NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedure overview of extracorporeal shockwave therapy for calcific tendinopathy in the shoulder

Calcific tendinopathy in the shoulder happens when calcium deposits build up in the tendons, causing pain and stiffness, although some people do not have any symptoms. In this procedure, a device is placed on the skin (extracorporeal) that delivers short pulses of sound (shockwaves) into the shoulder. The aim is to reduce pain and improve shoulder function.

Contents

Abbreviations

Word or phrase	Abbreviation
Confidence interval	CI
Constant-Murley score	CMS
Disabilities of the Arm, Shoulder, and Hand questionnaire	DASH
Interquartile range	IQR
Extracorporeal shock wave therapy	ESWT
Radial shock wave therapy	RSWT
Relative risk	RR
Randomised controlled trial	RCT
Shoulder Pain and Disability Index	SPADI
Standard deviation	SD
Standardised mean difference	SMD
Visual analogue scale	VAS

Introduction

The National Institute for Health and Care Excellence (NICE) prepared this interventional procedure overview to help members of the interventional procedures advisory committee (IPAC) make recommendations about the safety and efficacy of an interventional procedure. It is based on a rapid review of the medical literature and professional opinion. It should not be regarded as a definitive assessment of the procedure.

Date prepared

This overview was prepared in January 2022 and updated in August 2022.

Procedure name

- Extracorporeal shockwave therapy for calcific tendinopathy in the shoulder.

Professional societies

- British Elbow and Shoulder Society

- The Chartered Society of Physiotherapy
- British Society of Skeletal Radiologists
- Royal College of Radiologists
- British Society for Rheumatology.

Description of the procedure

Indications and current treatment

Calcific tendinopathy (also known as calcific tendonitis) is a disorder of the shoulder characterised by the formation of deposits of calcium crystals in 1 or more of the rotator cuff tendons. It can cause symptoms such as pain in the upper arm and shoulder, reduced range of movement, stiffness and weakness. The exact cause is unknown.

Most cases of calcific tendinopathy resolve in time without treatment. In the early stages, symptom management includes painkillers and anti-inflammatory medication. If symptoms persist, physiotherapy may be needed. Other treatment options include steroid injection, percutaneous lavage or barbotage (using a needle to suck up or break up the calcium deposits), or surgery.

What the procedure involves

Extracorporeal shockwave therapy (ESWT) is a non-invasive treatment in which a device is used to pass controlled, short-duration acoustic shockwaves through the skin to the affected area. This produces transient pressure disturbances, which break up calcium deposits. There are 2 different types of ESWT. In focused ESWT the energy generated converges at a selected depth in the body tissues where the maximal pressure is reached. In radial ESWT the maximal pressure is at the skin surface and then diverges as it penetrates deeper.

Local anaesthesia is sometimes used for pain relief during the procedure and ultrasound guidance can be used to assist with positioning the device.

Treatment protocols for ESWT vary according to the energy density and frequency of shockwaves.

The mechanism by which this therapy might have an effect on tendinopathy is unknown. The aim is to reduce pain and improve function.

Outcome measures

Shoulder Pain and Disability Index (SPADI)

The SPADI is a self-completed questionnaire with 13 items assessing pain level and extent of difficulty with activities of daily living that use the upper extremities. The pain subscale has 5 items and the disability subscale has 8 items. The patient chooses the number that best describes their level of pain and extent of difficulty using the involved shoulder. The total SPADI score is expressed as a percentage between 0 and 100. A higher score means more pain and disability.

Constant-Murley score (CMS)

The CMS is a 100-point scale that measures the level of pain and the ability to do activities of daily living. The test is divided into 4 subscales: pain (15 points; 0 is maximal pain and 15 is no pain), activities of daily living (20 points; higher scores better), strength (25 points; 1 point per 0.5 kg) and range of motion: forward elevation, external rotation, abduction and internal rotation of the shoulder (40 points; higher scores better). A higher score means less pain and better function.

Disabilities of the Arm, Shoulder and Hand (DASH)

The DASH questionnaire is a 30-item questionnaire that measures the ability to do certain upper extremity activities. It is a self-completed questionnaire that rates difficulty and interference with daily life on a 5 point Likert scale. The score ranges from 0 to 100 and higher scores indicate a greater level of disability and severity.

Efficacy summary

Pain relief

In a systematic review of 2,281 patients with rotator cuff disease, with or without calcification, pain relief of 50% or greater was reported as an outcome in 1 of the included randomised controlled trials (RCTs). In this RCT, 41% (14/34) of patients who had ESWT reported pain relief of 50% or greater compared with 38% (15/40) of those in the placebo group (relative risk [RR] 1.10, 95% confidence interval [CI] 0.62 to 1.94) at 3-month follow up. In the same systematic review, the mean pain score across 9 trials was 3.02 points in the placebo group and 0.78 points better with shockwave therapy (range 0.17 to 1.4 better; clinically important change was 1.5 points; n=608). Subgroup analyses indicated that there were no between-group differences in pain outcomes in patients who did or did not have calcific deposits in the rotator cuff (Surace 2020).

In an RCT of 45 patients with calcific shoulder tendinopathy who had focused ESWT, radial ESWT or both, the mean difference in visual analogue scale (VAS)

pain scores at 3-month follow up compared with baseline were 4.40, 4.47 and 6.58 respectively (p=0.014; Abo Al-khaira 2021).

In a non-randomised comparative study of 60 patients with calcific or non-calcific rotator cuff tendinosis, the VAS pain score at 1 year after ESWT improved from 5.5 to 2.9 (p=0.001) in patients with non-calcified tendinosis, from 5.4 to 1.5 (p<0.001) in patients with translucent calcified tendinosis and from 5.4 to 3.8 (p=0.02) in patients with dense calcified tendinosis (p=0.011 between groups; Wu 2019).

In an RCT of 82 patients with calcific tendonitis of the rotator cuff, the mean VAS pain score reduced by 2.6 in patients who had ESWT and 3.9 in patients who had ultrasound-guided needling (p=0.05) at 1-year follow up compared with baseline (Louwerens 2020). In an RCT of 42 patients with calcified rotatory cuff tendinopathy, the mean numeric pain rating scale reduced from 7.8 at baseline to 3.3 in patients who had ESWT with physiotherapy, and from 7.9 to 4.8 in those who had physiotherapy alone (p=0.041 between groups), at 12-week follow up (Fatima 2022). An RCT of 61 patients with calcific tendonitis of the shoulder compared ultrasound-guided needle puncture, radial ESWT and a combination of the 2 procedures. Within-group comparisons at the 1.5- and 3-month follow up showed statistically significant improvements in the pain VAS during sleep, rest, and activity. There were no statistically significant differences in mean VAS between the treatment groups. When compared with the radial ESWT group, both the ultrasound-guided needle puncture group (p=0.031) and the combined treatment group (p=0.013) had statistically significantly more patients reaching the minimal clinically important difference at the 3-month follow up (Kuo 2022).

In a cohort study of 268 patients, the intensity of pain at 1 year after ESWT was lower in those patients who had complete resorption (mean score 1.0; n=134) compared with those who had incomplete resorption (mean score 3.8; n=107; p<0.001 between groups). In both groups, the reduction in pain intensity at 1 year compared with baseline was statistically significant (p<0.001; Chou 2017).

Function

In the systematic review of 2,281 patients, the mean function score was 66 points in the placebo group and 7.9 points better with shockwave therapy (range 1.6 to 14 points better; clinically important difference was 10 points; 9 trials, n=612). Subgroup analyses indicated that there were no between-group differences in function outcomes in patients who did or did not have calcific deposits in the rotator cuff (Surace 2020).

In the RCT of 45 patients with calcific shoulder tendinopathy, the mean decrease in shoulder disability questionnaire scores at 3-month follow up compared with baseline was 51.7 in those who had focused ESWT, 55.7 in those who had radial ESWT and 70.4 in those who had both (p=0.034; Abo Al-khaira 2021).

SPADI score

In an RCT of 143 patients with subacromial pain, with or without calcification in the rotator cuff, 54% (37/64) of patients who had active radial ESWT and supervised exercises had a reduction in SPADI score that exceeded 19.7 points at 1 year compared with 51% (38/66) of patients who had sham radial ESWT and supervised exercises (odds ratio 0.96, 95% CI 0.47 to 1.9, p=0.89). The mean SPADI score at 1 year was 26.9 in the active radial ESWT group and 28.3 in the sham group (p=0.71; Kvalvaag 2018). Shorter term outcomes from this study were also included in the systematic review of 2,281 patients.

CMS

In the non-randomised comparative study of 60 patients with calcific or non-calcific rotator cuff tendinosis, the overall CMS at 1 year after ESWT improved from 52.5 to 78.7 (p=0.001) in patients with non-calcified tendinosis, from 49.7 to 86.9 (p<0.001) in patients with translucent calcified tendinosis and from 53.8 to 71.1 (p=0.001) in patients with dense calcified tendinosis (p=0.007 between groups; Wu 2019).

In the RCT of 82 patients with calcific tendonitis of the rotator cuff, the mean CMS improved by 15.7 points in patients who had ESWT and 20.9 points in patients who had ultrasound-guided needling (p=0.13) at 1-year follow up compared with baseline (Louwerens 2020). In the RCT of 42 patients, the mean CMS improved from 35.8 at baseline to 75.2 in patients who had ESWT with physiotherapy and from 34.3 to 72.4 in those who had physiotherapy alone (p=0.057 between groups), at 12-week follow up (Fatima 2022). In the RCT of 61 patients, the CMS improved from 41.0 at baseline to 62.1 in patients who had ultrasound-guided needle puncture, from 47.3 to 64.2 in those who had radial ESWT and from 41.1 to 69.1 in those who had both procedures at 3-month follow up (p<0.001 within groups and 0.449 between groups; Kuo 2022).

In a non-randomised comparative study of 115 patients with symptomatic chronic calcific tendonitis of the shoulder, there was no statistically significant difference in CMS when comparing 1 session of ESWT with 2 sessions of ESWT. The mean CMS at baseline, 6 months and 4 years was 49, 67 and 88 in patients who had 1 session of ESWT (p<0.001) and 44, 69 and 85 in patients who had 2 sessions of ESWT (p<0.05; Daecke 2002).

In the cohort study of 268 patients, the Constant score 1 year after ESWT was higher in those patients who had complete resorption (mean score 90.0) compared with those who had incomplete resorption (mean score 68.1; p<0.001 between groups). In both groups, the improvement at 1 year compared with baseline was statistically significant (p<0.001; Chou 2017).

Patient-reported success

In the systematic review of 2,281 patients, 39% (58/150) of patients who had shockwave therapy and 26% (35/137) of patients in the placebo group reported a successful outcome at the end of the study (RR 1.59, 95% CI 0.87 to 2.91; 6 trials, n=287; Surace 2020).

In the non-randomised comparative study of 60 patients with calcific or non-calcific rotator cuff tendinosis, the proportion of patients who were complaint-free at 1 year after ESWT was 15% (3/20) for patients with non-calcified tendinosis, 70% (14/20) for patients with translucent calcified tendinosis and 25% (5/20) for patients with dense calcified tendinosis (p=0.006 between groups; Wu 2019).

In the RCT of 82 patients with calcific tendonitis of the rotator cuff, an improvement in symptoms was reported by 67% (26/41) of patients who had ESWT and 78% (31/41) of patients who had ultrasound-guided needling at 1-year follow up (p=0.25). Mean patient satisfaction scores at 1 year were 7.6 for ESWT and 7.0 for ultrasound-guided needling (p=0.30; Louwerens 2020).

In the non-randomised comparative study of 115 patients with calcific tendonitis of the shoulder, the proportion of patients reporting subjective success at 4-year follow up was 78% in those who had 1 session of ESWT and 87% in those who had 2 sessions (p=not significant between groups; Daecke 2002).

In the cohort study of 268 patients, 81% (109/134) of patients who had complete calcific resorption were complaint-free 1 year after ESWT compared with 23% (25/107) of patients who had incomplete resorption (p<0.001; Chou 2017).

Quality of life

In the RCT of 143 patients, the health-related quality of life score (EQ-5D) at baseline was 0.53 in the active radial ESWT group and 0.58 in the sham group. At 1 year, the scores had improved to 0.71 and 0.73 respectively (p=0.94; Kvalvaag 2018). In the RCT of 61 patients, there were no statistically significant differences between the 3 treatment groups in general health score (SF-36) at 3-month follow up (Kuo 2022).

Calcification resorption

In the systematic review of 2,281 patients, shockwave therapy was associated with an increased rate of complete resolution of calcium deposits by the end of the trial, but this was of uncertain clinical significance (Surace 2020).

In the RCT of 45 patients, the mean calcification size decreased by 5.72 mm in the focused ESWT group, 5.58 mm in the radial ESWT group and 8.83 mm in the combined ESWT group at 3-month follow up (p=0.025). Complete resorption of calcification was seen in 20% (3/15) of patients who had focused ESWT, 27%

(4/15) of patients who had radial ESWT and 67% (10/15) of patients who had combined focused and radial ESWT (Abo Al-khaira 2021).

In the RCT of 82 patients with calcific tendonitis of the rotator cuff, full resorption of calcific deposits at 6 months was reported in 34% (14/41) of patients who had ESWT and 68% (27/41) of patients who had ultrasound-guided needling ($p<0.001$; Louwerens 2020). In the RCT of 61 patients, the calcifications had disappeared completely in 10% of the patients in each group and partially in 91% of patients who had ultrasound-guided needle puncture, 80% in patients who had radial ESWT and 85% of the patients who had both procedures. There were no statistically significant differences between the 3 groups (Kuo 2022).

In the non-randomised comparative study of 115 patients with calcific tendonitis of the shoulder, the proportion of patients with complete or partial resorption of calcification at 4-year follow up was 93% both in patients who had 1 session of ESWT and in those who had 2 sessions (Daecke 2002).

In the cohort study of 268 patients, there was complete resorption of calcification in 56% (134/241) of patients. Mean duration of symptoms was 12.5 months (range 6 to 48) in the complete resorption group and 26.6 months (range 12 to 126) in the incomplete resorption group ($p<0.001$; Chou 2017).

Additional treatment

In the RCT of 143 patients, 27% (17/64) of patients in the active radial ESWT group had additional treatments during the 1-year follow up compared with 18% (12/66) of patients in the sham group (Kvalvaag 2018).

In the RCT of 82 patients with calcific tendonitis of the rotator cuff, additional interventions for persistent pain or symptoms were reported in 42% (17/41) of patients who had ESWT and 22% (9/41) of patients who had ultrasound-guided needling ($p=0.058$; Louwerens 2020).

In the non-randomised comparative study of 115 patients with calcific tendonitis of the shoulder, 23% of patients who had 1 session of ESWT and 37% of patients who had 2 sessions of ESWT had no further treatment between 6 months and 4 years after ESWT. The types of treatment in the remaining patients included physiotherapy and subacromial injections, singly or in combination, and surgery (Daecke 2002).

