Medical Policy

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Title: Extracorporeal Shock Wave Therapy (ESWT) for Plantar Fasciitis and Other Musculoskeletal Conditions

Professional
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Populations	Interventions	Comparators	Outcomes
Individuals: • With plantar fasciitis	Interventions of interest are: • Extracorporeal shock wave therapy	Comparators of interest are: • Conservative therapy (eg, stretching, heel supports)	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life

Populations	Interventions	Comparators	Outcomes
		• Nonsteroidal anti-inflammatory therapy • Local corticosteroid injection	• Medication use • Treatment-related morbidity
Individuals: • With lateral epicondylitis	Interventions of interest are: • Extracorporeal shock wave therapy	Comparators of interest are: • Conservative therapy (eg, physical therapy, rest) • Nonsteroidal anti-inflammatory therapy	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life • Medication use • Treatment-related morbidity
Individuals: • With shoulder tendinopathy	Interventions of interest are: • Extracorporeal shock wave therapy	Comparators of interest are: • Conservative therapy (eg, physical therapy, rest) • Nonsteroidal anti-inflammatory therapy	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life • Medication use • Treatment-related morbidity
Individuals: • With Achilles tendinopathy	Interventions of interest are: • Extracorporeal shock wave therapy	Comparators of interest are: • Conservative therapy (eg, heel lift, rest) • Nonsteroidal anti-inflammatory therapy	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life • Medication use • Treatment-related morbidity
Individuals: • With patellar tendinopathy	Interventions of interest are: • Extracorporeal shock wave therapy	Comparators of interest are: • Conservative therapy (eg, icing, support) • Nonsteroidal anti-inflammatory therapy	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life • Medication use • Treatment-related morbidity
Individuals: • With medial tibial stress syndrome	Interventions of interest are: • Extracorporeal shock wave therapy	Comparators of interest are: • Conservative therapy (eg, icing, support)	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life • Medication use • Treatment-related morbidity
Individuals: • With osteonecrosis of the femoral head	Interventions of interest are: • Extracorporeal shock wave therapy	Comparators of interest are: • Medication therapy (eg, alendronate) • Hip arthroplasty	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life • Medication use • Treatment-related morbidity

Populations	Interventions	Comparators	Outcomes
Individuals: • Acute fracture nonunion or delayed union	Interventions of interest are: • Extracorporeal shock wave therapy	Comparators of interest are: • Surgical therapy	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life • Medication use • Treatment-related morbidity
Individuals: • With spasticity	Interventions of interest are: • Extracorporeal shock wave therapy	Comparators of interest are: • Medication therapy • Intrathecal medication therapy	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life • Medication use • Treatment-related morbidity

DESCRIPTION

Extracorporeal shock wave therapy (ESWT) is a noninvasive method used to treat pain with shock or sound waves directed from outside the body onto the area to be treated, (eg, the heel in the case of plantar fasciitis). Shock waves are generated at high- or low-energy intensity, and treatment protocols can include more than 1 treatment. ESWT has been investigated for use in a variety of musculoskeletal conditions.

OBJECTIVE

The objective of this evidence review is to examine whether the use of extracorporeal shock wave treatment for plantar fasciitis, lateral epicondylitis, tendinopathy (shoulder, Achilles, and patellar), medial tibial stress syndrome, osteonecrosis of the femoral head, acute fracture nonunion or delayed union, or spasticity improves the net health outcome

BACKGROUND

Chronic Musculoskeletal Conditions

Chronic musculoskeletal conditions (eg, tendinitis) can be associated with a substantial degree of scarring and calcium deposition. Calcium deposits may restrict motion and encroach on other structures, such as nerves and blood vessels, causing pain and decreased function. One hypothesis is that disruption of calcific deposits by shock waves may loosen adjacent structures and promote resorption of calcium, thereby decreasing pain and improving function.

Plantar Fasciitis

Plantar fasciitis is a common ailment characterized by deep pain in the plantar aspect of the heel, particularly on arising from bed. While the pain may subside with activity, in some patients the pain persists, interrupting activities of daily living. On physical examination, firm pressure will elicit a tender spot over the medial tubercle of the calcaneus. The exact etiology of plantar fasciitis is unclear, although repetitive injury is suspected. Heel spurs are a common associated finding, although it is unproven that heel spurs cause the pain. Asymptomatic heel spurs can be found in up to 10% of the population.

Tendinitis and Tendinopathies

Common tendinitis and tendinopathy syndromes are summarized in Table 1. Many tendinitis and tendinopathy syndromes are related to overuse injury.

Table 1. Tendinitis and Tendinopathy Syndromes

Disorder	Location	Symptoms	Conservative Therapy	Other Therapies
Lateral epicondylitis ("tennis elbow")	Lateral elbow (insertion of wrist extensors)	Tenderness over lateral epicondyle and proximal wrist extensor muscle mass; pain with resisted wrist extension with elbow in full extension; pain with passive terminal wrist flexion with elbow in full extension	• Rest • Activity modification • NSAIDs • Physical therapy • Orthotic devices	Corticosteroid injections; joint debridement (open or laparoscopic)
Shoulder tendinopathy	Rotator cuff muscle tendons, most commonly supraspinatus	Pain with overhead activity	• Rest • Ice • NSAIDs • Physical therapy	Corticosteroid injections
Achilles tendinopathy	Achilles tendon	Pain or stiffness 2-6 cm above the posterior calcaneus	• Avoidance of aggravating activities • Ice when symptomatic • NSAIDs • Heel lift	Surgical repair for tendon rupture
Patellar tendinopathy ("jumper's knee")	Proximal tendon at lower pole of patella	Pain over anterior knee and patellar tendon; may progress to tendon calcification and/or tear	• Ice • Supportive taping • Patellar tendon straps • NSAIDs	•

NSAIDs: nonsteroidal anti-inflammatory drugs.

Fracture Nonunion and Delayed Union

The definition of a fracture nonunion remains controversial, particularly the duration necessary to define nonunion. One proposed definition is a failure of progression of fracture healing for at least 3 consecutive months (and at least 6 months after the fracture) accompanied by clinical symptoms of delayed/nonunion (pain, difficulty weight bearing). The following criteria to define nonunion were used to inform this review:

- at least 3 months since the date of fracture;
- serial radiographs have confirmed that no progressive signs of healing have occurred;
- the fracture gap is 1 cm or less; and
- the patient can be adequately immobilized and is of an age likely to comply with nonweight-bearing limitation.

The delayed union can be defined as a decelerating healing process, as determined by serial radiographs, together with a lack of clinical and radiologic evidence of union, bony continuity, or bone reaction at the fracture site for no less than 3 months from the index injury or the most recent intervention. (In contrast, nonunion serial radiographs show no evidence of healing.)

Other Musculoskeletal and Neurologic Conditions
Other musculoskeletal conditions include medial tibial stress syndrome, osteonecrosis (avascular necrosis) of the femoral head, coccydynia, and painful stump neuromas. Neurologic conditions include spasticity, which refers to a motor disorder characterized by increased velocity-dependent stretch reflexes. It is a characteristic of upper motor neuron dysfunction, which may be due to a variety of pathologies.

Treatment
Most cases of plantar fasciitis are treated with conservative therapy, including rest or minimization of running and jumping, heel cups, and nonsteroidal-anti-inflammatory drugs. Local steroid injection may also be used. Improvement may take up to 1 year in some cases. For tendinitis and tendinopathy syndromes, conservative treatment often involves rest, activity modifications, physical therapy, and anti-inflammatory medications (see Table 1).

Extracorporeal Shock Wave Therapy
Also known as orthotripsy, extracorporeal shock wave therapy (ESWT) has been available since the early 1980s for the treatment of renal stones and has been widely investigated for the treatment of biliary stones. ESWT uses externally applied shock waves to create a transient pressure disturbance, which disrupts solid structures, breaking them into smaller fragments, thus allowing spontaneous passage and/or removal of stones. The mechanism by which ESWT might have an effect on musculoskeletal conditions is not well-defined.

Other mechanisms are also thought to be involved in ESWT. Physical stimuli are known to activate endogenous pain control systems, and activation by shock waves may "reset" the endogenous pain receptors. Damage to endothelial tissue from ESWT may result in increased vessel wall permeability, causing increased diffusion of cytokines, which may, in turn, promote healing. Microtrauma induced by ESWT may promote angiogenesis and thus aid healing. Finally, shock waves have been shown to stimulate osteogenesis and promote callous formation in animals, which is the basis for trials of ESWT in delayed union or nonunion of bone fractures.

There are 2 types of ESWT: focused and radial. Focused ESWT sends medium- to high-energy shockwaves of single pressure pulses lasting microseconds, directed on a specific target using ultrasound or radiographic guidance. Radial ESWT (RSW) transmits low- to medium-energy shockwaves radially over a larger surface area. The U.S. Food and Drug Administration (FDA) approval was first granted in 2002 for focused ESWT devices and in 2007 for RSW devices.

REGULATORY STATUS
Currently, 6 focused ESWT devices have been approved by FDA through the premarket approval process for orthopedic use (see Table 2). FDA product code: NBN.

Table 2. FDA approved Extracorporeal Shock Wave Therapy Devices

Device Name	Approval Date	Delivery System Type	Indication
OssaTron® device (HealthTronics)	2000	Electrohydraulic delivery system	• Chronic proximal plantar fasciitis, ie, pain persisting >6 mo and unresponsive to conservative management • Lateral epicondylitis
Epos™ Ultra (Dornier)	2002	Electromagnetic delivery system	Plantar fasciitis
Sonocur® Basic (Siemens)	2002	Electromagnetic delivery system	Chronic lateral epicondylitis (unresponsive to conservative therapy for >6 mo)
Orthospec™ Orthopedic ESWT (Medispec)	2005	Electrohydraulic spark-gap system	Chronic proximal plantar fasciitis in patients ≥18 y
Orbasone™ Pain Relief System (Orthometrix)	2005	High-energy sonic wave system	Chronic proximal plantar fasciitis in patients ≥18 y
Duolith® SD1 Shock Wave Therapy Device (Storz Medical AG)	2016	Electromagnetic delivery system	Chronic proximal plantar fasciitis in patients ≥18 y with history of failed alternative conservative therapies >6 mo

FDA: U.S. Food and Drug Administration.

Both high-dose and low-dose protocols have been investigated. A high-dose protocol consists of a single treatment of high-energy shock waves (1300 mJ/mm^2). This painful procedure requires anesthesia. A low-dose protocol consists of multiple treatments, spaced 1 week to 1 month apart, in which lower dose shock waves are applied. This protocol does not require anesthesia. The FDA labeled indication for the OssaTron® and Epos™ Ultra devices specifically describes a high-dose protocol, while the labeled indication for the Sonocur® device describes a low-dose protocol.

In 2007, Dolorclast® (EMS Electro Medical Systems), a radial ESWT, was approved by FDA through the premarket approval process. Radial ESWT is generated ballistically by accelerating a bullet to hit an applicator, which transforms the kinetic energy into radially expanding shock waves. Radial ESWT is described as an alternative to focused ESWT and is said to address larger treatment areas, thus providing potential advantages in superficial applications like tendinopathies. The FDA approved indication is for the treatment of patients 18 years and older with chronic proximal plantar fasciitis and a history of unsuccessful conservative therapy. FDA product code: NBN.

POLICY

A. Extracorporeal shock wave therapy (ESWT) using a high-dose protocol may be considered **medically necessary** for chronic intractable plantar fasciitis refractory to standard therapy with a minimum of six months of active professional treatment including four of the six:

   1. Non-steroidal anti-inflammatory drugs (NSAIDs)

   2. Cortisone injections

   3. Arch support, or heel cups

   4. Stretching exercises for calf muscles and plantar fascia

   5. Physical therapy

   6. Strapping immobilization or night splints

B. Extracorporeal shock wave therapy (ESWT) using a high-dose protocol is considered **experimental / investigational** for other musculoskeletal conditions, including, but not limited to, tendinitis of the elbow (epicondylitis, tennis elbow).

C. Extracorporeal shock wave therapy (ESWT) using a low-dose protocol or radial extracorporeal shock wave therapy is considered **experimental / investigational** as a treatment of musculoskeletal conditions, including, but not limited to, plantar fasciitis; tendinopathies including tendinitis of the shoulder, Achilles tendinitis, tendinitis of the elbow (lateral epicondylitis), and patellar tendinitis; stress fractures; delayed union and nonunion of fractures; avascular necrosis of the femoral head; and spasticity.

DOCUMENTATION
Medical record submission (minimal range: last six months of medical records).

UTILIZATION
1. The use of a high-energy (electrohydraulic or electromagnetic shock) machine approved by the FDA for chronic plantar fasciitis is covered. All other machines are considered experimental / investigational.
2. Ambulatory surgery center and outpatient hospital setting are the appropriate place for service.
3. Regional and/or IV sedation is needed for pain control during the procedure
4. A maximum of 3 ESWT per heel with at least 6 months between treatments will be allowed.

RATIONALE

This evidence review was created in May 2001 and has been updated regularly with searches using the PubMed database. The most recent literature update was performed through September 2, 2020.

This review was informed by a TEC Assessment (2001) that concluded extracorporeal shock wave therapy (ESWT) met TEC criteria as a treatment for plantar fasciitis in patients who had not responded to conservative therapies.[1,] Another TEC Assessment (2003) reviewed the subsequent literature on ESWT for musculoskeletal conditions with a focus on 3 conditions: plantar fasciitis, tendinitis of the shoulder, and tendinitis of the elbow.[2,] The 2003 TEC Assessment came to different conclusions, specifically, that ESWT did not meet TEC criteria as a treatment of plantar fasciitis or other musculoskeletal conditions. In 2004, updated TEC Assessments were completed for plantar fasciitis and tendinitis of the elbow.[3,4,] These Assessments concluded that ESWT did not meet TEC criteria for the treatment of these conditions.

The most clinically relevant outcome measures of ESWT used for musculoskeletal conditions are pain and functional limitations. Pain is a subjective, patient-reported measure. Therefore, pain outcomes require quantifiable pre- and posttreatment measures. Pain is most commonly measured with a visual analog scale (VAS). Quantifiable pre- and posttreatment measures of functional status are also used, such as 12-Item Short-Form Health Survey and 36-Item Short-Form Health Survey. Minor adverse events of ESWT are common but transient, including local pain, discomfort, trauma, bleeding, and swelling. More serious adverse events of ESWT may potentially include neurologic damage causing numbness or tingling, permanent vascular damage, or rupture of a tendon or other soft tissue structure.

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function-including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent 1 or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

MUSCULOSKELETAL AND NEUROLOGIC CONDITIONS

Plantar Fasciitis

Clinical Context and Therapy Purpose

The purpose of ESWT is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as conservative therapy (eg, stretching, heel supports), nonsteroidal anti-inflammatory therapy, and local corticosteroid injection, in patients with plantar fasciitis.

The question addressed in this evidence review is: Does the use of extracorporeal shock wave therapy for plantar fasciitis improve the net health outcome?

The following PICO was used to select literature to inform this review.

Patients

The relevant population of interest is individuals with plantar fasciitis.

Interventions

The therapy being considered is extracorporeal shock wave therapy.

