High-Energy Extracorporeal Shock-Wave Therapy (ESWT) for the Treatment of Chronic Plantar Fasciitis

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High-Energy Extracorporeal Shock-Wave Therapy (ESWT) for the Treatment of Chronic Plantar Fasciitis

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ABSTRACT

Background: **Few reports about the success of high-energy extracorporeal shock-wave therapy in cases of plantar fasciitis exist, even fewer about long-term results. This study investigated results of high-energy extracorporeal shock wave therapy applied to patients with recalcitrant plantar fasciitis.** ***Materials and Methods:*** **Ninety ESWT were applied to 63 patients (73 heels; 25 male and 38 female; average age 54 (29 to 77) years) from November 1999 to July 2003. All patients had plantar fasciitis for more than 6 months and failure of all non-surgical treatment for more than 3 months. A Dornier Lithotripter S, equipped with an electromagnetic shock-wave emitter was used. Routinely, 1000 shock wave impulses (frequency 2 per second, energy flux density (ED) 0.35 mJ/mm^2 at 10.5 kV, total dose 350 mJ/mm^2) were applied per treatment. Followup was carried out 6 weeks after ESWT, then a second clinic evaluation and a final followup at an average of 73 months after ESWT by telephone.** ***Results:*** **The success of ESWT, defined as a 30% VAS reduction, was seen in 81% at 6-week followup, at 88% at last clinic followup and in 96% at final phone followup.** ***Conclusion:*** **High-energy ESWT (0.35 mJ/mm^2) was successful in the treatment of plantar fasciitis and the good short-term results seemed to be maintained over time.**

Level of Evidence: IV, Retrospective Case Series

Key Words: ESWT; Extracorporeal Shock Wave Treatment; Fasciitis Plantaris; Heel Spur; VAS

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INTRODUCTION

Plantar heel pain is a common medical condition caused by irritation and overload of structures stabilizing the plantar arch of the foot.[13,1] Symptoms often show a typical diurnal variation with a maximum amount in the morning at the first contact of the foot on the floor (start-up pain). Diminution of the inflammatory edema caused by compression when walking constitutes a potential mechanism underlying improvement of symptoms during the day.[4] Typically, on exam, one will find a point of maximum tenderness close to the origin of the plantar fascia. A plantar heel spur, which may be observed in symptom-free patients as well, may be found after prolonged inflammation.[3,4,22,15,19] When non-surgical treatment, such as analgesics, orthotics, night-splints, local steroid injection, cryotherapy and stretching of the plantar fascia, fails, extracorporeal shock wave therapy (ESWT) is one other treatment option, especially in the light of inconsistent surgical results.[2,11,12,18,24]

Investigations about the natural course of plantar fasciitis are often only available as followup investigations of placebo or reference-groups and are usually limited to 1 year. Long-term results of ESWT are not found in current literature and followup is usually not carried out beyond 1 year which may reflect the possibly self-limited course of plantar fasciitis.[3]

Focused and non-focused radial shock-waves are used and different methods of generation of shock-waves (electrohydraulic, electromagnetic, piezoelectric, ballistic) are available.[8,20] Differences regarding energy flux density (high/low-energy) need to be taken into consideration. Usually, low-energy ESWT does not require nerve-blocks, whereas high-energy ESWT is too painful without them. ESWT at our institution comes from sharing the Lithotripter (with very high possible energy flux density of 1.9 mJ/mm^2) with the urology department. Only high-energy ESWT could be applied, due to a minimum energy flux density of 0.35 mJ/mm^2 (10.5 kV).

Table 1: Inclusion Criteria

Diagnose	Pain history	Age	(failed) Conservative Treatment > 3 months
Plantar Fasciitis (with or without heel spur)	>6 months	>18 years	NSAID Cryotherapy Ultrasound Stretching & Padding (Insoles) Local Steroid-Injection

Because of the lack of standardization of shock-wave emitters, treatment protocols and clinical evaluation, data from different investigations are difficult to compare.[8,20]

Likewise, several studies do not provide the complete data of the emitting device, nor all the parameters defining the shock-waves themselves[8] (e.g., kV or mJ/mm^2 respectively).

