NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedure overview of extracorporeal shockwave therapy for refractory plantar fasciitis

Plantar fasciitis is a painful condition affecting the connective tissue that stretches between the heel and the middle of the foot. It is usually caused by overuse, injury or biomechanical abnormalities. In extracorporeal shockwave therapy, a machine is used to deliver sound waves to the painful area. It is not known exactly how it works, but it is thought that it might stimulate healing of the fascia.

Introduction

This overview has been prepared to assist members of the Interventional Procedures Advisory Committee (IPAC) in making recommendations about the safety and efficacy of an interventional procedure. It is based on a rapid review of the medical literature and specialist opinion. It should not be regarded as a definitive assessment of the procedure.

Date prepared

This overview was prepared in January 2009.

Procedure name

- Extracorporeal shockwave therapy for refractory plantar fasciitis

Specialty societies

- British Orthopaedic Association
- British Orthopaedic Foot and Ankle Society
- British Orthopaedic Foot Surgery Society
- British Society for Rheumatology
- British Society of Skeletal Radiologists
- Royal College of Radiologists.

Description

Indications and current treatment

Plantar fasciitis is generally a self-limiting condition characterised by chronic degeneration of the plantar fascia causing pain on the underside of the heel. It is usually caused by injury or biomechanical abnormalities and may be associated with microtears, inflammation or fibrosis.

Conservative treatments include rest, application of ice, analgesic medication, non-steroidal anti-inflammatory drugs (NSAIDs), orthotic devices, physiotherapy, eccentric training/stretching and corticosteroid injection. Surgery to release the plantar fascia from the bone or to relieve muscular tightness may be considered in patients with refractory symptoms.

What the procedure involves

Extracorporeal shockwave therapy (ESWT) is a non-invasive treatment in which a device is used to pass acoustic shockwaves through the skin to the affected area. Ultrasound guidance may be used to assist with positioning of the device. The shockwaves are generated using electrohydraulic, electromagnetic or piezoelectric energy.

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 because high-energy ESWT can be painful; however, there is evidence that local anaesthesia may influence the outcome of ESWT.

The mechanism by which this therapy might have an effect on tendinopathy is not well defined.

List of studies included in the overview

This overview is based on 2528 patients from seven randomised controlled trials (RCTs), one cross-sectional survey and one retrospective review.

Other studies that were considered to be relevant to the procedure but were not included in the main extraction table (table 2) have been listed in appendix A.

Efficacy

Five RCTs compared ESWT (various treatment protocols) with sham ESWT, one with conservative treatment including NSAIDs, and one with a single corticosteroid injection for the treatment of chronic plantar fasciitis.

An RCT of 293 patients reported that 47% (67/144) of ESWT patients and 30% (42/141) of sham ESWT patients had treatment success at 3-month follow-up (defined as at least 50% reduction in pressure-induced pain and

pain during walking, at least 1-point reduction in 5-point visual analogue scale [VAS], and no requirement for pain medication) ($p = 0.008$)[1].

An RCT of 272 patients reported that 34% (43/127) of ESWT patients and 30% (39/129) of sham ESWT patients had treatment success at 3-month follow-up (defined as Roles and Maudsley score of 1 or 2 and no additional treatment; $p = 0.5927$). Additional treatment was sought by 36% (41/113) of ESWT patients and 56% (64/115) of sham ESWT patients at 12-month follow-up ($p < 0.008$)[2].

In an RCT of 252 patients, 61% (75/125) of ESWT patients and 42% (49/118) of sham ESWT patients had treatment success at 3 months (defined as at least 60% reduction from baseline on at least two of: VAS score for pain in morning, pain during daily activities and pressure-induced pain) ($p = 0.0014$). The mean composite pain score (combined VAS scores for pain during the morning, pain during daily activity and pressure-induced pain) decreased by 73 points from baseline to 3-month follow-up in the ESWT group compared with 45 points in the sham ESWT group ($p = 0.0220$). By 12-month follow-up, the composite pain score had decreased by 85 points in the ESWT group and by 48 points in the sham ESWT group ($p = 0.0086$)[3].

A review of 225 patients (246 feet) reported treatment success (defined as achieving four of the following six criteria: greater than 50% improvement in VAS for patients first morning steps or during daily activities or exercise; American Orthopaedic Foot and Ankle Society (AOFAS) score increase of at least 30 points (scoring system not described); Roles and Maudsley score of 1 or 2; greater than 50% reduction in pain on compression of the medial calcaneal tuberosity) for 71% (174/246) of procedures at 3-month follow-up and 78% (192/246) of procedures at a mean of 30.2-month follow-up[12].

In an RCT of 172 patients, the mean reduction in pain score (assessed by 5-point VAS) from baseline to 3-month follow-up was 3.39 in the ESWT group ($n = 112$) compared with 1.78 in the sham ESWT group ($n = 56$) ($p < 0.001$)[4].

An RCT of 166 patients reported no statistically significant differences between the ESWT ($n = 81$) and sham ESWT ($n = 85$) groups in the change in pain score from baseline to 3 months for overall pain, pain in the morning and pain during activity (assessed by 10-cm VAS), and that both groups improved over time. There was also no difference between the groups in the duration of walking without need to rest for pain (assessed at 3 months)[5].

An RCT compared pain scores (assessed using 10-cm VAS) in 125 patients randomised to ESWT ($n = 61$) or corticosteroid injection ($n = 64$) and an additional 19 non-randomised patients who declined treatment. Mean pain scores were 5.52, 5.47 and 5.47 in each group respectively at baseline, 3.69, 1.48 and 3.58 at 3 months, and 0.84, 0.84 and 2.42 at 12 months[6].

An RCT comparing ESWT ($n = 76$) with conservative treatment ($n = 65$) reported that 69% of ESWT patients and no control patients had an excellent treatment result (no heel pain), 14% and 55% of each group respectively had

a good result (> 50% reduction in baseline pain), 6% and 36% had a fair result (25-50% reduction in heel pain), and 11% and 9% respectively had a poor result (less than 25% reduction in heel pain)[7].

In the cross-sectional survey, 874 patients with plantar fasciitis who had ESWT were surveyed within 3 months of treatment. The mean pain score (rated from 1 [no pain] to 10 [very severe pain]) decreased from 8.76 before treatment (assessed retrospectively) to 4.48 after treatment (difference significant at 1% level on Wilcoxon signed rank test). The mean mobility score (rated from 1 [total mobility] to 10 [complete immobility]) improved from 6.67 before treatment to 3.74 after treatment (difference significant at 1% level on Wilcoxon signed rank test)[8].

In the review of 225 patients, 7% (16/225) reported pain during treatment which resolved within a mean of 6.7 days. At 12-month follow-up, mean VAS score for pain on first morning step had decreased from 8.44 to 3.17; mean VAS pain score on daily activity had decreased from 8.89 to 2.87 and mean Roles and Maudsley scores had decreased from 3.75 to 1.71 (scoring systems not described)[12].

Safety

In the RCT of 293 patients, the most frequent complication in both the ESWT and sham ESWT groups were pain and mild numbness / dysaesthesia (reported as principally related to the ankle block anaesthesia)[1].

In the review of 225 patients treated by ESWT 3% (7/225) of patients had numbness and dysthesia in the distribution of the medial and lateral plantar nerves that resolved spontaneously within 12.6 days[12].

The RCT of 272 patients reported that 12% (16/135) of ESWT patients and 4% (5/136) of sham ESWT patients had skin reddening, 5% (7/135) and 1% (2/136) of each group respectively had pain, and 2% (3/135) of ESWT patients had local swelling[2].

The RCT of 252 patients reported that 26% (33/125) of ESWT patients had device-related adverse events compared with 8% (10/118) of sham ESWT patients. The most common adverse event in both groups was pain during treatment[3].

In the RCT of 172 patients, two ESWT patients had bruising of the treated area and one had local swelling. There were no adverse events in the sham ESWT group[4].

In the RCT of 166 patients, one ESWT patient experienced heat and numbness, one ESWT patient had bruising, one sham ESWT patient experienced a burning sensation and one patient in each group had pain during treatment[5].

The RCT comparing ESWT with conservative treatment reported no systemic or local complications or device-related problems[7].

