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Efficacy of extracorporeal shockwave therapy, compared to corticosteroid injections, on pain, plantar fascia thickness and foot function in patients with plantar fasciitis: A systematic review and meta-analysis

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Abstract

Objective: To compare the efficacy of extracorporeal shock waves versus corticosteroids injections on pain, thickness of plantar fascia and foot function in patients with plantar fasciitis. Secondarily, to assess the efficacy of radial and focused extracorporeal shock waves and the most appropriated intensity (high, medium or low).

Data sources: PubMed, SCOPUS, CINAHL and PEDro, until April 2024, according to Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines.

Review methods: Randomized controlled trials comparing the efficacy of extracorporeal shock waves versus corticosteroids injections on pain intensity and sensitivity, thickness of plantar fascia and foot function in patients with plantar fasciitis. Methodological quality and risk of bias were assessed using PEDro Scale and Cochrane Risk of Bias Tool. Pooled effect was calculated using the standardized mean difference (SMD) and its 95% confidence interval (95%CI).

Results: Sixteen studies involving 1121 patients, showing a mean of 6 points in PEDro scale, were included. At three months, extracorporeal shock waves were better than corticosteroids injections in reducing pain (SMD −0.6; 95%CI −1.1 to −0.11) and thickness of the plantar fascia (SMD −0.4; 95%CI −0.8 to −0.01) and increasing foot function (SMD 0.27; 95%CI 0.12–0.44). At six months, extracorporeal shock waves are more effective in reducing pain (SMD −0.81; 95%CI −1.6 to −0.06) and increasing foot function (SMD 0.67; 95%CI 0.45–0.89). Local pain and slight erythema were the most frequent adverse events.

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Conclusions: Extracorporeal shock waves are a safe therapy, presenting more efficacy than corticosteroids injections in improving pain, thickness of plantar fascia and foot function at mid-term.

Keywords
Plantar fasciitis, extracorporeal shock waves, corticosteroids injections, pain, thickness of the plantar fascia, foot function

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Introduction

Plantar fasciitis contributes 15% of foot injuries,[1] affecting 10% of the world's population over a lifetime, mainly between 45 and 64 years.[2] Plantar fasciitis is characterized by localized pain in the heel area,[3] especially with the first steps in the morning or after long period of inactivity,[4,5] and reduced foot function and quality of life.[6] Plantar fasciitis involves structural changes in the insertion of the plantar fascia, increasing the thickness of the plantar fascia (increase of 2.16 mm, compared to healthy subjects).[7] However, others risk factors, such as body mass index, weight-bearing activities, foot muscle strength and kinematic characteristics during running (i.e., decreased ankle dorsiflexion and first metatarsophalangeal joint extension) can produce plantar fasciitis.[8–11]

Currently, pharmacotherapy and physiotherapy are the minimally invasive non-surgical approaches more used,[12,13] although 20% of these patients did not respond adequately presenting disability for more than one year.[14] Corticosteroids injections therapy, usually infiltrated alongside local anesthetics, are one of the most widely used pharmacological treatments due to their low cost, easy accessibility and high success rate for short-term pain reduction,[15] although its effects seems disappear at 12 weeks.[16] Locally reduces inflammation of the soft tissue where it is injected.[17] Extracorporeal shock wave therapy is a physical therapy with mechanical effects, that applying mechanical waves on a medium with deformation capacity, is used to reduce disability in plantar fasciitis[18,19] with few adverse effects.[20] Extracorporeal shockwaves produces biological changes in the tissue,[21] leading to the proliferation of growth factors associated with tissue regeneration, and anti-inflammatory cytokines.[22–25] Extracorporeal shockwaves can be applied in two modalities, radial or focused, although there is no consensus on which modality may be more effective.[26,27] Radial extracorporeal shockwaves disperses the energy from the applicator, in contrast to focused, which concentrates energy at a tissue point.[26] Finally, the intensity applied can be low (>0.1 milliJoules/millimeter^2), medium (0.1–0.2) or high (>0.2).[28]

Separately, some reviews have showed the effectiveness of both therapies on plantar fasciitis.[19,29,30] Previously, three reviews compared the efficacy of both therapies in the management of plantar fasciitis,[31–33] although it is not clear what of them could be more efficient. The low number of studies included, the restrictions in the literature search, the new studies published since July 2018, and to know what modality and intensity of extracorporeal shockwaves is more effective, encourage us to perform a new meta-analysis. Our aim was to compare the efficacy between extracorporeal shockwaves and corticosteroids injections in reducing pain and thickness of the plantar fascia and increasing foot function in plantar fasciitis. Additionally, to evaluate the most appropriate modality and intensity of extracorporeal shockwaves to apply to these patients.

Methods

This systematic review with meta-analysis was carried out following the guidelines of the *Preferred Reporting Items for Systematic Reviews and Meta-Analyses* (PRISMA 2020 version)

statetement,[34] the *Cochrane Handbook for Systematic Reviews of Interventions,*[35] and the AMSTAR 2 checklist.[36] The protocol was previously registered in PROSPERO: CRD42022324261.

Two authors, independently, searched in PubMed Medline, SCOPUS, CINAHL Complete, PEDro and the reference lists of reviews and original studies previously published until April, 2024. The keywords used in the search strategy, which were taken from Medical Subjects Headings, were 'fasciitis, plantar', 'extracorporeal shockwave therapy' and 'adrenal cortex hormones' and entry terms, such as 'shockwave therapy' and 'corticosteroid injection'. Boolean operators (AND/OR) were used to combine the terms in databases selected (Supplementary Table S1). Filters related to publication date and language were not applied. A third expertise author supervised this stage.

Two authors independently screened the retrieved references by title/abstract, and discrepancies were discussed with a third researcher. The inclusion criteria followed the PICOS criteria[37]: (population) patients with plantar fasciitis; (intervention) extracorporeal shockwaves; (comparator) corticosteroids injections; (outcomes) pain, pain sensitivity, thickness of the plantar fascia and foot function; and (study design) parallel or crossover (up to the first crossover) randomized controlled trials. The included studies must report quantitative data to perform the meta-analysis. The exclusion criteria were as follows: (1) studies that included patients with different pathologies of the foot in addition to plantar fasciitis; and (2) studies conducted in animals or simulation studies.

