Contents lists available at ScienceDirect

# Heliyon



journal homepage: www.cell.com/heliyon

Research article

CelPress

# Small needle-knife versus extracorporeal shock wave therapy for the treatment of plantar fasciitis: A systematic review and meta-analysis

Chaoqun Feng<sup>a,1</sup>, Junjie Yao<sup>b,1</sup>, Yizhou Xie<sup>a</sup>, Min Zhao<sup>c</sup>, Youpeng Hu<sup>a</sup>, Ziang Hu<sup>d</sup>, Ruoyan Li<sup>a</sup>, Haoyang Wu<sup>a</sup>, Yuanxin Ge<sup>a</sup>, Fei Yang<sup>a,\*\*</sup>, Xiaohong Fan<sup>a,\*</sup>

<sup>a</sup> Department of Orthopedics, Hospital of Chengdu University of Traditional Chinese Medicine, Chengdu, 610072, PR China

<sup>b</sup> College of Acupuncture and Tuina, Changchun University of Chinese Medicine, Changchun, Jilin 130117, PR China

<sup>c</sup> Acupuncture School, Hospital of Chengdu University of Traditional Chinese Medicine, Chengdu, 610097, PR China

<sup>d</sup> The TCM Hospital of Longquanyi District, Chengdu, 610100, PR China

ARTICLE INFO

Keywords: Extracorporeal shock wave Plantar fasciitis Small needle-knife Systematic review Meta-analysis

#### ABSTRACT

*Background:* Plantar fasciitis (PF) is the most common cause of chronic heel pain among adults. Extracorporeal shock wave therapy (ESWT) is the recommended in the current guidelines, and the small needle-knife yields acceptable clinical effects for musculoskeletal pain.

*Objective:* To systematically compare the efficacy of the small needle-knife versus ESWT for the treatment of PF.

*Methods*: The present review was registered in the International Prospective Register of Systematic Reviews (i.e., "PROSPERO", CRD42023448813). Two of the authors searched electronic databases for randomized controlled trials (RCTs) comparing the small needle-knife versus ESWT for the treatment of PF, and collected outcomes including curative effect, pain intensity, and function. Risk of bias was assessed using the Cochrane Handbook Risk of Bias tool and the quality of the RCTs was evaluated according to the Jadad Scale. The same authors independently performed data extraction from the included studies, which were imported into Review Manager version 5.4.1(Copenhagen: Nordic Cochrane Centre, The Cochrane Collaboration, 2020) for metaanalysis.

*Results*: The initial literature search retrieved 886 studies, of which 6 were eventually included in this study. Meta-analysis revealed no significant difference in curative effect (OR = 1.87; 95 % CI [0.80, 4.37], p = .15) nor short-term pain improvement (MD = 2.20; 95 % CI [-2.77, 7.16], p = .39) between the small needle-knife and ESWT. However, the small needle-knife may be more effective than ESWT for pain improvement in mid-term (MD = 9.11; 95 % CI [5.08, 13.15], p < .00001) and long-term follow-ups (MD = 10.71; 95 % CI [2.18, 19.25], p < .00001). Subgroup analysis revealed that the small needle-knife combined with a corticosteroid injection yielded a statistically significant difference in reduction of pain intensity at all follow-ups (MD = 4.84; 95 % CI [1.33, 8.36], p = .007; MD = 10.99; 95 % CI [8.30, 13.69], p < .00001; MD = 17.87; 95 % CI

\* Corresponding author.

\*\* Corresponding author.

*E-mail addresses*: fengchaoqun@stu.cdutcm.edu.cn (C. Feng), 2671032365@qq.com (J. Yao), 411801003@qq.com (Y. Xie), 742667026@qq.com (M. Zhao), 986664919@qq.com (Y. Hu), huziang1994@126.com (Z. Hu), 772628506@qq.com (R. Li), 316252532@qq.com (H. Wu), 771213944@qq.com (Y. Ge), 5577@cdutcm.edu.cn (F. Yang), fanxiaohong@cdutcm.edu.cn (X. Fan).

<sup>1</sup> Chaoqun Feng and Junjie Yao contributed equally to this work.

#### https://doi.org/10.1016/j.heliyon.2024.e24229

Received 27 August 2023; Received in revised form 4 January 2024; Accepted 4 January 2024

Available online 6 January 2024

2405-8440/© 2024 The Authors. Published by Elsevier Ltd. This is an open access article under the CC BY-NC-ND license (http://creativecommons.org/licenses/by-nc-nd/4.0/).

[15.26, 20.48], p < .00001). Meta-analysis revealed no statistical differences in short-term (MD = 1.34; 95 % CI [-3.19, 5.86], p = .56) and mid-term (MD = 2.75; 95 % CI [-1.21, 6.72], p = .17) functional improvement between the needle-knife and ESWT groups. In a subgroup analysis of moderate-quality studies, the small needle-knife demonstrated a favorable effect on mid-term functional improvement (MD = 1.58; 95 % CI [0.52, 2.65], p = .004), with low heterogeneity ( $\chi^2 = 0.77$ , p = .038, I<sup>2</sup> = 0 %). **Conclusion**: Pain reduction and functional improvement are essential for the treatment of PF. Therefore, treatment using the small needle-knife may be superior to ESWT. Results of this systematic review and meta-analysis may provide alternative treatment options for patients with PF as well as more reliable, evidence-based recommendations supporting use of the small needle-knife.