In the RCT comparing ESWT with a single corticosteroid injection (n = 125), 6 ESWT patients had throbbing pain and erythema requiring ice, 4 ESWT patients had severe headache or migraine and 8 patients who received a corticosteroid injection had pain requiring analgesia or ice for a mean duration of 7 days[6].

The review of 225 patients reported that 2% (5/225) of patients had eechymsis and petechiae at the treatment area that resolved spontaneously before 3 month follow-up. Another patient reported a superficial skin infection along the medial hindfoot that did not require surgical treatment[12].

Literature review

Rapid review of literature

The medical literature was searched to identify studies and reviews relevant to ESWT for refractory plantar fasciitis. Searches were conducted of the following databases, covering the period from their commencement to 27/11/08 and updated on 23/04/09: MEDLINE, PREMEDLINE, EMBASE, Cochrane Library and other databases. Trial registries and the Internet were also searched. No language restriction was applied to the searches (see appendix C for details of search strategy).

The following selection criteria (table 1) were applied to the abstracts identified by the literature search. Where selection criteria could not be determined from the abstracts the full paper was retrieved.

Table 1 Inclusion criteria for identification of relevant studies

Characteristic	Criteria
Publication type	Clinical studies were included. Emphasis was placed on identifying good quality studies. Abstracts were excluded where no clinical outcomes were reported, or where the paper was a review, editorial, or a laboratory or animal study. Conference abstracts were also excluded because of the difficulty of appraising study methodology, unless they reported specific adverse events that were not available in the published literature.
Patient	Patients with refractory plantar fasciitis.
Intervention/test	Extracorporeal shockwave therapy.
Outcome	Articles were retrieved if the abstract contained information relevant to the safety and/or efficacy.
Language	Non-English-language articles were excluded unless they were thought to add substantively to the English-language evidence base.

Existing assessments of this procedure

1. A Cochrane systematic review on interventions (all types) for plantar heel pain was published in 2003. The review identified 19 trials of various interventions (n = 1626). The review concluded that there was conflicting evidence for the effectiveness of low-energy ESWT in reducing pain in the short-term (6 and 12 weeks) and therefore its effectiveness remains equivocal[9].

2. The Canadian Agency for Drugs and Technologies in Health published an assessment on ESWT for chronic plantar fasciitis (heel pain) in 2007[10]. The summary findings were:
    - "Results from randomized controlled trials have been conflicting. Six trials reported data that favour ESWT over placebo or conservative treatment for efficacy outcomes while three trials showed no significant difference between the ESWT group and the placebo group.
    - The lack of convergent findings from randomized trials of ESWT for chronic plantar fasciitis suggests uncertainty about its effectiveness. The evidence reviewed in this bulletin does not support the use of this technology for this condition."

3. The Institute for Clinical Systems Improvement (USA) published a technology assessment report of ESWT for plantar fasciitis in 2004[11]. The report concluded that:
    - "The scientific evidence to date does not permit a conclusion to be reached regarding the efficacy of ESWT for plantar fasciitis. ESWT is a safe, non-surgical treatment."

Related NICE guidance

Below is a list of NICE guidance related to this procedure. Appendix B gives details of the recommendations made in each piece of guidance listed below.

Interventional procedures

- Extracorporeal shockwave therapy for refractory tendinopathies (plantar fasciitis and tennis elbow). NICE interventional procedures guidance 139 (2005). Available from www.nice.org.uk/IPG139
- Extra-corporeal shockwave lithotripsy for calcific tendonitis (tendinopathy) of the shoulder. NICE interventional procedures guidance 21 (2003). Available from www.nice.org.uk/IPG21
- Autologous blood injection for refractory tendonitis. NICE interventional procedures guidance (2009). Available from www.nice.org.uk/IPG279

Table 2 Summary of key efficacy and safety findings on extracorporeal shockwave therapy for refractory plantar fasciitis

Abbreviations: RCT, randomised controlled trial; ESWT, extracorporeal shockwave therapy; VAS, visual analogue scale;

<table>
<tr><th>Study details</th><th>Key efficacy findings</th><th>Key safety findings</th><th>Comments</th></tr>
<tr>
<td>Ogden (2004)[1]

Study type: RCT (double-blind)
Country: USA (multicentre)
Study period: 1996–2003
Study population: patients with plantar fasciitis
n = 293
Age: 49 years (mean)
Sex: 66% female

Inclusion criteria: chronic heel pain (moderate-to-severe heel pain at the origin of the proximal plantar fascia at the medial calcaneal tuberosity) for ≥ 6 months that failed to respond to conservative treatment; objective assessment of pain in the proximal plantar fascia ≥ 5cm on 10-cm VAS; patient self-assessment of pain after the first 5 minutes of walking in the morning ≥ 5 cm on 10-cm VAS

Exclusion criteria: positive result to monofilament sensory test (for possible peripheral neuropathy) at 2 or more of 10 sites; pain in the contralateral heel of > 4 cm on VAS.

Technique: ESWT (n = 148) applied to point of maximum plantar surface tenderness after complete ankle-block anaesthesia at 1 session (100 shocks at 0.12–0.22 mJ/mm^2 to assess anaesthesia, followed by 1400 shocks at 0.22 mJ/mm^2). Total energy applied: 325</td>
<td>Treatment success
Assessed at 3 and 12 months, success defined as all of:
1. ≥ 50% improvement in the dolorimeter (pressure sensor)-induced baseline pain score, with a required score of ≤ 4 on VAS
2. ≥ 50% improvement in patient-assess pain on walking
3. ≥ 1 point improvement on 5-point VAS scale or maintenance of 0 or 1 baseline score for patient self-assessment of activity
4. no pain medications necessary between 10 and 12 weeks after treatment

<table>
<tr><th></th><th>ESWT</th><th>Sham</th><th>p-value</th></tr>
<tr><td>3 months</td><td>47% (67/144)</td><td>30% (42/141)</td><td>0.008</td></tr>
<tr><td>12 months</td><td>45% (65/144)</td><td>18% (25/141)</td><td>0.002</td></tr>
</table>
Additional treatments
After 3 months, ESWT patients who did not have treatment success were allowed to have a second treatment and sham ESWT patients were allowed to crossover to the active treatment arm of the study).
• ESWT group: Of the 53% (77/144) patients who did not have treatment success at 3 months, 47 (61%) chose to have a second ESWT treatment. Of these, 22 had treatment success at 3 months and 20 did not (5 were lost to follow-up).
• Sham ESWT group: Of the 70% (99/141) patients who did not have treatment success at 3 months, 84 (85%) chose to have active ESWT. Of these, 36 had treatment success at 3 months and 42 did not (6 were lost to follow-up).</td>
<td>The most frequent complications in all groups were pain after treatment and mild neurological symptoms (numbness or dysaesthesia) principally related to the ankle-block anaesthesia. All patients had complete resolution of neurological symptoms at 3-month follow-up (raw data not reported).</td>
<td>This study was included in the original overview for ‘Extracorporeal shockwave therapy for refractory tendinopathies (plantar fasciitis and tennis elbow)’. NICE interventional procedures guidance 139 (2005).

Loss to follow-up: ESWT group: 97% (144/148) were evaluated at 3 months and 60% (89/148) at 12 months. Sham ESWT group: 97% (141/145) were evaluated at 3 months and 44% (64/145) at 12 months.

Analysis: intention-to-treat analysis was not used

Duration of symptoms was significantly associated with success (p = 0.001). Patients with shorter duration of symptoms had higher treatment response rates. (Both groups were similar with respect to the mean duration of symptoms prior to the study).</td>
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<td>mJ/mm^2).

Sham ESWT (n = 143) was applied using the same settings after 3 subcutaneous injections (1 mL) of local anaesthetic. A styrofoam block was placed against the treatment head to absorb the shockwaves and a fluid-filled intravenous bag was used to mimic the water-filled treatment head.

Device: OssaTron (HealthTronics Surgical Services, Marietta, Georgia and High Medical Technologies, Lengwil, Switzerland).

