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

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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

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

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 within 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 ten times less energy. Low energy defocused ESWT or soft focused acoustical wave pattern is used for wound healing.

Although the mechanism of therapeutic effect for 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 Tendonitis

Conclusive evidence recommending ESWT as a treatment for Achilles tendinopathy is lacking. Studies comparing high energy, single-treatment protocols with low energy, multiple-treatment protocols, and studies comparing 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 tendonitis have been limited to studies using animal models. There are no adequate prospective clinical studies demonstrating the effectiveness of ESWT for Achilles tendonitis.

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 inclusion criteria were met. The sample size was 157 participants in the experimental group and 187 participants in the control group. The results demonstrated that the very low -quality evidence suggested that ESWT was no more effective in decreasing pain than any other conservative treatment (D: −0.8; 95% CI: −3.15, 1.56; $p > .5$). However, the heterogeneity of the studies 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, an evidence rating was too low to allow conclusions. Therefore, no strong recommendations can be made for the use of ESWT in patients with Achilles tendinopathy. The limitations of the study include 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, EMBASE, CINAHL, and CENTRAL] was performed with a total of 283 articles identified. Of these, seven randomized controlled trials (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 utilized radial ESWT only, one study used a combination of radial and focused ESWT, one study compared radial and focused ESWT, and two studies used focused ESWT only. The length of follow-up ranged from three to 16 months. Overall, four of the seven RCTs included found a

statistically significant improvement in outcome measures with the use of ESWT compared to control. The other three studies observed no statistically significant improvement in outcome measures with the use of ESWT compared to control, each observed a significant improvement in the ESWT groups from baseline. The author concluded ESWT appeared to be safe and at least as effective as 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 suggests that further high-quality studies with 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 patients should receive.

In 2019, Stania et al. published results from a systematic review of research reports on ESWT in patients 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 were included based on the following criteria: full-text article published in English and including comprehensive description of shock wave application. Twenty-two articles met the inclusion criteria. Most studies on the effectiveness of ESWT for Achilles tendinopathy included in this review were RCTs. Two case-control studies, a case series study, prospective audit, 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, the high diversity of application methodologies, and the 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 fulfil the criteria for evidence-based medicine.

In 2017, the Washington State Health Care Authority 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 while running or playing sports, but there was no difference between groups while working or using the stairs. One RCT reported significant improvement in function when comparing ESWT to sham. The strength of evidence for this indication was low and there was no evidence found on the intermediate or long-term outcomes.

Guidance from the National Institute for Health and Care Excellence (NICE) concluded that although the evidence on ESWT for refractory Achilles tendinopathy raises no major safety concerns, evidence on 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 patient selection, treatment protocols, use of local anesthesia and the type and duration of energy applied. Studies should include validated outcome measures and have a minimum of one year of follow-up (NICE, 2016).

Calcific Tendonitis of the Shoulder (Rotator Cuff)

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 for some patients with chronic calcific shoulder tendinitis; additional standardization of energy levels and treatment protocols are needed as well as additional data to address safety concerns and assess in which patient population benefits outweigh harm.

Xue et al. (2024) conducted a systematic review and meta-analysis on the effects of extracorporeal shock wave therapy (ESWT) for rotator cuff tendinopathy. A total of seventeen studies (n = 1131) from 2006-2023 were included in the review. The results showed that compared with the control group, ESWT for pain, function, range of movement (ROM) and external rotation were statistically significant, with a total effective rate (TER) (OR = 3.64, 95% CI 1.85, 7.14, p = 0.0002). However, ROM-Abduction (SMD = 0.72, 95% CI -0.22, 1.66, p = 0.13) was not statistically significant. The authors concluded 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 lack of random allocation and concealment methods leading to selection bias, and language limitations.