# 1. Introduction

Plantar fasciitis (PF) constitutes a group of syndromes caused by chronic degeneration and biomechanical changes in the proximal plantar aponeurosis and is the most common cause of chronic heel pain among adults [1,2]. Pain is characterized most noticeably during the initial steps after a period of inactivity, which usually regresses after walking for a period but eventually worsens following excessive walking or running [3,4]. The number of individuals affected by PF is high, the disease is prone to occur repeatedly and is difficult to treat [5]. It not only has a severe, negative impact on the activities of daily living of affected individuals but places high economic and resource burdens on individuals and healthcare systems in various countries [6–10]. The pathological mechanisms underlying PF remain unclear. Although many therapeutic methods are available, there is no consensus regarding a "gold standard" treatment [11]. According to guidelines from the Orthopaedic Section of the American Physical Therapy Association (APTA) and the American College of Foot and Ankle Surgeons (ACFAS) [1,12], modern medicine advocates taping, stretching, education, and customized insoles or foot orthoses as core therapies. However, this is associated with many problems, such as prolonged treatment period and poor patient acceptance and compliance. Guidelines recommend extracorporeal shock wave therapy (ESWT) for patients who do not respond to such core therapies.

The small needle-knife is a new product based on Western medicine surgical techniques and traditional Chinese medicine (TCM) acupuncture therapy, thus combining the dual effects of acupuncture and surgery, which has yielded good clinical efficacy in the management of musculoskeletal pain disorders [13]. Several meta-analyses have demonstrated that treatment of PF using the small needle-knife is safe and effective [14–16]. Presently, however, a lack of systematic reviews comparing small needle-knives and ESWT persists. As such, we analyzed randomized controlled trials (RCTs) comparing the small needle-knife versus ESWT for the treatment of PF. We objectively evaluated their clinical efficacies according to the systematic review research method, aiming to provide evidence-based medical information to patients choosing the most appropriate treatment options. Our results may contribute to optimizing TCM diagnosis and treatment strategies for PF.

# 2. Methods

#### 2.1. Information sources and search strategies

A systematic literature search of the PubMed, EMBASE, Cochrane Library, Web of Science, ClinicalTrials.gov, China National Knowledge Infrastructure (CNKI), Chongqing VIP Chinese Science and Technology Periodical (VIP), China Biology Medicine (CBM), and Wanfang Databases for relevant studies, published from inception to July 2023, was performed. Keywords used in the search included the following: (plantar fasciitis OR policeman's heel OR heel pain OR heel spur syndrome OR chronic plantar fasciitis OR plantar fasciopathy OR calcaneodynia) AND (small needle knife OR needle-knife OR acupuncture therapy OR acupotomy). Furthermore, the reference lists of the retrieved articles were also manually searched to identify other, potentially eligible studies. The literature search was limited to studies published in English and Chinese. This systematic review and meta-analysis was registered in the International Prospective Register of Systematic Reviews (PROSPERO) database (CRD42023448813). All search strategies are described in Supplemental Appendix 1.

#### 2.2. Eligibility criteria

Studies fulfilling the following criteria were included: participants were diagnosed as adult patients with PF; the small needle-knife was selected as the primary intervention in the experimental group and ESWT was used in the control group (patients who underwent treatment with both methods were excluded); outcome measures included the total effective rate or pain intensity; and an RCT design. Duplicate publications and/or data were excluded.

#### 2.3. Study selection and data extraction

The search results were imported into NoteExpress version 3.7.0, and study selection was performed independently by two of the authors. First, duplicate publications were excluded. Second, the titles and abstracts of the remaining studies were screened for potential eligibility. Third, potentially eligible studies were subjected to further full-text analysis to finalize study inclusion. The study

selection results of the two authors were cross-checked, with any discrepancies resolved by a senior reviewer. Data extraction was performed independently by the same authors using a standardized data extraction checklist. The extracted data included the following: first author's name; year of publication; country; study design; number of participants; disease duration; intervention measures; intervention duration; outcome measures; and follow-up duration. Pain intensity and functional scores for each outcome measure were transformed to scales graded from 0 to 100 points. Outcome measures were categorized according to length of follow-up, if data were available. Therefore, follow-up of 1 month was defined as short term, 3 months as medium term, and >5 months as long term.

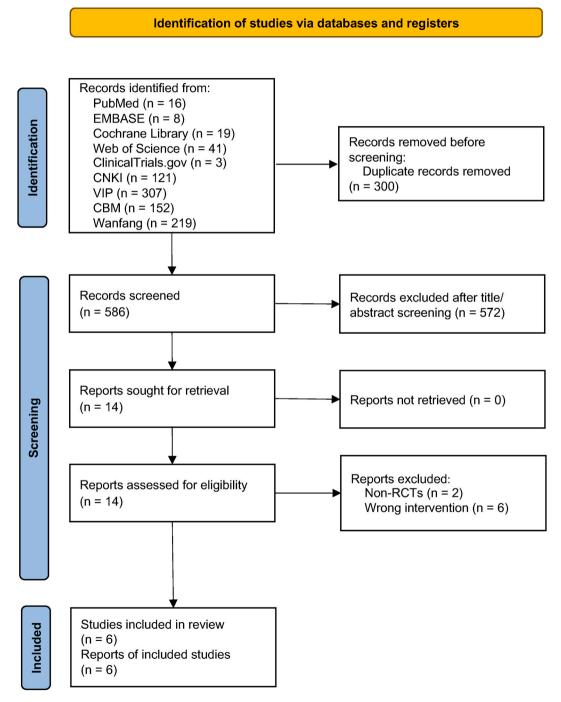


Fig. 1. PRISMA flow diagram.

# Table 1

4

Characteristics of eligible studies.

