Washington State Health Care Authority

# Extracorporeal shock wave therapy for musculoskeletal conditions

## Draft evidence report

*December 16, 2016*

**Health Technology Assessment Program (HTA)**
Washington State Health Care Authority
PO Box 42712
Olympia, WA 98504-2712
(360) 725-5126
www.hca.wa.gov/about-hca/health-technology-assessment
shtap@hca.wa.gov

# Extracorporeal Shock Wave Therapy

**Provided by:**


**Spectrum Research, Inc.**

---

**Prepared by:**

Joseph R. Dettori, PhD, MPH
Erika Brodt, BS
Cassandra Winter, BS

***December 16, 2016***

**With assistance from:**
Krystle Pagarigan, BS

This technology assessment report is based on research conducted by a contracted technology assessment center, with updates as contracted by the Washington State Health Care Authority. This report is an independent assessment of the technology question(s) described based on accepted methodological principles. The findings and conclusions contained herein are those of the investigators and authors who are responsible for the content. These findings and conclusions may not necessarily represent the views of the HCA/Agency and thus, no statement in this report shall be construed as an official position or policy of the HCA/Agency.

The information in this assessment is intended to assist health care decision makers, clinicians, patients and policy makers in making sound evidence-based decisions that may improve the quality and cost-effectiveness of health care services. Information in this report is not a substitute for sound clinical judgment. Those making decisions regarding the provision of health care services should consider this report in a manner similar to any other medical reference, integrating the information with all other pertinent information to make decisions within the context of individual patient circumstances and resource availability.

# TABLE OF CONTENTS

## TABLES

## FIGURES

# Abbreviations

**AOFAS**: American Orthopaedic Foot and Ankle Society
**ASES**: American Shoulder and Elbow Surgeons (standardized shoulder assessment)
**CI**: confidence interval
**CMS**: Constant-Murley score (functional assessment of the shoulder)
**DASH**: Disabilities of the Arm, Shoulder, and Hand
**EQ-5D**: EuroQoL 5-Dimension Questionnaire
**EQ-VAS**: EuroQoL Visual Analog Scale
**ESWT**: extracorporeal shock wave therapy
**F/U**: follow-up
**FADI**: Foot and Ankle Disability Index
**FFI**: Foot Function Index
**HA**: hyaluronic acid
**HHS**: Harris Hip Score
**HOS**: Hamstring Outcome Score
**HR**: hazards ratio
**HR-QoL:** Health-Related Quality of Life
**IQR**: inter-quartile range
**LA**: local anesthetic
**LEFS**: Lower Extremity Function Scale
**MCPIE**: Mayo Clinic Performance Index of the Elbow
**MD**: mean difference
**NC**: not calculable
**NR**: not reported
**NRS**: Numerical Rating Scale
**NS**: not statistically significant
**NSAID**: nonsteroidal anti-inflammatory drug
**OA**: osteoarthritis
**PRTEE**: Patient-Rated Tennis Elbow Evaluation
**QoL**: quality of life
**RCT**: randomized controlled trial
**RR**: risk ratio
**SD**: standard deviation
**SF-36**: Short Form-36
**SMD**: standardized mean difference
**SPADI**: Shoulder Pain and Disability Index
**TENS**: transcutaneous electrical nerve stimulation
**VAS**: Visual Analog Scale
**VISA-A:** Victorian Institute of Sports Assessment-Achilles
**WMD:** weighted mean difference

# Executive Summary

## Introduction

Extracorporeal shockwave therapy (ESWT) is a treatment utilized for a variety of healing applications in soft tissue and bone-related musculoskeletal disorders[68] A shock wave is an intense, but very short energy wave traveling faster than the speed of sound. Specific conditions where ESWT is commonly utilized include refractory or chronic pain associated with ligament injuries, muscle strain injuries, osteoarthritis, and tendinopathies. ESWT has gained significant acceptance in Europe, South America, Asia and North America for treatment of these conditions.[77]

The study of the effects of shock waves on humans were first described as the result of accidental depth charge detonations in 1916 during WWI.[39] In WWII, castaways who were exposed to water bomb explosions were noted to suffer severe lung injuries but showed no overt clinical signs of traumatic injury.[47] In 1980, high energy focused extracorporeal shock waves were clinically introduced in Munich, Germany, to disintegrate urinary stones (i.e., lithotripsy)[32] and became the gold standard for the initial treatment of urolithiasis.[74] In the 1980s shock waves were shown to have osteogenic potential. Animal experiments confirmed that shock waves facilitated fracture healing. Osteoblasts activation and increased bone density as a result of shock waves was confirmed by histological investigations.[26,27] In 1988, Valchanou conducted a case series evaluating the effect of high-energy ESWT on the treatment of delayed and nonunion fractures.[76] The authors reported 85% fracture union rate. Urologic lithotripters were used in the early application of orthopedic problems, and this was soon followed by shock wave devices specifically designed for orthopedic and traumatic indications. In the early 1990s, effect of treatment for calcific tendinopathy of the shoulder by focused ESWT were first published.[42,43] Shortly thereafter, studies were published evaluating the effect of ESWT on lateral epicondylitis, Achilles tendonitis, and plantar fasciitis with or with heel spurs.[26,34,38,63,65] The Food and Drug Administration, in October of 2000, approved OssaTron device (HealthTronics, Marietta, GA) for chronic plantar fasciitis and in 2003 for chronic lateral epicondylitis of the elbow.

## Policy Context

Extracorporeal shock wave therapy (ESWT) is a noninvasive treatment based on ultrasound technology. ESWT is used for a variety of conditions including treatment of kidney stones. ESWT for soft tissue injuries is applied with the goal of promoting healing. ESWT may have multiple effects thought to impact healing including breaking calcium deposits and causing an inflammatory response that may stimulate tissue healing. The concern for the efficacy and safety of ESWT are high, while the concern regarding cost is medium/high.

## Objectives

The primary aim of this assessment is to systematically review and synthesis published evidence on the efficacy, safety, and cost-effectiveness of focused extracorporeal shock wave therapy (ESWT) for the treatment of musculoskeletal conditions.

## Key Questions

In patients with musculoskeletal conditions such as tendinopathy, plantar fasciitis, heel spurs, subacromial shoulder pain, or osteoarthritis:

1. What is the evidence of the short- and long-term efficacy and effectiveness of ESWT compared with standard alternative treatment options, sham, or no treatment?

2. What is the evidence regarding short- and long-term harms and complications of ESWT compared with standard alternative treatment options, sham, or no treatment?

3. Is there evidence of differential efficacy, effectiveness, or safety of ESWT compared with standard alternative treatment options, sham, or no treatment? Include consideration of age, sex, race, ethnicity, socioeconomic status, payer, and worker's compensation?

4. What is the evidence of cost-effectiveness of ESWT compared with standard alternative treatment options or no treatment?

Inclusion and exclusion criteria are summarized as follows:

- **Population:** Patients with tendinopathy or tendinitis, plantar fasciitis, heel spurs, subacromial shoulder pain, or osteoarthritis. (Kidney stones; gallstones; cutaneous wounds; muscle spasticity; as well as dental, cosmetic, bony non-unions, fractures, carpal tunnel syndrome, shin splints, greater trochanteric pain syndrome, coccydynia, Dupuytren's disease, myofacscial pain, cardiovascular, osteonecrosis, postoperative patients and neurological conditions will be excluded).
- **Intervention:** Focused or Radial ESWT (ESWT used in conjunction with surgery will be excluded.)
- **Comparators:** Standard alternative treatment(s), sham, or no treatment. (Comparisons of ESWT such as different modalities (e.g., radial vs. focused ESWT, high- vs. low-energy ESWT) will be excluded.)
- **Outcomes:** Function (primary), pain (primary), adverse events (primary), quality of life, patient satisfaction, medication use, surgery, cost-effectiveness (e.g., cost per improved outcome), cost-utility (e.g., cost per quality adjusted life year (QALY), incremental cost effectiveness ratio (ICER) outcomes.
- **Study design**: Focus will be on studies with the least potential for bias such as high quality systematic reviews of randomized controlled trials and randomized controlled trials and full economic studies.

## Methods

The scope of this report and final key questions were refined based on input from clinical experts from a variety of disciplines and public comments received on draft key questions. Clinical expert input was sought to confirm critical outcomes on which to focus.

A formal, structured systematic search of the peer-reviewed literature was performed across a number of databases including PubMed to identify relevant peer reviewed literature as well as other sources (National Guideline Clearinghouse, Center for Reviews and Dissemination Database) to identify pertinent clinical guidelines and previously performed assessments.

Studies were selected for inclusion based on pre-specified criteria detailed in the full report. All records were screened by two independent reviewers. Selection criteria included a focus on studies with the least potential for bias that were written in English and published in the peer-reviewed literature.

Pertinent studies were critically appraised independently by two reviewers evaluating the methodological quality and potential for bias based on study design as well as factors which may bias studies. An overall Strength of Evidence (SoE) combines the appraisal of study limitations with consideration of the number of studies and the consistency across them, directness and precision of the findings to describe an overall confidence regarding the stability of estimates as further research is available. The SoE for was assessed by two researchers following the principles for adapting GRADE (Grades of Recommendation Assessment, Development and Evaluation).[21,22] The strength of evidence was based on the highest quality evidence available for a given outcome. Briefly, bodies of evidence consisting of RCTs were initially considered as High strength of evidence. The strength of evidence could be downgraded based on the limitations (i.e., risk of bias, consistency of effect, directness of outcome, precision of effect estimate, and reporting bias). When assessing the SoE for studies performing subgroup analysis, we also considered whether the subgroup analysis was preplanned (*a priori*) and whether a test for homogeneity or interaction was done. There are also situations where the studies could be upgraded if the study had large magnitude of effect (strength of association). The final strength of evidence was assigned an overall grade of high, moderate, low, or insufficient, which are defined as follows:

• High - Very confident that effect size estimates lie close to the true effect for this outcome; there are few or no deficiencies in the body of evidence; we believe the findings are stable.

• Moderate – Moderately confident that effect size estimates lie close to the true effect for this outcome; some deficiencies in the body of evidence; we believe the findings are likely to be stable but some doubt remains.

• Low – Limited confidence that effect size estimates lie close to the true effect for this outcome; major or numerous deficiencies in the body of evidence; we believe that additional evidence is needed before concluding that findings are stable or that the estimate is close to the true effect.

• Insufficient – We have no evidence, are unable to estimate an effect or have no confidence in the effect estimate for this outcome; OR no available evidence or the body of evidence has unacceptable efficiencies precluding judgment.

We summarized evidence separately for the two types of ESWT, focused and radial, and by the conditions for which treatment was given. The conditions included upper and lower extremity tendinopathies, plantar fasciitis and osteoarthritis.

We conducted meta-analyses when there were two or more studies with similar indications, interventions, control groups and outcomes. We grouped control treatments according to whether the control was a sham treatment, corticosteroid, or other standard conservative care (e.g., physical therapy).

Outcomes were stratified by duration of follow-up as short term (≤3 months), intermediate term (>3 months to <1 year), and long term (≥1 year). When more than one follow-up time was reported within a category, we used data from the longest duration available within that category. Most studies reported pain associated with the presence or absence of activity, or during a time of the day (morning or at night). Pain was measured on a visual analog scale (VAS) or a numerical rating scale (NRS) of 0 to 10 or 0 to 100 (higher scores indicate greater pain). We converted all pain scales to 0 (no pain) to 10 (worst possible pain). Function was assessed using a variety of measures specific to the anatomy or condition being treated.

## Results

**Number of studies for each comparison of efficacy for included conditions.**

Overall, 61 randomized trials (in 63 publications) were included. The selection of the studies are summarized in Figure 4. The comparisons evaluated and their respective studies are listed below; comparisons of interest not listed in the table below had no comparative evidence available that met the inclusion criteria. Diagnoses for which comparative evidence were identified include tendinopathies (lateral epicondyle tendinopathy of the elbow, Achilles tendinopathy, patellar tendinopathy, shoulder tendinopathies), plantar fasciitis, and knee osteoarthritis.

| Comparisons | Studies |
|---|---|
| **PLANTAR FASCIITIS** | |
| FESWT vs. Sham | 12 RCTs[8,18,19,23,37,44,49,58,62,66,70,73] |
| FESWT vs. Active Control | |
| FESWT vs. CSI | 2 RCTs[54,79] |
| FESWT vs. Conservative Care | 2 RCTs[4,25] |
| FESWT vs. EPFR | 1 RCT[56] |
| RESWT vs. Sham | 3 RCTs (4 publications) [16,30,31,45] |
| RESWT vs. Active Control | |
| RESWT vs. US | 2 RCTs[20,36] |
| **TENDINOPATHIES** | |
| **Lateral Epicondyle Tendinopathy** | |

| Comparisons | Studies |
|---|---|
| FESWT vs. Sham | 7 RCTs[5,6,24,46,53,59,69] |
| FESWT vs. Active Control | |
| FESWT vs. CSI | 2 RCTs[10,50] |
| FESWT vs. Percutaneous Tenotomy | 1 RCT[55] |
| RESWT vs. Sham | 2 RCTs[1,45] |
| **Shoulder Tendinopathies** | |
| **Rotator Cuff Tendinopathy** | |
| FESWT vs. Sham | 7 RCTs (8 publications)[7,12,15,17,28,52,67,71] |
| FESWT vs. Active Control | |
| FESWT vs. US-guided needling plus CSI | 1 RCT[33] |
| FESWT vs. TENS | 1 RCT[51] |
| RESWT vs. Sham | 1 RCT[35] |
| FESWT vs. Active Control | |
| FESWT vs. UGPL | 1 RCT[11] |
| **Adhesive Capsulitis** | |
| FESWT vs. Sham | 1 RCT[75] |
| FESWT vs. Active Control | |
| FESWT vs. Oral Steroid Therapy | 1 RCT[2] |
| RESWT vs. Sham | 1 RCT[29] |
| **Subacromial Shoulder Pain** | |
| RESWT vs. Sham | 1 RCT (2 publications)[13,14] |
| **Bicipital Tenosynovitis of the Shoulder** | |
| RESWT vs. Sham | 1 RCT[41] |
| RESWT vs. Sham | |
| **Achilles Tendinopathy** | |
| FESWT vs. Sham | 2 RCTs[9,57] |
| RESWT vs. Active Control | |
| RESWT vs. Eccentric Exercise | 2 RCTs[60,64] |
| RESWT + Eccentric Exercise vs. Eccentric Exercise Alone | 1 RCT[61] |
| RESWT vs. No Treatment | 1 RCT[64] |
| **Patellar Tendinopathy** | |
| FESWT vs. Sham | 1 RCT[72] |
| FESWT vs. Active Control | |
| FESWT vs. Conservative Management | 1 RCT[78] |

| Comparisons | Studies |
|---|---|
| **KNEE OSTEOARTHRITIS** | |
| FESWT vs. Active Control | |
| FESWT + Isokinetic Muscular Strengthening vs. Isokinetic Muscular Strengthening Alone | 1 RCT[3] |
| FESWT + Isokinetic Muscular Strengthening vs. US + Isokinetic Muscular Strengthening Alone | 1 RCT[3] |
| RESWT vs. Sham | 1 RCT[80] |

CSI: corticosteroid injection; EPFR: Endoscopic Partial Plantar Fascia Release; FESWT: Focused Extracorporeal Shock Wave Therapy; RCT: randomized control trial; RESWT: Radial Extracorporeal Shock Wave Therapy; TENS: transcutaneous electrical nerve stimulation; UGPL: ultrasound guided percutaneous lavage; US: ultrasound.

**KQ1 Summary of Results:**

***Plantar Fasciitis***

**Focused ESWT versus Sham:** We report on five pain outcomes: pain when first walking in the morning; pain during activities; pain composite measure made of 2 or more pain scales; pain not otherwise specified (NOS); and pain at rest. A significantly higher proportion of patients receiving FESWT versus sham reported a 50% reduction in pain when first walking in the morning compared with baseline at 3 month follow-up across 5 studies,[18,19,37,70,73] pooled RR 1.38 (95% CI, 1.15 to 1.66) (strength of evidence, HIGH). Intermediate and long-term results are less clear for pain when first walking in the morning: using mean differences from baseline, one study favors FESWT over sham at 6 month follow-up,[58] and two studies found no difference after 12 months of follow-up[23,58] (strength of evidence, LOW for both time periods). A higher proportion of patients achieved a successful pain composite outcome at 3 months across 4 studies,[18,19,44,48,49] pooled RR 1.55 (95% CI, 1.29 to 1.85) (strength of evidence HIGH). There were no differences between groups in the short-term with respect to pain with activities (3 studies),[8,37,48,49] pain at rest (2 studies),[8,23] and pain NOS (2 studies).[44,62] The strength of the evidence for these results ranged from MODERATE to LOW.

Function was less frequently reported. One study[37] found no difference between groups in the short-term (strength of evidence, LOW). There was LOW evidence from another small study at 6 and 12 month follow-ups reporting significantly greater improvement in function, both statistically and clinically, in favor of FESWT vs. sham.[58]

**Focused ESWT versus Active Control**

*Focused ESWT vs. CSI*: CSI resulted in better pain relief with first steps in the morning than FESWT in the short-term but not in the long-term (strength of evidence MODERATE).[54] There is INSUFFICIENT evidence for other pain outcomes[79] and no evidence for functional outcomes.

*Focused ESWT vs. Conservative Care*: There was INSUFFICIENT evidence to determine if FESWT or conservative care (iontophoresis and NSAIDS or stretching exercises) was superior with respect to improved pain or function from two small studies in the short- or intermediate-term pain.[4,25] There is no evidence comparing groups in the long-term.

*FESWT versus Endoscopic Partial Plantar Fascia Release (EPFR)***:** There was no difference between FESWT and EPFR with respect to improvement in pain when first walking in the morning or in function as measured by the AOFAS Ankle-Hindfoot scale (strength of evidence, LOW).[56]

**Radial ESWT versus Sham:** RESWT was better than sham in three studies[16,30,31,45] in all short-, intermediate- and long-term pain outcomes to include pain when first walking in the morning, pain with activities, pain NOS and composite pain measures (strength of evidence, MODERATE for short- and intermediate-term results and LOW for long-term results). There is no evidence for functional outcomes.

**Radial ESWT versus Active Control:**

*Radial ESWT vs. Ultrasound***:** There was INSUFFICIENT evidence in the short-, intermediate- or long-term to determine the effect of RESWT versus ultrasound therapy with respect to pain when first walking in the morning, achieving pain-free status, or pain with walking.[20] RESWT was better than ultrasound in one study[36] with respect to improvement in pain NOS in the short and intermediate-term (strength of evidence, LOW).

***Lateral Epicondyle Tendinopathy (LET)***

**Focused ESWT versus Sham:** We report on three pain outcomes: pain with resistance to wrist extension; pain not otherwise specified (NOS); pain at night. With respect to pain with resistance to wrist extension, patients receiving FESWT were twice as likely to achieve ≥50% improvement over baseline in the short-term compared with those receiving sham in two studies,[53,59] RR 2.2 (95% CI, 1.6 to 3.1) (strength of evidence, MODERATE). There is no evidence during intermediate-term and INSUFFICIENT evidence in the long-term assessing pain with resistance to wrist extension. There is INSUFFICIENT evidence from three small studies[5,6,46] to determine the effect of FESWT vs. sham on pain NOS in the short-term, and there is no intermediate- or long-term evidence for this outcome. There is no difference during the short-term in improvement in night pain between FESWT and sham in two studies (strength of evidence, LOW).[5,69] There is no intermediate- or long-term evidence for this outcome.

There was statistically significant improvement in function during the short-term as measured by the Upper Extremity Functional Scale (UEFS) in two studies,[53,59] MD 9.1, but no difference after 12 months[59] (strength of evidence, MODERATE). The UEFS lacks psychometric testing and no MCID has been established. There is no intermediate-term evidence for function.

**Focused ESWT versus Active Control:**

*FESWT versus CSI:* There is insufficient evidence from two RCTs[10,50] to determine the effect of FESWT compared with CSI on pain or function in the short-, intermediate-, or long-term.

*FESWT versus Percutaneous Tenotomy:* There is insufficient evidence from one small RCT[55] to determine the effect of FESWT compared with percutaneous tenotomy with respect to improvement in pain in the short- or long-term. There is no evidence on pain in the intermediate-term. There is no evidence on function for any time period.

**Radial ESWT versus Sham:** There is insufficient evidence from two small RCTs[1,45] to determine the effect of RESWT compared with sham with respect to improvement in pain or function in the short-term. There is no evidence for the intermediate- or long-term.

### *Shoulder Tendinopathy*

#### *Rotator Cuff Tendinopathy*

**Focused ESWT vs. Sham:** Four different pain outcomes were reported: pain not otherwise specified (NOS), pain at night, pain at rest, and pain with activity. Though the proportion of patients who achieved pain success, defined as ≥50% improvement on VAS, was not statistical different between groups in the short-term in one trial[71] (LOW strength of evidence), two trials[17,28] found that FESWT resulted in statistically and clinically greater improvement in pain NOS compared with sham over the short- (MD 3.14; 95% CI 0.70, 5.58), intermediate- (MD 3.76; 95% CI 1.73, 5.78), and long-term (MD 4.56; 95% CI 2.90, 6.22) (LOW strength of evidence for short- and intermediate-term; MODERATE for long-term). No statistical differences were seen between groups in pain at night over short- and intermediate-term follow-up as reported by one trial[71] or pain at rest and with activity over the short- and long-term as reported by another trial[67] (all LOW strength of evidence).

Function was evaluated using three different measures: the Constant score, the Shoulder Pain and Disability Index (SPADI), and the Disabilities of the Arm, Shoulder and Hand (DASH) score. Results were inconsistent across trials. Three studies reported no significant difference between groups in function success, defined as the proportion of patients achieving ≥30 point improvement in Constant score or 80% of the normal value (2 RCTs)[15,67] or ≥50% improvement in SPADI (1 RCT)[71] over the short-term (LOW strength of evidence for all). MODERATE quality evidence from another trial found a significantly greater proportion of FESWT compared with sham patents achieved ≥30% improvement in the Constant score at short-term (RR 2.70; 95% CI 1.47, 4.94), intermediate-term (RR 3.94; 95% CI 1.97, 7.86), and long-term (RR 3.07; 95% CI 1.57, 6.01) follow-up.[17] One trial[71] reported no statistical differences between groups in function improvement on the SPADI over short- and intermediate-term follow-up (LOW strength of evidence), whereas FESWT resulted in a statistically greater improvement in function according to the Constant score over the short-term in five trials[7,15,17,28,67] and the long-term in two trials[17,28] (LOW strength of evidence).

**Focused ESWT vs. Active Control:**
*FESWT vs. US-guided needling plus corticosteroid injection*: No statistically significant differences were seen in pain or function over the short- and intermediate-term in one trial[33]; however, at long-term follow-up, FESWT resulted in statistically and clinically less improvement in pain NOS (MD -2.4) and function according to the American Shoulder and Elbows Surgeons score (MD -24.1) and the Simple Shoulder Test (MD -8.3) compared with US-guided needling plus corticosteroid injection. The strength of evidence was LOW for all outcomes and time points.

*FESWT vs. TENS*: There was INSUFFICIENT evidence from one small RCT[51] to determine if FESWT or TENS is superior with regards to pain and function improvement over the short-term. There was no evidence over the intermediate- or long-term.

**Radial ESWT vs. Sham:** There was INSUFFICIENT evidence from one small RCT[35] to determine if RESWT or sham is superior with regards to pain and function improvement over the short- and intermediate-term. There was no evidence over the long-term.

**Radial ESWT vs. Active Control:**
*RESWT vs. US-guided Percutaneous Lavage (UGPL)*: There was INSUFFICIENT evidence from one small RCT[11] to determine if RESWT or UGPL is superior with regards to pain improvement over the short-, intermediate- or long-term. There was no evidence for function.

***Adhesive Capsulitis of the Shoulder***

**Focused ESWT vs. Sham:** There was INSUFFICIENT evidence from one small RCT[75] to determine if FESWT or sham is superior with regards to pain and function over the short- and intermediate-term. There was no evidence over the long-term.

**Focused ESWT vs. Active Control:**
*FESWT vs. Oral Steroids*: There was INSUFFICIENT evidence from one small RCT[2] to determine if FESWT or oral steroid therapy is superior with regards to function over the short-term. There was no evidence for pain or for results over the intermediate- or long-term.

**Radial ESWT vs. Sham:** RESWT resulted in a statistically and clinically greater improvement in pain at rest and with activity (MODERATE strength of evidence) and function (HIGH strength of evidence) over both the short- and intermediate-term, as reported by one small RCT.[29] Specifically, the mean difference between groups in the DASH scores was over five times higher than the clinically important threshold at both time points: MD 55.6 (95% CI 50.5, 60.8) and MD 55.3 (95% CI 49.8, 60.7, -49.8), respectively. There was no evidence over the long-term.

***Subacromial Shoulder Pain***

**FESWT:** No studies were identified.

**RESWT vs. Active Control:**
*RESWT vs. Supervised exercise*: One small RCT reported no differences between the groups in pain improvement at any time point.[13,14] Regarding function, statistically, but not clinically, less improvement was noted over the short- and intermediate-term in patients who received RESWT compared with supervised exercise; no differences were seen between groups in function over the long-term. The strength of evidence was MODERATE for all short- and intermediate-term outcomes and LOW for all long-term outcomes.

***Bicipital Tenosynovitis of the Shoulder***

**FEWST:** No studies were identified.

**RESWT vs. Sham:** One small RCT[41] reported significantly better pain and function outcomes following RESWT compared with sham over the short- (LOW strength of evidence) and long-term (MODERATE strength of evidence). There was no evidence over the medium-term.

***Achilles Tendinopathy***

**Focused ESWT vs. Sham:** FESWT resulted in statistically and clinically greater pain improvement (NRS 0-10, worst) while running/playing sports (pooled MD 1.90; 95% CI 1.06, 2.73) and walking (pooled MD 1.65; 95% CI 0.79, 2.51) across two small RCTs,[9,57] and while at rest in one trial (MD 1.92; 95% CI 0.76, 3.08)[9]; there were no statistical differences between groups in pain while working and walking up/down stairs as reported by one RCT. Regarding function, one small RCT reported statistically and clinically greater improvement in function (AOFAS)[57] following FESWT versus sham while the other trial[9] found no statistical difference between groups in improvement on the FIL. The strength of evidence is LOW for all outcomes. There was no evidence over the intermediate- or long-term.

**Radial ESWT vs. Active Control:**
*RESWT vs. eccentric exercise*: No statistical differences between groups were seen in improvement in pain during the day and function over the short-term as reported by two small trials.[60,64] The strength of evidence is LOW for all outcomes. There was no evidence over the intermediate- or long-term.

*RESWT plus eccentric exercise vs. eccentric exercise alone*: As reported by one small trial,[61] statistically greater improvement was seen in the RESWT group for both pain during the day on NRS (MD 1.3; 95% CI 0.6, 2.0) and function according to the VISA-A (MD 13.9; 95% CI 8.6, 19.2) over the short-term. The strength of evidence is LOW for all outcomes. There was no evidence over the intermediate- or long-term.

**Radial ESWT vs. No Treatment:** There was no statistical differences between groups for pain over the short-term. Improvement in function on the VISA-A was statistically greater following RESWT compared to a wait-and-see strategy (MD 13.3; 95% CI 8.4, 18.2).[64] The strength of evidence is LOW for all outcomes. There was no evidence over the intermediate- or long-term.

***Patellar Tendinopathy***

**Focused ESWT vs. Sham:** There was INSUFFICIENT evidence from one small RCT[72] to determine if FESWT or sham is superior with regards to pain and function over the short-term. There was no evidence over the intermediate- or long-term.

**Focused ESWT vs. Active Control:**
*FESWT vs. conservative management*: One small RCT[78] reported statistically and clinically greater improvements in long-term pain and function following FESWT compared with conservative management; at 24-36 months, the mean difference between groups was over three times the clinically important threshold for both VAS pain going up and down stairs (MD 4.8; 95% CI 4.2, 5.3) and VISA-P scores (MD 47.6; 95% CI 44.0, 51.2). The strength of evidence was LOW for both outcomes. There was no evidence over the short- or medium-term.

***Knee Osteoarthritis***

**FESWT vs. Active Control:**
*FESWT plus isokinetic muscular strengthening vs. isokinetic muscular strengthening alone*: FESWT plus isokinetic muscular strengthening resulted in statistically and clinically greater improvement in pain compared with isokinetic muscular strengthening alone over short- and medium-term follow-up as

reported by one small RCT[3] (LOW strength of evidence). For function, the strength of evidence was INSUFFICIENT. There was no evidence over the long-term.

*FESWT plus isokinetic muscular strengthening vs. Ultrasound plus isokinetic muscular strengthening*: As reported by one small trial,[3] FESWT plus isokinetic muscular strengthening resulted in statistically, but not clinically, greater improvement in pain compared with ultrasound plus isokinetic muscular strengthening over short- and medium-term follow-up (LOW strength of evidence). For function, the strength of evidence was INSUFFICIENT. There was no evidence over the long-term.

**RESWT vs. Sham:** One small RCT[80] reported significantly better short-term pain (VAS) and function (WOMAC, Lequesne index) improvement following RESWT compared with sham (all LOW strength of evidence); the mean differences between groups were clinically important for pain and for function according to the WOMAC. There was no evidence over the medium- or long-term.

**KQ2: Summary of Results**

All included comparative studies were evaluated for harms and complications. In addition, case series and case reports specifically designed to evaluate harms were considered for inclusion; one case report[40] was identified that met the inclusion criteria.

We considered the following outcomes as potentially serious based on clinical expert input: tendon rupture, aseptic necrosis, humeral head necrosis, neurovascular complications, neurological disorders, infections, adverse reaction/allergy to anesthetic agents, systemic complications, and death.

**Summary of results:** Serious or potentially serious adverse events were reported in 52 of the 61 included studies.[1-9,11-20,23,24,28-31,35-37,41,44,45,49-56,58-61,64,66,67,69-71,73,75,78-80] They were rare: 10 of 2,553 patients were reported in the ESWT across studies, risk 0.39% (95% CI, 0.19 to 0.72%). Three were deaths, two were tendon ruptures and five were allergic reactions associated with local anesthetics. Of the deaths, two were noted to be from causes unrelated to the treatment, while no details were given concerning the third death. The tendon ruptures occurred in two patients two weeks following FESWT for Achilles tendinopathy. Allergy or reaction to local anesthetic was reported in five patients receiving FESWT. In the control groups, 5 of 2,209 patients were reported as having serious or potentially serious adverse events, risk 0.23% (95% CI, 0.07 to 0.53%). All five events were allergy or reaction to local anesthetic. The strength of evidence for serious or potentially serious adverse events, LOW.

Non-serious adverse events were common following ESWT but were reported inconsistently. The most common included pain/discomfort during treatment; transient reddening of the skin; mild/transient neurological symptoms (i.e., myalgia, dysesthesia, hypesthesia, paresthesia); and petechaie, bleeding or hematoma.

More detailed summaries can be found in the Appendix I of the full report.

**KQ3: Summary of Results**

For this key question, RCTs that stratified on patient characteristics of interest, permitting evaluation of effect modification were considered for inclusion. Subgroups of interest included (but were not limited to): age, sex, race, ethnicity, socioeconomic status, payer, and worker's compensation. All RCTs included

to evaluate the efficacy or safety of ESWT versus comparators of interest were assessed. More detailed summaries can be found in the tables below.

**Focused ESWT versus Sham:** There is no differential effect in one study of sex, age or body weight on FESWT in patients with plantar fasciitis (strength of evidence, LOW).[44] In treating rotator cuff tendinopathy, high intensity versus sham compared with low intensity versus sham produces better results in two studies with respect to pain improvement in the short- and intermediate-term, and reoccurrence of pain in the intermediate-term (strength of evidence, LOW).[17,52] There is INSUFFICIENT evidence that duration of symptoms modifies treatment effect in patients with lateral epicondyle tendinopathy.[5] There is INSUFFICIENT evidence that sex modifies treatment effect in patients with Achilles tendinopathy.[57]

**Focused ESWT versus Active Control:** There is no evidence.

**Radial ESWT versus Sham:** There is insufficient evidence that the presence of calcium formation in the rotator cuff modifies the treatment effect in patients with rotator cuff tendinopathy.[35]

**Radial ESWT versus Active Control:** There is no evidence.
More detailed summaries can be found in the text and tables below.

**KQ4: Summary of Results**
No formal economic analyses were identified that met the inclusion criteria.

## Strength of Evidence Summaries

The following summaries of evidence have been based on the highest quality of studies available. Additional information on lower quality studies is available in the report. A summary of the primary outcomes for each key question are provided in the tables below and are sorted by comparator. Details of other outcomes are available in the report.

**Key Question 1 Strength of Evidence Summary: Plantar Fasciitis Efficacy Results**

| Outcome | Follow-up | RCTs | N | Conclusion | Quality |
|---|---|---|---|---|---|
| **Plantar Fasciitis: Focused ESWT vs. Sham** | | | | | |
| **Pain in AM, success (%)** (≥50% or 60% ↓ pain with first morning steps) | Short-term | 5 RCTs (Speed, Kudo, Gollwitzer 07, Gollwitzer 15, Theodore) | 625 | RR 1.38 (95% CI, 1.15 to 1.66) Conclusion: Significantly greater improvement with FESWT vs. sham. | ⊕⊕⊕⊕ HIGH |
| | Intermediate-and long-term | 0 RCTs | | No evidence. | ⊕◯◯◯ INSUFFICIENT |
| **Pain in AM, MD** (VAS 0-10, worst) | Short-term | 5 RCTs (Kudo, Ogden, Cosentino, Theodore, Haake) | 860 | MD 1.41 (95% CI, -.023 to 3.04) Conclusion: No difference between FESWT vs. sham. | ⊕⊕⊕◯ MODERATE |

| Outcome | Follow-up | RCTs | N | Conclusion | Quality |
|---|---|---|---|---|---|
| | Intermediate-term | 1 RCTs | 45 | MD 2.5 (95% CI, -.023 to 3.04)<br>Conclusion: No difference between FESWT vs. sham. | ⊕⊕◯◯<br>LOW |
| | Long-term | 2 RCTs<br>(Rompe, Haake) | 317 | MD 1.54 (95% CI, -0.91 to 3.99)<br>Conclusion: No difference between FESWT vs. sham. | ⊕⊕◯◯<br>LOW |
| **Pain w/ activities, success (%)**<br>(≥60% pain improvement over baseline) | Short-term | 2 RCTs<br>(Gollwitzer 07, Gollwitzer 15) | 287 | RR 1.27 (0.98, 1.66)<br>Conclusion: No difference between FESWT vs. sham. | ⊕⊕⊕◯<br>MODERATE |
| | Intermediate-and long-term | 0 RCTs | | No evidence. | ⊕◯◯◯<br>INSUFFICIENT |
| **Pain w/ activities, MD**<br>(VAS 0-10, worst) | Short-term | 3 RCTs<br>(Kudo, Ogden, Cosentino) | 450 | MD 1.80 (95% CI, -1.29 to 4.89)<br>Conclusion: No difference between FESWT vs. sham. | ⊕⊕◯◯<br>LOW |
| | Intermediate-and long-term | 0 RCTs | | No evidence. | ⊕◯◯◯<br>INSUFFICIENT |
| **Pain composite, success (%)**<br>(≥50-60% ↓ pain and ≤4 VAS and or ≥50% ↓ pain with pressure) | Short-term | 4 RCTs<br>(Ogden, Gollwitzer 07, Gollwitzer 15, Malay) | 739 | RR 1.55 (95% CI, 1.29 to 1.85)<br>Conclusion: Significantly greater improvement with FESWT vs. sham. | ⊕⊕⊕⊕<br>HIGH |
| | Intermediate-and long-term | 0 RCTs | | No evidence. | ⊕◯◯◯<br>INSUFFICIENT |
| **Pain NOS, MD**<br>(VAS 0-10, worst) | Short-term | 2 RCTs<br>(Kudo, Ogden, Cosentino) | 254 | MD 0.28 (95% CI, -0.54 to 1.09)<br>Conclusion: No difference between FESWT vs. sham. | ⊕⊕◯◯<br>LOW |
| | Intermediate-and long-term | 0 RCTs | | No evidence. | ⊕◯◯◯<br>INSUFFICIENT |
| **Pain at rest, MD**<br>(VAS 0-10, worst) | Short-term | 2 RCTs<br>(Haake,, Cosentino) | 316 | MD 2.5 (95% CI, -2.01 to 7.01)<br>Conclusion: No difference between FESWT vs. sham. | ⊕⊕◯◯<br>LOW |
| | Intermediate-and long-term | 0 RCTs | | No evidence. | ⊕◯◯◯<br>INSUFFICIENT |
| **Function AOFAS Ankle- Hindfoot, success (%)**<br>(none or mild on the pain domain) | Short-term | 1 RCT<br>(Kudo) | 105 | RR 1.47 (95% CI, 0.93 to 2.33)<br>Conclusion: No difference between FESWT vs. sham. | ⊕⊕⊕◯<br>MODERATE |
| | Intermediate-and long-term | 0 RCTs | | No evidence. | ⊕◯◯◯<br>INSUFFICIENT |
| **Function AOFAS Ankle- Hindfoot, MD**<br>(0-100, best) | Short-term | 1 RCTs<br>(Kudo) | 105 | MD -4.5 (95% CI, -17.4 to 8.4)<br>Conclusion: No difference between FESWT vs. sham. | ⊕⊕⊕◯<br>MODERATE |
| | Intermediate-term | 1 RCT<br>(Rompe) | 45 | MD 17.8 (95% CI, 11.3 to 24.3)<br>Conclusion: Statistically and clinically greater improvement with FESWT vs. sham. | ⊕⊕◯◯<br>LOW |

| Outcome | Follow-up | RCTs | N | Conclusion | Quality |
|---|---|---|---|---|---|
| | Long-term | 1 RCT (Rompe) | 45 | MD 12.0 (95% CI, 6.3 to 17.7) Conclusion: Statistically and clinically greater improvement with FESWT vs. sham. | ⊕⊕◯◯ LOW |
| **Plantar Fasciitis: Focused ESWT vs. CSI** | | | | | |
| **Pain in AM, MD** (VAS 0-10, worst) | Short-term | 1 RCT (Porter) | 125 | MD -2.16 (95% CI, -3.14 to -1.18) Conclusion: Significantly greater improvement with CSI vs. FESWT. | ⊕⊕⊕◯ MODERATE |
| | Intermediate-and long-term | 0 RCTs | | No evidence. | ⊕◯◯◯ INSUFFICIENT |
| | Long-term | 1 RCT (Porter) | 125 | MD 0.05 (95% CI, -0.99 to 1.09) Conclusion: Conclusion: No difference between CSI vs. FESWT. | ⊕⊕⊕◯ MODERATE |
| **Pain composite, success (%)** Loss of heel tenderness, ↓ pain 50% from baseline | Short-term | 1 RCT (Yucel) | 60 | RR 0.96 (95% CI, 0.77 to 1.20) Conclusion: Insufficient strength of evidence precludes firm conclusions. | ⊕◯◯◯ INSUFFICIENT |
| | Intermediate-and long-term | 0 RCTs | | No evidence. | ⊕◯◯◯ INSUFFICIENT |
| **Pain NOS, MD** (VAS 0-10, worst) | Short-term | 1 RCT (Yucel) | 60 | MD -1.2 (-2.03 to -.037) Conclusion: Insufficient strength of evidence precludes firm conclusions. | ⊕◯◯◯ INSUFFICIENT |
| | Intermediate-and long-term | 0 RCTs | | No evidence. | ⊕◯◯◯ INSUFFICIENT |
| **Function, any** | Short-, intermediate-and long-term | 0 RCTs | | No evidence. | ⊕◯◯◯ INSUFFICIENT |
| **Plantar Fasciitis: Focused ESWT vs. Conservative Care** | | | | | |
| **Pain in AM, success (%)** (VAS ≤3) | Short-term | 1 RCT (Hammer) | 49 | RR 0.90 (95% CI, 0.59 to 1.38) Conclusion: Insufficient strength of evidence precludes firm conclusions. | ⊕◯◯◯ INSUFFICIENT |
| | Intermediate-term | 1 RCT (Hammer) | 49 | RR 0.86 (95% CI, 0.64 to 1.17) Conclusion: Insufficient strength of evidence precludes firm conclusions. | ⊕◯◯◯ INSUFFICIENT |
| | Long-term | 0 RCTs | | No evidence. | ⊕◯◯◯ INSUFFICIENT |
| **Pain NOS, MD** (VAS 0-10, worst) | Short-term | 2 RCTs (Hammer, Chew) | 84 | Not calculable Conclusion: Insufficient strength of evidence precludes firm conclusions. | ⊕◯◯◯ INSUFFICIENT |
| | Intermediate-term | 2 RCTs (Hammer, Chew) | 84 | Not calculable | ⊕◯◯◯ INSUFFICIENT |

| Outcome | Follow-up | RCTs | N | Conclusion | Quality |
|---|---|---|---|---|---|
| | | | | Conclusion: Insufficient strength of evidence precludes firm conclusions. | |
| | Long-term | 0 RCTs | | No evidence. | ⊕◯◯◯ INSUFFICIENT |
| **Pain at rest, MD** (VAS 0-10, worst) | Short-term | 1 RCT (Hammer) | 49 | MD -1.2 (95% CI, -2.03 to 0.37) Conclusion: Insufficient strength of evidence precludes firm conclusions. | ⊕◯◯◯ INSUFFICIENT |
| | Intermediate- and long-term | 0 RCTs | | No evidence. | ⊕◯◯◯ INSUFFICIENT |
| **Function AOFAS Ankle- Hindfoot, MD** (0-100, best) | Short-term | 1 RCT (Chew) | 35 | Not calculable Conclusion: Insufficient strength of evidence precludes firm conclusions. | ⊕◯◯◯ INSUFFICIENT |
| | Intermediate-term | 1 RCT (Chew) | 35 | Not calculable Conclusion: Insufficient strength of evidence precludes firm conclusions. | ⊕◯◯◯ INSUFFICIENT |
| | Long-term | 0 RCTs | | No evidence. | ⊕◯◯◯ INSUFFICIENT |
| **Plantar Fasciitis: Focused ESWT vs. Endoscopic Partial Plantar Fascia Release (EPFR)** | | | | | |
| **Pain in AM, MD** (VAS 0-10, worst) | Short-term | 1 RCT (Radwan) | 65 | Not calculable Conclusion: No difference between FESWT vs. EPFR. | ⊕⊕◯◯ LOW |
| | Intermediate-term | 0 RCTs | | No evidence. | ⊕◯◯◯ INSUFFICIENT |
| | Long-term | 1 RCT (Radwan) | 65 | Not calculable Conclusion: No difference between FESWT vs. EPFR. | ⊕⊕◯◯ LOW |
| **Function AOFAS Ankle- Hindfoot, MD** (0-100, best) | Short-term | 1 RCT (Radwan) | 65 | Not calculable Conclusion: No difference between FESWT vs. EPFR. | ⊕⊕◯◯ LOW |
| | Intermediate-term | 0 RCTs | | No evidence. | ⊕◯◯◯ INSUFFICIENT |
| | Long-term | 1 RCT (Radwan) | 65 | Not calculable Conclusion: No difference between FESWT vs. EPFR. | ⊕⊕◯◯ LOW |
| **Plantar Fasciitis: Radial ESWT vs. Sham** | | | | | |
| **Pain in AM, success (%)** (≥60% ↓ pain with first with first morning steps) | Short-term | 1 RCT (Gerdesmeyer) | 243 | RR 1.26 (95% CI, 1.00 to 1.59) Conclusion: Significantly greater improvement with RESWT vs. sham. | ⊕⊕⊕◯ MODERATE |
| | Intermediate-and long-term | 0 RCTs | | No evidence. | ⊕◯◯◯ INSUFFICIENT |

| Outcome | Follow-up | RCTs | N | Conclusion | Quality |
|---|---|---|---|---|---|
| **Pain w/ activity, success (%)** (≥60% ↓ pain with activity over baseline) | Short-term | 1 RCT (Gerdesmeyer) | 243 | RR 1.48 (95% CI, 1.14 to 1.91) Conclusion: Significantly greater improvement with RESWT vs. sham. | ⊕⊕⊕◯ MODERATE |
| | Intermediate-and long-term | 0 RCTs | | No evidence. | ⊕◯◯◯ INSUFFICIENT |
| **Pain composite, success (%)** (≥60% ↓ pain over baseline in ≥2 of following: pain with first morning steps, with activities, with pressure) | Short-term | 1 RCT (Gerdesmeyer) | 243 | RR 1.44 (95% CI, 1.12 to 1.86) Conclusion: Significantly greater improvement with RESWT vs. sham. | ⊕⊕⊕◯ MODERATE |
| | Intermediate-and long-term | 0 RCTs | | No evidence. | ⊕◯◯◯ INSUFFICIENT |
| **Pain NOS, success (%)** (>50% ↓ pain or ↑ ≥3 points over baseline) | Short-term | 1 RCT (Ibrahim) | 50 | RR Not calculable Conclusion: Significantly greater improvement with RESWT vs. sham. | ⊕⊕◯◯ LOW |
| | Intermediate-term | 2 RCT (Ibrahim, Mehra) | 73 | RR 6.32 (95% CI, 2.83 to 14.1) Conclusion: Significantly greater improvement with RESWT vs. sham. | ⊕⊕⊕◯ MODERATE |
| | Long-term | 1 RCT (Ibrahim) | 50 | RR 3.60 (95% CI, 1.58 to 8.18) Conclusion: Significantly greater improvement with RESWT vs. sham. | ⊕⊕◯◯ LOW |
| **Pain NOS, MD** (VAS 0-10, worst) | Short-term | 1 RCT (Ibrahim) | 50 | MD 6.2 (95% CI, 5.75, 6.65) Conclusion: Significantly greater improvement with RESWT vs. sham. | ⊕⊕⊕◯ MODERATE |
| | Intermediate-term | 2 RCT (Ibrahim, Mehra) | 73 | RR 6.32 (95% CI, 2.83 to 14.1) Conclusion: Significantly greater improvement with RESWT vs. sham. | ⊕⊕⊕◯ MODERATE |
| | Long-term | 1 RCT (Ibrahim) | 50 | RR 3.80 (95% CI, 3.23 to 4.37) Conclusion: Significantly greater improvement with RESWT vs. sham. | ⊕⊕◯◯ LOW |
| **Plantar Fasciitis: Radial ESWT vs. Ultrasound** | | | | | |
| **Pain NOS, success (%)** (VAS ≤1) | Short-term | 1 RCT (Grecco) | 40 | RR 0.9 (95% CI, 0.47 to 1.73) Conclusion: Insufficient strength of evidence precludes firm conclusions. | ⊕◯◯◯ INSUFFICIENT |
| | Intermediate-and long-term | 0 RCTs | | No evidence. | ⊕◯◯◯ INSUFFICIENT |
| | Long-term | 1 RCT (Grecco) | 40 | RR 1.56 (95% CI, 0.89 to 2.73) Conclusion: Insufficient strength of evidence precludes firm conclusions. | ⊕◯◯◯ INSUFFICIENT |
| **Pain in AM, success (%)** (VAS ≤1 with first morning steps) | Short-term | 1 RCT (Grecco) | 40 | RR 1.08 (95% CI, 0.70 to 1.66) Conclusion: Insufficient strength of evidence precludes firm conclusions. | ⊕◯◯◯ INSUFFICIENT |

| Outcome | Follow-up | RCTs | N | Conclusion | Quality |
|---|---|---|---|---|---|
| | Intermediate-and long-term | 0 RCTs | | No evidence. | ⊕◯◯◯ INSUFFICIENT |
| | Long-term | 1 RCT (Grecco) | 40 | RR 1.06 (95% CI, 0.80 to 1.41) Conclusion: Insufficient strength of evidence precludes firm conclusions. | ⊕◯◯◯ INSUFFICIENT |
| **Pain NOS, MD** (VAS 0-10, worst) | Short-term | 1 RCT (Konjen) | 30 | MD 2.4 (95% CI, 2.35 to 2.45) Conclusion: Significantly greater improvement with RESWT vs. sham. | ⊕⊕◯◯ LOW |
| | Intermediate-and long-term | 0 RCTs | | | |
| | Long-term | 1 RCT (Konjen) | 30 | MD 3.1 (95% CI, 3.02 to 3.18) Conclusion: Significantly greater improvement with RESWT vs. sham. | ⊕⊕◯◯ LOW |

AOFAS: American Orthopedic Foot and Ankle Society; CI: confidence interval; CSI: corticosteroid injection; MD: mean difference; NOS: not otherwise specified; PRTEE: Patient RatedTennis Elbow Evaluation; RR: risk ratio; UEFS: upper extremity functional scale; VAS: visual analog scale.

**Key Question 1 Strength of Evidence Summary: Lateral Epicondyle Tendinopathy Efficacy Results**

| Outcome | Follow-up | RCTs | N | Conclusion | Quality |
|---|---|---|---|---|---|
| **Lateral Epicondyle Tendinopathy: FESWT vs. Sham** | | | | | |
| **Pain w/ resistance, success (%)** (≥50% pain improvement from baseline) | Short-term | 2 RCTs (Rompe, Pettrone) | 192 | RR 2.19 (95% CI, 1.55 to 3.11) Conclusion: Significantly greater improvement with FESWT vs. sham. | ⊕⊕⊕◯ MODERATE |
| | Intermediate-and long-term | 0 RCTs | | No evidence. | ⊕◯◯◯ INSUFFICIENT |
| **Pain w/ resistance, MD** (VAS 0-10, worst) | Short-term | 3 RCTs (Rompe, Pettrone, Melikyan) | 258 | MD 0.30 (95% CI, -1.76 to 2.35) Conclusion: No difference between FESWT vs. sham. | ⊕⊕⊕◯ MODERATE |
| | Intermediate-term | 0 RCTs | | No evidence. | ⊕◯◯◯ INSUFFICIENT |
| | Long-term | 2 RCTs (Rompe, Melikyan) | 144 | MD -0.05 (95% CI, -2.60 to 2.40) Conclusion: Insufficient strength of evidence precludes firm conclusions. | ⊕◯◯◯ INSUFFICIENT |
| **Pain NOS, MD** (VAS 0-10, worst) | Short-term | 3 RCTs (Chung, Melikyan, Collins) | 299 | MD 0.24 (95% CI, -0.52 to 1.01) Conclusion: Insufficient strength of evidence precludes firm conclusions. | ⊕◯◯◯ INSUFFICIENT |
| | Intermediate-and long-term | 0 RCTs | | No evidence. | ⊕◯◯◯ INSUFFICIENT |
| **Pain at night, MD** (VAS 0-10, worst) | Short-term | 2 RCTs (Chung 04, Speed 02) | 135 | MD 0.11 (95 CI, -1.55 to 1.77) Conclusion: No difference between FESWT vs. sham. | ⊕⊕◯◯ LOW |

| Outcome | Follow-up | RCTs | N | Conclusion | Quality |
|---|---|---|---|---|---|
| | Intermediate-and long-term | 0 RCTs | | No evidence. | ⊕◯◯◯ INSUFFICIENT |
| **Function UEFS, MD** (8-80, worst) | Short-term | 2 RCTs (Rompe, Pettrone) | 177 | MD 9.13 (95% CI, 4.83 to 13.44) Conclusion: Significantly greater improvement with FESWT vs. sham. No MCID for this outcome. | ⊕⊕⊕◯ MODERATE |
| | Intermediate-term | 0 RCTs | | No evidence. | ⊕◯◯◯ INSUFFICIENT |
| | Long-term | 1 RCT (Rompe) | 78 | MD 6.6 (95% CI, -1.68 to 14.88) Conclusion: No difference between FESWT vs. sham. | ⊕⊕◯◯ LOW |
| **Grip Strength (kg)** | Short-term | 4 RCTs (Rompe, Pettrone, Melikyan, Chung) | 308 | MD 0.73 (95% CI, -1.63 to 3.10) Conclusion: No difference between FESWT vs. sham. | ⊕⊕◯◯ LOW |
| | Intermediate-term | 0 RCTs | | No evidence. | ⊕◯◯◯ INSUFFICIENT |
| | Long-term | 2 RCTs (Rompe, Melikyan) | 141 | MD -0.02 (95% CI, -3.29 to 3.24) Conclusion: No difference between FESWT vs. sham. | ⊕⊕⊕◯ MODERATE |
| **Lateral Epicondyle Tendinopathy: FESWT vs. CSI** | | | | | |
| **Pain NOS, success (%)** (≥50% improvement from baseline) | Short-term | 1 RCT (Crowther) | 73 | MD 0.72 (95% CI, 0.54 to 0.96) Conclusion: Insufficient strength of evidence precludes firm conclusions. | ⊕◯◯◯ INSUFFICIENT |
| | Intermediate-and long-term | 0 RCTs | | No evidence. | ⊕◯◯◯ INSUFFICIENT |
| **Pain w/ resistance** (VAS 0-10, worst) | Short-term | 1 RCT (Ozturan) | 73 | % change not calculable Conclusion: Insufficient strength of evidence precludes firm conclusions. | ⊕◯◯◯ INSUFFICIENT |
| | Intermediate-term | 1 RCT (Ozturan) | 73 | % change not calculable Conclusion: Insufficient strength of evidence precludes firm conclusions. | ⊕◯◯◯ INSUFFICIENT |
| | Long-term | 1 RCT (Ozturan) | 73 | % change not calculable Conclusion: Insufficient strength of evidence precludes firm conclusions. | ⊕◯◯◯ INSUFFICIENT |
| **Function UEFS, MD** (8-80, worst) | Short-term | 1 RCT (Ozturan) | 73 | % change not calculable Conclusion: Insufficient strength of evidence precludes firm conclusions. | ⊕◯◯◯ INSUFFICIENT |
| | Intermediate-term | 1 RCT (Ozturan) | 73 | % change not calculable | ⊕◯◯◯ INSUFFICIENT |

| Outcome | Follow-up | RCTs | N | Conclusion | Quality |
|---|---|---|---|---|---|
| | | | | Conclusion: Insufficient strength of evidence precludes firm conclusions. | |
| | Long-term | 1 RCT (Ozturan) | 73 | % change not calculable<br>Conclusion: Insufficient strength of evidence precludes firm conclusions. | ⊕◯◯◯ INSUFFICIENT |
| **Lateral Epicondyle Tendinopathy: FESWT vs. Percutaneous Tenotomy** | | | | | |
| **Pain w/ resistance, success (%)** (≥50% short- and (≥80% long-term improvement from baseline) | Short-term | 1 RCT (Radwan) | 56 | RR 0.85 (95% CI, 0.65 to 1.12)<br>Conclusion: Insufficient strength of evidence precludes firm conclusions. | ⊕◯◯◯ INSUFFICIENT |
| | Intermediate-term | 0 RCTs | | No evidence. | ⊕◯◯◯ INSUFFICIENT |
| | Long-term | 1 RCT (Radwan) | 56 | RR 0.77 (95% CI, 0.48 to 1.23)<br>Conclusion: Insufficient strength of evidence precludes firm conclusions. | ⊕◯◯◯ INSUFFICIENT |
| **Lateral Epicondyle Tendinopathy: RESWT vs. Sham** | | | | | |
| **Pain at rest, MD** (VAS 0-10, worst) | Short-term | 1 RCT (Capan 16) | 45 | MD 0.1 (95% CI -1.41 to 1.61)<br>Conclusion: Insufficient strength of evidence precludes firm conclusions. | ⊕◯◯◯ INSUFFICIENT |
| | Intermediate-and long-term | 0 RCTs | | No evidence. | ⊕◯◯◯ INSUFFICIENT |
| **Pain w/ activity, MD** (VAS 0-10, worst) | Short-term | 1 RCT (Capan) | 45 | MD 1.2 (95% CI -0.33 to 2.73)<br>Conclusion: Insufficient strength of evidence precludes firm conclusions. | ⊕◯◯◯ INSUFFICIENT |
| | Intermediate-and long-term | 0 RCTs | | No evidence. | ⊕◯◯◯ INSUFFICIENT |
| **Function, PRTEE, MD** (0-100, worst) | Short-term | 1 RCT (Capan) | 45 | MD 4.8 (95% CI -2.75to 12.35)<br>Conclusion: Insufficient strength of evidence precludes firm conclusions. | ⊕◯◯◯ INSUFFICIENT |
| | Intermediate-and long-term | 0 RCTs | | No evidence. | ⊕◯◯◯ INSUFFICIENT |
| **Pain NOS, success (%)** (VAS 0-10, worst) | Short-term | 1 RCT (Mehra) | 24 | RR 8.46 (95% CI, 1.28 to 56.1)<br>Conclusion: Insufficient strength of evidence precludes firm conclusions. | ⊕◯◯◯ INSUFFICIENT |
| | Intermediate-and long-term | 0 RCTs | | No evidence. | ⊕◯◯◯ INSUFFICIENT |

CI: confidence interval; MD: mean difference; NOS: not otherwise specified; PRTEE: Patient Rated Tennis Elbow Evaluation; RR: risk ratio; UEFS: upper extremity functional scale; VAS: visual analog scale.
Reasons for downgrading (-) or upgrading (+):

**Key Question 1 Strength of Evidence Summary: Rotator Cuff Tendinopathy Efficacy Results**

| Outcome | Follow-up | RCTs | N | Conclusion | Quality |
|---|---|---|---|---|---|
| **Rotator Cuff Tendinopathy: Focused ESWT vs. Sham** | | | | | |
| **Pain success** (≥50% ↑ on VAS 0-10) | Short-term | 1 RCT (Speed) | 74 | RR 1.1 (95% CI 0.62, 1.9)<br>Conclusion: No statistical difference between groups. | ⊕⊕◯◯ LOW |
| | Intermediate-term and Long-term | 0 RCTs | | No evidence. | ⊕◯◯◯ INSUFFICIENT |
| **Pain NOS** (VAS 0-10, worst) | Short-term | 2 RCTs (Gerdesmeyer, Hsu) | 178 | MD 3.14 (95% CI 0.70, 5.58)<br>Conclusion: Statistically and clinically greater improvement with FESWT vs. sham. | ⊕⊕◯◯ LOW |
| | Intermediate-term | 2 RCTs (Gerdesmeyer, Hsu) | 180 | MD 3.76 (95% CI 1.73, 5.78)<br>Conclusion: Statistically and clinically greater improvement with FESWT vs. sham. | ⊕⊕◯◯ LOW |
| | Long-term | 2 RCTs (Gerdesmeyer, Hsu) | 146 | MD 4.56 (95% CI 2.90, 6.22)<br>Conclusion: Statistically and clinically greater improvement with FESWT vs. sham. | ⊕⊕⊕◯ MODERATE |
| **Pain at night** (VAS 0-10, worst) | Short-term | 1 RCT (Speed) | 74 | MD -0.56 (95% CI -1.38, 0.26)<br>Conclusion: No statistical difference between groups. | ⊕⊕◯◯ LOW |
| | Intermediate-term | 1 RCT (Speed) | 74 | MD -0.08 (95% CI -0.9, 0.74)<br>Conclusion: No statistical difference between groups. | ⊕⊕◯◯ LOW |
| | Long-term | 0 RCTs | | No evidence. | ⊕◯◯◯ INSUFFICIENT |
| **Pain at rest and with activity** (VAS 0-10, worst) | Short-term | 1 RCT (Schmitt) | 38 | Rest: MD 0.87 (95% CI -0.3, 2.04)<br>Activity: MD 1.06 (95% CI -0.25, 2.37)<br>Conclusion: No statistical difference between groups. | ⊕⊕◯◯ LOW |
| | Intermediate-term | 0 RCTs | | No evidence. | ⊕◯◯◯ INSUFFICIENT |
| | Long-term | 1 RCT (Efe) | 29 | Rest: MD 0.05 (95% CI -1.19, 1.29)<br>Activity: MD -0.8 (95% CI -2.36, 0.76)<br>Conclusion: No statistical difference between groups. | ⊕⊕◯◯ LOW |
| **Function success** (≥30 pt. ↑ in CSS | Short-term | 2 RCTs (Galasso, Schmitt) | 58 | RR 1.52 (95% CI 0.63, 3.65)<br>Conclusion: No statistical difference between groups | ⊕⊕◯◯ LOW |

| Outcome | Follow-up | RCTs | N | Conclusion | Quality |
|---|---|---|---|---|---|
| or score 80% of normal) | | | | | |
| | Intermediate- and Long-term | 0 RCTs | | No evidence. | ⊕○○○ INSUFFICIENT |
| **Function success** (≥30% ↑in CSS) | Short-term | 1 RCT (Gerdesmeyer) | 132 | RR 2.70 (95% CI 1.47, 4.94) Conclusion: Significantly greater proportion of patients in the FESWT compared with sham group achieved function success. | ⊕⊕⊕○ MODERATE |
| | Intermediate-term | 1 RCT (Gerdesmeyer) | 135 | RR 3.94 (95% CI 1.97, 7.86) Conclusion: Significantly greater proportion of patients in the FESWT compared with sham group achieved function success. | ⊕⊕⊕○ MODERATE |
| | Long-term | 1 RCT (Gerdesmeyer) | 132 | RR 3.07 (95% CI 1.57, 6.01) Conclusion: Significantly greater proportion of patients in the FESWT compared with sham group achieved function success. | ⊕⊕⊕○ MODERATE |
| **Function success** (≥50% point improvement on SPADI) | Short-term | 1 RCT (Speed) | 74 | RR 0.78 (95% CI 0.44, 1.39) Conclusion: No statistical difference between groups. | ⊕⊕○○ LOW |
| | Intermediate-term and Long-term | 0 RCTs | | No evidence. | ⊕○○○ INSUFFICIENT |
| **Function** (CCS 0-100 (best)) | Short-term | 5 RCTs (Consentino, Galasso, Gerdesmeyer, Hsu, Schmitt,) | 306 | MD 20.3 (95% CI 10.1, 30.5) Conclusion: Statistically greater improvement with FESWT vs. sham; we were unable to identify a clinically important threshold. | ⊕⊕○○ LOW |
| | Intermediate-term | 3 RCTs (Consentino, Gerdesmeyer, Hsu) | 233 | MD 25.8 (95% CI 14.1, 37.4) Conclusion: Statistically greater improvement with FESWT vs. sham; we were unable to identify a clinically important threshold. | ⊕○○○ INSUFFICIENT |
| | Long-term | 2 RCTs (Gerdesmeyer, Hsu) | 157 | MD 19.3 (95% CI 0.77, 37.8) Conclusion: Statistically greater improvement with FESWT vs. sham; we were unable to identify a clinically important threshold. | ⊕⊕○○ LOW |
| **Function** (SPADI 0-100 (worst)) | Short-term | 1 RCT (Speed) | 74 | MD -0.9 (95% CI -8.58, 6.78) Conclusion: No statistical difference between groups. | ⊕⊕○○ LOW |
| | Intermediate-term | 1 RCT (Speed) | 74 | MD 4.9 (95% CI -3.14, 12.9) Conclusion: No statistical difference between groups. | ⊕⊕○○ LOW |

| Outcome | Follow-up | RCTs | N | Conclusion | Quality |
|---|---|---|---|---|---|
| | Long-term | 0 RCTs | | No evidence. | ⊕◯◯◯ INSUFFICIENT |
| **Function** (DASH 0-100 (worst)) | Short- and Intermediate term | 0 RCTs | | No evidence. | ⊕◯◯◯ INSUFFICIENT |
| | Long-term | 1 RCT (Efe) | 29 | Mean 39.8 ± 17.1 vs. 38.8 ± 14.1<br>Conclusion: Insufficient strength of evidence precludes firm conclusions. | ⊕◯◯◯ INSUFFICIENT |
| **Rotator Cuff Tendinopathy: Focused ESWT vs. US-guided needling + corticosteroid injection** | | | | | |
| **Pain NOS** (VAS 0-10, worst) | Short-term | 1 RCT (Kim) | 54 | MD 0.3 (95% CI NC)<br>Conclusion: No statistical difference between groups. | ⊕⊕◯◯ LOW |
| | Intermediate- term | 1 RCT (Kim) | 54 | MD -1.2 (95% CI NC)<br>Conclusion: No statistical difference between groups. | ⊕⊕◯◯ LOW |
| | Long-term | 1 RCT (Kim) | 54 | MD -2.4 (95% CI NC)<br>Conclusion: Statistically and clinically less pain improvement with FESWT vs. US-guided needling plus steroid injection. | ⊕⊕◯◯ LOW |
| **Function** (ASES 0-100 best; SST 0-100, best) | Short-term | 1 RCT (Kim) | 54 | ASES: MD -4.5 (95% CI NC)<br>SST: MD 2.1 (95% CI NC)<br>Conclusion: No statistical difference between groups. | ⊕⊕◯◯ LOW |
| | Intermediate- term | 1 RCT (Kim) | N=54 | ASES: MD -17.2 (95% CI NC)<br>SST: MD 0.9 (95% CI NC)<br>Conclusion: No statistical difference between groups. | ⊕⊕◯◯ LOW |
| | Long-term | 1 RCT (Kim) | N=54 | ASES: MD -24.1 (95% CI NC)<br>SST: MD -8.3 (95% CI NC)<br>Conclusion: Statistically and clinically less improvement in the FESWT compared with US-guided needling group on both outcome measures. | ⊕⊕◯◯ LOW |
| **Rotator Cuff Tendinopathy: FESWT vs. TENS** | | | | | |
| **Pain NOS** (VAS 0-10, worst) | Short-term | 1 RCT (Pan) | N=62 shoulders | MD 2.3 (95% CI 1.2, 3.5)<br>Conclusion: Insufficient strength of evidence precludes firm conclusions. | ⊕◯◯◯ INSUFFICIENT |
| | Intermediate- and long-term | 0 RCTs | | No evidence. | ⊕◯◯◯ INSUFFICIENT |
| **FunctionSuccess** (CSS ≥85) | Short-term | 1 RCT (Pan) | N=62 | RR 1.7 (95% CI 1.0, 2.7) | ⊕◯◯◯ INSUFFICIENT |

| Outcome | Follow-up | RCTs | N | Conclusion | Quality |
|---|---|---|---|---|---|
| | | | shoulders | Conclusion: Insufficient strength of evidence precludes firm conclusions. | |
| | Intermediate- and long-term | 0 RCTs | | No evidence. | ⊕◯◯◯ INSUFFICIENT |
| **Function** (CSS 0-100, best) | Short-term | 1 RCT (Pan) | N=62 shoulders | MD 16.5 (95% CI 9.9, 23.0)<br>Conclusion: Insufficient strength of evidence precludes firm conclusions. | ⊕◯◯◯ INSUFFICIENT |
| | Intermediate- and long-term | 0 RCTs | | No evidence. | ⊕◯◯◯ INSUFFICIENT |
| **Rotator Cuff Tendinopathy: Radial ESWT vs. Sham** | | | | | |
| **Pain NOS** (VAS 0-10, worst) | Short-term | 1 RCT (Kolk) | 77 | MD 0 (95% CI -7.6, 7.6)<br>Conclusion: Insufficient strength of evidence precludes firm conclusions. | ⊕◯◯◯ INSUFFICIENT |
| | Intermediate- term | 1 RCT (Kolk) | 69 | MD 3.0 (95% CI -5.0, 11.0)<br>Conclusion: Insufficient strength of evidence precludes firm conclusions. | ⊕◯◯◯ INSUFFICIENT |
| | Long-term | 0 RCTs | | No evidence. | ⊕◯◯◯ INSUFFICIENT |
| **Function** (CSS 0-100, best; SST 0-100, best) | Short-term | 1 RCT (Kolk) | 77 | CSS: MD 1.7 (95% CI -3.7, 7.1)<br>SST: MD 0.2 (95% CI -0.75, 1.15)<br>Conclusion: Insufficient strength of evidence precludes firm conclusions. | ⊕◯◯◯ INSUFFICIENT |
| | Intermediate- term | 1 RCT (Kolk) | 69 | CSS: MD 4.0 (95% CI -1.4, 9.4)<br>SST: MD 0.3 (95% CI -0.75, 1.35)<br>Conclusion: Insufficient strength of evidence precludes firm conclusions. | ⊕◯◯◯ INSUFFICIENT |
| | Long-term | 0 RCTs | | No evidence. | ⊕◯◯◯ INSUFFICIENT |
| **Rotator Cuff Tendinopathy: Radial ESWT vs. US-guided Percutaneous Lavage (UGPL)** | | | | | |
| **Pain Success** (proportion pain free) | Short- and Intermediate-term | 0 RCTs | | No evidence. | ⊕◯◯◯ INSUFFICIENT |
| | Long-term | 1 RCT (Del Castillo-Gonzalez) | 201 | RR 0.7 (95% CI 0.6, 0.9)<br>Conclusion: Insufficient strength of evidence precludes firm conclusions. | ⊕◯◯◯ INSUFFICIENT |
| **Pain NOS** (VAS 0-10, worst) | Short-term | 1 RCT (Del Castillo-Gonzalez) | 201 | Mean 5.2 vs. 3.2<br>Conclusion: Insufficient strength of evidence precludes firm conclusions. | ⊕◯◯◯ INSUFFICIENT |

| Outcome | Follow-up | RCTs | N | Conclusion | Quality |
|---|---|---|---|---|---|
| | Intermediate- term | 1 RCT (Del Castillo-Gonzalez) | 201 | Mean 4.0 vs. 2.2<br>Conclusion: Insufficient strength of evidence precludes firm conclusions. | ⊕◯◯◯ INSUFFICIENT |
| | Long-term | 1 RCT (Del Castillo-Gonzalez) | 201 | Mean 3.2 vs. 1.3<br>Conclusion: Insufficient strength of evidence precludes firm conclusions. | ⊕◯◯◯ INSUFFICIENT |
| **Function (any)** | Any | 0 RCTs | | No evidence. | ⊕◯◯◯ INSUFFICIENT |

ASES: American Shoulder and Elbow Surgeons score; CI: confidence interval; CSS: Constant Shoulder Score; DASH: Disabilities of the Arm, Shoulder and Hand questionnaire; MD: mean difference; NOS: not otherwise specified; RCT: randomized controlled trial; SPADI: Shoulder Pain and Disability Index; VAS: visual analog scale.

