

Intralesional Corticosteroid Injection Versus Extracorporeal Shock Wave Therapy for Plantar Fasciopathy

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Objective: To compare the efficacy of low-energy extracorporeal shock wave therapy (ESWT) and intralesional corticosteroid injection (CSI) for the treatment of plantar fasciopathy present for at least 6 weeks.

Design: A prospective, randomized, controlled, observer-blinded study over a period of 12 months.

Setting: Primary care and hospital setting.

Patients: A total of 132 patients were enrolled in the study, and 125 completed the study. Nineteen nonrandomized patients acted as a surrogate control group.

Interventions: All patients performed a standardized Achilles tendon and plantar fascia stretching program. The patients were randomly allocated to either treatment group A or B. Group A received a single CSI, while group B were referred for a course of low-dose ESWT comprising 3 treatments over a period of 3 weeks. Group C consisted of 19 nonrandomized patients who performed the standardized stretching program only.

Main Outcome Measurements: The worst daily pain recorded on a visual analogue scale (VAS), and the tenderness at the plantar fascia insertion as determined by an algometer. These measures were recorded immediately prior to the commencement of treatment and 3 months and 12 months posttreatment.

Results: With regard to VAS pain scores, values for the CSI (1.48; 0–7) were significantly lower than both ESWT (3.69; 0–8), and controls (3.58; 2–5) at 3 months. At 12 months, VAS scores for CSI (0.84; 0–7) and ESWT (0.84; 0–4) were both significantly lower than controls (2.42; 1–4). The tenderness values at 3 months were significantly higher for CSI (9.42; 7–11) than both ESWT (6.72; 4–11) and controls (7.63; 6–9). $P < 0.05$ was used throughout.

Conclusions: Corticosteroid injection is more efficacious and multiple times more cost-effective than ESWT in the treatment of plantar fasciopathy that has been symptomatic for more than 6 weeks.

Key Words: prospective, plantar fasciopathy, chronic, corticosteroid injection, ESWT

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Inferior heel pain is a common presenting problem to the primary care clinician, and plantar fasciopathy (PF) is the most common cause.^{1–3} Although there have been some advances in our understanding of the pathology of PF, treatment options remain legion. It is predominantly a self-limiting condition but may run a prolonged course, and patients will often elect to undergo painful, expensive, and potentially hazardous treatments in the hope of curtailing their symptoms.

There is no professional consensus with regard to the best form of treatment of PF, and the results of treatment are inconsistent.^{4,5} Rather than scientific data, the choice of treatment may be profoundly influenced by subjective factors such as the personal preference of the clinician and/or patient, or the affordability of, familiarity with, and availability of alternative treatments.

The institution of the nonoperative treatment within 6 weeks of the onset of symptoms has been shown to correlate more closely with success than the specific nature of the treatment.^{6–8} Once the condition has become chronic, the response to any form of treatment is less predictable.³ Two treatment options for PF are extracorporeal shock wave therapy (ESWT) and intralesional corticosteroid injection (CSI). Although not first-line treatments, either of these modalities may be employed for those cases that have failed to improve within 6 weeks.

Shock waves are focused 3-dimensional single-pressure pulses of microsecond duration and peak pressures of 35 to 120 MPa. For medical use, shock waves are produced by a generator and concentrated into small focal areas of 2 to 8 mm in diameter to optimize the therapeutic effects and minimize injury to neighboring tissues. The resultant shock wave energy per unit area is referred to as the *energy flux density* (EFD), which is an important parameter of shock wave dosage. ESWT can be classified as high-energy or low-energy, depending upon whether the EFD is greater than or less than 0.12 mJ/mm², respectively. ESWT treatments are commonly described in terms of the number of shocks, the generator frequency of the machine, and the EFD setting. High-energy ESWT is painful, often requires the use of local anesthesia and/or sedation, and is administered as a single treatment. Low

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energy ESWT is usually painless and typically administered over 3 sessions, 1 week apart, without local anesthesia or sedation.