Author/year C	Country	Study design	No. (G1/ G2)	Age (year)	Disease duration (month)	Intervention measures		Intervention duration		Outcome measures	Follow-up (month)	Adverse events		Jada score	Quality assessment
						G1	G2	G1	G2			G1	G2		
Guo et al. (2015)	China	RCT	32/32	$\begin{array}{c} 65.65 \pm \\ 2.75 \end{array}$	$2.11\pm0.22$	ESWT	SNK + CI	1/2-3d, 3sess.	1sess.	Pain (NRS-101)	1, 3, 5	0	0	3	Moderate
Huang et al. (2014)	China	RCT	30/30	$\begin{array}{c} 45.22 \pm \\ 5.80 \end{array}$	$\textbf{9.9} \pm \textbf{2.89}$	ESWT	SNK + Laser	1/5-7d, 3sess.	1/1w, 3sess.	Pain (Maryland) Function (Maryland)	1, 3, 6	0	0	3	Moderate
Jiang et al. (2020)	China	RCT	30/30	$\begin{array}{l} 45.38 \pm \\ 7.19 \end{array}$	$7.91 \pm 2.79$	ESWT	SNK	2/1w, 6sess.	1/1w, 3sess.	Pain (VAS) Function (AOFAS, Maryland) Curative effect	1, 3	0	0	3	Moderate
Ren et al. (2019)	China	RCT	30/30	$\begin{array}{c} 44.49 \pm \\ 14.03 \end{array}$	$6.37 \pm 3.29$	ESWT	SNK	2/1w, 6sess.	1/5-7d, 3sess.	Pain (VAS) Function (AOFAS) Curative effect	1, 3	0	0	2	Moderate
Wang et al. (2017)	China	RCT	39/36	$\begin{array}{c} 55.63 \pm \\ 5.17 \end{array}$	$10.74 \pm 1.97$	ESWT	SNK	1/3d, 3sess.	NR	Pain (Maryland) Function (Maryland)	1	0	0	3	Moderate
Zhang et al. (2020)	China	RCT	38/38	$\begin{array}{c} 69.79 \pm \\ 3.24 \end{array}$	$8.02\pm4.46$	ESWT	SNK + CI	1/2-3d, 3sess.	1sess.	Pain (VAS) Function (SCL-36) 1L-1β, TNF- αCurative effect	1, 3, 6	0	0	3	Moderate

G = group; w = week; sess. = session; NR = not reported; NRS-101 = 101-point numeric rating scale; VAS = visual analog scale; AOFAS= American orthopedic foot and ankle society. SCL-36 = symptom checklist 36; ESWT: extracorporeal shock wave therapy; SNK: Small needle-knife; CI: Corticosteroid injection.

#### 2.4. Risk of bias assessment in individual studies

Two authors independently assessed the risk of bias using the assessment tool suggested in the Cochrane Handbook for Systematic Reviews of Interventions [17]. Assessment of risk of bias included the following aspects: selection bias (random sequence generation and allocation concealment); performance bias (blinding of participants and personnel); detection bias (blinding of outcome assessment); attrition bias (incomplete outcome data); and reporting bias (selective reporting). The risk of bias for each item was classified as "low", "unclear", or "high". Any disagreements were resolved by consensus or arbitrated by a senior reviewer, if needed. RCT quality was assessed according to the Jadad Scale [18].

# 2.5. Statistical analysis

Meta-analysis was performed using Review Manager version 5.4.1 (Copenhagen: Nordic Cochrane Centre, The Cochrane Collaboration, 2020). The odds ratio (OR) with corresponding 95% confidence interval (CI) was used as an effect measure for dichotomous data, and mean difference (MD) with corresponding 95% CI was used for continuous data. Heterogeneity was measured using the  $I^2$  statistic and p-values. If  $p \le .1$  and  $I^2 \ge 50$ %, a random-effects model was used to pool the outcomes of studies; otherwise, a fixed-effects model was used. Subgroup analysis was used to identify potential sources of heterogeneity in the studies. Sensitivity analysis was performed by removing individual studies, one at a time, and recalculating the pooled estimates to explore the influence of individual RCTs. Because the number of eligible studies was limited, publication bias was not screened for. Cohen's kappa index was calculated to assess inter-rater agreement between the two primary reviewers [19].

# 3. Results

#### 3.1. Study selection and characteristics

The initial literature search retrieved 886 studies for consideration (PubMed, n = 16; Embase, n = 8; Cochrane Library, n = 19; Web of Science, n = 41; ClinicalTrials.gov, n = 3; CNKI, n = 121; VIP, n = 307; CBM, n = 152; and Wanfang, n = 219). No additional studies were included after screening the reference lists of the retrieved studies investigating treatment for PF. After removing 300 duplicates, the titles and abstracts of 586 studies were screened to identify those fulfilling the inclusion criteria, of which 6 were included after a detailed, full-text review [20–25]. The overall agreement between the two primary reviewers for the eligible studies was excellent (kappa = 0.91). The Preferred Reporting Items for Systematic Reviews and Meta-Analyses (i.e., "PRISMA") flow-diagram illustrating the study selection process is presented in Fig. 1.

Characteristics of the eligible studies included in this systematic review and meta-analysis are summarized in Table 1. In total, 395 subjects were included, of which 196 and 199 were allocated to the experimental and control groups, respectively. Three experimental groups treated patients with PF using the small needle-knife alone [22–24], 2 with the small needle-knife plus corticosteroid injection [20,25], and 1 with the small needle-knife plus laser treatment [21]. All control groups were treated with ESWT alone, with frequencies ranging from 3 to 6 sessions (mean, 4 sessions). Three studies reported curative effects [22,23,25], and all reported pain-related outcomes. Function-related outcomes were assessed in all studies except the study by Guo et al. [20].