A Hayes Health Technology Assessment (2022, updated August 2024) 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 patients with calcific tendinitis of the shoulder. Evidence comparing ESWT with clinical alternatives yielded conflicting findings or was limited in quantity. Primary complications were pain or discomfort during or just after treatment, bruising, and swelling. Hayes noted the overall quality of evidence was low and while ESWT appears to be safe and effective,

continued research is needed to determine optimal ESWT treatment parameters, clarify comparative benefit versus alternative treatments, and establish treatment durability. Follow-up beyond twelve months was also recommended.

According to the NICE guidance on the use of ESWT for calcific tendonitis of the shoulder, 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 only be used in the context of research and further research should include RCTs comparing the procedure with current best practice (NICE, 2022).

Shao et al. (2022) conducted an RCT to investigate the effect of ESWT on short-term functional and structural outcomes after rotator cuff repair. Two groups randomized to either the ESWT group (n = 19) or the control group (n = 1 9) participated in five weeks of advanced rehabilitation three months after rotator cuff repair. The ESWT group also received 2000 pulses of shockwave therapy once a week for five weeks. All individuals had clinical and magnetic resonance imaging (MRI) examinations at three months (baseline) and at six months (follow-up) after surgery. Thirty-two participants completed all assessments. Pain and function improved in both groups. At six 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 radial ESWT reduced early shoulder pain and accelerated proximal supraspinatus tendon healing at the suture anchor site post rotator cuff repair. However, the authors note 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 small sample size, short follow-up period, and the study only included individuals with medium to large rotator cuff tears. The authors suggest further studies are needed to evaluate the correlation between energy flux density and biological effects.

Surace et al. (2020) reviewed thirty-two RCTs and controlled clinical trials involving 2281 participants with rotator cuff disease with or without calcific deposits. The primary comparison was shock wave therapy compared to placebo with a 3-month follow-up. The findings favored ESWT vs. placebo for pain levels [standardized mean difference (MD) -0.49, 95% CI –0.88 to –0.11] and functional status (standardized MD0.62, 95% CI 0.13 to 1.11). The adverse events were more frequent with ESWT than placebo (relative risk 3.61, 95%CI 2.00 to 6.52). The authors concluded 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 searching for studies on the use of ESWT therapy without surgical treatment with symptoms duration more than two months, and at least six months of follow-up for treating rotator cuff tendinopathy, subacromial impingement, and medial and lateral epicondylitis (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 safe and effective treatment of soft tissue diseases of the upper limbs. Even in the minority cases when unsatisfied results were recorded, high energy shockwaves were nevertheless suggested in prevision of surgical treatment. The authors however reported a moderate overall risk of bias that could have influenced their analysis.

Bannuru et al. (2014) conducted a systematic review (n = 28 RCTs/1307 subjects) of the evidence to assess the efficacy of ESWT in patients with calcific and non-calcific tendinitis. The outcome measures included pain, function and calcification resolution which was 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 non-calcific 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

Canadian Agency for Drugs and Technologies in Health (CADTH)

A 2016 report issued by the CADTH reviewed evidence on the effectiveness of shockwave therapy for pain associated with upper extremity orthopedic disorders including rotator cuff tendinopathy and epicondylitis. Evidence from four systematic reviews suggests that, in comparison with placebo, shockwave therapy using high energy is effective in reducing pain in calcific tendinitis of the shoulder. Evidence suggests that that there is no significant benefit with ESWT compared to placebo or other treatments in case of non-calcific tendinitis of the shoulder. It should be noted however, that there is considerable overlap in the studies included in the four systematic reviews, hence findings are not mutually exclusive. The authors noted it appears that in general, the techniques for using SWT 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 SWT. Other issues include determination of precise doses and optimal frequency of application, whether the shockwaves 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 treatment to reduce pain (CADTH, 2016).