Extracorporeal shock wave therapy has been shown to be effective in the treatment of various musculoskeletal complaints, but the dose of ESWT used is not standardized, and most studies lack a placebo group.⁹⁻¹⁵ ESWT is relatively expensive, with treatment costs of \$600 to \$800 AU. Intralesional CSI is cheap by comparison, \$60 to \$70 for the treatment, and has been shown to be more effective in the treatment of other enthesopathies, such as lateral epicondylitis.¹⁶

This study compared the efficacy of CSI and low-dose ESWT for the treatment of proximal plantar fasciopathy of duration of at least 6 weeks, using a randomized controlled prospective study.

METHODS

Subjects

Adult patients who presented to a sports physician or general practitioner with proximal plantar fasciopathy manifest for at least 6 weeks were considered for the study. Eligible subjects had to satisfy the inclusion and exclusion criteria shown in Tables 1 and 2. All subjects were informed of the nature of the study as well as the potential side effects of both forms of treatment. Patients participated voluntarily and were offered no monetary or other incentives to take part in the study.

A total of 132 patients were enrolled in the study over a period of 5 years. All patients had unilateral symptoms. Seven of the patients were lost to follow-up, and their results were not included in the analysis. Data were complete for the remaining 125 patients.

Procedures

All subjects were instructed to perform a standardized stretching program for the soleus, gastrocnemius, and plantar fascia. Each stretch was held for 2 minutes and performed at least 4 times daily. They were allowed to continue with physical activity within their pain tolerance and to use ice massage if required for pain.

Each heel was randomly allocated to either of the treatment groups using identical envelopes. Group A received a corticosteroid injection, while Group B patients were referred for ESWT. Another 19 heels were eligible for the study, but these patients declined either the CSI or ESWT. These nonrandomized patients comprised group C. With the exception of the continued use of shoe orthoses, prescribed for conditions other than PF, no additional treatment was permitted during the trial periods, including new orthoses, night splints,

TABLE 1. Inclusion Criteria (Diagnostic Criteria) for Chronic Proximal Plantar Fasciitis

1. Presenting complaint was plantar heel pain, worse on rising in the morning and/or after periods of sitting or lying, and present for at least 6 weeks.
2. On examination, the site of maximal tenderness was at the calcaneal attachment of the plantar fascia.
3. Pain aggravated by hopping on the foot and relieved with tie-beam taping.

TABLE 2. Exclusion Criteria for the Study

1. Previous surgery, CSI, or ESWT for heel pain.
2. Clinical features suggestive of seronegative spondyloarthropathy.
3. Clinical features suggestive of regional pain syndrome.
4. Rheumatoid arthritis, DM, local or systemic infection, PVD, metabolic disease such as gout, clotting disorder, anticoagulant therapy, or the presence of a cardiac pacemaker.
5. Age less than 18 years.
6. Pregnant.
7. Nerve-related symptoms (Baxter nerve entrapment, radiculopathy, tarsal tunnel syndrome).
8. Dysfunction of the knee, ankle, or foot.
9. Work-related or compensable injury.

and nonsteroidal anti-inflammatories. Patients were asked to report any possible side effects.

CSI Technique

The corticosteroid injection was performed from the medial side as described by Cyriax,¹⁷ and by the same physician on each occasion. Care was taken not to violate the fat pad and to avoid injection into the skin or subcutaneous tissues. One milliliter betamethasone (5.7 mg) and 2 mL of lignocaine 1% were injected into the site of maximal tenderness. The medial calcaneal tuberosity was infiltrated until the patient declared that his/her tenderness and symptoms had gone. This was done in an attempt, albeit crude, to ensure that the corticosteroid had been injected into the appropriate area. Patients were instructed not to take part in any running or impact activities for at least 10 days following the injection.

ESWT Protocol

Patients randomized to group B each received 3 applications of 1000 pulses of an energy flux density of 0.08/mm². The shock waves were applied using an electrohydraulic shock wave generator. Common ultrasound gel was used as a contact medium. One thousand impulses were applied 3 times at weekly intervals. Neither local anesthesia nor sedation was used.