**Key Question 1 Strength of Evidence Summary: Adhesive Capsulitis Efficacy Results**

| Outcome | Follow-up | RCTs | N | Conclusion | Quality |
|---|---|---|---|---|---|
| **Adhesive Capsulitis of the Shoulder: Focused ESWT vs. Sham** | | | | | |
| **Pain** (SPADI pain subscale 0-50 (worst)) | Short-term | 1 RCT (Vahdatpour) | N=36 | MD 17.9 (95% CI 13.3, 22.5)<br>Conclusion: Insufficient strength of evidence precludes firm conclusions. | ⊕◯◯◯ INSUFFICIENT |
| | Intermediate-term | 1 RCT (Vahdatpour) | N=36 | MD 19.4 (95% CI 14.8, 24.0)<br>Conclusion: Insufficient strength of evidence precludes firm conclusions. | ⊕◯◯◯ INSUFFICIENT |
| | Long-term | 0 RCTs | | No evidence. | ⊕◯◯◯ INSUFFICIENT |
| **Function**(SPADI disability subscale 0-80 (worst)) | Short-term | 1 RCT (Vahdatpour) | N=36 | MD 26.5 (95% CI 20.9, 32.2)<br>Conclusion: Insufficient strength of evidence precludes firm conclusions. | ⊕◯◯◯ INSUFFICIENT |
| | Intermediate-term | 1 RCT (Vahdatpour) | N=36 | MD 30.6 (95% CI 25.4, 35.8)<br>Conclusion: Insufficient strength of evidence precludes firm conclusions. | ⊕◯◯◯ INSUFFICIENT |
| | Long-term | 0 RCTs | | No evidence. | ⊕◯◯◯ INSUFFICIENT |
| **Adhesive Capsulitis of the Shoulder: Focused ESWT vs. Oral Steroids** | | | | | |
| **Pain (any)** | Any | 0 RCTs | | No evidence. | ⊕◯◯◯ INSUFFICIENT |
| **Function**(CSS 0-100 (best); OSS 12-60 (worst)) | Short-term | 1 RCT (Chen) | N=34 | CSS: mean 75 vs. 66<br>OSS: mean 31 vs. 33<br>Conclusion: Insufficient strength of evidence precludes firm conclusions. | ⊕◯◯◯ INSUFFICIENT |
| | Intermediate- and long-term | 0 RCTs | | No evidence. | ⊕◯◯◯ INSUFFICIENT |

| Outcome | Follow-up | RCTs | N | Conclusion | Quality |
|---|---|---|---|---|---|
| **Adhesive Capsulitis of the Shoulder: Radial ESWT vs. Sham** | | | | | |
| **Pain rest and activity** (VAS 0-10 (worst)) | Short-term | 1 RCT (Hussein) | N=106 | MD 3.5 (95% CI 3.2, 3.7) Conclusion: Statistically and clinically greater improvement with RESWT vs. sham. | ⊕⊕⊕○ MODERATE |
| | Intermediate-term | 1 RCT (Hussein) | N=106 | MD 4.4 (95% CI 4.1, 4.6) Conclusion: Statistically and clinically greater improvement with RESWT vs. sham. | ⊕⊕⊕○ MODERATE |
| | Long-term | 0 RCTs | | No evidence. | ⊕○○○ INSUFFICIENT |
| **Function**(DASH 0-100 (worst)) | Short-term | 1 RCT (Hussein) | N=106 | MD 55.6 (95% CI 50.5, 60.8) Conclusion: Statistically and clinically greater improvement with RESWT vs. sham. | ⊕⊕⊕⊕ HIGH |
| | Intermediate-term | 1 RCT (Hussein) | N=106 | MD 55.3 (95% CI 49.8, 60.7) Conclusion: Statistically and clinically greater improvement with RESWT vs. sham. | ⊕⊕⊕⊕ HIGH |
| | Long-term | 0 RCTs | | No evidence. | ⊕○○○ INSUFFICIENT |

CI: confidence interval; CSS: Constant Shoulder Score; DASH: Disabilities of the Arm, Shoulder and Hand questionnaire; MD: mean difference; OSS: Oxford Shoulder Score; RCT: randomized controlled trial; SPADI: Shoulder Pain and Disability Index; VAS: visual analog scale.

**Key Question 2 Strength of Evidence Summary: Serious or Potentially Serious Adverse Events Results**

| Outcome | RCTs | N | Conclusion | Quality |
|---|---|---|---|---|
| **Serious or potentially serious adverse events** | 52 RCTs | 4762 | 0.39% (95% CI, 0.19 to 0.72%) ESWT 0.23% (95% CI, 0.07 to 0.53%) control | ⊕⊕○○ LOW |

**Key Question 3 Strength of Evidence Summary: Differential Efficacy and Harms**

| Exposure | Outcome | Follow-up | RCTs | N | Conclusion | Quality |
|---|---|---|---|---|---|---|
| **Plantar Fasciitis: Focused ESWT vs. Sham** | | | | | | |
| **Sex Age Body weight** | Pain NOS, MD | Short-term | 1 RCT (Malay) | 168 | Conclusion: No modifying effect of sex, age or body weight | ⊕⊕○○ LOW |
| **Rotator Cuff Tendinopathy: Focused ESWT vs. Sham** | | | | | | |
| **Energy Intensity** | Pain in AM, MD | Short and intermediate-term | 1 RCT (Gerdesmeyer) | 134 | Conclusion: FESWT significantly better than sham | ⊕⊕○○ LOW |

| Exposure | Outcome | Follow-up | RCTs | N | Conclusion | Quality |
|---|---|---|---|---|---|---|
| | | | | | with high intensity, but not with low intensity shock wave. | |
| | Reoccurrence of pain | Intermediate-term | 1 RCT (Peters) | 90 | Conclusion: Insufficient strength of evidence precludes firm conclusions. | ⊕◯◯◯ INSUFFICIENT |
| **Lateral Epicondyle Tendinopathy: Focused ESWT vs. Sham** | | | | | | |
| **Symptom duration** | Pain success (%) | Short-term | 1 RCT (Chung) | 60 | Conclusion: Insufficient strength of evidence precludes firm conclusions. | ⊕◯◯◯ INSUFFICIENT |
| **Achilles Tendinopathy: Focused ESWT vs. Sham** | | | | | | |
| **Sex** | AOFAS | Short-term | 1 RCT (Rasmussen) | 48 | Conclusion: Insufficient strength of evidence precludes firm conclusions. | ⊕◯◯◯ INSUFFICIENT |
| **Rotator Cuff Tendinopathy: Radial ESWT vs. Sham** | | | | | | |
| **Calcium formation** | Pain NOS, MD | Short- and intermediate-term | 1 RCT (Kolk) | 75 | Conclusion: Insufficient strength of evidence precludes firm conclusions. | ⊕◯◯◯ INSUFFICIENT |
| | Simple Shoulder Test | Short- and intermediate-term | 1 RCT (Kolk) | 75 | Conclusion: Insufficient strength of evidence precludes firm conclusions. | ⊕◯◯◯ INSUFFICIENT |

AOFAS: American Orthopedic Foot and Ankle Scale; CI: confidence interval; MD: mean difference; NOS: not otherwise specified

**REFERENCES**


1. Capan N, Esmaeilzadeh S, Oral A, Basoglu C, Karan A, Sindel D. Radial Extracorporeal Shock Wave Therapy Is Not More Effective Than Placebo in the Management of Lateral Epicondylitis: A Double-Blind, Randomized, Placebo-Controlled Trial. American journal of physical medicine & rehabilitation / Association of Academic Physiatrists 2016;95:495-506.
2. Chen CY, Hu CC, Weng PW, et al. Extracorporeal shockwave therapy improves short-term functional outcomes of shoulder adhesive capsulitis. Journal of shoulder and elbow surgery / American Shoulder and Elbow Surgeons [et al] 2014;23:1843-51.
3. Chen TW, Lin CW, Lee CL, et al. The efficacy of shock wave therapy in patients with knee osteoarthritis and popliteal cyamella. The Kaohsiung journal of medical sciences 2014;30:362-70.
4. Chew KT, Leong D, Lin CY, Lim KK, Tan B. Comparison of autologous conditioned plasma injection, extracorporeal shockwave therapy, and conventional treatment for plantar fasciitis: a randomized trial. PM & R : the journal of injury, function, and rehabilitation 2013;5:1035-43.
5. Chung B, Wiley JP. Effectiveness of extracorporeal shock wave therapy in the treatment of previously untreated lateral epicondylitis: a randomized controlled trial. The American journal of sports medicine 2004;32:1660-7.
6. Collins ED, Hildreth DH, Jafarnia KK. A clinical study of extracorporeal shock waves (ESW) for treatment of chronic lateral epicondylitis. Current orthopaedic practice2011:185-92.

7. Cosentino R, De Stefano R, Selvi E, et al. Extracorporeal shock wave therapy for chronic calcific tendinitis of the shoulder: single blind study. Annals of the rheumatic diseases 2003;62:248-50.

8. Cosentino R, Falsetti P, Manca S, et al. Efficacy of extracorporeal shock wave treatment in calcaneal enthesophytosis. Annals of the rheumatic diseases 2001;60:1064-7.

9. Costa ML, Shepstone L, Donell ST, Thomas TL. Shock wave therapy for chronic Achilles tendon pain: a randomized placebo-controlled trial. Clinical orthopaedics and related research 2005;440:199-204.

10. Crowther MA, Bannister GC, Huma H, Rooker GD. A prospective, randomised study to compare extracorporeal shock-wave therapy and injection of steroid for the treatment of tennis elbow. The Journal of bone and joint surgery British volume 2002;84:678-9.

11. Del Castillo-Gonzalez F, Ramos-Alvarez JJ, Rodriguez-Fabian G, Gonzalez-Perez J, Jimenez-Herranz E, Varela E. 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 2016;52:145-51.

12. Efe T, Felgentreff M, Heyse TJ, et al. Extracorporeal shock wave therapy for non-calcific supraspinatus tendinitis - 10-year follow-up of a randomized placebo-controlled trial. Biomedizinische Technik Biomedical engineering 2014;59:431-7.

13. Engebretsen K, Grotle M, Bautz-Holter E, Ekeberg OM, Juel NG, Brox JI. Supervised exercises compared with radial extracorporeal shock-wave therapy for subacromial shoulder pain: 1-year results of a single-blind randomized controlled trial. Physical therapy 2011;91:37-47.

14. Engebretsen K, Grotle M, Bautz-Holter E, et al. Radial extracorporeal shockwave treatment compared with supervised exercises in patients with subacromial pain syndrome: single blind randomised study. BMJ (Clinical research ed) 2009;339:b3360.

15. Galasso O, Amelio E, Riccelli DA, Gasparini G. Short-term outcomes of extracorporeal shock wave therapy for the treatment of chronic non-calcific tendinopathy of the supraspinatus: a double-blind, randomized, placebo-controlled trial. BMC musculoskeletal disorders 2012;13:86.

16. Gerdesmeyer L, Frey C, Vester J, et al. Radial extracorporeal shock wave therapy is safe and effective in the treatment of chronic recalcitrant plantar fasciitis: results of a confirmatory randomized placebo-controlled multicenter study. The American journal of sports medicine 2008;36:2100-9.

17. Gerdesmeyer L, Wagenpfeil S, Haake M, et al. Extracorporeal shock wave therapy for the treatment of chronic calcifying tendonitis of the rotator cuff: a randomized controlled trial. Jama 2003;290:2573-80.

18. Gollwitzer H, Diehl P, von Korff A, Rahlfs VW, Gerdesmeyer L. Extracorporeal shock wave therapy for chronic painful heel syndrome: a prospective, double blind, randomized trial assessing the efficacy of a new electromagnetic shock wave device. The Journal of foot and ankle surgery : official publication of the American College of Foot and Ankle Surgeons 2007;46:348-57.

19. Gollwitzer H, Saxena A, DiDomenico LA, et al. Clinically relevant effectiveness of focused extracorporeal shock wave therapy in the treatment of chronic plantar fasciitis: a randomized, controlled multicenter study. The Journal of bone and joint surgery American volume 2015;97:701-8.

20. Grecco MV, Brech GC, Greve JM. One-year treatment follow-up of plantar fasciitis: radial shockwaves vs. conventional physiotherapy. Clinics (Sao Paulo, Brazil) 2013;68:1089-95.

21. Guyatt G, Oxman AD, Akl EA, et al. GRADE guidelines: 1. Introduction-GRADE evidence profiles and summary of findings tables. J Clin Epidemiol 2011;64:383-94.

22. Guyatt GH, Oxman AD, Schunemann HJ, Tugwell P, Knottnerus A. GRADE guidelines: a new series of articles in the Journal of Clinical Epidemiology. J Clin Epidemiol 2011;64:380-2.

23. Haake M, Buch M, Schoellner C, et al. Extracorporeal shock wave therapy for plantar fasciitis: randomised controlled multicentre trial. BMJ (Clinical research ed) 2003;327:75.

24. Haake M, Konig IR, Decker T, Riedel C, Buch M, Muller HH. Extracorporeal shock wave therapy in the treatment of lateral epicondylitis : a randomized multicenter trial. The Journal of bone and joint surgery American volume 2002;84-a:1982-91.

25. Hammer DS, Rupp S, Kreutz A, Pape D, Kohn D, Seil R. Extracorporeal shockwave therapy (ESWT) in patients with chronic proximal plantar fasciitis. Foot & ankle international 2002;23:309-13.

26. Haupt G. Use of extracorporeal shock waves in the treatment of pseudarthrosis, tendinopathy and other orthopedic diseases. The Journal of urology 1997;158:4-11.

27. Haupt G, Haupt A, Ekkernkamp A, Gerety B, Chvapil M. Influence of shock waves on fracture healing. Urology 1992;39:529-32.

28. Hsu CJ, Wang DY, Tseng KF, Fong YC, Hsu HC, Jim YF. Extracorporeal shock wave therapy for calcifying tendinitis of the shoulder. Journal of shoulder and elbow surgery / American Shoulder and Elbow Surgeons [et al] 2008;17:55-9.

29. Hussein AZ, Donatelli RA. The efficacy of radial extracorporeal shockwave therapy in shoulder adhesive capsulitis: A prospective, randomised, double-blind, placebo-controlled, clinical study. European Journal of Physiotherapy2016:63-76.

30. Ibrahim MI, Donatelli RA, Hellman M, Hussein AZ, Furia JP, Schmitz C. Long-term results of radial extracorporeal shock wave treatment for chronic plantar fasciopathy: A prospective, randomized, placebo-controlled trial with two years follow-up. Journal of orthopaedic research : official publication of the Orthopaedic Research Society 2016.

31. Ibrahim MI, Donatelli RA, Schmitz C, Hellman MA, Buxbaum F. Chronic plantar fasciitis treated with two sessions of radial extracorporeal shock wave therapy. Foot & ankle international 2010;31:391-7.

32. Jocham D, Chaussy C, Schmiedt E. Extracorporeal shock wave lithotripsy. Urologia internationalis 1986;41:357-68.

33. Kim YS, Lee HJ, Kim YV, Kong CG. 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 / American Shoulder and Elbow Surgeons [et al] 2014;23:1640-6.

34. Ko JY, Chen HS, Chen LM. Treatment of lateral epicondylitis of the elbow with shock waves. Clinical orthopaedics and related research 2001:60-7.

35. Kolk A, Yang KG, Tamminga R, van der Hoeven H. Radial extracorporeal shock-wave therapy in patients with chronic rotator cuff tendinitis: a prospective randomised double-blind placebo-controlled multicentre trial. The bone & joint journal 2013;95-b:1521-6.

36. Konjen N, Napnark T, Janchai S. A comparison of the effectiveness of radial extracorporeal shock wave therapy and ultrasound therapy in the treatment of chronic plantar fasciitis: a randomized controlled trial. Journal of the Medical Association of Thailand = Chotmaihet thangphaet 2015;98 Suppl 1:S49-56.

37. Kudo P, Dainty K, Clarfield M, Coughlin L, Lavoie P, Lebrun C. Randomized, placebo-controlled, double-blind clinical trial evaluating the treatment of plantar fasciitis with an extracoporeal shockwave therapy (ESWT) device: a North American confirmatory study. Journal of orthopaedic research : official publication of the Orthopaedic Research Society 2006;24:115-23.

38. Lakshmanan P, O'Doherty DP. Chronic achilles tendinopathy: treatment with extracorporeal shock waves. Foot and Ankle Surgery 2004;10:125-30.

39. Lance RM, Capehart B, Kadro O, Bass CR. Human Injury Criteria for Underwater Blasts. PloS one 2015;10:e0143485.

40. Lin TC, Lin CY, Chou CL, Chiu CM. Achilles tendon tear following shock wave therapy for calcific tendinopathy of the Achilles tendon: A case report. Physical Therapy in Sport 2012;13:189-92.

41. Liu S, Zhai L, Shi Z, Jing R, Zhao B, Xing G. Radial extracorporeal pressure pulse therapy for the primary long bicipital tenosynovitis a prospective randomized controlled study. Ultrasound in medicine & biology 2012;38:727-35.

42. Loew M, Jurgowski W. [Initial experiences with extracorporeal shockwave lithotripsy (ESWL) in treatment of tendinosis calcarea of the shoulder]. Z Orthop Ihre Grenzgeb 1993;131:470-3.

43. Loew M, Jurgowski W, Thomsen M. [Effect of extracorporeal shockwave therapy on tendinosis calcarea of the shoulder. A preliminary report]. Urologe A 1995;34:49-53.

44. Malay DS, Pressman MM, Assili A, et al. Extracorporeal shockwave therapy versus placebo for the treatment of chronic proximal plantar fasciitis: results of a randomized, placebo-controlled, double-blinded, multicenter intervention trial. The Journal of foot and ankle surgery : official publication of the American College of Foot and Ankle Surgeons 2006;45:196-210.

45. Mehra A, Zaman T, Jenkin AI. The use of a mobile lithotripter in the treatment of tennis elbow and plantar fasciitis. The surgeon : journal of the Royal Colleges of Surgeons of Edinburgh and Ireland 2003;1:290-2.

46. Melikyan EY, Shahin E, Miles J, Bainbridge LC. Extracorporeal shock-wave treatment for tennis elbow. A randomised double-blind study. The Journal of bone and joint surgery British volume 2003;85:852-5.

47. Mittermayr R, Antonic V, Hartinger J, et al. Extracorporeal shock wave therapy (ESWT) for wound healing: technology, mechanisms, and clinical efficacy. Wound Repair Regen 2012;20:456-65.

48. Ogden JA, Alvarez R, Levitt R, Cross GL, Marlow M. Shock wave therapy for chronic proximal plantar fasciitis. Clinical orthopaedics and related research 2001:47-59.

49. Ogden JA, Alvarez RG, Levitt RL, Johnson JE, Marlow ME. Electrohydraulic high-energy shock-wave treatment for chronic plantar fasciitis. The Journal of bone and joint surgery American volume 2004;86-a:2216-28.

50. Ozturan KE, Yucel I, Cakici H, Guven M, Sungur I. Autologous blood and corticosteroid injection and extracoporeal shock wave therapy in the treatment of lateral epicondylitis. Orthopedics 2010;33:84-91.

51. Pan PJ, Chou CL, Chiou HJ, Ma HL, Lee HC, Chan RC. Extracorporeal shock wave therapy for chronic calcific tendinitis of the shoulders: a functional and sonographic study. Archives of physical medicine and rehabilitation 2003;84:988-93.

52. Peters J, Luboldt W, Schwarz W, Jacobi V, Herzog C, Vogl TJ. Extracorporeal shock wave therapy in calcific tendinitis of the shoulder. Skeletal radiology 2004;33:712-8.

53. Pettrone FA, McCall BR. Extracorporeal shock wave therapy without local anesthesia for chronic lateral epicondylitis. The Journal of bone and joint surgery American volume 2005;87:1297-304.

54. Porter MD, Shadbolt B. Intralesional corticosteroid injection versus extracorporeal shock wave therapy for plantar fasciopathy. Clinical journal of sport medicine : official journal of the Canadian Academy of Sport Medicine 2005;15:119-24.

55. Radwan YA, ElSobhi G, Badawy WS, Reda A, Khalid S. Resistant tennis elbow: shock-wave therapy versus percutaneous tenotomy. International orthopaedics 2008;32:671-7.

56. Radwan YA, Mansour AM, Badawy WS. Resistant plantar fasciopathy: shock wave versus endoscopic plantar fascial release. International orthopaedics 2012;36:2147-56.

57. Rasmussen S, Christensen M, Mathiesen I, Simonson O. Shockwave therapy for chronic Achilles tendinopathy: a double-blind, randomized clinical trial of efficacy. Acta orthopaedica 2008;79:249-56.

58. Rompe JD, Decking J, Schoellner C, Nafe B. Shock wave application for chronic plantar fasciitis in running athletes. A prospective, randomized, placebo-controlled trial. The American journal of sports medicine 2003;31:268-75.

59. Rompe JD, Decking J, Schoellner C, Theis C. Repetitive low-energy shock wave treatment for chronic lateral epicondylitis in tennis players. The American journal of sports medicine 2004;32:734-43.

60. Rompe JD, Furia J, Maffulli N. Eccentric loading compared with shock wave treatment for chronic insertional achilles tendinopathy. A randomized, controlled trial. The Journal of bone and joint surgery American volume 2008;90:52-61.

61. Rompe JD, Furia J, Maffulli N. Eccentric loading versus eccentric loading plus shock-wave treatment for midportion achilles tendinopathy: a randomized controlled trial. The American journal of sports medicine 2009;37:463-70.

62. Rompe JD, Hopf C, Nafe B, Burger R. Low-energy extracorporeal shock wave therapy for painful heel: a prospective controlled single-blind study. Archives of orthopaedic and trauma surgery 1996;115:75-9.

63. Rompe JD, Kullmer K, Riehle HM, et al. Effectiveness of low-energy extracorporal shock waves for chronic plantar fasciitis. Foot Ankle Surg 1996;2:215-21.

64. Rompe JD, Nafe B, Furia JP, Maffulli N. Eccentric loading, shock-wave treatment, or a wait-and-see policy for tendinopathy of the main body of tendo Achillis: a randomized controlled trial. The American journal of sports medicine 2007;35:374-83.

65. Rompe JD, Riedel C, Betz U, Fink C. Chronic lateral epicondylitis of the elbow: A prospective study of low-energy shockwave therapy and low-energy shockwave therapy plus manual therapy of the cervical spine. Archives of physical medicine and rehabilitation 2001;82:578-82.

66. Saxena A, Fournier M, Gerdesmeyer L, Gollwitzer H. Comparison between extracorporeal shockwave therapy, placebo ESWT and endoscopic plantar fasciotomy for the treatment of chronic plantar heel pain in the athlete. Muscles Ligaments Tendons J 2012;2:312-6.

67. Schmitt J, Haake M, Tosch A, Hildebrand R, Deike B, Griss P. Low-energy extracorporeal shock-wave treatment (ESWT) for tendinitis of the supraspinatus. A prospective, randomised study. The Journal of bone and joint surgery British volume 2001;83:873-6.

68. Speed C. A systematic review of shockwave therapies in soft tissue conditions: focusing on the evidence. British journal of sports medicine 2014;48:1538-42.

69. Speed CA, Nichols D, Richards C, et al. Extracorporeal shock wave therapy for lateral epicondylitis--a double blind randomised controlled trial. Journal of orthopaedic research : official publication of the Orthopaedic Research Society 2002;20:895-8.

70. Speed CA, Nichols D, Wies J, et al. Extracorporeal shock wave therapy for plantar fasciitis. A double blind randomised controlled trial. Journal of orthopaedic research : official publication of the Orthopaedic Research Society 2003;21:937-40.

71. Speed CA, Richards C, Nichols D, et al. Extracorporeal shock-wave therapy for tendonitis of the rotator cuff. A double-blind, randomised, controlled trial. The Journal of bone and joint surgery British volume 2002;84:509-12.

72. Taunton J, Taunton KM, Khan KM. Treatment of patellar tendinopathy with extracorporeal shock wave therapy. BCMJ 2003;45.

73. Theodore GH, Buch M, Amendola A, Bachmann C, Fleming LL, Zingas C. Extracorporeal shock wave therapy for the treatment of plantar fasciitis. Foot & ankle international 2004;25:290-7.

74. Thiel M, Nieswand M, Dorffel M. The use of shock waves in medicine--a tool of the modern OR: an overview of basic physical principles, history and research. Minimally invasive therapy & allied technologies : MITAT : official journal of the Society for Minimally Invasive Therapy 2000;9:247-53.

75. Vahdatpour B, Taheri P, Zade AZ, Moradian S. Efficacy of extracorporeal shockwave therapy in frozen shoulder. International journal of preventive medicine2014:875-81.

76. Valchanou VD, Michailov P. High energy shock waves in the treatment of delayed and nonunion of fractures. International orthopaedics 1991;15:181-4.

77. Wang CJ. Extracorporeal shockwave therapy in musculoskeletal disorders. Journal of orthopaedic surgery and research 2012;7:11.

78. Wang CJ, Ko JY, Chan YS, Weng LH, Hsu SL. Extracorporeal shockwave for chronic patellar tendinopathy. The American journal of sports medicine 2007;35:972-8.

79. Yucel I, Ozturan KE, Demiraran Y, Degirmenci E, Kaynak G. Comparison of high-dose extracorporeal shockwave therapy and intralesional corticosteroid injection in the treatment of plantar fasciitis. Journal of the American Podiatric Medical Association 2010;100:105-10.

80. Zhao Z, Jing R, Shi Z, Zhao B, Ai Q, Xing G. Efficacy of extracorporeal shockwave therapy for knee osteoarthritis: a randomized controlled trial. The Journal of surgical research 2013;185:661-6.

# 1. Appraisal

## 1.1 Background and Rationale

Extracorporeal shockwave therapy (ESWT) is a treatment utilized for a variety of healing applications in soft tissue and bone-related musculoskeletal disorders[167] A shock wave is an intense, but very short energy wave traveling faster than the speed of sound. Specific conditions where ESWT is commonly utilized include refractory or chronic pain associated with ligament injuries, muscle strain injuries, osteoarthritis, and tendinopathies. ESWT has gained significant acceptance in Europe, South America, Asia and North America for treatment of these conditions.[186]

The study of the effects of shock waves on humans were first described as the result of accidental depth charge detonations in 1916 during WWI.[100] In WWII, castaways who were exposed to water bomb explosions were noted to suffer severe lung injuries but showed no overt clinical signs of traumatic injury.[119] In 1980, high energy focused extracorporeal shock waves were clinically introduced in Munich, Germany, to disintegrate urinary stones (i.e., lithotripsy)[84] and became the gold standard for the initial treatment of urolithiasis.[177] In the 1980s shock waves were shown to have osteogenic potential. Animal experiments confirmed that shock waves facilitated fracture healing. Osteoblasts activation and increased bone density as a result of shock waves was confirmed by histological investigations.[67,68] In 1988, Valchanou conducted a case series evaluating the effect of high-energy ESWT on the treatment of delayed and nonunion fractures.[181] The authors reported 85% fracture union rate. Urologic lithotripters were used in the early application of orthopedic problems, and this was soon followed by shock wave devices specifically designed for orthopedic and traumatic indications. In the early 1990s, effect of treatment for calcific tendinopathy of the shoulder by focused ESWT were first published.[107,108] Shortly thereafter, studies were published evaluating the effect of ESWT on lateral epicondylitis, Achilles tendonitis, and plantar fasciitis with or with heel spurs.[67,93,99,150,155] The Food and Drug Administration, in October of 2000, approved OssaTron device (HealthTronics, Marietta, GA) for chronic plantar fasciitis and in 2003 for chronic lateral epicondylitis of the elbow.

### Policy Context

Extracorporeal shock wave therapy (ESWT) is a noninvasive treatment based on ultrasound technology. ESWT is used for a variety of conditions including treatment of kidney stones. ESWT for soft tissue injuries is applied with the goal of promoting healing. ESWT may have multiple effects thought to impact healing including breaking calcium deposits and causing an inflammatory response that may stimulate tissue healing. The concern for the efficacy and safety of ESWT are high, while the concern regarding cost is medium/high.

### Objectives

The primary aim of this assessment is to systematically review and synthesis published evidence on the efficacy, safety, and cost-effectiveness of focused extracorporeal shock wave therapy (ESWT) for the treatment of musculoskeletal conditions.

## 1.2 Key Questions

In patients with musculoskeletal conditions such as tendinopathy, plantar fasciitis, heel spurs, subacromial shoulder pain, or osteoarthritis:

1. What is the evidence of the short- and long-term efficacy and effectiveness of ESWT compared with standard alternative treatment options, sham, or no treatment?

2. What is the evidence regarding short- and long-term harms and complications of ESWT compared with standard alternative treatment options, sham, or no treatment?

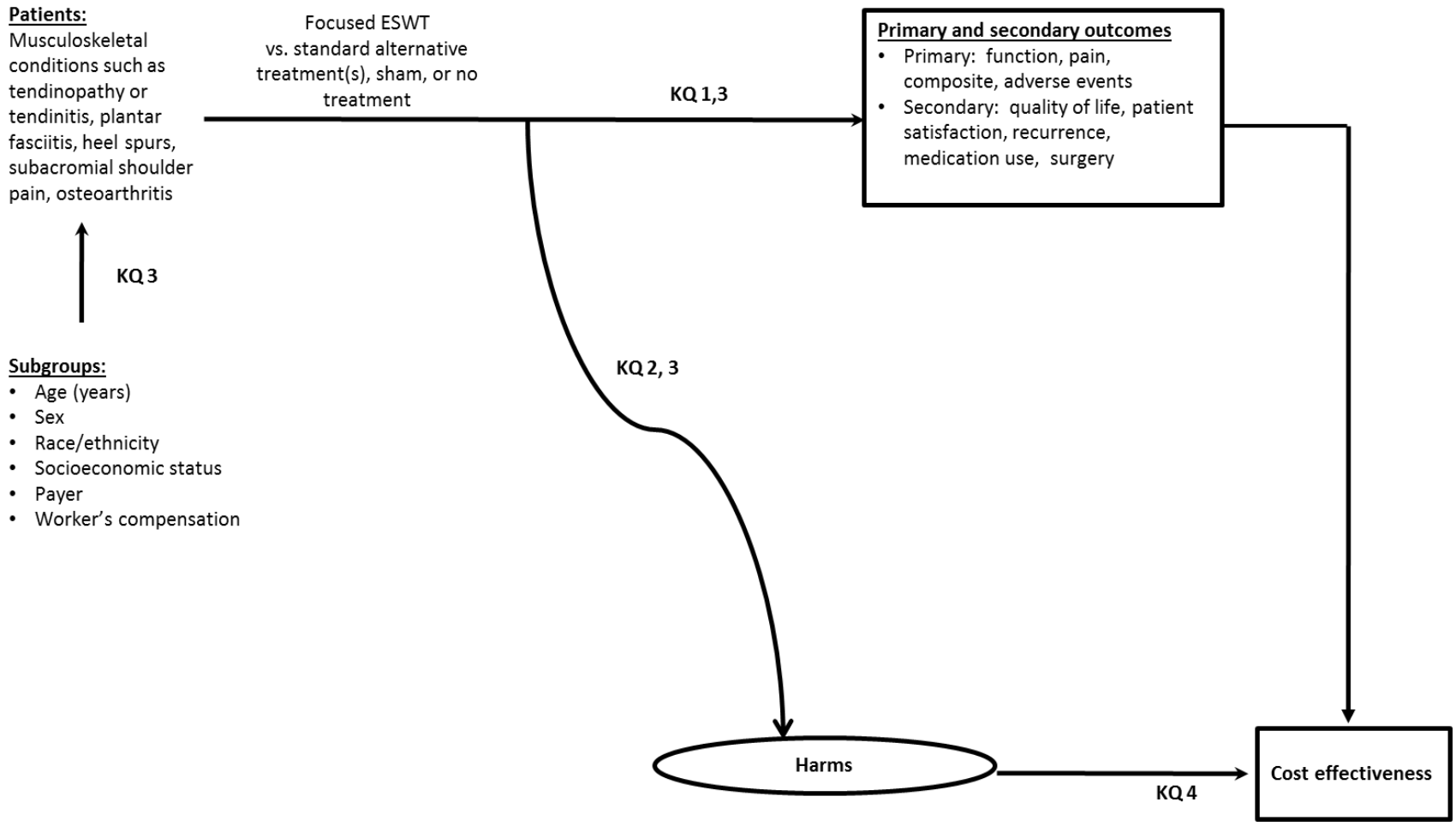
3. Is there evidence of differential efficacy, effectiveness, or safety of ESWT compared with standard alternative treatment options, sham, or no treatment? Include consideration of age, sex, race, ethnicity, socioeconomic status, payer, and worker's compensation?

4. What is the evidence of cost-effectiveness of ESWT compared with standard alternative treatment options or no treatment?

Inclusion and exclusion criteria are summarized as follows:

- **Population:** Patients with tendinopathy or tendinitis, plantar fasciitis, heel spurs, subacromial shoulder pain, or osteoarthritis. (Kidney stones; gallstones; cutaneous wounds; muscle spasticity; as well as dental, cosmetic, bony non-unions, fractures, carpal tunnel syndrome, shin splints, greater trochanteric pain syndrome, coccydynia, Dupuytren's disease, myofacscial pain, cardiovascular, osteonecrosis, postoperative patients and neurological conditions will be excluded).
- **Intervention:** Focused or Radial ESWT (ESWT used in conjunction with surgery will be excluded.)
- **Comparators:** Standard alternative treatment(s), sham, or no treatment. (Comparisons of ESWT such as different modalities (e.g., radial vs. focused ESWT, high- vs. low-energy ESWT) will be excluded.)
- **Outcomes:** Function (primary), pain (primary), adverse events (primary), quality of life, patient satisfaction, medication use, surgery, cost-effectiveness (e.g., cost per improved outcome), cost-utility (e.g., cost per quality adjusted life year (QALY), incremental cost effectiveness ratio (ICER) outcomes.
- **Study design**: Focus will be on studies with the least potential for bias such as high quality systematic reviews of randomized controlled trials and randomized controlled trials and full economic studies.

**Figure 1. Analytic framework**



## 1.3 Outcomes Assessed

The studies included in this assessment used a variety of measures to evaluate treatment outcomes, which are outlined in Table 1. The primary outcome measures were those which measured function and pain; these were designated primary outcomes a priori based on clinical expert input. Information on the minimal clinically important difference (MCID) was obtained for the population being evaluated whenever statistical differences were found between groups.

**Table 1. Outcome measures used in included studies**

| Outcome Measure | Assessed By | Components | Score Range | Interpretation | MCID* |
|---|---|---|---|---|---|
| Elbow | | | | | |
| Disabilities of the Arm, Shoulder and Hand (DASH)[74] | Patient | 3 modules (one required, two optional)<br><br>Module 1: ability to perform (required); 6 subscales<br>Activities of daily living (105 points)<br>Social activities (5 points)<br>Work activities (5 points)<br>Symptoms (25 points)<br>Sleeping (5 points)<br>Confidence (5 points)<br><br>Module 2: ability to perform sports/performing arts (optional) (20 points)<br>Module 3: ability to perform work (optional) (20 points) | Scores normalized to 100; total score ranges from 0 to 100. | The higher the score, the lower the function. | For musculoskeletal upper extremities: 10.2[160] |
| Grip Strength (with JAMAR dynamometer) | Physician | NR | NR | The higher the value, the greater the grip strength. | NR |
| Patient-Related Tennis Elbow Evaluation (PRTEE)[154] | Patient | 2 subscales (15 items):<br>Pain<br>Function (further divided into specific | 0 to 100 (total score) | The higher the score, the greater the pain and functional impairment. | For elbow epicondylitis: MCID defined as "a little better" |

| Outcome Measure | Assessed By | Components | Score Range | Interpretation | MCID* |
|---|---|---|---|---|---|
| | | activities and usual activities) | | | Total PRTEE: 7/100, 22% of baseline score<br><br>MCID defined as "much better" or "completely recovered"<br>Total PRTEE: 11/100 or 37% of baseline score<br><br>MCID for subgroups <40/100 at baseline: 7/100 or 35%<br><br>MCID for subgroups for ≥40/100: 21 or 40%: 21 or 40%[133] |
| Upper Extremity Functional Scale[135] | Patient | 8 items representing common activities affecting upper extremity function. | 1 to 10 (per item)<br>8 to 80 (total score) | The higher the score, the lower the upper extremity function. | NR |
| Plantar Fasciitis | | | | | |
| Visual Analog Scale (VAS)§ | Patient | Patients are asked to indicate on a scale line (100 mm in length) where they rate their pain level of the day.<br>One variation of this measure includes changing the length of the line. | 0 to variable maximum typically of 10 or 100 (total score) | The higher the score, the greater the pain.<br>No pain: 0 to 4 mm<br>Mild pain: 5 to 44 mm<br>Moderate pain: 45 to 74 mm<br>Severe pain: 74 to 100 mm | For plantar fasciitis: 9 mm[101] |
| 11-point Pain Intensity Numerical Rating Scale (PI-NRS) | Patient | One item, asks the individual to select a number from a scale indicating their neuropathic pain of the day. | 0 to 10 (item score) | The higher the score, the greater the pain. | For chronic musculoskeletal pain: 15%[156] |
| Pain in the morning when taking first steps (VAS) | Patient | NR | 0 to 100 OR 0 to 10 | The higher the score, the greater the pain in the morning when taking first steps. | For plantar fasciitis: NR |

| Outcome Measure | Assessed By | Components | Score Range | Interpretation | MCID* |
|---|---|---|---|---|---|
| Pain at rest (VAS) | Patient | NR | 0 to 100 OR 0 to 10 | The higher the score, the greater the pain at rest. | For plantar fasciitis: NR |
| Pain with activity (VAS) | Patient | NR | 0 to 100 OR 0 to 10 | The higher the score, the greater the pain with activity. | For plantar fasciitis: NR |
| Roles and Maudsley Outcome Score | Patient | Pain scale where:<br>1 = excellent, no pain, full movement, full activity<br>2 = good, occasional discomfort, full movement, and full activity<br>3 = fair, some discomfort after prolonged activity<br>4 = poor, pain limiting activities | 1 to 4 (total score) | The higher the score, the greater the pain. | For plantar fasciitis: NR |
| Ankle-Hindfoot Scale of the American Orthopaedic Foot and Ankle Society (AOFAS) | Clinician | 3 subscales (9 items):<br>Pain (40 points)<br>Function (50 points)<br>Alignment (10 points) | 0 to 100 (total score) | The lower the score, the greater the disability.<br><br>Score 100-91: excellent<br>Score 90-81: good<br>Score 80-71: fair<br>Score <70: poor | For unspecified ankle etiology: 8.90 |
| Achilles Tendinopathy | | | | | |
| Visual Analog Scale function | Patient | Patients are asked to evaluate functional impairment during activities of daily living including climbing up and down stairs, walking on a flat surface, going out for a long walk, or performing household work on a scale of 1 to 10. Item scores are averaged to produce a function score. | 0 to 10 (item score and total score) | The higher the score, the greater the functional impairment. | For Achilles Tendinopathy: NR |
| Pain walking up stairs (VAS) | Patient | NR | 0 to 10 | The higher the scale, the greater | For Achilles Tendinopathy: NR |

| Outcome Measure | Assessed By | Components | Score Range | Interpretation | MCID* |
|---|---|---|---|---|---|
| | | | | the pain during walking up stairs | |
| Pain walking (VAS) | Patient | Patients are asked to complete a 100-mm visual analog pain scale while walking. | 0 to 100 OR 0 to 10 | The higher the scale, the greater the pain during walking | For Achilles Tendinopathy: NR |
| Pain sports (VAS) | Patient | Patients are asked to complete a 100-mm visual analog pain scale while playing sports. | 0 to 100 | The higher the scale, the greater the pain during playing sports | For Achilles Tendinopathy: NR |
| Pain working (VAS) | Patient | NR | 0 to 10 | The higher the scale, the greater the pain while working | For Achilles Tendinopathy: NR |
| Pain running (VAS) | Patient | NR | 0 to 10 | The higher the scale, the greater the pain while running | For Achilles Tendinopathy: NR |
| Victorian Institute of Sports Assessment-Achilles (VISA-A) | Patient | 3 subscales (8 items):<br>Pain<br>Activity<br>Functional status | 0 to 100 (total score) | The lower the score, the greater the Achilles disability. | For non-insertional Achilles Tendinopathy: 10[164]<br>15[171]<br><br>For insertional Achilles Tendinopathy: 6.5[114] |
| 11-point Pain Intensity Numerical Rating Scale (PI-NRS) | Patient | One item, asks the individual to select a number from a scale indicating their neuropathic pain of the day. | 0 to 10 (item score) | The higher the score, the greater the pain. | For chronic musculoskeletal pain: 1 point or 15% |
| FIL (Functional Index of Lower Limb Activity)[157] | Patient | 12 items (0 to 100 on a VAS) divided into three sections regarding common basic activities of daily life, more demanding daily physical activities, and work-related or more vigorous activites. | 0 to 100 (the mean of the scores for each of the 12 items) | The higher the score, the greater the functional disability | For Achilles Tendinopathy: NR |

| Outcome Measure | Assessed By | Components | Score Range | Interpretation | MCID* |
|---|---|---|---|---|---|
| EuroQol 5-Dimension Questionnaire (EQ5D) | Patient | Patients are asked to pick a statement that best describes their health state regarding 5 different dimensions pertaining to:<br>Mobility<br>Self-care<br>Usual activities<br>Pain/discomfort<br>Anxiety/depression | -0.109 to 1 | The higher the score, the better the health state | For Achilles Tendinopathy:<br>NR |
| EQoL health score | Patient | Each dimension from the EQ-5D is rated on a scale from 1 (no problems) to 5 (extreme problems) | A 5-digit number is produced to represent level of problems in each dimension. | The higher the digit for each dimension, the greater the problems. | For Achilles Tendinopathy:<br>NR |
| Knee OA | | | | | |
| Lequesne Index | Patient | 3 subscales (11 items):<br>Pain<br>Walking distance<br>Activities of daily living<br><br>Two indices available: hip and knee. Both scored the same, have identical subscales, etc.<br>The 1997 update made minor changes to morning stiffness items and added "algofunctional index" to the name. | 0 to variable maximum (item score)<br>0 to 24 (total score) | The higher the score, the greater the impairment.<br>Extremely severe: >14<br>Very severe: 11 to 13<br>Severe: 8 to 10<br>Moderate: 5 to 7<br>Minor: 1 to 4<br>No severity: 0 | For Knee OA: NR |
| Western Ontario and McMaster OA index (WOMAC) | Patient | 3 subscales:<br>Pain (5 items)<br>Stiffness (2 items)<br>Physical function (17 items) | Likert Scale:<br>0 to 4 (item score)<br>0 to 96 (total score) | The higher the score, the greater the pain, stiffness, and functional limitations. | For Knee OA[172]<br>Total WOMAC: 10.1<br>Pain: 2.1<br>Stiffness: 1.2<br>Function: 6.5<br><br>For general knee problems:<br>*Traumatic*<br>Pain: 10.9 |

| Outcome Measure | Assessed By | Components | Score Range | Interpretation | MCID* |
|---|---|---|---|---|---|
| | | | | | Stiffness: 16.8<br>Function: 21.0<br>Overall: 18.6<br>*Non-Traumatic*<br>Pain: 15.4<br>Stiffness: 13.8<br>Function: 12.0<br>Overall: 12.9<br>*Combined*<br>Pain: 16.8<br>Stiffness: 20.3<br>Function: 23.0<br>Overall: 19.1 |
| Patellar Tendinopathy | | | | | |
| Victorian Institute of Sports Assessment Patella (VISA-P) | Patient | 3 subscales (8 items):<br>Symptoms<br>Function<br>Ability to perform sports | 0 to variable maximum (item score)<br>0 to 100 (total score) | The higher the score the lower the patellar disability. | For patellar tendinopathy: 14 points[69] |
| Blazina Scale | Patient | 4 phases/stages:<br>Phase 1: pain after activity only<br>Phase 2: pain/discomfort during and after activity does not interfere with participation<br>Phase 3: Pain during and after activity interferes with competition<br>Phase 4: complete tendon disruption | Phase 1 to phase 4 | The higher the phase, the greater the disruption | For patellar tendinopathy: |
| Shoulder | | | | | |
| Constant Shoulder Score[29] | Physician | Pain (15 points), activities of daily living (20 points), shoulder motion (40 points), power of affected arm (25 points) | 0 to 100 | The higher the score, the lower the shoulder disability. | For shoulder disability: NR |
| Oxford Shoulder Score[39] | Patient | 12 items, 5 points each | 12 to 60 | The higher the score, the greater the shoulder disability. | For shoulder disability: 6.0[39] |

| Outcome Measure | Assessed By | Components | Score Range | Interpretation | MCID* |
|---|---|---|---|---|---|
| Shoulder Pain and Disability Index (SPADI)[179] | Patient | Pain (5 items, 10 points each) and disability (10 items, 10 points each) | 0 to 100 | The higher the score, the greater the pain and disability related to shoulder complaints. | For musculoskeletal upper extremity (proximal): 13.2 points[160]<br><br>For rotator cuff disease: 15.4 points[46] |
| Disabilities of the Arm, Shoulder and Hand (DASH) | Patient | 3 modules (one required, two optional)<br><br>Module 1: ability to perform (required); 6 subscales<br>Activities of daily living (105 points)<br>Social activities (5 points)<br>Work activities (5 points)<br>Symptoms (25 points)<br>Sleeping (5 points)<br>Confidence (5 points)<br><br>Module 2: ability to perform sports/performing arts (optional) (20 points)<br>Module 3: ability to perform work (optional) (20 points) | Scores normalized to 100; total score ranges from 0 to 100. | The higher the score, the lower the function. | For musculoskeletal upper extremities: 10.2 |
| American Shoulder and Elbow Surgeons (ASES) Standardized Shoulder Assessment Form | Patient, clinician | Patient Self-Evaluation:<br>Pain (7 items)<br>Instability (1 item)<br>Activities of daily living (10 items)<br><br>Clinician Assessment:<br>Strength (4 items)<br>Instability (8 items) | Items that are scored on a 0 to variable maximum 3 or 10 point scale and normalized to 100; total score ranges from 0 to 100 | The lower the score, the greater pain and disability. | Shoulder Dysfunction: 6.4<br><br>12-17 (depending on 15-item function, 15 item pain, or 4 item improvement questionnaires; which are 12.01, |

| Outcome Measure | Assessed By | Components | Score Range | Interpretation | MCID* |
|---|---|---|---|---|---|
| | | Range of motion (5 items)<br>Tenderness, crepitus, impingement (11 items) | | | 16.92, and 16.72 respectively)<br><br>7 |
| Simple Shoulder Test (SST) | Patient | 12 yes or no questions concerning the ability to perform 12 activities of daily living. | 0 to 100 (total score)<br><br>Reported as a percentage of questions answered in the affirmative. | The higher the score, the greater the shoulder function. | For rotator cuff disease:<br>Range 0-12: 2.05 (fifteen item function) or 2.33 (4 item assessment), 2 points overall<br><br>For asymptomatic rotator cuff tear:<br>For range 0-100, 17 to 19 |
| L'Insalata shoulder questionnaire[106] | Patient | 7 domains:<br>Global Assessment (0 to 15 points)<br>Pain (8 to 40 points)<br>Daily activities (4 to 20 points)<br>Recreational and athletic activities (3 to 15 points)<br>Work (2 to 10 points) | 17 to 100 points | The higher the score, the less severe the symptoms related to the functional status of the shoulder | 2 points for each domain[98] |
| Manual Muscle Test (MMT) | Physician | NR | 0 to 5 | The higher the score, the greater the muscle strength | NR |

*MCIDs were only found if an outcome was significant in any of the results of this report. Those that are significant in the results, but not found searching the literature, then the MCID is reported as NR.

†Note that 20 meter walk test in Forogh is jogging, while other studies use walking within the same outcome measure

‡The measures used for the three subscales vary depending on the study.

§ Multiple versions and modifications to this outcome measure were reported in the studies included in this report.

**One study (Sanchez 2012) utilized a non-standard “normalized” WOMAC scoring system for each subscale, where each subscale was 0-100(worst).

## 1.4 Washington State Utilization and Cost Data

# 2. Background

## *2.1. Epidemiology and Burden of Disease*

Musculoskeletal disorders describe a range of conditions involving muscle, bone, and connective tissues, and are a common cause of long-term pain and disability.[194] Musculoskeletal injuries present across a broad spectrum of ages and can be acute or chronic in nature: acute injuries are characterized by tearing and hematoma formation after trauma,[120] while chronic injuries result from overuse and aging, as the body loses its ability to heal microtears induced by repeated use. In the United States alone, soft tissue injuries represent 45% of all musculoskeletal injuries.[5]

The burden of musculoskeletal disease is great. A study in over 14,000 Austrian subjects indicated that two-fifths of the population suffered from some type of musculoskeletal disease,[183] while in the United States at least one-third of adults are affected by joint pain, swelling, or limitation of movement.[195] In general, musculoskeletal disorders have low mortality rates but are associated with high morbidity rates, which commonly translate to long-term disability and subsequent lack of physical activity.[118] In one epidemiologic study evaluating musculoskeletal injuries in over 6,000 sedentary and physically active adults, nearly one-third of the population permanently stopped their exercise regimen after injury.[72] Musculoskeletal disorders represent a burden on society in both direct costs to the health care system and indirect costs through loss of work and productivity, including forced early retirement, as well as their impact on the psychosocial status of affected people.[36,118,195]

### 2.1.1. Tendinopathies

While the etiology of tendinopathies are not well-understood,[109] tendinopathy disorders can arise from repetitive motions and overuse of tendons.[4] Tendons are responsible for facilitating movement by connecting bone and muscle, and result in disrupted tissue healing.[110] The pathogenesis of tendinopathies includes a defective healing response, and histologically manifests as tendon enlargement, neovascularization, calcium deposits, and the presence of calfcification.[109] Tendinopathies, also described as tendinosis or tendonitis, can be inflammatory (tendinitis) or non-inflammatory and degenerative in nature (tendinosis).[2] Tendinopathies result in reduced activities of daily living and reduced sports participation;[111] and are estimated to account for 30-50% of all sports-related injuries.[82,86] Additionally, tendinopathy-related pain is not necessarily connected to evident tissue damage.[143] Treatment of tendinopathies can be difficult due to the heterogeneity of cases; tendinopathies are a result of both extrinsic (e.g., work load) and intrinsic (e.g., biomechanics, age) factors, and as such, it has been proposed that tendinopathies exist on a continuum upon which treatment should be based.[31] Further, according to clinical expert input, success of treatment largely depends on the stage of the tendinopathy, with end-stage tendinopathies unlikely to respond to any treatment while earlier stages may be highly responsive to a variety of appropriate treatments.

Tendinopathies included in this report and described in more detail below include lateral epicondylitis, Achilles tendinopathy, patellar tendinopathy, and rotator cuff tendinopathy.

*Lateral Epicondylitis (Tennis Elbow)*

Lateral epicondylitis, colloquially known as tennis elbow, stems from overuse of the extensor carpi radialis muscle and associated tendons through repetitive microtrauma.[40] The term epicondylitis describes chronic tendinosis with little inflammation.[121] Symptoms of elbow epicondylitis include pain and burning lateral to the elbow that radiates to the extensor muscle, weak grip strength, and painful resistance against dorsiflexion of the wrist.[40] A 1998 study in Washington State regarding the incidence of work-related disorders found that the claims rate for elbow epicondylitis was 11.7 claims per 10,000 full-time workers.[165] Several factors have been shown to be associated with an increased risk for lateral epicondylitis. Recreational tennis players develop tennis elbow more frequently than experienced players, due primarily to faulty stroke biomechanics and the use of improper equipment.[40] A study in a Finnish population indicated that smoking, type 2 diabetes, repetitive work tasks involving use of the hands or wrists, and work tasks involving the use of vibrating tools were found to be associated with lateral epicondylitis.[162] Additionally, increased age is a risk factor for lateral epicondylitis, with incidence being highest among those aged 30 to 55.[65]

*Achilles Tendinopathy*

Achilles tendinopathy can from microtears stemming from overuse of the Achilles tendon,[163] although one study has indicated that approximately 2% of cases are caused by chronic diseases such as a rheumatoid arthritis or other inflammatory joint diseases[83] and another study indicated that 30% of their patient population had Achilles tendinopathy not directly associated with activity.[144] Symptoms include pain during and after physical activity, tenderness upon touch, swelling, and stiffness after long periods of inactivity, such as when first waking in the morning.[163] It most commonly affects elite endurance athletes, [97] particularly those involved in track and field, volleyball, badminton, and basketball.[111] It disproportionately affects more men than women (prior to menopause),[30] and is more common in older athletes than younger athletes.[81] Additionally, high body mass index (BMI)[51] and floroquinone use is associated with greater risk of Achilles tendinopathy.[90] It is frequently diagnosed with magnetic resonance imaging (MRI) and ultrasound, although X-rays can be helpful for determining Achilles calcification.[185]

*Patellar Tendinopathy*

Patellar tendinopathy, or Jumper's Knee, is another condition resulting from overuse that describes inflammation or injury to the tendon that attaches either the thigh or lower leg bones to the kneecap.[139] Common among athletes in sports that require repeated jumping, such as volleyball or basketball,[50] it is estimated to have an incidence of around 20% in this population.[81] Ultrasound is more accurate than MRI for diagnosing patellar tendinopathy.[191]

*Rotator Cuff Tendinopathy*

The etiology of rotator cuff tendinopathy is unclear, but is caused by a combination of intrinsic and extrinsic factors.[116] It can be caused by shoulder impingement, which leads to a diminished vascular supply resulting in inflammation and degeneration of the tendon.[13,178] Symptoms of a rotator cuff tendinopathy are dull, increasing pain the area of the four rotator cuff tendons and tenderness in the shoulder-joint, especially when reaching overhead (person is unable to reach higher than 90 degrees abduction) and behind the back, lifting and sleeping on the affected side; the pain is often associated with growing weakness of the shoulder. It is common in swimmers,[87,89] elderly athletes,[89] patients who

are wheelchair-bound,[87] and patients with high BMI.[51] Conservative methods, such as rest, ice, medication and physical therapy, are often sufficient to treat rotator cuff tendinopathies; however, some injuries may be severe enough that surgery is required.

*Plantar Fasciitis*

Plantar fasciitis describes typically bilateral inflammation or irritation in the fascia covering the heel due to repetitive strain and microtears[196] from activities such as long periods of standing or a sudden increase in exercise. Symptoms include severe morning plantar heel pain that eases with activity but then increases throughout the day, as well as tenderness upon palpitation.[166] Risk factors include spending large amounts of time on one's feet, unaccustomed running,[166] limited ankle mobility, obesity, and diabetes mellitus.[38,141] Plantar fasciitis accounts for over 800,000 hospital visits annually in the United States.[142] Most cases respond to conventional treatment,[80] which includes pain medication, stretching, and orthotics.

