NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedure overview of extracorporeal shockwave therapy for refractory tennis elbow

Tennis elbow is a condition affecting the tendons of the elbow which connect the muscles of the forearm to the upper arm 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 outer part of the elbow, 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 of the tendons.

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 tennis elbow

Specialty societies

- British Orthopaedic Association
- British Society of Skeletal Radiologists
- Royal College of Radiologists
- British Society for Rheumatology.

Description

Indications and current treatment

Tennis elbow (also known as lateral epicondylitis) is characterised by chronic degeneration at the origin of the extensor carpi radialis brevis muscle on the lateral epicondyle of the humerus. It is usually caused by injury or overuse. Symptoms include pain, weakness and stiffness of the outer elbow.

Conservative treatments include rest, application of ice, analgesic medication, non-steroidal anti-inflammatory drugs (NSAIDs), orthotic devices, physiotherapy, eccentric training/stretching and corticosteroid injection.

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 821 patients from 7 randomised controlled trials (RCTs).

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 and one with single steroid injection for the treatment of refractory tennis elbow. The other RCT compared two ESWT treatment protocols.

In an RCT of 272 patients, 26% and 25% of the ESWT and sham ESWT groups respectively had successful treatment at 3-month follow-up (defined as a Roles and Maudsley score of 1 or 2 out of 4 and no requirement for additional treatment). By 12 months, 29% and 35% of each group respectively had received additional treatment for lateral epicondylitis[1].

In an RCT of 114 patients, 61% and 29% of each group respectively had successful treatment (at least 50% reduction in pain visual analogue scale [VAS] at 3-month follow-up) on the Thomsen resisted wrist extension test ($p = 0.001$). The ESWT group had significantly less pain (assessed by VAS), better arm function (assessed by the Upper Extremity Function Scale) and more positive self-assessment of their disease state than the sham ESWT group at 3-month follow-up ($p < 0.05$ for all outcomes)[2].

An RCT of ESWT and sham ESWT (n = 75) reported that 35% and 34% respectively had at least a 50% improvement in VAS score for pain during the day at 3-month follow-up. For pain during the night, 30% and 43% respectively had at least a 50% improvement in VAS score at 3-month follow-up[3].

In an RCT of 74 patients, both pain (during a typical week, assessed by VAS) and arm function (assessed by the Disabilities of the Arm, Shoulder and Hand function score) improved significantly from baseline to 12-month follow-up in both the ESWT and sham ESWT groups. There were no statistically significant differences in either pain or function between the groups at any time[4].

An RCT of 78 patients comparing ESWT and sham ESWT reported a significantly greater improvement in pain (assessed by the Thomsen resisted wrist extension test) at 12-month follow-up in the ESWT group ($p = 0.028$). There was no significant difference between the groups in the mean improvement in arm function (assessed by the Upper Extremity Function Scale) at 12 months ($p = 0.078$)[5].

An RCT compared two treatment protocols of ESWT (group 1: 1000 shocks per session, group 2: 10 shocks per session) in 100 patients. A ‘good’ or ‘excellent’ treatment result (defined as a Roles and Maudsley score of 1 or 2) was reported in 52% and 12% of patients respectively at 6 weeks, and 48% and 6% respectively at 6 months[6].

In an RCT comparing ESWT and steroid injection (n = 93), 60% and 84% of patients respectively had treatment success (defined as at least 50% improvement in VAS score) at 3-month follow-up ($p < 0.05$)[7].

Safety

In the RCT of 272 patients, transient skin reddening was the most common adverse event in both the ESWT and sham ESWT groups (31% and 8% respectively). Pain was reported in 11% and 4% of patients respectively and transient swelling in 7% and 6% respectively[1].

An RCT of 114 patients reported pain in 50% of the ESWT group and 22% of the sham ESWT group, and a local reaction in 11% and 9% respectively. Eighteen percent of patients in the ESWT group experienced nausea compared with none in the sham ESWT group[2].

In the RCT of 75 patients, 2 patients in the ESWT group had worsened symptoms after two treatment sessions and withdrew from the study[3].

Literature review

Rapid review of literature

The medical literature was searched to identify studies and reviews relevant to extracorporeal shockwave therapy for refractory tennis elbow. 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 tennis elbow.
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.

1. A Cochrane systematic review on the use of shockwave therapy to treat lateral elbow pain was published in 2005. The review identified 9 trials comparing ESWT with placebo (n = 1006) and 1 trial comparing ESWT with steroid injection (n = 93). Owing to conflicting results, the

review concluded that there was not enough evidence to show whether shockwave therapy is beneficial for chronic lateral elbow pain[8].

