



## Original research

## Approaches to optimize focused extracorporeal shockwave therapy (ESWT) based on an observational study of 363 feet with recalcitrant plantar fasciitis<sup>☆</sup>



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## HIGHLIGHTS

- Focused ESWT needs to be applied only once in many cases.
- None of the treatment parameters assessed relevantly affected outcome.
- None of the anamnestic or sociodemographic parameters assessed affected outcome.
- Treatment success was independent of the physician applying ESWT.
- Further research should focus on the number of treatment sessions as well as the minimum energy flux density needed.

## ARTICLE INFO

## Article history:

Received 6 October 2015

Received in revised form

5 January 2016

Accepted 18 January 2016

Available online 20 January 2016

## Keywords:

Extracorporeal shockwave

High energy shock waves

Plantar fasciitis

Treatment outcome

Pain management

Heel spur

## ABSTRACT

**Introduction:** Extracorporeal shockwave therapy (ESWT) is an established second-line treatment option for plantar fasciitis. Longer term results of focused ESWT are rare in literature. This study assessed the treatment success-rates of single session ESWT compared to repetitive ESWT treatment sessions, the mid-term results as well as treatment- or patient-related factors influencing the outcome of focused ESWT for plantar fasciitis.

**Methods:** 284 patients (363 feet) received ESWT for plantar fasciitis and answered a questionnaire on socio-demographic and anamnestic data immediately before as well as 19–77 weeks after the first application of ESWT.

**Results:** 76 percent of patients treated only once and 74 percent of all patients reported satisfying pain relief (with up to three treatment sessions). This was consistent in the mid-term and over different physicians as well as independent of assessed patient- or treatment-related factors.

**Discussion:** Applying repeated ESWT in weekly intervals by default may be helpful in reducing healing time for those patients requiring more than one treatment session. Prospective research is needed to find out whether further treatment sessions are justifiable in patients who indicate no improvement after two or three treatment sessions.

**Conclusions:** In many cases, focused ESWT needs to be applied only once. Further research should focus on the number of treatment sessions as well as the minimum energy flux density needed.

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<sup>☆</sup> We certify that no party having direct interest in the results of the research supporting this article has or will confer a benefit on us or on any organization which we are associated with AND, if applicable, we certify that all financial and material support for this research (eg, NIH or NHS grants) and work are clearly identified in the title page of the manuscript.

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## 1. Introduction

Plantar fasciitis is a common and often disabling condition: In the US about one million patient visits every year are due to plantar fasciitis [1]. The pathogenesis of plantar fasciitis is not sufficiently resolved so far, hence it is difficult to distinguish between patients who recover spontaneously and those who respond to some form of treatment. A review in 2012 evaluated conservative as well as surgical treatment options and assumed that only local corticosteroid injections, stretching exercises, orthotic devices (night splints, heel pads), extracorporeal shockwave therapy (ESWT) and several surgical procedures show treatment effects with higher level evidence [2]. There are several trials suggesting that radial [3] as well as focused [4–6] shockwave therapies show satisfying short-term results in treatment of plantar fasciitis regarding pain intensity. The comparability of existing literature is difficult as different devices and treatment schemes are applied. In addition, follow-up periods of longer than 12 weeks are rare in literature [4,7,8]. A clinical trial published in 2009 already assessed patient-related factors that may influence the outcome of ESWT treatment for chronic plantar fasciitis and assumed that previous corticoid injections, body mass index, duration of symptoms, presence of bilateral symptoms, and plantar fascia thickness did not influence the outcome, while the presence of diabetes mellitus, psychological issues, and older age were found to negatively influence ESWT outcome [9].

Existing randomized controlled trials (RCTs) concerning focused ESWT assessed the outcome of a treatment protocol containing three treatment sessions in weekly or even monthly intervals [10–13] although there is no evidence for the necessity of repeated treatment in many cases.