*Greater Trochanteric Pain Syndrome (GTPS)*

Greater trochanteric pain syndrome is characterized by chronic lateral hip pain exacerbated by resistive hip abduction, passive hip adduction and palpation.[88,173] GTPS is more prevalent in the fourth to sixth decades of life. In one study of community dwellers ages 50 to 79 years, the prevalence of GTPS was nearly 18%.[161] Once thought to be limited to trochanteric bursitis, GTPS is now recognized as pain in the region in which the etiology is not fully known. Pain generators may be associated with the gluteus maximus, medius or minimus bursae; musclotendinous attachments; or the iliotibial band.[14,103] Most cases respond to conservative treatment, however recurrence is not uncommon.[193] Surgical intervention for refractory cases has been reported in several small case series.[44,113]

### 2.1.2. Osteoarthritis

Osteoarthritis (OA) describes chronic degenerative joint disease that results from the breakdown of cartilage and bone. At the molecular level, cytokines and inflammatory mediators are released and chondrocytes are activated during osteoarthritis, releasing a multitude of signaling molecules causing restructuring of the surrounding tissue and bone.[174] As of 2010, osteoarthritis was ranked as the 11$^{th}$ leading cause in the world for years lived with disability (YLDs) and overall is the third most prevalent musculoskeletal disorder, accounting for an estimated 17.1 million YLDs.[184]

*Osteoarthritis of the Knee*

Osteoarthritis of the knee is the most common presentation of OA. Symptoms include knee pain, stiffness, swelling, and decreased range of motion. The 2010 Global Burden of Disease project indicated that 3.64% of the world population has knee OA, with the disease being more prevalent in women (4.75%) than men (2.56%); this gender differential was confirmed in a 2010 systematic review.[15] In 2000, it was estimated that 40% of people over 70 have osteoarthritis of the knee.[128] Additional risk factors include age, obesity, prior injury, and repetitive use.[15,140]

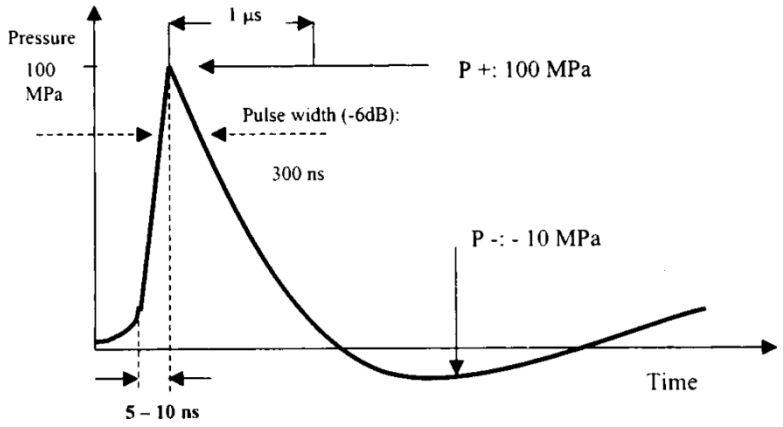
*Osteoarthritis of the Hip*

Hip osteoarthritis can be characterized by sharp or dull hip pain, stiffness, joint deformity, and reduced range of motion.[102] Risk factors include previous hip disorders, trauma, or obesity.[102] Hip osteoarthritis is the second most prevalent manifestation of osteoarthritis after the knee.[10]

## *2.2. Technology: Extracorporeal Shock Wave Therapy*

Extracorporeal shock waves are pressure waves that propagate in three dimensions. They can travel through gas, liquids and solids. A shockwave is a special, non-linear type of pressure wave characterized by a very rapidly rising positive pressure impulse (from 5 to 120 MPa in around 5 ns) followed by a negative pressure of -20 MPa.[122,149] The total duration of a shockwave is around 10 μs.[18,182] Both the positive and the negative phase of a shockwave can have an effect on interfaces between tissues with different density (acoustic impedance).[182] Shockwaves with high pressure may hit a tissue interface during the positive phase and can be reflected or pass through to gradually become absorbed. The negative phase of the shockwave causes "cavitation bubbles" at the tissue interfaces. These bubbles burst with high speed, generating a second wave of shockwaves known as microjets.[122,127,182]

**Figure 2. Characteristics of therapeutic shock waves.[127]**

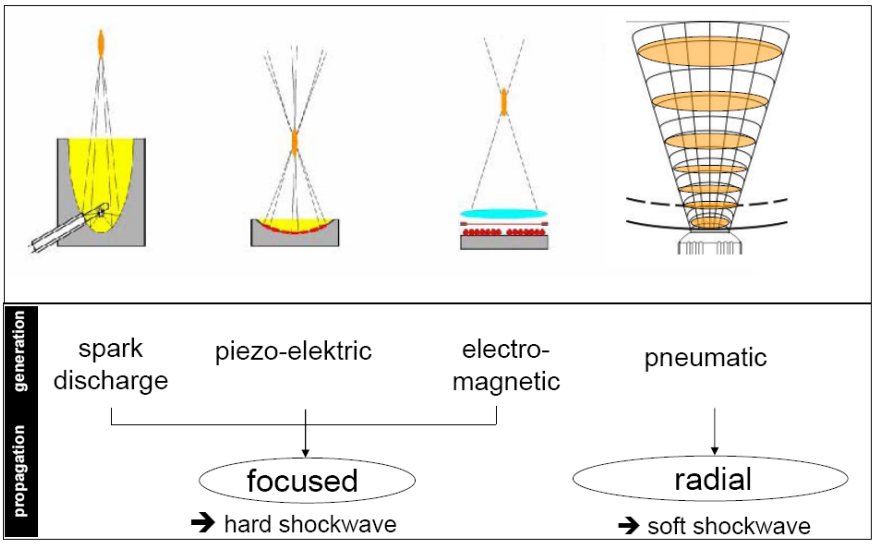



There are three main techniques through which focused shockwaves are generated; electrohydraulic, electromagnetic, and piezoelectric.[186] Focused extracorporeal shockwave therapy (FESWT) is called focused because a pressure field is generated that converges at selected depth in the body tissue. Each technology produces a pulse that breaks the speed of sound, thereby creating a shockwave. The three techniques all generate waves in water inside their applicators.[182] Electrohydraulic principle represents the first generation of orthopedic shockwave machines. Electrohydraulic shockwaves are high-energy acoustic waves generated by the underwater explosion with high-voltage electrode spark discharge, with the shock waves focused by an ellipsoid reflector.[127] Electromagnetic shockwave is generated through an electromagnetic technique of passing an electric current through a coil to produce a strong magnetic field. A lens is used to focus the waves, with the focal point being defined by the length of the focus lens. The piezoelectric shockwave is generated by an electric pulse, and the shockwave focused by thousands of small crystals in the applicator head. The arrangements of the crystals cause self-focusing of the waves toward the target center.

A fourth technology, radial shockwave therapy (RESWT) is generated by compressed air that strikes a bullet contained in a cylinder.[182] Radial shock waves differs from focused shockwaves in two important ways. First, in order for an energy wave to called a shockwave, it must travel faster than the speed of sound (1500 m/sec). At this speed, the “shock” wave is generated.[182] In contrast, RESWT travel only around 10 m/sec, markedly slower than a shockwave. Second, the wave form produced by RESWT is

slower, less intense, elongated and sinusoidal in appearance compared with FESWT. Third, the energy produced by the pressure wave is highest at the skin surface and then diverges and weakens as it penetrates deeper. Energy produced by FESWT, as mentioned above, converges to a focal point at varying tissue depths.[182]

**Figure 3. Four techniques to generate therapeutic shock waves.**




The most common standardized measurement of energy intensity in the field is referred to as "energy flux density", expressed in millijoules per millimeter (mJ/mm2).[78] Energy flux density can be defined as the amount or concentration of energy in the focus area. In addition to the energy flux density, the impulse frequency is a parameter that can be manipulated. The impulse frequency is the number of shockwaves that is applied per second. The impulse frequency and with the energy flux density provide a total amount of energy at the focal point.[186] The level of energy is referred to as high, medium or low; however, there is little consensus among investigators as to what constitutes these categories. One author's "high energy" setting may be a "low energy" setting to a different author.

### 2.2.1. Mechanism of Action

The mechanism of action of ESWT in tendinopathies is not fully understood. Several mechanisms have been described in explaining the effects of ESWT. One such mechanism includes neovascularization. Wang et al[187] showed that the number of neovessels increase at the normal tendon–bone junction after shock wave treatment. New capillary and muscularized vessels were seen in rabbit Achilles tendon specimens obtained 4 and 8 weeks after shock wave application.[189] This ingrowth was associated with early release of angiogenesis- related markers. Furthermore, myofibroblasts with haphazard appearance and intermediate orientation fibers were seen in those animals receiving shock wave. There is some evidence that ESWT may enhance tendon repair through the stimulation and increase of growth factors TGFb1 and IGF-I.[3] These growth factors appear to be capable of stimulating cell proliferation and matrix metabolism in tendon tissue. In addition, it has been shown that TGF-b1 acts as an inhibitor of macrophages-induced extracellular matrix degradation and inflammation during wound healing.[49] Tenocytes can respond to mechanical stimulation by increasing TGF-b1 gene expression.[9]

These findings suggest that tendon tissue can convert shock wave stimulation into biochemical signals via release of TGF-b1 and IGF-I for tendinitis repair.[3,9]

In a study on the effect of ESWT on Shetland ponies, Bosch et al[16] reported an increase in glycosaminoglycan and protein synthesis 3 hours after treatment. The level of degraded collagen was increased as well. However, 6 weeks after treatment, there was a decrease of glycosaminoglycan and degraded collagen. The authors concluded that the stimulating short-term effect of ESWT might accelerate the initiation of the healing process in injured tendons. The effect of ESWT on normal fibroblasts was investigated by Berta et al.[12] The investigators, in an in vitro study of human fibroblasts, demonstrated an increase in fibroblast proliferation 6-9 days after shock wave administration. mRNA expression was higher in treated fibroblasts than in untreated controls for TGFbeta-1 on day 6 and day 9, for collagen type I on day 6, and for collagen type III on day 9. These data support the contention that ESWT activates factors involved in the repair process of connective tissue.

### 2.2.2. ESWT procedures

Techniques for using extracorporeal shock wave therapy for musculoskeletal problems have not yet been standardized and the precise dosages and the optimal frequency of application are still being investigated. Some use local anesthesia in conjunction with ESWT due to pain and discomfort associated with the treatment. However, there is debate as to whether anesthesia should be used. Some investigators suggest that ESWT is less effective when used in the presence of local anesthesia.[152] For example, it has been shown that ESWT dose-dependently activates and sensitizes primary afferent nociceptive C-fibers, and that both activation and sensitization were prevented if local anesthesia was applied.[92] This suggests that local anesthesia alters the biological responses of ESWT. It is unclear whether the application ESWT should be directed to the site of pathology or on the site of maximal tenderness. If directed to the site of pathology, fluoroscopic or ultrasound guidance is used to identify the area to be treated. If directed on the site of maximal tenderness, patient response to pressure determines the area to be treated.[151]

### 2.2.3. Consequences and adverse events

Commonly reported side effects or adverse events of ESWT include pain during and shortly after the intervention, local edema, erythema, paresthesia and bruising. Contraindications against ESWT include use over or near bone growth center until bone growth is complete, malignancy in or near the treatment area, infection in the area to be treated, coagulation disorder or taking anti-coagulant medications, prosthetic device in the area to be treated, over ischemic tissues in individuals with vascular disease, nerve or nerve root irritation, pregnancy and pacemakers[1,25]

### 2.2.4. Comparator Treatments

Common comparator treatments in clinical trials evaluating ESWT include exercise, corticosteroid injections, needling with lavage, transcutaneous nerve stimulation, surgery, and exercise.

#### 2.2.4.1. Corticosteroid injections

Injectable corticosteroids are commonly used to treat pain and inflammation and improve mobility in individuals with musculoskeletal disorders. Disorders frequently treated with corticosteroids include rheumatic arthritis, synovitis, bursitis, epicondylitis, tendonitis, and fasciitis.[17] Corticosteroids are thought to interfere with the inflammatory and immune response of synovial tissues at several response levels, although the complete mechanism is not yet fully understood.[7,27]Injections may be delivered to the intra- or extra-articular space, although intra-articular injections are more commonly used and more

widely studied.[27] Five corticosteroids have been approved by the FDA for intra-articular injections: methylprednisolone acetate, triamcinolone acetate, betamethasone acetate, betamethasone sodium phosphate, triamcinolone hexacetonide and dexamethasone.[7] For the treatment of knee osteoarthritis, the American College of Rheumatology generally recommends the use of intra-articular corticosteroids,[71] although there is little evidence to support their use in the long term.[11]

#### 2.2.4.2. Needling with Lavage (barbotage)

Needling denotes the process of repeatedly passing a needle through the tendon to disrupt collagen fibers and induce bleeding without injecting any substance.[79] Needling with lavage (barbotage) is used to treat calcific tendinopathy by guiding a needle under ultrasound imaging into the calcification. Attempt to aspirate/withdraw calcification is made. The tendon is then bathed in saline and local anaesthetic.[41,42]

#### 2.2.4.3. Transcutaneous Electrical Nerve Stimulation (TENS)

Transcutaneous electrical nerve stimulations (TENS) is a pain-management tool that acts by producing low-voltage electrical currents in the skin. These currents are thought to alter pain signals in the nervous system, providing relief. TENS is often used in patients with knee osteoarthritis and chronic musculoskeletal pain, and has been shown to be successful in the short-term for knee osteoarthritis pain relief. [22] It has not shown efficacy in the treatment of tendinopathy of the elbow[23] or shoulder.[43] TENS is considered safe if used properly; serious adverse events are rare.[85]

#### 2.2.4.4. Surgery

Common surgical techniques for musculoskeletal disorders include decompression and debridement for tendinopathies; and arthroscopy, arthroplasty, and osteotomy in osteoarthritis. Surgery is usually the last option for tendinopathy treatment, as failure rates for debridement and/or decompression are has high as 20% to 30%.[4]

#### 2.2.4.5. Exercise

Among those with knee osteoarthritis, land-based exercise has been shown to provide short-term but not long-term improvements in pain and physical function, and short-term improvements in quality of life.[52] For patients with hip osteoarthritis, exercise is effective at reducing pain and improving physical function in both the short- and long-term.[53]

Additionally, eccentric exercises, which cause muscle lengthening during excessive loading,[105] are also used in conservative care protocols for musculoskeletal injuries. Eccentric exercise protocols are used in treatment of lateral elbow epicondylitis, patellar tendinopathy, and Achilles tendon injuries, and shoulder tendinopathy.[54] Although more high-quality RCTs are needed to prove the effectiveness of eccentric exercise for treatment of these conditions, eccentric exercise is a cost-effective and feasible treatment option.[54]

## *2.3. Clinical Guidelines*

The National Guideline Clearhouse (NGC), PubMed, and Google Scholar were searched for guidelines related to the use of ESWT in patients with elbow epicondylitis, plantar fasciitis, shoulder tendinopathy (rotator cuff, subacromial/nonspecific pain, frozen shoulder), Achilles tendinopathy, patellar tendinopathy, or osteoarthritis of the knee. Key word searches were performed: (“ESWT”) OR

("extracorporeal shock wave therapy") OR ("extracorporeal shockwave therapy") OR ("shock wave therapy"). Eight guidelines were identified.

Guidelines from the following sources are summarized:

- American Academy of Family Practice
- American College of Foot and Ankle Surgeons
- American College of Occupational and Environmental Medicine (ACOEM)
- Colorado Division of Workers Compensation
- Dutch Orthopedic Association

Details of each included recommendation for the use of ESWT for the treatment of elbow epicondylitis, plantar fasciitis, shoulder tendinopathy (rotator cuff, subacromial/nonspecific pain, frozen shoulder), Achilles tendinopathy, patellar tendinopathy, or osteoarthritis of the knee, including the class/grade of recommendation and level of evidence, can be found in Table 2.
A summary of the guidelines from available full-texts from the more prominent organizations in which the level of recommendation was evaluated is provided below.

**Plantar Fasciitis**

**American College of Foot and Ankle Surgeons, 2010:** *The Diagnosis and Treatment of Heel Pain:* ESWT is recommended for the treatment of chronic plantar heel pain, but only after failing ≥6 months of other treatments.

**American College of Occupational and Environmental Medicine (ACOEM), 2011:** *Occupational medicine practice guidelines:* ESWT is recommended for chronic plantar fasciitis in select patients with chronic recalcitrant conditions.

**Tendinopathies**

**American College of Foot and Ankle Surgeons, 2010:** *The Diagnosis and Treatment of Heel Pain:* ESWT is recommended for the treatment of Achilles tendinopathy.

**American College of Occupational and Environmental Medicine (ACOEM), 2011:** *Occupational medicine practice guidelines:* Extracorporeal shock wave therapy is recommended for the treatment of calcific rotator cuff tendinitis and chronic recalcitrant Achilles Tendinopathy; it is not recommended for chronic lateral epicondyalgia. The ACOEM has no recommendation for use in patellar tendinosis.

**Colorado Division of Workers Compensation, 2015:** *Shoulder Injury Medical Treatment Guidelines:* ESWT is indicated for patients with calcific tendinitis of the shoulder who have not achieved functional goals after 2-3 months of active therapy.

**Dutch Orthopedic Association, 2014:** *Guideline for the Diagnosis and Treatment of Subacromial Pain Syndrome: A multidisciplinary review:* High-energy ESWT is recommended for the treatment of chronic subacromial calcific tendinopathy; it is not recommended for non-calcific tendinopathy or for acute cases.

**Knee Osteoarthritis**
No Clinical Guidelines identified.

**Table 2. Summary of Clinical Guidelines**

| Guideline | Evidence Base | Recommendation | Rating/ Strength of Recommendation |
|---|---|---|---|
| **American College of Occupational and Environmental Medicine (ACOEM)**<br><br>Occupational medicine practice guidelines (2011)<br><br>Shoulder Disorders | NR | ESWT is strongly recommended for calcific rotator cuff tendinitis. | Strongly recommended (A)* |
| **American College of Occupational and Environmental Medicine (ACOEM)**<br><br>Occupational medicine practice guidelines (2011)<br><br>Ankle and Foot Disorders | NR | ESWT is not recommended for acute, sub-acute, or post-operative Achilles Tendinopathy.<br><br>ESWT is recommended as an adjunct to eccentric exercise for chronic, recalcitrant Achilles Tendinopathy.<br><br>ESWT is recommended for chronic plantar fasciitis in select patients with chronic recalcitrant conditions. | Insufficient- Not Recommended (Consensus-based) (I)*<br><br>Recommended (C)*<br><br>Insufficient- Recommended (Consensus-based) (I)* |
| **American College of Occupational and Environmental Medicine (ACOEM)**<br><br>Occupational medicine practice guidelines (2012)<br><br>Elbow Disorders | NR | ESWT is not recommended for acute, subacute, or chronic lateral epicondylalgia. | Strongly Not Recommended (A)* |
| **American College of Occupational and Environmental Medicine (ACOEM)**<br><br>Knee disorders | NR | The ACOEM has no recommendation on ESWT for patellar tendinosis. | Insufficient- No Recommendation (Consensus-based) (I)* |

| Guideline | Evidence Base | Recommendation | Rating/ Strength of Recommendation |
|---|---|---|---|
| **Colorado Division of Workers' Compensation**<br><br>Shoulder Injury Medical Treatment Guidelines (2015) | 105 studies, type NR | Indications for use of ESWT include:<br>• Patients with calcific tendinitis who have not achieved functional goals after 2-3 months of active therapy<br>Calcium deposits must be Type I, homogenous calcification with well-defined borders, or Type II, heterogeneous with sharp borders or homogeneous with no defined border | NR |
| **Dutch Orthopedic Association**<br><br>Guideline for the Diagnosis and Treatment of Subacromial Pain Syndrome: A multidisciplinary review by the Dutch Orthopedic Association (2014) | NR | High-energy extracorporeal shockwave therapy (ESWT) is more effective than placebo in reducing pain and improving shoulder function in patients with tendinosis calcarea.<br><br>ESWT (all forms) is no more effective than placebo or other treatments in reducing pain or in improving shoulder function of patients without calcium deposition in the tendons<br><br>Use of high-energy ESWT can be considered for proven subacromial calcium deposits. ESWT is not recommended in the acute phase. | Level 1† |
| **American Academy of Family Practice**<br><br>Common Overuse Tendon Problems: Review and Recommendation for Treatment (2005) | 1 animal study, 1 RCT | Extracorporeal shock wave therapy appears to be a safe, noninvasive, effective but expensive means of pain relief for a number of chronic tendinopathies. | Grade B‡ Recommendation |
| **American College of Foot and Ankle Surgeons**<br><br>The Diagnosis and Treatment of Heel Pain (2010) | Plantar Heel Pain<br>30 studies, type NR<br><br>Achilles Conditions<br>4 studies, type NR | ESWT is recommended for the treatment of chronic plantar heel pain, but only after receiving at least six months of other treatments (e.g., home physical therapy, corticosteroid injections, night splits, etc.).<br><br>ESWT is recommended for the treatment of Achilles enthesopathy and Tendinopathy | Grade B§ Recommendation<br><br>Grade B§ Recommendation |

ESWT: Extracorporeal shockwave therapy; NR: not reported; RCT: Randomized Controlled Trial
*American College of Occupational and Environmental Medicine Strength of Recommendations:
Strongly Recommended (A): The intervention is strongly recommended for appropriate patients. The intervention improves important health and functional outcomes based on high quality evidence, and the Evidence-Based Practice Panel (EBPP) concludes that benefits substantially outweigh harms and costs.

Moderately Recommended (B): The intervention is recommended for appropriate patients. The intervention improves important health and functional outcomes based on intermediate quality evidence that benefits substantially outweigh harms and costs.
Recommended (C): The intervention is recommended for appropriate patients. There is limited evidence that the intervention may improve important health and functional benefits.
Insufficient- Recommended (Consensus-based) (I): The intervention is recommended for appropriate patients and has nominal costs and essentially no potential for harm. The EBPP feels that the intervention constitutes best medical practice to acquire or provide information in order to best diagnose and treat a health condition and restore function in an expeditious manner. The EBPP believes based on the body of evidence, first principles, or collective experience that patients are best served by these practices, although the evidence is insufficient for an evidence-based recommendation.
Insufficient- No Recommendation (Consensus-based) (I): The evidence is insufficient to recommend for or against routinely providing the intervention. The EBPP makes no recommendation, Evidence that the intervention is effective is lacking, of poor quality, or conflicting and the balance of benefits, harms, and costs cannot be determined.
Insufficient- Not Recommended (Consensus-based) (I): The evidence is insufficient for an evidence-based recommendation. The intervention is not recommended for appropriate patients because of high costs or high potential for harm to the patient.
Not Recommended (C): Recommendation against routinely providing the intervention. The EBPP found at least intermediate evidence that harms and costs exceed benefits based on limited evidence.
Moderately Not Recommended (B): Recommendation against routinely providing the intervention to eligible patients. The EBPP found at least intermediate evidence that the intervention is ineffective, or that harms or costs outweigh benefits.
Strongly Not Recommended (A): Strong recommendation against providing the intervention to eligible patients. The EBPP found high quality evidence that the intervention is ineffective, or that harms or costs outweigh benefits.
† Dutch Orthopedic Association Strength of Recommendations:
Level 1: For therapeutic intervention studies: high-quality studies. For diagnostic accuracy research or prognosis, etiology or side effects: A1-level study or at least 2 independently conducted A-2 level studies.
Level 2: For therapeutic intervention studies: moderate-quality studies. For diagnostic accuracy research or prognosis, etiology or side effects: one A2-level study or at least 2 independently conducted B-level studies.
Level 3: For therapeutic intervention studies: low-quality studies. For diagnostic accuracy research or prognosis, etiology or side effects: one B-level study or at least 2 independently conducted C-level studies.
Level 4: For therapeutic intervention studies: very low-quality studies. For diagnostic accuracy research or prognosis, etiology or side effects: one C-level study.
‡ American Academy of Family Practice (AAFP) Strength of Recommendation Taxonomy (SORT):
A: Consistent, good-quality, patient-oriented evidence
B: Inconsistent or limited-quality, patient-oriented evidence
C: Consensus, disease- oriented evidence, usual practice, expert opinion, or case series.
§American College of Foot and Ankle Surgeons Grades of Recommendations:
Grade A: Treatment options are supported by strong evidence (consistent with Level I or II studies).
Grade B: Treatment options are supported by fair evidence (consistent with Level III or IV studies).
Grade C: Treatment options are supported by either conflicting or (Level IV studies).
Grade I: Insufficient evidence to make a recommendation.

## *2.4. Previous Systematic Review/Technology Assessments*

Health Technology Assessments (HTAs) were found by searching for *"ESWT" OR "Extracorporeal shockwave therapy" OR "Extracorporeal shock wave therapy"* in PubMed, the University of York Centre for Reviews and Dissemination database, the NICE Guidance Database, Canadian Agency for Drugs and Technology in Health (CADTH) and Google Scholar. A total of seven HTAs were identified: five report on PRP, one reports on ABI, and one reports on both PRP and ABI (Table 3). The following provides a summary of outcomes from HTAs in which the strength of evidence for each conclusion was evaluated. None of the included SRs and HTAs provided levels of recommendations for their evidence base.

Systematic reviews were found by searching PubMed using the search strategies in Appendix B**.** A total of six systematic reviews were summarized (Table 4): one reported on autologous blood injection (ABI) and six reported on platelet rich plasma (PRP) injections.

**Table 3. Previous Health Technology Assessments**

| Assessment (year) | Search Dates | Diagnosis | Treatments Evaluated | Evidence Base Available | Primary Conclusions | Critical Appraisal |
|---|---|---|---|---|---|---|
| **NICE Interventional Procedure Programme (2011)**<br><br>National Institute for Health and Care Excellence (NICE)<br><br>*Extracorporeal shockwave therapy for refractory greater trochanteric pain syndrome* | Database inception—September 28, 2010 | Refractory greater trochanteric pain syndrome | ESWT | 2 non-randomized comparative studies, 2 case series | This procedure should only be used with special arrangements for clinical governance, consent, and audit or research<br><br>**Efficacy:** Evidence on the efficacy of ESWT for refractory greater trochanteric pain syndrome is limited in quality and quantity<br>• One non-randomized comparative study reported an increased proportion of patients who had either completely recovered or had improved symptoms<br>• A non-randomized comparative study reported significantly higher mean pain scores in ESWT compared to an injection group<br>• A non-randomized comparative study reported significantly lower mean pain scores, a significantly higher proportion of patients with excellent or good scores, and significantly higher mean Harris hip scores in the ESWT group compared to the non-operative therapy group<br><br>**Safety:** Evidence on the safety of ESWT for refractory greater trochanteric pain syndrome is limited in quality and quantity<br>• A non-randomized comparative study reported that a lower percentage of patients that received ESWT experienced increased pain and a comparable percentage of patients experienced adverse events related to ESWT in comparison to the home-training and injection groups<br>• One non-randomized comparative study reported a significantly higher percentage of patients in the ESWT group experienced irritated skin compared to an injection group<br><br>**Economic:** NR<br><br>**Future Research:** NR | NR? |
| **NICE Interventional Procedure Programme (2009)** | Database inception—April 23, 2009 | Refractory tennis elbow | ESWT | 7 RCTs, 10 studies (type NR) | This procedure should only be used with special arrangements for clinical governance, consent, and audit or research | NR? |

| Assessment (year) | Search Dates | Diagnosis | Treatments Evaluated | Evidence Base Available | Primary Conclusions | Critical Appraisal |
|---|---|---|---|---|---|---|
| National Institute for Health and Care Excellence (NICE)<br><br>*Interventional procedure overview of extracorporeal shockwave therapy for refractory tennis elbow* | | (lateral epicondylitis) | | | **Efficacy:** The current evidence on the efficacy of ESWT is inconsistent<br>• One RCT found no difference in success rates between ESWT and sham ESWT<br>• An RCT reported higher treatment success in patients that received a steroid injection compared to the ESWT group<br>• One RCT reported comparable percentages of patients that experienced a 50% improvement in VAS score between ESWT and sham ESWT groups<br><br>**Safety:** ESWT for refractory tennis elbow raises no major safety concerns<br>• Two RCTs found that higher percentages of patients reported pain in ESWT groups than in sham ESWT groups<br>• One RCT reported a higher occurrence of transient skin reddening in ESWT patients compared with sham ESWT patients<br>• An RCT found comparable reports of local reaction (not otherwise described) between ESWT and shame ESWT groups but a higher percent of reported nausea in patients that received ESWT | |
| **NICE Interventional Procedure Programme (2009)**<br><br>National Institute for Health and Care Excellence (NICE)<br><br>*Interventional procedure overview of extracorporeal shockwave therapy for refractory Achilles tendinopathy* | Database inception—April 23, 2009 | Achilles tendinopathy | ESWT | 4 RCTs, 2 case-control studies, 1 case series, 1 SR, 2 studies (type NR) | This procedure should only be used with special arrangements for clinical governance, consent, and audit or research<br><br>**Efficacy:** The current evidence on the efficacy of ESWT is inconsistent<br>• One RCT found statistically similiar improvement in patient assessed recovery and Achilles tendon function between patients receiving ESWT and eccentric loading<br>• An RCT reported statistically better self-rated recovery, tenderness, and pain in ESWT patients compared to eccentric loading patients<br>• Two RCTs found no significant differences in outcome measures between ESWT and sham ESWT patients | |

| Assessment (year) | Search Dates | Diagnosis | Treatments Evaluated | Evidence Base Available | Primary Conclusions | Critical Appraisal |
|---|---|---|---|---|---|---|
| | | | | | **Safety:** ESWT for refractory tennis elbow raises no major safety concerns<br>• One RCT reported transient skin reddening in all ESWT patients<br>• In one of the case-control studies, two patients had pain during ESWT and one had transient numbness | |
| **NICE Interventional Procedure Programme (2009)**<br><br>National Institute for Health and Care Excellence (NICE)<br><br>*Interventional procedure overview for extracorporeal shockwave therapy for refractory plantar fasciitis* | Database inception—April 23, 2009 | Refractory plantar fasciitis | ESWT | 7 RCTs, 1 cross-sectional survey, 1 retrospective review, 1 study (type NR) | This procedure should only be used with special arrangements for clinical governance, consent, and audit or research<br><br>**Efficacy:** The current evidence on the efficacy of ESWT is inconsistent<br>• A higher percentage of ESWT patients reported treatment success compared to sham ESWT patients in 2 RCTs<br>• In 2 RCTs, pain scores decreased more for ESWT patients than sham ESWT patients<br>• One RCT reported no statistical difference between ESWT and sham ESWT in the change of pain from baseline<br>• An RCT comparing ESWT and CSI found the two groups had similar pain reduction over 12 months<br><br>**Safety:** ESWT for refractory tennis elbow raises no major safety concerns<br>• One RCT reported a higher percent of ESWT patients experienced skin reddening than sham ESWT patients but both groups had a comparable percentage of patients that experienced pain<br>• In one RCT, a significantly higher number of patients in the ESWT group experienced adverse events in comparison to sham ESWT patients<br>• Comparing ESWT to CSIs, one RCT found comparable rates of adverse events between groups | NR? |

CSI, corticosteroid injection; ESWT, extracorporeal shock wave therapy; NICE, National Institute for Health and Care Excellence; NR, not reported; RCT, randomize control trial; SR, systematic review;

**Table 4. Selected Previous Systematic Reviews**

| SR, Search dates | Purpose | Condition | Comparison | Primary Outcomes | Evidence Base | Risk of Bias Assessed | Quantitative Synthesis | Primary Conclusions |
|---|---|---|---|---|---|---|---|---|
| Mani-Babu (2015)<br>Database inception to February 2013<br>PubMed, EMBASE, Web of Knowledge, Cochrane, CINAHL | To evaluate the effectiveness of ESWT for lower limb tendinopathies | Greater trochanteric pain syndrome | ESWT vs. rest, anti-inflammatory medication, stretching, strengthening exercises, CSIs, home training, or home training | Function<br>Degree or recovery (Likert scale), RM<br><br>Pain<br>VAS | 1 RCT and 1 case control | Yes | No | Function<br>Data suggests that ESWT was superior to various non-operative interventions in restoring function.<br><br>Pain<br>ESWT was superior to various non-operative interventions in pain reduction. ESWT produced inferior outcomes at 1 month but superior outcomes beyond 12 months in comparison to CSIs<br><br>Overall: ESWT is a viable short and long term treatment option for GTPS |
| Mani-Babu (2015)<br><br>Database inception to February 2013<br><br>PubMed, EMBASE, Web of Knowledge, Cochrane, CINAHL | To evaluate the effectiveness of ESWT for lower limb tendinopathies | Patellar tendinopathy | ESWT vs. placebo, knee strap, surgery, NSAIDs, exercise programs, modification of activity | Function<br>VISA-P, vertical jump test, RM, US assessment<br><br>Pain<br>VAS | 3 RCTs, 2 prospective studies, 1 retrospective study, 1 case control, | Yes | No | Function<br>One RCT found a significant improvement in function in patients that received ESWT in comparison to placebo. Two prospective studies found that ESWT was comparable to surgery and better than non-operative treatments in improving function over the short term. One RCT did not find a difference in function outcomes between treatment groups.<br><br>Pain |

| SR, Search dates | Purpose | Condition | Comparison | Primary Outcomes | Evidence Base | Risk of Bias Assessed | Quantitative Synthesis | Primary Conclusions |
|---|---|---|---|---|---|---|---|---|
| | | | | | | | | Long term data from a prospective study suggests that ESWT was comparable to surgery and better than non-operative treatments in reducing pain. Two prospective studies found that ESWT was comparable to surgery and better than non-operative treatments in reducing pain over the short term.<br><br><u>Overall</u>: Evidence is limited but the data indicates that ESWT may be a promising short and long term treatment option for treating PT |
| Mani-Babu (2015)<br>Database inception to February 2013<br>PubMed, EMBASE, Web of Knowledge, Cochrane, CINAHL | To evaluate the effectiveness of ESWT for lower limb tendinopathies | Achilles tendinopathy | ESWT vs. rest, footwear modification, anti-inflammatory medication, gastrocnemius-soleus stretching and strengthening, eccentric loading | <u>Function</u><br>VISA-P, vertical jump test, AOFAS, Functional Index of Lower Limb, EQoL, RM<br><br><u>Pain</u><br>VAS<br><br><u>Quality of life</u><br>EQoL | 5 RCTs, 4 prospective studies, 2 case controls | Yes | No | <u>Function</u><br>Although evidence was limited, 7 studies found that ESWT produced greater short and long term improvements in function compared to non-operative treatment, with the exception of one short-term RCT. Three short term RCTs comparing ESWT and eccentric loading indicated dependency of success based on type of AT[i]. One RCT found that combining ESWT and eccentric loading showed significantly greater improvement in function than eccentric loading alone<br><br><u>Pain</u> |

| SR, Search dates | Purpose | Condition | Comparison | Primary Outcomes | Evidence Base | Risk of Bias Assessed | Quantitative Synthesis | Primary Conclusions |
|---|---|---|---|---|---|---|---|---|
| | | | | | | | | With the exception of one short-term RCT studies found that ESWT produced greater short and long term reduction in pain compared to non-operative treatment, however evidence was limited. One RCT found that combining ESWT and eccentric loading showed significantly greater reduction in pain than eccentric loading alone<br><br><u>Quality of Life</u><br>NR<br><br><u>Overall</u><br>Overall, the results indicate that ESWT Is an effective short-term intervention for AT and can be used as an alternative to other non-operative interventions. Combining ESWT and eccentric loading should be considered in clinical practice |
| Bannuru (2014)<br><br>Database inception—November 1, 2013 | To assess the efficacy of ESWT in patients with calcific and noncalcific tendinitis | Shoulder tendinitis | High energy vs low energy ESWT, ESWT vs placebo, exercise, radiation therapy, TENS, | <u>Function</u><br>Constant-Murley score, ROM, Shoulder Pain and Disability Index, UCLA Shoulder Rating | 28 RCTs | Yes | Yes | <u>Function</u><br>7 RCTs reported on function outcomes in high and low energy ESWT vs placebo and all seven found that both high and low energy ESWT improved function significantly over placebo. In 8 RCTs comparing low vs high energy ESWT, high energy ESWT |

| SR, Search dates | Purpose | Condition | Comparison | Primary Outcomes | Evidence Base | Risk of Bias Assessed | Quantitative Synthesis | Primary Conclusions |
|---|---|---|---|---|---|---|---|---|
| MEDLINE, Web of Science, the Cochrane Central Register of Controlled Trials, EMBASE, Google scholar | | | | Scale (function subscale)<br><br><u>Pain</u><br>VAS<br><br><u>Calcification resolution</u><br>Measured radiographically or sonographically<br><br><u>Adverse Events</u><br>Petechiae, local erythema, small bruises and hematomas, acute pain | | | | improved shoulder function significantly more than low-energy ESWT. 1 RCT found significant improvement in function with ESWT over placebo with noncalcific tendinitis while 2 RCTs found no difference. Results of 3 RCTs suggested that function outcomes may be dose dependent.<br><br><u>Pain</u><br>7 RCTs reported on pain outcomes in high and low energy ESWT vs placebo and all seven found that high energy ESWT reduced pain significantly more than placebo. Results for low energy ESWT on pain outcomes were inconclusive. 5 trials comparing high energy vs low energy ESWT found no difference in pain outcomes. Results of 3 RCTs suggested that pain outcomes may be dose dependent.<br><br><u>Calcification Resolution</u><br>5 RCTs reported on calcification resolution in high and low energy ESWT vs placebo and found that reduction of calcification was significantly greater in high energy ESWT than in placebo whereas results |

| SR, Search dates | Purpose | Condition | Comparison | Primary Outcomes | Evidence Base | Risk of Bias Assessed | Quantitative Synthesis | Primary Conclusions |
|---|---|---|---|---|---|---|---|---|
| | | | | | | | | for low energy ESWT were inconclusive. In 8 RCTs comparing low vs high energy ESWT, high energy EWST seemed to be more efficient in resolving calcium deposits.<br><br>Adverse Events<br>NR<br><br>Overall<br>High energy ESWT was effective for the treatment of calcific tendinitis of the shoulder in terms of reducing pain, improving function, and inducing resorption of calcifications. Low energy ESWT was not as effective as high energy ESWT but it did improve shoulder function in patients with calcific tendinitis. ESWT did not seem to effectively treat noncalcific tendinitis. |
| Buchbinder (2006)<br><br>Database inception—August 2006 | To determine the effect of ESWT as a treatment for lateral epicondylitis | Lateral epicondylitis | ESWT vs placebo, CSI | Pain<br>VAS, Thomsen test<br><br>Treatment Success<br>50% improvement in pain with | 2 SRs, 1 RCT | Yes | No | Pain<br>A pooled analysis from 1 SR found no significant difference in pain improvement between ESWT and placebo. 1 RCT suggested that ESWT was more effective at reducing pain than sham.<br><br>Treatment Success |

| SR, Search dates | Purpose | Condition | Comparison | Primary Outcomes | Evidence Base | Risk of Bias Assessed | Quantitative Synthesis | Primary Conclusions |
|---|---|---|---|---|---|---|---|---|
| MEDLINE, Embase, The Cochrane Library | | | | resisted wrist extention | | | | In 1 SR, a pooled analysis of 2 RCTs found that ESWT had a significantly higher level of treatment success compared to placebo. However, 4 RCTs excluded from the pooled analysis did not support this finding.<br><br>Overall<br>ESWT seems no more effective at improving pain than placebo. Results of the effect of ESWT on treatment success in comparison to placebo are inconclusive. |
| Dizon (2013)<br><br>1990-2010<br><br>ScienceDirect, British Medical Journal, Bandolier, PubMed Central, Ovid, Cochrane Library, Free Medical Journals, eMedicine, Medscape, BioMed | To evaluate the effectiveness of ESWT in chronic plantar fasciitis | Plantar fasciitis | ESWT vs placebo, physical therapy | Function<br>RM<br><br>Pain<br>VAS, pain reduction during steps in the morning and during activity and at night<br><br>Adverse Events<br>Various | 11 RCTs | Yes | Yes | Function<br>5 RCTs found that ESWT was more effective than placebo in improving in both moderate and high intensity ESWT<br><br>Pain<br>Pooled analysis showed no difference between ESWT and placebo in decreasing overall pain or activity although the results were both near a significant value. High energy ESWT was found to be significantly more effective at decreasing morning pain in comparison to placebo while low energy ESWT was not. |

| SR, Search dates | Purpose | Condition | Comparison | Primary Outcomes | Evidence Base | Risk of Bias Assessed | Quantitative Synthesis | Primary Conclusions |
|---|---|---|---|---|---|---|---|---|
| Central, Free Full Text, New England Journal of Medicine, EBSCO, Google Scholar | | | | | | | | <u>Adverse Events</u><br>ESWT was found to have more adverse events with calcaneal pain and calcaneal erythema than control. There was no difference between ESWT and the control group in the occurrence of local edema, local paresthesia, and local bruising<br><br><u>Overall</u><br>Pooled data indicated that ESWT is an effective treatment strategy in reducing pain from PF. Moderate and high energy ESWT indicated an improvement in functional outcomes but higher energy ESWT was associated with a significant increase in calcaneal pain and erythema. |

AT, Achilles tendinopathy; CSI, corticosteroid injection; ESWT, extracorporeal shock wave therapy; PF, plantar fasciitis; PT, patellar tendinopathy; RM, Roles and Maudsley; ROM, range of motion; TENS, transcutaneous electrical nerve stimulation; US, ultrasound; VAS, visual analog scale; VISA-P, Victorian Institute of Sports Assessment

## *2.5. Medicare and Representative Private Insurer Coverage Policies*

Individual payer websites, the Centers for Medicare and Medicaid Services (CMS) website, and Google were searched for coverage decisions on the use of ESWT for tendinopathy, tendinitis, plantar fasciitis, heel spurs, subacromial shoulder pain, and osteoarthritis. Policy plans were identified from five payers, two of which are bellwether national payers. Coverage policies for four of the five payers are consistent and do not support coverage of ESWT across numerous pathologies, including all those of interest to this report. One payer, Aetna, covers ESWT for treatment of calcific tendinopathy of the shoulder.

Coverage decisions are summarized briefly below and policy details are provided in Table 5.

**Centers for Medicare Service (CMS)**

There is currently no National Coverage Determination for ESWT for any conditions published from the Centers for Medicare and Medicaid Services. A single Local Coverage Determination applicable to South Carolina, Virginia, West Virginia, and North Carolina has been published and considers ESWT to be investigational in the treatment of musculoskeletal conditions.

**United Healthcare Medical Policy: Extracorporeal Shock Wave Therapy (ESWT)**

United Healthcare considers the efficacy of ESWT, whether low energy, high energy or radial wave, as unproven and not medically necessary for all indications, including but not limited to the treatment of:

- Achilles tendonitis
- Calcaneal spur
- Calcific tendonitis of the shoulder (rotator cuff)
- Chronic plantar fasciitis (including plantar fibromatosis and plantar nerve lesion)
- Lateral epicondylitis (tennis elbow)
- Medial epicondylitis (golfers elbow)
- Tenosynovitis of the foot or ankle
- Tibialis tendinitis

**Aetna Policy: Extracorporeal Shock-Wave Therapy for Musculoskeletal Indications and Soft Tissue Injuries**

Aetna considers ESWT medically necessary for calcific tendinopathy of the shoulder of at least 6 months' duration with calcium deposit of 1 cm or greater and who have failed to respond to appropriate conservative therapies.

Aetna considers ESWT experimental and investigational for the following indications because there is insufficient evidence of effectiveness of ESWT:

- Achilles tendonitis (tendinopathy)
- Patellar tendinopathy
- Rotator cuff tendonitis (shoulder pain)
- Subacromial impingement syndrome
- Other musculoskeletal indications (including calcaneal spur, hammer toe, tibialis tendinitis, and tenosynovitis of the foot or ankle)

**Univera Medical Policy: Extracorporeal Shock Wave Therapy (ESWT) for Musculoskeletal Conditions and Soft Tissue Wounds**

Univera views the data published in the peer-reviewed literature on ESWT as insufficient to draw conclusions about the effectiveness of either focused or radial ESWT for treatment of musculoskeletal conditions. Outcomes of trials on clinically relevant measures are inconsistent and interpretation complicated by variations in treatment protocols.

**Premera Blue Cross Medical Policy: Extracorporeal Shock Wave Treatment for Plantar Fasciitis and Other Musculoskeletal Conditions**

Premera does not cover Extracorporeal shock wave therapy (ESWT), using either a high- or low-dose protocol or radial ESWT, for the treatment of musculoskeletal conditions, including the following, because its use is considered investigational:

- Plantar fasciitis
- Tendinopathies including tendinitis of the shoulder
- Tendinitis of the elbow (lateral epicondylitis)
- Achilles tendinitis
- Patellar tendinitis

**Anthem Medical Policy: Extracorporeal Shock Wave Therapy for Orthopedic Conditions**

Anthem considers the use of ESWT as investigational and not medically necessary for the treatment musculoskeletal conditions, including but not limited to:

- Chronic plantar fasciitis
- Calcified shoulder tendinitis
- Chronic lateral epicondylitis
- Elbow tendinitis

**Table 5. Overview of payer technology assessments and policies**

| Payer Policy Date | Lit search dates | Evidence base available | Policy | Rationale/ comments |
|---|---|---|---|---|
| **Centers for Medicare and Medicaid Services (CMS)** | NA | NA | None | There are currently no National Coverage Decisions published from the Centers for Medicare and Medicaid Services |
| **United Healthcare**<br><br>*Extracorporeal Shock Wave Therapy (ESWT)*<br><br>POLICY #: 2016T0269R<br><br>Effective Date: 07/01/2016 | NA | <u>Achilles Tendinopathy:</u><br>1 RCT<br><br><u>Calcaneal Spur:</u><br>4 RCTs<br>1 SR<br>1 HTA<br>6 studies, type NR<br><br><u>Chronic Plantar Fasciitis:</u><br>1 Meta-analysis<br>2 HTAs<br>4 RCT s<br>5 studies, type NR<br>1 SR<br>1 cohort study<br>1 guidance statement<br>2 clinical guidelines<br><br><u>Lateral epicondylitis:</u><br>7 studies, type NR<br>1 RCT<br>2 HTAs<br>1 clinical guideline<br>1 guidance statement<br><br><u>Medial epicondylitis:</u><br>NR<br><br><u>Tenosynovitis:</u><br>NA* | Extracorporeal shock wave therapy (ESWT), whether low energy, high energy or radial wave, is unproven and not medically necessary for all indications, including but not limited to the treatment of:<br><br>• Achilles tendonitis<br>• Calcaneal spur<br>• Calcific tendonitis of the shoulder (rotator cuff)<br>• Chronic plantar fasciitis (including plantar fibromatosis and plantar nerve lesion)<br>• Lateral epicondylitis (tennis elbow)<br>• Medial epicondylitis (golfers elbow)<br>• Tenosynovitis of the foot or ankle<br>• Tibialis tendinitis | CPT codes: 0019T, 0101T, 0102T, 28890 |

| Payer Policy Date | Lit search dates | Evidence base available | Policy | Rationale/ comments |
|---|---|---|---|---|
| | | Tibialis Tendinitis:<br>NA* | | |
| **Aetna**<br><br>*Extracorporeal Shock-Wave Therapy for Musculoskeletal Indications and Soft Tissue Injuries*<br><br>POLICY #: 0649<br><br>Last review: 10/23/2015<br>Next review: 07/22/2016 | NA | Calcific tendinopathy:<br>3 SRs<br>3 RCT<br>Clinical guidelines, number NR<br><br>Musculoskeletal conditions†:<br>1 SR<br>1 HTA<br><br>Achilles tendonitis:<br>1 NICE guideline<br>11 studies, type NR<br><br>Subacromial shoulder pain:<br>1 RCT<br><br>Epicondylitis:<br>21 RCTs<br>3 SRs<br><br>Patellar tendinopathy:<br>1 study, type NR<br>1 SR<br><br>Plantar fasciitis:<br>1 review‡ | Aetna considers ESWT medically necessary for calcific tendinopathy of the shoulder of at least 6 months' duration with calcium deposit of 1 cm or greater and who have failed to respond to appropriate conservative therapies.<br><br>Aetna considers ESWT experimental and investigational for the following indications because there is insufficient evidence of effectiveness of ESWT:<br>• Achilles tendonitis (tendinopathy)<br>• Patellar tendinopathy<br>• Rotator cuff tendonitis (shoulder pain)<br>• Subacromial impingement syndrome<br>• Other musculoskeletal indications (including calcaneal spur, hammer toe, tibialis tendinitis, and tenosynovitis of the foot or ankle) | CPT codes covered if criteria met: 0019T, 0101T<br><br>CPT codes not covered for indications listed in CPB: 0102T, 28890<br><br>ICD-10 codes covered if criteria met: M75.30-M75.32, M25.711-M25.719, M75.30-M75.42, M75.80-M75.92, M65.871-M65.879, M75.100-M75.22, M75.40-M75.92, M76.60-M76.62, M76.811-M76.829, M77.00-M77.32, M77.30-M77.32, R29.898 |
| **Univera**<br><br>POLICY #: 2.01.31<br><br>Last review: 06/16/2016<br>Next review: NR | NR | Multiple studies, type and number NR§ | There is insufficient data published in the peer-reviewed literature to draw conclusions about the effectiveness of either focused or radial ESWT for treatment of musculoskeletal conditions. Outcomes of trials on clinically relevant measures are inconsistent and | CPT codes: 0019T, 0101T, 0102T, 28890<br><br>ICD9 codes: 728.71, 726.73, 726.11, 726.32 |

| Payer Policy Date | Lit search dates | Evidence base available | Policy | Rationale/ comments |
|---|---|---|---|---|
| | | | interpretation complicated by variations in treatment protocols. | ICD10 codes: M72.2, M75.30-M75.32, M77.10-M77.12, M77.30-M77.32 |
| **Premera Blue Cross**<br><br>POLICY #: 2.01.40<br><br>Last review: 08/09/16<br>Next review: NR | 2001-May 2016 | Plantar fasciitis<br>1 TEC assessment<br>SRs, number NR<br>Meta-analyses, number NR<br>RCTs, number NR<br><br>Lateral epicondylitis<br>1 TEC assessment<br>2 SRs<br>6 RCTs<br><br>Shoulder tendinopathy<br>4 SRs<br>3 RCTs<br>1 study, type NR<br><br>Achilles tendinopathy<br>1 literature review<br>1 SR and meta-analysis<br>2 RCTs<br><br>Patellar Tendinopathy<br>1 literature review<br>1 SR and meta-analysis<br><br>Include "practice guidelines and position statements"? | Extracorporeal shock wave therapy (ESWT), using either a high- or low-dose protocol or radial ESWT, is considered investigational as a treatment of musculoskeletal conditions, including but not limited to:<br>• plantar fasciitis<br>• tendinopathies including tendinitis of the shoulder<br>• tendinitis of the elbow (lateral epicondylitis)<br>• Achilles tendinitis<br>• patellar tendinitis | CPT codes: 0019T, 0101T, 0102T, 28890 |
| **Anthem**<br><br>POLICY #: SURG.00045<br><br>Last review: 05/05/2016<br>Next review: NR | NR | Plantar fasciitis<br>12 RCTs<br>2 studies, type NR<br>4 SRs and meta-analyses<br><br>Lateral epicondylitis<br>2 RCTs | Use of ESWT is considered investigational and not medically necessary for the treatment musculoskeletal conditions, including but not limited to:<br>• Chronic plantar fasciitis<br>• Calcified shoulder tendinitis<br>• Chronic lateral epicondylitis | CPT codes: 28890, 0019T, 0101T, 0102T<br><br>ICD-10 codes: 6A930ZZ, 6A931ZZ |

| Payer Policy Date | Lit search dates | Evidence base available | Policy | Rationale/ comments |
|---|---|---|---|---|
| | | 1 SR<br>4 SRs and meta-analyses<br><br><u>Shoulder Tendinitis</u><br>3 studies, type NR<br>2 RCTs<br>1 meta-analysis<br><br><u>Knee OA</u><br>1 RCT | • Elbow tendinitis | |

CMS, Center for Medicare and Medicaid Services; CPT; Current Procedural Terminology; ESWT, Extracorporeal Shock Wave Therapy; HTA, Health Technology Assessment; ICD, International Classification of Diseases; NR, Not reported; OA, osteoarthritis; RCT, Randomized Control Trial; SR, Systematic Review; TEC, Technology Evaluation Center

*A detailed search of the medical peer-reviewed literature did not identify any clinical studies that evaluated extracorporeal shock wave therapy for the treatment of tibialis tendonitis or tenosynovitis. The clinical evidence was reviewed in April 2016 with no additional information identified that would change the conclusion.

†Further details not reported.

‡UpToDate review.

§Only had list of references used, no breakdown of information

# 3. The Evidence

## *3.1. Methods of the Systematic Literature Review*

### 3.1.1. Objectives

The aim of this report is to systematically review, critically appraise, analyze and synthesize research evidence evaluating the comparative efficacy, effectiveness, and safety of ESWT in adults for treating musculoskeletal conditions such as tendinopathy, plantar fasciitis, heel spurs, subacromial shoulder pain, or osteoarthritis. The differential effectiveness and safety of ESWT for subpopulations will be evaluated, as will the cost effectiveness.

### 3.1.2. Key Questions

In patients with musculoskeletal conditions such as tendinopathy, plantar fasciitis, heel spurs, subacromial shoulder pain, or osteoarthritis:

1. What is the evidence of the short- and long-term efficacy and effectiveness of focused ESWT compared with standard alternative treatment options, sham, or no treatment?

2. What is the evidence regarding short- and long-term harms and complications of focused ESWT compared with standard alternative treatment options, sham, or no treatment?

3. Is there evidence of differential efficacy, effectiveness, or safety of focused ESWT compared with standard alternative treatment options, sham, or no treatment? Include consideration of age, sex, race, ethnicity, socioeconomic status, payer, and worker's compensation?

4. What is the evidence of cost-effectiveness of focused ESWT compared with standard alternative treatment options or no treatment?

### 3.1.3. Inclusion/exclusion criteria

Inclusion and exclusion criteria are summarized in Table 6. Briefly, included studies met the following requirements with respect to participants, intervention, comparators, outcomes, and study design:

- **Population**: Patients with tendinopathy or tendinitis, plantar fasciitis, heel spurs, subacromial shoulder pain, or osteoarthritis. (Kidney stones; gallstones; cutaneous wounds; muscle spasticity; as well as dental, cosmetic, bony non-unions, fractures, carpal tunnel syndrome, shin splints, greater trochanteric pain syndrome, coccydynia, Dupuytren's disease, myofacscial pain, cardiovascular, osteonecrosis, postoperative patients and neurological conditions will be excluded).
- **Intervention:** Focused or radial ESWT (ESWT used in conjunction with surgery and radial extracorporeal shockwave therapy will be excluded.)

- **Comparators:** Standard alternative treatment(s), sham, or no treatment. (Comparisons of ESWT such as different modalities (e.g., radial vs. focused ESWT, high- vs. low-energy ESWT) will be excluded.)
- **Outcomes:** Function (primary), pain (primary), adverse events (primary), quality of life, patient satisfaction, medication use, surgery, cost-effectiveness (e.g., cost per improved outcome), cost-utility (e.g., cost per quality adjusted life year (QALY), incremental cost effectiveness ratio (ICER) outcomes.
- **Studies:** Focus will be on studies with the least potential for bias such as high quality systematic reviews of randomized controlled trials and randomized controlled trials and full economic studies.

**Table 6. Summary of inclusion and exclusion criteria**

| Study Component | Inclusion | Exclusion |
|---|---|---|
| **Population** | Patients with any of the following conditions:<br>• Tendinopathy or tendinitis<br>• Plantar fasciitis<br>• Heel spurs<br>• Subacromial shoulder pain<br>• Osteoarthritis | • Kidney stones<br>• Gallstones<br>• Cutaneous wounds<br>• Neurosurgery<br>• Ophthalmological conditions<br>• Cosmetic conditions<br>• Maxillofacial surgery<br>• Urological conditions<br>• Cardiothoracic conditions<br>• Dental conditions<br>• Muscle spasticity<br>• Cerebral palsy<br>• Bony non-unions or fractures<br>• Greater trochanteric pain syndrome<br>• Shin splints (medial tibial stress syndrome)<br>• Carpal tunnel syndrome<br>• Coccydynia<br>• Dupuytren's disease (hand deformity)<br>• Osteonecrosis<br>• Chronic pelvic pain syndrome<br>• Myofascial pain<br>• Postoperative patients |
| **Intervention** | • Focused extracorporeal shock wave therapy (ESWT)<br>• Radial extracorporeal shock wave therapy (ESWT) | • ESWT used in conjunction with surgery |
| **Comparator** | • Standard alternative treatment(s)<br>• Sham<br>• No treatment | • Comparisons of different ESWT modalities (e.g., radial vs. focused ESWT, high- vs. low-energy ESWT)<br>• Comparisons of timing of ESWT (e.g., early vs. delayed ESWT)<br>• Laser |
| **Outcomes** | *Primary outcomes*<br>• Function (based on validated measures)<br>• Pain | • Non-clinical outcomes<br>• Intermediate outcomes |

| Study Component | Inclusion | Exclusion |
|---|---|---|
| | • Composite<br>• Adverse events<br><br>*Secondary outcomes*<br>• Quality of life<br>• Patient satisfaction<br>• Medication use<br>• Surgery | |
| **Study Design** | Focus will be on studies with the least potential for bias.<br>**Key Questions 1-2:**<br>• High quality systematic reviews will be considered if available.<br>• Randomized controlled trials (RCTs)<br>**Key Question 2:**<br>• Randomized controlled trials (RCTs)<br>• Data from non-randomized comparative studies at low risk of bias may be considered for safety if needed to supplement RCT safety data<br>• Case series designed specifically to evaluate harms/adverse events may be considered for rare events or long-term follow-up in the absence of high quality comparative studies<br>**Key Question 3:**<br>• RCTs which stratify on patient or other characteristics and formally evaluate statistical interaction (effect modification)<br>**Key Question 4:**<br>• Only full, formal economic studies (i.e., cost-effectiveness, cost-utility, cost-minimization, and cost-benefit studies) will be considered. | • Indirect comparisons<br>• Non-comparative studies (case series) (except as described to evaluate harms if there are not adequate comparative studies)<br>• Incomplete economic evaluations such as costing studies<br>• Studies with fewer than 10 patients per treatment group<br>• Case reports<br>Studies in which <80% of patients have a condition or treatment of interest |
| **Publication** | • Studies published in English in peer reviewed journals or publically available FDA reports | • Abstracts, editorials, letters<br>• Duplicate publications of the same study which do not report on different outcomes<br>• Single reports from multicenter trials<br>• White papers<br>• Narrative reviews<br>• Articles identified as preliminary reports when results are published in later versions<br>• Conference proceedings |

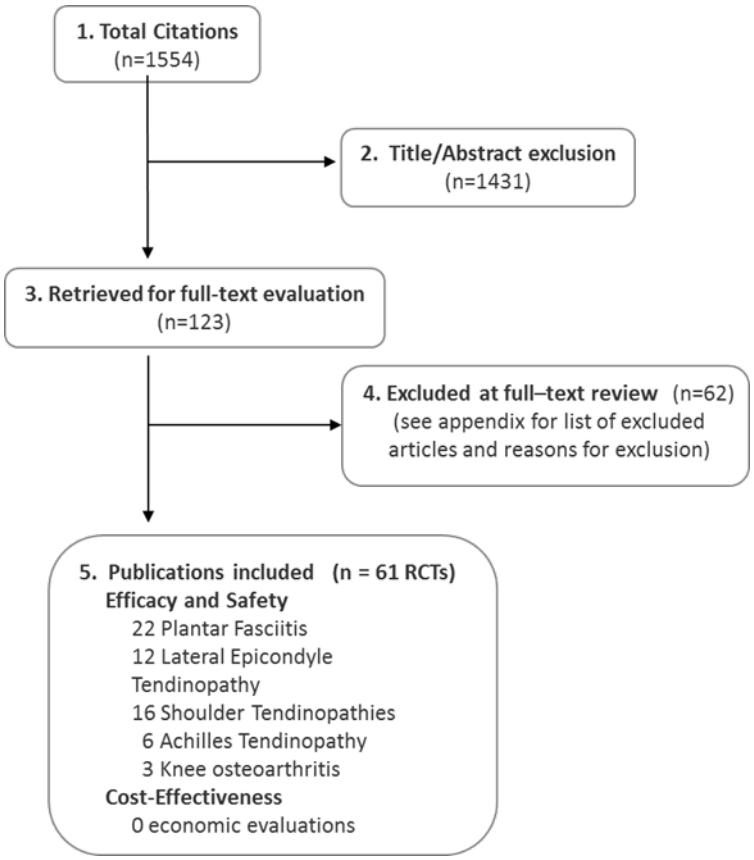
### 3.1.4. Data sources and search strategy

We searched electronic databases from inception to 11/1/2016 to identify publications assessing ESWT. Electronic databases searched include PubMed, the Cochrane Central Register of Controlled Trials, the Cochrane Database of Systematic Reviews, and the National Guideline Clearinghouse (see Appendix B

for full search strategy). We also hand searched the reference lists of relevant studies and the bibliographies of systematic reviews.

The clinical studies included in this report were identified using the algorithm shown in Appendix A. The search took place in four stages. The first stage of the study selection process consisted of the comprehensive electronic search and bibliography check. We then screened all possible relevant articles using titles and abstracts in stage two. This was done by two individuals independently. Those articles that met a set of *a priori* retrieval criteria were included. Articles were selected for full-text review if they included ESWT for tendinopathy or tendinitis, plantar fasciitis or heel spurs, subacromial shoulder pain, or osteoarthritis. We excluded conference abstracts, non-English-language articles, and studies of nonhuman subjects. Any disagreement between screeners that were unresolved resulted in the article being included for the next stage. Stage three involved retrieval of the full text articles remaining. The final stage of the study selection algorithm consisted of the selection of those studies using a set of *a priori* inclusion criteria, again, by two independent investigators. Discrepancies were resolved through discussion and if necessary adjudicated by a third investigator. A list of excluded articles along with the reason for exclusion is available in Appendix C. The remaining articles form the evidence base for this report.

**Figure 4. Flow chart of literature search results**



### 3.1.5. Data extraction

Reviewers extracted the following data from the clinical studies: study design, study period, setting, country, sample size, inclusion and exclusion criteria, study population characteristics, preoperative diagnoses, study interventions, follow-up time, use of imaging guidance, use of anesthesia, characteristics of the control intervention, study outcomes and adverse events. For economic studies, data related to sources used, economic parameters and perspectives, results, and sensitivity analyses were abstracted. An attempt was made to reconcile conflicting information among multiple reports presenting the same data. Detailed study and patient characteristics is available in Appendix F, all results are available in the results section of this document and in Appendices G and H.

### 3.1.6. Quality assessment: Overall Strength of evidence (SoE), Risk of Bias, and QHES evaluation

The method used by Spectrum Research, Inc. (SRI) for assessing the quality of evidence of individual studies as well as the overall strength of evidence (SoE) for each primary outcome incorporates aspects of the rating scheme developed by the Oxford Centre for Evidence-based Medicine[123], precepts outlined by the Grades of Recommendation Assessment, Development and Evaluation (GRADE) Working Group,[6] and recommendations made by the Agency for Healthcare Research and Quality (AHRQ).[192] Economic studies were evaluated according to The Quality of Health Economic Studies (QHES) instrument developed by Ofman et al.[124] Based on these quality criteria, each study chosen for inclusion for a Key Question was given a RoB (or QHES) rating; details of each rating are available in Appendix E. Standardized abstraction guidelines were used to determine the RoB (or QHES) rating for each study included in this assessment.

The SoE for all primary health outcomes was assessed by two researchers following the principles for adapting GRADE (Grades of Recommendation Assessment, Development and Evaluation) as outlined by the Agency for Healthcare Research and Quality (AHRQ).[8,61,62] The strength of evidence was based on the highest quality evidence available for a given outcome. In determining the strength of body of evidence regarding a given outcome, the following domains were considered:

- Risk of bias: the extent to which the included studies have protection against bias
- Consistency: the degree to which the included studies report results that are similar in terms of range and variability.
- Directness: describes whether the evidence is directly related to patient health outcomes.
- Precision: describes the level of certainty surrounding the effect estimates.
- Publication bias: is considered when there is concern of selective publishing.

When assessing the SoE for studies performing subgroup analysis, we also considered whether the subgroup analysis was preplanned *(a priori)* and whether a test for homogeneity or interaction was done.

Bodies of evidence consisting of RCTs were initially considered as High strength of evidence, while those comprised of nonrandomized studies began as Low strength of evidence. The strength of evidence could be downgraded based on the limitations described above. There are also situations where the studies could be upgraded if the study had large magnitude of effect (strength of association). The final strength

of evidence was assigned an overall grade of high, moderate, low, or insufficient, which are defined as follows:

- High - Very confident that effect size estimates lie close to the true effect for this outcome; there are few or no deficiencies in the body of evidence; we believe the findings are stable.
- Moderate – Moderately confident that effect size estimates lie close to the true effect for this outcome; some deficiencies in the body of evidence; we believe the findings are likely to be stable but some doubt remains.
- Low – Limited confidence that effect size estimates lie close to the true effect for this outcome; major or numerous deficiencies in the body of evidence; we believe that additional evidence is needed before concluding that findings are stable or that the estimate is close to the true effect.
- Insufficient – We have no evidence, are unable to estimate an effect or have no confidence in the effect estimate for this outcome; OR no available evidence or the body of evidence has unacceptable efficiencies precluding judgment.

Similar methods for determining the overall quality (strength) of evidence related to economic studies have not been reported, thus the overall strength of evidence for outcomes reported in Key Question 4 was not assessed.

### 3.1.7. Analysis

We summarized evidence separately for FESWT and RESWT, and by the conditions for which treatment was given. The conditions included upper and lower extremity tendinopathies, plantar fasciitis and osteoarthritis.

We conducted meta-analyses when there were two or more studies with similar indications, interventions, control groups and outcomes. We grouped control treatments according to whether the control was a sham treatment, corticosteroid, or other standard conservative care (e.g., physical therapy).