2. The Canadian Agency for Drugs and Technologies in Health published an assessment on extracorporeal shock wave treatment for chronic lateral epicondylitis (tennis elbow) in 2007[9]. The summary findings were:

    - "Results from randomized controlled trials have been conflicting. Half of the studies showed statistically significant improvement in pain in the treatment group, and half of the studies had data showing no benefit over placebo for any measured outcomes.
    - Limited evidence shows that ESWT is cheaper than arthroscopic surgery, open surgery, and other conservative therapies, such as steroid infiltrations and physiotherapy, that continue for more than six weeks.
    - The lack of convincing evidence regarding its effectiveness does not support the use of ESWT for chronic lateral epicondylitis."

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 tennis elbow

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 (2002)[1]

Study type: RCT (double-blind)
Country: Germany (multicentre)
Study period: not stated
Study population: patients with lateral epicondylitis.
n = 272
Age: 47 years (mean: ESWT), 46 years (mean: sham)
Sex: 54% female (ESWT), 52% female (sham)
Duration of symptoms: 28 months (mean: ESWT); 23 weeks (mean: sham)

Inclusion criteria: epicondylitis of the radial humerus, ≥ 6 months unsuccessful conservative treatment, ≥ 2 weeks since the last conservative therapy

Exclusion criteria (included): local arthrosis / arthritis or rheumatoid arthritis, preliminary operation on the epicondyle to be treated or bilateral symptoms, under 18 years of age, pregnancy.

Technique: low-energy ESWT (n = 135) applied after local anaesthesia to the area of insertion of the muscles at the lateral epicondyle of the humerus (with ultrasound guidance) at 3 weekly sessions (2000 shocks, 0.07 – 0.09 mJ/mm^2).
Device: various devices were used.
Sham ESWT (n = 137) applied after local</td>
<td>Treatment outcome
Assessed using the Roles and Maudsley scale
<table><tr><th></th><th>ESWT</th><th>Sham</th></tr><tr><td>6 weeks</td><td></td><td></td></tr><tr><td>1 (excellent)</td><td>2% (2/125)</td><td>3% (4/125)</td></tr><tr><td>2 (good)</td><td>26% (32/125)</td><td>20% (25/125)</td></tr><tr><td>3 (fair)</td><td>33% (41/125)</td><td>27% (34/125)</td></tr><tr><td>4 (poor)</td><td>40% (50/125)</td><td>50% (62/125)</td></tr><tr><td>3 months</td><td></td><td></td></tr><tr><td>1 (excellent)</td><td>6% (7/120)</td><td>6% (7/121)</td></tr><tr><td>2 (good)</td><td>26% (31/120)</td><td>27% (33/121)</td></tr><tr><td>3 (fair)</td><td>42% (50/120)</td><td>31% (38/121)</td></tr><tr><td>4 (poor)</td><td>27% (32/120)</td><td>36% (43/121)</td></tr><tr><td>12 months</td><td></td><td></td></tr><tr><td>1 (excellent)</td><td>28% (29/105)</td><td>28% (28/101)</td></tr><tr><td>2 (good)</td><td>38% (40/105)</td><td>38% (38/101)</td></tr><tr><td>3 (fair)</td><td>27% (28/105)</td><td>27% (27/101)</td></tr><tr><td>4 (poor)</td><td>8% (8/105)</td><td>8% (8/101)</td></tr></table>Treatment success
Defined as Roles and Maudsley score of 1 or 2 at 3 months <u>and</u> no additional treatment
<table><tr><th></th><th>ESWT</th><th>Sham</th></tr><tr><td>Success</td><td>26% (32/124)</td><td>25% (31/122)</td></tr><tr><td>Failure</td><td>74% (92/124)</td><td>75% (91/122)</td></tr></table>At 12-month follow-up, 30 ESWT patients (29%) and 35 sham ESWT patients (35%) reportedly received additional therapeutic measures (7 and 3 respectively had undergone surgery).</td>
<td><table><tr><th></th><th>ESWT</th><th>Sham</th></tr><tr><td>Skin reddening</td><td>31% (42/134)</td><td>8% (11/136)</td></tr><tr><td>Pain</td><td>11% (15/134)</td><td>4% (6/136)</td></tr><tr><td>Petechiae/ bleeding/ haematomas</td><td>10% (14/134)</td><td>5% (7/136)</td></tr><tr><td>Swelling</td><td>7% (9/134)</td><td>6% (8/136)</td></tr><tr><td>Migraine</td><td>2% (3/134)</td><td>0% (0/136)</td></tr><tr><td>Syncope</td><td>2% (3/134)</td><td>0% (0/136)</td></tr><tr><td>Unwell/ nausea/ dizziness</td><td>2% (3/134)</td><td>1% (1/136)</td></tr><tr><td>Cold/ influenza/ bronchitis</td><td>2% (2/134)</td><td>1% (1/136)</td></tr><tr><td>Allergy to local anaesthetic</td><td>2% (2/134)</td><td>0% (0/136)</td></tr><tr><td>Elbow irradiated/ sensitive</td><td>1% (1/134)</td><td>1% (1/136)</td></tr><tr><td>Other</td><td>4% (5/134)</td><td>2% (3/136)</td></tr></table></td>
<td>The safety data (but not the efficacy data) were 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: One patient assigned to ESWT withdrew from the study after randomisation. Efficacy data were not available for 14 (10%) of ESWT patients and 16 (12%) of control patients (4 of these ESWT patients and 1 of these control patients were considered to have treatment failure because they had additional treatment).

