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Complications of extracorporeal shockwave therapy in plantar fasciitis: Systematic review

R.L. Roerdink, M. Dietvorst, B.v.d. Zwaard, H. van der Worp, J. Zwerver

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Title: Complications of extracorporeal shockwave therapy in plantar fasciitis: Systematic review

Abstract:

Background

Extracorporeal shockwave therapy (ESWT) seems to be an effective treatment for plantar fasciitis (PF) and is assumed to be safe. No systematic reviews have been published that specifically studied the complications and side effects of ESWT in treating PF. Aim of this systematic review is therefore to evaluate the complications and side effects of ESWT in order to determine whether ESWT is a safe treatment for PF.

Methods

For this systematic review the databases PubMed, MEDLINE, Cochrane and Embase were used to search for relevant literature between 1 January 2005 and 1 January 2017. PRISMA guidelines were followed.

Results

Thirty-nine studies were included for this review, representing 2493 patients (2697 heels) who received between 6424 and 6497 ESWT treatment sessions, with an energy flux density between 0.01 mJ/mm^2 and 0.64 mJ/mm^2 and a frequency of 1000-3800 SWs. Average follow-up was 14.7 months (range: 24 hours - 6 years). Two complications occurred: precordial pain and a superficial skin infection after regional anaesthesia. Accordingly, 225 patients reported pain during treatment and 247 reported transient red skin after treatment. Transient pain after treatment, dysesthesia, swelling, ecchymosis and/or petechiae, severe headache, bruising and a throbbing sensation were also reported.

Conclusion

ESWT is likely a safe treatment for PF. No complications are expected at one-year follow-up. However, according to the current literature long-term complications are unknown. Better descriptions

of treatment protocols, patient characteristics and registration of complications and side effects, especially pain during treatment, are recommended.

Key words: complications, side effects, adverse events, plantar fasciitis, ESWT, extracorporeal shock wave therapy, plantar fasciopathy, safe, safety.

1. Introduction

Plantar fasciitis (PF) is the most common cause of heel pain and accounts for up to 15% of all foot symptoms requiring medical care.[1][2][1-3] It is associated with significant morbidity, resulting in activity limitations for the affected patients.[4-7] PF accounts for approximately 1% of all patient visits to orthopaedic surgeons in the United States.[4]

The aetiology of PF is poorly understood.[2,8] PF is thought to be caused by biomechanical overstress of the insertion of the plantar fascia on the calcaneal tuberosity.[2] Discussion of its biomechanical aetiology usually involves the windlass mechanism and an increased tension of the plantar fascia during gait.[2] Mechanical overload, irrespective of whether it is the result of biomechanical deviations, obesity, or work habits of prolonged standing and running, may contribute to the symptoms. This makes it more likely to be a chronic degenerative process than acute inflammation.[2]

Diagnosis can be made with reasonable certainty on the basis of clinical assessment alone.[5] PF is characterised by pain at the calcaneal origin of the plantar fascia that is usually worse with the first steps in the morning or after a period of inactivity. The pain becomes worse by extended duration of weight bearing. Additional to these findings, there is localised tenderness during palpation at the insertion of the fascia during physical examination.[9,10]

The standard treatments of PF are conservative measures that include insoles, shoe modification, physical therapy, stretching exercises, night splints and nonsteroidal anti-inflammatory drugs (NSAIDs).[1,3] After failure of these conservative treatments, corticosteroid injections can be given.[1,3] For intractable cases, surgical procedures like

fasciotomy are performed.[1,3] An alternative non-invasive treatment can be Extracorporeal Shock Wave Therapy (ESWT), which is used in various forms of tendinopathy, including PF.[2,8,11]

Shockwave treatment is commonly used in the management of tendon injuries and there is increasing evidence for its clinical effectiveness.[12] There is a paucity of fundamental (in vivo) studies investigating the biological actions of shockwave therapy. Destruction of calcifications, pain relief and mechanotransduction-initiated tissue regeneration and remodelling of the tendon are considered to be the most important working mechanisms.[12] A shockwave is a special, non-linear type of pressure wave with a short rise time (around 10μs).[13,14] There are two types of shockwave therapy for the generation and application on human tendons: focused shockwave therapy (FSWT) and radial shockwave therapy (RSWT). Focused shockwaves are characterised by a pressure field that converges at a selected depth in the body tissues, where the maximal pressure is reached.[11,14] FSWT can be generated using three methods: electrohydraulic, electromagnetic and piezoelectric.[11,14] The difference between the three methods of generation is the time at which the shockwave forms.[15] Radial shockwaves are characterised by a diverging pressure field, which reaches maximal pressure at the source, and they are not generated in water.[14]

When applying ESWT several important variables should be taken into account. Next to the type of ESWT, variety may occur in the amount of shockwaves given (SWs), number of treatment sessions and in-between intervals, administration of anaesthesia and energy flux density (EFD, in mJ/mm^2). EFD refers to the concentrated SW energy per unit area and is a term used to reflect the flow of SW energy perpendicularly to the direction of propagation; it is taken as one of the most important descriptive parameters of SW dosage.[16] Low-energy ESWT is an EFD of ≤0.12 mJ/mm2, and high-energy ESWT is >0.12 mJ/mm^2.[16,17]

The heterogeneity of systems (FSWT vs. RSWT), treatment protocols and study populations, and the fact that there seem to be responders and non-responders, continue getting in the way of giving firm recommendations on an optimal shockwave therapy approach.[12]

Many studies have investigated the effectiveness of ESWT in treating PF. Studies published before 2005 show variable outcomes. This may have been due to the limited experience of the healthcare providers who performed the ESWT and/or the shockwave devices they used. The literature now shows a decade-old trend. Recent systematic reviews and meta-analyses show ESWT to be an effective treatment with success rates between 50% and 94%.[2,16,18]

Efficacy of ESWT for PF has been established in the current literature and assumptions about patient safety have been made in several studies over the past ten years.[11,19] The 2010 guideline of the American College of Foot and Ankle Surgeons described it to be a safe treatment for PF.[20] However, little has been published about the complications and side effects of ESWT. There are indeed known complications that occurred for other indications during ESWT. For example, two cases of osteonecrosis in the humeral head after ESWT have been described after treating tendons of the shoulder.[21,22]

Patient safety in ESWT for PF should be evaluated, and fascia ruptures, osteonecrosis and damage to nerves or other structures must be taken into account. More insight into side effects like pain, which might interfere with treatment course and compliance, is also important.

