2.01.40	Extracorporeal Shock Wave Treatment for Plantar Fasciitis and Other Musculoskeletal Conditions		
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Section:	2.0 Medicine	**Page:**	Page 1 of 49

Policy Statement

I. Extracorporeal shock wave therapy using either a high- or low-dose protocol or radial extracorporeal shock wave therapy is considered **investigational** as a treatment of musculoskeletal conditions, including but not limited to:
   A. Achilles tendinitis
   B. Avascular necrosis of the femoral head
   C. Delayed union and nonunion of fractures spasticity
   D. Patellar tendinitis
   E. Plantar fasciitis
   F. Stress fractures
   G. Tendinitis of the elbow (lateral epicondylitis)
   H. Tendinopathies including tendinitis of the shoulder

NOTE: Refer to Appendix A to see the policy statement changes (if any) from the previous version.

Policy Guidelines

Coding
See the Codes table for details.

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.

Related Policies

- Bone Morphogenetic Protein
- Electrical Bone Growth Stimulation of the Appendicular Skeleton
- Low Intensity Pulsed Ultrasound Fracture Healing Device

Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program [FEP]) prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

Regulatory Status

Selected ESWT devices that have been approved or cleared by FDA are included in Table 1.

Table 1. Food and Drug Administration-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 mo and unresponsive to conservative management • Lateral epicondylitis
Epos™ Ultra (Dornier)	2002	Electromagnetic delivery system	Plantar fasciitis
Sonocur® Basic (Siemens)	2002	Electromagnetic delivery system	Chronic lateral epicondylitis (unresponsive to conservative therapy for >6 mo)
Orthospec™ Orthopedic ESWT (Medispec)	2005	Electrohydraulic spark-gap system	Chronic proximal plantar fasciitis in patients ≥18 y
Orbasone™ Pain Relief System (Orthometrix)	2005	High-energy sonic wave system	Chronic proximal plantar fasciitis in patients ≥18 y
Duolith® SD1 Shock Wave Therapy Device (Storz Medical AG)	2016	Electromagnetic delivery system	Chronic proximal plantar fasciitis in patients ≥18 y with history of failed alternative conservative therapies >6 mo

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

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

Rationale

Background

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 2. Many tendinitis and tendinopathy syndromes are related to overuse injury.

Table 2. Tendinitis and Tendinopathy Syndromes

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

NSAIDs: nonsteroidal anti-inflammatory drugs.

Fracture Nonunion and Delayed Union

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

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

The delayed union can be defined as a decelerating healing process, as determined by serial radiographs, together with a lack of clinical and radiologic evidence of union, bony continuity, or

bone reaction at the fracture site for no less than 3 months from the index injury or the most recent intervention. (In contrast, nonunion serial radiographs show no evidence of healing.)

Other Musculoskeletal and Neurologic Conditions

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

Treatment

Most cases of plantar fasciitis are treated with conservative therapy, including rest or minimization of running and jumping, heel cups, and nonsteroidal-anti-inflammatory drugs. Local steroid injection may also be used. Improvement may take up to 1 year in some cases.

For tendinitis and tendinopathy syndromes, conservative treatment often involves rest, activity modifications, physical therapy, and anti-inflammatory medications (Table 2).

Extracorporeal Shock Wave Therapy

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

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

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

Literature Review

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 posttreatment measures of functional status are also used, such as the 12-Item Short-Form Health Survey and 36-Item Short-Form Health Survey. Minor adverse events of ESWT are common but transient, including local pain, discomfort, trauma, bleeding, and swelling. More serious adverse events of ESWT may potentially include neurologic damage causing numbness or tingling, permanent vascular damage, or rupture of a tendon or other soft tissue structure.

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function including benefits and harms. Every clinical condition has specific outcomes that are

important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.
To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent 1 or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. Randomized controlled trials 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.

Promotion of greater diversity and inclusion in clinical research of historically marginalized groups (e.g., People of Color [African-American, Asian, Black, Latino and Native American]; LGBTQIA (Lesbian, Gay, Bisexual, Transgender, Queer, Intersex, Asexual); Women; and People with Disabilities [Physical and Invisible]) allows policy populations to be more reflective of and findings more applicable to our diverse members. While we also strive to use inclusive language related to these groups in our policies, use of gender-specific nouns (e.g., women, men, sisters, etc.) will continue when reflective of language used in publications describing study populations.

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 was used to select literature to inform this review.

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 1 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 (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% to 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 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.

Review of Evidence

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[1,2,3,] and improving functional status in the short-term (Tables 4 to 6).[1,2,] 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.[4,] The treatment success rate of the 5 trials (N=448) 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<.001). In a pooled analysis of 2 trials (N=105) 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.[5,] The literature search, conducted through September 2015, identified 9 trials for inclusion (N=1174). Meta-analyses focused on pain reduction at 12 weeks of

follow-up: overall, at first step in the morning, and during daily activities. Three RCTs also provided data to analyze improvement in the Roles and Maudsley score to excellent or good at 12-week follow-up.

A 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]).[6,] The literature search, conducted through July 2016, identified 9 trials for inclusion (N=935). An outcome in all 9 trials was "therapeutic success" rate, defined as the 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 a 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.[7,] 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=.04; I^2=85%). However, high-intensity ESWT is more effective than corticosteroid injection (2 to 3 months post-treatment: MD, 1.12; 95% CI, 0.52 to 1.72; p=.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 had 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 were 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.[8,] 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 also not included in the results summary table (Table 6) because its comparator is a corticosteroid injection rather than placebo.