Analysis: primary efficacy data remained robust when the data were stratified by centre and by ESWT device.

Roles and Maudsley scale: subjective 4-point rating scale used by investigators to rate the outcome of ESWT treatment from 1 to 4 (1 = excellent result, no symptoms; 2 = good result, significant improvement; 3 = fair</td>
</tr>
</table>

anaesthesia at the same settings but with a polyethylene foil filled with air and fixed with ultrasound gel in front of the coupling cushion to reflect the shockwaves. Follow-up: **12 months** Conflict of interest: none stated			result, somewhat improved;4 = poor result, same or worse symptoms).

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

Study details	Key efficacy findings	Key safety findings	Comments
Pettrone (2005)[2] Study type: **RCT (double-blind)** Country: USA (multicentre) Study period: not stated Study population: patients with chronic lateral epicondylitis. **n = 114** Age: 47 years (mean: total study population) Sex: 56% female (total study population) Inclusion criteria: chronic lateral epicondylitis for ≥ 6 months, pain resistant to ≥ 2 of 3 conventional therapies (physical therapy, non-steroidal anti-inflammatory medication, corticosteroid injection), tenderness on palpation of the lateral epicondyle and reproducible pain on wrist extension (Thomsen test) ≥ 4 on 10-cm VAS. Exclusion criteria (included): < 18 years of age, elbow injection within 6 weeks, physical therapy within 4 weeks, anti-inflammatory or acetaminophen use within 1 week, bilateral epicondylitis, upper extremity arthritis, radial nerve entrapment, prior surgery for epicondylitis. Technique: ESWT (n = 56) applied to the area of maximal tenderness identified by palpation at 3 weekly sessions (2000 shocks, 0.06 mJ/mm^2). Device: Sonocur	**Treatment success** *Defined as ≥ 50% improvement in Thomsen test score at 3 months.* • ESWT: 61% (34/56) • Placebo: 29% (17/58) • p-value = 0.001 **Pain** *Assessed using 10-cm VAS.* 		ESWT	Sham	p-value
Baseline	74 ±16	76 ± 16	Not stated
3 months	38 ± 28 (n = 56)	51 ± 30 (n = 58)	< 0.02 | **Function** *Assessed using Upper Extremity Function Scale.* |	ESWT	Sham	p-value
Baseline	4.7 ± 1.8	4.6 ± 1.8	Not stated
3 months	2.3 ± 1.6 (n = 53)	3.2 ± 2.1 (n = 54)	< 0.01 | **Patient-reported evaluation of disease state** *No further information about this outcome measure was reported.* |	ESWT	Sham	p-value
Baseline	70 ± 16	66 ± 17	Not stated
3 months	33 ± 28 (n = 53)	46 ± 28 (n = 54)	0.0013		**Adverse events** *Device-related adverse events* |	ESWT	Sham
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Pain	50% (28/56)	22% (13/58)
Nausea	18% (10/56)	0
Local reaction	11% (6/56)	9% (5/58)
Sweating	9% (5/56)	0
Dizziness	7% (4/56)	0
Hypertonia	5% (3/56)	6% (3/58)
Hypaesthesia	5% (3/56)	2% (1/58)
Paraesthesia	5% (3/56)	14% (8/58) | Other adverse events occurred in one or two patients such as: joint stiffness, myalgia, tremor, vasodilation, pallor in the ESWT group and accidental injury, headache, peripheral oedema, twitching and sinusitis in the sham ESWT group.	**Loss to follow-up: 6** Three patients randomised to each group withdrew before 3-month follow-up. Two ESWT patients withdrew due to intolerance of the treatment and 1 withdrew because of pre-existing thrombocytopenia. The 3 sham ESWT patients withdrew to seek alternative treatment. 7 ESWT patients did not complete 12-month follow-up. **Analysis:** intention-to-treat (last observation carried forward) **Thomsen resisted wrist extension test:** performed with the shoulder flexed to 60°, elbow extended, forearm pronated, and wrist extended 30°. Pressure is applied on the dorsum of the hand to stress the extensor carpi radialis and brevis. The patients recorded their pain score using a10cm VAS. **Upper Extremity Function Scale:** 8-item scale in which daily activities (such as sleeping, writing, opening jars) are rated on a scale from 1, no difficulty to 10, cannot perform activity. The whole scale is rated as the average score for each item (a

<table>
<tr>
<td>ESWT system (Siemens).
Sham ESWT (n = 58) applied at the same settings but using a sound-reflecting pad between the patient and the device to absorb the shockwaves.

