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Shock wave therapy for chronic plantar fasciopathy

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Introduction: Relevant data of randomized-controlled studies on shock wave treatment for chronic plantar fasciopathy are statistically and clinically heterogeneous.

Methods: Randomized trials were identified form a current search of the Cochrane Bone, Joint and Muscle Trauma Group specialized register of trials, the Cochrane Central Register of Controlled Trials, MEDLINE and reference lists of articles and dissertations. We identified and retrieved a total of 17 articles. Methodological quality criterial included appropriate randomization, allocation concealment, blinding, number lost of follow-up and intention to treat analysis. Significant heterogeneity between studies precluded pooled analyses. Instead, individual trial results were described in the text.

Results: We identified conflicting results in the 17 studies, involving more than 2100 participants. There was considerable heterogeneity in terms of methodological quality, treatment regimen, patient selection and follow-up period.

Conclusions: With current studies heterogenous in terms of the duration of the disorder; type, frequency and total dose of shock wave therapy (SWT); period of time between SWT; type of management and control group; timing of follow-up and outcomes assessed, a pooled meta-analysis of SWT for chronic plantar fasciopathy was considered inappropriate. Neverhteless, there was a preponderance of well-designed studies showing favourable results. It appears that one should only consider SWT for plantar fasciopathy after more common, accepted and proven non-invasive treatments have failed.

Keywords: plantar fasciopathy/plantar fasciitis/shock wave therapy

Introduction

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The widely used term 'plantar fasciitis' describes a painful heel with inflammation of the plantar fascia at its origin. Although an inflammatory condition is implied by the use of the suffix '-itis', this condition is

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not inflammatory. There is much evidence that this disorder is associated with degenerative changes in the fascia, which may best be classified as a 'fasciosis' rather than fasciitis.[1]

We use the term 'plantar fasciopathy' (PF) in the same way that overuse tendon problems are better named 'tendinopathy'.[2] As management must be based on sound understanding of pathology and physiology, common management approaches for PF should be re-examined.

In the USA, more than 2 million individuals are treated for PF on an annual basis, accounting for 11–15% of professional visits related to foot pain. Up to 10% of the US population will experience plantar heel pain during the course of a lifetime. The cause of PF, with or without a plantar heel spur (Fig. 1), is poorly understood and is probably multifactorial.[3] In runners, PF appears to be associated with overuse, training errors and improper or excessively worn footwear. Sudden increases in weightbearing activity, particularly those involving running, can cause microtrauma to the plantar fascia at a rate that exceeds the body's ability to recover. When PF occurs in sedentary adults, it is often attributable to poor intrinsic muscle strength and poor force attenuation, secondary to acquired pes planus, and compounded by a decrease in the body's healing capacity.[1,4,5]

Diagnosis

The diagnosis of PF is usually straightforward. Pain worse on waking up in the morning or after a period of rest is highly suggestive of PF. The pain often improves after walking, but may recur after prolonged, continued or more stressful activity. The second highly characteristic feature is the location of the pain, usually at the origin of the plantar fascia from the medial tubercle of the calcaneus. The pain may be

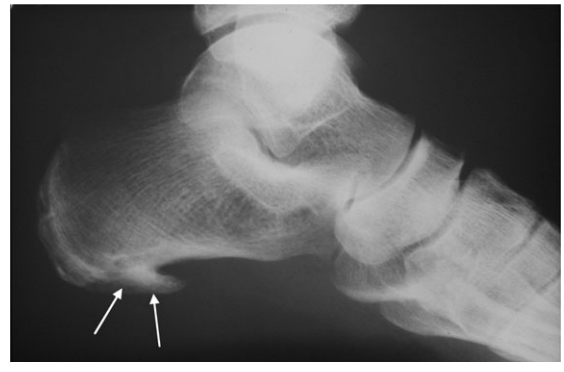

Fig. 1 Radiographically evident heel spur (taken from Rompe[33]).

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aggravated by passive dorsiflexion of the toes in patients with a more severe condition. Heel pad swelling may accompany chronic PF.[4]

Mostly, diagnostic imaging is not helpful in diagnosing PF, but it should be considered to rule out other causes of heel pain or to establish the diagnosis of PF when in doubt. Plain radiographs frequently reveal a heel spur on the inferior surface of the calcaneus. The heel spur may be an incidental finding as heel spurs are not uncommon in asymptomatic individuals. Plain radiographs may also rule out calcaneal stress fracture and other rare bony lesions. When radiographs are normal, bone scans are useful for distinguishing PF from calcaneal stress fracture. Ultrasonography may be useful, although, like other imaging techniques, it is not routinely used. Magnetic resonance imaging can also be used to visualize the plantar fascia with sagittal and coronal images. In PF, a marked increase in the plantar fascial thickness can be detected, together with variable features of moderately increased signal density in the substance of the fascia, and abnormally increased signal intensity in adjacent subcutaneous tissue, and in the calcaneus at the plantar fascial insertion site (Fig. 2).[6–8]

Conservative management

The role of various management strategies should be considered in the light of the self-limiting nature of PF, with >80% of patients experiencing resolution within 12 months, regardless of management. As there are few data from high-quality, randomized, controlled trials that support the efficacy of these conservative management modalities, the most prudent approach is to employ conservative modalities first.

