagulation, bilateral heel pain in need of medical treatment, and pregnancy. The complete list of exclusion criteria is provided in the Appendix.

Study Interventions

Focused shock waves were generated electromagnetically with the Duolith SD1 shock wave device (Storz Medical). The total energy flux density was increased continuously from 0.01 to 0.25 mJ/mm^2 within 500 introductory impulses. Thereafter, 2000 treatment impulses with 0.25 mJ/mm^2 (four impulses per second) were administered per session, and the intervention was repeated up to a total of three sessions in weekly intervals.

The placebo group received identical sham intervention with an air-filled standoff that prevented the transmission of shock waves. The placebo handpiece was identical in design, shape, and weight to ensure that there was no way for the participants to identify the placebo handpiece.

The applicator was directed to the most tender point, controlling proper placement by patient-controlled feedback, and was adjusted during treatment if necessary. No radiograph or ultrasound was used. The participants had the option to request local anesthesia.

The participants were allowed to use a standardized rescue medication throughout the study (2 g of acetaminophen per day for up to fourteen days following the last intervention; thereafter, 2 g of acetaminophen per week). No other therapies were allowed.

Primary Outcome Measures

One of the primary outcomes was the overall reduction of heel pain, measured by percentage change of the VAS composite score twelve weeks after the last intervention compared with the score at baseline. The heel pain composite score was defined as the sum of three single VAS scales: (1) heel pain while taking the first steps in the morning, (2) heel pain while doing daily activities, and (3) heel pain while applying a standardized local pressure with the F-Meter.

The blinded investigator (one of whom [B.F.] was an author of this study) used the F-Meter to measure pressure sensitivity at the point of maximum tenderness. The pressure level that just elicited unbearable pain (a VAS score of 10 points) was quantified by the F-Meter and was documented as an individual baseline value for each participant. At each follow-up visit, the same individual F-Meter pressure was then applied and the subject was asked to score the pain on the VAS. An increased pressure pain tolerance resulted in a decreased scoring in the VAS.

Functional improvement was measured by the Roles and Maudsley score[23], which is a four-level grading scale: excellent indicates no pain, full movement, and activity; good indicates occasional discomfort, full movement, and activity; fair indicates some discomfort after prolonged activity; and poor indicates pain-limiting activities. Because we wished to maintain the overall alpha level for the study, both of the primary efficacy criteria would need to be significantly superior (one-sided $p < 0.025$) to prove the superiority of the intervention. Primary outcome measures were analyzed with the last value carried forward to replace missing values and with correction for interfering analgesic therapy. Potential limitations of using percentage changes in pain VAS scales were avoided by the use of robust nonparametric statistics.

Secondary Outcome Measures

Secondary outcome measures included the investigator's (one of whom [B.F.] was an author of this study) global judgment of effectiveness (on a 5-point scale ranging from very good to poor), rates of success defined as at least 60% pain reduction in the single VAS scores, the overall rate of success with regard to heel pain defined as at least 60% decrease of heel pain in at least two of the three VAS measurements, the Roles and Maudsley score rate of success defined as a rating of excellent or good, and the consumption of concomitant analgesic medication (all at twelve weeks after treatment). Additionally, participants' judgment of satisfaction with therapy was assessed on a nonvalidated 7-point scale (ranging from very satisfied to very unsatisfied) at that time (follow-up 1).

Furthermore, the VAS composite score, the Roles and Maudsley score, and success rates were assessed at the time of follow-up 2 for the subpopulation that demonstrated sufficient response to treatment at the time of follow-up 1.

Safety Criteria

All subjects with at least one intervention were included in the safety analysis population. All local tissue effects and adverse events were recorded.