To our knowledge there are no systematic reviews that specifically focus on the complications of ESWT in treating PF. Hence this study aims to systematically review which complications and side effects of ESWT have been reported and how often in order to determine whether ESWT is a safe treatment for PF.

2. Methods

This systematic review was conducted using the recommendations of the Cochrane Adverse Effects Methods Group about systematic reviews of adverse effects, and it was performed in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) guidelines (see Fig. 1 for flow diagram).[23,24]

2.1 Inclusion and exclusion criteria

The databases PubMed, MEDLINE, Cochrane and Embase were used to search for relevant literature. Studies were pre-selected based on the following inclusion criteria: humans; date of publication between 1 January 2005 and 31 December 2016; full text available in English, German or Dutch; the title or abstracts suggested a study about patients with PF treated with ESWT. Conference publications, letters to authors, notes, systematic reviews and meta-analyses were excluded.

2.2 Search strategy

Using a PICO (P: patients with plantar fasciitis, I: ESWT, C: –, O: side effects and complications), the following search was conducted with filters for articles from the year 2005: *((((extracorporeal shockwave therapy) OR eswt) OR shockwave therapy)) AND ((((plantar fasciitis) OR heel spur) OR heel pain) OR plantar fasciopathy).* We also performed expanded searches with the terms ‘complications’, ‘side effects’ and ‘adverse effects’.

2.3 Study selection and data extraction

Two reviewers completed the same search in the databases and article extraction independently. A pre-selection was made by screening titles and abstracts of the studies. Next, eligibility was assessed by reading the full text to determine whether side effects and/or complications were mentioned. Articles that described side effects and/or complications were included. Search results were compared afterwards and disagreements were settled by discussion, with the possibility to consult a third reviewer in case of uncertainties.

Complications were defined as: unexpected or uncomfortable symptoms during or after treatment that did not resolve within two weeks, or a treatment-caused unintended and undesirable event or condition that requires extra medical care or which affects the patient's health and functioning for a period of time, with or without irreparable damage. Side effects were defined as unexpected or uncomfortable symptoms during or after treatment that resolved within two weeks of treatment. If the incidence of reported complications and/or side effects were not provided, we tried to complete our data by contacting the authors.

The overall incidence of complications and the incidence per complication were calculated over the total study population of all included studies. Outcomes were given in percentages. Patient numbers from studies that reported the number of complications were included in the denominator in order to calculate the minimal known incidence. Although the actual incidence in those cases is higher, it could give an indication of the severity of complications. The same method was used for the incidence of side effects. Dropouts at final follow-up without explanation were noted.

2.4 Methodological quality

PRISMA guidelines were followed.[23] Within this review only studies that specifically reported whether there were complications and/or side effects were included. There is a lack of evidence for the relevance of quality tools to analyse complications and side effects.[24] Assessing the methodological quality on the primary outcomes of the included studies is not useful.[24] The outcomes may be of high quality, but this probably does not correlate with the outcomes about complications and side effects.[24] To estimate the quality of our results, we determined how complications and/or side effects were assessed based on the advice of the Cochrane Adverse Effects Methods Group.[24] Given the character of this review and the heterogeneity of the included study designs, it was not possible to conduct a standard risk-of-bias assessment.

151 2.5 Statistical evaluation

152 From the extracted papers 2x2 tables were constructed, with number of participants with or
153 without pain during ESWT treatment in the columns. Variables tested for their possible
154 influence on pain were: dosage (≤12 mJ/mm^2 or >12 mJ/mm^2), type of ESWT (radial
155 [RSWT] or focused [FSWT]), type of administration (gradually rising or constant level) and
156 use of a local anaesthetic (yes or no). Odds ratios (OR) and 95% confidence intervals (95%
157 CI) were calculated for each of these variables.

158 **3. Results**

159 3.1 Study selection

160 Thirty-nine studies were included for this review (selection process is shown in Figure 1). The
161 search results are provided in Table 1. The expanded searches with the terms 'complications',
162 'side effects' and 'adverse effects' resulted in fewer hits and did not add to the present search.
163 We therefore choose to withdraw those searches. Two studies described the same study
164 group, but with a different follow-up.[37,62] The study with the longest follow-up was
165 included for this review.[37]

166 3.2 Study characteristics

167 2493 patients were included in this study, representing 2697 heels receiving between 6424
168 and 6497 ESWT sessions. The review included RCTs (n=25), prospective comparative
169 studies (n=2), prospective cohort studies (n=9) and retrospective cohort studies (n=3). Table 1
170 displays the characteristics per study. None of the studies fully explained their methods for
171 assessing complications and/or side effects, although some did partially (n=13). Most of the
172 studies (n=26) mentioned complications and/or side effects, but did not explain how these
173 were assessed. Some studies did not report the incidence of side effects. We tried to complete
174 our data by contacting the authors of those studies, which was successful in two cases.[38,59]

175 3.3 Patient characteristics

Age range was 18-87 years. The exact ratio of male/female patients is unknown, because some studies (n=5) did not mention this. Pain duration preceding treatment ranged from 2-240 months. 126 patients were lost to follow-up without further explanation.

3.4 Treatment characteristics

Fourteen studies (n=14) did not mention essential treatment details, like used EFD, type of ESWT and/or device used.

3.4.1 Dose

319 patients were treated with low-dose ESWT (range 0.04-0.12 mJ/mm^2) and 1645 patients received high-dose ESWT (range 0.13-0.64 mJ/mm^2). 197 patients were treated with EFD between 0.01-0.15 mJ/mm^2. For 332 patients the used EFD is not known.

3.4.2 Type of ESWT

FSWT was used in most studies (n=22), some studies used RSWT (n=12), and five studies did not describe their type of ESWT (n=5).

3.4.3 Number of treatments and intervals

Treatments varied from one to eight sessions. Eleven out of 39 studies performed a single-session treatment (28%). Nineteen studies (49%) had weekly intervals between the sessions. Furthermore, two studies had daily intervals, another one had three-day intervals, two studies had two-week intervals, three studies had four weeks to three months intervals, and for one study intervals are unknown.

