NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedure overview of extracorporeal shockwave therapy for refractory Achilles tendinopathy

Achilles tendinopathy is a condition of the tendon which connects the calf muscles to the heel bone. It may be associated with tiny tears in the fibres of the tendon and is usually caused by overuse or injury. Symptoms include pain in the lower calf and back of the heel, weakness or stiffness. 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 may stimulate healing.

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 Achilles tendinopathy

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

Achilles tendinopathy is characterised by chronic degeneration of the Achilles tendon usually caused by injury or overuse. Symptoms include pain, swelling, weakness and stiffness of the back of lower calf and heel.

Conservative treatments include rest, application of ice, orthotic devices, physiotherapy, analgesic medication, non-steroidal anti-inflammatory drugs, corticosteroid injection and eccentric training/stretching. Surgery may rarely be considered in patients with refractory symptoms with the aim of repairing partial tears in the Achilles tendon.

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.

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

List of studies included in the overview

This overview is based on 314 patients from 4 randomised controlled trials (RCTs), 2 case–control studies and 1 case series.

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

An RCT of 75 patients compared ESWT, eccentric loading and a wait-and-see policy for the treatment of non-insertional Achilles tendinopathy. Patient-assessed recovery from baseline (defined as a score of 1 or 2 on a 6-point Likert scale ranging from completely recovered to much worse), was reported in 53% (13/25), 60% (15/25) and 24% (6/25) of each group respectively at 4-month follow-up. Improvement in Achilles tendon function from baseline to 4-month follow-up (assessed using the VISA-A score) was 20, 25 and 7 points in each group respectively. There were no statistically significant differences between the ESWT and eccentric loading groups in any outcome measures.

However, both groups had significantly better results than the wait-and-see group in all outcomes measures[1].

In an RCT by the same investigators comparing ESWT and eccentric loading for the treatment of insertional Achilles tendinopathy (n = 50), patient-assessed recovery (defined as in the above study) was reported in 64% (16/25) and 28% (7/125) of each group respectively at 4-month follow-up ($p < 0.020$). Patients who had ESWT had significantly better self-rated recovery, tenderness and pain threshold than patients treated by eccentric loading[2].

An RCT comparing ESWT with sham ESWT in patients with Achilles tendinopathy (n = 49) reported no significant differences between groups on all outcome measures (VAS for pain on walking, pain at rest, pain during sports or quality of life)[3].

An RCT comparing ESWT with sham ESWT for Achilles tendinopathy (n = 48) reported that pain (assessed using VAS) improved over time in both groups and that there was no significant difference between groups (raw data not reported)[4].

A case–control study compared 34 patients who had ESWT and 34 patients who had non-operative treatments for non-insertional Achilles tendinopathy. Pain (assessed using VAS) improved from 8.2 to 2.2 at 12 months ($p < 0.001$) in ESWT patients and from 8.4 to 5.6 in controls ($p > 0.001$). An 'excellent' or 'good' outcome (assessed using Roles and Maudesly scale) was reported in 85% of ESWT patients and 27% of controls[5]. In an equivalent study from the same centre but in patients with insertional Achilles tendinopathy, pain improved from 7.9 to 2.8 ($p < 0.001$) in ESWT patients (n = 35) and from 8.6 to 7.0 in controls (n = 33). An 'excellent' or 'good' treatment outcome was reported in 83% percent of ESWT patients and 39% of controls[6].

A case series of 15 patients with 16 cases of non-insertional Achilles tendinopathy treated with ESWT, reported overall improvement in symptoms in 14 cases (88%) and no improvement in 2 cases (12%). Eleven patients improved significantly and returned to near-normal activities. Mean pain score (assessed using a VAS) improved from 4.1 (± 2.0) before treatment to 0.7 (± 1.2) after treatment (mean follow-up: 21 months; $p < 0.001$)[8].

Safety

Transient skin reddening occurred in all ESWT patients in the RCT of 75 patients and in 3 patients each in the two case–control studies (n = 68 in both studies)[5,6]. In one of the case–control studies, 2 patients had pain during ESWT and 1 patient had transient numbness for 24 hours after ESWT[5].

Calf ache was reported in some patients who had eccentric loading in the RCT of 75 patients (numbers not reported), and in an equal number ('the majority') of patients in both groups in the RCT of 49 patients (numbers not

reported)[1,3]. Two patients in this RCT had Achilles tendon rupture 2 weeks after the first ESWT treatment session due to falls[3].

Literature review

Rapid review of literature

The medical literature was searched to identify studies and reviews relevant to extracorporeal shockwave therapy for refractory Achilles tendinopathy. Searches were conducted of the following databases, covering the period from their commencement to 26/11/08: 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 Achilles tendinopathy.
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

There were no published assessments from other organisations identified at the time of the literature search.

