Extracorporeal shockwave therapy for refractory plantar fasciitis:
Evidence update and cost analysis

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Summary

Extracorporeal shockwave therapy (ESWT) involves the external application of powerful sound waves through skin to painful joints and tendons. It has been used in a range of conditions including plantar fasciitis (PF). PF is a painful disorder affecting the plantar fascia tendon under the heel. PF can affect both feet and can be severely disabling to the extent that walking and standing is painful.

ESWT for PF has been appraised by NICE in 2009. The outcome was equivocal, with guidance that the treatment is only performed under specific governance arrangements and a further recommendation for specific additional studies on ESWT for PF.

Since the publication of the NICE guidance and accompanying appraisal report, an additional five relevant comparative studies were identified for this appraisal. None of these studies meet the criteria specified by NICE in its 2009 guidance. The results of these studies are, again, equivocal but overall less positive than previous studies. There is little compelling evidence that ESWT confers additional or greater benefit in the management of PF compared with other treatments. PF is a condition which itself demonstrates a relatively high rate of spontaneous resolution.

Neither the NICE appraisal nor this appraisal identified any serious safety issues. ESWT is frequently associated with mild transient pain during administration and for a short period afterwards. For this reason a local anaesthetic is often used. Other effects may include skin reddening and tenderness.

The cost of provision of ESWT for PF is not known. The cost of treatment has been based on specialist outpatient appointments only and is estimated at about £255 per course of three treatment sessions per foot. Courses per foot are unlikely to be repeated. This cost is similar to that estimated for other PF treatments such as physiotherapy, supervised stretching programmes, orthoses, or a series of steroid injections. The cost of ESWT is substantially less than the cost of surgery such as plantar fasciotomy. ESWT for PF is not likely to be cost-effective compared with treatments delivered in primary care such as use of simple analgesic anti-inflammatory drugs and self-administered stretching programmes.

Indications from a local clinical specialist are that ESWT would be used as a late treatment for specialist-referred refractory cases and prior to last-line surgical treatment. It should therefore be considered as a conservative and sparing treatment in that regard.
Introduction

Plantar fasciitis (PF) is a musculoskeletal disorder affecting the plantar fascia. The plantar fascia is a thick tendon attached to the heel bone which runs from under the heel and then fans outwards towards the toes on each foot. It is a major structural tendon in the foot and provides support to the arch of the foot amongst other functions. Plantar fasciitis is generally a self-limiting condition characterised by chronic degeneration of the plantar fascia causing pain on the under- and in-side of the heel. It is usually caused by injury or biomechanical abnormalities and may be associated with micro-tears, inflammation or fibrosis. Conservative treatments include rest, application of ice, analgesic medication, non-steroidal anti-inflammatory drugs, orthotic devices, physiotherapy, eccentric training and stretching and direct corticosteroid injections. Surgery to release the plantar fascia from the bone or to relieve muscular tightness, plantar fasciotomy, may be considered in patients with severe and refractory symptoms. ¹,²

Extracorporeal shockwave therapy (ESWT) is a non-invasive treatment in which a device is used to pass acoustic shockwaves (sound waves) through the skin to the affected area. Ultrasound guidance may be used to assist with positioning of the device. The shockwaves are generated using a variety of electric energy sources. Treatment protocols for ESWT vary according to the energy density and frequency of shockwaves. ESWT may be applied in a series of treatments or a single session. Local anaesthesia may be administered before treatment as high-energy ESWT can be painful by itself. The mechanisms by which ESWT might elicit its effects in PF specifically, or tendinopathy more generally, have not been conclusively ascertained. ¹,²

The National Institute of Health and Clinical Excellence published interventional procedure guidance regarding ESWT for refractory PF in August 2009 (box 1). ¹

Box 1. NICE guidance on ESWT for PF. ¹

1.1. The evidence on ESWT for refractory PF raises no major safety concerns; however, current evidence on its efficacy is inconsistent. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research.