Two authors independently extracted the data from the selected studies using standardized forms. Discrepancies or doubts were resolved by consulting a third author. From each study, the following data were extracted: basic information (authorship and publication date, setting and funding); characteristics of the participants (number of groups and participants, age, sex and time since plantar fasciitis diagnosis); data related to extracorporeal shockwaves (protocol applied in sessions, weeks and duration of each session, intensity, pulses per session); corticosteroids injections data (number of injections, dose and drugs or anesthetic injected); and data related to variables (measurements and follow-up [post-intervention, 4–6 weeks and 3, 6 and 12 months). When a study provided standard error or range and interquartile range from non-skewed distributions, it could be transformed into a standard deviation.[35]

Methodological quality was assessed using the PEDro scale.[38] The PEDro scale categorizes the methodological quality as 'excellent' (10-9 points), 'good' (8-6 points), 'fair' (5-4 points) and 'poor' (3 points or less).[39] The PEDro scale has shown high reliability and validity to assess methodological quality in RCT.[40] In accordance with Armijo-Olivo et al., the Cochrane Risk of Bias tool was used[41] to assess the risk of bias because it is more appropriate than the PEDro scale for the assessment of the risk of bias in physical therapy clinical trials.[42] Cochrane Risk of Bias tool is comprised by seven items: sequence generation and allocation concealment for selection bias; blinding of participants and staff, and evaluators for performance and detection biases, respectively; incomplete outcome data for attrition bias; selective outcome reporting for reporting bias; and others. For each item, the risk of bias can be low ('+'), high ('-') or unclear ('?'). These assessments were carried out by two authors independently, and disagreements were resolved by consulting a third author.

The quality of the evidence of findings in meta-analyses was assessed using the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) tool.[43] The quality of evidence is determined according to five items: risk of bias in individual studies, inconsistency, indirect evidence, imprecision and risk of publication bias. All of these items, except risk of bias in individual studies, were assessed using the GRADE checklist of Meader.[44] Combining these items allow us to show findings with four different levels of evidence: high (if findings are robust), moderate (when a future study can change the current findings), low (the level of confidence is low) and very low (findings are uncertain). If one item did not meet the level of evidence, one level was downgraded.

Meta-analysis was conducted using *Comprehensive Meta-Analysis version 4.0*.[45] Meta-analysis was only performed if data from at least two studies for the

same variable were obtained. The effect size was estimated using Cohen's standardized mean difference (SMD) and its 95% confidence interval (95% CI)[46] in a random-effects model for continuous data displayed in forest plots.[47,48] According to Kinney et al., the effect size in rehabilitation research could be small (0.08–0.15), medium (0.19–0.36) or large (0.41–0.67).[49] The mean difference between groups to compare the findings to the minimal important difference (MID) in outcomes assessed with the same measurement was additionally calculated. Minimal important difference, previously known as minimally important clinical difference, is defined as '*the smallest difference in score in the domain of interest which patients perceive as beneficial and which would mandate, in the absence of troublesome side effects and excessive cost, a change in patients' management*'.[50] Comparing the study results with the MID value for a measurement test is the most effective method to examine the clinical importance or relevance.[51] Only pain was assessed with the same measurement: Visual Analogue Scale for pain intensity. Although 1.9–2 cm or a change of 30% with respect to baseline is considered as the 'norm' MID for the visual analogue scale for pain intensity, Landorf et al. showed that 9 mm was the MID for the visual analogue scale for pain, specifically in patients with plantar fasciitis.[52] The risk of publication bias was assessed with the *P value* for Egger's test[53] and the trim-and-fill estimation.[54] Heterogeneity was measured according to the degree of inconsistency (I^2) and with the *P value* for the Q-test.[55,56] $I^2 > 50\%$ and *P* for Q-test <0.1 indicate statistical heterogeneity.

Sensitivity analysis (leave-one-out method) was used to assess the contribution of each study to the pooled effect. Three subgroup analyses according to the extracorporeal shockwaves application (radial or focused), intensity (low, medium or high)[28] and time since diagnosis of patients when the study began (acute or chronic) were carried out. In addition, we performed a qualitative analysis to report the adverse events of each therapy.

Results

Two hundred thirty-one references were retrieved from the preliminary searches (225 from databases and 6 from additional searches). After removing 92 duplicate references, 139 studies were assessed by title/abstract. One hundred three studies were excluded for not being relevant and 20 for not meet the inclusion criteria. Finally, 16 randomized controlled trials[57–72] were included in the meta-analysis. The PRISMA flow chart (Figure 1) displays the study selection process.

Studies were carried out from 2005 to 2023, providing data from 1121 participants diagnosed with chronic (>3 months)[58–67,70–72] and acute plantar fasciitis (<3 months)[57,68,69] and a mean age of 45 (6) years (65% women). The mean initial visual analogue scale for pain intensity was 7 (1.3) and in visual 4.3 (2) mm of thickness of the plantar fascia. Five hundred sixty-one (44.5 (6) years) received extracorporeal shock waves, and 560 received corticosteroids injections (41.3 (13) years). In 13 studies,[57–62,64–72] extracorporeal shock waves were compared to corticosteroids injections therapy, and in three studies, a physical therapy program with of stretching for the gastrocnemius and plantar fascia or ultrasound therapy was complementarily added to the extracorporeal shock waves and corticosteroids injections groups.[61,63,70] Extracorporeal shock waves were applied in a range of sessions from 1 to 5 and once per week in the majority of the studies. The pulses per session range varied between 1000 and 3000, with 2000 pulses per session being the most frequent. Ten studies applied extracorporeal shock waves with high intensity,[58–64,66,68,71] four with medium,[57,65,67,69] and two with low.[70,72] Eight studies applied radial extracorporeal shock waves,[57–61,63,65,67] four focused,[62,68,71,72] and four did not report the modality employed.[64,66,69,70] The corticosteroids that were injected included betamethasone, methylprednisolone and triamcinolone (between 7 and 40 mg/ml). Lidocaine, prilocaine, xylocaine and mepivacaine, among others, were the anesthetics injected together with corticosteroids. Only one study reported receiving external funding.[61] Table 1 details the characteristics of the studies included.

Pain intensity was assessed using the visual analogue scale[57–70,72]; pain sensitivity was assessed with algometry[70] and visual analogue scale[62];