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 Achilles tendinopathy

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>Rompe (2007)[1]

Study type: RCT (single-blind)
Country: USA
Study period: not stated
Study population: patients with non-insertional tendinopathy (of the main body of the Achilles tendon).
n = 75
Age: 48 years (mean: ESWT), 51 years (mean: eccentric loading), 46 years (mean wait and see)
Sex: 64% female (mean: ESWT), 56% female (mean: eccentric loading), 64% female (mean: wait and see)

Inclusion criteria: chronic midportion (non-insertional) Achilles tendinopathy for ≥ 6 months, failed non-operative management (all patients had undergone a combination of ≥ 1 peritendinous local anaesthetic injection and/or corticosteroid, a trial of anti-inflammatory medications, use of orthotics and/or a heel lift and physiotherapy), aged between 18 and 70 years.

Exclusion criteria (included): peritendinous local anaesthetic injection and/or corticosteroid within 4 weeks, bilateral tendinopathy, other conditions that could contribute to posterior ankle pain (such as osteoarthritis).</td>
<td>Patient-assessed recovery
Assessed at 4 months using a 6-point Likert scale (self-rated from 1 [completely recovered] to 6 [much worse] compared with baseline), reported as percent of patients with a good recovery score (1 or 2; ‘completely recovered’ or ‘much improved’).
<table>
<tr><th></th><th>ESWT</th><th>Eccentric loading</th><th>Wait-and-see</th></tr>
<tr><td>4 months</td><td>53% (13/25)</td><td>60% (15/25)</td><td>24% (6/25)</td></tr>
<tr><td>p-value (vs wait-and-see group)</td><td>0.001</td><td>< 0.001</td><td>n/a</td></tr>
</table>
Achilles tendon function
Assessed using the Victorian Institute of Sport Assessment-Achilles (VISA-A) score, reported as mean score and standard deviation.
<table>
<tr><th></th><th>ESWT</th><th>Eccentric loading</th><th>Wait-and-see</th></tr>
<tr><td>Baseline</td><td>50 (± 12)</td><td>51 (± 12)</td><td>48 (± 9)</td></tr>
<tr><td>4 months</td><td>70 (± 16)</td><td>76 (± 19)</td><td>55 (± 13)</td></tr>
<tr><td>p-value (vs baseline)</td><td>< 0.01</td><td>< 0.01</td><td>not stated</td></tr>
</table>
Pain threshold
Minimum pressure that induced pain in the most tender part of the tendon, reported as mean kg.
<table>
<tr><th></th><th>ESWT</th><th>Eccentric loading</th><th>Wait-and-see</th></tr>
<tr><td>Baseline</td><td>1.4 (± 0.8)</td><td>1.5 (± 0.6)</td><td>1.6 (± 0.8)</td></tr>
<tr><td>4 months</td><td>2.8 (0.9)</td><td>3.1 (± 1.1)</td><td>2.1 (± 1.0)</td></tr>
<tr><td>p–value (vs baseline)</td><td>p < 0.001</td><td>p < 0.001</td><td>p < 0.001</td></tr>
</table>
Tenderness
Assessed using an 11-point Likert scale of pain when a pressure of 3 kg was applied to the most tender part of the tendon (rated from 0</td>
<td>There were no serious complications.
All patients had transient reddening of the skin after ESWT.
Patients reported ache in the calf after eccentric loading.</td>
<td>Exclusions: 122 patients were screened but 46 were excluded for not meeting inclusion criteria and 1 patient withdrew from the study.

Analysis: intention-to-treat (last observation carried forward using baseline data).

Loss to follow-up (n = 5): Eccentric loading: 2, wait-and-see: 2; ESWT: 1.

Victorian Institute of Sport Assessment-Achilles (VISA-A) score: validated 8-item questionnaire of Achilles tendon problems rated from 1 to 100 (an asymptomatic person would score 100)</td>
</tr>
</table>

<table>
<tr>
<td>Technique: All treatments were started after a washout period of 12 weeks after any non-operative therapy. Patients were randomised to repetitive low-energy ESWT (n = 25), eccentric loading (n = 25) or wait-and-see policy (n = 25).

ESWT: applied to the area of maximum tenderness at 3 weekly sessions (2000 shocks per session, 0.1 mJ/mm^2). Device: Swiss DolorCast (EM, Electromedical systems)

Eccentric loading: patients were taught how to perform calf strengthening exercises with progressive weight loading (form assessed over several weeks by a medical assistant). Exercises were to be done twice a day for 12 weeks.

Wait-and-see policy: patients were encouraged not to have additional treatment.

Follow-up: 4 months

Conflict of interest: none stated</td>
<td>[no pain] to 10 [very severe pain], reported as mean rating and standard deviation.