Safety summary

Overall

In the systematic review of 2,281 patients, 26% (41/156) of those who had shockwave therapy had an adverse event within 12 months compared with 7%

(10/139) of patients in the placebo group (RR 3.61, 95% CI 2.00 to 6.52; 5 trials). These included pain, localised redness, bleeding or bruising and increased shoulder pain after treatment. There were no serious adverse events reported (Surace 2020).

Humeral head osteonecrosis

Two case reports of humeral head osteonecrosis after ESWT for rotator cuff tendinopathy and shoulder calcific tendonitis were identified; 1 happened 3 months after the procedure and the other after 40 months (Liu 2006, Durst 2002).

Pain during procedure

The mean VAS pain scores during the intervention were 6.2 in the ESWT group and 4.5 in the ultrasound-guided needling group ($p<0.001$) in the RCT of 82 patients (Louwerens 2020).

Bursitis

Severe symptoms of subacromial bursitis were reported in 2% (1/41) of patients who had ESWT and 12% (5/41) of patients who had ultrasound-guided needling within 2 months of the intervention in the RCT of 82 patients. These resolved after a subacromial corticosteroid injection (Louwerens 2020).

Hypertrophic bursitis was reported in 3 out of the 22 patients who had surgery within 4 years of ESWT in the non-randomised comparative study of 115 patients (Daecke 2002).

Frozen shoulder

Frozen shoulder was reported in 1 patient who had ESWT and 1 who had ultrasound-guided needling in the RCT of 82 patients (Louwerens 2020).

Anecdotal and theoretical adverse events

In addition to safety outcomes reported in the literature, professional experts are asked about anecdotal adverse events (events that they have heard about) and about theoretical adverse events (events that they think might possibly occur, even if they have never happened).

For this procedure, professional experts did not describe any additional anecdotal adverse events. They considered that the following were theoretical adverse events: haematoma and possible risk of injury to tendon.

The evidence assessed

Rapid review of literature

The medical literature was searched to identify studies and reviews relevant to extracorporeal shockwave therapy for calcific tendinopathy in the shoulder. The following databases were searched, covering the period from their start to 20 June 2022: 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 the literature search strategy). Relevant published studies identified during consultation or resolution that are published after this date may also be considered for inclusion.

The inclusion criteria 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.

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 calcific tendinopathy in the shoulder.
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.

List of studies included in the IP overview

This IP overview is based on about 2,950 patients from 1 systematic review, 5 RCTs (1 of which is also included in the systematic review), 2 non-randomised comparative studies, 1 cohort study and 2 case reports (Surace 2020, Kvalvaag

2018, Abo Al-Khaira 2021, Wu 2019, Louwerens 2020, Fatima 2022, Kuo 2022, Daecke 2002, Chou 2017, Liu 2006, Durst 2002).

Other studies that were considered to be relevant to the procedure but were not included in the main summary of the key evidence are listed in the appendix.

Summary of key evidence on extracorporeal shockwave lithotripsy for calcific tendinopathy in the shoulder

Study 1 Surace S (2020)

Study details

Study type	Systematic review (Cochrane)
Country	Trials were set in Italy, Germany, Austria, Norway, the Netherlands, UK, China, France, Taiwan, Spain, Turkey, and South Korea
Recruitment period	Search date: November 2019
Study population and number	n=2,281 (32 trials) People with rotator cuff disease, with or without calcification
Age and sex	Mean age ranged from 48 to 56 years (in 16 studies); 61% female (in 30 studies)
Patient selection criteria	Study selection criteria for review: RCTs and controlled clinical trials that used quasi-randomised methods to allocate participants, investigating participants with rotator cuff disease with or without calcific deposits. Trials of comparisons of shockwave therapy versus any other intervention were included. Major outcomes were pain relief greater than 30%, mean pain score, function, patient-reported global assessment of treatment success, quality of life, number of participants experiencing adverse events and number of withdrawals due to adverse events. Patient selection: inclusion criteria or definitions of the included conditions (or both) varied between trials.
Technique	Shockwave treatments were heterogeneous across trials and varied in the machines used to generate the shock waves, number and size of energy pulses, and the number of treatment sessions (1 to 6 sessions varying from 7 to 16 days apart). Twelve trials compared shockwave therapy to placebo, 11 trials compared high-dose shockwave therapy (0.2 mJ/mmN to 0.4 mJ/mmN and above) to low-dose shockwave therapy. Single trials compared shockwave therapy to ultrasound-guided glucocorticoid needling, ultrasound-guided hyaluronic acid injection, transcutaneous electric nerve stimulation, no treatment or exercise; dual session shockwave therapy to single session therapy; and different delivery methods of shockwave therapy. Of the 32 trials, 7 specified that radial shockwave therapy was used.
Follow up	For most studies, follow up was 3 to 12 months; 1 had a mean follow up of 23 months
Conflict of interest/source of funding	Two studies were funded by manufacturers of shockwave machines, 7 studies were funded by grants from research foundations or universities, 3 studies were provided with the shockwave machines, 9 studies explicitly reported they received no funding while 13 studies did not report either way.

Analysis

Follow-up issues: 22 (68%) trials were rated as low risk of attrition bias because they had no dropouts or the losses to follow up, exclusions or attrition was sufficiently small that it was unlikely to have biased the results.

There was a high risk of attrition bias in 8 (26%) trials, which had differential dropout across groups or reasons for dropout were related to treatment.

Study design issues: RCTs and controlled clinical trials that used quasi-randomised methods to allocate participants, investigating participants with rotator cuff disease with or without calcific deposits, were included. Trials of comparisons of shockwave therapy versus any other intervention were included, but the primary comparator was placebo. All trials were susceptible to bias, and the evidence was graded as low to moderate certainty. Overall, 24/32 (75%) trials were susceptible to selection bias, 20 (62%) trials at risk of performance bias, 20 (62%) trials at risk of detection bias and 14 (45%) trials at risk of selective reporting bias. When possible, analyses were based on intention-to-treat data from the individual trials. Many trials did not report major outcomes or presented outcome data incompletely and attempts to obtain unpublished data from trialists were largely unsuccessful. None of the trials measured quality of life.

Study population issues: 23 trials only included participants with calcific tendonitis, 7 trials only included participants without calcific deposits and 2 trials included participants with or without calcific deposits. Only 1 trial reported data for participants with and without calcific deposits separately.

The following trials were included: Albert 2007; Cacchio 2006; Cosentino 2003; De Boer 2017; Del Castillo-Gonzales 2016; Duymaz 2019; Engebretsen 2009; Farr 2011; Frizziero 2017; Galasso 2012; Gerdesmeyer 2003; Haake 2002; Hearnden 2009; Hsu 2008; Ioppolo 2012; Kim 2014; Kolk 2013; Kvalvaag 2017; Li 2017; Loew 1999; Melegati 2000; Pan 2003; Perlick 2003; Peters 2004; Pleiner 2004; Rompe 1998; Sabeti 2007; Sabeti-Aschraf 2005; Schmitt 2001; Schofer 2009; Speed 2002; Tornese 2011.

Key efficacy findings

Number of patients analysed: 2,281

Shockwave therapy versus placebo for rotator cuff disease with or without calcification at 3 months

Pain relief of 50% or greater

- Shockwave therapy=41.2% (14/34)
- Placebo=37.5% (15/40), RR 1.10 (95% CI 0.62 to 1.94); 1 study (n=74); low-quality evidence (downgraded for bias and imprecision)

Mean pain (0 to 10 scale, higher scores indicate more pain)

- 3.02 points in the placebo group and 0.78 points better (range 0.17 better to 1.4 better; clinically important change was 1.5 points) with shock wave therapy, SMD=-0.49 (95% CI -0.88 to -0.11); 9 trials, n=608; moderate-quality evidence (downgraded for bias)

Mean function (0 to 100 scale, higher scores indicate better function)

- 66 points in the placebo group and 7.9 points better (1.6 better to 14 better; clinically important difference was 10 points) with shock wave therapy, SMD=0.62 (95% CI 0.13 to 1.11); 9 trials, n=612; moderate-quality evidence (downgraded for bias)

Participant-reported success (follow up: end of studies)

- Shockwave therapy=38.7% (58/150)
- Placebo=25.6% (35/137), RR 1.59 (95% CI 0.87 to 2.91); 6 trials (n=287); low-quality evidence (downgraded for bias and imprecision)

Subgroup analyses indicated that there were no between-group differences in pain and function outcomes in participants who did or did not have calcific deposits in the rotator cuff.

Shockwave therapy was associated with an increased rate of complete resolution of calcium deposits by the end of the trial, but this was of uncertain clinical significance.

It is uncertain whether shock wave therapy has any benefits over ultrasound-guided glucocorticoid needling, transcutaneous electrical nerve stimulation, exercise or no treatment, or different regimens of shockwave therapy. There was only low certainty evidence from single or few small studies, subject to bias and imprecision.

It is uncertain whether higher doses of shockwave therapy has any benefit and more adverse events over lower doses, because of very low certainty evidence.

Key safety findings

Shockwave therapy versus placebo for rotator cuff disease with or without calcification

Withdrawals because of adverse events or treatment intolerance

- Shockwave therapy=32.4% (11/34)
- Placebo=32.5% (13/40), RR 0.75 (95% CI 0.43 to 1.31); 7 trials (n=581); low-quality evidence (downgraded for bias and imprecision)

Adverse events (12-month follow up)

- Shockwave therapy=26.3% (41/156)
- Placebo=7.2% (10/139), RR 3.61 (95% CI 2.00 to 6.52); 5 trials (n=295); low-quality evidence (downgraded for bias and imprecision)

There were no serious adverse events reported. The type of adverse events included pain (sometimes described as severe), localised redness, bleeding or bruising and increased shoulder pain after treatment.

Study 2 Kvalvaag E (2018)

Study details

Study type	RCT
Country	Norway
Recruitment period	2012 to 2014
Study population and number	n=143 (69 radial ESWT and supervised exercises, 74 sham radial ESWT and supervised exercises) Patients with subacromial pain syndrome lasting at least 3 months, with or without calcification in the rotator cuff
Age and sex	Active radial ESWT: mean age=47.6 years, 54% (37/69) female Sham radial ESWT: mean age=46.0 years, 55% (41/74) female
Patient selection criteria	Inclusion criteria: patients aged 25 to 70 years with subacromial pain lasting at least 3 months, dysfunction or pain on abduction, normal passive glenohumeral range of motion, pain on at least 1 of 2 isometric tests (abduction or external rotation), and a positive Hawkins impingement sign. Exclusion criteria: previous surgery on the affected shoulder, instability, rheumatoid arthritis, full-thickness tear of the rotator cuff, cervical radiculopathy, infection, inability to complete questionnaires or follow treatment plan, contraindications to shockwave therapy (use of anticoagulant drugs, bleeding disorder, epilepsy, pregnancy or pacemaker), previous experience with shockwave therapy, cortisone injection in affected shoulder within last 6 weeks, SPADI score below 20.
Technique	Device: Enimed Swiss DolorClast. A 'power' handpiece was used, which generates more energy than a regular handpiece. Treatment consisted of 2,000 impulses on each painful shoulder tendon with a pressure between 1.5 and 3.0 bar (0.01 to 0.35 mJ/mm^2), depending on what the patient could tolerate. Treatment sessions were offered once a week for 4 weeks. The sham probe was similar to the active one in design, shape and sound, but no shockwaves were conducted. All patients had supervised exercises with experienced physiotherapists, once per week for the first 4 weeks and then twice per week for the next 8 weeks. Each session lasted 40 minutes.
Follow up	1 year
Conflict of interest/source of funding	The authors reported no conflicts of interest. The study was funded by Sophies Minde Ortopedi. The funder had no role in the design of the study, data collection, analysis or interpretation, or writing the article.

Analysis

Follow-up issues: Of the 143 randomised patients, 93% (64/69) of patients in the active radial ESWT group and 89% (66/74) of patients in the sham group completed the 1-year assessment.

Study design issues: Randomised controlled single-centre trial. Patients were randomly allocated to the treatment groups in blocks of 20, by an independent assistant not involved with any other part of the study. The

patients, physiotherapists, the writing group and the outcome assessor were all blinded to treatment allocation. The main aim of the study was to evaluate if radial ESWT had any additional effect after 1 year when used as an adjunct with supervised exercises. The study was designed to detect a difference of 10 points in SPADI scores between the 2 treatment groups. The sample size was calculated as 50 in each group. The authors noted that the study may be underpowered to detect a difference in the subgroup of patients with calcification in the rotator cuff. Function questions were scored 0 (no problem) to 10 (not possible).

Study population issues: Demographic and baseline characteristics were similar in the 2 groups.

Other issues: This publication reports longer term outcomes for a study that is also included in the systematic review by Surace et al. (2020).

Key efficacy findings

Number of patients analysed: 143 (69 active radial ESWT, 74 sham)

Proportion of patients with reduction in SPADI score that exceeded the smallest detectable difference of 19.7 points at 1 year

- Active radial ESWT=53.6% (37/64)
- Sham radial ESWT=51.4% (38/66), odds ratio 0.96, 95% CI 0.47 to 1.9, p=0.89

Mean (SD) scores and differences in outcome at 1 year, from linear regression analysis

Outcome measure	Active radial ESWT - baseline	Active radial ESWT – 1 year	Sham - baseline	Sham – 1 year	Treatment effect (95% CI)	p value
SPADI	51.8 (17.5)	26.9 (27.3)	51.9 (16.7)	28.3 (24.2)	-1.6 (-10.2 to 6.96)	0.71
Pain at rest (0 to 10)	4.4 (2.4)	2.2 (2.5)	4.3 (2.2)	2.3 (2.4)	-0.1 (-0.1 to 0.7)	0.73
Pain during activity (0 to 10)	6.4 (2.1)	3.5 (2.8)	6.7 (1.8)	3.6 (2.1)	-0.1 (-1.1 to 0.87)	0.80
Function – 'can you carry a shopping bag (5 kg)?' (0 to 10)	4.9 (3.1)	3.2 (3.2)	5.5 (2.7)	3.3 (3.1)	-0.3 (-0.7 to 1.3)	0.60
Function – 'can you take something down from a shelf?' (0 to 10)	6.6 (2.4)	3.4 (3.3)	6.4 (2.9)	3.7 (3.2)	-0.3 (-1.4 to 0.8)	0.59
Health-related quality of life (EQ-5D) (-0.59 to 1)	0.53 (0.29)	0.71 (0.26)	0.58 (0.24)	0.73 (0.25)	-0.0 (-0.1 to 0.1)	0.94

Prespecified subgroup analysis (patients with medium and large size calcification [over 5 mm] in the rotator cuff at baseline)

- Mean difference in SPADI score between 2 treatment arms at 1 year = -6.3, 95% CI -22.4 to 9.8, p=0.44

Additional treatment during follow-up period

- Active radial ESWT=26.6% (17/64); 6 patients had surgery
- Sham=18.2% (12/66); 5 patients had surgery

Analysis of possible predictors of pain and disability after 1 year

- Low patient expectations were the strongest predictor of a negative outcome. Other predictors of a poorer outcome were: single marital status at baseline, frequent use of pain medication, not working at baseline, low self-reported general health status, and few supervised exercise sessions.

