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Effect of extracorporeal shockwave therapy on plantar fascia thickness in plantar fasciitis: a systematic review and meta-analysis of randomized controlled trials

Mario Simental-Mendía¹ · Luis E. Simental-Mendía² · Adriana Sánchez-García³ · Amirhossein Sahebkar^{4,5} · Tannaz Jamialahmadi⁶ · Félix Vilchez-Cavazos¹ · Víctor M. Peña-Martínez¹ · Carlos Acosta-Olivo¹

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Abstract

Objective Extracorporeal shockwave therapy (ESWT) has been used as a therapeutic option for plantar fasciitis. The objective was to investigate the effect of ESWT over the plantar fascia thickness.

Methods MEDLINE, Embase, Web of Science, and SCOPUS databases were searched for randomized controlled trials evaluating the effect of ESWT in patients with plantar fasciitis, comparing ESWT with another treatment. Meta-analysis was conducted using a random-effects model and the generic inverse variance method. Meta-regression and subgroup analyses were also carried out.

Results A total of 14 studies (867 participants) were included. ESWT significantly decreased plantar fascia thickness (weighted mean difference [WMD], -0.21 mm [95% CI -0.39, -0.02]; p=0.03). No significant improvement in pain was observed (WMD, -0.51 cm [95% CI -1.04, 0.01]; p=0.06) compared with non-surgical interventions.

Conclusions Our results suggest that plantar fascia thickness is significantly decreased after ESWT intervention in patients with plantar fasciitis. However, pain relief was not significantly improved compared to other non-surgical interventions.

Keywords Plantar fasciitis · Plantar fascia · Pain · Extracorporeal shockwave therapy · Systematic review · Meta-analysis

Carlos Acosta-Olivo dr.carlosacosta@gmail.com

- ¹ Orthopedic Trauma Service, School of Medicine, Universidad Autonoma de Nuevo Leon, University Hospital "Dr. José Eleuterio González", Ave. Francisco I. Madero and Ave. Dr. José Eleuterio González, 64460 Monterrey, Nuevo León, Mexico
- ² Biomedical Research Unit, Delegación Durango, Instituto Mexicano del Seguro Social, Durango, Mexico
- ³ Endocrinology Division, School of Medicine, Universidad Autonoma de Nuevo Leon, University Hospital "Dr. José Eleuterio González", Monterrey, Mexico
- ⁴ Biotechnology Research Center, Pharmaceutical Technology Institute, Mashhad University of Medical Sciences, Mashhad, Iran
- ⁵ Applied Biomedical Research Center, Mashhad University of Medical Sciences, Mashhad, Iran
- ⁶ Department of Nutrition, School of Medicine, Mashhad University of Medical Sciences, Mashhad, Iran

Introduction

Plantar fasciitis is the most common cause of hindfoot pain and is related to multifactorial causes [1]. The main risk factors frequently related to plantar fasciitis are high body mass index (2 7 kg/m²), increased occupational standing time on hard surfaces, and a majority of the workday on feet [2, 3].

Shoe modifications, shoe insoles, stretching exercises, or corticosteroid injections are common primary interventions to treat plantar fasciitis [4]. When these interventions fail, it is common to resort to other types of therapies such as extracorporeal shock wave therapy (ESWT). ESWT is a non-invasive therapy used in the treatment of several orthopedic problems [5, 6]. Multiple studies have reported that ESWT exhibits better results on functional and pain outcomes, as well as fewer complications when compared with other interventions including placebo, low-level laser therapy, ultrasound, and local corticosteroid injection [7–9]. Compared with corticosteroids, ESWT does not seem to have a deleterious effect on tendon tissue, which could be considered an advantage [5].

The thickness of the plantar fascia is not often evaluated in clinical trials. This parameter could be a relevant outcome (objective measure) to assess the effect of a treatment. The normal thickness of the plantar fascia is considered at a maximum of 4 mm and ≥ 4.5 mm in patients with tendinopathy [10]. After a therapeutic intervention, a return-to-normal to the fascia thickness would be expected when symptomatic relief is reported, but this is not always the case.

Different studies (including meta-analysis) have analyzed the use of ESWT in patients with plantar fasciitis, showing improvements in pain and functional scores [7, 8, 11–13]; however, there has been no systematic assessment regarding the effect of this therapy on the fascia thickness. Therefore, the purpose of this systematic review and meta-analysis of randomized controlled trials (RCT) was to evaluate the effect of ESWT on plantar fascia thickness in patients with plantar fasciitis.

Methods

The conduction of this systematic review and meta-analysis was based on the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) guidelines [14]. The protocol was previously registered in a public database (PROSPERO CRD42021243774).