Results of the 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 Extracorporeal Shock Wave Therapy for Plantar Fasciitis

Study	Aqil (2013)[2,]	Dizon (2013)[1,]	Zhiyun (2013)[3,]	Yin (2014)[4,]	Lou (2017)[5,]	Sun (2017)[6,]	Li (2018)[17,]	Xiong (2019)[8,]
Buchbinder (2002)								

Study	Aqil (2013)[2],	Dizon (2013)[1],	Zhiyun (2013)[3],	Yin (2014)[4],	Lou (2017)[5],	Sun (2017)[6],	Li (2018)[17],	Xiong (2019)[8],	Guevara (2018)

Study	Dates	Trials	Participants	N (Range)	Design	Duration
Lou (2017)[5]	2001-2015	91	Patients with recalcitrant PF	1174 (NA)	RCTs	Primary outcomes=12 weeks; studies up to >12 months
Sun (2017)[6]	1996–2015	9	Patients with chronic PF	935 (29 to 246)	RCTs	3 weeks to 6 months
Li (2018)[7]	2005–2018	9	Adults with PF and without injection history	658 (40 to 125)	RCTs	6 weeks to 1 year
Xiong (2019)[8]	2005-2018	6	Patients with PF	454 (40 to 125)	RCTs	-

NA: not available; PF: plantar fasciitis; RCT: randomized controlled trial; VAS: visual analog scale.

Table 6. Results of Systematic Reviews and Meta-Analyses Assessing Extracorporeal Shock Wave Therapy 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)[2]					
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	<.02	<.001	.003	.02	-
Dizon (2013)[1]					
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	.004	.06	.07	-	.0001
Zhiyun (2013)[33]					
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	-	<.0001	-	-	-
Yin (2014)[4]					
L-ESWT					
MD	-	1.51[2]	-		
RR	-		-	-	1.41
95% CI	-	0.77 to 2.26	-	-	1.08 to 1.82
p-value	-	<.001	-	-	.01
H-ESWT					
MD	-	1.4	-	-	
RR	-		-	-	1.33
95% CI	-	0.57 to 2.23	-	-	0.94 to 1.9
p-value	-	.11	-	-	.11
Lou (2017)[5]					
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	.001	<.0001	.0009	-	<.0001
I^2 %	0	0	-		0
Sun (2017)[6]					
OR	-	-	-	2.58	-
SMD	-	1.01	-	-	-

Study	60% VAS Score Reduction from Baseline (or >50% reduction and VAS score ≤4 cm)				Roles & Maudsley Score
95% CI	-	-0.01 to 2.03	-	1.97 to 3.39	-
Z score	-	1.94	-	6.88	-
p-value	-	.05	-	<.0001	-
I^2 %	-	96	-	38	-

CI: confidence interval; H-ESWT: high-intensity/energy shockwave therapy; L-ESWT: low-intensity/energy shockwave therapy; MD: mean difference; OR: odds ratio; RR: risk ratio; SMD: standard mean difference; VAS: visual analog scale; 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 3 studies that measured Roles and Maudsley scores but did not statistically combine the results. However, all 3 studies showed statistically significant improvements for the ESWT group at 12 weeks.
[2] Yin et al compared ESWT value for pain relief before and after treatment.
[3] Zhivun compared 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.[9,] 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=.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 an 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 U.S. Food and Drug Administration (FDA) premarket approval of the Dolorclast.[10,] The trial randomized 252 patients, 129 to RSW and 122 to sham treatment. Patients had heel pain for at least 6 months and had failed at least 2 nonpharmacologic and 2 pharmacologic treatments. Over 90% of patients were compliant with the 3 weekly treatment schedule. Outcome measures were composite heel pain (pain on first steps of the day, with activity and as measured with Dolormeter), change in VAS pain score, and Roles and Maudsley score measured at 12 weeks and 12 months. Success was defined as a reduction of 60% or more in 2 of 3 VAS scores, or patient ability to work and complete activities of daily living, treatment satisfaction, and requiring no further treatment. Secondary outcomes at 12 weeks included changes in Roles and Maudsley score, 36-Item Short-From Health Survey Physical Component Summary score, 36-Item Short-Form Health Survey Mental Component Summary score, investigator's and patient's judgment of effectiveness, and patient recommendation of therapy to a friend. At 12-week follow-up, RSW resulted in a decrease of the composite VAS score by 72.1% versus 44.7% after placebo (p=.022). Success rates for the composite heel pain score were 61% and 42% (p=.002). Statistically significant differences were noted in all secondary measures. A number of limitations prevent definite conclusions from being reached including: 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.[11,] 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.[12,] 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 Randomized Controlled Trials Assessing Extracorporeal Shock Wave Therapy for Plantar Fasciitis

Study; Trial	Countries	Sites	Participants	Interventions	
				Active	*Comparator*
Gollwitzer (2015)[9,]	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)
Gerdesmeyer (2008)[10,]	US, EU	8	Patients with ≥6 months painful heel syndrome resistant to nonsurgical treatment; score ≥5 on 3 VAS scores; failed ≥2 non-pharmacological and 2 pharmacological treatments; sufficient 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)
FDA, Orbasone (2005)[12,]	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 to 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)[11,]	US	3	Adults (non-pregnant) with proximal PF for >6 months; under treatment ≥4 months; VAS score upon first steps ≥5 cm; failed 2 pharmacological and 2 nonpharmacological treatments; washout period; (n=172)	Total of 3800 shocks; (n=115)	Total of 3800 shocks; contact membrane of device lined with internal foam insert to absorb shockwaves; (n=57)

EU: European Union; FDA: U.S. Food and Drug Administration; PF: plantar fasciitis; VAS: visual analog scale;.