3.4.4 Anaesthesia

Ten studies (26%) used local anaesthesia for at least part of their study group. One study admitted conscious sedation anaesthesia.

3.4.5 Used devices

Used devices were: Swiss dolorclast (n=7), Epos ultra (n=5), Duolith (n=4), Ossatron (n=3), Piezoson 100 (n=2), Sonocur plus (n=2), Modulith SLK (n=2), Vibrolith (n=1), D-actor 200 (n=1), Orthospec (n=1), Lithotripter (n=1), Minilith SL1 (n=1), Stonelith V5 lithotripter (n=1), D-Actor 200 (n=1), Masterpuls MP 100 (n=1) and Masterpuls MP 200 (n=1). Five studies did not specify which device was used.

3.4.6 Follow-up

Average follow-up was 14.7 months (range: 24 hours-6 years). It was not described whether the studies with 2-6 years follow-up registered complications at final follow-up.

3.5 Findings

3.5.1 Complications

Thirty-three studies described whether complications occurred (n=2229). Two complications (0.09%) within this study population occurred in two different studies.[26,46] One study mentioned one patient with precordial pain and an electrocardiogram (ECG) that showed a partial bundle branch block.[46] The other study, in which a tibial nerve block was given at every treatment session, described a single case of superficial skin infection that did not require surgical treatment.[26]

3.5.2 Side effects

Thirty studies mentioned whether side effects occurred (n=2105), yet only 25 reported on the incidence. The other five studies did report side effects like pain during treatment, transient

redness of the skin and ecchymosis, but did not describe the incidence. Based on the studies that reported incidence of events, 403 out of 1946 patients (20.7%) had side effects of ESWT. Pain during treatment was reported 225 times (11.6%), transient red skin after treatment occurred 249 times. Dysesthesia (n=9), swelling (n=9), ecchymosis and/or petechiae (n=7), severe headache (n=4), bruising (n=3), throbbing sensation (n=2) and pain after treatment <1 week (n=2) were also reported.

3.5.3 Pain

Several variables seem to influence the risk for patients to report pain during treatment. Ten out of 20 (50%) studies using high-dose ESWT and two out of nine low-dose studies (22%) reported pain during treatment. Low-dose ESWT results in a reduced risk of pain during treatment compared to high-dose ESWT (OR: 0.549 [95% CI: 0.373-0.806]). Gradually progressively administered ESWT has a lower chance for reporting pain during treatment compared to direct administration at a constant EFD level (OR: 0.048 [95% CI: 0.025-0.0916]). FSWT appears to decrease the risk of patients reporting pain during treatment compared to RSWT (OR: 0.069 [95% CI: 0.049-0.097]). Local anaesthesia seems to result in a lower chance of pain during treatment (OR 0.655 [95% CI: 0.459-0.935]).

4. Discussion

This is the first study in which reports on ESWT were systematically reviewed for incidence and type of complications and side effects when treating PF. Of the studies that were assessed for eligibility (n=53), most described whether complications occurred (n=39). Only in two studies complications actually occured. Twenty-five out of 30 studies described frequency of side effects. Pain during treatment (n=9) and transient red skin (n=5) were the most reported side effects in the included studies. Transient redness of the skin is commonly reported, but has no therapeutic or clinical relevancy.

This study represents literature from 2005 to 2016. In our opinion, current literature of the past decade is representative of today's ESWT approach because of the currently used devices, executive healthcare providers and treatment protocols. Most studies did not specifically describe how they registered complications and/or side effects, resulting in poor quality of the individual outcomes per study on these items. However, combining the data represents all current available evidence about complications and side effects from ESWT for PF.

In a large group of patients (n=2229) only two complications were described. Neither seems to be directly related to treatment with ESWT. A case of a superficial skin infection along the medial hind foot is described by Chuckpaiwong et al.[26] They used local anaesthesia in every treatment. Even though it is not mentioned as a possible explanation, the skin infection may be due to the injections used for a tibial nerve block instead of directly related to the effect of the shockwaves on the skin.[26]

The other complication occurred in the study of Notarnicola et al. One patient had precordial pain during treatment with a partial bundle branch block on his ECG.[46] We have searched for cardiac complications during or after ESWT. A review of Roehrig et al. describes cardiac arrhythmias in animal studies.[63] No references are provided. A related finding from a study by Perouansky et al., focused on the urinary tract, describes an acute myocardial infarction after ESWT for lithotripsy. The urinary tract is a different anatomical region with specific approaches and treatment protocols.[64] Since we did not find any other cardiac arrhythmias due to ESWT for musculoskeletal pathologies in humans, one can conclude these cardiac complications are very uncommon, and it is doubtful whether a partial bundle branch block is directly related to ESWT. Still, some caution is needed when applying ESWT in cardiac patients, as stress and anxiety can trigger cardiac events.

Pain during treatment was the most reported side effect (n=225 out of n= 1820 participants). We evaluated whether specific ESWT characteristics were related to a higher incidence of pain. Our statistical analysis shows that using FSWT (OR: 0.069 [95% CI: 0.049-0.097]), low-dose ESWT (OR 0.549 [95% CI: 0.37-0.81]), gradually progressively administered ESWT (OR: 0.048 [95% CI: 0.025-0.0916]) and local anaesthesia (0.655 [95% CI: 0.459-0.935]) are associated with less pain during treatment.

Based on the efficacy of different treatments, one might consider the choice between FSWT or RSWT and low- or high-dose ESWT as standard therapy. A recent systematic review by Speed et al. concluded that low-dose therapy is ineffective for PF.[16] Two RCTs included in our systematic review comparing low -and high-dose ESWT showed no significant differences in efficacy though.[41,42] Neither study was included by Speed et al.; one did not meet their inclusion criteria (no suitable sham treatment) and the other fell outside the range of publication years.[16,41,42] From the perspective of our findings, low-dose ESWT and its effectiveness for pain might need better evaluation.