Follow-up: 12 months
Conflict of interest: none stated</td>
<td>Grip strength
Assessed by dynamometry (kg).
<table><tr><th></th><th>ESWT</th><th>Sham</th><th>p-value</th></tr><tr><td>Baseline</td><td>32 ± 12</td><td>33 ± 13</td><td>Not stated</td></tr><tr><td>3 months</td><td>38 ± 5
(n = 53)</td><td>37 ± 15
(n = 54)</td><td>0.09</td></tr></table>
Treatment crossover
Patients who did not have treatment success after 3 months could choose to have their treatment group revealed to them and placebo patients could cross over into the active ESWT group
• At 3 months, 59% (34/58) of sham ESWT patients crossed over into active ESWT and were therefore not available for comparison.

1-year follow-up
• Of the 46 ESWT patients evaluated at 1 year, 93% reported at least a 50% improvement in pain (81% [43/53] with intention-to-treat analysis).
• Of the 14 sham ESWT patients who had not crossed over to active ESWT and were seen at 1 year, all 14 had achieved a 50% reduction in pain; however, this is only 26% of the original sham ESWT study group.</td>
<td></td>
<td>higher score indicates worse function)</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>Rompe (1996)[6]

Study type: RCT (double-blind)
Country: Germany
Study period: not stated
Study population: patients with lateral elbow pain
n = 100
Age: 44 years (mean: group 1), 42 years (mean: group 2)
Sex: 60% female (group 1), 56% female (group 2)
Duration of pain: 25 months (mean: group 1), 22 months (mean: group 2)

Inclusion criteria: pain in the lateral epicondyle for ≥ 12 months induced by ≥ 2 of palpations of the lateral epicondyle, resisted wrist extension (Thomsen test), resisted finger extension, chair test (lift a 3.5-kg chair with shoulder flexed), unsuccessful conservative therapy in the previous 6 months.

Exclusion criteria (included): < 18 years of age, dysfunction of the shoulder, neck or thorax, local arthritis, generalised polyarthritis, generalised neurological abnormality.

Technique: all patients had no other treatment for 6 weeks before ESWT. All patients had 3 weekly sessions of “low-energy” ESWT applied to the anterior aspect of the lateral epicondyle and at 3 points around this site at a radius of 1.5 – 2 cm. ESWT group 1 (n = 50): 1000 shocks per session, 0.08 mJ/mm^2. ESWT group 2 (n = 50): 10 shocks per session, 0.08 mJ/mm^2. Device: Osteostar (Siemens).

Follow-up: 6 months
Conflict of interest: none stated</td>
<td>Pain
Assessed using VAS, reported as mean % change in pain score from baseline to 6 months.

<table>
<tr><th></th><th>Group 1</th><th>Group 2</th><th>P -value</th></tr>
<tr><td>Night pain</td><td>-79% (± 22)</td><td>+4% (± 7)</td><td>< 0.001</td></tr>
<tr><td>Resting pain</td><td>-68% (±19)</td><td>+22% (± 18)</td><td>< 0.001</td></tr>
<tr><td>Pressure pain</td><td>-65% (±18)</td><td>-4% (± 11)</td><td>< 0.001</td></tr>
<tr><td>Thomsen test</td><td>-61% (±21)</td><td>-4% (± 9)</td><td>< 0.001</td></tr>
<tr><td>Finger extension</td><td>-63% (±20)</td><td>+9% (± 8)</td><td>< 0.001</td></tr>
<tr><td>Chair test</td><td>-66% (±19)</td><td>-0.3% (± 8)</td><td>< 0.001</td></tr>
</table>
Treatment outcome
Assessed using the Roles and Maudsley scale.

<table>
<tr><th></th><th>Group 1</th><th>Group 2</th></tr>
<tr><td>3 weeks</td><td></td><td></td></tr>
<tr><td>1 (excellent)</td><td>22% (11/50)</td><td>0</td></tr>
<tr><td>2 (good)</td><td>32% (16/50)</td><td>5% (10/50)</td></tr>
<tr><td>3 (fair)</td><td>36% (18/50)</td><td>32% (16/50)</td></tr>
<tr><td>4 (poor)</td><td>10% (5/50)</td><td>48% (24/50)</td></tr>
<tr><td>6 weeks</td><td></td><td></td></tr>
<tr><td>1 (excellent)</td><td>20% (10/50)</td><td>0</td></tr>
<tr><td>2 (good)</td><td>32% (16/50)</td><td>12% (6/50)</td></tr>
<tr><td>3 (fair)</td><td>36% (18/50)</td><td>20% (10/50)</td></tr>
<tr><td>4 (poor)</td><td>12% (6/50)</td><td>68% (34/50)</td></tr>
<tr><td>6 months</td><td></td><td></td></tr>
<tr><td>1 (excellent)</td><td>22% (11/50)</td><td>0</td></tr>
<tr><td>2 (good)</td><td>26% (13/50)</td><td>6% (3/50)</td></tr>
<tr><td>3 (fair)</td><td>42% (21/50)</td><td>24% (12/50)</td></tr>
<tr><td>4 (poor)</td><td>10% (5/50)</td><td>70% (35/50)</td></tr>
</table>
</td>
<td>No safety outcomes were reported.</td>
<td>Loss to follow-up: 15
15 patients withdrew from the study during the first 6 weeks and were not included in analyses.