Table 8. Summary of Key Results of Randomized Controlled Trials Assessing Extracorporeal Shock Wave Therapy for Plantar Fasciitis

Study	VAS Pain Score Improvement	Functional Improvement
Gollwitzer (2015)[9,]		
p-value (MW effect size)[3]	.0027 (0.6026)	.0006 (0.6135)
Lower-bound 95% CI	0.5306	0.5466
ESWT mean % from baseline (95% CI)	-54.5 (-61.4 to -47.7)	-
Placebo mean % from baseline (95% CI)	-40.3 (-47.5 to -33.1)	-

Study	VAS Pain Score Improvement	Functional Improvement
ESWT mean score (95% CI)[4]	-	2.5 (2.3 to 2.7)
Placebo mean score (95% CI)	-	2.9 (2.7 to 3.1)
Gerdesmeyer (2008)[10,]		
ESWT reduction in VAS composite %	72.1	-
Placebo reduction in VAS composite %	44.7	-
p-value	.0220	-
ESWT success rate %[1]	60.98	58.402
Placebo success rate %	42.24	41.52
p-value (MW effect size)	.0020 (-)	.0031 (0.5973)
FDA, Orbasone (2005)[12,]		
ESWT 12-wk mean score (SE)	3.11 (0.30)	-
Range	0 to 9.8	-
Placebo 12-wk mean score (SE)	5.51 (0.35)	-
Range	0 to 10	-
p-value	.0002	-
% ESWT with 40% reduction in VAS	70.8	-
% Placebo with 40% reduction in VAS	36.6	-
FDA, Orthospec (2005)[11,]		
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	.045	-
ESWT effectiveness rate %[7]	-	64.3
Placebo effectiveness rate %	-	57.1
p-value	-	.33

CI: confidence interval; ESWT: extracorporeal shockwave therapy; FDA: US Food and Drug Administration; MW: Mann-Whitney; SE: standard error; VAS: visual analog scale.
[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 Randomized Controlled Trials Assessing Extracorporeal Shock Wave Therapy for Plantar Fasciitis

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Follow-Up[e]
Gollwitzer (2015)[9,]					
Gerdesmeyer (2008)[10,]					
FDA, Orbasone (2005)[12,]	3. Allocation concealment unclear				
FDA, Orthospec (2005)[11,]	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 Randomized Controlled Trials Assessing Extracorporeal Shock Wave Therapy for Plantar Fasciitis

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]
Gollwitzer (2015)[9]						
Gerdesmeyer (2008)[10]						3. Confidence intervals not reported
FDA, Orbasone (2005)[12]	1. Allocation concealment unclear		1. Registration unclear		1. Power calculations not reported	3. Confidence intervals and p-values not reported
FDA, Orthospec (2005)[11]	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.[13] Outcome measures included a 0-to-100 VAS assessing morning pain, the American Orthopaedic Foot and Ankle Society (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.

Randomized controlled trials comparing ESWT and RSW with corticosteroid injection and conservative treatment (exercise, orthotic support) have been performed, with mixed findings.[14,-,17] As the follow-up period for these studies is 3 months or less, the clinical significance of these results is uncertain.[18] 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.[19]

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.[20,] 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-blind 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 3 months, but it is not evident that the longer-term disease natural history is altered with ESWT. Currently, it is not possible to conclude definitively that ESWT improves outcomes for patients with plantar fasciitis.

Lateral Epicondylitis

Clinical Context and Therapy Purpose

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

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

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 UEFS • Roles and Maudsley function scores of "good" or "excellent" • Grip strength improvement	Generally measured for up to 12 weeks
Medication use	• Nonuse of pain medication	Generally measured for up to 12 weeks

UEFS: Upper Extremity Function Scale; 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.

Review of Evidence

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."[21,] A systematic review by Dingemanse et al (2014), which evaluated electrophysical therapies for epicondylitis, found conflicting evidence on the short-term benefits of ESWT.[22,] 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 the humerus.[23,] 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.[24,] 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.[25,] A systematic review and network 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.[26,]

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.[27,] 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.[28,] 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.[29,]

Randomized Controlled Trials

Relevant RCTs are summarized in 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.[30,] 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.[31,] 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) compared ESWT (n=20) with kinesiotaping (n=20) as part of a 3-week treatment in patients with newly diagnosed lateral epicondylitis.[32,] 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 vs. 4.0; p=.01), a better hand grip strength score (26.8 vs. 20.6; p=.005), and a lower Roles and Maudsley score (1.7 vs. 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) published results from an RCT (N=30) comparing RSW plus physical therapy with physical therapy alone in patients with lateral epicondylitis.[33,] Outcomes included VAS pain and grip strength. Significant differences were seen in grip strength by 12 weeks of follow-up; the MD 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 MD between groups was -1.8 (95% CI, -3.0 to -0.5), favoring RSW. This RCT is not included in the summary table because it compares RSW with a physical therapy program that includes ultrasound therapy.