Local anaesthesia appears to have a smaller impact on the incidence of pain than adjusting the type and EFD. Two RCTs demonstrated that the application of local anaesthesia during ESWT might contribute to decreased effects when compared with the same treatment without anaesthesia.[40,52] The mechanisms underlying this phenomenon are not yet fully understood.[65-67]

Gradually progressively administered ESWT and FSWT both seem to reduce the chances of experiencing pain during treatment. These findings contradict Schmitz et al., who described low-dose RSWT as generally less painful and better tolerated by patients than FSWT.[68] However, most studies that used progressive administration also used FSWT, therefore causal pathways are unclear and we are unable to assess which of the choices actually leads to the protective effect against pain. As RSWT and FSWT do not seem to differ in their

efficacy[68], it would be useful to study these variables separately.

Other possible ways to reduce pain during treatment that we could not ascertain with the information provided in the articles from the review might be the use of other techniques to administer the SWs. By adjusting the direction of FSWT as described by Tornesse et al, a tangential technique seems to be more tolerable.[56] Unfortunately, there are no other studies about this method.

There are some limitations that should be taken into account when interpreting the results of this study. It cannot be determined whether there are associations between pain during treatment and given SWs, treatment frequencies, treatment intervals and used devices. This is due to the large variety in these items and the heterogeneity of study designs.

Another limitation is that the results of this study cannot be generalised to all patients with PF. Patients with a history of osteomyelitis, rheumatic disorders, plantar fascia ruptures, former foot surgery, corticosteroid injections for PF, malignancy of the lower extremities and pregnancy were excluded from all studies. For these patients it is uncertain whether the technique should be used and whether complications can be expected.

Bias in the review process has been minimised, but is still present. We noticed contradictions in reported events between the reviewed studies. Some studies describe pain during treatment and redness of the skin in almost their entire study population. Others only mention that no side effects occurred. Several studies state that no complications occurred but fail to mention the reasons for dropouts (n=126) at final follow-up. It is questionable whether those studies claiming no side effects used the same assessment criteria than studies that did report side effects. There are also multiple variations in EFD, shockwaves, number of treatments, gradual administration techniques and treatment intervals. Some of the reviewed studies (n=14) did not mention essential treatment details, which should be included in every study about ESWT, like the used EFD, type of ESWT and/or used device. This makes it more

difficult to compare outcomes. Overall, the differences between treatments and study designs and the inconsistency in registering complications and side effects makes our results prone to bias.

With respect of the aforementioned limitations, this review shows very unlikely expectations of any treatment-related complications when treating PF with ESWT. No cases of osteonecrosis, fascia ruptures, neoplasm or other treatment-related complications have been confirmed by this study. However, average follow-up was 14.7 months and there is a lack of evidence for 5- or 10-years follow-up. Neoplasm, fascia ruptures and osteonecrosis could occur as long-term complications. This is not known and should be evaluated.

An important and commonly reported side effect is pain during treatment. Pain seems to be influenced by the type of ESWT, EFD, direct or progressive administration and use of anaesthesia. Pain could be a reason for patients to cease therapy.[19,32] More insight into pain level in relation to treatment protocol can be clinically relevant towards making ESWT an even better-tolerated treatment for PF. Less pain helps reduce number of dropouts. We therefore recommend, besides a better description of treatment protocol and study population, improving registration of complications and side effects, especially pain during treatment.

5. Conclusions and recommendations

This study showed that both low- and high-dose ESWT are safe treatments for PF. Complications during the first follow-up year after the last ESWT treatment are very unlikely. Long-term complications are not described in the current literature. Common side effects are pain during treatment and transient erythema. Pain during treatment could be a reason for patients to cease therapy. We therefore recommend registering complications and side effects accurately, especially pain during treatment. This may be helpful in developing the most effective and best-tolerated treatment protocols.

6. Conflicts of interest

The Authors declare that they have no conflicts of interest that are relevant to the content of this review.

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Study	Study design	Number of treated patients	Patient chararacteristics (age in years, sex, pain duration (PD))	Treatment	Follow-up	Machine used	Effectiveness	Side effects	Complications
Chew et al.[25]	RCT	19	- Mean age 45 (37-53) - M/F 11/8 - PD mean 18 months (7-24)	- low-high dose - gradually progressive administered FSWT - 0.42mJ/mm^2 - 2000 SWs - 2 sessions, weekly interval	6 months	EPOS Ultra (Dornier)	Visual analogue scale (VAS) for pain decreased by more than 1 point (p=0.36), AOFAS ankle hindfoot scale improved (p=0.004)	No	No
Chuckpaiwong et al.[26]	Retrosp cohort study	225 (246 heels)	- Mean age 48.8 ± 10.1 - M/F 74/172 - PD mean 30.4 months (6-240)	- high dose - FSWT - 0.36mJ/mm^2 - 3500 SWs - single session - tibial nerve block 5-8ml 1% lidocaine	30.2 ± 8.7 months	Epos Ultra (Dornier)	78.0% of treatments were successful (p=unknown)	- pain during treatment (n=16) - dysesthesia foot (n=7) - ecchymosis and petechiae (n=5)	superficial skin infection (n=1)
Dastgir et al.[27]	Prosp cohort study	62 (70 heels)	- Mean age 39 ± 5 (25-51) - M/F 32/30 - PD > 6 months	- low-high dose - gradually progressive administered shockwaves - 0.11-0.15 mJ/ mm^2 - 2500-3000 SWs - 3 sessions, weekly intervals	24 weeks	?	Significant decrease in pain on the visual analogue scale (p<0.027), significant improvement in pain score (p<0.009) and functional score (p<0.001)	No	No
Dogramaci et al.[28]	RCT	25	- Mean age 51.76 ±9.1 - M/F 15/10 - PD mean 14.52 months ±7.64	- EFD ? - RSWT - 1000 SWs - single session - tibial nerve block 3 ml, 2% prilocaine and 3 ml local injection area of application	6 months	Vibrolith (Elmed)	Results in treatment group were higher than control group (P < 0.001)		No
Dorotka et al.[29]	RCT	41	- Mean age group 1: 52 ± 8, group 2: 57 ± 14 - M/F ? - PD > 6 months	- low dose - FSWT - 0.08 mJ/mm^2 - 1000 SWs - 3 sessions, weekly intervals	12 weeks	Modulith SLK (Storz Medical)	Most parameters showed improved results at follow-up compared to pre-treatment; overall success rate was 71% (p=un known)		No
Eslamian et al.[30]	RCT	20 (31 feet)	- Mean age 41.45 ± 8.05 - M/F 2/18 - PD mean 8.5 weeks ± 4.53	- high dose - gradually progressive administered RSWT - 0.20 mJ/mm^2 - 2000 SWs - 5 sessions, 3-day intervals	2 months	Swiss Dolorclast (Electro Medical Systems)	VAS changes for morning and daytime pain and Foot Function Index (FFI) were significant (P< 0.001), 55% patients thought good/excellent results were achieved	Transient pain at initial sessions which resolved after therapy continuation.	No
Furia et al.[31]	Prosp cohort study	56 (65 feet)	- Mean age 47.7 (31-71) - M/F 19/34 - PD mean 22 months (range 9-120)	- high dose - gradually progressive administered FSWT - 0.13-0.36mJ/mm^2 - 3800 SWs - single session - sural nerve block w 1% lidocaine	12 weeks	Epos lithotripter (Dornier)	VAS for pain dropped 9.2–2.4 (P<.05), RAND-Physical Functioning score improved 40.4–91.5 (P<.05), RAND-Pain score improved 33.3–90 (P<.05); 50 heels (83.3%) were assigned an excellent or good result	- pain one week after ESWT (n=2) - pain during ESWT gone <15 minutes after (n=1) - mild bruising at injection site gone	No

