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Extracorporeal Shock Wave Therapy for Musculoskeletal Indications and Soft Tissue Injuries

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Coverage

Extracorporeal shock wave therapy (ESWT) **is considered experimental, investigational and/or unproven** for all musculoskeletal indications and soft tissue injuries 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;
- Avascular necrosis of the femoral head;
- Delayed union and nonunion of fractures;
- Spasticity; and
- Wound healing.

Policy Guidelines

None.

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 (e.g., 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.

Chronic Musculoskeletal Conditions

Chronic musculoskeletal conditions (e.g., 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	• Rest • Activity modification • NSAIDs • Physical therapy • Orthotic devices	Corticosteroid injections; joint debridement (open or laparoscopic)

		terminal wrist flexion with elbow in full extension		
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 policy:

- 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 non-weight 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 Conditions/Neurologic Conditions/Soft Tissue Injuries

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. Examples of soft tissue injuries include both burn and soft tissue wounds.

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 two 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

Selected ESWT devices that have been approved or cleared by the U.S. FDA are included in Table 2.

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, i.e., pain persisting >6 months 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 months)
Orthospec™ Orthopedic ESWT (Medispec)	2005	Electrohydraulic spark-gap system	Chronic proximal plantar fasciitis in patients ≥18 years
Orbasone™ Pain Relief System (Orthometrix)	2005	High-energy sonic wave system	Chronic proximal plantar fasciitis in patients ≥18 years
Duolith® SD1 Shock Wave Therapy Device (Storz Medical AG)	2016	Electromagnetic delivery system	Chronic proximal plantar fasciitis in patients ≥18 years with history of failed alternative conservative therapies >6 months

FDA: 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 the 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. The Storz Medical Duolith SD1 shock wave therapy device (Storz Medical) received FDA approval for similar indications in January 2016. FDA product code: NBN. (1)

The Sanuwave dermaPACE System received FDA approval in December 2017 and is indicated to provide focal acoustic pressure shockwaves in the treatment of chronic, full-thickness diabetic foot ulcers with wound areas measuring no larger than 16 cm^2, which extend through the epidermis, dermis, tendon, or capsule, but without bone exposure. The dermaPACE System is indicated for adults (22 years and older), diabetic patients presenting with diabetic foot ulcers greater than 30 days in duration and is indicated for use in conjunction with standard diabetic ulcer care. FDA product code: PZL. (2)

Rationale

This medical policy has been updated regularly with searches using the PubMed database. The most recent literature update was performed through April 12, 2024.

The most clinically relevant outcome measures of extracorporeal shock wave treatment (ESWT) used for musculoskeletal conditions are pain and functional limitations. Pain is a subjective, patient-reported measure. Therefore, pain outcomes require quantifiable pre- and post-treatment measures. Pain is most commonly measured with a visual analog scale (VAS). Quantifiable pre- and post-treatment measures of functional status are also used, such as the 12-Item Short-Form Health Survey (SF-12) and 36-Item Short-Form Health Survey (SF-36). 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.

Medical policies 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, two domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one 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 (e.g., stretching, heel supports), nonsteroidal anti-inflammatory therapy, and local corticosteroid injection, in individuals with plantar fasciitis.

The following PICO were used to select literature to inform this policy.

Populations

The relevant population of interest is individuals with plantar fasciitis.

Interventions

The therapy being considered is ESWT.

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 (e.g., the heel). Shock waves are generated at high- or low-energy intensity, may be radial or focused, and treatment protocols can include more than one treatment. ESWT has been investigated for use in a variety of musculoskeletal conditions.

Comparators

Comparators of interest include conservative therapy (e.g., stretching, heel supports), nonsteroidal anti-inflammatory therapy, and local corticosteroid injection.

Outcomes

The general outcomes of interest are pain symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity. See table 3.

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

VAS: Visual Analogue Scale.

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.

Systematic Reviews

Meta-analyses of RCTs published in 2013 have reported that ESWT for plantar fasciitis is better than or comparable to placebo in reducing pain (3-5) and improving functional status in the short-term (Tables 4 to 6). (3, 4) However, the 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 (e.g., 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 (e.g., 3 months) is uncertain.

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. (6) The treatment success rate of the 5 trials (n=448 patients) that evaluated low-intensity ESWT showed it was more likely than the control to be successful (pooled relative risk, 1.69; 95% confidence interval [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.

A meta-analysis by Lou et al. (2017) evaluated the efficacy of ESWT without local anesthesia in patients with recalcitrant plantar fasciitis. (7) 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.

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]). (8) The literature search, conducted through July 2016, identified 9 trials for inclusion (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 6.

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. (9) 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 [MD], -1.67; 95% CI, -3.31 to -0.04; P=0.04; I^2=85%). However, high-intensity ESWT is more effective than corticosteroid injection (2–3 months post-treatment: MD, 1.12; 95% CI, 0.52–1.72; P=0.0003; I^2=59%). One study followed patients for 12 months post-treatment and found no significant difference in pain outcomes, and another found no significant difference in recurrence rates or functional scores between ESWT and corticosteroid injection. Four ESWT recipients in a single 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 a corticosteroid injection rather than placebo.

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. (10) The analysis included 6 RCTs with 454 patients and revealed a significant difference in VAS score (MD, -0.96; 95% CI, -1.28 to -0.63; p<.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.

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) (4)	Dizon (2013) (3)	Zhiyun (2013) (5)	Yin (2014) (6)	Lou (2017) (7)	Sun (2017) (8)	Li (2018)[1] (9)	Xiong (2019) (10)
Buchbinder (2002)		X						
Chow (2005)		X						
Eslamian (2016)							X	
Fariba (2016)								X
Gerdesmeyer (2008)	X	X		X	X	X		
Gollwitzer (2007)	X	X	X	X	X	X		
Gollwitzer (2015)					X			
Gollwitzer (2017)						X		
Greve (2009)		X					X	
Guevara (2018)							X	
Haake (2003)		X					X	
Hocaoglu (2017)							X	
Ibrahim (2010)	X	X		X		X		
Istemi (2010)								X
Kudo (2006)		X	X					
Lai (2018)							X	X
Malay (2006)	X	X	X		X	X		
Mardani-Kivi (2015)							X	
Mark (2005)								X
Marks (2008)	X			X		X		
Nayera (2012)								X
Ogden (2004)			X					
Porter (2005)							X	
Radwan (2012)				X				
Rompe (1996)						X		
Rompe (2002)						X		
Rompe (2003)	X			X				
Saber (2012)							X	

Sehriban (2017)								X
Sorrentino (2008)							X	
Speed (2003)	X	X		X	X	X		
Theodore (2004)		X	X					
Yucel (2010)							X	

ESWT: extracorporeal shockwave therapy.
[1] Only 7 trials mentioned in meta-analysis.

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

Study	Dates	Trials	Participants	N (Range)	Design	Duration
Aqil (2013) (4)	2003-2010	7	PF patients with continued symptoms after 3 months of consecutive therapy	663 (25-243)	RCTs	12 weeks
Dizon (2013) (3)	2002-2010	11	Patients with chronic PF	1287 (32-272)	RCTs	Immediately after treatment to 1 year
Zhiyun (2013) (5)	2004-2007	5	Adults with recalcitrant PF; baseline pain ≥5 points on VAS	716 (40-293)	RCTs (double-blind)	12 weeks
Yin (2014) (6)	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
Lou (2017) (7)	2001-2015	91	Patients with recalcitrant PF	1174 (NA)	RCTs	Primary outcomes=12 weeks;

						studies up to >12 months
Sun (2017) (8)	1996-2015	9	Patients with chronic PF	935 (29-246)	RCTs	3 weeks to 6 months
Li (2018) (9)	2005-2018	9	Adults with PF and without injection history	658 (40-125)	RCTs	6 weeks to 1 year
Xiong (2019) (10)	2005-2018	6	Patients with PF	454 (40-125)	RCTs	-

NA: not available; PF: plantar fasciitis; n: number of participants; RCT: randomized controlled trial; VAS: visual analog scale used to measure pain.