A small RCT by Capan et al (2016) comparing RSW (n=28) with sham RSW (n=28) for lateral epicondylitis did not find significant differences between groups in grip strength or function.[34,] However, this trial might have been underpowered to detect a difference.

Lizis (2015) compared ESWT with therapeutic ultrasound among 50 patients who had chronic tennis elbow.[35,] 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.[36,] This trial randomized 59 patients with lateral epicondylitis to ESWT, physical therapy, or a single corticosteroid injection. Outcome measures were VAS pain, grip strength, and pinch strength by dynamometer. The authors reported that VAS pain scores improved significantly in all 3 groups at all 3 follow-up time points out to 6 months, but they reported no between-group differences. No consistent changes were reported for grip strength or on ultrasonography. This RCT is not included in the summary table because it compares ESWT with corticosteroid injections, and the physical therapy comparator includes ultrasound therapy.

Staples et al (2008) reported on a double-blind controlled trial of ESWT for epicondylitis in 68 patients.[37,] 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[38,] without local

anesthesia) weekly for 3 weeks or placebo.[39,] Patients were followed for 12 weeks, and benefit demonstrated with the following outcomes: VAS pain (0 to 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 Upper Extremity Function Scale 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 Randomized Controlled Trials Assessing Extracorporeal Shock Wave Therapy for Lateral Epicondylitis

Study; Trial	Countries	Sites	Dates	Participants	Interventions	
					Active	*Comparator*
Kaplan (2023)[30,]	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, 1.7 Bar, 1800 pulses, 0.02-0.60 mj/mm^2 for 3 minutes and 45 seconds (n=30)	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)
Capan (2016)[34,]	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)
Staples (2008)[37,]	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)
Pettrone & McCall (2005)[39,]	US	3	-	Patients with LE ≥6 months; pain resistant ≥2 of 3 conventional therapies; pain ≥40 mm on VAS with	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

Study; Trial	Countries	Sites	Dates	Participants	Interventions	
				resisted wrist extension; (n=114)		machine application head; (n=58)

ESWT: extracorporeal shockwave therapy; FSW: focused extracorporeal shockwave therapy; LE: lateral epicondylitis; RSW: radial extracorporeal shockwave therapy; VAS: visual analog scale.

Table 13. Summary of Key Results of Randomized Controlled Trials Assessing Extracorporeal Shock Wave Therapy for Lateral Epicondylitis

Study	Pain Improvement		Grip Strength[1]	
	≤6 wks	3 mos	≤6 wks	3 mos
Kaplan (2023)[30,]				
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)[34,]				
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	<.001	<.001	.002	.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	.001	<.001	.001	.017
% difference between groups	0.758	0.882	0.578	0.768
Staples (2008)[37,]				
	-	-	-	-
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	26.0 (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 to 17.3[4]	-0.22 to 0.12	-0.13 to 0.20
p-value	.84	.95	.57	-
Pettrone & McCall (2005)[39,]				
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	-	.02	-	.09
ESWT % pts w/pain reduction	-	61[5]	-	-
Placebo % pts w/pain reduction	-	29[5]	-	-
p-value	-	.0001	-	

CI: confidence interval; ESWT: extracorporeal shockwave therapy; FSW: focused extracorporeal shockwave therapy; MD: mean difference; pts: patients; PRTEE: Patient-Rated Tennis Elbow Evaluation; RSW: radial extracorporeal shockwave therapy; SD: standard deviation; SE: standard error of the mean; VAS: visual analog scale.

[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 function scores.

[4] VAS pain index (range, 0-100).

[5]Pain reduction of ≥50% on Thomsen test.

[6]Functional improvement assessed using Upper Extremity Functional Scale

[7]Disabilities of the Arm, Shoulder, and Hand questionnaire function scores.

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

Table 14. Study Relevance Limitations of Randomized Controlled Trials Assessing Extracorporeal Shock Wave Therapy for Lateral Epicondylitis

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Follow-Up[e]
Kaplan (2023)[30],				3. CONSORT flow diagram included, but no reporting of harms	
Capan (2016)[34],				3. CONSORT flow diagram included, but no reporting of harms	
Staples (2008)[37],					
Pettrone & McCall (2005)[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 Randomized Controlled Trials Assessing Extracorporeal Shock Wave Therapy for Lateral Epicondylitis

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]
Kaplan (2023)[30],		2. Not blinded outcome assessment	1. Not registered			
Capan (2016)[34],			1. Not registered	6. No intent-to-treat analysis	1. Calculations not reported	
Staples (2008)[37],			1. Not registered		3. Underpowered	
Pettrone & McCall (2005)[39],	3. Unclear how randomized		1. Not registered			

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.

Section Summary: Lateral Epicondylitis

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

Shoulder Tendinopathy

Clinical Context and Therapy Purpose

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

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

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 • 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	• CMS • SPADI • 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

ASES: American Shoulder and Elbow Surgeons; CMS: Constant-Murley Score; SPADI: Shoulder Pain And Disability Index; 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.