Eligibility criteria

Studies were screened for inclusion based on the following criteria: RCT (parallel or cross-over design); patients \geq 18 years old with a clinically or image-based diagnosis of plantar fasciitis (regardless of its evolution time), in which plantar fasciitis is defined as pain at the plantar medial aspect of the heel, tenderness at the plantar aspect of the medial calcaneal tuberosity around the fascia insertion, and the presence of "start-up pain" (on first walking in the morning or after a period of rest that gets better after walking for a while) [15]; intervention with ESWT compared to any other nonsurgical intervention; measurement of the plantar fascia thickness (at baseline and follow-up) employing an imaging study and evaluation of pain score (i.e., Visual Analogue Scale, Numeric Rating Scale). A minimum follow-up of 1 month was required.

There was no language restriction (if an article was included in a language other than English, a translator would be contacted to translate the study). Studies with insufficient data interfering with the analysis of any of the outcomes of interest were excluded. Studies involving surgical interventions were also excluded.

Information sources and search strategy

A search strategy was designed together with a librarian and the main investigators of the project. A combination of MeSH terms and keywords (plantar heel pain, chronic plantar fasciitis, chronic heel pain, plantar fasciopathy, extracorporeal shockwave therapy) were selected to find original articles or abstracts. MEDLINE, Embase, Web of Science, and Scopus databases were searched from each database's inception to June 2022. We searched for additional references addressing our study questions in other systematic reviews and searched for unpublished clinical trials on ClinicalTrials.gov so that any possible missing study was considered.

Study selection process

Four independent authors, working as independent pairs, screened titles, abstracts, and full-text manuscripts for eligibility. A pilot screening process for the title and abstract and full-text phases was performed before formally beginning with each phase. The chance-adjusted agreement was quantified using the kappa statistic [16] and disagreements were resolved by consensus between authors. We used the Distiller Systematic Review Software (DistillerSR) for the management of the study data during the selection process.

Data collection process

Data were extracted independently and in duplicate using a standardized electronic data extraction format. Selected studies were reviewed for the following data: (1) first author's name; (2) year of publication; (3) study design; (4) target population; (5) number of participants in each intervention arm; (6) therapy applicated; (7) method of measurement and anatomical site of measurement of plantar fascia thickness; (8) if therapy was image-guided; (9) age, gender, and body mass index of study participants; (10); thickness of the plantar fascia, and (11) pain score values.

Risk of bias and quality of evidence

A systematic assessment of the risk of bias in each individual included study was performed with the Cochrane Risk of Bias 2.0 tool (RoB 2.0), which covers bias in each of the following domains: randomization process, deviations from the intended interventions, missing outcome data, measurement of the outcome, selection of the reported result, and overall bias [17]. There are five possible answers for each domain (yes, probably yes, no, probably not, and no information); according to the answers, an algorithm classifies the risk of

Fig. 1 Flow diagram for the

study selection process



bias as low, some concerns, or high. Any disagreement in assessing the quality of the study was resolved by consensus between the authors.

Meta-regression and subgroup analyses

A meta-regression analysis was carried out to investigate the impact of duration of follow-up after treatment with ESWT on plantar thickness and pain. Subgroup analysis was performed to compare the effects of ESWT on the plantar fascia thickness between a subset of trials with different types of control treatment. A further subanalysis was carried out to detect whether stretching exercises, in addition to applied therapy, influenced the outcomes of interest.

Publication bias

A funnel plot was generated for each outcome to visually inspect publication bias. Begg's rank correlation and Egger's weighted regression test were employed to assess the presence of publication bias based on a funnel plot. When there was evidence of funnel plot asymmetry, potentially missing studies were imputed using the "trim and fill" method.

Quantitative data synthesis

A meta-analysis was performed to address if there was a statistically significant difference in plantar fascia thickness and pain between pre-intervention and post-intervention data. Data were collated in millimeters for plantar fascia thickness and in centimeters for pain score (using a 0–10 cm Visual Analogue Scale [VAS], were 0 represents no pain and 10 represents the worst pain) [18]. Changes in pain relief