In our study, we aimed to investigate the long-term effect of high-energy ESWT for recalcitrant plantar fasciitis. The success of ESWT was analyzed with regard to the duration of pain before ESWT, BMI, absence or presence of a heel-spur and the application of regional or local anesthesia.

MATERIALS AND METHODS

Ninety ESWT were applied to 63 patients (73 heels; 25 male and 38 female; average age 54 (range, 29 to 77) years) from November 1999 to July 2003. All patients had a diagnosis of plantar fasciitis, 16 with heel spurs, and 47 without heel-spur. Inclusion criteria are summarized in Table 1. Exclusion criteria included local soft-tissue infection, malignant disease, coagulation disorders (including iatrogenic reasons, e.g., acetylsalicylic acid), pregnancy, pacemaker, epileptic disorders and allergy to local anesthetics.

X-rays of the heel were obtained at the time of first ESWT. Prior to randomization to local (at the origin of the plantar ligament, 23 patients) or regional anesthesia (of the tibial nerve posterior to the medial malleolus, 40 patients) (Figure 1), using Mepivacaine (medium duration anilide type local anesthetic) 2% (5 to 10 ml), the point of maximum tenderness was localized by the treating physician, palpating the plantar fascia.

Treatment was applied by one of three orthopaedic surgeons with the patient in a supine position (Figure 2). A small amount of ultrasound-coupling gel was put on the coupling head of the device. The precise focus zone on the coupling head was indicated by a single shot, creating tiny bubbles inside the gel. The patient's plantar heel was then put perpendicular exactly onto the focus zone. An NSAID (Mefenaminic acid 500 mg bid), cryotherapy and reduction of physical activities were used for 1 week after ESWT. Insoles were allowed during the course of followup, but were not allowed to be changed.[9]

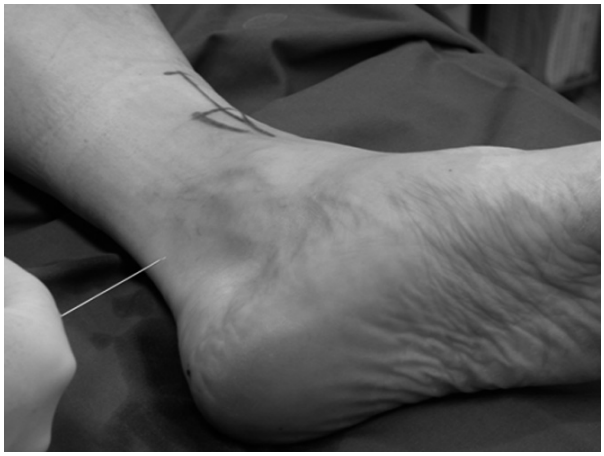

Fig. 1: Regional anesthesia. Blocking of the tibial nerve.

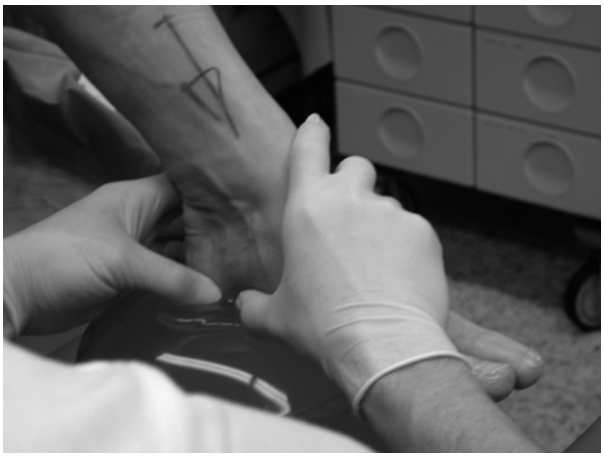

Fig. 2: Therapy. Foot placed perpendicular to the coupling head.