ESWT is a noninvasive method used to treat pain with shock or sound waves directed from outside the body onto the area to be treated (eg, the heel). Shock waves are generated at high- or low-energy intensity, may be radial or focused, and treatment protocols can include more than 1 treatment. ESWT has been investigated for use in a variety of musculoskeletal conditions.

Comparators

Comparators of interest include conservative therapy (eg, stretching, heel supports), nonsteroidal anti-inflammatory therapy, and local corticosteroid injection. Comparators are managed by podiatrists, physical therapists, and primary care providers in an outpatient clinical setting.

Outcomes

The general outcomes of interest are pain symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity.

Table 3. Outcomes of Interest for Individuals with Plantar Fasciitis

Outcomes	Details	Timing
Pain reduction	• VAS assessment, with successful pain reduction of 50–60% or ≥4 cm reduction in score • Roles and Maudsley pain scores of "good" or "excellent" • Pain comparison both to baseline and to control group measurements • Patient-assessed and investigator-assessed pain levels	Generally measured for up to 12 weeks
Functional improvement	• Roles and Maudsley function score of "good" or "excellent"	Generally measured for up to 12 weeks

Outcomes	Details	Timing
	• Patient ability to work and perform activities of daily living	
Quality of life	• Patient-reported satisfaction with treatment	Generally measured for up to 12 weeks

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess longer term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought. Studies with duplicative or overlapping populations were excluded.

Review of Evidence

Systematic Reviews

Eight studies met the inclusion criteria for the TEC Assessment (2004).[3,] Five double-blind RCTs, reporting on 992 patients, were considered high quality. Overall, evidence included in this Assessment showed a statistically significant effect on the between-group difference in morning pain measured on a 0-to-10 VAS score. Uncertain was the clinical significance of the change. The absolute value and effect size were small. Complete information on the number needed to treat to achieve 50% to 60% reduction in morning pain came from 2 studies of high-energy ESWT (and including confidential data provided by Dornier). The combined number needed to treat was 7 (95% confidence interval [CI], 4 to 15). Improvements in pain measures were not associated with improvements in function. The effect size for improvement in pain with activity was not significant, based on reporting for 81% of patients in all studies and 73% of patients in high-energy ESWT studies. Success in improvement in Roles and Maudsley score was reported for fewer than half the patients: although statistically significant, confidence intervals were wide. Where reported, improvement in morning pain was not accompanied by a significant difference in the quality of life measurement (12-Item Short-Form Health Survey Physical and Mental Component Summary scores) or use in pain medication.

A meta-analysis by Xiong et al (2019) compared the efficacy of shock wave therapy with corticosteroid injections for managing plantar fasciitis in terms of pain and functionality.[5,] The analysis included 6 RCTs with 454 patients and revealed a significant difference in VAS score (mean difference, -0.96; 95% CI, -1.28 to -0.63; $P<0.00001$, $I^2=96\%$), favoring shock wave therapy. This analysis is not included in the results summary table (Table 6) because its comparator is a corticosteroid injection rather than placebo.

In their systematic review and meta-analysis, Li et al (2018) assessed RCTs to determine whether ESWT or corticosteroid injections are more effective in plantar fasciitis pain reduction (measured using VAS), treatment success, recurrence rate, function scores, and adverse events.[6,] The review included 9 RCTs with a total of 658 cases in which 330 participants received ESWT and 328 received corticosteroid injection. Meta-analyses showed that corticosteroid injection is more effective than low-intensity ESWT at VAS reduction (3 months post-treatment:

mean difference, -1.67; 95% CI -3.31 to -0.04; P=0.04; I2=85%). However, high-intensity ESWT is more effective than corticosteroid injection (2–3 months post-treatment: mean difference, 1.12; 95% CI, 0.52 to 1.72; P=0.0003; I2=59%). One study followed patients for 12 months post-treatment and found no significant different in pain outcomes, and I found no significant difference in recurrence rates or functional scores between ESWT and corticosteroid injection. Four ESWT recipients in 1 trial reported severe headache or migraine following the procedure; no severe adverse effects were reported for corticosteroid injection. Though corticosteroid injection is more readily available than ESWT, the authors reported that ESWT recipients have a faster return to full activities after the procedure. One limitation of this systematic review is the inclusion of only 9 trials with 658 cases, only 2 of which followed up for as long as 1 year. Also, the doses of corticosteroid injection varied across studies, which may affect heterogeneity. This study is not included in the results summary table (Table 6) because its comparator is corticosteroid injection rather than placebo.

The meta-analysis by Sun et al (2017) evaluated the efficacy of all ESWT, then conducted subgroup analyses on the type of ESWT (focused shock wave [FSW], radial shock wave [RSW]).[7,] The literature search, conducted through July 2016, identified 9 trials for inclusion (total N=935 patients). An outcome in all 9 trials was "therapeutic success" rate, defined as a proportion of patients experiencing a decrease in VAS pain score from baseline more than a threshold of either at least 50% or at least 60%. Only 4 studies provided data on reducing pain (3 FSW, 1 RSW). Pooled results are summarized in Table 3.

A meta-analysis by Lou et al (2017) evaluated the efficacy of ESWT without local anesthesia in patients with recalcitrant plantar fasciitis. The literature search, conducted through September 2015, identified 9 trials for inclusion (total N=1174 patients). Meta-analyses focused on pain reduction at 12 weeks of follow-up: overall, at first step in the morning, and during daily activities. Three RCTs also provided data to analyze improvement in the Roles and Maudsley score to excellent or good at 12-week follow-up.

A systematic review and meta-analysis by Yin et al (2014) evaluated 7 RCTs or quasi-RCTs of ESWT for chronic (≥6 months) recalcitrant plantar fasciitis.[8,] Treatment success rate of the 5 trials (n=448 patients) that evaluated low-intensity ESWT showed it was more likely than the control treatment to be successful (pooled relative risk, 1.69; 95% CI, 1.37 to 2.07; p<0.001). In a pooled analysis of 2 trials (n=105 subjects) that evaluated high-intensity ESWT, there was no difference between ESWT and control in treatment success. A strength of this analysis was restricting the population to patients with at least 6 months of symptoms because this clinical population is more difficult to treat and less likely to respond to interventions. However, a weakness was the heterogeneity in the definition of "treatment success" across trials, which makes interpreting the pooled analysis challenging.

Meta-analyses of RCTs published in 2013 have reported that ESWT for plantar fasciitis is better than or comparable to placebo in reducing pain[9,10,11,] and improving functional status in the short-term.[9,10,] However, RCTs were subject to a number of limitations. They reported inconsistent results, and heterogeneity across them sometimes precluded meta-analysis of pooled data. Outcomes measured and trial protocols (eg, dose intensities, type of shockwaves, the frequency of treatments) also lacked uniformity. Also, given that plantar fasciitis often resolves within a 6-month period, longer follow-up would be required to compare ESWT results with the natural

resolution of the condition. The clinical significance of results reported at shorter follow-up (eg, 3 months) is uncertain.

Results of meta-analyses must be interpreted with caution due to the following limitations: lack of uniform measurement of outcomes, heterogeneity in ESWT protocols (focused and radial, low- and high-intensity/energy, the number of shocks per treatment, treatment duration, and differing comparators), and lack of functional outcomes.

Table 4. Comparison of Systematic Reviews Assessing ESWT for Plantar Fasciitis

Study	Aqil (2013)[10]	Dizon (2013)[9]	Li (2018)[16]	Lou (2017)[12]	Sun (2017)[7]	Xiong (2019)[5]	Yin (2014)[8]	Zhiyun (2013)[11]
Buchbinder (2002)		●						
Chow (2005)		●						
Eslamian (2016)			●					
Fariba (2016)						●		
Gerdesmeyer (2008)	●	●		●	●		●	
Gollwitzer (2007)	●	●		●	●		●	●
Gollwitzer (2015)				●				
Gollwitzer (2017)					●			
Greve (2009)		●	●					
Guevara (2018)			●					
Haake (2003)		●	●					
Hocaoglu (2017)			●					
Ibrahim (2010)	●	●			●		●	
Istemi (2010)						●		
Kudo (2006)		●						●
Lai (2018)			●			●		

Study	Aqil (2013)[10]	Dizon (2013)[9]	Li (2018)[16]	Lou (2017)[12]	Sun (2017)[7]	Xiong (2019)[5]	Yin (2014)[8]	Zhiyun (2013)[11]
Malay (2006)	●	●		●	●			●
Mardani-Kivi (2015)			●					
Mark (2005)						●		
Marks (2008)	●				●		●	
Nayera (2012)						●		
Ogden (2004)								●
Porter (2005)			●					
Radwan (2012)							●	
Rompe (1996)					●			
Rompe (2002)					●			
Rompe (2003)	●						●	
Saber (2012)			●					
Sehriban (2017)						●		
Sorrentino (2008)			●					
Speed (2003)	●	●		●	●		●	
Theodore (2004)		●						●
Yucel (2010)			●					

ESWT: extracorporeal shockwave therapy.
[1] Li (2018) and Xiong (2019) are not included in the results summary table (Table 6) because the comparator in the studies is corticosteroid injections rather than placebo.

Table 5. Characteristics of Systematic Reviews and Meta-Analyses Assessing ESWT for Plantar Fasciitis

Study	Dates	Trials	Participants	N (Range)	Design	Duration
Aqil (2013)[10,]	2003–2010	7	PF patients with continued symptoms after 3 months of consecutive therapy	663 (25–243)	RCTs	12 weeks
Dizon (2013)[9,]	2002–2010	11	Patients with chronic PF	1287 (32–272)	RCTs	Immediately after treatment–1 year
Li (2018)[6,]	2005–2018	9	Adults with PF and without injection history	658 (40–125)	RCTs	6 weeks–1 year
Lou (2017)[12,]	2001-2015	9[1]	Patients with recalcitrant PF; (n=1174)	1174 (NA)	RCTs	Primary outcomes=12 weeks; studies up to >12 months
Sun (2017)[7,]	1996–2015	9	Patients with chronic PF	935 (29–246)	RCTs	3 weeks–6 months
Xiong (2019) [5,]	2005-2018	6	Patients with PF	454 (40-125)	RCTs	-
Yin (2014)[8,]	2003–2012	7	Adults with PF ≥6 months; single-site heel pain with local pressure at origin of proximal plantar fascia on the medial calcaneal tuberosity	550 (25–243)	RCTs	3–12 months
Zhiyun (2013)[11,]	2004–2007	5	Adults with recalcitrant PF; baseline pain ≥5 points on VAS	716 (40–293)	RCTs (double blind)	12 weeks

PF: plantar fasciitis; n: number of participants; NA: not available; VAS: visual analog scale used to measure pain.
[1] Only 7 trials mentioned in meta-analysis.

Table 6. Results of Systematic Reviews and Meta-Analyses Assessing ESWT for Plantar Fasciitis Compared with Placebo

Study	60% VAS Score Reduction from Baseline (or >50% reduction and VAS score ≤4 cm)				Roles & Maudsley Score
	First Steps	Overall Heel Pain	Daily Activities	Composite	
Aqil (2013)[10,]					
RR	1.30	-	1.44	-	-[1]
SMD	-	0.60		0.38	-
95% CI	1.04–1.62	0.34–0.85	1.13–1.84	0.05–0.72	-

Study	60% VAS Score Reduction from Baseline (or >50% reduction and VAS score ≤4 cm)				Roles & Maudsley Score
Z score	2.29	4.64	2.96	2.27	-
P-value	<0.02	<0.001	0.003	0.02	-
Dizon (2013)[9,]					
WMD	-0.77	-4.39	0.59	-	-
OR					0.57
95% CI	-1.30 to -0.25	-9.05–0.27	0.33–1.05	-	0.43–0.76
P-value	0.004	0.06	0.07	-	0.0001
Lou (2017)[12,]					
RR	1.32	1.50	1.37	-	1.51
95% CI	1.11–1.56	1.27–1.77	1.14–1.65	-	1.26–1.81
Z score	3.19	4.84	3.31	-	4.51
P-value	0.001	<0.0001	0.0009	-	<0.0001
I^2 %	0	0	-		0
Sun (2017)[7,]					
OR	-	-	-	2.58	-
SMD	-	1.01	-	-	-
95% CI	-	-0.01–2.03	-	1.97–3.39	-
Z score	-	1.94	-	6.88	-
P-value	-	0.05	-	<0.0001	-
I^2 %	-	96	-	38	-
Yin (2014)[8,]					
L-ESWT					
MD	-	1.51[2]	-		
RR	-		-	-	1.41
95% CI	-	0.77–2.26	-	-	1.08–1.82
P-value	-	<0.001	-	-	0.01
H-ESWT					
MD	-	1.4	-	-	1.33
RR	-		-	-	0.94–1.9
95% CI	-	0.57–2.23	-	-	0.11
P-value	-	0.11	-	-	
Zhiyun (2013)[311,]					
Success rate % (12 weeks)	-	46.5–62.5	-	-	-
OR	-	2.25	-	-	-
95% CI	-	1.66–3.06	-	-	-
Z score	-	5.19	-	-	-
P-value	-	<0.0001	-	-	-

CI: confidence interval; MD: mean difference; VAS: visual analog scale used to measure pain; SMD: standard mean difference; WMD: weighted mean difference; FSW: focused shockwave; RSW: radial shockwave; OR: odds ratio; RR: risk ratio.
L-ESWT: low-intensity/energy shockwave therapy; H-ESWT: high-intensity/energy shockwave therapy.
[1] Aqil et al gathered data on 3 studies that measured Roles and Maudsley scores but did not statistically combine the results. However, all 3 studies showed statistically significant improvements for the ESWT group at 12 weeks.
[2] Yin et al compared ESWT value for pain relief before and after treatment.
[3] Zhivun compared HESWT to placebo.

Randomized Controlled Trials

Trials With Sham Controls

Several representative RCT trials are discussed next. For example, Gollwitzer et al (2015) reported on results of a sham-controlled randomized trial, with patients and outcome assessments blinded, evaluating ESWT for plantar fasciitis present for at least 6 months and refractory to at least 2 nonpharmacologic and 2 pharmacologic treatments.[13,] A total of 250 subjects were enrolled (126 in the ESWT group, 124 in the placebo group). The trial's primary outcome was an overall reduction of heel pain, measured by percentage change of the VAS composite score at 12 weeks. Median decrease for the ESWT group was -69.2% and -34.5% for the placebo group (effect size, 0.603; p=0.003). Secondary outcomes included success rates defined as decreases in heel pain of at least 60% from baseline. Secondary outcomes generally favored the ESWT group. Most patients reported satisfaction with the procedure. Strengths of this trial included intention-to-treat analysis, use of validated outcome measures, and at least some reporting of changes in success rates (rather than percentage decrease in pain) for groups. There was some potential for bias because treating physicians were unblinded.

