Extracorporeal Shock Wave Therapy (ESWT) for Musculoskeletal Conditions and Soft Tissue Indications

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Instructions for Use

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Community Plan Policy

- Extracorporeal Shock Wave Therapy (ESWT) for Musculoskeletal Conditions and Soft Tissue Indications

Application

UnitedHealthcare Commercial

This Medical Policy applies to UnitedHealthcare Commercial benefit plans.

UnitedHealthcare Individual Exchange

This Medical Policy applies to Individual Exchange benefit plans.

Coverage Rationale

Extracorporeal shock wave therapy (ESWT), whether low energy, high energy, or radial wave, is unproven and not medically necessary for any musculoskeletal or soft tissue indications due to insufficient evidence of efficacy.

Note: This policy does not address extracorporeal shock wave lithotripsy (ESWL) used for the treatment of:

- Gallstones
- Kidney stones
- Pancreatic stones
- Salivary stones

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other policies and guidelines may apply.

CPT Code	Description
0101T	Extracorporeal shock wave involving musculoskeletal system, not otherwise specified

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CPT Code	Description
0102T	Extracorporeal shock wave performed by a physician, requiring anesthesia other than local, and involving the lateral humeral epicondyle
0512T	Extracorporeal shock wave for integumentary wound healing, including topical application and dressing care; initial wound
0513T	Extracorporeal shock wave for integumentary wound healing, including topical application and dressing care; each additional wound (List separately in addition to code for primary procedure)
0864T	Low-intensity extracorporeal shock wave therapy involving corpus cavernosum, low energy
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

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Description of Services

Extracorporeal shock wave therapy (ESWT) devices are similar to the lithotripters used for breaking up kidney stones in urology. They produce low- or high-energy pulses arising from acoustic energy, called shock waves, which can be focused and then propagated through water in body tissues. When focused on a boundary between tissues of differing densities, the shock wave is altered, and energy is emitted. The shock waves for orthopedic indications are the same as those used to break up kidney stones but have 10 times less energy. Low-energy defocused ESWT or soft focused acoustical wave pattern is used for wound healing.

Although the mechanism of therapeutic effect of ESWT has not been established, it has been proposed that shock waves may have a direct mechanical effect through the rapid buildup of positive pressure and/or a more indirect effect through the implosion of bubbles in the interstitial fluid. These forces may reduce transmission of pain signals from sensory nerves, cause calcium deposits to disintegrate, break down scar tissue, cause a transient inflammatory response, and/or stimulate tissue healing. (Hayes, 2022)

Clinical Evidence

Achilles Tendinitis

Conclusive evidence that recommends extracorporeal shock wave therapy (ESWT) as a treatment for Achilles tendinopathy is lacking. Studies that compare high-energy, single-treatment protocols with low-energy, multiple-treatment protocols and studies that compare various dosing intervals and energy flux densities are also needed to determine optimal treatment parameters. A standardized method to evaluate results may also be helpful. Published articles on ESWT for Achilles tendinitis have been limited to studies that use animal models. There are no adequate prospective clinical studies that demonstrate the effectiveness of ESWT for Achilles tendinitis.

Majidi et al. (2024) conducted a systematic review and meta-analysis that evaluated randomized controlled trials (RCTs) of ESWT for tendinopathy. Eligible studies included two groups, one receiving ESWT (radial or focused) and another receiving alternative treatments without ESWT, and measured pain using the visual analog scale (VAS) from 0 to 10 as the primary end point. Overall, 45 clinical trials were analyzed, encompassing individuals with plantar fasciitis (PF), chronic Achilles tendinopathy, lateral epicondylitis (LE), rotator cuff tendinopathy, and patellar tendinopathy, with mean ages of individuals ranging from 38 to 54 years and body mass index values between 22.8 and 32 kg/m^2. Statistical analysis used Stata 17 and a random-effects DerSimonian-Laird model to calculate standardized mean differences (SMDs). ESWT significantly reduced pain in PF (SMD, -1.63; 95% CI, -3.04 to -0.21), LE (SMD, -0.63; 95% CI, -1.11 to -0.16), chronic Achilles tendinopathy (SMD, -1.38; 95% CI, -1.66 to -1.10), and rotator cuff tendinopathy (SMD, -2.37; 95% CI, -3.58 to -1.15), while patellar tendinopathy showed an increase in pain (SMD, 1.36; 95% CI, 0.99-1.73). Completion counts included 5,088 records identified, 2,290 duplicates removed, and 45 studies retained for analysis. The authors concluded that ESWT significantly reduces mean pain in individuals with different types of tendinopathy, with focused ESWT (f-ESWT) being more effective than radial ESWT. There are limitations, including the absence of subgroup analyses based on key clinical variables such as pain duration and the presence of other underlying diseases or musculoskeletal disorders. A further limitation is that subgroup analyses could not be conducted to assess the effect of ESWT on average pain across different types of tendinopathy because relevant data were not reported in the initial studies.

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Stania et al. (2023) conducted a systematic review and meta-analysis to determine the efficacy of ESWT as a monotherapy for Achilles tendinopathy. There were 373 articles identified from various countries; only six RCTs remained after the inclusion criteria were met. The sample size was 157 individuals in the experimental group and 187 individuals in the control group. The results demonstrated that the very low-quality evidence suggests that ESWT was no more effective in decreasing pain than any other conservative treatment (D, -0.8; 95% CI, -3.15 to 1.56; $p > 0.5$). However, the heterogeneity of the studies that were included was high, and no significant differences were found between the ESWT and control groups' pooled scores. The authors concluded that despite high or medium methodological quality of the analyzed RCTs, the evidence rating was too low to allow conclusions. Therefore, no strong recommendations can be made for the use of ESWT in individuals with Achilles tendinopathy. The limitations of the study include a small sample size, short-term follow-up, and low-quality evidence.

Feeney (2022) conducted a systematic review to evaluate the use of ESWT in the management of midportion Achilles tendinopathy. A search of databases [MEDLINE (PubMed), AMED (Allied and Complementary Medicine Database), Embase, CINAHL (Cumulative Index to Nursing and Allied Health Literature), and CENTRAL (Cochrane Central Register of Controlled Trials)] was performed, with a total of 283 articles identified. Of these, seven RCTs were eligible for inclusion in the review. The mean sample size of the included studies was 57. Five studies diagnosed midportion Achilles tendinopathy based on history and physical examination, while two confirmed the presence of Achilles tendinopathy by combining history and physical examination with ultrasound findings. Three studies used radial ESWT only, one study used a combination of radial and f-ESWT, one study compared radial and f-ESWT, and two studies used f-ESWT only. The length of follow-up ranged from 3 to 16 months. Overall, four of the seven RCTs that were included found a statistically significant improvement in outcome measures with the use of ESWT compared with control. The other three studies observed no statistically significant improvement in outcome measures with the use of ESWT compared with control, and each observed a significant improvement in the ESWT groups from baseline. The author concluded that ESWT appeared to be safe and at least as effective as the control in the management of Achilles tendinopathy. Additionally, the most effective intervention may be a combination of eccentric loading exercises with a course of ESWT. The author suggested that further high-quality studies that include larger sample sizes and a combination of treatments are needed to determine the most effective treatment, dose, time between treatments, and frequency (Hz) of ESWT that individuals should receive.

Stania et al. (2019) published results from a systematic review of research reports on ESWT in individuals with Achilles tendinopathy to help practicing physiotherapists establish the most effective intervention parameters. A search was conducted using the following databases: PubMed, Scopus, EBSCOhost, and Web of Science. The papers were checked for relevant content, and they were included if they were a full-text article published in English and included a comprehensive description of shock wave application. Overall, 22 articles met the inclusion criteria. Most studies on the effectiveness of ESWT for Achilles tendinopathy that were included in this review were RCTs. Two case-control studies, a case series study, a prospective audit, a clinical trial protocol, and a pilot study were also considered. The majority were prospective studies. Only a few authors presented the findings from retrospective observations. The two modalities of shock wave therapy used for Achilles tendinopathy are focused shock waves and radial shock waves. The authors concluded that the complexity of the biological response to shock waves, high diversity of application methodologies, and lack of objective measurements all prevent ESWT effectiveness for Achilles tendinopathy from being fully determined. There are knowledge gaps yet to be researched, and the results of experimental studies remain contradictory. The authors noted that there is a need for further multidirectional and multicenter, randomized controlled studies on the effectiveness of shock waves for Achilles tendinopathy that should fulfill the criteria for evidence-based medicine.

The Washington State Health Care Authority (2017) conducted a Health Technology Assessment to review the evidence for the efficacy of ESWT for treating Achilles tendinopathy. Two small RCTs showed significant pain improvement in individuals while they ran or played sports, but there was no difference between groups while working or using the stairs. One RCT reported significant improvement in function when comparing ESWT with sham. The strength of evidence for this indication was low, and there was no evidence found on the intermediate or long-term outcomes.

The National Institute for Health and Care Excellence (NICE) (2016) concluded that although the evidence on ESWT for refractory Achilles tendinopathy raises no major safety concerns, evidence on the efficacy of the procedure is inconsistent. NICE encourages further research into ESWT for Achilles tendinopathy, which may include comparative data collection. Studies should clearly describe the selection of individuals, treatment protocols, use of local anesthesia, and type and duration of energy applied. Studies should include validated outcome measures and have a minimum of 1 year of follow-up.

Calcific Tendinitis of the Shoulder (Rotator Cuff)

A review of the recent clinical evidence suggests that based on conflicting findings, high-energy ESWT is promising but not yet proven for improving pain and shoulder function in clinically significant ways in some individuals with chronic

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calcific shoulder tendinitis; additional standardization of energy levels and treatment protocols is needed, as well as additional data to address safety concerns and assess in which population of individuals do benefits outweigh harm.

Yao et al. (2025) conducted a systematic review and network meta-analysis of RCTs that evaluated treatments for rotator cuff calcific tendinitis. Overall, 33 trials that were published between 2003 and 2023, with a total of 2,102 individuals, were included, requiring radiographic or ultrasound-confirmed diagnosis and outcomes on function, pain relief, or calcific deposit resolution; individuals had a median age of 52.2 years, 37.9% were male, and symptom duration ranged from 3 to 41.2 months. Analyses used a bayesian framework with RJAGS and GeMTC in R, expressing continuous outcomes as SMDs with 95% CI and ranking effectiveness by surface under the cumulative ranking curve (SUCRA) values. For functional improvement, comprehensive physical therapy (PT) ranked first, followed by high-energy ESWT plus PT (SMD, 11.24; 95% CI, 0.79-21.77), while for pain relief, radial ESWT plus PT ranked first. In surgical treatments, arthroscopic bursectomy debridement plus arthroscopic subacromial decompression showed no significant difference from bursectomy alone (SMD, -0.01, 95% CI, -0.54 to 0.57 for function; SMD, -0.02, 95% CI, -0.51 to 0.43 for pain). Calcific deposit resolution was assessed radiologically, with ultrasound-guided needling plus subacromial corticosteroid (CS) injection achieving complete resolution in 56.82% of cases. The prespecified secondary end points included pain relief and calcific deposit resolution. The authors concluded that comprehensive PT provided the greatest functional improvement among nonsurgical interventions; radial ESWT PT was most effective for pain relief; arthroscopic bursectomy debridement alone was comparable to combined decompression; and ultrasound-guided needling plus subacromial CS injection was effective for calcific deposit removal. These support evidence-based, personalized treatment planning for rotator cuff calcific tendinitis. There are limitations; although all included studies were RCTs, differences in their design and execution may have introduced heterogeneity despite the generally high quality of evidence. A key limitation is the absence of RCTs that directly compare surgical and nonsurgical treatments, preventing a clear estimation of their relative clinical effects. The study also has limitations in scope, as it represents the first network meta-analysis on this topic and may not fully capture all relevant treatment variations or outcomes such as functional improvement, pain relief, and calcific deposit resolution.