Follow-up: 12 months
Conflict of interest: none stated</td>
<td>Pain
Assessed by 10-cm VAS, reported as mean score.
<table>
<tr><th></th><th>ESWT</th><th>Sham</th><th>p-value</th></tr>
<tr><td>Baseline</td><td></td><td></td><td></td></tr>
<tr><td>During the morning</td><td>8.08</td><td>8.14</td><td>Not stated</td></tr>
<tr><td>During daily activities</td><td>3.49</td><td>3.53</td><td>Not stated</td></tr>
<tr><td>3 months</td><td></td><td></td><td></td></tr>
<tr><td>During the morning</td><td>3.43</td><td>4.28</td><td>0.014</td></tr>
<tr><td>During daily activities</td><td>1.72</td><td>1.88</td><td>Not significant (> 0.05)</td></tr>
<tr><td>12 months</td><td></td><td></td><td></td></tr>
<tr><td>During the morning</td><td>1.41</td><td>3.54</td><td>0.015</td></tr>
<tr><td>During daily activities</td><td>0.83</td><td>1.56</td><td>Not significant (> 0.05)</td></tr>
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<td></td>
<td></td>
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</table>

Abbreviations: RCT, randomised controlled trial; ESWT, extracorporeal shockwave therapy; VAS, visual analogue scale.

<table>
<tr><th>Study details</th><th>Key efficacy findings</th><th>Key safety findings</th><th>Comments</th></tr>
<tr>
<td>Haake M (2003)[2]

Study type: RCT (double-blind)
Country: Germany (multicentre)
Study period: March 1999 – Feb 2001
Study population: patients with plantar fasciitis.
Duration of pain: 13 months (median: both study groups)
n = 272
Age: 53 years (mean: both study groups)
Sex: 73% female (ESWT), 78% female (sham ESWT)

Inclusion criteria: plantar fasciitis with radiologically proved heel spur (three positive clinical signs: pain in the morning or after sitting a long time, local pain where the fascia attaches to the heel, increasing pain with extended walking or standing), 6 months failed conservative treatment, no therapy for previous 4 weeks.

Exclusion criteria (included): bilateral plantar fasciitis, arthrosis/arthritis of the foot, infections or tumours of the lower extremity, rheumatoid arthritis, neurological abnormalities, nerve entrapment, operative treatment of heel spur

Technique: ESWT (n = 135) applied to the heel spur at the insertion of the fascia (under ultrasound guidance, after injection of local anaesthesia) at 3 fortnightly sessions (4000 shocks, 0.08 mJ/mm^2). Total energy applied: 960 mJ/mm^2. Device: Dornier Epos Ultra lithotripter (Dornier Medizintechnik, Germany) Sham ESWT (n = 137) applied under the same conditions but a polythene foil filled with air was</td>
<td>Treatment success
Defined as Roles and Maudsley score of 1 or 2 at 3 months and the patient received no additional treatment.
<table><tr><th></th><th>ESWT</th><th>Sham</th><th>p-value</th></tr><tr><td>3 months</td><td>34% (43/127)</td><td>30% (39/129)</td><td>0.5927</td></tr></table>Treatment outcome (12 months)
Roles and Maudsley score of 1 or 2 at 12 months (of patients who were evaluated at 12-month follow-up).
<table><tr><th></th><th>ESWT</th><th>Sham</th><th>p-value</th></tr><tr><td>12 months</td><td>81% (91/113)</td><td>76% (87/115)</td><td>Not stated</td></tr></table>Additional treatment (12 months)
(of patients who were evaluated at 12-month follow-up)
• ESWT: 36% (41/113)
• Sham ESWT: 56% (64/115)
• p < 0.008 (Chi-squared t-test)

Pain
All pain scores assessed by 11-point Likert scale, reported as mean score (number of patients at each follow-up).
<table><tr><th></th><th>ESWT</th><th>Sham</th></tr><tr><td>Baseline</td><td></td><td></td></tr><tr><td>Pain at rest</td><td>3.9 (n= 135)</td><td>3.7 (n = 137)</td></tr><tr><td>Pain at night</td><td>3.0 (n = 135)</td><td>2.8 (n = 136)</td></tr><tr><td>Pain with pressure</td><td>7.0 (n = 133)</td><td>7.3 (n = 134)</td></tr><tr><td>Morning pain</td><td>7.8 (n = 135)</td><td>7.7 (n = 136)</td></tr></table></td>
<td>Number of complications
<table><tr><th></th><th>ESWT</th><th>Sham</th></tr><tr><td>3 months</td><td>47% (67/144)</td><td>30% (42/141)</td></tr><tr><td>12 months</td><td>45% (65/144)</td><td>18% (25/141)</td></tr></table>Side effects
<table><tr><th></th><th>ESWT</th><th>Sham</th></tr><tr><td>Skin reddening</td><td>12% (16/135)</td><td>4% (5/136)</td></tr><tr><td>Pain</td><td>5% (7/135)</td><td>1% (2/136)</td></tr><tr><td>Local swelling</td><td>2% (3/135)</td><td>0% (0/136)</td></tr><tr><td>Total</td><td>18% (24/135)</td><td>9% (12/135)</td></tr></table>• Odds ratio for number of side effects in ESWT compared with sham ESWT group: 2.26 (95% CI 1.02 – 5.18)
• Other less common side effects included: haematoma, nausea, dizziness, hair loss and sleep disturbance (raw data not reported).</td>
<td>This study was included in the original overview for ‘Extracorporeal shockwave therapy for refractory tendinopathies (plantar fasciitis and tennis elbow)’ (2005). NICE interventional procedures guidance 139.

Only patients with heel spurs were included.

Exclusions: 470 patients were screened, 198 did not meet criteria.

Contamination: 3 sham ESWT patients accidentally received 3 sessions of ESWT and 1 ESWT patient received sham ESWT.

Loss to follow-up at 3 months: 6% 8 ESWT patients were lost due to heel spur, unintentional injury, family death or unknown reasons; 8 sham ESWT patients were lost due to study withdrawal, thrombosis, other surgery, or unknown reasons.

Loss to follow-up at 12 months: 17%
23 ESWT patients; 22 sham ESWT patients.

Roles and Maudsley score: a self-assessed 4-point rating scale</td>
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<td>used to reflect the shock waves.

Follow-up: 12 months

Conflict of interest: none stated</td>
<td>
<table>
<tr><td>Minutes of pain free walking</td><td>22 (n = 133)</td><td>26 (n = 134)</td></tr>
<tr><td colspan="3">3 months</td></tr>
<tr><td>Pain at rest</td><td>2.4 (n= 127)</td><td>2.4 (n = 129)</td></tr>
<tr><td>Pain at night</td><td>1.5 (n = 127)</td><td>1.8 (n = 129)</td></tr>
<tr><td>Pain with pressure</td><td>4.0 (n = 126)</td><td>4.3 (n = 129)</td></tr>
<tr><td>Morning pain</td><td>4.0 (n = 127)</td><td>4.5 (n = 129)</td></tr>
<tr><td>Minutes of pain free walking</td><td>69 (n = 99)</td><td>53 (n = 98)</td></tr>
<tr><td colspan="3">12 months</td></tr>
<tr><td>Pain at rest</td><td>0.9 (n= 112)</td><td>0.9 (n = 115)</td></tr>
<tr><td>Pain at night</td><td>0.8 (n = 112)</td><td>0.7 (n = 115)</td></tr>
<tr><td>Pain with pressure</td><td>1.7 (n = 111)</td><td>1.8 (n = 115)</td></tr>
<tr><td>Morning pain</td><td>1.5 (n = 112)</td><td>1.7 (n = 114)</td></tr>
<tr><td>Minutes of pain free walking</td><td>131 (n = 51)</td><td>115 (n = 53)</td></tr>
</table>
</td>
<td></td>
<td>used by investigators to report results of ESWT. Score ranges from 1 to 4 (1 = excellent result, no symptoms, 2 = good result, significant improvement, 3 = fair result, somewhat improved, 4 = poor results same or worse symptoms)</td>
</tr>
</table>

Abbreviations: RCT, randomised controlled trial; ESWT, extracorporeal shockwave therapy; VAS, visual analogue scale;