In 2005, results were reported from the U.S. Food and Drug Administration (FDA) regulated trials delivering ESWT with the Orthospec and Orbasone Pain Relief System. In the RCT evaluating Orthospec, investigators conducted a multicenter, double-blind, sham-controlled trial randomizing 172 participants with chronic proximal plantar fasciitis failing conservative therapy to ESWT or to sham treatments.[14,] At 3 months, the ESWT arm had lower investigator-assessed pain levels with the application of a pressure sensor (0.94 points lower on a 10-point VAS; 95% CI, 0.02 to 1.87). However, this improvement was not found for patient-assessed activity and function. In the trial supporting the FDA approval of Orbasone, investigators conducted a multicenter, randomized, sham-controlled, double-blind trial evaluating 179 participants with chronic proximal plantar fasciitis.[15,] At 3 months, both active and sham groups improved in patient-assessed pain levels on awakening (by 4.6 and 2.3 points, respectively, on a 10-point VAS; absolute difference between groups, 2.3; 95% CI, 1.5 to 3.3). While ESWT was associated with more rapid and statistically significant improvement in a mixed-effects regression model, insufficient details were provided to evaluate the analyses.

Gerdesmeyer et al (2008) reported on a multicenter, double-blind RCT of RSW conducted for FDA premarket approval of the Dolorclast.[16,] The trial randomized 252 patients, 129 to RSW and 122 to sham treatment. Patients had heel pain for at least 6 months and had failed at least 2 nonpharmacologic and 2 pharmacologic treatments. Over 90% of patients were compliant with the 3 weekly treatment schedule. Outcome measures were composite heel pain (pain on first steps of the day, with activity and as measured with Dolormeter), change in VAS pain score, and Roles and Maudsley score measured at 12 weeks and 12 months. Success was defined as a reduction of 60% or more in 2 of 3 VAS scores, or patient ability to work and complete activities of daily living, treatment satisfaction, and requiring no further treatment. Secondary outcomes at 12 weeks included changes in Roles and Maudsley score, 36-Item Short-From Health Survey Physical Component Summary score, 36-Item Short-Form Health Survey Mental Component Summary score, investigator's and patient's judgment of effectiveness, and patient recommendation of therapy to a friend. At 12-week follow-up, RSW resulted in a decrease of the composite VAS score by 72.1% versus 44.7% after placebo (p=0.022). Success rates for the composite heel pain score were 61% and 42% (p=0.002). Statistically significant differences were noted in all secondary measures. A number of limitations prevent definite conclusions from

being reached: the limited data on specific outcomes (eg, presenting percent changes rather than actual results of measures); inadequate description of prior treatments; use of a composite outcome measure; no data on the use of rescue medication; and uncertainty in the clinical significance of changes in outcome measures.

Table 7. Summary of Key Characteristics of RCTs Assessing ESWT for Plantar Fasciitis

Study; Trial	Countries	Sites	Participants	Interventions	
				Active	Comparator
Gerdesmeyer (2008)[16,]	US, EU	8	Patients with ≥6 months painful heel syndrome resistant to nonsurgical treatment; score ≥5 on 3 VAS scores; failed ≥ 2 non-pharmacological and 2 pharmacological treatments; sufficient wash out period; (n=254)	2000 impulses radial shockwaves; energy flux density 0.16 mJ/mm^2 (8 impulses per second); 3 bi-weekly sessions; (n=129)	Identical placebo handpiece; same schedule as active group but with no energy administered; (n=122)
Gollwitzer (2015)[13,]	US	5	Patients with ≥6 months PF; failed ≥4 non-surgical treatments, including ≥2 non-pharmacological and ≥2 pharmacological treatments; (n=250)	2000 impulses. maximum 0.25 mJ/mm^2 (4 impulses per second); up to 3 weekly sessions; (n=126)	Identical placebo handpiece for sham intervention; air-filled standoff prevented transmission of shockwaves; (n=124)
FDA, Orbasone (2005)[15,]	US	3	Patients ≥21 years; proximal PF ≥6 months and in prescribed stretching program; failed ≥4 conventional treatments; score ≥6 cm on VAS scale; (n=179)	Single treatment of 2000 pulses at 20–21 KV; frequency 110 pulses per minute; total energy density <1000 mJ/mm^2; injection of approx. 10 mL of 0.5% bupivacaine; (n=96)	Sham treatment with no water pumped into reflector head, preventing shockwave energy from reaching patient's foot; (n=83)
FDA, Orthospec (2005) [14,]	US	3	Adults (non-pregnant) with proximal PF for >6 months; under treatment ≥4 months; VAS score upon first steps ≥5 cm; failed 2 pharmacological and 2 nonpharmacological treatments; washout period; (n=172)	Total of 3800 shocks; (n=115)	Total of 3800 shocks; contact membrane of device lined with internal foam insert to absorb shockwaves; (n=57)

RCT: randomized controlled trial; VAS: visual analog scale; PF: plantar fasciitis; FDA: U.S. Food and Drug Administration.

Table 8. Summary of Key Results of RCTs Assessing ESWT for Plantar Fasciitis

Study	VAS Pain Score Improvement	Functional Improvement
Gerdesmeyer (2008)[16,]		
ESWT reduction in VAS composite %	72.1	-
Placebo reduction in VAS composite %	44.7	-
P-value	0.0220	-
ESWT success rate %[1]	60.98	58.40[2]
Placebo success rate %	42.24	41.52
P-value (MW effect size)	0.0020 (-)	0.0031 (0.5973)
Gollwitzer (2015)[13,]		
P-value (MW effect size)[3]	0.0027 (0.6026)	0.0006 (0.6135)
Lower-bound 95% CI	0.5306	0.5466
ESWT mean % from baseline (95% CI)	-54.5 (-61.4 to -47.7)	-
Placebo mean % from baseline (95% CI)	-40.3 (-47.5 to -33.1)	-
ESWT mean score (95% CI)[4]	-	2.5 (2.3–2.7)
Placebo mean score (95% CI)	-	2.9 (2.7–3.1)
FDA, Orbasone (2005)[15,]		
ESWT 12-wk mean score (SE)	3.11 (0.30)	-
Range	0–9.8	-
Placebo 12-wk mean score (SE)	5.51 (0.35)	-
Range	0–10	-
P-value	0.0002	-
% ESWT with 40% reduction in VAS	70.8	-
% Placebo with 40% reduction in VAS	36.6	-
FDA, Orthospec (2005)[14,]		
ESWT mean change from baseline[6]	-2.51	-
Placebo mean change from baseline	-1.57	-
Difference	-0.94	-
95% CI	-1.87 to -0.02	-
P-value	0.045	-
ESWT effectiveness rate %[7]	-	64.3
Placebo effectiveness rate %	-	57.1
P-value	-	0.33

CI: confidence interval; RCT: randomized controlled trial; ESWT: extracorporeal shockwave therapy; SD: standard deviation; MW: Mann-Whitney; wk: week.
[1] Based on overall VAS score.
[2] Roles and Maudsley Score of "excellent" or "good."
[3] Based on composite VAS score.
[4] Roles and Maudsley Score.
[5] Based on pain at first steps VAS score.
[6] Physician's assessment of pain at first steps VAS score.
[7] Patient's assessment.

The purpose of the limitations tables (see Tables 9 and 10) is to display notable limitations identified in each study. This information is synthesized as a summary of the body of evidence following each table and provides the conclusions on the sufficiency of evidence supporting the position statement.

Table 9. Study Relevance Limitations of RCTs Assessing ESWT for Plantar Fasciitis

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Follow-Up[e]
Gerdesmeyer (2008)[16,]					
Gollwitzer (2015)[13,]					
FDA, Orbasone (2005)[15,]	3. Allocation concealment unclear				
FDA, Orthospec (2005)[14,]	3. Allocation concealment unclear	1. Few details provided.			

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
a Population key: 1. Intended use population unclear; 2. Clinical context is unclear; 3. Study population is unclear; 4. Study population not representative of intended use.
b Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4. Not the intervention of interest.
c Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively.
d Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. No CONSORT reporting of harms; 4. Not establish and validated measurements; 5. Clinical significant difference not prespecified; 6. Clinical significant difference not supported.
e Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms.

Table 10. Study Design and Conduct Limitations of RCTs Assessing ESWT for Plantar Fasciitis

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Follow-Up[d]	Power[e]	Statistical[f]
Gerdesmeyer (2008)[16,]						3. Confidence intervals not reported
Gollwitzer (2015)[13,]						
FDA, Orbasone (2005)[15,]	1. Allocation concealment unclear		1. Registration unclear		1. Power calculations not reported	3. Confidence intervals and p-values not reported
FDA, Orthospec (2005)[14,]	1. Allocation concealment unclear		1. Registration unclear		1. Power calculations not reported	3. Confidence intervals not reported for function

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
a Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias.
b Blinding key: 1. Not blinded to treatment assignment; 2. Not blinded outcome assessment; 3. Outcome assessed by treating physician.
c Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.
d Follow-Up key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials).
e Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference.
f Statistical key: 1. Intervention is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2.

Intervention is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4.Comparative treatment effects not calculated.

Several smaller trials (<50 patients) have shown inconsistent results.[17,18,19,20,] They are not included in the summary tables.

Trials With Active Comparators

Radwan et al (2012) compared ESWT with endoscopic plantar fasciotomy in 65 patients who had refractory plantar fasciitis and had failed at least 3 lines of treatment in the preceding 6 months.[21,] Outcome measures included a 0-to-100 VAS assessing morning pain, the American Orthopedic Foot and Ankle (AOFAS) Ankle-Hindfoot Scale score, and patient subjective assessment using the 4-item Roles and Maudsley score. Improvements were similar in both treatment groups at the 1-year follow-up; however, a larger proportion of patients in the surgery group continued to report success at years 2 and 3 compared with those of the ESWT group.

RCTs comparing ESWT and RSW with corticosteroid injection and conservative treatment (exercise, orthotic support) have been performed, with mixed findings.[22,23,24,]As the follow-up period for these studies are 3 months or less, the clinical significance of these results are uncertain.[25,]

Section Summary: Plantar Fasciitis

Numerous RCTs were identified, including several well-designed double-blinded RCTs, that evaluated ESWT for the treatment of plantar fasciitis. Several systematic reviews and meta-analyses have been conducted, covering numerous studies, including studies that compared ESWT with corticosteroid injections. Pooled results were inconsistent. Some meta-analyses reported that ESWT reduced pain, while others reported nonsignificant pain reduction. Reasons for the differing results included lack of uniformity in the definitions of outcomes and heterogeneity in ESWT protocols (focused versus radial, low- versus high-intensity/energy, number and duration of shocks per treatment, number of treatments, and differing comparators). Some studies reported significant benefits in pain and functional improvement at 3 months, but it is not evident that the longer-term disease natural history is altered with ESWT. Currently, it is not possible to conclude definitively that ESWT improves outcomes for patients with plantar fasciitis.

LATERAL EPICONDYLITIS

Clinical Context and Therapy Purpose

The purpose of ESWT is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as conservative therapy (eg, physical therapy) and nonsteroidal anti-inflammatory therapy, in patients with lateral epicondylitis.

The question addressed in this evidence review is: does the use of extracorporeal shock wave therapy for lateral epicondylitis improve the net health outcome?

The following PICO was used to select literature to inform this review.

Patients

The relevant population of interest is individuals with lateral epicondylitis.

Interventions
The therapy being considered is ESWT.

Comparators
Comparators of interest include conservative therapy (eg, physical therapy) and nonsteroidal anti-inflammatory therapy. Comparators are actively managed by orthopedic surgeons, physical therapists, and primary care providers in an outpatient clinical setting.

Outcomes
The general outcomes of interest are symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity.

Table 11. Outcomes of Interest for Individuals with Lateral Epicondylitis

Outcomes	Details	Timing
Symptoms	• Pain improvement via VAS assessment • Thomsen Provocation Test score for pain • Roles and Maudsley pain scores of "good or excellent"	Generally measured for up to 12 weeks.
Functional outcomes	• Change in Upper Extremity Function Scale (UEFS) • Roles and Maudsley function scores of "good" or "excellent" • Grip strength improvement	Generally measured for up to 12 weeks.
Medication use	• Nonuse of pain medication	Generally measured for up to 12 weeks.

Study Selection Criteria
Methodologically credible studies were selected using the following principles:
- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess longer term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought. Studies with duplicative or overlapping populations were excluded.

Review of Evidence

Systematic Reviews
Six randomized, double-blinded, placebo-controlled trials enrolling 808 patients with lateral epicondylitis (tendinitis of the elbow) met inclusion criteria for the TEC Assessment (2004).[4,] Four trials were rated good quality and are summarized next. Three trials used low-energy ESWT and 1 used high-energy ESWT. Two trials reported positive effects on pain, 1 trial had mixed results, and another large sham-controlled study reported negative results with ESWT.

In the Sonocur trial (2002), 114 patients were randomized to low-energy ESWT or sham ESWT for 3 treatment sessions administered at 1-week intervals.[26,] The main outcome measures were

percent response on a self-reported pain scale (at least 50% improvement on 0-to-100 VAS) and change in Upper Extremity Function Scale (UEFS) scores. Results for the 2 main outcome measures at 3 months showed greater improvement in the ESWT group. The response rate was 60% in the active treatment group and 29% in the placebo group ($p<0.001$). UEFS score improved by 51% in the active treatment group and by 30% in the placebo group ($p<0.05$).

Rompe et al (2004) randomized 78 tennis players to 3 treatments at weekly intervals of low-energy or sham ESWT.[27,] Outcomes included pain ratings during wrist extension and Thomsen Provocation Test score, Roles and Maudsley score, UEFS score, grip strength, and satisfaction with a return to activities. At the 3-month follow-up, the ESWT group significantly improved on all outcomes except grip strength compared with placebo. Treatment success (at least a 50% decrease in pain) was 65% for the ESWT group and 28% for the placebo group ($p<0.01$); and 65% of the ESWT group, compared with 35% of the placebo group, expressed satisfaction with their return to activities ($p=0.01$).

The OssaTron trial (2000) randomized 183 patients to a single session of high-energy or sham ESWT.[28,] Treatment success was a 50% improvement on investigator- and patient-assessed pain using a 0-to-10 VAS and no or rare use of pain medication. At the 8-week follow-up, the ESWT group had a greater rate of treatment success (35%) than the placebo group (22%; $p<0.05$). The main driver for group differences in treatment success was the investigator-assessed pain (48% versus 29%, respectively; $p<0.01$); self-assessment of pain (81% versus 70%, respectively; $p=0.06$) and nonuse of pain medication (81% versus 70%, respectively; $p=0.09$) improved only marginally.

Haake et al (2002) randomized 272 patients to 3 sessions of low-energy or sham ESWT. Treatment success was defined as achieving a Roles and Maudsley score of 1 or 2 with no need for additional treatments.[29,] At 12 weeks, the ESWT success rate was 25.8% and the placebo success rate was 25.4%. The percentage of Roles and Maudsley scores below 3 did not differ between groups at either the 12-week (31.7% ESWT versus 33.1% placebo) or 1-year (65.7% ESWT versus 65.3% placebo) follow-ups. Moreover, the groups did not differ on any of 5 pain assessment measures or on grip strength.