Initiation of conservative management within 6 weeks after onset of symptoms is commonly believed to hasten recovery from PF, but this assumption is unproven. Many physical therapy modalities have been proposed. Support for the use of ice, heat, creams, massage and for strengthening of the intrinsic muscles of the foot rarely comes from controlled data.[9]

Stretching of the calf muscles and plantar fascia and taping or strapping of the foot are commonly recommended, but these interventions have generally been assessed in combination with others, making it difficult to interpret the results of any individual intervention. A recent randomized-controlled trial involving 101 participants showed that heel pain was either eliminated or much improved at 8 weeks in 24 of 46 patients (52%) who undertook stretching the plantar fascia when compared with 8 of 36 patients (22%) who reported such results after participating in a programme to stretch the Achilles tendon.[10,11]

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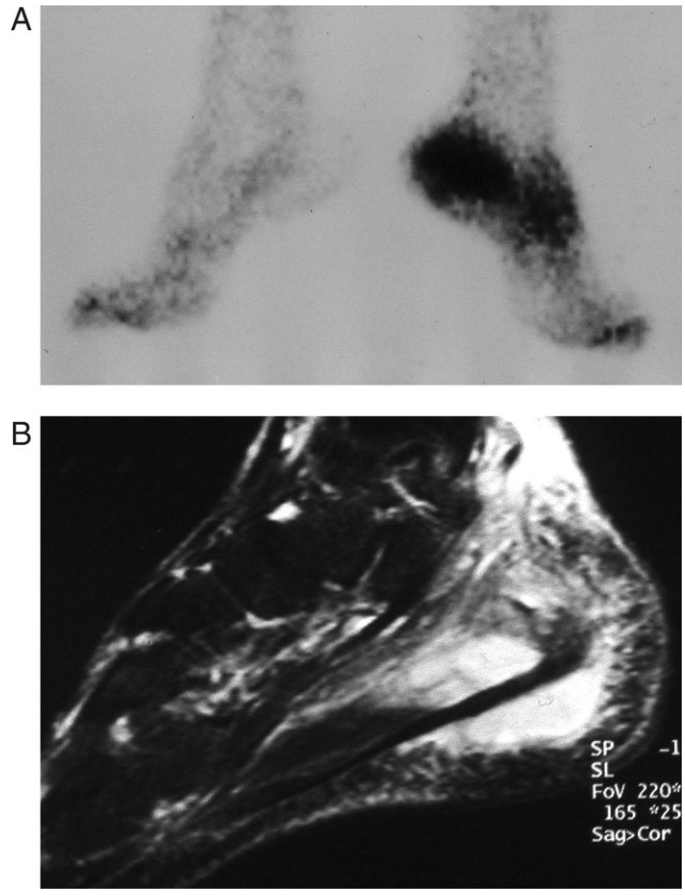

Fig. 2 Infection at the insertion of the plantar fascia after repeated corticosteroid injections. (A) Bone scintigraphy; (B) MRI (taken from Rompe[33]).

Hyland *et al.*[12] examined the effects of a calcaneal and Achilles tendon taping technique versus stretching of the plantar fascia, control (no treatment) and sham taping in a randomized controlled trial in 41 patients. Calcaneal taping was a more effective tool for the relief of plantar heel pain. For the best clinical results at 4 weeks, Osborne and Allison[13] found that taping combined with acetic acid was the preferred option, compared with taping combined with dexamethasone or saline iontophoresis. Radford *et al.*[14] randomly allocated participants to low-Dye taping and sham ultrasound, or to sham ultrasound alone. Subjects receiving low-Dye taping reported a small improvement in 'first-step' pain after 1 week of treatment when compared to those who did not receive taping.

Randomized, placebo-controlled trials did not demonstrate any benefit using magnetic insoles, and small randomized, placebo-controlled trials

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found no significant benefit of ultrasonography, laser treatment, iontophoresis or exposure to an electron-generating device.[6,15]

A wide variety of pre-fabricated and custom-made orthoses, including heel pads and cups that are variously designed to elevate and cushion the heel, provide medial arch support, or both are used to manage PF. There are no data on the efficacy of these devices when compared with placebo or no treatment, and the available data on their efficacy in comparison with those of other interventions are conflicting or limited.[16–20]

Night splints to keep the ankle in a neutral position with or without dorsiflexion of the metatarsophalangeal joints during sleep have been evaluated in three randomized, controlled trials, with conflicting results.[18,21,22]

Non-steroidal anti-inflammatory drugs are used for temporary pain relief, but offer no support for resolution of the condition. Randomized, placebo-controlled trials have not been conducted to assess their benefit.[6,23]

Treatment with corticosteroids resulted in short-term benefits only.[6] One trial, involving 91 participants, showed that 1 ml of prednisolone acetate (25 mg) with 1 ml of local anaesthetic (LA), injected with the use of a medial approach, resulted in significantly greater improvement in pain at 1 month than did injection of LA alone. At 3 and 6 months, there were no differences between the groups in pain measures, but a high rate of loss to follow-up precluded the drawing of conclusions.[24]

In recent controlled trials, botulinum toxin A injections led to superior results when compared with placebo.[25,26] No side effects were noted.

Surgical management

Despite the number and variety of conservative management modalities available, ~20–30% of those patients treated with traditional measures progress to a chronic condition.[4]

Surgical options for the management of PF resistant to conservative management include endoscopic and open fasciotomy. In various case series, favourable outcomes were reported in >75% of patients who underwent surgery, although the recovery times varied and were sometimes months, and persistent pain occurred in up to a quarter of patients who were followed for an average of ≥2 years. Recent uncontrolled reports on open complete plantar fasciotomy in conjunction with tarsal tunnel release for chronic PF with neuritic symptoms and on open partial plantar fasciotomy with release of the nerve to the abductor digiti minimi showed 90% and 77% rates of good and

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excellent results, respectively, after >2 years of follow-up.[27,28] Davies *et al.*[29] found less favourable results. In their uncontrolled prospective study, 43 patients (47 heels) underwent decompression of the nerve to abductor digiti minimi with partial plantar fascia release for intractable chronic PF. All the patients had failed to respond to non-operative management. At 31 months, only 20 of 41 patients (49%) were totally satisfied with the outcome. Weil *et al.*[30] reviewed the results of 40 feet treated with shock wave therapy (SWT) after a mean follow-up time of 8 months. The results of a similar demographic class of patients having undergone a percutaneous plantar fasciotomy were compared with the results of this cohort of shock wave patients. About 82% of the patients treated with SWT reported successful outcome when compared with 83% with a percutaneous plantar fasciotomy.