Study details	Key efficacy findings	Key safety findings	Comments
Gerdesmeyer (2008)[3] Study type: **RCT (double blind)** Country: Germany Study period: not stated Study population: patients with chronic plantar fasciitis n = **252** Age: 52 years (mean: both study groups) Sex: 70% female (ESWT), 66% female (sham ESWT) Inclusion criteria: ≥ 6 month history of chronic plantar heel syndrome (diagnosis confirmed by physical examination with a typical point of maximum tenderness over the medial tubercle of the calcaneus), 2 failed pharmacological and 2 failed non-pharmacological treatments, ≥ 5 on pain VAS, Roles and Maudsley score of 3 or 4. Exclusion criteria (included): rheumatic or other systemic inflammatory disease, osteomyelitis, active infection or history of chronic infection in treatment area, neurological or vascular insufficiencies, nerve entrapment syndrome, coagulation problems. Technique: Radial ESWT (n = 129) applied to most tender point of the medial calcaneal tubercle, at 3 fortnightly sessions (2000 shocks per session, 0.16 mJ/mm^2). Total energy applied: 960 mJ/mm^2. Device: Dornier Epos Ultra lithotripter (Dornier Medizintechnik, Germany) Sham ESWT (n = 122) applied to the same area using the same sound effects but no energy was applied. Follow-up: **3 months** Conflict of interest: none stated	** p-values are based on one-sided tests of significance and the predefined level of significance was 0.025.* **Pain (composite score)** *Sum of 10-cm VAS score for pain during first steps of the day, pain during daily activities and pressure-induced pain (using the Dolormeter standardised local pressure inducer), reported as mean percentage change from baseline.* **ESWT** | **Sham** | **p-value** 3 months: -72.1% | -44.7% | 0.0220 12 months: -84.8% | -43.2% | 0.0086 **Treatment success** *Defined as at least 60% improvement from baseline on at least 2 of: pain in morning, pain during daily activities and pressure-induced pain, assessed by 10-cm VAS.* **ESWT** | **Sham** | **p-value** 3 months: 61% (75/125) | 42% (49/118) | 0.0014 12 months: 63% (78/125) | 44% (51/118) | 0.0144 **Treatment outcome** *Proportion of patients with Roles and Maudsley score of 1 or 2 at 3 months.* **ESWT** | **Sham** | **p-value** 3 months: 58% (73/125) | 42% (49/118) | 0.0031 ***Patient recommendation*** *Proportion of patients recommending therapy to a friend* **ESWT** | **Sham** | **p-value** 3 months: 91% (04/125) | 69% (76/118) | < 0.0001	**ESWT:** • 50 device-related adverse events in 33 patients (26%; 33/125); 46 events were pain and discomfort during treatment lasting for a maximum of 10 minutes and no patients requested local anaesthetic even though it was offered. **Sham ESWT:** • 11 adverse events in 10 patients (8%; 10/118); 7 events were pain and discomfort during treatment.	**Loss to follow-up:** 3 enrolled patients did not receive treatment (2 before randomisation and 1 after). 15 ESWT patients and 11 sham ESWT patients withdrew before the first follow-up. The primary outcome (composite pain score at 3 months) could be assessed in 90% of patients. **Analysis:** intention-to-treat analysis (last observation carried forward) was used based on patients who had at least 1 treatment session and at least 1 follow-up evaluation (ESWT: n = 125; sham ESWT: n = 118 All randomised patients in each group were analysed for safety.

Abbreviations: RCT, randomised controlled trial; ESWT, extracorporeal shockwave therapy; VAS, visual analogue scale;

<table>
<tr><th>Study details</th><th>Key efficacy findings</th><th>Key safety findings</th><th>Comments</th></tr>
<tr>
<td>Malay (2006)[4]

Study type: RCT (double-blind)
Country: USA
Study period: not stated
Study population: patients with recalcitrant proximal plantar fasciitis
n = 172
Age: 51 years (mean: ESWT), 52 years (mean: sham ESWT)
Sex: 31% female (ESWT), 37% female (sham ESWT)
Duration of foot pain: 32 months (mean: ESWT), 26 months (mean: sham ESWT)

Inclusion criteria: diagnosis of proximal plantar fasciitis (on basis of history and physical examination) with symptoms ≥ 6 months, been treated by a licensed healthcare professional ≥ 4 months, ≥ 5 on pain VAS, single site of tenderness with local pressure over the calcaneal tuberosity on passive dorsiflexion of the foot, 2 failed pharmacological and 2 failed non-pharmacological treatments, over 18 years of age.

Exclusion criteria (included): pregnancy, cardiac, neurological, hepatic, renal, metabolic or haematological disease or impairment, previous surgery for plantar fasciitis.

Technique: Patients were randomised 2:1 to ESWT (n = 115) and sham ESWT (n = 57).ESWT applied to the heel, at 1 session (3800 shocks starting at lowest energy setting [1], and increased at 3.5 minute intervals until highest energy level [7] was reached). Device: Orthospec ESWT device (Medispec Ltd). Sham ESWT (n = 57) applied at the same settings but a foam-insulation membrane was used to absorb the shockwaves.

Follow-up: 12 months
Conflict of interest: study sponsored by manufacturer</td>
<td>Investigator-assessed pain
Assessed by study investigator using 5-point VAS, reported as mean change from baseline.
<table>
<tr><th></th><th>ESWT</th><th>Sham</th><th>p-value</th></tr>
<tr><td>1 month</td><td>-1.61 (n = 111)</td><td>-1.27 (n = 54)</td><td>0.34</td></tr>
<tr><td>2 months</td><td>-2.30 (n = 111)</td><td>-1.31 (n = 54)</td><td>0.026</td></tr>
<tr><td>3 months</td><td>-2.51 (n = 112)</td><td>-1.57 (n = 56)</td><td>0.045</td></tr>
</table>
Patient-assessed pain
Assessed by patient using 5-point VAS, reported as mean change from baseline
<table>
<tr><th></th><th>ESWT</th><th>Sham</th><th>p-value</th></tr>
<tr><td>1 month</td><td>-2.23 (n = 110)</td><td>-2.12 (n = 54)</td><td>0.79</td></tr>
<tr><td>2 months</td><td>-2.67 (n = 111)</td><td>-1.94 (n = 54)</td><td>0.102</td></tr>
<tr><td>3 months</td><td>-3.39 (n = 112)</td><td>-1.78 (n = 56)</td><td>< 0.001</td></tr>
</table>
Pain – by radiographic evidence of plantar heel spur
Assessed by study investigator using 5-point VAS, reported as mean change from baseline.
<table>
<tr><th></th><th>ESWT</th><th>Sham</th><th>p-value</th></tr>
<tr><td>Plantar spur absent</td><td>-3.67 (n = 68)</td><td>-2.19 (n = 36)</td><td>0.012</td></tr>
<tr><td>Plantar spur present</td><td>-2.06 (n = 45)</td><td>-1.99 (n = 20)</td><td>0.96</td></tr>
</table>
</td>
<td>ESWT
• 3 patients (3%) reported 1 adverse event each. Two patients had bruising at the site of ESWT application that was considered to be device-related; 1 patient had local swelling that was determined to be unrelated to the device.

Sham ESWT
• No adverse events.</td>
<td>Loss to follow-up: 3 enrolled patients did not receive treatment (2 before randomisation, 1 after).
15 ESWT patients and 11 sham ESWT patients withdrew before the first follow-up.