The first follow up was carried out 6 weeks after ESWT in clinic with a second one at an average of 17.9 (range, 2 to 43) months after ESWT. A telephone-interview, using a standardized questionnaire (Figure 3), was performed at an average of 72 (range 53 to 109) months after the most recent ESWT (Figure 4) but 18 patients were lost to followup. The

Questionnaire Fasciitis plantaris

Name: Protocolno.:

Phone: Date of Follow-up:

Diagnose: (Fasciitis plantaris), heel spur yes/no

Side: (left/right)

Bodysize:(cm) (current) bodyweight/BMI:

Illness/Medication:

Number of ESWT (1, 2 or 3):

Current pain: yes/no VAS:

If yes, how long pain-free after ESWT (months):

Trauma: yes/no Which?: When?:

Sports-activity?:

Therapy/Operations since last ESWT?: yes/no

If yes, which?:

Satisfied with ESWT?:

If no, why not?:

Free Text:

Investigator:

Fig. 3: Questionnaire.

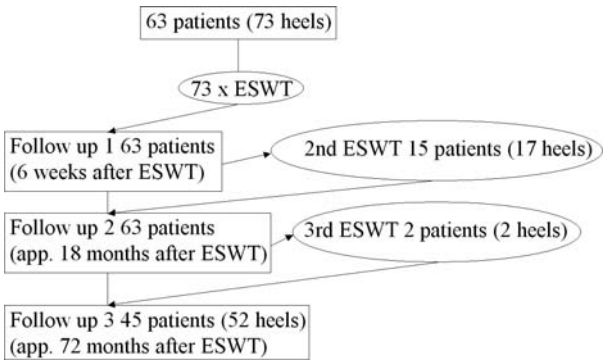

Fig. 4: Flow of patients through the study.

first followup was carried out by one orthopaedic surgeon, who was not involved in the ESWT. Assessment of heel pain before ESWT and at all followups was made using the Visual Analog Scale (VAS, 0, no pain, 10, strongest imaginable pain), the main reference being overall pain in the course of day with an additional reference of start-up pain in the morning.

A Dornier Lithotripter S, equipped with an electromagnetic shock-wave emitter EMSE 220f XXP (Dornier, Wessling, BRD), was used (Figure 5). At the 1st ESWT, the number of shock wave impulses, each at 0.35 mJ/mm^2, was 1060 (minimum 1000, maximum 2000), average total dose

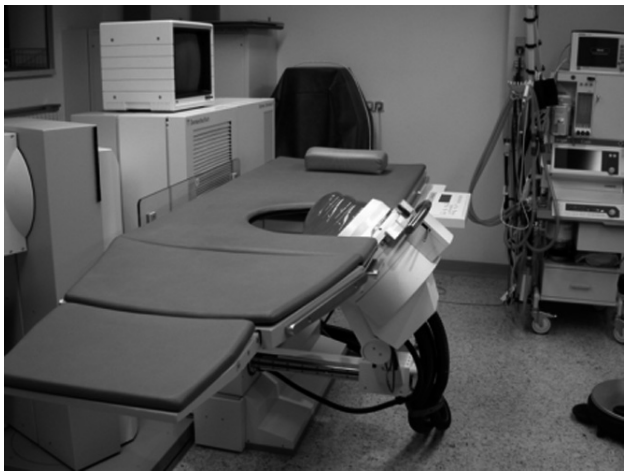

Fig. 5: The Lithotripter Doli S (Dornier, Wessling, BRD).

was 371 (minimum 350, maximum 700) mJ/mm^2. Fifteen patients (17 heels) received 2 treatments, at an average within the limits of 3 months (minimum 2, maximum 5), the number of shock wave impulses, each at 0.35 mJ/mm^2, averaged 2154 (minimum 2000, maximum 3500), average total dose was 754 (minimum 700, maximum 1225). Two patients received a third treatment, 3.5 and 2 months after the second ESWT, respectively, the number of shock wave impulses, each at 0.35 mJ/mm^2, was 3000 and 4200 respectively, the cumulative dose applied was 1050 and 1470 mJ/mm^2. It should be noted that minor changes, caused by the status of maintenance of the shock-wave emitter may occur (variation of $\pm$ 0.02 mJ/mm^2).