Outcomes were stratified by duration of follow-up as short term (≤3 months), intermediate term (>3 months to <1 year), and long term (≥1 year). When more than one follow-up time was reported within a category, we used data from the longest duration available within that category. Most studies reported pain associated with the presence or absence of activity, or during a time of the day (morning or at night). Pain was measured on a visual analog scale (VAS) or a numerical rating scale (NRS) of 0 to 10 or 0 to 100 (higher scores indicate greater pain). We converted all pain scales to 0 (no pain) to 10 (worst possible pain). Function was assessed using a variety of measures specific to the anatomy or condition being treated. Other outcome measures not used in the meta-analyses are detailed in the evidence tables.

In the meta-analyses, we calculated a risk ratio (RR) and 95% confidence intervals for dichotomous outcomes of pain or function "success" (e.g., >50% improvement in pain scores or function scores, or as otherwise defined in the trials) and composite measures of success (e.g., ≥50% improvement in pain and a required score of ≤ 4 on VAS and no pain medication necessary two weeks before follow-up) using the Mantel-Haenszel method. For continuous measures, we pooled weighted mean difference (WMD) according to the inverse of their variances. The mean difference was calculated using the change

between the follow-up and baseline scores. We imputed missing standard deviations using the mean standard deviation from other studies in the analysis. When calculating the standard deviation of the change score the correlation between baseline and follow-up measures was assumed to be 0.8. For interpreting the clinical importance of mean changes in outcome scores, we defined a minimum clinically important difference for pain measures as an improvement in 1.5 points on a 0 to 10 pain scale. MCID used for functional measures are listed in Table 1. We used a random effects model to account for inter-study variability.

We assessed the presence of statistical heterogeneity among the studies by using the standard Cochran's chi-square test, and the magnitude of heterogeneity by using the $I^2$ statistic.[70] When statistical heterogeneity was present, we performed sensitivity analyses first by omitting obvious outliers. In cases where there were no obvious outliers, we repeated the analysis excluding poor quality studies. When an analysis only contained high quality studies, we did sensitivity analysis using the profile likelihood method[32] and compared results. All results and figures were produced using Review Manager v5.2.6.

# 4. Results

## *4.1. Key Question 1: Efficacy and effectiveness*

### 4.1.1. Number of studies retained

Overall, 61 randomized trials (in 63 publications) were included. The selection of the studies are summarized in Figure 4. The comparisons evaluated and their respective studies are listed in Table 7; comparisons of interest not listed in the table below had no comparative evidence available that met the inclusion criteria. Diagnoses for which comparative evidence were identified include tendinopathies (lateral epicondyle tendinopathy of the elbow, Achilles tendinopathy, patellar tendinopathy, shoulder tendinopathies), plantar fasciitis, and knee osteoarthritis.

**Table 7. Number of studies for each comparison of efficacy for included conditions.**

| Comparisons | Studies |
|---|---|
| **PLANTAR FASCIITIS** | |
| FESWT vs. Sham | 12 RCTs[34,58,59,63,96,112,126,145,149,158,169,176] |
| FESWT vs. Active Control | |
| FESWT vs. CSI | 2 RCTs[134,197] |
| FESWT vs. Conservative Care | 2 RCTs[24,66] |
| FESWT vs. EPFR | 1 RCT[137] |
| RESWT vs. Sham | 3 RCTs (4 publications) [56,76,77,115] |
| RESWT vs. Active Control | |
| RESWT vs. US | 2 RCTs[60,95] |
| **TENDINOPATHIES** | |
| **Lateral Epicondyle Tendinopathy** | |
| FESWT vs. Sham | 7 RCTs[25,28,64,117,132,146,168] |
| FESWT vs. Active Control | |
| FESWT vs. CSI | 2 RCTs[37,129] |
| FESWT vs. Percutaneous Tenotomy | 1 RCT[136] |
| RESWT vs. Sham | 2 RCTs[19,115] |
| **Shoulder Tendinopathies** | |
| **Rotator Cuff Tendinopathy** | |
| FESWT vs. Sham | 7 RCTs (8 publications)[33,45,55,57,73,131,159,170] |
| FESWT vs. Active Control | |
| FESWT vs. US-guided needling plus CSI | 1 RCT[91] |

| Comparisons | Studies |
|---|---|
| FESWT vs. TENS | 1 RCT[130] |
| RESWT vs. Sham | 1 RCT[94] |
| FESWT vs. Active Control | |
| FESWT vs. UGPL | 1 RCT[42] |
| **Adhesive Capsulitis** | |
| FESWT vs. Sham | 1 RCT[180] |
| FESWT vs. Active Control | |
| FESWT vs. Oral Steroid Therapy | 1 RCT[20] |
| RESWT vs. Sham | 1 RCT[75] |
| **Subacromial Shoulder Pain** | |
| RESWT vs. Sham | 1 RCT (2 publications)[47,48] |
| **Bicipital Tenosynovitis of the Shoulder** | |
| RESWT vs. Sham | 1 RCT[106] |
| RESWT vs. Sham | |
| **Achilles Tendinopathy** | |
| FESWT vs. Sham | 2 RCTs[35,138] |
| RESWT vs. Active Control | |
| RESWT vs. Eccentric Exercise | 2 RCTs[147,153] |
| RESWT + Eccentric Exercise vs. Eccentric Exercise Alone | 1 RCT[148] |
| RESWT vs. No Treatment | 1 RCT[153] |
| **Patellar Tendinopathy** | |
| FESWT vs. Sham | 1 RCT[175] |
| FESWT vs. Active Control | |
| FESWT vs. Conservative Management | 1 RCT[188] |
| **KNEE OSTEOARTHRITIS** | |
| FESWT vs. Active Control | |
| FESWT + Isokinetic Muscular Strengthening vs. Isokinetic Muscular Strengthening Alone | 1 RCT[21] |
| FESWT + Isokinetic Muscular Strengthening vs. US + Isokinetic Muscular Strengthening Alone | 1 RCT[21] |
| RESWT vs. Sham | 1 RCT[198] |

CSI: corticosteroid injection; EPFR: Endoscopic Partial Plantar Fascia Release; FESWT: Focused Extracorporeal Shock Wave Therapy; RCT: randomized control trial; RESWT: Radial Extracorporeal Shock Wave Therapy; TENS: transcutaneous electrical nerve stimulation; UGPL: ultrasound guided percutaneous lavage; US: ultrasound

### 4.1.2. Plantar Fasciitis

**Summary of results**

**Focused ESWT versus Sham:**

We report on five pain outcomes: pain when first walking in the morning; pain during activities; pain composite measure made of 2 or more pain scales; pain not otherwise specified (NOS); and pain at rest. A significantly higher proportion of patients receiving FESWT versus sham reported a 50% reduction in pain when first walking in the morning compared with baseline at 3 month follow-up across 5 studies, pooled RR 1.38 (95% CI, 1.15 to 1.66) (strength of evidence, HIGH). Intermediate and long-term results are less clear for pain when first walking in the morning: using mean differences from baseline, one study favors FESWT over sham at 6 month follow-up, and two studies found no difference after 12 months of follow-up (strength of evidence, LOW for both time periods). A higher proportion of patients achieved a successful pain composite outcome at 3 months across 4 studies, pooled RR 1.55 (95% CI, 1.29 to 1.85) (strength of evidence HIGH). There were no differences between groups in the short-term with respect to pain with activities (3 studies), pain at rest (2 studies), and pain NOS (2 studies). The strength of the evidence for these results ranged from MODERATE to LOW.

Function was less frequently reported. One study found no difference between groups in the short-term (strength of evidence, LOW). There was LOW evidence from another small study at 6 and 12 month follow-ups reporting significantly greater improvement in function, both statistically and clinically, in favor of FESWT vs. sham.

**Focused ESWT versus Active Control**

*Focused ESWT vs. CSI*: CSI resulted in better pain relief with first steps in the morning than FESWT in the short-term but not in the long-term (strength of evidence MODERATE). There is INSUFFICIENT evidence for other pain outcomes and no evidence for functional outcomes.

*Focused ESWT vs. Conservative Care*: There was INSUFFICIENT evidence to determine if FESWT or conservative care (iontophoresis and NSAIDS or stretching exercises) was superior with respect to improved pain or function from two small studies in the short- or intermediate-term pain. There is no evidence comparing groups in the long-term.

*FESWT versus Endoscopic Partial Plantar Fascia Release (EPFR)*: There was no difference between FESWT and EPFR with respect to improvement in pain when first walking in the morning or in function as measured by the AOFAS Ankle-Hindfoot scale (strength of evidence, LOW)

**Radial ESWT versus Sham:** RESWT was better than sham in three studies in all short-, intermediate- and long-term pain outcomes to include pain when first walking in the morning, pain with activities, pain NOS and composite pain measures (strength of evidence, MODERATE for short- and intermediate-term results and LOW for long-term results). There is no evidence for functional outcomes.

**Radial ESWT versus Active Control**

*Radial ESWT vs. Ultrasound*: There was INSUFFICIENT evidence in the short-, intermediate- or long-term to determine the effect of RESWT versus ultrasound therapy with respect to pain when first walking in the morning, achieving pain-free status, or pain with walking. RESWT was better than ultrasound in one study with respect to improvement in pain NOS in the short and intermediate-term (strength of evidence, LOW).

#### 4.1.2.1. Focused ESWT vs. SHAM for Plantar Fasciitis

***Studies included***

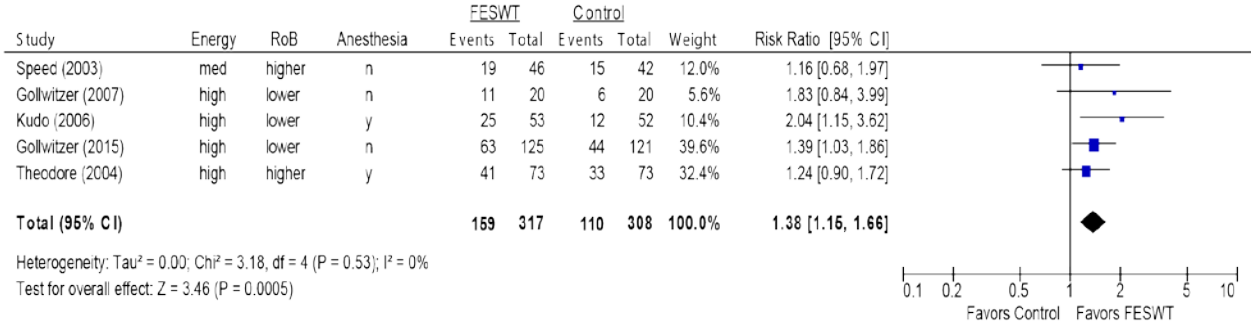
Twelve RCTs[34,58,59,63,96,112,126,145,149,158,169,176] were included that enrolled as few as 24 and as many as 293 patients. Detailed information on patient and study characteristics is available in Appendix Table F1. The mean duration of symptoms in 10 studies ranged from 8 to 24 months. Two studies did not state the mean duration but included only patients with symptoms >6 months.[59,158] Most of the patients were females (67%). The mean age ranged from 42 to 56 years. Two studies used low intensity FESWT,[63,149] two used medium intensity,[145,169] six used high intensity (Collins 2011),[58,59,96,126,158,176] and two studies did not report the intensity level.[34,112] Four used a local anesthetic in conjunction with the FESWT (Theodore 2004, Haake 2003, Kudo 2006, Ogden 2004) and seven used none (Cosentino 2001, Rompe 1996 and 2003, Speed 2003, Gollwitzer 2007 and 2015, Malay 2006 ). One trial did not state whether anesthesia was used (Rompe 1996). Five trials were at LOW risk of bias (Ogden 2004, Haake 2003, Kudo 2006, Gollwitzer 2007 and 2015), two at MODERATELY LOW risk of bias (Malay 2006, Rompe 2003), and five at MODERATELY HIGH risk of bias (Theodore 2004, Rompe 1996, Cosentino 2001, Speed 2003, Saxena 2012). Risk of bias assessment for all studies is found in Appendix Table E1.

***Efficacy Results***

**Pain**

*Short-term pain:* The proportion of patients that achieved pain success when first walking in the morning 3 months after treatment was higher in those receiving FESWT compared with sham in five trials,[58,59,96,169,176] pooled risk ratio (RR) 1.4 (95% CI, 1.2 to 1.7), Figure 5. Success in early morning walking was defined as ≥50% (1 study) or 60% (4 studies) improvement in pain over baseline.

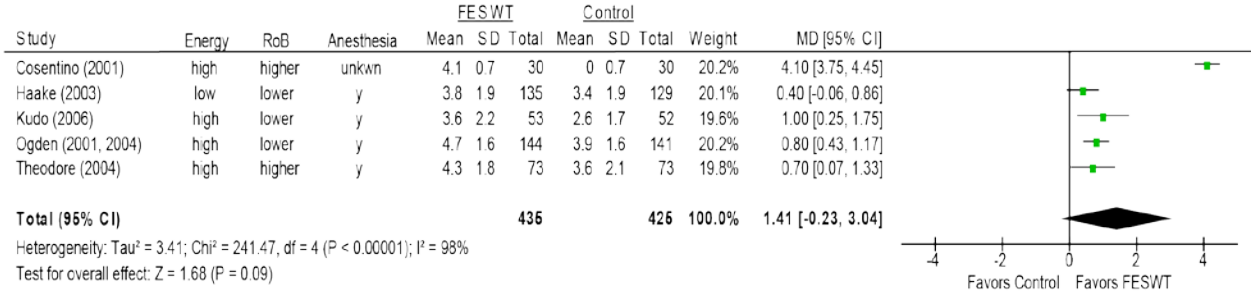
**Figure 5. Focused ESWT vs. SHAM in plantar fasciitis: PROPORTION WITH PAIN SUCCESS WHEN FIRST WALKING IN THE MORNING (≥50 OR 60% pain improvement compared with baseline), SHORT-TERM FOLLOW-UP**




Five studies at 3 month follow-up recorded the mean change from baseline in pain when first walking in the morning (VAS 0-10, worst).[34,63,96,126,176] There was no statistical difference in pain in the pooled analysis, MD 1.41 (95% CI, -0.23 to 3.04), Figure 6. This analysis resulted in a large amount of heterogeneity ($I^2$=98%). Therefore, we evaluated separately the higher quality studies with the lower risk of bias (Haake 2003, Kudo 2006, Ogden 2004). The mean difference pooling the higher quality

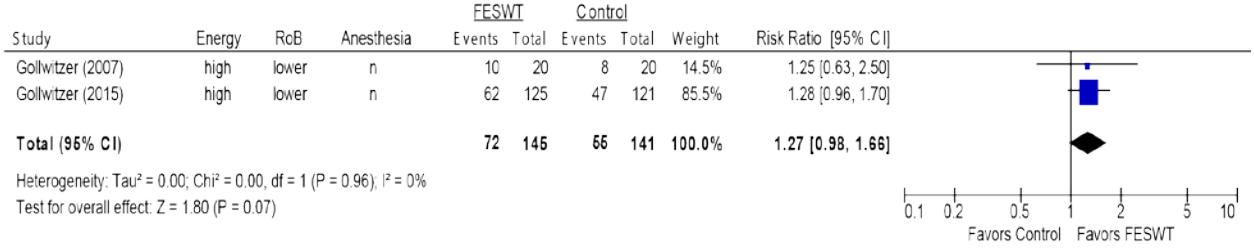
studies was 0.69 (95% CI, 0.37 to 1.00), $I^2$=21%, Appendix xx. Though statistically significant, the MD did not meet the clinically important threshold of 1.5.

**Figure 6. Focused ESWT vs. SHAM in plantar fasciitis: MEAN CHANGE IN PAIN FROM BASELINE WHEN FIRST WALKING IN THE MORNING (VAS 0-10), SHORT-TERM FOLLOW-UP**



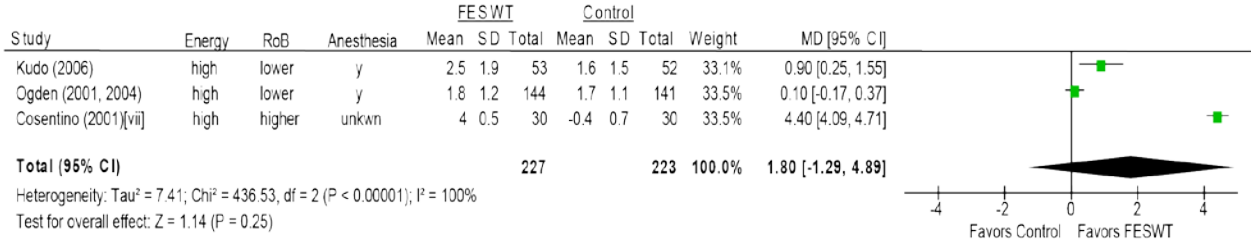

There was no statistical significance in the proportion of patients with pain success during activities in two studies at 3 month follow-up, RR 1.27 (95% CI, 0.98 to 1.66), *p*=.07, Figure 7.[58,59] Pain success during activities(VAS 0-10, worst) was defined as >60% decrease in pain during daily activities compared with baseline. Both studies have low risk of bias.

**Figure 7. Focused ESWT vs. SHAM in plantar fasciitis: PROPORTION WITH PAIN SUCCESS DURING ACTIVITIES, SHORT-TERM FOLLOW-UP**



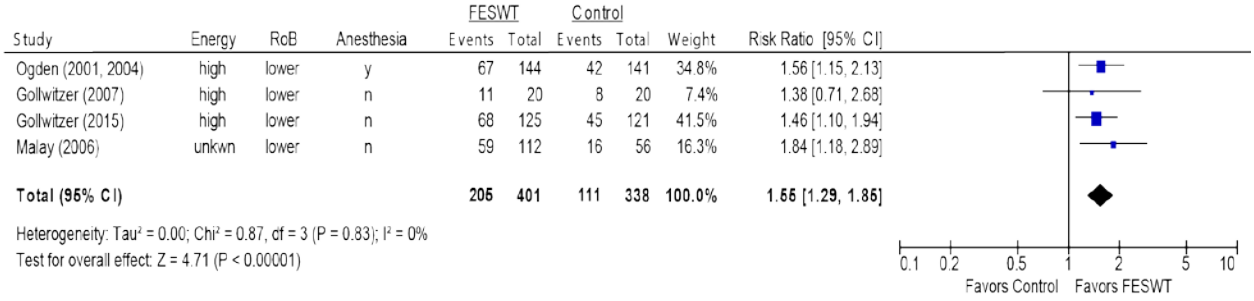

Likewise, there was no difference between groups from three studies that reported the mean change in pain from baseline during activities, MD 1.8 (95% CI, -1.3, 4.9), Figure 8. This analysis resulted in a large amount of heterogeneity ($I^2$=100%). Therefore, we evaluated separately the higher quality studies with the lower risk of bias (Kudo 2006, Ogden 2004). The mean difference pooling the higher quality studies was 0.44 (95% CI, -0.33 to 1.22), $I^2$=80%, Appendix xx. Given that high heterogeneity remained, we evaluated this outcome using the profile likelihood method. The estimates were similar.

**Figure 8. Focused ESWT vs. SHAM in plantar fasciitis: MEAN CHANGE IN PAIN FROM BASELINE DURING ACTIVITIES (VAS 0-10, WORST), SHORT-TERM FOLLOW-UP**



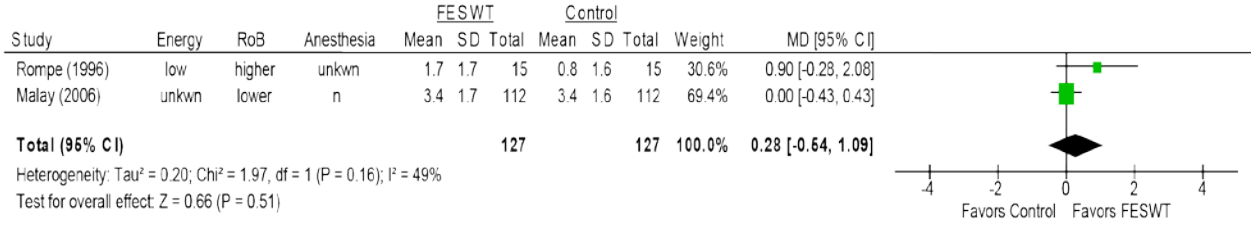

Four studies report results using a composite pain outcome that includes 2 or more pain components. One study included as a successful composite pain outcome ≥ 50% improvement in the dolorimeter (pressure sensor)-induced baseline pain score, with a required score of ≤ 4 on VAS; ≥ 50% improvement in patient-assess pain on walking; ≥ 1 point improvement on 5-point VAS scale or maintenance of 0 or 1 baseline score for patient self-assessment of activity; no pain medications necessary between 10 and 12 weeks after treatment.[126] Two defined the composite measure as >60% decrease in pain over baseline in ≥2 of 3 pain scores (pain with first morning steps, pain with activities, pain with pressure);[58,59] while one study defined it as achieving ≥50% improvement in pain and a score ≤4 on visual analog scale.[112] The proportion of patients achieving a successful composite pain score was higher in the FESWT group, RR 1.55 (1.29 to 1.85), Figure 9.

**Figure 9. Focused ESWT vs. SHAM in plantar fasciitis: PROPORTION WITH COMPOSITE PAIN SUCCESS, SHORT-TERM FOLLOW-UP**



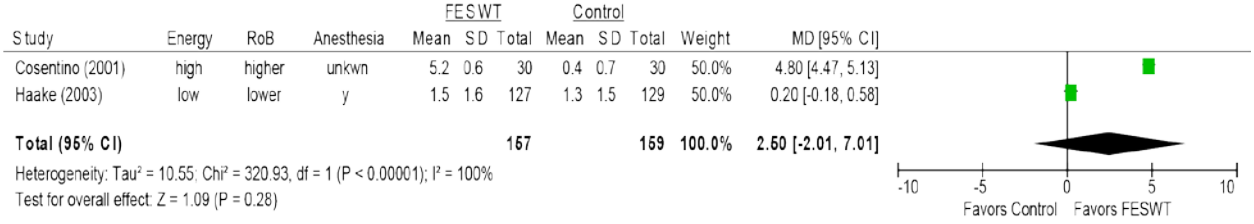

Two studies report a mean difference in pain not otherwise specified (NOS) from baseline at 1.5[149] and 3 month follow-up.[112] Further description of pain in these studies was absent. There was no difference between treatments in the pooled estimate, mean difference (MD) 0.28 (-0.54, 1.09), Figure 10.

**Figure 10. Focused ESWT vs. SHAM in plantar fasciitis: CHANGE IN MEAN PAIN SCORE (NOS) FROM BASELINE (VAS 0-10, WORSE), SHORT-TERM FOLLOW-UP**




There was no difference in pain at rest as reported by two studies,[34,63] MD 2.5 (95% CI, -2.0 to 7.0), Figure 11. Due to the large amount of heterogeneity ($I^2$=100%), we evaluated separately the higher quality study with the lower risk of bias (Haake 2003). There was no difference between the treatments, MD 0.2 (95% CI, -2, 0.6).

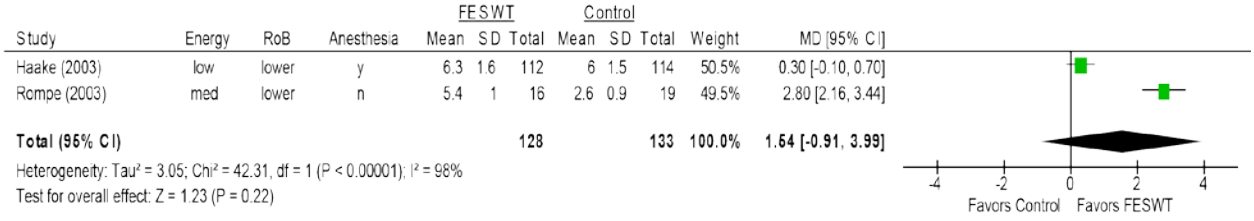
**Figure 11. Focused ESWT vs. SHAM in plantar fasciitis: CHANGE IN MEAN PAIN SCORE AT REST FROM BASELINE (VAS 0-10, WORSE), SHORT-TERM FOLLOW-UP**




*Intermediate term pain:* One study moderately low risk of bias study reported 6 month follow-up assessing pain (VAS 0-10, worst) when first walking in the morning.[145] The improvement in pain from baseline was significantly greater in the ESWT group compared to sham, 4.8 versus 2.3 (MD 2.5, p <.001). This MD markedly exceeds the clinically important difference of 1.5.

*Long-term pain:* Two studies, one low[63] and one moderately low[145] risk of bias, reported long-term (12 month) pain (VAS 0-10, worst) when first walking in the morning. There was no difference in the pooled estimate, MD 1.54 (95% CI, -0.91 to 3.99), Figure 12. This analysis resulted in a large amount of heterogeneity ($I^2$=98%). Given that both studies were of lower risk of bias, we evaluated this outcome using the profile likelihood method. The estimates were similar. It should be noted that there were differences in the study population that could account for the heterogeneity. The participants in the study by Haake 2003 were slightly older than in Rompe 2003, mean age 53 versus 45 years, and a smaller proportion of males, 25% versus 48%. Furthermore, the population in Rompe 2003 was a group of runners who ran ≥30 miles per week. The running status of patients in the Haake 2003 study is not known.

**Figure 12. Focused ESWT vs. SHAM in plantar fasciitis: MEAN CHANGE IN PAIN FROM BASELINE WHEN FIRST WALKING IN THE MORNING (VAS 0-10), LONG-TERM FOLLOW-UP**




**Function**

*Short-term function:* Functional outcome as measured by the Ankle-Hindfoot Scale of the American Orthopedic Foot and Ankle Score (AOFAS) was reported in a single study at 3 month follow-up.[96] There was no difference in the proportion of patients achieving a score of none or mild on the pain domain, 51% versus 35%, RR 1.47 (95% CI, 0.93, 2.33), *p* = .12. There was no difference between groups comparing the mean AOFAS Ankle Hindfoot total score (0-100, best) at 3 month follow-up, 30.3 versus 25.8 (MD -4.5; 95% CI, -17.4 to 8.4). This study was judged to have low risk of bias.

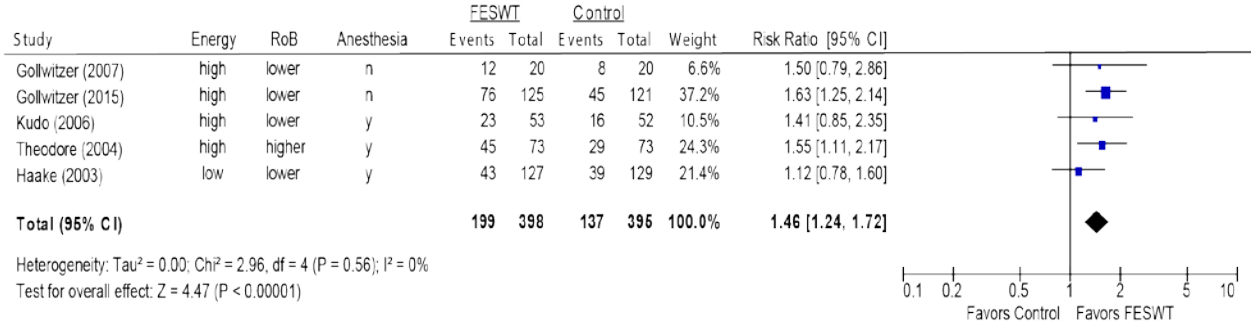
*Intermediate-term function:* One moderately low risk of bias study reported AOFAS Ankle-Hindfoot total score (0-100, best) at 6 month follow-up.[145] The functional score was higher in the FESWT group versus sham, MD 17.8 (95% CI, 11.3 to 24.3). The mean difference of 17.8 points between the groups exceeds the MCID of 8.9 points.

*Long-term function:* One moderately low risk of bias study reported AOFAS Ankle-Hindfoot total score (0-100, best) at 12 month follow-up.[145] The functional score was higher in the FESWT group versus sham, MD 12.0 (95% CI, 6.3 to 17.7). The difference of 12.0 points between the groups exceeds the MCID of 8.9 points.

**Other Outcomes Measures**

*Roles Maudsley (RM):* There was a greater proportion of patients achieving a good or excellent score 3 months after treatment as measured by the RM across five studies,[58,59,63,96,176] pooled risk ratio 1.46 (95% CI, 1.25, 1.72), Figure 13. One very small study (Rompe 2004) followed 25 patients for 12 months and found no difference in the proportion of patients with a good or excellent score between groups, 27% in the FESWT and 43% in the sham group.[158]

**Figure 13. Focused ESWT vs SHAM in plantar fasciitis: PROPORTION WITH GOOD OR EXCELLENT ROLES MAUDSLEY SCORE, SHORT-TERM FOLLOW-UP**




#### 4.1.2.2. Focused ESWT vs. Active Control for Plantar Fasciitis

***Studies included***

Six RCTs[24,66,134,137,190,197] were identified that evaluated the efficacy of FESWT compared with active control for chronic plantar fasciitis. Comparisons included FESWT versus CSI (2 trials; Porter 2005, Yucel 2010), FESWT versus conservative care to include physical therapy modalities, exercises, NSAIDs, and or corticosteroid injections (3 trials; Chew 2013, Wang 2006, Hammer 2002) and FESWT versus endoscopic plantar fascial release (EPFR). Detailed information on patient and study characteristics is available in Appendix Table F1. Two trials were considered to be at moderately low risk of bias,[134,137] while four were grades as moderately high risk of bias[24,66,190,197] (see Appendix E1 for details regarding risk of bias rating).

***Efficacy Results***

**Focused ESWT vs. Corticosteroid Injection (CSI)**

Two trials compared FESWT against corticosteroid injections. The first randomized 61 patients to receive three treatments of FESWT with a week in between and 64 patients to receive one CSI at the point of maximum tenderness.[134] The second study randomized 27 patients to receive one treatment of high energy FESWT following a local nerve block and 33 patients to receive CSI at the point of maximum tenderness.[197] Porter 2005[134] is considered moderately low risk of bias due to unknown random sequence generation, no intention to treat, and unknown differential loss to follow-up. Yucel 2010[197] is judged moderately high risk of bias for unknown random sequence generation, unknown concealed allocation, unknown blind assessment, co-interventions not applied equally, and baseline differences in patient characteristics that could potentially confound the results.

**Pain**

*Short-term pain*: One trial (Yucel 2010) reported no difference between groups at 3 months in the proportion of patients achieving a successful composite pain outcome defined as loss of heel tenderness with a decrease in VAS pain scale or heel tenderness index score of at least 50% from baseline; 82% in the FESWT group versus 85% in the CSI group. There was no difference between groups in the mean

change of pain NOS (VAS 0-10, worst) from baseline to 3 month follow-up, 4.1 versus 5.3. A second trial (Porter 2005) found a greater improvement in mean change from baseline in pain when first walking in the morning (VAS 0-10, worst) in favor of the CSI group, MD -2.16 (95% CI, -3.14 to -1.18), which exceeds the MCID of 1.5.

*Intermediate-term pain*: There is no evidence during the intermediate-term.

*Long-term pain*: Twelve month follow-up was reported in one trial[134] that found no difference between FESWT and CSI in the mean change from baseline in pain when first walking in the morning, MD -0.05.

**Function**

No functional outcomes measures assessed for this comparison.

**Focused ESWT vs. Conservative Care**

Two randomized controlled trials compared FESWT to conservative care of physical therapy stretching exercises or modality treatment and NSAIDs.[24,66] The first study (Hammer 2002)[66] randomized 48 patients to receive three treatments of low intensity FESWT with a week in between (n=24) or conservative care consisting of Iontophoresis with diclofemac and oral non-steroidal anti-inflammatory medication. The mean age was 49.5 years and 31.9% were males. This study was judged to be moderately high risk of bias due to unknown random sequence generation and concealed allocation, no blind assessment and unequal patient characteristics between groups at baseline.

The second study (Chew 2013)[24] randomized 19 patients to receive two sessions of high energy FESWT one week apart plus physical therapy stretching routine, and 16 patients to receive a physical therapy stretching routine alone. In addition, this study included another experimental arm, autologous conditioned plasma, which is not included in this assessment. The mean age was 46.1 years and 53.7% were male. This study has moderately high risk of bias due to unknown random sequence generation, no intention to treat, low follow-up rate, unequal patient characteristics between groups at baseline.

**Pain**

*Short-term pain:* There was no difference in two studies between FESWT and conservative care with respect to pain NOS after 3 months.[24,66] One study (Chew 2013) reported no difference in the median pain score at 3 month follow-up (VAS, 1-10, worst), 4 (range 0 to 7) in the FESWT group and 4 (range 1 to 9) in the conservative care group; while another (Hammer 2002) reported no difference in the mean change from baseline in pain (MD 0.3, $p > .05$) at three month follow-up. The same study reported no difference in pain at rest at 3 month follow-up (MD 1.6, $p > .05$) or pain success defined as less than 3 points on the 10 point VAS scale (RR 0.90; 95% CI, 0.59 to 1.38).

*Intermediate-term pain*: There was no difference in two studies between FESWT and conservative care with respect to pain NOS in the intermediate-term.[24,66] One study (Chew 2013) reported no difference in the median pain score at 6 month follow-up (VAS, 1-10, worst), 3 (range 0 to 7) in the FESWT group and 3 (range 1 to 9) in the conservative care group; while another (Hammer 2002) reported no difference in the mean change from baseline in pain (MD -0.3, $p > .05$) at six month follow-up. The same study reported no difference in pain at rest at 6 month follow-up (MD 1.1, $p > .05$) or pain success defined as less than 3 points on the 10 point VAS scale (RR 0.91; 95% CI, 0.68 to 1.22).

*Long-term pain*: There is no evidence during the long-term.

**Function**

*Short-term function:* Functional outcome as measured by the AOFAS Ankle-Hindfoot Scale was reported in a single study in the short-term, (Chew 2013).[24] There was no difference between groups comparing the median AOFAS Ankle-Hindfoot total score (0-100, best) at 3 month follow-up, 85 (range, 72 to 100) versus 80 (range, 53 to 90), $p>.05$. This study was judged to have moderately high risk of bias for reasons stated above.

*Intermediate-term function*: Functional outcome as measured by the AOFAS Ankle-Hindfoot Scale was reported in a single study in the intermediate-term, (Chew 2013). There was no difference between groups comparing the median AOFAS Ankle-Hindfoot total score (0-100, best) at 6 month follow-up, 90 (range, 72 to 100) versus 87 (range, 73 to100), $p>.05$. This study was judged to have moderately high risk of bias for reasons stated above.

*Long-term function*: There is no evidence during the long-term.

**Focused ESWT vs. Endoscopic Partial Plantar Fascia Release (EPFR)**

One randomized controlled trial compared FESWT to EPFR.[137] The investigators randomized 34 patients to receive one treatment of high intensity FESWT under conscious sedation or 31 patients to receive EPFR under general of spinal anesthesia. The mean age was 38.7 years and 61.5% were males. The mean duration of symptoms was 17.7 months. This study was judged to be moderately low risk of bias due to non-blinded assessment and slightly different post treatment routines (unequal co-interventions).

**Pain**

*Short-term pain:* There was no difference 3 months after treatment in one study (Radwan 2012)[137] between FESWT and EPFR with respect to pain when first walking in the morning, median pain score (VAS, 1-10, worst), 4.0 (interquartile range, 3.5 to 5.5) in the FESWT group and 4.1 (interquartile range 3.0 to 4.9) in the EPFR group.

*Intermediate-term pain:* There is no evidence during the intermediate-term.

*Long-term pain*: There was no difference 12 months after treatment between FESWT and EPFR with respect to pain when first walking in the morning, median pain score (VAS, 1-10, worst), 4.0 (interquartile range, 3.5 to 5.5) in the FESWT group and 4.1 (interquartile range 3.0 to 4.9) in the EPFR group. [137]

**Function**

*Short-term function:* Functional outcome as measured by the AOFAS Ankle-Hindfoot Scale was reported in a single study in the short-term, (Radwan 2012). [137] There was no difference between the FESWT and EPFR groups comparing the median AOFAS Ankle-Hindfoot total score (0-100, best) at 3 month follow-

up, 70 (interquartile range, 54 to 79) versus 68 (interquartile range, 65 to 75), *p*>.05. This study was judged to have moderately low risk of bias for reasons stated above.

*Intermediate-term function*: There is no evidence during the intermediate-term.

*Long-term function*: Functional outcome as measured by the AOFAS Ankle-Hindfoot Scale was reported in a single study in the long-term, (Radwan 2012). There was no difference between FESWT and EPFR groups comparing the median AOFAS Ankle-Hindfoot total score (0-100, best) at 12 month follow-up, 81 (interquartile range, 73 to 85) versus 77 (interquartile range, 73 to 84), *p*>.05. This study was judged to have moderately high risk of bias for reasons stated above.

**Other Outcomes Measures**

*Roles Maudsley (RM):* There was no difference between FESWT and EPFR groups in the proportion of patients achieving a good or excellent score 3 or 12 months after treatment as measured by the RM, 64.7% in the FESWT group versus 51.6% in the EPFR group in the short-term and 70.6% versus 77.4% in the long-term.

#### 4.1.2.3. Radial ESWT vs. SHAM for Plantar Fasciitis

***Studies included***

Three RCTs were included. One study (Gerdesmeyer 2008)[56] randomized 129 patients to receive 3 sessions of medium intensity RESWT at two week intervals and 122 patients to receive sham. Neither group received local anesthesia. The study population mean age was 52 years, 32% were males, and the mean duration of symptoms was 11 months. Another study Ibrahim 2010, 2016)[76,77] randomized 25 patients to receive two sessions of medium intensity RESWT at a one week interval and 25 patients to receive sham. Neither group received local anesthesia. The study population mean age was 53 years, 36% were males, and the symptom duration was ≥6 months. The third study (Mehra 2003)[115] enrolled 13 patients to receive three sessions of RESWT at weekly intervals and 10 patients to receive sham. Both groups received local anesthesia. The study population mean age was not reported, 66% were males, and the mean duration of symptoms was 11 months. Detailed information on patient and study characteristics is available in Appendix Table F1. The trial by Gerdesmeyer 2008 was the strongest study with a low risk of bias. Ibrahim was graded as having moderately low risk of bias due to unequal distribution of patient characteristics between groups at baseline that were not accounted for in the analysis. The study by Mehra 2003 was judged to have a moderately high risk of bias due to unclear random sequence generation, unclear intention to treat, unreported baseline characteristics to assess the potential for confounding in one study. Risk of bias assessment for all studies is found in Appendix Table E1.

***Efficacy***

**Pain**

*Short-term pain:* The proportion of patients that achieved pain success when first walking in the morning 3 months after treatment was higher in those receiving RESWT compared with sham in one trial (Gerdesmeyer),[56] 61% versus 48 %, risk ratio (RR) 1.26 (95% CI, 1.00 to 1.59), Table 8. Success in early

morning walking was defined as ≥ 60% improvement in pain over baseline. Results were similar in the same study with respect to pain with activity success (RR 1.48; 95% CI, 1.14 to 1.91), and composite pain success (RR 1.44; 95% CI, 1.12 to 1.86). Pain with activity success was defined as >60% decrease in pain over baseline with activity, and composite pain success was defined as >60% decrease in pain over baseline in ≥2 of 3 pain scores (pain with first morning steps, pain with activities, pain with pressure). In a second trial,[76,77] pain NOS success, defined as >50% improvement from baseline, was achieved in 96% of the RESWT group and 0% in the sham group. Furthermore, RESWT had a significantly larger improvement in pain NOS from baseline, MD 6.2. This markedly exceeds the MCID of 1.5 (Table 1).

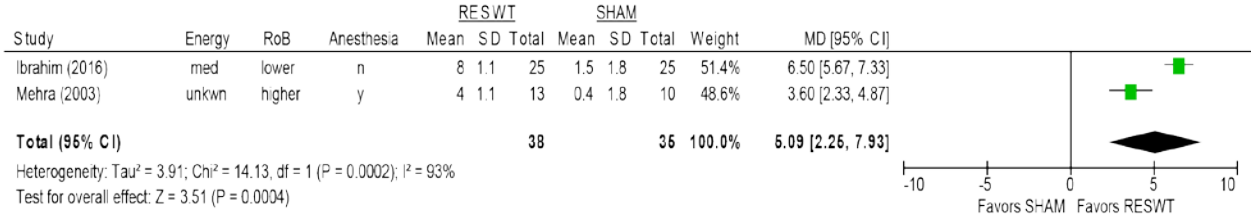
**Table 8. Short-term pain outcomes comparing Radial ESWT with sham**

| Author | Outcome | RESWT | Sham | Effect size (RR or MD) | p-value |
|---|---|---|---|---|---|
| Gerdesmeyer | Pain in AM success[1] | 60.8 (76/125) | 48.3% (57/118) | 1.26 (1.00, 1.59) | .051 |
| 2008 | Pain with activity success[2] | 60.0% (75/125) | 40.7% (48/118) | 1.48 (1.14, 1.91) | <.001 |
| | Composite pain success[3] | 61.0% (75/123) | 42.2% (49/116) | 1.44 (1.12, 1.86) | <.001 |
| Ibrahim | Pain NOS success[4] | 96.0% (24/25) | 0% (0/25) | not calculable | <.001 |
| 2010, 2016 | Pain NOS mean Δ from baseline | 7.4 (n=24) | 1.2 (n=25) | 6.2 | <.001 |

[1] Achieving ≥60% improvement in pain from baseline during the first few minutes of walking in the morning.
[2] >60% decrease in pain from baseline with activity.
[3] >60% decrease in pain from baseline in ≥2 of 3 pain scores (pain with first morning steps, pain with activities, pain with pressure).
[4] >50% improvement in pain from baseline.

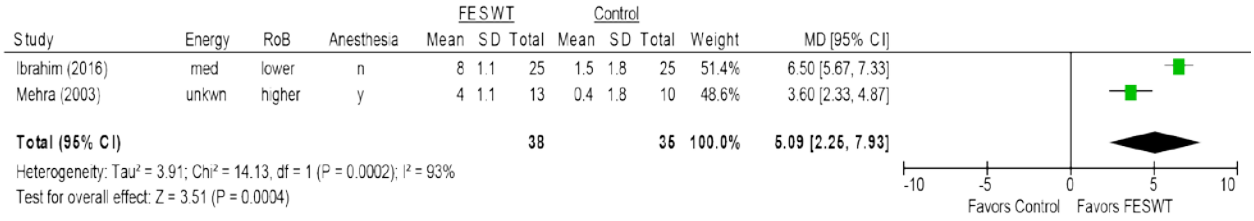
*Intermediate-term pain*: A higher proportion of patients achieved pain success in the RESWT group compared with the sham group in two studies 6 months after treatment, 97% versus 11%, RR 6.32 (95% CI, 2.83 to 14.1), Figure 14.[77,115] Pain success was defined as >50% improvement in pain over baseline in one study (Ibrahim 2016) and improvement of ≥3 over baseline in another (Mehra 2003).

**Figure 14. Radial ESWT vs. SHAM in plantar fasciitis: PROPORTION WITH PAIN SUCCESS, INTERMEDIATE-TERM FOLLOW-UP**




The mean difference in pain NOS in the same two studies also favored RESWT, MD 5.1 (95% CI, 2.3 to 7.9), which far exceeds the MCID of 1.5, Figure 15.

**Figure 15. Radial ESWT vs. SHAM in plantar fasciitis: MEAN CHANGE IN PAIN NOS FROM BASELINE (VAS 0-10), INTERMEDIATE-TERM FOLLOW-UP**

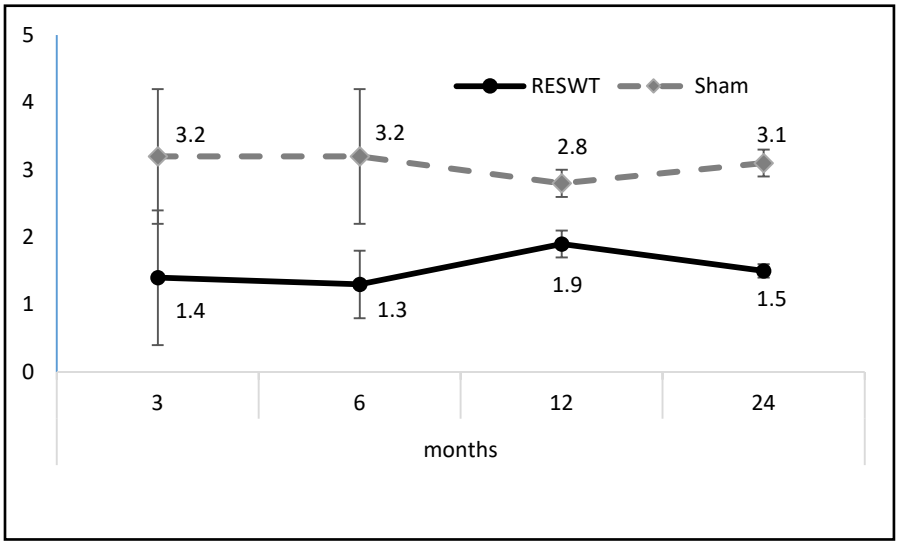



*Long-term pain*: One study followed patients for two years (Ibrahim 2016). A higher proportion of patients achieved pain success (>50% improvement in pain from baseline) in the RESWT group compared with the sham group, 72% versus 20% 12 months following treatment (RR 3.60; 95% CI, 1.58 to 8.18), and 96% versus 25% 24 months following treatment (RR 3.82; 95% CI, 1.90, 7.69). Furthermore, RESWT had a significant improvement in pain NOS from baseline compared with sham 24 months after treatment, MD 3.8. This markedly exceeds the MCID of 1.5.

**Other Outcomes Measures**

*Roles Maudsley (RM):* There was significant difference between groups in the RM score (1-4, worst) at 3, 6, 12 and 24 months in one study judged to have moderately low risk of bias (Ibrahim 2016), Figure 16.

**Figure 16. Roles Maudsley Outcomes Scores in Radial ESWT compared with SHAM at 3, 6, 12 and 24 months follow-up in one study (Ibrahim 2016).**



#### 4.1.2.4. Radial ESWT vs. Active Control for Plantar Fasciitis

#### 4.1.2.5.
#### RESWT vs. Ultrasound Therapy (US)

***Studies included***

Two RCTs were included. One study (Grecco 2013)[60] randomized 20 patients to receive three sessions of RESWT of 3 bar intensity at weekly intervals and 20 patients to receive 10 twice weekly sessions of ultrasound, 1.2 W/cm$^2$. The study population mean age was 49.6 years, 15% were males, and the mean duration of symptoms was ≥3 months. Both groups received additional co-interventions that included muscle and plantar fascia stretching. Another study Konjen 2015)[95] randomized 15 patients to receive six sessions of RESWT of 2 bar intensity at weekly intervals and 15 patients to receive 10 twice weekly sessions of ultrasound, 1.2 W/cm$^2$. The study popluation mean age was 45 years, 20% were males, and the mean symptom duration was 11 months. Both groups received additional co-interventions that included muscle and plantar fascia stretching, and shoe modification. Detailed information on patient and study characteristics is available in Appendix Table F1. The trial by Konjen 2015 was the stronger study with a moderately low risk of bias due to unknown blind assessment. Grecco was graded as having moderately high risk of bias due to no random sequence generation, unclear concealment allocation, and no blind assessment. Risk of bias assessment for all studies is found in Appendix Table E1.

***Efficacy Results***

**Pain**

*Short-term pain:* There was no difference between RESWT and US therapy in the proportion of patients reporting no pain at 3 month follow-up in one study of moderately high risk of bias (Grecco 2013)[60], 45% versus 50%. Additionally the same study reported no difference between groups with respect to the proportion of patients with pain success when first walking in the morning, 70% versus 65%, and no difference on pain success during ambulation, 70% versus 75%. Pain success was defined as 0 or 1 on VAS (0-10, worst). A second study[95] of higher quality reported a significant decrease in pain NOS with RESWT compared with US 3 months after treatment, MD 2.4 ($p$ =.001), which exceeds the MCID of 1.5.

*Intermediate-term pain:* One study of moderately low risk of bias (Konjen, 2015) reported a significant decrease in pain NOS with RESWT compared with US 6 months after treatment, MD 4.1 ($p$ <.001), which markedly exceeds the MCID of 1.5.

*Long-term pain:* One study of moderately high risk of bias (Grecco 2013) reported no statistical difference between RESWT and US therapy in the proportion of patients reporting no pain at 12 month follow-up (Grecco 2013), 70% versus 45%. Additionally the same study reported no difference between groups with respect to the proportion of patients with pain success when first walking in the morning, 85% versus 80%, and no difference on pain success during ambulation, 75% versus 95%. Pain success was defined as 0 or 1 on VAS (0-10, worst).

### 4.1.3. Lateral Epicondyle Tendinopathy (LET)

**Summary of results**

**Focused ESWT versus Sham:**

We report on three pain outcomes: pain with resistance to wrist extension; pain not otherwise specified (NOS); pain at night. With respect to pain with resistance to wrist extension, patients receiving FESWT were twice as likely to achieve ≥50% improvement over baseline in the short-term compared with those receiving sham in two studies, RR 2.2 (95% CI, 1.6 to 3.1) (strength of evidence, MODERATE). There is no evidence during intermediate-term and INSUFFICIENT evidence in the long-term assessing pain with resistance to wrist extension. There is INSUFFICIENT evidence from three small studies to determine the effect of FESWT vs. sham on pain NOS in the short-term, and there is no intermediate- or long-term evidence for this outcome. There is no difference during the short-term in improvement in night pain between FESWT and sham in two studies (strength of evidence, LOW). There is no intermediate- or long-term evidence for this outcome.

There was statistically significant improvement in function during the short-term as measured by the Upper Extremity Functional Scale (UEFS) in two studies, MD 9.1, but no difference after 12 months (strength of evidence, MODERATE). The UEFS lacks psychometric testing and no MCID has been established. There is no intermediate-term evidence for function.

**Focused ESWT versus Active Control**

*FESWT versus CSI:* There is insufficient evidence from two RCTs to determine the effect of FESWT compared with CSI on pain or function in the short-, intermediate-, or long-term.

*FESWT versus Percutaneous Tenotomy:* There is insufficient evidence from one small RCT to determine the effect of FESWT compared with percutaneous tenotomy with respect to improvement in pain in the short- or long-term. There is no evidence on pain in the intermediate-term. There is no evidence on function for any time period.

**Radial ESWT versus Sham:** There is insufficient evidence from two small RCTs to determine the effect of RESWT compared with sham with respect to improvement in pain or function in the short-term. There is no evidence for the intermediate- or long-term.

#### 4.1.3.1. FESWT vs. SHAM for LET

***Studies included***

Seven RCTs[25,28,64,117,132,146,168] were included that enrolled between 60 and 272 patients. Detailed information on patient and study characteristics is available in Appendix, Table F2. The mean duration of symptoms in six studies ranged from 5 to 25 months with one study only reporting that "extensive conservative treatment" was tried and that patients were on a wait list for surgery.[117] The proportion of patients that were males ranged from 42% to 60% across studies. The mean age ranged from 43 to 47 years. Three studies used low intensity FESWT (Haake 2002, Rompe 2004, Pettrone 2005), two used medium intensity (Speed 2002, Chung 2004), one used high intensity (Collins 2011), and one study did not report the intensity level (Melikyan 2013). Two used a local anesthetic in conjunction with the FESWT (Haake 2002, Collins 2011) and five used none (Rompe 2004, Pettrone 2005, Melikyan 2013, Chung 2004, Speed 2002). Three trials were at LOW risk of bias (Chung 2004, Haake 2002, Rompe

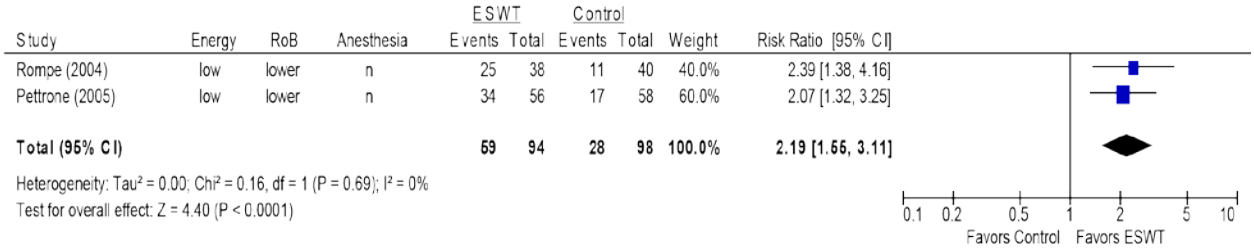
2004), one at MODERATELY LOW risk of bias (Pettrone 2005), and three at MODERATELY HIGH risk of bias (Collins 2011, Melikyan 2003, Speed 2002). Risk of bias assessment for all studies is found in Appendix, Table E2.

***Efficacy Results***

**Pain**

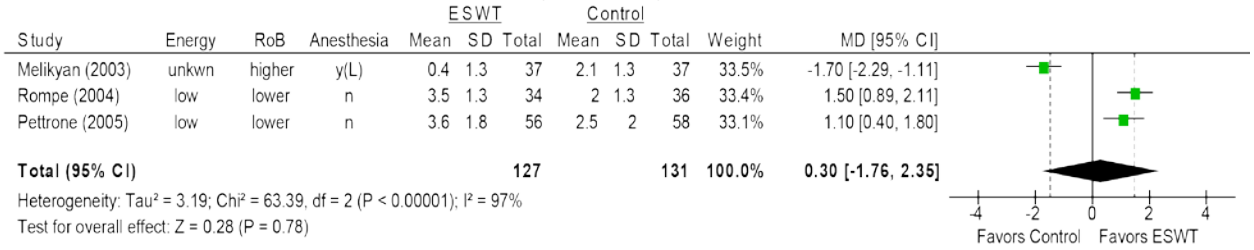
*Short-term pain:* The proportion of patients that achieved pain success with resistive wrist extension 3 months after treatment was higher in those receiving FESWT compared with sham in two trials,[132,146] pooled risk ratio (RR) 2.2 (95% CI, 1.6 to 3.1), Figure 17. Success was defined as ≥50% improvement over baseline during the Thomsen test.

**Figure 17. Focused ESWT vs. SHAM in lateral epicondyle tendinopathy: PROPORTION SUCCESS WITH PAIN DURING RESISTANCE, SHORT-TERM FOLLOW-UP**



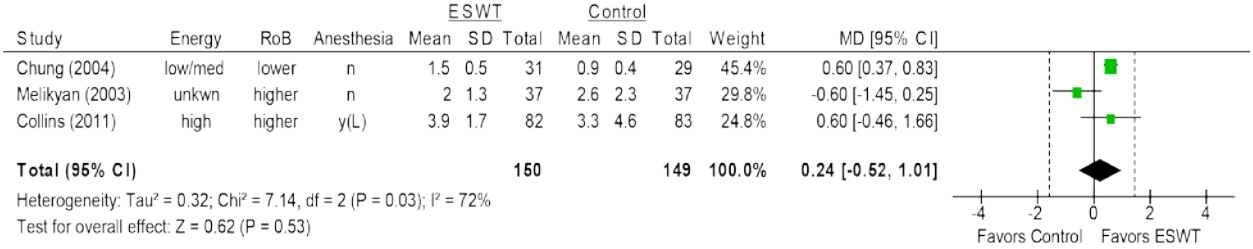

Three studies recorded the mean change from baseline in pain during resistance to the wrist extensor muscles, two via the Thomsen test[132,146] and one using a 5 Kg weight.[117] There was no difference in pain in the pooled analysis, MD 0.30 (95% CI, -1.76 to 2.35), Figure 18. This analysis resulted in a large amount of heterogeneity ($I^2$=97%). Therefore, we evaluated separately the higher quality studies with the lower risk of bias (Rompe 2004, Pettrone 2005). The mean difference pooling the higher quality studies was 1.33 (95% CI, 0.87 to 1.79), $I^2$=0%, Appendix I. Though statistically significant, the MD did not meet the clinically important threshold.

**Figure 18. Focused ESWT vs. SHAM in lateral epicondyle tendinopathy: CHANGE IN MEAN PAIN SCORE DURING RESISTANCE TO WRIST EXTENSION (VAS 0-10), SHORT-TERM FOLLOW-UP**



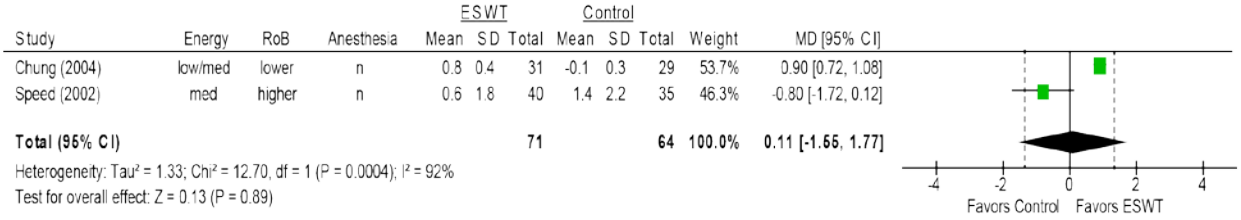
Three studies report a mean difference in pain NOS from baseline at a 2 to 3 month follow-up.[25,28,117] Further description of pain in these studies was absent. There was no difference between treatments in the pooled estimate, mean difference (MD) 0.24 (-0.52, 1.01), Figure 19. Due to the large amount of heterogeneity ($I^2$=72%), we evaluated separately the higher quality study with the lower risk of bias (Chung 2004). The mean difference in this higher quality study was 0.60 (95% CI, 0.37 to 0.83), Appendix I. Though statistically significant, the MD did not meet the clinically important threshold.

**Figure 19. Focused ESWT vs SHAM in lateral epicondyle tendinopathy: CHANGE IN PAIN NOS SCORE (VAS 0-10) FROM BASELINE, SHORT-TERM FOLLOW-UP**




There was no difference in night pain as reported by two studies,[25,168] MD 0.1 (95% CI, -1.6 to 1.8), Figure 20. Due to the large amount of heterogeneity ($I^2$=92%), we evaluated separately the higher quality study with the lower risk of bias (Chung 2004). The study results statistically favored FESWT, but the mean difference was less than the cutoff deemed to be clinically important, MD 0.9 (95% CI, 0.7 to 1.1), Appendix I.

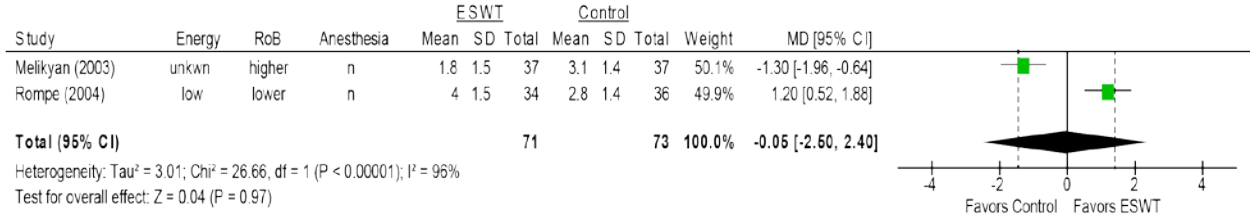
**Figure 20. Focused ESWT vs SHAM in lateral epicondyle tendinopathy: CHANGE IN NIGHT PAIN SCORE (VAS 0-10) FROM BASELINE, SHORT-TERM FOLLOW-UP**




*Intermediate term pain:* There is no evidence during the intermediate term.

*Long-term pain:* Two studies report long-term pain with resistive wrist extension at 12 months follow-up.[117,146] There was no difference in the pooled estimate, MD -0.1 (95% CI, -2.5 to 2.4), Figure 21. This analysis resulted in a large amount of heterogeneity ($I^2$=96%). Therefore, we evaluated separately the higher quality study with the lower risk of bias (Rompe 2004). The study found a statistical difference in the long-term 12 month benefit of FESWT versus sham, MD 1.2 (95% CI, 0.5 to 1.9); however this was less than the clinical important difference of 1.5.

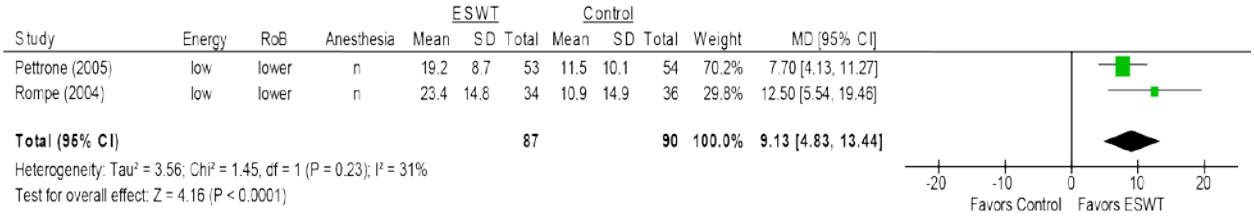
**Figure 21. Focused ESWT vs SHAM in lateral epicondyle tendinopathy: CHANGE IN PAIN SCORE (VAS 0-10) WITH RESISTANCE FROM BASELINE, LONG-TERM FOLLOW-UP**




**Function**

*Short-term function:* Functional outcome as measured by the upper extremity functional scale (UEFS) was reported in two studies and was significantly improved in patients receiving FESWT versus sham, pooled MD 9.1 (95% CI, 4.8 to 13.4),[132,146] Figure 22. Both studies were either low or moderately low risk of bias. There was no difference in the Disabilities of the Arm, Shoulder and Hand (DASH) Score in one low quality (high risk of bias) study.[117] Concerns about the lower quality study include uncertainty around random sequence generation and concealed allocation, intention to treat, differential loss to follow-up and unequal baseline prognostic characteristics between groups.

**Figure 22. Focused ESWT vs SHAM in lateral epicondyle tendinopathy: CHANGE IN UPPER EXTREMITY FUNCTIONAL SCALE FROM BASELINE, SHORT-TERM FOLLOW-UP**



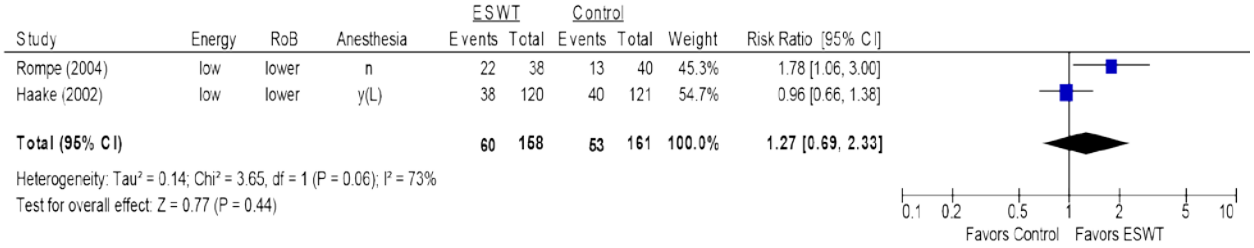

*Intermediate-term function:* There is no evidence during the intermediate term.

*Long-term function:* There was no difference between groups at 12 months in function as measured by the UEFS in one study[146], MD 6.6 (95% CI, -1.68 to 14.88) or the DASH in another[117], MD -0.35 (unable to calculate confidence interval for lack of data).

**Other Outcomes Measures**

*Roles Maudsley (RM):* There was no difference in the proportion of patients achieving a good or excellent score 3 months after treatment as measured by the RM in two studies,[64,146] pooled risk ratio 1.3 (95% CI, 0.7, 2.3), Figure 23. This analysis resulted in a large amount of heterogeneity ($I^2$=73%). Both studies were low risk of bias, therefore we evaluated RM using the profile likelihood method. The estimates were similar. One study (Rompe 2004) followed patients for 12 months and found a difference in the proportion of patients with a good or excellent score in favor of FESWT, RR 1.6 (95% CI, 1.0 to 2.5).