<table>
<tr><th></th><th>ESWT</th><th>Eccentric loading</th><th>Wait-and-see</th></tr>
<tr><td>Baseline</td><td>6.4 (± 4.4)</td><td>7.1 (± 3.6)</td><td>6.8 (± 3.1)</td></tr>
<tr><td>4 months</td><td>2.6 (± 4.2)</td><td>1.7 (± 3.9)</td><td>4.3 (± 7.0)</td></tr>
<tr><td>p-value (vs baseline)</td><td>p < 0.001</td><td>p < 0.001</td><td>p < 0.001</td></tr>
</table>
Between group differences
• There were no statistically significant differences in any outcome measures (4 months) between the ESWT and eccentric loading groups.
• Both ESWT and eccentric loading groups had significantly better results across all outcome measures (4 months) than the wait-and-see group.</td>
<td></td>
<td></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
Rompe (2008)[2] Study type: **RCT (single-blind)** Country: USA Study period: not stated Study population: patients with <u>insertional</u> Achilles tendinopathy. n = **50** Age: 40 years (mean) Sex: 60% female Inclusion criteria: chronic insertional Achilles tendinopathy for ≥ 6 months (defined as localised pain over the distal part of the tendon at its insertion onto the calcaneus, with local tenderness and reduced activity. Established tests were used to rule out more extensive tendinopathy or paratendinopathy involving the body of the tendon), failed non-operative management (all patients had undergone a combination of ≥ 1 peritendinous local anaesthetic injection and/or corticosteroid, a trial of anti-inflammatory medications, use of orthotics and/or a heel lift and physiotherapy), aged between 18 and 70 years Exclusion criteria (included): ultrasound evidence of thickening of the tendon and/or irregular tendon structure with hypoechoic area and/or an irregular fibre orientation in the midportion of the tendon, ultrasound evidence of superficial or retrocalcaneal fluid as a sign of bursitis, peritendinous	**Patient-assessed recovery** *Assessed at 4 months using a 6-point Likert scale (self-rated from 1 [completely recovered] to 6 [much worse] compared with baseline), reported as percent of patients with a good recovery score (1 or 2).* **ESWT** | **Eccentric loading** | **p-value** 4 months | 64% (16/25) | 28% (7/25) | < 0.020 **Pain** *Assessed at 4-month follow-up; see Rompe 2007 for details of assessment scales (Note: lower score = less pain).* **ESWT** | **Eccentric loading** | **p-value** Achilles tendon function (VISA-A score 1–100) | 79 ± 10 | 63 ± 12 | 0.005 Patient-assessed recovery (score 0–6) | 2.8 ± 1.6 | 3.7 ± 1.5 | 0.043 Tenderness (score 0–10) | 2.4 ± 4.2 | 4.4 ± 3.2 | 0.021 Pain threshold (kg) | 3.5 ± 1.1 | 2.2 ± 1.6 | 0.002 **Treatment crossover** *Patients were allowed to crossover to the other treatment group or choose any other treatment if they did not feel that they had completely recovered or had much improvement at 4-month follow-up.* • All 18 patients in the eccentric loading group (72%) who had failed treatment opted to have ESWT • Of the 9 patients in the ESWT group who had failed treatment, 8 opted to have eccentric loading and 1 opted to have surgery. • After 15 months of follow-up, no side effects were reported in either treatment group and no patient who was followed-up sustained an Achilles rupture (n = 21 in each study group).	No side effects were reported in either study group after 15 months of follow-up (n = 21 in each study group).	**Exclusions:** 23 enrolled patients did not meet inclusion criteria or were unwilling to participate. **Analysis:** intention-to-treat (last observation carried forward using baseline data). **Loss to follow-up (n = 5):** 2 eccentric loading patients discontinued treatment due to persistent pain and 1 refused to attend the follow-up appointment. 2 ESWT patients refused to attend the follow-up appointment.

injection within previous 4 weeks Technique: patients were randomised to repetitive low-energy ESWT (n = 25) or eccentric loading (n = 25). ESWT: applied to the area of maximum tenderness at 3 weekly sessions (2000 shocks per session, 0.12 mJ/mm^2). Device: Swiss DolorCast (EM, Electromedical systems). Eccentric loading: patients were taught how to perform calf strengthening exercises with progressive weight loading (form assessed after over several weeks by a medical assistant). Exercises were to be done twice a day for 12 weeks. Follow-up: **15 months** Conflict of interest: none stated			