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

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

In 2024 Cortés-Pérez et al. conducted a systematic review and meta-analysis comparing the efficacy of ESWT versus CS injections on pain, thickness of plantar fascia and foot function in patients with PF. Sixteen RCTs (n = 1121 participants) were included in the review with acute and chronic PF. The participants (ESWT 561; CS injections 560) were analyzed post-intervention from four to six weeks, and three, six and twelve months. Regarding pain intensity, the results demonstrated in the immediate post-evaluation, no differences were found between CS injections and ESWT. Differences favoring ESWT in reducing pain intensity were observed in three and six months. At three months high-intensity ESWT is the most indicated dose in reducing thickness of PF. On foot function, ESWT was favored over CS injections at three and six months. At one year follow-up no significant differences were shown between therapies. The authors concluded ESWT is a safe therapy. Findings suggest radial and high-intensity dose 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.

A double-blind, RCT by Gezginaslan and Başar (2021) was performed to investigate the effect of density and number of sessions ESWT on pain, fatigue, disability, physical function, and quality of life in patients with PF. Between September 2019 and December 2019, a total of 94 patients with the diagnosis of PF were included in the study. All patients were randomly divided into three groups. Group 1 (n = 33) received a total of seven sessions of high-energy flux density (H-ESWT) (0.26 mJ/mm2) , group 2 (n = 31) received a total of three sessions of H-ESWT (0.26 mJ/mm2), group 3 (n = 30) received total of seven sessions of low-energy flux density (< 0.08 mJ/mm2) with three days interval. At baseline and one month after the treatment, the VAS, Short Form-36, Foot Function Index (FFI), Functional Assessment of Chronic Illness Therapy (FACIT)-Fatigue Scale, and Six-Minute Walking Test (6MWT) scores were compared among the groups. Of the patients, 69 were females and 25 were males with a mean age of 45.0 ±8.43 (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 ($p > .05$). However, there was a statistical decrease in the VAS, FACIT, and FFI scores in all groups after treatment compared to baseline, although only the 6MWT, and Short Form-36 subscale scores were statistically higher ($p < .05$). There was also a statistical difference in the scale scores in Group 1 versus Group 2 and in Group 2 versus Group 3. The authors concluded the study results suggest that H-ESWT for high number of sessions is more effective than LESWT for low number of sessions on pain, quality of life, physical function, fatigue, and disability in patients with PF. The short-term follow-up (one 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.

Asheghan et al. (2020) completed a RCT to compare the effectiveness of ultrasound-guided dextrose prolotherapy with radial extracorporeal shock wave therapy (ESWT) in the treatment of chronic PF. This RCT was conducted on 59 patients with chronic PF. The patients were randomly assigned into two groups receiving three sessions of radial ESWT (29 patients) vs. two sessions of ultrasound-guided intrafascial 2 cc dextrose 20% injection (30 patients). The following outcome measures were assessed before and then six 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 of pain and function in both study groups at six weeks and 12 weeks after the treatments. A reduction was noted for plantar fascia thickness at these intervals (all $p < .05$). The inter-group 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. Dextrose prolotherapy has comparable efficacy to radial ESWT in reducing pain, daily-life functional limitation, and plantar fascia thickness in patients with PF. No serious adverse effects were observed in either group. The authors concluded that dextrose prolotherapy 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. This study has several limitations. The authors were not able to completely blind the patients, most participants were female, and results may not be generalized to the male population, and there was no control group. Further studies with a larger sample size and long-term follow-up are needed.

A RCT by Cinar et al. (2020) was performed to determine whether a combination of ESWT with standard care (exercise and orthotic support) improves functional ability in patients with PF when compared to 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, ESWT group received 2000 shock waves with 0.02 mJ/mm2 for three