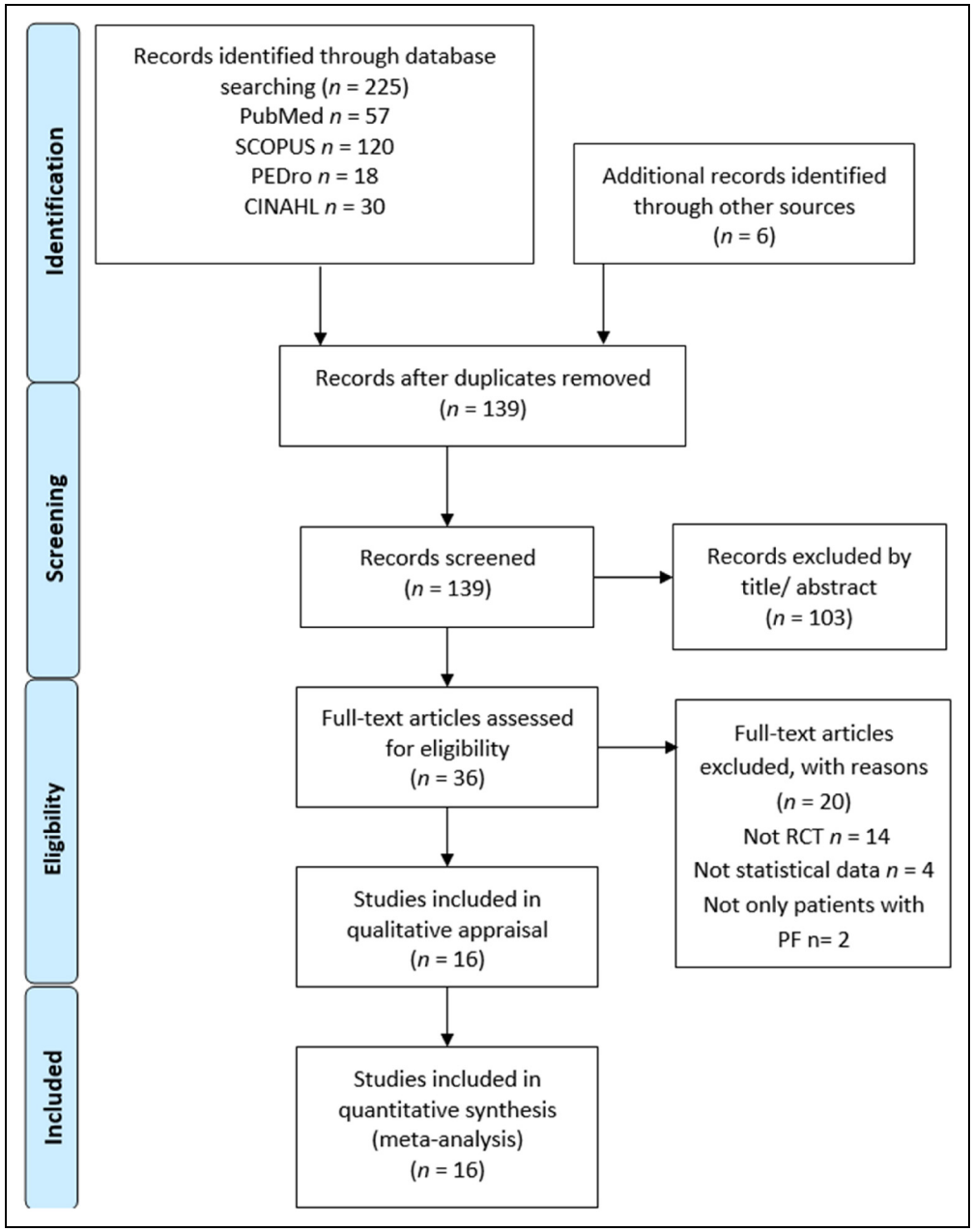

Figure 1. Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) flow diagram for the study selection process.

thickness of the plantar fascia was assessed in millimeters with ultrasonography and magnetic resonance images[61,63,66–68,71,72]; and foot function was assessed with the American Orthopaedic Foot & Ankle Society score,[58,59,64] the Foot Function Index,[57,60,61,67] the 100-point scoring system,[68]

Table 1. Characteristics of the studies included in the meta-analysis ($n = 16$), in alphabetical order.

Study	Total sample characteristics	ESWT group	CSI group	Outcomes		
				Time-point assessment	Variable (test)	Qualitative findings
Eslamian, F et al. 2016 (Iran)	40 patients with PF (42 years; 33F:7 M) in acute phase (9 weeks since diagnosis). Initial pain: 7.4	20 participants received radial ESWT Equipment: DolorClast Classic PSS: 2000 Energy: 0.2 mJ/mm² 5 sessions, 1 session each 3 days	20 participants received a single injection of 40 mg of methylprednisolone + 1 ml of lidocaine (1%).	1 month	Pain (VAS)	No intra-group differences were found. No between-groups differences were found ($P = 0.191$).
					Function (FFI)	No intra-group differences were found. No between-groups differences were found ($P = 0.072$).
Guevara-Serna, JA et al 2018 (Colombia)	60 patients with PF (51 years; 40F:20 M) in chronic phase (> 3 months since diagnosis) Initial pain: 7.4	36 participants received radial ESWT Equipment: BTL5000 PSS: 2500 Energy: 0.2 mJ/mm² 4 sessions, 1 session each 8–10 days	24 participants received an injection of 3 ml of lidocaine with epinephrine + 2 ml methylprednisolone acetate (40 mg/ml).	Post-intervention, 3, 6 and 12 months	Pain (VAS)	No intra-group differences were found. At 3 months, significant reduction in pain intensity ($P = 0.035$) in favour of the ESWT group.
					Function (AOFAS)	No intra-group differences were found. No between-groups differences were found in post-intervention ($P = 0.98$) and at 3, 6 and 12 months ($P = 0.99$, $P = 0.97$, $P = 0.93$, respectively).
Hai, J et al 2021 (China)	52 patients with PF (46 years; 23F:29 M) in chronic phase (4 months since diagnosis) Initial pain: 7.8	26 participants received radial ESWT Equipment: EMS DolorClast PSS: 2000 Energy: 0.12–0.16 mJ/mm² 2 sessions, 1 session each 2 weeks.	26 participants received an injection of betamethasone (1 ml) + lidocaine 2% (2 ml).	Post-intervention, 1 and 3 months	Pain (VAS)	No intra-group differences were found. In post-intervention, significant reduction in pain intensity ($P = 0.001$) in favour of the CSI group. At 3 months, significant reduction in pain intensity ($P < 0.001$) in favour of the ESWT group.

(Continued)

Table 1. (Continued)