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

Study details	Key efficacy findings	Key safety findings	Comments
Rasmussen (2008)[4] Study type: **RCT (double-blind)** Country: Denmark Study period: Oct 2004 – Jan 2005 Study population: patients with chronic Achilles tendinopathy. n = **48** Age: 46 years (mean: ESWT); 49 years (mean: sham) Sex: 67% female (ESWT); 50% female (sham) Inclusion criteria: chronic symptoms of Achilles tendinopathy for ≥3 months (area of swelling moving with dorsiflexion and plantarflexion of the ankle, tenderness in neutral position or slightly plantarflexed, and tenderness exacerbated by dorsiflexion of the ankle), patients who have full working capacity, over 18 years of age Technique: all patients were first given conservative treatment (eccentric training and stretching exercises) at 4 sessions over 4 weeks. Patients were randomised to repetitive high-energy ESWT (n = 25) or sham ESWT (n = 25). ESWT: applied to the area of swelling and tenderness at 4 weekly sessions (2000 shocks, 0.12–0.51 mJ/mm^2). Device: not stated. Sham ESWT: applied to the same area with 2000 shocks per session but at energy of 0 mJ/mm^2. Follow-up: **3 months** Conflict of interest: none stated	**Pain** *Assessed at 3-month follow-up using American Orthopaedic Foot and Ankle Society scale of function, pain and alignment (scored from 0–100 where 100 represents the best result).* **ESWT** / **Sham** Pre-treatment: 70 (± 6.8) / 74 (± 12.0) Post-treatment: 88 (± 12.0) / 81 (± 16.0) p-value: Not stated / Not stated **Pain – VAS** *Assessed using VAS (points scale not stated) at 3-month follow-up for pain on walking, pain on walking upstairs, pain on working and pain on running.* • Weekly mean VAS pain scores reduced over time (across all measures of pain) in both groups. There was no statistically significant difference between the groups (raw data not reported).	No safety outcomes were reported.	**Exclusions:** 66 patients were assessed for eligibility but 15 did not meet inclusion criteria. 51 patients were enrolled but 3 were not randomised because they wanted to choose their own treatment. **Analysis:** Intention-to-treat analyses were conducted on all patients who were randomised. **Loss to follow-up (n = 3):** 1 patient opted to have knee arthroscopy and was excluded from the study; 2 patients did not attend the final 3-month follow-up.

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

Study details	Key efficacy findings	Key safety findings	Comments
Costa (2005)[3] Study type: **RCT (double-blind)** Country: UK Study period: April 2001 – Nov 2001 Study population: patients with chronic Achilles tendinopathy. All patients had tenderness on ankle dorsiflexion (insertional pain: 6%, midsubstance fusiform swelling: 94%). n = **49** Age: 59 years (mean: ESWT); 48 years (mean: sham) Sex: 59% female (ESWT); 56% female (sham) Inclusion criteria: aged > 18 years (patients were included regardless of previous treatment or any underlying degenerative joint disease – 94% of patients had had previous treatment for Achilles pain). Exclusion criteria: contraindications to shockwave therapy (pregnancy, local malignancy, coagulopathy or a pacemaker) Technique: patients were randomised to repetitive ESWT (n = 22) or sham ESWT (n = 27). ESWT: applied to the area of tenderness (using ultrasound guidance) at 3 monthly sessions (1500 shocks, maximum 0.2 mJ/mm^2 according to individual patient tolerance). Device: Storz Modulith SLK (Storz AG, Switzerland) Sham ESWT: applied at same settings but with bubble wrap covered in an opaque cloth between the head of the machine and the tendon to dissipate shockwaves. Follow-up: **3 months** Conflict of interest: none stated	There were no differences between the ESWT and control groups on any outcomes measures. All outcomes were assessed at 3-month follow-up. **Pain** *Assessed using 10-cm VAS.* **ESWT** | **Sham** | **p-value** On walking: 35 (± 34) | 50 (± 36) | 0.127 At rest: 27 (± 31) | 35 (± 34) | 0.408 During sports: 48 (± 31) | 58 (± 38) | 0.338 **Ankle range of motion** *Assessed using a goniometer.* **ESWT** | **Sham** | **p-value** Dorsiflexion: 16 (± 15) | 20 (± 12) | 0.323 Plantarflexion: 43 (± 14) | 38 (± 14) | 0.323 **Walking on tiptoe** **ESWT** | **Sham** | **p-value** Unable: 27% (6/22) | 30% (8/27) | Not stated < 5 s: 18% (4/22) | 19% (5/27) | 0.587 5–10 s: 20% (1/22) | 15% (4/27) | Not stated > 10 s: 50% (11/22) | 37% (10/27) | Not stated **Quality of life** *Assessed by the EQoL questionnaire.* **ESWT** | **Sham** | **p-value** EQoL-5D: 0.11 (± 0.24) | 0.07 (± 0.24) | 0.604 Health score: 1.55 (± 35) | -4.23 (± 20) | 0.495 **Lower limb function** *Assessed by the Functional Index of Lower Limb Ability.* **ESWT** | **Sham** | **p-value** FIL score: 0.95 (± 0.96) | 0.24 (± 0.24) | 0.137	During the study, 2 patients had tendon Achilles rupture. Both patients (aged 62 and 65 years) were in the treatment group and both ruptures occurred within 2 weeks of their first treatment. One patient fell down a step at home and the other fell while stepping out of an ambulance. Both chose non-operative treatment; one patient had complete resolution of symptoms and the other had persistent pain. There were no major complications. The majority of patients (equal numbers in both groups) reported aching in the calf in the 48 hours after treatment.	Mean age of the control group was 11 years younger than that of the treatment group. **Analysis**: intention-to-treat (last observation carried forward using baseline data). **Loss to follow-up:** 7 patients did not attend 3-month follow-up. In 1 patient, pain had resolved after 2 treatment sessions and he did not want to take time off work (reason for not attending was unknown in 6 patients). **EQoL:** European Quality of Life generalised health status questionnaire consisting of the EQoL-5D (score of 5 daily activities of living) and the EQoL health score (summary score of general health). **Functional Index of Lower Limb Ability:** validated lower-limb-specific activity questionnaire (the scale of this index was not reported).