Key safety findings

- No safety outcomes were reported.

Study 3 Abo Al-Khaira M (2021)

Study details

Study type	RCT
Country	Egypt
Recruitment period	2016 to 2019
Study population and number	n=45 (15 focused ESWT, 15 radial ESWT, 15 combined ESWT) Patients with calcific shoulder tendinopathy
Age and sex	Mean 50.9 years (range 30 to 68); 62% (28/45) female
Patient selection criteria	Inclusion criteria: patients with clinically diagnosed calcific shoulder tendinopathy with no improvement after 3 months of treatment with conventional physical therapy such as ultrasound, laser, and exercise, or medical treatment or local corticosteroid injection. Exclusion criteria: age under 18 years, malignancy, clotting problems, use of anticoagulants, other causes of shoulder pain such as previous trauma or operation of the shoulder, shoulder arthritis, referred pain to the shoulder region from sites extrinsic to the shoulder joint such as the cervical spine, brachial plexus, thoracic outlet, peripheral nerve affection, wound or local infection in the shoulder and hemiplegia.
Technique	Device: DUOLITH SD1 Tower (STORZ MEDICAL AG.) Focused ESWT: 1,500 shocks, with energy level 0.3 mj/mm^2 and frequency 4 Hz. Radial ESWT: 2,000 shocks, with energy level 2.5 bars and frequency 10 Hz. Combined ESWT: 1,500 shocks and 2,000 shocks with the above parameters. Patients of the 3 groups had 4 sessions, 1 week apart, lasting 10 to 15 minutes. The contact head was positioned at the marked site of calcification which was defined by sonography before each treatment. A cold pack was sometimes applied after the session to relieve pain and discomfort. No medications or exercise were prescribed during treatment.
Follow up	3 months
Conflict of interest/source of funding	None

Analysis

Follow-up issues: There were no losses to follow up. All patients were evaluated by musculoskeletal ultrasound before treatment, at 1 week and at 3 months after the last session.

Study design issues: Patients were randomly allocated to 1 of 3 treatment groups by using simple random numbers (not further described). All patients had the allocated treatment. No blinding was described. The authors stated that a power size calculation was done, but no details were given.

Study population issues: There were no statistically significant differences in baseline characteristics between the 3 groups.

Key efficacy findings

Number of patients analysed: 45 (15 focused ESWT, 15 radial ESWT, 15 combined focused and radial ESWT)

- There was a statistically significant clinical, functional, and ultrasonographic improvement at 1 week and 3 months after treatment in the 3 groups ($p<0.001$).
- Combined focused and radial ESWT was statistically significantly better than focused or radial ESWT alone in all clinical, functional, and ultrasonographic parameters studied at 1 and 3 months after treatment ($p<0.001$).
- Complete resorption of calcification was seen in 20% (3/15) of patients in group 1 (focused ESWT), 27% (4/15) of patients in group 2 (radial ESWT) and 67% (10/15) of patients in group 3 (combined focused and radial ESWT).

Shoulder pain, range of motion, functional, and ultrasonographic outcome 3 months after treatment

Variable	Group 1 - before	Group 1 - after	p	Group 2 - before	Group 2 - after	p	Group 3 - before	Group 3 - after	p
VAS (0 to 10); median (IQR)	8 (2)	4 (3)	<0.001	7 (2)	3 (3)	<0.001	8 (2)	0 (3)	<0.001
Abduction (0 to 180); mean (SD)	114.0 (27.2)	151.7 (19.6)	<0.001	106.0 (38.3)	151.0 (27.0)	<0.001	87.3 (29.6)	174.0 (6.3)	<0.001
Internal rotation (0 to 90); mean (SD)	39.0 (15.3)	66.0 (11.2)	<0.001	39.7 (19.0)	75.7 (10.2)	<0.001	29.0 (8.7)	78.7 (7.4)	<0.001
Shoulder disability questionnaire (0 to 100); mean (SD)	85.8 (16.2)	34.2 (23.1)	<0.001	84.9 (14.4)	29.2 (18.6)	<0.001	87.5 (14.9)	17.2 (15.8)	<0.001
Calcification size (mm); median (SD)	8.7 (8.3)	3 (4)	<0.001	9 (7.2)	4.7 (5)	<0.001	11 (8.2)	0 (5.3)	<0.001

Group 1=focused ESWT, group 2=radial ESWT, group 3=combined focused and radial ESWT

Mean difference between baseline and 3 months, mean (SD)

Variable	Group 1	Group 2	Group 3	p value
VAS	4.40 (2.35)	4.47 (1.72)	6.58 (1.92)	0.014
Abduction	37.7 (22.6)	45.0 (34.1)	86.7 (31.3)	<0.001
Internal rotation	27.0 (13.2)	36.0 (16.3)	49.7 (13.6)	<0.001
Shoulder disability questionnaire	51.7 (19.9)	55.7 (20.6)	70.4 (16.8)	0.034
Calcification size (mm)	5.72 (3.64)	5.58 (2.79)	8.83 (3.49)	0.025

Key safety findings

- Reported side effects were pain during the treatment session, mild haematoma, and petechia (2 patients in group 2 and 2 patients in group 3). Most symptoms disappeared within minutes or hours after treatment.

Study 4 Wu KT (2019)

Study details

Study type	Non-randomised comparative study (comparing patients with different types of tendinosis)
Country	Taiwan
Recruitment period	1998 to 2015
Study population and number	n=60 (20 non-calcified tendinosis, 20 translucent calcified tendinosis type 2 and 3, 20 dense calcified tendinosis type 1) Patients with symptomatic calcific and non-calcific rotator cuff tendinosis
Age and sex	Non-calcified tendinosis: mean age 52.4 years (range 42 to 68); 65% (13/20) female Translucent calcified tendinosis: mean age 53.3 years (range 32 to 78); 65% (13/20) female Dense calcified tendinosis: mean age 53.0 years (range 32 to 78); 70% (14/20) female
Patient selection criteria	Patients with clinical symptoms, such as pain or disability, which lasted for more than 6 months, confirmed by ultrasonography or MRI. Patients with symptoms that did not respond to conservative treatment, such as physiotherapy, non-steroidal anti-inflammatories, or analgesics, for 3 months were referred for ESWT if they had no contraindications, which included pregnancy, coagulopathy, acute infection, or malignancy. Patients who had a full-thickness tear or type 2 or 3 acromion were also excluded.
Technique	The electrohydraulic shockwave was produced using Ossatron (Sanuwave, Georgia) or Orthospec equipment (Medispec Ltd., Israel). 3,000 impulses were delivered at 16 kv to 18 kv (0.32mJ/mm^2 energy flux density) with the Ossatron or at level 7 (0.32mJ/mm^2) for the Orthospec under image guide on the tendon with calcific deposition and on the point of maximal tenderness in patients without calcification. The procedures were done without anaesthesia or analgesics. All current treatments were discontinued 2 weeks before ESWT until 4 weeks after ESWT.
Follow up	12 months
Conflict of interest/source of funding	None

Analysis

Study design issues: Retrospective, non-randomised comparative study, aiming to compare the outcomes of ESWT on non-calcific rotator cuff tendinosis and different types of calcific tendinosis. Patients were divided into 3 groups: non-calcified tendinosis, type 1 calcification (well-circumscribed, dense, formative calcification), and type 2 and 3 calcification (type 2 is clearly circumscribed, translucent, cloudy, and dense calcification, and type 3 is cloudy, translucent and resorptive). Of 291 eligible patients who met the inclusion criteria, 1:1:1 propensity score matching was done, with potential confounders of functional outcome including age, gender, VAS, strength, activity, motion, and overall CMS. A total of 20 patients from each pool of patients were matched successfully.

IP overview: Extracorporeal shockwave therapy for calcific tendinopathy in the shoulder

Regarding overall satisfaction, patients with more than 80% symptom improvement were defined as complaint-free, 50 to 79% as significantly better, 25 to 49% as slightly better, and lower than 24% as unchanged. Patients who were considered 'complaint-free' and 'significantly better' at the final follow up were regarded as having a high level of satisfaction.

Study population issues: There were no statistically significant differences at baseline regarding age, gender, or side of the affected shoulder. Mean duration of symptoms was longer in group 2 (20.3 months, p=0.016) than in group 1 (13.4 months) and group 3 (9.8 months).

Key efficacy findings

Number of patients analysed: 60

Pain score and functional outcomes 1 year after ESWT, mean (SD); range

Variable	Non-calcified tendinosis, n=20	Translucent calcified tendinosis, n=20	Dense calcified tendinosis, n=20	p value
VAS - before	5.5 (0.76); 4 to 7	5.4 (1.04); 2 to 8	5.4 (0.94); 3 to 7	0.944
VAS - after	2.9 (2.86); 0 to 9	1.5 (2.48); 0 to 6	3.8 (2.46); 0 to 6	0.011
p value	0.001	<0.001	0.02	
CMS pain score - before	4.6 (0.88); 2 to 6	4.1 (1.00); 2 to 6	4.6 (0.6); 3 to 5	0.091
CMS pain score - after	7.7 (2.13); 3 to 10	8.8 (2.00); 4 to 10	6.5 (2.16); 4 to 10	0.004
p value	0.001	<0.001	0.003	
CMS night pain - before	2.6 (0.83); 1 to 4	2.6 (0.94); 1 to 4	2.6 (0.5); 2 to 3	0.985
CMS night pain - after	4.2 (1.04); 2 to 5	4.3 (1.13); 2 to 5	3.3 (1.20); 2 to 5	0.012
p value	<0.001	<0.001	0.03	
Strength - before	12.6 (3.66); 5 to 20	11.2 (3.23); 5 to 16	12.7 (3.08); 7 to 18	0.349
Strength - after	19.2 (5.22); 8 to 25	22.4 (5.10); 8 to 25	18.4 (4.69); 10 to 25	0.002
p value	<0.001	<0.001	0.001	
Activity - before	10.8 (3.16); 5 to 5	10.0 (2.51); 6 to 16	10.7 (2.56); 6 to 16	0.626
Activity - after	16.1 (4.16); 10 to 23	17.6 (4.24); 6 to 20	14.7 (4.13); 8 to 20	0.031
p value	0.001	<0.001	0.002	
Motion - before	22.0 (8.41); 8 to 34	21.9 (7.99); 6 to 36	23.3 (5.20); 16 to 36	0.721
Motion - after	31.7 (7.18); 14 to 38	33.9 (7.77); 16 to 40	28.3 (7.06); 18 to 40	0.030
p value	0.002	<0.001	0.005	
Overall CMS - before	52.5 (14.5); 21 to 74	49.7 (9.03); 33 to 62	53.8 (7.66); 42 to 64	0.409
Overall CMS - after	78.7 (18.3); 38 to 98	86.9 (19.7); 40 to 100	71.1 (17.8); 44 to 98	0.007
p value	0.001	<0.001	0.001	

Satisfaction rates, n (%), p=0.006

Variable	Non-calcified tendinosis, n=20	Translucent calcified tendinosis, n=20	Dense calcified tendinosis, n=20

Complaint-free	3 (15)	14 (70)	5 (25)
Significantly better	7 (35)	1 (5)	6 (30)
Slightly better	5 (25)	1 (5)	2 (10)
Unchanged	5 (25)	4 (20)	7 (35)

Key safety findings

- No safety outcomes were reported.

Study 5 Louwerens J (2020)

Study details

Study type	RCT
Country	The Netherlands
Recruitment period	2014 to 2017
Study population and number	n=82 (41 high-energy ESWT, 41 ultrasound-guided needling) Patients with symptomatic calcific tendonitis of the rotator cuff
Age and sex	ESWT: mean age 51.6 years; 66% (27/41) female Ultrasound-guided needling: mean age 52.7 years; 63% (26/41) female
Patient selection criteria	Inclusion criteria: age >18 years, clinical sign of subacromial pain syndrome, standardised radiographs showing a calcific deposit with a diameter of at least 5 mm in size, morphologic type 1 and type 2 deposits according to Gartner (type 1, sharply outlined and densely structured; type 2, sharply outlined and inhomogeneous or homogenous with no defined border), symptoms for more than 4 months, a completed and unsuccessful nonsurgical treatment program including nonsteroidal anti-inflammatory drugs, physiotherapy and at least 1 subacromial corticosteroid injection. Exclusion criteria: ultrasonic signs of a partial or full rotator cuff tendon tear, clinical or radiographic signs of a resorption phase, defined as increased pain in combination with a morphologic type 3 deposit (cloudy and transparent in structure) on radiographs, calcific deposits in multiple tendons of the rotator cuff, osteoarthritis of the glenohumeral or acromioclavicular joint, adhesive capsulitis, previous shoulder surgery, ESWT or ultrasound-guided needling to the affected shoulder, instability of the shoulder, rheumatoid arthritis, neurologic disorders or dysfunction of the upper limb and the inability to give informed consent.
Technique	ESWT device: Piezowave2 system (Richard Wolf GmbH, Germany). Patients had 4 sessions of high-energy ESWT with a 1-week interval. Each session consisted of 2,000 piezoelectric pressure pulses, focused on the calcific deposit, at a frequency of 4 Hz with a total energy flux density of 0.351 mJ/mm^2 resulting in a total energy amount of 2,808 mJ. The calcific deposit was localised by ultrasound with the patient positioned in a supine position. The shoulder was cooled with ice packs after treatment if necessary. Ultrasound-guided needling: a double-needle technique was used with repeated perforation of the deposit and subsequent aspiration and lavage. Patients had a single procedure, which was combined with a corticosteroid ultrasound-guided subacromial bursa injection. After treatment, both groups followed a standardised physical therapy program including active and passive exercise mobilisation techniques.
Follow up	1 year
Conflict of interest/source of funding	1 author reported grants from Spaarne General Hospital and nonfinancial support from Richard Wolf GmbH, during the conduct of the study, 1 author reported personal fees from Zimmer Biomet, grants from Zimmer Biomet, and grants from Stryker, outside the conduct of the study, 1 author reported grants from Wright Medical Group and grants

	from Smith & Nephew, outside the submitted work and 1 reported personal fees from DePuy Synthes and Link Lima, outside the submitted work.

Analysis

Follow-up issues: Both treatment groups had visits with the coordinating investigator before the intervention and at 6 weeks, 3 months, 6 months, and 1 year after treatment. One patient was lost to follow up at 3 months.

Study design issues: A research nurse allocated the patients to 1 of 2 treatment groups using computer-generated block randomisation (10 patients per block). The primary outcome measure was the CMS (range 0 to 100 points). A difference of 12 points was defined as the minimal clinically important difference between the treatment groups. With an assumed standard deviation of 20 points a sample size of 44 participants per group was computed to achieve a power of 80% to detect a 12-point difference. Although the final sample size was smaller than this, a post-hoc analysis showed that the study was appropriately powered to detect a statistically significant and clinically relevant difference of 12 points in the CMS score. Primary analysis was done on an intention-to-treat basis. The radiographs were analysed by an independent physician, blinded for the allocated treatment.