Other systematic reviews published since the 2004 Assessment have reached similar conclusions when comparing ESWT with placebo or no additional treatment. A Cochrane review by Buchbinder et al (2005) concluded, "there is 'Platinum' level evidence [the strongest level of evidence] that shock wave therapy provides little or no benefit regarding pain and function in lateral elbow pain."[30,] A systematic review by Dingemanse et al (2014), which evaluated electrophysical therapies for epicondylitis, found conflicting evidence on the short-term benefits of ESWT.[31,] No evidence demonstrated any long-term benefits with ESWT over placebo for epicondylitis treatment. A meta-analysis by Zheng et al (2020) of 9 studies concluded that ESWT does not reduce the mean overall pain compared with placebo in lateral epicondylitis of humerus.[32,] A systematic review and meta-analysis by Yoon et al (2020) of 12 studies revealed that ESWT lacks clinically important pain reduction or improvement in grip strength compared with sham stimulation or no additional treatment in patients with lateral epicondylitis.[33,]

Interestingly, some systematic reviews revealed a potential benefit of ESWT in patients with lateral epicondylitis when comparing with other treatment methods outside conservative and nonsteroidal anti-inflammatory therapy. A systematic review and meta-analysis by Yao et al

(2020) of 13 studies revealed improved VAS scores (p=0.0004) and grip strength (p<0.00001) with ESWT compared with other methods including placebo, autologous blood injection, corticosteroid injection, physiotherapy, wrist-extensor splints, laser, and/or kinesiotaping.[34,] A meta-analysis by Yan et al (2019) of 5 studies demonstrated improvement in VAS scores (p<0.0001), grip strength (p<0.00001), and subjective scores of elbow function (p=0.0008) with ESWT compared with ultrasonics.[35,] A meta-analysis by Xiong et al (2019) of 4 studies revealed improved VAS scores (p<0.00001) and grip strength (p<0.00001) with shock wave therapy compared with corticosteroid injections.[36,]

Randomized Controlled Trials

Several small RCTs on ESWT for lateral epicondylitis have been published since the 2004 TEC Assessment.

Guler et al (2020) compared ESWT (n=20) with kinesiotaping (n=20) as part of 3-week treatment in patients with newly diagnosed lateral epicondylitis.[37,] Outcomes included VAS pain, grip strength, and functional assessment as measured by Roles and Maudsley score. At 8 week follow-up, kinesiotaping revealed a lower VAS score (2.52 versus 4.0; p=0.01), a better hand grip strength score (26.8 versus 20.6; p=0.005), and a lower Roles and Maudsley score (1.7 versus 2.2; p=0.02) compared with ESWT. This RCT is not included in the summary table because it compares ESWT to kinesiotaping as opposed to conservative or nonsteroidal anti-inflammatory therapy.

Yang et al (2017) published results from an RCT (N=30) comparing RSW plus physical therapy with physical therapy alone in patients with lateral epicondylitis.[38,] Outcomes included VAS pain and grip strength. Significant differences were seen in grip strength by 12 weeks of follow-up; the mean difference in grip strength between groups was 7.7 (95% CI, 1.3 to 14.2), favoring RSW. Significant differences in VAS pain (10-point scale) were not detected until 24 weeks of follow-up; the mean difference between groups was -1.8 (95% CI, -3.0 to -0.5), favoring RSW. This RCT is not included in the summary table because it compares RSW with a physical therapy program that includes ultrasound therapy.

A small RCT by Capan et al (2016) comparing RSW (n=28) with sham RSW (n=28) for lateral epicondylitis did not find significant differences between groups in grip strength or function.[39,] However, this trial might have been underpowered to detect a difference. This RCT is not included in the summary tables because the comparator is ultrasound as opposed to conservative or nonsteroidal anti-inflammatory therapy.

Lizis (2015) compared ESWT with therapeutic ultrasound among 50 patients who had chronic tennis elbow.[40,] For most pain measures assessed, the pain was lower in the ESWT group immediately posttreatment and at 3 months, except pain on gripping, which was higher in the ESWT group. While trial results favored ESWT, it had a high risk of bias, in particular, due to lack of blinding of participants and outcome assessors, which make interpretation of results difficult.

Gunduz et al (2012) compared ESWT with 2 active comparators.[41,] This trial randomized 59 patients with lateral epicondylitis to ESWT, physical therapy, or a single corticosteroid injection. Outcome measures were VAS pain, grip strength, and pinch strength by dynamometer. The authors reported that VAS pain scores improved significantly in all 3 groups at all 3 follow-up time points out to 6 months, but they reported no between-group differences. No consistent

changes were reported for grip strength or on ultrasonography. This RCT is not included in the summary table because it compares ESWT with corticosteroid injections, and the physical therapy comparator includes ultrasound therapy.

Staples et al (2008) reported on a double-blind controlled trial of ESWT for epicondylitis in 68 patients.[42,] Patients were randomized to 3 ESWT treatments or 3 treatments at a subtherapeutic dose at weekly intervals. There were significant improvements in most of the 7 outcome measures for both groups over 6 months of follow-up but no between-group differences. The authors found little evidence to support the use of ESWT for this indication.

Pettrone and McCall (2005) reported on results from a multicenter, double-blind, randomized trial of 114 patients receiving ESWT in a "focused" manner (2000 impulses at 0.06 mJ/mm^{2,} without local anesthesia) weekly for 3 weeks or placebo.[43,] Patients were followed for 12 weeks, and benefit demonstrated with the following outcomes: VAS pain (0-10 points) declined at 12 weeks in the treatment group from 7.4 to 3.8; among placebo patients, from 7.6 to 5.1. A reduction in pain on the Thomsen Provocation Test of at least 50% was demonstrated in 61% of those treated compared with 29% in the placebo group. Mean improvement on a 10-point UEFS activity score was 2.4 for ESWT-treated patients compared with 1.4 in the placebo group-a difference at 12 weeks of 0.9 (95% CI, 0.18 to 1.6). Although this trial found a benefit of ESWT for lateral epicondylitis over 12 weeks, the placebo group also improved significantly; whether the natural history of disease was altered with ESWT is unclear.

Table 12. Summary of Key Characteristics of RCTs Assessing ESWT for Lateral Epicondylitis

Study; Trial	Countries	Sites	Dates	Participants	Interventions	
					Active	**Comparator**
Capan (2016)[39,]	Turkey	1	-	Patients with unilateral LE for >3 months unresponsive to other treatments; (n=56)	rESWT with 2000 pulses; 10 Hz frequency; 1.8 bar of air pressure; 3 weekly sessions; (n=28)	3 sham treatments of rESWT; same dosage and schedule as active but with no contact between applicator head and skin; (n=28)
Pettrone & McCall (2005)[43,]	US	3	-	Patients with LE ≥6 months; pain resistant ≥2 of 3 conventional therapies; pain ≥40 mm on VAS with resisted wrist extension; (n=114)	ESWT with 2000 pulses; 0.06 mJ/mm^2; 3 weekly sessions; (n=56)	3 sham treatments of ESWT with same settings as active but with sound-reflecting pad between patient and machine application head; (n=58)

Study; Trial	Countries	Sites	Dates	Participants	Interventions	
Staples (2008)[42,]	Australia	1	1998–2001	Adults with lateral elbow pain for ≥6 weeks; normal anteroposterior and lateral elbow radiographs; reproducibility of pain by ≥2 pain tests; (n=68)	ESWT with 2000 pulses; energy level= maximum tolerated by patient; 240 pulses per minute; 3 weekly sessions; (n=36)	ESWT with 100 pulses; maximum energy ≤0.03 mJ/mm^2; 90 pulses per minute; 3 weekly sessions; (n=32)

RCT: randomized controlled trial; ESWT: extracorporeal shockwave therapy; LE: lateral epicondylitis; rEWST: radial extracorporeal shockwave therapy.

Table 13. Summary of Key Results of RCTs Assessing ESWT for Lateral Epicondylitis

Study	Pain Improvement		Functional Improvement		Grip Strength	
	≤6 wks	3 mos	≤6 wks	3 mos	≤6 wks	3 mos
Capan (2016)[39,]						
rESWT (SD)	3.4 (2.9)	2.1 (2.2)	19.3 (10.9)	14.7 (12.3)	15.96 (9.61)	17.30 (10.33)
rESWT MD from baseline (SD)	-1.9 (2.2)	-3.2 (2.3)	-10.9 (11.3)	-15.4 (13.4)	5.35 (6.82)	1.35 (3.87)
% difference	-36.7	-59.1	-33.4	-49.2	76.3	17.8
P-value	<0.001	<0.001	<0.001	<0.001	0.002	0.074
Control (SD)	3.5 (2.9)	2.6 (2.8)	21.9 (12.6)	19.2 (13.6)	10.14 (6.42)	12.18 (6.01)
Control MD from baseline (SD)	-2.2 (2.4)	-3.1 (2.7)	-7.9 (10.1)	-10.6 (11.6)	3.68 (4.56)	2.05 (3.46)
% difference	-39.6	-54.8	-28.9	-37.8	110.0	57.0
P-value	0.001	<0.001	0.001	0.001	0.001	0.017
% changes between groups P-value	0.758	0.882	0.617	0.323	0.578	0.768
Pettrone & McCall (2005)[43,]						
ESWT mean (SD)	-	37.6 (28.7)	-	2.3 (1.6)	-	38.2 (5)
Change %	-	49	-	51	-	23
Control mean (SD)	-	51.3 (29.7)	-	3.2 (2.1)	-	37.4
Change %	-	32	-	30	-	12
P-value	-	0.02	-	0.01	-	-
ESWT % pts w/pain reduction[6]	-	61	-	-	-	-
Placebo % pts w/pain reduction	-	29	-		-	-
P-value	-	0.0001	-	-	-	0.09
Staples (2008)[42,]						
ESWT (SD)	-	-	-	-	-	-

Study	Pain Improvement		Functional Improvement		Grip Strength	
ESWT mean (SE) change	27.7 (5.7)	26.1 (6.5)	15.3 (2.4)	18.9 (2.7)	0.17 (0.06)	0.35 (0.06)
Control (SD)	-	-	-		-	-
Control mean (SE) change	26.0 (6.4)	26.7 (6.0)	9.0 (3.8)	10.9 (3.4)	0.22 (0.07)	0.31 (0.06)
Between-group difference	1.7	-0.6	6.3	8.1	-0.05	0.04
95% CI	-18.8–15.3	-18.4–17.3	-2.5–15.1	-0.5–16.7	-0.22–0.12	-0.13–0.20
P-value	0.84	0.95	0.16	0.07	0.57	-

CI: confidence interval; ; RCT: randomized controlled trial; ; ESWT: extracorporeal shockwave therapy; NS: Not statistically significant but p-value not specified; SD: standard deviation; MD: mean difference; SE: standard error of the mean; VAS: visual analog scale; pts: patients; w/: with; NA: not applicable.
1 Pain assessed using at-rest VAS.
2 Patient-Related Tennis Elbow Evaluation (PRTEE) function scores.
3 Grip strength in kilograms.
4 VAS pain index range = 0–100.
5 Grip strength in kilograms.
6 Pain reduction of ≥50% on Thomsen test.
7 Based on VAS pain index (0–100).
8 Disabilities of the Arm, Shoulder, and Hand (DASH) questionnaire function scores.
9 Maximum pain-free grip strength measured with a squeeze dynamometer.

The purpose of the limitations tables (see Tables 14 and 15) is to display notable limitations identified in each study. This information is synthesized as a summary of the body of evidence following each table and provides the conclusions on the sufficiency of evidence supporting the position statement.

Table 14. Study Relevance Limitations of RCTs Assessing ESWT for Lateral Epicondylitis

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Follow-Up[e]
Capan (2016)[39,]				3. CONSORT flow diagram included, but no reporting of harms	
Pettrone & McCall (2005)[43,]					
Staples (2008)[42,]					

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
a Population key: 1. Intended use population unclear; 2. Clinical context is unclear; 3. Study population is unclear; 4. Study population not representative of intended use.
b Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4. Not the intervention of interest.
c Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively.
d Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. No CONSORT reporting of harms; 4. Not establish and validated measurements; 5. Clinical significant difference not prespecified; 6. Clinical significant difference not supported.
e Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms.

Table 15. Study Design and Conduct Limitations of RCTs Assessing ESWT for Lateral Epicondylitis

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Follow-Up[d]	Power[e]	Statistical[f]
Capan (2016)[39,]			1. Not registered	6. No intent-to-treat analysis	1. Calculations not reported	
Pettrone & McCall (2005)[43,]	3. Unclear how randomized		1. Not registered			
Staples (2008)[42,]			1. Not registered		3. Underpowered	

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
a Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias.
b Blinding key: 1. Not blinded to treatment assignment; 2. Not blinded outcome assessment; 3. Outcome assessed by treating physician.
c Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.
d Follow-Up key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials).
e Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference.
f Statistical key: 1. Intervention is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Intervention is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported;
4.Comparative treatment effects not calculated.

Section Summary: Lateral Epicondylitis

The most direct evidence on the use of ESWT to treat lateral epicondylitis comes from multiple small RCTs, which did not consistently show outcome improvements beyond those seen in control groups. The highest quality trials tend to show no benefit, and systematic reviews have generally concluded that the evidence does not support a treatment benefit over placebo or no treatment.

SHOULDER TENDINOPATHY

Clinical Context and Therapy Purpose

The purpose of ESWT is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as conservative therapy (eg, physical therapy) and nonsteroidal anti-inflammatory therapy, in patients with shoulder tendinopathy.

The question addressed in this evidence review is: Does the use of ESWT for shoulder tendinopathy improve the net health outcome?

The following PICO was used to select literature to inform this review.

Patients

The relevant population of interest is individuals with shoulder tendinopathy.

Interventions
The therapy being considered is ESWT.

Comparators
Comparators of interest include conservative therapy (eg, physical therapy) and nonsteroidal anti-inflammatory therapy. Comparators are actively managed by orthopedic surgeons, physical therapists, and primary care providers in an outpatient clinical setting.

Outcomes
The general outcomes of interest are symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity.

Table 16. Outcomes of Interest for Individuals with Shoulder Tendinopathy

Outcomes	Details	Timing
Symptoms	• Pain reduction via VAS assessment • American Shoulder and Elbow Surgeons (ASES) scale for pain • L'Insalata Shoulder Questionnaire for pain • Reduction in size of deposit as assessed by radiograph or ultrasound[1]	1 week to 1 year
Functional outcomes	• Constant-Murley Score (CMS) • Shoulder Pain And Disability Index (SPADI) • American Shoulder and Elbow Surgeons (ASES) scale for function • Simple Shoulder Test	1 week to 1 year
Quality of life	• Patients' subjective assessment of improvement	1 week to 1 year

1 For studies that assessed calcific tendinitis.

Study Selection Criteria
Methodologically credible studies were selected using the following principles:
- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess longer term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought. Studies with duplicative or overlapping populations were excluded.

Review of Evidence

Systematic Reviews
A systematic review and network meta-analysis of RCTs by Wu et al (2017) compared the effectiveness of nonoperative treatments for chronic calcific tendinitis.[44,] The literature review, conducted through April 2016, identified 14 RCTs (total N=1105 patients) for inclusion. Treatments included in the network meta-analysis were ultrasound-guided needling (UGN), RSW, high-energy FSW (H-FSW), low-energy FSW (L-FSW), ultrasound therapy, and transcutaneous

electrical nerve stimulation. Trials either compared the treatments with each other or with sham/placebo. Outcomes were pain (VAS range, 0 [no pain] to 10 [worst pain]), functional assessment (Constant-Murley Score [CMS], up to 100 [asymptomatic]), and calcific deposit change ("no change," "partial resolution," or "complete resolution," assessed by radiograph or ultrasound). Treatments most effective in reducing pain and resolving calcific deposits were UGN, RSW, H-FSW. The only treatment significantly improving function was H-FSW. Table 17 lists the treatments, from most effective to the least effective, by outcome, as determined by network meta-analysis.