Brindisino et al. (2024) conducted a systematic review with meta-analysis that evaluated the effectiveness of ESWT for rotator cuff calcific tendinopathy, including 21 RCTs, with 1,401 individuals and 1,418 shoulders. Eligible adults had radiographically or ultrasonographically confirmed calcific tendinopathy, and interventions comprised focal, radial, high-energy, and low-energy ESWT compared with sham ESWT, PT, ultrasound-guided needling procedures (USGNPs), and other conservative or minimally invasive treatments. Random-effects models were used to pool mean differences (MDs) and risk ratios, assessing heterogeneity by chi-square and I^2 tests and evidence certainty by GRADE (Grading of Recommendations Assessment, Development, and Evaluation), with primary outcomes of pain and function at 6, 12, 24, and 48 weeks and complete resorption of calcification. ESWT showed significantly less pain reduction than USGNPs at less than 24 and 48 weeks (MD, 1.17, 95% CI, 0.37-1.98, p = 0.004; MD, 1.31, 95% CI, 0.42-2.20, p = 0.004) but greater pain and functional improvement than sham ESWT at 24 weeks (MD, -5.72, 95% CI, -6.37 to -5.07, p < 0.00001; SMD, 2.94, 95% CI, 0.39-5.48, p = 0.02). High-energy ESWT was superior to low-energy ESWT in pain and function at less than 24 weeks (MD, -1.83, 95% CI, -3.52 to -0.14, p = 0.03; MD, 14.60, 95% CI, 5.53-23.66, p = 0.002) and in complete resorption at 12 weeks (risk ratio, 2.53; 95% CI, 1.22-5.24; p = 0.001). The prespecified secondary end points included disability and quality of life. The authors concluded that USGNPs were statistically but not clinically superior to ESWT in pain reduction, while ESWT was clinically better than sham ESWT, and high-energy ESWT was superior to low-energy ESWT. Key limitations include the very low certainty of evidence for pooled results showing no functional improvement and for comparisons between ESWT vs sham, ESWT vs USGNP, and high- vs low-energy shock wave therapy. There are limitations related to the characteristics of the included RCTs, as many did not assess the outcomes of interest and reported incomplete data; none were rated as having an overall low risk of bias. The absence of a clear consensus on the cutoff that defined high- and low-energy shock wave therapy further limits the interpretability of the research findings.

Xue et al. (2024) conducted a systematic review and meta-analysis on the effects of ESWT for rotator cuff tendinopathy. Overall, 17 studies (n = 1,131) from 2006 to 2023 were included in the review. The results showed that compared with the control group, ESWT for pain, function, range of movement, and external rotation were statistically significant, with a total effective rate [odds ratio (OR), 3.64; 95% CI, 1.85-7.14; p = 0.0002]. However, range of movement abduction (SMD, 0.72; 95% CI, -0.22 to 1.66; p = 0.13) was not statistically significant. The authors concluded that ESWT may be a promising approach for the treatment of rotator cuff tendinopathy. Due to the limited quality and number of included trials, additional high-quality, prospective clinical studies are needed to verify these conclusions. Limitations of the study include the lack of random allocation and concealment methods, which lead to selection bias, and language limitations.

A Hayes Health Technology Assessment (2022; updated August 2025) evaluated the efficacy of ESWT for treating symptomatic calcific tendinitis of the shoulder when conservative therapies have failed. Twelve RCTs were included in the assessment. ESWT was associated with improvement in function from baseline and reduction of pain in some individuals with calcific tendinitis of the shoulder. Evidence that compared ESWT with clinical alternatives yielded conflicting findings

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or was limited in quantity. The primary complications were pain or discomfort during or just after treatment, bruising, and swelling. Hayes noted that the overall quality of evidence was low and that while ESWT appears to be safe and effective, continued research is needed to determine optimal ESWT treatment parameters, clarify comparative benefit vs alternative treatments, and establish treatment durability. Follow-up beyond 12 months was also recommended.

The NICE (2022) guidance on the use of ESWT for calcific tendinitis of the shoulder states that current evidence shows no major safety concerns in the short term. However, evidence on efficacy is noted as inadequate. NICE recommends that ESWT for calcific tendinopathy in the shoulder should be used in the context of research and that further research should include RCTs that compare the procedure with current best practice.

Shao et al. (2023) conducted an RCT to investigate the effect of ESWT on short-term functional and structural outcomes after rotator cuff repair. Two groups, which were randomized to either the ESWT group (n = 19) or the control group (n = 19), participated in 5 weeks of advanced rehabilitation 3 months after rotator cuff repair. The ESWT group also received 2,000 pulses of shock wave therapy once a week for 5 weeks. All participants had clinical and magnetic resonance imaging examinations at 3 months (baseline) and at 6 months (follow-up) after surgery. Overall, 32 participants completed all assessments. Pain and function improved in both groups. At 6 months post repair, pain intensity was lower, and American Shoulder and Elbow Surgeons form scores were higher in the ESWT group than in the control group (all p values < 0.01). Signal/noise quotient near the suture anchor site decreased significantly from baseline to follow-up in the ESWT group (p = 0.008) and was significantly lower than that in the control group (p = 0.036). Muscle atrophy and the fatty infiltration index did not differ between groups. The authors concluded that radial ESWT reduced early shoulder pain and accelerated proximal supraspinatus tendon healing at the suture anchor site post rotator cuff repair. However, the authors noted that in terms of functional outcomes at the short-term follow-up, radial ESWT does not appear to be superior to advanced rehabilitation. Limitations include a small sample size and short follow-up period; additionally, the study only included participants with medium to large rotator cuff tears. The authors suggested that further studies are needed to evaluate the correlation between energy flux density and biological effects.

Surace et al. (2020) reviewed 32 RCTs and controlled clinical trials that involved 2,281 participants with rotator cuff disease with or without calcific deposits. The primary comparison was shock wave therapy compared with placebo, with a 3-month follow-up. The findings favored ESWT vs placebo for pain levels (SMD, -0.49; 95% CI, -0.88 to -0.11) and functional status (SMD, 0.62; 95% CI, 0.13-1.11). The adverse events were more frequent with ESWT than placebo (relative risk, 3.61; 95% CI, 2.00-6.52). The authors concluded that there were very few clinically important benefits of ESWT and uncertainty regarding its safety based on the currently available low- to moderate-certainty evidence.

Testa et al. (2020) completed a systematic review of two electronic medical databases. They searched for studies on the use of ESWT therapy without surgical treatment, with a symptom duration of more than 2 months and at least 6 months of follow-up for treating rotator cuff tendinopathy, subacromial impingement, and medial epicondylitis and LE. After screening 822 articles that met the initial criteria, 26 articles were selected that met their criteria after a full-text review. The authors concluded that ESWT is a safe and effective treatment for soft tissue diseases of the upper limbs. Even in the minority of cases when unsatisfied results were recorded, high-energy shock waves were nevertheless suggested in prevision of surgical treatment. However, the authors reported a moderate overall risk of bias that could have influenced their analysis.

Bannuru et al. (2014) conducted a systematic review (28 RCTs/1,307 individuals) of the evidence to assess the efficacy of ESWT in individuals with calcific and noncalcific tendinitis. The outcome measures included pain, function, and calcification resolution, which were evaluated only in calcific tendinitis trials. High-energy ESWT was found to be statistically significantly better than placebo for both pain and function. The results for low-energy ESWT favored ESWT for function, while results for pain were inconclusive. The reduction in calcification was significantly greater after high-energy ESWT than after placebo treatment; results for low-energy ESWT were inconclusive. No significant benefit was found between ESWT and placebo for noncalcific tendinitis. The authors concluded that high-energy ESWT is effective for improving pain and shoulder function in chronic calcific shoulder tendinitis and can result in complete resolution of calcifications.

Clinical Practice Guidelines

American Physical Therapy Association (APTA)

In 2025, the APTA published clinical guidelines on the diagnosis and treatment of rotator cuff calcific tendinopathy. The guideline for ESWT treatment in rotator cuff calcific tendinopathy states, “Clinicians may use or recommend ESWT to reduce pain and disability in adults with rotator cuff calcific tendinopathy" (evidence level: grade C).

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Canadian Agency for Drugs and Technologies in Health (CADTH)

The CADTH (2016) report reviewed evidence on the effectiveness of shock wave therapy for pain associated with upper extremity orthopedic disorders, including rotator cuff tendinopathy and epicondylitis. Evidence from four systematic reviews suggests that compared with placebo, shock wave therapy using high energy is effective in reducing pain in calcific tendinitis of the shoulder. Evidence suggests that there is no significant benefit with ESWT compared with placebo or other treatments in cases of noncalcific tendinitis of the shoulder. However, it should be noted that there is considerable overlap in the studies included in the four systematic reviews; therefore, the findings are not mutually exclusive. The authors noted that it appears that in general, the techniques for using shock wave therapy for all orthopedic disorders still need to be standardized. There appears to be a lack of consensus regarding the definitions for high- and low-energy shock wave therapy. Other issues include determination of precise doses and optimal frequency of application, whether the shock waves should be directed to the target area by radiological or ultrasound imaging, and whether local anesthetic injections should be used in the target area prior to treatment to reduce pain.

Chronic Plantar Fasciitis (Including Plantar Fibromatosis and Plantar Nerve Lesion)

Evidence in the form of RCTs regarding the efficacy of ESWT for PF is conflicting and inconsistent.

Tien et al. (2026) conducted a systematic review and network meta-analysis of 63 RCTs that included 4,170 individuals and evaluated minimally invasive, device-based, and conservative therapies for PF. Eligible studies enrolled adults who were aged 18 years or older with PF and had no prior surgical intervention; studies compared interventions such as ESWT, prolotherapy, platelet-rich plasma, botulinum toxin A, CS, autologous blood, local anesthetic, and dextrose injections against each other or conservative treatments. The primary outcomes were pain intensity, foot function, and plantar fascia thickness, which were measured using validated scales and imaging across short-, mid-, and long-term follow-up periods. A frequentist random-effects network meta-analysis calculated SMDs with 95% CIs. For pain relief, botulinum toxin A injection was most effective in the short term (SMD, 2.09; 95% CI, 1.28-2.91), while prolotherapy with dextrose was most effective in the mid- and long term (SMD, 1.15; 95% CI, 0.10-2.20). For foot function, CS injection yielded the largest short-term gains, and platelet-rich plasma and local anesthetic injections ranked highest in mid- and long-term improvement, respectively. For plantar fascia thickness, botulinum toxin A was most effective in the short term (SMD, 1.64; 95% CI, 0.56-2.73), and platelet-rich plasma was superior in mid- and long-term reduction (SMD, 0.95; 95% CI, 0.40-1.50). No prespecified secondary end points were reported. The authors concluded that treatment strategies for PF should be tailored to symptom duration and therapeutic goals, with botulinum toxin A providing rapid pain relief, dextrose prolotherapy (DPT) offering mid- to long-term analgesic benefits, platelet-rich plasma and ESWT providing sustained functional and structural improvements, and CS injection being effective for short-term function gains. There are limitations, including inconsistent reporting of adverse events across trials, which prevented a formal safety synthesis. Key limitations include moderate to high heterogeneity across comparisons, which was largely due to differences in intervention protocols, and local inconsistencies in results for certain treatments such as botulinum toxin A injection, prolotherapy, and placebo. Outcome measurements lacked standardized scoring systems, which limited comparability across studies. The use of plantar fascia thickness as an objective outcome represents a surrogate measure rather than a direct clinical end point.