								<48 hours (n=1)	
Gerdesmeyer et al.[32]	RCT	129	- Mean age 52.4 ± 12 - M/F 38/87 - PD >6 months, mean 25.6	- high dose - RSWT - 0.16 mJ/mm^2 - 2000 SW - 3 sessions every 2 weeks (±4 days)	12 months	Swiss Dolorclast (Electro Medical Systems)	ESWT proved significantly superior to placebo in reducing VAS for pain (P < .025)	pain and discomfort during treatment reported 46 times, together with 4 non-serious nonspecified side effects (n=33)	No
Gollwitzer et al.[19]	RCT	126	- Mean age 50.0 ± 11.2 - M/F 40/85 - PD >6 months	- high dose - FSWT - 0.25 mJ/mm^2 - 2000 SWs - 3 sessions, weekly intervals	12 months	Duolith SD1 (Storz Medical)	VAS scores for pain dropped by 69.2% compared to 34.5% in control group (p=0.0027)	65 device-related side effects: pain/discomfort during/after treatment, swelling (n=34)	No
Gollwitzer et al.[33]	RCT	20	- Mean age 53.9 ± 12.5 (30-72) - M/F 11/9 - PD mean 11.3 months ± 7.4 (range 6-28)	- high dose - gradually progressive administered shockwaves - 0.25 mJ/mm^2 - 2000 SWs - 3 sessions, weekly intervals	12 weeks	Duolith SD1 (Storz Medical)	ESWT resulted in a 73.2% reduction in composite heel pain, a 32.7% greater reduction than that achieved with placebo	No	No
Grecco et al.[34]	RCT	20 (33 heels)	- Mean age 49.6 ± 11.8 (25-68) - M/F 3/17 - PD >3 months	- low dose - RSWT - EFD? - 2000 SWs - 3 sessions, weekly intervals	12 months	Swiss Dolorclast (Electro Medical Systems)	Comparison between ESWT and physiotherapy showed no statistically significant difference in any parameter used for the evaluation. Both treatments were effective for improving pain and functional ability.		No
Greve et al.[35]	RCT	16	- Mean age 47.3 ± 10.3 (25-68) - M/F ? - PD >3 months	- low dose - RSWT - EFD? - 2000 SWs - 3 sessions, weekly intervals	3 months	Swiss Dolorclast (Electro Medical Systems)	Both treatments were effective to reduce pain and improve functional abilities. Effect of shockwaves appeared to be quicker than physiotherapy after treatment onset (p>0.05)		No
Hofling et al.[36]	Prosp cohort study	21 (22 heels)	- Mean age 50 ± 10 (30-68) - M/F 5/17 - PD mean 22 months (6-108)	- low-energy - gradually progressive administered - FSWT - EFD? - 2500-3000 SWs - single session	72 ± 15 days	Modulith SLK (Storz Medical)	Significant decrease in overall pain (VAS 5.5 ± 1.8 vs. 3.3 ± 2.7, p = 0.001), maximum pain (7.7 ± 2.1 vs. 4.0 ± 3.9, p = 0.008) and ADL pain (5.3 ± 2.1 vs. 2.5 ± 2.6, p = 0.018). Night pain decreased to a lesser extent (2.4 ± 2.5 vs. 1.3 ± 2.1, p = 0.317).	Pain during treatment	No
Ibrahim et al.[37]	RCT	25	- Mean age 56.6 (26-87) - M/F 7/18 - PD >6 months	- high dose - RSWT - 0.16 mJ/mm^2 - 2000 SWs - 2 sessions, weekly interval	2 years	Swiss Dolorclast (Electro Medical Systems)	Mean pre-treatment VAS for rESWT and placebo groups: 8.5 and 8.9, resp. Mean VAS scores for rESWT and placebo groups 1, 3, 6, 12 and 24 months post-treatment: 0.6, 1.1, 0.5, 2.3; 1.4 (p<0.001); 7.6, 7.7, 7.4, 6.9; and 5.6 (p < .001) resp.	- pain and/or discomfort during treatment (n=3) - minor red skin (n=1)	No
Krishnan et	Prosp	25	- Age 30-70	- high dose	4 weeks	D-Actor 200	23 patients (92%) reported	pain during treatment	No