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) (4)					
RR	1.30	-	1.44	-	-[1]
SMD	-	0.60		0.38	-
95% CI	1.04 to 1.62	0.34 to 0.85	1.13 to 1.84	0.05 to 0.72	-
Z score	2.29	4.64	2.96	2.27	-
P-value	<0.02	<0.001	0.003	0.02	-
Dizon (2013) (3)					
WMD	-0.77	-4.39	0.59	-	-
OR					0.57
95% CI	-1.30 to -0.25	-9.05 to 0.27	0.33 to 1.05	-	0.43 to 0.76
P-value	0.004	0.06	0.07	-	0.0001
Lou (2017) (7)					
RR	1.32	1.50	1.37	-	1.51
95% CI	1.11 to 1.56	1.27 to 1.77	1.14 to 1.65	-	1.26 to 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) (8)					
OR	-	-	-	2.58	-
SMD	-	1.01	-	-	-
95% CI	-	-0.01 to 2.03	-	1.97 to 3.39	-
Z score	-	1.94	-	6.88	-

P-value	-	0.05	-	<0.0001	-
I^2%	-	96	-	38	-
Yin (2014) (6)					
L-ESWT					
MD	-	1.51[2]	-	-	-
RR	-	-	-	-	1.41
95% CI	-	0.77 to 2.26	-	-	1.08 to 1.82
P-value	-	<0.001	-	-	0.01
H-ESWT					
MD	-	1.4	-	-	
RR	-	-	-	-	1.33
95% CI	-	0.57 to 2.23	-	-	0.94 to 1.9
P-value	-	0.11	-	-	0.11
Zhiyun (2013)[3] (5)					
Success rate % (12 weeks)	-	46.5 to 62.5	-	-	-
OR	-	2.25	-	-	-
95% CI	-	1.66 to 3.06	-	-	-
Z score	-	5.19	-	-	-
P-value	-	<0.0001	-	-	-

CI: confidence interval; FSW: focused shockwave; H-ESWT: high-intensity/energy shockwave therapy; L-ESWT: low-intensity/energy shockwave therapy; MD: mean difference; OR: odds ratio; RR: risk ratio; RSW: radial shockwave; SMD: standard mean difference; VAS: visual analog scale used to measure pain; WMD: weighted mean difference.

Li (2018) and Xiong (2019) are not included in the results summary table because the comparator in the studies is corticosteroid injections rather than placebo.

[1] Aqil et al. gathered data on three studies that measured Roles and Maudsley scores but did not statistically combine the results. However, all three 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 H-ESWT to placebo.

Randomized Controlled Trials

Trials With Sham Controls

Several representative RCTs are discussed next (Tables 7 through 10). 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. (11) 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.

Gerdesmeyer et al. (2008) reported on a multicenter, double-blind RCT of RSW conducted for FDA premarket approval of the Dolorclast. (12) 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% vs 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 (e.g., 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.

In 2005, results were reported from the 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. (13) 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. (14) 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.

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

Study, Trial	Countries	Sites	Participants	Interventions	
				Active	***Comparator***

Gerdesmeyer (2008) (12)	US, EU	8	Patients with ≥6 months painful heel syndrome resistant to nonsurgical treatment; score ≥5 on 3 VAS scores; failed ≥2 non-pharmaco-logical and 2 pharmacological treatments; sufficient washout 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) (11)	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) (14)	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) (13)	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	Total of 3800 shocks; (n=115)	Total of 3800 shocks; contact membrane of device lined with internal foam insert to absorb

			and 2 nonpharmacological treatments; washout period; (n=172)		shockwaves; (n=57)

ESWT: extracorporeal shockwave therapy; EU: European Union; FDA: US Food and Drug Administration; PF: plantar fasciitis; RCT: randomized controlled trial; US: United States; VAS: visual analog scale.

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

Study	VAS Pain Score Improvement	Functional Improvement
Gerdesmeyer (2008) (12)		
ESWT reduction in VAS composite %	72.1	-
Placebo reduction in VAS composite %	44.7	-
P-value	0.0220	-
ESWT success rate %[1]	60.98	58.402
Placebo success rate %	42.24	41.52
P-value (MW effect size)	0.0020 (-)	0.0031 (0.5973)
Gollwitzer (2015) (11)		
P-value (MW effect size)[3]	0.0027 (0.6026)	0.006 (0.6135)
Lower-bound 95% CI	0.5306	0.5466
ESWT mean % from baseline (95% CI)[4]	-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) (14)		
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) (13)		
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; ESWT: extracorporeal shockwave therapy; MW: Mann-Whitney; RCT: randomized controlled trial; SD: standard deviation; SE: standard error; VAS: visual analog scale; 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.

Tables 9 and 10 display notable limitations identified in each study.

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) (12)					
Gollwitzer (2015) (11)					
FDA, Orbasone (2005) (14)	3. Allocation concealment unclear				
FDA, Orthospec (2005) (13)	3. Allocation concealment unclear	1. Few details provided.			

FDA: US Food and Drug Administration.

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]	Data Completeness[d]	Power[e]	Statistical[f]
Gerdesmeyer (2008) (12)						3. Confidence intervals not reported
Gollwitzer (2015) (11)						
FDA, Orbasone (2005) (14)	1. Allocation concealment unclear		1. Registration unclear		1. Power calculations not reported	3. Confidence intervals and p-values not reported
FDA, Orthospec (2005) (13)	1. Allocation concealment unclear		1. Registration unclear		1. Power calculations not reported	3. Confidence intervals not reported for function

FDA: US Food and Drug Administration.

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] Data /completeness 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.

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. (15) Outcome measures included a 0-to-100 VAS assessing morning pain, the American Orthopaedic 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. (16-19) As the follow-up period for these studies are 3 months or less, the clinical significance of these results is uncertain. (20) One RCT found that ESWT plus stretching exercises had similar efficacy to instrument-assisted soft-tissue mobilization plus stretching exercises through 8 weeks of follow-up, but at 6 months soft-tissue mobilization was more effective than ESWT. (21)

In a double-blind RCT, Bahar-Ozdemier et al. (2021) evaluated the effects of ESWT alone (n=15), ESWT plus low-dye kinesiotaping (n=15), and ESWT plus sham kinesiotaping (n=15) in 45 patients with plantar fasciitis. (22) Main outcome measures included VAS change, the heel tenderness index, and foot function index. Low-dye kinesiotaping plus ESWT was more effective on foot function improvement than ESWT and sham kinesiotaping or ESWT alone in the 4-week duration of follow-up. However, the combination did not provide a significant benefit on pain and heel tenderness due to plantar fasciitis.

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 vs. radial, low- vs. 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 three 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 (e.g., physical therapy) and nonsteroidal anti-inflammatory therapy, in individuals with lateral epicondylitis.

The following PICO were used to select literature to inform this policy.

Populations
The relevant population of interest is individuals with lateral epicondylitis.

Interventions
The therapy being considered is ESWT.

Comparators
Comparators of interest include conservative therapy (e.g., physical therapy) and nonsteroidal anti-inflammatory therapy.

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
Mediation use	e of pain medication	Generally measured for up to 12 weeks

VAS: visual analog score.

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.

Systematic Reviews

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." (23) A systematic review by Dingemanse et al. (2014), which evaluated electrophysical therapies for epicondylitis, found conflicting evidence on the short-term benefits of ESWT. (24) 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. (25) 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. (26) A meta-analysis by Karanasios et al. (2021) of 27 randomized trials (N=1871) found that ESWT (alone or as an additive intervention) compared with sham or other control treatment in patients with lateral elbow tendinopathy did not provide clinically meaningful improvement in pain intensity, elbow disability, or grip strength. (27) A systematic review and meta-analysis by Liu et al. (2022) of 40 RCTs found that ESWT was the optimal intervention for improving short-term and medium-term grip strength compared to several injection therapies. (28)

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 ($p=.0004$) and grip strength ($p<.00001$) with ESWT compared with other methods including placebo, autologous blood injection, corticosteroid injection, physiotherapy, wrist-extensor splints, laser, and/or kinesiotaping. (29) A meta-analysis by Yan et al. (2019) of 5 studies demonstrated improvement in VAS scores ($p<.0001$), grip strength ($p<.00001$), and subjective scores of elbow function ($p=.0008$) with ESWT compared with ultrasonics. (30) A meta-analysis by Xiong et al. (2019) of 4 studies revealed improved VAS scores ($p<.00001$) and grip strength ($p<.00001$) with shock wave therapy compared with corticosteroid injections. (31)

Randomized Controlled Trials

Relevant RCTs are summarized in Tables 12 through 15.