Alsulaimani et al. (2026) conducted a parallel-group superiority RCT in a private physiotherapy clinic in Melbourne, Australia, to compare radial ESWT vs sham for insertional Achilles tendinopathy. Participants were adults who were aged 18 years or older and had symptoms for at least 3 months that were confirmed by ultrasound; those with prior ESWT, Achilles surgery or rupture, other ankle conditions, or systemic disorders were excluded. Overall, 76 participants (53% female; mean age, 51 years) were randomized equally to radial ESWT or sham groups, receiving three sessions at 5- to 10-day intervals, with identical education and exercise programs. The primary outcome was movement-evoked pain measured on a 100-mm VAS immediately before and after each session, analyzed using linear mixed modeling with an intention-to-treat approach. Follow-up was achieved in 96% of participants, and there was no between-group difference in movement-evoked pain after any session (MDs, -0.4, 95% CI, -1.6 to 0.8; 0.4, 95% CI, -0.8 to 1.6; and -0.4, 95% CI, -1.6 to 0.8). The prespecified secondary end point was pressure pain threshold, which was measured locally and remotely. The authors concluded that radial ESWT demonstrated no greater efficacy than sham in reducing immediate movement-evoked pain in adults with insertional Achilles tendinopathy, and any observed benefit was likely driven by nonspecific effects rather than conditioned pain modulation. Key limitations include uncertainty about the minimum effective dose and the inability to blind the physiotherapist who was administering the intervention, which could have introduced bias despite scripted interactions. There are limitations, including the use of a sham rather than a truly inert control intervention and the lack of measurement of cointerventions that participants may have used alongside the study treatments. Additional limitations include the possibility that participants' expectations or early pain reduction from exercise and education lessened the apparent efficacy of later radial shock wave sessions. The study also has limitations in generalizability, as participants were volunteers who were recruited mainly through social media and clinical networks, potentially excluding individuals who were less digitally connected.

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Ines et al. (2025) conducted a 12-month RCT in a Tunisian rehabilitation department that compared radial ESWT with physiotherapy combined with ultrasound for PF. Eligible adults who were aged 18 to 70 years, had heel pain that lasted more than 3 months, and had a baseline VAS pain score of ≥ 5 were randomized using sealed envelopes, with outcome assessment by a blinded evaluator. Overall, 129 participants were analyzed (66 radial ESWT; 63 physiotherapy) and were predominantly female (78%), had a mean age of 50.33 years, and had a mean body mass index of 29.2 kg/m². The radial ESWT group received six weekly sessions at 10 Hz, 2,000 pulses, and 2.5 bar, while the physiotherapy group received 12 sessions of stretching, massage, and ultrasound over 4 weeks. Pain relief was the primary outcome, which was measured by VAS at baseline, end of treatment, and 1, 3, 6, and 12 months; both groups had significant within-group VAS reductions ($p < 0.001$), with no significant differences between groups at any time point (e.g., 3 months: 4.33 ±2 vs 4.5 ±1.99; $p = 0.479$). The overall success rate at 3 months was 73% (54% radial ESWT vs 46% physiotherapy; $p = 0.25$). The prespecified secondary end points included baropodometric parameters such as foot load distribution, plantar pressure, and contact area. The authors concluded that both radial ESWT and physiotherapy combined with ultrasound therapy were effective for PF, with no significant difference between them. There are limitations, including the absence of participant blinding, which may have introduced participant-related bias. Additional limitations include the lack of assessment of foot posture and dynamic podiatric profile, which reduced the completeness of biomechanical evaluation. Reporting of continuous outcomes was limited, as measures such as overall pain, first-step pain, and function were converted into a single overall success rate for heel pain at follow-up.

Tung et al. (2024) conducted a systematic review and meta-analysis of RCTs that compared ESWT with other conservative treatments for PF. Eligible studies were English-language trials that were published after 2013 and reported VAS pain scores, plantar fascia thickness, or Foot Function Index (FFI), with at least 12 weeks of follow-up. Fifteen trials, including 1,123 individuals, were analyzed using a random-effects model due to heterogeneity, and SMDs were calculated at the last postintervention time point. ESWT showed significantly greater improvement than placebo for VAS pain (SMD, 7.53; 95% CI, 5.84-9.22; $p < 0.00001$) and FFI (SMD, 1.07; 95% CI, 0.08-2.07; $p = 0.03$). Platelet-rich plasma outperformed ESWT for postintervention VAS (SMD, -1.05; 95% CI, -1.53 to -0.57; $p < 0.0001$) and FFI (SMD, -0.84; 95% CI, -1.38 to -0.30; $p = 0.002$), while custom orthotics also improved FFI more than ESWT (SMD, -0.74; 95% CI, -1.19 to -0.28; $p = 0.001$). No other significant differences were found between ESWT and other modalities for the three metrics analyzed. The prespecified secondary end points were plantar fascia thickness and FFI. The authors concluded that ESWT was an effective, noninvasive treatment for PF and showed superior results compared with placebo, orthotics, PT, and CS injections, while platelet-rich plasma produced greater improvement in pain and FFI but is a more technically demanding procedure. There are limitations, including reliance on pooled data rather than individual patient-level information and a small number of studies in certain subgroups, which may have constrained the depth of analysis. Additional limitations include potential heterogeneity among included RCTs and the selective search and inclusion process, which may have influenced the overall representativeness of the evidence.

Cortés-Pérez et al. (2024) conducted a systematic review and meta-analysis that compared the efficacy of ESWT vs that of CS injections on pain, thickness of plantar fascia, and foot function in individuals with PF. Sixteen RCTs (n = 1,121 individuals) were included in the review with acute and chronic PF. The individuals (ESWT, 561; CS injections, 560) were analyzed post intervention from 4 to 6 weeks and 3, 6, and 12 months. Regarding pain intensity, the results demonstrated that in the immediate post evaluation, no differences were found between CS injections and ESWT. Differences favoring ESWT in reducing pain intensity were observed in 3 and 6 months. At 3 months, high-intensity ESWT was the most indicated dose in reducing the thickness of PF. On foot function, ESWT was favored over CS injections at 3 and 6 months. At the 1-year follow-up, no significant differences were shown between therapies. The authors concluded that ESWT is a safe therapy. Findings suggest that radial and high-intensity doses are the most adequate for improving pain and foot function. Limitations in the study include low-level evidence, generalizability, methodology quality, risk of bias, inadequate concealment, and heterogeneity.

Asheghan et al. (2021) completed an RCT to compare the effectiveness of ultrasound-guided DPT with that of radial ESWT in the treatment of chronic PF. This RCT was conducted in 59 participants with chronic PF. The participants were randomly assigned into two groups that received three sessions of radial ESWT (29 participants) vs two sessions of ultrasound-guided intrafascial 2-cc dextrose 20% injection (30 participants). The following outcome measures were assessed before and then 6 weeks and 12 weeks after the treatments: pain intensity by VAS, daily life and exercise activities by Foot and Ankle Ability Measure (FAAM), and the plantar fascia thickness by ultrasonographic imaging. The VAS and FAAM scales showed improvements in pain and function in both study groups at 6 weeks and 12 weeks after the treatments. A reduction was noted in plantar fascia thickness at these intervals (all $p < 0.05$). The intergroup comparison revealed that except for the FAAM Sport subscale, which favored ESWT, the interaction effects of group and time were not significant for other outcome measures. DPT has comparable efficacy to radial ESWT in reducing pain, daily life functional limitation, and plantar fascia thickness in individuals with PF. No serious adverse effects were observed in either group. The authors concluded that DPT and ESWT have comparable outcomes; however, ESWT appears to be a good alternative choice due to lower costs and possible equal or better effectiveness in clinical practice.

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This study has several limitations. The authors could not completely blind the participants, most participants were female, and the results may not be generalized to the male population; additionally, there was no control group. Further studies that include a larger sample size and long-term follow-up are needed.

A Hayes Health Technology Assessment (2016; updated March 2021) evaluated radial ESWT as a noninvasive treatment option for chronic PF in individuals who experienced failure of conservative therapy for at least 6 months. The evidence base included 10 RCTs reported across 11 publications, including comparisons with sham treatment, other active therapies, and f-ESWT. The overall quality of evidence was rated as low. The findings suggest that radial ESWT may decrease individual-reported pain and improve short-term functional outcomes. However, the results across studies were conflicting and limited by a lack of long-term follow-up and high loss to follow-up rates. Although radial ESWT may provide short-term symptomatic improvement of PF, the evidence remains inconsistent, and additional blinded, controlled, long-term studies are needed to better establish safety and efficacy.

Gezginaslan and Başar (2021) performed a double-blinded RCT to investigate the effect of density and number of sessions of ESWT on pain, fatigue, disability, physical function, and quality of life in participants with PF. Between September 2019 and December 2019, 94 participants with the diagnosis of PF were included in the study. All participants were randomly divided into three groups. Group 1 (n = 33) received a total of seven sessions of high-energy flux density ESWT (H-ESWT; 0.26 mJ/mm^2), group 2 (n = 31) received a total of three sessions of H-ESWT (0.26 mJ/mm^2), and group 3 (n = 30) received a total of seven sessions of low-energy flux density (< 0.08 mJ/mm^2) with a 3-day interval. At baseline and 1 month after the treatment, the VAS, 36-Item Short Form Survey, FFI, Functional Assessment of Chronic Illness Therapy (FACIT) - Fatigue Scale, and 6 Minute Walk Test (6MWT) scores were compared among the groups. Of the participants, 69 were females, and 25 were males; the mean age was 45.0 ±8.43 years (range, 25-67 years). There were no statistical differences in the age, sex, demographic characteristics, and baseline VAS, FFI, 6MWT, and FACIT scores between the groups ($p > 0.05$). However, there was a statistical decrease in the VAS, FACIT, and FFI scores in all groups after treatment compared with baseline, although only the 6MWT and 36-Item Short Form Survey subscale scores were statistically higher ($p < 0.05$). There was also a statistical difference in the scale scores in group 1 vs group 2 and in group 2 vs group 3. The authors concluded that the study results suggest that H-ESWT for a high number of sessions is more effective than low-energy shock wave therapy for a low number of sessions on pain, quality of life, physical function, fatigue, and disability in individuals with PF. The short-term follow-up (1 month) did not allow for assessment of intermediate- and long-term outcomes. A small sample size (n = 94) makes it difficult to determine whether these conclusions can be generalized to a larger population. Further investigation is needed before the clinical usefulness of this procedure is proven.

A Hayes Health Technology Assessment (2016; updated February 2021) evaluated f-ESWT as a noninvasive treatment option in adults with chronic PF who experienced failure of conservative therapy for at least 6 months. The evidence base included 17 RCTs that compared f-ESWT with sham treatment, steroid injections, surgery, usual care, autologous conditioned plasma, and low-dose ESWT. The overall quality of evidence was rated as moderate. The findings suggest that f-ESWT may decrease patient-reported pain, improve pressure pain thresholds, and enhance short-term functional outcomes. However, the results across studies were inconsistent, and evidence regarding quality-of-life improvement and long-term effectiveness was limited. Most adverse effects were mild and transient, including pain or discomfort during or after treatment, redness, swelling, and bruising. Although f-ESWT may provide short-term symptomatic relief for chronic PF, the evidence remains conflicting, and additional well-designed, blinded, long-term studies are needed to better establish its safety, efficacy, and durability of benefit.