1.3. NICE encourages further research into ESWT for refractory PF. Future research should take the form of clinical studies with clearly described patient selection and treatment protocols, including a description of local anaesthesia use and the type of energy applied. The studies should include validated outcome measures and be based on a minimum of 1-year follow-up. NICE may review the procedure on publication of further evidence.

The NHS North East Treatment Advisory Group has been requested by a member commissioning organisation to conduct an update of the NICE evidence overview ² and to include a cost analysis of ESWT for PF.
Clinical evidence of efficacy and safety

NICE conducted an evidence overview of ESWT for PF which was published in 2009 with evidence taken from available sources up to April 2009. The NICE review focused on nine studies with more than 2,500 patients. This appraisal report is intended to serve as an evidence update to the NICE review and should only be read in conjunction with it.

Five new studies were identified, most were two-way randomised controlled comparisons against a range of comparators; steroid injections, sham treatment, stretching regimen, and fasciotomy. In total 284 patients were included in these studies (range 25 to 102).

The studies are summarised in table 1.

Summary of the new clinical evidence for ESWT in PF

Only five additional studies were identified for this appraisal report. These studies essentially demonstrate no difference between ESWT and sham treatment, steroid injections, or a relatively intensive stretching programme. The stretching programme was the largest study with the longest follow-up and demonstrated that, in the longer term (15 months), there was no difference between treatments. The stretching programme was more effective in the shorter-term.

Cross-study comparisons are compounded by a large degree of heterogeneity, especially with respect to the ESWT regimen applied. Most, but not all, utilised co-administration of local anaesthetic and this could in part or even whole explain the apparent efficacy of ESWT.

None of the studies meet the criteria specified by NICE in its 2009 guidance (see box 1).

Adverse effects and other safety sequelae are poorly reported. However no new or additional safety concerns were identified in the studies in table 1. Indeed, ESWT often presents a more favourable adverse effect profile than comparator treatments.

A number of other studies of ESWT were identified however these were excluded from table 1 for a variety of reasons such as being a comparison of two ESWT regimens, non-comparative case series, or placebo comparison.
### Table 1. Key studies of ESWT for PF published since publication of the relevant NICE evidence overview.

<table>
<thead>
<tr>
<th>Ref</th>
<th>Study design</th>
<th>Primary outcome measure</th>
<th>Outcomes</th>
<th>Safety</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>3</td>
<td>Prospective, non-randomised, single-centre, case series. Low-energy ESWT (n = 20) vs. endoscopic fasciotomy (n = 17). Mean follow-up: 7.6 months vs. 11.0 months.</td>
<td>Change in pre- to post-operative pain score measured on 11-point VAS</td>
<td>Mean pain score reduced from 9.0 to 2.1 and from 9.1 to 1.6 respectively. Post-operative outcomes (ESWT vs. fasciotomy): limitation of functional activities; nil 50% vs. 59%; minimal 35% vs. 35%; moderate 10% vs. 6%; severe 5% vs. 0%. Patient satisfaction: Complete 75% vs. 82%; with reservations 15% vs. 12%; unsatisfied 10% vs. 6%</td>
<td>Fasciotomy: Two complications; one superficial wound infection, resolved after 5 days of oral antibiotics; one heel numbness, relieved completely after 6 weeks. No clinical or radiological postoperative foot deformities or arch changes. Mean recovery before return to work or daily activities was 6 weeks with fasciotomy vs. 2 weeks with ESWT</td>
<td>Over 60% of patients had severe pre-operative functional limitation.</td>
</tr>
<tr>
<td>4</td>
<td>Double-blind, randomised controlled study. ESWT (n = 16) vs. sham treatment (n = 9) Treatment consisted of three sessions, each three days apart.</td>
<td>Not stated. Patient’s pain assessed using 100 mm VAS.</td>
<td>ESWT vs. sham, respectively: &gt; 50% reduction in VAS after 6 months; 56% vs. 44% (p = 0.44). Actual VAS scores not reported.</td>
<td>None reported.</td>
<td>More patients in intervention group were using anti-inflammatory painkillers at baseline (81% vs. 33%). Primary aim of study appears to have been use of novel ESWT device.</td>
</tr>
<tr>
<td>5</td>
<td>Observer-blinded, randomised controlled study. Low-energy ESWT (n = 48) vs. stretching (n = 54). ESWT treatment consisted of three sessions, each one week apart. Stretching consisted of an 8-week 3-times daily, self-administered programme.</td>
<td>Change in PS-FFI score (summed) from baseline to month two. PS-FFI (pain subscale of the validated Foot Function Index): range 0 to 70, higher scores indicate worse pain.</td>
<td>Reduction in mean PS-FFI scores, ESWT vs. stretching, respectively: Two months: 7 vs. 21 points (p &lt; 0.001) Four months: 16 vs. 25 points (p &lt; 0.001) 15 months: 29 vs. 29 points (p = 0.950) ESWT: All patients experienced transient reddening after therapy. ≥ 5 point increase on Pain Numeric Rating Scale (0 = no pain; 10 = worst pain imaginable): ESWT 85% vs. stretching 15%. No other clinically relevant adverse effects observed. No device-related complications occurred.</td>
<td>Patients on stretching programme required to record in daily diary and received regular telephone contacts. Relatively little loss-to-follow-up even at 15 months (40 and 42 patients remaining, respectively).</td>
<td></td>
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</tbody>
</table>
### Table 1 continued.