Kaplan et al. (2023) reported on an investigator-blinded trial that randomized 87 patients with lateral epicondylitis to FSW, RSW, or sham treatment. (32) Both ESWT groups experienced significant reductions in Patient-Rated Tennis Elbow Evaluation (PRTEE) scores from baseline to weeks 5 and 13 ($p<.001$); the sham group did not demonstrate statistically significant differences from baseline to week 5 or 13 ($p>.05$). The difference between sham and both focused and RSW groups was significant for all PRTEE score changes (pain, function, and total) ($p<.001$). Additionally, FSW was superior to RSW for changes in PRTEE pain, function, and total scores from baseline to weeks 5 and 13.

Aldajah et al. (2022) compared ESWT (n=20) with conventional physiotherapy (n=20) in patients with lateral epicondylitis. (33) All patients received 5 sessions during the treatment program. Outcome measures included changes in VAS for pain intensity, the Disabilities of the Arm, Shoulder, and Hand (DASH) questionnaire for upper extremity function, and dynamometer for maximal grip strength. Patients in both groups improved significantly after treatment in terms of VAS, DASH scores, and maximal grip strength from baseline. However, patients in the ESWT arm performed better than those in the physiotherapy arm for all outcomes. This RCT is not included in the summary table because it compares ESWT with a physiotherapy program that includes ultrasound therapy.

Guler et al. (2020) (34) compared ESWT (n=20) with kinesiotaping (n=20) as part of 3-week treatment in patients with newly diagnosed lateral epicondylitis. 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=.01), a better hand grip strength score (26.8 versus 20.6; p=.005), and a lower Roles and Maudsley score (1.7 versus 2.2; p=.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) (35) published results from an RCT (N=30) comparing RSW plus physical therapy with physical therapy alone in patients with lateral epicondylitis. 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) (36) comparing RSW (n=28) with sham RSW (n=28) for lateral epicondylitis did not find significant differences between groups in grip strength or function. However, this trial might have been underpowered to detect a difference.

Lizis (2015) (37) compared ESWT with therapeutic ultrasound among 50 patients who had chronic tennis elbow. 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. This RCT is not included in the summary tables because the comparator is ultrasound as opposed to conservative or nonsteroidal anti-inflammatory therapy.

Gunduz et al. (2012) compared ESWT with 2 active comparators. (38) 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) (39) reported on a double-blind controlled trial of ESWT for epicondylitis in 68 patients. 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. (41) 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***
Kaplan (2023) (32)	Turkey	1	2019-2020	Patients with newly diagnosed (<3 months) LE	RSW: 4 Hz, 1.2 Bar, 500 pulse, 0.144 mJ/mm^2 for 2 minutes and 5 seconds + 8 Hz, 1.5 Bar, 1800 pulse, 0.180 mJ/mm^2 for 3 minutes and 45 seconds (n=29) FSW: 4Hz, 1.5 Bar, 500 pulses, 0.02-0.60 mj/mm^2 for 2 minutes and 5 seconds + 8Hz,	Sham ESWT (1 Hz, 1 Bar, 500 pulse for 2 minutes and 5 seconds + 1 Hz, 1 Bar, 1800 pulse for 3 minutes and 45 seconds (n=28)

					1.7 Bar, 1800 pulses, 0.02-0.60 mj/mm^2 for 3 minutes and 45 seconds (n=30)	
Capan (2016) (36)	Turkey	1	-	Patients with unilateral LE for >3 months unresponsive to other treatments; (n=56)	RSW with 2000 pulses; 10 Hz frequency; 1.8 bar of air pressure; 3 weekly sessions; (n=28)	3 sham treatments of RSW; same dosage and schedule as active but with no contact between applicator head and skin; (n=28)
Pettrone & McCall (2005) (41)	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)
Staples (2008) (39)	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)

ESWT: extracorporeal shockwave therapy; LE: lateral epicondylitis; RCT: randomized controlled trial; RSW: radical extracorporeal shockwave therapy; VAS: visual analog scale; FSW: focused extracorporeal shockwave therapy.

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

Study	Pain Improvement		Grip Strength[1]	
	≤6 wks	3 mos	≤6 wks	3 mos
Kaplan (2023) (32)				
FSW mean change from baseline PRTEE score	18.8±13.9	17.8±13.1	-	-
RSW mean change from baseline PRTEE score	11.8±9.1	11.7±10.5	-	-
Sham mean change from baseline PRTEE score	1.3±7.1	1.0±6.5	-	-
p-value (FSW and RSW vs. sham)	<.001	<.001	-	-
Capan (2016) (36)				
RSW (SD)	3.4 (2.9)[2]	2.1 (2.2)[2]	15.96 (9.61)	17.30 (10.33)
RSW MD from baseline (SD)	-1.9 (2.2)[2]	-3.2 (2.3)[2]	5.35 (6.82)	1.35 (3.87)
% difference	-36.7[2]	-59.1[2]	76.3	17.8
P-value	<0.001	<0.001	0.002	0.074
Control (SD)	3.5 (2.9)[2]	2.6 (2.8)[2]	10.14 (6.42)	12.18 (6.01)
Control MD from baseline (SD)	-2.2 (2.4)[2]	-3.1 (2.7)[2]	3.68 (4.56)	2.05 (3.46)
% difference	-39.6[2]	-54.8[2]	110.0	57.0
P-value	0.001	<0.001	0.001	0.017
% difference between groups	0.758	0.882	0.578	0.768
Pettrone & McCall (2005) (41)				
ESWT mean (SD)	-	37.6 (28.7)[4]	-	38.2
Change %	-	49[4]	-	23
Control mean (SD)	-	51.3 (29.7)[4]	-	37.4
Change %	-	32[4]	-	12
P-value	-	0.02	-	0.09
ESWT % pts w/pain reduction	-	61[5]	-	-
Placebo % pts w/pain reduction	-	29[5]	-	-
P-value	-	0.001	-	
Staples (2008) (39)				
ESWT mean (SE) change	27.7 (5.7)[4]	26.1 (6.5)[4]	0.17 (0.06)	0.35 (0.06)
Control mean (SE) change	26.3 (6.4)[4]	26.7 (6.0)[4]	0.22 (0.07)	0.31 (0.06)
Between-group difference	1.7[4]	-0.6[4]	-0.05	0.04

95% CI	-18.8 to 15.3[4]	-18.4-17.3[4]	-0.22-0.12	-0.13-0.20
P-value	0.84	.95	0.57	-

CI: confidence interval; ESWT: extracorporeal shockwave therapy; FSW: focused extracorporeal shockwave therapy; MD: mean difference; mos: months; NS: Not statistically significant but p-value not specified; RCT: randomized controlled trial; RSW: radial extracorporeal shockwave therapy; SD: standard deviation; SE: standard error of the mean; VAS: visual analog scale; pts: patients; w/: with; wks: weeks.
[1] Grip strength in kilograms measured with a squeeze dynamometer.
[2] Pain assessed using at-rest VAS (range, 0-10).
[3] Patient-Related Tennis Elbow Evaluation (PRTEE) function scores.
[4] VAS pain index (range, 0–100).
[5] Pain reduction of ≥50% on Thomsen test.
[6] Functional improvement assessed using Upper Extremely Functional Scale.
[7] Disabilities of the Arm, Shoulder, and Hand (DASH) questionnaire function scores.

Tables 14 and 15 display notable limitations identified in each study.

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

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Follow-Up[e]
Kaplan (2023) (32)				3. CONSORT flow diagram included, but no reporting of harms	
Capan (2016) (36)				3. CONSORT flow diagram included, but no reporting of harms	
Pettrone & McCall (2005) (41)					
Staples (2008) (39)					

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]	Data Completeness[d]	Power[e]	Statistical[f]
Kaplan (2023) (32)		2. Not blinded outcome assessment	1. Not registered			
Capan (2016) (36)			1. Not registered	6. No intent-to-treat analysis	1. Calculations not reported	
Pettrone & McCall (2005) (41)	3. Unclear how randomized		1. Not registered			
Staples (2008) (39)			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.

<u>Section Summary: Lateral Epicondylitis</u>

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 (e.g., physical therapy) and nonsteroidal anti-inflammatory therapy, in individuals with shoulder tendinopathy.

The following PICO were used to select literature to inform this policy.

Populations

The relevant population of interest is individuals with shoulder tendinopathy.

Interventions

The therapy being considered is ESWT.

Comparators

Comparators of interest include conservative therapy (e.g., physical therapy) and nonsteroidal anti-inflammatory therapy.

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

VAS: visual analog scale.

[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.