Cinar et al. (2020) performed an RCT to determine whether a combination of ESWT with standard care (exercise and orthotic support) improves functional ability in participants with PF compared with standard care alone. Participants with PF were randomly allocated into two groups: ESWT (n = 23) and control (n = 21). All participants received a home exercise program with orthotic support. In addition, the ESWT group received 2,000 shock waves with 0.02 mJ/mm^2 for three sessions. Functional outcomes were measured by the Function subscale of the American Orthopaedic Foot & Ankle Society (AOFAS-F) score and 12 Minute Walk Test, including walking speed and cadence. The scores were recorded at baseline and the third week and third month after the treatment. An analysis was performed using repeated-measures analysis of variance and an intention-to-treat approach using multiple imputations. The results showed that there was improvement in the AOFAS-F total score and walking speed over 3 months in both groups ($p < 0.001$ and $p = 0.04$, respectively); improvements in the AOFAS-F were particularly in activity limitation ($p = 0.001$), walking distance ($p = 0.02$), and walking surface ($p = 0.02$). Groups were comparable with each other for both walking speed and AOFAS-F in any assessment time ($p > 0.05$). However, groups performed differently in cadence; there was an increase in cadence in the ESWT group, whereas there was a decline in the control at the third month ($p = 0.07$). The results revealed that ESWT did not have an additive benefit over usual care to improve foot function and walking performance in participants with PF over 3 months post treatment. There are limitations to this study. Gait function was not evaluated. A small sample size makes it

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difficult to decide whether these conclusions can be generalized to a larger population. The findings of this study need to be validated by well-designed studies.

Lai et al. (2018) published the results of a prospective RCT that evaluated and compared the therapeutic effects of ESWT and CS injections in participants with chronic PF. The study also examined the correlation between plantar fascia thickness changes and clinical outcomes. Participants were included if they had more than 2 months without an injection and had been treated with conservative treatment for 1 month, without improvement before proceeding to ESWT or CS injection treatment. Participants (110) were randomly assigned to receive ESWT or CS injection. The authors summarized that ESWT was more efficient in reducing chronic fasciitis pain after 12 weeks than CS injection. Furthermore, the increase in plantar fascia thickness after ESWT resulted in a more efficient clinical outcome. However, further long-term studies that include large populations of individuals are needed to validate the findings of this study.

Sun et al. (2017) performed a meta-analysis of RCTs (nine studies/935 individuals) to compare the effectiveness of general ESWT, focused shock wave, and radial shock wave with that of placebo for chronic PF. Limitations of the analysis include the lack of comparison with established treatment methods. The authors concluded that focused shock wave may be associated with a higher success rate and greater pain reduction than sham therapy in individuals with chronic PF. However, additional high-quality clinical trials and systematic reviews are needed to demonstrate the efficacy of ESWT (e.g., focused shock wave, radial shock wave therapies) and determine whether radial shock wave therapy is an ideal alternative therapeutic method to conservative treatment and surgery.

Gollwitzer et al. (2015) published the results of a double-blinded RCT that involved 250 participants with PF who were randomized to ESWT or placebo intervention and followed up for 12 weeks post treatment. The authors reported that the VAS composite score showed a significant difference in the reduction of heel pain in the ESWT group vs the placebo group (69.2% vs 34.5%). They also stated that the ESWT group demonstrated significantly superior results on the Roles and Maudsley score, which is a subjective 4-point participant assessment of pain and limitations of activity. No test for the accuracy of the blinding was conducted.

Clinical Practice Guidelines

American College of Foot and Ankle Surgeons (ACFAS)

In 2017, the ACFAS released a consensus statement on the diagnosis and treatment of adult-acquired infracalcaneal heel pain. This document includes the following statement: “Extracorporeal shockwave therapy (ESWT) is safe and effective in the treatment of plantar fasciitis.” A general observation across all studies was that approximately 70% of patients with chronic or subacute PF who underwent ESWT had experienced meaningful improvement in their heel pain at 12 weeks. However, ESWT does not appear to be an effective first-line option for patients with acute PF. This consensus does not consider the issues raised above regarding conflicting findings and potential bias in study results from questionable or lack of blinding, use of subjective and self-reported data, and other methodological issues. (Schneider et al., 2018)

Delayed or Nonunion Fractures

Conclusive evidence that recommends ESWT as an effective treatment for delayed or nonunion fractures is lacking.

Searle et al. (2023) conducted a systematic review and meta-analysis published in the Cochrane Library to assess the effects of low-intensity ultrasound (LIPUS), high-intensity focused ultrasound, and ESWT as part of the treatment of acute fractures in adults. The review included 21 studies (1,543 fractures) in 1,517 individuals; no studies tested high-intensity focused ultrasound. The results showed very low-certainty evidence for the effect of LIPUS on health-related quality of life at up to 1 year after surgery for lower limb fractures (MD, 0.06; 95% CI, -3.85 to 3.97; favors LIPUS; three studies; 393 individuals). There was no difference in time to return to work after people had complete fractures of the upper and lower limbs (MD, 1.96 days; 95% CI, -2.13 to 6.04 days; favors control; two studies; 370 individuals; low-certainty evidence). There was little or no difference in delayed union or nonunion up to 12 months after surgery (risk ratio, 1.25; 95% CI, 0.50-3.09; favors control; seven studies; 746 individuals; moderate-certainty evidence) or any difference in skin irritation between groups. There was uncertainty whether ESWT reduces pain at 12 months after surgery in fractures of the lower limb (MD, -0.62; 95% CI, -0.97 to -0.27; favors ESWT); the difference between pain scores was not clinically important, and evidence was low. The effect of ESWT on delayed or nonunion at 12 months was a low certainty of evidence (risk ratio, 0.56; 95% CI, 0.15-2.01; one study; 57 individuals). There were no treatment-related adverse events for ESWT. Data were not reported for health-related quality of life, functional recovery, time to return to normal activities, or time to fracture union. The authors concluded that the effectiveness of ultrasound and shock wave therapy for acute fractures in terms of patient-reported outcomes was uncertain. Future studies that have high-quality evidence are needed. The limitations of the study include a high risk of bias, small sample sizes, and inconsistencies in study findings.

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Kwok et al. (2022) completed a systematic review to evaluate the use of ESWT in the treatment of foot and ankle fracture nonunions. Four databases were searched to identify relevant studies in the available literature. Eight studies were reviewed, demonstrating union rates of 65% to 100% and 90% to 100% at 3 and 6 months following ESWT treatment, respectively. No major complications were seen in any of the studies. Minor complications included local soft tissue swelling, petechiae, bruising, and pain. The authors concluded that the literature that is currently available is limited to case series of relatively small sample sizes, which highlights the need for prospective RCTs to further investigate the efficacy of ESWT in the treatment of foot and ankle fracture nonunions.

Willems et al. (2019) evaluated ESWT for the treatment of delayed or nonunion fractures in a systematic review. The authors found that high-quality RCTs are still needed to validate the efficacy and safety of this treatment. The review included 30 peer-reviewed studies that consisted of two RCTs and 28 prospective and retrospective cohort studies and involved a total of 2,027 delayed unions and nonunions in adults. Delayed unions that were treated with ESWT had a union rate of 86% (n = 314), while nonunions that were treated with ESWT had a 73% (n = 1,782) overall union rate. The overall union rate of nonunions that were treated with surgery was 81% (n = 80). Although the results showed similar union rates between ESWT and surgery-treated individuals, none of the ESWT group had adverse events that required further care; there were severe adverse events noted in the surgery group. The authors found a lot of heterogeneity in and between the studies such as fractures of different bones, use of different energy settings, number of treatments, and number of shock waves applied with the ESWT; additionally, there was a lack of consensus as to when the biological end point was reached, at which no further bone healing occurs. The authors concluded that high-quality RCTs should be conducted on the effect of ESWT, with homogeneous groups and shock wave parameters, so that treatment recommendations can be made.

Erectile Dysfunction

There is insufficient quality evidence to conclude that ESWT is effective for erectile dysfunction (ED); therefore, additional research that involves larger, well-designed studies is needed to establish its safety and efficacy.

Sandoval-Salinas et al. (2026) conducted a multicenter, open-label RCT in Colombia and Mexico, enrolling 186 men who were aged 18 years or older, had organic ED of at least 6 months' duration, and were not receiving pharmacological treatment. Participants were randomized 1:1 to receive either six weekly sessions of low-intensity ESWT (Li-ESWT) or the same protocol plus five additional monthly maintenance sessions, with 93 men per group. The primary outcome was the International Index of Erectile Function - Erectile Function (IIEF-EF) score at 24 weeks, which was analyzed using both intention-to-treat and per-protocol approaches, while the secondary outcomes included achievement of the minimal clinically important difference (MCID), erection hardness, self-esteem, and adverse events. At 24 weeks, median IIEF-EF scores were 18 in the weekly group and 22 in the maintenance group (adjusted p = 0.147), with 35.8% vs 62.8% achieving the MCID (adjusted p = 0.02; relative risk, 1.69; 95% CI, 1.2-2.3). Completion rates were 87.1% in the weekly group and 75.3% in the maintenance group. No significant differences were observed between groups in erection hardness or self-esteem, and no adverse events that were attributable to therapy were reported. The prespecified secondary end points were MCID achievement, erection hardness, self-esteem, and adverse events. The authors concluded that both groups had increases in IIEF-EF score medians compared with baseline, but no significant differences were found between groups; however, the difference in MCID achievement after 24 weeks was noteworthy. Key limitations include the absence of penile duplex Doppler ultrasound for diagnosing organic ED and for follow-up, which restricted objective evaluation of vascular changes. There are limitations related to the maintenance protocol, as participant adherence was lower than expected, and missing data from those who discontinued treatment could have introduced bias. The study also lacked a sham control group, which limited the ability to separate true treatment effects from placebo responses. Another limitation is the reliance on participant self-reporting to verify abstention from other ED treatments, which may have introduced reporting bias.

Cayan et al. (2026) conducted a systematic review and meta-analysis of 12 RCTs that included men who were in stable sexual relationships for more than 6 months and had ED for more than 6 months, defined by an IIEF-EF of < 26, IIEF-5 of < 22, or Erection Hardness Score (EHS) of ≤ 2; low-intensity shock wave therapy (LiSWT) vs sham or no treatment was evaluated, with treatment protocols ranging from 2 to 9 weeks and 1,500 to 6,000 pulses per session. The primary outcomes, changes in IIEF-5 and IIEF-EF scores, showed significant improvements that favored LiSWT (IIEF-5: SMD, 1.19, 95% CI, 0.47-1.91, p = 0.001; IIEF-EF: SMD, 1.24, 95% CI, 1.02-1.45, p < 0.001). The authors concluded that LiSWT improves IIEF-5 and IIEF-EF scores but shows no significant effects on other functional or vascular parameters; additionally, its clinical relevance appears limited for most individuals. There are limitations, including the very small number of included studies per outcome, which constrained statistical power for heterogeneity measures such as Cochran Q and I^2, and generally small sample sizes, with short follow-up periods that leave long-term efficacy uncertain. Key limitations include missing baseline and standard error values, as well as the absence of patient-level data that is needed for stratified analyses by age, comorbidities, or baseline severity. Measurement limitations involved high heterogeneity across the IIEF-5, EHS, and Doppler outcomes; inconsistent LiSWT energy and pulse protocols; and variable sham

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designs that reduce interpretability and hinder subgroup or meta-regression analyses. The limited and divergent study protocols, inconsistent manufacturer guidance, and lack of consistent, significant improvements across several end points restrict generalizability and make it difficult to draw firm conclusions for clinical guideline implementation.