Roles and Maudsley scale: subjective 4-point rating scale used by investigators to rate the outcome of ESWT treatment from 1 to 4 (1 = excellent result, no symptoms; 2 = good result, significant improvement; 3 = fair result, somewhat improved; 4 = poor result, 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
Crowther (2002)[7] Study type: **RCT** Country: UK Study period: not stated Study population: patients with chronic lateral epicondylitis. n = **93** Age: 49 years (all patients) Sex: 52% male (ESWT), % 52 male (injection) Inclusion criteria: over 18 years old, classic history of tennis elbow for ≥ 4 months and no surgical intervention or injection in the previous year, tenderness over the lateral epicondyle and reproducible pain with resisted finger and wrist extension Exclusion criteria: dysfunction of the shoulder, neck or thorax, local arthritis, generalised polyarthritis, generalised neurological abnormality, upper limb nerve entrapment, pregnancy, infection, tumour, clotting disorder, anticoagulant therapy, cardiac pacemaker. Technique: ESWT (n = 51) was applied to the area of maximal tenderness at the extensor origin of the lateral epicondyle of the humerus (using ultrasound guidance) at 3 weekly sessions (2000 shocks, maximum 0.1mJ/mm^2). Device: Storz Minilith SL1 lithotripter (Storz Medical). Injection (n = 42) patients received one injection of 20 mg triamcinolone with 1.5 ml of 1% lignocaine into the point of maximal tenderness. Follow-up: **3 months** Conflict of interest: none stated	**Treatment success** *Defined as ≥ 50% improvement in pain (assessed by 100-point VAS, 3 months after last treatment).* • ESWT: 60% (29/48) • Injection: 84% (21/25) • Chi-squared t-test: p < 0.05 **Pain** *Assessed using VAS (rated from 0, no pain to 100, maximal pain), reported as mean score.* | | ESWT | Injection | |---|---|---| | Baseline | 61 | 67 | | 6 weeks | 35 | 21 | | 3 months | 31 | 12 | p-values not stated **Additional treatments** Ten of the 19 ESWT patients and 2 of the 4 injection patients with treatment failure were referred for surgical release.	No safety outcomes were reported.	**Loss to follow-up: 20** Three patients randomised to ESWT withdrew before completing treatment; 17 patients randomised to injection refused treatment. Loss to follow-up after treatment was not reported. Patients were not blinded to treatment group. It is unclear whether outcome assessors were blinded to treatment group.

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

Study details	Key efficacy findings	Key safety findings	Comments
Speed (2002)[3] Study type: **RCT (double-blind)** Country: UK Study period: not stated Study population: patients with chronic lateral epicondylitis n = **75** Age: 47 years (ESWT), 48 years (sham ESWT) Sex: 53% female (ESWT), 60% female (sham ESWT) Mean duration of pain: 16 years (ESWT), 12 years (sham ESWT) Inclusion criteria: > 18 years of age, unilateral lateral elbow pain for ≥ 3 months (point tenderness at or near the common extensor tendon insertion at the lateral epicondyle and pain at the lateral epicondyle reproduced with resisted extension of the middle finger distal to the proximal interphalangeal joint). Exclusion criteria (included): additional elbow pathology, generalised polyarthritis, neurological abnormalities, anticoagulant therapy, treatment to affected area within 6 weeks, pregnancy, diabetes. Technique: ESWT (n = 40) applied to the site of maximum tenderness using ultrasound guidance at 3 monthly sessions (1500 shocks per session, 0.12 mJ/mm^2 Sham ESWT (n = 35) applied at a minimum power setting (0.04 mJ/mm^2) with the treatment head deflated, no coupling gel and no skin contact. Device: Osteostar (Siemens). Follow-up: **6 months** Conflict of interest: none stated	**Treatment success** *Defined as ≥ 50%improvement in VAS from baseline to 3 months.* **Daytime pain** *Assessed using VAS.* **Night-time pain** *Assessed using VAS.*	Two ESWT patients had worsened symptoms after 2 treatment sessions and withdrew from the study. No other adverse events were reported.	**Loss to follow-up: 2** Two ESWT patients withdrew after 2 treatment sessions due to worsened symptoms.