Table 1 Chan	acteristics of th	re included stud	lies										
Author	Study design	Target popu- lation	Follow-up	ц	Study groups	Additional stretching exercises	Anatomical region of plantar fas- cia thickness measure- ment	Measure- ment method	Age, years	Female (n, %)	BMI (kg/ m ²)	Plantar fascia thick- ness (mm)	Pain score (VAS, cm)
Armagan Alpturker	Rand- omized.	Plantar fas- ciitis and	1 month	20	Low-level laser therapy	Yes	Insertion into calca-	MRI	37.0±10.3	10 (50.0)	27.2±5.0	4.4 ± 1.0	7.6 ± 1.0
et al. [23]	single- blinded, controlled	spondy- loarthritis		20	Extracor- poreal shock wave therapy		neus		38.6±9.6	10 (50.0)	28.4±5.2	4.5 ± 0.4	7.8 ±0.8
Asheghan et al. [28]	Rand- omized, controlled	Chronic plantar fasciitis	3 months	29	Extracor- poreal shock wave therapy	Yes	Insertion into calca- neus	Ultrasound	43.7 ± 7.6	20 (69.0)	26.5±3.6	4.5 ± 0.6	7.2±1.3
				30	Prolotherapy				46.5 ± 6.5	19 (63.3)	25.3 ± 4.2	4.7 ± 0.4	7.5 ± 1.1
Caner et al.	Rand-	Plantar fas-	11 weeks	16	Extracor-	No	Insertion	Ultrasound	43.8 ± 8.2	7 (70.0)	30.2 ± 3.9	3.6 ± 0.7	8.4 ± 1.4
[27]	omized, double- blinded,	ciitis and spondy- loarthritis			poreal shock wave therapy		into calca- neus						
	controlled			21	Sham-ESWT				48.5 ± 7.6	9 (75.0)	31.1 ± 5.4	4.1 ± 1.1	7.8 ± 0.6
Chew et al. [24]	Rand- omized, single-	Chronic unilateral plantar	6 months	19	Autologous conditioned plasma	Yes	Insertion into calca- neus	Ultrasound	46 (38–51) ^a	9 (47.4)	23.4 (21.9– 27.7) ^a	6.4 (5–7) ^a	7 (5–8) ^a
	blinded, controlled	fasciitis		19	Extracorpor- eal shock- wave	Yes			45 (37–53) ^a	8 (42.1)	25.3 (23.1– 27.2) ^a	5.4 (5–6) ^a	7 (6 - 8) ^a
				16	Stretching exercises	No			47.5 (41–53) ^a	8 (50.0)	24.7 (22.6– 27.4) ^a	5.55 (5–7) ^a	6 (5–8) ^a
Hocaoglu et al. [11]	Rand- omized, single- blinded	Unre- sponsive plantar fasciitis	6 months	36	Radial extra- corporeal shockwave therapy	No	Insertion into calca- neus	Ultrasound	50.2±8.3	30 (83.3)	28.4±2.0	4.8 (4.1– 7.2) ^b	8.0 (5.0– 10.0) ^c
				36	Corticosteroid injection	No			47.9±7.9	32 (88.9)	29.1 ± 2.3	$4.7 (4.0-6.1)^{b}$	$9.0\ (5.0-10.0)^{c}$
Huo et al. [29]	Rand- omized, controlled	Plantar fasciitis	6 months	39	Extracor- poreal shock wave therapy	No	Insertion into calca- neus	Ultrasound	56.9±8.3	16 (41.0)	25.2 ± 3.5	5.2 ± 0.5	$6.9 \pm 1.0^{\text{d}}$
				38	Corticosteroid injection	No			58.3±7.3	16 (42.1)	25.6 ± 3.3	5.2 ± 0.4	7.1±1.2 ^d

Table 1 (cont	tinued)												
Author	Study design	Target popu- lation	Follow-up	я.	Study groups	Additional stretching exercises	Anatomical region of plantar fas- cia thickness measure- ment	Measure- ment method	Age, years	Female (n, %)	BMI (kg/ m ²)	Plantar fascia thick- ness (mm)	Pain score (VAS, cm)
Lai et al. [30]	Rand- omized, controlled	Plantar fasciitis	3 months	47	Extracor- poreal shock wave therapy	No	Insertion into calca- neus	Ultrasound	54.5±8.6	26 (55.3)	QN	3.7±0.7	6.2 ±1.1
				50	Corticosteroid injection	No			54.6±8.6	28 (56.0)		3.8±0.6	6.2±1.1
Lee et al. [31]	Randomized	Plantar fasciitis	3 months	30	Low-energy ESWT	No	Insertion into calca-	Ultrasound	55.28 ± 9.2	5 (16.6)	24.02 ± 1.5	4.32 ± 0.46	3.06 ± 1.22
				30	Medium- energy ESWT	No	neus		51.2±11.2	2 (6.6)	23.74±2.1	4.33±0.43	3.13 ± 0.77
Tezel et al. [25]	Rand- omized, single- blinded	Plantar fasciitis	6 weeks	36 42	Kinesiotaping Extracor- poreal shock wave therapy	Yes	Insertion into calca- neus	Ultrasound	46.8±9.2 46.2±12.1	29 (80.6) 35 (83.3)	32.2 ± 4.9 31.9 ± 7.2	4.5±2.8 4.5±2.5	7.5 ±2.2 7.3 ±2.4
Ulusoy et al. [12]	Rand- omized,	Chronic recal-	1 month	20	Low level laser therapy	Yes	Insertion into calca-	MRI	53.4±14.7	16 (80.0)	31.9 ± 5.6	4.3 ± 0.7	6.9 ± 1.3
	single- blinded	citrant plantar		20	Ultrasound therapy		neus		51.0 ± 9.6	17 (85.0)	30.2 ± 4.5	4.8 ± 0.7	6.7 ± 1.1
		fasciitis		20	Extracor- poreal shockwave therapy				54.5±6.9	16 (80.0)	32.0±4.1	5.2±1.0	6.6 ±1.1
Vahdatpour et al. [33]	Rand- omized, placebo- controlled	Plantar heel pain	3 months	50 50	Extracor- poreal shock wave therapy	Yes	Two cm distal of the medial calcaneal	Ultrasound	50.6±10.0	13 (65%)	28.8±4.0	4.1±1.3	7.7±1.0
Xu et al. [9]	Rand- omized, controlled	Plantar fasciitis	6 months	49	Extracor- boreal shock wave therapy	Yes	Insertion into calca- neus	Ultrasound	40.1 ±0.7 48.5 ±7.5	12 (00%) 37 (75.5)	23.7±2.0 23.7±2.0	4.1 ±0.6 5.3 ±0.6	5.3±1.9
				47	Corticosteroid injection				47.2±8.7	31 (66.0)	23.1 ± 2.0	5.2 ± 0.5	5.1 ± 1.7