Our study was performed to assess the influence of the following parameters on treatment outcome as well as mid-term results of *focused* ESWT:

- outcome after a single treatment session
- outcome after up to three treatment sessions in patients who didn't satisfactorily respond to a single session
- whether further patient- or treatment-related factors influence the outcome of ESWT as treatment option for plantar fasciitis

## 2. Patients and methods

Many patients suffering from plantar fasciitis are referred to our tertiary referral hospital by an orthopedic specialist for ESWT. Patients aged over 18 years with clinically verified plantar fasciitis and radiologically verified heel spur were included in this study. Patients who underwent prior surgery due to this indication as well as pregnant women were excluded. X-rays and a clinical examination enabled us to exclude other pathologies possibly etiologic for this type of pain and to reveal a shortening of soleus and/or gastrocnemius muscles. Patients were asked to fill out an informed consent form and a questionnaire assessing socio-demographic data as well as anamnestic data concerning their plantar fasciitis (pain intensity under load and while resting on an eleven-point numeric rating scale (NRS) [14], onset of pain, past treatments, impairment of activities like sports, sick days) before treatment. This procedure was performed every time the patient visited our site for ESWT (treatment time points T1 – T3) before ESWT was applied.

The device used at our site is a Storz Duolith SD1 Tower (Storz Medical AG, 8274 Tägerwil, Switzerland). This type of device was already used for a recent RCT by Gollwitzer et al. and showed a median reduction of VAS in recalcitrant plantar fasciitis of nearly 70% [13]. Treatments were performed independently by orthopedic

residents, certified for ESWT and/or after a supervision period of 3 months. We applied the following ESWT scheme to each patient:

- Single application session with focused ESWT (electromagnetically generated shockwaves) without any local anesthesia application
- Positioning of the ESWT-transducer at the maximum point of tenderness [15,16]
- 1500 shockwave impulses [16]
  - Energy flux: .15 up to .25 mJ/mm<sup>2</sup> (depending on the patients pain tolerance) [16]
  - ESWT head is prepared with Storz's distance piece no. 1 (30 mm) to adapt the depth of the focus to 15–45 mm (according to user manual)
  - No more than 400 impulses in the same transducer position to prevent tissue alterations aside from the plantar fascia
- One night of inpatient stay after ESWT to document eventual adverse events
- Oral anticoagulation as well as platelet aggregation inhibitors should be paused for 10 days before ESWT if possible
- After ESWT patients are advised to avoid great efforts regarding the treated feet for 7 days
- We recommended patients to do a reassessment at their orthopedic specialist after 4–6 weeks. If needed, patients are referred to our site again for a further session according to the scheme described above (up to 2 repetitions of this procedure are deemed reasonable [16]- > treatment timepoints T2, T3). Dependent on patients' compliance and outcome of the reassessment the time span between treatment time points differs individually.

Energy flux and number of shockwave impulses are chosen by the physicians according to the patients' tolerance of pain since, according to Chow et al. [17], the maximum tolerable energy density should be a more effective treatment protocol than a fixed energy density. The use of local anesthetic was avoided for reasons of efficacy [18]. At our site we only performed ESWT, we did not initiate any additional treatment, such as stretching or orthotics.

In 2013 we sent questionnaires to a group of patients, who were treated with ESWT at our site in 2012 due to plantar fasciitis with heel spur (time point TC) - Fig. 1 illustrates a workflow diagram. This questionnaire mainly contained the same anamnestic questions, in order to compare the development of pain and the level of patients' physical activity. Additionally patients' satisfaction with ESWT outcome, pain level during treatment, as well as other treatments received afterwards were assessed. To estimate the subjective satisfaction a nominal scale with four possible answers (from 'absolutely satisfied' to 'dissatisfied') was used to prevent the existence of a neutral (middle) position. Patients received one questionnaire for each treated foot. The study is approved by the local ethics committee and was performed according to the principles outlined in the Declaration of Helsinki.

## 3. Statistics

To summarize the basic features of the data descriptive statistics were used. Percentages were computed for categorical variables. Depending on the scaling of the variables, means and ranges or medians and interquartile ranges (IQR) were calculated.