	ESWT	Sham
Pain during the day	35% (14/40)	37% (13/35)
Pain during the night	30% (12/40)	43% (15/35)

	ESWT	Sham
Baseline	73 (15)	67 (22)
1 month	66 (23)	61 (23)
p-value (vs baseline)	*Not significant*	*Not significant*
2 months	55 (27)	54 (29)
p-value (vs baseline)	*< 0.001*	*< 0.01*
3 months	48 (31)	52 (32)
p-value (vs baseline)	*< 0.001*	*< 0.001*

	ESWT	Sham
Baseline	40 (28)	44 (32)
1 month	49 (27)	34 (34)
p-value (vs baseline)	*< 0.05*	*Not significant*
2 months	36 (28)	33 (34)
p-value (vs baseline)	*Not significant*	*< 0.05*
3 months	34 (30)	30 (36)
p-value (vs baseline)	*Not significant*	*< 0.05*

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>Melikyan (2003)[4]

Study type: RCT (double-blind)
Country: UK
Study period: not stated
Study population: patients with tennis elbow
n = 74
Age: 43 years (total study population)
Sex: 58% female (total study population)

Inclusion criteria: pain localised to lateral epicondyle, tenderness over lateral epicondyle, supracondylar ridge and first 2cm of the extensor muscle, previous conservative treatment, and increased pain on resisted wrist extension and on elbow extension with full wrist extension.

Exclusion criteria (included): pain over radial and posterior interosseous nerve, positive resisted supination test, pain over radiohumeral joint, exacerbation of pain on neck movement, previous surgery for lateral epicondylitis, less than 18 years of age.

Technique: ESWT (n = 37) applied to common extensor origin (with ultrasound guidance) at 3 sessions (timing not stated) starting at a low energy setting (1– 3) with intensity gradually increasing as tolerated to ≥ level 6 (333 mJ/mm^2 per session; total energy dose was 1000 mJ/mm^2).
Sham ESWT (n = 37) applied at the same settings but with a foam pad between the device and arm to reflect the shockwaves. Device: Dornier Epos Ultra (Dornier MedTech).

Follow-up: 12 months
Conflict of interest: none stated</td>
<td>Function
Assessed by the Disabilities of the Arm, Shoulder and Hand (DASH) function score (lower score = better function)
• Both study groups had a statistically significant decrease in mean score (i.e. improvement in function) from baseline to 1-, 3- and 12-month follow-up (p < 0.001; raw data not reported)
• There were no significant differences between the groups at any follow-up visit.

Pain (while lifting a dumbbell)
Assessed using VAS (pain while lifting a 5-kg dumbbell; lower score = less pain).
• Both study groups had a statistically significant decrease in mean pain score from baseline to 1-, 3- and 12-month follow-up (p < 0.001; raw data not reported)
• There were no significant differences between the groups at any follow-up.

Pain (during a typical week)
Assessed using VAS (average level of pain during a typical week; rated from 0 [no pain] to 100 [maximal pain]).
<table>
<tr><th></th><th>ESWT</th><th>Sham</th><th>p-value</th></tr>
<tr><td>Baseline</td><td>57.3</td><td>56.4</td><td>Not significant</td></tr>
<tr><td>12 months</td><td>23.9</td><td>19.5</td><td>Not significant</td></tr>
<tr><td>p-value</td><td>< 0.001</td><td>< 0.001</td><td></td></tr>
</table>
Alternative treatments
• 46% (17/37) ESWT patients eventually had surgical release of the common extensor origin compared with 43% (16/37) of sham ESWT patients.
• Chi-squared t-test (between group difference): p = 0.829</td>
<td>No safety outcomes were reported.</td>
<td>Exclusions: 55 patients were excluded because it was not possible to make a firm diagnosis of tennis elbow or because exclusion criteria were met.
12 patients withdrew from the study after randomisation, but before they had a full course of treatment, and were excluded from analyses.

Loss to follow-up: not stated

Disabilities of the Arm, Shoulder and Hand (DASH) function questionnaire: 30 self-reported items assessing physical function and symptoms (devised by the American Academy of Orthopedic Surgeons – no further details provided).</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 (2004)[5] Study type: **RCT (double-blind)** Country: Germany Study period: not stated Study population: tennis players with chronic lateral epicondylitis n = **78** Age: 45 years (mean: ESWT), 45 years (mean: sham) Sex: 53% male (ESWT), 50% male (sham) Duration of pain: 24 months (mean: ESWT), 25 months (mean: sham) Inclusion criteria: playing recreational tennis ≥ 1 hour per week, epicondylalgia of the radial humerus for ≥ 12 months, positive magnetic resonance imaging, pain unresponsive to rest, ≥ 3 conventional conservative treatments longer than 2 months previously, VAS score ≥ 4. Exclusion criteria (included): local arthritis, rheumatoid arthritis, cervical compression syndrome, previous operation on the epicondyle to be treated. Technique: ESWT (n = 38) applied to the area of pain (ultrasound guided) at 3 weekly sessions (2000 shocks, starting at lowest energy level and increasing to level 2 within 100 shocks, 0.09 mJ/mm^2, total dose: 0.54 mJ/mm^2) Sham ESWT (n = 40) was applied at the same settings but with a polyethylene foil filled with air and fixed with ultrasound gel in front of the coupling cushion to reflect the shockwaves. Device: Sonocur (Siemens). Follow-up: **6 months** Conflict of interest: none stated	**Pain** *Assessed using the Thomsen test, reported as mean change from baseline* **Function** *Assessed using the Upper Extremity Function Scale, reported as mean change from baseline.* **Treatment outcome** *Assessed using the Roles and Maudsley scale, reported as mean change from baseline.*	All patients had temporary skin reddening. **ESWT** • 95% (36/38) ESWT patients reported pain during treatment. • 21% (8/38) of ESWT patients had nausea during treatment. **Sham ESWT** • 53% (21/40) of sham ESWT reported pain during treatment. • 1 patient had nausea during treatment.	**Exclusions:** 15 did not meet inclusion criteria or refused consent **Loss to follow-up: 8** 4 patients from each study group withdrew from the study during before 3-month follow-up and were not included in analyses. **Analysis:** intention-to-treat (last observation carried forward) **Thomsen resisted wrist extension test:** performed with the shoulder flexed to 60°, elbow extended, forearm pronated, and wrist extended 30°. Pressure is applied on the dorsum of the hand to stress the extensor carpi radialis and brevis. The patients recorded their pain score using a10-cm VAS. **Upper Extremity Function Scale:** 8-item scale in which daily activities (such as sleeping, writing, opening jars) are rated on a scale from 1(no difficulty) to 10 (cannot perform activity). The whole scale is rated from 8 to 80 (a higher score indicates worse function). **Roles and Maudsley scale:** subjective 4-point rating scale used by investigators to rate the outcome of ESWT treatment from 1 to 4 (1 = excellent result, no symptoms; 2 = good result, significant improvement; 3 = fair result, somewhat improved; 4 = poor result, same or worse symptoms).

