**NATIONAL INSTITUTE FOR CLINICAL EXCELLENCE**

# INTERVENTIONAL PROCEDURES PROGRAMME

## Interventional procedure overview of Extracorporeal shock wave lithotripsy for calcific tendonitis (tendinopathy) of the shoulder

### Introduction

This overview has been prepared to assist members of IPAC advise on the safety and efficacy of an interventional procedure previously reviewed by SERNIP. It is based on a rapid survey of published literature, review of the procedure by Specialist Advisors and review of the content of the SERNIP file. It should not be regarded as a definitive assessment of the procedure.

### Procedure name

Extracorporeal shock wave lithotripsy for calcific tendonitis (tendinopathy) of the shoulder

### SERNIP procedure number

148

### Specialty society

*British Orthopaedic Association*

### Indication(s)

Historically, Maladie Duplay first described calcific tendonitis over 100 years ago[1] and Painter reinforced this, describing evidence of soft-tissue calcification in the shoulder joint in 1907.[2,3]

Calcifying tendonitis commonly occurs[4] in the shoulder joint, specifically the supraspinatus tendon of the rotator cuff, where calcification (crystalline calcium phosphate) is deposited on the tendon.[3,5] The specific cause is unknown[3] but possible causes include rotator cuff vascular insufficiency, degenerative changes, metabolic disturbances and chondroid (similar to cartilage) metaplasia (change in cellular structure from injury or stress).[6]

The incidence of calcifying tendonitis is inconsistent but is generally found in adults between the ages of 30 and 50 years; in women slightly more than men and in the right shoulder more than the left shoulder.[3]

Calcification can be found in both asymptomatic and painful shoulders and therefore, calcification may not be the cause of the pain.[3,6] When calcifying tendonitis is symptomatic, it may present as:

- Chronic, relatively mild pain with sporadic episodes which may radiate down the arm or to the neck (formative phase)
- Mechanical symptoms may arise from a large calcific deposit which may impede elevation of the shoulder and cause pain
- Severe acute pain due to an inflammatory response (resorptive phase).[3]

Other complaints include a weak shoulder joint, catching, stiffness and cracking.[3]

The diagnosis is easily made using radiographs. MRI scans can also be used to describe the morphologic status.[3] Prognosis of this condition, if left untreated, may lead to loss of shoulder function and chronic pain.

**Summary of procedure**

Extracorporeal shock wave lithotripsy (ESWT) gives short duration sonic pulses over a calcific deposit to break it up and allow improved shoulder function and less pain.

Open shoulder surgery has been regarded as the gold standard treatment[1] and the introduction of shoulder arthroscopy introduced a minimally invasive approach. ESWT is an established technique for the treatment of renal calculi and has since been used in orthopaedics.[7] ESWT for calcific tendonitis was first used in Germany and Austria in 1992.[8] The goal of ESWT is to reduce pain and improve function in the affected shoulder.[6] This is an alternative approach when conservative approaches are refractory, such as NSAIDS, corticosteroids, regular physiotherapy, needling, aspiration and lavage.[1,3,5,6]

ESWT is non-invasive and has been reported as having low complication rates.[3] Local subcutaneous haematomas[5] are the most common complication reported which develop in most patients[3] as a result of cell death, although g bone or tissue growth stimulation can also occur[7]. If other structures such as bone and cartilage are hit by high-energy shock waves, injury may occur.[8] Patients are able to return to work 2 days after treatment.[5]

The mechanism of ESWT on calcifying tendonitis is unknown.[4,6] Two theories have been discussed-

- Direct mechanical disintegration outcome on the deposit
- Continuing 'hyper-stimulation analgesia'[8]

There are three techniques for generating shock waves [7]-

- electrohydraulic,
- electromagnetic
- piezoelectric principles

In clinical practice, shock waves are usually aimed at the painful site of the tendon (biofeedback method) and not through the use of radiographic or

ultrasound guidance. Fluoroscopy has been reported to be successful but most patients are treated without this assistance.[8]