al.[38]	cohort study		- M/F 9/16 - PD >6 months, mean 214 days	- RSWT - 0.16 mJ/mm^2 - 1000 SWs - 5 sessions, daily		(Storz Medical)	moderate-to-high satisfaction with ESWT, 22 of them reported high satisfaction and their % of post-procedure improvement in heel pain was 96.4% (SD . 6.16) with average pain rating of 0.77 (SD . 1.10) – highly significant (P < 0.0001).	(n=16)	
Kudo et al.[39]	RCT	58	- Mean age 51.1 ± 10.6 - M/F 18/40 - PD >6 months	- high dose - gradually progressive administered FSWT - 0.64 mJ/mm^2 - 3.500 SWs - single session - medial calcaneal nerve block 1% xylocaine 5ml	12 months	Epos Ultra (Dornier)	In active treatment group, mean pain score decreased 7.5–3.9 at 3 months (p<0.0001), resulting in mean % improvement of 49.1%. In placebo group, mean pain score decreased 7.9–5.3 at 3 months (p<0.0001), a mean % improvement of 33.3%.	Ecchymosis, transient paresthesias.	No
Labek et al.[40]	RCT	60	- Mean age 53 (29-77) - M/F 16/44 - PD 6-60 months	Group A: - low dose - FSWT - 0.04 mJ/mm^2 - no anaesthesia Group B: - high dose - FSWT - 0.18 mJ/mm^2 w local anaesthesia 2% mepivacaine 4 ml Group C: - low dose - FSWT - 0.09 mJ/mm^2 w local anaesthesia - 1500 SWs - 3 sessions, daily	6 weeks	Sonocur Plus (Siemens)	Group A improved in the VAS from 6.4 (SD: 1.7) to 2.2 (SD: 2.6) points, group B from 6.7 (SD: 1.5) to 4.1 (SD: 2.4) points, group C from 6.2 (SD: 1.6) to 3.8 (SD: 2.5) points	No	No
Lee et al.[41]	RCT	60	Group 1 (n=30): - Mean age 55.3 ± 9.2 - M/F 25/5 - PD >3 months Group 2 (n=30): - Mean age 51.2 ± 11.2 - M/F 28/2 - PD >3 months	Group 1: - low dose - FSWT - 0.08 mJ/mm^2 Group 2: - high dose - FSWT - 0.16 mJ/mm^2 - 1000 SWs - 3 sessions, weekly intervals	3 months	Epos Ultra (Dornier)	Significant VAS and Roles & Maudsley score improvement, and PF thickness reduction were observed in both groups (p<0.01)	No	No
Liang et al.[42]	RCT	53 (78 heels)	Group 1 (n=25): - Mean age 47 ± 11.0 - M/F 7/18 - PD >6 months Group 2 (n=28): - Mean age 52.1 ± 9.7	Group 1: - low dose - FSWT - 0.12 mJ/mm^2 Group 2: - high dose - FSWT - 0.56 mJ/mm^2	6 months	Piezoson 100 (Richard Wolf)	Overall success rates were 58% for high-dose and 62% for low-dose treatments for pain and function improvements	No	No

			- M/F 9/19 - PD >6 months	- 2000 SWs - 3 sessions, weekly intervals					
Malay et al.[43]	RCT	115	- Mean age 50.8 ± 10.1 (28-75) - M/F 36/79 - PD >6 months	- EFD? - gradually progressive administered FSWT - 3800 SWs - single session	12 months	Orthospec (clinical centres)	Mean reduction of 2.51 on pain VAS in shockwave group and 1.57 in placebo group (P=0.045). Mean reduction of 3.39 on VAS for pain in shockwave group and 1.78 in placebo group (P <0.001)	- Bruising (n=2) - Local swelling (n=1)	No
Malliaropoulos et al.[44]	Retrosp cohort study	68 patients (78 heels)	- Mean age 47.3 ± 11.3 (18-75) - M/F 29/39 - PD mean 11.2 months	- EFD ? - intensity was lowered in cases of too much pain - RSWT - 2000 SWs - 4-8 sessions, unknown intervals	12 months	Masterpuls MP 200 (Storz Medical)	Mean pre-treatment VAS score at 6.9 reduced to 3.6 one month after last session, and to 2.2 and 0.9 after 3 months and 1 year, resp. Success rates estimated at 19% (1 month), 70% (3 months) and 98% (1 year).	No	-
Metzner et al.[45]	Retrosp cohort study	63 (73 heels)	- Mean age 54 (29-77) - M/F 25/38 - PD >6 months	- high dose - FSWT - 0.35 mJ/mm^2 - 1000-3500 SWs - 2-3 sessions, 2-3 months apart - tibial nerve block or local anaesthesia, Mepivacaine 2% 5-10ml	Average 72 months (53-109)	Dornier Lithotripter S (Dornier)	Success of ESWT, defined as a 30% VAS reduction, seen in 81% at 6-week follow-up, 88% at last clinical follow-up and 96% at final phone follow-up.	Short-term limited erythema	No
Notarnicola et al.[46]	Prosp cohort study	135	- Age ≥18 - M/F ? - PD>6 months	- high dose - gradually progressive administered FSWT - 0.01-0.15 mJ/mm^2 - 2000 SWs - 3 sessions, weekly intervals	2 months	MiniLith SL1 (Storz Medical)	After SW treatment for tendinopathies and plantar fasciitis, 54.9% success rate		Precordial pain and ECG showed partial bundle-branch block (n=1)
Othman et al.[47]	Prosp compar study	20	- Mean age 46 (27-62) - M/F 7/13 - PD 7-72 months	- high dose - gradually progressive administered 0.22-0.27 mJ/mm^2 - 1500-3000 SWs - single session - local anesthesia 5cc 0.5% bupivacaine	6-11 months	?	Average VAS for pain decreased 9–2.1; 50% had no functional activity limitations, 35% minimal activity limitations, 10% moderate activity limitations, 5% severe activity limitations.		No
Ozan et al.[48]	Prosp compar cohort study	40	- Mean age 46 (25-62) - M/F 25/15 - PD 9.3 months (6-19)	- EFD? - RSWT - 2000 SWs - 4 sessons, weekly intervals	6 months	Masterpuls MP 100 (Storz Medical)	No significant difference in baseline and posttreatment values between the groups. Both groups significantly improved Roles & Maudsley and VAS scores.		No
Porter et al.[17]	RCT	61	- Mean age 38.6 (18-81) - M/F 22/39 - PD 6-54 weeks	- low dose - FSWT - 0.08 mJ/mm^2 - 1000 SWs - 3 sessions weekly intervals	12 months	**?**	At 12 months, VAS scores for pain (0.84; 0–4) were significantly lower than controls (2.42; 1–4).	- severe headache (n=4) - pain and erythema (n=6)	
Radwan et al.[49]	RCT	34	- Mean age 37.7 ± 9.42 (23-61) - PD mean 18 ± 10.9 months (6-60)	- high dose - gradually progressive administered FSWT - 0.22 mJ/mm^2	3 years	Ossatron (High Medical Technology)	Using Roles & Maudsley, 70.6 % success rate (p=0.19)	- paresthesia (n=2) - petechiae and ecchymosis (n=2)	No