# 3.2. Risk of bias assessment

The risk of bias assessment of the included RCTs is presented in Fig. 2. All studies described the generation of random sequences,

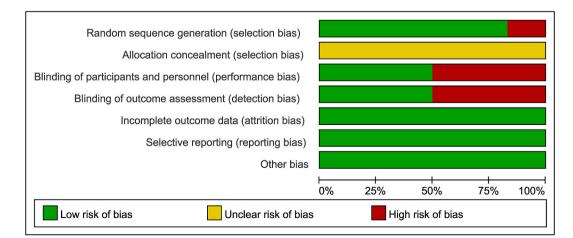


Fig. 2. Risk of bias graph.

including 4 using the random number table method [21,22,24,25], 1 using random lots [20], and 1 reporting randomization without specifying a specific randomization method [23]. Allocation concealment was not described in any of the included studies. The most frequent bias was the inability to blind participants and therapists. None of the outcome data were lost to follow-up. Outcome data for all participants were recorded. Jadad scores ranged from 2 to 3, with five trials scoring 3 (moderate quality) and 1 trial scoring 2 (low quality).

# 3.3. Meta-analysis of measured outcomes

# 3.3.1. Curative effect

Three studies provided data regarding curative effects between the control and experimental groups [22,23,25], and a fixed-effect model was used to report the pooled effect sizes. Meta-analysis revealed no significant differences in the treatment of PF between the small needle-knife and ESWT groups(OR = 1.87; 95 % CI [0.80, 4.37], p = .15), with low heterogeneity between studies ( $\chi^2$  = 1.31, p = .52, I<sup>2</sup> = 0 %) (Fig. 3).

# 3.3.2. Pain intensity

All included studies reported pain-related outcomes [20–25]. In the short-term follow-up subgroup, meta-analysis revealed that the small needle-knife did not yield a significant difference in pain reduction compared with the control groups (MD = 2.20; 95 % CI [-2.77, 7.16], p = .39), and there was considerable heterogeneity between trials ( $\chi^2 = 63.77$ , p < .00001, I<sup>2</sup> = 92 %). In the mid-term follow-up subgroup, meta-analysis revealed that a small needle-knife was more effective than ESWT for pain improvement (MD = 9.11; 95 % CI [5.08, 13.15], p < .00001), with significant heterogeneity ( $\chi^2 = 27.18$ , p < .00001, I<sup>2</sup> = 85 %). The small needle-knife also yielded a significant long-term effect in reducing pain intensity compared with the control group (MD = 10.71; 95 % CI [2.18, 19.25], p < .00001), although heterogeneity was significant ( $\chi^2 = 43.68$ , p < .00001, I<sup>2</sup> = 95 %)(Fig. 4). Given the significant heterogeneity among the studies, subgroup analyses were also performed according to intervention type and quality of the RCTs (Table 2).

The subgroup of combination of small needle-knife plus corticosteroid injection demonstrated significant statistical differences in pain intensity reduction compared with the control group over the 3 follow-up periods (MD = 4.84; 95 % CI [1.33, 8.36], p = .007; MD = 10.99; 95 % CI [8.30, 13.69], p < .00001; MD = 17.87; 95 % CI [15.26, 20.48], p < .00001). However, there was significant heterogeneity in all follow-up periods ( $\chi^2$  = 3.24, p = .07, I<sup>2</sup> = 69 %;  $\chi^2$  = 2.33, p = .13, I<sup>2</sup> = 57 %;  $\chi^2$  = 2.55, p = .11, I<sup>2</sup> = 61 %). In the subgroup of moderate-quality studies, the small needle-knife group was statistically superior to the control group in terms of mid-term and long-term pain reduction (MD = 8.11; 95 % CI [3.95, 12.28], p = .00001; MD = 10.71; 95 % CI [2.18, 19.25], p = .01), although significant heterogeneity persisted ( $\chi^2$  = 23.78, p < .00001, I<sup>2</sup> = 87 %;  $\chi^2$  = 43.68, p < .00001, I<sup>2</sup> = 95 %).

### 3.3.3. Function

Five studies assessed the effect of the small needle-knife versus ESWT in improving patient function [21–25]. The pooled data demonstrated no statistical differences in short-term (MD = 1.34; 95 % CI [-3.19, 5.86], p = .56) and mid-term efficacy (MD = 2.75; 95 % CI [-1.21, 6.72], p = .17) between small-needle knife therapy and ESWT in improving function. There was considerable heterogeneity in the short-term ( $\chi^2$  = 41.82, p < .00001, I<sup>2</sup> = 90 %) and mid-term follow-up studies( $\chi^2$  = 6.39, p = .04, I<sup>2</sup> = 69 %) (Fig. 5). Unfortunately, only 1 RCT reported long-term functional follow-up [21], which was insufficient for meta-analysis.

The only valuable comparison was observed in the subgroup analysis of moderate quality studies, in which the small needle-knife demonstrated a significant mid-term effect in terms of functional improvement over ESWT (MD = 1.58; 95 % CI [0.52, 2.65], p = .004), with low heterogeneity ( $\chi^2 = 0.77$ , p = .038,  $I^2 = 0$  %) (Table 3). In the short-term follow-up subgroup of small needle-knife combined with corticosteroid injection and the mid-term subgroup of low-quality studies, the small needle-knife demonstrated a significant effect on ESWT in improving function (MD = 10.40; 95 % CI [7.38, 13.42], p < .00001; MD = 6.40; 95 % CI [2.56, 10.24], p = .001). However, both subgroup analyses were based on a single study design.