Desai et al. (2025) conducted a systematic review and meta-analysis to evaluate the published literature on ESWT for the treatment of ED. Overall, 87 studies were eligible for inclusion and comprised 40 case series, 15 cohort studies, and 32 RCTs; 19 were included in the meta-analysis. There was substantial heterogeneity across all the 87 eligible studies relating to the type of ESWT device and shock wave used, demographics of ESWT-treated groups, treatment protocols, safety events, missing data, and treatment outcomes. While ESWT shows promise, future high-quality research should address this heterogeneity to potentially offer the first truly regenerative treatment for ED.

Juan-Casas et al. (2025) conducted a systematic review and meta-analysis that evaluated the efficacy of ESWT for the treatment of ED. Experimental studies in men who were aged 18 to 80 years and had ED of at least 6 months' duration were included, and those with psychogenic, neurological, or cardiac conditions, prior pelvic surgery, or penile deformities were excluded. Fifteen studies were analyzed, mostly RCTs, with interventions ranging from 2 to 36 weeks and doses between 1,500 and 54,000 pulses per treatment cycle. The meta-analysis used the difference in means for erectile function, as measured by the IIEF, and applied random-effects models when heterogeneity exceeded 50%. Across 654 individuals from 10 trials, ESWT significantly improved erectile function compared with controls, with an MD of 2.96 points (95% CI, 1.93-4.61; $p < 0.001$; $I^2 = 63.45$). The prespecified secondary end points included erection quality, sexual satisfaction, penile hemodynamics, and ability to maintain sexual intercourse. The authors concluded that ESWT significantly improves erectile function and is effective for treating ED, with a single treatment cycle of four sessions over 2 weeks and at least 6,000 pulses per session being effective in the short and long term; they stated that it can be considered a therapeutic alternative to drugs or vacuum erection devices when applied throughout the crura and both corpora cavernosa of the penis. There are limitations, including that many variables were measured subjectively through participant questionnaires rather than objective instruments, which may reduce the validity of the findings. Key limitations include high risks of bias in several randomized trials due to incomplete data and inadequate blinding, as well as critical bias that was identified in the quasiexperimental studies.

Fatima et al. (2025) conducted an updated meta-analysis of RCTs that compared Li-ESWT with sham therapy in individuals with vasculogenic ED. Twelve RCTs that comprised 862 men were included. The scores for at least one of the following were included and assessed: the IIEF-EF domain score, increase in the EHS, and improvement in Sexual Encounter Profile (SEP) 2 and SEP-3. Among the studies, 504 received Li-ESWT, and 378 received sham therapy. Four studies reported 12 sessions of Li-ESWT, two reported four sessions, two reported six sessions, and two reported five sessions. One included men who were partial responders to phosphodiesterase 5 (PDE5) inhibitors and received 12 sessions of Li-ESWT following a 4-week washout period. In another, 40 men received 5,000 shocks per session and were assessed for the IIEF-EF, EHS, SEP-2, and SEP-3. Follow-up ranged from 4 to 52 weeks. The results for the mean IIEF-EF score showed a significant increase in the treatment group compared with sham (MD, 2.28; 95% CI, 1.32-3.24; $p < 0.0001$), with the posttreatment score ranging from 11 to 22 vs 8.14 to 18.80. This change was similar at the 1-, 3-, 6-, 9-, and 12-month follow-up. This increase was similar between the PDE5 inhibitor responders and nonresponders. In the eight RCTs that reported results of EHS scores, the results showed significant improvement in the treatment group (MD, 5.44; 95% CI, 2.40-12.33; $I^2 = 65\%$; $p = 0.001$). These were similar between the PDE5 inhibitor responders and nonresponders and individuals with kidney transplant. In the three RCTs that reported results of SEP-2 and SEP-3 at 4, 7, and 12 weeks, there were no significant improvements between the groups (risk ratio, 1.16; 95% CI, 0.93-1.45; $p = 0.18$). The authors concluded that Li-ESWT is effective in treating ED. These results are limited by an overall small number of individuals across the RCTs and lack of objective data measurement parameters (e.g., penile Doppler ultrasound). Furthermore, standardization of treatment protocols, types of lithotripters, and number of sessions is lacking. Additional research that includes larger numbers of individuals, longer follow-up, and standardized protocols is needed to validate these findings.

A Hayes Evidence Analysis Brief (2024) evaluated the evidence related to Li-ESWT for the treatment of ED. A literature search identified 10 abstracts that evaluated Li-ESWT for the treatment of ED, including six RCTs and four systematic reviews/meta-analyses. Six evidence-based guidelines based on systematic reviews provided generally conflicting or inconsistent recommendations. Two guidelines recommended low intensity as a treatment for ED. Three guidelines recommended against the use of Li-ESWT or considered it to be investigational. One guideline stated that due to a paucity of evidence, no recommendation can be made at this time. The findings of this review of the full-text clinical practice guidelines and position statements demonstrate that the guidance appears to confer no/unclear support for lower-intensity ESWT for the treatment of ED.

Medrano-Sánchez et al. (2024) conducted an umbrella review that followed PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines and included five systematic reviews and meta-analyses, which were

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published between 2013 and June 2023 and evaluated Li-ESWT for vascular-origin ED. Eligible studies were systematic reviews with meta-analyses that compared Li-ESWT with placebo in men with vasculogenic ED, encompassing 56 RCTs and 3,908 individuals, with methodological quality assessed using the AMSTAR (A Measurement Tool to Assess Systematic Reviews) tool by two independent reviewers and a third who resolved discrepancies. The primary outcomes were erectile function, as measured by the IIEF-EF, and penile hardness, as measured by the EHS; Li-ESWT significantly improved IIEF-EF and EHS scores compared with placebo, with one study reporting an IIEF-EF increase of up to 5 points and greater improvement at 6 to 12 months of follow-up. Optimal results were associated with an energy flux density of 0.09 mJ/mm² and 1,500 to 2,000 pulses per session, with penile hemodynamics measured by peak systolic velocity also improving significantly. The prespecified secondary end points included SEP-2, SEP-3, safety, and individuals' satisfaction. The authors concluded that Li-ESWT may enhance erectile function, both subjectively and objectively, in men with vasculogenic ED; this represents a novel, low-risk therapeutic alternative, with greater efficacy at lower energy density and shorter treatment durations, and was described as a safe and minimally invasive option for improving erectile function. Key limitations include substantial heterogeneity across studies and populations of individuals with differing etiologies of ED, which made it difficult to establish clear conclusions about the efficacy of Li-ESWT or define an optimal treatment protocol. There are limitations related to the measurement and data quality, as outcome variables were not consistently analyzed, and follow-up periods were short, preventing reliable long-term evaluation of treatment effects. Additional limitations involved the influence of comorbid factors such as age and metabolic disease, variability in concurrent use of PDE5 inhibitors, and absence of MCID analysis in several studies. Generalizability is limited because devices, treatment parameters, and individuals' characteristics varied widely, and the mechanism of action of Li-ESWT remains uncertain.

An ECRI Clinical Evidence Assessment (2018; updated 2023) analyzed the evidence on ESWT for the treatment of ED and its comparison with other noninvasive therapies. The clinical literature search criteria yielded five systematic reviews and one economy study on ESWT's safety and effectiveness for ED. The ECRI report concluded that evidence from many RCTs synthesized in the meta-analyses shows that Li-ESWT poses minimal risks but does not achieve noticeable or meaningful improvements in erectile function in most individuals with ED. The editors stated that their confidence in this evidence is low because the studies that were included in the meta-analysis were largely at a high risk of bias and variable in terms of individuals' characteristics, ED etiology, and lower-intensity technique. Overall, additional RCTs may be useful to support stronger conclusions.

Canadian Agency for Drugs and Technologies in Health (CADTH)

A 2025 Health Technology Review by the CADTH evaluated the effectiveness of ESWT treatment for ED. The report concluded that ESWT may improve clinical outcomes in males with ED compared with sham or no treatment. There may be differences in the effectiveness of ESWT treatment in subpopulations. ESWT is safe, with few treatment-related adverse events. However, data on the clinical effectiveness of different protocols of ESWT are limited.

American Urological Association (AUA)

In 2018, the AUA published clinical guidelines on the diagnosis and treatment of ED. The guideline regarding ESWT treatment for ED states that for men with ED, Li-ESWT should be considered investigational (conditional recommendation; evidence level: grade C).

Hammer Toe

A detailed search of the medical peer-reviewed literature did not identify any clinical studies that evaluated ESWT for the treatment of hammer toe.

Lateral Epicondylitis (Tennis Elbow)

Evidence regarding the safety and efficacy of ESWT for LE is conflicting and inconsistent.

Jin et al. (2026) conducted a systematic review and network meta-analysis that evaluated the efficacy of different types and intensities of ESWT for LE. Thirteen studies (11 RCTs and two cohort studies), including 938 individuals, compared focused and radial ESWT at low, medium, or high energy levels against exercise, sham ESWT, or waiting for therapy. For the primary outcome of pain reduction, radial ESWT at medium energy was most effective at 1 month (SMD, -3.65; 95% credible interval, -4.41 to -2.90), and f-ESWT at low energy (f-ESWT-L) was superior at 6 months (SMD, -2.10; 95% credible interval, -2.72 to -1.50) compared with sham or waiting for therapy. ESWT was found to be an effective treatment for pain and functional improvement in LE, with radial ESWT at medium energy providing superior short-term analgesia and f-ESWT-L offering greater long-term pain relief and functional benefits; low-intensity radial ESWT also showed advantages for upper limb function. There are limitations, including that the ranking with a SUCRA identified f-ESWT-L as optimal for 3-month pain reduction but that its clinical relevance remains uncertain. Additional limitations arise from the distinct clinical value that was observed across different ESWT types and intensities, which complicates direct comparison

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of treatment effects. The study's findings indicate short-term pain relief with medium-intensity radial ESWT, long-term improvement with f-ESWT-L, and benefits in upper limb function with low-intensity radial ESWT within the context of the study's methodological constraints. Although the statistical models were robust and outcomes appeared stable, the overall evidence base remains limited and warrants confirmation in larger, high-quality studies.

Amélie et al. (2026) conducted a systematic review of RCTs that compared ESWT with sham ESWT or PT for chronic lateral elbow tendinopathy, including 11 RCTs that were published between 1996 and 2022, with four rated as a low risk of bias. Individuals were adults who were aged 18 to 80 years with clinically confirmed LE, and intervention protocols typically involved three weekly ESWT sessions using low- to high-energy flux densities (0.02-0.60 mJ/mm²) vs sham or PT comparators. The primary outcome, which was pain measured by the VAS, showed mixed results; Pettrone and McCall reported significant pain reduction ($p < 0.024$), Rompe and Aldajah found significant improvements ($p < 0.001$), and Staples, Karaca, and Haake found no significant differences ($p > 0.05$). The authors concluded that the current evidence does not conclusively support ESWT as superior to placebo or PT but that the positive effects in some studies suggest potential benefit in specific subgroups. They concluded that ESWT may be a valuable adjunct to PT in managing chronic lateral elbow tendinopathy. There are limitations, including substantial heterogeneity in grip strength assessments and variability in ESWT treatment protocols, which complicate comparisons across studies and hinder the development of standardized, evidence-based treatment approaches. Key limitations include a high risk of bias and inconsistent patterns between symptom duration and treatment effect, as well as the absence of information on prior exercise programs or other treatments that were attempted before study enrollment. Measurement limitations involved interchangeable terminology that may have influenced both reported outcomes and placebo effects, together with uncertain objectivity and clinical relevance of ultrasound assessments. Generalizability is limited by the restriction to English-language, freely available RCTs and by the lack of publication date limits, which may have introduced selection bias.