<table>
<thead>
<tr>
<th>Ref</th>
<th>Study design</th>
<th>Primary outcome measure</th>
<th>Outcomes</th>
<th>Safety</th>
<th>Comments</th>
</tr>
</thead>
</table>
| 6   | Randomised trial  
High-energy ESWT (n = 30) vs. ultrasound guided steroid injection (n = 30).  
ESWT consisted of two sessions two weeks apart, each with local anaesthetic.  
Steroid injection was repeated after two weeks. Local anaesthetic used on both occasions. | Not stated.  
Patients assessed according to PF scoring system and ultrasound measurement of PF thickness. | 12-week follow-up.  
PF mean thickness decreased from 5.9 to 3.4 mm with ESWT and from 6.0 mm to 3.5 mm with steroid injections.  
PF mean score improved from 47 to 86 points with ESWT and from 47 to 84 points with steroid injections. | Six patients had recurrent PF symptoms, three patients from each treatment group. The time before recurrence ranged from 5 to 7 months (mean 6.1).  
There were no haematoma, bruising or swelling over the treated area in both groups. | At a mean follow-up of 4.3 months (range 3 to 6 months), 90% of patients in both groups showed good to excellent results according to PF score.  
Two patients in each group showed poor response to treatment. |
| 7   | Randomised trial  
Single episode of ESWT plus local anaesthetic (n = 27) vs. single injection of steroid plus local anaesthetic (n = 33). | Self-assessed pain using 100 mm visual analogue scale.  
Clinician-assessed heel tenderness.  
Successful treatment defined as decrease ≥ 50% from baseline to 3 months in VAS or heel tenderness score. | Successful treatment achieved in 82% with ESWT and 85% with steroid injections.  
VAS mean score improved by 5.3 and 4.0 points respectively (between group p > 0.05).  
Heel tenderness mean score (range 0 to 3) improved by 0.9 and 0.8 points respectively (between group p > 0.05). | Steroid injection: All patients had pain during injection that lasted an average of 5 days (range 2 to 9). Four patients required analgesia. No infections or other major complications.  
ESWT: None of the patients has pain during treatment. Two patients had a mild throbbing sensation that lasted an average of 5 days (range 3 to 7) but did not require analgesia. Two patients had mild erythema. | |