#### 3.4. Adverse events

Six studies did not report data regarding side effects or adverse events during the treatment and follow-up periods.

	Experim	ental	Contr	ol		Odds Ratio	Odds Ratio
Study or Subgroup	Events	Total	Events	Total	Weight	M-H, Fixed, 95% Cl	M-H, Fixed, 95% Cl
Jiang 2020	26	30	25	30	41.5%	1.30 [0.31, 5.40]	
Ren 2019	25	30	23	30	47.7%	1.52 [0.42, 5.47]	
Zhang 2020	37	38	33	38	10.8%	5.61 [0.62, 50.48]	
Total (95% CI)		98		98	100.0%	1.87 [0.80, 4.37]	
Total events	88		81				
Heterogeneity: Chi <sup>2</sup> = '	1.31, df = 2	(P = 0.					
Test for overall effect: Z = 1.45 (P = 0.15)							0.01 0.1 1 10 100 Favours [experimental] Favours [control]

Fig. 3. The meta-analysis results of curative effects.

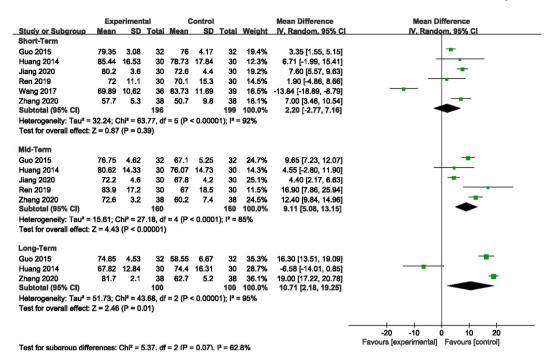


Fig. 4. The meta-analysis results of pain intensity.

# Table 2

Subgroup analysis of pain intensity.

Outcomes	Subgroups	;	Number of Studies	Effects estimate (95 % CI), p value	Heterogeneity
Pain intensity (Short-term follow- up)	SNK	ESWT	3	MD = -1.37; 95 % CI [-15.37, 12.63], p = .85	$\chi^2 = 60.16,  p$ < .00001, $I^2 = 97$ %
	SNK + CI	ESWT	2	$\text{MD} = 4.84;95 \ \% \ \text{CI} \ [1.33,8.36], p = .007$	$\chi^2 = 3.24, p = .07, I^2 = 69~\%$
Pain intensity (Mid-term follow-	SNK	ESWT	2	MD = 9.85; 95 % CI [-2.30, 22.00], p = .11	$\chi^2 = 6.93, p = .008, I^2 = 86 \%$
up)	SNK + CI	ESWT	2	MD = 10.99; 95 % CI [8.30, 13.69], p <.00001	$\chi^2=2.33,p=.13,I^2=57~\%$
Pain intensity (Long-term follow-	SNK	ESWT	0	NR	NR
up)	SNK + CI	ESWT	2	MD = 17.87; 95 % CI [15.26, 20.48], p < .00001	$\chi^2=2.55,p=.11,I^2=61~\%$
Pain intensity (Short-term follow- up)	Jada score $\geq 3$		5	$MD = 2.24;95 \ \% \ CI \ [-3.30,7.77],p = .43$	$\chi^2 = 63.28,p$ < .00001, $I^2 = 94$ %
	Jada score < 3		1	MD = 1.90; 95 % CI [-4.86, 8.66], p = .58	NR
Pain intensity (Mid-term follow- up)	Jada score $\geq 3$		4	MD = 8.11; 95 % CI [3.95, 12.28], p = .00001	$\chi^2 = 23.78,p$ < .00001, $I^2 = 87$ %
	Jada score < 3		1	MD = 16.90; 95 % CI [7.86, 25.94], p = .0002	NR
Pain intensity (Long-term follow- up)	ow- Jada score≥3		3	MD = 10.71;95~%~CI~[2.18,19.25],p = .01	$\chi^2 =$ 43.68, p < .00001, $I^2 = 95$ %
-	Jada score < 3		0	NR	NR

NR = not reported; SNK: Small needle-knife; CI: Corticosteroid; ESWT: extracorporeal shock wave therapy.

#### 4. Discussion

PF is a common public health problem involving the foot and ankle, and mechanical factors are believed to contribute to its main causes. ESWT is the recommended treatment modality in both the APTA and ACFAS guidelines [1,12], and PF is the first orthopedic disease approved by the Food and Drug Administration for treatment with ESWT [26]. Although ESWT is generally considered to be a safe and effective treatment for chronic PF, it is undeniable that some patients cannot tolerate the pain of ESWT, and some continue to experience pain, edema, ecchymosis, hypoesthesia, paresthesia, and even foot spasm after the procedure [27]. If anesthetics are administered during ESWT to reduce intraoperative pain, efficacy may also decrease [28,29]. However, accumulating evidence suggests that needle therapy can also be used to treat PF. An updated meta-analysis suggested a positive effect of trigger-point dry needling in improving pain intensity and pain-related disability in patients with PF of musculoskeletal origin [30]. Some results from

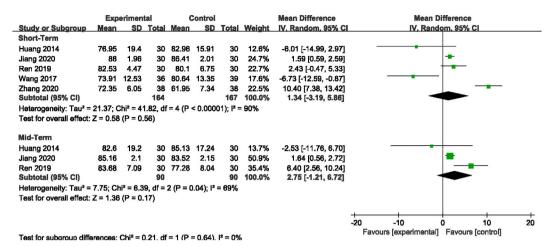


Fig. 5. The meta-analysis results of function.