Review of Evidence

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.[40,] 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 nonoperative and operative treatments for chronic calcific tendonitis.[41,] A literature review through February 2022 identified 27 RCTs (N=2352). Outcomes were pain (VAS; minimal clinically important difference, 2.4), functional assessment (CMS; minimal clinically important difference, 10.4), and calcific deposit resolution. The pooled MD in VAS was -3.83 for ESWT versus -4.83 for ultrasound-guided needling and -4.65 for operative interventions. The pooled MD 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.[42,] The literature review, conducted through April 2016, identified 14 RCTs (N=1105) for inclusion. Treatments included in the network meta-analysis were ultrasound-guided needling (UGN), RSW, H-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, and 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).[42,]
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.[43,] 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, Loppolo et al (2013) identified 6 RCTs that compared ESWT with sham treatment or placebo for calcific shoulder tendinopathy.[44,] 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 Extracorporeal Shock Wave Therapy for Shoulder Tendinopathy

Study	Arirachakaran (2017)[43,]	Ioppolo (2013)[44,]	Wu (2017)[42,]	Angileri (2023)[41,]	Kamonseki (2023)[40,]
Ainsworth (2007)					

Study	Arirachakaran (2017)[43],	Ioppolo (2013)[44],	Wu (2017)[42],	Angileri (2023)[41],	Kamonseki (2023)[40],
Louwerens (2020)					

Study	VAS/NRS/CMS Score Improvement/Pain Reduction	CMS/SPADI/Functional Improvement	Decrease in Calcium Deposit Size
p-value	<.00001	<.00001	-
Arirachakaran (2017) [43]			
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 to 17.6	-24.7 to 2.2
p-value	<.05	<.05	>.05
Ioppolo (2013) [44]			
Pooled total resorption ratio	-	-	27.19
95% CI	-	-	7.20 to 102.67
p-value			.552
Pooled partial resorption ratio	-	-	16.22
95% CI	-	-	3.33 to 79.01
p-value			.845
H-FSW			
Wu (2017) [42]			
WMD	4.18	-	-
95% CrI	1.99 to 6.37	-	-
L-FSW			
WMD	1.94	-	-
95% CrI	-0.42 to 4.30	-	-
RSW			
WMD	6.12	-	-
95% CrI	3.91 to 8.34	-	-

CI: confidence interval; CMS: Constant-Murley Score; CrI: credible interval; ESWT: extracorporeal shockwave therapy; H-FSW: high-energy focused extracorporeal shockwave therapy; L-FSW: low-energy focused extracorporeal shockwave therapy; MD: mean difference; NRS: numerical rating scale;RSW: radial extracorporeal shockwave therapy; SPADI: Shoulder Pain And Disability Index; UMD: unstandardized mean difference; VAS: visual analog scale; 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.[45] 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.[46] Three were considered high quality. High-energy ESWT was associated with significant improvements in functional outcomes, with a MD at 3 months of 9.88 (95% CI, 0.04 to 10.72; p<.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=.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.[47] 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.[48,] 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.[49,] 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.[50,] 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).[51,52,] Patients received 4 treatments of RSW or sham at 1-week intervals. After 24 weeks of follow-up, both groups improved from baseline, with no significant differences between groups. Within a prespecified subgroup of patients with calcification in the rotator cuff, there was a statistically significant improvement in the group receiving ESWT compared with sham treatment (p=.18). After 1 year, there was no statistically significant difference in improvements between RSW and sham when groups were analyzed together and separately.

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

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

Kim et al (2014) compared UGPL plus SAI with ESWT in patients who had unilateral calcific shoulder tendinopathy and ultrasound-documented calcifications of the supraspinatus tendon.[54,] Sixty-two patients were randomized. Fifty-four patients were included in the data analysis (8 subjects were lost to follow-up). ESWT was performed for 3 sessions once weekly. The radiologic evaluation was blinded, although it was not specified whether evaluators for pain and functional outcomes were blinded. After an average follow-up of 23.0 months (range, 12.1 to 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=.001) and on the Simple Shoulder Test from 38.2% to 91.7% (p=.03). In the ESWT group, scores on the American Shoulder and Elbow Surgeons scale improved from 49.9 to 78.3 (p=.026) and on the Simple Shoulder Test from 34.0% to 78.6% (p=.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=.001).

An example of a high-energy versus low-energy trial is that by Schofer et al (2009), which assessed 40 patients with rotator cuff tendinopathy.[55,] An increase in function and reduction of pain were found in both groups (p<.001). Although improvement in the Constant score was greater in the high-energy group, there were no statistically significant differences in any outcomes studied (Constant score, pain, subjective improvement) at 12 weeks, or at 1 year posttreatment.
At least 1 RCT has evaluated patients with bicipital tendinitis of the shoulder.[56,] This trial by Liu et al (2012) randomized 79 patients with tenosynovitis to ESWT or to sham treatment. ESWT was given for 4 sessions over 4 weeks. Outcomes were measured at up to 12 months using a VAS for pain and the L'Insalata Shoulder Questionnaire. The mean decrease in the VAS score at 12 months was greater for the ESWT group (4.24 units) than for the sham group (0.47 units; p<.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 was used to select literature to inform this review.

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] • Roles and Maudsley pain scores of "good" or "excellent"	4 weeks to >1 year
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.