The patients' arm is rotated slightly or flexed[8] exposing the area where the calcific deposit is located. A fluid medium or gel[7] is applied to the skin with the focal spot of the device over deposit during the entire treatment.[8] ESWT allows controlled sonic pulses of short duration to produce transient pressure disturbances[7] in the shoulder with the aim of fragmenting deposits.[9]

## Literature review

A systematic search of MEDLINE, PREMEDLINE, EMBASE, Current Contents, PubMed, Cochrane Library and Science Citation Index using Boolean search terms was conducted, from the inception of the databases until October 2002. The York Centre for Reviews and Dissemination, Clinicaltrials.gov, National Research Register, SIGLE, Grey Literature Reports (2002), relevant online journals and the Internet were also searched in October 2002. Searches were conducted without language restriction.

Articles were obtained on the basis of the abstract containing safety and efficacy data on extracorporeal shock wave lithotripsy for calcific tendonitis in the form of randomised controlled trials (RCTs), other controlled or comparative studies, case series and case reports. If there were more than 5 RCTs only these were reported. Foreign language papers were included if they contained safety and efficacy data and were considered to add substantively to the English language evidence base.

Five RCTs were retrieved and analysed. No case series or case reports have therefore been included.

## List of studies found

Total number of studies: 5

- Randomised controlled trials 3
- Foreign language RCT
  (data extracted from English language abstract) 1[10]
- Quasi-randomised controlled trial 1

## Summary of key efficacy and safety findings

See following tables;

## Abbreviations:

| | |
|---|---|
| ESWT | Extracorporeal shock wave lithotripsy / treatment |
| NSAIDS | Non steroidal anti-inflammatory drugs |
| VAS | Visual Analogue Scale |

| Authors, date, location, number of patients, length of follow-up, selection criteria | Key efficacy findings | Key safety findings | Appraisal/Comments |
|---|---|---|---|
| **Randomised controlled trials** | | | |
| **Haake *et al.*[8] 2002, Germany**<br><br>50 patients, September 1998 to December 1999, 1 year follow-up<br><br>Comparison-<br>**Group 1- Calcific Deposit Group** (25 patients);<br>❑ ESWT in 2 sessions (1 week interval),<br>❑ with local anaesthesia , directed at calcific deposit;<br>**Group 2- Tuberculum Majus Group** (25 patients);<br>❑ ESWT in 2 sessions (1 week interval),<br>❑ local anaesthesia, directed at supraspinatus tendon.<br><br>*Selection criteria:*<br>Diagnosis- calcifying tendonitis; deposit stage I or II (Gartner) with at least 0.5 cm diameter.<br>Inclusion criteria- symptomatic calcifying tendonitis for a minimum duration of 6 months; failed conservative treatment for minimum of 10 physiotherapy sessions, 2 subacromial injections, 6 sessions of physiotherapy and intake of NSAIDS; no treatment in the last 4 weeks; free range of movement or at least 90 degrees abduction and free rotation. | Constant and Murley Score:<br>*Before intervention*:<br>❑ Group 1- 49.98 SD [10.9];<br>❑ Group 2- 47.17 SD [16.2]<br>*1 year follow-up*:<br>❑ Group 1- 116.24 SD [11.5];<br>❑ Group 2- 83.51 SD [26.4].<br><br>Number of successful treatments (1 year):<br>❑ Group 1- 25/25 (100%);<br>❑ Group 2- 10/24 (42%).<br><br>Subjective improvements (1 year):<br>❑ Group 1- 81.36, SD [19.1];<br>❑ Group 2- 47.04 SD [36.5]<br><br>Pain during rest:<br>*before intervention*:<br>❑ Group 1- 7.08 SD [2.7];<br>❑ Group 2- 7.17 SD [2.5];<br>*I year follow-up*:<br>❑ Group 1- 1.48 SD [0.9];<br>❑ Group 2- 3.75 SD [2.9].<br><br>Pain during activity:<br>*Before intervention*:<br>❑ Group 1- 8.56 SD [1.6];<br>❑ Group 2- 8.54 SD [1.9];<br>*1 year follow-up*:<br>❑ Group 1- 2.76 SD [1.9];<br>❑ Group 2- 6.04 SD [2.9]. | *"No significant side effects of treatment seen during or after treatment".* | *Potential for bias:* randomised into two parallel group – method of allocation concealment not stated. Assessment was done by blinded independent assessors.<br>Losses to follow-up not stated.<br><br>*Outcome measures and their validity*:<br>Assessed by blinded, independent observers. Constant and Murley Score Questionnaire measuring pain at rest and in activity and patient satisfaction. Clinical relevance and success was defined as 80% of the normal value (age-corrected). The study did not state if this was a validated tool.<br>No deviation from study protocol occurred.<br><br>*Other comments*: Group 1 had better outcomes with pain and treatment satisfaction compared with Group 2. |