Table 17. Ranking of Nonoperative Treatments for Chronic Calcific Tendinitis, by Outcome

Pain Reduction (8 Trials)		**Functional Assessment (7 Trials)**		**Calcific Deposit Change (14 Trials)**	
Treatment	Difference From Control (95% CrI)	Treatment	Difference From Control (95% CrI)	Treatment	Difference From Control (95% CrI)
UGN	8.0 (4.9 to 11.1)	H-FSW	25.1 (10.3 to 40.0)	UGN	6.8 (3.8 to 9.9)
RSW	6.1 (3.9 to 8.3)	TENS	8.7 (-13.5 to 30.9)	RSW	6.2 (3.2 to 9.1)
H-FSW	4.2 (2.0 to 6.4)	L-FSW	7.6 (-7.2 to 22.5)	H-FSW	2.4 (1.5 to 3.4)
TENS	3.2 (-0.1 to 6.5)	Ultrasound	3.3 (-15.0 to 21.6)	Ultrasound	2.1 (0.4 to 3.8)
L-FSW	1.9 (-0.4 to 4.3)			TENS	1.9 (-0.8 to 4.6)
Ultrasound	1.1 (-1.7 to 3.9)			L-FSW	1.2 (0.1 to 2.2)

Adapted from Wu et al (2017).[44,]
CrI: credible interval; H-FSW: high-energy focused extracorporeal shockwave; L-FSW: low-energy focused extracorporeal shockwave; RSW: radial extracorporeal shockwave; TENS: transcutaneous electrical nerve stimulation; UGN: ultrasound-guided needling.

A systematic review and network meta-analysis of RCTs by Arirachakaran et al (2017) evaluated ESWT, ultrasound-guided percutaneous lavage (UGPL), subacromial corticosteroid injection (SAI), and combined treatments for rotator cuff calcific tendinopathy.[45,] The literature search, conducted through September 2015, identified 7 RCTs for inclusion. Six of the trials had ESWT as 1 treatment arm, with the following comparators: placebo (4 trials), UGPL plus ESWT (1 trial), and UGPL plus SAI (1 trial). One trial compared UGPL plus SAI with SAI alone. Outcomes were CMS (5 trials), VAS pain (5 trials), and size of calcium deposit (4 trials). Network meta-analysis results are summarized below:

- VAS pain:
  - ESWT, UGPL plus SAI, and SAI alone were more effective in reducing pain than placebo
  - Compared with each other, ESWT, UGPL plus SAI, and SAI alone did not differ statistically

- CMS:
  - ESWT was statistically more effective than placebo
  - No other treatment comparisons differed statistically

- Size of calcium deposit:
    - UGPL plus SAI was statistically more effective than placebo and SAI alone
    - ESWT was statistically better than SAI alone, but not more effective than placebo.

In a systematic review and meta-analysis, Ioppolo et al (2013) identified 6 RCTs that compared ESWT with sham treatment or placebo for calcific shoulder tendinopathy.[46,] Greater shoulder function and pain improvements were reported at 6 months with ESWT than placebo. Most studies were considered low quality.

Table 18. Comparison of Systematic Reviews with Meta-Analyses Assessing ESWT for Shoulder Tendinopathy

Study	Arirachakaran(2017)[45,]	Ioppolo (2013)[46,]	Wu (2017)[44,]
Ainsworth (2007)	●		
Albert (2007)			●
Cacchio (2006)	●	●	●
Cosentino (2003)	●	●	●
Cosentino (2004)			●
del Castillo-Gonzalez (2016)			●
de Witte (2013)	●		
Ebenbichler (1999)			●
Gerdesmeyer (2003)	●	●	●
Hearnden (2009)		●	●
Hsu (2008)	●	●	●
Ioppolo (2012)			●
Kim (2014)	●		●
Krasny (2005)	●		
Loew (1999)			●
Pan (2003)			●
Peters (2004)		●	
Pleiner (2004)			●
Rompe (1998)			●

ESWT: extracorporeal shockwave therapy

Table 19. Characteristics of Systematic Reviews with Meta-Analyses Assessing ESWT for Shoulder Tendinopathy

Study	Dates	Trials	Participants	N (Range)	Design	Duration
Arirachakaran (2017) [45,]	2003–2008	4	Patients with rotator cuff calcific tendinopathy	882 (136–302)	RCTs	6–12 months
Ioppolo (2013) [46,]	2003–2009	6	Adults with shoulder pain or tenderness from calcific tendinitis with type I or II calcification	460 (20–144)	RCTs	1 week–1 year
Wu (2017) [44,]	1998–2016	5	Adults with clinical symptoms related to calcific tendinitis of the shoulder	370 (20–144)	RCTs	1 month–1 year

Table 20. Results of Systematic Reviews with Meta-Analyses Assessing ESWT, H-ESWT, L-ESWT, and rESWT for Shoulder Tendinopathy

Study	VAS Score Improvement/Pain Reduction	CMS/SPADI/Functional Improvement	Decrease in Calcium Deposit Size
ESWT			
Arirachakaran (2017) [45,]			
I^2 %	95.8	92.4	97.4
UMD	-4.4	23.3	-11.3 mm
95% CI	-6.3 to -2.3	9.8–17.6	-24.7–2.2
P-value	<0.05	<0.05	>0.05
Ioppolo (2013) [46,]			
Pooled total resorption ratio	-	-	27.19
95% CI	-	-	7.20–102.67
P-value			0.552
Pooled partial resorption ratio	-	-	16.22
95% CI	-	-	3.33–79.01
P-value			0.845
H-FSW			
Wu (2017) [44,]			
WMD	4.18	-	-
95% CrI	1.99–6.37	-	-
L-FSW			

Study	VAS Score Improvement/Pain Reduction	CMS/SPADI/Functional Improvement	Decrease in Calcium Deposit Size
WMD	1.94	-	-
95% CrI	-0.42–4.30	-	-
rESWT			
WMD	6.12	-	-
95% CrI	3.91–8.34	-	-

CI: confidence interval; H-ESWT: high-energy/intensity extracorporeal shockwave therapy; L-ESWT: low-energy/intensity extracorporeal shockwave therapy; rESWT: radial extracorporeal shockwave therapy; VAS: visual analog scale used to measure pain; CMS: Constant-Murley Score; SPADI: Shoulder Pain And Disability Index; SMD: standard mean difference; OR: odds ratio; CSI: corticosteroid injection; RR: risk ratio; UMD: unstandardized mean difference; WMD: weighted mean difference; H-FSW: high-energy focused extracorporeal shockwave therapy; L-FSW: low-energy focused extracorporeal shockwave therapy; CrI: credibility interval; SE: supervised exercise; MD: mean difference.

The following systematic reviews are mostly qualitative in nature and are not included in the summary tables.

In a systematic review by Yu et al (2015) of RCTs of various passive physical modalities for shoulder pain, which included 11 studies considered at low risk of bias, 5 studies reported on ESWT.[47,] Three, published from 2003 to 2011, assessed calcific shoulder tendinopathy, including 1 RCT comparing high-energy ESWT with low-energy ESWT (N=80), 1 RCT comparing RSW with sham ESWT (N=90), and 1 RCT comparing high-energy ESWT with low-energy ESWT and sham ESWT (N=144). All 3 trials reported statistically significant differences between groups for change in VAS score for shoulder pain.

In another meta-analysis of RCTs comparing high-energy with low-energy ESWT, Verstraelen et al (2014) evaluated 5 studies (total N=359 patients) on calcific shoulder tendinitis.[48,] Three were considered high quality. High-energy ESWT was associated with significant improvements in functional outcomes, with a mean difference at 3 months of 9.88 (95% CI, 0.04 to 10.72; p<0.001). High-energy ESWT was more likely to lead to resolution of calcium deposits at 3 months (pooled odds ratio, 3.4; 95% CI, 1.35 to 8.58; p=0.009). The pooled analysis could not be performed for 6-month follow-up data.

Bannuru et al (2014) published a systematic review of RCTs comparing high-energy ESWT with placebo or low-energy ESWT for the treatment of calcific or noncalcific shoulder tendinitis.[49,] All 7 studies comparing ESWT with placebo for calcific tendinitis reported significant improvements in pain or functional outcomes associated with ESWT. Only high-energy ESWT was consistently associated with significant improvements in both pain and functional outcomes. Eight studies comparing high- with low-energy ESWT for calcific tendinitis did not demonstrate significant improvements in pain outcomes, although shoulder function improved. Trials were reported to be of low quality with a high risk of bias.

Huisstede et al (2011) published a systematic review of RCTs that included 17 RCTs on calcific (n=11) and noncalcific (n=6) tendinopathy of the rotator cuff.[50,] Moderate-quality evidence was found for the efficacy of ESWT versus placebo for calcific tendinopathy, but not for noncalcific

tendinopathy. High-frequency ESWT was found to be more efficacious than low-frequency ESWT for calcific tendinopathy.

Randomized Controlled Trials

An RCT by Kvalvaag et al (2017) randomized patients with subacromial shoulder pain to RSW plus supervised exercise (n=74) or to sham treatment plus supervised exercise (n=69).[51,52,] Patients received 4 treatments of RSW or sham at 1-week intervals. After 24 weeks of follow-up, both groups improved from baseline, with no significant differences between groups. Within a prespecified subgroup of patients with calcification in the rotator cuff, there was a statistically significant improvement in the group receiving ESWT compared with sham treatment (p=0.18). After 1 year, there was no statistically significant difference in improvements between RSW and sham when groups were analyzed together and separately.

An RCT by Kim et al (2016) evaluated the use of ESWT in patients with calcific tendinitis.[53,] All patients received nonsteroidal anti-inflammatory drugs, transcutaneous electrical nerve stimulation, and ultrasound therapy (N=34). A subset (n=18) also received ESWT, 3 times a week for 6 weeks. CMS was measured at 2, 6, and 12 weeks. Both groups improved significantly from baseline. The group receiving ESWT improved significantly more than the control group; however, the lack of a sham control limits interpretability of results.

The following are select trials included in the systematic reviews described above.

Kim et al (2014) compared UGPL plus SAI with ESWT in patients who had unilateral calcific shoulder tendinopathy and ultrasound-documented calcifications of the supraspinatus tendon.[54,] Sixty-two patients were randomized. Fifty-four patients were included in the data analysis (8 subjects were lost to follow-up). ESWT was performed for 3 sessions once weekly. The radiologic evaluation was blinded, although it was not specified whether evaluators for pain and functional outcomes were blinded. After an average follow-up of 23.0 months (range, 12.1-28.5 months), functional outcomes improved in both groups: for the UGPL plus SAI group, scores on the American Shoulder and Elbow Surgeons scale improved from 41.5 to 91.1 (p=0.001) and on the Simple Shoulder Test from 38.2% to 91.7% (p=0.03). In the ESWT group, scores on the American Shoulder and Elbow Surgeons scale improved from 49.9 to 78.3 (p=0.026) and on the Simple Shoulder Test from 34.0% to 78.6% (p=0.017). Similarly, VAS pain scores improved from baseline to the last follow-up in both groups. At the last follow-up visit, calcium deposit size was smaller in the UGPL plus SAI group (0.5 mm) than in the ESWT group (5.6 mm; p=0.001).

An example of a high-energy versus low-energy trial is that by Schofer et al (2009), which assessed 40 patients with rotator cuff tendinopathy.[55,] An increase in function and reduction of pain were found in both groups (p<0.001). Although improvement in the Constant score was greater in the high-energy group, there were no statistically significant differences in any outcomes studied (Constant score, pain, subjective improvement) at 12 weeks, or at 1 year posttreatment.

At least 1 RCT has evaluated patients with bicipital tendinitis of the shoulder.[56,] This trial by Liu et al (2012) randomized 79 patients with tenosynovitis to ESWT or to sham treatment. ESWT was given for 4 sessions over 4 weeks. Outcomes were measured at up to 12 months using a VAS for pain and the L'Insalata Shoulder Questionnaire. The mean decrease in the VAS score at 12 months was greater for the ESWT group (4.24 units) than for the sham group (0.47 units;

p<0.001). There were similar improvements in the L'Insalata Shoulder Questionnaire, with scores in the ESWT group improving by 22.8 points.

Section Summary: Shoulder Tendinopathy
A number of small RCTs, summarized in several systematic reviews and meta-analyses, have evaluated the use of ESWT to treat shoulder tendinopathy. Network meta-analyses focused on 3 outcomes: pain reduction, functional assessment, and change in calcific deposits. One network meta-analysis separated trials using H-FSW, L-FSW, and RSW. It reported that the most effective treatment for pain reduction was UGN, followed by RSW and H-FSW. The only treatment showing a benefit in functional outcomes was H-FSW. For the largest change in calcific deposits, the most effective treatment was UGN, followed by RSW and H-FSW. Although some trials have reported a benefit for pain and functional outcomes, particularly for high-energy ESWT for calcific tendinopathy, many available trials have been considered poor quality. More high-quality trials are needed to determine whether ESWT improves outcomes for shoulder tendinopathy.

ACHILLES TENDINOPATHY

Clinical Context and Therapy Purpose
The purpose of ESWT is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as conservative therapy (eg, physical therapy) and nonsteroidal anti-inflammatory therapy, in patients with Achilles tendinopathy.
The question addressed in this evidence review is: Does the use of ESWT for Achilles tendinopathy improve the net health outcome?

The following PICO was used to select literature to inform this review.

Patients
The relevant population of interest is individuals with Achilles tendinopathy.

Interventions
The therapy being considered is ESWT.

Comparators
Comparators of interest include conservative therapy (eg, physical therapy) and nonsteroidal anti-inflammatory therapy. Comparators are actively managed by orthopedic surgeons, physical therapists, and primary care providers in an outpatient clinical setting.

Outcomes
The general outcomes of interest are symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity.

Table 21. Outcomes of Interest for Individuals with Achilles Tendinopathy

Outcomes	Details	Timing
Symptoms	• Pain improvement via VAS assessment • Victorian Institute of Sports Assessment-Achilles (measures redness, warmth, swelling, tenderness, edema) • American Orthopedic Foot And Ankle Score (AOFAS) for pain[1] • Roles and Maudsley pain scores of "good" or "excellent"	4 weeks to > 1 year
Functional outcome	• American Orthopedic Foot And Ankle Score (AOFAS) for function • Roles and Maudsley function scores of "good" or "excellent"	4 weeks to > 1 year
Quality of life		
Medication use		

1 Researchers concluded that AOFAS might not be appropriate to evaluate treatment of Achilles tendinopathy.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess longer term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought. Studies with duplicative or overlapping populations were excluded.