Tabl	e	3

Subgroup analysis of function.

Outcomes	Subgroups		Number of Studies	Effects estimate (95 % CI), p value	Heterogeneity
Function (Short-term follow-	SNK	ESWT	3	MD = 0.29; 95 % CI [-3.01, 3.60], p = .86	$\chi^2=8.01,p=.02,I^2=75~\%$
up)	SNK + CI	ESWT	1	MD = 10.40; 95 % CI [7.38, 13.42], p < .00001	NR
Function (Mid-term follow-up)	SNK	ESWT	2	MD = 3.65; 95 % CI [-0.96, 8.26], p = .12	$\chi^2 = 5.48, p = .02, I^2 = 82~\%$
	SNK + CI	ESWT	0	NR	NR
Function (Short-term follow-	Jada score	≥3	4	MD = 0.61; 95 % CI [-5.90, 7.13], p = .85	$\chi^2 = 41.78, p < .00001, I^2 = 93 \%$
up)	Jada score	< 3	1	MD = 2.43; 95 % CI [-0.47, 5.33], p = .10	NR
Function (Mid-term follow-up)	Jada score≥3		2	MD = 1.58; 95 % CI [0.52, 2.65], p = .004	$\chi^2 = 0.77,  p = .038,  I^2 = 0 \; \%$
	Jada score	< 3	1	$\text{MD} = 6.40;95 \;\%\;\text{CI}\;[2.56,10.24],p = .001$	NR

NR = not reported.

RCTs revealed that the combination of needle therapy with manipulation, exercise, stretching and ultrasound therapy can enhance the curative effect of PF [31,32]. As a complementary and alternative therapy, the small needle-knife yields a significant clinical effect on musculoskeletal diseases and, as such, has promising prospects for popularization and application. Presently, the results of several RCTs suggest that the small needle-knife can effectively reduce symptoms in patients with PF and improve the levels of inflammatory factors [20–25]. However, there is no evidence-based data for its comparison with ESWT. Finally, the curative effects, pain intensity, and function were analyzed in our study.

Results of the present systematic review and meta-analysis revealed no statistical differences in the curative effect between the small needle-knife and ESWT, although multiple RCTs have reported that the small needle-knife was superior to the ESWT. Previous studies have reported variable success rates of ESWT in terms of pain reduction, ranging from 55 % to 88 %, during short or mid-term follow-ups [33-35], while our study ranged from 76 % to 86 %. We speculate that this difference is related to the selection of different types or intensities of ESWT. In fact, there has been controversy regarding the effectiveness of different types of ESWT, and no consensus has been reached so far [36]. In view of the fact that pain reduction and functional improvement are essential for PF treatment, this meta-analysis found that the small needle-knife was more effective than ESWT for pain improvement in the mid-term and long-term follow-ups. Similar to the findings of the current study, the effect of the small needle-knife on long-term pain improvement was found to be better in other studies [14,15]. PF is caused by excessive load and extension of the plantar fascia, resulting in local stress changes at the attachment of the plantar fascia and calcaneal nodules. A cadaveric study demonstrated that partial plantar fasciotomy can be achieved via percutaneous plantar fascia release with a conventional hypodermic needle without causing any nerve damage [38]. Small needle-knife therapy can also effectively separate and decompress the contracture of diseased tissue, which can fundamentally solve the problem at the heel [37]. This may explain why it provides better mid-term and long-term pain relief. We also observed significant heterogeneity among the included studies. Comprehensive subgroup analyses were performed based on different variables to attenuate the observed heterogeneity. However, heterogeneity did not change according to the length of follow-up, intervention type, or RCT quality. A subgroup analysis found that a small needle-knife combined with glucocorticoid injection helped reduce pain intensity in patients with PF in the 3 follow-up periods. Subgroups analysis of moderate-quality studies revealed that pain reduction at mid-term and long-term follow-up with the small needle-knife was better than that with ESWT. In contrast, functional data demonstrated the advantage of using the small needle-knife at mid-term follow-up only in a subgroup of moderate-quality studies. On the one hand, this may be because the sample size was small and only 2 studies reported function in the

#### C. Feng et al.

mid-term stage, resulting in insufficient, relevant data. However, this may be because the American Orthopaedic Foot and Ankle Score lacks specificity for PF [39]. This further contributed to the low quality of the evidence, and its actual effect may differ from the calculated result.

In addition, compared with ESWT, the small needle-knife has fewer side effects, and patients treated with the small needle-knife can return to the activities of daily living and work sooner. However, the mechanism by which the small needle-knife impacts kinematics, dynamics, muscle activity, and sensory feedback in altering tissue load is unclear and warrants further study.

The present study had some limitations. First, the ESWT parameters and the operational details of the small needle-knife in the included studies were not completely consistent. Second, the 6 included studies were all from China, and only 1 had negative results; as such, clinicians need to be alert to the possibility of bias for these positive results. Third, the lack of blinding in the studies may have contributed to the overestimation of these outcomes. As such, the results should be interpreted with caution.

# 5. Conclusion

This was the first systematic review and meta-analysis to compare the small needle-knife and ESWT for the treatment of PF. Overall, the results demonstrated similar curative effects for the small needle-knife and ESWT in the treatment of PF. However, treatment using the small needle-knife may provide an interesting alternative with better outcomes in terms of pain reduction and functional improvement than ESWT in the management of PF. The results of this systematic review and meta-analysis provide reliable, evidence-based data supporting the use of small needle-knives. The conclusions of evidence-based medicine can promote further scientific research and provide more reliable data. Therefore, high-quality RCTs with multiple centers and large samples are needed to further demonstrate the efficacy of the small needle-knife in the treatment of PF, and continual investigation into the pathological mechanisms underlying PF is also warranted.