A first evaluation investigated differences between persons who returned the questionnaire and those who did not regarding socio-demographic variables. In case of categorical data Chi-2 tests were applied, in case of continuous variables differences were tested for significance using t-tests for independent variables. Changes in NRS scores after treatment were tested using analyses of variance for

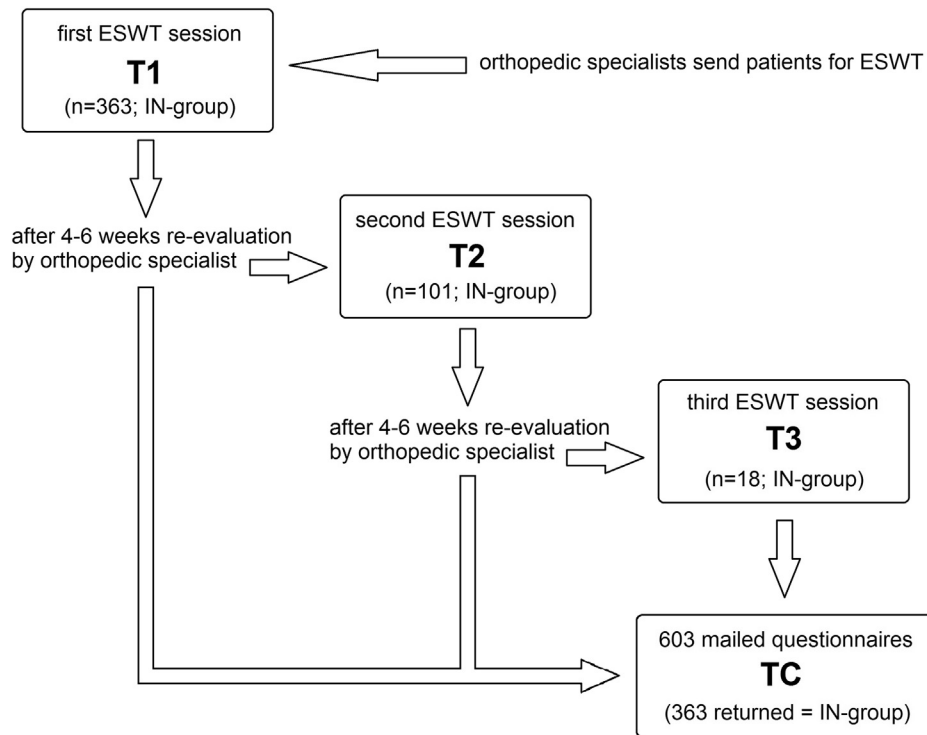


Fig. 1. Workflow diagram.

repeated measures. To assess whether certain treatment factors influence the outcome of ESWT, analyses of variance for repeated measures were computed for the main outcome factor (which is the difference between NRS scores under load), with the treatment factors as independent variables and 'duration of symptoms' as covariate.

The assumptions for t-tests and analyses of variance are:

- 1) normal distributions of the independent variables and
- 2) equal variances among the groups of the independent variables.

Normal distribution was checked visually by inspection of the histograms. The validity of assumptions of equity of the variances was established by Levene tests. For correlations between continuous variables a Pearson's correlation coefficient was calculated. A p-value of  $\leq .05$  was defined as level of significance for all statistical tests. The statistics were computed using the SPSS 21 software (IBM SPSS Statistics, IBM Corp 2012, New York).

#### 4. Results

284 patients (363 treated feet) completed and returned the questionnaire mentioned above. The mean time span between patients' first treatment with ESWT at our site and returning the questionnaire was 296.94 ( $\pm 101.99$ ; 136–541) days, between patients' last treatment session and return of the questionnaire 262.06 ( $\pm 111.09$ ; 14–529) days. Socio-demographic data of patients assessed: 70.2% female; mean age 50.24 years ( $\pm 11.04$ ; range 27–81); mean BMI 29.49 ( $\pm 5.02$ ; range 18–46); 49.3% employed, 39.4% retired, no sick days due to plantar fasciitis in 88.4% of patients.