Review of Evidence

Systematic Reviews

Mani-Babu et al (2015) reported on results of a systematic review of studies evaluating ESWT for lower-limb tendinopathies.[57,] Reviewers included 20 studies, 11 of which evaluated ESWT for Achilles tendinopathy (5 RCTs, 4 cohort studies, 2 case-control studies). In the pooled analysis, reviewers reported that evidence was limited, but showed that ESWT was associated with greater short-term (<12 months) and long-term (>12 months) improvements in pain and function compared with nonoperative treatments, including rest, footwear modifications, anti-inflammatory medication, and gastrocnemius-soleus stretching and strengthening. Reviewers noted that findings from RCTs of ESWT for Achilles tendinopathy were contradictory, but that some evidence supported short-term improvements in function with ESWT. Reviewers warned that results be interpreted cautiously due to the heterogeneity in patient populations (age, insertional versus mid-portion Achilles tendinopathy) and treatment protocols.

Al-Abbad and Simon (2013) conducted a systematic review of 6 studies on ESWT for Achilles tendinopathy.[58,] Selected for the review were 4 small RCTs and 2 cohort studies. Satisfactory evidence was found in 4 studies demonstrating the effectiveness of ESWT in the treatment of

Achilles tendinopathy at 3 months. However, 2 RCTs found no significant difference between ESWT and placebo in the treatment of Achilles tendinopathy. These trials are described next.[59,60,]

Randomized Controlled Trials

Pinitkwamdee et al (2020) conducted a double-blind, randomized trial to compare the effectiveness of low-energy ESWT (n=16) with sham controls (n=15) in patients with chronic insertional Achilles tendinopathy.[61,] The primary outcomes consisted of changes in VAS pain scores and VAS foot and ankle pain scores at time points ranging from 2 to 24 weeks. At 24 weeks, low-energy ESWT and sham controls revealed similar changes in VAS and VAS foot and ankle pain scores. But ESWT had a significant improvement in VAS scores compared with sham controls at weeks 4 to 12, based on which, authors concluded that ESWT may provide a short period of therapeutic effect.

Lynen et al (2017) published results from an RCT comparing 2 peri-tendinous hyaluronan injections (n=29) with 3 ESWT applications (n=30) for the treatment of Achilles tendinopathy.[62,]The primary outcome was percent change in VAS pain score at the 3-month follow-up. Other measurements included the Victorian Institute of Sports Assessment-Achilles, clinical parameters (redness, warmth, swelling, tenderness, edema), and patients' and investigators' impression of treatment outcome. Follow-up was conducted at 4 weeks, 3 months, and 6 months. Pain decreased in both groups from baseline, though percent decrease in pain was statistically larger in the hyaluronan injections group than in the ESWT group at all follow-up time points. Secondary outcomes also showed larger improvements in the hyaluronan injections group.

The 2 trials described next were included in the systematic reviews.

Rasmussen et al (2008) reported on a single-center, double-blind controlled trial with 48 patients, half randomized after 4 weeks of conservative treatment to 4 sessions of active RSW and half to sham ESWT.[60,] The primary end point was AOFAS score measuring function, pain, and alignment and VAS pain score. AOFAS score after treatment increased from 70 to 88 in the ESWT group and from 74 to 81 in the control (p=0.05). The pain was reduced in both groups, with no statistically significant difference between groups. The authors suggested that the AOFAS might not be appropriate to evaluate treatment of Achilles tendinopathy.

Costa et al (2005) reported on a randomized, double-blind, placebo-controlled trial of ESWT for chronic Achilles tendon pain treated monthly for 3 months.[59,] The trial randomized 49 participants and was powered to detect a 50% reduction in VAS pain scores. No differences in pain relief at rest or during sports participation were found at 1 year. Two older ESWT-treated participants experienced tendon ruptures.

Section Summary: Achilles Tendinopathy

Two systematic reviews of RCTs and 2 RCTs published after the systematic reviews have evaluated the use of ESWT for Achilles tendinopathy. In the most recent systematic review, a pooled analysis found that ESWT reduced both short- and long-term pain compared with nonoperative treatments, although these reviewers warned that results were inconsistent across the RCTs and that there was heterogeneity across patient populations and treatment protocols. An RCT published after the systematic review compared ESWT with hyaluronan injections and reported improvements in both treatment groups, although significantly higher in the injection

group. Another RCT found no difference in pain scores between low-energy ESWT and sham controls at week 24, but ESWT may provide short therapeutic effects at weeks 4 to 12.

PATELLAR TENDINOPATHY

Clinical Context and Therapy Purpose

The purpose of ESWT is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as conservative therapy (eg, physical therapy) and nonsteroidal anti-inflammatory therapy, in patients with patellar tendinopathy.

The question addressed in this evidence review is: Does the use of ESWT for patellar tendinopathy improve the net health outcome?

The following PICO was used to select literature to inform this review.

Patients

The relevant population of interest is individuals with patellar tendinopathy.

Interventions

The therapy being considered is ESWT.

Comparators

Comparators of interest include conservative therapy (eg, physical therapy) and nonsteroidal anti-inflammatory therapy. Comparators are actively managed by orthopedic surgeons, physical therapists, and primary care providers in an outpatient clinical setting.

Outcomes

The general outcomes of interest are symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity.

Table 22. Outcomes of Interest for Individuals with Patellar Tendinopathy

Outcomes	Details	Timing
Symptoms	• Pain reduction via VAS assessment • Patellar tendon thickness • Victorian Institute of Sports Assessment-Patellar Tendon • McGill Pain Questionnaire • Roles and Maudsley score for pain • Likert scale/numerical rating scale for pain • Swelling	< 1 month to 1 year
Functional Outcomes	• Range of motion • Knee Outcome Survey Activities of Daily Living • Vertical jump test • Roles and Maudsley score for function • International Knee Documentation Committee scale	< 1 month to 1 year

Study Selection Criteria
Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess longer term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought. Studies with duplicative or overlapping populations were excluded.

Review of Evidence

Systematic Reviews
Liao et al (2018) examined RCTs to determine the clinical efficacy of ESWT of different shockwave types, energy levels, and durations to treat knee tendinopathies and other knee soft tissue disorders.[63,] Their review included 19 RCTs, encompassing 1189 participants. Of the participants, 562 underwent ESWT and 627 received a placebo or other conservative treatment. Analysis revealed that ESWT results in significant improvements in pain levels, with pooled standard mean difference of -1.49 (95% CI, -2.11 to -0.87; P<0.0001; I^2=95%) compared with the control groups. This effect resulted regardless of follow-up duration, type of shockwave, application level, or control intervention type. Four trials reported range of motion (ROM) recovery, specifically from focused SWT (FoSWT) and radial SWT (RaSWT), with significant pooled standard mean differences of 2.61 (95% CI, 2.11–3.12; P<0.0001; I^2=0%). In general, low-energy FoSWT was more effective in increasing treatment success rate than high-energy FoSWT; however, high-energy RaSWT was more effective than low-energy RaSWT. No severe adverse effects were reported with ESWT. Meta-analysis limitations include, but are not limited to, heterogeneity across trials; no consideration for other application parameters (rate of shocks, number of treatments, and treatment intervals); and high risk of selection, blinding, performance, and other biases.

Van Leeuwen et al (2009) conducted a literature review to study the effectiveness of ESWT for patellar tendinopathy and to draft a treatment protocol.[64,] Reviewers found that most of the 7 selected studies had methodologic deficiencies, small numbers and/or short follow-up periods, and variation in treatment parameters. Reviewers concluded ESWT appears to be a safe and promising treatment but could not recommend a treatment protocol.

In the systematic review of ESWT for lower-extremity tendinopathies (previously described), Mani-Babu et al (2015) identified 7 studies of ESWT for patellar tendinopathy (2 RCTs, 1 quasi-RCT, 1 retrospective cross-sectional study, 2 prospective cohort studies, 1 case-control study).[57,] The 2 RCTs came to different conclusions: 1 found no difference in outcomes between ESWT and placebo at 1, 12, or 22 weeks, whereas the other found improved outcomes on vertical jump test and Victorian Institute of Sport Assessment-Patellar scores at 12 weeks with ESWT compared with placebo. Two studies that evaluated outcomes beyond 24 months found ESWT comparable to patellar tenotomy surgery and better than nonoperative treatments.

Randomized Controlled Trials
An RCT by Thijs et al (2017) compared the use of ESWT plus eccentric training (n=22) with sham shock wave therapy plus eccentric training (n=30) for the treatment of patellar

tendinopathy.[65,] Patients were physically active with a mean age 28.6 years (range, 18-45 years). ESWT and sham shock wave were administered in 3 sessions, once weekly. Patients were instructed to perform eccentric exercises, 3 sets of 15 repetitions twice daily for 3 months on a decline board at home. Primary outcomes were Victorian Institute of Sport Assessment-Patellar score and pain score during functional knee loading tests (10 decline squats, 3 single leg jumps, 3 vertical jumps). Measurements were taken at baseline, 6, 12, and 24 weeks. There were no statistically significant differences between the ESWT and sham shock wave groups for any of the primary outcome measurements at any follow-up except for the vertical jump test at week 6.

In an RCT of patients with chronic patellar tendinopathy (N=46), despite at least 12 weeks of nonsurgical management, Smith and Sellon (2014) reported that improvements in pain and functional outcomes were significantly greater ($p<0.05$) with plasma-rich protein injections than with ESWT at 6 and 12 months, respectively.[66,]

Section Summary: Patellar Tendinopathy
The trials on the use of ESWT for patellar tendinopathy have reported inconsistent results and were heterogeneous in treatment protocols and lengths of follow-up.

MEDIAL TIBIAL STRESS SYNDROME

Clinical Context and Therapy Purpose
The purpose of ESWT is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as icing or support, in patients with medial tibial stress syndrome.

The question addressed in this evidence review is: Does the use of ESWT for medial tibial stress syndrome improve the net health outcome?

The following PICO was used to select literature to inform this review.

Patients
The relevant population of interest is individuals with medial tibial stress syndrome.

Interventions
The therapy being considered is ESWT.

Comparators
The comparator of interest is conservative therapy (eg, icing, support). Comparators are actively managed by orthopedic surgeons, physical therapists, and primary care providers in an outpatient clinical setting.

Outcomes
The general outcomes of interest are symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity.

Table 23. Outcomes of Interest for Individuals with Medial Tibial Stress Syndrome

Outcomes	Details	Timing
Symptoms	• 6-point Likert scale for pain • Self-reported pain during bone pressure, muscle pressure, or while running	1 to 15 months from baseline

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess longer term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought. Studies with duplicative or overlapping populations were excluded.

Review of Evidence

Randomized and Nonrandomized Studies

Newman et al (2017) published a double-blind, sham-controlled randomized trial on the use of ESWT for the treatment of 28 patients with medial tibial stress syndrome (MTSS; commonly called shin splints).[67,] Enrolled patients had running-related pain for at least 21 days confined to the posteromedial tibia, lasting for hours or days after running. Patients received treatments (ESWT or sham) at weeks 1, 2, 3, 5, and 9 and were instructed to keep activity levels as consistent as possible. At week 10 measurements, there was no difference between the treatment and control groups in self-reported pain during bone pressure, muscle pressure, or during running. There was no difference in pain-limited running distances between groups.

Rompe et al (2010) published a report on the use of ESWT in medial tibial stress syndrome.[68,] In this nonrandomized cohort study, 47 patients with MTSS for at least 6 months received 3 weekly sessions of RSW and were compared with 47 age-matched controls at 4 months. Mild adverse events were noted in 10 patients: skin reddening in 2 patients and pain during the procedure in 8 patients. Patients rated their condition on a 6-point Likert scale. Successful treatment was defined as self-rating "completely recovered" or "much improved." The authors reported a success rate of 64% (30/47) in the treatment group compared with 30% (14/47) in the control group. In a comment, Barnes (2010) raised several limitations of this nonrandomized study, including the possibility of selection bias.[69,]

Section Summary: Medial Tibial Stress Syndrome

Evidence for the use of ESWT for MTSS includes a small RCT and a small nonrandomized study. The RCT showed no differences in self-reported pain measurements between study groups. The nonrandomized trial reported improvements with ESWT, but selection bias limited the strength of the conclusions.

OSTEONECROSIS OF THE FEMORAL HEAD

Clinical Context and Therapy Purpose
The purpose of ESWT is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as medication (eg, alendronate) or hip arthroplasty, in patients with osteonecrosis of the femoral head.
The question addressed in this evidence review is: Does the use of ESWT for osteonecrosis of the femoral head improve the net health outcome?
The following PICO was used to select literature to inform this review.

Patients
The relevant population of interest is individuals with osteonecrosis of the femoral head.

Interventions
The therapy being considered is ESWT.

Comparators
Comparators of interest include medication and hip arthroplasty. Comparators are actively managed by orthopedic surgeons, physical therapists, and primary care providers in an inpatient (for hip arthroplasty) or outpatient clinical setting.

Outcomes
The general outcomes of interest are symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity.

Table 24. Outcomes of Interest for Individuals with Osteonecrosis of the Femoral Head

Outcomes	Details	Timing
Symptoms	• Pain reduction via VAS assessment • Harris Hip Scores for pain • Radiographic reduction of bone marrow edema on magnetic resonance imaging	3 months to > 24 months
Functional outcomes	• Harris Hip Scores for function	3 months to > 24 months

Study Selection Criteria
Methodologically credible studies were selected using the following principles:
- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess longer term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought. Studies with duplicative or overlapping populations were excluded.

Review of Evidence

Systematic Reviews
In their meta-analysis, Hao et al (2018) compared the effectiveness of ESWT with other treatment strategies in improving pain scores and Harris Hip Score (HHS) for patients with

osteonecrosis of the femoral head (ONFH).[70,] Their search for interventional studies published in Chinese or English yielded 4 articles with a total of 230 patients, most of whom were in stages I–III of ONFH. Before treatment, no significant differences in pain scores (P=0.1328) and HHSs (P=0.287) were found between the ESWT group (n=130) and control group (n=110). Post-treatment, the ESWT group reported significantly higher improvement in pain scores than the control group (standard mean difference , -2.1148; 95% CI, -3.2332 to -0.9965; Z=3.7063; P=0.0002), as well as higher HHSs (standard mean difference , 2.1377; 95% CI, 1.2875–2.9880; Z=4.9281; P<0.001). However, the analysis revealed no significant improvements in pain scores before and after treatment (P=0.005), but it did reveal significant improvements in the HHS (P<0.001). Patient follow-up time across studies ranged from 3 to 25 months. This analysis has several limitations: only 1 RCT is included out of 4 studies; small sample size results in more pronounced heterogeneity between studies; the studies are of poor quality; publication bias was detected for the HHS after treatment; and only 2 studies reported pain scores.

A systematic review by Zhang et al (2016) evaluated evidence on the use of ESWT for osteonecrosis of the femoral head.[71,] The literature search, conducted through July 2016, identified 17 studies for inclusion (9 open-label studies, 4 RCTs, 2 cohort studies, 2 case reports). Study quality was assessed using the Oxford Centre of Evidence-Based Medicine Levels of Evidence (I = highest quality and V = lowest quality, and each level can be subdivided a through c). Four studies were IBM, 2 studies were IIb, and 11 studies were IV. Most studies included patients with Association Research Circulation Osseous categories I through III (out of 5 stages of osteonecrosis). Outcomes in most studies were VAS pain score and Harris Hip Score, a composite measure of pain and hip function. Reviewers concluded that ESWT can be a safe and effective method to improve motor function and relieve pain, particularly in patients with early-stage osteonecrosis. Studies that included imaging results showed that bone marrow edema could be relieved, but that necrotic bone was not reversed. Evidence limitations included the heterogeneity of treatment protocol (numbers of sessions, energy intensities, focus sizes differed among studies) and most studies were of low quality.