| Authors, date, location, number of patients, length of follow-up, selection criteria | Key efficacy findings | Key safety findings | Appraisal/Comments |
|---|---|---|---|
| **Rompe *et al.*[1] 2001, GERMANY**<br><br>79 patients, 1996 to 1998, follow-up 2 years<br><br>*Comparison-*<br>**Group 1-** open shoulder surgery, 29 patients;<br>**Group 2**- ESWT on 50 patients.<br><br>*Selection criteria:*<br>Calcific deposit with diameter of at least 1.0 cm; deposit was homogenous in appearance with well defined borders; not homogenous in structure with sharp outline or homogenous in structure with no defined border; shoulder pain for more than 12 months; clinical signs of subacromial impingement; unsuccessful conservative therapy in the previous 6 months; no evidence of bone related anatomic outlet impingement or functional impingement as seen on x-ray or MRI scans. | Clinical Outcomes at 2 years:<br>❑ *Group 1*- excellent 56%, good 35% and poor 10%;<br>❑ *Group 2*- excellent 46%, good 18% and poor 35%.<br><br>Radiologic outcomes at 1 year:<br>❑ *Group 1*- calcium deposit had disappeared in 85% of patients; 15% had minor particles observed;<br>❑ *Group 2*- complete resorption in 47%, partial resorption in 33% and no change in 20%.<br><br>End point at 2 years:<br>❑ Significantly more excellent and good outcomes in patients in Group 1 with Gartner Type I deposits than Group 2<br>❑ $p < 0.0001$<br><br>Hospital stay (average days):<br>❑ *Group 1*- 12;<br>❑ *Group 2*- 3.1<br><br>Absence from work (average weeks):<br>❑ *Group 1*- 9.1;<br>❑ *Group 2*- 2.5.<br><br>Subjective rating- pain relief at 2 years:<br>❑ *Group 1*- complete relief 55%, significant reduction 29%, slight improvement 5%, no improvement 11%;<br>❑ *Group 2*- complete relief 43%, significant reduction 24%, slight improvement 4%, no improvement 29%. | Complications:<br>❑ *Group 1*- 1/29 (3.4%) deep wound infection<br>❑ *Group 2*- transient subcutaneous haematoma. | *Potential for bias:*<br>Quasi-randomised - all patients contacted health insurance companies for reimbursement for ESWT- 29 patients were denied and were treated with open surgery; remaining 50 patients had ESWT. The assignment of patients was done independently of the author's institution. Losses to follow-up not stated.<br><br>*Outcome measures and their validity*:<br>evaluated by independent treating orthopaedic surgeon. University of Los Angeles Score Questionnaire measured clinical outcomes of pain and function before and after treatment and X-rays measured morphologic features determining resorption of calcific deposits (none, partial or complete).<br><br>*Other comments*:<br>20/79 patients (25%) lost to follow-up; they did not differ epidemiologically from included patients. The Gartner Classification was used for calcium deposit sizing. |