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>Furia (2006)[6]

Study type: case–control study (multicentre)
Country: USA
Study period: June 2003 – Jan 2004
Study population: patients with chronic insertional Achilles tendinopathy who were treated with ESWT (cases); matched patients treated in same period with other traditional non-operative methods, usually because of insurance denial (controls)
n = 68 (35 cases + 33 controls)
Age: 50 years (mean: cases); 53 years (mean: controls)
Sex: 63% female (cases); 67% female (controls)

Inclusion criteria: chronic insertional Achilles tendinopathy for ≥ 6 months (moderate-to-severe posterior heel pain at bone–tendon junction extending ≤ 2 cm proximal from heel base, swelling, impaired function). All patients had antero-posterior and lateral radiographs of the affected ankle that revealed posterior calcaneal spurs or calcifications next to the calcaneus.

Exclusion criteria (included): rheumatoid arthritis, retrocalcaneal bursa pain, calcifications in Achilles tendon or retrocalcaneal bursa area, pain > 2 cm proximal from tendon insertion, Achilles tendon surgery, < 18 years

Technique: high-energy ESWT applied to the area of maximal tenderness beginning at the bone–tendon insertion and extending proximally for 2–3cm (using ultrasound guidance) after patient's choice of either local anaesthesia (n =12) or ankle block (n = 23); 3000 shocks per session (200 shocks at increasing energies, 2800 shocks at [0.21 mJ/mm^2). Device: Dornier Epos (Dornier MedTech Inc, USA).

Follow-up: 12 months
Conflict of interest: none stated</td>
<td>Pain
Assessed using 10-cm VAS.
<table>
<tr><th></th><th>ESWT</th><th>Control</th></tr>
<tr><td>Baseline</td><td>7.9 (± 2.0)</td><td>8.6 (± 1.1)</td></tr>
<tr><td>1 month</td><td>4.2 (± 2.4)</td><td>8.2 (± 1.1)</td></tr>
<tr><td>p-value (baseline vs 1 month)</td><td>< 0.001</td><td>> 0.05</td></tr>
<tr><td>3 months</td><td>2.9 (± 2.1)</td><td>7.2 (± 1.3)</td></tr>
<tr><td>p-value (baseline vs 3 months)</td><td>< 0.001</td><td>> 0.05</td></tr>
<tr><td>12 months</td><td>2.8 (± 2.0)</td><td>7.0 (± 1.4)</td></tr>
<tr><td>p-value (baseline vs 12 months)</td><td>< 0.001</td><td>> 0.05</td></tr>
</table>
Treatment outcome
Assessed using the Roles and Maudsley scale.
<table>
<tr><th></th><th>ESWT</th><th>Control</th></tr>
<tr><td>1 month</td><td></td><td></td></tr>
<tr><td>1 (excellent)</td><td>6 (17%)</td><td>2 (6%)</td></tr>
<tr><td>2 (good)</td><td>7 (20%)</td><td>10 (30%)</td></tr>
<tr><td>3 (fair)</td><td>18 (51%)</td><td>15 (45%)</td></tr>
<tr><td>4 (poor)</td><td>4 (11%)</td><td>6 (18%)</td></tr>
<tr><td>3 months</td><td></td><td></td></tr>
<tr><td>1 (excellent)</td><td>6 (17%)</td><td>2 (6%)</td></tr>
<tr><td>2 (good)</td><td>23 (66%)</td><td>11 (33%)</td></tr>
<tr><td>3 (fair)</td><td>3 (9%)</td><td>15 (45%)</td></tr>
<tr><td>4 (poor)</td><td>3 (9%)</td><td>5 (15%)</td></tr>
<tr><td>12 months</td><td></td><td></td></tr>
<tr><td>1 (excellent)</td><td>6 (17%)</td><td>2 (6%)</td></tr>
<tr><td>2 (good)</td><td>23 (66%)</td><td>11 (33%)</td></tr>
<tr><td>3 (fair)</td><td>3 (9%)</td><td>15 (45%)</td></tr>
<tr><td>4 (poor)</td><td>3 (9%)</td><td>5 (15%)</td></tr>
</table>
</td>
<td>Complications: 5
• 2 patients had pain during treatment that resolved after the procedure.
• 2 patients had transitory reddening of the skin that resolved spontaneously.
• 1 patient had transitory numbness on the plantar aspect of the heel that resolved spontaneously within 24 hours.</td>
<td>There were no differences in mean age or duration of symptoms between the ESWT and control groups.