	ESWT	Sham	p-value
3 months	3.5 (± 2.0)	2.0 (± 1.9)	0.001
12 months	4.0 (± 2.5)	2.8 (± 2.2)	0.028

	ESWT	Sham	p-value
3 months	23 (± 15)	11 (± 15)	< 0.001
12 months	25 (± 16)	19 (± 17)	0.078

	ESWT	Sham	p-value
3 months	1.4 (± 0.9)	0.7 (± 0.9)	0.001
12 months	1.5 (± 0.9)	1.1 (± 0.9)	0.070

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 (e.g. the duration of symptoms required for inclusion ranged from 3 to 12 months).
- Some studies had a large amount of patients withdrawing or lost to follow-up (e.g. 15 in Rompe et al. 1996).

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) and Nicola Maffuli (British Orthopaedic Foot and Ankle society).

- Three Specialist Advisers had performed the procedure before and one had not.
- One Adviser thought it was a novel procedure, one thought it was a minor variation on an established technique and two thought it was established practice
- The Advisers thought that comparators included: physiotherapy, steroid injection, NSAIDs, rest, and surgical release for refractory cases.
- The Advisers thought that adverse events included: bruising and transient reddening of the area treated. They considered that theoretical adverse events may include rupture of the common extensor tendon (however, since surgical division of this tendon is a recognised treatment, this is not likely to cause any problems and could theoretically relieve symptoms). One Adviser reported an anecdotal case of skin damage.
- The Advisers thought that key efficacy outcomes included: relief of symptoms and functional improvement. One Adviser stated that there were no uncertainties about the efficacy of the procedure and another stated that it efficacy was unproven.
- Two Advisers thought that it would be likely to be carried in a minority of hospitals (one stated that non-image-guided radial ESWT may be more widely available). One Adviser thought this procedure is likely to be carried out in most 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 for tennis elbow.

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

Issues for consideration by IPAC

- In the original overview and guidance (ESWT for refractory tendinopathies [plantar fasciitis and tennis elbow]), only one study of patients with tennis elbow was included. The study from the original overview was Haake et al. 2002, which only reported safety outcomes for an RCT of 272 patients.
- 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

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3. Speed CA, Nichols D, Richards C et al. (2002) Extracorporeal shock wave therapy for lateral epicondylitis – a double blind randomised controlled trial. Journal of Orthopaedic Research 20: 895-898.
4. Melikyan EY, Shahin E, Miles J et al. (2003) Extracorporeal shock-wave treatment for tennis elbow. A randomised double-blind study. Journal of Bone and Joint Surgery 85B-: 852-855.
5. Rompe JD, Decking J, Schoellner C et al. (2004) Repetitive low-energy shock wave treatment for chronic lateral epicondylitis in tennis players. American Journal of Sports Medicine 32: 734-743.
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7. Crowther MA, Bannister GC, Huma H et al. (2002) A prospective randomised study to compare extracorporeal shock-wave and injection of steroid for the treatment of tennis elbow. Journal of Bone and Joint Surgery 84B: 678-679.
8. Buchbinder R, Green SE, Youd JM et al. (2005) Shock wave therapy for lateral elbow pain. Cochrane Database of Systematic Reviews: Issue 4.
9. Canadian Agency for Drugs and Technologies in Health. (2007) Extracorporeal shock wave treatment for chronic lateral epicondylitis (tennis elbow). Issues in Emerging Health Technologies 96.