Success of ESWT was defined as a clinically relevant reduction of pain, represented by decrease of 30% (approximately 2 points) of the initial VAS score, according to Farrad et al.[5] With regard to prior guidelines, a second evaluation, defined as a decrease of the initial VAS score of 50%, was carried out.[5,23,6] Additionally, VAS needed to be less than or equal to four at the time of followup and no further need for intervention according to the patients' self-assessment had to be present to meet criteria for successful treatment.[17] The study was carried out strictly according to the guidelines proposed in the Declarations of Helsinki (amended version). Statistical evaluation was carried out using One Way ANOVA (Sigmastat 3.1, Systat Software, Erkrath, Germany).

RESULTS

The success of ESWT, defined as a 30% VAS reduction, was observed in 81% at 6 weeks followup, at 88% at the second followup and in 96% at final phone followup. The success of ESWT, defined as a 50% VAS reduction, was seen in 50% at first followup, in 62% at second followup

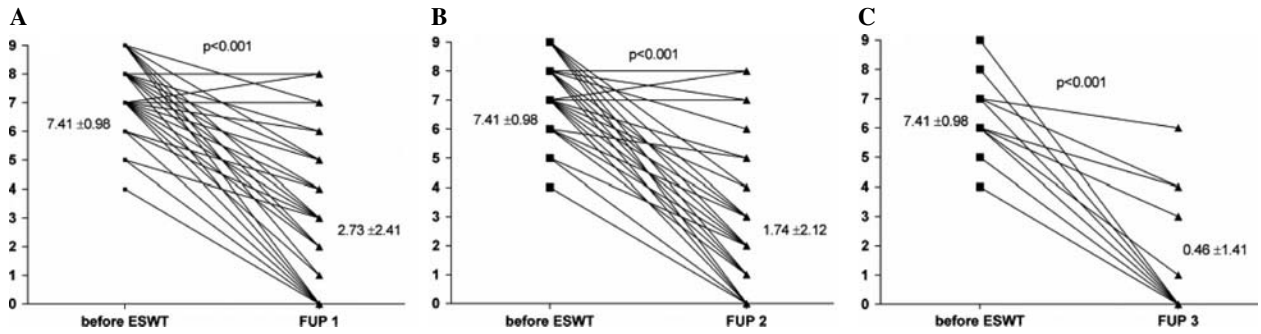

Fig. 6: Development of VAS-values including patients with second or third ESWT. Mean VAS-values in the graph show statistically significant decrease of pain after ESWT.

and in 90% at final phone followup. A decrease of start-up pain in the morning of at least 30% was seen in 84% at second followup and a decrease of 50% in 81%. Average duration of pain before ESWT was 16.4 months. VAS-scores are shown in Figure 6.

The Body mass index (BMI) at the time of 1st ESWT averaged 28.3 (20.9–39.6).

Twelve patients with BMI 20–25 were rated as of normal weight with a corresponding VAS-score of 7.8 (±0.9). Average VAS at followup 1 was 1.9 (±2.1), at second followup 1.1 (±1.4) and at final followup 0.5 (±1.3) in these patients.

Fifty-one patients with BMI>25, classified as overweight, had an average VAS-value of 7.3 (±1.0) before ESWT, of 2.9 (±2.4) at first followup, 1.9 (±2.2) at second followup.

At final followup, they had an average VAS-value of 0. 5 (±1.4) which was not different from normal weight subjects.

Sixteen patients with plantar heel spur had an average VAS-value of 7.0 (±1.1) before ESWT, of 2.1 (±2.3) at first followup, of 1.0 (±1.8) at second followup and for the 11 patients available at final followup 0 (±0). Forty-seven patients without a plantar heel spur had an average VAS-value of 7.6 (±0.8) before ESWT, of 3.0 (±2.4) at first followup, of 2.0 (±2.2) at second followup and for the 34 patients available for final followup 0.7 (±1.6). Thus, clinical results were not different in patients with or without heel-spur.

Local anesthesia was given to 23 patients with an average VAS-value of 7.0 (±0.9) before ESWT, who had a VAS of 1.4 (±2.21) at first followup, of 1.2 (±1.9) at second followup and for the 13 patients available for final followup 0.3 (±0.9).

Regional anesthesia was given to 40 patients with an average VAS-value of 7.6 (±1.0) before ESWT, who then had a VAS of 3.4 (±2.2) at first followup, of 2.0 (±2.2) at second followup and for the 32 patients available for final followup an average VAS-value of 0.6 (±1.6) (Table 2). The results for patients with a single treatment did not differ significantly compared to patients who received more than one treatment (Figure 7).