The traditional, non-operative methods used to treat controls were not described.

Roles and Maudsley scale:
4-point rating scale used to report results of ESWT 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

<table>
<tr><th>Study details</th><th>Key efficacy findings</th><th>Key safety findings</th><th>Comments</th></tr>
<tr>
<td>Furia (2008)[5]

Study type: case–control study
Country: USA
Study period: April 2005 – March 2006
Study population: patients with an established diagnosis of chronic non-insertional Achilles tendinopathy who were treated with ESWT (cases); matched patients who were treated in the same time interval with additional forms of traditional non-operative methods (usually because of insurance denial) but did not receive ESWT (controls)
n = 34 (+ 34 controls)
Age: 51 years (mean: cases); 50 years (mean: controls)
Sex: 71% female (cases); 65% female (controls)

Inclusion criteria: chronic non-insertional Achilles tendinopathy for ≥ 6 months (moderate to severe posterior heel pain at bone-tendon junction extending no more than 2cm proximal from base of heel, swelling, impaired function). All cases had antero-posterior and lateral radiographs of the affected ankle that revealed posterior calcaneal spurs or calcifications next to the calcaneus.

Exclusion criteria (included): rheumatoid arthritis, pain in retrocalcaneal bursa, calcifications in the Achilles tendon, calcifications and/or spurs in the retrocalcaneal bursa area, pain in tendon > 2 cm proximal from the insertion, Achilles tendon surgery, aged < 18 years.

Technique: high-energy ESWT applied to the area of maximal tenderness beginning at the bone–tendon</td>
<td>Pain
Assessed using 10-cm VAS.
<table>
<tr><th></th><th>ESWT</th><th>Control</th></tr>
<tr><td>Baseline</td><td>8.2 (± 0.9)</td><td>8.4 (± 0.9)</td></tr>
<tr><td>1 month</td><td>4.4 (± 0.9)</td><td>7.1 (± 0.9)</td></tr>
<tr><td>p-value (baseline vs 1 month)</td><td>p < 0.001</td><td>p = 0.08</td></tr>
<tr><td>3 months</td><td>2.9 (± 1.2)</td><td>6.5 (± 0.6)</td></tr>
<tr><td>p-value (baseline vs 3 months)</td><td>p < 0.001</td><td>p = 0.06</td></tr>
<tr><td>12 months</td><td>2.2 (± 1.2)</td><td>5.6 (± 0.7)</td></tr>
<tr><td>p-value (baseline vs 12 months)</td><td>p < 0.001</td><td>p < 0.001</td></tr>
</table>
Results of ESWT
Assessed using the Roles and Maudsley scale.
<table>
<tr><th></th><th>ESWT</th><th>Control</th></tr>
<tr><td>1 month</td><td></td><td></td></tr>
<tr><td>1 (excellent)</td><td>6 (18%)</td><td>0</td></tr>
<tr><td>2 (good)</td><td>18 (53%)</td><td>7 (21%)</td></tr>
<tr><td>3 (fair)</td><td>10 (29%)</td><td>19 (56%)</td></tr>
<tr><td>4 (poor)</td><td>0</td><td>8 (23%)</td></tr>
<tr><td>3 months</td><td></td><td></td></tr>
<tr><td>1 (excellent)</td><td>12 (35%)</td><td>0</td></tr>
<tr><td>2 (good)</td><td>17 (50%)</td><td>9 (27%)</td></tr>
<tr><td>3 (fair)</td><td>5 (15%)</td><td>17 (50%)</td></tr>
<tr><td>4 (poor)</td><td>0</td><td>8 (23%)</td></tr>
<tr><td>12 months</td><td></td><td></td></tr>
<tr><td>1 (excellent)</td><td>12 (35%)</td><td>0</td></tr>
<tr><td>2 (good)</td><td>17 (50%)</td><td>9 (27%)</td></tr>
<tr><td>3 (fair)</td><td>5 (15%)</td><td>17 (50%)</td></tr>
<tr><td>4 (poor)</td><td>0</td><td>8 (23%)</td></tr>
</table>
Occupation and sporting activities
• 14/18 (78%) of patients in the ESWT group who participated in regular sport were able to return to their preferred sport.</td>
<td>Complications: 3
• 2 patients had pain during treatment that resolved after the procedure
• 1 patient had transitory reddening of the skin that resolved spontaneously</td>
<td>There were no differences in mean age or duration of symptoms between the ESWT and control groups.