Systematic Reviews

A systematic review and meta-analysis of RCTs by Kamonseki et al. (2023) compared ESWT to sham treatment or other active treatments on pain intensity and shoulder function in patients with non-calcific rotator cuff tendinopathy. (42) A literature search through June 2023 identified 9 RCTs (N=543). The Constant-Murley Score (CMS) was used to assess pain intensity and shoulder function. In the short-term (≤3 months), ESWT was superior to sham treatment for reduction in pain intensity (5 studies; MD, -0.28; 95% CI, -0.55 to -0.01). In the intermediate- (≥3 to 12 months [2 studies]) and long-term (≥12 months [1 study]), the difference between ESWT and sham treatment did not reach statistical significance for reduction in pain intensity. For the function outcomes, the difference between ESWT and sham treatment did not reach statistical significance at ≤3 months (5 studies), ≥3 to 12 months (2 studies), or ≥12 months (1 study). Comparisons between ESWT and other active therapies were limited to analyses of single trials comparing ESWT to exercise, steroid injections, and hyaluronic acid injections; there were no statistically significant differences in the short- or intermediate-term.

A systematic review and meta-analysis of RCTs by Angileri et al. (2023) compared the efficacy of non-operative and operative treatments for chronic calcific tendonitis. (43) A literature review through February 2022 identified 27 RCTs (N=2352). Outcomes were pain (VAS; minimal clinically important difference, 2.4), functional assessment (Constant-Murley Score [CMS]; minimal clinically important difference, 10.4), and calcific deposit resolution. The pooled mean difference in VAS was -3.83 for ESWT versus -4.83 for ultrasound-guided needling and -4.65 for operative interventions. The pooled mean difference in CMS score was 18.30 for ESWT versus 22.01 for ultrasound-guided needling and 38.35 for operative interventions. Complete resolution of calcific deposits occurred in a mean of 27.3% of patients who received ESWT, 66.7% of patients who received ultrasound-guided needling, and 85% for individuals who had surgery. The authors concluded that surgical treatment was more effective than nonoperative interventions, but that all modalities are likely to lead to clinically significant improvements.

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 (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)	Angileri (2023) (43)	Kamonseki (2023) (42)
Ainsworth (2007)	X				
Albert (2007)			X	X	
Battaglia (2017)				X	
Cacchio (2006)	X	X	X	X	
Clement (2015)				X	
Cosentino (2003)	X	X	X	X	
Cosentino (2004)			X		
del Castillo-Gonzalez (2016)			X	X	
de Witte (2013)	X			X	
de Witte (2017)				X	
Ebenbichler (1999)			X		
Efe (2014)					X
Frassanito (2018)				X	
Frizziero (2017)					X
Galasso (2012)					X
Gerdesmeyer (2003)	X	X	X		
Hearnden (2009)		X	X		
Hsu (2008)	X	X	X		
Ioppolo (2012)			X	X	
Kim (2014)	X		X	X	
Kolk (2013)					X
Krasny (2005)	X			X	
Kvalva (2017)					X
Lee (2022)					X
Li (2017)					X
Loew (1999)			X		

Louwerens (2020)				X	
Orlandi (2017)				X	
Pan (2003)			X	X	
Papadopoulos (2019)				X	
Perlick (2003)				X	
Perron (1997)				X	
Peters (2004)		X			
Pieber (2018)				X	
Pleiner (2004)			X	X	
Rompe (1998)			X		
Rubenthalier (2003)				X	
Sabeti-Aschraf (2005)				X	
Sabeti (2014)				X	
Sconfienza (2012)				X	
Schmitt (2021)					X
Speed (2022)					X
Tornese (2011)				X	
Zhu (2008)				X	

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
Kamonseki (2023) (42)	Through June 2023	9	Patients with non-calcific rotator cuff tendinopathy	543 (20 to 143)	RCTs	≤3 months to ≥12 months
Angileri (2023) (43)	1997-2020	27	Patients with chronic calcific tendinitis	2352 (20 to 462)	RCTs	0.75 to 120 months
Arirachakaran (2017) (45)	2003-2008	4	Patients with rotator cuff calcific tendinopathy	882 (136 to 302)	RCTs	6-12 months
Ioppolo (2013) (46)	2003-2009	6	Adults with shoulder pain or tenderness from calcific tendinitis	460 (20 to 144)	RCTs	1 week-1 year

			with type I or II calcification			
Wu (2017) (44)	1998-2016	5	Adults with clinical symptoms related to calcific tendinitis of the shoulder	370 (20 to 144)	RCTs	1 month-1 year

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

Table 20. Results of Systematic Reviews with Meta-Analyses Assessing Different Forms of Extracorporeal Shock Wave Therapy for Shoulder Tendinopathy

Study	VAS/NRS/CMS Score Improvement/Pain Reduction	CMS/SPADI/Functional Improvement	Decrease in Calcium Deposit Size
ESWT			
Kamonseki (2023) (42)			
MD from pretreatment (≤3 months) (95% CI vs. sham treatment); p-value	-0.28 (-0.55 to -0.01); p=.04	-0.15 (-0.48 to 0.18); p=.36	-
MD from pretreatment (≥3 to 12 months) (95% CI vs. sham treatment)	-0.25 (-0.57 to 0.07); p=.13	-0.15 (-0.59 to 0.30); p=.51	-
MD from pretreatment (≥12 months) (95% CI vs. sham treatment)	0.18 (-0.55 to 0.91); p=.63	-0.21 (-0.94 to 0.52); p=.57	-
Angileri (2023) (43)			
I^2 %	94	82	-
Mean difference from pre-treatment	-3.83	18.30	-
95% CI	-5.38 to -2.27	1095 to 25.66	-
p-value	<.00001	<.00001	-
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			
WMD	1.94	-	-
95% CrI	-0.42-4.30	-	-
RSW			
WMD	6.12	-	-
95% CrI	3.91-8.34	-	-

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

ElGendy et al. (2022) conducted a single-blind RCT in patients with shoulder impingement syndrome. (51) Patients were randomized to 4 weeks of conventional physical therapy plus local corticosteroid injection (n=20), physical therapy alone (n=20), or physical therapy plus ESWT (n=20). Outcomes were assessed at 4 and 12 weeks. There were no differences between groups at 4 weeks. At week 12, ESWT was numerically more effective than corticosteroid injection in improving shoulder internal rotation and abduction, Shoulder Pain and Disability Index, and distance of the subacromial space; statistical differences were not reported.

Lee et al. (2022) conducted a small (n=26) RCT in patients with supraspinatus tendinitis that compared ESWT and ultrasound-guided steroid injection to the shoulder. (52) At 1 month, VAS (p=.015), American Shoulder and Elbow Society score (p=.005), and constant score (a measure of range of motion, muscular strength, subjective pain, patient satisfaction, and physical testing; p=.044) were better in the steroid injection group; however, at 3 months of follow-up outcomes were similar between treatments (all p>.05).

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). (53, 54) 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. All patients received nonsteroidal anti-inflammatory drugs, transcutaneous electrical nerve stimulation, and ultrasound therapy (N=34). (55) A subset (n=18) also received ESWT, 3 times a week for 6 weeks. Constant-Murley Score (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 ultrasound-guided percutaneous lavage (UGPL) plus subacromial corticosteroid injection (SAI) with ESWT in patients who had unilateral calcific shoulder tendinopathy and ultrasound-documented calcifications of the supraspinatus tendon. (56) 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. (57) 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. (58) 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. For non-calcific tendinopathy, 1 meta-analysis found that ESWT exhibited a small improvement in shoulder pain compared to sham ESWT at short-term follow-up (≤3 months). However, ESWT was not superior to sham ESWT in improving function at short- or long-term follow up (≥12 months), and ESWT was not superior to other treatments. 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 (e.g., physical therapy) and nonsteroidal anti-inflammatory therapy, in individuals with Achilles tendinopathy.

The following PICO were used to select literature to inform this policy.

Populations

The relevant population of interest is individuals with Achilles tendinopathy.

Interventions

The therapy being considered is ESWT.

Comparators

Comparators of interest include conservative therapy (e.g., physical therapy) and nonsteroidal anti-inflammatory therapy.

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 • VISA-Achilles (measures redness, warmth, swelling, tenderness, edema) • AOFAS for pain[1]	4 weeks to > 1 year

	• Roles and Maudsley pain scores of "good" or "excellent"	
Functional outcome	• AOFAS for function • Roles and Maudsley function scores of "good" or "excellent"	4 weeks to > 1 year

AOFAS: American Orthopedic Foot and Ankle Score; VAS: visual analog scale; VISA: Victorian Institute of Sports Assessment.