Study population issues: Demographics and baseline clinical characteristics were similar for both groups except for the distribution of the Gartner types (32% [13/41] of shoulders in the ESWT group were type 1 compared with 51% [21/41] in the ultrasound-guided needling group). The mean duration of symptoms was 3 years.

Key efficacy findings

Number of patients analysed: 82 (41 ESWT, 41 ultrasound-guided needling)

Change from baseline scores (intention-to-treat)

Outcome	ESWT, mean (95% CI)	Ultrasound-guided needling, mean (95% CI)	p value
CMS – 6 weeks	7.6 (3.5 to 11.7)	5.1 (0.8 to 9.4)	0.40
CMS – 3 months	9.9 (5.4 to 14.4)	7.0 (2.4 to 11.7)	0.37
CMS – 6 months	13.3 (7.8 to 18.8)	12.4 (7.1 to 17.6)	0.80
CMS – 1 year	15.7 (10.1 to 21.3)	20.9 (16.9 to 24.8)	0.13
DASH – 6 weeks	-12.3 (-17.2 to -7.4)	-5.0 (-9.9 to -0.2)	0.04
DASH – 3 months	-13.2 (-19.3 to -7.1)	-6.4 (-12.4 to -0.4)	0.11
DASH – 6 months	-17.6 (-24.1 to -11.1)	-13.6 (-18.5 to -8.7)	0.32
DASH – 1 year	-20.7 (-27.2 to -14.2)	-20.1 (-25.4 to -14.8)	0.87
VAS pain – 6 weeks	-1.6 (-2.3 to -0.9)	-0.9 (-1.7 to 0.03)	0.19
VAS pain – 3 months	-1.7 (-2.6 to -0.7)	-1.1 (-2.1 to -0.1)	0.41
VAS pain – 6 months	-2.3 (-3.3 to -1.3)	-2.9 (-3.6 to -2.2)	0.28
VAS pain – 1 year	-2.6 (-3.7 to -1.6)	-3.9 (-4.6 to -3.1)	0.05

Patient-reported change in symptoms at 1 year, p=0.25

Patient-reported outcome	ESWT, n (%)	ultrasound-guided needling, n (%)
(strong) decline	3 (8)	1 (3)
neutral	10 (26)	8 (20)
(strong) improvement	26 (67)	31 (78)

Resorption of calcific deposits at 6 months, p<0.001

Degree of resorption	ESWT, n (%)	ultrasound-guided needling, n (%)
No change	17 (42)	0 (0)
Less than 50%	6 (15)	1 (3)
More than 50%	4 (10)	12 (30)
Full resorption	14 (34)	27 (68)

Patient satisfaction

- Mean satisfaction scores at 1 year: ESWT=7.6, ultrasound-guided needling=7.0 (p=0.30)

Additional interventions because of persistent pain or symptoms

- ESWT=41.5% (17/41; 5 subacromial infiltration, 5 ultrasound-guided needling, 7 arthroscopic surgery)
- Ultrasound-guided needling=22.0% (9/41; 9 subacromial infiltration), p=0.058

Key safety findings

- The mean VAS pain scores during the intervention were 6.2 in the ESWT group and 4.5 in the ultrasound-guided needling group (p<0.001).
- There were no serious adverse events.
- 2 patients developed a frozen shoulder (1 in each group).
- 2.4% (1/41) of patients who had ESWT 12.2% (5/41) of patients who had ultrasound-guided needling reported severe symptoms of subacromial bursitis within 2 months of the intervention, which resolved after a subacromial corticosteroid injection.

Study 6 Fatima A (2022)

Study details

Study type	Randomised controlled trial
Country	Pakistan
Recruitment period	2020 to 2021
Study population and number	n=42 (21 ESWT and routine physiotherapy, 21 routine physiotherapy alone) Patients with calcified rotator cuff tendinopathy
Age and sex	• ESWT and physiotherapy: mean age=48.7 years, sex not reported • Physiotherapy alone: mean age=49.8 years, sex not reported
Patient selection criteria	Selection criteria: age between 30 and 65 years, painful lateral aspect of shoulder and pain exacerbation with overhead activity, all genders, reduced range of motion, symptoms present from last 3 months, positive Neer's impingement test, and the ultrasound showing calcific changes in the rotator cuff. Exclusion criteria: marked atrophy or weakness of any shoulder girdle muscle, previous surgery, recent corticosteroid use or nerve blockage, malignancy, and coagulation abnormalities.
Technique	The experimental group had high-energy ESWT using a radial SWT BLT-6000 device (UK) in addition to routine physical therapy. About 2,000 shockwaves of 0.32mJ/mm^2 per treatment were given as 12 sessions for the first 6 weeks (2 sessions/week). No local anaesthetic was used. Routine treatment was offered to all patients in 12 sessions for 6 weeks (2 sessions/week), and it included: pulsed short-wave diathermy with frequency 27.12MHz, ultrasonic therapy with frequency 1.0MHz and intensity 1.45 w/cm, and transcutaneous electrical nerve stimulator 2 to 200 Hz with output current <20Ma with 200 μ seconds along with continuous mode. Shoulder strengthening and stretching exercises were done for 5 seconds with 10 repetitions.
Follow up	12 weeks
Conflict of interest/source of funding	None

Analysis

Follow up issues: Out of the 42 patients, 20 (95%) patients in each group completed the study.

Study design issues: Randomised controlled trial to evaluate the effects of high-energy ESWT on objective and subjective outcomes among patients with calcified rotator cuff tendinopathy. Patients were randomly allocated to both groups using a computer-generated randomised method. The randomisation allocation was sealed in opaque envelopes. The assessor and biostatistician were blinded to the intervention given until the completion of the trial. The physiotherapist who provided the treatment was not blinded. The primary endpoint was the change of the 11-point numeric pain rating scale (0=no pain, 10=maximum pain) from baseline to 12 weeks. A difference of 1.5 points was considered clinically relevant. The Western Ontario rotator cuff index was used to assess quality of life. This is a self-administered questionnaire with 21 items and 5 domains (scores range from

0 to 100%, with lower scores indicating lower functional status). Ultrasonography was examined to check the size of calcium deposits before and after treatment in both groups. Changes between radiographs were graded as no, partial (minor changes in mass or appearance), and total or subtotal resorption (80% reduction in calcific masses).

A sample size of 30 was estimated (15 in each group) to give 95% confidence interval and 90% power of the study.

Key efficacy findings

Number of patients analysed: 40 (20 ESWT and physiotherapy, 20 physiotherapy alone)

Between-group differences before and after treatment (n=40)

Outcome	Group	Mean	SD	Mean rank	p value
Numeric pain rating scale (baseline)	ESWT	7.8	1.36	19.75	
	control	7.9	1.20	21.25	0.677
Numeric pain rating scale (6 weeks)	EWST	5.0	1.62	16.68	
	control	6.0	1.48	24.33	0.035
Numeric pain rating scale (12 weeks)	ESWT	3.3	1.78	19.03	
	control	4.75	1.94	21.98	0.041
Constant and Murley score (baseline)	ESWT	35.8	13.44	21.90	
	control	34.3	13.98	19.10	0.448
Constant and Murley score (6 weeks)	ESWT	54.5	11.64	20.85	
	control	55.8	16.09	20.15	0.850
Constant and Murley score (12 weeks)	ESWT	75.2	13.35	21.53	
	control	72.4	15.45	19.48	0.057
Ultrasound (baseline)	ESWT	13.8	1.21	18.50	
	control	14.4	0.00	22.50	0.082
Ultrasound (after treatment)	ESWT	12.46	2.00	20.30	
	control	12.4	1.55	20.70	0.035
Western Ontario rotator cuff index (baseline)	ESWT	37.1	14.35	20.93	
	control	36.9	13.90	20.08	0.817
Western Ontario rotator cuff index (after treatment)	ESWT	70.55	15.26	21.25	
	control	67.9	16.1	19.75	0.038

Key safety findings

No safety outcomes were reported.

Study 7 Kuo Y (2022)

Study details

Study type	Randomised controlled trial
Country	Taiwan
Recruitment period	2013 to 2014
Study population and number	n=61 (21 ultrasound-guided needle puncture, 20 radial shock wave therapy, 20 combination of both treatments) Patients with calcific tendinitis of the shoulder
Age and sex	• Needle puncture: mean age=58.2 years, 62% (13/21) female • Radial shockwave therapy: mean age=57.6 years, 60% (12/20) female • Combined treatment: mean age=56.6 years, 65% (13/20) female
Patient selection criteria	Inclusion criteria: age between 20 and 75 years, at least a 3-month history of unilateral shoulder discomfort, radiological evidence of both type 1 and type 2 calcification or ultrasound-based evidence of arc-shaped calcification. Exclusion criteria: pregnancy, clotting disorders, anticoagulant or antiplatelet treatment, cardiac pacemaker, chronic inflammatory joint disease, infection or tumour of the shoulder, adhesive capsulitis, hyperalgesia of the shoulder because of resorption of a calcific deposit, Garner's type 3 calcification, or Chiou's nodular or cystic calcification.
Technique	Radial shockwave therapy was delivered at 2Hz (2,000 shock waves, energy level 0.26 mJ/mm^2 once a week for 3 weeks. Acetaminophen was prescribed as a rescue medication. All needle punctures were guided by ultrasound. After injecting 3 lidocaine (1%) into the subcutaneous tissue, muscle layer, and subdeltoid bursa, multiple punctures (10 to 20, depending on plaque size) were done without aspiration or barbotage. The needle tract was monitored with ultrasound to ensure that the needle penetrated through the calcific plaque but not the rotator cuff. Patients in the combined treatment group had 3 weekly rounds of radial shockwave therapy after needle puncture.
Follow up	3 months
Conflict of interest/source of funding	None

Analysis

Follow up issues: An additional patient was randomised to the radial shockwave therapy group but was lost to follow up and excluded from the analysis.

Study design issues: Single-blind randomised controlled trial. An assignment scheme was generated from a table of random numbers. All assessments were done by a masked assessor who was a trained study assistant. The patients were instructed not to reveal any treatment details to the assessor. The primary outcome measure was the VAS to assess pain. Pain was measured using 3 VASs (horizontal lines measuring 100mm in length, with 0 on the left indicating no pain and 100 on the right indicating severe pain) pertaining to shoulder pain at rest, during movement, and during sleep. The minimal clinically important difference of the pain VAS was considered to be 1.4 cm. The secondary outcome measures were the Constant scores, the 36-

Item SF-36 for general health status, and the ROM of the affected shoulder. The calcific deposit size was measured with ultrasonography at baseline and during follow-up at 1.5 and 3 months. Resorption of the calcific deposit was graded as none, partial, or complete by an assessor who was blinded to the treatment allocation. The sample size calculation was based on the primary outcome (pain VAS during activity at 3-month follow-up). A total of 63 patients was needed to achieve a power of 80% at a type 1 error level of 0.05 and effect size of 0.5.

Study population issues: There were no statistically significant differences in baseline demographic or clinical characteristics.

Key efficacy findings

Number of patients analysed: 61

- Within-group comparisons at the 1.5- and 3-month follow-up showed statistically significant improvements in the pain VAS during sleep, rest, and activity. There were no statistically significant differences in VAS between the treatment groups.
- After 3 months of follow up, the calcifications had disappeared completely in 9.5%, 10%, and 10% of the patients and partially in 90.5%, 80%, and 85% of the patients in the USNP, RSWT, and combined groups, respectively. No statistically significant differences were noted among the 3 groups.

Scores from questionnaires for the 3 treatment groups at baseline and follow up, mean (SD)

Outcome measure	Group	Baseline	1.5 months	3 months	p (time)	p (group)	Interaction group*time
VAS - sleep	USNP	6.76 (3.40)	4.14 (2.89)	2.71 (2.19)	<0.001	0.477	0.871
	RSWT	5.75 (2.77)	3.90 (3.51)	2.65 (3.12)			
	Both	5.60 (3.56)	3.60 (2.93)	1.75 (2.61)			
VAS – rest	USNP	4.29 (3.95)	2.19 (2.71)	0.95 (1.40)	<0.001	0.336	0.213
	RSWT	2.90 (2.95)	0.90 (1.52)	1.55 (2.31)			
	Both	2.85 (3.62)	1.05 (1.99)	0.80 (2.31)			
VAS – activity	USNP	7.38 (2.44)	4.10 (2.12)	3.00 (2.53)	<0.001	0.561	0.144
	RSWT	5.50 (2.33)	4.05 (2.31)	3.15 (3.00)			
	Both	6.60 (2.66)	3.75 (2.29)	2.70 (2.52)			
Constant score	USNP	40.95 (11.94)	52.52 (14.62)	62.14 (16.54)	<0.001	0.449	0.089
	RSWT	47.25 (14.73)	57.45 (12.95)	64.15 (16.91)			
	Both	41.10 (10.24)	56.65 (11.07)	69.10 (13.54)			
SF-36 physical functioning	USNP	70.95 (13.29)	76.90 (15.85)	82.38 (14.80)	<0.001	0.149	0.080
	RSWT	68.00 (17.50)	66.25 (15.38)	70.25 (16.74)			
	Both	61.25 (20.58)	70.50 (19.66)	75.75 (22.38)			

Outcome measure	Group	Baseline	1.5 months	3 months	p (time)	p (group)	Interaction group*time
SF-36 Role physical	USNP	32.14 (38.03)	50.00 (44.72)	61.90 (48.49)	<0.001	0.576	0.097
	RSWT	46.25 (45.36)	61.25 (44.04)	52.95 (43.14)			
	Both	17.50 (29.36)	46.25 (42.36)	61.25 (50.96)			
SF-36 Bodily pain	USNP	50.19 (21.82)	61.62 (18.71)	70.52 (16.55)	<0.001	0.353	0.808
	RSWT	45.95 (16.10)	54.80 (14.54)	62.15 (6.28)			
	Both	45.50 (16.89)	58.25 (15.12)	68.15 (16.70)			
SF-36 General health	USNP	56.57 (23.29)	53.76 (22.45)	68.10 (20.1)	0.370	0.248	0.180
	RSWT	57.55 (15.38)	56.30 (13.86)	55.15 (15.54)			
	Both	60.55 (20.58)	64.65 (21.31)	68.05 (20.18)			
SF-36 Vitality	USNP	58.81 (15.64)	55.48 (13.41)	60.24 (16.69)	0.117	0.726	0.160
	RSWT	54.50 (17.98)	56.25 (17.46)	58.38 (17.10)			
	Both	49.50 (22.41)	57.50 (19.90)	55.50 (19.80)			
SF-36 Social functioning	USNP	73.81 (19.33)	75.00 (22.36)	79.76 (20.72)	0.898	0.916	0.306
	RSWT	78.13 (16.66)	77.50 (17.01)	71.25 (19.49)			
	Both	75.63 (19.65)	78.75 (16.27)	78.13 (17.15)			
SF-36 Role emotional	USNP	65.08 (40.11)	69.84 (40.70)	84.13 (30.95)	0.005	0.589	0.010
	RSWT	68.33 (43.90)	75.00 (37.27)	61.93 (43.68)			
	Both	40.00 (42.71)	68.33 (38.20)	80.00 (42.44)			
Mental health	USNP	64.76 (14.78)	59.62 (17.48)	63.05 (18.02)	0.445	0.462	0.386
	RSWT	66.20 (17.91)	65.00 (12.44)	74.80 (45.99)			
	Both	62.60 (14.35)	67.20 (13.46)	65.00 (15.24)			

Numbers of patients whose changes of the values in the pain VAS during activity reached the minimal clinical important difference (1.4)

Follow up	USNP, n=21	RSWT, n=20	Both, n=20	p value: USNP compared with RSWT	p value: USNP compared with both	p value: RSWT compared with both
1.5 months	17	10	15	0.037	0.645	0.102
3 months	18	11	17	0.031	0.675	0.013

- Patients in all 3 treatment groups showed improvements in active and passive flexion, abduction, and external rotation, except for active internal rotation over time, but the result was not statistically significantly different between groups. Only active external rotation showed a statistically significant difference in the improvement change over time among the 3 groups, favouring the USNP and combined treatment groups.