Alharbi (2025) conducted a systematic review and meta-analysis of RCTs that compared ESWT vs ultrasound therapy for LE, including nine RCTs with 654 individuals who had tennis elbow. The primary outcome was pain intensity, which was assessed using the VAS, and ESWT showed greater pain reduction than ultrasound (MD, -0.90; 95% CI, -1.28 to -0.52; $p < 0.0001$). The authors concluded that ESWT appears more effective than ultrasound therapy in reducing pain in LE but that this superiority does not extend to functional improvement. There are limitations, including reliance on clinically diagnosed LE in Białek et al. (2018), which was an RCT from Poland that included 50 individuals defined by pain with resisted wrist extension, decreased grip strength, and functional limitations. The evidence base also included a total of 198 clinically diagnosed individuals based on typical symptom presentation, pain during resisted wrist extension, and functional limitations. Most studies had short-term follow-up periods, typically 6 to 8 weeks, which may not fully capture functional recovery that often occurs later than pain relief. Additional limitations include substantial heterogeneity in pain and functional outcomes across trials; potential confounding from combined interventions; insufficient or inconsistent reporting of outcomes such as grip strength, individuals' satisfaction, or return to work; and publication bias that could not be ruled out.

Zhang et al. (2024) conducted a systematic review and meta-analysis that aimed to compare the effectiveness and safety of ESWT and local CS injection (LCI) for chronic LE. A systematic review and meta-analysis was conducted and followed the PRISMA guidelines. PubMed, Embase, the Cochrane Library, and Web of Science were searched for eligible studies. Meta-analyses were conducted using Manager V.5.4.1. Pooled effect sizes were expressed as the weighted MD (WMD) or OR with 95% CIs. Overall, six RCTs were included. Compared with LCI, ESWT had an inferior change in the VAS (Δ VAS; WMD, 1.14; 95% CI, 0.80-1.48; $I^2 = 20\%$; $p < 0.001$), Δ grip strength (WMD, -4.01; 95% CI, -5.57 to -2.44; $I^2 = 36\%$; $p < 0.001$), and change in Δ Patient-Rated Tennis Elbow Evaluation score (WMD, 8.64; 95% CI, 4.70-12.58; $I^2 = 0\%$; $p < 0.001$) at the 1-month follow-up; superior Δ VAS (WMD, -1.15; 95% CI, -1.51 to -0.80; $I^2 = 6\%$; $p < 0.001$), Δ grip strength (WMD, 2.04; 95% CI, 0.90-3.18; $I^2 = 3\%$; $p = 0.0005$), and Δ Patient-Rated Tennis Elbow Evaluation score (WMD, -9.50; 95% CI, -14.05 to -4.95; $I^2 = 58\%$; $p < 0.001$) at the 3-month follow-up; and superior Δ VAS (WMD, -1.81; 95% CI, -2.52 to -1.10; $I^2 = 33\%$; $p < 0.001$) and Δ grip strength (WMD, 3.06; 95% CI, 0.90-5.21; $I^2 = 0\%$; $p = 0.005$) at the 6-month follow-up. The two groups had a similarly low rate of adverse events (OR, 0.69; 95% CI, 0.05-8.60; $I^2 = 67\%$; $p = 0.77$), and all adverse events were mild. The authors concluded that both ESWT and LCI are effective and safe in treating chronic LE. Compared with LCI, ESWT showed inferior short-term (1-month) but superior long-term (3-month and 6-month) outcomes regarding pain relief and function recovery, with a similar rate of mild adverse events. This study has some limitations. First, the number of available studies was limited due to the restriction of a head-to-head RCT design in the literature. Second, despite well-matched groups of individuals in both interventions, differences in crucial factors such as sports level, severity of LE, ESWT equipment specifications, LCI composition, rehabilitation protocols, and follow-up durations across studies were inevitable. Third, a subgroup analysis to separately compare radial ESWT or f-ESWT and LCI was not conducted in this study due to the limited sample sizes available. Last, only two of the included studies reported outcomes beyond 6 months, leaving results at longer follow-ups absent. Consequently, outcomes that can only be observed at the long-term follow-up, such as the tendon assessment, remain absent in this study. Well-designed,

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comparative studies that include larger populations of individuals are needed to further describe safety and clinical outcomes.

Çetin et al. (2024) conducted a randomized prospective study that compared the clinical outcomes in participants with LE who were treated with local massage, CS injection, and ESWT. After exclusions, the study included 38 participants (group 1/local massage, nine; group 2/CS injection, 13; group 3/ESWT, 16) who had not received any treatment for the LE in the last 6 months. All three groups were clinically evaluated using the VAS, Disabilities of the Arm, Shoulder, and Hand (DASH), and DASH-Work Model scores at the initial examination, at the beginning of the study, and at the 2-week, 3-month, and 6-month follow-ups. The results demonstrated that in group 1, all three scores decreased significantly in the first 2 weeks, but no significant difference was observed in any of the scores at the 6-month follow-up. Group 2 had a significant decrease in all scores at 2 weeks, whereas no statistically significant decrease was observed in any of the scores at 6 months. However, a significant decrease was observed in VAS and DASH scores at 3 months. Group 3 had statistically significant decreases in all scores throughout the follow-up period. The authors concluded that ESWT was superior to both local massage and CS injection treatments throughout the study and at the final follow-up. However, there are relatively few studies that show the superiority of these treatments over one another, and there is still no consensus on a standard, effective method used for LE. Further studies on combined treatment modalities are needed on this subject. Limitations include a small sample size, study design, and short follow-up.

Liu et al. (2022) completed a systematic review and network meta-analysis to examine the efficacy of ESWT and injection therapies by synthesizing direct and indirect evidence for all pairs of competing therapies for LE. The PubMed, Embase, and Web of Science databases were searched for all appropriate RCTs, with assessment of the effect of ESWT or injection therapies. The primary outcome was short-term (≤ 3 months) and medium-term (> 3 months but ≤ 12 months) pain, while the secondary outcomes were grip strength and patient-reported outcome measures. All outcomes were assessed using SMDs with 95% CIs and were ranked using SUCRA probabilities to determine a hierarchy of treatments. A sensitivity analysis was performed to eliminate potential therapeutic effects of normal saline and exclude trials that included individuals with acute LE. Overall, 40 RCTs were included to evaluate ESWT and five different injection therapies, including CSs, autologous whole blood, platelet-rich plasma, botulinum toxin A, and DPT. DPT (-.78; -1.34 to -.21), ESWT (.57; -.89 to -.25), platelet-rich plasma (-.48; -.85 to -.11), and botulinum toxin A (-.43; -.84 to -.020) outperformed placebo for short-term pain relief; ESWT (-.44; -.85 to -.04) outperformed placebo for medium-term pain relief. DPT was ranked as the most optimal short-term and medium-term pain reliever (SUCRA, 87.3% and 98.6%, respectively). ESWT was ranked as the most optimal short-term and medium-term grip strength recovery (SUCRA, 79.4% and 86.4%, respectively). The authors concluded that DPT and ESWT were the best two treatment options for pain control and that ESWT was the best treatment option for grip strength recovery. CSs were not recommended for the treatment of LE. More evidence is required to confirm the superiority in pain control of DPT among all these treatment options in LE. Limitations to the study include no standardized treatment protocol for each treatment, as well as no standardized protocols and treatment modalities in ESWT. The effectiveness of ESWT may change with the evolution of the times and advancement of machines. Further research that includes RCTs is needed to validate these findings.

Özmen et al. (2021) performed a comparison study to determine the clinical and sonographic effects of ultrasound therapy, ESWT, and Kinesio taping (KT) in LE. Overall, 40 participants with LE were included in the study. The participants were randomly assigned to three treatment groups: ultrasound (n = 13), ESWT (n = 14), and KT (n = 13) groups. The VAS scores decreased in all groups ($p < 0.05$). Grip strength increased after 8 weeks in only the KT group ($p < 0.05$). The Patient-Rated Tennis Elbow Evaluation scale scores significantly decreased after 2 weeks and after 8 weeks in the ultrasound group and ESWT groups and after 8 weeks in the KT group ($p < 0.05$). Common extensor tendon thickness decreased after 8 weeks in only the ESWT group ($p < 0.05$). The authors concluded that ultrasound therapy, KT, and ESWT are effective in reducing pain and improving functionality. However, none of these treatment methods were found to be superior to others in reducing pain and improving functionality. Limitations of the study include a small sample size (40 participants) and short duration of follow-up. Also, there was no exercise intervention in addition to the treatment methods applied. Grip strength may be increased by strengthening the forearm muscles.

Atalay and Gezginaslan (2020) completed an RCT to evaluate the effectiveness of neural therapy (NT) vs that of ESWT in the treatment of LE. Between August 2018 and November 2018, 76 participants with LE (26 males, 50 females; mean age, 44.8 ±9.5 years; range, 29-65 years) were randomly allocated to either NT or ESWT one session weekly for a total of 3 weeks. The subjective pain severity was evaluated using the VAS, and the Duruoz Hand Index (DHI) was used to assess the functional disability before and after treatment and at 12 weeks. When the before and after treatment and 12-week variances of values were compared between the ESWT and NT groups, there were no differences in the VAS and DHI scores between the groups' ($p > 0.05$) VAS score at 12 weeks (effect size, 0.18; 95% CI, -0.358 to 1.619) or DHI score (effect size, 0.13; 95% CI, -7.627 to 4.390). However, in the groups, there were differences in VAS and DHI scores between before treatment and after treatment ($p < 0.05$) and between before treatment and at 12 weeks of follow-up ($p < 0.05$). No adverse events occurred in this study. The authors concluded that the results of this study show that both

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ESWT and NT have similar effects in reducing pain and hand function in individuals with LE. However, neither of the two treatment modalities showed superiority. There are some limitations to this study. The number of participants in the study is small, which could have decreased the power of the study. As there was no control group, the authors could not determine the effect of the two therapeutic methods. Other limitations of the study include the lack of blinding; qualitative data/feedback from participants, the nontreatment group, or the routine care group; and long-term outcomes. Further investigation, with large-scale, prospective, placebo-controlled studies that evaluate long-term outcomes, is needed.

Yao et al. (2020), in a systematic review and meta-analysis, found that additional high-quality RCTs are still needed to validate that ESWT safely and effectively relieves the pain and functional impairment from LE. The meta-analysis included 13 published RCTs that included 1,035 individuals, of whom 501 individuals received ESWT, and 534 received other treatments. Due to the heterogeneity of the studies, the authors performed a pooled analysis of the data, which they concluded showed significantly lower VAS scores (0 indicating no pain and 10 the worst pain) that were indicative of early recovery and significantly increased grip strength in the ESWT treatment group. There were also several limitations of the meta-analysis that were identified by the authors, including different ESWT instruments, treatment protocols, diagnostic criteria, and the fact that the majority of the studies were conducted in one country. The authors concluded that future RCTs should address these limitations.

Yoon et al. (2020) completed a systematic review and meta-analysis that was focused on the effect of ESWT on LE for reducing pain and improving grip strength as well; however, the analysis also investigated the effects of ESWT according to the specific type applied, symptom duration, and follow-up duration. In this review, 12 studies, with 1,104 individuals, were included in the meta-analysis, with 10 of the 12 studies having also been included in the Yao et al. systematic review and meta-analysis. This meta-analysis concluded that ESWT did not show clinically important improvement in pain reduction and grip strength; however, the authors concluded that radical ESWT was more effective than f-ESWT and that individuals with a longer duration of symptoms had more improvement. The authors also noted that the effects did not last beyond 24 weeks. Limitations that were noted are the heterogeneity of the studies included in the review and the diversity of the treatment protocols, shock wave devices, and length of treatment among the studies. The authors recommended future studies on specific conditions and parameters to establish optimal protocol settings for ESWT for LE.