[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.

Systematic Reviews

Mani-Babu et al. (2015) reported on results of a systematic review of studies evaluating ESWT for lower-limb tendinopathies. (59) 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 vs mid-portion Achilles tendinopathy) and treatment protocols.

Al-Abbad and Simon (2013) conducted a systematic review of 6 studies on ESWT for Achilles tendinopathy. (60) 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. (61, 62)

Randomized Controlled Trials

Stania et al. (2023) performed a randomized trial that compared ESWT, ultrasound therapy, and placebo ultrasound for pain control in 39 patients with Achilles tendinopathy. (63) Outcomes were measured at 1 and 6 weeks after the completion of therapy. Activity-related pain was

lower with ESWT compared to ultrasound therapy at 6 weeks (p<.05). Intensity of pain at rest was similar between groups at both time points.

Abdelkader et al. (2021) performed a double-blind, randomized trial that compared ESWT (n=25) with sham control (n=25) in patient with unilateral non-insertional Achilles tendinopathy. (64) Scores were improved in both ESWT and control groups at 1 month on the Victorian Institute of Sports Assessment-Achilles (VISA-A) questionnaire (85 and 53.4, respectively) and the VAS (1 and 7, respectively), as well as at 16 months on the VISA-A (80 and 67, respectively) and the VAS (3 and 5.6, respectively). At both time points, scores were statistically and clinically superior with ESWT than with sham control (both p=.0001).

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. (65) 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. (66) The primary outcome was percent change in VAS pain score at the 3-month follow-up. Other measurements included the VISA-A, 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. (62) 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. (61) 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 4 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. Another RCT found scores were statistically and clinically improved with ESWT compared with sham control at 1 month and 16 months on measures of pain and function. The most recent RCT found that activity-related pain was lower with ESWT at 6 weeks compared to ultrasound therapy, but there was no difference in pain at rest.

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 (e.g., physical therapy) and nonsteroidal anti-inflammatory therapy, in individuals with patellar tendinopathy.

The following PICO were used to select literature to inform this policy.

Populations

The relevant population of interest is individuals with patellar tendinopathy.

Interventions

The therapy being considered is ESWT.

Comparators

Comparators of interest include conservative therapy (e.g., physical therapy) and nonsteroidal anti-inflammatory therapy.

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	< 1 month to 1 year

	• Victorian Institute of Sports Assessment-Patellar Tendon • McGill Pain Questionnaire • Roles and Maudsley score for pain • Likert scale/numerical rating scale for pain • Swelling	
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

VAS: visual analog scale.

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.

Systematic Reviews

Stania et al. (2022) conducted a systematic review and meta-analysis of 7 RCTs of ESWT in patients with patellar tendinitis. (67) Compared to control groups at 6 months or more after therapy completion, VAS scores and VISA for Patella scores were similar between groups. The analyses were limited by heterogeneity (I^2=98% and 99%, respectively) and the authors stated that generalized conclusions could not be drawn.

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. (68) Their review included nineteen 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 (SMD) 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 FSW and RSW, with significant pooled SMD of 2.61 (95% CI, 2.11 to 3.12; P<0.0001; I^2=0%). In general, low-energy FSW was more effective in increasing treatment success rate than high-energy FSW; however, high-energy RSW was more effective

than low-energy RSW. 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. (69) 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). (59) The 2 RCTs came to different conclusions: one 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 VISA–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. (70) 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 VISA–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. (71)

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 individuals with medial tibial stress syndrome.

The following PICO were used to select literature to inform this policy.

Populations
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 (e.g., icing, support).

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.

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 (commonly called shin splints). (72) 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. (73) In this nonrandomized cohort study, 47 patients with medial tibial stress syndrome 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. (74)

Section Summary: Medial Tibial Stress Syndrome
Evidence for the use of ESWT for medial tibial stress syndrome 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 (e.g., alendronate) or hip arthroplasty, in individuals with osteonecrosis of the femoral head.

The following PICO were used to select literature to inform this policy.

Populations
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.

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	3 months to > 24 months

	• Radiographic reduction of bone marrow edema on magnetic resonance imaging	
Functional Outcomes	Harris Hip Scores for function	3 months to > 24 months

VAS: visual analog scale.

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.

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). (75) 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 (SMD, -2.1148; 95% CI, -3.2332 to -0.9965; Z=3.7063; P=0.0002), as well as higher HHSs (SMD, 2.1377; 95% CI, 1.2875 to 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 one RCT is included out of four 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 two 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. (76) 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 Ib, 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 HHS, 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). (77) 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; 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 (e.g., 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 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 individuals with acute fracture nonunion or delayed union.

The following PICO were used to select literature to inform this policy.

Populations

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.

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

VAS: visual analog scale.

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.

Systematic Reviews

Sansone et al. (2022) published a systematic review and meta-analysis involving 23 studies that evaluated the effectiveness of ESWT in the treatment of nonunion fracture in long bones. (78) The review included 2 RCTs, a single non-randomized controlled trial, and 20 observational studies (14 retrospective; 6 prospective), with a total of 1838 cases of delayed union or nonunion. Only data for 1200 of the 1838 cases were included in the meta-analysis since several studies did not separate results from long bones from those of other bones. Healing occurred in 876 (73%) of the 1200 total long bones after ESWT. Hypertrophic cases were associated with a 3-fold higher healing rate as compared to oligotrophic or atrophic cases (p=.003). Bones in the metatarsal region were the most receptive to ESWT with a healing rate of 90%, followed by the tibiae (75.5%), femurs (66.9%), and humeri (63.9%). Increased healing rates were observed among patients who had shorter periods between the injury and ESWT (p<.02). Six months of follow-up was generally too brief to fully evaluate the healing potential of ESWT with several studies demonstrating increasing healing rates at follow-ups beyond 6 months after the last ESWT. Limitations included that the authors in 7 included studies did not distinguish between delayed union and nonunion when describing the patient population. In several other studies, the patient population was described clearly; however, data from delayed unions and nonunions were reported together. Incomplete data reporting also contributed to a lack of identifying and differentiating treatment protocols for ESWT.

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. (79) 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

Wang et al. (2007), which was the single RCT included in the Zelle et al. (2010) review, randomized 56 trauma patients with femur or tibia fractures to a single ESWT treatment following surgical fixation while still under anesthesia. (80) 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.

Cacchio et al. (2009) published a multicenter RCT after the Zelle et al. (2010) review, which randomized 126 patients into 3 groups: low-energy ESWT, high-energy ESWT therapy, or surgery. (81) 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), included in the Sansone et al. (2022) review, evaluated the use of human autologous bone mesenchymal stem cells combined with ESWT for the treatment of nonunion long bones. (82) 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 systematic reviews, relatively small RCTs with methodologic limitations (e.g., heterogeneous outcomes and treatment protocols), and 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 individuals with spasticity.

The following PICO were used to select literature to inform this policy.

Populations

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.

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
Functional outcomes	Brunnstrom Recovery Stage tool to assess motor recover	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.

Systematic Reviews

Otero-Luis et al. (2024) performed a meta-analysis of 14 RCTs and 2 crossover trials evaluating the effect of ESWT on spasticity secondary to various etiologies, including stroke, cerebral palsy, and multiple sclerosis. (83) The control group treatments were not specified. Results demonstrated that ESWT showed significant reductions in spasticity levels as indicated by Modified Ashworth Scale scores, both in upper limbs (MD, -1.05; 95% CI, -1.39 to -0.71) and lower limbs (MD, -0.40; 95% CI, -0.77 to -0.03). However, at 12 weeks post-intervention, the efficacy of ESWT did not reach statistical significance compared to control (MD, -0.47; 95% CI, -1.30 to 0.35). Limitations of this meta-analysis include small sample sizes and heterogeneity due to differences between populations (i.e., age, etiology) and ESWT protocols.

Mihai et al. (2021) performed a meta-analysis of 7 RCTs to estimate the effect of ESWT on lower limb post-stroke spasticity at long-term follow-up (≥3 weeks after treatment). (84) Compared with control, ESWT did not significantly improve Modified Ashworth Scale score at up to 12 weeks (7 studies; N=146; standardized MD, 0.32; 95% CI, -0.01 to 0.65; I^2=0%) or VAS score at up to 12 weeks (2 studies; N=50; standardized MD, 0.35; 95% CI, -0.21 to 0.91; I^2=0%), but did significantly improve passive range of motion at up to 12 weeks (3 studies; N=69; standardized mean difference, 0.69; 95% CI, 0.20 to 1.19; I^2=0%). Limitations of this meta-analysis include the small number of available studies, as well as small sample sizes.