Key safety findings

The paper states that ‘no side effects were observed in the patients’.

Study 8 Daecke W (2002)

Study details

Study type	Non-randomised comparative study (1 versus 2 sessions of high-energy ESWT)
Country	Germany
Recruitment period	1995 to 1996
Study population and number	n=115 (56 had 1 session of ESWT and 59 had 2 sessions) Patients with symptomatic chronic calcific tendonitis of the shoulder
Age and sex	Mean 49 years (range 28 to 77); 42% (48/115) female
Patient selection criteria	Inclusion criteria: painful calcific tendonitis for more than 12 months and conservative treatment (physiotherapy and subacromial steroid injections) for at least 6 months without effect. The calcific deposit had to have a homogeneous structure or a sharp outline (Gartner type 1 or 2) and to be a minimum of 15 mm in diameter. Exclusion criteria: acute subacromial impingement, ultrasound or MRI documentation of a rotator cuff tear, degenerative arthritis of the shoulder seen on radiography, generalised polyarthritis, neurologic disorders, pregnancy, infections, and tumours.
Technique	Device: electromagnetic lithotripter (Compact; Dornier Med Tech, Germany). Local anaesthesia by subcutaneous injection was used. Patients were divided into 2 groups: 1 group had 1 session of 2,000-impulse high-dose shockwave therapy, and the other group had 2 sessions of the identical therapy 1 week apart. From low shockwave energy at the start, the intensity was increased within the first 300 impulses up to an energy flux density of 0.3 mJ/mm^2. After ESWT, patients were asked not to have any specific subsequent treatment for at least 6 months but were encouraged to use the arm in daily activities.
Follow up	4 years
Conflict of interest/source of funding	

Analysis

Follow-up issues: The follow-up rate was 87% after 3 months and 72% after 6 months. Four years after ESWT, 92% of the initial patient population (n=115) was interviewed. The effects of ESWT not followed by any other therapy within the first 6 months were evaluated in 59% (n=68) of the original 115 patients.

Study design issues: Prospective, non-randomised comparative study evaluating the long-term effects and complications of high-energy ESWT. Patients were divided into 2 groups in order of enrolment in the study, to have either 1 or 2 sessions of high-dose ESWT. Outcome was determined by functional examination, radiographs of the shoulder, and the patients' own assessments at 3 months, 6 months, and 4 years after treatment. Freedom from pain or only slight discomfort was an indication that the treatment had been subjectively effective.

Study population issues: Mean duration of pain was 5 years (range 1 to 36).

Key efficacy findings

Number of patients analysed: 115

- 20% (23/115) of patients had surgery on the affected shoulder after the procedure.
- 23% of patients who had 1 session of ESWT and 37% of patients who had 2 sessions of ESWT had no further treatment between 6 months and 4 years after ESWT. The types of treatment included physiotherapy and subacromial injections, singly or in combination, and surgery.

Proportion of patients with radiological changes (complete or partial resorption of calcification) after ESWT (%), n=68

Time after ESWT	1 session of ESWT	2 sessions of ESWT	p value
3 months	30	52	Not reported
6 months	47	77	0.046
4 years	93	93	Not reported
P value	<0.05	<0.05	

Proportion of patients reporting subjective success rates after ESWT (%), n=68

Time after ESWT	1 session of ESWT	2 sessions of ESWT	p value
3 months	32	50	Not significant
6 months	45	53	Not significant
4 years	78	87	Not significant
p value	<0.001	<0.001	

Mean CMS after ESWT, mean (SD), n=68

Time after ESWT	1 session of ESWT	2 sessions of ESWT	p value
Baseline	49 (13)	44 (12)	Not significant
3 months	62 (16)	62 (17)	Not significant
6 months	67 (17)	69 (19)	Not significant
4 years	88 (8)	85 (8)	Not significant
p value	<0.001	<0.05	

Key safety findings

- Subdermal hematoma was a minor early complication (number of patients not reported)

- After 4 years, there were no late complications on clinical examination or radiography. There was no evidence of necrosis of the humeral head or rotator cuff disease induced by ESWT. In the 22 patients who had endoscopic (7) or open (15) surgery (removal of calcium deposit, bursectomy, and decompression in some cases), no severe damage to the shoulder joint was seen. Intraoperative findings indicated hypertrophic bursitis in 3 patients. Severe damage to the shoulder joint after ESWT was also excluded by operative evaluation.

Study 9 Chou W (2017)

Study details

Study type	Cohort study
Country	Taiwan
Recruitment period	1998 to 2014
Study population and number	n=268 Patients with symptomatic calcific tendonitis of the shoulder
Age and sex	Mean 52.5 years; 72% (167/232) female
Patient selection criteria	Patients with a painful shoulder caused by calcific tendonitis that failed to respond to oral medication and physiotherapy within 3 months were included. Calcific deposits were identified radiologically as homogeneous hyperdense areas of varying shape. The diagnosis was initially made on plain radiographs, ultrasound or MRI to confirm the diagnosis and to exclude the possibility of a rotator cuff tear or other conditions including malignancy. Contraindications for ESWT included pregnancy, acute infection, malignant tumour and coagulopathy, fracture or calcific tendonitis coexisting with a rotator cuff tear.
Technique	Electrohydraulic shockwave devices used were either Ossatron (Sanuwave, Georgia) or Orthospec equipment (Medispec Ltd., Israel). Each affected shoulder received 3,000 impulses of the shockwave at 16 kv to 18 kv (0.32 mJ/mm^2 energy flux density) for Ossatron or Level seven (0.32 mJ/mm^2) for Orthospec under ultrasound control in line with the point of maximal tenderness. The total ESWT dosage at each session was 960 (mJ/mm^2). Patients who needed a second treatment had the procedure again, 3 months after the first procedure. All patients were asked to stop their current treatment for 2 weeks before ESWT.
Follow up	1 year
Conflict of interest/source of funding	One author is a member of the advisory committee of Sanuwave (Georgia); this study was done independent of the appointment.

Analysis

Follow-up issues: Of the 268 patients, 27 (10%) were lost to follow up. Plain radiographs of the shoulder were used to assess change in calcification at 3, 6 and 12 months.

Study design issues: Retrospective cohort study, to identify factors that are prognostic of the outcome of ESWT for calcific tendonitis of the shoulder. One year after ESWT, patients were grouped according to the level of resorption of calcification. Clinical evaluation included intensity of pain (VAS) and pain score, power, activity and movement. Stepwise multiple regression analysis was done for each parameter to determine which characteristics were independently associated with the outcomes of ESWT.

Study population issues: The mean duration of symptoms was 18.8 months (range 6 to 126).

Key efficacy findings

Number of patients analysed: 241

- Complete resorption of calcification=55.6% (134/241)
- Mean duration of symptoms was 12.5 months (range 6 to 48) in the complete resorption group and 26.6 months (range 12 to 126) in the incomplete resorption group (p<0.001).

Radiographical results

Variable	Complete resorption (n=134)	Incomplete resorption (n=107)	p value
Mean calcification size (mm) (SD)	13.0 (6.7)	23.9 (8.9)	<0.001
Gartner and Heyer classification, % (n) – type 1	6.7 (9/134)	64.5 (69/107)	<0.001
Gartner and Heyer classification, % (n) – type 2	61.9 (83/134)	21.5 (23/107)	-
Gartner and Heyer classification, % (n) – type 3	31.4 (42/134)	14.0 (15/107)	-
Location: acromion (muscle part)	2.2 (3/134)	5.6 (6/107)	<0.001
Location: supraspinatus/infraspinatus (tendon part)	97.8 (131/134)	94.4 (101/107)	-

Clinical results before and after ESWT

Variable	Complete resorption (n=134)	Incomplete resorption (n=107)	p value
Intensity of pain – before (SD; range)	5.5 (1.1; 2 to 8)	5.5 (0.9; 3 to 8)	0.983
Intensity of pain – after (SD; range)	1.0 (2.0; 0 to 6)	3.8 (2.4; 0 to 7)	<0.001
p value	<0.001	<0.001	
Pain score – before (SD; range)	4.2 (0.8; 1 to 6)	4.3 (0.8; 2 to 6)	0.109
Pain score – after (SD; range)	8.8 (2.1; 3 to 10)	6.1 (2.4; 3 to 10)	<0.001
p value	<0.001	< 0.001	
Power – before (SD; range)	13.7 (3.5; 5 to 21)	13.1 (3.0; 5 to 20)	0.150
Power – after (SD; range)	22.7 (4.0; 10 to 25)	17.5 (5.1; 8 to 25)	<0.001
p value	<0.001	<0.001	
Activity – before (SD; range)	12.6 (2.8; 5 to 19)	12.1 (2.8; 6 to 18)	0.122
Activity – after (SD; range)	18.8 (2.5; 8 to 20)	14.9 (4.0; 6 to 20)	<0.001
p value	<0.001	<0.001	
Movement – before (SD; range)	20.4 (6.4; 6 to 36)	20.5 (6.0; 8 to 38)	0.895
Movement – after (SD; range)	35.0 (7.3; 6 to 40)	26.3 (8.5; 10 to 40)	<0.001
p value	<0.001	<0.001	
Constant score – before (SD; range)	53.7 (10.2; 24 to 37)	52.8 (8.0; 37 to 67)	0.435

Constant score – after (SD; range)	90.0 (16.4; 33 to 100)	68.1 (19.8; 37 to 100)	<0.001
p value	<0.001	<0.001	
Complaint-free, % (n)	81.4 (109/134)	23.4 (25/107)	<0.001
Significantly better, % (n)	3.7 (5/134)	19.6 (21/107)	<0.001
Slightly better, % (n)	3.0 (4/134)	11.2 (12/107)	0.011
Unchanged, % (n)	11.9 (16/134)	45.8 (49/107)	<0.001

Stepwise multiple logistic regression analysis of factors associated with the outcome of ESWT

Factor	Comparison	Odds Ratio (95% CI)	P value
Duration of symptoms (months)	Per 1-month increase	1.06 (1.02 to 1.10)	0.006
Classification	Type 1 versus others	24.8 (9.42 to 65.4)	<0.001
Calcification size (mm)	Per 1 mm increase	1.19 (1.12 to 1.27)	<0.001

Key safety findings

No safety outcomes were reported.

Study 10 Liu H (2006)

Study details

Study type	Case report
Country	Taiwan
Recruitment period	Not reported
Study population and number	n=1 Patient with humeral head osteonecrosis after ESWT for rotator cuff tendinopathy
Age and sex	49 year old female
Patient selection criteria	Not applicable
Technique	The patient had 1 session of ESWT each week for 3 consecutive weeks with a piezoelectric system (Piezoson 100; Richard Wolf, Germany). The impulse rate was 3,000 shocks per session with an energy of 0.78 mJ/mm^2. The total energy was 2,340 mJ/mm^2.
Follow up	3 months
Conflict of interest/source of funding	None

Key safety findings

The patient had a history of shoulder pain for 10 months. An MRI scan showed shoulder impingement with a partial tear of the supraspinatus tendon on the humeral side, subacromial and subdeltoid bursitis, and biceps tenosynovitis. There was no evidence of osteonecrosis of the humeral head. A follow up MRI at 3 months after the ESWT showed a newly developed area of osteonecrosis in the left humeral head. Another MRI at 7 months after the ESWT showed progression of the osteonecrosis. The shoulder pain became intolerable, and the patient had surgical core decompression of the humeral head 2 months later. During this hospital stay, an investigation for known predisposing factors for osteonecrosis was negative and the clinical history included no known predisposing factors.

Study 11 Durst H (2002)

Study details

Study type	Case report
Country	Switzerland
Recruitment period	1996
Study population and number	n=1 Patient with humeral head osteonecrosis after ESWT for shoulder calcific tendonitis
Age and sex	59 year old female
Patient selection criteria	Not applicable
Technique	The patient had 3 sessions of ESWT over the period of 1 month. At each session, 1,600 to 1,700 impulses were given at a level of 12 to 13 kV.
Follow up	3 years and 4 months
Conflict of interest/source of funding	None

Key safety findings

The patient presented with chronic shoulder pain (duration not stated), which had not responded to 3 subacromial injections of cortisone. Radiographs showed a deposit of calcium 28x10 mm in the tendon of the supraspinatus. After ESWT, there was a 79% reduction in the size of the calcium deposit seen on radiographs and no evidence of humeral head osteonecrosis. At 3 years and 4 months after ESWT, the patient had shoulder pain again and radiographs showed partial necrosis of the humeral head. This was confirmed by MRI. Investigations for known predisposing factors for osteonecrosis were negative.

Validity and generalisability of the studies

- There are a number of RCTs, including data from the UK.
- The systematic review by Surace et al. (2020) includes studies on non-calcific tendinopathies as well as calcific tendinopathies.
- Of the 32 trials included in the systematic review, 12 compared shockwave therapy with placebo.
- There are different devices with different mechanisms for producing shockwaves and treatment parameters varied across the studies. Some studies used radial shockwave therapy and others used focused shockwave therapy.
- Most studies only reported outcomes up to 12 months after ESWT. One study reported outcomes up to 4 years (Daecke et al. 2002).
- Inclusion criteria varied between studies.
- Outcome measures varied between studies.

Existing assessments of this procedure

A clinical practice guideline on the non-invasive management of soft tissue disorders of the shoulder from the Ontario Protocol for Traffic Injury Management collaboration was published in 2021 (Yu et al. 2021). This was based on 7 systematic reviews examining the effectiveness and safety of non-invasive interventions for the management of soft tissue disorders of the shoulder. The recommendations state that shockwave therapy should not be offered for shoulder pain with duration more than 3 months, but clinicians may consider it for shoulder pain with calcific tendonitis.

The Canadian Agency for Drugs and Technologies in Health published a bulletin on extracorporeal shock wave treatment for chronic rotator cuff tendonitis in 2007 (Ho 2007). This stated that the evidence 'supports the use of high-energy ESWT for chronic calcific rotator cuff tendonitis, but not for non-calcific rotator cuff tendonitis. High-quality RCTs with larger sample sizes are needed to provide stronger evidence.'