**Figure 23. Focused ESWT vs SHAM in lateral epicondyle tendinopathy: PROPORTION WITH GOOD OR EXCELLENT ROLES MAUDSLEY SCORE, SHORT-TERM FOLLOW-UP**




*Composite success:* Three studies reported the proportion of patients achieving a successful composite score.[26,28,64] All composite scores varied in the components making up the score. There was no difference between groups in the short-term in two high quality studies, Table 9. One low quality study showed a statistical difference with a RR of 1.6 in favor of FESWT. Concerns about the lower quality study include uncertainty around random sequence generation and concealed allocation, and intention to treat.

**Table 9. Proportion of patients achieving a composite measure in three studies.**

| Author | Definition | F/U (mos) | FESWT | CONTROL | RR (95% CI) | RoB |
|---|---|---|---|---|---|---|
| Haake 2002 | RM of 1 or 2, and patient not receiving any additional conservative or operative treatment during observed time-interval | 3 | 25.8% (32/124) | 25.4% (31/122) | 1.0 (0.7 to 1.6) | Low |
| Chung 2004 | ≥50% reduction in overall pain, pain score ≤4.0 cm, and no use of pain medication for 2 weeks before evaluation | 2 | 39% (12/31) | 31% (9/29) | 1.2 (0.6 to 2.5) | Low |
| Collins 2011 | 50% improvement in investigator's assessment of pain and pain score of ≤4.0, 50% improvement in self-assessed pain with activity and pain score of ≤4.0, no analgesics | 2 | 35.5% (33/93) | 22.2% (20/90) | 1.6 (0.99 to 2.6) | Moderately High |

*Grip strength:* Four studies reported the change in grip strength in the short-term[25,117,132,146] and two in the long-term.[117,146] There was no differences between groups at either time period, pooled MD 0.73 (95% CI, -1.63 to 3.10) in the short-term, Figure 24, and -0.02 (95%CI, -3.3 to 3.2) in the long-term, Figure 25. The short-term analysis resulted in a large amount of heterogeneity ($I^2$=65%). Therefore, we evaluated separately the higher quality studies with the lower risk of bias (Rompe 2004, Pettrone 2005, Chung 2004). Heterogeneity continued to be large among those studies ($I^2$=75%). Therefore we evaluated short-term grip strength using the profile likelihood method. The estimates were similar.

**Figure 24. Focused ESWT vs SHAM in lateral epicondyle tendinopathy: CHANGE IN GRIP STRENGTH (kg) FROM BASELINE, SHORT-TERM FOLLOW-UP**

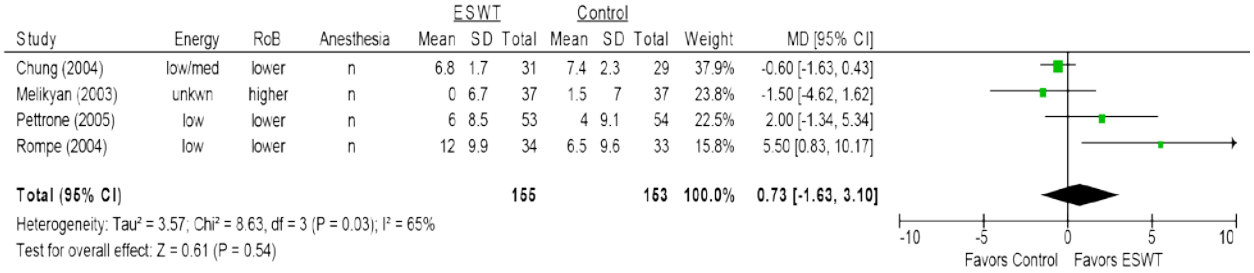
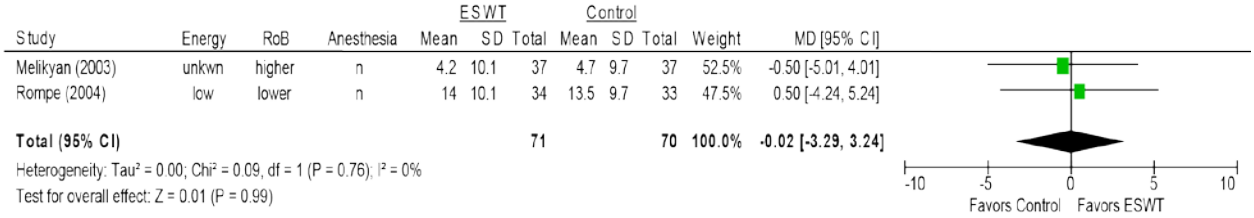



**Figure 25. Focused ESWT vs SHAM in lateral epicondyle tendinopathy: CHANGE IN GRIP STRENGTH FROM BASELINE, LONG-TERM FOLLOW-UP**




#### 4.1.3.2. Focused ESWT vs. Active Control for LET

***Studies included***

Three RCTs were identified that evaluated the efficacy of FESWT compared with active control for chronic lateral epicondyle tendinopathy. Comparisons included FESWT versus CSI (2 trials; Crowther 2002, Ozturan 2010) and FESWT versus percutaneous tenotomy (1 trial; Radwan 2008). Detailed information on patient and study characteristics is available in Appendix Table F2. All three trials were considered to be at moderately high risk of bias (see Appendix E2 for details regarding risk of bias rating).

***Efficacy Results***

**Focused ESWT vs. Corticosteroid Injection (CSI)**

Two trials compared FESWT against corticosteroid injections. The first randomized 51 patients to receive three treatments of FESWT with a week in between and 42 patients to receive one CSI at the point of maximum tenderness.[37] After random assignment, 17 (40%) of those randomized to receive CSI refused treatment. The second study randomized 20 patients each to receive FESWT or CSI.[129] In addition, this study included another experimental arm, autologous blood injection, which is not included in this assessment. Both studies have methodological weaknesses and as a result are considered as moderately high risk of bias.

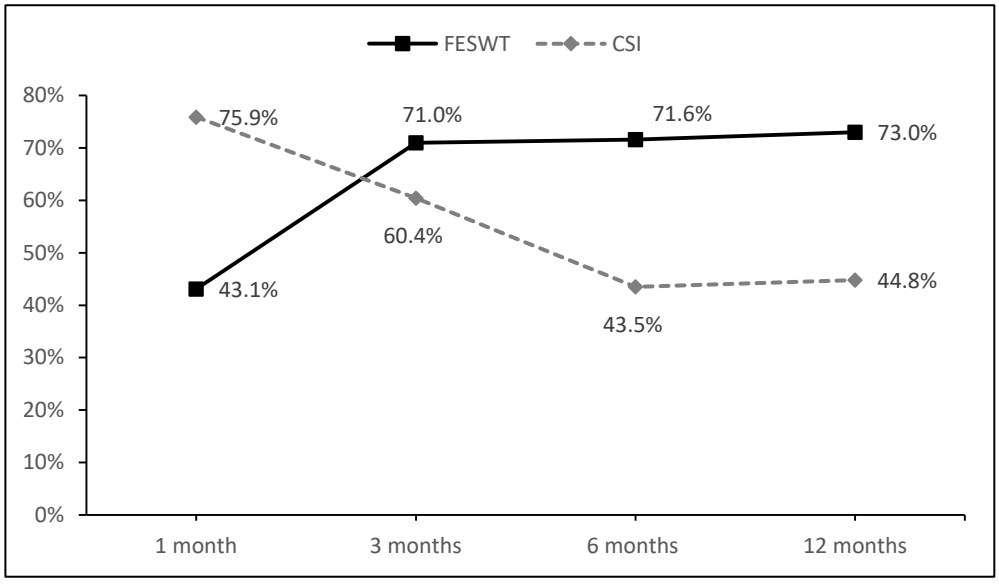
**Pain**

*Short-term pain*: One trial (Crowther 2002)[37] reported a statistically smaller proportion of patients receiving FESWT achieved at least 50% improvement in pain NOS at 3 month follow-up compared with CSI, 60% versus 84%. A second trial (Ozturan 2010)[129] found a 43% mean improvement in pain with resistance to wrist extension via the Thomsen Test in the FESWT group 4 weeks following treatment compared with 76% in the CSI group, P<.001. However, by three month follow-up, there was no statistical difference between the groups, mean improvement 71% versus 60%, respectively. Both these studies suffered from significant methodological flaws. In Crowther 2002, there was unclear random sequence generation, no intention to treat analysis, unclear blinding, large lost to follow-up, differential loss to follow-up and unequal baseline characteristics between groups. The study by Ozturan 2010 suffered from unclear random sequence generation, concealed allocation and intention to treat analysis. Furthermore, there was no assessor blinding and unequal baseline characteristics between groups.

*Intermediate-term pain*: Six month follow-up was reported in one trial (Ozturan 2010) that found FESWT group had a significantly higher mean improvement in pain compared with CSI, 71.6% versus 43.5% (Figure 26). Methodological concerns are stated above.

*Long-term pain*: Twelve month follow-up was reported in one trial (Ozturan 2010) that found FESWT group had a significantly higher mean improvement in pain compared with CSI, 73.0% versus 44.8%. (Figure 26) Methodological concerns are stated above.

**Figure 26. Percent mean improvement over baseline pain during Thomsen Test over time comparing Focused ESWT and CSI in one study (Ozturan 2010).**



**Function**

*Short-term function:* Functional outcome as measured by the upper extremity functional scale (UEFS) was reported in one poor quality study.[129] At the 1 month follow-up, the FESWT group showed a significantly less mean improvement in the functional score (39.8%) compared with the CSI group (60.5%) in the UEFS. No statistically significant difference was found between groups at 3 month follow-up, 63.7% versus 55.7% improvement, respectively. Methodological concerns Include unclear random sequence generation, concealed allocation and intention to treat analysis. Furthermore, there was no assessor blinding and unequal baseline characteristics between groups.

*Intermediate-term function:* At the 6 month evaluation (Ozturan 2010), the UEFS had increased in the FESWT group showing a mean improvement of 61.5% compared with mean improvement of 41.8% in the CSI, P<.001. Methodological concerns for this study are listed above.

*Long-term function:* At the 12 month evaluation (Ozturan 2010), the UEFS had increased in the FESWT group showing a mean improvement of 60.9% compared with mean improvement of 40.9% in the CSI, P<.001. Methodological concerns for this study are listed above.

**Focused ESWT vs. Percutaneous Tenotomy**

***Studies included***

One study compared FESWT to percutaneous tenotomy.[136] The study population consisted of mostly males (59%) with a mean age of 29.7 years. Symptoms duration ranged from 6 to 60 months. Methodological concerns of this study include unknown random sequence generation, no intention to treat analysis, and no assessor blinding. The risk of bias for this study was moderately high.

**Pain**

*Short-term pain:* There was no difference in one study (Radwan 2008) between groups after 3 months in the proportion of patients achieving ≥50% improvement in pain with resistance to wrist extension via the Thomsen Test, 72.4% in the FESWT group versus 85.2% in the tenotomy group.

*Intermediate-term pain:* There is no evidence during the intermediate-term.

*Long-term pain:* There was no difference in one study (Radwan 2008) between groups after 12 months in the proportion of patients achieving ≥80% improvement in pain with resistance to wrist extension via the Thomsen Test, 48.3% in the FESWT group versus 63.8% in the tenotomy group.

**Other Outcomes Measures**

*Roles Maudsley (RM):* There was no difference in the proportion of patients achieving a good or excellent score 3 or 12 months after treatment as measured by the RM, 65.5% in the FESWT group versus 74.1% in the tenotomy group in the short-term and 62.1% versus 77.8% in the long-term.[136]

#### 4.1.3.3. Radial ESWT vs. SHAM for LET

***Studies included***

Two very small RCTs were included, one that enrolled 23 patients with a mean duration of symptoms of 11 months[115] and one that enrolled 56 patients with symptom duration of 8 months.[19] Detailed

information on patient and study characteristics is available in Appendix Table F2. Both trials are MODERATELY HIGH risk of bias.(Mehra 2003, Capan 2016) Methodological concerns include unknown random sequence generation, unknown intention to treat, unreported baseline characteristics to assess the potential for confounding in one study (Mehra 2003); and unknown concealed allocation, no intention to treat and uneven distribution of prognostic characteristics at baseline with no adjustment in the second study (Capan 2016). Risk of bias assessment for all studies is found in Appendix Table E2.

***Efficacy***

**Pain**

*Short-term pain:* There was no difference between groups in one small RCT (Capan) in the mean change from baseline in pain at rest (MD 0.1); pain with activity (MD 1.2); Roles Maudsley Score (MD 0.0); Patient Reported Tennis Elbow Evaluation pain (MD 3.5), function (MD 4.8) and total (md 8.3).
*Intermidate-term pain:* In the mid-term in one very small study (Mehra 2003) reported a higher proportion of patients achieving pain success, defined as ≥3 points improvement from baseline pain score, in the RESWT group (10/13) compared with sham (1/11), RR 8.5 (95% CI, 1.3 to 56.1).
*Long-term pain:* There is no evidence during the long-term.

**Function**

There are no functional outcome measures comparing RESWT versus sham for lateral epicondyle tendinopathy.

### 4.1.4. Shoulder Tendinopathies

**Summary of results**

***Rotator Cuff Tendinopathy***

**Focused ESWT vs. Sham**
Four different pain outcomes were reported: pain not otherwise specified (NOS), pain at night, pain at rest, and pain with activity. Though the proportion of patients who achieved pain success, defined as ≥50% improvement on VAS, was not statistical different between groups in the short-term in one trial (LOW strength of evidence), two trials found that FESWT resulted in statistically and clinically greater improvement in pain NOS compared with sham over the short- (MD 3.14; 95% CI 0.70, 5.58), intermediate- (MD 3.76; 95% CI 1.73, 5.78), and long-term (MD 4.56; 95% CI 2.90, 6.22) (LOW strength of evidence for short- and intermediate-term; MODERATE for long-term). No statistical differences were seen between groups in pain at night over short- and intermediate-term follow-up as reported by one trial or pain at rest and with activity over the short- and long-term as reported by another trial (all LOW strength of evidence).

Function was evaluated using three different measures: the Constant score, the Shoulder Pain and Disability Index (SPADI), and the Disabilities of the Arm, Shoulder and Hand (DASH) score. Results were inconsistent across trials. Three studies reported no significant difference between groups in function success, defined as the proportion of patients achieving ≥30 point improvement in Constant score or

80% of the normal value (2 RCTs) and ≥50% improvement in SPADI (1 RCT), over the short-term (LOW strength of evidence for all). MODERATE quality evidence from another trial found a significantly greater proportion of FESWT compared with sham patents achieved ≥30% improvement in the Constant score at short-term (RR 2.70; 95% CI 1.47, 4.94), intermediate-term (RR 3.94; 95% CI 1.97, 7.86), and long-term (RR 3.07; 95% CI 1.57, 6.01) follow-up. One trial reported no statistical differences between groups in function improvement on the SPADI over short- and intermediate-term follow-up (LOW strength of evidence), whereas FESWT resulted in a statistically greater improvement in function according to the Constant score over the short-term in five trials and the long-term in two trials (LOW strength of evidence).

**Focused ESWT vs. Active Control**

*FESWT vs. US-guided needling plus corticosteroid injection*: No statistically significant differences were seen in pain or function over the short- and intermediate-term in one trial; however, at long-term follow-up, FESWT resulted in statistically and clinically less improvement in pain NOS (MD -2.4) and function according to the American Shoulder and Elbows Surgeons score (MD -24.1) and the Simple Shoulder Test (MD -8.3) compared with US-guided needling plus corticosteroid injection. The strength of evidence was LOW for all outcomes and time points.

*FESWT vs. TENS*: There was INSUFFICIENT evidence from one small RCT to determine if FESWT or TENS is superior with regards to pain and function improvement over the short-term. There was no evidence over the intermediate- or long-term.

**Radial ESWT vs. Sham**

There was INSUFFICIENT evidence from one small RCT to determine if RESWT or sham is superior with regards to pain and function improvement over the short- and intermediate-term. There was no evidence over the long-term.

**Radial ESWT vs. Active Control**

*RESWT vs. US-guided Percutaneous Lavage (UGPL)*: There was INSUFFICIENT evidence from one small RCT to determine if RESWT or UGPL is superior with regards to pain improvement over the short-, intermediate- or long-term. There was no evidence for function.

***Adhesive Capsulitis of the Shoulder***

**Focused ESWT vs. Sham**

There was INSUFFICIENT evidence from one small RCT to determine if FESWT or sham is superior with regards to pain and function over the short- and intermediate-term. There was no evidence over the long-term.

**Focused ESWT vs. Active Control**

*FESWT vs. Oral Steroids*: There was INSUFFICIENT evidence from one small RCT to determine if FESWT or oral steroid therapy is superior with regards to function over the short-term. There was no evidence for pain or for results over the intermediate- or long-term.

**Radial ESWT vs. Sham**

RESWT resulted in a statistically and clinically greater improvement in pain at rest and with activity (MODERATE strength of evidence) and function (HIGH strength of evidence) over both the short- and intermediate-term, as reported by one small RCT. Specifically, the mean difference between groups in

the DASH scores was over five times higher than the clinically important threshold at both time points: MD 55.6 (95% CI 50.5, 60.8) and MD 55.3 (95% CI 49.8, 60.7, -49.8), respectively. There was no evidence over the long-term.

***Subacromial Shoulder Pain***

**FESWT:** No studies were identified.

**RESWT vs. Active Control**

*RESWT vs. Supervised exercise*: One small RCT reported no differences between the groups in pain improvement at any time point. Regarding function, statistically, but not clinically, less improvement was noted over the short- and intermediate-term in patients who received RESWT compared with supervised exercise; no differences were seen between groups in function over the long-term. The strength of evidence was MODERATE for all short- and intermediate-term outcomes and LOW for all long-term outcomes.

***Bicipital Tenosynovitis of the Shoulder***

**FEWST:** No studies were identified.

**RESWT vs. Sham**

One small RCT reported significantly better pain and function outcomes following RESWT compared with sham over the short- (LOW strength of evidence) and long-term (MODERATE strength of evidence). There was no evidence over the medium-term.

***Rotator Cuff Tendinopathy***

#### 4.1.4.1. Focused ESWT vs. SHAM for Rotator Cuff Tendinopathy

***Studies included***

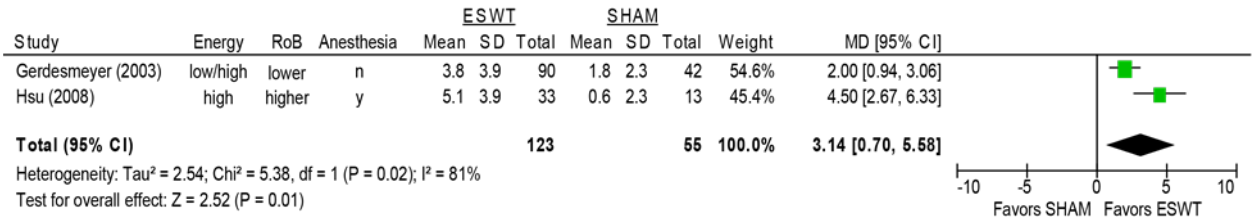
A total of seven trials (in 8 publications)[33,45,55,57,73,131,159,170] were identified that evaluated the efficacy of FESWT compared with sham for the treatment of calcific (4 trials)[33,57,73,131] and noncalcific (3 trials)[45,55,159,170] tendinopathy of the rotator cuff. Detailed information on patient and study characteristics is available in Appendix Table F3. Sample sizes ranged from 20 to 144; the majority of patients were female (~60%) and the mean age ranged from 50.9 to 55.4 years. The mean duration of symptoms in five studies ranged widely from 12.0 to 53.3 months.[33,55,57,73,170] Two studies did not state the mean duration but included only patients with symptoms ≥6 months.[45,131,159] Three trials used low intensity,[45,55,57,159] two used moderate intensity[131,170] and four used high intensity[33,57,73,131]; two studies stratified results in the FESWT group by energy intensity, low[57] and moderate[131] versus high intensity in both trials. Three trials used local anesthetic in conjunction with the FESWT[45,55,73,159] and three used none[33,131,170]; one trial stated that local anesthetic was prohibited but that adequate intravenous analgesia and/or sedation were provided as necessary.[57] One trial was at LOW risk of bias,[57] three at MODERATELY LOW risk of bias,[45,55,159,170] and three at MODERATELY HIGH risk of bias.[33,73,131] Risk of bias assessment for all studies is found in Appendix Table E3.

***Efficacy Results***

**Pain**

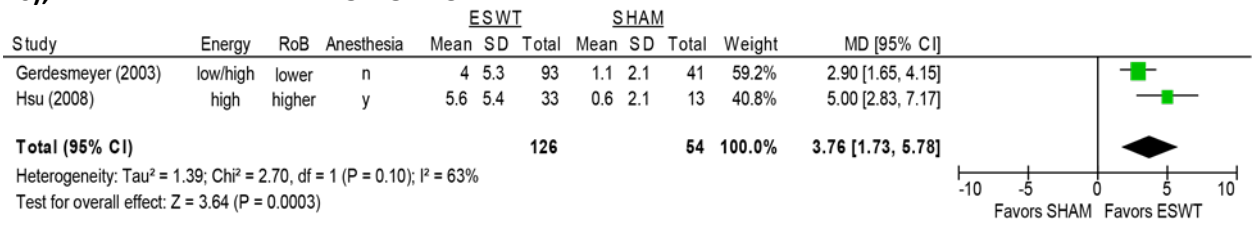
*Short-term pain:* One trial reported the proportion of patients who achieved ≥50% improvement in pain at night over baseline (VAS 0-10, worst) with no statistical difference between the FESWT and the sham groups after 3 months: 41% (14/34) vs. 38% (15/40), respectively.[170] Two studies recorded the mean change from baseline in pain (not otherwise specified, NOS) on VAS.[57,73] In the pooled analysis, there was a statistically significant difference between groups in pain improvement at 3 months favoring FESWT, pooled MD 3.14 (95% CI 0.70, 5.58), Figure 27. This analysis resulted in a large amount of heterogeneity ($I^2$=81%). Therefore, we evaluated separately the higher quality study with the lower risk of bias (Gerdesmeyer 2003).[57] The mean difference in the higher quality study was statistically significant favoring FESWT, MD 2.00 (95% CI 0.94, 3.06), and is considered to be clinically important. One study recorded the mean change from baseline in pain at night (VAS 0-10, worst); there was no significant difference in change scores between groups at the 3-month follow-up: MD -0.56 (95% CI -1.38, 0.26).[170] Another trial reported improvement in pain at rest and with activity (VAS 0-10, worst) at 3 months; there was no difference between groups in mean change scores (over baseline) for either pain measure, respectively, MD 0.87 (95% CI -0.3, 2.04) and MD 1.06 (95% CI -0.25, 2.37).[159]

**Figure 27. Focused ESWT vs. SHAM in rotator cuff tendinopathy: MEAN CHANGE IN PAIN NOS (VAS 0-10), SHORT-TERM FOLLOW-UP**



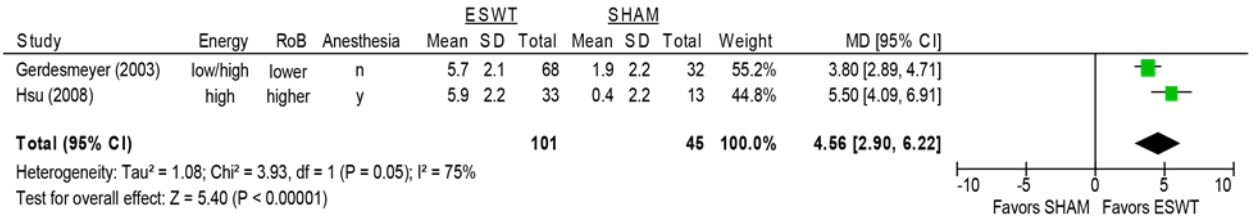

*Intermediate-term pain:* One trial reported the proportion of patients who had recurrence of pain at 6 months and found a statistically significant difference between groups, with fewer patients in the FESWT group complaining of pain, 87% (26/30) versus 100% (29/29) in the sham group,[131] RR 0.87 (95% CI 0.75, 0.99). Two studies recorded the mean change from baseline in VAS pain NOS.[57,73] There was a statistically significant difference in pain improvement at 6 months favoring the FESWT group in the pooled analysis, MD 3.76 (95% CI 1.73, 5.78), Figure 28. This analysis resulted in a large amount of heterogeneity ($I^2$=63%). Therefore, we evaluated separately the higher quality study with the lower risk of bias (Gerdesmeyer 2003).[57] The MD in the higher quality study was 2.90 (95% CI 1.65, 4.15); this difference was statistically significant in favor of FESWT and met the clinically important threshold. One study recorded the mean change from baseline in pain at night (VAS 0-10, worst) by 6 months of follow-up; there was no significant difference in change scores between groups: MD -0.08 (95% CI -0.9, 0.74).[170]

**Figure 28. Focused ESWT vs. SHAM in rotator cuff tendinopathy: MEAN CHANGE IN PAIN NOS (VAS 0-10), INTERMEDIATE-TERM FOLLOW-UP**




*Long-term pain:* Two studies recorded the mean change from baseline in VAS pain (NOS) scores.[57,73] In the pooled analysis, there was a statistically significant difference between groups in pain improvement at 12 months favoring FESWT, pooled MD 4.56 (95% CI 2.90, 6.22), Figure 29. This analysis resulted in a large amount of heterogeneity ($I^2$=75%). Therefore, we evaluated separately the higher quality study with the lower risk of bias (Gerdesmeyer 2003.[57] The mean difference in the higher quality study was statistically significant favoring FESWT, MD 3.80 (95% CI 2.89, 4.71), and is considered to be clinically important. Another trial reported improvement in pain at rest and with activity (VAS 0-10, worst) at 120 months of follow-up; there was no difference between groups in mean change scores (over baseline) for either pain measure, respectively, MD 0.05 (95% CI -1.19, 1.29) and MD -0.8 (95% CI -2.36, 0.76).[45](Efe 2014)

**Figure 29. Focused ESWT vs. SHAM in rotator cuff tendinopathy: MEAN CHANGE IN PAIN NOS (VAS 0-10), LONG-TERM FOLLOW-UP**




**Function**

*Short-term function:* The proportion of patients that achieved function success after 3 months of follow-up was not statistically different between those receiving FESWT compared with sham in two trials[45,55,159]; pooled risk ratio (RR) 1.52 (95% CI, 0.63 to 3.65), Figure 30. Success was defined as an increase in the age-corrected Constant score of ≥30 points or an absolute score of 80% of the normal value. One trial reported that a significantly greater proportion of patients who received FESWT achieved ≥30% improvement (over baseline) in Constant score at 3 months compared with those in the sham group, RR 2.70 (95% CI 1.47, 4.94).[57] One trial reported the proportion of patients achieving ≥50% improvement on the SPADI with no statistical difference seen between the groups: FESWT, 35% (12/34) versus sham, 45% (18/40) at 3 months.[170] Five studies recorded the mean change from baseline in Constant score.[33,55,57,73,159] In the pooled analysis, there was a statistically significant difference between groups in improvement in function at 3 months favoring FESWT, pooled MD 20.3 (95% CI 10.1, 30.5), Figure 31. This analysis resulted in a large amount of heterogeneity ($I^2$=81%). Therefore, we evaluated separately the higher quality studies with the lower risk of bias (Gerdesmeyer 2003, Schmitt 2001,

Galasso 2012).[55,57,159] The mean difference pooling the higher quality studies was 13.9 (95% CI 3.54, 24.2), $I^2$=62%, Appendix I. Because the heterogeneity remained high, we analyzed the results using the profile likelihood method. The estimate was similar. However, we were unable to identify a clinically important threshold for the Constant score. Another trial reported improvement in function according to the SPADI; there was no difference between groups in mean change scores (over baseline) at 3 months, MD -0.9 (95% CI -8.58, 6.78).[170]

**Figure 30. Focused ESWT vs. SHAM in rotator cuff tendinopathy: PROPORTION WITH FUNCTION SUCCESS, SHORT-TERM FOLLOW-UP**

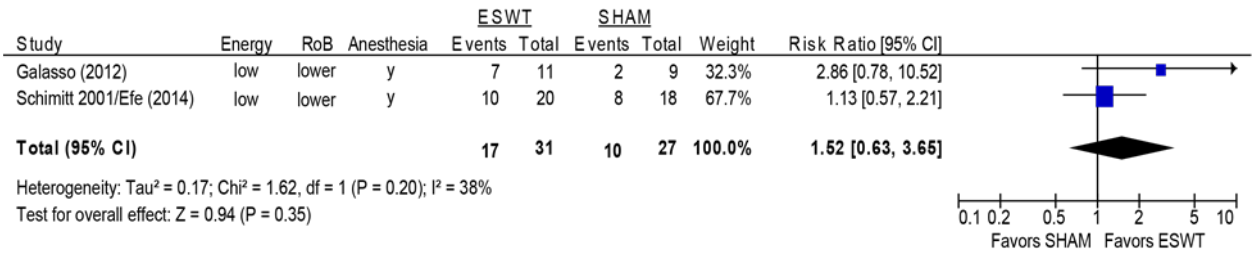
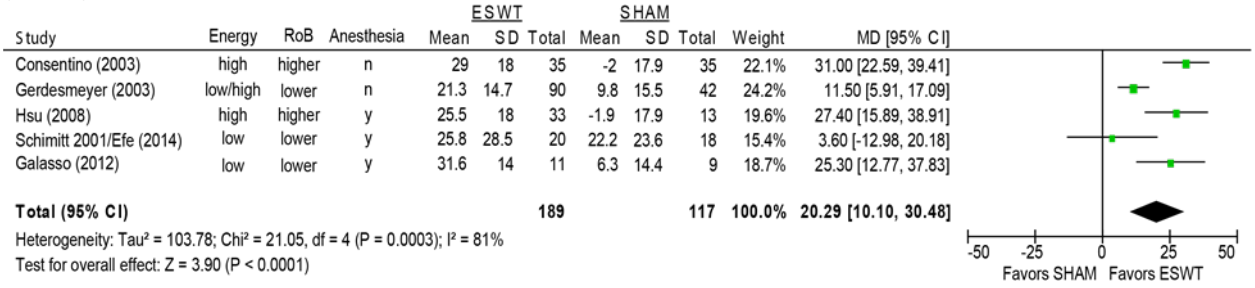
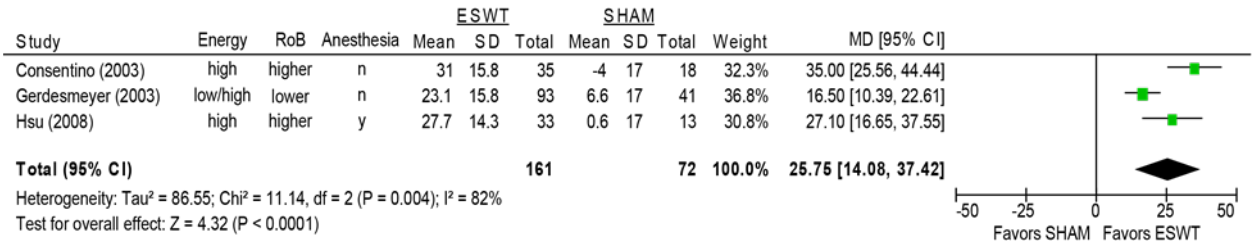



**Figure 31. Focused ESWT vs. SHAM in rotator cuff tendinopathy: MEAN CHANGE IN CONSTANT SCORE (0-100), SHORT-TERM FOLLOW-UP**



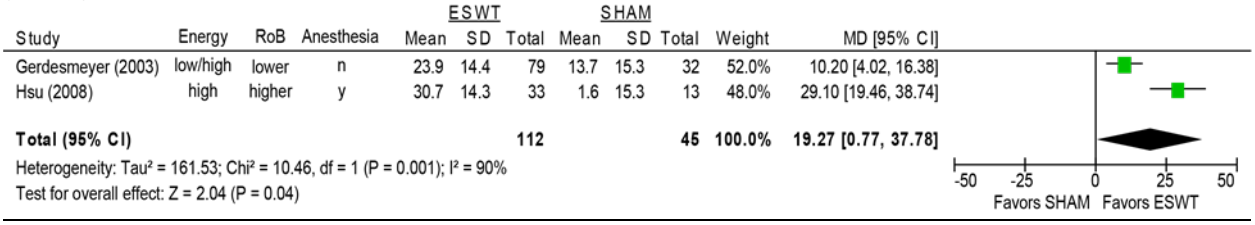

*Intermediate-term function:* The proportion of patients that achieved ≥30% improvement (over baseline) in Constant score after 6 months of follow-up was statistically higher following FESWT compared with sham in one trial, RR 3.94 (95% CI 1.97, 7.86).[57] Three studies recorded the mean change from baseline in Constant score at 6 months of follow-up.[33,57,73] In the pooled analysis, there was a statistically significant difference between groups in improvement in function favoring FESWT, pooled MD 25.8 (95% CI 14.1, 37.4), Figure 32. This analysis resulted in a large amount of heterogeneity ($I^2$=82%). Therefore, we evaluated separately the higher quality study with the lower risk of bias (Gerdesmeyer 2003).[57] The mean difference in the higher quality study was 16.5 (95% CI 10.4, 22.6). This difference was statistically significant favoring FESWT, however, we were unable to identify a clinically important threshold for this outcome measure. Another trial reported improvement in function according to the SPADI; there was no difference between groups in mean change scores at 6 months, MD 4.9 (95% CI -3.14, 12.9).[170]

**Figure 32. Focused ESWT vs. SHAM in rotator cuff tendinopathy: MEAN CHANGE IN CONSTANT SCORE (0-100), INTERMEDIATE-TERM FOLLOW-UP**




*Long-term function:* The proportion of patients that achieved ≥30% improvement (over baseline) in Constant score after 12 months of follow-up was statistically higher following FESWT compared with sham in one trial, RR 3.07 (95% CI 1.57, 6.01).[57] Two studies recorded the mean change from baseline in Constant score at 12 months of follow-up.[57,73] In the pooled analysis, there was a statistically significant difference between groups in improvement in function favoring FESWT, pooled MD 19.3 (95% CI 0.77, 37.8), Figure 33. This analysis resulted in a large amount of heterogeneity ($I^2$=90%). Therefore, we evaluated separately the higher quality study with the lower risk of bias (Gerdesmeyer 2003).[57] The mean difference in the higher quality study was 10.2 (95% CI 4.02, 16.4); this difference was statistically significant favoring FESWT, however, we were unable to identify a clinically important threshold for the Constant score. Another trial recorded the mean change from base in age-corrected Constant scores at 120 months and found no statistically significant difference in function improvement between the groups, MD 7.5 (95% CI -6.46, 21.5).[45](Efe 2014) One trial reported mean DASH scores (0-100, worst) at 120 months follow-up with no significant difference seen between the FESWT (39.8 ± 17.1) and sham group (38.8 ± 14.1),[45] Appendix Table G3; however baseline scores were not reported so it is unclear if there was a difference between groups in improvement in function over the long-term.

**Figure 33. Focused ESWT vs. SHAM in rotator cuff tendinopathy: MEAN CHANGE IN CONSTANT SCORE (0-100), LONG-TERM FOLLOW-UP**




**Other outcomes**

*Resorption of Calcium Deposits:* Three trials conducted in patients with calcific tendinopathy recorded the proportion of patients who experienced calcium resorption following treatment. Over the short-term (1 month follow-up), one trial reported that, in the FESWT group, complete resorption of the calcium deposits was achieved in 31% (11/35) of patients and partial resorption in 40% (14/35), while the calcium deposits remained unchanged in all patients who received sham (n=35).[33] Similarly, a second trial with intermediate-term follow-up (6 months) reported complete or partial resorption in all patients who received FESWT (51% (31/61) and 49% (30/61), respectively) compared with no change in any of

the patients randomized to sham (n=29).[131] The third trial reported that over the long-term (12 months follow-up) complete resorption of the calcium deposits occurred in 21% (7/33) of patients in the FESWT group versus 0% (0/13) in the sham group; partial resorption in 36.3% (11/33) versus 15.3% (2/13), respectively; and no change in 45% (15/33) versus 85% (11/13), respectively.[73]

#### 4.1.4.2. Focused ESWT vs. Active Control for Rotator Cuff Tendinopathy

***Studies included***

Two RCTs were identified that evaluated the efficacy of FESWT versus active controls for the treatment of chronic calcific rotator cuff tendinopathy: comparisons included ultrasound (US)-guided needling plus corticosteroid injection in one trial (moderately low risk of bias)[91] and transcutaneous electrical nerve stimulation (TENS) in the other (moderately high risk of bias).[130] Both trials performed FESWT using high energy (range, 0.26 to 0.36 mJ/mm$^2$); local anesthetic was not used in one trial(Pan 2003) while the other did not report this information. Brief overviews are provided below, and detailed information on patient and study characteristics is available in Appendix Table F3; for risk of bias ratings, see Appendix Table E3.

***Efficacy Results***

**FESWT vs. US-guided needling plus corticosteroid injection**

One RCT randomized patients with chronic (>3 months duration), calcific tendinopathy of the shoulder to receive FESWT (n=32) or US-guided needling plus injection of 40 mg of methylprednisolone acetate (n=30).[91] The majority of patients were female (91%) and the mean age of the two groups was 57.4 and 53.9 years, respectively. Mean duration of symptoms was not reported. Patients were excluded if they had signs rotator cuff tear or a history of invasive treatment for the affected shoulder. FESWT was performed using high-energy shockwaves (0.36 mJ/mm$^2$); the authors did not provide information on the use of local anesthetic. This study was considered to be at moderately low risk of bias.

**Pain**

The authors report no statistical difference between groups in baseline pain; however, patients in the FESWT group reported slightly less pain (lower scores): 6.3 vs. 6.8.

*Short-term pain:* There was no statistical difference in pain not otherwise specified (NOS) between the FESWT and the US-guided needling group at 3 months according to the VAS (0-10, worst): mean 2.5 versus 3.3; mean difference (MD) in change scores was 0.3.[91]

*Intermediate-term pain:* There was no statistical difference in VAS pain scores between the FESWT and the US-guided needling group at 6 months: 2.5 versus 1.8; MD in change scores was -1.2.[91]

*Long-term pain:* At 12 months of follow-up, the FESWT group showed significantly worse pain (higher mean VAS scores) compared with the US-guided needling group: 3.3 versus 1.4; the MD in change scores was -2.4 which is considered a clinically important difference.[91] By last follow-up (mean 23.0 months), the difference between groups was no longer statistically significant, 2.4 versus 1.1 (MD in change scores -1.8) (Appendix Table G3).

**Function**

The authors report no statistical difference between groups in baseline function; however, patients in the FESWT group reported somewhat better function (lower scores) on the American Shoulder and Elbow Surgeons (ASES) (49.9 vs. 41.5) and somewhat worse function (higher scores) on the Simple Shoulder Test (34.0 vs. 38.2).

*Short-term function:* There was no statistical difference between the FESWT and the US-guided needling group in function scores at 3 months as measured by the ASES (0-100, best) and SST (0-100, best), respectively: mean 72.5 versus 68.6 (MD between change scores, -4.5) and mean 56.9 versus 59.0 (MD between change scores, 2.1).[91]

*Intermediate-term function:* There was no statistical difference between the FESWT and the US-guided needling group in function scores at 6 months as measured by the ASES (76.4 vs. 85.2) and the SST (70.8 vs. 74.1)[91]; MD between change scores, respectively, was -17.2 and 0.9.

*Long-term function:* At 12 months of follow-up, the FESWT group showed significantly worse function (lower mean scores) on the ASES and the SST compared with the US-guided needling group, respectively: 74.6 versus 90.3 and 70.8 versus 83.3; the MD in change scores was –24.1 and -8.3 both of which are considered to be clinically important differences.[91] By last follow-up (mean 23.0 months), the difference between groups was no longer statistically significant: AESE, 78.3 versus 91.1 and SST, 78.6 vs. 91.7, respectively (MD in change scores –21.2 and -8.9) (Appendix Table G3).

**Other Outcomes**

*Resorption of Calcium Deposits:* The proportion of patients achieving complete resorption of calcium deposits by last follow-up (mean 23.0 months) was significantly lower in the FESWT versus US-guided needling group: 42.6% (12/29) versus 72.2% (18/25); RR 0.57 (95% CI 0.35, 0.95).[91] There no was difference between groups in the proportion of patients with partial resorption: 16.7% versus 11.1%, respectively (Appendix Table G3). Though mean size of the calcium deposit was reduced in both groups by last follow-up, FESWT resulted in significantly less reduction when compared with the US-guided needling group: mean change from baseline was 5.4 mm versus 14.3 mm, respectively, p=0.001.

**FESWT vs. TENS**

In one RCT, patients with chronic, calcific tendinopathy of the shoulder were randomized to receive FESWT (n=32) or TENS (n=28).[130] The groups were similar with regard to the mean duration of symptoms which was 24.2 months overall. The majority of patients were female (65%) and the mean age of the two groups was 55.2 and 58.0 years, respectively. One FESWT patient and two TENS patients had bilateral disease. Patients with rotator cuff tear or who had undergone previous surgery (to include percutaneous needle aspiration) or glucocorticosteriod injection within the last 3 months were excluded. FESWT was performed using high-energy shockwaves (range, 0.26 to 0.32 mJ/mm$^2$ depending on the patient's tolerance) and was completed without the use of local anesthetic. This study was considered to be at moderately high risk of bias.

**Pain**

*Short-term pain:* The mean change from baseline in VAS pain (NOS) scores (0-10, worst) was reported at 3 months of follow-up. There was a significant difference in pain improvement favoring the FESWT

group (over the TENS groups), MD 2.3 (95% CI 1.2, 3.5) (Appendix Table G3); the difference between groups is considered to be clinically important.[130]

*Intermediate-term pain:* No evidence.

*Long-term pain:* No evidence.

**Function**

*Short-term function:* At 3 months of follow-up, the proportion of shoulder that achieved a Constant score ≥85 was statistically higher in the FESWT compared with the TENS group: 69% (23/33 shoulders) versus 43% (12/29 shoulders); RR 1.7 (95% CI 1.0, 2.7).[130] The proportion of shoulders showed improvement from baseline on the Manual Muscle Test (MMT) was similar between groups at this timepoint: 69.7% (23/33 shoulders) versus 62.1% (18/29 shoulders), respectively. The mean change from baseline in Constant score (0-100, best) was also reported at 3 months. Patients who received FESWT reported significantly greater improvement in function compared with those who received TENS, MD 16.5 (95% CI 9.9, 23.0) (Appendix Table G3); we were unable to find a clinically important threshold for this outcome measure.

*Intermediate-term function:* No evidence.

*Long-term function:* No evidence.

**Other Outcomes**

*Change in Type and Resorption of Calcium Deposits:* The proportion of shoulders with a change in the type of calcific plaque was significantly higher following FESWT versus TENS, 48.5% (16/33 shoulders) versus 10.3% (3/29), RR 4.7 (95% CI, 1.5, 14.5); for patients in the FESWT group, the majority of calcific plaques were transformed to fragmented or punctuated-type deposits by 3 months of follow-up.[130] At baseline, the size of the calcium deposits were similar between groups. By 3 months, patients who underwent FESWT showed a significantly greater reduction in the size of the deposit compared with those in the TENS group, MD 2.7 mm (95% CI 1.1, 4.4) (Appendix Table G3).

#### 4.1.4.3. Radial ESWT vs. SHAM for Rotator Cuff Tendinopathy

***Studies included***

One RCT was identified which evaluated the efficacy of RESWT compared with sham for the treatment of chronic rotator cuff tendinopathy.[94] Detailed information on patient and study characteristics is available in Appendix Table F3. Briefly, a total of 82 subjects were randomized (44 to RESWT and 38 to sham. The mean age was similar between groups (overall, 47.1 years) as was the mean duration of symptoms (overall, 23.6 months); however, there were some differences in baseline characteristics. In the RESWT group, there was a higher proportion of patients who were female (73% vs. 66%), whose dominant hand was affected (55% vs. 44%), and who had received previous corticosteroid injections for

this condition (84% vs. 66%). Additionally, more patients in the RESWT group felt that pain (NOS) (16% vs. 8%) was one of the most important symptoms whereas in the sham group, pain at night (32% vs. 20%) was more important. RESWT was performed using a low energy level (0.11 mJ/mm$^2$); no pain medication or local anesthetic were used. This trial was considered to be a moderately high risk of bias due to several methodological limitations (see Appendix E3 for details regarding risk of bias).

***Efficacy Results***

**Pain**

*Short-term pain:* The mean change from baseline in VAS pain (NOS) scores (0-10, worst) was reported at 3 months. There was no difference between the RESWT and sham group in pain improvement, MD 0 (95% CI -7.6, 7.6).[94]

*Intermediate-term pain:* Similarly, there was no difference between the RESWT and sham group at 6 months in the mean change from baseline on VAS pain: MD 3.0 (95% CI -5.0, 11.0)[94]
(Appendix Table G3)

*Long-term pain:* No evidence.

**Function**

*Short-term function:* The mean change from baseline in Constant score (0-100, best) and the Simple Shoulder Test (SST) (0-100, best) was reported at 3 months. There was no difference between the RESWT and sham group in function improvement on either measure: MD 1.7 (95% CI -3.7, 7.1) and MD 0.2 (95% CI -0.75, 1.15), respectively.[94]

*Intermediate-term function:* Similarly, there was no difference between the RESWT and sham group at 6 months in the mean change from baseline in Constant score (MD 4.0, 95% CI -1.4, 9.4) and the SST (MD 0.3 (95% CI -0.75, 1.35).[94] (Appendix Table G3)

*Long-term function:* No evidence.

**Other outcomes**

None reported.

#### 4.1.4.4. Radial ESWT vs. Active Control for Rotator Cuff Tendinopathy

***Studies included***

One RCT was identified which evaluated the efficacy of RESWT compared with US-guided percutaneous lavage (UGPL) (plus corticosteroid injection) for the treatment of calcific rotator cuff tendinopathy.[42] Detailed information on patient and study characteristics is available in Appendix Table F3. Briefly, a total of 201 subjects were analyzed (out of 243 randomized); 80 in the RESWT and 121 in the UGPL group. Of note, 41 patients were lost to follow-up in the RESWT group compared to only one patient in the UGPL group, a loss-to-follow-up rate of 34% versus 1%, respectively. Baseline characteristics were poorly described and not stratified by treatment group. The majority of patients were female (68.2%) and the mean age of the population was 49 ± 7 years. The authors do not report the mean duration of symptoms or state whether or not they are chronic in nature. RESWT was performed using a high energy level (0.20 $mJ/mm^2$); no local anesthetic was used. For the UGPL procedure, it is standard to use local anesthetic. This trial was considered to be a moderately high risk of bias due to several methodological limitations including high differential loss to follow-up between groups (34% in the RESWT group vs. 1% in the UGPL group); see Appendix Table E3 for details regarding risk of bias.

***Efficacy Results***

**Pain**

*Short-term pain:* The authors report that RESWT resulted in significantly less pain reduction (i.e., higher VAS scores, 0-10) at 3 months than UGPL: 5.2 versus 3.2 (estimated from graph in article, raw data not provided),[42] Appendix Table G3. These results should be interpreted with caution, however, given the large differential loss to follow-up between groups.

*Intermediate-term pain:* Similarly, patients who received RESWT reported significantly less reduction in pain at 6 months compared with the UGPL group as reported by the authors: 4.0 versus 2.2, respectively (estimated from graph in article, raw data not provided).[42] These results should be interpreted with caution, however, given the large differential loss to follow-up between groups.

*Long-term pain:* At 12 months, the proportion of patients who were pain free was significantly lower in the RESWT group (65.0%; 52/80) compared with the UGPL group (89.3%; 108/121); RR 0.7 (95% CI 0.6, 0.9).[42] The authors also report that RESWT resulted in significantly less pain reduction at 12 months than UGPL: 3.2 versus 1.3, respectively (estimated from graph in article, raw data not provided). Again, these results should be interpreted with caution, however, given the large differential loss to follow-up between groups.

**Function**

No evidence.

**Other outcomes**

*Resolution of calcification:* The proportion of patients who achieved complete resolution of calcification was significantly lower in the RESWT group compared with the UGPL group: 55.6% (45/80) versus 86.8%

(105/121); RR 0.6 (95% CI 0.5, 0.8)[42] (Appendix Table G3). These results should be interpreted with caution, however, given the large differential loss to follow-up between groups.

***Adhesive Capsulitis of the Shoulder***

#### 4.1.4.5. Focused ESWT vs. SHAM for Adhesive Capsulitis of the Shoulder

***Studies included***

One RCT was included that evaluated the efficacy of FESWT compared with sham for the treatment of adhesive capsulitis of the shoulder.[180] Detailed information on patient and study characteristics is available in Appendix Table F3. Briefly, a total of 40 subjects (20 randomized to each group) were enrolled. Over half of the population was female (69%) with similar proportions in both groups; mean age was slightly lower in the FESWT group: 56.1 vs. 60.3 years. No patient had undergone previous shoulder surgery. FESWT was performed using energy levels ranging from 0.1 to 0.3 mJ/mm$^2$ (low to high energy) depending on the tolerance level of the patient; all patients received analgesics (meloxicam 15 mg daily). Additionally, all patients were advised to perform Pendulum exercises and to stretch the back of the involved shoulder twice a day. This trial was considered to be a moderately high risk of bias due to several methodological limitations (see Appendix Table E3 for details regarding risk of bias).

***Efficacy Results***

**Pain**

*Short-term pain:* According to the authors, there were no differences at baseline between the groups. At 2 months, patients in the FESWT group showed significantly greater improvement on the Shoulder Pain and Disability Index (SPADI) pain subscale (0-50, worst) compared with those in the sham group: MD 17.9 (95% CI 13.3, 22.5)[180] (Appendix Table G4). We were unable to find a clinically important threshold for the pain subscale of the SPADI.

*Intermediate-term pain:* Through 5 months of follow-up, patients in the FESWT group continued to show significantly more improvement in SPADI pain subscale scores compared with those in the sham group (MD 19.4; 95% CI 14.8, 24.0).[180] Again, we were unable to find a clinically important threshold for the pain subscale of the SPADI.

*Long-term pain:* No evidence.

**Function**

*Short-term function:* According to the authors, there were no differences at baseline between the groups; however, patients randomized to receive FESWT showed slightly more disability (i.e., higher mean SPADI disability subscale score: 59.3 ± 9.6 vs. 50.4 ± 8.6) prior to treatment. At 2 months, patients in the FESWT group reported significantly greater improvement on the SPADI disability scale (0-80,

worst) compared with those in the sham group: MD 26.5 (95% CI 20.9, 32.2)[180] (Appendix Table G4). We were unable to find a clinically important threshold for the disability subscale of the SPADI.

*Intermediate-term function:* Through 5 months of follow-up, patients in the FESWT group continued to show significantly more improvement in SPADI disability subscale scores compared with those in the sham group (MD 30.6; 95% CI 25.4, 35.8).[180] Again, we were unable to find a clinically important threshold for the disability subscale of the SPADI.

*Long-term function:* No evidence.

**Other Outcomes**

No evidence.

#### 4.1.4.6. Focused ESWT vs. Active Control for Adhesive Capsulitis of the Shoulder

***Efficacy Results***

***Studies included***

One RCT evaluated the efficacy of FESWT (n= 19) compared with oral steroid therapy (prednisolone) (n=21) for the treatment of primary adhesive capsulitis of the shoulder.[20] The majority of the population was female, with no difference in proportions between groups. Mean ages were also similar between treatment groups; overall mean age of the patients was 53.4 years. Detailed information on patient and study characteristics is available in Appendix Table F3. FESWT was performed using a high energy level (0.6 mJ/mm$^2$); the authors did not indicated whether anesthetic was used. In addition, all patients were trained to follow a home-based exercise physical therapy program. This trial was considered to be a moderately high risk of bias (see Appendix Table E3 for details regarding risk of bias).

**Pain**

No evidence.

**Function**

*Short-term function:* Baseline function was similar between groups. At the 3 month evaluation, the FESWT group showed significantly better function compared with the steroid group in both the Constant Shoulder Score (CSS; 0-100, best) and Oxford Shoulder Score (OSS; 12-60, worst) evaluations: 75 versus 66 points (p=0.041) and 31 vs. 33 points (p=0.045), respectively,[20] Appendix Table G4. We were unable to find a clinically meaningful threshold for either outcome measure.

*Intermediate-term function:* No evidence.

*Long-term function:* No evidence.

**Other Outcomes**

No evidence.

#### 4.1.4.7. Radial ESWT vs. SHAM for Adhesive Capsulitis of the Shoulder

***Efficacy Results***

***Studies included***
One RCT evaluated the efficacy of RESWT compared with sham for the treatment of primary adhesive capsulitis of the shoulder.[75] A total of 106 patients were randomized, 53 to each treatment group. Over half (60%) of the population was female, with a mean age of 55.8 years and a mean duration of symptoms of 11.6 months; there were no differences in the distribution of these variables between groups. No patient had undergone prior shoulder surgery. Detailed information on patient and study characteristics is available in Appendix Table F3. RESWT was performed using a moderate energy level (0.16 $mJ/mm^2$); no local anesthetics or analgesic drugs were administered. All patients were instructed to perform a home-based exercise program; compliance was similar between groups. This trial was considered to be a moderately low risk of bias (see Appendix Table E3 for details regarding risk of bias ratings).

**Pain**

*Short-term pain:* Baseline pain intensity during rest and activity was similar between groups. RESWT resulted in significantly greater improvement in VAS pain scores (0-10, worst) compared with the sham group: the MD at 1 month was 3.5 (95% CI 3.2, 3.7) which is considered to be a clinically important difference (Appendix Table G4).[75]

*Intermediate-term pain:* At the 6-month evaluation, the RESWT group continued to show significantly greater improvement in VAS pain (during rest and activity) scores compared with the sham group: MD 4.4 (95% CI 4.1, 4.6)[75]; again, this difference met the clinically important threshold.

*Long-term pain:* No evidence.

**Function**

*Short-term function:* Baseline function was similar between groups. At 1 month, the RESWT group showed significantly more improvement compared with the sham group as assessed by the Disabilities of the Arm, Shoulder and Hand (DASH) questionnaire (0-100, worst): the MD was 55.6 (95% CI 50.5, 60.8) which far exceeds the clinically important threshold of 10.2 (Appendix Table G4).[75]

*Intermediate-term function:* At the 6-month evaluation, the RESWT group continued to show significantly greater improvement DASH scores compared with the sham group: MD 55.3 (95% CI 49.8, 60.7)[75]; again, the MD is well above the cut-off deemed to be clinically important.

*Long-term function:* No evidence.

**Other Outcomes**

*Incidences of painful activities*: Over both the short- and intermediate-term, significantly more patients who received RESWT reported having no incidences of painful activities: 68% (36/53) versus 4% (2/53) at 1 month and 93% (49/53) versus 0% (0/53) at 6 months.[75] In the sham group, the vast majority of patients reported three or more incidences of painful activities over these time periods (76% and 87%, respectively) (Appendix Table G4).

***Subacromial Shoulder Pain***

#### 4.1.4.8. Radial ESWT vs. Active Control for Subacromial Shoulder Pain

***Studies included***

One RCT (across two publications) was included that evaluated the efficacy of RESWT compared with supervised exercise for the treatment of chronic subacromial shoulder pain.[47,48] Detailed information on patient and study characteristics is available in Appendix Table F3. Briefly, a total of 104 subjects (52 randomized to each group) were enrolled; females comprised 50% of the population and the overall mean age was 48 years (groups were comparable regarding these variables). Patients who were randomized to RESWT had experienced a somewhat longer duration of symptoms than those relegated to exercise (31% vs. 19% of patients, respectively, reported symptoms lasting more than 24 months) and slightly fewer had received prior corticosteroid injections (38% vs. 52%). No patient had undergone previous shoulder surgery. RESWT was performed with a pressure between 2.5 and 4.0 Bar, without the use of local anesthetic. This trial was considered to be a moderately low risk of bias (see Appendix Table E3 for details regarding risk of bias ratings).

***Efficacy Results***

**Pain**

According to the authors, there were no differences between the groups in baseline pain scores (Likert scale 1-9, worst).

*Short-term pain:* At 3 months, improvement in pain scores measured both at rest and during exercise did not differ statistically between patients who had undergone RESWT compared with those who received supervised exercise[48]: adjusted MD -0.3 (95% CI -0.9, 0.3) and adjusted MD -0.5 (95% CI -1.3, 0.4), respectively (Appendix Table G5).

*Intermediate-term pain:* No statistically significant differences were seen through 4.5 months of follow-up between the RESWT group compared with the supervised exercise group, respectively, for improvement in pain both at rest (adjusted MD -0.2; 95% CI -0.7, 0.3) and during activity (adjusted MD -0.6, 95% CI -1.3, 0.2)[48] (Appendix Table G5).

*Long-term pain:* Similarly, at the 12 month evaluation, improvement in pain scores was not significantly different between treatments; pain at rest, adjusted MD -0.4 (95% CI -0.7, 0.3); and pain during activity, adjusted MD -0.4 (95% CI -1.4, 0.4)[47] (Appendix Table G5).

**Function**

According to the authors, there was no difference between the groups in functional status at baseline.

*Short-term function:* At 3 months, patients in the RESWT group reported significantly less improvement in SPADI scores (0-100, worst) compared with those in the supervised exercise group: the adjusted mean difference (MD) between groups was -10.3 (95% CI -19.8, -0.8)[48] (Appendix Table G5); however, the MD was less than the cut-off deemed to be clinically meaningful. Function was also assessed by asking patients to rate their ability to carry a shopping bag (~5 kg) and to take something down from a cupboard; the RESWT and exercise groups reported similar mean scores at 3 months for both activities (Appendix Table G5).

*Intermediate-term function:* Through 4.5 months of follow-up, a significantly lower proportion of patients who received RESWT showed a clinically meaningful improvement, defined as a change of at least 19.6 points on the SPADI: 36% (18/50) vs. 64% (32/50) treated with exercise ($p<0.01$); RR 0.56 (95% CI 0.37, 0.86).[48] Additionally, the difference in mean change scores on the SPADI was statistically significant in favor of the supervised exercise group (MD -8.4; 95% CI -16.5, -0.6) (Appendix Table G5); however, the difference did not meet the clinically important threshold. Function was also assessed by asking patients to rate their ability to carry a shopping bag (~5 kg) and to take something down from a cupboard with no significant differences seen between treatment groups at 4.5 months for both activities (Appendix Table G5).

*Long-term function:* By the 12 month evaluation, the proportion of patients with clinically meaningful improvement (≥19.6 points on the SPADI) was no longer statistically different between treatments; slightly fewer patients in the RESWT group compared with the exercise group met this criteria (52% vs. 60%; RR 0.86, 95% CI 0.60, 1.24).[47] Similarly, the adjusted mean difference in SPADI change scores was not statistically significant at this time point (MD -7.6; 95% CI -16.6, 0.5) (Appendix Table G5). Function was also assessed by asking patients to rate their ability to carry a shopping bag (~5 kg) and to take something down from a cupboard; the RESWT and exercise groups reported similar mean scores at 12 months for both activities (Appendix Table G5).

**Other Outcomes**

*Work status:* At each time point measured, the proportion of patients who had returned to work was lower in the RESWT compared with the supervised exercise group; however, the difference was only significant at the intermediate-term follow-up evaluation (4.5 months)[48]: 52% (26/50) versus 76% (38/50); RR 0.68 (95% CI 0.50, 0.93) (Appendix Table G5).

*Drug treatment:* No difference was seen between the RESWT and exercise group in the proportion of patients taking medication for pain, sleep problems, or depression at 4.5 months (44% vs. 36%, respectively)[48] and 12 months (30% vs. 27%, respectively),[47] Appendix Table G5.

*Emotional distress:* As measured by the Hopkins Symptoms Checklist-25 (scale 1-4), mean scores for emotional distress were similar between the RESWT (1.5 points) and exercise (1.4 points) group at 12 months (Appendix Table G5).[47]

***Bicipital Tenosynovitis***

#### 4.1.4.9. Radial ESWT vs. SHAM for Bicipital Tenosynovitis of the Shoulder

***Studies included***

One RCT was included that evaluated the efficacy of RESWT compared with sham for the treatment of chronic primary long bicipital tenosynovitis of the shoulder joint.[106] Detailed information on patient and study characteristics is available in Appendix Table F3. Briefly, a total of 79 patients were analyzed (of 90 recruited) including 54 randomized to RESWT and 25 given sham treatment; the mean duration of symptoms was 22.4 and 18.3 months, respectively. RESWT was performed at a pressure of 3 bar and local anesthesia was not used. The majority of patients were male with somewhat fewer randomized to radial ESWT (63% vs. 72%); mean patient age was similar between the groups (~55 years). Many of the patients were porters, swimmers and ping-pong players. No patient had undergone previous shoulder surgery. This trial was considered to be at moderately low risk of bias (see Appendix Table E3 for details regarding risk of bias ratings).

***Efficacy Results***

**Pain**

There was no differences between the groups in baseline pain scores.

*Short-term pain:* At 3 months, mean VAS pain scores (0-10, worst) were significantly improved in patients who had undergone RESWT compared with those who received sham treatment[106]: the mean difference (MD) was 3.8 (95% CI 3.4, 4.1) which is considered to be clinically meaningful (Appendix Table G6).

*Intermediate-term pain:* No evidence.

*Long-term pain:* By the 12 month evaluation, 78% (42/54) of patients treated with RESWT achieved a good clinical result (i.e., VAS score <2 or a decrease of ≥4 points compared with baseline score) whereas no patients in the sham group achieved this outcome.[106] Additionally, the MD in VAS pain scores between groups was statistically significant in favor of ESWT and reached the clinically important threshold: MD 3.8 (95% CI 3.5, 4.1) (Appendix Table G6).

**Function**

There was no significant difference between the groups in functional status at baseline.

*Short-term function:* At 3 months, patients in the RESWT group showed significantly greater improvement in L'Insalata Shoulder scores (17-100, best) compared with those in the sham group[106]: MD 20.6 (95% CI 18.6, 22.6). We were unable to find a clinically meaningful threshold for the overall score for this outcome measure (Appendix Table G6).

*Intermediate-term function:* No evidence.

*Long-term function:* By the 12 month evaluation, the proportion of patients obtaining good symptom and function recovery, defined as achieving a L'Insalata Shoulder score >85 or an increase of >20 points when compared with baseline scores, was significantly greater following treatment with RESWT compared with sham[106]: 78% (45/54) vs. 12% (3/25); RR 6.9 (95% CI 2.4, 20.2) (Appendix Table G6). Similarly, mean L'Insalata scores were significantly improved with RESWT: MD 16.6 (95% CI 14.5, 18.6). Again, we were unable to find a clinically meaningful threshold for this outcome measure.

**Other Outcomes**

No evidence.

### 4.1.5. Achilles Tendinopathy

**Summary of results**

**Focused ESWT vs. Sham:** FESWT resulted in statistically and clinically greater pain improvement (NRS 0-10, worst) while running/playing sports (pooled MD 1.90; 95% CI 1.06, 2.73) and walking (pooled MD 1.65; 95% CI 0.79, 2.51) across two small RCTs, and while at rest in one trial (MD 1.92; 95% CI 0.76, 3.08); there were no statistical differences between groups in pain while working and walking up/down stairs as reported by one RCT. Regarding function, one small RCT reported statistically and clinically greater improvement in function (AOFAS) following FESWT versus sham while the other found no statistical difference between groups in improvement on the FIL. The strength of evidence is LOW for all outcomes. There was no evidence over the intermediate- or long-term.

**Radial ESWT vs. Active Control:**
*RESWT vs. eccentric exercise*: No statistical differences between groups were seen in improvement in pain during the day and function over the short-term as reported by two small trials. The strength of evidence is LOW for all outcomes. There was no evidence over the intermediate- or long-term.