Study	Total sample characteristics	ESWT group	CSI group	Outcomes		
				Time-point assessment	Variable (test)	Qualitative findings
Hassan-Jillani, SR et al 2020 (Pakistan)	126 patients with PF (52 years; 52F:74 M) in chronic phase (12 months since diagnosis) Initial pain: 6.3 Initial TPF: 4	63 participants received ESWT Equipment: NR PSS: 1000–1500 Energy: 0.28 mJ/mm² 2 sessions, 1 session each 2 weeks	63 participants received 2 injections of 2 ml of betamethasone (4 mg/ml) + 1 ml lidocaine (2%)	6 weeks	Pain (VAS)	No between-groups differences were found ($P = 0.481$).
					TPF (US)	Significant reduction in TPF ($P = 0.008$) in favour of the ESWT group.
Hocaoglu, S et al 2017 (Turkey)	72 patients with PF (49 years; 62F:10 M) in chronic phase (8 months since diagnsosis) Initial pain: 8.5 Initial TPF: 5	36 participants received radial ESWT Equipment: Vibrolith Ortho PSS: 2000 Energy: 0.16 mJ/mm² 3 sessions, 1 session per week	36 participants received an injection of 1 ml of betamethasone sodium + 0.5 ml of pilocaine	1, 3 and 6 months	Pain (VAS)	A significant reduction in pain intensity in ESWT group at 1, 3 and 6 months was found ($P < 0.001$) and in CSI group at 1 month ($P < 0.001$).
					Function (FFI)	A significant increase in foot function in ESWT group at 1, 3 and 6 months was found ($P < 0.001$) and in CSI group at 1 and 3 months ($P < 0.001$).
					TPF (US)	No intra-group and between-groups differences at 1, 3 and 6 months ($P > 0.05$)
Lai, TW et al 2018 (China)	97 patients with PF (55 years; 54F:43 M) in acute phase (8 weeks since diagnosis) Initial pain: 6.3 Initial TPF: 0.4	47 participants received focused ESWT Equipment: OthospecTM PSS: 1500 Energy: 0.290,15 mJ/mm² 2 sessions of 30 min, 1 per week	50 participants received an injection of 20 mg of triamcinolone acetonite + 2 ml xylocaine (2%)	1 and 3 months	Pain (VAS)	Significant reduction in pain intensity in favour of the ESWT group at 1 and 3 months ($P = 0.001$ and $P < 0.001$).
					TPF (US)	Significant improvement of TPF in favour of the ESWT group at 1 month ($P = 0.048$), but not at 3 months ($P = 0.326$).

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Table 1. (Continued)

Study	Total sample characteristics	ESWT group	CSI group	Outcomes		
				Time-point assessment	Variable (test)	Qualitative findings
					Function (100 PSS)	At 1 month, no between-groups differences ($P = 0.391$), but yes at 3 months ($P < 0.001$) in favour of the ESWT group.
Mardani-Kivi, M et al 2015 (Iran)	68 patients with PF (44 years; 57F:11 M) in acute phase (< 6 weeks since diagnosis) Initial pain: 5	34 participants received ESWT Equipment: Electrohydraulic system PSS: 2000 Energy: 0.15 mJ/mm² 3 sessions, 1 per week	34 participants received an injection of 1 ml of methylprednisolone acetate (40 mg) + 1 ml of lidocaine (2%)	6 weeks and 3 months	Pain (VAS)	Intra-group differences at 6 weeks and at 3 months ($P < 0.0001$). Significant reduction in pain intensity in favour of the ESWT group at 6 weeks and at 3 months ($P < 0.001$)
Moneim, NHA et al 2023 (Egypt)	50 patients with PF (43 years; 50F:0 M) in chronic phase (8 months since diagnosis) Initial pain: 8.6 Initial TPF: 4	25 participants received radial ESWT Equipment: NR PSS: 2000 Energy: 2.5 bar (High) 4 sessions, 1 per week	25 participants received an injection of 1 ml of triamcinolone acetonide and 2 ml of lidocaine (1%)	1 and 3 months	Pain (VAS)	No statistically significant differences between groups were found at 1 month ($P = 0.163$). At 3 months, in ESWT group, pain was more reduced ($P = 0.004$)
					TPF (US)	TPF was more reduced in CSI group ($P = 0.004$), but no differences were found at 3 months ($P = 0.216$)
					Function (PFPDS)	No statistically significant differences between groups were found at 1 ($P = 0.163$) and 3 months ($P = 0.07$).
Orhan, O et al 2023 (Turkey)	44 patients with PF (37.2 years; 37F:7 M) in chronic phase (> 6	22 participants received ESWT Equipment: Auto Wave 695	22 participants received an injection of 40 mg/ml of methylprednisolone	6 weeks and 3 and 6 months	Pain (VAS)	Significant reduction in pain intensity in favour of the CSI group at 6 weeks (P < 0.001). No differences

(Continued)

Table 1. (Continued)

Study	Total sample characteristics	ESWT group	CSI group	Outcomes		
				Time-point assessment	Variable (test)	Qualitative findings
	weeks since diagnosis) Initial pain: 7.8	PSS: 2000 Energy: 3 bar (High) 4 sessions, 2 per week				were found at 3 months ($P = 0.331$). At six months, pain was lower in ESWT group ($P < 0.001$).
					Function (AOFAS)	No differences between groups were found at six weeks ($P = 0.666$). Statistically significant differences favours ESWT were reported at 3 ($P = 0.006$) and 6 months ($P = 0.003$)
Porter, MD et al 2005 (Australia)	125 patients with PF (39 years; 83F:42 M) in chronic phase (14 weeks since diagnosis) Initial pain: 5.5 Stretching for the soleus, gastrocnemius and plantar fascia was added to ESWT and CSI group	61 participants received ESWT Equipment: Electrohydraulic system PSS: 1000 Energy: 0.08 mJ/mm² 3 sessions, 1 per week	64 participants received an injection of 1 ml of betamethasone (5.7 mg) + 2 ml of lignocaine (1%)	3 and 12 month	Pain (VAS)	No intra-group differences were found. No between-groups differences were found.
					PPT (Algom.)	No intra-group differences were found. No between-groups differences were found.
Saber, N et al 2012 (Egypt)	60 patients with PF (34 years; 33F:27 M) in chronic phase (> 6 months since diagnosis) Initial TPF: 6	30 participants received focused ESWT PSS: 1000–1500 Energy: 0.28 mJ/mm² 2 sessions, with 2 weeks between sessions	30 participants received 2 injections: 2 ml of betamethasone (4 mg/ml) + zylocaine hydrochloride (0.5%).	3 months	TPF (US)	Significant intra-group improvement in TPF in CSI group ($P < 0.001$) and in ESWT group ($P < 0.001$). No between-groups differences were found ($P = 0.155$).
					Function (MAYO CSS)	Significant intra-group improvement in foot

(Continued)

Table 1. (Continued)