sessions. Functional outcomes were measured by function subscale of American Orthopedic Foot and Ankle Society (AOFAS-F) score and 12 minutes walking test including walking speed, cadence. The scores were recorded at baseline, third week and third month after the treatment. Analysis was performed using repeated measures ANOVA, and an intention to treat approach using multiple imputations. Results showed that there was improvement in AOFAS-F total score and walking speed over three months in both groups ($p < 0.001$, $p = 0.04$ respectively); improvements in 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 where there was an increase in cadence in ESWT group whereas a decline in 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 patient with PF over three months post-treatment. There are limitations to this study. Gait function was not evaluated. A small sample size makes it 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 which evaluated and compared the therapeutic effects of ESWT and corticosteroid injections (CSI) in patients with chronic PF. The study also examined the correlation between plantar fascia thickness changes and clinical outcomes. Patients were included if they had more than two months without an injection and had been treated with conservative treatment for one month, without improvement before proceeding to ESWT or CSI treatment. Patients (110) were randomly assigned to receive ESWT or CSI. The authors summarized that ESWT was more efficient in reducing chronic fasciitis pain after 12 weeks than corticosteroid injection. Furthermore, the increase in plantar fascia thickness after ESWT, the more efficient the clinical outcome. However, further long-term studies with large patient populations are needed to validate the findings of this study.

Sun et al. (2017) performed a meta-analysis of RCTs (n = 9 studies/935 subjects) to compare the effectiveness of general ESWT, focused shock wave (FSW), and radial shock wave (RSW) to placebo for chronic PF. Limitations of the analysis include the lack of comparison to established treatment methods. The authors concluded that FSW may be associated with higher success rate and greater pain reduction compared to sham therapy in chronic PF patients. However, additional high-quality clinical trials and systemic reviews are needed to demonstrate the efficacy of ESWT (e.g., FSW, RSW therapies) and determine whether RSW therapy is an ideal alternative therapeutic method to conservative treatment and surgery.

Gollwitzer et al. (2015) published the results of a double-blind RCT involving 250 subjects with PF randomized to ESWT or placebo intervention and followed 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, a subjective 4-point patient 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 for the diagnosis and treatment of adult acquired infracalcaneal heel pain. This document includes the 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. ESWT, however, does not appear to be an effective first-line option for patients with acute PF. This consensus does not take into account 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 the other methodological issues (Schneider, 2017).

Delayed or Nonunion Fractures

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

The Cochrane Library published a systematic review and meta-analysis conducted by Searle et al. (2023) to assess the effects of low-intensity ultrasound (LIPUS), high-intensity focused ultrasound (HIFUS) and ESWT as part of the treatment of acute fractures in adults. The review included twenty-one studies (n = 1543 fractures) in 1517 participants, no studies tested HIFUS. The results showed very low-certainty evidence for the effect of LIPUS on HRQoL at up to one year after surgery for lower limb fractures [MD 0.06, 95% confidence interval (CI) -3.85 to 3.97, favors LIPUS; 3 studies, 393 participants]. 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, favors control; 2 studies, 370 participants; low-certainty evidence). There is little or no difference in delayed union or non-union up to twelve months after surgery (RR 1.25, 95% CI 0.50 to 3.09,

favors control; 7 studies, 746 participants; moderate-certainty evidence) nor any difference in skin irritation between groups. There was uncertainty whether ESWT reduces pain at twelve 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 non-union at twelve months was low certainty of evidence (RR 0.56, 95% CI 0.15 to 2.01; 1 study, 57 participants). There were no treatment-related adverse events for ESWT. Data was not reported for HRQoL, functional recovery, time to return to normal activities, or time to fracture union. The authors concluded the effectiveness of ultrasound and shock wave therapy for acute fractures in terms of patient-reported outcomes was uncertain. Future studies of high-quality evidence are needed. The limitations of the study include high risk of bias, small sample sizes, and inconsistencies in study findings.

A systematic review was completed by Kwok et al. (2022) to evaluate the use of ESWT in the treatment of foot and ankle fracture non-unions. Four databases were searched to identify relevant studies in the available literature. Eight studies were reviewed, demonstrating union rates of 65%-100% and 90-100% at three and six 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, highlighting the need for prospective RCTs to further investigate the efficacy of ESWT in the treatment of foot and ankle fracture non-unions.