Analysis: intention-to-treat analysis (last observation carried forward) was used based on patients who had at least 1 follow-up evaluation (n = 168).</td>
</tr>
</table>

Abbreviations: RCT, randomised controlled trial; ESWT, extracorporeal shockwave therapy; VAS, visual analogue scale;

<table>
<tr><th>Study details</th><th>Key efficacy findings</th><th>Key safety findings</th><th>Comments</th></tr>
<tr>
<td>Buchbinder (2002)[5]

Study type: RCT (double-blind)
Country: Australia
Study period: 1999-2001
Study population: patients with plantar fasciitis
n = 166
Age: 52 years (mean: ESWT), 54 years (mean: sham ESWT)
Sex: 31% female (ESWT), 37% female (sham ESWT)
Duration of foot pain: 36 months (median: ESWT), 43 months (median: sham ESWT)

Inclusion criteria: older than 18 years of age, heel pain felt maximally over the plantar aspect for ≥ 6 weeks, ultrasound confirmed lesion. When symptoms were bilateral, the more symptomatic side was included in the study

Exclusion criteria (included): generalised inflammatory arthritis, previous surgery to the heel, previous ESWT to any site, oral and/or topical non-steroidal anti-inflammatory medications in previous 2 weeks, local corticosteroid injection in previous month, oral glucocorticosteroids in previous 6 weeks

Technique: ESWT (n = 81) applied to the thickest portion of the plantar fascia adjacent to the calcaneus (with ultrasound guidance), at 3 weekly sessions (2000 or 2500 shocks, starting at lowest energy setting [1], increasing to highest tolerable level [1-9: 0.02 – 0.33 mJ/mm^2). Mean total energy applied: 1408 mJ/mm^2 (actual dose varied between patients).
Device: EPOS Ultra (Dornier MedTech America Inc.)
Sham ESWT (n = 85) applied to the same area at minimum energy level (100 shocks, 0.02 mJ/mm^2). Mean total energy applied: 6.0 mJ/mm^2.

Follow-up: 3 months
Conflict of interest: none stated</td>
<td>Pain and function
Outcomes assessed at 3 months, reported as mean change in score from baseline.
<table>
<tr><th></th><th>ESWT</th><th>Sham</th><th>p-value</th></tr>
<tr><td>Overall pain (VAS 0–100)</td><td>26.3</td><td>25.7</td><td>0.99</td></tr>
<tr><td>Pain in morning (VAS 0–100)</td><td>23.7</td><td>23.5</td><td>0.92</td></tr>
<tr><td>Pain during activity (VAS 0–100)</td><td>25.1</td><td>26.6</td><td>0.68</td></tr>
<tr><td>Maryland Foot Score (0–100, higher score indicates better function)</td><td>15.0</td><td>13.9</td><td>0.85</td></tr>
<tr><td>SF-36 Physical Function Score (0–100, higher score indicates better health)</td><td>7.5</td><td>9.8</td><td>0.49</td></tr>
</table>
Walking ability
There were no statistically significant differences between the study groups in walking ability (duration of walking without need for a rest to relieve painful heel, measured using a 6-point scale where 0 = < 5 minutes and 5 = > 60 minutes).</td>
<td>ESWT
• 1 patient had pain
• 1 patient experienced heat and numbness
• 1 patient had bruising.

Sham ESWT
• 1 patient had pain
• 1 patient experienced a burning sensation.</td>
<td>This study was included in the original overview for ‘Extracorporeal shockwave therapy for refractory tendinopathies (plantar fasciitis and tennis elbow)’ (2005). NICE interventional procedures guidance 139.

Analysis: intention-to-treat analysis was used.

Loss to follow-up: 5 patients withdrew from study prior to the first follow-up visit at 6 weeks. These patients were excluded from the efficacy analysis.

Patients were able to continue wearing orthotics and splints as prescribed, but no new devices were allowed.

Maryland Foot Score: a disability index of pain and function of the foot (scored from 0 to 100 where 100 is normal, < 60 is poor).

Short-form 36 (SF-36) Health Survey: survey of generic health-related quality of life. 36-items, 8 subscales each rated from to 100 with higher scores indicating better health (one subscale is the Physical Function Score).</td>
</tr>
</table>

Abbreviations: RCT, randomised controlled trial; ESWT, extracorporeal shockwave therapy; VAS, visual analogue scale;

<table>
<tr><th>Study details</th><th>Key efficacy findings</th><th>Key safety findings</th><th>Comments</th></tr>
<tr>
<td>Wang (2006)[7]

Study type: RCT (double-blind)
Country: Taiwan
Study period: Feb 1998 – Dec 1999
Study population: patients with chronic plantar fasciitis
n = 149
Age: 53 years (mean: ESWT), 52 years (mean: control)
Sex: 76% female (ESWT), 62% female (control)
Duration of symptoms: 9.8 years (mean: ESWT), 9.4 years (mean: control)

Inclusion criteria: plantar fasciitis diagnosis established by clinical examination and radiographs (radiographic evidence of heel spur not required)

Exclusion criteria: systematic or local infection, obstructive peripheral vascular disease, metabolic disease, less than 18 years of age

Technique: patients were randomised to ESWT (n = 79) or conservative treatment (n = 70).
ESWT: applied to affected area (focused with a control guide on the device) at 1 session (1500 shocks, 0.32 mJ/mm^2). Device: Ossatron (High Medical Technology, Switzerland). A second or third session was recommended to patients with inadequate response 30-45 days after the first.
Conservative treatment: all patients were initially treated with non-steroidal anti-inflammatory medication with additional therapies (orthotics, physical therapy, exercise programme or cortisone injection) where required.

Follow-up: 64 months (mean: ESWT), 40 months (mean: control)
Conflict of interest: none stated</td>
<td>Pain
Assessed using 10-cm VAS, reported as mean score, mean follow-up for ESWT group: 64 months, mean follow-up for control group: 40 months.
<table>
<tr><th></th><th>ESWT (n = 76)</th><th>Control (n = 65)</th><th>p-value</th></tr>
<tr><td>Baseline</td><td>4.0 ± 1.3</td><td>4.1 ± 1.1</td><td>0.179</td></tr>
<tr><td>Post-treatment</td><td>0.2 ± 0.7</td><td>4.2 ± 1.7</td><td>< 0.001</td></tr>
<tr><td>p-value</td><td>< 0.001</td><td>0.478</td><td></td></tr>
</table>
Function
Sum score (out of 30) for pain at work, pain during sports / free time, pain at night (rated from 0 [severe restriction] to 10[no restriction]).
<table>
<tr><th></th><th>ESWT (n = 76)</th><th>Control (n = 65)</th><th>p-value</th></tr>
<tr><td>Baseline</td><td>14.1 ± 4.0</td><td>13.8 ± 1.6</td><td>0.165</td></tr>
<tr><td>Post-treatment</td><td>29.6 ± 1.9</td><td>14.0 ± 1.63</td><td><0.001</td></tr>
<tr><td>p-value</td><td>< 0.001</td><td>0.190</td><td></td></tr>
</table>
Treatment outcome
Rated as excellent (no heel pain on all activities of daily living, including sports), good (< 50% of original heel pain on certain activities), fair (50-75% of original heel pain or poor (> 75% of original heel pain).
<table>
<tr><th></th><th>ESWT (n = 76)</th><th>Control (n = 65)</th></tr>
<tr><td>Excellent</td><td>69%</td><td>0</td></tr>
<tr><td>Good</td><td>14%</td><td>55%</td></tr>
<tr><td>Fair</td><td>6%</td><td>36%</td></tr>
<tr><td>Poor</td><td>11%</td><td>9%</td></tr>
</table>
Additional treatment
• 2 ESWT patients chose to have surgery and 7 ESWT patients had other treatments including herbal medicine.</td>
<td>There were no systemic or local complications or device-related problems.</td>
<td>Loss to follow-up: 8 randomised patients were lost to follow-up (3 ESWT patients, 5 control patients).

Analysis: intention-to-treat analysis was not used.

75% of patients had heel spurs on radiographs before treatment. Radiographs before and after treatment showed no discernable difference in the size or shape of the heel spur.

It is questionable whether this trial actually was double blind.</td>
</tr>
</table>

Abbreviations: RCT, randomised controlled trial; ESWT, extracorporeal shockwave therapy; VAS, visual analogue scale;

<table>
<tr><th>Study details</th><th>Key efficacy findings</th><th>Key safety findings</th><th>Comments</th></tr>
<tr>
<td>Porter (2005)[6]

Study type: RCT (single-blind)
Country: Australia
Study period: not stated
Study population: patients with proximal plantar fasciopathy
n = 125
Age: not stated
Sex: not stated

Inclusion criteria: plantar heel pain worse in morning and/or after sitting/lying for ≥ 6 weeks, maximal tenderness at calcaneal attachment of plantar fascia, pain aggravated by hopping and relieved with tie-beam taping.