Observed side-effects consisted only of short-term limited erythema of the skin in the area of ESWT application.

DISCUSSION

Though contradictory reports concerning effectiveness of ESWT are found, positive results seem to dominate.[18,20,9,17] Even though the success of ESWT seems to depend on the total dose rather than energy flux density,[8,16] differences between high and low-energy ESWT need to be taken into account. High-energy ESWT, in our experience, can not be applied without nerve block. The area of maximum tenderness can easily be located and marked by the ESW therapist before application of local anesthesia and is described as the target by most authors except when ultrasound is used to guide application to the thickest portion of the plantar fascia adjacent to the calcaneus.[3]

Local anesthesia at the point of maximum tenderness (origin of the plantar fascia), may decrease the effectiveness of ESWT. However, this has been investigated for low-energy ESWT up to the present.[14,7,21]

Due to the retrospective nature of our investigation, our study lacks a placebo control group. However, we believe the application of sham-shock wave in the course of high-energy ESWT would be difficult even in a prospective trial. Ogden et al. used a styrofoam block and Gollwitzer et al. used an air-chambered polyethylene foil positioned between the patient and the coupling head for blinding.[17,8] Energy flux density was 18 kV (which would equal 1.5 mJ/mm^2 in our shock-wave emitter!) in the first study and 0.25 mJ/mm^2 in the second study.

As mentioned above, our shock-wave device was not able to produce less than 0.35 mJ/mm^2 (10.5 kV), which prevents the application of sham-shock waves especially since even their energy level has been described as possibly effective, which could impair the validity of a placebo group.[3]

Many authors differentiate heel pain into start-up pain in the morning, pain when walking, and pain in the evening. Heel-pain generated by local pressure even when using a special pressure inducing device appeared dependent on the

Table 2: Results

	Follow up 1	Follow up 2	Follow up 3
30% VAS-Reduction	81%	88%	96%
50% VAS-Reduction	50%	62%	90%
Decrease of Morning Start-Up Pain		84%	
BMI 20–25 VAS 7.83 (before ESWT)	VAS 1.92	VAS 1.08	VAS 0.5
BMI >25 VAS 7.33 (before ESWT)	VAS 2.89	VAS 1.87	VAS 0.45
Heel spur VAS 6.95 (before ESWT)	VAS 2.05	VAS 1.0	VAS 0.0
No Heel spur VAS 7.6 (before ESWT)	VAS 3.0	VAS 2.04	VAS 0.65
Local Anaesthesia VAS 7.0 (before ESWT)	VAS 1.44	VAS 1.16	VAS 0.26
Regional Anaesthesia VAS 7.63 (before ESWT)	VAS 3.4	VAS 2.04	VAS 0.58

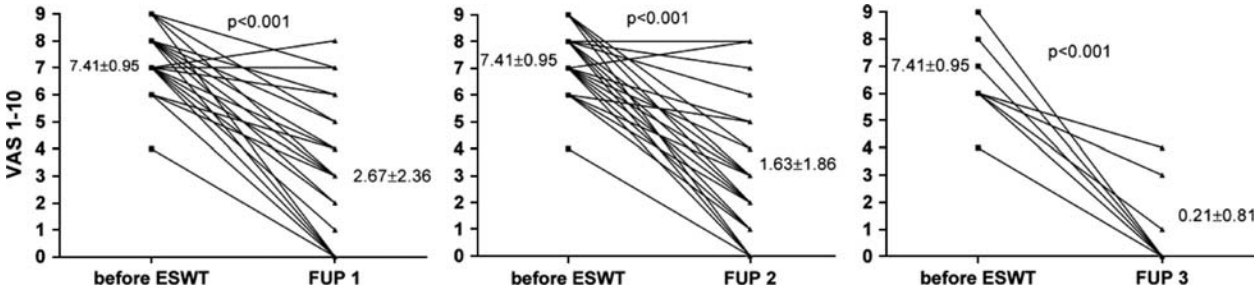

Fig. 7: Development of VAS-values, patients with single treatment only. No significant difference compared to the results displayed in Figure 6.

examiner to us so we chose VAS-values during the course of the day as the main reference. Thus, inter-observer variability did not influence the results of our investigation.