Potential complications of surgery include transient swelling of the heel pad, calcaneal fracture, injury of the posterior tibial nerve or its branches and flattening of the longitudinal arch with resultant midtarsal pain. Cheung *et al.*[31] recommended release of <40% of the plantar fascia to minimize the effect on arch instability and to maintain normal foot biomechanics.

Most surgical studies, however, are uncontrolled, non-randomized and use a variety of outcome criteria. For this reason, it is difficult to accurately assess the results of surgical intervention. Controlled trials are required to verify these findings. Patient expectations should be considered in pre-operative counselling.[6]

Shock wave treatment

Physical principles

A shock wave is defined as an acoustic wave at the front of which pressure rises from the ambient value to its maximum within a few nanoseconds. Typical characteristics are high peak-pressure amplitudes (500 bar) with rise times of <10 ns, a short lifecycle (10 ms) and a frequency spectrum (16 Hz–20 MHz) ranging from the audible to the far ultrasonic level. This rapid rise is followed by periods of pressure dissipation and negative pressure before gradually returning to the ambient pressure (Fig. 3). The shock wave entering the tissue may be reflected or dissipated, depending on the properties of the tissue. The energy of the shock wave may act through mechanical forces generated directly or indirectly via cavitation.

Although the focal point or area of maximal therapeutic effect is at some fixed distance away from the shock wave generator in traditional electrohydraulic, electromagnetic and piezoelectric machines, the radial

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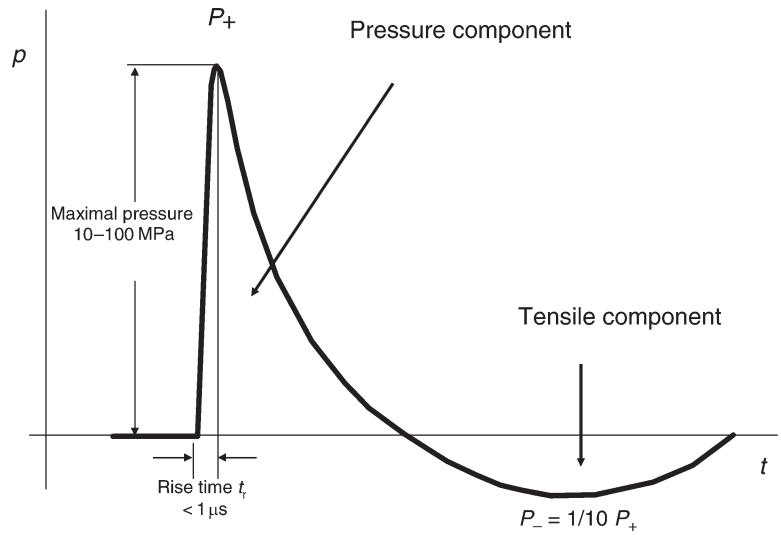

Fig. 3 A typical shock wave is characterized by a positive pressure step (P_+) having an extremely short rise time t_r, followed by an exponential decay to ambient pressure. Its duration is typically some hundred nanoseconds (taken from Rompe[33]).

principle has a focal point that differs from the other three technologies. The focal point of the radial principle is directly at the device–skin interface and is dispersed in a megaphone fashion from the head of the radial device.

Independent of the device, many physical effects depend on the energy involved. The concentrated shock wave energy per focal area is one important variable. Physicist use the term 'energy flux density' (unit: mJ/mm^2) to illustrate the fact that the shock wave energy flows through an area with perpendicular orientation to the direction of propagation. Low-energy flux application (<0.2 mJ/mm^2) is generally tolerated well, with mild-to-moderate discomfort. High-energy flux applications (>0.2 mJ/mm^2) usually require local or regional anaesthesia.

Localizing the delivery of SWT is another factor that influences the outcome of SWT and makes comparison of studies difficult. Two methods of localization are commonly used. Image-guided focusing may be accomplished via guided ultrasound, fluoroscopy or computed tomography. These methods of focusing allow delivery of shock waves to a very specific area. Unfortunately, the pain-generating area of pathology may not correlate with these anatomic locations. A second method of localization is clinical focusing, in which the shock waves are directed to the most painful area with the aid of patient feedback. This method is the most reliable at directing the shock waves to the painful region. Clinical focusing allows adjustment of the shock wave

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direction on a patient-by-patient basis. Because of the need for patient input, no anaesthetics can be used with this method, a fact that limits the amount of energy that may be delivered through the shock wave. High-energy shock waves are poorly tolerated in the absence of anaesthesia.