*RESWT plus eccentric exercise vs. eccentric exercise alone*: As reported by one small trial, statistically greater improvement was seen in the RESWT group for both pain during the day on NRS (MD 1.3; 95% CI 0.6, 2.0) and function according to the VISA-A (MD 13.9; 95% CI 8.6, 19.2) over the short-term. The strength of evidence is LOW for all outcomes. There was no evidence over the intermediate- or long-term.

**Radial ESWT vs. No Treatment:** There was no statistical differences between groups for pain over the short-term. Improvement in function on the VISA-A was statistically greater following RESWT

compared to a wait-and-see strategy (MD 13.3; 95% CI 8.4, 18.2). The strength of evidence is LOW for all outcomes. There was no evidence over the intermediate- or long-term.

#### 4.1.5.1. Focused ESWT vs. SHAM for Achilles Tendinopathy

***Studies included***

Two RCTs that evaluated the efficacy of FESWT compared with sham for the treatment of chronic Achilles tendinopathy were identified and included patients with both non-insertional and insertional tendinopathy (only 6% of patients had the latter diagnosis in one trial[35]; the other trial did not indicate the proportion of patients with either type of tendinopathy.[138] Detailed information on patient and study characteristics is available in Appendix Table F4. Briefly, a similar number of patients (the majority of which were female) were randomized in both trials (N = 48 and 49); the mean age of the populations was 47.5 and 52.6 years. In one trial, the mean age between groups was statistically different with those in the sham group being 10 years younger; additionally 11% were professional athletes compared to 0% in the FEWST.[35] The mean symptom duration was 19.5 months in one trial; the other trial did not provided a mean duration but required that patients had had symptoms for longer than 3 months. Both trials used a variable amount of energy depending on the individual's pain tolerance with one using between 0.12 (moderate) and 0.51 (high) $mJ/mm^2$ and the other titrating to a maximum of 0.2 (high) $mJ/mm^2$. Neither study used local anesthetics. Both trials were considered to be at moderately low risk of bias (see Appendix Table E4 for details regarding risk of bias ratings).

***Efficacy Results***

**Pain**

*Short-term pain:* After 3 months of follow-up, compared with those who received sham treatment, patients in the FESWT group reported a statistically significant improvement in VAS pain scores (0-10, worst) across two trials both while running or playing sports (pooled MD 1.90 (95% CI 1.06, 2.73)) (Figure 34) and walking (pooled MD 1.65 (95% CI 0.79, 2.51)) (Figure 35); for both measures, the MD in change scores is considered to be clinically important.[35,138] One trial also reported mean change from baseline in VAS pain at rest and found a statistically significant difference between groups favoring FESWT at 3 months of follow-up, MD 1.92 (95% CI 0.76, 3.08)[35]; this difference met the clinically important threshold. Mean VAS scores for pain while working and walking stairs were also reported at 3 months by the other trial with no significant difference seen between the FESWT and sham group in either measure[138]; however, when we compared the difference between mean change scores from baseline the MDs (1.6 and 2.8, respectively) favored FESWT (Appendix Table G7). Standard deviations were not reported so it is unclear if these differences are statistically significant.

**Figure 34. Focused ESWT vs. SHAM in Achilles tendinopathy: MEAN CHANGE IN PAIN WHILE RUNNING OR PLAYING SPORTS (VAS 0-10), SHORT-TERM FOLLOW-UP**

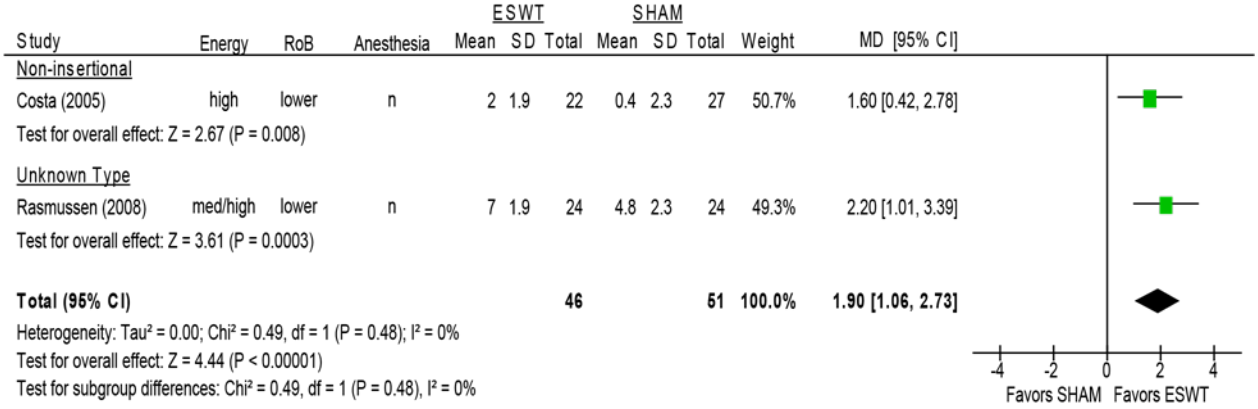
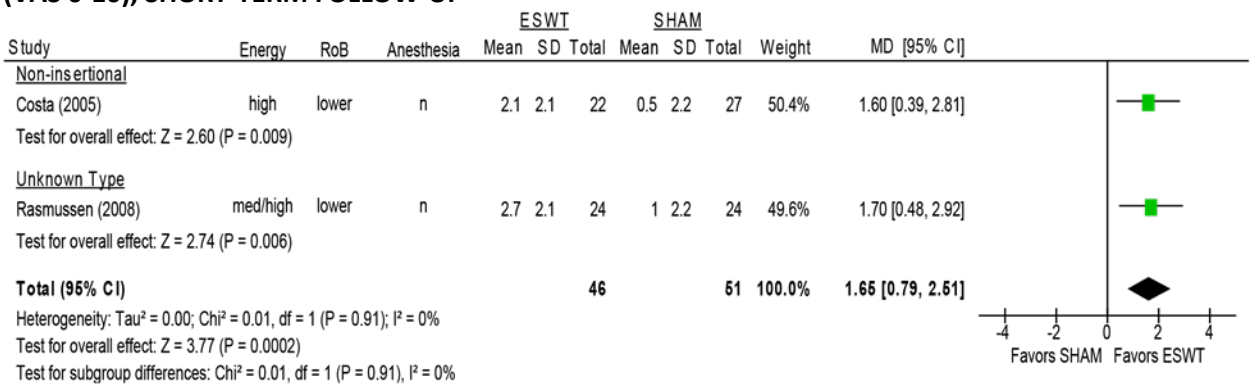



**Figure 35. Focused ESWT vs. SHAM in Achilles tendinopathy: MEAN CHANGE IN PAIN WHILE WALKING (VAS 0-10), SHORT-TERM FOLLOW-UP**




*Intermediate-term pain:* No evidence.

*Long-term pain:* No evidence.

**Function**

*Short-term function:* One of the trials measured function according to the American Orthopaedic Foot and Ankle Society (AOFAS) score (0-100, best) and reported a statistically significant improvement in the FESWT group versus the sham group after 3 months of follow-up[138]: the MD between groups was 11 (95% CI 3.14, 18.9), which is considered to be a clinically important difference. The second trial reported mean scores on the function index of lower limb activity (FIL, scale unclear) and reported no significant differences between the FESWT group (0.95 ± 0.96) and the sham group (0.24 ± 0.24) at 3 months (p=0.137)[35]; however, baseline scores were not provided so it is unclear if there was a difference between groups in improvement on the FIL. This same trial reported no statistical difference between groups, respectively, in the proportion of patients able to walk on their tiptoes for longer than 5 seconds (55% vs. 52%) or able to jump (36% vs. 52%) (Appendix Table G7).

*Intermediate-term function:* No evidence.

*Long-term function:* No evidence.

**Other outcomes**

*Quality of life:* One of the trials reported mean scores on the European Quality of Life 5 Dimensions questionnaire (EQ-5D; -0.109 to 1 (best)) at 3 months and found no statistical difference between the FESWT and the sham group: 0.11 ± 0.24 and 0.07 ± 0.24, respectively (p=0.604)[35]; however, baseline scores were not provided so it is unclear if there was a difference between groups in improvement on the EQ-5D (Appendix Table G7).

#### 4.1.5.2. Radial ESWT vs. Active Control for Achilles Tendinopathy

***Studies included***

Three RCTs were identified that evaluated the efficacy of RESWT compared with active treatment for chronic Achilles tendinopathy: comparisons included RESWT versus eccentric exercise (2 trials)[147,153] and RESWT plus eccentric exercise versus eccentric exercise alone (1 trial).[148] Two trials performed RESWT using low energy (i.e., 0.1 mJ/mm$^2$)[148,153] and one using moderate energy (i.e., 0.12 mJ/mm$^2$)[147]; none of the trials applied local anesthetic. Detailed information on patient and study characteristics is available in Appendix Table F4. All three trials were considered to be at moderately low risk of bias (see Appendix Table E4 for details regarding risk of bias ratings).

***Efficacy Results***

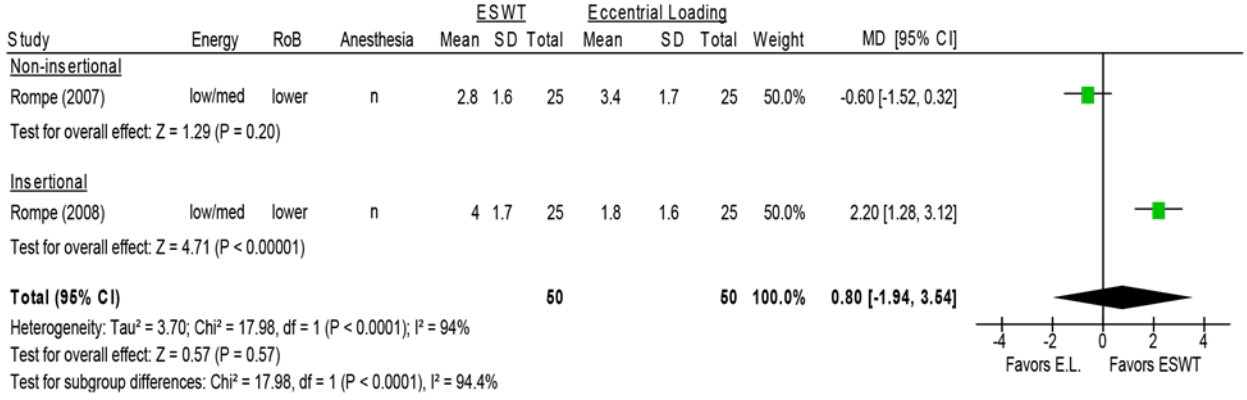
**RESWT vs. Eccentric Loading**

Two trials randomized 50 patients each (25 in each group) to receive RESWT or eccentric training for the treatment of chronic insertional[147] and non-insertional[153] Achilles tendinopathy. The latter trial also included a wait-and-see group, which will be discussed separately below. The majority (60%) of patients in both trials were female, however, the two trial differed with regard to overall mean age and the proportion of athletes enrolled: in the trial evaluating insertional Achilles tendinopathy, patients were younger (39.8 years vs. 49.7 years) and more often athletic (58% vs. 32%); there was no difference in age between treatment groups within the trials, whereas, fewer athletes were randomized to RESWT versus eccentric training (28% vs. 36%) in the trial of non-insertional tendinopathy. Prior treatment with cortisone injections (≥2 injections) was more common in the eccentric training compared with the RESWT group in both trials (56%-64% vs. 48%) as was previous shock wave treatment in one trial (16% vs. 4%) (Rompe 2007) (no patient in the other trial had received prior shock wave therapy). No patient in either trial had undergone previous surgery. RESWT was performed using low energy (i.e., energy flux density of 0.1 mJ/mm$^2$) in one trial[153] and moderate energy (i.e., 0.12 mJ/mm$^2$) in the other.[147] Local anesthetic was not used in either trial.

**Pain**

*Short-term pain:* After 3 months of follow-up, there was no significant difference between the RESWT and eccentric loading group in pain improvement (i.e., pain during the day as measured by the NRS (0-10, worst)) according to the pooled effect estimate across two trials[147,153]: MD 0.80 (95% CI -1.94, 3.54) (Figure 36). This analysis resulted in a large amount of heterogeneity ($I^2$=94%). Therefore, we evaluated the two studies separately. In the study evaluating RESWT for treatment of non-insertional Achilles tendinopathy, the MD between groups was not statistically significant (-0.60; 95% CI -1.52, 0.32).[153] However, the second study enrolled patients with insertional Achilles tendinopathy and reported a statistically significant improvement in pain favoring the RESWT group, MD 2.20 (95% CI 1.28, 3.12)[147]; the MD is considered to be clinically important. Both trials were considered to be at moderately low risk of bias.

**Figure 36. Focused ESWT vs. Eccentric Loading in Achilles tendinopathy: MEAN CHANGE IN PAIN DURING THE DAY (NRS 0-10), SHORT-TERM FOLLOW-UP**



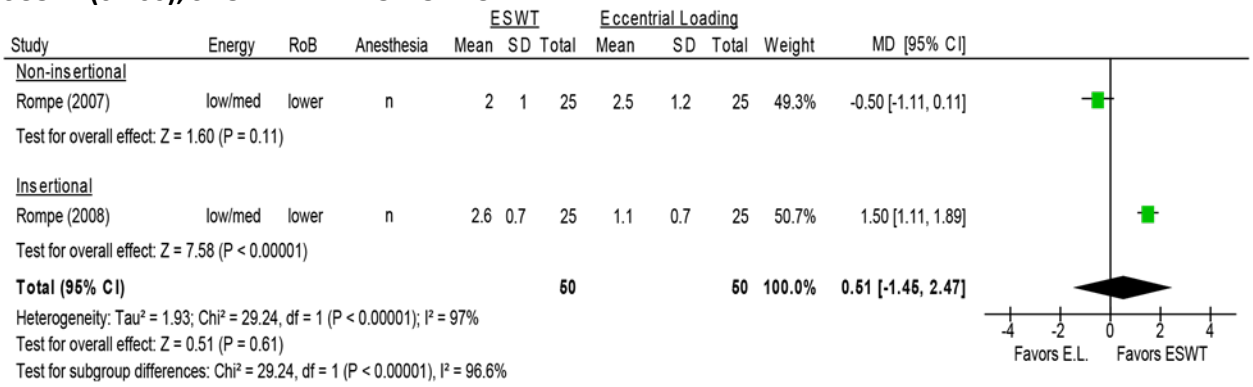

*Intermediate-term pain:* No evidence.

*Long-term pain:* No evidence.

**Function**

*Short-term function:* There was no significant difference between the RESWT and eccentric loading group in improvement VISA-A scores (0-100, best) 3 months following the end of treatment, according to the pooled effect estimate: MD 0.51 (95% CI -1.45, 2.47)[147,153] (Figure 37). This analysis resulted in a large amount of heterogeneity ($I^2$=97%). Therefore, we evaluated the two studies separately. In the study evaluating RESWT for treatment of non-insertional Achilles tendinopathy, the MD between groups was not statistically significant (-0.50; 95% CI -1.11, 0.11).[153] The second study enrolled patients with insertional Achilles tendinopathy and reported a statistically significant improvement in function favoring the RESWT group, MD 1.50 (95% CI 1.11, 1.89)[147]; however, the MD did not meet the clinically important threshold. Both trials were considered to be at moderately low risk of bias.

**Figure 37. Focused ESWT vs. Eccentric Loading in Achilles tendinopathy: MEAN CHANGE IN VISA-A SCORE (0-100), SHORT-TERM FOLLOW-UP**




*Intermediate-term function:* No evidence.

*Long-term function:* No evidence.

**Other Outcomes**

*Patient-perceived improvement success:* Patients were asked to rate the extent to which they felt their condition had improved using a 6-point Likert scale; patients who rated themselves 1 (completely recovered) or 2 (much improved) were considered treatment successes; all others were considered treatment failures. After 3 months, there was no statistically significant difference between the RESWT and eccentric loading groups in the proportion of patients achieving success across both trials[147,153]: 58% (29/50) vs. 44% (22/50), pooled RR 1.37 (95% CI 0.52, 3.59) (Figure 38). This analysis resulted in a large amount of heterogeneity ($I^2$=97%). Therefore, we evaluated the two studies separately. In the study evaluating treatment of non-insertional Achilles tendinopathy,[153] there was no statistical difference in the proportion of patients who achieved success in the RESWT (53%; 13/25) compared with the eccentric loading group (60% (15/25); RR 0.87 (95% CI 0.53, 1.42)). However, in the second study, which enrolled patients with insertional Achilles tendinopathy, a significantly higher proportion of patients randomized to ESWT achieved success: 76% (19/25) versus 28% (7/25); RR 2.29 (95% CI 1.11, 1.89).[147] Conversely, when considering the mean improvement in general assessment scores (rated by the patients using the same 6-point Likert scale as above), the trial of non-insertional tendinopathy showed a statistically significant difference in change scores between groups which favored eccentric loading (MD -0.70; 95% CI -1.23, -0.17) and there was no difference between the two groups in the trial assessing insertional tendinopathy (MD 0.40; 95% CI, -0.18, 0.98); the pooled estimate was not statistically significant: MD -0.16 (95% CI -1.24, 0.92) (Figure 39). Both trials were considered to be at moderately low risk of bias.

**Figure 38. Focused ESWT vs. Eccentric Loading in Achilles tendinopathy: PROPORTION WITH PATIENT-PERCEIVED IMPROVEMENT SUCCESS, SHORT-TERM FOLLOW-UP**

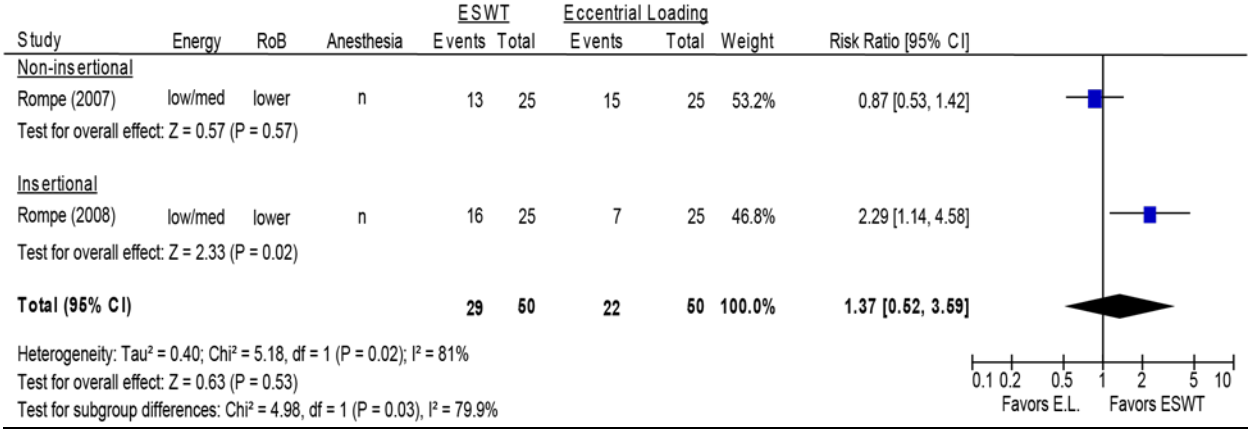
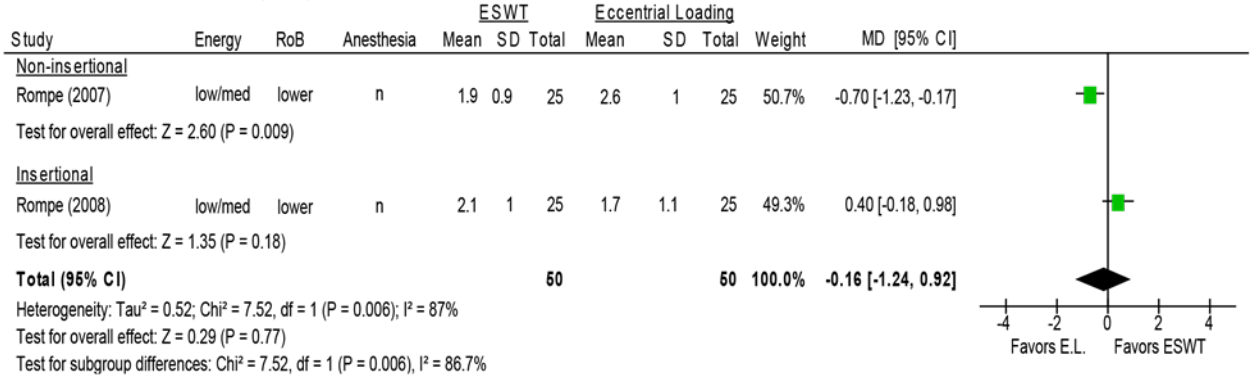



**Figure 39. Focused ESWT vs. Eccentric Loading in Achilles tendinopathy: MEAN CHANGE IN GENERAL ASSESSMENT SCORE (1-6), SHORT-TERM FOLLOW-UP**




*Analgesic use*: One trial (of patients with insertional Achilles tendinopathy)[147] reported that a significantly smaller proportion of patients who had undergone ESWT had used paracetamol or naproxen during the 3-month follow-up period: 28% (7/25) versus 76% (19/25); RR 0.37 (95% CI 0.19, 0.71).

**RESWT plus Eccentric Loading vs. Eccentric Loading Alone**

The third trial randomized patients with chronic non-insertional Achilles tendinopathy to RESWT plus eccentric exercise (n=34) or eccentric exercise alone (n=34).[148] The majority of patients were female (56%) with similar proportions in both groups; however, patients in the RESWT plus eccentric training group were somewhat older than those undergoing eccentric training alone (53.1 vs. 46.2 years). No information regarding athleticism was provided. Regarding previous treatments, a greater proportion of patients randomized to RESWT had received two or more cortisone injections (88% vs. 65%). No patient had received previous shock wave therapy or had undergone prior surgery. RESWT was performed using low energy (i.e., energy flux density of 0.1 mJ/mm$^2$) and without the use of local anesthetic.

**Pain**

*Short-term pain:* Baseline scores were similar between groups. After 3 months of follow-up, patients who had received RESWT plus eccentric training reported significantly greater improvement in pain during the day (NRS 0-10, worst) than those who had undergone eccentric training alone according to the ITT analysis: MD 1.3 (95% CI 0.6, 2.0)[148] (Appendix Table G7); the difference between groups met the clinically important threshold for this measure.

*Intermediate-term pain:* No evidence.

*Long-term pain:* No evidence.

**Function**

*Short-term function:* Baseline scores were similar between groups. After 3 months, according to the intention-to-treat analysis (ITT), patients who had received RESWT plus eccentric training showed significantly improved function according to the VISA-A questionnaire (0-100, best) compared with those in the eccentric training only group: the MD was 13.9 (95% CI 8.6, 19.2)[148] (Appendix Table G7); we were unable to find a validated clinically important threshold for this outcome measure for non-insertional Achilles tendinopathy.

*Intermediate-term function:* No evidence.

*Long-term function:* No evidence.

**Other Outcomes**

*Patient-perceived improvement success:* Patients were asked to rate the extent to which they felt their condition had improved using a 6-point Likert scale; patients who rated themselves 1 (completely recovered) or 2 (much improved) were considered treatment successes; all others were considered treatment failures. After 3 months, a significantly higher proportion of patients who had received RESWT plus eccentric training group were considered successes, compared with eccentric training alone: 82% (28/34) versus 56% (19/34), p=0.001 (Appendix Table G7); RR 1.5 (95% CI 1.1, 2.1). [148]

#### 4.1.5.3. Radial ESWT vs. No Treatment for Achilles Tendinopathy

***Studies included***

One of the above trials, which evaluated the efficacy of RESWT (n=25) in patients with chronic non-insertional Achilles tendinopathy, included a third set of patients randomized to a wait-and-see group (n=25) in which patients were encouraged to await further spontaneous improvement.[153] In both treatment groups, the majority of patients were female (60%) and only a fourth (28%) were athletes; however, patients randomized to RESWT were somewhat older (mean 51.2 years vs. 46.4 years in wait-and-see group). Regarding prior treatments, slightly more RESWT patients had received two or more cortisone injections (48% vs. 40%), 4% of patients in both groups had shock wave therapy previously,

and no patient had undergone surgery. RESWT was performed using low energy (i.e., energy flux density of 0.1 mJ/mm$^2$) and without the use of local anesthetic.

***Efficacy Results***

**Pain**

*Short-term pain:* Compared with those in the wait-and-see group, patients in the RESWT group reported less pain (NRS 0-10, worst) during the day at baseline (6.8 ± 0.9 vs. 7.9 ± 0.9). After 3 months of follow-up, the authors report significantly lower pain scores in the ESWT group according to the intention-to-treat analysis (ITT) analysis[153]: 4.0 ± 2.2 vs. 5.9 ± 2.2, p<0.001 (Appendix Table G7); however, when we compared the difference between mean change scores the results were no longer statistically significant: MD 0.8 (95% CI -0.02, 1.6).

*Intermediate-term pain:* No evidence.

*Long-term pain:* No evidence.

**Function**

*Short-term function:* Baseline function scores were similar between groups. After 3 months, according to the ITT analysis, patients who had received RESWT showed significant improvement on the VISA-A questionnaire (0-100, best) compared with those in the wait-and-see group: the MD was 13.3 (95% CI 8.4, 18.2)[153] (Appendix Table G7); we were unable to find a validated clinically important threshold for this outcome measure for non-insertional Achilles tendinopathy.

*Intermediate-term function:* No evidence.

*Long-term function:* No evidence.

**Other Outcomes**

*Patient-perceived improvement success:* Patients were asked to rate the extent to which they felt their condition had improved using a 6-point Likert scale; patients who rated themselves 1 (completely recovered) or 2 (much improved) were considered treatment successes; all others were considered treatment failures. After 3 months, a significantly greater proportion of patients who received RESWT were considered successes compared with those in the wait-and-see group: 52% (13/25) versus 24% (6/25), p=0.001 (Appendix Table G7); RR 2.2 (95% CI 0.98, 4.8).[153]

### 4.1.6. Patellar Tendinopathy

**Summary of results**

**Focused ESWT vs. Sham:** There was INSUFFICIENT evidence from one small RCT to determine if FESWT or sham is superior with regards to pain and function over the short-term. There was no evidence over the intermediate- or long-term.

**Focused ESWT vs. Active Control**

*FESWT vs. conservative management*: One small RCT reported statistically and clinically greater improvements in long-term pain and function following FESWT compared with conservative management; at 24-36 months, the mean difference between groups was over three times the clinically important threshold for both VAS pain going up and down stairs (MD 4.8; 95% CI 4.2, 5.3) and VISA-P scores (MD 47.6; 95% CI 44.0, 51.2). The strength of evidence was LOW for both outcomes. There was no evidence over the short- or medium-term.

#### 4.1.6.1. Focused ESWT vs. SHAM for Patellar Tendinopathy

***Studies included***

One RCT was included that evaluated the efficacy of FESWT compared with sham for the treatment of chronic (>3 months duration) patellar tendinopathy.[175] Detailed information on patient and study characteristics is available in Appendix Table F5. Briefly, a total of 20 subjects (10 randomized to each group) who participated regularly in running and/or jumping sports and who had a diagnosis of patellar tendinopathy were included. Half of the population was male, and ages ranged from 23 to 52 years (demographics were not reported by study group). No patient had undergone previous surgery or prior ESWT treatment for this condition. FESWT was performed using moderate energy shockwaves (0.17 $mJ/mm^2$) without the use of local anesthetic. This trial was considered to be a moderately high risk of bias due to a number of methodological limitations (see Appendix Table E5 for details regarding risk of bias).

***Efficacy Results***

**Pain**

*Short-term pain:* The only data provided for pain came from anecdotal reports.[175] When queried at 3 months, 56% of patients in the FESWT group compared with no patient in the sham group reported a decrease in pain and an increase in function; one patient (14%) in the sham group reported a decrease in pain with no corresponding change in function (Appendix Table G8). Additionally, 22% of patients in the FESWT experienced pain when going up or down stairs but considered themselves improved overall (not reported for the sham group).

*Intermediate-term pain:* No evidence.

*Long-term pain:* No evidence.

**Function**

*Short-term function:* According to the authors, there were no differences at baseline between the groups; however the FESWT group had slightly better function scores than the sham group (54.4 vs. 49.9). At 3 months, patients in the FESWT group reported significantly better VISA-P scores (0-100, best) compared with those in the sham group[175]: 61.4 vs. 53.2, $p<0.05$ (Appendix Table G8); however, the MD (which takes baseline scores into account) was only 3.7 and did not meet the clinically important threshold. Additionally, patients who underwent FESWT improved their vertical jump score by 1.5

inches at 3 months compared with baseline scores, while those in the sham group showed no improvement in this measure ($p<0.05$).

*Intermediate-term function:* No evidence.

*Long-term function:* No evidence.

**Other Outcomes**

No evidence.

#### 4.1.6.2. Focused ESWT vs. Active Control for Patellar Tendinopathy

***Studies included***

One RCT evaluated the efficacy of FESWT compared with conservative management consisting of NSAIDs, physiotherapy, an exercise regimen, and use of a knee strap for the treatment of chronic patellar tendinopathy.[188] A total of 54 knees in 50 patients were analyzed (3 FESWT patients and 1 conservative patient had bilateral tendinopathy). Detailed information on patient and study characteristics is available in Appendix Table F5. Briefly, about half the population participated in sports, primarily basketball and jogging; 54% were male, with a mean age of 29.8 years. Patients receiving ESWT had experienced a somewhat longer duration of symptoms (mean 16.2 vs. 11.3 months) and were followed for a slightly longer period of time (32.7 vs. 28.6 months, respectively) compared with the conservative group. FESWT was performed using moderate energy shockwaves (0.18 $mJ/mm^2$) without the use of local or regional anesthesia. This trial was considered to be a moderately high risk of bias due to a number of methodological limitations (see Appendix Table E5 for details regarding risk of bias).

***Efficacy Results***

**Pain**

*Short-term pain:* No evidence.

*Intermediate-term pain:* No evidence.

*Long-term pain:* Baseline pain was similar between groups. Results were considered satisfactory if they had ≥75% improvement in pain with ≤4.0 on a VAS scale while using stairs and did not take any pain medication (Appendix Table G8); a statistically greater proportion of knees that received FESWT achieved satisfactory results compared with those who received conservative treatment: 90% (27/30 knees) versus 50% (12/24 knees); RR 1.8 (95% CI 1.2, 2.7).[188] Additionally, VAS scores (0-10, worst) assessed for pain going up and down stairs were significantly improved in the FESWT (n=30 knees) compared with the conservative group (n=24 knees) at 24 to 36 months of follow-up: MD 4.8 (95% CI 4.2, 5.3); this difference in mean change scores is well above the clinically important threshold of 1.5.

**Function**

*Short-term function:* No evidence.

*Intermediate-term function:* No evidence.

*Long-term function:* Baseline function as measured by the VISA-P (0-100, best) was similar between groups. After 24 to 36 months of follow-up, patients who received FESWT showed significantly improved VISA-P scores compared with those who received conservative treatment[188]: the MD was 47.6 (95% CI 44.0, 51.2) which far exceeds the cut-off of 14 points deemed to be clinically important. The mean percentage of functional improvement of the knee (i.e., overall subjective assessment at follow-up compared with the baseline status before treatment) was 84.8% ± 20.5% versus 56.7% ± 26.7%, respectively (Appendix Table G8).

**Other Outcomes**

*Overall clinical outcomes:* Clinical outcomes were classified as excellent or good using the following criteria, respectively: no knee pain in all activities including sports; and knee having ≥75% improvement and mild pain with a VAS <4 in all activities including sports (all other outcomes were graded fair or poor, see Appendix Table G8). Significantly more patients in the FESWT group achieved either an excellent or a good outcome at 24 to 36 months compared with patients in the conservative care group (90% [27/30 knees] vs. 50% [12/24 knees]); specifically, an excellent outcome was seen in 43% versus 0% of the groups, respectively, p<0.001.[188]

*Return to sport:* By 24 to 36 months of follow-up, all patients were able to return to playing sports; however, 67% (10/15) of patients who had undergone FESWT were able to return at the same level of play as before the injury, whereas all patients who received conservative treatment returned to sport at a lower level (Appendix Table G8).

### 4.1.7. Knee Osteoarthritis

**Summary of results**

**FESWT vs. Active Control**

*FESWT plus isokinetic muscular strengthening vs. isokinetic muscular strengthening alone*: FESWT plus isokinetic muscular strengthening resulted in statistically and clinically greater improvement in pain compared with isokinetic muscular strengthening alone over short- and medium-term follow-up as reported by one small RCT (LOW strength of evidence). For function, the strength of evidence was INSUFFICIENT. There was no evidence over the long-term.

*FESWT plus isokinetic muscular strengthening vs. Ultrasound plus isokinetic muscular strengthening*: As reported by one small trial, FESWT plus isokinetic muscular strengthening resulted in statistically, but not clinically, greater improvement in pain compared with ultrasound plus isokinetic muscular strengthening over short- and medium-term follow-up (LOW strength of evidence). For function, the strength of evidence was INSUFFICIENT. There was no evidence over the long-term.

**RESWT vs. Sham:** One small RCT reported significantly better short-term pain (VAS) and function (WOMAC, Lequesne index) improvement following RESWT compared with sham (all LOW strength of evidence); the mean differences between groups were clinically important for pain and for function according to the WOMAC. There was no evidence over the medium- or long-term.

#### 4.1.7.1. Focused ESWT vs. Active Control for Knee Osteoarthritis

***Studies included***

One RCT was identified that evaluated the efficacy of FESWT for the treatment of bilateral moderate knee OA and popliteal cyamella.[21] FESWT plus isokinetic muscular strengthening exercises (n=30) was compared with two active control groups: isokinetic exercises alone (n=30) or plus pulse ultrasound (US) treatment (n=30). FESWT was performed with an impulse energy flux density of 0.03 to 0.4 mJ/mm$^2$ (low to high energy) depending on the size of the popliteal cyamella; the authors did not state whether local anesthetic was used. Patient demographics were poorly reported and not stratified by group (all demographics include a fourth "control" group that was excluded from our analysis since it was unclear what constituted a "control" in this instance). Overall, the majority of the population was female (85%) with a mean age of 63 years; the duration of knee pain ranged from 10 to 144 months. No other demographic information was provided. Detailed information on patient and study characteristics is available in Appendix Table F6. This trial was considered to be at moderately high risk of bias due to a number of methodological flaws (see Appendix Table E6 for details regarding risk of bias).

***Efficacy Results***

**FESWT plus isokinetic muscular strengthening vs. isokinetic muscular strengthening alone**

**Pain**
Baseline scores on the VAS pain scale (0-10, worst) were similar between groups. Pain was assessed for both knees.

*Short-term pain:* At 2 months, treatment with FESWT plus isokinetic muscular strengthening (n=56 knees) resulted in significantly better improvement in VAS scores for pain walking or standing compared with isokinetic muscular strengthening exercises alone (n=54 knees)[21]: the MD was 1.9 (95% CI 1.6, 2.2) which is considered to be clinically meaningful (Appendix Table G9).

*Intermediate-term pain:* Patients in the FESWT group continued to show significantly greater improvement in VAS scores for pain walking or standing through 6 months of follow-up compared with those who underwent isokinetic muscular strengthening exercises alone[21]: MD 2.1 (95% CI 1.8, 2.4) (Appendix Table G9). The MD met the clinically important threshold.

*Long-term pain:* No evidence.

**Function**
Baseline score on the Lequesne's index (0-24, worst) were similar between groups.

*Short-term function:* At 2 months, patients who had received FESWT plus isokinetic muscular strengthening showed significantly improved function scores compared with those who underwent isokinetic muscular strengthening exercises alone: mean difference (MD) 1.3 (95% CI 0.9, 1.8)[21] (Appendix Table G9). We were unable to find a clinically meaningful threshold for this outcome measure.

*Intermediate-term function:* Patients in the FESWT group continued to show significantly greater improvement on the Lequesne's index through 6 months of follow-up compared with patients in the isokinetic exercise alone group: MD 3.2 (95% CI 2.7, 3.7)[21] (Appendix Table G9). Again, we were unable to find a clinically meaningful threshold for this outcome measure.

*Long-term function:* No evidence.

**Other Outcomes**

*Changes in popliteal cyamella:* There were no case of popliteal cyamella disappearing radiologically after treatment; at 3 months the size was reduced in 30% (9/30) of patients in the FESWT plus isokinetic exercise group compared with none in the isokinetic muscular strengthening exercises alone group (Appendix Table G9).[21]

**FESWT plus isokinetic muscular strengthening vs. pulse US treatment plus isokinetic muscular strengthening**

**Pain**
Baseline scores on the VAS pain scale (0-10, worst) were similar between groups. Pain was assessed for both knees.

*Short-term pain:* At 2 months, treatment with FESWT plus isokinetic muscular strengthening resulted in significantly more improvement in pain scores compared with US plus isokinetic muscular strengthening: MD 0.7 (95% CI 0.4, 1.1)[21] (Appendix Table G9); however the MD did not meet the clinically important threshold.

*Intermediate-term pain:* Patients in the FESWT plus isokinetic exercise group continued to show significantly greater improvement in VAS pain scores through 6 months of follow-up compared with those who underwent US plus isokinetic exercises: MD 0.9 (95% CI 0.6, 1.2)[21] (Appendix Table G9); however the MD was less than the cut-off deemed to be clinically meaningful.

*Long-term pain:* No evidence.

**Function**
Baseline scores on the Lequesne's index (0-24, worst) were similar between groups.

*Short-term function:* At 2 months, patients who had received FESWT plus isokinetic muscular strengthening showed significantly greater improvement in function scores than those who underwent

US plus isokinetic muscular strengthening: MD 0.6 (95% CI 0.1, 1.1)[21] (Appendix Table G9). We were unable to find a clinically meaningful threshold for this outcome measure.

*Intermediate-term function:* Patients in the FESWT plus isokinetic exercise group continued to show significantly better improvement on the Lequesne's index through 6 months of follow-up compared with the US plus isokinetic exercise group: MD 1.7 (95% CI 1.2, 2.2)[21] (Appendix Table G9). Again, we were unable to find a clinically meaningful threshold for this outcome measure.

*Long-term function:* No evidence.

**Other Outcomes**

*Changes in popliteal cyamella:* There were no case of popliteal cyamella disappearing radiologically after treatment; at 3 months the size was reduced in 30% (9/30) of patients in the FESWT plus isokinetic muscular strengthening group compared with none in the US plus isokinetic muscular strengthening group (Appendix Table G9).[21]

#### 4.1.7.2. Radial ESWT vs. SHAM for Knee Osteoarthritis

***Studies included***

One RCT was identified that evaluated the efficacy of RESWT compared with sham treatment for Kellgren and Lawrence grade II or III knee OA.[198] Patients were required to have had knee pain for a minimum of 3 months (mean duration not reported). A total of 70 patients were randomized, 34 to RESWT and 36 to sham. Mean patient age was 60.9 years and the majority of the population was female, with fewer females in the radial ESWT (59%) versus the sham group (69%). RESWT was performed using high-energy shockwaves (0.25 mJ/mm$^2$); the authors did not report whether a local anesthetic was used. Detailed information on patient and study characteristics is available in Appendix Table F6. This trial was considered to be at moderately low risk of bias (see Appendix Table E6 for details regarding risk of bias).

***Efficacy Results***

**Pain**

*Short-term pain:* At 3 months, treatment with RESWT resulted in a significantly greater improvement in VAS scores for pain while walking (0-10, worst) compared with sham treatment[198]; the MD of 2.6 (95% CI 2.2, 3.0) met the threshold for a clinically meaningful difference (Appendix Table G9).

*Intermediate-term pain:* No evidence.

*Long-term pain:* No evidence.

**Function**

*Short-term function:* According to the intention-to-treat analysis, patients who underwent RESWT showed significantly ($p<0.01$) greater improvement in function scores compared with those who received sham[198]: at 3 months the MD between groups was 2.1 (95% CI 0.9, 3.4) for the Lequesne index (0-24, worst) and 10.6 (95% CI 5.4, 15.8) for the WOMAC Osteoarthritis Index (0-96, worst) (Appendix Table G9). For the WOMAC, the MD is considered to be clinically important; we were unable to find a clinically meaningful threshold for the Lequesne index.

*Intermediate-term function:* No evidence.

*Long-term function:* No evidence.

**Other Outcomes**

*Patient perception of disease severity:* Using a 5-point Likert scale – 1, very poor; 2, poor; 3, fair; 4, good; and 5, very good – patients were asked to rate their current condition when considering all the ways that knee OA affects them. At baseline, most patients rated themselves as fair (mean scores for 3.09 ± 0.67 for RESWT and 3.11 ± 0.67 for sham). By 3 months, patient perception of clinical severity was significantly better for the RESWT group than for the sham group: 3.94 ± 0.92 versus 3.42 ± 0.81, $p<0.01$ (Appendix Table G9).[198]

## *4.2. Key Question 2: Harms and Complications*

### 4.2.1. Number of studies retained

All included comparative studies were evaluated for harms and complications. In addition, case series and case reports specifically designed to evaluate harms were considered for inclusion; one case report[104] was identified that met the inclusion criteria.

We considered the following outcomes as potentially serious based on clinical expert input: tendon rupture, aseptic necrosis, humeral head necrosis, neurovascular complications, neurological disorders, infections, adverse reaction/allergy to anesthetic agents, systemic complications, and death.

**Summary of results:** Serious or potentially serious adverse events were reported in 52 of the 61 included studies. They were rare: 10 of 2,553 patients were reported in the ESWT across studies, risk 0.39% (95% CI, 0.19 to 0.72%). Three were deaths, two were tendon ruptures and five were allergic reactions associated with local anesthetics. Of the deaths, two were noted to be from causes unrelated to the treatment, while no details were given concerning the third death. The tendon ruptures occurred in two patients two weeks following FESWT for Achilles tendinopathy. Allergy or reaction to local anesthetic was reported in five patients receiving FESWT. In the control groups, 5 of 2,209 patients were reported as having serious or potentially serious adverse events, risk 0.23% (95% CI, 0.07 to 0.53%). All five events were allergy or reaction to local anesthetic. The strength of evidence for serious or potentially serious adverse events, LOW.

Non-serious adverse events were common following ESWT but were reported inconsistently. The most common included pain/discomfort during treatment; transient reddening of the skin; mild/transient neurological symptoms (i.e., myalgia, dysesthesia, hypesthesia, paresthesia); and petechaie, bleeding or hematoma.

### 4.2.2. Plantar Fasciitis

*FESWT vs. Sham:* Adverse events were assessed by 11 RCTs that evaluated the comparative efficacy of FESWT versus Sham in patients with plantar fasciitis.[34,58,59,63,96,112,125,126,145,158,169,176] No serious adverse events were reported across the trials; specifically, one trial reported no neurological complications or infections,[145] Table 10. Several minor complications were reported in both groups the most common of which were treatment-associated pain (5 trials),[59,63,96,125,126,176] local swelling/edema (4 trials),[59,63,96,176] mild neurological symptoms (i.e., numbness, dyesthesia, hypesthesia, parathesia) (3 trials),[96,125,126,176] and ecchymosis/petechia (2 trials)[96,176] (Appendix Table H1). With the exception of pain during treatment in one trial (73% vs. 7%)[176] and reddening of the skin in another (12% vs. 4%)[63], which were more common with FESWT versus sham, there was no statistical difference between groups in the frequency of minor complications. Two trials reported that no complications occurred.[34,158]

*FESWT vs. Active Controls:* Adverse events were reported by five RCTs that evaluated the comparative efficacy of FESWT versus Active Controls in patients with plantar fasciitis.[24,134,137,190,197] Control groups included corticosteroid injections and conventional treatment (e.g., NSAIDs, orthotics, physical therapy, exercise program, cortisone injection). One death occurred in the FESWT group during follow-up in one trial however, it was attributed to causes unrelated to the treatment.[190] No other trial reported serious adverse events. One trial reported less pain with FESWT than corticosteroid injection (6% vs. 15%) but the difference was not statistically significant due to the small sample size,[197] (Appendix Table H1). Local pain and erythema/ecchymosis were the most common minor complications. Two trials reported that no complications occurred.[24,190]

*RESWT vs. Sham:* Adverse events were reported by three RCTs that evaluated the comparative efficacy of RESWT versus Sham in patients with plantar fasciitis.[56,76,77,115] No serious adverse events, to include tendon rupture in one trial,[56] were reported (Table 10). All three trials reported pain/discomfort during the treatment (which occurred somewhat more often with RESWT than sham) and reddening of the skin (no difference between groups). (Appendix Table H1).

*RESWT vs. Active Controls:*

Two trials reported that no complications occurred following the use of RESWT compared with ultrasound.[60,95] (Appendix Table H1).

### 4.2.3. Tendinopathies

*FESWT vs. Sham:* A total of 15 trials that evaluated the comparative efficacy of FESWT versus Sham reported adverse events; six trials were in patients with elbow epicondylitis,[25,28,64,132,146,168] eight were in patients with shoulder tendinopathy (7 rotator cuff tendinopathy[33,45,55,57,73,131,159,170]; 1 adhesive capsulitis[180]) and one was in patients with Achilles tendinopathy.[35] Serious complications were rare

across the trials; only three trials reported the occurrence of serious adverse events (Table 10). In one trial evaluating elbow epicondylitis, one FESWT patient with preexisting coronary heart disease died of cardiac failure, but the death was not causally linked to the shock wave therapy (0.7% vs. 0% in sham group).[64] Allergy or reaction to local anesthetic was reported by two elbow epicondylitis trials, with no statistical difference in frequency between the FESWT versus sham group (1.5% vs. 0% and 3% vs. 6%, respectively).[28,64] In another trial, two patients experienced Achilles tendon rupture (9.0%), both within 2 weeks of their first FESWT treatment for Achilles tendinopathy, compared with no cases in the Sham group.[35] In addition, we found a case report of Achilles tendon rupture possibly related to FESWT.[104] The patient had developed chronic Achilles tendinitis postoperatively (calcaneal osteotomy) and had not responded to any conservative treatments; the rupture occurred 2 months after FESWT treatment in the absence of trauma or accident. Two trials of rotator cuff tendinopathy specifically stated there were no incidences of unexpected/severe adverse events or clinically significant adverse effects[57] or neurovascular complications.[73] Various minor complications were reported across the trials and were, in general, more common following FESWT (Appendix Tables H2-4, 7). The most common minor events reported were pain/discomfort during treatment (8 trials),[25,28,57,64,131,146,170] local erythematous changes (e.g., petechaie, bleeding, hematoma) (6 trials)(Gerdesmeyer 2003, Hsu 2008, Peters 2004, Haake 2002, Collins, Pettrone 2005), nausea/dizziness (4 trials),[25,64,132,146] and transient reddening of the skin (2 trials),[64,146] Four trials reported that no adverse events or side effects were seen in either group.[33,45,55,159,180]

*FESWT vs. Active Controls*: No serious adverse events were reported across five trials that evaluated the comparative efficacy of FESWT compared with an active control; two were in patients with elbow epicondylitis,[129,136] two were in shoulder tendinopathies (rotator cuff[130] and adhesive capsulitis[20] and one was in patients with patellar tendinopathy.[188] The latter trial specifically reported that there were no serious systemic or local complications during the study period, Table 10. Control groups included corticosteroid injection (CSI), percutaneous tenotomy, TENS, oral steroid therapy, and conservative management (NSAIDS, physiotherapy, exercise regimen, knee strap). The most common minor adverse events reported in the FESWT group included erythemous changes (i.e., erythema/petechial bleeding/hematoma) (3 trials)[20,129,130] and mild/transient neurological symptoms (i.e., myalgia, transient numbness, hypoesthesia, parathesia) (3 trials)[20,130,136]; complications in the control group were often not reported or poorly reported (Appendix Tables H2-4, 8). In one trial that compared FESWT with CSI, all patients in both groups complained of pain during treatment; nausea, erythema, swelling and tremor were reported in 21%, 21%, 16%, and 5% of patients in the FESWT group compared with no patient in the CSI group reporting these complications.[129]

*RESWT vs. Sham:* Four trials that evaluated the comparative efficacy of RESWT versus Sham in patients with elbow epicondylitis(2 trials)[19,115] and shoulder tendinopathies (rotator cuff[94] and adhesive capsulitis[75]) assessed adverse events. No serious adverse events were reported in any trial. Minor complications reported included discomfort or pain, redness, and hematoma with no statistical difference between groups. Two trials reported that no complication occurred in either group.[19,94] (Appendix Table H2-4).

*RESWT vs. Active Control*: Adverse events were reported by five trials that evaluated the comparative efficacy of RESWT versus an active control group for the treatment of Achilles tendinopathy in two trials[147,148,153] and shoulder tendinopathies in three trials (1 rotator cuff tendinopathy,[42] 1 long bicep tenosynovitis,[106] 1 subacromial pain[47]). Control groups included ultrasound-guided percutaneous lavage,

eccentric loading, and supervised exercise. One death was noted as loss-to-follow-up at 12 months in the RESWT group in one trial of patients with subacromial shoulder pain; however no cause or description was provided so it is unclear if this death was related in any way to the treatment,[47] Table 10. No other serious adverse events occurred in either group across the trials to include Achilles tendon rupture and unspecified serious complications as reported by three trials[147,148,153] and humeral head necrosis and rotator cuff-related disease (induced by ESWT) in one trial.[106] Minor complications were inconsistently reported across trials and included discomfort/pain during treatment, skin reddening (but no bruising), and transient numbness (Appendix Table H3, 5-7).

*RESWT vs. No Treatment*: One trial that evaluated the comparative efficacy of RESWT versus Wait-and-See in patients with Achilles tendinopathy reported adverse events.[153] No serious adverse events occurred in either group, to include Achilles tendon rupture and unspecified serious complications.(Table 10) Skin reddening (but no bruising) occurred in all RESWT patients (Appendix Table H7).

### 4.2.4. Osteoarthritis of the Knee

*FESWT vs. Active Controls*: One trial, which evaluated the comparative efficacy of FESWT (plus isokinetic muscular strengthening) compared with isokinetic muscular strengthening alone and with ultrasound therapy, reported that no side effects (e.g., swelling, erythema, or skin erosion) occurred during or after FESWT,[21] Appendix Table H9.

*RESWT vs. Sham*: No adverse events occurred in either group as reported by one trial which evaluated the comparative efficacy of RESWT versus sham (Appendix Table H9).[198]

**Table 10. Serious Adverse Events**

| Serious or Potentially Serious Adverse Event | RCT | ESWT n/N | Control n/N | ESWT % (95% CI) | Control % (95% CI) |
|---|---|---|---|---|---|
| Total | n = 52 | 10/2553 | 5/2209 | 0.39% (0.19 to 0.72%) | 0.23% (0.07 to 0.53%) |
| Focused ESWT | n = 36 | 9/1900 | 5/1610 | 0.47% (0.22 to 0.90%) | .31% (.10 to .72%) |
| Radial ESWT | n = 16 | 1/653 | 0/599 | 0.15 (.00 to .85%) (1/653) | 0.0% (0.0 to .61%) |
| | | Comparison | | ESWT % (n/N) | Control % (n/N) |
| Plantar Fasciitis | | | | | |
| Tendon rupture | Gerdesmeyer 2008 | RESWT vs. Sham | | 0% (0/125) | 0% (0/118) |
| Neurological (NOS) | Rompe 2003 | FESWT vs. Sham | | 0% (0/22) | 0% (0/22) |
| Infection | Rompe 2003 | FESWT vs. Sham | | 0% (0/22) | 0% (0/22) |
| Death (unrelated to treatment) | Wang 2006 | FESWT vs. Conservative Treatment* | | 1.3% (1/79) | 0% (0/70) |
| No adverse events occurred | Cosentino 2001 | FESWT vs. Sham | | 0% (0/30) | 0% (0/30) |
| | Saxena 2012 | FESWT vs. Sham | | 0% (0/11) | 0% (0/14) |
| | Chew 2013 | FESWT vs. Conservative Treatment* | | 0% (0/19) | 0% (0/16) |
| | Grecco 2013 | RESWT vs. Ultrasound | | 0% (0/20) | 0% (0/20) |
| | Konjen 2015 | RESWT vs. Ultrasound | | 0% (0/15) | 0% (0/15) |
| Elbow Epicondylitis | | | | | |
| Allergy/Reaction to Anesthetic | Haake 2002 | FESWT vs. Sham | | Per patient: 1.5% (2/134)<br>Per procedure: 0.5% (2/399) | Per patient: 0% (0/136)<br>Per procedure: 0% (0/402) |
| | Collins 2011 | FESWT vs. Sham | | 3% (3/93) | 6% (5/90) |
| Death (not causally linked to ESWT)† | Haake 2002 | FESWT vs. Sham | | Per patient: 0.7% (1/134)<br>Per procedure: 0.3% (1/399) | Per patient: 0% (0/136)<br>Per procedure: 0% (0/402) |
| No adverse events occurred | Capan 2016 | RESWT vs. Sham | | 0% (0/28) | 0% (0/28) |
| Rotator Cuff Tendinopathy | | | | | |
| Unexpected/severe adverse events | Gerdesmeyer 2003 | FESWT vs. Sham | | 0% (0/96) | 0% (0/48) |
| Clinically significant adverse effects‡ | Gerdesmeyer 2003 | FESWT vs. Sham | | 0% (0/96) | 0% (0/48) |
| Neurovascular complications | Hsu 2008 | FESWT vs. Sham | | 0% (0/33) | NR |

| Serious or Potentially Serious Adverse Event | RCT | ESWT n/N | Control n/N | ESWT % (95% CI) | Control % (95% CI) |
|---|---|---|---|---|---|
| No adverse events occurred | Cosentino 2003 | FESWT vs. Sham | | 0% (0/35) | 0% (0/35) |
| | Galasso 2012 | FESWT vs. Sham | | 0% (0/11) | 0% (0/9) |
| | Schmitt 2001/Efe 2012 | FESWT vs. Sham | | 0% (0/20) | 0% (0/20) |
| | Kolk 2013 | RESWT vs. Sham | | 0% (0/44) | 0% (0/36) |
| Achilles Tendinopathy | | | | | |
| Tendon rupture | Costa 2005 | FESWT vs. Sham | | 9.0% (2/22) | 0% (0/27) |
| | Rompe 2007 | RESWT vs. Eccentric Loading and vs. Wait-and-See | | 0% (0/24) | 0% (0/23) and 0% (0/23) |
| | Rompe 2008 | RESWT vs. Eccentric Loading | | 0% (0/23) | 0% (0/22) |
| | Rompe 2009 | RESWT + Eccentric Loading vs. Eccentric Loading alone | | 0% (0/30) | 0% (0/31) |
| Serious complications (NOS) | Rompe 2007 | RESWT vs. Eccentric Loading and vs. Wait-and-See | | 0% (0/24) | 0% (0/23) and 0% (0/23) |
| | Rompe 2008 | RESWT vs. Eccentric Loading | | 0% (0/23) | 0% (0/22) |
| | Rompe 2009 | RESWT + Eccentric Loading vs. Eccentric Loading alone | | 0% (0/30) | 0% (0/31) |
| Adhesive Capsulitis | | | | | |
| No adverse events occurred | Vahdatpour 2014 | FESWT vs. Sham | | 0% (0/19) | 0% (0/17) |
| Subacromial pain | | | | | |
| Death (cause NR) | Engebretsen 2009/ 2011 | RESWT vs. Supervised Exercise | | 2.2% (1/46) | 0% (0/48) |
| Primary Long Bicep Tenosynovitis | | | | | |
| Humeral head necrosis | Liu 2012 | RESWT vs. Supervised Exercise | | 0% (0/54) | NR |
| Rotator cuff-related disease (induced by ESWT) | Liu 2012 | RESWT vs. Supervised Exercise | | 0% (0/54) | NR |
| Knee Osteoarthritis | | | | | |
| No adverse events occurred | Chen 2014 | FESWT vs. Isokinetic Strengthening and vs. US + Isokinetic Strengthening | | 0% (0/30) | 0% (0/30) and 0% (0/30) |
| | Zhao 2013 | RESWT vs. Sham | | 0% (0/34) | 0% (0/36) |

FESWT: Focused Extracorporeal Shock Wave Therapy; IMS: NOS: not otherwise specified; NR: not reported; RCT: randomized controlled trial; RESWT: Radial Extracorporeal Shock Wave Therapy; US: Ultrasound.

*Conservative treatment included:

Wang: NSAIDs, orthotics, physical therapy, an exercise program, and/or a local cortisone injection.

Chew: stretching exercises and orthotics.

†In the FESWT group, one patient with preexisting coronary heart disease died of cardiac failure, but the death was not causally linked to the shock wave therapy.

‡ Includes neurologic disorders, tendon rupture, infection, bone edema, aseptic necrosis, or muscle hematoma.

## *4.3. Key Question 3: Differential Efficacy and Harms in Subpopulations*

### 4.3.1. Number of studies retained

For this key question, RCTs that stratified on patient characteristics of interest, permitting evaluation of effect modification were considered for inclusion. Subgroups of interest included (but were not limited to): age, sex, race, ethnicity, socioeconomic status, payer, and worker's compensation. All RCTs included to evaluate the efficacy or safety of ESWT versus comparators of interest were assessed.

**Summary of results:**

**Focused ESWT versus Sham:** There is no differential effect in one study of sex, age or body weight on FESWT in patients with plantar fasciitis (strength of evidence, LOW). In treating rotator cuff tendinopathy, high intensity versus sham compared with low intensity versus sham produces better results in two studies with respect to pain improvement in the short- and intermediate-term, and reoccurrence of pain in the intermediate-term (strength of evidence, LOW). There is INSUFFICIENT evidence that duration of symptoms modifies treatment effect in patients with lateral epicondyle tendinopathy. There is INSUFFICIENT evidence that sex modifies treatment effect in patients with Achilles tendinopathy.

**Focused ESWT versus Active Control:** There is no evidence.

**Radial ESWT versus Sham:** There is insufficient evidence that the presence of calcium formation in the rotator cuff modifies the treatment effect in patients with rotator cuff tendinopathy.

**Radial ESWT versus Active Control:** There is no evidence.

***Focused ESWT vs. Sham***

### 4.3.2. Plantar Fasciitis

One trial (Malay 2006)[112] provided subgroup analyses assessing the mean change in pain from baseline in the study of FESWT versus sham in the treatment of plantar fasciitis. The study found no modifying effect of sex, age or body weight on treatment in plantar fasciitis. Whether the subgroup analysis was preplanned is unknown. Statistical interaction terms were calculated. There were no subgroup analysis on harms reported.

### 4.3.3. Rotator Cuff Tendinopathy

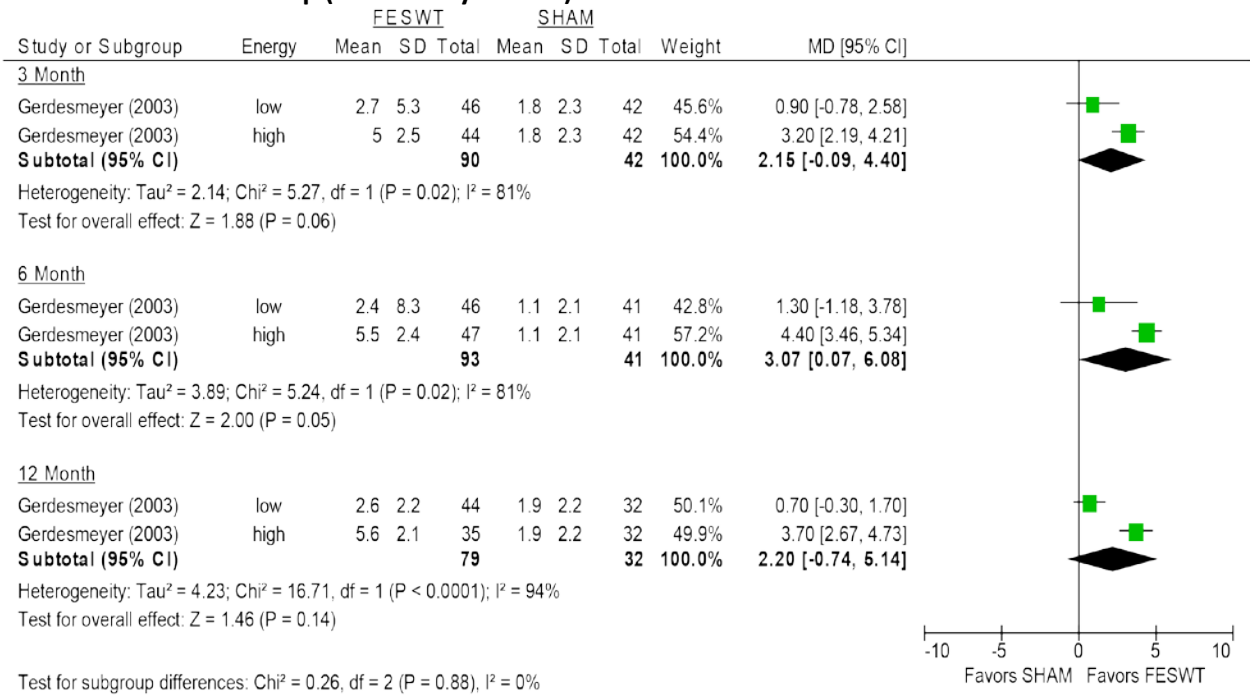
Two articles provided subgroup analyses in patients receiving FESWT in rotator cuff tendinopathy (Peters 2004, Gerdesmeyer 2003). Comparing FESWT with sham, Peters 2004[131] and Gerdesmeyer 2003[57] both found energy intensity modified the effect of treatment in direct comparisons. Peters 2004[131] evaluated the proportion of patients with recurrence of pain at 6 month follow-up. No patient (0/30) had reoccurrence of pain in the high energy group, while 87% (26/30) had reoccurrence in the low energy group. All patients in the sham group had reoccurrence, Table 11. The analysis was preplanned, but no test for homogeneity was conducted. There were no severe adverse events reported in any subgroup strata.

**Table 11. The effect of high versus low energy on treatment in rotator cuff tendinopathy assessing reoccurrence of pain at 6 months (Peters 2004).**

| Energy | FESWT | Sham |
|---|---|---|
| High (0.44 mJ/mm$^2$) | 0% (0/30) | 100% (29/29) |
| Low (0.15 mJ/ mm$^2$) | 87% (26/30) | 100% (29/29) |

Gerdesmeyer 2003[57] noted a modifying effect of energy level on the change in pain from baseline in shoulder tendinopathy. Patients receiving high energy (0.32 mJ/mm$^2$) improved significantly more than patients receiving low energy (0.08 mJ/mm$^2$) compared with sham at 3, 6 and 12 month follow-up, Figure 40. The analysis was preplanned, but no test for homogeneity was conducted. There were no severe adverse events reported in any subgroup strata.

**Figure 40. The effect of energy level on the change in pain from baseline in shoulder tendinopathy, 3, 6 and 12 month follow-up (Gerdesmeyer 2003).**




### 4.3.4. Lateral Epicondyle Tendinopathy

One article (Chung 2005)[26] reported the effect of symptom duration on treatment assessing pain success (≥50% improvement over baseline at 8-week follow-up). They found that symptom duration had modifying effect on treatment such that patients with symptoms for a shorter period (≤16 weeks) responded better with FESWT compared with sham, while patients with longer symptom duration (>16 weeks) responded worse than sham, Table 12. Whether the subgroup analyses was preplanned is unknown. Interaction terms were calculated. There were no subgroup analyses on harms reported.