Study	Total sample characteristics	ESWT group	CSI group	Outcomes		
				Time-point assessment	Variable (test)	Qualitative findings
						function in CSI group ($P < 0.001$) and in ESWT group ($P < 0.001$). No between-groups differences were found ($P = 0.296$).
Sorrentino, F et al 2008 (Italy)	60 patients with PF (54 years; 34F:26 M) in chronic phase (4 months since diagnosis) Initial pain: 7.4	30 participants received focused ESWT Equipment: Piezoson 100 PSS: 2000 Energy: 0.03 mJ/mm² 4 sessions, 1 per week	30 participants received an injection of 1 ml of methylprednisolone + 0.6 ml of mepivacaine hydrochloride (3%)	6 weeks	Pain (VAS) TPF (US)	No between-groups differences were found. No between-groups differences were found.
Turhan, Y et al 2019 (Turkey)	32 patients with PF (41 years; 21F:11 M) in chronic phase (> 6 months since diagnosis) Initial pain: 9	16 participants received radial ESWT Equipment: Swiss DoloClast Master® PSS: 2000 Energy: 3 bar (High) 3 sessions, 1 per week	16 participants received an injection of 1 ml of betamethasone (40 mg/ml) + 2 ml of bupivacaine (5 mg/ml)	6 weeks and 3 months	Pain (VAS) Function (AOFAS)	Significant intra-group reduction in pain intensity in ESWT and CSI group ($P < 0.001$). No between-groups differences were found at 6 weeks ($P = 0.293$) and 3 months ($P = 0.436$). Significant intra-group reduction in pain intensity in ESWT and CSI group ($P < 0.001$). No between-groups differences were found at 6 weeks ($P = 0.081$) and 3 months ($P = 0.478$).
Uğurlar, M et al 2018 (Turkey)	79 patients with PF (40 years; 40F:39 M) in chronic phase (15 months since	39 participants received radial ESWT Equipment: Chattanooga	40 participants received an injection of 1 ml of betamethasone (40 mg/ml) + 2 ml of bupivacaine (5 mg/ml)	1, 3, 6 and 12 months	Pain (VAS)	Significant intra-group reduction in pain intensity in ESWT group at 12 months ($P < 0.05$) and in CSI at 1 month (P

(Continued)

Table 1. (Continued)

Study	Total sample characteristics	ESWT group	CSI group	Outcomes		
				Time-point assessment	Variable (test)	Qualitative findings
	diagnosis) Initial pain: 7.5	Intelectet® RPW PSS: 2000 Energy: 4 bar (High) 3 sessions, 1 per week				<0.05). No between-groups differences were found.
					Function (FFI)	Significant intra-group improvement in foot function in ESWT group at 12 months ($P<0.05$) and in CSI at 1 month ($P<0.05$). No between-groups differences were found.
Xu, D et al 2020 (China)	96 patients with PF (48 years; 68F:32 M) in acute phase (4 weeks since diagnosis) Initial pain: 5.2 Initial TPF: 5.2 Stretching for the gastrocnemius and passive dorsiflexion of the toes was added to ESWT and CSI group	49 participants received radial ESWT Equipment: DolorClass PSS: 2000 Energy: 0.2–0.3 mJ/mm^2 3 sessions of 30 min, 1 per week	47 participants received an injection of methylprednisolone (40 mg) + 1 ml lidocaine (1%)	1, 3 and 6 months	Pain (VAS)	Significant intra-group reduction in pain intensity in ESWT group and CSI group at 1 month ($P<0.001$) and in ESWT group at 6 months ($P=0.002$). Significant reduction in pain intensity in favour ESWT group at 3 and 6 months ($P=0.003$ and $P<0.001$).
					TPF (US)	Significant intra-group improvement in TPF in ESWT group at 3 months ($P<0.001$) and in CSI group at 3 and 6 months ($P<0.001$ and $P=0.034$). Significant improvement in TPF in favour ESWT group at 6 months ($P=0.045$).
					Function (FFI)	Significant intra-group increase in foot function in ESWT group at 1 and at 6 months ($P<0.001$

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Table 1. (Continued)

Study	Total sample characteristics	ESWT group	CSI group	Outcomes		
				Time-point assessment	Variable (test)	Qualitative findings
						and $P = 0.042$) and in CSI group at 6 months ($P = 0.004$). Significant improvement in foot function in favour ESWT group at 3 and 6 months ($P = 0.041$ and $P = 0.002$).
Yucel, I et al 2010 (Turkey)	60 patients with PF (44 years; 42F:18 M) in chronic phase (39 weeks since diagnosis) Initial pain: 5.8 Initial TPF: 5.2	27 participants received focused ESWT Equipment: Stonelith-V5 Lithotripter PSS: 3000 Energy: High 1 session	33 participants received an injection of 0.5 ml of betamethasone dipropionate (6.43 mg/ml) and betamethasone sodium phosphate (2.63 mg/ml) + 0.5 ml of prilocaine hydrochloride (2% and 20 mg/ml)	3 months	Pain (VAS)	Significant intra-group reduction in pain intensity in ESWT group and CSI group ($P < 0.05$). No between-groups differences were found ($P < 0.05$).
					PPT (VAS)	Significant intra-group improvement in PPT in ESWT group and CSI group ($P < 0.05$). No between-groups differences were found ($P < 0.05$).

ESWT: extracorporeal shock-wave therapy; CSI: corticosteroid injections; F: female; M: male; TPF: thickness of plantar fascia; PSS: pulses per second; Mg: milligrams; MRI: magnetic resonance image; AOFAS: American Orthopaedic Foot & Ankle Society; ml: milliliters; mJ: millijules; VAS: visual analogue scale; FFI: foot function index; 100PSS: 100 point scoring system; MAYO CSS: Mayo clinical scoring system; NS: not specified; US: ultrasounds; PPT: pain pressure threshold; ALGOM: algometer.

the Mayo Clinic scoring system[71] and the Plantar Fasciitis Pain and Disability Scale.[63]

The methodological quality mean of the studies was 6 (0.9) points in the PEDro assessment. Nine studies were of good quality,[57,58,61,66–70,72] and seven studies of fair quality[59,60,62–65,71] (Supplementary Table S2). The Cochrane Risk of Bias tool reported performance bias (blinding of participant items missed) in all studies, detection bias (blinding of assessor items missed) in ten studies,[58–66,69] and selection bias (concealment of randomization sequence items missed or doubtful) in eight studies[57,59,60,62–64,66,71] (Supplementary Table S3).

Pain intensity

Pain was assessed in 15 studies,[57–70,72] showing that the efficacy of extracorporeal shock waves in reducing pain was major than corticosteroids injections at three months of follow-up (SMD −0.6; 95% CI −1.1 to −0.11; $I^2 = 4.3\%$), reducing pain 1.3 points on the visual analogue scale for pain (95% CI −1.45 to −1.1); and at six months (SMD −0.81; 95% CI −1.6 to −0.06; $I^2 = 0\%$) being able to reduce pain −1.26 points (95% CI −2.26 to −0.25). In contrast, no statistically significant differences ($P > 0.05$) were shown between therapies after finishing the intervention, at 4–6 weeks, and at one year of follow-up (Table 2, Figure 2). The risk of publication bias is shown in the assessment at three months (Supplementary Figure S1). Sensitivity did not show variation with respect to the original effect.

Subgroup analysis revealed that radial was the most efficacious modality of application at three (SMD −0.7; 95% CI −1.11 to −0.25) and six months (SMD −0.9; 95% CI −1.47 to −0.33). In addition, high-intensity extracorporeal shock waves were the most indicated to reduce pain at three (SMD −0.94; 95% CI −1.5 to −0.4) and six months (SMD −0.75; 95% CI −1.01 to −0.41). No statistically significant differences between the effect of extracorporeal shock waves and corticosteroids injections were found between acute and chronic patients.