Outcome Measures

All patients were assessed before treatment, 3 months posttreatment, and 12 months posttreatment. On each occasion, they were asked to rate the pain that they experienced on rising in the morning or after periods of sitting (whichever was worse). Their pain was rated on a visual analogue scale (VAS) with 0 indicating no pain and 10 the worst imaginable pain.

A pressure algometer was used to measure tenderness threshold (TT) in a manner similar to that described by Tsai et al.¹⁸ The pressure algometer is a force gauge fitted with a 1-cm² area and is calibrated in kilograms per square centimeter. The algometer was applied to the tender area on the medial calcaneal tuberosity at 90° to the skin surface. The minimum pressure required to elicit pain was defined as the TT recorded on the 11-kg-ranged algometer. The maximal pressure applied was 11 kg/cm², and if no pain could be elicited with this pressure, it was defined as a TT of 11 kg/cm².

Ethical Considerations

All subjects were fully informed about the nature of the trial and its rationale. They were all informed of the potential adverse effects of both ESWT and CSI, and all gave their consent to take part in the study and to be randomized to either treatment group.

Statistical Analysis

The 3 groups were compared using generalized linear models for repeated measures of VAS and TT scores, with orthogonal contrasts. The software package used was SPSS version 10.0.

RESULTS

The number of subjects in each group, their ages, the gender ratio, and their symptom duration are summarized in Table 3. Only 4 patients were wearing orthotic shoe inserts at the start of the study. These had been fabricated by other practitioners for shin splints (3 subjects) or Morton neuroma (1 subject).

Table 4 summarizes the mean VAS and TT scores for each of the groups immediately before treatment and at 3 months and 12 months posttreatment. Before treatment, all 3 groups had similarly high levels of pain. The 3 study groups were significantly different in their self-reported pain levels posttreatment (Fig. 1). Over the 12-month follow-up, however, pain levels reduced for all groups, but the trends between groups were significantly different. Three months posttreatment, patients who received CSI had significantly lower levels of pain than those who received ESWT or those who were not randomized to a treatment group (Table 5). At 12 months posttreatment, patients who received either CSI or ESWT had similar levels of average pain at the low end of the scale, while nonrandomized patients had significantly higher levels of pain (Table 5).

Similar trends were found for TT. Before treatment, the study groups had similar levels of low threshold. Threshold levels increased for all 3 groups posttreatment (Fig. 2). Over the follow-up, threshold levels increased, but the trends between the groups were significantly different. At 3 months, patients who received CSI had significantly higher average thresholds than patients who received ESWT or who were not randomized into either treatment arm (Table 6). By 12 months, all 3 groups had similar levels of average thresholds at the high end of the range. Unlike the other 2 groups, patients who received CSI plateaued in their average threshold levels by 3 months, with the 3-month and 12-month follow-up waves producing similar threshold levels for this group.

TABLE 3. Characteristics of the Subjects in the 3 Groups (Range in Parentheses)

Group	Number	Male:Female	Age in Years	Symptom Duration in Weeks
A	64	20:44	39.9 (21–80)	14.6 (6–50)
B	61	22:39	38.6 (18–81)	12.7 (6–54)
C	19	6:13	38.1 (21–65)	8 (6–12)
Total	144	48:96	38.9 (18–81)	11.8 (6–50)

When the genders were analyzed separately, there was no difference between them in terms of VAS and TT scores within each treatment group. Within each treatment group, there were some nonresponders who demonstrated no improvement in their scores over the 12 months. In group A (ESWT), there were 9 patients whose VAS scores remained unchanged and 8 whose TT scores remained unchanged. In group B (CSI), the corresponding numbers of nonresponders were 5 and 8, respectively, and in group C (nonrandomized), 2 and 4, respectively.

Of the 64 heels that received CSI, there were no infections and no cases of rupture of the plantar fascia. There were 8 cases of postinjection pain that required analgesia and/or ice application. The mean duration of these symptoms was 7 days (range, 2–14 days). All patients found the injection painful. Of the 61 heels treated with ESWT, 6 reported throbbing pain and erythema requiring ice application. Four reported a severe headache or migraine.