**Table 12. The effect of symptom duration on treatment for lateral epicondyle tendinopathy assessing short-term pain success (≥50% improvement over baseline) at 8 week follow-up (Chung 2005).**

| | FESWT | Sham | Interaction |
|---|---|---|---|
| Duration | | | |
| ≤16 weeks | 50% (8/16) | 14% (2/14) | p= .03 |
| >16 weeks | 27% (4/15) | 47% (7/15) | |

#### 4.3.5. Achilles Tendinopathy

One study reported a subgroup analysis looking at the effect of sex on treatment (Rasmussen 2008).[138] They reported that women who received FESWT had better AOFAS scores compared with women who received sham at 3 month follow-up. This was not the case for men (data not shown). There was no difference between sexes with respect to improvement in pain. This analysis was not preplanned and no test for homogeneity was conducted. There were no subgroup analyses on harms reported.

**Focused ESWT versus Active Control:** There is no evidence.

**Radial ESWT versus Sham:** One article provided subgroup analyses in patients receiving RESWT in rotator cuff tendinopathy (Kolk 2013).[94] The investigators assessed whether the presence of calcium in the rotator cuff modified the treatment effect RESWT. There was no significant difference in patients with calcifying or non-calcifying tendinopathy between RESWT and sham at 3 or 6 month follow-up with respect to the change in pain or change in Simple Shoulder Test compared with baseline. Whether the subgroup analysis was preplanned is unknown. Test for homogeneity was not conducted. There were no severe adverse events reported in any subgroup strata.

**Radial ESWT versus Active Control:** There is no evidence.

## *4.4. Key Question 4: Cost effectiveness*

#### 4.4.1. Number of studies retained

No formal economic analyses were identified that met the inclusion criteria.

# 5. Strength of Evidence (SoE) Summary Tables

The following summaries of evidence have been based on the highest quality of studies available. Additional information on lower quality studies is available in the report. A summary of the primary outcomes for each key question are provided in the tables below and are sorted by comparator. Details of other outcomes are available in the report.

## *5.1. Strength of Evidence Summary: Plantar Fasciitis Efficacy Results*

| Outcome | Follow-up | RCTs | N | Serious Risk of Bias | Serious Inconsistency | Serious Indirectness | Serious Imprecision | Conclusion | Quality |
|---|---|---|---|---|---|---|---|---|---|
| **Plantar Fasciitis: Focused ESWT vs. Sham** | | | | | | | | | |
| **Pain in AM, success (%)** (≥50% or 60% ↓ pain with first morning steps) | Short-term | 5 RCTs (Speed, Kudo, Gollwitzer 07, Gollwitzer 15, Theodore) | 625 | No | No | No | No | RR 1.38 (95% CI, 1.15 to 1.66)<br>Conclusion: Significantly greater improvement with FESWT vs. sham. | ⊕⊕⊕⊕ HIGH |
| | Intermediate- and long-term | 0 RCTs | | | | | | No evidence. | ⊕◯◯◯ INSUFFICIENT |
| **Pain in AM, MD** (VAS 0-10, worst) | Short-term | 5 RCTs (Kudo, Ogden, Cosentino, Theodore, Haake) | 860 | No | Yes[2] (-1) | No | No | MD 1.41 (95% CI, -.023 to 3.04)<br>Conclusion: No difference between FESWT vs. sham. | ⊕⊕⊕◯ MODERATE |
| | Intermediate-term | 1 RCTs (Rompe) | 45 | No | Unknown | No | Yes[3] (-2) | MD 2.5 (95% CI, -.023 to 3.04)<br>Conclusion: No difference between FESWT vs. sham. | ⊕⊕◯◯ LOW |
| | Long-term | 2 RCTs (Rompe, Haake) | 317 | No | Yes[2] (-1) | No | Yes[3] (-1) | MD 1.54 (95% CI, -0.91 to 3.99)<br>Conclusion: No difference between FESWT vs. sham. | ⊕⊕◯◯ LOW |
| **Pain w/ activities, success (%)** (≥60% pain improvement over baseline) | Short-term | 2 RCTs (Gollwitzer 07, Gollwitzer 15) | 287 | No | No | No | Yes[3] (-1) | RR 1.27 (0.98, 1.66)<br>Conclusion: No difference between FESWT vs. sham. | ⊕⊕⊕◯ MODERATE |
| | Intermediate- and long-term | 0 RCTs | | | | | | No evidence. | ⊕◯◯◯ INSUFFICIENT |

| Outcome | Follow-up | RCTs | N | Serious Risk of Bias | Serious Inconsistency | Serious Indirectness | Serious Imprecision | Conclusion | Quality |
|---|---|---|---|---|---|---|---|---|---|
| **Pain w/ activities, MD** (VAS 0-10, worst) | Short-term | 3 RCTs (Kudo, Ogden, Cosentino) | 450 | No | Yes[2] (-1) | No | Yes[3] (-1) | MD 1.80 (95% CI, -1.29 to 4.89) Conclusion: No difference between FESWT vs. sham. | ⊕⊕◯◯ LOW |
| | Intermediate- and long-term | 0 RCTs | | | | | | No evidence. | ⊕◯◯◯ INSUFFICIENT |
| **Pain composite, success (%)** (≥50-60% ↓ pain and ≤4 VAS and or ≥50% ↓ pain with pressure) | Short-term | 4 RCTs (Ogden, Gollwitzer 07, Gollwitzer 15, Malay) | 739 | No | No | No | No | RR 1.55 (95% CI, 1.29 to 1.85) Conclusion: Significantly greater improvement with FESWT vs. sham. | ⊕⊕⊕⊕ HIGH |
| | Intermediate- and long-term | 0 RCTs | | | | | | No evidence. | ⊕◯◯◯ INSUFFICIENT |
| **Pain NOS, MD** (VAS 0-10, worst) | Short-term | 2 RCTs (Rompe 1996, Malay) | 254 | Yes[1] (-1) | No | No | Yes[3] (-1) | MD 0.28 (95% CI, -0.54 to 1.09) Conclusion: No difference between FESWT vs. sham. | ⊕⊕◯◯ LOW |
| | Intermediate- and long-term | 0 RCTs | | | | | | No evidence. | ⊕◯◯◯ INSUFFICIENT |
| **Pain at rest, MD** (VAS 0-10, worst) | Short-term | 2 RCTs (Haake,, Cosentino) | 316 | No | Yes[2] (-1) | No | Yes[3] (-1) | MD 2.5 (95% CI, -2.01 to 7.01) Conclusion: No difference between FESWT vs. sham. | ⊕⊕◯◯ LOW |
| | Intermediate- and long-term | 0 RCTs | | | | | | No evidence. | ⊕◯◯◯ INSUFFICIENT |
| **Function AOFAS Ankle- Hindfoot, success (%)** (none or mild on the pain domain) | Short-term | 1 RCT (Kudo) | 105 | No | Unknown | No | Yes[3] (-1) | RR 1.47 (95% CI, 0.93 to 2.33) Conclusion: No difference between FESWT vs. sham. | ⊕⊕⊕◯ MODERATE |
| | Intermediate- and long-term | 0 RCTs | | | | | | No evidence. | ⊕◯◯◯ INSUFFICIENT |
| **Function AOFAS Ankle- Hindfoot, MD** (0-100, best) | Short-term | 1 RCTs (Kudo) | 105 | No | Unknown | No | Yes[3] (-1) | MD -4.5 (95% CI, -17.4 to 8.4) Conclusion: No difference between FESWT vs. sham. | ⊕⊕⊕◯ MODERATE |
| | Intermediate-term | 1 RCT (Rompe) | 45 | No | Unknown | No | Yes[3] (-2) | MD 17.8 (95% CI, 11.3 to 24.3) | ⊕⊕◯◯ LOW |

| Outcome | Follow-up | RCTs | N | Serious Risk of Bias | Serious Inconsistency | Serious Indirectness | Serious Imprecision | Conclusion | Quality |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | Conclusion: Statistically and clinically greater improvement with FESWT vs. sham. | |
| | Long-term | 1 RCT (Rompe) | 45 | No | Unknown | No | Yes[3] (-2) | MD 12.0 (95% CI, 6.3 to 17.7)<br>Conclusion: Statistically and clinically greater improvement with FESWT vs. sham. | ⊕⊕◯◯ LOW |
| **Plantar Fasciitis: Focused ESWT vs. CSI** | | | | | | | | | |
| **Pain in AM, MD** (VAS 0-10, worst) | Short-term | 1 RCT (Porter) | 125 | No | Unknown | No | Yes[3] (-1) | MD -2.16 (95% CI, -3.14 to -1.18)<br>Conclusion: Significantly greater improvement with CSI vs. FESWT. | ⊕⊕⊕◯ MODERATE |
| | Intermediate- and long-term | 0 RCTs | | | | | | No evidence. | ⊕◯◯◯ INSUFFICIENT |
| | Long-term | 1 RCT (Porter) | 125 | No | Unknown | No | Yes[3] (-1) | MD 0.05 (95% CI, -0.99 to 1.09)<br>Conclusion: Conclusion: No difference between CSI vs. FESWT. | ⊕⊕⊕◯ MODERATE |
| **Pain composite, success (%)** Loss of heel tenderness, ↓ pain 50% from baseline | Short-term | 1 RCT (Yucel) | 60 | Yes[1] (-1) | Unknown | No | Yes[3] (-2) | RR 0.96 (95% CI, 0.77 to 1.20)<br>Conclusion: Insufficient strength of evidence precludes firm conclusions. | ⊕◯◯◯ INSUFFICIENT |
| | Intermediate- and long-term | 0 RCTs | | | | | | No evidence. | ⊕◯◯◯ INSUFFICIENT |
| **Pain NOS, MD** (VAS 0-10, worst) | Short-term | 1 RCT (Yucel) | 60 | Yes[1] (-1) | Unknown | No | Yes[3] (-2) | MD -1.2 (-2.03 to -.037)<br>Conclusion: Insufficient strength of evidence precludes firm conclusions. | ⊕◯◯◯ INSUFFICIENT |
| | Intermediate- and long-term | 0 RCTs | | | | | | No evidence. | ⊕◯◯◯ INSUFFICIENT |
| **Function, any** | Short-, intermediate- and long-term | 0 RCTs | | | | | | No evidence. | ⊕◯◯◯ INSUFFICIENT |
| **Plantar Fasciitis: Focused ESWT vs. Conservative Care** | | | | | | | | | |
| **Pain in AM, success (%)** (VAS ≤3) | Short-term | 1 RCT (Hammer) | 49 | Yes[1] (-1) | Unknown | No | Yes[3] (-2) | RR 0.90 (95% CI, 0.59 to 1.38)<br>Conclusion: Insufficient strength of evidence precludes firm conclusions. | ⊕◯◯◯ INSUFFICIENT |

| Outcome | Follow-up | RCTs | N | Serious Risk of Bias | Serious Inconsistency | Serious Indirectness | Serious Imprecision | Conclusion | Quality |
|---|---|---|---|---|---|---|---|---|---|
| | Intermediate-term | 1 RCT (Hammer) | 49 | Yes[1] (-1) | Unknown | No | Yes[3] (-2) | RR 0.86 (95% CI, 0.64 to 1.17)<br>Conclusion: Insufficient strength of evidence precludes firm conclusions. | ⊕◯◯◯ INSUFFICIENT |
| | Long-term | 0 RCTs | | | | | | No evidence. | ⊕◯◯◯ INSUFFICIENT |
| **Pain NOS, MD** (VAS 0-10, worst) | Short-term | 2 RCTs (Hammer, Chew) | 84 | Yes[1] (-1) | No | No | Yes[3] (-2) | Not calculable<br>Conclusion: Insufficient strength of evidence precludes firm conclusions. | ⊕◯◯◯ INSUFFICIENT |
| | Intermediate-term | 2 RCTs (Hammer, Chew) | 84 | Yes[1] (-1) | No | No | Yes[3] (-2) | Not calculable<br>Conclusion: Insufficient strength of evidence precludes firm conclusions. | ⊕◯◯◯ INSUFFICIENT |
| | Long-term | 0 RCTs | | | | | | No evidence. | ⊕◯◯◯ INSUFFICIENT |
| **Pain at rest, MD** (VAS 0-10, worst) | Short-term | 1 RCT (Hammer) | 49 | Yes[1] (-1) | Unknown | No | Yes[3] (-2) | MD -1.2 (95% CI, -2.03 to 0.37)<br>Conclusion: Insufficient strength of evidence precludes firm conclusions. | ⊕◯◯◯ INSUFFICIENT |
| | Intermediate- and long-term | 0 RCTs | | | | | | No evidence. | ⊕◯◯◯ INSUFFICIENT |
| **Function AOFAS Ankle- Hindfoot, MD** (0-100, best) | Short-term | 1 RCT (Chew) | 35 | Yes[1] (-1) | Unknown | No | Yes[3] (-2) | Not calculable<br>Conclusion: Insufficient strength of evidence precludes firm conclusions. | ⊕◯◯◯ INSUFFICIENT |
| | Intermediate-term | 1 RCT (Chew) | 35 | Yes[1] (-1) | Unknown | No | Yes[3] (-2) | Not calculable<br>Conclusion: Insufficient strength of evidence precludes firm conclusions. | ⊕◯◯◯ INSUFFICIENT |
| | Long-term | 0 RCTs | | | | | | No evidence. | ⊕◯◯◯ INSUFFICIENT |
| **Plantar Fasciitis: Focused ESWT vs. Endoscopic Partial Plantar Fascia Release (EPFR)** | | | | | | | | | |
| **Pain in AM, MD** (VAS 0-10, worst) | Short-term | 1 RCT (Radwan) | 65 | No | Unknown | No | Yes[3] (-2) | Not calculable<br>Conclusion: No difference between FESWT vs. EPFR. | ⊕⊕◯◯ LOW |

| Outcome | Follow-up | RCTs | N | Serious Risk of Bias | Serious Inconsistency | Serious Indirectness | Serious Imprecision | Conclusion | Quality |
|---|---|---|---|---|---|---|---|---|---|
| | Intermediate-term | 0 RCTs | | | | | | No evidence. | ⊕◯◯◯ INSUFFICIENT |
| | Long-term | 1 RCT (Radwan) | 65 | No | Unknown | No | Yes[3] (-2) | Not calculable<br>Conclusion: No difference between FESWT vs. EPFR. | ⊕⊕◯◯ LOW |
| **Function AOFAS Ankle- Hindfoot, MD** (0-100, best) | Short-term | 1 RCT (Radwan) | 65 | No | Unknown | No | Yes[3] (-2) | Not calculable<br>Conclusion: No difference between FESWT vs. EPFR. | ⊕⊕◯◯ LOW |
| | Intermediate-term | 0 RCTs | | | | | | No evidence. | ⊕◯◯◯ INSUFFICIENT |
| | Long-term | 1 RCT (Radwan) | 65 | No | Unknown | No | Yes[3] (-2) | Not calculable<br>Conclusion: No difference between FESWT vs. EPFR. | ⊕⊕◯◯ LOW |
| **Plantar Fasciitis: Radial ESWT vs. Sham** | | | | | | | | | |
| **Pain in AM, success (%)** (≥60% ↓ pain with first with first morning steps) | Short-term | 1 RCT (Gerdesmeyer) | 243 | No | Unknown | No | Yes[3] (-1) | RR 1.26 (95% CI, 1.00 to 1.59)<br>Conclusion: Significantly greater improvement with RESWT vs. sham. | ⊕⊕⊕◯ MODERATE |
| | Intermediate- and long-term | 0 RCTs | | | | | | No evidence. | ⊕◯◯◯ INSUFFICIENT |
| **Pain w/ activity, success (%)** (≥60% ↓ pain with activity over baseline) | Short-term | 1 RCT (Gerdesmeyer) | 243 | No | Unknown | No | Yes[3] (-1) | RR 1.48 (95% CI, 1.14 to 1.91)<br>Conclusion: Significantly greater improvement with RESWT vs. sham. | ⊕⊕⊕◯ MODERATE |
| | Intermediate- and long-term | 0 RCTs | | | | | | No evidence. | ⊕◯◯◯ INSUFFICIENT |
| **Pain composite, success (%)** (≥60% ↓ pain over baseline in ≥2 of following: pain with first morning steps, with | Short-term | 1 RCT (Gerdesmeyer) | 243 | No | Unknown | No | Yes[3] (-1) | RR 1.44 (95% CI, 1.12 to 1.86)<br>Conclusion: Significantly greater improvement with RESWT vs. sham. | ⊕⊕⊕◯ MODERATE |
| | Intermediate- and long-term | 0 RCTs | | | | | | No evidence. | ⊕◯◯◯ INSUFFICIENT |

| Outcome | Follow-up | RCTs | N | Serious Risk of Bias | Serious Inconsistency | Serious Indirectness | Serious Imprecision | Conclusion | Quality |
|---|---|---|---|---|---|---|---|---|---|
| activities, with pressure) | | | | | | | | | |
| **Pain NOS, success (%)** (>50% ↓ pain or ↑ ≥3 points over baseline) | Short-term | 1 RCT (Ibrahim) | 50 | No | Unknown | No | Yes[3] (-2) | RR Not calculable<br>Conclusion: Significantly greater improvement with RESWT vs. sham. | ⊕⊕◯◯ LOW |
| | Intermediate-term | 2 RCT (Ibrahim, Mehra) | 73 | No | No | No | Yes[3] (-2) | RR 6.32 (95% CI, 2.83 to 14.1)<br>Conclusion: Significantly greater improvement with RESWT vs. sham. | ⊕⊕⊕◯ MODERATE[4] |
| | Long-term | 1 RCT (Ibrahim) | 50 | No | Unknown | No | Yes[3] (-2) | RR 3.60 (95% CI, 1.58 to 8.18)<br>Conclusion: Significantly greater improvement with RESWT vs. sham. | ⊕⊕◯◯ LOW |
| **Pain NOS, MD** (VAS 0-10, worst) | Short-term | 1 RCT (Ibrahim) | 50 | No | Unknown | No | Yes[3] (-2) | MD 6.2 (95% CI, 5.75, 6.65)<br>Conclusion: Significantly greater improvement with RESWT vs. sham. | ⊕⊕⊕◯ MODERATE[4] |
| | Intermediate-term | 2 RCT (Ibrahim, Mehra) | 73 | No | No | No | Y Yes[3] (-2) | RR 6.32 (95% CI, 2.83 to 14.1)<br>Conclusion: Significantly greater improvement with RESWT vs. sham. | ⊕⊕⊕◯ MODERATE[4] |
| | Long-term | 1 RCT (Ibrahim) | 50 | No | Unknown | No | Yes[3] (-2) | RR 3.80 (95% CI, 3.23 to 4.37)<br>Conclusion: Significantly greater improvement with RESWT vs. sham. | ⊕⊕◯◯ LOW |
| **Plantar Fasciitis: Radial ESWT vs. Ultrasound** | | | | | | | | | |
| **Pain NOS, success (%)** (VAS ≤1) | Short-term | 1 RCT (Grecco) | 40 | Yes[1] (-1) | Unknown | No | Yes[3] (-2) | RR 0.9 (95% CI, 0.47 to 1.73)<br>Conclusion: Insufficient strength of evidence precludes firm conclusions. | ⊕◯◯◯ INSUFFICIENT |
| | Intermediate- and long-term | 0 RCTs | | | | | | No evidence. | ⊕◯◯◯ INSUFFICIENT |
| | Long-term | 1 RCT (Grecco) | 40 | Yes[1] (-1) | Unknown | No | Yes[3] (-2) | RR 1.56 (95% CI, 0.89 to 2.73)<br>Conclusion: Insufficient strength of evidence precludes firm conclusions. | ⊕◯◯◯ INSUFFICIENT |
| **Pain in AM, success (%)** | Short-term | 1 RCT (Grecco) | 40 | Yes[1] (-1) | Unknown | No | Yes[3] (-2) | RR 1.08 (95% CI, 0.70 to 1.66)<br>Conclusion: Insufficient strength of evidence precludes firm conclusions. | ⊕◯◯◯ INSUFFICIENT |

| Outcome | Follow-up | RCTs | N | Serious Risk of Bias | Serious Inconsistency | Serious Indirectness | Serious Imprecision | Conclusion | Quality |
|---|---|---|---|---|---|---|---|---|---|
| (VAS ≤1 with first morning steps) | Intermediate- and long-term | 0 RCTs | | | | | | No evidence. | ⊕◯◯◯ INSUFFICIENT |
| | Long-term | 1 RCT (Grecco) | 40 | Yes[1] (-1) | Unknown | No | Yes[3] (-2) | RR 1.06 (95% CI, 0.80 to 1.41) Conclusion: Insufficient strength of evidence precludes firm conclusions. | ⊕◯◯◯ INSUFFICIENT |
| **Pain NOS, MD** (VAS 0-10, worst) | Short-term | 1 RCT (Konjen) | 30 | No | Unknown | No | Yes[3] (-2) | MD 2.4 (95% CI, 2.35 to 2.45) Conclusion: Significantly greater improvement with RESWT vs. sham. | ⊕⊕◯◯ LOW |
| | Intermediate- and long-term | 0 RCTs | | | | | | | |
| | Long-term | 1 RCT (Konjen) | 30 | No | Unknown | No | Yes[3] (-2) | MD 3.1 (95% CI, 3.02 to 3.18) Conclusion: Significantly greater improvement with RESWT vs. sham. | ⊕⊕◯◯ LOW |

AOFAS: American Orthopedic Foot and Ankle Society; CI: confidence interval; CSI: corticosteroid injection; MD: mean difference; NOS: not otherwise specified; PRTEE: Patient RatedTennis Elbow Evaluation; RR: risk ratio; UEFS: upper extremity functional scale; VAS: visual analog scale.

Reasons for downgrading (-) or upgrading (+):

1. Serious risk of bias: the majority of studies violated one or more of the criteria for good quality RCT (or cohort study) related to the outcome reported (see Appendix for details)
2. Inconsistency: differing estimates of effects across trials
3. Imprecise effect estimate for a continuous outcome: wide (or unknown) confidence interval and/or small sample size
4. Upgraded 1 for large effect size

## *5.2. Strength of Evidence Summary: Lateral Epicondyle Tendinopathy Efficacy Results*

| Outcome | Follow-up | RCTs | N | Serious Risk of Bias | Serious Inconsistency | Serious Indirectness | Serious Imprecision | Conclusion | Quality |
|---|---|---|---|---|---|---|---|---|---|
| **Lateral Epicondyle Tendinopathy: FESWT vs. Sham** | | | | | | | | | |
| **Pain w/ resistance, success (%)** (≥50% pain improvement from baseline) | Short-term | 2 RCTs (Rompe, Pettrone) | 192 | No | No | No | Yes[3] (-1) | RR 2.19 (95% CI, 1.55 to 3.11) Conclusion: Significantly greater improvement with FESWT vs. sham. | ⊕⊕⊕◯ MODERATE |
| | Intermediate-and long-term | 0 RCTs | | | | | | No evidence. | ⊕◯◯◯ INSUFFICIENT |
| **Pain w/ resistance, MD** (VAS 0-10, worst) | Short-term | 3 RCTs (Rompe, Pettrone, Melikyan) | 258 | No | No | No | Yes[3] (-1) | MD 0.30 (95% CI, -1.76 to 2.35) Conclusion: No difference between FESWT vs. sham. | ⊕⊕⊕◯ MODERATE |
| | Intermediate-term | 0 RCTs | | | | | | No evidence. | ⊕◯◯◯ INSUFFICIENT |
| | Long-term | 2 RCTs (Rompe, Melikyan) | 144 | No | Yes[2] (-2) | No | Yes[3] (-1) | MD -0.05 (95% CI, -2.60 to 2.40) Conclusion: Insufficient strength of evidence precludes firm conclusions. | ⊕◯◯◯ INSUFFICIENT |
| **Pain NOS, MD** (VAS 0-10, worst) | Short-term | 3 RCTs (Chung, Melikyan, Collins) | 299 | Yes[1] (-1) | Yes[2] (-1) | No | Yes[3] (-1) | MD 0.24 (95% CI, -0.52 to 1.01) Conclusion: Insufficient strength of evidence precludes firm conclusions. | ⊕◯◯◯ INSUFFICIENT |
| | Intermediate-and long-term | 0 RCTs | | | | | | No evidence. | ⊕◯◯◯ INSUFFICIENT |
| **Pain at night, MD** (VAS 0-10, worst) | Short-term | 2 RCTs (Chung 04, Speed 02) | 135 | No | Yes[2] (-1) | No | Yes[3] (-1) | MD 0.11 (95 CI, -1.55 to 1.77) Conclusion: No difference between FESWT vs. sham. | ⊕⊕◯◯ LOW |
| | Intermediate-and long-term | 0 RCTs | | | | | | No evidence. | ⊕◯◯◯ INSUFFICIENT |
| **Function UEFS, MD** (8-80, worst) | Short-term | 2 RCTs (Rompe, Pettrone) | 177 | No | No | No | Yes[3] (-1) | MD 9.13 (95% CI, 4.83 to 13.44) Conclusion: Significantly greater improvement with FESWT vs. sham. No MCID for this outcome. | ⊕⊕⊕◯ MODERATE |

| Outcome | Follow-up | RCTs | N | Serious Risk of Bias | Serious Inconsistency | Serious Indirectness | Serious Imprecision | Conclusion | Quality |
|---|---|---|---|---|---|---|---|---|---|
| | Intermediate-term | 0 RCTs | | | | | | No evidence. | ⊕◯◯◯ INSUFFICIENT |
| | Long-term | 1 RCT (Rompe) | 78 | No | Unknown | No | Yes[3] (-2) | MD 6.6 (95% CI, -1.68 to 14.88)<br>Conclusion: No difference between FESWT vs. sham. | ⊕⊕◯◯ LOW |
| **Grip Strength (kg)** | Short-term | 4 RCTs (Rompe, Pettrone, Melikyan, Chung) | 308 | No | Yes[2] (-1) | No | Yes[3] (-1) | MD 0.73 (95% CI, -1.63 to 3.10)<br>Conclusion: No difference between FESWT vs. sham. | ⊕⊕◯◯ LOW |
| | Intermediate-term | 0 RCTs | | | | | | No evidence. | ⊕◯◯◯ INSUFFICIENT |
| | Long-term | 2 RCTs (Rompe, Melikyan) | 141 | No | No | No | Yes[3] (-1) | MD -0.02 (95% CI, -3.29 to 3.24)<br>Conclusion: No difference between FESWT vs. sham. | ⊕⊕⊕◯ MODERATE |
| **Lateral Epicondyle Tendinopathy: FESWT vs. CSI** | | | | | | | | | |
| **Pain NOS, success (%)** (≥50% improvement from baseline) | Short-term | 1 RCT (Crowther) | 73 | Yes[1] (-1) | Unknown | No | Yes[3] (-2) | MD 0.72 (95% CI, 0.54 to 0.96)<br>Conclusion: Insufficient strength of evidence precludes firm conclusions. | ⊕◯◯◯ INSUFFICIENT |
| | Intermediate-and long-term | 0 RCTs | | | | | | No evidence. | ⊕◯◯◯ INSUFFICIENT |
| **Pain w/ resistance** (VAS 0-10, worst) | Short-term | 1 RCT (Ozturan) | 73 | Yes[1] (-2) | Unknown | No | Yes[3] (-2) | % change not calculable<br>Conclusion: Insufficient strength of evidence precludes firm conclusions. | ⊕◯◯◯ INSUFFICIENT |
| | Intermediate-term | 1 RCT (Ozturan) | 73 | Yes[1] (-2) | Unknown | No | Yes[3] (-2) | % change not calculable<br>Conclusion: Insufficient strength of evidence precludes firm conclusions. | ⊕◯◯◯ INSUFFICIENT |
| | Long-term | 1 RCT (Ozturan) | 73 | Yes[1] (-2) | Unknown | No | Yes[3] (-2) | % change not calculable<br>Conclusion: Insufficient strength of evidence precludes firm conclusions. | ⊕◯◯◯ INSUFFICIENT |

| Outcome | Follow-up | RCTs | N | Serious Risk of Bias | Serious Inconsistency | Serious Indirectness | Serious Imprecision | Conclusion | Quality |
|---|---|---|---|---|---|---|---|---|---|
| **Function UEFS, MD** (8-80, worst) | Short-term | 1 RCT (Ozturan) | 73 | Yes[1] (-2) | Unknown | No | Yes[3] (-2) | % change not calculable<br>Conclusion: Insufficient strength of evidence precludes firm conclusions. | ⊕◯◯◯ INSUFFICIENT |
| | Intermediate-term | 1 RCT (Ozturan) | 73 | Yes[1] (-2) | Unknown | No | Yes[3] (-2) | % change not calculable<br>Conclusion: Insufficient strength of evidence precludes firm conclusions. | ⊕◯◯◯ INSUFFICIENT |
| | Long-term | 1 RCT (Ozturan) | 73 | Yes[1] (-2) | Unknown | No | Yes[3] (-2) | % change not calculable<br>Conclusion: Insufficient strength of evidence precludes firm conclusions. | ⊕◯◯◯ INSUFFICIENT |
| **Lateral Epicondyle Tendinopathy: FESWT vs. Percutaneous Tenotomy** | | | | | | | | | |
| **Pain w/ resistance, success (%)** (≥50% short- and (≥80% long-term improvement from baseline) | Short-term | 1 RCT (Radwan) | 56 | Yes[1] (-1) | Unknown | No | Yes[3] (-2) | RR 0.85 (95% CI, 0.65 to 1.12)<br>Conclusion: Insufficient strength of evidence precludes firm conclusions. | ⊕◯◯◯ INSUFFICIENT |
| | Intermediate-term | 0 RCTs | | | | | | No evidence. | ⊕◯◯◯ INSUFFICIENT |
| | Long-term | 1 RCT (Radwan) | 56 | Yes[1] (-1) | Unknown | No | Yes[3] (-2) | RR 0.77 (95% CI, 0.48 to 1.23)<br>Conclusion: Insufficient strength of evidence precludes firm conclusions. | ⊕◯◯◯ INSUFFICIENT |
| **Lateral Epicondyle Tendinopathy: RESWT vs. Sham** | | | | | | | | | |
| **Pain at rest, MD** (VAS 0-10, worst) | Short-term | 1 RCT (Capan 16) | 45 | Yes[1] (-1) | Unknown | No | Yes[3] (-2) | MD 0.1 (95% CI -1.41 to 1.61)<br>Conclusion: Insufficient strength of evidence precludes firm conclusions. | ⊕◯◯◯ INSUFFICIENT |
| | Intermediate-and long-term | 0 RCTs | | | | | | No evidence. | ⊕◯◯◯ INSUFFICIENT |
| **Pain w/ activity, MD** (VAS 0-10, worst) | Short-term | 1 RCT (Capan) | 45 | Yes[1] (-1) | Unknown | No | Yes[3] (-2) | MD 1.2 (95% CI -0.33 to 2.73)<br>Conclusion: Insufficient strength of evidence precludes firm conclusions. | ⊕◯◯◯ INSUFFICIENT |
| | Intermediate-and long-term | 0 RCTs | | | | | | No evidence. | ⊕◯◯◯ INSUFFICIENT |
| **Function, PRTEE, MD** | Short-term | 1 RCT (Capan) | 45 | Yes[1] (-1) | Unknown | No | Yes[3] (-2) | MD 4.8 (95% CI -2.75to 12.35) | ⊕◯◯◯ INSUFFICIENT |

| Outcome | Follow-up | RCTs | N | Serious Risk of Bias | Serious Inconsistency | Serious Indirectness | Serious Imprecision | Conclusion | Quality |
|---|---|---|---|---|---|---|---|---|---|
| (0-100, worst) | | | | | | | | Conclusion: Insufficient strength of evidence precludes firm conclusions. | |
| | Intermediate-and long-term | 0 RCTs | | | | | | No evidence. | ⊕◯◯◯ INSUFFICIENT |
| **Pain NOS, success (%)** (VAS 0-10, worst) | Short-term | 1 RCT (Mehra) | 24 | Yes[1] (-2) | Unknown | No | Yes[3] (-2) | RR 8.46 (95% CI, 1.28 to 56.1) Conclusion: Insufficient strength of evidence precludes firm conclusions. | ⊕◯◯◯ INSUFFICIENT[4] |
| | Intermediate-and long-term | 0 RCTs | | | | | | No evidence. | ⊕◯◯◯ INSUFFICIENT |

CI: confidence interval; MD: mean difference; NOS: not otherwise specified; PRTEE: Patient Rated Tennis Elbow Evaluation; RR: risk ratio; UEFS: upper extremity functional scale; VAS: visual analog scale.

Reasons for downgrading (-) or upgrading (+):

1. Serious risk of bias: the majority of studies violated one or more of the criteria for good quality RCT (or cohort study) related to the outcome reported (see Appendix for details)
2. Inconsistency: differing estimates of effects across trials
3. Imprecise effect estimate for a continuous outcome: wide (or unknown) confidence interval and/or small sample size
4. Upgraded 1 for large effect size

### *5.3. Strength of Evidence Summary: Rotator Cuff Tendinopathy Efficacy Results*

| Outcome | Follow-up | RCTs | N | Serious Risk of Bias | Serious Inconsistency | Serious Indirectness | Serious Imprecision | Conclusion | Quality |
|---|---|---|---|---|---|---|---|---|---|
| **Rotator Cuff Tendinopathy: Focused ESWT vs. Sham** | | | | | | | | | |
| **Pain success** (≥50% ↑ on VAS 0-10) | Short-term | 1 RCT (Speed) | 74 | No | Unknown | No | Yes[3,4] (-2) | RR 1.1 (95% CI 0.62, 1.9)<br>Conclusion: No statistical difference between groups. | ⊕⊕◯◯ LOW |
| | Intermediate-term and Long-term | 0 RCTs | | | | | | No evidence. | ⊕◯◯◯ INSUFFICIENT |
| **Pain NOS** (VAS 0-10, worst) | Short-term | 2 RCTs (Gerdesmeyer, Hsu) | 178 | No | Yes[2] (-1) | No | Yes[3] (-1) | MD 3.14 (95% CI 0.70, 5.58)<br>Conclusion: Statistically and clinically greater improvement with FESWT vs. sham. | ⊕⊕◯◯ LOW |
| | Intermediate-term | 2 RCTs (Gerdesmeyer, Hsu) | 180 | No | Yes[2] (-1) | No | Yes[3] (-1) | MD 3.76 (95% CI 1.73, 5.78)<br>Conclusion: Statistically and clinically greater improvement with FESWT vs. sham. | ⊕⊕◯◯ LOW |
| | Long-term | 2 RCTs (Gerdesmeyer, Hsu) | 146 | No | Yes[2] (-1) | No | Yes[3] (-1) | MD 4.56 (95% CI 2.90, 6.22)<br>Conclusion: Statistically and clinically greater improvement with FESWT vs. sham. | ⊕⊕⊕◯ MODERATE[5] |
| **Pain at night** (VAS 0-10, worst) | Short-term | 1 RCT (Speed) | 74 | No | Unknown | No | Yes[3] (-2) | MD -0.56 (95% CI -1.38, 0.26)<br>Conclusion: No statistical difference between groups. | ⊕⊕◯◯ LOW |
| | Intermediate-term | 1 RCT (Speed) | 74 | No | Unknown | No | Yes[3] (-2) | MD -0.08 (95% CI -0.9, 0.74)<br>Conclusion: No statistical difference between groups. | ⊕⊕◯◯ LOW |
| | Long-term | 0 RCTs | | | | | | No evidence. | ⊕◯◯◯ INSUFFICIENT |
| **Pain at rest and with activity** | Short-term | 1 RCT (Schmitt) | 38 | No | Unknown | No | Yes[3] (-2) | Rest: MD 0.87 (95% CI -0.3, 2.04)<br>Activity: MD 1.06 (95% CI -0.25, 2.37) | ⊕⊕◯◯ LOW |

| Outcome | Follow-up | RCTs | N | Serious Risk of Bias | Serious Inconsistency | Serious Indirectness | Serious Imprecision | Conclusion | Quality |
|---|---|---|---|---|---|---|---|---|---|
| (VAS 0-10, worst) | | | | | | | | Conclusion: No statistical difference between groups. | |
| | Intermediate-term | 0 RCTs | | | | | | No evidence. | ⊕◯◯◯ INSUFFICIENT |
| | Long-term | 1 RCT (Efe) | 29 | No | Unknown | No | Yes[3] (-2) | Rest: MD 0.05 (95% CI -1.19, 1.29)<br>Activity: MD -0.8 (95% CI -2.36, 0.76)<br>Conclusion: No statistical difference between groups. | ⊕⊕◯◯ LOW |
| **Function success** (≥30 pt. ↑ in CSS or score 80% of normal) | Short-term | 2 RCTs (Galasso, Schmitt) | 58 | No | No | No | Yes[3] (-2) | RR 1.52 (95% CI 0.63, 3.65)<br>Conclusion: No statistical difference between groups | ⊕⊕◯◯ LOW |
| | Intermediate- and Long-term | 0 RCTs | | | | | | No evidence. | ⊕◯◯◯ INSUFFICIENT |
| **Function success** (≥30% ↑in CSS) | Short-term | 1 RCT (Gerdesmeyer) | 132 | No | Unknown | No | Yes[3] (-1) | RR 2.70 (95% CI 1.47, 4.94)<br>Conclusion: Significantly greater proportion of patients in the FESWT compared with sham group achieved function success. | ⊕⊕⊕◯ MODERATE |
| | Intermediate-term | 1 RCT (Gerdesmeyer) | 135 | No | Unknown | No | Yes[3] (-1) | RR 3.94 (95% CI 1.97, 7.86)<br>Conclusion: Significantly greater proportion of patients in the FESWT compared with sham group achieved function success. | ⊕⊕⊕◯ MODERATE |
| | Long-term | 1 RCT (Gerdesmeyer) | 132 | No | Unknown | No | Yes[3] (-1) | RR 3.07 (95% CI 1.57, 6.01)<br>Conclusion: Significantly greater proportion of patients in the FESWT compared with sham group achieved function success. | ⊕⊕⊕◯ MODERATE |
| **Function success** (≥50% | Short-term | 1 RCT (Speed) | 74 | No | Unknown | No | Yes[3,4] (-2) | RR 0.78 (95% CI 0.44, 1.39) | ⊕⊕◯◯ LOW |

| Outcome | Follow-up | RCTs | N | Serious Risk of Bias | Serious Inconsistency | Serious Indirectness | Serious Imprecision | Conclusion | Quality |
|---|---|---|---|---|---|---|---|---|---|
| point improvement on SPADI) | | | | | | | | Conclusion: No statistical difference between groups. | |
| | Intermediate-term and Long-term | 0 RCTs | | | | | | No evidence. | ⊕◯◯◯ INSUFFICIENT |
| **Function** (CCS 0-100 (best)) | Short-term | 5 RCTs (Consentino, Galasso, Gerdesmeyer, Hsu, Schmitt,) | 306 | No | Yes[2] (-1) | No | Yes[3] (-1) | MD 20.3 (95% CI 10.1, 30.5) Conclusion: Statistically greater improvement with FESWT vs. sham; we were unable to identify a clinically important threshold. | ⊕⊕◯◯ LOW |
| | Intermediate-term | 3 RCTs (Consentino, Gerdesmeyer, Hsu) | 233 | Yes[1] (-1) | Yes[2] (-1) | No | Yes[3] (-1) | MD 25.8 (95% CI 14.1, 37.4) Conclusion: Statistically greater improvement with FESWT vs. sham; we were unable to identify a clinically important threshold. | ⊕◯◯◯ INSUFFICIENT |
| | Long-term | 2 RCTs (Gerdesmeyer, Hsu) | 157 | No | Yes[2] (-1) | No | Yes[3] (-1) | MD 19.3 (95% CI 0.77, 37.8) Conclusion: Statistically greater improvement with FESWT vs. sham; we were unable to identify a clinically important threshold. | ⊕⊕◯◯ LOW |
| **Function** (SPADI 0-100 (worst)) | Short-term | 1 RCT (Speed) | 74 | No | Unknown | No | Yes[3] (-2) | MD -0.9 (95% CI -8.58, 6.78) Conclusion: No statistical difference between groups. | ⊕⊕◯◯ LOW |
| | Intermediate-term | 1 RCT (Speed) | 74 | No | Unknown | No | Yes[3] (-2) | MD 4.9 (95% CI -3.14, 12.9) Conclusion: No statistical difference between groups. | ⊕⊕◯◯ LOW |
| | Long-term | 0 RCTs | | | | | | No evidence. | ⊕◯◯◯ INSUFFICIENT |
| **Function** (DASH 0-100 (worst)) | Short- and Intermediate term | 0 RCTs | | | | | | No evidence. | ⊕◯◯◯ INSUFFICIENT |
| | Long-term | 1 RCT (Efe) | 29 | Yes[1] (-1) | Unknown | No | Yes[3] (-2) | Mean 39.8 ± 17.1 vs. 38.8 ± 14.1 Conclusion: Insufficient strength of evidence precludes firm conclusions. | ⊕◯◯◯ INSUFFICIENT |

| Outcome | Follow-up | RCTs | N | Serious Risk of Bias | Serious Inconsistency | Serious Indirectness | Serious Imprecision | Conclusion | Quality |
|---|---|---|---|---|---|---|---|---|---|
| **Rotator Cuff Tendinopathy: Focused ESWT vs. US-guided needling + corticosteroid injection** | | | | | | | | | |
| **Pain NOS** (VAS 0-10, worst) | Short-term | 1 RCT (Kim) | 54 | No | Unknown | No | Yes[3] (-2) | MD 0.3 (95% CI NC)<br>Conclusion: No statistical difference between groups. | ⊕⊕◯◯ LOW |
| | Intermediate-term | 1 RCT (Kim) | 54 | No | Unknown | No | Yes[3] (-2) | MD -1.2 (95% CI NC)<br>Conclusion: No statistical difference between groups. | ⊕⊕◯◯ LOW |
| | Long-term | 1 RCT (Kim) | 54 | No | Unknown | No | Yes[3] (-2) | MD -2.4 (95% CI NC)<br>Conclusion: Statistically and clinically less pain improvement with FESWT vs. US-guided needling plus steroid injection. | ⊕⊕◯◯ LOW |
| **Function** (ASES 0-100 best; SST 0-100, best) | Short-term | 1 RCT (Kim) | 54 | No | Unknown | No | Yes[3] (-2) | ASES: MD -4.5 (95% CI NC)<br>SST: MD 2.1 (95% CI NC)<br>Conclusion: No statistical difference between groups. | ⊕⊕◯◯ LOW |
| | Intermediate-term | 1 RCT (Kim) | N=54 | No | Unknown | No | Yes[3] (-2) | ASES: MD -17.2 (95% CI NC)<br>SST: MD 0.9 (95% CI NC)<br>Conclusion: No statistical difference between groups. | ⊕⊕◯◯ LOW |
| | Long-term | 1 RCT (Kim) | N=54 | No | Unknown | No | Yes[3] (-2) | ASES: MD -24.1 (95% CI NC)<br>SST: MD -8.3 (95% CI NC)<br>Conclusion: Statistically and clinically less improvement in the FESWT compared with US-guided needling group on both outcome measures. | ⊕⊕◯◯ LOW |
| **Rotator Cuff Tendinopathy: FESWT vs. TENS** | | | | | | | | | |
| **Pain NOS** (VAS 0-10, worst) | Short-term | 1 RCT (Pan) | N=62 shoulders | Yes[1] (-1) | Unknown | No | Yes[3] (-2) | MD 2.3 (95% CI 1.2, 3.5)<br>Conclusion: Insufficient strength of evidence precludes firm conclusions. | ⊕◯◯◯ INSUFFICIENT |
| | Intermediate- and long-term | 0 RCTs | | | | | | No evidence. | ⊕◯◯◯ INSUFFICIENT |

| Outcome | Follow-up | RCTs | N | Serious Risk of Bias | Serious Inconsistency | Serious Indirectness | Serious Imprecision | Conclusion | Quality |
|---|---|---|---|---|---|---|---|---|---|
| **FunctionSuccess** (CSS ≥85) | Short-term | 1 RCT (Pan) | N=62 shoulders | Yes[1] (-1) | Unknown | No | Yes[3] (-2) | RR 1.7 (95% CI 1.0, 2.7)<br>Conclusion: Insufficient strength of evidence precludes firm conclusions. | ⊕◯◯◯ INSUFFICIENT |
| | Intermediate- and long-term | 0 RCTs | | | | | | No evidence. | ⊕◯◯◯ INSUFFICIENT |
| **Function** (CSS 0-100, best) | Short-term | 1 RCT (Pan) | N=62 shoulders | Yes[1] (-1) | Unknown | No | Yes[3] (-2) | MD 16.5 (95% CI 9.9, 23.0)<br>Conclusion: Insufficient strength of evidence precludes firm conclusions. | ⊕◯◯◯ INSUFFICIENT |
| | Intermediate- and long-term | 0 RCTs | | | | | | No evidence. | ⊕◯◯◯ INSUFFICIENT |
| **Rotator Cuff Tendinopathy: Radial ESWT vs. Sham** | | | | | | | | | |
| **Pain NOS** (VAS 0-10, worst) | Short-term | 1 RCT (Kolk) | 77 | Yes[1] (-1) | Unknown | No | Yes[3] (-2) | MD 0 (95% CI -7.6, 7.6)<br>Conclusion: Insufficient strength of evidence precludes firm conclusions. | ⊕◯◯◯ INSUFFICIENT |
| | Intermediate-term | 1 RCT (Kolk) | 69 | Yes[1] (-1) | Unknown | No | Yes[3] (-2) | MD 3.0 (95% CI -5.0, 11.0)<br>Conclusion: Insufficient strength of evidence precludes firm conclusions. | ⊕◯◯◯ INSUFFICIENT |
| | Long-term | 0 RCTs | | | | | | No evidence. | ⊕◯◯◯ INSUFFICIENT |
| **Function** (CSS 0-100, best; SST 0-100, best) | Short-term | 1 RCT (Kolk) | 77 | Yes[1] (-1) | Unknown | No | Yes[3] (-2) | CSS: MD 1.7 (95% CI -3.7, 7.1)<br>SST: MD 0.2 (95% CI -0.75, 1.15)<br>Conclusion: Insufficient strength of evidence precludes firm conclusions. | ⊕◯◯◯ INSUFFICIENT |
| | Intermediate-term | 1 RCT (Kolk) | 69 | Yes[1] (-1) | Unknown | No | Yes[3] (-2) | CSS: MD 4.0 (95% CI -1.4, 9.4)<br>SST: MD 0.3 (95% CI -0.75, 1.35)<br>Conclusion: Insufficient strength of evidence precludes firm conclusions. | ⊕◯◯◯ INSUFFICIENT |
| | Long-term | 0 RCTs | | | | | | No evidence. | ⊕◯◯◯ INSUFFICIENT |
| **Rotator Cuff Tendinopathy: Radial ESWT vs. US-guided Percutaneous Lavage (UGPL)** | | | | | | | | | |

| Outcome | Follow-up | RCTs | N | Serious Risk of Bias | Serious Inconsistency | Serious Indirectness | Serious Imprecision | Conclusion | Quality |
|---|---|---|---|---|---|---|---|---|---|
| **Pain Success** (proportion pain free) | Short- and Intermediate-term | 0 RCTs | | | | | | No evidence. | ⨁◯◯◯ INSUFFICIENT |
| | Long-term | 1 RCT (Del Castillo-Gonzalez) | 201 | Yes[1] (-2) | Unknown | No | Yes[3] (-1) | RR 0.7 (95% CI 0.6, 0.9)<br>Conclusion: Insufficient strength of evidence precludes firm conclusions. | ⨁◯◯◯ INSUFFICIENT |
| **Pain NOS** (VAS 0-10, worst) | Short-term | 1 RCT (Del Castillo-Gonzalez) | 201 | Yes[1] (-2) | Unknown | No | Yes[3] (-1) | Mean 5.2 vs. 3.2<br>Conclusion: Insufficient strength of evidence precludes firm conclusions. | ⨁◯◯◯ INSUFFICIENT |
| | Intermediate-term | 1 RCT (Del Castillo-Gonzalez) | 201 | Yes[1] (-2) | Unknown | No | Yes[3] (-1) | Mean 4.0 vs. 2.2<br>Conclusion: Insufficient strength of evidence precludes firm conclusions. | ⨁◯◯◯ INSUFFICIENT |
| | Long-term | 1 RCT (Del Castillo-Gonzalez) | 201 | Yes[1] (-2) | Unknown | No | Yes[3] (-1) | Mean 3.2 vs. 1.3<br>Conclusion: Insufficient strength of evidence precludes firm conclusions. | ⨁◯◯◯ INSUFFICIENT |
| **Function (any)** | Any | 0 RCTs | | | | | | No evidence. | ⨁◯◯◯ INSUFFICIENT |

ASES: American Shoulder and Elbow Surgeons score; CI: confidence interval; CSS: Constant Shoulder Score; DASH: Disabilities of the Arm, Shoulder and Hand questionnaire; MD: mean difference; NOS: not otherwise specified; RCT: randomized controlled trial; SPADI: Shoulder Pain and Disability Index; VAS: visual analog scale.

Reasons for downgrading (-) or upgrading (+):

1. Serious risk of bias: the majority of studies violated one or more of the criteria for good quality RCT (or cohort study) related to the outcome reported (see Appendix for details)
2. Inconsistency: differing estimates of effects across trials
3. Imprecise effect estimate for a continuous outcome: wide (or unknown) confidence interval and/or small sample size
4. Upgraded 1 for large effect size

## *5.4. Strength of Evidence Summary: Adhesive Capsulitis of the Shoulder*

| Outcome | Follow-up | RCTs | N | Serious Risk of Bias | Serious Inconsistency | Serious Indirectness | Serious Imprecision | Conclusion | Quality |
|---|---|---|---|---|---|---|---|---|---|
| **Adhesive Capsulitis of the Shoulder: Focused ESWT vs. Sham** | | | | | | | | | |
| **Pain** (SPADI pain subscale 0-50 (worst)) | Short-term | 1 RCT (Vahdatpour) | N=36 | Yes[1] (-1) | Unknown | No | Yes[3] (-2) | MD 17.9 (95% CI 13.3, 22.5)<br>Conclusion: Insufficient strength of evidence precludes firm conclusions. | ⊕○○○ INSUFFICIENT |
| | Intermediate-term | 1 RCT (Vahdatpour) | N=36 | Yes[1] (-1) | Unknown | No | Yes[3] (-2) | MD 19.4 (95% CI 14.8, 24.0)<br>Conclusion: Insufficient strength of evidence precludes firm conclusions. | ⊕○○○ INSUFFICIENT |
| | Long-term | 0 RCTs | | | | | | No evidence. | ⊕○○○ INSUFFICIENT |
| **Function**(SPADI disability subscale 0-80 (worst)) | Short-term | 1 RCT (Vahdatpour) | N=36 | Yes[1] (-1) | Unknown | No | Yes[3] (-2) | MD 26.5 (95% CI 20.9, 32.2)<br>Conclusion: Insufficient strength of evidence precludes firm conclusions. | ⊕○○○ INSUFFICIENT |
| | Intermediate-term | 1 RCT (Vahdatpour) | N=36 | Yes[1] (-1) | Unknown | No | Yes[3] (-2) | MD 30.6 (95% CI 25.4, 35.8)<br>Conclusion: Insufficient strength of evidence precludes firm conclusions. | ⊕○○○ INSUFFICIENT |
| | Long-term | 0 RCTs | | | | | | No evidence. | ⊕○○○ INSUFFICIENT |
| **Adhesive Capsulitis of the Shoulder: Focused ESWT vs. Oral Steroids** | | | | | | | | | |
| **Pain (any)** | Any | 0 RCTs | | | | | | No evidence. | ⊕○○○ INSUFFICIENT |
| **Function**(CSS 0-100 (best); OSS 12-60 (worst)) | Short-term | 1 RCT (Chen) | N=34 | Yes[1] (-1) | Unknown | No | Yes[3, 4] (-2) | CSS: mean 75 vs. 66<br>OSS: mean 31 vs. 33<br>Conclusion: Insufficient strength of evidence precludes firm conclusions. | ⊕○○○ INSUFFICIENT |
| | Intermediate- and long-term | 0 RCTs | | | | | | No evidence. | ⊕○○○ INSUFFICIENT |

| Outcome | Follow-up | RCTs | N | Serious Risk of Bias | Serious Inconsistency | Serious Indirectness | Serious Imprecision | Conclusion | Quality |
|---|---|---|---|---|---|---|---|---|---|
| **Adhesive Capsulitis of the Shoulder: Radial ESWT vs. Sham** | | | | | | | | | |
| **Pain rest and activity** (VAS 0-10 (worst)) | Short-term | 1 RCT (Hussein) | N=106 | No | Unknown | No | Yes[3] (-1) | MD 3.5 (95% CI 3.2, 3.7)<br>Conclusion: Statistically and clinically greater improvement with RESWT vs. sham. | ⊕⊕⊕◯ MODERATE |
| | Intermediate-term | 1 RCT (Hussein) | N=106 | No | Unknown | No | Yes[3] (-1) | MD 4.4 (95% CI 4.1, 4.6)<br>Conclusion: Statistically and clinically greater improvement with RESWT vs. sham. | ⊕⊕⊕◯ MODERATE |
| | Long-term | 0 RCTs | | | | | | No evidence. | ⊕◯◯◯ INSUFFICIENT |
| **Function**(DASH 0-100 (worst)) | Short-term | 1 RCT (Hussein) | N=106 | No | Unknown | No | Yes[3] (-1) | MD 55.6 (95% CI 50.5, 60.8)<br>Conclusion: Statistically and clinically greater improvement with RESWT vs. sham. | ⊕⊕⊕⊕ HIGH[4] |
| | Intermediate-term | 1 RCT (Hussein) | N=106 | No | Unknown | No | Yes[3] (-1) | MD 55.3 (95% CI 49.8, 60.7)<br>Conclusion: Statistically and clinically greater improvement with RESWT vs. sham. | ⊕⊕⊕⊕ HIGH[4] |
| | Long-term | 0 RCTs | | | | | | No evidence. | ⊕◯◯◯ INSUFFICIENT |

CI: confidence interval; CSS: Constant Shoulder Score; DASH: Disabilities of the Arm, Shoulder and Hand questionnaire; MD: mean difference; OSS: Oxford Shoulder Score; RCT: randomized controlled trial; SPADI: Shoulder Pain and Disability Index; VAS: visual analog scale.

Reasons for downgrading (-) or upgrading (+):

1. Serious risk of bias: the majority of studies violated one or more of the criteria for good quality RCT (or cohort study) related to the outcome reported (see Appendix for details)
2. Inconsistency: differing estimates of effects across trials
3. Imprecise effect estimate for a continuous outcome: wide (or unknown) confidence interval and/or small sample size
4. Upgraded 1 for large effect size

## 5.5. Strength of Evidence Summary: Subacromial Shoulder Pain Efficacy Results

| Outcome | Follow-up | RCTs | N | Serious Risk of Bias | Serious Inconsistency | Serious Indirectness | Serious Imprecision | Conclusion | Quality |
|---|---|---|---|---|---|---|---|---|---|
| **Subacromial Shoulder Pain: Radial ESWT vs. Supervised Exercise** | | | | | | | | | |
| **Pain at rest and during activity** (Likert scale 1-9 (worst)) | Short-term | 1 RCT (Engebretsen2009) | 102 | No | Unknown | No | Yes[3] (-1) | Rest: adj. MD -0.3 (95% CI -0.9, 0.3)<br>Activity: adj. MD -0.5 (95% CI -1.3, 0.4)<br>Conclusion: No statistical difference between groups. | ⊕⊕⊕○ MODERATE |
| | Intermediate-term | 1 RCT (Engebretsen2009) | 100 | No | Unknown | No | Yes[3] (-1) | Rest: adj. MD -0.2 (95% CI -0.7, 0.3)<br>Activity: adj. MD -0.6 (95% CI -1.3, 0.2)<br>Conclusion: No statistical difference between groups. | ⊕⊕⊕○ MODERATE |
| | Long-term | 1 RCT (Engebretsen2011) | 94 | No | Unknown | No | Yes[3] (-2) | Rest: adj. MD -0.4 (95% CI -0.7, 0.3)<br>Activity: adj. MD -0.4 (95% CI -1.4, 0.4)<br>Conclusion: No statistical difference between groups. | ⊕⊕○○ LOW |
| **Function success** (≥19.6 point improve-ment on SPADI | Short-term | 0 RCTs | | | | | | No evidence. | ⊕○○○ INSUFFICIENT |
| | Intermediate-term | 1 RCT (Engebretsen2009) | 100 | No | Unknown | No | Yes[3] (-1) | RR 0.56 (95% CI 0.37, 0.86)<br>Conclusion: Significantly lower proportion of RESWT compared with supervised exercise patients achieved function success. | ⊕⊕⊕○ MODERATE |
| | Long-term | 1 RCT (Engebretsen2011) | 94 | No | Unknown | No | Yes[3] (-2) | RR 0.86 (95% CI 0.60, 1.24)<br>Conclusion: No statistical difference between groups. | ⊕⊕○○ LOW |
| **Function**(SPADI 0-100 (worst)) | Short-term | 1 RCT (Engebretsen2009) | 102 | No | Unknown | No | Yes[3] (-1) | Adj. MD -10.3 (95% CI -19.8, -0.8)<br>Conclusion: Statistically, but not clinically, less improvement with RESWT vs. supervised exercise. | ⊕⊕⊕○ MODERATE |
| | Intermediate-term | 1 RCT (Engebretsen2009) | 100 | No | Unknown | No | Yes[3] (-1) | Adj. MD -8.4 (95% CI -16.5, -0.6) | ⊕⊕⊕○ MODERATE |

| Outcome | Follow-up | RCTs | N | Serious Risk of Bias | Serious Inconsistency | Serious Indirectness | Serious Imprecision | Conclusion | Quality |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | Conclusion: Statistically, but not clinically, less improvement with RESWT vs. supervised exercise. | |
| | Long-term | 1 RCT (Engebretsen2011) | 94 | No | Unknown | No | Yes[3] (-2) | Adj. MD -7.6 (95% CI -16.6, 0.5)<br>Conclusion: No statistical difference between groups. | ⊕⊕◯◯ LOW |

Adj: adjusted; CI: confidence interval; MD: mean difference; RCT: randomized controlled trial; SPADI: Shoulder Pain and Disability Index.

Reasons for downgrading (-) or upgrading (+):

1. Serious risk of bias: the majority of studies violated one or more of the criteria for good quality RCT (or cohort study) related to the outcome reported (see Appendix for details)
2. Inconsistency: differing estimates of effects across trials
3. Imprecise effect estimate for a continuous outcome: wide (or unknown) confidence interval and/or small sample size
4. Upgraded 1 for large effect size

## 5.6. Strength of Evidence Summary: Bicipital Tenosynovitis of the Shoulder Efficacy Results

| Outcome | Follow-up | RCTs | N | Serious Risk of Bias | Serious Inconsistency | Serious Indirectness | Serious Imprecision | Conclusion | Quality |
|---|---|---|---|---|---|---|---|---|---|
| **Primary Long Bicipital Tenosynovitis of the Shoulder: RESWT vs. Sham** | | | | | | | | | |
| **Pain success** (VAS score <2 or a decrease of ≥4 points) | Short- and Intermediate term | 0 RCTs | | | | | | No evidence. | ⊕◯◯◯ INSUFFICIENT |
| | Long-term | 1 RCT (Liu) | N=79 | No | Unknown | No | Yes[3] (-2) | 78% (42/54) vs. 0% (0/25)<br>Conclusion: Significantly higher proportion of patients who received RESWT achieved a good clinical result compared with sham. | ⊕⊕⊕◯ MODERATE[5] |
| **Pain NOS** (VAS 0-10 (worst) | Short-term | 1 RCT (Liu) | N=79 | No | Unknown | No | Yes[3] (-2) | MD 3.8 (95% CI 3.4, 4.1)<br>Conclusion: Statistically and clinically greater improvement with RESWT vs. sham. | ⊕⊕◯◯ LOW |
| | Intermediate-term | 0 RCTs | | | | | | No evidence. | ⊕◯◯◯ INSUFFICIENT |
| | Long-term | 1 RCT (Liu) | N=79 | No | Unknown | No | Yes[3] (-2) | MD 3.8 (95% CI 3.5, 4.1)<br>Conclusion: Statistically and clinically greater improvement with RESWT vs. sham. | ⊕⊕◯◯ LOW |
| **Function success** (L'Insalata Shoulder score >85 or an increase of >20 points) | Short- and Intermediate-term | 0 RCTs | | | | | | No evidence. | ⊕◯◯◯ INSUFFICIENT |
| | Long-term | 1 RCT (Liu) | N=79 | No | Unknown | No | Yes[3] (-2) | RR 6.9 (95% CI 2.4, 20.2)<br>Conclusion: Significantly higher proportion of patients who received RESWT obtained good symptom and function recovery compared with sham. | ⊕⊕⊕◯ MODERATE[5] |
| **Function** (L'Insalata Shoulder Score 17-100 (best)) | Short-term | 1 RCT (Liu) | N=79 | No | Unknown | No | Yes[3] (-2) | MD 20.6 (95% CI 18.6, 22.6)<br>Conclusion: Statistically greater improvement with RESWT vs. sham; we were unable to find a clinically meaningful threshold. | ⊕⊕◯◯ LOW |
| | Intermediate-term | 0 RCTs | | | | | | No evidence. | ⊕◯◯◯ INSUFFICIENT |

| Outcome | Follow-up | RCTs | N | Serious Risk of Bias | Serious Inconsistency | Serious Indirectness | Serious Imprecision | Conclusion | Quality |
|---|---|---|---|---|---|---|---|---|---|
| | Long-term | 1 RCT (Liu) | N=79 | No | Unknown | No | Yes[3] (-2) | MD 16.6 (95% CI 14.5, 18.6)<br>Conclusion: Significantly greater improvement with RESWT vs. sham; we were unable to find a clinically meaningful threshold. | ⊕⊕◯◯ LOW |

CI: confidence interval; MD: mean difference; NOS: not otherwise specified; RCT: randomized controlled trial; RR: risk ratio; VAS: visual analog scale.
Reasons for downgrading (-) or upgrading (+):

1. Serious risk of bias: the majority of studies violated one or more of the criteria for good quality RCT (or cohort study) related to the outcome reported (see Appendix for details)
2. Inconsistency: differing estimates of effects across trials
3. Imprecise effect estimate for a continuous outcome: wide (or unknown) confidence interval and/or small sample size
4. Upgraded 1 for large effect size.