Review of Evidence

Systematic Reviews

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

Al-Abbad and Simon (2013) conducted a systematic review of 6 studies on ESWT for Achilles tendinopathy.[58,] Selected for the review were 4 small RCTs and 2 cohort studies. Satisfactory evidence was found in 4 studies demonstrating the effectiveness of ESWT in the treatment of Achilles tendinopathy at 3 months. However, 2 RCTs found no significant difference between ESWT and placebo in the treatment of Achilles tendinopathy. These trials are described next.[59,60,]

Randomized Controlled Trials

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.[61,] 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 patients with unilateral noninsertional Achilles tendinopathy.[62,] 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.[63,] 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.[64,] 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 injection group.

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

Rasmussen et al (2008) reported on a single-center, double-blind controlled trial with 48 patients, half randomized after 4 weeks of conservative treatment to 4 sessions of active RSW and half to sham ESWT.[60,] The primary end point was AOFAS score measuring function, pain, and alignment and VAS pain score. AOFAS score after treatment increased from 70 to 88 in the ESWT group and from 74 to 81 in the control (p=.05). The pain was reduced in both groups, with no statistically significant difference between groups. The authors suggested that the AOFAS might not be appropriate to evaluate treatment of Achilles tendinopathy.

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

Section Summary: Achilles Tendinopathy

Two systematic reviews of RCTs and 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 was used to select literature to inform this review.

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 • VISA-Patellar Tendon • McGill Pain Questionnaire • Roles and Maudsley score for pain • Likert scale/numerical rating scale for pain • Swelling	<1 month to 1 year
Functional Outcomes	• Range of motion • Knee Outcome Survey Activities of Daily Living • Vertical jump test • Roles and Maudsley score for function • International Knee Documentation Committee scale	<1 month to 1 year

VAS: visual analog scale; VISA: Victorian Institute of Sports Assessment.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

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

Review of Evidence

Systematic Reviews

Stania et al (2022) conducted a systematic review and meta-analysis of 7 RCTs of ESWT in patients with patellar tendinitis.[65,] 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.[66,] Their review included 19 RCTs, encompassing 1189 participants. Of the participants, 562 underwent ESWT and 627 received a placebo or other conservative treatment. Analysis revealed that ESWT results in significant improvements in pain levels, with a pooled standard MD of -1.49 (95% CI, -2.11 to -0.87; p<.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 standard MD of 2.61 (95% CI, 2.11 to 3.12; p<.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.[67,] Reviewers found that most of the 7 selected studies had methodologic deficiencies, small numbers and/or short follow-up periods, and variation in treatment parameters. Reviewers concluded ESWT appears to be a safe and promising treatment but could not recommend a treatment protocol.

In the systematic review of ESWT for lower-extremity tendinopathies (previously described), Mani-Babu et al (2015) identified 7 studies of ESWT for patellar tendinopathy (2 RCTs, 1 quasi-RCT, 1 retrospective cross-sectional study, 2 prospective cohort studies, 1 case-control study).[57,] The 2 RCTs came to different conclusions: 1 found no difference in outcomes between ESWT and placebo at 1, 12, or 22 weeks, whereas the other found improved outcomes on vertical jump test and 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.[68,] Patients were physically active with a mean age of 28.6 years (range, 18 to 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<.05) with plasma-rich protein injections than with ESWT at 6 and 12 months, respectively.[69,]

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 was used to select literature to inform this review.

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.

Review of Evidence

Randomized and Nonrandomized Studies

Newman et al (2017) published a double-blind, sham-controlled randomized trial on the use of ESWT for the treatment of 28 patients with medial tibial stress syndrome (commonly called shin splints).[70,] 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.[71,] 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.[72,]

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 was used to select literature to inform this review.

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 • Radiographic reduction of bone marrow edema on magnetic resonance imaging	3 months to >24 months
Functional outcomes	• HHS for function	3 months to >24 months

HHS: Harris Hip Score; 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.

Review of Evidence

Systematic Reviews

In their meta-analysis, Hao et al (2018) compared the effectiveness of ESWT with other treatment strategies in improving pain scores and Harris Hip Score (HHS) for patients with osteonecrosis of the femoral head.[73,] 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 through III of osteonecrosis of the femoral head. Before treatment, no significant differences in pain scores (p=.1328) and HHS (p=.287) were found between the ESWT group (n=130) and control group (n=110). Post-treatment, the ESWT group reported significantly higher improvement in pain scores than the control group (standard MD, -2.1148; 95% CI, -3.2332 to -0.9965; Z=3.7063; p=.0002), as well as higher HHSs (standard MD, 2.1377; 95% CI, 1.2875 to 2.9880; Z=4.9281; p<.001). However, the analysis revealed no significant improvements in pain scores before and after treatment (p=.005), but it did reveal significant improvements in the HHS (p<.001). Patient follow-up time across studies ranged from 3 to 25 months. This analysis had several limitations including: only 1 RCT was included out of 4 studies; small sample size resulted in more pronounced heterogeneity between studies; the studies were of poor quality; publication bias was detected for the HHS after treatment; and only 2 studies reported pain scores.

A systematic review by Zhang et al (2016) evaluated evidence on the use of ESWT for osteonecrosis of the femoral head.[74,] 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).[75,] 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 design, 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 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 was used to select literature to inform this review.

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.