| Authors, date, location, number of patients, length of follow-up, selection criteria | Key efficacy findings | Key safety findings | Appraisal/Comments |
|---|---|---|---|
| **Loew *et al.*[2] 1999 GERMANY**<br><br>195 patients, July 1993 to December 1996. Follow-up maximum of 6 months.<br><br>*Comparison-*<br>**Part A:** July 1993 to December 1994; 80 patients divided into groups of 20-<br>**Group 0** had no treatment;<br>**Group 1** had 1 single 2000-impulse session of low energy treatment;<br>**Group 2** had high energy session of 2000-impulse;<br>**Group 3** had 2 sessions of high energy treatment with an interval of 1 week.<br>**Part B:** January 1995 to December 1996; 115 patients divided into 2 subgroups-<br>**Group 2B** 56 patients all treated like those in group 2,<br>**Group 3B** 59 patients treated like those in group 3.<br><br>*Selection criteria*:<br>Shoulder pain for at least 12 months, resistant to regular physiotherapy and subacromial injections of steroids, calcific deposit greater than 1.5 cm in diameter with signs of disintegration or resorption, Type I or II Gartner Classification. | Part A: 80 patients examined at 3 months<br>*Subjective pain relief*<br>❑ Group 0- 1/20 subjective improvement, 0/10 completely painfree;<br>❑ Group 1- 6/20 (p= 0.096)<br>❑ Group 2- 12/20 (p= 0.007)<br>❑ Group 3- 14/20 (p= 0.0001)<br>*Radiological disappearance or disintegration of calcium deposits*<br>❑ Group 0- 2/20<br>❑ Group 1- 4/20 (p= 0.375)<br>❑ Group 2- 11/20 (p= 0.0024)<br>❑ Group 3- 12/20 (p= 0.0009)<br><br>Part B: 2B= 42, 3B= 49 patients (79%) examined at 6 months<br>*Pain relief* ($p > 0.05$)<br>❑ 2B 19/42 (45%)<br>❑ 3B 26/49 (53%)<br>*Constant scores*:<br>❑ Before- 2B 49.3; 3B 67.7<br>❑ After- 2B 44.4; 3B 69.9<br><br>Radiological disappearance or disintegration of calcium deposits: (p= 0.046)<br>❑ 2B 47%<br>❑ 3B 77% | No safety data reported. | *Potential for bias:*<br>Randomly assigned to a control and three subgroups in part A. There is no mention on how patients were allocated into Part B two groups.<br>Blinding and losses to follow-up were not stated.<br><br>*Outcome measures and their validity:*<br>Objective measures using radiography; subjective measures using the Constant and Murley Score- not stated if validated.<br><br>*Other comments:*<br>Radiological classification using the Gartner Classification Scale<br><br>Type<br>I Homogenous structure, sharp outline<br>II Not homogenous structure, sharp outline, or homogenous structure, no defined outline<br>III Not homogenous, no defined outline |

| Authors, date, location, number of patients, length of follow-up, selection criteria | Key efficacy findings | Key safety findings | Appraisal/Comments |
|---|---|---|---|
| **Seil R *et al.*[10] 1999**<br>Abstract of foreign language article.<br><br>50 patients, 6 month follow-up<br><br>*Comparison-*<br>**Group 1**: 3 x 5000 low dose impulses without anaesthetic;<br>**Group 2**: 1 x 5000 high dose impulses with intravenous analgesia. | Constant score improved:<br>❑ Group 1- from 64.5 to 77.5<br>❑ Group 2- from 67.2 to 79.5<br>❑ $p < 0.05$<br><br>VAS improved<br>❑ Group 1- from 76.8 to 48.8<br>❑ Group 2- from 75.4 to 45.6<br><br>X-rays- complete or subtotal calcific resorption<br>❑ Group 1- 8 (32%)<br>❑ Group 2- 12 (48%) | No safety data reported in the abstract | *Potential for bias*:<br>All patients were assigned at random to two groups, but no further details were provided regarding allocation concealment, blinding or losses to follow-up<br><br>*Outcome measures and their validity:*<br>Visual Analogue Scale (VAS)- valid tool, Constant Score- not stated if valid or not. |