Table 1 (con	tinued)											
Author	Study design	Target popu- lation	Follow-up	n Study groups	Additional stretching exercises	Anatomical region of plantar fas- cia thickness measure- ment	Measure- ment method	Age, years	Female (n, %)	BMI (kg/ m ²)	Plantar fascia thick- ness (mm)	Pain score (VAS, cm)
Yan et al. [32]	Rand- omized, controlled	Plantar fasciitis	3 months	53 Extracor- poreal shockwave therapy	No	Insertion into calca- neus	Ultrasound	41.3±8.6	80 (52.3)	22.8±3.4	5.4 ± 1.5	8.3±1.6
				49 Orthopaedic insole	No						5.3 ± 1.5	8.3±1.6
				51 Extracor- poreal shockwave ther- paedic insole	No						5.5 ± 1.5	8.1±1.7
Yinilmez Sanmak et al. [26]	Rand- omized, single- blinded,	Plantar fasciitis	1 month	17 Extracor- poreal shock wave therapy	No	Insertion into calca- neus	Ultrasound	49 (32–67) ^c	14 (82.4)	29.6 (25.3– 36.4) ^c	4.7 (3.8– 6.8)°	8 (2–10) ^c
	controlled			17 Low-level laser therapy	No			53 (32–67) ^c	15 (88.2)	30.2 (20.8– 44.2) ^c	4.6 (3.4– 6.0) ^c	8 (4–10) ^c
Values are ex	cpressed as mea	n±SD										

BMI body mass index, VAS visual analog scale, NRS numeric rating scale, MRI magnetic resonance imaging, ND no data

^amedian (IQR)

^bmean (range) ^cmedian (range)

dNRS

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Fig.2 Quality assessment of the included studies according to the Cochrane Risk of Bias Tool 2.0

were compared to minimal clinically important difference (MCID) criteria in plantar fasciitis to assess if the changes were clinically meaningful.

The statistical analysis was performed using the Review Manager V5.3 and the Comprehensive Meta-Analysis software. Meta-analysis was conducted using a random-effects model (DerSimonian-Laird method) and the generic inverse variance method. The effect size on thickness and pain score is presented as weighted mean difference (WMD) and 95% confidence interval (CI) based on the measurements at baseline and follow-up registered in means and standard deviation (SD). When SD for baseline or follow-up for the outcome of interest in a study arm was not available, it was calculated by obtaining a t statistic and a subsequent suitable standard error (SE) [19]. If the (SE) was reported, the SD was estimated using the following formula: $SD = SE \times$ sqrt (n), where n is the number of subjects. When the outcome measures were reported as the median and interquartile range (or, 95% CI), mean and SD values were estimated as previously described [20, 21]. We performed a sensitivity analysis through the leave-one-out method to assess the individual study impact on the overall effect size. This is, removing one study each time and repeating the analysis for every outcome[22].

The exploration of consistency, specifically focusing on the heterogeneity of the studies to include, was examined by applying Cochrane's Q Statistic test considering a p-value of <0.05 as statistically significant. In turn, the I² statistic was carried out, taking into consideration 0–25% of heterogeneity between studies as unimportant, >25–50% as moderate, and > 50% as important heterogeneity.