In a systematic review by Willems et al (2019) evaluating ESWT for treatment of delayed or non-union fractures, 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 consisting of two RCTs and 28 prospective and retrospective cohort studies involving a total of 2027 delayed unions and nonunions in adults. Delayed unions treated with ESWT had a union rate of 86% (n = 314) while nonunions treated with ESWT had a 73% (n = 1782) overall union rate. The overall union rate of nonunions treated with surgery was 81% (n = 80). Although the results showed similar union rates between ESWT and surgery-treated patients, none of the ESWT group had adverse events that required further care while there were severe adverse events noted in the surgery group. The authors found a lot of heterogeneity within and between the studies such as fractures of different bones, the use of different energy settings, number of treatments and number of shock waves applied with the ESWT and a lack of consensus as to when the biological endpoint is reached in 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 ESWT is effective for erectile dysfunction (ED) therefore, additional research involving larger, well-designed studies is needed to establish its safety and efficacy.

In a 2025 systematic review and meta-analysis, Desai et al. evaluated the published literature on ESWT for the treatment of ED. Eighty-seven studies were eligible for inclusion, and were comprised of 40 case series, 15 cohort studies and 32 RCTs, and nineteen were included in the meta-analysis. There was substantial heterogeneity across all of the 87 eligible studies relating to the type of ESWT device and shockwave used, demographic of ESWT treated groups, treatment protocols, safety events, missing data, and treatment outcomes. While EWST shows promise, future high-quality research should address this heterogeneity to potentially offer the first truly regenerative treatment for ED.

Fatima et al. (2025) conducted an updated meta-analysis of RCTs comparing low-intensity extracorporeal shockwave therapy (Li-ESWT) to sham therapy in individuals with vasculogenic erectile dysfunction. Twelve RCTs comprised of 862 men were included. The scores for at least one of the following were included: the International Index of Erectile Function – Erectile Function (IIEF-EF) domain score, increase in the Erection Hardness Score (EHS), and improvement in Sexual Encounter Profile (SEP) 2 and SEP-3 were assessed. 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 5 sessions. One included men who were partial responders to PDE5 inhibitors who received 12 sessions of Li-ESWT following a four week washout period. In another, 40 men received 5000 shocks/session and were assessed for IIE F-EF, EHS, SEP2, SEP3, and GAQ1. Follow-up ranged from four to 52 weeks. The results for the mean IIEF-EF score showed significant increase in the treatment group compared to sham [MD: 2.28; 95% CI (1.32, 3.24); $p < 0.0001$], with the post treatment score ranging from 11-22 versus 8.14 to 18.80. This change was similar at one, three, six, nine and 12 month follow up. This increase was similar between the PDE5i responders and non-responders. 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); $I2 = 65\%$, p-value = 0.001]. These were similar between the PDE5i responders and non-responders, and kidney-transplant patients. In the three RCTs reporting results of SEP-2 and SEP-3, at four, seven and twelve weeks showed no significant improvements between the groups [RR: 1.16 (95% CI : 0.93, 1.45), p-value = 0.18]. The authors concluded that Li- ESWT is effective in treating ED. These results are limited by an overall small number of participants across the RCTs, a lack of objective data measurement parameters (e.g., penile Doppler ultrasound). Furthermore, there

is a lack of standardized treatment protocols, types of lithotripters as well as number of sessions. Additional research with larger numbers of participants, longer follow-up and standardized protocols are needed to validate these findings.

A Hayes Evidence Analysis Brief (2024) evaluated the evidence related to low-intensity ESWT for the treatment of ED. A literature search identified 10 abstracts evaluating low intensity 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 recommend low-intensity as a treatment for ED. Three guidelines recommend against use of low-intensity ESWT or consider it to be investigational. One guideline states that due to 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 guidance appears to confer no/unclear support for lower-intensity ESWT for treatment of ED.