To be effective, shock waves must be administered to the correct anatomic location, and sufficient shock wave energy must be delivered to effect the cellular and subcellular histologic, structural and/or biochemical changes that will improve patients' symptoms. Comparison of studies using different forms of shock wave focusing must be performed, knowing that SWT may have been delivered to different anatomic and pathologic areas.[32–34]

Effects on musculoskeletal tissue

The rationale for SWT in clinical use is inhibition of pain receptors and stimulation of soft-tissue healing.[32]

Haake *et al.*[35–37] repeatedly failed to provide evidence for a specific biological response when evaluating changes in the activity of spinal cord neurones in a rat model after shock wave application. The results of these experiments are contradicted by recent studies using more sophisticated techniques.[38–45] In the periphery, SWT leads to selective dysfunction of sensory unmyelinated nerve fibres without affecting the large myelinated nerve fibres responsible for motor function. For high-energy treatment, this selective destruction of sensory unmyelinated nerve fibres within the focal zone of SWT may contribute to clinically evident long-term analgesia. For low-energy application, analgesia may result from shock wave-induced destruction of sensory nerve fibres with liberation of neuropeptides, such as calcitonin gene related peptide (CGRP), resulting in a local neurogenic inflammation in the focal area with subsequent prevention of sensory nerve endings from re-innervating this area. Centrally, the findings of a reduction in the number of neurons immunoreactive to CGRP and substance P without a reduction in the total number of neurons within the lower lumbar dorsal root ganglia (DRG) probably are a secondary effect following the decrease in the number of sensory nerve fibres in the focal zone of shock wave application. Similar results were reported for neurons immunoreactive for CGRP within the DRG of the mouse after transection of the sciatic nerve. Therefore, both the peripheral and central nervous system may play a pivotal role in mediating shock wave-induced long-term analgesia. In the only human experiment, Klonschinski *et al.*[40] investigated whether the biological effects of SWT differ between application with and without an LA. SWT was applied

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to the skin either after local pre-treatment with lidocain cream LA or without LA to the corresponding location of the contralateral limb. Increasing energy flux density led to a significant increase of pain. LA significantly attenuated this pain and significantly inhibited C-fibre activity, with a significant reduction in local vasodilation. Reduction in vasodilation correlated positively with the amount of energy flux density applied. SWT without LA resulted in a dose-dependent lower pressure pain threshold, i.e. sensitization, than did SWT with LA. Together, SWT in a dose-dependent fashion activated and sensitized primary afferent nociceptive C-fibres in human skin. LA substantially altered the biological responses after SWT.

With regard to soft-tissue healing, Taiwanese research groups[46–48] investigated the effect of low-energy SWT on neovascularization at the tendon–bone junction in rabbits. Low-energy SWT (LESWT) produced a significantly higher number of neo-vessels and angiogenesis-related markers, including endothelial nitric oxide synthase, vessel endothelial growth factor and proliferating cell nuclear antigen than the control without SWT. Only an optimal number of 200–500 impulses of LESWT promoted healing of Achilles tendinopathy by inducing TGF-beta1 and IGF-I and increased the contact between bone and tendon as well as tensile strength.

Side effects

High-energy SWT (HESWT) can potentially cause injury to tendon, whereas low-energy applications failed to produce injury. In the rabbit, HESWT (0.6–0.9 mJ/mm^2) damaged the tendon and paratenon, including an increase in the diameter and fibrinoid necrosis, as well as an inflammatory reaction in the peritendinous area. These changes were still evident 4 weeks after shock wave application.[49,50] Application of high-energy shock waves (1.2 mJ/mm^2) to a calcified turkey gastrocnemius tendon resulted in significant ($P < 0.05$) impairment of tensile strength, whereas shock waves of 0.6 mJ/mm^2 had no effect on tensile strength.[51]

SWT is often used near articular cartilage. In a study of the effect of SWT on normal rabbit articular cartilage, Vaterlein *et al.*[52] reported no changes in the cartilage on macroscopic, radiologic or histologic examination at 3–24 weeks after administration of 2000 pulses of shock waves at 1.2 mJ/mm^2. This amount of energy is much higher than what used clinically in any human study. Articular cartilage injury has not been reported after SWT in humans.

In human application, depending largely on the amount of energy flux density used, SWT is painful, may aggravate symptoms for a short

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period of time and may induce reversible local swelling, reddening and formation of haematoma.

Clinical results

Considerable controversy has emerged regarding the use of SWT for plantar heel pain.[34,53–56]

Randomized trials were identified from a current search of The Cochrane Musculoskeletal Injuries Group specialized register of trials (December 2006), the Cochrane Central Register of Controlled Trials (The Cochrane Library issue 3, 2003), MEDLINE (from 1966 to December 2006), EMBASE (from 1982 to September 2006) and reference lists of articles and dissertations. Only English, French and German language publications were considered. Further citations were sought from the reference sections of papers retrieved and from contacting experts in the field to identify studies 'in the pipeline'.

In December 2006, it was decided to include the following search terms for specific interventions. The reference lists of all identified studies and correspondence relating to those studies were also searched:

- Shock wave therapy or shockwave therapy or shock wave treatment;
- AND plantar fasciitis or plantar heel pain or plantar fasciosis or plantar fasciopathy;
- AND random$ (Table 1).

Following Thomson *et al.*[56] we considered all randomized controlled trials of plantar heel pain treatments for inclusion in the review. Trials comparing SWT with placebo or another treatment modality or different doses of SWT were considered. Participants with a clinically

Table 1 Summary of the search strategy used and the number of hits for each item and total

Search number	Search term	No. of hits
1	Shock wave therapy	4020
2	Shockwave therapy	944
3	Shock wave treatment	4094
4	Plantar fasciitis	428
5	Plantar heel pain	307
6	Plantar fasciopathy	6
7	Plantar fasciosis	1
7	Random*	494 449
8	No. 1 or 2 or 3	4883
9	No. 4 or 5 or 6 or 7	574
10	Nos. 7 and 8	426
11	Nos. 7 and 9	77
12	Nos. 10 and 11	34

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confirmed diagnosis of plantar heel pain were included. Adult participants in any trial whether they were part of the general population, athletes or individuals with seronegative arthropathies and enthesopathies were also considered for inclusion. Any age group was admissible. We excluded trials evaluating treatments for plantar heel pain arising from calcaneal fractures, calcaneal tumours, previous surgery for plantar heel pain or posterior heel pain.