Aydın and Atiç (2018) performed a prospective RCT that compared the efficacy of ESWT with that of wrist-extensor splint (WES) application in the treatment of LE. Participants were included if they had been treated based on a diagnosis of unilateral LE. Participants were excluded if they had bilateral LE, carpal tunnel syndrome, cubital tunnel syndrome, previous elbow surgery, previous conservative and surgical treatment for LE, neurological deficits in the upper extremity, systemic disease, other diseases in the neck and shoulder region, lateral epicondylar tendon ruptures, tumors in the forearm and elbow, osteoporosis, and hemophilia. The participants were randomized into two groups. Group one received ESWT four times per week using the DolorClast device, and group two received a WES. The primary outcomes measured were the effectiveness of ESWT compared with that of WES in decreasing pain, improving grip strength, increasing quality of life, and alleviating arm pain during daily life activities in the treatment of LE. Evaluation data were collected before and after treatment at weeks 4, 12, and 24. In both groups, there were significant improvements in decreasing pain, increasing grip strength, and improving quality of life at 4, 12, and 24 weeks compared with pretreatment values. However, there was no statistically significant difference between the two groups at the three time points. The authors noted that the limitations of the study are the small participant population and use of the participant-reported questionnaires.

Capan et al. (2016) conducted a double-blinded, randomized, placebo-controlled trial in outpatient clinics of a medical faculty hospital. Overall, 56 participants with LE were randomized to radial ESWT or sham radial ESWT groups. Both the participants and the outcome-assessing investigator were blinded to group assignment. The radial ESWT was administered to the painful epicondyle at the elbow at each session at three once-weekly sessions. Sham radial ESWT was applied without the contact of the applicator to the same area. Study participants were assessed at baseline and at 1 and 3 months after treatment using a VAS for pain, Roles and Maudsley scale, and Patient-Rated Tennis Elbow Evaluation for pain and function. Grip strength of the affected extremity was also measured using a hand dynamometer. Both the radial ESWT and sham radial ESWT groups had a significant improvement in all outcome measures at posttreatment follow-up points. Favorable absolute and percentage changes in assessments at 1 and 3 months post treatment did not show any significant difference between groups. The authors concluded that radial ESWT does not seem to be more effective either in reducing pain or improving function or grip strength in individuals with LE, at least at 3 months after treatment, compared with sham radial ESWT.

Refractory Greater Trochanteric Pain Syndrome

There is insufficient quality evidence to conclude that ESWT is effective for greater trochanteric pain syndrome (GTPS); therefore, additional research that involves larger, well-designed studies is needed to establish its safety and efficacy.

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Rau et al. (2026) conducted a systematic review that evaluated focused and radial ESWT for tendinopathies of the hip and pelvis, including GTPS, calcific tendinopathy, and proximal hamstring tendinopathy. The review included 18 studies (eight RCTs, three cohort or case control, one quality improvement, and six case reports) that included 927 individuals (682 females, 245 males; mean age, 50.7 years), most of whom had chronic tendinopathy of at least 3 to 6 months' duration; 586 received ESWT. Interventions typically involved three to four weekly sessions, delivering 2,000 to 3,000 pulses per session using either focused or radial ESWT compared with conservative therapy, sham ESWT, ultrasound, CS injection, or eccentric exercise. Pain and function were the primary outcomes, as measured by the VAS, numeric rating scale, Harris Hip Score, Lower Extremity Functional Scale, and Roles and Maudsley scores, showing statistically significant improvement in 17 of 18 studies, with greater benefit vs several comparators and an overall adverse event rate of 12% (65 of 557 individuals). The authors concluded that ESWT is safe and effective for GTPS, proximal hamstring tendinopathy, and calcific tendinopathy, with pain and functional improvements across modalities. There are limitations, including wide variation in the quality of the cohort studies and randomized trials, with several judged to have a higher risk of bias. Key limitations include nonuniform ESWT protocols and outcome assessments, which hindered quantitative synthesis of the evidence. The evidence was further limited because only one study combined focused and radial ESWT, and none conducted direct head-to-head comparisons between these modalities. Generalizability is constrained, as most studies did not distinguish between calcific tendinopathy and other diagnoses when evaluating outcomes, and several case reports focused solely on hip and pelvic calcific tendinopathy, which represent a narrow segment of the ESWT literature.

Bremer et al. (2025) conducted a systematic review to guide clinical practice by synthesizing evidence concerning gluteal tendinopathy management. Five electronic databases were searched for RCTs of medium or high quality and a low risk of bias that measured pain and function in adults with clinically diagnosed gluteal tendinopathy. The PEDro (Physiotherapy Evidence Database) scale and Cochrane risk-of-bias tool 2.0 were used to assess internal validity and risk of bias. Overall, 27 studies were identified through electronic databases, including grey literature. Efficacy was determined by comparison to minimal intervention. Methodological heterogeneity prevented meta-analysis; however, the authors calculated SMDs and 95% CIs for individual study arms to facilitate comparison between interventions. Four interventions from four RCTs demonstrated efficacy. Exercise and education revealed moderate-strength evidence of a medium effect on pain (SMD, 0.95; 95% CI, 0.58-1.33) and function (SMD, 0.91; 95% CI, 0.53-1.28) in the short term, with small effects in the medium and long term. CS injection had moderate-strength evidence of a small effect on pain (SMD, 0.51; 95% CI, 0.16-0.86) in the short term. Platelet-rich plasma injection was superior in the short term compared with CS injection for function (SMD, 0.46; 95% CI, 0.00-0.91). For pain, f-ESWT demonstrated superiority in the long term (SMD, 5.77; 95% CI, 4.84-6.71) compared with CS injection. The authors concluded that exercise and education can be cautiously recommended as the core approach for pain management and function, potentially supplemented by CSs or f-ESWT, while definitive trials of promising interventions are needed to derive robust practice recommendations. This systematic review has limitations; it was a single study that had large CIs and short-term results only. The findings of this systematic review need to be validated by well-designed studies. Further investigation is needed before the clinical usefulness of ESWT is proven.

Datt Anand et al. (2025) conducted a systematic review and meta-analysis of RCTs and randomized crossover trials in adults (≥ 18 years) who were diagnosed with GTPS (confirmed by ultrasound/magnetic resonance imaging or diagnostic criteria) and had positive physical examination findings; the clinical efficacy of ESWT vs that of sham or conservative/nonsurgical interventions was compared. Seven trials, with 714 individuals, were analyzed (six included in the meta-analysis); trial sample sizes ranged from 44 to 229, and the ages of individuals ranged from 46 to 64 years. The primary outcome was pain intensity, which was standardized to a 0-to-10 scale when different measures (VAS and numeric rating scale) were used and pooled using SMDs with 95% CIs under a random-effects model, with f-ESWT and radial ESWT analyzed separately. For f-ESWT vs control/alternative treatments, pooled pain intensity across medium follow-ups showed a statistically significant decrease (SMD, -1.96; 95% CI, -3.22 to -0.71; $p = 0.002$) but not in the long term. f-ESWT was found to be more effective in improving lower extremity function in GTPS (SMD, 0.61; 95% CI, 0.41-0.81; $Z = 6.02$; $p < 0.00001$). Radial ESWT did not offer any significant benefit for reducing pain intensity over control/alternative treatments in either short-, medium-, or long-term follow-ups (SMD, -0.03; 95% CI, -0.41 to 0.35; $Z = 0.16$; $p = 0.87$). The prespecified secondary end points were lower extremity function. The authors concluded that f-ESWT can improve pain intensity and lower extremity function more significantly than the control/alternative treatment and described f-ESWT as a viable, effective, and safe alternative for the management of GTPS. There are limitations, including that the studies at a high risk of bias may have introduced variability, increased heterogeneity, and made it difficult to draw consistent conclusions. The meta-analysis included a relatively small number of studies, with limited sample sizes, which may limit generalizability. Heterogeneity may also reflect variability in ESWT treatment protocols, as well as differences in interventions that were used in comparator groups. Restricting inclusion to English-language studies may have excluded relevant studies in other languages and influenced the overall conclusions, and the very small evidence base may have contributed to publication bias.

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Harding et al. (2024) conducted a systematic review and meta-analysis to investigate the efficacy of shock wave therapy on pain and function in the management of GTPS compared with alternative treatment interventions. The study included a total of 1,221 individuals, of whom 849 underwent shock wave therapy; posttreatment follow-up ranged from 1 week to 2 years. The results demonstrated that in RCTs, large treatment effects were identified across all follow-up time points for pain in shock wave therapy groups. Following shock wave therapy in non-RCTs, a large treatment effect for pain was consistently seen across all time points. Moderate to large functional treatment effects of shock wave therapy in RCTs were seen at all follow-up time points. In non-RCTs, shock wave therapy resulted in moderate treatment effects at all time points. The authors concluded that although moderate-strength evidence was found, shock wave therapy was not significantly beneficial compared with control for pain or function over time. Further robust RCTs that investigate the impact of optimal treatment protocols of shock wave therapy on acute vs chronic symptomology would be beneficial for optimizing individuals' care. Limitations in the study include methodological heterogeneity, a risk of bias, and a lack of standardization.

ECRI (2020) published an Executive Summary on the use of ESWT for chronic lateral hip pain/GTPS, with a focus on the safety and efficacy of ESWT used with or in place of PT, pain medication, and other nonsurgical treatments. The review included one systematic review (n = 295) of controlled studies and two RCTs (n = 103 and n = 50) that were not included in the systematic review. The Executive Summary concluded that the evidence is inconclusive due to the limited data available and high risk of bias in the studies reviewed because of a lack of randomization or complete blinding, a small size, high attrition, and a single-center focus. Other published data that were not included in the review were excluded because the risk of bias was higher and because there were too few individuals per treatment. ECRI recommended large, multicenter studies to validate available data and to assess long-term outcomes related to pain recurrence and re-treatment.

Ramon et al. (2020) completed a randomized, multicenter clinical trial in 103 participants with chronic GTPS. The participants were divided into two groups, both of which were treated with three weekly sessions of f-ESWT, with the test group (n = 53) receiving an energy flux density of 0.20 mJ/mm^2 and the control group (n = 50) receiving the lowest energy flux density of the device (0.01 mJ/mm^2) using the same brand of device. Each participant was assessed at baseline and 1, 2, 3, and 6 months after the last session by clinicians who were blinded to the group allocation. The authors concluded that f-ESWT and a specific home exercise program are safe and effective for GTPS, with a success rate of 86.8% at 2 months after treatment that was maintained until the end of the 6-month follow-up. Limitations that were identified by the authors include a lack of follow-up beyond 6 months; lack of exact data on participants' adherence to the home exercise protocol; and imbalance of participation by women (n = 74) to men (n = 29) in a sample size of only 103, which may not detect important differences in responses to the intervention between the sexes. Additionally, the control group received some of the lowest doses of ESWT, so it could be considered a quasi-placebo group. The authors recommended further high-quality RCTs to confirm the long-lasting effectiveness of f-ESWT for GTPS.

Tenosynovitis of the Foot or Ankle

A detailed search of the medical peer-reviewed literature did not identify any clinical studies that evaluated ESWT for the treatment of tenosynovitis of the foot or ankle.

Tibialis Tendinitis

A detailed search of the medical peer-reviewed literature did not identify any clinical studies that evaluated ESWT for the treatment of tibialis tendinitis.

Wounds

ESWT mechanisms of action for wound healing are not fully elucidated in the literature. The current understanding is that the mechanical effects of the shock waves on cells trigger biological responses that enhance tissue perfusion and angiogenesis.