TABLE III Secondary Efficacy Criteria at Twelve Weeks (Follow-up 1)

Secondary Efficacy Criteria*	Intention-to-Treat Group: Extracorporeal Shock Wave Therapy† (N = 125)	Intention-to-Treat Group: Placebo† (N = 121)	P Value	Odds Ratio	No. of Patients Needed to Treat
Success rate‡					
Heel pain overall§	54.4% (45.3% to 63.3%)	37.2% (28.6% to 46.4%)	0.0035#	2.015	5.8
Heel pain while taking first steps of the day**	50.4% (41.3% to 59.5%)	36.4% (27.8% to 45.6%)	0.0136#	1.778	7.1
Heel pain during daily activity**	49.6% (40.5% to 58.7%)	38.8% (30.1% to 48.1%)	0.0464#	1.550	9.3
Heel pain with F-Meter**	53.6% (44.5% to 62.6%)	42.2% (33.2% to 51.5%)	0.0380#	1.586	8.7
Roles and Maudsley score††	60.8% (51.7% to 69.4%)	37.2% (28.6% to 46.4%)	0.0001#	2.620	4.2
Investigator's global judgment of effectiveness: very good or good‡‡	73.9% (88 of 119)	54.4% (62 of 114)	0.0110§§		
Subject's global judgment of therapy satisfaction: very satisfied or satisfied‡‡	47.9% (57 of 119)	33.3% (38 of 114)	0.0021§§		
Concomitant analgesic medication‡##	74.4% (65.8% to 81.8%)	71.1% (62.1% to 79.0%)	0.7420#	0.846	

*All results have the last value carried forward to replace missing values and score correction for interfering concomitant therapy. †According to the predefined criteria for response to treatment to continue the study after follow-up 1, a sufficient response was considered to be at least 60% reduction in pain on two of three VAS scores (heel pain overall success rate) or, alternatively, if all three of the following criteria were fulfilled: the study participant was able to work, the participant was satisfied with the treatment outcome, and no concomitant therapy to control heel pain was required. The response to treatment for the decision to continue until follow-up 2 was eighty-one patients (64.8%) in the extracorporeal shock wave therapy group and fifty-six patients (46.3%) in the placebo group. ‡The values are given as the mean percentage of patients, with the 95% confidence interval in parentheses. §Success was defined as a decrease of heel pain of at least 60% from baseline for at least two of three heel pain VAS measurements. #The p values of the one-sided test for superiority were determined with use of the unconditional exact Röhmel-Mansmann test. **Success was defined as a decrease of heel pain of at least 60% from baseline. ††These values were the percentage of subjects with a Roles and Maudsley score of excellent or good at the time of follow-up 1. ‡‡The values are given as the percentage of patients, with the number of patients responding out of the total number of patients who completed follow-up 1 in parentheses. §§The p values of the one-sided test for superiority were determined with use of the Wilcoxon-Mann-Whitney test (ordinal scale). ##This value was based on the frequency count of patients with at least one concomitant analgesic therapy during the study.

Additionally, the investigator's global judgment of tolerability was assessed on a 7-point rating scale twelve weeks after the last treatment.

Statistical Analysis

The sample size calculation was based on the model of stochastic superiority within the Wilcoxon-Mann-Whitney test for the primary outcome measure of percentage change of the VAS composite score. The following stipulations were made: a relevant Mann-Whitney effect size of 0.64, an alpha (one-sided) of 0.025, and a beta of 0.10 (power of 90%). Because of the expected usual losses (for example, dropouts), the sample size for the study was enhanced to 125 participants per group.

To keep the multiple levels of alpha, the efficacy of the extracorporeal shock wave therapy was proven if both primary criteria of effectiveness (the VAS composite score and the Roles and Maudsley score) showed a significant result with a value of $p < 0.025$ (one-sided).

To identify differences in effect size between the groups, the Mann-Whitney effect size with predefined benchmarks was used. In accordance with Colditz et al.[24], we used benchmarks that corresponded to a Mann-Whitney effect size of 0.5 for equality (active therapy was neither better nor worse than the placebo), 0.44 or 0.56 for small inferiority or superiority, 0.36 or 0.64 for medium (clinically important) inferiority or superiority, and 0.29 for large inferiority or 0.71 for large superiority.

Primary and secondary criteria were evaluated by univariate Wilcoxon-Mann-Whitney tests. In addition, secondary criteria were combined by a multivariate directional Wilcoxon test (the Wei-Lachin procedure). Statistical analyses were performed by an independent institute (idv-Data Analysis and Study Planning, Gauting, Germany), using its REPORT, TESTIMATE, and AE-Base software programs, which is in accordance with the recommendations of the ICH E9 Biostatistics Guideline[25].