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. (85) Compared with sham therapy, ESWT significantly improved the Modified Ashworth Scale scores (MD, -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 (MD, -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. (86) At long-term follow-up, ESWT significantly reduced Modified Ashworth Scale scores (weighted MD, -0.36; 95% CI, -0.53 to -0.19; p<.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. (87) Compared with controls, ESWT significantly improved Modified Ashworth Scale scores (MD, -0.62; 95% CI, -1.05 to -0.18; p<.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. (88) Studies included evaluated ESWT as sole therapy and reported pre- and postintervention Modified Ashworth Scale (MAS) scores. Five studies were selected, 4 examining spasticity in the ankle plantar flexor and one examining spasticity in the wrist and finger flexors; 3 studies evaluated poststroke spasticity and 2 evaluated spasticity associated with cerebral palsy. Immediately post-ESWT, MAS scores improved significantly compared with baseline (standardized MD, - 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 MD, -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

Brunelli et al. (2022) conducted a pilot RCT in 40 patients with poststroke spasticity. (89) Patients were randomized to radial shock wave (RSW) or conventional physiotherapy and assessed for change in Modified Ashworth Scale scores of the shoulder, elbow, and wrist. Follow-up occurred at 1 month after the last RSW session. Significant differences in Modified Ashworth Scale elbow scores were noted after the second RSW session and remained until the end of follow-up. Scores at the shoulder were only significantly better in the RSW group at the 1-month follow-up.

Vidal et al. (2020) performed a randomized, controlled, crossover trial that compared radial ESWT with botulinum toxin type A in reducing plantar flexor muscle spasticity in 68 patients with cerebral palsy. (90) After 6 months, patients crossed over to the alternative treatment. Spasticity was evaluated using the Tardieu scale, which measures resistance to passive movement at slow and fast velocities measured with a goniometer. Treatment success was defined as improvement in dorsiflexion by ≥10° of the gastrocnemius muscle or the soleus muscle at 2 months after each intervention. In the first phase, success rates were similar between RSW and botulinum toxin type A (45.7% and 36.4%, respectively; p=.469). Following crossover, significantly more patients achieved response with RSW (39.4% vs. 11.4%; p=.011), which the authors attributed to a carry-over effect of RSW from the first phase of treatment.

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. (91) 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 RSW, and 66.7% for the antagonist muscle group receiving RSW, with statistical significance at p<.01 among the 3 groups. The authors concluded that RSW 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 posttroke upper limb spasticity among 42 patients with chronic stroke. (92) 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. (93) 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 vs placebo); for the group with both spastic agonist and antagonist muscles treated, there was a 0.5-point improvement (p= not significant (NS) vs 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 systematic review evidence are 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

Extracorporeal shock wave treatment (ESWT) has been investigated in small studies for other conditions, including coccydynia in a case series of 2 patients, (94), and an RCT involving 34 patients (95), painful neuromas at amputation sites in an RCT assessing 30 subjects, (96) and chronic distal biceps tendinopathy in a case-control study of 48 patients. (97)

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. (59) ESWT was associated with some benefits compared with placebo or home therapy.

ESWT for Wounds

Butterworth et al. (2015) investigated the effectiveness of extracorporeal shock wave therapy for the treatment of lower limb ulceration. (98) Five studies were reviewed; three were randomized trials, one was a quasi-experimental study and one a case series. Findings

suggested that ESWT may be effective in improving wound healing and decreasing wound size and is a safe treatment option with few complications. However, study quality was lacking, with both external and internal validity across studies rated poorly. It is difficult therefore, to generalize these study findings.

Zhang et al. (2017) aimed to assess the effectiveness of ESWT compared with that of the standard care treatment for the healing of chronic wounds, irrespective of etiology, in clinical practice. (99) Randomized controlled trials that investigated the effect of ESWT on chronic wounds with different etiologies from 2000 to 2017 were included in this review. Seven randomized controlled trials involving 301 subjects were included in this review. Meta-analyses revealed that the use of ESWT as an adjunct to wound treatment could significantly accelerate the impaired healing process of chronic wounds. Compared with the control treatment, ESWT markedly increased the wound healing rate by 1.86-fold (OR = 2.86, 95% CI: 1.63-5.03, $p = 0.0003$) and the percentage of the wound healing area by 30.46% (standardized mean difference [SMD] = 30.46; 95% CI, 23.80-37.12; $p < 0.00001$). In addition, the wound healing time was reduced by 19 days (SMD = -19.11, 95% CI, -23.74-(-14.47), $p < 0.00001$) in chronic wound patients. No serious complications or adverse effects were observed secondary to the application of ESWT. The above data suggested that ESWT as an adjunct to wound treatment could more significantly improve the healing process of chronic wounds than the standard care treatment alone. Reviewers concluded that more high-quality, well-controlled randomized trials are needed to evaluate the efficacy of ESWT in clinical practice.

In 2018, Zhang et al. published an update to the previous systematic review and meta-analysis to include acute soft tissue wounds as well as chronic wounds (n=10 RCTs/473 subjects) in determining the effectiveness of ESWT compared to conventional wound therapy (CWT). (100) The meta-analysis showed that ESWT statistically significantly increased the healing rate of acute and chronic soft tissue wounds 2.73-fold and improved wound-healing area percentage by 30.45%. ESWT reduced wound-healing time by 3 days for acute soft tissue wounds and 19 days for chronic soft tissue wounds and the risk of wound infection by 53% when compared with CWT alone. As with the earlier review, reviewers again concluded that higher-quality and well-controlled RCTs are needed to further assess the role of ESWT for acute and chronic soft tissue wounds.

Snyder et al. (2018) performed two multicentre, randomized, sham-controlled, double-blinded, phase III clinical trials using focused ESWT compared with sham examining diabetic foot ulcers (DFUs) that did not reduce in volume by ≥50% over 2 weeks standard treatment immediately prior to randomization. (101) Patients were randomized to either standard care and focused ESWT (pulsed acoustic cellular expression. dermaPACE System, SANUWAVE Health Inc.) active therapy, or standard care and sham therapy. Both active and sham therapy were administered four times in 2 weeks in study 1 and a maximum of eight times over 12 weeks in study 2. Standard care continued in both studies throughout the 12-week treatment phase. The two studies evaluated 336 patients; 172 patients treated with active therapy and 164 managed with a sham device. The primary efficacy endpoint for all subjects who received at least one episode of treatment was the incidence of complete wound closure within 12 weeks. Although there

was a trend towards greater complete wound closure in the Study 1 active group during the first 12 weeks of the study, the primary efficacy endpoint was not met. In Study 2 there were no significant differences between the primary efficacy outcomes for active therapy and sham-treated subjects at the 12, 20 or 24-week time points. Even with pooling of the data from the two studies, the primary efficacy endpoint was not met, with the rate of complete closure not significantly different at 12 weeks between the active and sham groups. Secondary outcomes were reported by Galiano et al. in 2019 (102). Wound area reduction and perimeter reduction were significantly greater in the active therapy group compared with the sham-treated group.

Huang et al. (2019) conducted a systematic review and meta-analysis of RCTs in order to assess the efficacy and safety of ESWT on the healing of DFUs. (103) Eight RCTs (N=339) were included. Patients were treated with ESWT plus standard wound care (SWC) (active) or with SWC or SWC with hyperbaric oxygen therapy (control). Follow-ups ranged from 5 to 24 weeks, with reviewers looking at wound surface area (WSA), percentage of re-epithelialization, population of complete cure, and unchanged and other related outcomes. While the analysis showed a statistically significant difference in WSA at the end of follow-up, there was no statistically significant difference in regard to complete cure between groups. While the reviewers concluded that ESWT is a feasible adjuvant treatment for DFUs, they did acknowledge the small number of participants in the studies as a limitation.