363 feet had been treated with ESWT (181 left (49.9%)), the average duration of symptoms before T1 was 14.18 ( $\pm 15.44$ ; 1–99) months. 262 (72.2%) were treated only once with ESWT (T1), 83 (22.9%) were treated twice (T1 + T2) and 18 (5.0%) needed a third

treatment session (T1 – T3). According to the nominal scale of subjective satisfaction mentioned above 46.9% of patients treated only once were absolutely satisfied, 29.4% were nearly absolutely satisfied, 7.6% were satisfied with reservations, and 16.0% were dissatisfied, but refused further treatment with ESWT. Although average NRS scores decreased between T1 and T2 ( $p = .003$ ) in patients treated more than once, a significant ( $p = .001$ ) and clinically relevant decrease in NRS scores occurred after T2 as Fig. 2 illustrates. Patients treated more than once showed no significant difference in outcome at TC compared with those treated only once ( $p = .71$ ). The time interval between T1 and T2 (108.69 ( $\pm 71.22$ ; 21–401) days) as well as T1 and T3 (186.28 ( $\pm 94.00$ ; 103–441) days) showed no significant influence when calculated as a covariate.

Overall 42.7% of patients were absolutely satisfied with the outcome of ESWT, 31.1% were nearly absolutely satisfied, 9.4% were satisfied with reservations, and 16.5% were dissatisfied. There was a

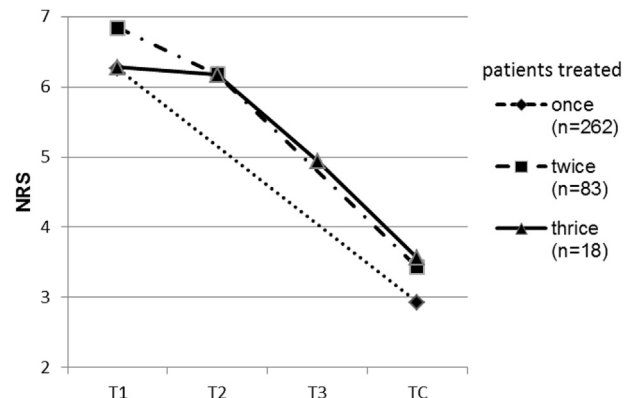


Fig. 2. Development of NRS scores (under load).

significant positive correlation between patients' satisfaction and their individual NRS difference between T1 and TC ( $p = \leq .001$ ).

The mean number of shockwave impulses applied was 1519.48 ( $\pm 147.76$ ; 1000–3000). The average maximum energy flux applied was .205 ( $\pm .063$ ; .05–.35) mJ/mm<sup>2</sup>, the average total energy applied was 9.64 ( $\pm 2.94$ ; 2.56–26.17) J. There was no significant correlation found between NRS difference and maximum energy flux or total energy applied.

The mean NRS scores dropped significantly between T1 and TC as Table 1 demonstrates: To further visualize the degree of changes in NRS, because NRS values are hard to compare between individuals, and because the aim of each treatment in this context is to make patients pain-free, we also calculated relative changes in NRS score between T1 and TC. In both cases an improved pain situation is indicated by a positive value, deterioration by a negative one. Because of the clinical relevance and the significant correlation between NRS score differences under load and unloaded ( $p = \leq .001$ ;  $r = .518$ ) we decided to discuss all of the following issues with regard to the absolute NRS difference under load (unless otherwise indicated).

Obesity [19] was more highly prevalent in patients assessed in this study than in the general population [20] (BMI > 30: 47.9% vs. 13.1%). Patients with bilateral plantar fasciitis did not differ significantly from those with unilateral heel pain in terms of BMI. There was a significant positive correlation between the duration of symptoms and BMI ( $p = \leq .001$ ). Table 2 describes the level of physical activity at T1 and TC as well as the change in NRS scores: The number of physically active people increased significantly ( $p = \leq .001$ ) and patients fully active at TC experienced most pain relief ( $p = \leq .001$ ).

Table 3 depicts the relationship of changes in NRS to potentially determining factors: Although some of the correlations are statistically significant none of them appears clinically relevant. In addition, we were not able to detect any clinically relevant differences between patients who were (nearly absolutely) satisfied after a single treatment session and those who were satisfied after two or three sessions. Again, bilateral symptoms, days since last treatment, and pain experienced while ESWT appeared statistically significant.

Pain (average NRS score) experienced while ESWT was 5.95 ( $\pm 2.80$ ; 0–10).

Patients who received exactly one intralesional corticosteroid injection ( $n = 50$ ) had a considerably better outcome (NRS difference under load 4.41 ( $\pm 2.62$ ;  $-2 - 10$ )) than those who received no ( $n = 164$ ) or at least two injections ( $n = 149$ ). A significant correlation between duration of symptoms and number of injections could not be found ( $p = .10$ ). No injections were administered within three weeks prior to ESWT.