Pain sensitivity

Pain sensitivity was analyzed with data from two studies.[62,70] The findings revealed a large effect favouring extracorporeal shock waves (SMD −1.46; 95% CI −2.32 to −0.6; $I^2 = 0\%$) in reducing pain sensitivity with algometry at three months of follow-up (Supplementary Figure S2, Table 2), compared to corticosteroids injections. Sensitivity analysis did not show differences in the original pooled effect.

Thickness of the plantar fascia

Through data from seven studies,[61,63,66–68,71,72] extracorporeal shock waves showed a statistically significant reduction in thickness of the plantar fascia (SMD −0.4; 95% CI −0.8 to −0.01; $I^2 =$ 37%) compared to corticosteroids injections at three months (Table 2, Figure 3). No statistically significant differences between therapies were shown at 4–6 weeks and at six months of follow-up ($P < 0.05$). Risk of publication bias was found at three months (Supplementary Figure S3). Sensitivity analysis did not report statistically significant differences.

The subgroup analysis did not reveal statistically significant differences between radial or focused extracorporeal shock waves at these time points ($P > 0.05$). At three months, high-intensity the most adequate intensity in reducing thickness of the plantar fascia (SMD −0.41; 95% CI −0.6 to −0.18). No statistically significant differences were found between acute or chronic patients at 4–6 weeks and three months, respectively ($P > 0.05$).

Foot function

Data were provided from ten studies.[57–61,63,64,67,68,71] The findings revealed a medium effect favouring extracorporeal shock waves at 3 (SMD 0.27; 95% CI 0.12–0.44; $I^2 = 0\%$) and at six months (SMD 0.67; 95% CI 0.45–0.89; $I^2 = 0\%$) (Table 2, Figure 4). No significant differences were found between therapies at 4–6 weeks and one year. The risk of publication bias at six months showed that it could underestimate the effect without this bias

Table 2. Main findings in meta-analyses.

		Summary of findings																	
		Effect size						Heterogeneity			Publication bias			Grade quality evidence					
												Trim and Fill							
Outcomes	Time-point assessment	K	N	N_s	SMD	95% CI	*P*	Q (*df*)	I^2	*P*	Funnel plot (Egger *P*)	Adj SMD	% var	Risk of bias	Incons	Indirect	Imprec	Pub bias	Quality evidence
PAIN	Post-interv	2	112	56	0.63	−0.57 to 1.83	0.31	2.9 (1)	34.2%	0.08	NP	NP	NP	Medium	Yes	No	Probable	Probable	Very low
	4–6 weeks	12	832	69.3	−0.35	−0.83 to 0.14	0.16	11.7 (11)	5.76%	0.38	Sym (036)	−0.35	0%	Medium	No	No	Yes	No	Moderate
	3 months	12	851	70.9	−0.6	−1.1 to −0.11	0.015	10.5 (11)	4.3%	0.48	Asym (0.05)	−0.75	25%	Medium	No	No	Yes	Yes	Low
	6 months	5	36	73.4	−0.81	−1.6 to −0.06	0.03	1.3 (3)	0%	0.72	Asym (0.41)	−0.88	8%	Medium	Low	No	Probable	No	Low
	12 months	3	264	88	−0.14	−1.1 to 0.82	0.78	0.11 (2)	0%	0.94	Sym (0.29)	−0.14	0%	Medium	No	No	Probable	No	Very low
PPT	3 months	2	185	92.5	−1.46	−2.32 to −0.6	0.001	2.6 (1)	0%	0.11	NP	NP	NP	Medium	No	No	Probable	Probable	Very low
PFT	4–6 weeks	6	558	93	−0.28	−0.64 to 0.08	0.128	3.1 (5)	0%	0.68	Asym (0.26)	−0.24	16%	Medium	No	No	Probable	Yes	Low
	3 months	5	402	80.4	−0.4	−0.8 to −0.01	0.047	6.6 (4)	37%	0.15	Asym (0.03)	−0.16	100%	Medium	Yes	No	Probable	Yes	Low
	6 months	2	195	97.5	−0.15	−0.76 to 0.45	0.62	1 (1)	0%	0.32	NP	NP	NP	Medium	Low	No	Probable	No	Very low
FUNCTION	4–6 weeks	8	523	65.4	0.08	−0.11 to 0.25	0.42	14.9 (7)	44.7%	0.03	Sym (0.37)	0.07	0%	Medium	Low	No	Probable	Yes	Low
	3 months	9	606	67.3	0.27	0.12 to 0.44	0.001	2.74 (8)	0%	0.94	Sym (0.8)	0.27	0%	Medium	No	No	Probable	No	Low
	6 months	5	367	73.4	0.67	0.45 to 0.89	<0.001	3.84 (4)	0%	0.42	Asym (0.22)	0.74	12%	Medium	No	No	Probable	Yes	Very low
	12 months	2	139	69.5	0.24	−0.01 to 0.57	0.16	0.16 (1)	0%	0.68	NP	NP	NP	Medium	No	No	Yes	Probable	Very low

PPT: pain pressure threshold; PFT: plantar fascia thickness; K: number of comparisons; N: number of participants in each meta-analysis; N_s: number of participants per study; SMD: standardized mean difference; 95% CI: 95% confidence interval; *P*: *P*-value; Q: Q-test; *df*: degree of freedom; I^2: degree of inconsistency; Adj: adjusted; % var: percentage of variation; Incons: inconsistency; Indirect: indirectness; Imprec: Imprecision; Sym: Symmetric; Asym: asymmetric; Post-interv: post-intervention; NP: not possible to calculate.