Exclusion criteria (included): previous surgery, corticosteroid injection or ESWT for heel pain, clinical features suggestive of seronegative spondyloarthropathy or regional pain syndrome, rheumatoid arthritis, under 18 years of age

Technique: all patients were instructed to perform a standardised stretching programme ≥ 4 times daily then randomised to one corticosteroid injection (n = 64), or ESWT (n = 61). ESWT was applied at 3 weekly sessions (1000 shocks, 0.08 mJ/mm^2. Device: not stated. 19 patients were randomised to either treatment group but declined ESWT or injection and performed the stretching programme only (they had no additional treatment).

Follow-up: 12 months
Conflict of interest: none stated</td>
<td>Pain
Assessed using 10-cm VAS for pain on rising in the morning or after periods of sitting or lying (whichever is worse), reported as mean score.
<table>
<tr><th></th><th>ESWT (n = 61)</th><th>Injection (n = 64)</th><th>Non-randomised patients – stretching only (n = 19)</th></tr>
<tr><td>Baseline</td><td>5.52</td><td>5.47</td><td>5.47</td></tr>
<tr><td>3 months</td><td>3.69</td><td>1.48</td><td>3.58</td></tr>
<tr><td>12 months</td><td>0.84</td><td>0.84</td><td>2.42</td></tr>
</table>
Tenderness threshold
Minimum pressure to elicit pain assessed using pressure alogometer applied to tender area, reported as mean pressure (kg).
<table>
<tr><th></th><th>ESWT (n = 61)</th><th>Injection (n = 64)</th><th>Non-randomised patients – stretching only (n = 19)</th></tr>
<tr><td>Baseline</td><td>5.2 kg</td><td>5.3 kg</td><td>5.7 kg</td></tr>
<tr><td>3 months</td><td>6.72 kg</td><td>9.42 kg</td><td>7.63 kg</td></tr>
<tr><td>12 months</td><td>9.54 kg</td><td>9.6 kg</td><td>9.84 kg</td></tr>
</table>
</td>
<td>ESWT
• 6 patients had throbbing pain and erythema requiring ice
• 4 patients had severe headache or migraine.

Injection
• 8 patients had pain requiring analgesia or ice for a mean duration of 7 days.</td>
<td>Exclusions: 7 enrolled patients were not included in analyses (it is not clear whether these patients dropped out after randomisation or did not meet inclusion criteria).

Blinding: Patients were not blinded to their treatment group but outcome assessors were.</td>
</tr>
</table>

Abbreviations: RCT, randomised controlled trial; ESWT, extracorporeal shockwave therapy; VAS, visual analogue scale;

Study details	Key efficacy findings	Key safety findings	Comments
Norris (2005)[8] Study type: **cross-sectional survey** Country: USA Study period: April 2003 (treatment between August 2002 and Dec 2002) Study population: patients with plantar fasciitis who had ESWT n = **874** Age: not stated Sex: not stated Inclusion criteria: not stated Methodology: surveys were mailed to all patients who had ESWT no later than 3 months after ESWT. The survey consisted of 16 questions relating to an individual's experiences before and after ESWT which were designed to isolate the impact of the treatment on pain and mobility. Response rate: 43% (377/874) (24 surveys discarded because the data were unreadable). Treatment technique: single-treatment, high-energy protocols recommended by manufacturers (Ossatron, Sanuwave Inc and Epos, Dornier MedTech America Inc). Total dose delivered (according to protocols): 1300 mJ/mm^2. Follow-up: **n/a** Conflict of interest: none stated	*Only percentages were reported (not raw data).* **Duration and intensity of symptoms and prior treatment** • 76% had experienced pain for ≥ 1 year, 95% had had pain for ≥ 6 months. • 87% used corticosteroid injections, 83% used orthotic devices, 73% used over-the-counter medications, 72% used prescription medications. • 21% had taken other actions to relieve their pain (5% mentioned stretching exercises, 5% used shoe inserts, 3% had plantar heel surgery before ESWT). **Pain** *Scored from 1 (no pain) to 10 (very severe pain), reported as percentage of patients.* Score | Pre-treatment | Post-treatment 1–2 | 0 | 37% 3–4 | 0 | 22% 5–6 | 5% | 12% 7–8 | 36% | 16% 9–10 | 59% | 13% • Mean pre-treatment pain score: 8.76 (95% CI 8.63 to 8.90) • Mean post-treatment pain score: 4.68 (95% CI 2.95 to 4.37) • Difference significant at 1% level (Wilcoxon signed rank test). **Mobility** *Scored from 1 (total mobility) to 10 (complete immobility)* Score | Pre-treatment | Post-treatment 1–2 | 8% | 49% 3–4 | 7% | 17% 5–6 | 22% | 16% 7–8 | 45% | 12% 9–10 | 18% | 6% • Mean pre-treatment pain score: 6.67 (95% CI 6.44 – 6.91) • Mean post-treatment pain score: 3.74 (95% CI 3.46 – 4.02) • Difference significant at 1% level (Wilcoxon signed-rank test).	No safety outcomes were reported.	

Abbreviations used: RCT, randomised controlled trial; ESWT, extracorporeal shockwave therapy; VAS, visual analogue scale;			
Study details	**Key efficacy findings**	**Key safety findings**	**Comments**

Abbreviations used: RCT, randomised controlled trial; ESWT, extracorporeal shockwave therapy; VAS, visual analogue scale;

<table>
<tr><th>Study details</th><th>Key efficacy findings</th><th>Key safety findings</th><th>Comments</th></tr>
<tr>
<td>Chickpaiwong et al (2009)[12]
Study type: Retrospective review
Country: Thailand
Study period: patients undergoing consecutive ESWT treatment from July 2002 - 2004
Study population: patients with plantar fasciitis who had ESWT
n = 225 patients (246 feet)
Age: mean 49 years old
Sex: 74 male, 172 female

Inclusion criteria: Plantar fasciitis for more than 6 months; failure to respond to at least 5 conservative modalities.
Exclusion criteria: No previous surgery or shockwave therapy, corticosteroid injection within 1 month of treatment, stress, fracture of the calcarieus, pregnancy, sensitivity to lidocaine, bleeding disorder, peripheral vasculopathy or complex regional pain syndrome.

Technique: tibial nerve block using 5 to 8ml of 1% lidocaine without epinephrine. Ultrasound visualization used. ESWT administered by Epos Dornier MedTech America Inc Ultra device. Single treatment session composed of 3800 shocks (300 graded shocks and 3500 shock at 0.36 mj/mm2.

Follow-up: mean 30.2 ± 8.7 months

Conflict of interest: none reported</td>
<td>Treatment success
Defined as achieving 4 of the following 6 criteria:
• Greater than 50% improvement in VAS for patients first morning steps or during daily activities or exercise; AOFAS score increase of at least 30 points(scoring system not described); Roles and Maudsley score of 1 or 2; Greater than 50% reduction in pain upon compression of the medial calcaneal tuberosity
<table>
<tr><th>Follow-up</th><th>% success (procedures)</th></tr>
<tr><td>3 months</td><td>71% (174)</td></tr>
<tr><td>12 months</td><td>77% (190)</td></tr>
<tr><td>30.2 ± 8.7 months</td><td>78% (192)</td></tr>
</table>
Multivariate analyses identified age, daily walking hours, diabetes mellitus, and presence of a documented psychological disorder as variables that significantly reduced the likelihood of treatment success.

Pain
7% (16) of patients experienced pain during treatment averaging 4.2 on the VAS. This pain resolved after treatment within a mean 6.7 days.
<table>
<tr><th></th><th>Pre-ESWT Mean (SD)</th><th>12-month follow-up Mean (SD)</th></tr>
<tr><td>VAS 1st step in morning</td><td>8.44 (1.19)</td><td>3.17 (2.44)</td></tr>
<tr><td>VAS daily activity</td><td>8.89 (1.22)</td><td>2.87 (1.98)</td></tr>
<tr><td>VAS sport activity</td><td>9.45 (1.31)</td><td>3.64 (2.01)</td></tr>
<tr><td>AOFAS</td><td>46.02 (11.35)</td><td>78.03 (17.57)</td></tr>
<tr><td>R & M score</td><td>3.75 (0.44)</td><td>1.71 (0.92)</td></tr>
</table>
Scoring system not described for any</td>
<td>3% (7) of patients had numbness and dysthesia in the distrubition of the medial and lateral plantar nerves that resolved spontaneously within 12.6 days.