In a systematic review by Hitchman et al. (2019), reviewers assessed 5 trials of 255 patients published between 2009 and 2016. (104) Three studies compared ESWT to standard wound care, and 2 studies compared ESWT to hyperbaric oxygen therapy. All studies contained unclear to high risk of bias assessed by the Cochrane Risk of Bias Tool. ESWT was superior to standard wound care at complete wound healing (OR 2.66, 95% CI, 1.03-6.87; I^2=0%) and time to healing (64.5 ± 8.06 days versus 81.17 ± 4.35 days). DFU healing improved more with ESWT than hyperbaric oxygen therapy (OR 2.45, 95% CI, 1.07-5.61; I^2=28%). Reviewers concluded that ESWT has the potential to improve healing in DFUs, although there is, as of yet, insufficient evidence to justify its use in routine clinical practice.

A prospective, randomized, controlled study was conducted in 2022 by Aguilera-Saez et al. on the effect of ESWT in the treatment of burn scars. (105) This study was designed with adult patients (18 years or older), who presented with burn hypertrophic scars of approximately 64 cm^2 surface area, regardless of whether the burn was healed with a skin graft or not from February 2017 to February 2019. Patients with burn scars were divided into two groups with twenty patients per group. The control group received the standard treatment for burn scars. The ESWT group received the standard treatment and treatment of burn scars with ESWT 512 impulses of 0.15 mJ/mm^2 in each session, twice per week for 4 weeks. We assessed the appearance of scar with the Vancouver Scar Scale (VSS), pruritus and pain with VAS before the start of the treatment and at 2 weeks and 5 months after the treatment. Both groups showed improvements in all variables through the study. However, these improvements were only statistically significant for the VSS at the 6th month for the control group and VSS and VAS pain and pruritus for the ESWT group. Nonetheless the results failed to show statistically significant differences between the ESWT and the control group neither at two weeks after treatment nor

at 5 months after treatment. Researchers question the relevance of ESWT as adjunctive treatment for burn scars as far as outward appearance, pain, and pruritus as end-results are concern. Researchers note that their study did not show significant differences between the ESWT and the control group for appearance, pain or pruritus. Nonetheless, ESWT as adjunctive treatment for postburn scars might prove a useful tool, but the scientific evidence is scarce and further studies are required to accurately assess the potential benefits of ESWT as an adjunctive treatment for burn scars.

Rassweiler et al. (2022) reported on the postoperative management of wound healing in four cases of Fournier's gangrene that were successfully treated with low-intensity shockwave therapy (LI-ESWT). (106) In three cases, LI-ESWT (3 sessions per week with 2000 shockwaves at 3 Hz applied at 0.25 mJ/mm^2) was able to close wound dehiscence secondary to plastic surgery with skin flaps. In one patient, LI-ESWT resulted in complete closure of an extensive wound with restoration of the local scrotal and penile skin. This is the first report of a successful application of LI-ESWT for this indication. Researchers point out that one advantage of ESWT for wound healing is that the effect can be seen directly, unlike in urological indications such as Peyronie's disease, erectile dysfunction, and lower urinary tract symptoms. In conclusion, the positive effect of LI-ESWT on healing is very interesting for urologists dealing with secondary wound healing, however, the biomolecular mechanism by which this treatment modality exerts its therapeutic effects remains unclear. Researchers agree that further controlled studies are needed to evaluate the extent to which these results are due to LI-ESWT.

In 2023, Hitchman et al. published an updated systematic review with the aim to appraise the evidence on the role of ESWT in DFU healing and the impact of different ESWT doses. (107) Databases were searched for trials comparing ESWT plus standard care to standard care alone in participants with DFUs. Search results were reviewed by two independent reviewers. The Cochrane Risk of Bias 2 tool and GRADE approach was used to assess bias and certainty. The primary outcome was time to healing. The search identified 345 papers after duplicates removed. Six trials consisting of 471 participants were included. There was unclear or high risk of bias across all domains. Time to ulcer healing was probably shorter in patients treated with ESWT compared with standard ulcer care alone (GRADE: low certainty). Patients treated with ESWT were more likely to heal at 20 weeks post-ESWT compared with those treated with standard ulcer care alone (GRADE: low certainty). Researchers not that there was significant heterogeneity. There was significant variation in number of shocks delivered per cm^2, number of treatment sessions per week and length of overall treatment in the included trials. This variation was due to be explored in a planned meta-analysis and subgroup analysis. However, this was not performed for two reasons. Firstly, after tabulating results from the four trials that reported time to ulcer healing it became apparent that pooling of these data would result in a statistically significant result favoring ESWT, mainly driven by the Snyder et al. trials. This would be misleading as heterogeneity between the trials would be unaccounted for and potentially lead to overestimation of ESWT treatment effect. Secondly, a high risk of bias in the trial methodology and low certainty in the evidence further risks a misleading result from a pooled analysis. Researchers say ESWT remains a promising new treatment, but the translation into

routine clinical practice is still limited by the low certainty of evidence surrounding its effectiveness, case selection, and optimum dose.

In a prospective randomized clinical trial, Vangaveti et al. (2023) compared the healing parameters of DFUs between patients undergoing the standard of care (SOC) alone and ESWT + SOC. (108) The secondary objective was to assess inflammatory markers in both study groups. The study was designed as a single-center, randomized trial to provide evidence on the effects of ESWT on DFU healing. Forty-eight participants were recruited, enrolled, and randomly allocated into the 2 study groups. Twenty-five patients were allocated to the ESWT + SOC group, and 23 patients were allocated into the SOC-only group for a treatment period of 6 weeks. The univariate binary analysis showed more patients with healed DFU in the ESWT + SOC group than the SOC-only group at 6 weeks, though the difference did not reach statistical significance (OR=3.2, p=.07). The adjusted multivariate binary analysis confirmed this finding; however, the effect size did not reach statistical significance at 6 weeks (OR=3.9, p=.08). The level of circulating inflammatory markers was similar in both groups of patients. It is the author's opinion that there is a potential benefit of ESWT on diabetic wound healing with further research warranted to determine its role in treatment of DFU. A larger trial with a more extended treatment period is, however, needed to substantiate findings.

In 2024, Dymarek et al. published a study aimed to evaluate the short-term effects of radial ESWT in older adults with chronic wounds. (109) This study involved a total of 31 wounds: pressure ulcers (PUs; n=22), venous leg ulcers (VLUs; n=7), and diabetic foot ulcers (DFUs; n=2). A single radial ESWT was performed with 300 + 100 shocks per cm^2, pressure of 2.5 bar, energy of 0.15 mJ/mm^2, and frequency of 5 Hz. Assessments using digital planimetry and clinical methods, utilizing the Wound Bed Score (WBS) and the Bates-Jansen Wound Assessment Tool (BWAT) were performed before the radial ESWT application (M0) and one week after (M1). The results noted a significant wound decrease in planimetry (pre-ESWT vs post-ESWT), with wound area from 9.4 cm^2 to 6.2 cm^2, length from 6.4 cm to 3.9 cm, and width from 2.8 cm to 2.1 cm ($p<0.001$). Additionally, a substantial clinical improvement was noted in both the WBS with a 31.25% increase and the BWAT with a 20.00% increase ($p<0.001$). It was also found a significant correlation between the planimetric and clinical outcomes for both tools: WBS ($r=-0.446$, $p=0.012$) and BWAT ($r=0.327$, $p=0.073$). Researchers note there have been limited reports on the use of ESWT in wound management. While ESWT application yields substantial immediate clinical effects that support the healing of chronic wounds in older adults, researchers suggested that additional research is necessary before considering the clinical implementation of ESWT for chronic wounds.

In June 2024, Nemeth et al. performed a retrospective case series analysis to evaluate the effect of ESWT on complex chronic wounds in patients with multiple comorbidities in a medically underserved outpatient wound care clinic setting. (110) Only subjects who had wounds that were refractory to the standard of care for more than 30 days were considered for ESWT. Thirteen patients were followed with a total of 18 wounds treated. All patients had baseline wound measurements taken. Pictures of the wounds were also taken at the time of the initial visit. Patients selected for ESWT received weekly treatments for a maximum recorded

duration of 12 weeks in the form of focused electro-hydraulic acoustic pulses. Wound beds were cleansed according to standard of care. After retrospectively analyzing the data, 3 subjects and a total of 5 wounds were excluded, leaving 10 total subjects and 13 wounds. Out of these wounds, 12 healed completely by or before week 12 of ESWT. All wounds demonstrated significant wound dimension reduction during the first 12 weeks of treatment. In conclusion, researchers suggest that ESWT could offer accessible, fast, safe, and cost-effective management of some complex chronic wounds, but that further research is needed to validate these findings.