DISCUSSION

Heel pain syndrome is a compilation of disorders affecting the inferior aspect of the heel—proximal plantar fasciitis, inferior calcaneal bursitis, local nerve entrapment, and fat pad syndrome. The professional consensus is that 70% to 90% of patients with nonspecific heel pain can be managed conservatively.^{19,20} Although there have been some advances in our understanding of the pathology of proximal plantar fasciopathy, this has not led to more successful treatment regimens. Histologic studies have demonstrated fibroblastic proliferation and chronic granulomatous tissue at the plantar fascia attachment, consistent with the proposed pathology of failure of the fascia under tension load, resulting in microtear formation.²¹ Our inclusion and exclusion criteria were designed to select patients with heel pain that was aggravated by weight bearing and relieved by supporting the plantar fascia with tie-beam taping.

There are little data to provide guidance to the clinician with regard to the indications for the various treatment options for heel pain. A variety of conservative treatments have been described, but there is a paucity of comparative studies, and few have been placebo-controlled.^{22–24} One study that compared these conservative measures (excluding ESWT) reported relief of pain in 90% of 132 painful heels overall, and stretching was rated as the most effective treatment.²⁵ The self-limiting nature of the condition makes it difficult to distinguish long-lasting effect of treatment from spontaneous improvement. All patients included in the study had been experiencing heel symptoms for at least 6 weeks. Rather than being an arbitrarily chosen figure, this period was selected on the basis of previous work, which has demonstrated that the initial 6 weeks may represent a window of opportunity.^{6–8} After this period, more expensive and/or invasive treatment may be warranted in the interest of curtailing or preventing chronic suffering.

Most patients with PF have tightness of the TA, and most clinicians would regard stretching of both components of the triceps surae as an important component of treatment.^{7,8,26–30} Pfeffer et al.⁷ have demonstrated the efficacy of muscle stretching both on its own and in combination with silicone heel cups.

TABLE 4. VAS and TT Scores of the Groups at Baseline, 3 Months and 12 Months Posttreatment (Range in Parentheses)

Group	Before Treatment		3 Months Post Treatment		12 Months Post Treatment	
	VAS	TT	VAS	TT	VAS	TT
A	5.47 (2–8)	5.3 (1–11)	1.48 (0–7)	9.42 (7–11)	0.84 (0–7)	9.6 (7–11)
B	5.52 (3–8)	5.2 (1–11)	3.69 (0–8)	6.72 (4–11)	0.84 (0–4)	9.54 (5–11)
C	5.47 (3–7)	5.7 (4–7)	3.58 (2–5)	7.63 (6–9)	2.42 (1–4)	9.84 (8–11)

The risks and costs associated with stretching are minimal, and patients may discover by themselves that stretching can provide symptomatic relief. For these reasons, we instructed all patients in the study to perform a standardized stretching regimen for the calves and plantar fascia.

Because there was no control group in our study, which was neither receiving nor self-administering any form of treatment, it was not possible for us to differentiate the effect of stretching from the natural history of the condition. Our group C patients declined any other treatment apart from stretching. They may have differed from those of groups A and B in a manner that could alter the natural history of their condition and/or the responsiveness to treatment—for example, the shorter duration of symptoms (Table 3).

After 12 months, all 3 groups had similar levels of tenderness, while group C had significantly higher levels of pain than the 2 treatment groups. Therefore, either form of treatment seems to have a significant benefit, in addition to any potentially therapeutic effect of stretching, with regard to pain at 3 months and 12 months. In terms of tenderness at 3 months, only CSI had a significant effect.