# Funding

This work is supported by grants from Natural Science Foundation of Sichuan Province (23NSFSC2296) and the Chinese Medicine Living Inheritance and Talent Team Building Project (CJJ2021048).

# **Data Availability**

Data will be made available on request.

### CRediT authorship contribution statement

Chaoqun Feng: Writing - original draft, Methodology, Conceptualization. Junjie Yao: Writing - original draft, Methodology, Conceptualization. Yizhou Xie: Writing - review & editing. Min Zhao: Methodology, Investigation, Data curation. Youpeng Hu: Visualization, Formal analysis. Ziang Hu: Methodology, Investigation, Data curation. Ruoyan Li: Visualization, Formal analysis. Haoyang Wu: Writing - original draft. Yuanxin Ge: Writing - original draft. Fei Yang: Writing - review & editing. Xiaohong Fan: Writing - review & editing.

#### Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

#### Acknowledgments

Not applicable.

### Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.heliyon.2024.e24229.

#### References

- [1] R.L. Martin, T.E. Davenport, S.F. Reischl, et al., Heel pain-plantar fasciitis: revision 2014[J], J. Orthop. Sports Phys. Ther. 44 (11) (2014) A1–A33.
- [2] C.C. Muth, Plantar fasciitis[J], JAMA 318 (4) (2017) 400.
- [3] P. Beeson, Plantar fasciopathy: revisiting the risk factors[J], Foot Ankle Surg. 20 (3) (2014) 160-165.
- [4] A.E. Fleischer, R.H. Albright, R.T. Crews, et al., Prognostic value of diagnostic sonography in patients with plantar fasciitis[J], J. Ultrasound Med. 34 (10) (2015) 1729–1735.
- [5] W.B. Bai, L.R. Lu, J. Lu, et al., Progress in diagnosis and treatment of plantar fasciitis[J], Chinese Journal of Bone and Joint Surgery 14 (9) (2021) 805–810.