2% (5) of patients had eechymsis and petechiae at the treatment area that resolved spontaneously before 3 month follow-up.

1 patient had a superficial skin infection along the medial hindfoot that did not require surgical treatment.</td>
<td></td>
</tr>
</table>

Abbreviations used: RCT, randomised controlled trial; ESWT, extracorporeal shockwave therapy; VAS, visual analogue scale;			
Study details	**Key efficacy findings**	**Key safety findings**	**Comments**

Validity and generalisability of the studies

- Studies in table 2 included a variety of treatment protocols, particularly with respect to the number of shockwaves applied, the number of treatment sessions, the energy density of shockwaves, the use of ultrasound guidance and the use of local anaesthetic.
- Sham ESWT varied across the studies. In most studies, sham ESWT involved the same treatment protocol as active ESWT, but using a device (such as a foam pad) to absorb the shockwaves. However, one study (Gerdesmeyer et al 2008) did not apply energy during sham ESWT and another (Buchbinder et al 2002) applied minimal energy (0.02 mJ/mm^2) and fewer shockwaves than in active ESWT with no device to absorb the shockwaves.
- Inclusion and exclusion criteria differed across the studies (e.g. the duration of symptoms required for inclusion ranged from 6 weeks to 6 months and 1 study [Wang et al 2006] had no inclusion criterion stipulating duration of symptoms).

Specialist Advisers' opinions

Specialist advice was sought from consultants who have been nominated or ratified by their Specialist Society or Royal College. The advice received is their individual opinion and does not represent the view of the society.

Simon Donnell (British Orthopaedic Association), James Rankine and David Silver (British Society of Skeletal Radiologists), Paul Halliwell, Bob Sharp, Stephen Milner and Nicola Maffuli (British Orthopaedic Foot and Ankle Society),

- Four Advisers thought the procedure was established practice and three thought it was a novel procedure.
- The Advisers all thought that the comparator was steroid injection. One adviser listed an additional comparator as low-dye taping, and dry needling was listed by a different adviser.
- The Advisers thought that adverse events included bruising, pain, local skin damage, and rupture of the plantar fascia (however, since division of the plantar fascia is a recognised surgical treatment for plantar fasciitis, this is not likely to cause any problems). One Adviser reported anecdotal cases of bruising.
- Four Advisers stated that there were no uncertainties about the safety of the procedure.
- The Advisers thought that the key efficacy outcome was relief of symptoms, including resolution of pain, return to sporting activities and decreased morning stiffness. One Adviser stated that the main uncertainty about efficacy was unpredictable outcomes, and another stated that it is better than placebo but questioned whether the therapeutic benefit is due to natural history. One Adviser stated that there is considerable doubt as to whether this procedure is

any more effective than conventional treatment and that this procedure is likely to have a significant placebo effect.

- One Adviser thought a theoretical adverse event could include exacerbation of the condition because of rupture of the plantar fascia. A different Adviser thought that the local soft tissue damage, thought to stimulate the healing process after shockwave treatment, may be a theoretical adverse risk.
- One Adviser stated that it should be performed using diagnostic ultrasound to target the tissues rather than applying it 'blind' (which requires training in musculoskeletal ultrasound). Another thought that training needs depend upon the type of equipment used. If ultrasound-guided ESWT is used then training in musculoskeletal ultrasound is necessary, whereas a radial type device can be used 'blindly'. One Adviser stated that clinicians must be able to diagnose the condition correctly and administer the appropriate number and frequency of shocks.
- Three Advisers thought that it would be likely to be carried in a minority of hospitals and four thought that it would be carried out in most general hospitals. One Adviser stated that non-image-guided radial ESWT may be more widely available. Another Adviser thought that uptake of the procedure would be low unless clear and robust clinical and cost-effectiveness data become available.
- One Adviser stated that it is unclear exactly which patients will benefit and exactly how to give the best treatment. A different adviser commented that the major issue is the choice of patient.

Patient commentary

NICE's Patient and Public Involvement Programme sent eight questionnaires to one trust for distribution to patients who had the procedure (or their carers). NICE received no completed questionnaires.

Issues for consideration by IPAC

- The studies reported no significant safety concerns.
- It has been suggested that the use of local anaesthesia and/or nerve block may affect outcomes (i.e. interferes with identifying target area for ESWT).

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11. Institute for Clinical Systems Improv ement (2004). ESWT for plantar fasciitis. Technology Assessment Report 86.
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Appendix A: Additional papers on extracorporeal shockwave therapy for refractory plantar fasciitis

The following table outlines the studies that are considered potentially relevant to the overview but were not included in the main data extraction table (table 2). It is by no means an exhaustive list of potentially relevant studies.

Article	Number of patients/ follow-up	Direction of conclusions	Reasons for non-inclusion in table 2
Greve JM, Grecco MV, Santos-Silva P R (2009) Comparison of radial shockwaves and conventional physiotherapy for treating plantar fasciitis. Clinics (Sao Paulo, Brazil) 64 (2): 97−103	n = 32	ESWT was no more effective than conventional physiotherapy at 3-month evaluation.	Studies with more patients are included in table 2.

Rompe JD,Furia J, Weil L et al. (2007) Shockwave therapy for chronic plantar fasciopathy. British Medical Bulletin 83: 183–208	n = 2100	Considerable heterogeneity in terms of methodological quality, treatment regimen, patient selection and follow-up period. A pooled meta-analysis of SWT for chronic plantar fasciopathy was considered inappropriate.	Paper is a review not a clinical study.
Labek G, Auersperg V, Ziernhold M, et al. (2005) Influence of local anesthesia and energy level on the clinical outcome of extracorporeal shock wave-treatment of chronic plantar fasciitis. Z Orthop Ihre Grenzgebiete 143: 240–6	n = 60	Local anaesthesia was shown to influenced the clinical results after low energy ESWT.	Focus of the paper was the effect of local anaesthesia on ESWT.
Rompe JD, Meurer A, Nafe B, et al. (2005) Repetitive low-energy shock wave application without local anesthesia is more efficient than repetitive low-energy shock wave application with local anesthesia in the treatment of chronic plantar fasciitis Journal of Orthopaedic Research; 23: 931–41	n = 60	67% of patients treated without local anaesthesia achieved 50% reduction of pain compared with 29% who had local anaesthesia (p<.001).	Focus of the paper was the effect of local anaesthesia on ESWT.
Ogden JA, Alvarez R, Levitt R, et al. (2001) Shock wave therapy for chronic proximal plantar fasciitis. Clinical Orthopaedics & Related Research 387:47-59.	n=302	56% of patients treated by ESWT had a successful result 3-months after first treatment. ESWT is a safe and effective non-surgical method for treating heel pain	No new safety outcomes and studies with more patients are included in table 2.
Chow IHW, Cheing GLY (2007) Comparison of different energy densities of extracorporeal shock wave therapy (ESWT) for the management of chronic heel pain. Clinical rehabilitation 21: 131–42	n = 57	The delivery of ESWT with a maximum tolerable energy density is a more effective treatment protocol than a fixed energy density in terms of relieving pain and restoring the functional activity of people suffering from chronic heel pain. The analgesic effects were maintained at least up to the 3-week follow-up	Studies with more patients are included in table 2.
Furia JP (2005) The safety and efficacy of high energy extracorporeal shock wave therapy in active, moderately active, and sedentary patients with chronic plantar fasciitis. Orthopedics 28: 685–92	n = 53	Fifty heels (83.3%) were assigned an excellent or good result. Extracorporeal shock wave therapy is an effective treatment for chronic plantar fasciitis.	Studies with more patients are included in table 2.
Kudo P, Dainty K., Clarfield M et al. (2006) Randomized, placebo-controlled, double-blind clinical trial evaluating the treatment of plantar fasciitis with an extracoporeal shockwave therapy (ESWT) device: a North American confirmatory study. Journal of Orthopaedic Research 24: 115–23.	n = 114	Significant differences (favoring ESWT) between ESWT and placebo in change from baseline to 3 months in pain during the first few minutes of walking (VAS) and in Roles and Maudsley scores.	Studies with more patients are included in table 2.
Lee GP, Ogden J.A., Cross GL (2003) Effect of Extracorporeal Shock Waves on Calcaneal Bone Spurs. Foot and Ankle International 24: 927–30	n = 435	Clinical outcome after ESWT was satisfactory in 168 patients (82%) with a radiographically demonstrable inferior heel spur and in 81 patients (79%) without such a heel spur. There was no correlation between the	Another study reporting on the same group patients is included in table 2.