Sixteen investigations were retrieved. Full articles describing trials were obtained, and two of the authors independently applied the inclusion and exclusion criteria to each trial and then extracted data regarding details of the patients (number, mean age and age range and inclusion and exclusion criteria), details of the interventions and nature and timing of outcome measures. Disagreements were resolved by discussion of the articles by the two reviewers. We wrote to trialists for additional information on trial methodology (method of randomization) and results (usually requests for data not presented in the original reports, such as standard deviations or some other measure of variance).

The methodological quality of included trials was assessed based upon whether the trials met key criteria (appropriate randomization, allocation concealment, blinding, number lost to follow-up and intention to treat analysis). Assessment was done according to Chalmers *et al.*[57] with two evaluation forms that include 29 individually scored items, allowing a maximum score of 100 (Table 2), and according to Jadad *et al.*[58] attributing to each trial a quality score out of a maximum of 6 points (Table 3).

This addressed the following questions.

(i) Was the generation of randomization sequence described?

(ii) Was the method of allocation concealment described?

(iii) Was an intention to treat analysis used?

(iv) What number of patients was lost to follow-up?

(v) Was the outcome assessment blind?

(vi) Was the patient blind to treatment allocation?

For better understanding, we categorized the 17 identified trials, involving a total of more than 2100 participants, depending on the reported type of energy flux density applied (low- versus high-energy) and the management regimen used for the control groups.

LESWT:

placebo control (7 trials; 909 participants);

treatment control: SWT under LA (2 trials; 146 participants);

treatment control: low-number SWT (3 trials; 328 participants);

treatment control: corticosteroid injection (1 trial; 151 participants).

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Table 2 Summary of 17 randomized controlled trials on the effectiveness of shock wave treatment for PF; quality score according to Chalmers *et al.*[57]

Reference	Number	Method of management	Primary outcome measure	Conclusions	Quality score%
Buch *et al.*[75]	150	Single HESWT versus sham No LA Chronic patients	Pain	SWT was more effective than sham therapy at the primary follow-up	83
Buchbinder *et al.*[69]	166	Repetitive LESWT (3 sessions of 2000 or 3 sessions of 2500 shocks; variable energy per shock applied) versus repetitive LESWT (3 sessions of 100 shocks), period between applications: 1 week No LA Acute and chronic patients	Pain	No significant difference between groups after the end of treatment and at the follow-up	82
Cosentino *et al.*[60]	60	Repetitive (6x) SWT versus sham, variable energy per shock applied, period between applications: 1 week LA Chronic patients	Pain	SWT was more effective than sham therapy at the primary follow-up	63
Haake *et al.*[65]	272	Three sessions of LESWT versus sham, period between applications: 1 week LA Chronic patients	Pain	No significant difference between groups after the end of treatment and at the follow-up	90
Krischek *et al.*[67]	50	Repetitive LESWT (3 sessions of 500 shocks) versus repetitive LESWT (3 sessions of 100 shocks), period between applications: 1 week No LA Chronic patients	Pain	No significant difference between groups at primary follow-up	45

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Table 2 *Continued*

Reference	Number	Method of management	Primary outcome measure	Conclusions	Quality score%
Kudo *et al.*[77]	114	Single HESWT with RA versus sham RA Chronic patients	Pain	SWT was more effective than sham therapy at the end of treatment and at the follow-up	88
Labek *et al.*[66]	60	Three sessions of LESWT, with LA) versus repetitive LESWT (3x, without LA), period between applications: 1 day No LA versus LA Chronic patients	Pain	SWT without LA was more effective than SWT with LA at the primary follow-up	51
Liang *et al.*[78]	50	Repetitive HESWT versus repetitive LESWT No LA Chronic patients	Pain	No difference between groups	64
Malay *et al.*[63]	172	Single LESWT versus sham No LA Chronic patients	Pain	SWT was more effective than sham therapy at the end of treatment and at the follow-up	84
Ogden *et al.*[71,72]	302	Single HESWT versus sham Regional versus LA Chronic patients	Pain	SWT was more effective than sham therapy at the primary follow-up	74
Porter *et al.*[70]	151	Three sessions of LESWT plus stretching versus corticosteroid injection plus stretching, period between applications: 1 week No LA Acute and chronic patients	Pain	No significant difference between groups after the end of treatment and at the follow-up	61

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Table 2 *Continued*

Reference	Number	Method of management	Primary outcome measure	Conclusions	Quality score%
Rompe *et al.*[59]	30	Three sessions of LESWT versus sham, period between applications: 1 week No LA Chronic patients	Pain	SWT was more effective than sham therapy at the primary follow-up	47
Rompe *et al.*[68]	112	Three sessions of 1000 shocks LESWT versus 3 sessions of 10 shocks LESWT, period between applications: 1 week No LA Chronic patients	Pain	SWT with 3 sessions of 1000 shocks was more effective at the primary follow-up	68
Rompe *et al.*[61]	45	Three sessions of LESWT versus sham, period between applications: 1 week No LA Chronic patients	Pain	SWT was more effective than sham therapy at the end of treatment and at the follow-up	85
Rompe *et al.*[45]	86	Three sessions of LESWT with LA versus 3 sessions of LESWT without LA, period between applications: 1 day No LA versus LA Chronic patients	Pain	SWT without LA was more effective than SWT with LA at the primary follow-up	77
Speed *et al.*[64]	88	Three sessions of LESWT versus sham, period between applications: 4 weeks No LA Chronic patients	Pain	No significant difference between groups after the end of treatment and at the follow-up	71
Weil *et al.*[62]	242	Three sessions of 2000 shocks LESWT versus sham, period between applications: 1 week No LA Chronic patients	Pain	SWT was more effective than sham therapy at the primary follow-up	68