Related NICE guidance

Below is a list of NICE guidance related to this procedure.

Interventional procedures

- Extracorporeal shockwave therapy for Achilles tendinopathy. NICE interventional procedures guidance 571 (2016). Available from http://www.nice.org.uk/guidance/IPG571
- Autologous blood injection for tendinopathy. NICE interventional procedures guidance 438 (2013). Available from http://www.nice.org.uk/guidance/IPG438
- Extracorporeal shockwave therapy for refractory greater trochanteric pain syndrome. NICE interventional procedures guidance 376 (2011). Available from http://www.nice.org.uk/guidance/IPG376
- Extracorporeal shockwave therapy for refractory tennis elbow. NICE interventional procedures guidance 313 (2009). Available from http://www.nice.org.uk/guidance/IPG313
- Extracorporeal shockwave therapy for refractory plantar fasciitis. NICE interventional procedures guidance 311 (2009). Available from http://www.nice.org.uk/guidance/IPG311
- Extracorporeal shockwave therapy for Peyronie's disease. NICE interventional procedures guidance 29 (2003). Available from http://www.nice.org.uk/guidance/IPG29

Additional information considered by IPAC

Professional experts' opinions

Expert advice was sought from consultants who have been nominated or ratified by their professional Society or Royal College. The advice received is their individual opinion and is not intended to represent the view of the society. The advice provided by professional experts, in the form of the completed questionnaires, is normally published in full on the NICE website during public consultation, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.

Four professional expert questionnaires were submitted and can be found on the NICE website.

Patient commentators' opinions

NICE's Public Involvement Programme was unable to gather patient commentary for this procedure.

Company engagement

A structured information request was sent to 8 companies who manufacture a potentially relevant device for use in this procedure. NICE received 1 completed submission. This was considered by the IP team and any relevant points have been taken into consideration when preparing this overview.

Issues for consideration by IPAC

None

References

1. Surace SJ, Deitch J, Johnston RV et al. (2020) Shock wave therapy for rotator cuff disease with or without calcification. The Cochrane Database of Systematic Reviews vol. 3: cd008962
2. Kvalvaag E, Roe C, Engebretsen KB et al. (2018) One year results of a randomized controlled trial on radial Extracorporeal Shock Wave Treatment, with predictors of pain, disability and return to work in patients with subacromial pain syndrome. European Journal of Physical and Rehabilitation Medicine 54: 341–50
3. Abo Al-Khair MA, El Khouly RM, Al Sattar Elsergany MA et al. (2021) Focused, radial and combined shock wave therapy in treatment of calcific shoulder tendinopathy. Physician and Sports Medicine 49: 480–7
4. Wu K-T, Chou W-Y, Wang C-J et al. (2019) Efficacy of Extracorporeal Shockwave Therapy on calcified and noncalcified shoulder tendinosis: a propensity score matched analysis. BioMed Research International 2019: 2958251
5. Louwerens JKG, Sierevelt IN, Kramer ET et al. (2020) Comparing ultrasound-guided needling combined with a subacromial corticosteroid injection versus high-energy extracorporeal shockwave therapy for calcific tendinitis of the rotator cuff: a randomized controlled trial. Arthroscopy: the Journal of Arthroscopic & Related Surgery 36: 1823–33e1
6. Fatima A, Ahmad A, Gilani SA et al. (2022) Effects of high-energy extracorporeal shockwave therapy on pain, functional disability, quality of life, and ultrasonographic changes in patients with calcified rotator cuff tendinopathy. BioMed Research International 2022: 1230857 https://doi.org/10.1155/2022/1230857
7. Kuo Y-C, Hsu W-C, Lin Y-J et al. (2022) Comparison of the effects of ultrasound- guided needle puncture, radial shock wave therapy, and combined treatments on calcific tendinitis of the shoulder: A single-blind randomized controlled trial. Journal of Back and Musculoskeletal Rehabilitation; 2022
8. Daecke W, Kusnierczak D, Loew M (2002) Long-term effects of extracorporeal shockwave therapy in chronic calcific tendinitis of the shoulder. Journal of Shoulder and Elbow Surgery 11: 476–80
9. Chou W-Y, Wang C-J, Wu K-T et al. (2017) Prognostic factors for the outcome of extracorporeal shockwave therapy for calcific tendinitis of the shoulder. The Bone & Joint Journal 99b: 1643–50
10. Liu H-M, Chao C-M, Hsieh J-Y et al. (2006) Humeral head osteonecrosis after extracorporeal shock-wave treatment for rotator cuff tendinopathy. The Journal of Bone & Joint Surgery 88: 1353–6

11. Durst HB, Blatter G, Kuster MS (2002) Osteonecrosis of the humeral head after extracorporeal shock-wave lithotripsy. The Journal of Bone and Joint Surgery. British volume 84: 744–6

12. Ho C (2007) Extracorporeal shock wave treatment for chronic rotator cuff tendonitis (shoulder pain) [Issues in emerging health technologies issue 96 part 3]. Ottawa: Canadian Agency for Drugs and Technologies in Health.

13. Yu, Hainan; Cote, Pierre; Wong, Jessica J; et al. (2021) Noninvasive management of soft tissue disorders of the shoulder: A clinical practice guideline from the Ontario Protocol for Traffic Injury Management (OPTIMa) collaboration. European Journal of Pain 25: 1644–67

Literature search strategy

Databases	Date searched	Version/files
MEDLINE (Ovid)	20/06/2022	1946 to June 17, 2022
MEDLINE In-Process (Ovid)	20/06/2022	1946 to June 17, 2022
MEDLINE Epubs ahead of print (Ovid)	20/06/2022	1946 to June 17, 2022
EMBASE (Ovid)	20/06/2022	1974 to 2022 June 17
EMBASE Conference (Ovid)	20/06/2022	1974 to 2022 June 17
Cochrane Database of Systematic Reviews – CDSR (Cochrane Library)	20/06/2022	Issue 6 of 12, June 2022
Cochrane Central Database of Controlled Trials – CENTRAL (Cochrane Library)	20/06/2022	Issue 5 of 12, May 2022
International HTA database (INAHTA)	20/06/2022	-

Trial sources searched

- Clinicaltrials.gov
- ISRCTN
- WHO International Clinical Trials Registry

Websites searched

- National Institute for Health and Care Excellence (NICE)
- NHS England
- Food and Drug Administration (FDA) - MAUDE database
- Australian Safety and Efficacy Register of New Interventional Procedures – Surgical (ASERNIP – S)
- Australia and New Zealand Horizon Scanning Network (ANZHSN)
- General internet search

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

Literature search strategy

1 ultrasonic therapy/
2 ultrasonic waves/
3 (ultrasound or ultrasonic*).tw.
4 extracorporeal shockwave therapy/
5 (Shock Wave* or shockwave* or shock-wave* or sonic pulse* or HIFU or RSWT or ESWT or ESWL or ESWLS).tw.
6 Lithotripsy/
7 (Lithotrip* or Litholapax*).tw.
8 ((Electrohydraulic* or Electromagnetic* or Piezoelectric) adj4 (system* or therap* or treat*)).tw.

9	or/1-8
10	Tendinopathy/
11	(Tendinit* or Tendoni* or Tendino* or Tendono*).tw.
12	Rotator Cuff/
13	rotator cuff*.tw
14	Shoulder/
15	shoulder*.tw.
16	(Teres Minor or Subscapularis or Infraspinatus or Supraspinatus).tw.
17	or/10-16
18	calcification, physiologic/
19	(calcium or calcif* or calcarea).tw.
20	18 or 19
21	17 and 20
22	9 and 21
23	PiezoWave*.tw.
24	22 or 23
25	Animals/ not Humans/
26	24 not 25

Appendix

The following table outlines the studies that are considered potentially relevant to the IP overview but were not included in the summary of the key evidence. It is by no means an exhaustive list of potentially relevant studies.

Case series with fewer than 30 patients have been excluded. Systematic reviews that were published before 2010 have also been excluded.

Additional papers identified

Article	Number of patients/ follow up	Direction of conclusions	Reasons for non-inclusion in summary of key evidence section
Al-Abbad H, Allen S, Morris S et al. (2020) The effects of shockwave therapy on musculoskeletal conditions based on changes in imaging: a systematic review and meta-analysis with meta-regression. BMC Musculoskeletal Disorders.21: 275	Systematic review and meta-analysis n=27 studies	Shockwave therapy altered the morphology of musculoskeletal conditions, potentially reflecting changes in underlying pathophysiological processes. The parameters of shockwave therapy dosage are not significant predictors of changes in imaging outcomes. Lack of adequate reporting of imaging outcomes limited the conclusions that could be drawn from the current review.	Mixed indications; review focuses on changes in imaging.
Albert J-D, Meadeb J, Guggenbuhl P et al. (2007) High-energy extracorporeal shock-wave therapy for calcifying tendinitis of the rotator cuff: a randomised trial. The Journal of Bone and Joint Surgery 89: 335–41	RCT (high versus low energy ESWT) n=80 Follow up: mean 110 days	High-energy shock-wave therapy statistically significantly improves symptoms in refractory calcifying tendinitis of the shoulder after 3 months of follow up, but the calcific deposit remains unchanged in size in most patients.	Included in systematic review (Surace 2020).
Arirachakaran A, Boonard M, Yamaphai S	Systematic review and	The network meta-analysis suggested that	A systematic review with a

et al. (2017) Extracorporeal shock wave therapy, ultrasound-guided percutaneous lavage, corticosteroid injection and combined treatment for the treatment of rotator cuff calcific tendinopathy: a network meta-analysis of RCTs. European Journal of Orthopaedic Surgery & Traumatology 27: 381–90	network meta-analysis n=7 studies	combined ultrasound-guided needling and subacromial corticosteroid injection significantly decreased shoulder pain VAS, improved Constant-Murley Score and decreased the size of calcium deposits, while also lowering risks of adverse events when compared to barbotage plus ESWT, ESWT and subacromial corticosteroid injection; therefore, the evidence points to ultrasound-guided needling as being the treatment of choice for nonsurgical options of treatment in calcific tendinitis of the shoulder.	more recent search date is included.
Avancini-Dobrovic V, Frlan-Vrgoc L, Stamenkovic D et al. (2011) Radial extracorporeal shock wave therapy in the treatment of shoulder calcific tendinitis. Collegium Antropologicum 35: 221–5	Case series n=30 Follow up: 6 months	Radial ESWT applied to shoulder calcific lesions of the rotator cuff resulted in pain relief, increase in the range of motion and increase in the muscular strength. As shown by X-ray, these results were followed by the decrease in the size of the rotator cuff calcifications.	Small case series.
Bannuru RR, Flavin NE, Vaysbrot E et al. (2014) High-energy extracorporeal shock-wave therapy for treating chronic calcific tendinitis of the shoulder: a systematic review. Annals of Internal Medicine 160: 542–9	Systematic review n=28 studies	Twenty RCTs compared ESWT energy levels and placebo and consistently showed that high-energy ESWT was better than placebo in decreasing pain and improving function and resorption of calcifications in calcific tendinitis.	A more recent systematic review is included.

Bechay J, Lawrence C, Namdari S (2020) Calcific tendinopathy of the rotator cuff: a review of operative versus nonoperative management. The Physician and Sports Medicine 48: 241–46	Review	Conservative management should be the first line of treatment for symptomatic calcific tendinopathy. If this fails, ESWT or Ultrasound-guided percutaneous irrigation is often effective and should be the next step in treatment.	No meta-analysis.
Cacchio A, Paoloni M, Barile A et al. (2006) Effectiveness of radial shock-wave therapy for calcific tendinitis of the shoulder: single-blind, randomized clinical study. Physical Therapy 86: 672–82	RCT (high versus low dose RSWT) n=90 Follow up: 6 months	The results suggest that using RSWT to manage calcific tendinitis of the shoulder is safe and effective, leading to a statistically significant reduction in pain and improvement of shoulder function after 4 weeks, without adverse effects.	Included in systematic review (Surace 2020).
Carlisi E, Lisi C, Dall'angelo A et al. (2018) Focused extracorporeal shock wave therapy combined with supervised eccentric training for supraspinatus calcific tendinopathy. European Journal of Physical and Rehabilitation Medicine 54: 41–7	Non-randomised comparative study n=22 Follow up: 9 weeks	Our study confirmed that focused ESWT is effective in reducing shoulder pain and improving function in calcific supraspinatus tendinopathy. Adding a supervised eccentric training, focused on the abductor muscles, was useful to improve maximum isometric abduction strength, but appeared to give no advantage in the short-term outcome of shock wave therapy.	Study focused on effect of supervised eccentric training as an adjunct to ESWT.
Carulli C, Tonelli F, Innocenti M et al. (2016) Effectiveness of extracorporeal shockwave therapy in three major tendon diseases. Journal of Orthopaedics and Traumatology 17: 15–20	Case series n=311 (129 calcific tendonitis of the shoulder) Follow up: 1 year	There were statistically significant results at follow-up regarding the mean numeric rating scale score (from 6.25 to 0.2) and the Constant Murley Score (from 66.7 to 79.4) for calcific tendonitis of the shoulder.	Mixed indications.