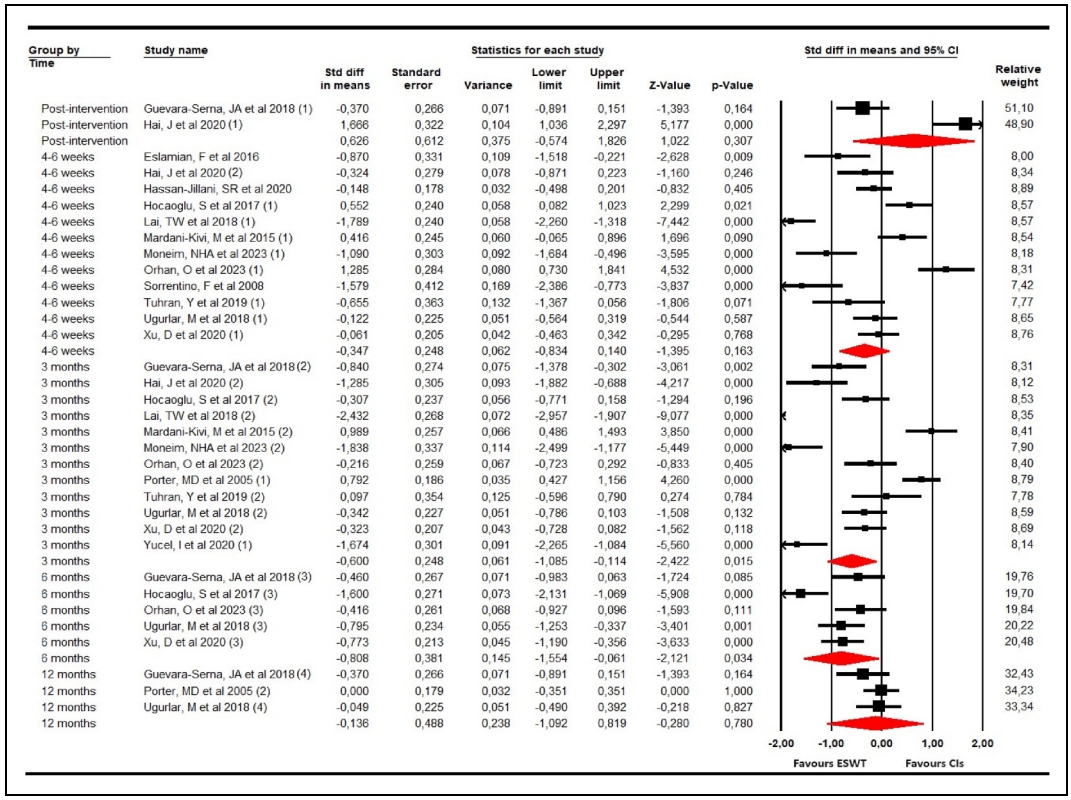

Figure 2. Forest plot for the comparison of extracorporeal shock wave therapy (ESWT) vs corticosteroids injections (cis) on pain intensity at post-intervention, 4–6 weeks, and 3, 6 and 12 months.

(Supplementary Figure S4). Sensitivity analysis did not show variation in the pooled effect.

At three months, subgroup analysis identified as focused extracorporeal shock waves as the best modality to increase foot function (SMD 0.55; 95% CI 0.9–1); and at six months, radial was the best option (SMD 0.72; 95% 0.14–1.31). High-intensity extracorporeal shock waves were the most indicated intensity to improve foot function at three (SMD 0.33; 95% CI 0.1–0.6) and six months (SMD 0.66; 95% CI 0.04–1.3). No statistically significant differences between the effect of therapies on were found between acute and chronic patients ($P > 0.05$).

Adverse events during therapies

Ten studies reported data on adverse events after therapies. Three studies[58,60,64,71] did not report adverse events during the study. The most common adverse events were local pain and slight erythema reported in both groups in two studies,[57,63] only in the extracorporeal shock waves group in three studies,[61,67,70] only in the corticosteroids injections group in one study.[62] After corticosteroids injections perceived pain lasted 2–9 day. Therefore, slight local pain and erythema are the most common adverse events in both therapies.

Discussion

The aim of this review was to compare the efficacy between extracorporeal shock waves and corticosteroids injections in reducing pain, thickness of the plantar fascia and increasing foot function in patients with plantar fasciitis. Secondarily, to assess the effect along time (post-intervention, 4–6

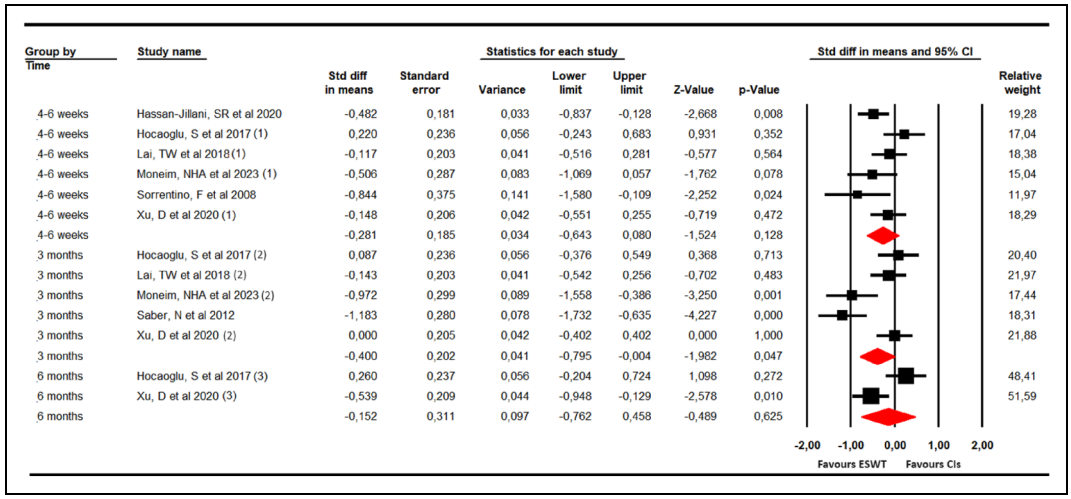

Figure 3. Forest plot for the comparison of extracorporeal shock wave therapy (ESWT) vs corticosteroids injections (cis) on thickness of the plantar fascia 4–6 weeks, 3 and 6 months.

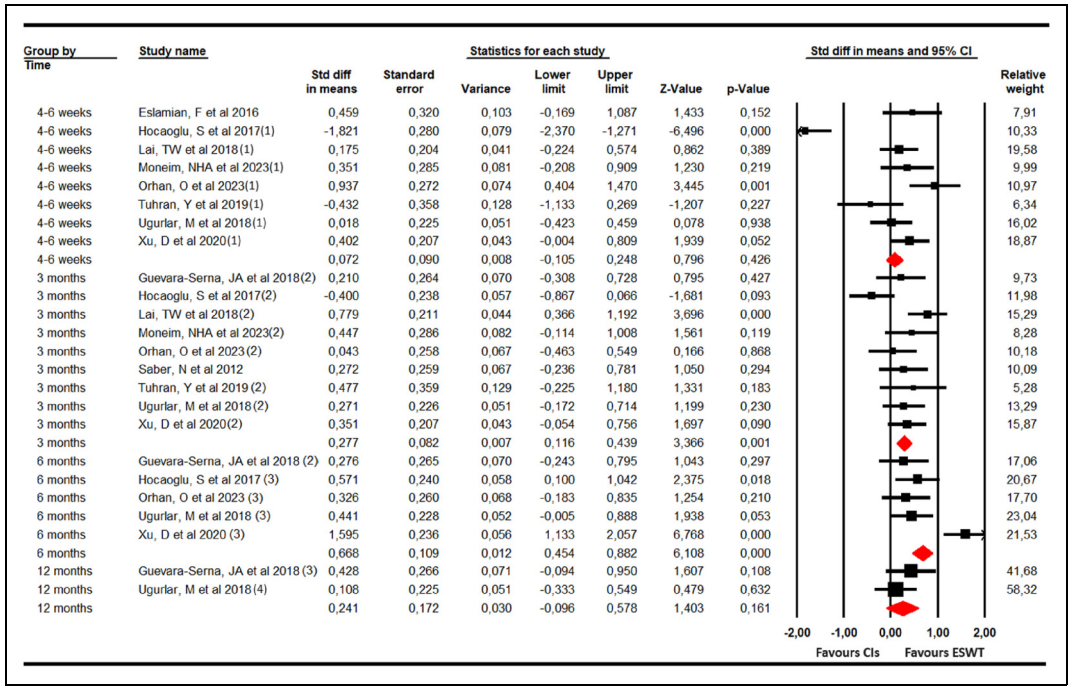

Figure 4. Forest plot for the comparison of extracorporeal shock wave therapy (ESWT) vs corticosteroids injections (cis) on foot function 4–6 weeks, and 3, 6 and 12 months.