Many studies do not state explicit data of the emitting device used, nor the entire parameters defining the shock-waves themselves[8] (e.g., studies, presenting kV or mJ/mm^2 respectively). In general, data in this respect should be presented as "mJ/mm^2" rather than "kV", as different emitters produce diverging energy flux densities using the same voltage.[20] Also, the definition of "high-energy" shock-wave is not clear.[20] In our study, radial shock-waves and energy flux density less than 0.2 to 0.25, which can be applied without nerve-block, were rated as "low-energy".[20,8] The total dose at an average of 484 (Minimum 350, Maximum 1470) mJ/mm^2, applied in our study, was rather small (cp. 1406 mJ/mm^2,[3] 960 mJ/mm^2,[7] 1500 mJ/mm^2,[8] 900 mJ/mm^2[18]), energy flux density (0.35 mJ/mm^2) on the other hand high.

With regard to studies using comparable high-energy energy flux density, Gollwitzer et al. (0.25 mJ/mm^2)[9] found a decrease of composite heel-pain of 73.2%, which admittedly was not statistically different from the placebo group, but was of clinical relevance. Perlick et al. (0.3 mJ/mm^2)[18] reported an improvement of discomfort of 85% (no reference-group, assessment by means of a questionnaire.

Also remarkable was the lateral positioning of the heel onto the coupling head).

In another study evaluating the effectiveness of ESWT using local anesthesia, shock-waves of varying energy flux density (0.09 and 0.18 mJ/mm^2 respectively) were applied to three cohorts. The cohort displaying the best results (50% pain reduction in 60% of cases) was comparable to our study with a total energy of 405 mJ/mm^2 but with low energy flux density and the lack of nerve-block.[14] Another study with comparable total dose of 320 mJ/mm^2, using radial shock-wave (0, 16 mJ/mm^2), showed success of ESWT in 72.1% (placebo-group 42.2%).[7] Buchbinder et al. found notable decrease of pain in both the experimental and the placebo-group with a high total dose (Minimum 1000 mJ/mm^2), but showed no benefit of ESWT over placebo.[3] Comparison of these few studies again illustrates the problem of the lack of standardization of ESWT.

Furthermore, success of therapy is often linked to varying parameters, partially in comparison to the placebo-groups, which again complicates comparison of the studies.

Usually, intervals between ESWT treatments of 1 day[14] and 1 week are reported in the literature.[3,8,10] In our study, with prolonged intervals between ESWT treatments, each ESWT-session should be evaluated for itself only. Even so, success of ESWT could be shown (regarding to a 30% VAS reduction, 81% at first followup and no significant differences of the results of all patients and patients with a single treatment only—see Figures 6 and 7). The retrospective character of our study explains the vast differences of followup intervals.

In some cases, when patients were seen shortly after ESWT with complaints unrelated to prior heel-pain so the success of ESWT of the plantar fascia was evaluated and noted in the charts. If patients did not show up at scheduled followup dates, they were called for evaluation—sometimes with long intervals between ESWT and followup.

We found BMI did not have a significant influence on clinical outcome, nor did the use of local or regional anesthesia or the presence or absence of a plantar heel spur.

CONCLUSION

In our opinion, we believe that high-energy ESWT of the plantar fascia, applied at the area of maximum pain, using a nerve-block, will achieve a decrease in discomfort, usually with one treatment without severe side-effects. This conclusion is based on the short-term clinical followup but the results seemed to be maintained over time at final phone followup with 30% VAS-reduction in 96% of patients, approximately. Six years after ESWT. Naturally, due to lack of a control-group, the natural course of the disease was not evaluated, which means that the definitive effect of ESWT on the long-term improvements cannot be derived from our study. However, a patient suffering from heel-pain will likely demand treatment and will not be satisfied with evidence of the self-limiting nature of the problem. We believe our study shows that ESWT represents a valuable, safe and effective treatment option for patients suffering from plantar fasciitis. In our study, we tried to facilitate comparison with other studies by using elementary, easily reproducible parameters for evaluation and displaying an accurate specification of the technical data.

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