PF score: Range 0 to 100, based on effect of treatment; excellent (90 to 100), good (80 to 89), fair (70 to 79) and poor (< 70). Pain accounts for the greatest weight.
**Cost analysis**

The cost of a single session of ESWT is not known. The treatment is not explicitly listed within the payment-by-results tariff. For the purpose of this analysis it will be assumed that ESWT is delivered within an orthopaedic follow-up appointment and that there are no extra tariff hardware or equipment costs. The cost of the relevant appointment is about £85. The number of appointments per treatment course is also not clear. The studies included in the NICE evidence overview and table 1 utilise various regimens consisting of a single episode to repeated episodes (sessions) of various intervals. In the case of bilateral PF, it is not clear whether both feet can be treated at the same time or if separate appointments would be required for each foot. It is assumed in this analysis that either one or two feet can be treated within the same appointment.

A local protocol is known to consist of three short sessions over three weeks for one or two feet per appointment. If it is assumed that each would incur only the cost of an orthopaedic follow-up outpatient appointment the cost per course is about £255. This analysis will assume that a patient would only ever receive a single course of treatment.

Alternative treatments include analgesic drugs, anti-inflammatory drugs, orthotic devices, physiotherapy, stretching programmes, steroid injections, and surgery. The majority of these interventions are relatively low cost and largely self-administered. Use of drug therapy could reasonably be managed within primary care or privately at minimal cost and these costs are not considered further. With respect to stretching programmes patients will require instruction and training, and possibly follow-up. Where physiotherapy is directly administered by a third party, a number of repeat appointments may be required. Use of a foot orthosis will incur the cost of a clinical appointment and potentially also the cost for each orthotic device separately. Some treatment modalities can be combined in multiple combinations, e.g. drug therapy, physiotherapy, stretching, and orthoses. All of these interventions, with the exception of surgery, could reasonably be managed within outpatient settings and therefore the cost per appointment will be the same as the cost per single session of ESWT, at about £85. Repeat visits would incur the same cost per appointment. Surgery, by way of plantar fasciotomy, would require an inpatient admission. The cost of such a stay for adult non-trauma patients ranges from about £950 for a minor foot procedure to £3,000 for an intermediate foot procedure, each of up to five day’s inpatient stay. It is likely that surgical treatment of bilateral PF would require a separate admission for each foot therefore the cost of surgery for bilateral PF would be double these values. The actual cost will depend on the payment-by-results tariff applied by the provider trust. Table 2 demonstrates indicative costs for each treatment.
Table 2. Indicative costs and associated variables for PF treatments

<table>
<thead>
<tr>
<th>Treatment modality</th>
<th>Number of appointments required</th>
<th>Separate hardware / equipment costs</th>
<th>Additional cost for bilateral PF</th>
<th>Cost per appointment / admission</th>
<th>Cost per course</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physiotherapy</td>
<td>Potentially multiple</td>
<td>No</td>
<td>No</td>
<td>£85</td>
<td>Minimum £170 based on two appointments</td>
<td>Could be delivered in primary care at minimal incremental cost</td>
</tr>
<tr>
<td>Stretching programme</td>
<td>Probably initial and follow-up</td>
<td>No</td>
<td>No</td>
<td>£85</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Foot orthoses</td>
<td>Probably initial for measuring, then fitting and follow-up</td>
<td>Possibly</td>
<td>Limited</td>
<td>£85</td>
<td>Minimum £255 based on three appointments</td>
<td></td>
</tr>
<tr>
<td>Steroid injections</td>
<td>Often repeated</td>
<td>No</td>
<td>No</td>
<td>£85</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ESWT</td>
<td>Often repeated sessions per course</td>
<td>No</td>
<td>No</td>
<td>£85</td>
<td>£255 based on three sessions per course</td>
<td>Courses unlikely to be repeated</td>
</tr>
<tr>
<td>Surgery</td>
<td>Inpatient stay ≤ 5 days.</td>
<td>No</td>
<td>Yes (double)</td>
<td>£950 to £3,000</td>
<td>Not applicable</td>
<td>Variable cost, depending on payment-by-results coding</td>
</tr>
</tbody>
</table>

There is limited data on the effect of ESWT on quality of life. Improvements in functional ability and other patient-orientated outcomes tend to correlate with objective measures of PF severity. Quality of life outcomes have not been reliably quantified.