				- 1500 SWs - single session - conscious sedation anesthesia					
Roca et al.[50]	RCT	36	- Mean age 50.4 ± 9.5 - M/F 8/28 - PD >6 months	- low dose - FSWT - 0.12 mJ/mm^2 - FSWT - 3000 SWs - single session	Between 1-2 months	Piezoson 100 (Richard Wolf)	Median (and interquartile range) of improvement in pain VAS when taking the first steps: 2 (1–4) points ($p<0.001$). Median (and interquartile range) of improvement in Roles & Maudsley scale: 1 (0–1) points ($p=0.006$)	No	-
Rompe et al.[51]	RCT	152	- Mean age 51.5 (27-73) - M/F 44/81 - PD mean 17 months (12-34)	- high dose - RSWT - 0.16 mJ/mm^2 - 2000 SWs - 3 sessions, weekly intervals	24 months	Device (not specified) (Electro Medical Systems)	66-69% of patients were satisfied with their results.	- redness (n=152) - pain during treatment (n=101)	No
Rompe et al.[52]	RCT	86	- Age ≥18 - M/F 35/51 - PD >6 months	- low dose - FSWT - 0.09 mJ/mm^2 - 2000 SWs - 3 sessions, weekly intervals - Group 1 (n=45) no anaesthesia, FSWT gradually progressively administered. - Group 2 (n=41) with local anaesthesia not specified, full dose directly administered.	12 months	Sonocur (Siemens)	Both groups showed improvement but group 1 had better results.	- redness (n=86) - pain during treatment (group 1: n=24) (group 2: n=3)	No
Saber et al.[53]	RCT	30	- Age mean 34.3 ± 7.2 - M/F 13/17 - PD >6 months	- high dose - 0.28 mJ/mm^2 - 1000-1500 SWs - 2 sessions, 2 weeks interval	Mean 20 weeks (12-24)	**?**	Both groups showed statistically significant improvement on Mayo Clinic scoring system; no statistically significant difference between study groups.	No	
Saxena et al.[54]	RCT	11	- Age mean 47.9 ± 12.6 - M/F ? - PD > 6 months	- high dose - gradually progressive administered FSWT - 0.24 mJ/mm^2 - 2000 SWs - 3 sessions, weekly intervals	12 months	Duolith (Storz Medical)	Statistical improvement in both groups in VAS and Roles & Maudsley scores. Endoscopic plantar fasciotomy was significantly better.	No	No
Scheuer et al.[55]	Prosp cohort study	284 (363 heels)	- Mean age 50.2 (27-81) - M/F 84/200 - PD 14.2 months (1-99)	- high dose - gradually progressive administered shockwaves - 0.15-0.25 mJ/mm^2 - 1500 SWs - 244 heels single session - 101 had 2 sessions, 4-6 weeks interval - 18 had 3 sessions, 4-6 weeks interval	Mean 296 days (136-541)	Duolith SD1 (Storz medical)	74% of all patients reported satisfying pain relief. Numeric rating scales for pain decreased ($p=0.001$).	No	No
Tornesse et al.[56]	RCT	55	Group A: - Age mean 59.3 ±	Group A (n=22): perpendicular technique	8 months	Epos ultra (Dornier)	Mayo Clinical Scoring System pretreatment scores were	Tangential technique proved more tolerable	

			12 - M/F 9/13 - pain duration 9.1 ± 5 months Group B: - Age mean 58.8 ± 12.3 - M/F 12/11 - pain duration 9.7 ± 5.6 months	- high dose - gradually progressive administered FSWT - 0.22 mJ/mm^2 Group B (n=23): tangential technique - high dose - gradually progressive administered FSWT - 0.22 mJ/mm^2 - 1800 SWs - 3 sessions, weekly intervals			homogeneous between groups (group A 55.2±18.7; group B 53.5±20; P<0.05). There was an increase in both groups (group A 90±10.5; group B 90.2±8.7) (p<0.05).	with treatment-induced pain.	
Wan et al.[57]	Prosp cohort study	16 (21 heels)	- Mean age 54 (35-71) - M/F 5/11 - PD >3 months	- high dose - gradually progressive administered RSWT - 0.16 mJ/mm^2 - 2000 SWs - 5 sessions, 3-7 days intervals	6 months	Swiss Dolorclast Classic (Electro Medical Systems)	Mean VAS reduction for pain on first step in the morning, daily activities and heel compression test: 2.62 (44.3%), 3 (38.3%), and 1.6 (36.8%), resp post-treatment.	No	
Wang et al.[58]	RCT	79 (85 heels)	- Mean age 53.2 ± 11.0 (21-75) - M/F 18/58 - PD mean 9.8 months ± 9.6 (60-72)	- high dose - FSWT - 0.32 mJ/mm^2 - 1500 SWs - 58 patients (60 heels) single session, 16 patients (19 heels) 2 sessions, 5 patients (6 heels) 3 sessions. 30-45 days intervals. - local anesthesia, xylocaine 2%	Mean 64 months (60-72)	Ossatron (High Medical Technology)	Significantly better pain and function scores as compared with the control group were seen (p<0.001). The overall results were 69.1% excellent, 13.6% good, 6.2% fair, 11.1% poor		No
Yalcin et al.[59]	Prosp cohort study	108	- Mean age 50.2 (20-78) - M/F 5/103 - PD 3-120 months	- high dose - gradually progressive administered RSWT - 0.40 mJ/mm^2 - 2000 SWs - 5 sessions, weekly intervals	Mean 7.3 months (1-60)	Swiss Dolorclast (Electro Medical Systems)	Statistically significant decrease in VAS for pain with a mean of 5.19	- local swelling (n=8) - redness (n=8) - transient increased pain (n=9)	No
Yucel et al.[60]	RCT	27	- Mean age 42.9 ± 7.08 (32-61) - M/F 13/14 - PD 22-50 weeks	- high dose - FSWT - EFD ? - 3000 SWs - single session - fivefold nerve block, 20 ml prilocaine hydrochloride 2%	3 months	Stonelith-V5 Lithotripter (PCK)	82% had successful response on VAS score for pain (p<0.05)	- mild throbbing sensation (n=2) - mild erythema (n=2)	No
Zhu et al.[61]	Prosp cohort study	12 (18 feet)	- Mean age 49.9 (33-63) - M/F ? - PD >6 months	- high dose - FSWT - 0.23 mJ/mm^2 - 1500 SWs - single session - full anaesthesia	24 hours	Ossatron (High Medical Technology)			No

Table 1. Included studies about ESWT for plantar fasciitis.