## 5.7. Strength of Evidence Summary: Achilles Tendinopathy Efficacy Results

| Outcome | Follow-up | RCTs | N | Serious Risk of Bias | Serious Inconsistency | Serious Indirectness | Serious Imprecision | Conclusion | Quality |
|---|---|---|---|---|---|---|---|---|---|
| **Achilles Tendinopathy: Focused ESWT vs. Sham** | | | | | | | | | |
| **Pain running/ sports** (VAS 0-10 (worst)) | Short-term | 2 RCTs (Costa, Rasmussen) | 97 | No | No | No | Yes[3] (-2) | MD 1.90 (95% CI 1.06, 2.73)<br>Conclusion: Statistically and clinically greater improvement with FESWT vs. Sham. | ⊕⊕◯◯ LOW |
| | Intermediate- and Long-term | 0 RCTs | | | | | | No evidence. | ⊕◯◯◯ INSUFFICIENT |
| **Pain walking** (VAS 0-10 (worst)) | Short-term | 2 RCTs (Costa, Rasmussen) | 97 | No | No | No | Yes[3] (-2) | MD 1.65 (95% CI 0.79, 2.51)<br>Conclusion: Statistically and clinically greater improvement with FESWT vs. Sham. | ⊕⊕◯◯ LOW |
| | Intermediate- and Long-term | 0 RCTs | | | | | | No evidence. | ⊕◯◯◯ INSUFFICIENT |
| **Pain rest** (VAS 0-10 (worst)) | Short-term | 1 RCT (Costa) | 49 | No | Unknown | No | Yes[3] (-2) | MD 1.92 (95% CI 0.76, 3.08)<br>Conclusion: Statistically and clinically greater improvement with FESWT vs. Sham. | ⊕⊕◯◯ LOW |
| | Intermediate- and Long-term | 0 RCTs | | | | | | No evidence. | ⊕◯◯◯ INSUFFICIENT |
| **Pain working** (VAS 0-10 (worst)) | Short-term | 1 RCT (Rasmussen) | 48 | No | Unknown | No | Yes[3] (-2) | Mean 1.1 vs. 1.2<br>Conclusion: No statistical difference between groups. | ⊕⊕◯◯ LOW |
| | Intermediate- and Long-term | 0 RCTs | | | | | | No evidence. | ⊕◯◯◯ INSUFFICIENT |
| **Pain walking stairs** (VAS 0-10 (worst)) | Short-term | 1 RCT (Rasmussen) | 48 | No | Unknown | No | Yes[3] (-2) | Mean 1.3 vs. 2.1<br>Conclusion: No statistical difference between groups. | ⊕⊕◯◯ LOW |
| | Intermediate- and Long-term | 0 RCTs | | | | | | No evidence. | ⊕◯◯◯ INSUFFICIENT |

| Outcome | Follow-up | RCTs | N | Serious Risk of Bias | Serious Inconsistency | Serious Indirectness | Serious Imprecision | Conclusion | Quality |
|---|---|---|---|---|---|---|---|---|---|
| **Function** (AOFAS (0-100 (best)) | Short-term | 1 RCT (Rasmussen) | 48 | No | Unknown | No | Yes[3] (-2) | MD 11.0 (95% CI 3.1, 18.9)<br>Conclusion: Statistically and clinically greater improvement with FESWT vs. Sham. | ⊕⊕◯◯ LOW |
| | Intermediate- and Long-term | 0 RCTs | | | | | | No evidence. | ⊕◯◯◯ INSUFFICIENT |
| **Function** (FIL scale NR) | Short-term | 1 RCT (Costa) | 49 | No | Unknown | No | Yes[3] (-2) | Mean 0.95 ± 0.96 vs. 0.24 ± 0.24<br>Conclusion: No statistical difference between groups. | ⊕⊕◯◯ LOW |
| | Intermediate- and Long-term | 0 RCTs | | | | | | No evidence. | ⊕◯◯◯ INSUFFICIENT |
| **Achilles Tendinopathy: Radial ESWT vs. Eccentric Exercise** | | | | | | | | | |
| **Pain during day** (NRS 0-10 (worst)) | Short-term | 2 RCTs (Rompe 2007, 2008) | 100 | No | Yes[2] (-1) | No | Yes[3] (-1) | MD 0.80 (95% CI -1.94, 3.54)<br>Conclusion: No statistical difference between groups. | ⊕⊕◯◯ LOW |
| | Intermediate- and Long-term | 0 RCTs | | | | | | No evidence. | ⊕◯◯◯ INSUFFICIENT |
| **Function** (VISA-A 0-100 (best)) | Short-term | 2 RCTs (Rompe 2007, 2008) | 100 | No | Yes[2] (-1) | No | Yes[3] (-1) | MD 0.51 (95% CI -1.45, 2.47)<br>Conclusion: No statistical difference between groups. | ⊕⊕◯◯ LOW |
| | Intermediate- and Long-term | 0 RCTs | | | | | | No evidence. | ⊕◯◯◯ INSUFFICIENT |
| **Achilles Tendinopathy: Radial ESWT + Eccentric Exercise vs. Eccentric Exercise alone** | | | | | | | | | |
| **Pain during day** (NRS 0-10 (worst)) | Short-term | 1 RCT (Rompe 2009) | 68 | No | Unknown | No | Yes[3] (-2) | MD 1.3 (95% CI 0.6, 2.0)<br>Conclusion: Statistically greater improvement with RESWT + eccentric exercise vs. eccentric exercise alone. | ⊕⊕◯◯ LOW |
| | Intermediate- and Long-term | 0 RCTs | | | | | | No evidence. | ⊕◯◯◯ INSUFFICIENT |
| **Function** (VISA-A 0-100 (best)) | Short-term | 1 RCT (Rompe 2009) | 68 | No | Unknown | No | Yes[3] (-2) | MD 13.9 (95% CI 8.6, 19.2)<br>Conclusion: Statistically greater improvement with RESWT + eccentric exercise vs. eccentric exercise alone; we were unable to find a clinically | ⊕⊕◯◯ LOW |

| Outcome | Follow-up | RCTs | N | Serious Risk of Bias | Serious Inconsistency | Serious Indirectness | Serious Imprecision | Conclusion | Quality |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | important threshold for non-insertional Achilles tendinopathy. | |
| | Intermediate- and Long-term | 0 RCTs | | | | | | No evidence. | ⊕◯◯◯ INSUFFICIENT |
| **Achilles Tendinopathy: Radial ESWT vs. No Treatment** | | | | | | | | | |
| **Pain during day** (NRS 0-10 (worst)) | Short-term | 1 RCT (Rompe 2007) | 50 | No | Unknown | No | Yes[3] (-2) | MD 0.8 (95% CI -0.02, 1.6)<br>Conclusion: No statistical difference between groups. | ⊕⊕◯◯ LOW |
| | Intermediate- and Long-term | 0 RCTs | | | | | | No evidence. | ⊕◯◯◯ INSUFFICIENT |
| **Function** (VISA-A 0-100 (best)) | Short-term | 1 RCT (Rompe 2007) | 50 | No | Unknown | No | Yes[3] (-2) | MD 13.3 (95% CI 8.4, 18.2)<br>Conclusion: Significantly greater improvement with RESWT vs. wait-and-see; we were unable to find a clinically important threshold for non-insertional Achilles tendinopathy. | ⊕⊕◯◯ LOW |
| | Intermediate- and Long-term | 0 RCTs | | | | | | No evidence. | ⊕◯◯◯ INSUFFICIENT |

CI: confidence interval; MD: mean difference; NRS: numerical rating scale; RCT: randomized controlled trial; VISA-A: Victorian Institute of Sports Assessment-Achilles.
Reasons for downgrading (-) or upgrading (+):

1. Serious risk of bias: the majority of studies violated one or more of the criteria for good quality RCT (or cohort study) related to the outcome reported (see Appendix for details)
2. Inconsistency: differing estimates of effects across trials
3. Imprecise effect estimate for a continuous outcome: wide (or unknown) confidence interval and/or small sample size
4. Upgraded 1 for large effect size.

## 5.8. Strength of Evidence Summary: Patellar Tendinopathy Efficacy Results

| Outcome | Follow-up | RCTs | N | Serious Risk of Bias | Serious Inconsistency | Serious Indirectness | Serious Imprecision | Conclusion | Quality |
|---|---|---|---|---|---|---|---|---|---|
| **Patellar Tendinopathy: Focused ESWT vs. Sham** | | | | | | | | | |
| **Pain** | Short-term | 1 RCT (Taunton) | 20 | Yes[1] (-1) | Unknown | No | Yes[3] (-2) | Conclusion: Insufficient strength of evidence precludes firm conclusions | ⊕○○○ INSUFFICIENT |
| | Intermediate- and Long-term | 0 RCTs | | | | | | No evidence. | ⊕○○○ INSUFFICIENT |
| **Function** (VISA-P 0-100 (best)) | Short-term | 1 RCT (Taunton) | 20 | Yes[1] (-1) | Unknown | No | Yes[3] (-2) | Mean 61.4 vs. 53.2<br>Conclusion: Insufficient strength of evidence precludes firm conclusions. | ⊕○○○ INSUFFICIENT |
| | Intermediate- and Long-term | 0 RCTs | | | | | | No evidence. | ⊕○○○ INSUFFICIENT |
| **Function** (Vertical jump score) | Short-term | 1 RCT (Taunton) | 20 | Yes[1] (-1) | Unknown | No | Yes[3] (-2) | Mean change from baseline: 1.5 vs. 0 inches<br>Conclusion: Insufficient strength of evidence precludes firm conclusions. | ⊕○○○ INSUFFICIENT |
| | Intermediate- and Long-term | 0 RCTs | | | | | | No evidence. | ⊕○○○ INSUFFICIENT |
| **Patellar Tendinopathy: Focused ESWT vs. Conservative Management** | | | | | | | | | |
| **Pain success** (≥75% pain improvement, VAS (stairs) ≤4.0, and no pain meds.) | Short- and Intermediate-term | 0 RCTs | | | | | | No evidence. | ⊕○○○ INSUFFICIENT |
| | Long-term | 1 RCT (Wang) | 54 knees in 50 patients | Yes[1] (-1) | Unknown | No | Yes[3] (-2) | RR 1.8 (95% CI 1.2, 2.7)<br>Conclusion: Significantly greater proportion of knees in the FESWT group achieved satisfactory results compared with conservative treatment. | ⊕○○○ INSUFFICIENT |
| **Pain going up and down stairs** | Short- and Intermediate-term | 0 RCTs | | | | | | No evidence. | ⊕○○○ INSUFFICIENT |

| Outcome | Follow-up | RCTs | N | Serious Risk of Bias | Serious Inconsistency | Serious Indirectness | Serious Imprecision | Conclusion | Quality |
|---|---|---|---|---|---|---|---|---|---|
| (VAS 0-10 (worst)) | Long-term | 1 RCT (Wang) | 54 knees in 50 patients | Yes[1] (-1) | Unknown | No | Yes[3] (-2) | MD 4.8 (95% CI 4.2, 5.3)<br>Conclusion: Statistically and clinically greater improvement with FESWT vs. conservative treatment. | ⊕⊕◯◯ LOW[5] |
| **Function** (VISA-P 0-100 (best)) | Short- and Intermediate-term | 0 RCTs | | | | | | No evidence. | ⊕◯◯◯ INSUFFICIENT |
| | Long-term | 1 RCT (Wang) | 54 knees in 50 patients | Yes[1] (-1) | Unknown | No | Yes[3] (-2) | MD 47.6 (95% CI 44.0, 51.2)<br>Conclusion: Statistically and clinically greater improvement with FESWT vs. conservative treatment. | ⊕⊕◯◯ LOW[5] |

CI: confidence interval; MD: mean difference; RCT: randomized controlled trial; VAS: visual analog scale; VISA-P: Victorian Institute of Sports Assessment-Patella.

Reasons for downgrading (-) or upgrading (+):

1. Serious risk of bias: the majority of studies violated one or more of the criteria for good quality RCT (or cohort study) related to the outcome reported (see Appendix for details)
2. Inconsistency: differing estimates of effects across trials
3. Imprecise effect estimate for a continuous outcome: wide (or unknown) confidence interval and/or small sample size
4. Upgraded 1 for large effect size.

## 5.9. Strength of Evidence Summary: Knee Osteoarthritis Efficacy Results

| Outcome | Follow-up | RCTs | N | Serious Risk of Bias | Serious Inconsistency | Serious Indirectness | Serious Imprecision | Conclusion | Quality |
|---|---|---|---|---|---|---|---|---|---|
| **Knee Osteoarthritis: Focused ESWT + Isokinetic Muscular Strengthening vs. Isokinetic Muscular Strengthening** | | | | | | | | | |
| **Pain NOS** (VAS 0-10, worst) | Short-term | 1 RCT (Chen) | N=110 knees in 55 pts. | Yes[1] (-1) | Unknown | No | Yes[3] (-1) | MD 1.9 (95% CI 1.6, 2.2)<br>Conclusion: Statistically and clinically greater improvement with FESWT vs. isokinetic muscular strengthening. | ⊕⊕◯◯ LOW |
| | Intermediate-term | 1 RCT (Chen) | N=102 knees in 51 pts. | Yes[1] (-1) | Unknown | No | Yes[3] (-1) | MD 2.1 (95% CI 1.8, 2.4)<br>Conclusion: Statistically and clinically greater improvement with FESWT vs. isokinetic muscular strengthening. | ⊕⊕◯◯ LOW |
| | Long-term | 0 RCTs | | | | | | No evidence. | ⊕◯◯◯ INSUFFICIENT |
| **Function** (Lequesne's index 0-24, worst) | Short-term | 1 RCT (Chen) | 55 | Yes[1] (-1) | Unknown | No | Yes[3] (-2) | MD 1.3 (95% CI 0.9, 1.8)<br>Conclusion: Insufficient strength of evidence precludes firm conclusions. | ⊕◯◯◯ INSUFFICIENT |
| | Intermediate-term | 1 RCT (Chen) | 51 | Yes[1] (-1) | Unknown | No | Yes[3] (-2) | MD 3.2 (95% CI 2.7, 3.7)<br>Conclusion: Insufficient strength of evidence precludes firm conclusions. | ⊕◯◯◯ INSUFFICIENT |
| | Long-term | 0 RCTs | | | | | | No evidence. | ⊕◯◯◯ INSUFFICIENT |
| **Knee Osteoarthritis: Focused ESWT + Isokinetic Muscular Strengthening vs. Pulse Ultrasound + Isokinetic Muscular Strengthening** | | | | | | | | | |
| **Pain NOS** (VAS 0-10, worst) | Short-term | 1 RCT (Chen) | N=110 knees in 55 pts. | Yes[1] (-1) | Unknown | No | Yes[3] (-1) | MD 0.7 (95% CI 0.4, 1.1)<br>Conclusion: Significantly greater improvement with FESWT vs. ultrasound + isokinetic muscular strengthening; however, the MD did not reach the clinically important threshold. | ⊕⊕◯◯ LOW |
| | Intermediate-term | 1 RCT (Chen) | N=102 knees in 51 pts. | Yes[1] (-1) | Unknown | No | Yes[3] (-1) | MD 0.9 (95% CI 0.6, 1.2)<br>Conclusion: Significantly greater improvement with FESWT vs. ultrasound + isokinetic muscular strengthening; however, the MD was less than the cut-off deemed to be clinically important. | ⊕⊕◯◯ LOW |

| Outcome | Follow-up | RCTs | N | Serious Risk of Bias | Serious Inconsistency | Serious Indirectness | Serious Imprecision | Conclusion | Quality |
|---|---|---|---|---|---|---|---|---|---|
| | Long-term | 0 RCTs | | | | | | No evidence. | ⊕◯◯◯ INSUFFICIENT |
| **Function** (Lequesne's index 0-24, worst) | Short-term | 1 RCT (Chen) | 55 | Yes[1] (-1) | Unknown | No | Yes[3] (-2) | MD 0.6 (95% CI 0.1, 1.1)<br>Conclusion: Insufficient strength of evidence precludes firm conclusions. | ⊕◯◯◯ INSUFFICIENT |
| | Intermediate-term | 1 RCT (Chen) | 51 | Yes[1] (-1) | Unknown | No | Yes[3] (-2) | MD 1.7 (95% CI 1.2, 2.2)<br>Conclusion: Insufficient strength of evidence precludes firm conclusions. | ⊕◯◯◯ INSUFFICIENT |
| | Long-term | 0 RCTs | | | | | | No evidence. | ⊕◯◯◯ INSUFFICIENT |
| **Knee Osteoarthritis: Radial ESWT vs. Sham** | | | | | | | | | |
| **Pain walking** (VAS 0-10 (worst)) | Short-term | 1 RCT (Zhao) | 70 | No | Unknown | No | Yes[3,4] (-2) | MD 2.6 (95% CI 2.2, 3.0)<br>Conclusion: Statistically and clinically greater improvement with RESWT vs. sham. | ⊕⊕◯◯ LOW |
| | Intermediate- and long-term | 0 RCTs | | | | | | No evidence. | ⊕◯◯◯ INSUFFICIENT |
| **Function** (WOMAC 0-96 (worst); Lequesne index 0-24 (worst)) | Short-term | 1 RCT (Zhao) | 70 | No | Unknown | No | Yes[3,4] (-2) | WOMAC: MD 10.6 (95% CI 5.4, 15.8)<br>Lequesne: MD 2.1 (95% CI 0.9, 3.4)<br>Conclusion: Statistically greater improvement with RESWT vs. sham; the MD is clinically important for the WOMAC but we were unable to find a clinically meaningful threshold for the Lequesne index. | ⊕⊕◯◯ LOW |
| | Intermediate- and long-term | 0 RCTs | | | | | | No evidence. | ⊕◯◯◯ INSUFFICIENT |

CI: confidence interval; MD: mean difference; NOS: not otherwise specified; RCT: randomized controlled trial; VAS: visual analog scale; WOMAC: Western Ontario and McMasters University Osteoarthritis Index.

Reasons for downgrading (-) or upgrading (+):

1. Serious risk of bias: the majority of studies violated one or more of the criteria for good quality RCT (or cohort study) related to the outcome reported (see Appendix for details)
2. Inconsistency: differing estimates of effects across trials
3. Imprecise effect estimate for a continuous outcome: wide (or unknown) confidence interval and/or small sample size
4. Upgraded 1 for large effect size.

## 5.10. Strength of Evidence Summary: Serious or Potentially Serious Adverse Events Results

| Outcome | RCTs | N | Serious Risk of Bias | Serious Inconsistency | Serious Indirectness | Serious Imprecision | Conclusion | Quality |
|---|---|---|---|---|---|---|---|---|
| **Serious or potentially serious adverse events** | 52 RCTs | 4762 | Yes[1] (-1) | Yes[2] (-1) | no | No | 0.39% (95% CI, 0.19 to 0.72%) ESWT<br>0.23% (95% CI, 0.07 to 0.53%) control | ⊕⊕◯◯ LOW |

Reasons for downgrading:

1. Serious risk of bias: the majority of studies violated one or more of the criteria for good quality RCT related to the outcome reported (see Appendix for details)
2. Inconsistency: differing estimates of effects or inconsistent identification of serious harms across trials
3. Imprecise effect estimate for a continuous outcome: wide (or unknown) confidence interval and/or small sample size

## 5.11. Strength of Evidence Summary: Differential Efficacy and Harms

| Exposure | Outcome | Follow-up | RCTs | N | Serious Risk of Bias | Serious Inconsistency | Serious Indirectness | Serious Imprecision | Conclusion | Quality |
|---|---|---|---|---|---|---|---|---|---|---|
| **Plantar Fasciitis: Focused ESWT vs. Sham** | | | | | | | | | | |
| **Sex**<br>**Age**<br>**Body weight** | Pain NOS, MD | Short-term | 1 RCT (Malay) | 168 | Yes[4] (-1) | No | No | Yes[3] (-1) | Conclusion: No modifying effect of sex, age or body weight | ⊕⊕◯◯ LOW |
| **Rotator Cuff Tendinopathy: Focused ESWT vs. Sham** | | | | | | | | | | |
| **Energy Intensity** | Pain in AM, MD | Short and intermediate-term | 1 RCT (Gerdesmeyer) | 134 | Yes[5] (-1) | No | No | Yes[3] (-1) | Conclusion: FESWT significantly better than sham with high intensity, but not with low intensity shock wave. | ⊕⊕◯◯ LOW |
| | Reoccurrence of pain | Intermediate-term | 1 RCT (Peters) | 90 | Yes[5] (-1) | No | No | Yes[3] (-2) | Conclusion: Insufficient strength of evidence precludes firm conclusions. | ⊕◯◯◯ INSUFFICIENT |
| **Lateral Epicondyle Tendinopathy: Focused ESWT vs. Sham** | | | | | | | | | | |
| **Symptom duration** | Pain success (%) | Short-term | 1 RCT (Chung) | 60 | Yes[4] (-1) | No | No | Yes[3] (-2) | Conclusion: Insufficient strength of evidence precludes firm conclusions. | ⊕◯◯◯ INSUFFICIENT |

| Exposure | Outcome | Follow-up | RCTs | N | Serious Risk of Bias | Serious Inconsistency | Serious Indirectness | Serious Imprecision | Conclusion | Quality |
|---|---|---|---|---|---|---|---|---|---|---|
| **Achilles Tendinopathy: Focused ESWT vs. Sham** | | | | | | | | | | |
| **Sex** | AOFAS | Short-term | 1 RCT (Rasmussen) | 48 | Yes[4,5] (-2) | Unknown | No | Yes[3] (-2) | Conclusion: Insufficient strength of evidence precludes firm conclusions. | ⊕○○○ INSUFFICIENT |
| **Rotator Cuff Tendinopathy: Radial ESWT vs. Sham** | | | | | | | | | | |
| **Calcium formation** | Pain NOS, MD | Short- and intermediate-term | 1 RCT (Kolk) | 75 | Yes[4,5] (-2) | Unknown | No | Yes[3] (-2) | Conclusion: Insufficient strength of evidence precludes firm conclusions. | ⊕○○○ INSUFFICIENT |
| | Simple Shoulder Test | Short- and intermediate-term | 1 RCT (Kolk) | 75 | Yes[4,5] (-2) | Unknown | No | Yes[3] (-2) | Conclusion: Insufficient strength of evidence precludes firm conclusions. | ⊕○○○ INSUFFICIENT |

AOFAS: American Orthopedic Foot and Ankle Scale; CI: confidence interval; MD: mean difference; NOS: not otherwise specified

Reasons for downgrading:

4. Serious risk of bias: the majority of studies violated one or more of the criteria for good quality RCT (or cohort study) related to the outcome reported (see Appendix for details)
5. Inconsistency: differing estimates of effects across trials
6. Imprecise effect estimate for a continuous outcome: wide (or unknown) confidence interval and/or small sample size
7. Subgroup analysis not preplanned or unknown
8. Statistical test for homogeneity or interaction not performed

## 5.12. Strength of Evidence Summary: Cost Effectiveness

No Evidence.

## References


1. Summary of Safety and Effectiveness Data, Orthospec Extracorporeal Shock Wave Therapy Device. 2005;Medispec Ltd http://www.accessdata.fda.gov/cdrh_docs/pdf5/P050004b.pdf, accessed 12/12/16.
2. (NICE) NIfHaCE. Autologous Blood Injection for Plantar Fascitis NHS National Institute for Health and Clinical Excellence (NICE); 2013:1-7.
3. Abrahamsson SO. Similar effects of recombinant human insulin-like growth factor-I and II on cellular activities in flexor tendons of young rabbits: experimental studies in vitro. Journal of orthopaedic research : official publication of the Orthopaedic Research Society 1997;15:256-62.
4. Andres BM, Murrell GA. Treatment of tendinopathy: what works, what does not, and what is on the horizon. Clinical orthopaedics and related research 2008;466:1539-54.
5. Anitua E, Sanchez M, Nurden AT, Nurden P, Orive G, Andia I. New insights into and novel applications for platelet-rich fibrin therapies. Trends in biotechnology 2006;24:227-34.
6. Atkins D, Best D, Briss PA, et al. Grading quality of evidence and strength of recommendations. BMJ (Clinical research ed) 2004;328:1490.
7. Ayhan E, Kesmezacar H, Akgun I. Intraarticular injections (corticosteroid, hyaluronic acid, platelet rich plasma) for the knee osteoarthritis. World J Orthop 2014;5:351-61.
8. Balshem H, Helfand M, Schunemann HJ, et al. GRADE guidelines: 3. Rating the quality of evidence. J Clin Epidemiol 2011;64:401-6.
9. Banes AJ, Horesovsky G, Larson C, et al. Mechanical load stimulates expression of novel genes in vivo and in vitro in avian flexor tendon cells. Osteoarthritis Cartilage 1999;7:141-53.
10. Battaglia M, Guaraldi F, Vannini F, et al. Efficacy of ultrasound-guided intra-articular injections of platelet-rich plasma versus hyaluronic acid for hip osteoarthritis. Orthopedics 2013;36:e1501-8.
11. Bellamy N, Campbell J, Robinson V, Gee T, Bourne R, Wells G. Intraarticular corticosteroid for treatment of osteoarthritis of the knee. The Cochrane database of systematic reviews 2006:CD005328.
12. Berta L, Fazzari A, Ficco AM, Enrica PM, Catalano MG, Frairia R. Extracorporeal shock waves enhance normal fibroblast proliferation in vitro and activate mRNA expression for TGF-beta1 and for collagen types I and III. Acta orthopaedica 2009;80:612-7.
13. Biberthaler P, Wiedemann E, Nerlich A, et al. Microcirculation associated with degenerative rotator cuff lesions. In vivo assessment with orthogonal polarization spectral imaging during arthroscopy of the shoulder. The Journal of bone and joint surgery American volume 2003;85-A:475-80.
14. Bird PA, Oakley SP, Shnier R, Kirkham BW. Prospective evaluation of magnetic resonance imaging and physical examination findings in patients with greater trochanteric pain syndrome. Arthritis Rheum 2001;44:2138-45.
15. Blagojevic M, Jinks C, Jeffery A, Jordan KP. Risk factors for onset of osteoarthritis of the knee in older adults: a systematic review and meta-analysis. Osteoarthritis Cartilage 2010;18:24-33.

16. Bosch G, Lin YL, van Schie HT, van De Lest CH, Barneveld A, van Weeren PR. Effect of extracorporeal shock wave therapy on the biochemical composition and metabolic activity of tenocytes in normal tendinous structures in ponies. Equine Vet J 2007;39:226-31.

17. Brinks A, Koes BW, Volkers AC, Verhaar JA, Bierma-Zeinstra SM. Adverse effects of extra-articular corticosteroid injections: a systematic review. BMC musculoskeletal disorders 2010;11:206.

18. Buizza A, Dell'Aquila T, Giribona P, Spagno C. The performance of different pressure pulse generators for extracorporeal lithotripsy: a comparison based on commercial lithotripters for kidney stones. Ultrasound in medicine & biology 1995;21:259-72.

19. Capan N, Esmaeilzadeh S, Oral A, Basoglu C, Karan A, Sindel D. Radial Extracorporeal Shock Wave Therapy Is Not More Effective Than Placebo in the Management of Lateral Epicondylitis: A Double-Blind, Randomized, Placebo-Controlled Trial. American journal of physical medicine & rehabilitation / Association of Academic Physiatrists 2016;95:495-506.

20. Chen CY, Hu CC, Weng PW, et al. Extracorporeal shockwave therapy improves short-term functional outcomes of shoulder adhesive capsulitis. Journal of shoulder and elbow surgery / American Shoulder and Elbow Surgeons [et al] 2014;23:1843-51.

21. Chen TW, Lin CW, Lee CL, et al. The efficacy of shock wave therapy in patients with knee osteoarthritis and popliteal cyamella. The Kaohsiung journal of medical sciences 2014;30:362-70.

22. Cherian JJ, Kapadia BH, Bhave A, et al. Use of Transcutaneous Electrical Nerve Stimulation Device in Early Osteoarthritis of the Knee. J Knee Surg 2015;28:321-7.

23. Chesterton LS, Lewis AM, Sim J, et al. Transcutaneous electrical nerve stimulation as adjunct to primary care management for tennis elbow: pragmatic randomised controlled trial (TATE trial). BMJ (Clinical research ed) 2013;347:f5160.

24. Chew KT, Leong D, Lin CY, Lim KK, Tan B. Comparison of autologous conditioned plasma injection, extracorporeal shockwave therapy, and conventional treatment for plantar fasciitis: a randomized trial. PM & R : the journal of injury, function, and rehabilitation 2013;5:1035-43.

25. Chung B, Wiley JP. Effectiveness of extracorporeal shock wave therapy in the treatment of previously untreated lateral epicondylitis: a randomized controlled trial. The American journal of sports medicine 2004;32:1660-7.

26. Chung B, Wiley JP, Rose MS. Long-term effectiveness of extracorporeal shockwave therapy in the treatment of previously untreated lateral epicondylitis. Clinical journal of sport medicine : official journal of the Canadian Academy of Sport Medicine 2005;15:305-12.

27. Cole BJ, Schumacher HR, Jr. Injectable corticosteroids in modern practice. The Journal of the American Academy of Orthopaedic Surgeons 2005;13:37-46.

28. Collins ED, Hildreth DH, Jafarnia KK. A clinical study of extracorporeal shock waves (ESW) for treatment of chronic lateral epicondylitis. Current orthopaedic practice2011:185-92.

29. Constant CR, Murley AH. A clinical method of functional assessment of the shoulder. Clinical orthopaedics and related research 1987:160-4.

30. Cook JL, Bass SL, Black JE. Hormone therapy is associated with smaller Achilles tendon diameter in active post-menopausal women. Scandinavian journal of medicine & science in sports 2007;17:128-32.

31. Cook JL, Purdam CR. Is tendon pathology a continuum? A pathology model to explain the clinical presentation of load-induced tendinopathy. British journal of sports medicine 2009;43:409-16.

32. Cornell JE, Mulrow CD, Localio R, et al. Random-effects meta-analysis of inconsistent effects: a time for change. Annals of internal medicine 2014;160:267-70.

33. Cosentino R, De Stefano R, Selvi E, et al. Extracorporeal shock wave therapy for chronic calcific tendinitis of the shoulder: single blind study. Annals of the rheumatic diseases 2003;62:248-50.

34. Cosentino R, Falsetti P, Manca S, et al. Efficacy of extracorporeal shock wave treatment in calcaneal enthesophytosis. Annals of the rheumatic diseases 2001;60:1064-7.

35. Costa ML, Shepstone L, Donell ST, Thomas TL. Shock wave therapy for chronic Achilles tendon pain: a randomized placebo-controlled trial. Clinical orthopaedics and related research 2005;440:199-204.

36. Cote P, van der Velde G, Cassidy JD, et al. The burden and determinants of neck pain in workers: results of the Bone and Joint Decade 2000-2010 Task Force on Neck Pain and Its Associated Disorders. Spine 2008;33:S60-74.

37. Crowther MA, Bannister GC, Huma H, Rooker GD. A prospective, randomised study to compare extracorporeal shock-wave therapy and injection of steroid for the treatment of tennis elbow. The Journal of bone and joint surgery British volume 2002;84:678-9.

38. D'Ambrogi E, Giurato L, D'Agostino MA, et al. Contribution of plantar fascia to the increased forefoot pressures in diabetic patients. Diabetes care 2003;26:1525-9.

39. Dawson J, Fitzpatrick R, Carr A. Questionnaire on the perceptions of patients about shoulder surgery. The Journal of bone and joint surgery British volume 1996;78:593-600.

40. De Smedt T, de Jong A, Van Leemput W, Lieven D, Van Glabbeek F. Lateral epicondylitis in tennis: update on aetiology, biomechanics and treatment. British journal of sports medicine 2007;41:816-9.

41. Del Castillo-Gonzalez F, Ramos-Alvarez JJ, Rodriguez-Fabian G, Gonzalez-Perez J, Calderon-Montero J. Treatment of the calcific tendinopathy of the rotator cuff by ultrasound-guided percutaneous needle lavage. Two years prospective study. Muscles Ligaments Tendons J 2014;4:407-12.

42. Del Castillo-Gonzalez F, Ramos-Alvarez JJ, Rodriguez-Fabian G, Gonzalez-Perez J, Jimenez-Herranz E, Varela E. 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 2016;52:145-51.

43. Desmeules F, Boudreault J, Roy JS, Dionne CE, Fremont P, MacDermid JC. Efficacy of transcutaneous electrical nerve stimulation for rotator cuff tendinopathy: a systematic review. Physiotherapy 2016;102:41-9.

44. Drummond J, Fary C, Tran P. The outcome of endoscopy for recalcitrant greater trochanteric pain syndrome. Archives of orthopaedic and trauma surgery 2016;136:1547-54.

45. Efe T, Felgentreff M, Heyse TJ, et al. Extracorporeal shock wave therapy for non-calcific supraspinatus tendinitis - 10-year follow-up of a randomized placebo-controlled trial. Biomedizinische Technik Biomedical engineering 2014;59:431-7.

46. Ekeberg OM, Bautz-Holter E, Keller A, Tveita EK, Juel NG, Brox JI. A questionnaire found disease-specific WORC index is not more responsive than SPADI and OSS in rotator cuff disease. J Clin Epidemiol 2010;63:575-84.

47. Engebretsen K, Grotle M, Bautz-Holter E, Ekeberg OM, Juel NG, Brox JI. Supervised exercises compared with radial extracorporeal shock-wave therapy for subacromial shoulder pain: 1-year results of a single-blind randomized controlled trial. Physical therapy 2011;91:37-47.

48. Engebretsen K, Grotle M, Bautz-Holter E, et al. Radial extracorporeal shockwave treatment compared with supervised exercises in patients with subacromial pain syndrome: single blind randomised study. BMJ (Clinical research ed) 2009;339:b3360.

49. Feinberg MW, Jain MK, Werner F, et al. Transforming growth factor-beta 1 inhibits cytokine-mediated induction of human metalloelastase in macrophages. J Biol Chem 2000;275:25766-73.

50. Ferretti A. Epidemiology of jumper's knee. Sports medicine (Auckland, NZ) 1986;3:289-95.

51. Franceschi F, Papalia R, Paciotti M. Obesity as a risk factor for tendinopathy: a systematic review. 2014;2014:670262.

52. Fransen M, McConnell S, Harmer AR, Van der Esch M, Simic M, Bennell KL. Exercise for osteoarthritis of the knee: a Cochrane systematic review. British journal of sports medicine 2015;49:1554-7.

53. Fransen M, McConnell S, Hernandez-Molina G, Reichenbach S. Exercise for osteoarthritis of the hip. The Cochrane database of systematic reviews 2014:CD007912.

54. Frizziero A, Trainito S, Oliva F, Nicoli Aldini N, Masiero S, Maffulli N. The role of eccentric exercise in sport injuries rehabilitation. British medical bulletin 2014;110:47-75.

55. Galasso O, Amelio E, Riccelli DA, Gasparini G. Short-term outcomes of extracorporeal shock wave therapy for the treatment of chronic non-calcific tendinopathy of the supraspinatus: a double-blind, randomized, placebo-controlled trial. BMC musculoskeletal disorders 2012;13:86.

56. Gerdesmeyer L, Frey C, Vester J, et al. Radial extracorporeal shock wave therapy is safe and effective in the treatment of chronic recalcitrant plantar fasciitis: results of a confirmatory randomized placebo-controlled multicenter study. The American journal of sports medicine 2008;36:2100-9.

57. Gerdesmeyer L, Wagenpfeil S, Haake M, et al. Extracorporeal shock wave therapy for the treatment of chronic calcifying tendonitis of the rotator cuff: a randomized controlled trial. Jama 2003;290:2573-80.

58. Gollwitzer H, Diehl P, von Korff A, Rahlfs VW, Gerdesmeyer L. Extracorporeal shock wave therapy for chronic painful heel syndrome: a prospective, double blind, randomized trial assessing the efficacy of a new electromagnetic shock wave device. The Journal of foot and ankle surgery : official publication of the American College of Foot and Ankle Surgeons 2007;46:348-57.

59. Gollwitzer H, Saxena A, DiDomenico LA, et al. Clinically relevant effectiveness of focused extracorporeal shock wave therapy in the treatment of chronic plantar fasciitis: a randomized, controlled multicenter study. The Journal of bone and joint surgery American volume 2015;97:701-8.

60. Grecco MV, Brech GC, Greve JM. One-year treatment follow-up of plantar fasciitis: radial shockwaves vs. conventional physiotherapy. Clinics (Sao Paulo, Brazil) 2013;68:1089-95.

61. Guyatt G, Oxman AD, Akl EA, et al. GRADE guidelines: 1. Introduction-GRADE evidence profiles and summary of findings tables. J Clin Epidemiol 2011;64:383-94.

62. Guyatt GH, Oxman AD, Schunemann HJ, Tugwell P, Knottnerus A. GRADE guidelines: a new series of articles in the Journal of Clinical Epidemiology. J Clin Epidemiol 2011;64:380-2.

63. Haake M, Buch M, Schoellner C, et al. Extracorporeal shock wave therapy for plantar fasciitis: randomised controlled multicentre trial. BMJ (Clinical research ed) 2003;327:75.

64. Haake M, Konig IR, Decker T, Riedel C, Buch M, Muller HH. Extracorporeal shock wave therapy in the treatment of lateral epicondylitis : a randomized multicenter trial. The Journal of bone and joint surgery American volume 2002;84-a:1982-91.

65. Hamilton PG. The prevalence of humeral epicondylitis: a survey in general practice. British Journal of General Practice 1986;36:464-5.

66. Hammer DS, Rupp S, Kreutz A, Pape D, Kohn D, Seil R. Extracorporeal shockwave therapy (ESWT) in patients with chronic proximal plantar fasciitis. Foot & ankle international 2002;23:309-13.

67. Haupt G. Use of extracorporeal shock waves in the treatment of pseudarthrosis, tendinopathy and other orthopedic diseases. The Journal of urology 1997;158:4-11.

68. Haupt G, Haupt A, Ekkernkamp A, Gerety B, Chvapil M. Influence of shock waves on fracture healing. Urology 1992;39:529-32.

69. Hernandez-Sanchez S, Hidalgo MD, Gomez A. Responsiveness of the VISA-P scale for patellar tendinopathy in athletes. British journal of sports medicine 2014;48:453-7.

70. Higgins JP, Thompson SG, Deeks JJ, Altman DG. Measuring inconsistency in meta-analyses. BMJ (Clinical research ed) 2003;327:557-60.

71. Hochberg MC, Altman RD, April KT, et al. American College of Rheumatology 2012 recommendations for the use of nonpharmacologic and pharmacologic therapies in osteoarthritis of the hand, hip, and knee. Arthritis Care Res (Hoboken) 2012;64:465-74.

72. Hootman JM, Macera CA, Ainsworth BE, Addy CL, Martin M, Blair SN. Epidemiology of musculoskeletal injuries among sedentary and physically active adults. Medicine and science in sports and exercise 2002;34:838-44.

73. Hsu CJ, Wang DY, Tseng KF, Fong YC, Hsu HC, Jim YF. Extracorporeal shock wave therapy for calcifying tendinitis of the shoulder. Journal of shoulder and elbow surgery / American Shoulder and Elbow Surgeons [et al] 2008;17:55-9.

74. Hudak PL, Amadio PC, Bombardier C. Development of an upper extremity outcome measure: the DASH (disabilities of the arm, shoulder and hand) [corrected]. The Upper Extremity Collaborative Group (UECG). Am J Ind Med 1996;29:602-8.

75. Hussein AZ, Donatelli RA. The efficacy of radial extracorporeal shockwave therapy in shoulder adhesive capsulitis: A prospective, randomised, double-blind, placebo-controlled, clinical study. European Journal of Physiotherapy2016:63-76.

76. Ibrahim MI, Donatelli RA, Hellman M, Hussein AZ, Furia JP, Schmitz C. Long-term results of radial extracorporeal shock wave treatment for chronic plantar fasciopathy: A prospective, randomized, placebo-controlled trial with two years follow-up. Journal of orthopaedic research : official publication of the Orthopaedic Research Society 2016.

77. Ibrahim MI, Donatelli RA, Schmitz C, Hellman MA, Buxbaum F. Chronic plantar fasciitis treated with two sessions of radial extracorporeal shock wave therapy. Foot & ankle international 2010;31:391-7.

78. Ioppolo F, Rompe JD, Furia JP, Cacchio A. Clinical application of shock wave therapy (SWT) in musculoskeletal disorders. European journal of physical and rehabilitation medicine 2014;50:217-30.

79. James SL, Ali K, Pocock C, et al. Ultrasound guided dry needling and autologous blood injection for patellar tendinosis. British journal of sports medicine 2007;41:518-21; discussion 22.

80. Jariwala AB, D; Jain, A. A guide to the recognition and treatment of plantar fasciitis. Primary Health Care 2011;21.

81. Jarvinen M. Epidemiology of tendon injuries in sports. Clinics in sports medicine 1992;11:493-504.

82. Jarvinen TA, Kannus P, Maffulli N, Khan KM. Achilles tendon disorders: etiology and epidemiology. Foot and ankle clinics 2005;10:255-66.

83. Jarvinen TA, Kannus P, Paavola M, Jarvinen TL, Jozsa L, Jarvinen M. Achilles tendon injuries. Current opinion in rheumatology 2001;13:150-5.

84. Jocham D, Chaussy C, Schmiedt E. Extracorporeal shock wave lithotripsy. Urologia internationalis 1986;41:357-68.

85. Jones IJ, Mark I. Transcutaneous electrical nerve stimulation. Continuing Education in Anaesthesia, Critical Care and Pain 2009:9.

86. Kannus P. Tendons--a source of major concern in competitive and recreational athletes. Scandinavian journal of medicine & science in sports 1997;7:53-4.

87. Kannus P, Niittymaki S, Jarvinen M, Lehto M. Sports injuries in elderly athletes: a three-year prospective, controlled study. Age and ageing 1989;18:263-70.

88. Karpinski MR, Piggott H. Greater trochanteric pain syndrome. A report of 15 cases. The Journal of bone and joint surgery British volume 1985;67:762-3.

89. Kaux JF, Forthomme B, Goff CL, Crielaard JM, Croisier JL. Current opinions on tendinopathy. Journal of sports science & medicine 2011;10:238-53.

90. Kim GK. The Risk of Fluoroquinolone-induced Tendinopathy and Tendon Rupture: What Does The Clinician Need To Know? J Clin Aesthet Dermatol 2010;3:49-54.

91. Kim YS, Lee HJ, Kim YV, Kong CG. 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 / American Shoulder and Elbow Surgeons [et al] 2014;23:1640-6.

92. Klonschinski T, Ament SJ, Schlereth T, Rompe JD, Birklein F. Application of local anesthesia inhibits effects of low-energy extracorporeal shock wave treatment (ESWT) on nociceptors. Pain medicine (Malden, Mass) 2011;12:1532-7.

93. Ko JY, Chen HS, Chen LM. Treatment of lateral epicondylitis of the elbow with shock waves. Clinical orthopaedics and related research 2001:60-7.

94. Kolk A, Yang KG, Tamminga R, van der Hoeven H. Radial extracorporeal shock-wave therapy in patients with chronic rotator cuff tendinitis: a prospective randomised double-blind placebo-controlled multicentre trial. The bone & joint journal 2013;95-b:1521-6.

95. Konjen N, Napnark T, Janchai S. A comparison of the effectiveness of radial extracorporeal shock wave therapy and ultrasound therapy in the treatment of chronic plantar fasciitis: a randomized controlled trial. Journal of the Medical Association of Thailand = Chotmaihet thangphaet 2015;98 Suppl 1:S49-56.

96. Kudo P, Dainty K, Clarfield M, Coughlin L, Lavoie P, Lebrun C. Randomized, placebo-controlled, double-blind clinical trial evaluating the treatment of plantar fasciitis with an extracoporeal shockwave therapy (ESWT) device: a North American confirmatory study. Journal of orthopaedic research : official publication of the Orthopaedic Research Society 2006;24:115-23.

97. Kujala UM, Sarna S, Kaprio J. Cumulative incidence of achilles tendon rupture and tendinopathy in male former elite athletes. Clinical journal of sport medicine : official journal of the Canadian Academy of Sport Medicine 2005;15:133-5.

98. L'Insalata JC, Warren RF, Cohen SB, Altchek DW, Peterson MG. A self-administered questionnaire for assessment of symptoms and function of the shoulder. The Journal of bone and joint surgery American volume 1997;79:738-48.

99. Lakshmanan P, O'Doherty DP. Chronic achilles tendinopathy: treatment with extracorporeal shock waves. Foot and Ankle Surgery 2004;10:125-30.

100. Lance RM, Capehart B, Kadro O, Bass CR. Human Injury Criteria for Underwater Blasts. PloS one 2015;10:e0143485.

101. Landorf KB, Radford JA. Minimal important difference: Values for the Foot Health Status Questionnaire, Foot Function Index and Visual Analogue Scale. The Foot 2008;18:15-9.

102. Osteoarthritis of the Hip (Hip Arthritis). 2015. 2016, at http://www.orthop.washington.edu/?q=patient-care/articles/hip/osteoarthritis-of-the-hip-hip-arthritis.html.)

103. Lequesne M. From "periarthritis" to hip "rotator cuff" tears. Trochanteric tendinobursitis. Joint, bone, spine : revue du rhumatisme 2006;73:344-8.

104. Lin TC, Lin CY, Chou CL, Chiu CM. Achilles tendon tear following shock wave therapy for calcific tendinopathy of the Achilles tendon: A case report. Physical Therapy in Sport 2012;13:189-92.

105. Lindstedt SL, LaStayo PC, Reich TE. When active muscles lengthen: properties and consequences of eccentric contractions. News Physiol Sci 2001;16:256-61.

106. Liu S, Zhai L, Shi Z, Jing R, Zhao B, Xing G. Radial extracorporeal pressure pulse therapy for the primary long bicipital tenosynovitis a prospective randomized controlled study. Ultrasound in medicine & biology 2012;38:727-35.

107. Loew M, Jurgowski W. [Initial experiences with extracorporeal shockwave lithotripsy (ESWL) in treatment of tendinosis calcarea of the shoulder]. Z Orthop Ihre Grenzgeb 1993;131:470-3.

108. Loew M, Jurgowski W, Thomsen M. [Effect of extracorporeal shockwave therapy on tendinosis calcarea of the shoulder. A preliminary report]. Urologe A 1995;34:49-53.

109. Lui PP, Maffulli N, Rolf C, Smith RK. What are the validated animal models for tendinopathy? Scandinavian journal of medicine & science in sports 2011;21:3-17.

110. Maffulli N, Khan KM, Puddu G. Overuse tendon conditions: time to change a confusing terminology. Arthroscopy : the journal of arthroscopic & related surgery : official publication of the Arthroscopy Association of North America and the International Arthroscopy Association 1998;14:840-3.

111. Maffulli N, Wong J, Almekinders LC. Types and epidemiology of tendinopathy. Clinics in sports medicine 2003;22:675-92.

112. Malay DS, Pressman MM, Assili A, et al. Extracorporeal shockwave therapy versus placebo for the treatment of chronic proximal plantar fasciitis: results of a randomized, placebo-controlled, double-blinded, multicenter intervention trial. The Journal of foot and ankle surgery : official publication of the American College of Foot and Ankle Surgeons 2006;45:196-210.

113. Mascarenhas R, Frank RM, Lee S, Salata MJ, Bush-Joseph C, Nho SJ. Endoscopic Treatment of Greater Trochanteric Pain Syndrome of the Hip. JBJS Rev 2014;2.

114. McCormack J, Underwood F, Slaven E, Cappaert T. The Minimum Clinically Important Difference on the Visa-a and Lefs for Patients with Insertional Achilles Tendinopathy. Int J Sports Phys Ther 2015;10:639-44.

115. Mehra A, Zaman T, Jenkin AI. The use of a mobile lithotripter in the treatment of tennis elbow and plantar fasciitis. The surgeon : journal of the Royal Colleges of Surgeons of Edinburgh and Ireland 2003;1:290-2.

116. Mehta S, Gimbel JA, Soslowsky LJ. Etiologic and pathogenetic factors for rotator cuff tendinopathy. Clinics in sports medicine 2003;22:791-812.

117. Melikyan EY, Shahin E, Miles J, Bainbridge LC. Extracorporeal shock-wave treatment for tennis elbow. A randomised double-blind study. The Journal of bone and joint surgery British volume 2003;85:852-5.

118. Merikangas KR, Ames M, Cui L, et al. The impact of comorbidity of mental and physical conditions on role disability in the US adult household population. Archives of general psychiatry 2007;64:1180-8.

119. Mittermayr R, Antonic V, Hartinger J, et al. Extracorporeal shock wave therapy (ESWT) for wound healing: technology, mechanisms, and clinical efficacy. Wound Repair Regen 2012;20:456-65.

120. Moraes VY, Lenza M, Tamaoki MJ, Faloppa F, Belloti JC. Platelet-rich therapies for musculoskeletal soft tissue injuries. The Cochrane database of systematic reviews 2013;12:Cd010071.

121. Nirschl RP. Elbow tendinosis/tennis elbow. Clinics in sports medicine 1992;11:851-70.

122. Notarnicola A, Moretti B. The biological effects of extracorporeal shock wave therapy (eswt) on tendon tissue. Muscles Ligaments Tendons J 2012;2:33-7.

123. OCEBM Levels of Evidence Working Group. The Oxford 2011 Levels of Evidence. 2011.

124. Ofman JJ, Sullivan SD, Neumann PJ, et al. Examining the value and quality of health economic analyses: implications of utilizing the QHES. J Manag Care Pharm 2003;9:53-61.

125. Ogden JA, Alvarez R, Levitt R, Cross GL, Marlow M. Shock wave therapy for chronic proximal plantar fasciitis. Clinical orthopaedics and related research 2001:47-59.

126. Ogden JA, Alvarez RG, Levitt RL, Johnson JE, Marlow ME. Electrohydraulic high-energy shock-wave treatment for chronic plantar fasciitis. The Journal of bone and joint surgery American volume 2004;86-a:2216-28.

127. Ogden JA, Toth-Kischkat A, Schultheiss R. Principles of shock wave therapy. Clinical orthopaedics and related research 2001:8-17.

128. Organization WH. The Burden of Musculoskeletal Conditions at the Start of the New Millenium. Geneva, Switzerland2003.

129. Ozturan KE, Yucel I, Cakici H, Guven M, Sungur I. Autologous blood and corticosteroid injection and extracoporeal shock wave therapy in the treatment of lateral epicondylitis. Orthopedics 2010;33:84-91.

130. Pan PJ, Chou CL, Chiou HJ, Ma HL, Lee HC, Chan RC. Extracorporeal shock wave therapy for chronic calcific tendinitis of the shoulders: a functional and sonographic study. Archives of physical medicine and rehabilitation 2003;84:988-93.

131. Peters J, Luboldt W, Schwarz W, Jacobi V, Herzog C, Vogl TJ. Extracorporeal shock wave therapy in calcific tendinitis of the shoulder. Skeletal radiology 2004;33:712-8.

132. Pettrone FA, McCall BR. Extracorporeal shock wave therapy without local anesthesia for chronic lateral epicondylitis. The Journal of bone and joint surgery American volume 2005;87:1297-304.

133. Poltawski L, Watson T. Measuring clinically important change with the Patient-rated Tennis Elbow Evaluation. Hand Therapy 2011;16:52-7.

134. Porter MD, Shadbolt B. Intralesional corticosteroid injection versus extracorporeal shock wave therapy for plantar fasciopathy. Clinical journal of sport medicine : official journal of the Canadian Academy of Sport Medicine 2005;15:119-24.

135. Pransky G, Feuerstein M, Himmelstein J, Katz JN, Vickers-Lahti M. Measuring functional outcomes in work-related upper extremity disorders. Development and validation of the Upper Extremity Function Scale. Journal of occupational and environmental medicine / American College of Occupational and Environmental Medicine 1997;39:1195-202.

136. Radwan YA, ElSobhi G, Badawy WS, Reda A, Khalid S. Resistant tennis elbow: shock-wave therapy versus percutaneous tenotomy. International orthopaedics 2008;32:671-7.

137. Radwan YA, Mansour AM, Badawy WS. Resistant plantar fasciopathy: shock wave versus endoscopic plantar fascial release. International orthopaedics 2012;36:2147-56.

138. Rasmussen S, Christensen M, Mathiesen I, Simonson O. Shockwave therapy for chronic Achilles tendinopathy: a double-blind, randomized clinical trial of efficacy. Acta orthopaedica 2008;79:249-56.

139. Jumper's Knee. 2015. at http://www.webmd.com/fitness-exercise/jumpers_knee.)

140. Richmond SA, Fukuchi RK, Ezzat A, Schneider K, Schneider G, Emery CA. Are joint injury, sport activity, physical activity, obesity, or occupational activities predictors for osteoarthritis? A systematic review. J Orthop Sports Phys Ther 2013;43:515-B19.

141. Riddle DL, Pulisic M, Pidcoe P, Johnson RE. Risk factors for Plantar fasciitis: a matched case-control study. The Journal of bone and joint surgery American volume 2003;85-a:872-7.

142. Riddle DL, Schappert SM. Volume of ambulatory care visits and patterns of care for patients diagnosed with plantar fasciitis: a national study of medical doctors. Foot & ankle international 2004;25:303-10.

143. Rio E, Moseley L, Purdam C, et al. The pain of tendinopathy: physiological or pathophysiological? Sports medicine (Auckland, NZ) 2014;44:9-23.

144. Rolf C, Movin T. Etiology, histopathology, and outcome of surgery in achillodynia. Foot & ankle international 1997;18:565-9.

145. Rompe JD, Decking J, Schoellner C, Nafe B. Shock wave application for chronic plantar fasciitis in running athletes. A prospective, randomized, placebo-controlled trial. The American journal of sports medicine 2003;31:268-75.

146. Rompe JD, Decking J, Schoellner C, Theis C. Repetitive low-energy shock wave treatment for chronic lateral epicondylitis in tennis players. The American journal of sports medicine 2004;32:734-43.

147. Rompe JD, Furia J, Maffulli N. Eccentric loading compared with shock wave treatment for chronic insertional achilles tendinopathy. A randomized, controlled trial. The Journal of bone and joint surgery American volume 2008;90:52-61.

148. Rompe JD, Furia J, Maffulli N. Eccentric loading versus eccentric loading plus shock-wave treatment for midportion achilles tendinopathy: a randomized controlled trial. The American journal of sports medicine 2009;37:463-70.

149. Rompe JD, Hopf C, Nafe B, Burger R. Low-energy extracorporeal shock wave therapy for painful heel: a prospective controlled single-blind study. Archives of orthopaedic and trauma surgery 1996;115:75-9.

150. Rompe JD, Kullmer K, Riehle HM, et al. Effectiveness of low-energy extracorporal shock waves for chronic plantar fasciitis. Foot Ankle Surg 1996;2:215-21.

151. Rompe JD, Maffulli N. Repetitive shock wave therapy for lateral elbow tendinopathy (tennis elbow): a systematic and qualitative analysis. British medical bulletin 2007;83:355-78.

152. Rompe JD, Meurer A, Nafe B, Hofmann A, Gerdesmeyer L. Repetitive low-energy shock wave application without local anesthesia is more efficient than repetitive low-energy shock wave application with local anesthesia in the treatment of chronic plantar fasciitis. Journal of orthopaedic research : official publication of the Orthopaedic Research Society 2005;23:931-41.

153. Rompe JD, Nafe B, Furia JP, Maffulli N. Eccentric loading, shock-wave treatment, or a wait-and-see policy for tendinopathy of the main body of tendo Achillis: a randomized controlled trial. The American journal of sports medicine 2007;35:374-83.

154. Rompe JD, Overend TJ, MacDermid JC. Validation of the Patient-rated Tennis Elbow Evaluation Questionnaire. Journal of hand therapy : official journal of the American Society of Hand Therapists 2007;20:3-10; quiz 1.

155. Rompe JD, Riedel C, Betz U, Fink C. Chronic lateral epicondylitis of the elbow: A prospective study of low-energy shockwave therapy and low-energy shockwave therapy plus manual therapy of the cervical spine. Archives of physical medicine and rehabilitation 2001;82:578-82.

156. Salaffi F, Stancati A, Silvestri CA, Ciapetti A, Grassi W. Minimal clinically important changes in chronic musculoskeletal pain intensity measured on a numerical rating scale. Eur J Pain 2004;8:283-91.

157. Salen BA, Spangfort EV, Nygren AL, Nordemar R. The Disability Rating Index: an instrument for the assessment of disability in clinical settings. J Clin Epidemiol 1994;47:1423-35.

158. Saxena A, Fournier M, Gerdesmeyer L, Gollwitzer H. Comparison between extracorporeal shockwave therapy, placebo ESWT and endoscopic plantar fasciotomy for the treatment of chronic plantar heel pain in the athlete. Muscles Ligaments Tendons J 2012;2:312-6.

159. Schmitt J, Haake M, Tosch A, Hildebrand R, Deike B, Griss P. Low-energy extracorporeal shock-wave treatment (ESWT) for tendinitis of the supraspinatus. A prospective, randomised study. The Journal of bone and joint surgery British volume 2001;83:873-6.

160. Schmitt JS, Di Fabio RP. Reliable change and minimum important difference (MID) proportions facilitated group responsiveness comparisons using individual threshold criteria. J Clin Epidemiol 2004;57:1008-18.

161. Segal NA, Felson DT, Torner JC, et al. Greater trochanteric pain syndrome: epidemiology and associated factors. Archives of physical medicine and rehabilitation 2007;88:988-92.

162. Shiri R, Viikari-Juntura E, Varonen H, Heliovaara M. Prevalence and determinants of lateral and medial epicondylitis: a population study. Am J Epidemiol 2006;164:1065-74.

163. Silbernagel K. Achilles Tendinopathy: Evaluation and Treatment. Göteborg, Sweden: The Sahlgrenska Academy at Göteborg University; 2006.

164. Silbernagel KG, Thomee R, Eriksson BI, Karlsson J. Continued sports activity, using a pain-monitoring model, during rehabilitation in patients with Achilles tendinopathy: a randomized controlled study. The American journal of sports medicine 2007;35:897-906.

165. Silverstein B, Welp E, Nelson N, Kalat J. Claims incidence of work-related disorders of the upper extremities: Washington state, 1987 through 1995. American journal of public health 1998;88:1827-33.

166. Singh D, Angel J, Bentley G, Trevino SG. Fortnightly review. Plantar fasciitis. BMJ (Clinical research ed) 1997;315:172-5.

167. Speed C. A systematic review of shockwave therapies in soft tissue conditions: focusing on the evidence. British journal of sports medicine 2014;48:1538-42.

168. Speed CA, Nichols D, Richards C, et al. Extracorporeal shock wave therapy for lateral epicondylitis--a double blind randomised controlled trial. Journal of orthopaedic research : official publication of the Orthopaedic Research Society 2002;20:895-8.

169. Speed CA, Nichols D, Wies J, et al. Extracorporeal shock wave therapy for plantar fasciitis. A double blind randomised controlled trial. Journal of orthopaedic research : official publication of the Orthopaedic Research Society 2003;21:937-40.

170. Speed CA, Richards C, Nichols D, et al. Extracorporeal shock-wave therapy for tendonitis of the rotator cuff. A double-blind, randomised, controlled trial. The Journal of bone and joint surgery British volume 2002;84:509-12.

171. Stevens M, Tan CW. Effectiveness of the Alfredson protocol compared with a lower repetition-volume protocol for midportion Achilles tendinopathy: a randomized controlled trial. J Orthop Sports Phys Ther 2014;44:59-67.

172. Strand V, Kelman A. Outcome measures in osteoarthritis: randomized controlled trials. Curr Rheumatol Rep 2004;6:20-30.

173. Strauss EJ, Nho SJ, Kelly BT. Greater trochanteric pain syndrome. Sports medicine and arthroscopy review 2010;18:113-9.

174. Sulzbacher I. Osteoarthritis: histology and pathogenesis. Wien Med Wochenschr 2013;163:212-9.

175. Taunton J, Taunton KM, Khan KM. Treatment of patellar tendinopathy with extracorporeal shock wave therapy. BCMJ 2003;45.

176. Theodore GH, Buch M, Amendola A, Bachmann C, Fleming LL, Zingas C. Extracorporeal shock wave therapy for the treatment of plantar fasciitis. Foot & ankle international 2004;25:290-7.

177. Thiel M, Nieswand M, Dorffel M. The use of shock waves in medicine--a tool of the modern OR: an overview of basic physical principles, history and research. Minimally invasive therapy & allied technologies : MITAT : official journal of the Society for Minimally Invasive Therapy 2000;9:247-53.

178. Urwin M, Symmons D, Allison T, et al. Estimating the burden of musculoskeletal disorders in the community: the comparative prevalence of symptoms at different anatomical sites, and the relation to social deprivation. Annals of the rheumatic diseases 1998;57:649-55.

179. Vahdatpour B, Sajadieh S, Bateni V, Karami M, Sajjadieh H. Extracorporeal shock wave therapy in patients with plantar fasciitis. A randomized, placebo-controlled trial with ultrasonographic and subjective outcome assessments. J Res Med Sci 2012;17:834-8.

180. Vahdatpour B, Taheri P, Zade AZ, Moradian S. Efficacy of extracorporeal shockwave therapy in frozen shoulder. International journal of preventive medicine2014:875-81.

181. Valchanou VD, Michailov P. High energy shock waves in the treatment of delayed and nonunion of fractures. International orthopaedics 1991;15:181-4.

182. van der Worp H, van den Akker-Scheek I, van Schie H, Zwerver J. ESWT for tendinopathy: technology and clinical implications. Knee surgery, sports traumatology, arthroscopy : official journal of the ESSKA 2013;21:1451-8.

183. Vavken P, Dorotka R. Burden of musculoskeletal disease and its determination by urbanicity, socioeconomic status, age, and sex: Results from 14,507 subjects. Arthritis Care Res (Hoboken) 2011;63:1558-64.

184. Vos T, Flaxman AD, Naghavi M, et al. Years lived with disability (YLDs) for 1160 sequelae of 289 diseases and injuries 1990-2010: a systematic analysis for the Global Burden of Disease Study 2010. Lancet (London, England) 2012;380:2163-96.

185. Vulpiani MC, Trischitta D, Trovato P, Vetrano M, Ferretti A. Extracorporeal shockwave therapy (ESWT) in Achilles tendinopathy. A long-term follow-up observational study. The Journal of sports medicine and physical fitness 2009;49:171-6.

186. Wang CJ. Extracorporeal shockwave therapy in musculoskeletal disorders. Journal of orthopaedic surgery and research 2012;7:11.

187. Wang CJ, Huang HY, Pai CH. Shock wave-enhanced neovascularization at the tendon-bone junction: an experiment in dogs. The Journal of foot and ankle surgery : official publication of the American College of Foot and Ankle Surgeons 2002;41:16-22.

188. Wang CJ, Ko JY, Chan YS, Weng LH, Hsu SL. Extracorporeal shockwave for chronic patellar tendinopathy. The American journal of sports medicine 2007;35:972-8.

189. Wang CJ, Wang FS, Yang KD, et al. Shock wave therapy induces neovascularization at the tendon-bone junction. A study in rabbits. Journal of orthopaedic research : official publication of the Orthopaedic Research Society 2003;21:984-9.

190. Wang CJ, Wang FS, Yang KD, Weng LH, Ko JY. Long-term results of extracorporeal shockwave treatment for plantar fasciitis. The American journal of sports medicine 2006;34:592-6.

191. Warden SJ, Kiss ZS, Malara FA, Ooi AB, Cook JL, Crossley KM. Comparative accuracy of magnetic resonance imaging and ultrasonography in confirming clinically diagnosed patellar tendinopathy. The American journal of sports medicine 2007;35:427-36.

192. West S, King V, Carey TS, et.al. Systems to Rate the Strength of Scientific Evidence. Evidence Report/Technology Assessment No. 47 (Prepared by the Research Triangle Institute-University of North Carolina Evidence-based Practice Center, Contract No. 290-97-0011). Agency for Healthcare Research and Quality, Rockville, MD; 2002.

193. Williams BS, Cohen SP. Greater trochanteric pain syndrome: a review of anatomy, diagnosis and treatment. Anesthesia and analgesia 2009;108:1662-70.

194. Wolff JM, Mattelaer P, Boeckmann W, Kraemer U, Jakse G. Evaluation of possible tissue damage in patients undergoing extracorporeal shock wave lithotripsy employing C-reactive protein. Scandinavian journal of urology and nephrology 1997;31:31-4.

195. Woolf AD, Pfleger B. Burden of major musculoskeletal conditions. Bulletin of the World Health Organization 2003;81:646-56.

196. Plantar Fasciitis. 2015. 2016, at http://emedicine.medscape.com/article/86143-overview.)

197. Yucel I, Ozturan KE, Demiraran Y, Degirmenci E, Kaynak G. Comparison of high-dose extracorporeal shockwave therapy and intralesional corticosteroid injection in the treatment of plantar fasciitis. Journal of the American Podiatric Medical Association 2010;100:105-10.

198. Zhao Z, Jing R, Shi Z, Zhao B, Ai Q, Xing G. Efficacy of extracorporeal shockwave therapy for knee osteoarthritis: a randomized controlled trial. The Journal of surgical research 2013;185:661-6.

[i]Studies showed similar outcome measures between ESWT and eccentric loading in mid-portion AT and superior outcomes to eccentric loading in insertional AT