In terms of incremental benefit, many of the patients studied had had PF for relatively long durations. Detailed break-downs of prior treatments were often absent or poorly described. It is not, therefore, clear where exactly ESWT was being introduced in the treatment pathway. The evidence from table 1 and from the NICE appraisal ² would indicate that ESWT is as effective as other treatment options. Therefore the incremental benefit is nil and the only factor influencing cost-effectiveness is the cost. Given the uncertainties around cost estimates the following statements can be assumed:

- Drug therapy is likely to be the most cost-effective treatment.
- Primary care non-drug treatments will be more cost-effective than the same treatment delivered by specialist providers.
- Non-drug treatments provided by specialists are of similar cost-effectiveness with the exception of surgery, which is likely to be the least cost-effective.
Points to consider

The additional evidence for ESWT in PF is of variable, but generally low, quality due to inadequate study descriptions, small patient numbers, lack of adequate treatment blinding, and short follow-up, amongst other factors. None of the studies meet the specification outlined by NICE in its 2009 guidance statement.

The overall evidence base of ESWT in PF is compounded by the use of different regimens and the new sources of evidence only serve to add to this confusion. It is not clear whether the sum of evidence can be considered generally for ESWT or whether evidence should be considered separately for each variable, such as; device used, energy applied, co-administration of local anaesthetic, duration of wave application, number of treatment episodes/sessions per course, amongst other factors.

Some of the evidence for ESWT calls into question whether the treatment has any tangible or observable effect on PF. In addition, the mode of action of ESWT in PF and other tendonopathies has not been elicited.

The newer studies generally indicate that ESWT is as effective as sham, surgery or steroid injections in PF. One study indicates that ESWT may be less effective than a specific and relative intensive stretching programme.

ESWT does not present any significant or durable safety issues. Indeed, it is often associated with a preferable adverse effect profile compared with other active treatments.

The actual cost of ESWT is not clear. It would likely be administered in an outpatient setting and is unlikely to be available in primary care. Uncertainties arise from whether hardware or equipment costs would be incurred, and the number of treatment episodes, and by extension, appointments per course. Based on a local treatment protocol the cost has been estimated at about £255 per course. A treatment course is assumed not to be repeated.

On the basis of the available evidence, ESWT is about as effective as other treatments for PF. Where treatments are provided in secondary care on an outpatient basis, the cost of ESWT is similar to that of other treatments for PF. ESWT is likely to be considerably less costly, and certainly less invasive, than surgery for PF.

Assessing the relative cost-effectiveness of ESWT for PF is compounded by a high rate of spontaneous resolution. It is probably about as cost-effective as other specialist-delivered treatments, other than surgery, but less cost-effective than treatments delivered in primary care including drug therapy. A primary care based intensive self-administered stretching programme is likely to be the most cost-effective non-drug intervention.
References

1. NICE. Interventional procedure guidance 311: Extracorporeal shockwave therapy for refractory plantar fasciitis. August 2009

2. NICE. Interventional procedure overview of extracorporeal shockwave therapy for refractory plantar fasciitis. IP 252/2/ January 2009

3. Othman AMA, Ragab EM. Endoscopic plantar fasciotomy versus extracorporeal shock wave therapy for treatment of chronic plantar fasciitis. Archives of Orthopaedic Trauma and Surgery 2010;130:1343-7


Author’s declaration: The author has no relevant pecuniary interests to declare. The author has suffered from bilateral PF for several years.