Results

Study selection process

A total of 1159 relevant publications were retrieved after the systematic literature search. After the removal of duplicate records, 1025 studies were screened through their titles and abstracts. Of them, 992 were excluded because they did not meet the inclusion criteria or could not be retrieved, leaving 33 reports for full-text screening. Then, 19 studies were excluded because of an inadequate study design (n=5), not reporting data on the thickness of the fascia (n=10), or not presenting feasible data to analyze (n=4). Finally, 14 studies

	E	SWT		Co	ontrol			Mean Difference	Mean Difference
Study or Subgroup	Mean [mm]	SD [mm]	Total	Mean [mm]	SD [mm]	Total	Weight	IV, Random, 95% CI	IV, Random, 95% CI
Armagan Alpturker 2020	-0.75	0.42	20	-0.77	0.86	20	8.1%	0.02 [-0.40, 0.44]	_
Asheghan 2020	-0.7	0.52	29	-1	0.4	30	11.3%	0.30 [0.06, 0.54]	
Caner 2022	-0.2	0.96	16	0.1	1.15	21	4.8%	-0.30 [-0.98, 0.38]	
Chew 2013	-0.94	2.92	19	-0.66	2.3	16	1.0%	-0.28 [-2.01, 1.45]	
Hocaoglu 2017	-0.95	1.79	36	-0.83	1.54	36	4.0%	-0.12 [-0.89, 0.65]	
Huo 2018	-1.2	0.49	39	-0.81	0.41	38	12.0%	-0.39 [-0.59, -0.19]	
Lai 2018	0.1	0.7	47	0.1	0.66	50	10.7%	0.00 [-0.27, 0.27]	- + -
Lee 2013	-0.26	0.44	30	-0.16	0.45	30	11.6%	-0.10 [-0.33, 0.13]	
Tezel 2020	-0.83	2.22	42	-0.88	2.42	36	2.5%	0.05 [-0.99, 1.09]	
Ulusoy 2017	-0.85	0.94	20	-0.55	0.71	20	6.6%	-0.30 [-0.82, 0.22]	
Vahdatpour 2012	-0.5	1.25	20	0.4	0.85	20	4.9%	-0.90 [-1.56, -0.24]	
Xu 2020	-0.8	0.95	49	-0.3	0.62	47	9.8%	-0.50 [-0.82, -0.18]	
Yan 2014	-0.75	1.55	53	-0.65	1.37	49	6.0%	-0.10 [-0.67, 0.47]	
Yinilmez Sanmak 2019	-1.07	0.74	17	-0.4	0.79	17	6.6%	-0.67 [-1.18, -0.16]	
Total (95% CI)			437			430	100.0%	-0.21 [-0.39, -0.02]	•
Heterogeneity: Tau ² = 0.06	6; Chi ² = 35.33	df = 13 (P	= 0.000	08); I² = 63%				-	-2 -1 0 1 2
l est for overall effect: Z =	2.22 (P = 0.03))							Favours ESWT Favours Control

Fig. 3 Forest plot showing the weighted mean difference and 95% confidence intervals for the effect of ESWT on plantar fascia thickness

 Table 2
 Results of leave-one-out sensitivity analysis for plantar fascia thickness

Study removed	Statistics with study remov	ed	
	Mean difference [95% CI]	<i>p</i> -value	I^2
Armagan Alpturker et al. [23]	-0.23 [-0.42, -0.03]	0.02	65%
Asheghan et al. [28]	-0.26 [-0.41, -0.12]	0.0004	32%
Caner et al. [27]	-0.20 [-0.39, -0.01]	0.04	66%
Chew et al. [24]	-0.21 [-0.39, -0.02]	0.03	66%
Hocaoglu et al. [11]	-0.21 [-0.40, -0.02]	0.03	66%
Huo et al. [29]	-0.18 [-0.38, 0.01]	0.07	59%
Lai et al. [30]	-0.23 [-0.44, -0.03]	0.02	64%
Lee et al. [31]	-0.23 [-0.44, -0.02]	0.04	66%
Tezel et al. [25]	-0.21 [-0.40, -0.03]	0.02	66%
Ulusoy et al. [12]	-0.20 [-0.40, -0.01]	0.04	66%
Vahdatpour et al. [33]	-0.17 [-0.35, 0.01]	0.06	61%
Xu et al. [9]	-0.17 [-0.36, 0.02]	0.07	61%
Yan et al. [32]	-0.22 [-0.41, -0.02]	0.03	66%
Yinilmez-Sanmak et al. [26]	-0.17 [-0.36, 0.01]	0.07	62%

A change in the p value indicates that the excluded study significantly influences the observed effect size

CI confidence interval

were included in the systematic review and meta-analysis. The detailed flow diagram for the selection of studies is depicted in Fig. 1.