Review of Evidence
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.[76,] 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.[77,] 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 that 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.[78,] 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<.001); mean percentage of weight bearing at 6 months was 87% and 78%, respectively (p=.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<.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.[79,] 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%, and 73%, respectively). All groups' healing rates improved at 12- and 24-month follow-ups, without significant between-group differences. Secondary endpoints 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.[80,] 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 a 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<.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 was used to select literature to inform this review.

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
Function outcomes	• Brunnstrom Recovery Stage tool to assess motor recovery	Up to 5 weeks post-therapy

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

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

Review of Evidence
Systematic Reviews
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.[81,] 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).[82,] 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 MD, 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.[83,] 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.[84,] 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.[85,] 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.[86,] Studies included evaluated ESWT as sole therapy and reported pre- and post-intervention Modified Ashworth Scale scores. Five studies were selected, 4 examining spasticity in the ankle plantar flexor and 1 examining spasticity in the wrist and finger flexors; 3 studies evaluated poststroke spasticity and 2 evaluated spasticity associated with cerebral palsy. Immediately post-ESWT, Modified Ashworth Scale scores improved significantly compared with baseline (standardized MD, -0.792; 95% CI, -1.001 to -0.583; p<.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<.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.[87,] Patients were randomized to 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 RSW with botulinum toxin type A in reducing plantar flexor muscle spasticity in 68 patients with cerebral palsy.[88,] 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 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 RSW on agonist muscles (n=27) and antagonist muscles (n=30) compared with control (n=25) in patients with stroke.[89,] 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.[90,] 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.[91,] 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 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 a single center design. More well-designed controlled trials in larger populations are needed to determine whether ESWT leads to clinically meaningful improvements in pain and/or functional outcomes for spasticity.

Extracorporeal Shock Wave Treatment for Other Conditions

ESWT has been investigated in small studies for other conditions, including coccydynia in a case series of 2 patients[92,] and an RCT involving 34 patients,[93,] painful neuromas at amputation sites in an RCT assessing 30 subjects,[94,] and chronic distal biceps tendinopathy in a case-control study of 48 patients.[95,]

The systematic review of ESWT for lower-extremity tendinopathies (previously described) by Mani-Babu et al (2015) reviewed 2 studies of ESWT for greater trochanteric pain syndrome, including 1 quasi-RCT comparing ESWT with home therapy or corticosteroid injection and 1 case-control study comparing ESWT with placebo.[57,] ESWT was associated with some benefits compared with placebo or home therapy.

Supplemental Information

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

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.[96,] 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 stated that ESWT is a safe and effective treatment for plantar fasciitis.[97,]

National Institute for Health and Care Excellence

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".[98,99,]
- 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".[100,]
- 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".[101,]
- 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.[102,]

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this review 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
NCT05883020	Effect of Radial Shockwave on Calf Muscle Spasticity in Patients With Cerebral Palsy	50	March 2024
NCT06076239	Effect of Extracorporeal Shock Wave Therapy in Impingement Syndrome (ESWT)	32	June 2022
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	LEICSTES=LEICeSter Tendon Extracorporeal Shock Wave Studies Assessing the Benefits of the Addition of Extracorporeal Shock	720	Dec 2024

NCT No.	Trial Name	Planned Enrollment	Completion Date
	Wave Treatment to a Home-Rehabilitation Programme for Patients with Tendinopathy		
NCT04332471	Treatment of Plantar Fasciitis With Radial Shockwave Therapy vs. Focused Shockwave Therapy: a Randomized Controlled Trial	114	Mar 2025
NCT05689593	Comparison of the Efficiency of Low Intensity Extracorporeal Shock Wave Therapy and Low Intensity Laser Therapy in Adhesive Capsulitis Treatment: a Randomized Controlled Study	60	Aug 2023
NCT05405140	Multiphasic Neuroplasticity Based Training Protocol With Shock Wave Therapy For Post Stroke Spasticity	32	Oct 2023
NCT05771220	The Effect of Extracorporeal Shockwave Therapy on Adhesive Capsulitis Shoulder: A Randomized Controlled Trial	40	Jul 2023
Unpublished			
NCT03472989	The Effectiveness of Radial Extracorporeal Shockwave Therapy (rESWT), Sham- rESWT, Standardized Exercise Program or Usual Care for Patients With Plantar Fasciopathy. Study Protocol for a Double-blind, Randomized Sham-Controlled Trial	200	Feb 2023
NCT05423366	Comparative Effects of Large Focused and Controlled Unfocused (Radial) Extracorporeal Shock Wave Therapies in the Treatment of Patellar Tendinopathy	75	Dec 2022
NCT05702606	Radial Extracorporeal Shock Wave Therapy for Management of Spasticity in Patients With Cerebral Palsy	73	Oct 2022
NCT05360316	The Effect of Extracorporeal Shock Wave Therapy Applied to the Plantar Region in Individuals With Hemiplegia on Mobility, Plantar Pressure Distribution and Sensory	60	May 2021
NCT03779919	The Therapeutic Effect of the Extracorporeal Shock Wave Therapy on Shoulder Calcific Tendinitis	90	May 2020
NCT03399968	Extracorporeal Shockwave Therapy (ESWT) in Patients Suffering From Complete Paraplegia at the Thoracic Level	25	May 2020
NCT02424084	Effects of Extracorporeal Shock Wave Therapy in Bone Microcirculation	80	Feb 2023

NCT: national clinical trial.