CSIs

Corticosteroid injections have been used to settle the symptoms of plantar fasciitis when other conservative measures fail.^{31–37} They are relatively invasive and carry a risk of complications: fat pad atrophy, osteomyelitis of the calcaneus, and iatrogenic rupture of the plantar fascia.^{38,39} Careful injection technique, meticulous aseptic technique, and avoidance of impact activities for 10 days postinjection may minimize these

risks. Tsai et al¹⁸ used ultrasound guidance to improve the accuracy of CSI, thus avoiding misinjection into the fat pad with its attendant risks of fat pad atrophy. These researchers demonstrated that all the hypoechoicity associated with plantar fasciitis had disappeared at 3 months, and no gross fascia rupture was evident in any of their patients. The mechanical properties of the fat pad were unaltered by the injection. They found that the therapeutic benefit of corticosteroid injection was 80% to 90% and similar to that demonstrated by Kane et al.³⁴ In our study, 64 injections were performed without any infections or ruptures. Six of our patients who received CSI experienced transient postinjection pain, which lasted a maximum of 2 weeks. Our study demonstrated that CSI results in a significant improvement in pain at 3 months relative to both ESWT and stretching only. At 12 months, the CSI group had pain levels similar to the ESWT group, but significantly less pain than the nonrandomized participants group. With regard to tenderness, the CSI group had significantly less tenderness than the ESWT and nonrandomized participants groups at

TABLE 5. Generalized Linear Model Parameter Estimates of Visual Analogue Pain Scores Over Time for the 3 Groups

Time Period	Indicators	B (SE)	t Value
Before treatment	Intercept	5.54 (.35)	16.0***
	Age	0.002 (.007)	0.3
	Symptom duration	−0.01 (.01)	−1.1
	Group A (CSI)	Reference	
	Group B (ESWT)	0.04 (.25)	0.2
	Group C (NRP)	−0.06 (.36)	−0.2
3 Months posttreatment	Intercept	2.51 (.40)	6.3***
	Age	−0.02 (.008)	−2.4*
	Symptom duration	−0.02 (.01)	−1.4
	Group A (CSI)	Reference	
	Group B (ESWT)	2.16 (.28)	7.7***
	Group C (NRP)	1.95 (.42)	4.7***
12 Months posttreatment	Intercept	1.00 (.31)	3.3**
	Age	−0.003 (.006)	−0.5
	Symptom duration	−0.003 (.009)	−0.3
	Group A (CSI)	Reference	
	Group B (ESWT)	−0.02 (.22)	−0.1
	Group C (NRP)	1.55 (.32)	4.8***

*P < 0.05; **P < 0.001; ***P < 0.0001.

Repeated-measures F test between treatment groups overtime = 15.7; df = 4,278; P < 0.0001.

CSI, n = 64; ESWT, n = 61; nonrandomized participants (NRP) n = 19.

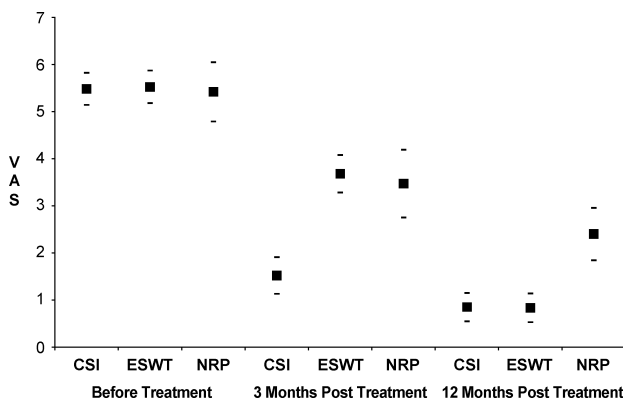


FIGURE 1. Adjusted mean VAS pain scores (95% CI) by treatment group over time. Adjusted for age and symptom duration. CSI, n = 64; ESWT, n = 61; nonrandomized participants (NRP), n = 19.