Catapano M, Robinson DM, Schowalter S et al. (2022) Clinical evaluation and management of calcific tendinopathy: an evidence-based review. Journal of Osteopathic Medicine 122: 141–51	Review	Current nonoperative management strategies consist of oral non-steroidal anti-inflammatories and physical therapy for those that are in the reparative phase or not significantly functionally limited. Those with resistant disease may need subacromial-subdeltoid corticosteroid injection, ultrasound-guided percutaneous lavage and extracorporeal shockwave therapy. The best results have been seen with ultrasound-guided percutaneous lavage.	Review, including management of all calcific tendinopathy, not just the shoulder. There is no meta-analysis and no new relevant papers are cited.
Charrin, J E; Noel, E R (2001) Shockwave therapy under ultrasonographic guidance in rotator cuff calcific tendinitis. Joint Bone Spine 68: 241–4	Case series n=32 Follow up: 24 weeks	Improvements in the pain and self-questionnaire scores were noted in 37% of patients after 12 weeks and 55% after 24 weeks. Plain radiographs were changed in 27% of patients after 12 weeks (with complete clearance of the calcific deposits in 7%) and in 24% of patients after 24 weeks (complete clearance in 17%).	Small case series.
Coletti N, Schiavetti S, Giusto F et al. (2008) Arthroscopy surgery versus shock wave therapy for chronic calcifying tendinitis of the shoulder. Journal of Orthopaedics and Traumatology 9: 179–85	Non-randomised comparative study n=46 Follow up: 24 months	Shock wave therapy is equivalent to arthroscopy, and so shock wave therapy should be preferred because of its non-invasiveness.	More recent studies with more patients or longer follow up are included.
Cosentino R, De Stefano R, Selvi E et al. (2003)	RCT (ESWT versus sham)	Because of its good tolerance, safety, and	Included in systematic

Extracorporeal shock wave therapy for chronic calcific tendinitis of the shoulder: single blind study. Annals of the Rheumatic Diseases 62: 248–50	n=70 Follow up: 6 months	clinical radiological response, ESWT can be considered as an alternative treatment for chronic calcific tendinitis of the shoulder.	review (Surace 2020).
De Boer FA, Mocking F, Van Kampen PM et al. (2017) Ultrasound guided needling vs radial shockwave therapy in calcific tendinitis of the shoulder: a prospective randomized trial. Journal of Orthopaedics 14: 466–69	RCT (RSWT versus ultrasound-guided needling) n=25 Follow up: 12 months	Compared to RSWT, ultrasound-guided needling resulted in lower pain and faster resorption of calcifications after 6 weeks. No statistically significant differences were found after 1 year.	Included in systematic review (Surace 2020).
Del Castillo-Gonzalez F, Ramos-Alvarez JJ, Rodriguez-Fabian G et al. (2016) Extracorporeal shockwaves versus ultrasound-guided percutaneous lavage for the treatment of rotator cuff calcific tendinopathy: a randomized controlled trial. European Journal of Physical and Rehabilitation Medicine 52: 145–51	RCT (ESWT versus ultrasound-guided lavage) n=243 Follow up: 12 months	Pain and the amount of calcification were statistically significantly reduced by both techniques at 3, 6 and 12 months ($p<0.001$ for each), but statistically significantly more so by ultrasound guided percutaneous lavage ($p<0.001$).	Included in systematic review (Surace 2020).
Duymaz T, Sindel D (2019) Comparison of radial extracorporeal shock wave therapy and traditional physiotherapy in rotator cuff calcific tendinitis treatment. Archives of Rheumatology 34: 281–87	RCT (radial ESWT plus physiotherapy versus physiotherapy alone) n=80 Follow up: end of treatment	Although all parameters of the patients in both groups improved, patients in the radial ESWT group had a statistically significant improvement in pain, range of movement and QuickDash scores ($p<0.001$, $p<0.001$, and $p<0.001$, respectively).	Included in systematic review (Surace 2020).
Engebretsen K, Grotle M, Bautz-Holter E et al. (2009) Radial extracorporeal shockwave treatment compared with	RCT (radial ESWT versus supervised exercise) n=104	A treatment effect in favour of supervised exercises at 6, 12, and 18 weeks was found. The adjusted treatment effect was -8.4 (95% CI -	Included in systematic review (Surace 2020).

supervised exercises in patients with subacromial pain syndrome: single blind randomised study. BMJ 339: b3360	Follow up: 12 months	16.5 to -0.6) points. A statistically significantly higher proportion of patients in the supervised exercises group improved (odds ratio 3.2, 95% CI 1.3 to 7.8). More patients in the shockwave treatment group had additional treatment between 12 and 18 weeks (odds ratio 5.5, 95% CI 1.3 to 26.4).	
Farr S, Sevelda F, Mader P et al. (2011) Extracorporeal shockwave therapy in calcifying tendinitis of the shoulder. Knee Surgery, Sports Traumatology, Arthroscopy 19: 2085–9	RCT (single high-dose ESWT versus 2 treatments of low-dose ESWT) n=30 Follow up: 12 weeks	This pilot study indicates that a single high-level ESWT may be as effective as 2 applications of a lower-dosed ESWT for calcifying tendinitis.	Included in systematic review (Surace 2020).
Frassanito P, Cavalieri C, Maestri R et al. (2018) Effectiveness of Extracorporeal Shock Wave Therapy and kinesio taping in calcific tendinopathy of the shoulder: a randomized controlled trial. European Journal of Physical and Rehabilitation Medicine 54: 333–40	RCT n=42 Follow up: 12 weeks	Kinesio taping associated with ESWT seems to improve the recovery in rotator cuff calcific tendinopathy with a faster therapeutic response compared to ESWT only.	Study assesses effect of kinesio taping as an adjunct to ESWT.
Gerdesmeyer L, Wagenpfeil S, Haake M et al. (2003) Extracorporeal shock wave therapy for the treatment of chronic calcifying tendonitis of the rotator cuff: a randomized controlled trial. JAMA 290: 2573–80	RCT (high-energy ESWT versus low-energy ESWT versus sham therapy) n=144 Follow up: 12 months	Both high-energy and low-energy ESWT appeared to provide a beneficial effect on shoulder function, as well as on self-rated pain and diminished size of calcifications, compared with placebo. Furthermore, high-energy ESWT appeared	Included in systematic review (Surace 2020).

		to be superior to low-energy ESWT.	
Haake M, Deike B, Thon A et al. (2002) Exact focusing of extracorporeal shock wave therapy for calcifying tendinopathy. Clinical Orthopaedics and Related Research 397: 323–31	RCT (ESWT focused on the origin of supraspinatus tendon versus ESWT focused on the calcific deposit) n=50 Follow up: 1 year	Statistical analyses showed a significant superiority of extracorporeal shock wave application at the calcified area in the primary end point (Constant and Murley score). Therefore, exact fluoroscopic focusing of ESWT at the calcific deposit for treatment of calcifying tendinopathy of the supraspinatus muscle is recommended.	Included in systematic review (Surace 2020).
Haake M, Wirth T, Rautmann M (2001) Extracorporeal shock wave therapy vs surgical treatment in calcifying tendinitis and non calcifying tendinitis of the supraspinatus muscle. European Journal of Orthopaedic Surgery and Traumatology 11: 21–24	Non-randomised comparative study n=60 Follow up: 3 months	ESWT appears to be an effective and relatively inexpensive treatment for supraspinatus muscle tendinitis and should be considered before surgical treatment is employed.	Studies with more patients or longer follow up are included.
Hawk C, Minkalis AL, Khorsan R et al. (2017) Systematic review of nondrug, nonsurgical treatment of shoulder conditions. Journal of Manipulative and Physiological Therapeutics 40: 293–319	Systematic review n=25 systematic reviews and 44 RCTs	Moderate evidence supported ESWT for calcific tendinitis rotator cuff associated disorders.	A more recent systematic review is included.
Hearnden A, Desai A, Karmegam A et al. (2009) Extracorporeal shock wave therapy in chronic calcific tendonitis of the shoulder--is it effective? Acta Orthopaedica Belgica 75: 25–31	RCT (ESWT versus placebo) n=20 Follow up: 6 months	This study confirms that ESWT is effective in treating chronic calcific tendonitis when compared with a placebo group. However, it was not as successful as previously claimed; half the	Included in systematic review (Surace 2020).

		patients did not have a satisfactory outcome and needed surgical excision. Patients found the procedure painful, which has not been previously alluded to.	
Hsu C-J, Wang D-Y, Tseng K-F et al. (2008) Extracorporeal shock wave therapy for calcifying tendinitis of the shoulder. Journal of Shoulder and Elbow Surgery 17: 55–9	RCT (ESWT versus sham treatment) n=46 Follow up: 12 months	ESWT shows promise for pain relief and functional restoration of calcific tendinitis with negligible complications.	Included in systematic review (Surace 2020).
Huisstede BMA, Gebremariam L, van der Sande R et al. (2011) Evidence for effectiveness of Extracorporal Shock-Wave Therapy (ESWT) to treat calcific and non-calcific rotator cuff tendinosis--a systematic review. Manual Therapy 16: 419–33	Systematic review n=17 RCTs	Only high-ESWT is effective for treating calcific rotator cuff tendinosis.	A more recent systematic review is included.
Ioppolo F, Tattoli M, Di Sante L et al. (2013) Clinical improvement and resorption of calcifications in calcific tendinitis of the shoulder after shock wave therapy at 6 months' follow-up: a systematic review and meta-analysis. Archives of Physical Medicine and Rehabilitation 94: 1699–706	Systematic review n=6 studies	There was a clinical improvement with a pooled total resorption ratio of 27.2 (95% CI, 7.2 to 102.7) and a pooled partial resorption ratio of 16.2 (95% CI, 3.3 to 79.0). Shockwave therapy increases shoulder function, reduces pain, and is effective in dissolving calcifications. These results were maintained over the following 6 months.	A more recent systematic review is included.
Ioppolo F, Tattoli M, Di Sante L et al. (2012) Extracorporeal shock-wave therapy for supraspinatus calcifying	RCT (high-energy ESWT versus low-energy ESWT)	In ESWT for supraspinatus calcifying tendinitis, an energy level of 0.20 mJ/mm^2 appears to be more	Included in systematic review (Surace 2020).

tendinitis: a randomized clinical trial comparing two different energy levels. Physical Therapy 92: 1376–85	n=46 Follow up: 12 months	effective than an energy level of 0.10 mJ/mm^2 in pain relief and functional improvement.	
Jakobeit C, Winiarski B, Jakobeit S et al. (2002) Ultrasound-guided, high-energy extracorporeal - shock-wave treatment of symptomatic calcareous tendinopathy of the shoulder. ANZ Journal of Surgery 72: 496–500	Case series n=80	68 patients (85%) had complete freedom from symptoms or only had minimal residual symptoms when stressing their shoulder joint. The calcification in 57 (71%) patients was completely resorbed after treatment and partially resorbed in 16 patients (20%). Complete resorption of the calcareous deposits led to freedom from symptoms.	Studies that were more recent, had more patients or longer follow up were included.
Kim EK, Kwak KI (2016) Effect of extracorporeal shock wave therapy on the shoulder joint functional status of patients with calcific tendinitis. Journal of Physical Therapy Science 28: 2522–24	RCT n=40	The treatment group showed a more significant decrease in pain at 2, 6, and 12 weeks compared to the control group ($p<0.05$).	Treatment included transcutaneous electrical nerve stimulation as well as ESWT.
Kim SJ, Lee HJ, Kim YV et al. (2014) Which method is more effective in treatment of calcific tendinitis in the shoulder? Prospective randomized comparison between ultrasound guided needling and extracorporeal shock wave therapy. Journal of Shoulder and Elbow Surgery 23:1640–46	RCT (ESWT versus ultrasound-guided needling) n=62 Follow up: mean 23 months	Both treatment modalities for calcific tendinitis improved clinical outcomes and eliminated calcium deposits. Ultrasound-guided needling treatment, however, was more effective in function restoration and pain relief in the short term.	Included in systematic review (Surace 2020).
Kolk A, Yang KG, Tamminga R et al. (2013) Radial extracorporeal shock-wave therapy in patients	RCT (radial ESWT versus placebo) n=82	A VAS score for pain, a Constant-Murley score and a simple shoulder test score statistically significantly improved in	Included in systematic review (Surace 2020).

with chronic rotator cuff tendinitis. A prospective randomised double-blind placebo-controlled multicentre trial. Bone & Joint Journal 95: 1521–6	Follow up: 6 months	both groups at 3 and 6 months compared with baseline (all p≤0.012). The scores were similar in both groups. Low-dose radial ESWT does not appear to reduce pain or improve function in patients with chronic rotator cuff tendinitis compared with placebo treatment.	
Krasny C, Enenkel M, Aigner N et al. (2005) Ultrasound-guided needling combined with shock-wave therapy for the treatment of calcifying tendonitis of the shoulder. The Journal of Bone and Joint Surgery 87: 501–7	RCT n=80 Follow up: mean 4 months	Ultrasound-guided needling in combination with high-energy shock-wave therapy is more effective than shock-wave therapy alone in patients with symptomatic calcific tendonitis, giving significantly higher rates of elimination of the calcium deposits, better clinical results and reduction in the need for surgery.	Study assessed the effect of combining ultrasound-guided needling with ESWT.
Kvalvaag E, Brox JI, Engebretsen KB et al. (2017) Effectiveness of radial extracorporeal shock wave therapy (rESWT) when combined with supervised exercises in patients with subacromial shoulder pain: a double-masked, randomized, sham-controlled trial. The American Journal of Sports Medicine 45: 2547– 54	RCT (supervised exercises plus radial ESWT versus supervised exercises plus sham radial ESWT) n=143 Follow up: 24 weeks	At 24 weeks, participants in both groups had improved (p<0.001) in SPADI score compared with baseline, but there were no differences between the groups (mean difference 0.7; 95% CI, -6.9 to 8.3; p=0.76). Prespecified subgroup analysis of patients with calcification in rotator cuff showed that the radial ESWT group had a greater improvement in SPADI score after 24 weeks (mean difference -12.8, 95% CI -24.8 to -0.8, p=0.018).	Included in systematic review (Surace 2020).

Lanza E, Piccoli F, Intrieri C et al. (2021) US-guided percutaneous irrigation of calcific tendinopathy of the rotator cuff in patients with or without previous external shockwave therapy. La Radiologia Medica 126: 117–23	Cohort study n=70 Follow up: mean 14 months	Previous unsuccessful ESWT did not affect the outcome of ultrasound guided percutaneous irrigation of calcific tendinopathy.	The intervention was ultrasound guided percutaneous irrigation in patients with or without previous ESWT.
Lee S-Y, Cheng B, Grimmer-Somers K (2011) The midterm effectiveness of extracorporeal shockwave therapy in the management of chronic calcific shoulder tendinitis. Journal of Shoulder and Elbow Surgery 20: 845–54	Systematic review n=9 studies	Because of variable treatment parameters (such as dosage), this review was unable to provide clear guidance of the dose-effect of the midterm effectiveness of ESWT. Studies of better methodologic design using standardised treatment protocols and studies with longer follow-up are needed.	A more recent systematic review is included.
Loew M, Daecke W Kusnierczak D et al. (1999) Shock-wave therapy is effective for chronic calcifying tendinitis of the shoulder. The Journal of Bone and Joint Surgery 81: 863–7	RCT (no treatment versus single session low-dose ESWT versus single session high-dose ESWT versus dual session high-dose ESWT) n=80 (part A), 115 (part B) Follow up: 6 months	The results showed energy-dependent success, with relief of pain ranging from 5% in the control group up to 58% after 2 high-energy sessions.	Included in systematic review (Surace 2020).
Lorbach O, Kusma M, Pape D et al. (2008) Influence of deposit stage and failed ESWT on the surgical results of arthroscopic treatment of calcifying tendonitis of the shoulder. Knee Surgery, Sports	Case series n=50 (24 had ESWT)	The type of calcific deposit and the preoperative treatment of the shoulder with ESWT did not have any significant impact on the postoperative results of arthroscopic surgery.	Study focuses on the effect of having unsuccessful ESWT before arthroscopic treatment.