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 5 systematic reviews and one economy study on ESWT's safety and effectiveness for ED. The ECRI report concluded evidence from many RCTs synthesized in the meta-analyses shows low-intensity ESWT poses minimal risks but does not achieve noticeable or meaningful improvements in erectile function in most patients with ED. The editors state their confidence in this evidence is low because the studies included in the meta-analysis were largely at high risk of bias and variable in terms of patient characteristics, ED etiology, and lower-intensity technique. Overall, additional RCT's may be useful to support stronger conclusions.

Canadian Agency for Drugs and Technologies in Health (CADTH)

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

American Urological Association

In 2018 the American Urological Association published clinical guidelines for the diagnosis and treatment of ED. The guideline regarding ESWT treatment for ED states:

- For men with ED, low-intensity 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 Lateral Epicondylitis (LE) is conflicting and inconsistent.

Zhang et al. (2024) conducted a systematic review and meta-analysis aimed to compare the effectiveness and safety of extracorporeal shock wave therapy (ESWT) and local corticosteroid injection (LCI) for chronic lateral epicondylitis (LE). A systematic review and meta-analysis were conducted following the Preferred Reporting Items for Systematic Review and Meta-analyses (PRISMA) guidelines. PubMed, EMBASE, 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 mean difference (WMD) or odds ratio (OR), with 95% confidence intervals (CIs). A total of six randomized controlled trials (RCTs) were included. Compared with LCI, ESWT had inferior change in visual analogue scale (Δ VAS) (WMD, 1.14; 95% CI, 0.80 to 1.48; I2 = 20%; $p < 0.001$), Δ grip strength (WMD, -4.01; 95% CI, -5.57 to -2.44; I2 = 36%; $p < 0.001$), change in patient-rated tennis elbow evaluation (Δ PRTEE) score (WMD, 8.64; 95% CI, 4.70 to 12.58; I2 = 0%; $p < 0.001$) at 1-month follow-up, but superior Δ VAS (WMD, -1.15; 95% CI, -1.51 to -0.80; I2 = 6%; $p < 0.001$), Δ grip strength (WMD, 2.04; 95% CI, 0.90 to 3.18; I2 = 3%; $p = 0.0005$), Δ PRTEE score (WMD, -9.50; 95% CI, -14.05 to -4.95; I2 = 58%; $p < 0.001$) at 3-month follow-up, and superior Δ VAS (WMD, -1.81; 95% CI, -2.52 to -1.10; I2 = 33%; $p < 0.001$), Δ grip strength (WMD, 3.06; 95% CI, 0.90 to 5.21; I2 = 0%; $p = 0.005$) at 6-month follow-up. The two groups had a similarly low rate of adverse events (OR, 0.69; 95% CI, 0.05 to 8.60; I2 = 67%; $p = 0.77$), all of which 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 patient groups 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 or focused 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 six months, leaving results at longer follow-ups absent. Consequently, outcomes that can only be observed at long-term follow-up, such as the tendon assessment, remain absent in this study. Well designed, comparative studies with larger patient populations are needed to further describe safety and clinical outcomes.

Cetin et al. (2024) conducted a randomized prospective study comparing the clinical outcomes of patients with LE treated with local massage, corticosteroid (CS) injection, and ESWT. After exclusions the study included thirty-eight patients (Group 1/local massage 9; Group 2/CS injection 13; Group 3/ESWT: 16) who had not received any treatment for the LE in the last six months. All three groups were clinically evaluated using the Visual Analog Scale (VAS) Disabilities of the Arm, Shoulder, and Hand (DASH), and DASH-Work Model (DASH-WM) scores at the initial examination at the beginning of the study and at two-week, three-month, and six-month follow-up. The results demonstrated in Group 1, all three scores decreased significantly in the first two weeks, but no significant difference was observed in any of the scores at the six-month follow-up. Group 2 showed a significant decrease in all scores at two weeks, whereas no statistically significant decrease was observed in any of the scores at six months. However, a significant decrease was observed in VAS and DASH scores at three months. Group 3 showed statistically significant decreases in all scores throughout the follow-up period. The authors concluded ESWT was superior to both local massage and CS injection treatments throughout the study and at 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 small sample size, study design and short follow-up.