Appendix A: Additional papers on extracorporeal shockwave therapy for refractory tennis elbow

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. Only studies with more than 50 patients or case reports of safety outcomes are presented here.

Article	Number of patients/follow-up	Direction of conclusions	Reasons for non-inclusion in table 2
Rompe JD, Maffulli N (2007) Repetitive shock wave therapy for lateral elbow tendinopathy (tennis elbow): a systematic and qualitative analysis. British Medical Bulletin 83(1): 355−78	n = 948	Three independent trials (406 participants) did not find any benefit of SWT over placebo (32 versus 33%; 35 versus 34%; 39 versus 31%).	Focus of the paper was the effect of local anaesthesia on ESWT.
Chung B, Wiley JP (2004) Effectiveness of extracorporeal shock wave therapy in the treatment of previously untreated lateral epicondylitis: a randomized controlled trial. The American Journal of Sports Medicine 32: 1660	n = 60	Despite improvement in pain scores and pain-free maximum grip strength within groups, there does not appear to be a meaningful difference between treating lateral epicondylitis with ESWT combined with forearm-stretching program and treating with forearm-stretching program alone, with respect to resolving pain within an 8-week period of commencing treatment.	Larger or more recent studies included in table 2.
Chung B, Wiley JP, Rose MS. (2005) Long-term effectiveness of extracorporeal shockwave therapy in the treatment of previously untreated lateral epicondylitis. Clinical Journal of Sport Medicine 15: 305−12	n = 60	The use of ESWT with a stretching program is not supported by this study, with the possible exception of the possible interaction effect of time of ESWT initiation from the time of onset of symptoms, which requires further investigation.	Larger or more recent studies included in table 2.
Furia JP. (2005) Safety and efficacy of extracorporeal shock wave therapy for chronic lateral epicondylitis. American Journal of Orthopedics (Chatham, Nj) 34: 13	n = 50	There were no significant complications. ESWT is an effective treatment for chronic lateral epicondylitis. Worker's compensation status did not affect outcomes.	Larger or more recent studies included in table 2.
Ko JY, Chen HA, Chen LM. (2001) Treatment of lateral epicondylitis of the elbow with shock waves. Clinical Orthopaedics and Related	n = 53	Considerable improvement was observed from 6 weeks to 6 months after the treatment. None of the patients' symptoms became worse. There were no device-related	Larger or more recent studies included in table 2.

Research 387: 60−7		problems, systemic or local complications.	
Radwan YA, ElSobhi G, Badawy WS et al. (2008) Resistant tennis elbow: shock-wave therapy versus percutaneous tenotomy. International Orthopaedics 32: 671−7	n = 56	The success rate (Roles and Maudsley score: excellent and good) at 3 months in the ESWT group was 65.5% and in the tenotomy group was 74.1%. ESWT appeared to be a useful non-invasive treatment method that reduced the necessity for surgical procedures	Larger or more recent studies included in table 2.
Rompe JD, Hopf C, Kullmer K et al. (1996) Low-energy extracorporeal shock wave therapy for persistent tennis elbow. International Orthopaedics 20: 23−7	n = 60	We found no significant differences between the 2 groups (30 vs 3000 shocks) before treatment, but there was significant relief of pain and improvement of function in group 1 (3000 shocks) with good or excellent outcome in 56% at the last evaluation.	Larger or more recent studies included in table 2.
Rompe JD, Lebrun CM (2005) Shock-wave treatment for chronic lateral epicondylitis in recreational tennis players. Clinical Journal of Sport Medicine 15: 198−9	n = 78	ESWT was more effective than sham treatment in reducing pain and improving function in patients with chronic lateral epicondylitis.	Larger or more recent studies included in table 2.
Spacca G, Necozione S, and Cacchio A. (2005) Radial shock wave therapy for lateral epicondylitis: a prospective randomised controlled single-blind study. Europa Medicophysica 41: 17−25	n = 62	The use of RSWT allowed a decrease of pain, and functional impairment, and an increase of the pain-free grip strength test, in patients with tennis elbow. RSWT is safe and effective and must be considered as possible therapy for the treatment of patients with tennis elbow.	Larger or more recent studies included in table 2.
Staples MP, Forbes A, Ptasznik R et al. (2008) A randomized controlled trial of extracorporeal shock wave therapy for lateral epicondylitis (tennis elbow). Journal of Rheumatology 35: 2038	n = 68	Our study found little evidence to support the use of ESWT for the treatment of lateral epicondylitis and is in keeping with recent systematic reviews of ESWT for lateral epicondylitis that have drawn similar conclusions.	Larger or more recent studies included in table 2.

Appendix B: Related NICE guidance for extracorporeal shockwave therapy for refractory tennis elbow

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 279 (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 tennis elbow

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	Tennis Elbow/
7	((Tenni* or Golf*) adj3 Elbow*).tw.
8	((Radial* or Humer* or Ulnar* or Medial* or Lateral*) adj3 Epicondylit*).tw.
9	or/6-8
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