Summary of Evidence

For treatment of plantar fasciitis using extracorporeal shock wave therapy (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. Relevant outcomes are symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity. 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 vs radial, low- vs 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 three months, but it is not evident that the longer-term disease natural history is altered with ESWT. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

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 generally concluded that the evidence does not support a treatment benefit over placed or no treatment. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

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 (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. For non-calcific tendinopathy, 1 meta-analysis found that ESWT exhibited a small improvement in shoulder pain compared to sham ESWT at short-term follow-up (≤3 months). However, ESWT was not superior to sham ESWT in improving function at short- or long-term follow up (≥12 months), and ESWT was not superior to other treatments. More high-quality trials are needed to determine whether ESWT improves outcomes for shoulder tendinopathy. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

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. Another RCT found scores were statistically and clinically improved with ESWT compared with sham control at 1 month and 16 months on measures of pain and function. The most recent RCT found that activity-related pain was lower with ESWT at 6 weeks compared to ultrasound therapy, but there was no difference in pain at rest. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have patellar tendinopathy who receive ESWT, the evidence includes systematic reviews and RCTs. Relevant outcomes are symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity. Systematic reviews and trials have reported inconsistent results and were heterogeneous in treatment protocols and lengths of follow-up. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

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 reported 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 that the technology results in an improvement in the net health outcome.

For individuals who have osteonecrosis of the femoral head who receive ESWT, the evidence includes 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, patent populations, and lengths of follow-up make conclusions on the efficacy of ESWT for osteonecrosis uncertain. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have nonunion or delayed union who receive ESWT, the evidence includes systematic reviews, relatively small RCTs with methodologic limitations (e.g., heterogeneous outcomes and treatment protocols), and 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 that the technology results in an improvement in the net health outcome.

For individuals who have spasticity who receive ESWT, the evidence includes RCTs and systematic reviews, primarily in patients with stroke and cerebral palsy. Relevant outcomes are symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity. Several studies have demonstrated improvements in spasticity measures after ESWT, but most studies have small sample sizes and single center designs. 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 that the technology results in an improvement in the net health outcome.

For individuals who have wounds who receive ESWT, the evidence includes systematic reviews, RCTs with methodologic limitations, and case series. Relevant outcomes are symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity. Several studies have demonstrated improvements in wounds after ESWT, but most studies have heterogeneous outcomes and treatment protocols. 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 wounds. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

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. (111) 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 an update to the American College of Foot and Ankle Surgeons clinical consensus statement, Schneider et al. (2018) stated that ESWT is a safe and effective treatment for plantar fasciitis. (112)

National Institute for Health and Care Excellence (NICE)

The NICE has published guidance on ESWT for a number of applications.

- 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." (113, 114)
- 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." (115)
- 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." (116)
- A guidance issued in 2022 stated that evidence on the efficacy of ESWT for calcific tendinopathy of the shoulder is inadequate. Despite a lack of safety concerns, the ESWT should only be used in the context of research. (117)

American College of Surgeons

In 2013, the American College of Surgeons published a preliminary summary of the safety and effectiveness of extracorporeal shock wave therapy for the facilitation of reepithelialization and closure of chronic and non-healing wounds. That guidance states "Due to the limitations of the evidence presented in this report, it is not possible to draw firm conclusions as to the efficacy of ESWT for the treatment of chronic superficial wounds… Therefore, more robust and high-quality clinical trials are required in the future. Future research should also consider the mechanisms of ESWT and wound healing." (40)

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this policy are listed in Table 27.

Table 27. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT06128616	Efficacy of Extracorporeal Shock Wave Therapy in Children With Cerebral Palsy	40	Sept 2024
NCT06329154	Clinical Study On Extracorporeal Shock Wave Therapy For Rotator Cuff Injuries	58	Feb 2025
NCT06128616	Efficacy of Extracorporeal Shock Wave Therapy in Children With Cerebral Palsy	40	Sept 2024
NCT04316026	Effectiveness of Shock Wave Therapy to Treat Upper Limb Spasticity in Hemiparetic Patients	48	Jun 2024
NCT02546128	LEICeSter Tendon Extracorporeal Shockwave Studies (LEICSTES)	720	Dec 2024
NCT04332471	Shockwave Therapy for Plantar Fasciitis RCT	114	Mar 2025
NCT05380544	Extracorporeal Shockwave Therapy for Diabetic Foot Ulcers (SOLEFUL1)	90	May 2032

NCT06210399	Shockwave Therapy in Patients With Chronic Wounds	30	Dec 2024
NCT06438224	Clinical Utility of ESWT in Restoring Hand Function of Patients With Nerve Injury and Hypertrophic Scars Due to Burns	120	Aug 2024
Unpublished			
NCT05423366	Comparative Effects of Focused and Unfocused (Radial) ESWT in the Treatment of Patellar Tendinopathy	75	Dec 2022
NCT05360316	Extracorporeal Shock Wave Therapy Applied to the Plantar Region in Individuals With Hemiplegia	60	May 2021
NCT03779919	The Therapeutic Effect of the Extracorporeal Shock Wave Therapy on Shoulder Calcific Tendinitis	90	May 2020 (unknown status)
NCT03399968	Extracorporeal Shockwave Therapy (ESWT) to Improve Function in Chronic ASIA-A Patients	25	May 2020 (unknown status)
NCT02424084	Bone Microcirculation after Extracorporeal Shock Wave Therapy	80	Feb 2023
NCT05883020	Effect of Radial Shockwave on Calf Muscle Spasticity in Patients With Cerebral Palsy	70	March 2024
NCT06076239	Effect of Extracorporeal Shock Wave Therapy in Impingement Syndrome (ESWT)	32	June 2022
NCT05689593	Comparison of Low-Intensity Extracorporeal Shockwave Therapy and Low-Intensity Laser Effects in Adhesive Capsulitis	65	Aug 2023
NCT02417779	Cutaneous Microcirculation After Extracorporeal Shock Wave Therapy	240	Feb 2023
NCT05405140	Multiphasic Neuroplasticity Based Training Protocol With Shock Wave Therapy For Post Stroke Spasticity	32	Oct 2023 (unknown status)

NCT: national clinical trial.

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	17999, 20999, 28890, 28899, 0101T, 0102T, 0512T, 0513T
HCPCS Codes	None

*Current Procedural Terminology (CPT®) ©2023 American Medical Association: Chicago, IL.

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Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does not have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been developed since this medical policy document was written. See Medicare's National Coverage at <https://www.cms.hhs.gov>.

Policy History/Revision	
Date	**Description of Change**
11/15/2024	Document updated with literature review. Coverage unchanged. References 32, 40, 42, 83, and 105-110 added; some revised/updated.
02/01/2024	Document updated with literature review. Coverage unchanged. References 19, 21, 22, 28, 32, 40, 48, 49, 60, 64, 75, 85, 91 added; some removed; others revised.
10/01/2022	Reviewed. No changes.
01/15/2022	Document updated with literature review; the two types of ESWT (focused and radial) defined. Coverage unchanged. The following references were added: 7, 14, 26, 34-41, 64, 65, 67, 68, 84-87 and 90).
02/15/2021	Reviewed. No changes.
03/15/2020	Document updated with literature review. Coverage unchanged. The following references were added: 1-2, 7, 61, 69, 87-91, and 93.
12/15/2018	Document updated with literature review. The following changes were made to Coverage: 1) Changed “treatment” to “therapy”; 2) Updated list of experimental, investigational and/or unproven examples. Added references: 5-6, 18, 20-22, 30, 37-39, 45-47, 55-57, 59, 61-62, 65, 68, 72, 79-81, 91. Title changed from: Extracorporeal Shock Wave Treatment for Musculoskeletal Indications and Soft Tissue Injuries.
10/15/2017	Reviewed. No changes.
11/01/2016	Document updated with literature review. Coverage unchanged.
07/01/2015	Reviewed. No changes.
07/15/2014	Document updated with literature review. Coverage unchanged.
01/01/2012	Document updated with literature review. Soft tissue injuries (i.e. wound healing) was added to the experimental, investigational, and unproven coverage position. Document title changed to Extracorporeal Shock Wave Treatment for Musculoskeletal Indications and Soft Tissue Injuries. CPT/HCPCS code(s) updated.
01/01/2010	Revised/updated entire document, no change in experimental, investigational, and unproven coverage position.
08/01/2007	Revised/updated entire document
09/01/2004	CPT/HCPCS code(s) updated (with bit changes)
03/05/2004	Rationale references revised
12/01/2000	Revised/updated entire document