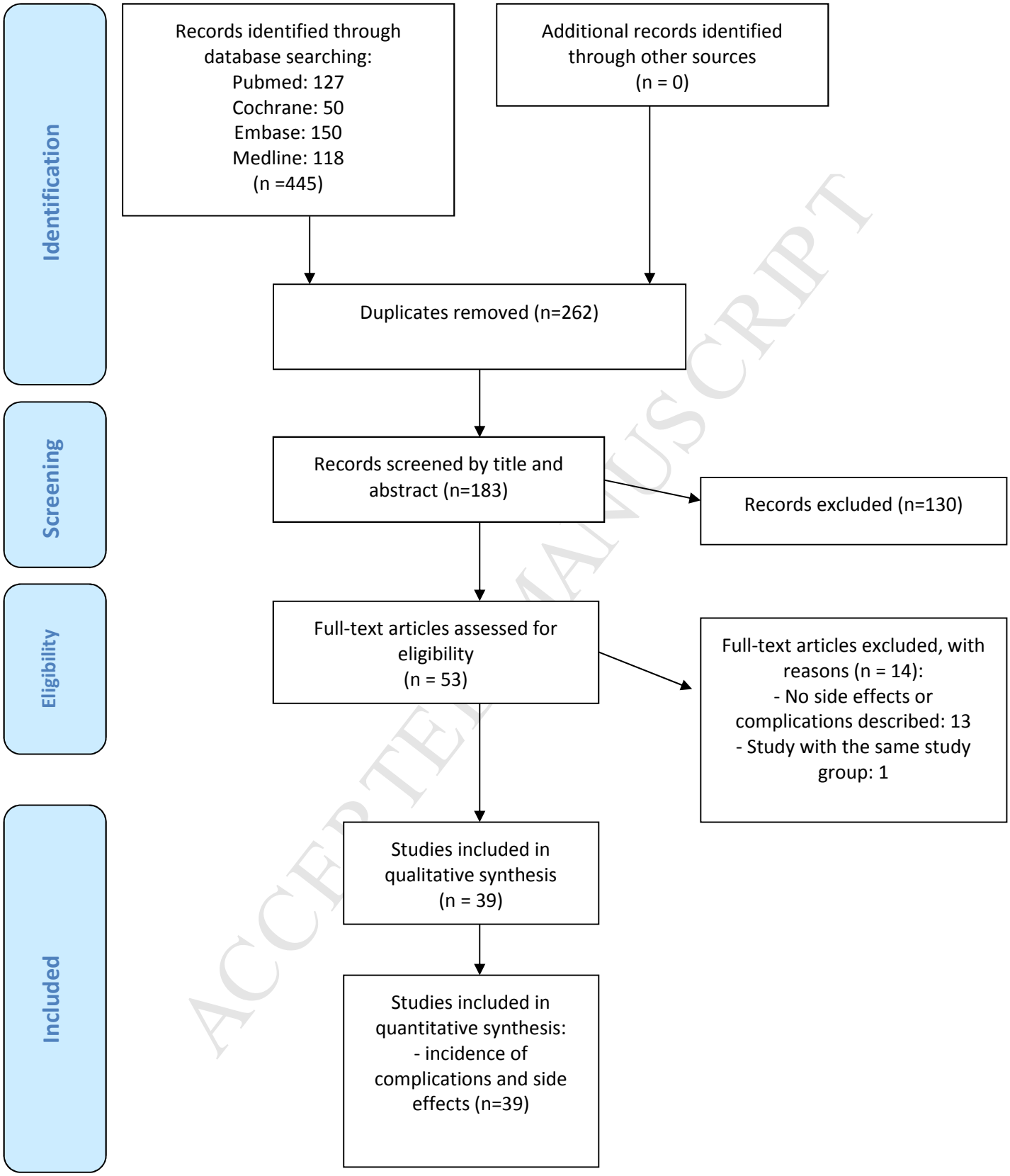

Figure 1. Flow chart of the results of the search strategy.

Highlights

- ESWT is likely a safe treatment for PF.
- No complications are expected at one-year follow-up.
- Better descriptions of treatment protocols, patient characteristics and registration of complications and side effects, especially pain during treatment, are recommended.

TITLE: COMPLICATIONS OF EXTRACORPOREAL SHOCKWAVE THERAPY IN PLANTAR FASCIITIS: SYSTEMATIC REVIEW

Running title: COMPLICATIONS ESWT IN PF

Author 1 (corresponding author): R.L. Roerdink, MPA-C, Physician Assistant, Department of Orthopaedic Surgery at Jeroen Bosch General Hospital, Henri Dunantstraat 1, 's-Hertogenbosch, 5223 GZ, The Netherlands. Email: r.roerdink@hotmail.com.

Author 2: M. Dietvorst, MD, Department of Orthopaedic Surgery at Máxima Medical Centre, The Netherlands. Email: martijndietvorst@gmail.com

Author 3: B.v.d. Zwaard, PhD, Department of Orthopaedic Surgery at Jeroen Bosch General Hospital, The Netherlands. Email: b.v.d.zwaard@jbz.nl

Author 4: H. van der Worp, PhD, Department of Sport & Exercise Medicine at University Medical Center Groningen, The Netherlands. Email: h.van.der.worp@umcg.nl

Author 5: J. Zwerver, MD, PhD, Department of Sport & Exercise Medicine at University Medical Center Groningen, The Netherlands. Email: j.zwerver@umcg.nl.

Conflicts of interest

Ramon Roerdink, Martijn Dietvorst, Babette van der Zwaard, Henk van der Worp and Hans Zwerver declare that they have no conflicts of interest.