Source of Funding

The present study was conducted as an FDA-approved study. Three authors (H.G., A.S., and J.C.V.) received funding from Storz Medical. Funds were used to pay for travel expenses, consultancy in study planning, and realization. The sponsors of this study did not have any influence on subject recruitment, data collection, data analysis, or preparation of the manuscript.

Results

Enrollment and Treatment

A total of 250 patients were enrolled over a fifty-week period and were randomly assigned to extracorporeal shock wave therapy (n = 126) or placebo intervention (n = 124). The flow of participants through the study is displayed in the Consolidated Standards of Reporting Trials (CONSORT) diagram (Fig. 1). Both groups showed comparable characteristics with respect to demographic variables, intensity and duration of heel pain (Table I), and previous therapies. No subject requested local anesthesia.

Primary Outcome Measures

The primary end points of the percentage change in the VAS composite score and the Roles and Maudsley score at twelve weeks compared with the scores at baseline could be assessed in

98.4% of the enrolled subjects (Fig. 1 and Table II). All participants providing post-baseline data were included in the analysis with the last value carried forward to replace missing values and the predefined adjustment of the VAS score in cases of interfering concomitant analgesic therapy (see Appendix).

The superiority of extracorporeal shock wave therapy compared with a placebo in chronic plantar fasciitis was confirmed to be proven for both primary outcome measures. The median composite score of heel pain (VAS) was reduced by 69.2% in the extracorporeal shock wave therapy group compared with 34.5% in the control group (p = 0.0027, one-sided). Furthermore, the difference in the Roles and Maudsley score was 0.4 point in favor of extracorporeal shock wave therapy (p = 0.0006, one-sided).

Secondary Outcome Measures

Secondary outcome measures are displayed in Table III. The combined overall result of the eight secondary criteria showed significance (p = 0.0015, one-sided) in favor of extracorporeal shock wave therapy. Five single secondary criteria showed significance: the investigator's global judgment of effectiveness (p = 0.0110), the subject's judgment of therapy satisfaction (p = 0.0021), the Roles and Maudsley success rate (p = 0.001), the heel pain overall success rate (p = 0.0035), and the single-VAS success rate for heel pain while taking the first steps in the morning (p = 0.0136).

To assess the stability of the results, different sensitivity analyses were performed for the primary efficacy criteria at the time of follow-up 1: a per-protocol analysis, a supportive analysis for the intention-to-treat data set without any correction for interfering analgesic therapy, a supportive sensitivity analysis for the intention-to-treat data set with correction for interfering analgesic therapy by means of the worst-rank score technique, a sensitivity analysis for the intention-to-treat data set counting all patients lost to follow-up as treatment failures, and an analysis of the data set with the data as available instead of the last value carried forward to replace missing values. All sensitivity analyses resulted in descriptively significant superiority of extracorporeal shock wave therapy compared with a placebo (all p values, <0.025). Thus, the results of the sensitivity analyses provide strong support for the results of the primary analysis (see Appendix).

One hundred and thirty-seven subjects met the criteria for treatment success at the time of follow-up 1 (sufficient response), and the rate of responders was 64.8% for the extracorporeal shock wave therapy group and 46.3% for the placebo group (Table III). Of the 137, 124 subjects continued the study in the follow-up 2 period (seventy-three subjects in the extracorporeal shock wave therapy group and fifty-one subjects in the placebo therapy group). At the time of follow-up 2, two subjects in the extracorporeal shock wave therapy group were lost to follow-up, and three subjects in the control (placebo) group discontinued early (one for an administrative reason, one for early recovery, and one for worsening with an adverse event). In the subpopulation that continued the study after follow-up 1, the percentage change of the VAS composite score from baseline increased from −84.0% at the time of follow-up 1 to −96.0% at the time of follow-up 2 in the extracorporeal shock wave therapy group compared with −84.0% at the time of follow-up 1 to −96.3% at the time of follow-up 2 in the placebo group. The mean change of the Roles and Maudsley score from baseline increased from −1.7 to −2.1 in the extracorporeal shock wave therapy group compared with −1.6 to −1.9 in the placebo group. Furthermore, the single VAS assessments showed comparable results. Thus, the successful status of the subjects at the time of follow-up 1 continued and increased during follow-up 2, confirming stability of treatment success for at least twelve months. The results of the analyses of the per-protocol population supported these results.