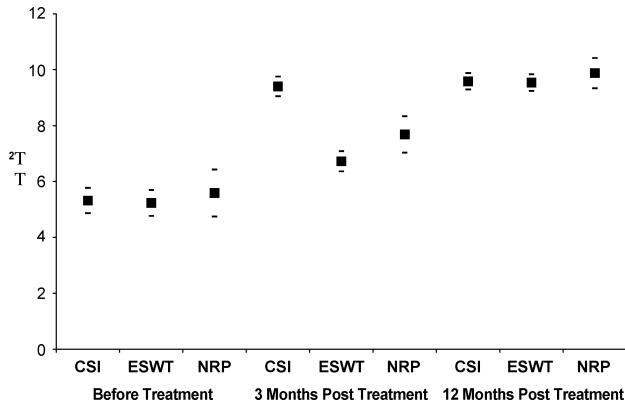


FIGURE 2. Adjusted mean TT responses (95% CI) in kg/cm² by treatment group over time. Adjusted for age and symptom duration. CSI, n = 64; ESWT, n = 61; nonrandomized participants (NRP), n = 19.

3 months, while at 12 months, all 3 groups were similar. These trends suggest that CSI produces a significant reduction in both pain and tenderness at 3 months, and the former is maintained for at least 12 months.

ESWT

Although the exact mechanism of action of ESWT is uncertain, the absence of complications, no immobilization, immediate return to work, and more rapid return to full activ-

ities make it an attractive alternative to surgery.⁴⁰ Several studies have demonstrated a beneficial result of ESWT for proximal plantar fasciitis, with success rates of 48% to 77%.^{12,40,41} Previous studies using ESWT have used different treatment protocols, some with local anesthetic infiltration with or without corticosteroid.^{12,25,40-44} A meta-analysis by Ogden et al⁴⁵ concluded that ESWT has success rates as high as 88% for chronic proximal PF, and suggested that it is a safer alternative to CSI.

In the present study, ESWT was significantly less effective with regard to pain and tenderness at 3 months than CSI and stretching alone. At 12 months, both CSI and ESWT were significantly more effective than stretching only with regard to pain.

Although the low-dose ESWT regimen that we used may be less efficacious than higher doses, the benefits include a lower incidence of adverse effects. In the present study, only 6 cases of local pain and erythema were reported. The low risk profile of ESWT makes it an attractive option, but there are significant cost considerations. Further studies may help to identify a subgroup of patients who are likely to benefit from ESWT, but on the basis of the present study, we can not justify the prescription of ESWT for chronic plantar fasciopathy.

CONCLUSIONS

Once plantar fasciopathy has persisted for more than 6 weeks, intralesional corticosteroid injection is more effective than ESWT within the first 3 months with regard to pain and tenderness, but at 12-month follow-up, there is no difference between the 2 treatments. At a fraction of the cost, CSI is multiple times more cost-effective. Careful injection technique and appropriate advice to the patient may minimize the risk of side effects associated with CSI.

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TABLE 6. Generalized Linear Model Parameter Estimates of Tenderness Threshold (kg/cm²) Over Time for the 3 Groups

Time Period	Indicators	B (SE)	t Value
Before treatment	Intercept	4.72 (.47)	10.2**
	Age	0.02 (.01)	2.5*
	Symptom duration	-0.02 (.01)	-1.8
	Group A (CSI)	Reference	
	Group B (ESWT)	-0.09 (.33)	-0.3
	Group C (NRP)	0.27 (.49)	-0.6
3 Months posttreatment	Intercept	8.75 (.36)	24.4**
	Age	0.01 (.007)	1.9*
	Symptom duration	0.007 (.01)	0.6
	Group A (CSI)	Reference	
	Group B (ESWT)	-2.68 (.25)	-10.5**
	Group C (NRP)	-1.72 (.38)	-4.6**
12 Months posttreatment	Intercept	9.78 (.30)	32.7**
	Age	-0.008 (.006)	-1.3
	Symptom duration	-0.01 (.009)	-1.1
	Group A (CSI)	Reference	
	Group B (ESWT)	-0.04 (.21)	-0.2
	Group C (NRP)	0.30 (.31)	0.9

*P < 0.05; **P < 0.0001.
 Repeated-measured F test between treatment groups over time = 16.4; df = 4,278; P < 0.0001.
 CSI n = 64; ESWT, n = 61; nonrandomized participants (NRP) n = 19.

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