A systematic review of ESWT for osteonecrosis (avascular necrosis) of the femoral head was conducted by Alves et al (2009).[72,] The literature search conducted through 2009 identified 5 articles, all from non-U.S. sites (2 RCTs, 1 comparative study, 1 open-label study, 1 case report; total N=133 patients). Of the 2 RCTs, 1 randomized 48 patients to the use of concomitant alendronate; both arms received ESWT treatments and therefore ESWT was not a comparator. The other RCT compared ESWT with a standard surgical procedure. All results noted a reduction in pain during the trial, which the authors attributed to ESWT. However, reviewers, when discussing the limitations of the available evidence, noted a lack of double-blind designs, small numbers of patients enrolled, short follow-up times, and nonstandard interventions (eg, energy level, the number of treatments).

Section Summary: Osteonecrosis of the Femoral Head
The body of evidence on the use of ESWT for osteonecrosis of the femoral head consists of 3 systematic reviews of small, mostly nonrandomized studies. Many of the studies were low quality and lacked comparators. While most studies reported favorable outcomes with ESWT, limitations such as the heterogeneity in the treatment protocols, patient populations, and lengths of follow-up make conclusions on the efficacy of ESWT for osteonecrosis uncertain.

NONUNION OR DELAYED UNION OF ACUTE FRACTURE

Clinical Context and Therapy Purpose

The purpose of ESWT is to provide a treatment option that is an alternative to or an improvement on surgical therapy for patients with acute fracture nonunion or delayed union.

The question addressed in this evidence review is: Does the use of ESWT for acute fracture nonunion or delayed union improve the net health outcome?

The following PICO was used to select literature to inform this review.

Patients

The relevant population of interest is individuals with acute fracture nonunion or delayed union.

Interventions

The therapy being considered is ESWT.

Comparators

The comparator of interest is surgical therapy. This comparator is actively managed by orthopedic surgeons in an inpatient or outpatient clinical setting.

Outcomes

The general outcomes of interest are symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity.

Table 25. Outcomes of Interest for Individuals with Acute Fracture Nonunion or Delayed Union

Outcomes	Details	Timing
Symptoms	• Pain reduction via VAS assessment • Radiographic evidence of healing	6 to 12 months
Functional outcomes	• Weight-bearing status	6 to 12 months

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess longer term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought. Studies with duplicative or overlapping populations were excluded.

Review of Evidence

Systematic Reviews

Zelle et al (2010) published a review of the English and German medical literature on ESWT for the treatment of fractures and delayed union/nonunion.[73,] Limiting the review to studies with

more than 10 patients, reviewers identified 10 case series and 1 RCT. The number of treatment sessions, energy levels, and definitions of nonunion varied across studies; union rates after the intervention were likewise defined heterogeneously, ranging from 40.7% to 87.5%. Reviewers concluded the overall quality of evidence was conflicting and of poor quality.

Randomized Controlled Trials

The RCT in the Zelle et al (2010) review reported on the use of ESWT in acute long bone fractures.[74,] Wang et al (2007) randomized 56 trauma patients with femur or tibia fractures to a single ESWT treatment following surgical fixation while still under anesthesia. Patients in the control group underwent surgical fixation but did not receive the ESWT. Patients were evaluated for pain and percent weight-bearing capability by an independent, blinded evaluator at 3, 6, and 12 months. Radiographs taken at these same intervals were evaluated by a radiologist blinded to study group assignment. Both groups showed significant improvements in pain scores and weight-bearing status. Between-group comparisons of VAS pain and weight bearing favored ESWT patients at each interval. At 6 months, patients who had received ESWT had VAS scores of 1.2 compared with 2.5 in the control group ($p<0.001$); mean percentage of weight bearing at 6 months was 87% and 78%, respectively ($p=0.01$). Radiographic evidence of union at each interval also favored the ESWT group. At 6 months, 63% (17/27) of the treatment group achieved fracture union compared with 20% (6/30) in the control group ($p<0.001$). The authors noted some limitations of the trial: the small number of patients enrolled, surgeries performed by multiple surgeons, and questions about the adequacy of randomization.

RCTs published after the review are described next. They include the multicenter RCT by Cacchio et al (2009), which randomized 126 patients into 3 groups: low-energy ESWT, high-energy ESWT therapy, or surgery.[75,] Nonunion fractures were defined as at least 6 months without evidence of radiographic healing. The primary end point was radiographic evidence of healing. Secondary end points were pain and functional status, collected by blinded evaluators. Neither patients nor treating physicians were blinded. At 6 months, healing rates in the low-energy ESWT, high-energy ESWT, and surgical arms were similar (70%, 71%, 73%, respectively). All groups' healing rates improved at 12- and 24-month follow-ups, without significant between-group differences. Secondary end points of pain and disability were also similar. Lack of blinding might have led to differing levels of participation in other aspects of the treatment protocol.

A study by Zhai et al (2016) evaluated the use of human autologous bone mesenchymal stem cells combined with ESWT for the treatment of nonunion long bones.[76,] Nonunion was defined as 6 or more months post fracture with no evidence of additional healing in the past 3 months. Patients were randomized to high-energy ESWT (n=31) or human autologous mesenchymal stem cells plus ESWT (n=32). ESWT was administered every 3 days, 4 times for upper-limb nonunion and 5 times for lower-limb nonunion. Outcome measures were no pain, no abnormal mobility, an x-ray showing blurred fracture line, and upper-limb holding 1 kg for 1 minute or lower-limb walking for 3 minutes. Success was defined as meeting all 4 criteria at 12 months. The human autologous stem cells plus ESWT group experienced an 84% healing rate. The ESWT alone group experienced a 68% healing rate ($p<0.05$).

Section Summary: Nonunion or Delayed Union of Acute Fracture

The evidence on the use of ESWT for the treatment of fractures or for fracture nonunion or delayed union includes several relatively small RCTs with methodologic limitations (eg, heterogeneous outcomes and treatment protocols), along with case series. The available

evidence does not permit conclusions on the efficacy of ESWT in fracture nonunion, delayed union, or acute long bone fractures.

SPASTICITY

Clinical Context and Therapy Purpose
The purpose of ESWT is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as medication and intrathecal medication therapy, in patients with spasticity.

The question addressed in this evidence review is: Does the use of ESWT for spasticity improve the net health outcome?

The following PICO was used to select literature to inform this review.

Patients
The relevant population of interest is individuals with spasticity.

Interventions
The therapy being considered is ESWT.

Comparators
Comparators of interest are medication and intrathecal medication therapy. Comparators are actively managed by orthopedic surgeons, physical therapists, and primary care providers, generally in an outpatient clinical setting.

Outcomes
The general outcomes of interest are symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity.

Table 26. Outcomes of Interest for Individuals with Spasticity

Outcomes	Details	Timing
Symptoms	• Modified Ashworth Scale for assessing resistance during soft-tissue stretching • Passive range of motion with goniometer	4 weeks to 3 months
Function outcomes	• Brunnstrom Recovery Stage tool to assess motor recovery	Up to 5 weeks post-therapy

Study Selection Criteria
Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess longer term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought. Studies with duplicative or overlapping populations were excluded.

Review of Evidence

Systematic Reviews

Cabanas-Valdes et al (2020) performed a meta-analysis of 16 RCTs evaluating the effectiveness of ESWT on spasticity of the upper limb in 764 patients who survived stroke.[77,] Compared with sham therapy, ESWT significantly improved the Modified Ashworth Scale scores (mean difference, -0.28; 95% CI, -0.54 to -0.03). The addition of ESWT to conventional physiotherapy also provided improvement in the Modified Ashworth Scale scores compared with conventional physiotherapy only (mean difference, -1.78; 95% CI, -2.02 to -1.53). Some limitations of this meta-analysis consist of studies with small sample sizes, unclear monitoring and follow-up procedures for interventions, and heterogeneity among the included studies.

Jia et al (2020) conducted a meta-analysis of 8 RCTs evaluating the effectiveness of ESWT on post-stroke spasticity in 301 patients.[78,] At long-term follow-up, ESWT significantly reduced Modified Ashworth Scale scores (weighted mean difference, -0.36; 95% CI, -0.53 to -0.19; $p<0.001$; $I^2=15\%$) compared with controls. Controls varied among included studies and comprised rehabilitation therapy, oral anti-spastic medications, sham therapy, botulinum toxin type A, stretching exercises, and/or physical therapy.

Kim et al (2019) performed a meta-analysis of 5 RCTs evaluating the effectiveness of ESWT on reducing spasticity in patients with cerebral palsy.[79,] Compared with controls, ESWT significantly improved Modified Ashworth Scale scores (mean difference, -0.62; 95% CI, -1.05 to -0.18; $p<0.00001$; $I^2=86\%$). Controls included placebo or no therapy.

Lee et al (2014) conducted a meta-analysis of studies evaluating ESWT for patients with spasticity secondary to a brain injury.[80,] Studies included evaluated ESWT as sole therapy and reported pre- and postintervention Modified Ashworth Scale scores. Five studies were selected, 4 examining spasticity in the ankle plantar flexor and 1 examining spasticity in the wrist and finger flexors; 3 studies evaluated poststroke spasticity and 2 evaluated spasticity associated with cerebral palsy. Immediately post-ESWT, Modified Ashworth Scale scores improved significantly compared with baseline (standardized mean difference, -0.792; 95% CI, -1.001 to -0.583; $p<0.001$). Four weeks post-ESWT, Modified Ashworth Scale scores continued to demonstrate significant improvements compared with baseline (standardized mean difference, -0.735; 95% CI, -0.951 to -0.519; $p<0.001$). A strength of this meta-analysis was its use of a consistent and well-definable outcome measure. However, the Modified Ashworth Scale does not account for certain clinically important factors related to spasticity, including pain and functional impairment.

Randomized Controlled Trials

Li et al (2020) assessed the effects of radial ESWT on agonist muscles (n=27) and antagonist muscles (n=30) compared with control (n=25) in patients with stroke.[81,] All patients received conventional physical therapy for 3 weeks. Radial ESWT was administered at 4-day intervals for 5 consecutive treatments on either agonist or antagonist muscles. After treatment and 4 weeks of follow-up, the changes in the Modified Ashworth Scale scores were 24% for the control group, 74.1% for the agonist muscle group receiving radial ESWT, and 66.7% for the antagonist muscle group receiving radial ESWT, with statistical significance at $p<0.01$ among the 3 groups. The authors concluded that radial ESWT is effective for spasticity after stroke and may have lasting effects up to 4 weeks after the treatment.

Wu et al (2018) evaluated whether ESWT is noninferior to botulinum toxin type A for poststroke upper limb spasticity among 42 patients with chronic stroke.[82,] At week 4, the change from baseline of the Modified Ashworth Scale score of the wrist flexors was -0.80 with ESWT and -0.9 with botulinum toxin type A; the difference between the 2 groups was within the prespecified margin of 0.5, meeting the noninferiority of ESWT to botulinum toxin type A.

The efficacy and safety of RSW in the treatment of spasticity in patients with cerebral palsy were examined in a small European RCT.[83,] As reported by Vidal et al (2011), the 15 patients in this trial were divided into 3 groups (ESWT in a spastic muscle, ESWT in both spastic and antagonistic muscle, placebo ESWT) and treated in 3 weekly sessions. Spasticity was evaluated in the lower limbs by passive range of motion with a goniometer and in the upper limbs with the Ashworth Scale (0 [not spasticity] to 4 [severe spasticity]) at 1, 2, and 3 months posttreatment. The blinded evaluation showed significant differences between the ESWT and placebo groups for range of motion and Ashworth Scale score. For the group in which only the spastic muscle was treated, there was a 1-point improvement on the Ashworth Scale (reported significant versus placebo); for the group with both spastic agonist and antagonist muscles treated, there was a 0.5-point improvement (p=NS versus placebo); and for the placebo group, there was no change. The significant improvements were maintained at 2 months posttreatment, but not at 3 months.

Section Summary: Spasticity
Limited RCT and systemic review evidence is available on the use of ESWT for spasticity, primarily in patients with stroke and cerebral palsy. Several studies have demonstrated improvements in spasticity measures after ESWT, but most studies have small sample sizes and single center design. More well-designed controlled trials in larger populations are needed to determine whether ESWT leads to clinically meaningful improvements in pain and/or functional outcomes for spasticity.

Extracorporeal Shock Wave Treatment for Other Conditions
ESWT has been investigated in small studies for other conditions, including coccydynia in a case series of 2 patients,[84,] painful neuromas at amputation sites in an RCT assessing 30 subjects,[85,] and chronic distal biceps tendinopathy in a case-control study of 48 patients.[86,] The systematic review of ESWT for lower-extremity tendinopathies (previously described) by Mani-Babu et al (2015) reviewed 2 studies of ESWT for greater trochanteric pain syndrome, including 1 quasi-RCT comparing ESWT with home therapy or corticosteroid injection and 1 case-control study comparing ESWT with placebo.[57,] ESWT was associated with some benefits compared with placebo or home therapy.

Summary of Evidence
For treatment of plantar fasciitis using ESWT, numerous randomized controlled trials (RCTs) were identified, including several well-designed double-blinded RCTs, that evaluated ESWT for the treatment of plantar fasciitis. Several systematic reviews and meta-analyses have been conducted, covering numerous studies, including studies that compared ESWT with corticosteroid injections. Pooled results were inconsistent. Some meta-analysis reported that ESWT reduced pain, while others reported nonsignificant pain reduction. Reasons for the differing results included lack of uniformity in the definitions of outcomes and heterogeneity in ESWT protocols (focused versus radial, low- versus high-intensity/energy, number and duration of shocks per treatment, number of treatments, and differing comparators). Some studies reported significant benefits in pain and functional improvement at 3 months, but it is not evident that the longer-

term disease natural history is altered with ESWT. Currently, it is not possible to conclude definitively that ESWT improves outcomes for patients with plantar fasciitis.