Significantly fewer patients made use of conservative treatment options after ESWT than before ( $p = \leq .001$ ), 55.4% of the feet received no further treatment after ESWT (68.2% still used insoles).

Patients who needed further therapy after ESWT as indicated above experienced less pain relief in total ( $p = \leq .001$ ), patients' satisfaction was negatively correlated with the number of

treatments received after ESWT ( $r = -.448$ ;  $p = \leq .001$ ). Two patients (.6%) underwent surgery between ESWT and TC - both indicated no satisfying outcome at TC.

No adverse events were detected in the first 24 h after ESWT (patients stayed for one night after treatment as inpatients), and there were also no adverse events reported by patients afterwards.

## 5. Discussion

In existing literature radial as well as focused ESWT are commonly applied two or three times in intervals of one week (or longer), but so far there is no evidence for the need of multiple applications of focused ESWT. Our findings show satisfying mid-term outcome of focused ESWT in patients suffering from plantar fasciitis with inferior calcaneal spur, supporting the good results found in several studies [5,6,21]. They corroborate the evidence of a recently published RCT on 246 subjects using the same device, where ESWT again was applied three times in weekly intervals. The placebo group in this RCT showed an improvement in 35% of patients with a remaining between-group difference of 35% pain reduction. This may be explainable by the natural progression of plantar fasciitis or may confirm the power of the placebo effect in pain studies. The natural progression seems less probable to us as the study only included patients with a history of plantar fasciitis resistant to at least four nonsurgical treatment modalities over at least six months [13]. Hence participants were patients suffering from chronic pain, like most patients in our study.

The main limitation of our study is its retrospective character. Some patients refused further treatment with ESWT although they were not satisfied after one or two treatment sessions.

We experienced satisfying results in many patients with only one session of focused ESWT. When more interventions were necessary treatment success was independent of the time interval between them. No parameters were detected that may predict the need of repeated treatment sessions.

The significant increase in patients' physical activity after ESWT is another positive indicator for treatment success. If the outcome is not satisfying after 4–8 weeks [22], we deem a second application to be reasonable. Applying repeated ESWT in weekly intervals by default may be helpful in reducing healing time for those patients requiring more than one treatment session. Prospective research is needed to find out whether the healing response can be accelerated by applying ESWT in multiple initial treatment sessions in weekly intervals compared to our scheme and whether further treatment sessions are justifiable in patients who indicate no improvement after two or three treatment sessions.

The good overall outcome was not relevantly correlated with any of the measurable treatment parameters (number of and time interval between ESWT sessions, maximum/total energy applied, physician applying ESWT), socio-demographic data (age, gender, BMI, employment status, sick days), or other conservative treatment options applied before or after ESWT. These results are similar to those of Chuckpaiwong et al. [9] while in contrast age did not have a negative influence on outcome according to our data. An

**Table 1**  
Changes in NRS between T1 and TC.

	Absolute difference under load	Absolute difference unloaded	Relative change under load	Relative change unloaded
mean	3.32	1.68	48.63	44.10
median	3.00	2.00	58.57	66.67
SD	2.98	2.78	42.43	61.07
range	18.00	16.00	188.89	200.00
min	-8.00	-6.00	-88.89	-100.00
max	10.00	10.00	100.00	100.00

**Table 2**  
Changes in physical activity between T1 and TC.

	Timepoint T1	Timepoint TC	Average change in NRS (T1–TC)
active without restrictions	1.4%	33.2%	–4.8
active with restrictions	42.4%	36.1%	–2.3
inactive due to heel pain	17.9%	4.8%	.0
generally no activity	38.3%	25.9%	–3.2