Characteristics of the included studies

Studies selected for analysis included 867 patients, 437 treated with ESWT, and 430 with nonsurgical therapy. All studies had a parallel design, six of them were single-blinded

[11, 12, 23–26], only one was double-blinded [27], and seven studies were not blinded [9, 28–33]. Two clinical trials included patients with spondyloarthritis in addition to plantar fasciitis [23, 27]. Studies were published between 2012 and 2022 and the follow-up ranged from one to six months. Seven studies included an additional stretching exercise program besides the received therapy [9, 12, 23–25, 28, 33]. Most studies measured the thickness of the fascia at the calcaneal insertion using ultrasound. Complete characteristics of the included RCTs are shown in Table 1.

Risk of bias assessment

Seven studies had a low risk of bias for the randomization process domain, while the other seven trials showed some concerns. Only two reports were at low risk of bias [11, 27] for the deviations from the intended intervention domain, the rest had some concerns. All studies, except one [27], had a low risk of bias for missing outcome data. For the measurement of the outcome and the selection of the reported result domains, all studies had a low risk of bias. Only one study was cataloged to be at an overall low risk of bias [11], the rest showed some concerns in at least one domain. The risk of bias in the included studies is summarized in Fig. 2.

Effect of ESWT on plantar fascia thickness and pain

Meta-analysis of data pooled from the 14 studies indicated that plantar fascia thickness significantly decreases after ESWT intervention as compared to other non-surgical interventions (WMD, -0.21 mm [95% CI -0.39, -0.02]; $p=0.03; \text{ I}^2=63\%; \text{ Fig. 3}$). This result was sensitive after the removal of four studies [9, 26, 29, 33] from the analysis

	E	SWT		Co	ontrol			Mean Difference	Mean Difference
Study or Subgroup	Mean [cm]	SD [cm]	Total	Mean [cm]	SD [cm]	Total	Weight	IV, Random, 95% CI	IV, Random, 95% CI
Armagan Alpturker 2020	-3.4	1.16	20	-2.7	1.12	20	8.8%	-0.70 [-1.41, 0.01]	
Asheghan 2020	-3.15	1.2	29	-3.05	1.05	30	9.3%	-0.10 [-0.68, 0.48]	
Caner 2022	-4.9	1.71	16	-2.8	1.97	21	6.8%	-2.10 [-3.29, -0.91]	
Chew 2013	-3.16	5.57	19	-2.34	5.08	16	1.8%	-0.82 [-4.35, 2.71]	
Hocaoglu 2017	-4.67	3.86	36	-4.33	3.86	36	4.8%	-0.34 [-2.12, 1.44]	
Lai 2018	-4.89	1.18	47	-3.26	1	50	9.8%	-1.63 [-2.07, -1.19]	
Lee 2013	-1.6	0.79	30	-1.06	1.07	30	9.7%	-0.54 [-1.02, -0.06]	
Tezel 2020	-2.42	1.59	42	-2.72	1.4	36	9.0%	0.30 [-0.36, 0.96]	+- -
Ulusoy 2017	-3.86	1.29	20	-3.94	1.63	20	8.0%	0.08 [-0.83, 0.99]	_
Vahdatpour 2012	-0.1	0.89	20	1.4	2.12	20	7.6%	-1.50 [-2.51, -0.49]	
Xu 2020	-3.2	1.66	49	-2.2	1.54	47	9.1%	-1.00 [-1.64, -0.36]	
Yan 2014	-4.73	1.61	53	-5.68	1.53	49	9.2%	0.95 [0.34, 1.56]	
Yinilmez Sanmak 2019	-1.75	2.38	17	-2.25	1.83	17	5.9%	0.50 [-0.93, 1.93]	
Total (95% CI)			398			392	100.0%	-0.51 [-1.04, 0.01]	◆
Heterogeneity: Tau ² = 0.68	3; Chi² = 71.41	, df = 12 (l	> < 0.0	0001); l² = 83	%			-	
Test for overall effect: Z =	1.91 (P = 0.06	6)							-4 -2 0 2 4 Favours ESWT Favours Control



Table 3	Results of	leave-one-out	sensitivity	analysis	for pair
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Study removed	Statistics with study remov	red	
	Mean difference [95% CI]	<i>p</i> -value	I^2
Armagan Alpturker et al. [23]	-0.50 [-1.07, 0.08]	0.09	85%
Asheghan et al. [28]	-0.56 [-1.13, 0.02]	0.06	84%
Caner et al. [27]	-0.40 [-0.93, 0.13]	0.14	83%
Chew et al. [24]	-0.51 [-1.04, 0.03]	0.06	85%
Hocaoglu et al. [11]	-0.52 [-1.07, 0.02]	0.06	85%
Lai et al. [30]	-0.38 [-0.86, 0.10]	0.12	74%
Lee et al. [31]	-0.51 [-1.11, 0.09]	0.10	85%
Tezel et al. [25]	-0.59 [-1.14, -0.04]	0.03	83%
Ulusoy et al. [12]	-0.56 [-1.12, -0.01]	0.05	84%
Vahdatpour et al. [33]	-0.43 [-0.98, 0.12]	0.12	84%
Xu et al. [9]	-0.46 [-1.04, 0.11]	0.11	84%
Yan et al. [32]	-0.66 [-1.13, -0.20]	0.005	75%
Yinilmez-Sanmak et al. [26]	-0.58 [-1.12, -0.03]	0.04	84%

A change in the p value indicates that the excluded study significantly influences the observed effect size

CI confidence interval

(Table 2). The exclusion of each study derived in a no significant change of plantar fascia thickness.