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Table 3 Summary of 17 randomized controlled trials on the effectiveness of shock wave treatment for PF; quality score according to Jadad *et al.*[58]

Author	Randomization sequence	Allocation concealment	Assessor blinded	Patient blinded	Loss to follow-up at primary endpoint%	Intention to treat	Quality score
Buch *et al.*[75]	Yes	Yes	Yes	Yes	2.7 (4 of 150)	No	5
Buchbinder *et al.*[69]	Yes	No	Yes	No	3.6 (6 of 166)	Yes	4
Cosentino *et al.*[60]	No	No	Yes	Not described	Not described	No	1
Haake *et al.*[65]	Yes	Yes	Yes	Yes	5.8 (16 of 272)	Yes	6
Krischek *et al.*[67]	No	No	Yes	No	0 (0 of 50)	No	2
Kudo *et al.*[77]	Yes	Yes	Yes	Yes	7.9 (9 of 114)	Yes	6
Labek *et al.*[66]	No	Yes	Yes	No	6.6 (4 of 60)	No	4
Liang *et al.*[78]	No	No	Yes	No	1.8 (1 of 53)	No	2
Malay *et al.*[63]	Yes	Yes	Yes	Yes	11.6 (20 of 172)	Yes	6
Ogden *et al.*[71,72]	No	No	Yes	Yes	1.5 (4 of 260)	No	3
Porter Shadbolt[70]	No	No	Yes	No	5.3 (7 of 132)	No	2
Rompe *et al.*[59]	No	No	Yes	Yes	16.7 (5 of 30)	No	1
Rompe *et al.*[68]	Yes	No	Yes	No	13.4 (15 of 112)	No	4
Rompe *et al.*[61]	Yes	No	Yes	Yes	13.3 (6 of 45)	No	4
Rompe *et al.*[45]	Yes	No	Yes	No	4.6 (4 of 86)	Yes	4
Speed *et al.*[64]	No	No	Yes	Yes	13.6 (12 of 88)	Yes	4
Weil *et al.*[62]	No	No	Yes	Yes	Not described	Yes	5

HESWT:

placebo control (3 trials; 566 participants);

low-energy treatment (1 trial; 53 participants).

Low-energy SWT

LESWT: placebo control

In the first controlled study ever to explore the pain-alleviating effect of LESWT in chronic PF, 30 patients received 3 sessions of 1000 impulses of 0.06 mJ/mm^2 at weekly intervals or placebo, without LA. Twelve weeks after the last treatment, patients experienced a significant alleviation of pain and improvement of function in the treatment group.[59] In 60 patients undergoing 6 sessions of 1200 low-energy impulses at weekly intervals or placebo, without LA, a significant decrease in visual analogue scale (VAS) was only seen in the treatment group at 12 weeks.[60] One study evaluated the outcome of LESWT of chronic PF in runners. Forty-five running athletes were either assigned to a treatment group that received 3 sessions of 2100 impulses of 0.09 mJ/mm^2 or placebo, without LA. At 24 weeks, 60% versus 27% of patients reported >50% reduction of pain on first walking in the morning (Fig. 4).[61] Using low-energy radial SWT, 242 randomized patients received active treatment with 3 sessions of 2000 pulses at weekly intervals or sham, without LA. About 57% versus 40% achieved successful alleviation of their morning pain.[62] Malay *et al.*[63] compared

Fig. 4 Shock wave treatment for PF (taken from Rompe[33]).

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the outcomes of 172 participants treated with a new planar SWT device with those treated with placebo. SWT with 3800 shocks or placebo was administered without LA. The amount of energy delivered was not specified in this study. At 12 weeks, 43% versus 20% of patients reported a 50% decrease of pain from baseline.

The studies from Rompe *et al.*[59] and Cosentino *et al.*[60] used image guidance (fluoroscopic or ultrasonic), whereas Rompe *et al.*[61], Weil[62] and Malay *et al.*[63] relied on clinical focusing to the point of maximum tenderness. Image guidance was used to direct the shock wave to the tip of the calcaneal spur, followed by clinical focusing of the shock wave to the area of maximal pain.

In all the trials described earlier, the repetitive treatments were administered at weekly intervals, and none used any form of LA. Follow-up was at least 12 weeks after SWT.

Speed *et al.*[64] changed the therapeutic regimen described earlier. Eighty-eight adults with chronic PF received either 3 sessions of 1500 impulses of 0.12 mJ/mm^2 or sham therapy without LA, at monthly intervals. Follow-up was 4 weeks only: 37% and 24% of the groups showed a 50% improvement from baseline with respect to pain (not significant). Haake *et al.*[65] also deviated from the therapeutic regimen described earlier. Two hundred and seventy-two patients with chronic PF were allocated to SWT with 3 sessions of 4000 impulses of 0.08 mJ/mm^2 under LA or placebo SWT under LA, at weekly intervals. The success rate 12 weeks after intervention was 34% in the SWT group and 30% in the placebo group (not significant).

LESWT: treatment control: shock wave application under LA

Labek *et al.*[66] were the first to focus on a possible interference of LA on the outcome after SWT. Sixty patients with a chronic PF were enrolled in a triple-arm pilot trial. Patients received either active SWT without LA [3 sessions of 1500 shocks of 0.09 mJ/mm^2 (group A)], SWT with LA [3 sessions of 1500 shocks of 0.18 mJ/mm^2 (group B)] or SWT with LA [3 sessions of 1500 shocks of 0.09 mJ/mm^2 (group C)], at weekly intervals. At 6 weeks, a reduction in pain of at least 50% was achieved in 60% of group A, 36% of group B and 30% of group C. LA significantly influenced the clinical results after LESWT in a negative way. Higher energy levels could not balance the disadvantage of this effect.