Traumatology 16: 516–21			
Louwerens JKG, Veltman ES, van Noort A et al. (2016) The effectiveness of high-energy extracorporeal shockwave therapy versus ultrasound-guided needling versus arthroscopic surgery in the management of chronic calcific rotator cuff tendinopathy: a systematic review. Arthroscopy: the Journal of Arthroscopic & Related surgery 32: 165–75	Systematic review n=22 studies	Patients can achieve good to excellent clinical outcomes after high-energy ESWT, ultrasound-guided needling, and arthroscopy for calcific tendinopathy of the shoulder.	A more recent systematic review is included (Surace 2020).
Louwerens JKG, Sierevelt IN, van Noort A et al. (2014) Evidence for minimally invasive therapies in the management of chronic calcific tendinopathy of the rotator cuff: a systematic review and meta-analysis. Journal of Shoulder and Elbow Surgery 23: 1240–9	Systematic review n=20 studies	High-energy extracorporeal shockwave therapy is the most thoroughly investigated minimally invasive treatment option in the short-term to midterm and has proven to be a safe and effective treatment.	A more recent systematic review that includes the same relevant studies is included (Surace 2020).
Maier M, Staupendahl D, Duerr HR et al. (1999) Castor oil decreases pain during extracorporeal shock wave application. Archives of Orthopaedic and Trauma Surgery 119: 423–7	Case series n=60	Castor oil had an advantage over ultrasound jelly and Vaseline in all indications used with regard to application pain. The positive effect of castor oil can be explained by its cavitation-free quality.	Mixed indications; study focuses on the use of castor oil to decrease pain during treatment.
Maier M, Stabler A, Lienemann A et al. (2000) Shockwave application in calcifying tendinitis of the shoulder--prediction of outcome by imaging. Archives of	Case series n=62 Follow up: mean 18 months	The results suggest that in patients with chronic calcifying tendinitis, the absence of contrast enhancement, especially around the deposit, is a strong predictive	Small case series.

Orthopaedic and Trauma Surgery 120: 493–98		parameter of a positive clinical outcome of ESWT.	
Malliaropoulos N, Thompson D, Meke M et al. (2017) Individualised radial extracorporeal shock wave therapy (rESWT) for symptomatic calcific shoulder tendinopathy: a retrospective clinical study. BMC Musculoskeletal Disorders 18: 513	Case series n=67 Follow up: 1 year	One-year success rate was estimated at 92% and 1-year recurrence rate was 7%. In this retrospective study an individualised rESWT protocol resulted in a high success rate with low number of recurrences.	Small case series.
Mangone G, Veliaj A, Viliani T et al. (2010) Radial extracorporeal shock-wave therapy in rotator cuff calcific tendinosis. Clinical Cases in Mineral and Bone Metabolism 7: 91–96	Non-randomised comparative study n=62 Follow up: 3 months	Patients who had high power laser therapy had good clinical results but returned to original syndrome 1 month after treatment. Radial ESWT gave improvement after treatment extended in time (3 months) in terms of pain and recover of functionality with a limited number of applications.	Small study with short follow up.
Moretti B, Garofalo R, Genco S et al. (2005) Medium-energy shock wave therapy in the treatment of rotator cuff calcifying tendinitis. Knee Surgery, Sports Traumatology, Arthroscopy 13: 405–10	Case series n=54 Follow up: 6 months	38 (70%) patients reported satisfactory functional results. Radiographs and sonographs showed a disappearance of calcium deposit in 29 patients (54%) and in 19 patients (35%) it appeared to be reduced more than a half. A correlation was found between residual calcium deposit and the clinical outcome, but some patients showed a reduced pain without modification of calcium deposit.	Small case series.

Moya D, Ramon S, Schaden W et al. (2018) The role of extracorporeal shockwave treatment in musculoskeletal disorders. Journal of Bone and Joint Surgery 100: 251–63	Review	Given its efficacy in pain reduction and functional outcomes, resorption rate, safety, non-invasiveness, reduced recovery time, and cost-effectiveness, the authors consider that high-energy focused ESWT is the treatment of choice in calcifying tendinopathy of the shoulder when conservative treatment has failed.	No meta-analysis. A more recent review is included.
Moya D, Ramon S, Guiloff L et al. (2015) Current knowledge on evidence-based shockwave treatments for shoulder pathology. International Journal of Surgery 24: 171–8	Review	There is evidence to support the use of shockwaves in certain shoulder pathologies. Its efficiency, safety and non-invasiveness justify its choice over surgical procedures in rotator cuff calcifications.	No meta-analysis. A more recent review is included.
Notarnicola A, Moretti L, Maccagnano G et al. (2016) Tendonitis of the rotator cuff treated with extracorporeal shock wave therapy: radiographic monitoring to identify prognostic factors for disintegration. Journal of Biological Regulators and Homeostatic Agents 30: 1195–202	Case series n=174 shoulders Follow up: 3 months	Calcification disappeared in 37% of shoulders, reduced in size in 22% and there was no change in 41%. The calcifications that disappeared were large according to Bosworth (p=0.004). The probability of disappearance of calcification increased with increasing age (p=0.011), for medium calcifications according to Bosworth (p=0.001), and calcifications of type A according to Mole (p=0.043).	Study focuses on effect of ESWT on calcification, assessed by imaging.
Pan P-J, Chou C-L, Chiou H-J et al. (2003) Extracorporeal shock wave therapy for chronic calcific tendinitis of the	RCT (ESWT versus trans-cutaneous electrical	In both groups, Constant score and VAS improved significantly at 2-, 4-, and 12-week follow-ups (p<0.05), and	Included in systematic review (Surace 2020).

shoulders: a functional and sonographic study. Archives of Physical Medicine and Rehabilitation 84: 988–93	nerve stimulation) n=60 Follow up: 12 weeks	the size of calcium deposits decreased significantly at the 4- and 12-week follow-ups. Moreover, the arc-shaped calcific plaques of the rotator cuff were markedly meliorated with ESWT.	
Perlick L, Luring C, Bathis H et al. (2003) Efficacy of extracorporal shock-wave treatment for calcific tendinitis of the shoulder: experimental and clinical results. Journal of Orthopaedic Science 8: 777–83	RCT (low-dose ESWT versus high-dose ESWT) n=80 Follow up: 1 year	Based on experimental and clinical results it is evident that disintegration of calcific deposits is dose dependent. Because of the time that elapses until changes became evident on the radiographs, an instant and sole mechanical effect on the calcific deposits is unlikely. Therefore, a combined mechanical and cellular mechanism for absorption of the calcific deposits must be presumed.	Included in systematic review (Surace 2020).
Peters J, Luboldt W, Schwarz W et al. (2004) Extracorporeal shock wave therapy in calcific tendinitis of the shoulder. Skeletal Radiology 33: 712–8	RCT (low-dose ESWT versus high-dose ESWT versus sham ESWT) n=90 Follow up: 6 months	ESWT in calcific tendinitis of the shoulder is effective. It does not have serious side effects at an energy level of 0.44 mJ/mm^2.	Included in systematic review (Surace 2020).
Pigozzi F, Giombini A, Parisi A et al. (2000) The application of shock-waves therapy in the treatment of resistant chronic painful shoulder. A clinical experience. The Journal of Sports Medicine and Physical Fitness 40: 356–61	Case series n=72 Follow up: 1 month	53% of patients had excellent results, 14% good, 13% fair and 20% poor. In the group with calcifying tendinitis, there was a reduction in 37% and no change in 63%.	Small case series with mixed indications.

Pleiner J, Crevenna R, Langenberger H et al. (2004) Extracorporeal shockwave treatment is effective in calcific tendonitis of the shoulder. A randomized controlled trial. Wiener klinische Wochenschrift 116: 536–41	RCT (ESWT versus placebo) n=43 Follow up: 7 months	As applied, ESWT with an energy flux density of 0.28 mJ/mm^2 led to a statistically significantly greater improvement in shoulder function and a slightly higher, nonsignificant, rate of >50% disintegration of calcific deposits compared with the control group. However, this did not result in reduction of pain.	Included in systematic review (Surace 2020).
Rebuzzi E, Coletti N, Schiavetti S et al. (2008) Arthroscopy surgery versus shock wave therapy for chronic calcifying tendinitis of the shoulder. J Orthop Traumatol 9: 179–85	Non-randomised comparative study n=46 Follow up: 2 years	Shock wave therapy was equivalent to arthroscopy, and so shock wave therapy should be preferred because of its non-invasiveness.	Small, non-randomised study.
Rompe JD, Burger R, Hopf C et al. (1998) Shoulder function after extracorporal shock wave therapy for calcific tendinitis. Journal of Shoulder and Elbow Surgery 7: 505–9	RCT (low-dose ESWT versus high-dose ESWT) n=100 Follow up: 24 weeks	After 24 weeks, 52% of the patients in group 1 (low dose) rated the results of treatment as good or excellent, compared with 68% in group 2 (high dose; p<0.01). No improvement was reported by 24% versus 10%, respectively, at the 24-week follow-up.	Included in systematic review (Surace 2020).
Rompe JD, Rumler F, Hopf C et al. (1995) Extracorporal shock wave therapy for calcifying tendinitis of the shoulder. Clinical Orthopaedics and Related Research 321: 196–201	Case series n=40 Follow up: 24 weeks	Partial or complete disintegration of the deposit was observed in 63% of patients. Statistical analysis showed significant improvement both of subjective and objective criteria. According to the Constant score, 60% of patients had normal values, and 73% had no or only occasional discomfort. Only	Small case series.

		6 patients (15%) reported no improvement.	
Sabeti M, Dorotka R, Goll A et al. (2007) A comparison of two different treatments with navigated extracorporeal shock-wave therapy for calcifying tendinitis - a randomized controlled trial. Wiener klinische Wochenschrift 119: 124–8	RCT (low-dose ESWT versus high-dose ESWT) n=47 Follow up: 12 weeks	Navigated shock-wave therapy significantly improves pain and shoulder function. Patients obtained nearly equal results after 3 low-energy or 2 middle-energy sessions of shock-wave treatment.	Included in systematic review (Surace 2020).
Sabeti-Aschraf M, Dorotka R, Goll A et al. (2005) Extracorporeal shock wave therapy in the treatment of calcific tendinitis of the rotator cuff. The American Journal of Sports Medicine 33: 1365–8	RCT (palpation-guided ESWT versus image-guided ESWT) n=50 Follow up: 12 weeks	Both groups had statistically significant improvements in the Constant and Murley score and the VAS after 12 weeks. The results from the navigation group were statistically significantly superior to those of the feedback group. In the navigation group, 6 calcium deposits disappeared and 9 altered, compared to 1 disappearance and 12 alterations in the feedback group. There were no severe complications.	Included in systematic review (Surace 2020).
Simpson M, Pizzari T, Cook T et al. (2020) Effectiveness of non-surgical interventions for rotator cuff calcific tendinopathy: A systematic review. Journal of Rehabilitation Medicine 52: jrm00119	Systematic review n=18 articles	There was moderate evidence for the benefit of high energy ESWT over low energy ESWT for pain and function between 3 and 6 months follow up, and benefit over placebo for improved function at up to 6 months follow up. There was moderate evidence for the benefit of ultrasound-guided percutaneous intervention over	Review includes a range of interventions. A systematic review with a more recent search date is included.

		medium or high-energy ESWT for reduced pain and calcific morphology when followed up over a 1-year period. Methodological concerns preclude definitive recommendations.	
Speed C (2014) A systematic review of shockwave therapies in soft tissue conditions: focusing on the evidence. British Journal of Sports Medicine 48: 1538–42	Systematic review n=23 studies	There is evidence that focused ESWT is effective in the treatment of plantar fasciitis, calcific tendinitis, and that radial pulse therapy is effective in plantar fasciitis. Where benefit is seen in focused ESWT, it appears to be dose dependent, with greater success seen with higher dose regimes. There is low level evidence for lack of benefit of low-dose focused ESWT and radial pulse therapy in non-calcific rotator cuff disease and mixed evidence in lateral epicondylitis.	Review included mixed indications. A more recent systematic review is included.
Tornese D, Mattei E, Bandi M et al. (2011) Arm position during extracorporeal shock wave therapy for calcifying tendinitis of the shoulder: a randomized study. Clinical Rehabilitation 25: 731–9	RCT (ESWT neutral position technique versus ESWT with hyper-extended internal rotation technique) n=35 Follow up: 3 months	Positioning the shoulder in hyperextension and internal rotation during extracorporeal shock wave therapy seems to be a useful technique to achieve resorption of calcific deposits.	Included in systematic review (Surace 2020).
Verstraelen FU, In den Kleef NJHM, Jansen L et al. (2014) High-energy versus low-energy	Systematic review n=5 RCTs	All 5 RCTs showed greater improvement in functional outcome (Constant-Murley score)	Review focuses on comparison on

extracorporeal shock wave therapy for calcifying tendinitis of the shoulder: which is superior? A meta-analysis. Clinical Orthopaedics and Related Research 472: 2816–25		in patients who had high-energy ESWT compared with patients who had low-energy ESWT at 3 and 6 months. The 3-month mean difference was 9.9 (95% CI, 9.0 to 10.7, p<0.001; 6-month data could not be pooled). Furthermore, high-energy ESWT more often resulted in complete resorption of the deposits at 3 months. The corresponding odds ratio was 3.4 (95% CI, 1.4 to 8.6) and p=0.009 (6-month data could not be pooled).	high and low-energy ESWT. A more recent systematic review is included, which includes the same studies.
Wang C-J, Yang KD, Wang F-S et al. (2003) Shock wave therapy for calcific tendinitis of the shoulder: a prospective clinical study with two-year follow-up. The American Journal of Sports Medicine 31: 425–30	Non-randomised comparative study (ESWT versus sham) n=43 Follow up: 24 to 30 months (study group)	The overall results in the study group were 61% excellent (20/33 shoulders), 30% good (10), 3% fair (1), and 6% poor (2), and those of the control group were 17% fair (1/6 shoulders) and 83% poor (5). The symptom recurrence rate in the study group was 7%. Dissolution of calcium deposits was complete in 58% of the study group, partial in 15%, and unchanged in 27%. Fragmentation was seen in 17% of the control group patients; in 83% deposits were unchanged. There was no recurrence of calcium deposits.	Small, non-randomised study.
Wu Y-C, Tsai W-C, Tu Y-K et al. (2017) Comparative effectiveness of	Systematic review and network meta-analysis	The present network meta-analysis demonstrates that ultrasound-guided	A more recent systematic review is included, which

nonoperative treatments for chronic calcific tendinitis of the shoulder: a systematic review and network meta-analysis of randomized controlled trials. Archives of Physical Medicine and Rehabilitation 98: 1678–92	n=14 studies	needling, radial ESWT, and high-energy focused ESWT alleviate pain and achieve complete resolution of calcium deposition. Compared with low-energy focused ESWT, transcutaneous electrical nerve stimulation, and ultrasound therapy, high-energy focused ESWT is the best therapy for providing functional recovery. Physicians should consider ultrasound-guided needling, radial ESWT, and high-energy focused ESWT as alternative effective therapies for chronic calcific tendinitis of the shoulder when initial conservative treatment fails.	has the same studies on ESWT.
Zoellner J, Nafe B, Rompe JD (2001) Shock wave therapy versus conventional surgery in the treatment of calcifying tendinitis of the shoulder. Clinical Orthopaedics and Related Research 387: 72–82	Non-randomised comparative study n=79 Follow up: 2 years	Surgery was superior compared with high-energy shock wave therapy for patients with homogenous deposits. For patients with inhomogenous deposits, high-energy ESWT was equivalent to surgery and should be given priority because of its non-invasiveness.	Small, non-randomised comparative study.