The traditional, nonoperative methods used to treat controls were not described.

Roles and Maudsley scale: 4-point rating scale used to report results of ESWT 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>

insertion and extending proximally for 2–3cm (using ultrasound guidance) after choice of either local anesthesia (n =12) or ankle block (n = 23); 3000 shocks per session were applied (200 shocks at increasing energy levels and the remaining 2800 shocks at level 5 [0.21 mJ/mm^2]). Device: Dornier Epos (Dornier MedTech Inc, USA). Follow-up: **12 months** Conflict of interest: none stated	• 10/16 (63%) of patients in the control group who participated in regular sport were able to return to their preferred sport. • 6/9 (67%) of patients in the ESWT group who worked in occupations that required extensive physical activity were able to return to their pre-injury occupations. • 3/6 (50%) of patients in the ESWT group who worked in occupations that required extensive physical activity were able to return to their pre-injury occupations.		

Abbreviations: RCT, randomised controlled trial; ESWT, extracorporeal shockwave therapy; VAS, visual analogue scale			
Study details	**Key efficacy findings**	**Key safety findings**	**Comments**
Lakshmanan (2004)[8] Study type: case series Country: UK Study period: not stated Study population: patients with recalcitrant non-insertional Achilles tendinopathy. n = **15** Age: 49 years (mean) Sex: 80% male Inclusion criteria: chronic Achilles pain for ≥ 6 months (diagnosis confirmed by ultrasound), failed non-operative management (non-steroidal anti-inflammatory drugs, physiotherapy, rest and heel-lift) Exclusion criteria: lesions in the Achilles tendon of more than 30% of the tendon width (excluded to avoid rupture of the tendon), insertional Achilles tendinopathy Technique: radial ESWT applied to the painful area in the tendon at 3 weekly sessions (2000 shocks, under 2.5 bar pressure). Device: EMS Swiss DolorCast. Follow-up: **21 months** Conflict of interest: none stated	**Symptoms** *Method of assessment/definition of improvement not stated, reported as numbers out of 16 cases in 15 patients.* • 88% (14/16) of patients had an overall improvement - 3 patients had excellent results with return to full training activities with no limitation - 11 patients had good results with significant improvement and return to near normal activities. • 2 patients (12%) had no improvement in symptoms. **Pain** *Assessed using a 10-cm VAS (1, no pain; 10, severe pain).* • Mean VAS score improved from 4.1 (± 2.0) before treatment to 0.7 (± 1.2) after treatment ($p < 0.001$). **Achilles tendon function** *Assessed using the Victorian Institute of Sport Assessment-Achilles (VISA-A) score .* • Mean VISA-A score improved from 46.6 (± 11.3) to 75.9 (± 19.1) ($p < 0.001$). **Ankle and hindfoot function** *Assessed using the Ankle Hindfoot Scale (AHS).* • Mean AHS score improved from 57.2 (± 15.3) to 87.0 (± 11.4) ($p < 0.001$). • Early morning ankle stiffness improved from 6.0 (± 1.9) to 8.2 (± 1.8) ($p = 0.01$). • Maximum walking distance improved from 3.3 (± 1.2) to 4.6 (± 0.5) ($p < 0.001$).	No safety outcomes were reported.	**Victorian Institute of Sport Assessment-Achilles (VISA-A) score:** validated 8-item questionnaire of Achilles tendon problems rated from 1 to 100 (asymptomatic). **Ankle Hindfoot Scale (AHS):** questionnaire assessing the severity of pain, the function, and the alignment of the ankle and hindfoot, rated from 0 to 100 (asymptomatic).

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).
- Inclusion and exclusion criteria differed across the studies (most studies required a minimum of 6 months duration of symptoms for inclusion; however, 1 study required 3 months and another did not have duration of symptoms inclusion criteria).
- Some studies assessed only patients with non-insertional or insertional tendinopathy.
- Patients in 2 RCTs could not be blinded to their treatment group making interpretation of outcomes more difficult.

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, Stephen Milner and Nicola Maffuli (British Orthopaedic Foot and Ankle Society).