On the other hand, a meta-analysis from 13 studies (one study was excluded for presenting data in a scale different from VAS) revealed that intervention with ESWT did not improve pain significantly compared with other nonsurgical interventions (WMD, -0.51 cm [95% CI -1.04, 0.01]; p=0.06; $I^2=83\%$; Fig. 4). Results of the leave-one-out sensitivity analysis indicated sensitivity to four studies [12, 25, 26, 32] for this outcome (Table 3). In this case, the exclusion of each study showed a significant change of pain relief, indicated by the change in p values and effect sizes.

Meta-regression and subgroup analyses

After the random-effects meta-regression by duration of treatment, no significant association was identified between the changes in plantar fascia thickness (slope: -0.014; 95% CI: -0.167, 0.137; p=0.848) or pain relief (slope: -0.168; 95% CI: -0.809, 0.472; p=0.607) with follow-up (Fig. 5). Follow-up in these studies does not allow us to identify a clear pattern in pain improvement or thickness reduction over time.

The results of the subanalysis indicated that ESWT and additional stretching exercises do not confer a significant improvement in plantar fascia thickness (WMD, -0.21 mm [95% CI -0.58, 0.17]; p = 0.28) (Supplementary Table 1) or pain relief (WMD, -0.46 mm [95% CI -0.95, 0.04]; p = 0.07) (Supplementary Table 2).

The subanalysis by type of comparator showed that ESWT significantly decreases plantar fascia thickness compared with corticosteroid injection (WMD, -0.28 mm [95% CI -0.53, -0.03]; p=0.03) and sham ESWT (WMD, -0.61 mm [95% CI -1.19, -0.02]; p=0.04) (Supplementary Table 3). Similarly, ESWT significantly improved pain relief compared with corticosteroid injection (WMD, -1.26 cm [95% CI -1.86, -0.66]; p < 0.0001) and sham ESWT (WMD, -1.75 cm [95% CI -2.52, -0.98]; p= < 0.0001) (Supplementary Table 4). The mean changes obtained for pain relief after subanalysis ($\Delta = 1.26$, $\Delta = 1.75$) were higher than the established MCID on the VAS for average pain in plantar fasciitis (0.8–0.9 cm) but did not reach the MCID for pain (1.9 cm) [34, 35].

Publication bias

Publication bias assessment revealed symmetric funnel plots and a lack of publication bias for plantar fascia thickness and pain. Hypothetic asymmetry was corrected by imputing potentially missing studies using the "trim and fill" method, however, no potentially missing study was imputed for any outcome (Fig. 6). Egger's regression test suggested the absence of publication bias in the meta-analyses of plantar fascia thickness (p=0.234) and pain (p=0.406). Similarly, Begg's rank correlation test suggested the absence of publication bias for plantar fascia thickness (p=0.435) and pain (p=0.392) outcomes.

Discussion

The results of the present systematic review and metaanalysis suggest that plantar fascia thickness, but not pain, is significantly decreased after ESWT intervention compared with other nonsurgical therapies in patients with plantar fasciitis. Other relevant outcomes (functional outcomes, return to work or daily activities) could not be assessed as the studies did not report sufficient information for meta-analysis. Mean changes in plantar fascia thickness and pain were not associated with the follow-up duration of the studies. A further subanalysis showed a better effect of ESWT compared with corticosteroid injection and sham ESWT by reducing both plantar fascia thickness and pain.

The thickness of the plantar fascia in asymptomatic subjects has been reported to range between 3 and 4 mm [36, 37], while an average of 5.55 mm has been correlated with symptomatic patients [38, 39]. A prospective study had previously reported a significant decrease in both thickness and pain after treatment with ESWT [40]. Nevertheless, our analysis identified a significant decrease in the plantar fascia thickness in the included studies, which was not associated Fig. 5 Meta-regression bubble plot of the association between mean changes in plantar fascia thickness (**A**) or pain (**B**) and follow-up



with a significant improvement in pain. One of the possible causes of this discrepancy could be the interstudy heterogeneity, which was higher for the pain outcome. One possible explanation for the observed heterogeneity might be that pain measurement in these studies is still a subjective evaluation. It should be noted that all included studies reported an improvement in the thickness of the plantar fascia and pain relief but the difference with respect to the control group was only statistically significant for the first parameter.