| Authors, date, location, number of patients, length of follow-up, selection criteria | Key efficacy findings | Key safety findings | Appraisal/Comments |
|---|---|---|---|
| **Rompe *et al*.[5] 1998 GERMANY**.<br><br>100 patients, 2 year study<br>Endpoint follow-up at 2 years post ESWT<br><br>*Comparison-*<br>**Group 1**- 50 patients, 1500 impulses of 0.06 mL/mm2 (low energy density), without local anaesthetic;<br>**Group 2**- 50 patients, 1500 impulses of 0.28 mL/mm2 (high energy density), under local anaesthetic.<br><br>*Selection criteria*:<br>Calcifying tendonitis of the supraspinatus for more than 12 months, unsuccessful conservative treatment in the previous 6 months; calcific deposits greater than 0.5 cm in diameter. | Constant score:<br>❑ *Group 1*- mean shoulder function 47 points (21 to 80) pre ESWT; 24 weeks mean increase of 51% to 71 points (53 to 100) ($p< 0.001$)<br>❑ *Group 2*- mean shoulder function 53 points (22 to 81) pre ESWT; 24 weeks mean increase of 64% to 88 points (48 to 100) ($p< 0.001$)<br><br>Radiologic Outcome (24 weeks):<br>❑ *Group 1*- 17/50 (34%) cases or partial resorption; 8/50 (16%) cases of complete resorption; no change in deposits in 25/50(50%);<br>❑ *Group 2*- 21/50 (42%) cases of partial resorption; 11/50 (22%) cases of complete resorption; no change in deposits in 18/50 (36%)<br><br>Subjective assessment:<br>*pre ESWT, 100% rated the condition of their shoulder as "poor". Post ESWT*,<br>❑ Group 1- 22% excellent, 30% good;<br>❑ Group 2- 28% excellent, 40% good;<br>❑ Significantly greater satisfaction in Group 2 ($p < 0.01$)<br><br>Additional treatment:<br>❑ *Group 1*- 10/50 (20%), 7/10 had NSAIDS, 2/10 had local anaesthetics<br>❑ *Group 2*- 6/50 (12%), 4/6 NSAIDS, 3/6 local anaesthetics and corticosteroids. | Complications:<br>Local subcutaneous haematomas (no data available) | *Potential for bias:*<br>Patients were "randomly assigned in blinded fashion" to the 2 groups, but no further detail regarding randomisation or allocation concealment was provided.<br>High drop out rate in the first 6 weeks (26/120). No reasons given for drop out.<br><br>*Outcome measures and their validity:*<br>Constant score not stated if a valid tool. |

## Specialist advisor's opinion / advisors' opinions

*Specialist advice was sought from the British Orthopaedic Association*

Extracorporeal shock wave lithotripsy for calcific tendonitis is a well established procedure in Europe, Japan and the USA and is performed by members of the British Orthopaedic Association and Rheumatology specialists. Less than 10% of specialists are doing the procedure as very few centres have this technology. Few centres will be able to afford the technology because of the initial outlay of expenses. This makes the potential impact on the NHS moderate.

*Safety-*
Aseptic necrosis of the humeral head after ESWT has been reported (J Bone Joint Surg Br 2002; 84(5):744-6).

*Efficacy-*
Disruption effect on the tendon from ESWT has been reported (J Bone Joint Surg Br 1998;80(3):546-52). Special precautions need to be taken and the treatment may be painful for the patient.

There are no registries or trials currently being performed. The few randomised controlled trials that had been completed are controversial.

## Issues for consideration by IPAC

The abovementioned comments concur with the randomised and quasi-randomised studies included. There appear to be few, if any, other comparative studies. There have been a number of case series and studies published that report safety data. However, they have been excluded for this rapid review since 5 randomised/quasi-randomised studies were available.

## References


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