- Four Advisers had never performed the procedure. Another stated that he used the procedure as first-line treatment for failed conservative ultrasound/magnetic resonance imaging-confirmed Achilles tendinopathy.
- Three Advisers thought the procedure was established practice and three thought it was a novel procedure. One Adviser commented that Achilles tendinopathy is much less well developed than in related conditions such as plantar fasciitis.
- The Advisers stated that the comparators were physiotherapy, eccentric loading exercises supervised by physiotherapists or ultrasound-guided needling and injection of blood product. Another stated that there is no standard practice, which reflects the fact that all the treatments are of unproven efficacy.
- The Advisers thought that adverse events included pain, bruising and weakening of the tendon leading to tendon rupture. One Adviser reported anecdotal cases of rupture in two older patients. One Adviser listed exacerbation of the condition as a theoretical risk, particularly when the pathology includes significant tendon degeneration. Two Advisers considered theoretical adverse events to include transient reddening of the treated area, and local soft tissue damage. One Adviser stated that a theoretical adverse

event could include excessive overtreatment which could cause complete disruption or late rupture of the Achilles tendon.
- Two 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 and improved function, decreased morning stiffness and resolution of pain. One Adviser stated that the efficacy is unproven and that there is uncertainty about whether it weakens the tendon. Another stated that there is uncertainty about whether it is better than placebo. One Adviser commented that this treatment is likely to have a significant placebo effect and it must be almost impossible to conduct a double-blind trial.
- Advisers 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 accurately diagnose the condition and administer appropriate length and frequency of shocks.
- Three Advisers thought that it would be likely to be carried in a minority of hospitals and three thought that it would be carried out in most general hospitals.

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 one completed questionnaire.

The Patient Commentator's views on the procedure were consistent with the published evidence and the opinions of the Specialist Advisers.

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).

References

1. Rompe JD, Nafe B, Furia JP et al. (2007) Eccentric loading, shock-wave treatment, or a wait-and-see policy for tendinopathy of the main body of tendo Achillis: a randomized controlled trial.[see comment][erratum appears in Am J Sports Med. 2007 Jul;35(7):1216]. American Journal of Sports Medicine 35 (3): 374-383.

2. Rompe JD, Furia J, Maffulli N. (2008) Eccentric loading compared with shock wave treatment for chronic insertional achilles tendinopathy. A randomized, controlled trial. Journal of Bone & Joint Surgery - American Volume 90 (1): 52-61.

3. Costa ML, Shepstone L, Donell ST et al. (2005) Shock wave therapy for chronic Achilles tendon pain: a randomized placebo-controlled trial.[see comment]. Clinical Orthopaedics & Related Research 440: 199-204.

4. Rasmussen S, Christensen M, Mathiesen I et al. (2008) Shockwave therapy for chronic Achilles tendinopathy: a double-blind, randomized clinical trial of efficacy. Acta Orthopaedica 79: 249-256.

5. Furia JP. (2008) High-energy extracorporeal shock wave therapy as a treatment for chronic noninsertional Achilles tendinopathy. American Journal of Sports Medicine 36: 502-508.

6. Furia JP. (2006) High-energy extracorporeal shock wave therapy as a treatment for insertional Achilles tendinopathy. American Journal of Sports Medicine 34: 733-740.

7. Lakshmanan P, O'Doherty DP. (2004) Chronic Achilles tendinopathy: Treatment with extracorporeal shock waves. Foot and Ankle Surgery 10: 125-130.

Appendix A: Additional papers on extracorporeal shockwave therapy for refractory Achilles tendinopathy

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.

There were no additional papers identified.

Appendix B: Related NICE guidance for extracorporeal shockwave therapy for refractory Achilles tendinopathy

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 Achilles tendinopathy

Database	Date searched	Version/files
Cochrane Database of Systematic Reviews – CDSR (Cochrane Library)	25/11/08	Issue 4, 2008
Database of Abstracts of Reviews of Effects – DARE (CRD website)	25/11/08	N/A
HTA database (CRD website)	25/11/08	N/A
Cochrane Central Database of Controlled Trials – CENTRAL (Cochrane Library)	25/11/08	Issue 4, 2008
MEDLINE (Ovid)	25/11/08	1950 to November Week 2 2008
MEDLINE In-Process (Ovid)	25/11/08	November 19, 2008
EMBASE (Ovid)	25/11/08	1980 to 2008 Week 47
CINAHL (Search 2.0, NLH)	25/11/08	1981 to present
BLIC (Dialog DataStar)	25/11/08	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 metaRegister of Controlled Trials - mRCT	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	Achilles Tendon/
7	Achill*.tw.
8	6 or 7
9	Tendinopathy/

10	Tendon Injuries/
11	Tendinopath*.tw.
12	Tendin*.tw.
13	Tendon*.tw.
14	(Tend* adj3 (Pain* or Injur* or Inflamm* or Ruptur*)).tw.
15	or/9-14
16	8 and 15
17	Achillodynia*.tw.
18	16 or 17
19	5 and 18
20	Animals/
21	Humans/
22	20 not (20 and 21)
23	19 not 22