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Documentation for Clinical Review

- No records required

Coding

This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy.

The following codes are included below for informational purposes. Inclusion or exclusion of a code(s) does not constitute or imply member coverage or provider reimbursement policy. Policy Statements are intended to provide member coverage information and may include the use of some codes for clarity. The Policy Guidelines section may also provide additional information for how to interpret the Policy Statements and to provide coding guidance in some cases.

Type	Code	Description
CPT®	0101T	Extracorporeal shock wave involving musculoskeletal system, not otherwise specified
	0102T	Extracorporeal shock wave performed by a physician, requiring anesthesia other than local, and involving the lateral humeral epicondyle

Type	Code	Description
	20999	Unlisted procedure, musculoskeletal system, general
	28890	Extracorporeal shock wave, high energy, performed by a physician or other qualified health care professional, requiring anesthesia other than local, including ultrasound guidance, involving the plantar fascia
HCPCS	None	

Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

Effective Date	Action
06/01/2001	New Policy Adoption
02/01/2002	Policy Review Policy expanded from BCBSA TEC (2002 Vol. 16, No. 20)
11/01/2002	Policy Review
06/01/2004	Policy Revision BSC CTAF Review: June 2004 - Plantar Fasciitis & Rotator Cuff Tendonitis; Plantar Fasciitis updated; RCT: new policy
10/01/2004	New Policy Adoption BSC CTAF Review: October 2004 (Lateral Epicondylitis)
03/01/2005	Criteria Revised Effective date Plantar Fasciitis policy modified
10/15/2007	Policy Review Policy updated BCBSA MPP (06/07) no change in decision. For Rotator cuff maintained CTAF 10/04 position, no change in position.
08/04/2009	Administrative Review
10/07/2011	Policy revision without position change
03/13/2012	Coding Update
05/29/2015	Policy revision without position change
08/01/2016	Policy revision without position change
12/01/2016	Coding update
08/01/2017	Policy revision without position change
08/01/2018	Policy revision without position change
08/01/2019	Policy revision without position change
05/01/2020	Administrative update. Policy statement updated.
08/01/2020	Annual review. No change to policy statement.
12/01/2020	No change to policy statement. Literature review updated.
08/01/2021	Annual review. No change to policy statement. Literature review updated.
02/01/2022	Coding update.
08/01/2022	Annual review. No change to policy statement. Literature review updated.
08/01/2023	Annual review. No change to policy statement. Policy guidelines and literature review updated.
08/01/2024	Annual review. Policy statement, guidelines and literature review updated.

Definitions of Decision Determinations

Medically Necessary: Services that are Medically Necessary include only those which have been established as safe and effective, are furnished under generally accepted professional standards to treat illness, injury or medical condition, and which, as determined by Blue Shield, are: (a) consistent with Blue Shield medical policy; (b) consistent with the symptoms or diagnosis; (c) not furnished primarily for the convenience of the patient, the attending Physician or other provider; (d) furnished at the most appropriate level which can be provided safely and effectively to the patient; and (e) not more costly than an alternative service or sequence of services at least as likely to produce equivalent

therapeutic or diagnostic results as to the diagnosis or treatment of the Member's illness, injury, or disease.

Investigational/Experimental: A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

Split Evaluation: Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

Prior Authorization Requirements and Feedback (as applicable to your plan)

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department at (800) 541-6652, or the Transplant Case Management Department at (800) 637-2066 ext. 3507708 or visit the provider portal at www.blueshieldca.com/provider.

We are interested in receiving feedback relative to developing, adopting, and reviewing criteria for medical policy. Any licensed practitioner who is contracted with Blue Shield of California or Blue Shield of California Promise Health Plan is welcome to provide comments, suggestions, or concerns. Our internal policy committees will receive and take your comments into consideration.

For utilization and medical policy feedback, please send comments to: MedPolicy@blueshieldca.com

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.

Appendix A

POLICY STATEMENT	
BEFORE Red font: Verbiage removed	**AFTER** Blue font: Verbiage Changes/Additions
Extracorporeal Shock Wave Treatment for Plantar Fasciitis and Other Musculoskeletal Conditions 2.01.40 **Policy Statement:** I. The following are considered **investigational**: A. Extracorporeal shock wave therapy (ESWT) to treat Achilles tendinitis and patellar tendinitis B. ESWT to treat avascular necrosis of the femoral head C. ESWT to treat delayed union and nonunion of fractures D. ESWT to treat plantar fasciitis E. ESWT to treat spasticity F. ESWT to treat stress fractures G. ESWT to treat tendinitis of the elbow (lateral epicondylitis) H. ESWT to treat tendinopathies including tendinitis of the shoulder I. ESWT to treat all other musculoskeletal conditions	**Extracorporeal Shock Wave Treatment for Plantar Fasciitis and Other Musculoskeletal Conditions 2.01.40** **Policy Statement:** I. Extracorporeal shock wave therapy using either a high- or low-dose protocol or radial extracorporeal shock wave therapy is considered **investigational** as a treatment of musculoskeletal conditions, including but not limited to: A. Achilles tendinitis B. Avascular necrosis of the femoral head C. Delayed union and nonunion of fractures spasticity D. Patellar tendinitis E. Plantar fasciitis F. Stress fractures G. Tendinitis of the elbow (lateral epicondylitis) H. Tendinopathies including tendinitis of the shoulder