weeks and 3, 6 and 12 months since the end of the intervention), and to assess the most adequate modality (radial or focused) and intensity (low, medium or high) of extracorporeal shock waves. Compared to previous reviews,[31–33] this is the meta-analysis that the major number of studies and participants included (16 randomized controlled trials providing data from 1121 patients). Since the last review, six new studies were published, and this contribution in an updated meta-analysis could help to establish findings more robust and generalizable. Additionally, opposite to the search of the previous reviews, we did not use language or publication date restrictions, allowing to retrieve and include more studies. So, this is the first meta-analysis that presents findings with the major statistical power, generalization and quality of evidence.

Regarding pain intensity, assessed with the visual analogue scale, in the immediate post-evaluation, no differences were found between corticosteroids and extracorporeal shock waves, due to opposite findings in the individual studies involved.[58,65] The possible immediate effect of corticosteroids can be related to the combined use with others analgesic drugs, which reduces perceived pain,[73] disappearing it over time. Differences favouring extracorporeal shock waves in reducing pain intensity were observed in the mid-term (3 and 6 months). Our results at three months agrees with the findings of Xiong, although our meta-analysis provides more evidence due to included ten studies more. Opposite, we disagree with a recent meta-analysis which did not show differences between therapies at three months, although it can be biased because only six studies were included.[33] Extracorporeal shock waves can reduce pain intensity in visual analogue scale 1.3 points more than corticosteroids, being these results clinically relevant for two reasons. Firstly, according to the novel effect size interpretation in rehabilitation research,[49] the effect size found in both meta-analyses was large. Secondly, the mean difference value obtained was greater than the minimally important difference for the visual analogue scale for pain intensity on these patients (0.9 points or 9 mm).[52] Finally, at one year of follow-up, no significant differences were shown between therapies. Additionally, and in line with previous studies,[27,74] our subgroup analysis corroborated that radial and high-intensity extracorporeal shock waves therapy may be a better protocol for pain reduction, although others postulated the focused as the most indicated.[26] Previous literature reports that medium intensity is the ideal option when applying focused[75,76] and high intensity when radial extracorporeal shock wave is used.[27] In addition, our meta-analysis showed a reduction of pain sensitivity at three months, corroborating the reduction in pain intensity.

In reducing the thickness of the plantar fascia, extracorporeal shock waves therapy is better than corticosteroids injections at three months, but not at 4–6 weeks or at 6 months. This finding represent a novelty and disagrees with the review of Xiong, who only included two studies in that analysis.[32] Although this finding is interesting and relevant, it must be taken into account with caution due to risk of publication bias could be overestimating the original pooled effect size. Additionally, subgroup analysis revealed that high-intensity extracorporeal shock waves are the most indicate dose in reducing thickness of the plantar fascia at three months.

On foot function, the effect of extracorporeal shock waves was major than corticosteroids injections at three and six months, but not at 4–6 weeks and one year of follow-up were found. These findings are inconsistent with those of Xiong, who did not show differences in foot function at three months with data from four studies. Furthermore, we reveal than while focused is most optimal at three months, radial application is more adequate at six months. Finally, the major clinical improvements on foot function were obtained using high-intensity dose.

This study presents some limitations. First, the low level of evidence and generalization in some subgroups analyses can be determined by the low number of studies included in them, the moderate methodological quality and risk of bias of individual studies and by others items such as inaccuracy, statistical heterogeneity or risk of publication bias that can alter (under or overestimating) the pooled effect. Secondly, biases, such as selection (related to an inadequate randomization concealment in

some studies), performance and detection (by the impossibility to blinding participants, therapists or evaluators) can alter the accuracy of the therapy effects producing a possible overestimation of the findings.[77,78] Finally, another limitation is that the difference in the effect between acute or chronic patients at 6 and 12 months of follow-up could not be evaluated, since the included studies did not enough report data from these periods.

In conclusion, this meta-analysis, including the major of studies to date, reports that extracorporeal shock waves therapy is a safe therapy and more effective than corticosteroids injections for the improvement of pain, thickness of plantar fascia and foot function in patients with plantar fasciitis in the mid-term (3–6 months after the intervention). Although corticosteroids injections seem to be more effective than in the short time, no differences were found between therapies. Finally, at 12 months of follow-up, there are not differences between the effect of both therapies. Additionally, our findings suggested that radial extracorporeal shock waves and high-intensity dose are the most adequate for improving pain and foot function. These findings are clinically relevant for physiotherapists, and we encourage to the researchers how maintain the effect of extracorporeal shock wave beyond six months.

Clinical messages

- For reduce pain and increasing foot function at mid-term (3–6 months), extracorporeal shock wave therapy is more effective than corticosteroids injections.
- The major improvement on pain and foot function is obtained using radial extracorporeal shock waves with high intensity.
- The thickness of the plantar fascia is reduced at mid term using high-intensity extracorporeal shock waves.
- Extracorporeal shock wave therapy is a safe and effective therapy, with local pain and slight erythema being the most frequent side effects.

Author contributions

Conception and design: Esteban Obrero-Gaitán, Irene Cortés-Pérez and Rafael Lomas-Vega; data acquisition: Ana Esteban Obrero-Gaitán, Laura Moreno-Montilla, Irene Cortés-Pérez and Rafael Lomas-Vega; quality assessment: Ángeles Díaz-Fernández, Alfonso Javier Ibáñez-Vera and Rafael Lomas-Vega; statistical analysis: Esteban Obrero-Gaitán and Irene Cortés-Pérez; writing-draft version: Esteban Obrero-Gaitán, Irene Cortés-Pérez and Laura Moreno-Montilla;; supervision and critically review: Ángeles Díaz-Fernández, Alfonso Javier Ibáñez-Vera and Rafael Lomas-Vega; project leader: Esteban Obrero-Gaitán. All authors gave final approval and agree to be accountable for all aspects of the work.

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Supplemental material

Supplemental material for this article is available online.

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