Tolerability and Safety Criteria

The tolerability of the study therapy was judged as very good or good in 89.1% (106 of 119) of the extracorporeal shock wave therapy subjects and in 91.2% (104 of 114) of the placebo subjects at twelve weeks. All 250 randomized subjects received at least one treatment and were included in the safety analysis population (Fig. 1). One hundred and one adverse events occurred prior to follow-up 1. A total of seventy-seven adverse events were found in forty-three patients in the extracorporeal shock wave therapy group. In the placebo group, twenty-four adverse events were seen in seventeen subjects. The preponderance of adverse events in the extracorporeal shock wave therapy group was due to known minor untoward effects of treatment (pain and/or discomfort during treatment, pain after treatment, and swelling); there were sixty-five such adverse events in thirty-four of 126 subjects in the extracorporeal shock wave therapy group and eleven such adverse events in seven of 124 subjects in the placebo group, with a rate difference of 21.4%). There were no other device-related adverse events and no group differences regarding the remaining adverse events that have been considered to not be related to treatment (twelve events in eleven subjects in the extracorporeal shock wave therapy group and thirteen events in eleven subjects in the placebo group).

Discussion

Extracorporeal shock wave therapy for plantar fasciitis has been investigated in multiple randomized controlled trials, providing evidence of effectiveness and safety[7,12,18,19,22,26]. However, previous studies on extracorporeal shock wave therapy also demonstrated a significant influence of treatment protocols on outcome[17,18,20,21]. Double-blind randomized controlled trials directing shock waves to anatomical landmarks rather than to the point of greatest tenderness, using lower energy levels or using local analgesia, failed to show superiority of extracorporeal shock wave therapy over a placebo[11,13,14]. A randomized controlled trial has demonstrated that local anesthesia significantly reduces the effectiveness of extracorporeal shock wave therapy[18], which may be explained by the inhibition of hyperstimulation, modification of the gate-control mechanism, and modification of pain mediators[3,13,16,27,28]. Because effectiveness of extracorporeal shock wave therapy is dependent on treatment parameters, pooling of data in systematic reviews is inadequate. Effectiveness should be analyzed individually for specific devices and treatment protocols.

At the primary end point, 98.4% of subjects were available for analyses, and all sensitivity analyses supported the final results.

The present study confirmed both significant and clinically relevant[29] superiority of extracorporeal shock wave therapy compared with the placebo, with a between-group difference of nearly 35% pain reduction. The relevant superiority of extracorporeal shock wave therapy was strongly supported by sensitivity analyses as well as secondary outcome measures. The rate of responders who continued the study after the twelve-week follow-up was 64.8% in the extracorporeal shock wave therapy group compared with 46.3% in the placebo group. Although a relevant number of participants did not reach the criteria for success, a clinically relevant superiority of extracorporeal shock wave therapy compared with the placebo was demonstrated; for example, the Roles and Maudsley success rate was 60.8% for the extracorporeal shock wave therapy group compared with 37.2% for the placebo group. Furthermore, the assessment of treatment responders demonstrated stability of treatment success for at least one year; the study design did not follow the nonresponders of both groups after the twelve-week follow-up.

Finally, the mean VAS score improvement of >30% in the placebo group confirms the power of the placebo effect in pain studies[1-4,7,8,12,15,22] and emphasizes the effectiveness of blinding in the present study.

In conclusion, focused extracorporeal shock wave therapy applied in weekly interventions (totaling 3 × 2000 impulses, 0.25 mJ/mm^2) without local analgesia demonstrated relevant clinical effectiveness in the treatment of chronic plantar fasciitis.

Appendix

eA Tables showing inclusion and exclusion criteria, time gaps and correction methods for interfering concomitant analgesic therapy, and results of the sensitivity analyses regarding the a priori-ordered primary efficacy criteria are available with the online version of this article as a data supplement at jbjs.org. ■

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