Su et al. (2026) developed a national expert consensus by the Wound Repair Committee of the Chinese Medical Doctor Association to standardize the clinical application of ESWT for diabetic foot ulcers (DFUs). Overall, 69 multidisciplinary experts participated, and consensus statements were formulated using the Delphi method, with two rounds of feedback and a consensus workshop. Eligible evidence included systematic reviews, RCTs, cohort studies, and expert consensus statements, which were appraised using established quality-assessment tools. The consensus defines evidence-graded indications, contraindications, and treatment parameters for ESWT in adult individuals with DFUs, specifying energy ranges of 1.0 to 2.5 bar for radial waves and 0.03 to 0.18 mJ/mm² for focused waves. The clinical studies cited in the consensus reported that ESWT at an energy flux density of 0.11 mJ/cm² significantly reduced wound size and median healing time without adverse effects. The primary outcome was wound healing improvement, which was measured by wound size reduction and time to ulcer closure, showing superior results in ESWT-treated individuals compared with

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controls. The authors concluded that the consensus provides standardized guidance for applying ESWT in DFU management, emphasizing individualized treatment integration with comprehensive care and combination with other therapies to optimize healing outcomes. There are limitations, including limited clinical evidence and a lack of rigorously designed studies, leaving uncertainty about optimal shock wave therapy parameters, treatment duration, and suitable wound types. A further limitation is the scarcity of evidence for ESWT in DFUs, which highlights the need for multicenter, large-scale clinical investigations to strengthen the evidence base.

Yang et al. (2025) conducted a double-blinded two-parallel-arm RCT at The Affiliated Hospital of Southwest Medical University from June 2020 to January 2023 to evaluate ESWT for deep dermal hand burns. Eligible adults who were aged 18 years or older, had clinically diagnosed deep dermal hand burns, and refused surgical treatment were randomized 1:1 to ESWT or routine dressing treatment (RT), with 20 participants in each group. The ESWT group received routine dressing plus ESWT on days 3, 5, and 7 after injury, while the RT group received identical care with the device turned off. The primary outcome was percentage of wound healing, which was calculated as [(wound area before treatment - wound area after treatment) / wound area before treatment] × 100%, measured on days 1 and 14 using eKare inSight 3D. At 14 days, wound healing was 0.78 (0.67-0.85) in the ESWT group and 0.33 (0.26-0.45) in the RT group ($p < 0.001$). Statistical analysis used an independent t test, Mann-Whitney U test, chi-square test, repeated measures analysis of variance, and Friedman test, as appropriate. The prespecified secondary outcomes were wound infection, pain (VAS), and scar formation (Vancouver Scar Scale). The authors concluded that ESWT effectively shortened healing time, reduced pain, controlled inflammation, and increased wound blood perfusion in deep dermal hand burns, which confirms its safety and clinical effectiveness. There is a limitation in that the uniform use of bovine basic fibroblast growth factor gel across both groups may have confounded the observed effects on angiogenesis and wound healing.

Wu et al. (2024) conducted a systematic review and meta-analysis to investigate the efficacy and safety of ESWT for DFUs. Overall, 10 RCTs of moderate methodological quality were included for data analysis, involving 754 individuals with DFUs. All studies used ESWT as the study group (383 feet) and either hyperbaric oxygen therapy (HOT; 59 feet) or standard of care (SOC; 263 feet) as the control group. The average age of individuals ranged from 56.5 to 67.8 years across studies. According to the studies, the average hemoglobin A_{1c} levels in individuals ranged from 7.8% to 9.08%, indicating a variation in the glycemic control among the study populations. The ulcer healing assessment time varied significantly, ranging from as short as 2 weeks to as long as 20 weeks. The findings showed that ESWT was associated with complete healed ulcers (risk ratio, 1.57; 95% CI, 1.26-1.95) and a lower rate of unchanged ulcers (risk ratio, 0.25; 95% CI, 0.14-0.42) compared with controls. A subgroup analysis further revealed that ESWT was better than both HOT and the SOC. Moreover, ESWT also improved the average transcutaneous partial oxygen pressure (MD, 1.71; 95% CI, 1.22-2.19; $p < 0.001$). However, the rate of ≥ 50% improved ulcers and treatment-emergent adverse events were not different between the ESWT and controls. The authors concluded that ESWT has shown promising efficacy and a favorable safety profile in the treatment of DFUs. However, the authors also recommended future studies to further elucidate possible mechanisms by which ESWT favors DFU healing. Additionally, more research is needed to determine which energy strategies may be the best option to improve DFU healing. This study has limitations. The average age of individuals, average duration of ulcers, average follow-up duration, ulcer healing assessment time, and specific interventions vary from one study to another, which could have introduced heterogeneity and negatively affected the robustness of the findings. Although 10 RCTs were included for data analysis, the sample size of nine studies was extremely small, which inevitably reduced the accuracy of the results. Therefore, future studies that include a larger sample size are needed to evaluate the role of ESWT in the treatment of DFUs. Finally, the studies that were reviewed demonstrated a critical need for stringent blood glucose control in the management of DFUs, as evidenced by the individuals' hemoglobin A_{1c} levels ranging from 7.8% to 9.08%. Despite this, the research primarily focused on evaluating specific treatments, including ESWT, HOT, and SOC, without thoroughly investigating how glycemic control itself influences ulcer healing outcomes. Future studies should be conducted to explore the role of blood glucose in the management of DFU healing to optimize therapeutic strategies.

Hitchman et al. (2023) conducted a systematic review to investigate the role of ESWT in DFU healing and the impact of different ESWT doses. In total, six RCTs that were published between 2009 and 2019 were analyzed. The primary outcome of the study was time to healing. The results demonstrated that time to ulcer healing was probably shorter in individuals who were treated with ESWT than in those who received standard ulcer care alone. Individuals who were treated with ESWT were more likely to heal at 20 weeks post ESWT compared with those who were treated with standard ulcer care alone. The authors concluded that ESWT remains a promising new treatment but that the translation into routine clinical practice is still limited by the low certainty of evidence surrounding its effectiveness, case selection, and optimum dose. Future trials are necessary and must be conducted in a scientific, rigorous way to prevent wasting of resources and improve DFU care. Limitations in the study include a risk of bias, small sample size, and heterogeneity.

ECRI (2020) published a Clinical Evidence Assessment on the dermaPACE system that focused on how the device compares with SOC and other chronic wound treatments. ECRI concluded that the evidence is somewhat favorable when

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comparing dermaPACE with SOC alone, as it appears to improve complete DFU healing rates at the 24-week follow-up and decreases time to wound closure. ECRI based their recommendation on two low-quality RCTs (n = 206; n = 130), which were multicenter and double blinded, based on pooled data from the same study individuals. ECRI also reviewed a third RCT from a single-center open-label study (n = 77; 84 ulcers) that compared dermaPACE with HOT in individuals with chronic DFUs and reported rates of complete wound closure, improved healing, unchanged ulcers, and adverse events. They did not find any published studies that evaluated the effectiveness of dermaPACE for treating chronic wound types other than DFUs. dermaPACE has been granted De Novo clearance by the U.S. Food and Drug Administration only for treating DFUs at this time, although it is intended to treat chronic wounds more broadly.

Huang et al. (2020) performed a systematic review and meta-analysis of eight RCTs (n = 339) to assess the safety and efficacy of ESWT on the healing of DFUs. The authors concluded that ESWT was associated with a greater reduction in the wound surface area, an increase of reepithelialization, and more individuals with complete cure at the end of treatment. All the included studies were conducted by different medical centers in different countries, with varied treatment protocols for treatment strength, frequency, and duration. Individuals' ages ranged from 56.2 to 67.8 years. The control groups in the studies also received various treatments, with standard wound care in six RCTs and HOT in two studies. The authors also found that ESWT was more effective than HOT in treating DFUs. Limitations identified by the authors include the application of ESWT only to DFU wounds, the small number of included studies in the meta-analysis (< 10), and the fact that cost-effectiveness was not reviewed.

Zhang et al. (2018) examined the effects of ESWT and conventional wound therapy (CWT) for acute and chronic soft tissue wounds in a systematic review and meta-analysis. Overall, 10 RCTs, involving 473 individuals, were included in this systematic review and meta-analysis. The meta-analysis showed that ESWT statistically significantly increased the healing rate of acute and chronic soft tissue wounds 2.73-fold (OR, 3.73; 95% CI, 2.30-6.04; $p < 0.001$) and improved wound healing area percentage by 30.45% (SMD, 30.45; 95% CI, 23.79-37.12; $p < 0.001$). ESWT reduced wound healing time by 3 days (SMD, -2.86; 95% CI, -3.78 to -1.95; $p < 0.001$) for acute soft tissue wounds and 19 days (SMD, -19.11; 95% CI, -23.74 to -14.47; $p < 0.001$) for chronic soft tissue wounds and the risk of wound infection by 53% (OR, 0.47; 95% CI, 0.24-0.92; $p = 0.03$) compared with CWT alone. Serious adverse effects were not reported. The authors concluded that ESWT showed better therapeutic effects on acute and chronic soft tissue wounds than CWT alone. However, the authors noted that higher-quality and well-controlled RCTs are needed to further evaluate the role of ESWT for acute and chronic soft tissue wounds.

Omar et al. (2017) performed a systematic review of 10 databases for clinical trials about ESWT in the management of chronic wound of lower extremity. These were published between 2000 and 2016. Overall, 11 studies, with 925 individuals, were found. Expert therapists assessed the methodological qualities of the selected studies using the PEDro scale and categorized each study according to Sackett levels of evidence. Eight studies were categorized as level II; two studies were categorized as level III; and one study was categorized as level V. In conclusion, this review demonstrated mild to moderate evidence to support the use of ESWT as an adjuvant therapy with a standardized wound care program. However, it is difficult to draw firm conclusions about the efficacy of ESWT. So, future research of high methodological quality is required to assess the efficacy and cost-effectiveness of this relatively new PT application.

Ottomann et al. (2011), in a phase 2 RCT, evaluated shock wave effects in burn wounds. A predefined cohort of 50 participants (six with incomplete data or loss to follow-up) with acute second-degree burns was randomized to receive standard therapy (burn wound debridement/topical antiseptic therapy) with (n = 22) or without (n = 22) defocused ESWT applied once to the study burn after debridement. The randomization sequence was computer generated, and participants were blinded to treatment allocation. The mean time to complete (≥ 95%) epithelialization in participants who did or did not undergo ESWT was 9.6 ±1.7 and 12.5 ±2.2 days, respectively. The authors concluded that the application of a single defocused shock wave treatment to the superficial second-degree burn wound after debridement/topical antiseptic therapy significantly accelerated epithelialization. However, they also indicated that this finding warrants confirmation in a larger phase 3 trial.

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

The FDA has classified extracorporeal shock wave therapy products as Class III devices through the premarket approval program under the product code NBN (generator, shock wave, for pain relief).

Devices used for extracorporeal shock wave therapy are extensive. Refer to the following website for more information, and search by product name in the device name section:
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed May 27, 2026)

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Policy History/Revision Information

Date	Summary of Changes
10/01/2026	**Supporting Information** • Updated *Clinical Evidence* and *References* sections to reflect the most current information • Archived previous policy version 2025T0269LL

Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the member specific benefit plan document must be referenced as the terms of the member specific benefit plan may differ from the standard plan. In the event of a conflict, the member specific benefit plan document governs. Before using this policy, check the member specific benefit plan document and any applicable federal or state mandates. UnitedHealthcare reserves the right to modify its policies and guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

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