**Table 3**  
Relationship of changes in NRS to potentially determining factors.

	p-value	Correlation (r)
pain experienced during ESWT	≤.001	–.213
total duration of symptoms	.03	–.115
former number of sick days	.05	.105
one (n = 205)/both (n = 79) feet treated	.02	–.021
former passive physical treatments (electrotherapy, mud and peat packs)	.03	–.095
days since last treatment	≤.001	–.227
maximum energy flux	.33	no significance
total energy applied	.85	
time interval between treatment sessions	.16	
physician applying ESWT	.08	
BMI	.56	
physical activity before ESWT	.52	
employment status	.21	
age	.84	
gender	.69	
physiotherapy before ESWT	.19	
oral analgesics before ESWT	.82	
orthopaedic insoles before ESWT	.37	

interesting finding was the considerably better outcome of patients (n = 50) who received exactly one local corticosteroid injection before ESWT. Maybe the reason why more frequent local corticosteroid applications turned out to have a negative effect is to be found in the suspected toxicity of local anesthetics and corticosteroids on tenocytes [23–26]. On the other hand local corticosteroid therapy was the only intervention with at least limited evidence for plantar heel pain due to a Cochrane review from 2003 [27]. In addition, several authors propose that intralesional injection of corticosteroids is at least as effective as ESWT when compared directly [28,29]. Apart from this our results are similar to those of Odgen et al. [30] who found no correlation between the outcome of ESWT and corticosteroid injections before ESWT and can therefore not support the findings of Melegati et al. [31] which propose that previous local steroid injections may negatively affect the result of ESWT.

The fact that patients who made use of further conservative treatments after ESWT in total experienced less pain relief implies that there are non-responders to conservative treatment.

Patients who benefited less experienced more pain during treatment. But the difference in average NRS is, like the degree of correlation, clinically less relevant, as the average scores of NRS express moderate to nearly severe pain even in satisfied patients [32,33]. It is probable that several psychological factors are responsible for negative reminiscences of treatment in patients who benefited less from it [34]. Pain experienced during ESWT was assessed retrospectively, and is therefore of course of limited validity, hence a limitation of this study.

Although ESWT caused at least moderate pain in many patients none of our patients needed local anesthetic during ESWT. Pain intensity during treatment seems to have no clinically relevant effect on its outcome. Hence our results actually cannot support the assumption that the delivery of ESWT with a maximum tolerable energy density is a more effective treatment protocol than a fixed energy density [17]. The fact that outcome showed only a very

slight correlation with pain during ESWT and no significant correlation with energy applied implies that as long as a minimum amount of energy is applied, the outcome is not affected by these parameters. This minimum energy necessary has to be evaluated in further research.

Due to recent literature a combination of ESWT and stretching exercises may be a very effective and rather economic treatment combination, whereas continued stretching could also prevent relapse [35,36]. This hypothesis has to be assessed in further prospective trials. Although we assessed clinical signs of muscle shortening, we did not assess whether patients had already been instructed in appropriate stretching exercises, which is a limitation of this study.

While some authors proposed ESWT as an end-stage treatment option [37,38] our results implicate that early treatment could eventually provide better results and hence perhaps prevent chronification. Like the authors of studies comparing ESWT with endoscopic release [39,40] we found benefits of ESWT such as no complications and no immobilization.

## 6. Conclusions

In many cases a single session of focused ESWT leads to satisfying pain relieve of the heel and increases in the functional activity level of patients suffering from this very common foot problem. We conclude that focused ESWT is an efficient treatment option for plantar fasciitis in terms of treatment success, safety, and its independence of socio-demographic, anamnestic, and treatment related factors. Further prospective research should focus on the number of treatment sessions as well as the minimum energy flux density needed to optimize medical and economical effectivity.

## Ethical approval

Ethical approval was given by the Ethikkommission der Stadt

Wien, (address: 1030 Wien, Thomas-Klestil-Platz 8). Reference number: EK 13-218-VK.

### Sources of funding

n/a.

### Author contribution

RS drafted the design of the study, carried out the data collection, participated in the statistical analyses, and drafted the manuscript. MF participated in the design and coordination of the study, participated in the project management, provided subjects and helped to draft the manuscript. JH(1) participated in the design of the study and performed the statistical analysis. JH(2) and PM conceived of the study, participated in its design and data collection and helped to draft the manuscript. MP drafted the design of the study, participated in the statistical analyses and project management, provided subjects and drafted the manuscript. All authors read and approved the final manuscript.

### Conflicts of interest

n/a.

### Trial registry number

n/a.

### Guarantor

Raphael Scheuer.

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