A confirmatory study was based on Labek's data. Eighty-six patients with chronic PF were randomly assigned to receive either 3 sessions of 2000 pulses of 0.09 mJ/mm^2 without LA, at weekly intervals, or identical SWT with LA. At 12 weeks, significantly more patients of

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group I achieved 50% reduction in pain when compared with group II (67% versus 29%).[45]

As in the experimental study from Klonschinski *et al.* (discussed earlier), LA applied prior to treatment reduced the efficiency of LESWT. The results of these trials directly question the negative findings of the placebo-controlled study from Haake *et al.*,[65] who had applied LESWT under LA, concluding that LESWT was ineffective in the management of chronic PF.

LESWT: treatment control: low number of shock waves

In 1998, Krischek *et al.*[67] enrolled 50 chronic patients; the first group receiving 3 sessions of 500 impulses and the second group 3 sessions of 100 impulses of 0.08 mJ/mm^2, at weekly intervals, under fluoroscopic control. The authors described a significantly better result after the treatment with 3 sessions of 500 impulses at 12 weeks. Rompe *et al.*[68] examined 112 patients with chronic PF who were allocated to either 3 sessions of 1000 pulses or 3 sessions of 10 pulses of 0.08 mJ/mm^2 under fluoroscopic-guided clinical focusing, at weekly intervals. At 24 weeks, 57%, compared with 10%, had an excellent or good result. Buchbinder *et al.*[69] enrolled 166 subjects with acute or chronic PF in a trial to determine whether ultrasound-guided SWT reduced pain in patients with PF. Patients were randomly assigned to receive either ultrasound-guided SWT with 3 sessions of 2000 or 3 sessions of 2500 shocks of 0.02–0.33 mJ/mm^2, given weekly for 3 weeks, or 3 sessions of 100 shocks of 0.02 mJ/mm^2. At 12 weeks, there were significant improvements in overall pain in both the active and the placebo groups, with no statistically significant differences in the degree of improvement between treatment groups for any measured outcomes.

Following Sems *et al.*,[34] the study of Buchbinder *et al.*[69] was very similar to that of Rompe *et al.*[68] in regard to the time between treatments. It was completely different in regard to the amount and energy of shock waves delivered. Although in Rompe *et al.*'s study, all patients in the treatment group received 3 sessions of 1000 impulses of 0.08 mJ/mm^2, the patients in Buchbinder *et al.*'s study underwent SWT of high variability, 2000 or 2500 impulses, 0.02–0.33 mJ/mm^2 (a 16-fold variation). At first sight, the patients in the two trials had similar mean duration of symptoms, but the study by Buchbinder *et al.* included patients experiencing symptoms for as little as 6 weeks, whereas Rompe *et al.*'s minimum was 6 months. The trial of Buchbinder *et al.* included patients with plantar heel pain and ultrasonic evidence of thickening of the plantar fascia. Rompe *et al.*'s criteria were pain at the insertion of the plantar fascia on the medial calcaneal tuberosity. These patient populations were not necessarily comparable. Although both studies used image guidance for the localization technique, the shock

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waves were focused on different areas. Rompe *et al.* focused the shock waves on the tip of the calcaneal spur followed by clinical focusing, whereas Buchbinder *et al.* used ultrasound to focus on the plantar fascia. This difference may be several millimetres, resulting in the delivery of shock waves to two very different areas. In this connection, Maier *et al.*[8] had reported that a pre-therapeutic finding of calcaneal bone marrow oedema on magnetic resonance imaging was a good predictor of successful outcomes with SWT. There was no correlation, however, between thickness of the plantar aponeurosis, soft-tissue signal changes or soft-tissue contrast uptake with clinical outcomes. This may explain the differences in outcomes in these two trials. Therefore, as Buchbinder *et al.*'s trial focused on the thickest part of the plantar fascia, this may be another explanation why the SWT aimed at the thickest part of the plantar fascia was not as effective as the treatment aimed at the calcaneal spur.

LESWT: treatment control: corticosteroid injection

Porter and Shadbolt[70] reported a comparison of the efficacy of LESWT and intralesional corticosteroid injection for the treatment of PF present for at least 6 weeks. One hundred and thirty-two patients were enrolled, 19 non-randomized patients acted as a surrogate control group. All patients performed a standardized Achilles tendon and plantar fascia stretching programme. The patients were randomly allocated to either SWT with 3 sessions of 1000 shocks of 0.08 mJ/mm^2 without LA, at weekly intervals, or a single corticosteroid injection. Nineteen non-randomized patients performed a standardized stretching programme only. At 12 weeks, the tenderness values at the plantar fascia insertion were significantly better after the corticosteroid injection than both after SWT and in the controls. SWT again was significantly better than the control. At 12 months after the end of treatment, patients who received either a single corticosteroid injection or SWT had similar levels of average pain at the low end of the scale, whereas non-randomized patients had significantly higher levels of pain. Of note, 10% of the patients who received a corticosteroid injection experienced transient post-injection pain which lasted up to 2 weeks.

High-energy SWT

HESWT: placebo control

Ogden *et al.*[71] performed a placebo-controlled trial of a single SWT with 1500 shocks of 0.22 mJ/mm^2, using ankle-block anaesthetic, in 302 patients with chronic PF. At 12 weeks, 62% versus 43% of the

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patients had a minimum 50% improvement over baseline in investigator assessment of pain. Outcomes of three other criteria also favoured the active treatment, but none was statistically significant. A further report[72] was considered a re-analysis of the previously published trial with substantially different sample sizes.[73,74] Although the results appeared similar, the authors now reported a significant difference in the mean score for the subjective self-assessment of pain at 12 weeks favouring the active treatment group. Twelve weeks after treatment, 47% of the actively treated patients had a completely successful result when compared with 30% of the placebo-treated patients. However, statistical comparison of mean scores for subjective self-assessment of pain at 12 weeks on the basis of the data published in the original trial report submitted to the US Food and Drug Administration demonstrated no significant difference between groups.