Another aspect to consider is the clinical relevance of the size of the effect obtained in the results for the decrease in the fascia thickness. (0.21 mm). If we consider that patients presented on average a thickness of 1 mm more than normal (around 5.0 mm), a decrease of 0.21 mm would not be enough to return the thickness to a normal value. However, it would be necessary to see the evolution of this parameter in the long term, since the longest follow-up reported in the analyzed studies was 6 months. A longer follow-up

time would probably allow establishing a direct relationship between the improvement in thickness or pain as a function of time. In our study, the meta-regression analysis did not reveal such a relationship, despite obtaining a significant reduction in fascia thickness.

Previous meta-analyses have reported that ESWT is more effective than corticosteroid injections and ultrasound therapy in relieving pain in plantar fasciitis [41–43], which is compliant with our results. Although the clinical efficacy of both treatments has been evaluated, differences in terms of changes in plantar fascia thickness have not been examined. Our results indicate that ESWT induces a greater decrease in plantar fascia thickness compared with corticosteroids. However, these findings are in the short-term (1–6 months); therefore, further long-term studies are necessary to confirm these results.

The precise mechanism of action of ESWT in musculoskeletal pathology is not entirely described. The evidence Fig. 6 Funnel plot detailing publication bias in the studies reporting the impact of ESWT on plantar fascia thickness (A) and pain (B). Open circles represent observed published studies while closed circles represent imputed unpublished studies using trim and fill method (no imputed studies were added)



so far suggests different levels at which shockwaves can act leading to a healing process: physical, chemical, and biological [44]. Shock waves physical stimuli trigger the release of biomolecules such as adenosine triphosphate (ATP) to activate different cellular signaling pathways [45]; they can also alter the function of ion channels in the cell membrane and the recruitment of calcium [46]. Changes in the cell membrane inhibiting the development of potentials to transmit painful stimuli, cavitation effect, acoustic microstreaming, or direct suppressive effects over the nociceptors are possible mechanisms [47, 48]. Finally, ESWT could induce pain relief and regeneration of soft tissues through direct action on nerve fibers (decreasing concentration of pro-inflammatory mediators or releasing endorphins) and induction of neovascularization, respectively [44, 49].

Some considerations have arisen regarding the ESWT effect, for which has been a reported treatment success rate ranging from 34 to 88% [50]. Such differences may be

due to differences in methodology strategies, criteria for patient selection, source of shockwaves (devices), levels of energy, total energy applied, and outcomes evaluated [50]. Regarding doses used, both low-energy (1000 impulses at 0.06–0.08 mJ/mm²) and medium-energy (1000 impulses at 0.06–0.08 mJ/mm²) shock waves have shown a therapeutic effect in plantar fasciitis [31, 51]. The parameters of the ideal treatment have not yet been precisely established.

Most of the studies measured the fascia thickness where the fascia leaves the calcaneal tuberosity avoiding beam absorption by the plantar sole, as previously suggested [52]. The most commonly used screening method among the included studies to detect changes in the plantar fascia thickness was ultrasound. Ultrasonography evaluation is considered a reliable method to measure the thickness of the plantar fascia, showing that plantar fasciitis could affect not only the insertion area but also other points of the plantar fascia. This method also allows monitoring the effect of different therapeutic interventions [53, 54].

The current meta-analysis has some limitations that should be considered. Although our results did not discriminate between radial and focused ESWT, both methods have been previously compared and found to be similar, being effective and safe for a number of musculoskeletal conditions. Regarding focused ESWT, the benefit seems to be dose-dependent, where higher doses are related to greater benefit [47]. Another limitation is that neither the regimen employed (frequency and dose of ESWT) nor the different systems/manufacturers were analyzed, which was beyond the scope of this review. Differences in methodological approaches may account for the high degree of heterogeneity detected in meta-analysis, which was handled using a random-effects model. Moreover, different therapeutic interventions served as controls in the meta-analysis; therefore, we conducted a subanalysis by type of comparator and additional stretching exercises. Finally, the follow-up of the patients was from the short to medium term; thus, more long-term RCTs are needed to confirm our results. This is relevant because many of the cases of plantar heel pain are usually self-limited [55].

Conclusions

The results of this meta-analysis indicate that ESWT can reduce plantar fascia thickness in patients with plantar fasciitis. In general, the studies report a clinical improvement of the patient (at least in pain perception) and a reduction in fascial thickness, both with ESWT and with other non-surgical interventions. However, pain relief was not significantly improved compared to other non-surgical interventions. A further subanalysis revealed superiority of ESWT by significantly improving both plantar fascia thickness and pain compared with corticosteroid injection and sham ESWT. A lack of robustness in the sensitivity analysis for pain and thickness outcomes suggests that further studies are mandatory to obtain reliable conclusions.

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Declarations

Conflict of interest None.

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