For individuals who have lateral epicondylitis who receive ESWT, the most direct evidence on the use of ESWT to treat lateral epicondylitis comes from multiple small RCTs, which did not consistently show outcome improvements beyond those seen in control groups. Relevant outcomes are symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity. The highest quality trials tend to show no benefit, and systematic reviews have generally concluded that the evidence does not support a treatment benefit over placebo or no treatment. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have shoulder tendinopathy who receive ESWT, a number of small RCTs, summarized in several systematic reviews and meta-analyses, comprise the evidence. Relevant outcomes are symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity. Network meta-analyses focused on 3 outcomes: pain reduction, functional assessment, and change in calcific deposits. One network meta-analysis separated trials using high-energy focused shock wave FSW (H-FSW), low-energy focused shock wave, and radial shock wave (RSW). It reported that the most effective treatment for pain reduction was ultrasound-guided needling, followed by RSW and H-FSW. The only treatment showing a benefit in functional outcomes was H-FSW. For the largest change in calcific deposits, the most effective treatment was ultrasound-guided needling followed by RSW and H-FSW. Although some trials have reported a benefit for pain and functional outcomes, particularly for high-energy ESWT for calcific tendinopathy, many available trials have been considered poor quality. More high-quality trials are needed to determine whether ESWT improves outcomes for shoulder tendinopathy. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have Achilles tendinopathy who receive ESWT, the evidence includes systematic reviews of RCTs and RCTs published after the systematic review. Relevant outcomes are symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity. In the most recent systematic review, a pooled analysis found that ESWT reduced both short- and long-term pain compared with nonoperative treatments, although reviewers warned that results were inconsistent across the RCTs and that there was heterogeneity across patient populations and treatment protocols. An RCT published after the systematic review compared ESWT with hyaluronan injections and reported improvements in both treatment groups, although the improvements were significantly higher in the injection group. Another RCT found no difference in pain scores between low-energy ESWT and sham controls at week 24, but ESWT may provide short therapeutic effects at weeks 4 to 12. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have patellar tendinopathy who receive ESWT, the trials have reported inconsistent results and were heterogeneous in treatment protocols and lengths of follow-up. Relevant outcomes are symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have medial tibial stress syndrome who receive ESWT, the evidence includes a small RCT and a small nonrandomized cohort study. Relevant outcomes are symptoms,

functional outcomes, quality of life, medication use, and treatment-related morbidity. The RCT showed no difference in self-reported pain measurements between study groups. The nonrandomized trial reported improvements with ESWT, but selection bias limited the strength of the conclusions. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have osteonecrosis of the femoral head who receive ESWT, the evidence includes 3 systematic reviews of small, mostly nonrandomized studies. Relevant outcomes are symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity. Many of the studies were low quality and lacked comparators. While most studies reported favorable outcomes with ESWT, limitations such as heterogeneity in the treatment protocols, patient populations, and lengths of follow-up make conclusions on the efficacy of ESWT for osteonecrosis uncertain. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have nonunion or delayed union who receive ESWT, the evidence includes several relatively small RCTs with methodologic limitations (eg, heterogeneous outcomes and treatment protocols), along with case series. Relevant outcomes are symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity. The available evidence does not permit conclusions on the efficacy of ESWT in fracture nonunion, delayed union, or acute long bone fractures. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have spasticity who receive ESWT, the evidence includes RCTs and systematic reviews, primarily in patients with stroke and cerebral palsy. Several studies have demonstrated improvements in spasticity measures after ESWT, but most studies have small sample sizes and single center designs. Relevant outcomes are symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity. More well-designed controlled trials in larger populations are needed to determine whether ESWT leads to clinically meaningful improvements in pain and/or functional outcomes for spasticity. The evidence is insufficient to determine the effects of the technology on health outcomes.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

American College of Foot and Ankle Surgeons

In 2010, Thomas et al revised guidelines on the treatment of heel pain on behalf of the American College of Foot and Ankle Surgeons.[87,] The guidelines identified extracorporeal shock wave therapy (ESWT) as a third tier treatment modality in patients who have failed other interventions, including steroid injection. The guidelines recommended ESWT as a reasonable alternative to surgery. In update to the American College of Foot and Ankle Surgeons clinical consensus statement, Schneider et al stated that ESWT is a safe and effective treatment for plantar fasciitis.[88,]

National Institute for Health and Care Excellence

The National Institute for Health and Care Excellence has published guidance on ESWT for a number of applications.

- A guidance issued in 2003 stated that current evidence on safety and efficacy for treatment of calcific tendonitis of the shoulder "appears adequate to support the use of the procedure."[89,]
- The 2 guidance documents issued in 2009 stated that current evidence on the efficacy of ESWT for refractory tennis elbow and plantar fasciitis "is inconsistent."[90,91,]
- A guidance issued in 2011 stated that evidence on the efficacy and safety of ESWT for refractory greater trochanteric pain syndrome "is limited in quality and quantity."[92,]
- A guidance issued in 2016 stated that current evidence on the efficacy of ESWT for Achilles tendinopathy "is inconsistent and limited in quality and quantity."[93,]

Canadian Agency for Drugs and Technologies in Health

A 2007 summary by the Canadian Agency for Drugs and Technologies in Health (CADTH) noted that results from randomized trials of ESWT for plantar fasciitis have been conflicting.[94,]The report noted that the "lack of convergent findings from randomized trials of ESWT for chronic plantar fasciitis suggests uncertainty about its effectiveness. The evidence reviewed … does not support the use of this technology for this condition."

Similarly, a 2007 report by CADTH on ESWT for chronic lateral epicondylitis noted conflicting results from randomized trials (RCTs), with half showing no benefit over placebo for any outcome measures.[95,] The report noted that "the lack of convincing evidence regarding its effectiveness does not support the use of ESWT for CLE [chronic lateral epicondylitis]."

A third 2007 summary by CADTH concluded that "the current evidence supports the use of high-energy ESWT for chronic calcific rotator cuff tendonitis that is recalcitrant to conventional conservative treatment, although more high-quality RCTs with larger sample sizes are required to provide more convincing evidence."[96,]

A 2016 update from CADTH addressed the use of shockwave therapy for pain associated with upper- extremity orthopedic disorders.[97,] Based on results from 7 systematic reviews (with overlapping randomized controlled trials), the Agency concluded the following (see Table 27).

In 2019, the CADTH document on non-opioid options for managing pain stated "for plantar fasciitis, limited evidence suggests shock wave therapy is more effective than placebo and equally effective as platelet-rich plasma injection, corticosteroid injection, or surgery."[98,] For greater trochanteric pain syndrome, shock wave therapy has limited evidence on being more effective than conservative treatment and inconsistent evidence on effectiveness compared with corticosteroid injection or home-based physical training. For patellar tendinopathy, shock wave therapy may be more effective than conservative treatment and equally effective to surgery (based on limited evidence), but evidence is inconsistent when comparing with placebo or corticosteroid injection. For medial tibial stress syndrome, shock wave therapy with either conservative treatment or a running program may have "added benefit." The statements on shock wave therapy outcomes in shoulder tendinitis are consistent with the information in Table 27.

Table 27. Conclusions on the Use of ESWT for Upper-Extremity Pain

Condition	Evidence	Comparator	Conclusions
Shoulder			
Calcific tendonitis	Systematic reviews	Placebo	Effective in reducing pain
Noncalcific tendonitis	Systematic reviews	Placebo or other treatments	No significant benefit
Tendonitis	Single RCTs	Exercise or radiotherapy	No significant benefit
Tendonitis	1 RCT	Transcutaneous electric nerve stimulation	Effective in reducing pain
Elbow			
Lateral epicondylitis	Systematic reviews	Placebo	Inconclusive
Lateral epicondylitis	Single RCTs	Physical therapy or percutaneous tenotomy	No significant benefit
Lateral epicondylitis	Single RCTs	Corticosteroid injections	Inconclusive

ESWT: extracorporeal shockwave treatment; RCT: randomized controlled trial.

U.S. Preventive Services Task Force Recommendations

Not applicable.

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this review are listed in Table 28.

Table 28. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT02424084	Effects of Extracorporeal Shock Wave Therapy in Bone Microcirculation	80	Dec 2020
NCT02668510	A Randomized Controlled Trial Comparing Extracorporeal Shock Wave Therapy with Platelet Rich Plasma versus Extracorporeal Shock Wave Therapy in a High Demand Cohort with Resistant Plantar Fasciitis	30	Dec 2018 (unknown)
NCT03472989	The Effectiveness of Radial Extracorporeal Shockwave Therapy (rESWT), Sham- rESWT, Standardized Exercise Program or Usual Care for Patients With Plantar Fasciopathy. Study Protocol for a Double-blind, Randomized Sham-Controlled Trial	200	Mar 2022
NCT04365478	Effects of an Early Radial Shock Waves Therapy on Spasticity of the Upper Limb and on Functional Outcome in Patients With Stroke in Subacute Phase	28	Aug 2020

NCT No.	Trial Name	Planned Enrollment	Completion Date
NCT04332471	Treatment of Plantar Fasciitis With Radial Shockwave Therapy vs. Focused Shockwave Therapy: a Randomized Controlled Trial	104	Oct 2021
Unpublished			
NCT02613455	Prospective Randomized Trial Comparing Corticosteroid Injection to High Energy Extracorporeal Shock Wave Therapy for Lateral Epicondylitis	80	Dec 2016 (unknown)
NCT02757664	Shock Wave Therapy, Associated to Eccentric Strengthening Versus Isolated Eccentric Strengthening for Treating Insertional Achilles Tendinopathy: Double Blinded Randomized Clinical Trial	119	Jun 2020
NCT02546128	LEICSTES=LEICeSter Tendon Extracorporeal Shock Wave Studies Assessing the Benefits of the Addition of Extracorporeal Shock Wave Treatment to a Home-Rehabilitation Programme for Patients with Tendinopathy	720	Jun 2020
NCT03779919	The Therapeutic Effect of the Extracorporeal Shock Wave Therapy on Shoulder Calcific Tendinitis	90	May 2020
NCT03399968	Extracorporeal Shockwave Therapy (ESWT) in Patients Suffering From Complete Paraplegia at the Thoracic Level	25	May 2020

NCT: national clinical trial.

CODING

The following codes for treatment and procedures applicable to this policy are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

CPT/HCPCS

20999	Unlisted procedure, musculoskeletal system, general
28890	Extracorporeal shock wave, high energy, performed by a physician or other qualified health care professional, requiring anesthesia other than local, including ultrasound guidance, involving the plantar fascia
0101T	Extracorporeal shock wave involving musculoskeletal system, not otherwise specified, high energy
0102T	Extracorporeal shock wave, high energy, performed by a physician, requiring anesthesia other than local, involving lateral humeral epicondyle

- There is a CPT code for extracorporeal shock wave therapy (ESWT) for plantar fasciitis performed using high energy: 28890.
- There are category III CPT codes for other high-energy ESWT indications: 0101T, 0102T.
- High-energy ESWT requires the use of anesthesia and is performed in a hospital or ambulatory surgery center. Low-energy ESWT is usually applied in the office without anesthesia.
- There is no specific CPT code for low-energy or radial ESWT. The unlisted CPT code for general musculoskeletal procedure should be used: 20999.

ICD-10 Diagnoses

M72.2	Plantar fascial fibromatosis
M77.31	Calcaneal spur, right foot
M77.32	Calcaneal spur, left foot

REVISIONS

04-21-2005	Added "with at least six months between ESWT procedures" to Policy #5.
12-15-2005	In "Coding" CPT/HCPCS section, deleted CPT code 0020T and added CPT code 28890.
10-26-2012	In the Medical Policy Title, added "and Other Musculoskeletal Conditions" to read " Extracorporeal Shock Wave Therapy (ESWT) for Plantar Fasciitis and Other Musculoskeletal Conditions"
	Description section updated.
	In the Policy section: ▪ New policy language revised from the following: 1. Minimal six months of diagnosed plantar fasciitis pain. 2. Minimal six months of active professional treatment for the plantar fasciitis including a required treatment with: a. Non-steroidal anti-inflammatory drugs (NSAIDs) or b. Cortisone injections and c. A minimum of three (3) of the five (5) following conservative treatments: • Over the counter arch supports, insoles, or heel cups

	• Physical therapy, stretching, ultrasound, massage • Strapping immobilization • Night Splints • Custom orthotic devices 3. Failure of treatment to reasonable resolve plantar fasciitis symptoms patient continues to have intractable activity limiting pain. 4. Extracorporeal shock wave therapy (orthotripsy) is medically necessary for plantar fasciitis (heel spurs and chronic heel pain). 5. A maximum of three (3) orthotripsy treatments per each heel with at least six months between ESWT procedures on the same heel. 6. Fasciotomy should be the last procedure attempted or used in those patients who do not meet criteria for ESWT. 7. Extracorporeal shock wave therapy ESWT for chronic plantar fasciitis is comparable in relative value to a plantar fasciotomy (28008). ▪ In the Utilization section, #1, removed "The use of a high-energy (electrohydraulic or electromagnetic shock) machine approved by the FDA for chronic plantar fasciitis is covered. All other machines are considered experimental / investigational" and inserted "FDA approved device required." ▪ In the Utilization section, removed Item #2, "Review prior to initial and additional treatments." ▪ In the Utilization section, removed Item #3, "Criteria apply to EACH heel independently." ▪ In the Utilization section, inserted Item #5, "A maximum of 3 EWST per heel with at least 6 months between treatments will be allowed.
	Rationale section updated.
	Reference section updated.
05-07-2013	Description section updated.
	Rationale section updated.
	In Coding section: ▪ Added ICD-10 diagnosis codes. *(Effective October 1, 2014)*
	Reference section updated.
04-15-2014	In Policy section: ▪ Added to Item A "four of the six" to read, "… may be considered medically necessary for chronic intractable plantar fasciitis refractory to standard therapy with a minimum of six months of active professional treatment including four of the six:"
04-14-2015	Updated Description section.
	Updated Rationale section.
	In Coding section: ▪ Added CPT codes 0019T, 0101T, and 0102T.
	Updated References section.
08-04-2016	Updated Description section.
	Updated Rationale section.
	In Coding section: ▪ Added coding bullets.
	Updated References section.
01-01-2017	In Coding section: ▪ Deleted CPT code: 0019T *(Termed code, effective December 31, 2016).* ▪ Updated coding bullets.
08-10-2017	Policy added to the bcbsks.com website on 07-11-2017.
	Updated Description section.
	In Policy section:

	▪ In Item A, added "using a high-dose protocol" to read, "Extracorporeal shock wave therapy (ESWT) using a high-dose protocol may be considered medically necessary for chronic intractable plantar fasciitis refractory to standard therapy with a minimum of six months of active professional treatment including four of the six:" ▪ In Item B, added "using a high-dose protocol" to read, "Extracorporeal shock wave therapy (ESWT) using a high-dose protocol is considered experimental / investigational for other musculoskeletal conditions, including, but not limited to, tendinitis of the elbow (epicondylitis, tennis elbow)." ▪ Added Item C, "Extracorporeal shock wave therapy (ESWT) using a low-dose protocol or radial extracorporeal shock wave therapy is considered experimental / investigational as a treatment of musculoskeletal conditions, including, but not limited to, plantar fasciitis; tendinopathies including tendinitis of the shoulder, Achilles tendinitis, tendinitis of the elbow (lateral epicondylitis), and patellar tendinitis; stress fractures; delayed union and nonunion of fractures; avascular necrosis of the femoral head; and spasticity."
	Updated Rationale section.
	In Coding section: ▪ Added CPT code 20999. ▪ Updated coding bullets.
	Updated References section.
08-01-2018	Updated Description section.
	Updated Rationale section.
	In Coding section: ▪ Removed ICD-9 codes.
	Updated References section.
07-17-2019	Updated Description section.
	Updated Rationale section.
	In Coding section: ▪ Revised nomenclature to CPT code: 28890.
	Updated References section.
03-11-2021	Medical policy was reviewed with no revision.

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