Buch *et al.*[75,76] examined 150 patients in another multicentre placebo-controlled study to assess the clinical safety and effectiveness of HESWT for chronic PF. The active group underwent a single application of 3800 pulses of 0.36 mJ/mm^2 or sham treatment, under regional anaesthesia. Ultrasound guidance was used. At 12 weeks, 62% of the patients in the active group reported good or excellent outcome and 40% in the placebo group (significant).

Using the same device, Kudo *et al.*[77] treated 114 patients with chronic PF. Treatment consisted of 3800 high-energy shock waves of 0.36 mJ/mm^2 in a single session under regional anaesthesia versus placebo treatment. At 12 weeks, 47% versus 23% of patients reported a >60% improvement from baseline in VAS scores for pain during the first few minutes of walking. In total, 43% versus 30% reported a good or excellent outcome, a statistically significant difference.

HESWT: treatment control: LESWT

Liang *et al.*[78] reported a randomized controlled pilot trial to assess the effects of HESWT versus LESWT in patients with chronic PF. A sample of 52 volunteers with chronic PF was treated with either high- or low-energy levels (3 sessions of 2000 shocks, either 0.12 mJ/mm^2 or 0.56 mJ/mm^2, weekly intervals). Outcome was assessed at 3 and 6 months, with successful treatment defined when the subject reported cured or greatly improved on the 6-point Likert scale, and no need for any other treatment. For the high-intensity group, the successful rate was 67.4% and 46.5% and for the low-energy group 41.2% and 61.8% There was no difference in success between the two groups.

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Concluding remarks

Up to 80–90% of patients with PF will experience symptomatic improvements with conservative management over 6 months. Surprisingly, there is little debate over the most effective conservative management options for PF, although there is an inappropriate lack of conclusive results from adequately designed randomized controlled trials. However, continued controversy abounds regarding the proper method of managing the 10–20% of PF patients who do not respond to conservative care in a timely fashion.

In such patients, the key question is whether one should plan SWT or progress to surgery.

Over the years, many different surgical procedures have been described for this specific group of patients. Procedures include sectioning the plantar fascia with removal of bone spur; sectioning the plantar fascia only; decompressing a branch of the lateral calcaneal nerve with partial sectioning of the plantar fascia; minimally invasive techniques with or without an endoscope and in-step fasciotomies. In uncontrolled case series, favourable outcomes were reported in $>75\%$ of patients who underwent surgery, although the recovery times varied and were sometimes months, and persistent pain occurred in up to a quarter of patients followed for an average of at least 2 years. To the best of our knowledge, there are no published controlled trials of surgery for PF. Without a control group, it is not possible to draw any conclusions about the value of surgery. Surgery has risks such as transient swelling of the heel pad, calcaneal fracture, injury of the posterior tibial nerve or its branches and flattening of the longitudinal arch with resultant midtarsal pain, which may delay recovery over months.

In contrast to surgery, either open or endoscopic, SWT does not require that patients avoid weightbearing or a prolonged time for return to work. Several studies have indicated that PF responds to SWT. SWT is non-invasive, well-tolerated and relatively inexpensive when compared with surgical treatment. SWT allows patients to return to activities of daily life within 1 or 2 days with immediate return to most jobs and normal daily shoe wear. Complications of SWT for PF have been virtually non-existent.

Because of the multiple variables inherent in the use of SWT in the management of PF, strict comparisons of published results are problematic. Currently, there is no consensus on the use of repetitive LESWT, which does not require LA, and on the use of HESWT, which requires LA or regional anaesthesia. There is no consensus for differentiating between low-energy and high-energy shock waves as multiple physical variables are involved. In the only randomized controlled trial (RCT) comparing an identical protocol of repetitive HESWT versus repetitive LESWT, no difference was found.

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This review makes clear that the statements from Haake *et al.*[65] and Buchbinder[6] negating substantive data for the use of SWT are outdated. On the basis of the preponderance of well-designed studies showing favourable results, it seems that the literature supports a therapeutic benefit and wide safety margin for SWT for managing chronic PF. It seems that one should only consider SWT after more common, accepted and proven non-invasive treatments have failed.

For patients with chronic PF, a conservative approach is recommended, as most patients will respond within 3–4 months. After thoroughly ruling out other aetiologies, patients are then given the choice between SWT and surgery. SWT produces pain relief within a couple of sessions, is safe and non-invasive and associated with only minor, transient side effects. Compared with surgery, recovery from SWT is generally less painful and occurs without significant morbidity. SWT circumvents the need for immobilization and restricted weight bearing and generally has a relatively short recovery time. Lost time from work is usually minimal, and often practically non-existent. In the end, financial concern is the only issue that may keep patients and physicians from opting for SWT.

At this time, one should consider SWT part of a care pathway for PF. Currently, there are two options available:

- repetitive LESWT at weekly intervals for 3–6 weeks, clinical focusing, without LA, beneficial outcome in ~60% of patients after 12 weeks;
- single HESWT, image-guided focusing, regional or block anaesthesia, beneficial outcome in ~50% of patients after 12 weeks.

Future research may reveal whether it is appropriate to introduce SWT earlier in the care pathway plan of PF patients. Additionally, it is possible that SWT will actually reduce overall costs if less money is spent on non-productive conservative care and physician visits and if there is less chance of lost productivity and days off work from pain, physician visits and surgical recovery.

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