#### C. Feng et al.

- [6] S.M. McClinton, J.A. Cleland, T.W. Flynn, Predictors of response to physical therapy intervention for plantar heel pain[J], Foot Ankle Int. 36 (4) (2015) 408–416.
- [7] H.B. Menz, K.P. Jordan, E. Roddy, et al., Characteristics of primary care consultations for musculoskeletal foot and ankle problems in the UK[J], Rheumatology 49 (7) (2010) 1391–1398.
- [8] K.B. Tong, J. Furia, Economic burden of plantar fasciitis treatment in the United States[J], Am. J. Orthoped. 39 (5) (2010) 227-231.
- [9] M.J. Thomas, R. Whittle, H.B. Menz, et al., Plantar heel pain in middle-aged and older adults: population prevalence, associations with health status and lifestyle factors, and frequency of healthcare use[J], BMC Musculoskelet Disord 20 (1) (2019) 337.
- [10] P.J. Bennett, Types of foot problems seen by Australian podiatrists[J], Foot 22 (1) (2012) 40-45.
- [11] D. Morrissey, M. Cotchett, A. Said J'Bari, et al., Management of plantar heel pain: a best practice guide informed by a systematic review, expert clinical reasoning and patient values, Br. J. Sports Med. 55 (19) (2021) 1106–1118.
- [12] J.L. Thomas, J.C. Christensen, S.R. Kravitz, et al., The diagnosis and treatment of heel pain: a clinical practice guideline–revision 2010[J], J. Foot Ankle Surg. 49 (3, Supplement) (2010) 51–519.
- [13] Y. Zhao, W. Fang, W.K. Qin, Thinking of therapeutic mechanism of small knife needle in treating closed myofascitis[J], Chin. Acupunct. Moxibustion 34 (9) (2014) 907–909.
- [14] B. Rao, T. Fang, F.S. Liu, et al., Meta-analysis of therapy comparison of acupotomy versus block therapy for heel pain[J], Journal of Basic Chinese Medicine 25 (9) (2019) 1280–1284.
- [15] H. Li, H.F. Qiao, P. Yang, et al., The efficacy of acupotomy therapy in calcaneodynia: a systematic review and meta-analysis[J], J. Emerg. Tradit. Chin. Med. 29 (9) (2020) 1546–1551.
- [16] A.M. Ruan, P. Chen, J. Zhou, et al., Meta analysis on clinical effect of acupotomy therapy on calcaneodynia[J], China Medical Herald 17 (27) (2020) 163–167.
  [17] J. Higgins, J. Thomas, J. Chandler, et al., Cochrane Handbook for Systematic Reviews of Interventions version 6.4 (updated August 2023), Cochrane, 2023.
- Available from, https://www.training.cochrane.org/handbook.
- [18] A.R. Jadad, R.A. Moore, D. Carroll, et al., Assessing the quality of reports of randomized clinical trials: is blinding necessary?[J], Contr. Clin. Trials 17 (1) (1996) 1–12.
- [19] J.R. Landis, G.G. Koch, The measurement of observer agreement for categorical data[J], Biometrics 33 (1) (1977) 159-174.
- [20] Q. Guo, J.K. Luo, C.X. Li, et al., Comparison research of extracorporeal shock wave therapy and small needle knife therapy combined with triamcinolone acetonide in elderly patients with calcaneodynia[J], Pract. Geriatr. 29 (4) (2015) 315–317.
- [21] F. Huang, X. Chen, J.P. Mu, et al., Clinical study on calcaneodynia treated with extracorporeal shock wave and laser needle knife[J], World Journal of Integrated Traditional and Western Medicine 9 (4) (2014) 395–398.
- [22] L. Jiang, Clinical Efficacy Observation of Shock Wave Combined with Acupotomy in Treatment of Plantar Fasciitis Type of calcaneodynia[D], Heilongjiang University of Traditional Chinese Medicine, 2020.
- [23] S.J. Ren, L. Jiang, Y.L. Liang, et al., Clinical efficacy observation of shockwave combined with acupotomy in treatment of plantar fasciitis type of calcaneodynia [J], Journal of Liaoning University of TCM (10) (2019) 176–179.
- [24] F.L. Wang, Comparison of clinical effects of extracorporeal shock wave and small needle knife in the treatment of heel pain[J], Medical Journal of Chinese People's Health 29 (20) (2017) 67–68.
- [25] H. Zhang, R. Zhang, M. Ren, Evaluation of VAS scores of small needle knife, extracorporeal shock wave and anti inflammatory analgesic solution in treatment of the elderly heel pain[J], Hebei Medical Journal 42 (12) (2020) 1867–1869.
- [26] J.A. Ogden, R.G. Alvarez, R. Levitt, et al., Shock wave therapy (Orthotripsy) in musculoskeletal disorders[J], Clin. Orthop. Relat. Res. (387) (2001) 22–40.
- [27] P. Kudo, K. Dainty, M. Clarfield, et al., Randomized, placebo-controlled, double-blind clinical trial evaluating the treatment of plantar fasciitis with an extracoporeal shockwave therapy (ESWT) device: a North American confirmatory study[J], J. Orthop. Res. 24 (2) (2006) 115–123.
- [28] H. Gollwitzer, A. Saxena, L.A. DiDomenico, et al., Clinically relevant effectiveness of focused extracorporeal shock wave therapy in the treatment of chronic plantar fasciitis: a randomized, controlled multicenter study[J], J Bone Joint Surg Am 97 (9) (2015) 701–708.
- [29] H. Gollwitzer, P. Diehl, A. von Korff, et al., Extracorporeal shock wave therapy for chronic painful heel syndrome: a prospective, double blind, randomized trial assessing the efficacy of a new electromagnetic shock wave device[J], J. Foot Ankle Surg. 46 (5) (2007) 348–357.
- [30] L. Llurda-Almuzara, N. Labata-Lezaun, T. Meca-Rivera, et al., Is dry needling effective for the management of plantar heel pain or plantar fasciitis? An updated systematic review and meta-analysis[J], Pain Med. 22 (7) (2021) 1630–1641.
- [31] J. Dunning, R. Butts, N. Henry, et al., Electrical dry needling as an adjunct to exercise, manual therapy and ultrasound for plantar fasciitis: a multi-center randomized clinical trial[J], PLoS One 13 (10) (2018) e205405.
- [32] S. Salehi, A. Shadmehr, G. Olyaei, et al., Effects of dry needling and stretching exercise versus stretching exercise only on pain intensity, function, and sonographic characteristics of plantar fascia in the subjects with plantar fasciitis: a parallel single-blinded randomized controlled trial[J], Physiother. Theory Pract. 39 (3) (2023) 490–503.
- [33] L. Tognolo, F. Giordani, C. Biz, et al., Myofascial points treatment with focused extracorporeal shock wave therapy (f-ESWT) for plantar fasciitis: an open label randomized clinical trial[J], Eur. J. Phys. Rehabil. Med. 58 (1) (2022) 85–93.
- [34] R.L. Purcell, I.G. Schroeder, L.E. Keeling, et al., Clinical outcomes after extracorporeal shock wave therapy for chronic plantar fasciitis in a predominantly active duty population[J], J. Foot Ankle Surg. 57 (4) (2018) 654–657.
- [35] G. Metzner, C. Dohnalek, E. Aigner, High-energy Extracorporeal Shock-Wave Therapy (ESWT) for the treatment of chronic plantar fasciitis[J], Foot Ankle Int. 31 (9) (2010) 790–796.
- [36] K.V. Chang, S.Y. Chen, W.S. Chen, et al., Comparative effectiveness of focused shock wave therapy of different intensity levels and radial shock wave therapy for treating plantar fasciitis: a systematic review and network meta-analysis[J], Arch. Phys. Med. Rehabil. 93 (7) (2012) 1259–1268.
- [37] Z. Hz, Principles of Needle-Knife medicine[M], People's Medical Publishing House Co., LTD, Beijing, 2002.
- [38] B. Catal, M. Keskinbora, E.N. Keskinoz, et al., Percutaneous plantar fascia release with needle: anatomic evaluation with cadaveric specimens[J], J. Foot Ankle Surg. 58 (5) (2019) 842–846.
- [39] J.A. Ogden, R.G. Alvarez, R.L. Levitt, et al., Electrohydraulic high-energy shock-wave treatment for chronic plantar fasciitis[J], J Bone Joint Surg Am 86 (10) (2004) 2216–2228.

# Abbreviations

- ACFAS: American College of Foot and Ankle Surgeons APTA: American Physical Therapy Association
- CBM: China Biology Medicine
- CI: Confidence Interval
- CNKI: China National Knowledge Infrastructure
- *ESWT:* Extracorporeal Shock Wave Therapy *MD:* Mean Difference
- OR: Odds Ratio
- PF. Plantar fasciitis
- RCT: Randomized Controlled Trial
- RCTs: Randomized Controlled Trials
- TCM: Traditional Chinese Medicine

VIP: Chongqing VIP Chinese Science and Technology Periodical