		presence or absence of the heel spur and the eventual treatment outcome.	
Liang HW, Wang TG, Chen WS et al. (2007) Thinner plantar fascia predicts decreased pain after extracorporeal shock wave therapy. Clinical Orthopaedics & Related Research 460: 219–25	n = 53	Patients with thinner plantar fascia experienced less pain after treatment. Overall success rates were 63% and 60% at 3 and 6 months. High- and low-intensity treatments were associated with similar improvements in pain and function.	Studies with more patients are included in table 2.
Moretti B, Garofalo R, Patella V et al. (2006) Extracorporeal shock wave therapy in runners with a symptomatic heel spur. Knee Surgery, Sports Traumatology, Arthroscopy 14: 1029–32	n =54	Clinical results were excellent in 59% of cases, good in 12%, satisfactory in 21% and distinctly unsatisfactory in 8%. There was a persistent improvement lasting 24 months.	Studies with more patients are included in table 2.
Ogden J, Alvarez RG, Cross GL et al. (2005) Plantar fasciopathy and orthotripsy: the effect of prior cortisone injection. Foot & Ankle International 26: 231–4	n = 555	The prior injection of cortisone did not affect the likelihood of a positive response to ESWT. Similarly, the absence of prior injection of cortisone did not affect the outcome.	
Rompe JD, Meurer A, Nafe B et al. (2005) Repetitive low-energy shock wave application without local anesthesia is more efficient than repetitive low-energy shock wave application with local anesthesia in the treatment of chronic plantar fasciitis. Journal of Orthopaedic Research 23: 931–41	n = 86	At 3 months, the average pain score was significantly lower in patients who had low-energy ESWT without local anaesthesia than those who the same treatment without local anaesthesia. Significantly more patients who had ESWT with local anaesthesia achieved 50% reduction of pain.	Studies with more patients are included in table 2.
Speed CA, Nichols D, Wies H (2003) Extracorporeal shock wave therapy for plantar fasciitis. A double blind randomised controlled trial. Journal of Orthopaedic Research 21: 937–940	n = 88	Both ESWT and sham ESWT patients showed significant improvements in pain over 6 months but there were no significant difference between the groups. At 3 months, 37% of ESWT patients and 24% of sham ESWT patients had a 50% improvement in pain from baseline.	Studies with more patients are included in table 2.
Theodore GH, Buch M, Amendola A et al. (2004) Extracorporeal shock wave therapy for the treatment of plantar fasciitis. Foot and Ankle International / American Orthopaedic Foot and Ankle Society [and] Swiss Foot and Ankle Society 25: 290–7	n = 150	There were no significant differences between ESWT and sham ESWT groups in any outcomes at 3 months. 56% of ESWT patients had success at 3 months and 94% had success at 12 months. In the sham ESWT group, 47% had success at 3 months (no score at 12 months).	Studies with more patients are included in table 2.

Appendix B: Related NICE guidance for extracorporeal shockwave therapy for refractory plantar fasciitis

Guidance	Recommendations
Interventional procedures	**Extracorporeal shockwave therapy for refractory tendinopathies (plantar fasciitis and tennis elbow). NICE interventional procedures guidance 139 (2005).** 1.1 Current evidence on extracorporeal shockwave therapy for refractory tendinopathies (specifically tennis elbow and plantar fasciitis) suggests that there are no major safety concerns. Evidence on efficacy is conflicting, and suggests that the procedure produces little benefit apart from a placebo response in some patients. Therefore, current evidence on efficacy does not appear adequate to support its use without special arrangements for consent, and for audit or research. 1.2 Clinicians wishing to undertake extracorporeal shockwave therapy for refractory tendinopathies should take the following actions. • Inform the clinical governance leads in their trusts. • Ensure that patients understand the uncertainty about the procedure's efficacy and provide them with clear written information. In addition, use of the Institute's Information for the public is recommended. • Audit and review clinical outcomes of all patients having extracorporeal shockwave therapy for refractory tendinopathies. The Institute may review the procedure upon publication of further evidence. **Extra-corporeal shockwave lithotripsy for calcific tendonitis (tendinopathy) of the shoulder. NICE interventional procedures guidance 21 (2003).** 1.1 Current evidence on the safety and efficacy extracorporeal shockwave lithotripsy for calcific tendonitis of the shoulder appears adequate support the use of the procedure, provided that normal arrangements are in place for consent, audit and clinical governance. **Autologous blood injection for refractory tendonitis. NICE interventional procedures guidance (2009).** 1.1 Current evidence on the safety and efficacy of autologous blood injection for tendinopathy is inadequate in quantity and quality. Therefore this procedure should only be used with special arrangements for clinical governance, consent and audit or research. 1.2 Clinicians wishing to undertake autologous blood injection for

	tendinopathy should take the following actions. • Inform the clinical governance leads in their Trusts. • Ensure that patients understand the uncertainty about the procedure's efficacy, especially in the long term, make them aware of alternative treatments and provide them with clear written information. In addition, use of NICE's information for patients ('Understanding NICE guidance') is recommended (available from www.nice.org.uk/IPG279publicinfo). • Audit and review clinical outcomes of all patients having autologous blood injection for tendinopathy (see section 3.1). 1.3 Future research should be in the context of randomised controlled trials that define chronicity of tendinopathy and clearly describe any previous or adjunctive treatments (including physiotherapy and 'dry needling') as well as the tendons treated. They should address the role of ultrasound guidance and include functional and quality of life outcomes with a minimum follow-up of 1 year. NICE may review the procedure upon publication of further evidence.

Appendix C: Literature search for extracorporeal shockwave therapy for refractory plantar fasciitis

Database	Date searched	Version/files
Cochrane Database of Systematic Reviews – CDSR (Cochrane Library)	26/11/08	Issue 4, 2008
Database of Abstracts of Reviews of Effects – DARE (CRD website)	26/11/08	N/A
HTA database (CRD website)	26/11/08	N/A
Cochrane Central Database of Controlled Trials – CENTRAL (Cochrane Library)	26/11/08	Issue 4, 2008
MEDLINE (Ovid)	27/11/08	1950 to November Week 3 2008
MEDLINE In-Process (Ovid)	27/11/08	November 26, 2008
EMBASE (Ovid)	27/11/08	1980 to 2008 Week 48
CINAHL (Search 2.0, NLH)	26/11/08	1981 to present
BLIC (Dialog DataStar)	26/11/08	1993 to date
National Research Register (NRR) Archive	11/09/08	N/A
UK Clinical Research Network (UKCRN) Portfolio Database	11/09/08	N/A
Current Controlled Trials *meta*Register of Controlled Trials - *m*RCT	11/09/08	N/A
Clinicaltrials.gov	11/09/08	N.A

The following search strategy was used to identify papers in MEDLINE. A similar strategy was used to identify papers in other databases.

1	High-Energy Shock Waves/
2	Lithotripsy/
3	((Shockwave* or Shock-wave*) adj3 (Therap* or Treatment* or Lithotrip*)).tw.
4	(ESWT or ESWL or ESWLS).tw.
5	or/1-4
6	Fasciitis, Plantar/
7	(Plantar* adj3 (Fasciit* or Fascit* or Heel*)).tw.
8	(Heel* adj3 (Spur* or Pain*) adj3 Syndrome*).tw.

9	or/6-18
10	5 and 9
11	200410*.ed.
12	200411*.ed.
13	200412*.ed.
14	2005*.ed.
15	2006*.ed.
16	2007*.ed.
17	2008*.ed.
18	or/11-17
19	10 and 18
20	Animals/
21	Humans/
22	20 not (20 and 21)
23	19 not 22