A systematic review and network meta-analysis by Liu et al. (2022) was completed to examine the efficacy of ESWT and injection therapies by synthesizing direct and indirect evidence for all pairs of competing therapies for LE. PubMed, EMBASE, and Web of Science databases were searched for all appropriate RCTs, assessing 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 standardized mean differences (SMDs) with 95% confidence intervals and were ranked using surface under the cumulative ranking curve (SUCRA) probabilities to determine a hierarchy of treatments. Sensitivity analysis was performed to eliminate potential therapeutic effects of normal saline (NS) and exclude trials that included patients with acute LE. Results: 40 RCTs were included to evaluate ESWT and five different injection therapies, including corticosteroids, autologous whole blood, platelet-rich plasma, botulinum toxin A (BoNT-A), and dextrose prolotherapy (DPT). DPT [-.78 (-1.34 to -.21)], ESWT [.57 (-.89 to -.25)], platelet-rich plasma [-.48 (-.85 to -.11)], and BoNT-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 ESWT was the best treatment option for grip strength recovery. Corticosteroids 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 on LE. Limitations to the study included 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 with RCTs is needed to validate these findings.

Özmen et al. (2021) performed a comparison study to determine the clinical and sonographic effects of ultrasound (US) therapy, ESWT, and Kinesio taping (KT) in LE. A total of 40 patients with LE were included in the study. The patients were randomly assigned to three treatment groups: US (n = 13), ESWT (n = 14), and KT (n = 13) groups. The VAS scores decreased in all groups ($p < 0.05$). Grip strength increased after eight weeks in only the KT group ($p < 0.05$). The Patient-Rated Tennis Elbow Evaluation Scale scores significantly decreased after two weeks and after eight weeks in the US group and ESWT groups, and after eight weeks in the KT group ($p < 0.05$). Common extensor tendon (CET) thickness decreased after eight weeks in only the ESWT group ($p < 0.05$). The authors concluded that the US 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 the pain and improving functionality. Limitations of the study include small sample size (40 patients) 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 a RCT to evaluate the effectiveness of neural therapy (NT) versus ESWT in the treatment of LE. Between August 2018 and November 2018, 76 patients 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 three weeks. The subjective pain severity was evaluated using the VAS and 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 weeks variances of values were compared between 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% confidence interval (CI): -0,358−1,619] or DHI score (effect size = 0, 13, 95 % CI: -7,627−4,390). However, within 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 follow up ($p < 0.05$). No adverse events occurred in this study. The authors concluded that the results of this study showed that both ESWT and NT have similar effects in reducing pain and hand function in patients with LE. However, neither of two the treatment modalities showed superiority. There are some limitations to this study. The number of subjects 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 two therapeutic methods. The lack of blinding, qualitative data/feedback from patients, non-treatment group or routine care group, and long-term outcomes are the other limitations of the study. Further investigation with large-scale, prospective, long-term outcomes, placebo-controlled studies are needed.

In a systematic review and meta-analysis by Yao et al. (2020), the authors 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 1035 patients, of which 501 patients 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) indicative of early recovery and significantly increased grip strength in the ESWT treatment group. There were also several limitations of the meta-analysis 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.

Another systematic review and meta-analysis completed in 2020 by Yoon et al. 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 1104 patients were included in the meta-analysis with ten of the 12 studies having also been included in the Yao systematic review and meta-analysis. This meta-analysis concluded that ESWT did not show clinically important improvement in pain reduction and grip strength although the authors did conclude that radical ESWT was more effective than focused ESWT and that patients with longer duration of symptoms had more improvement while the effects did not last beyond 24 weeks. Yoon et al. also noted 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 comparing the efficacy of ESWT to wrist-extensor splint (WES) application in the treatment of LE. Patients were included if they had been treated based on a diagnosis of unilateral LE. Patients 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 patients were randomized into two groups. Group one received ESWT four times per week using the DolorClast device and group two received a wrist extensor splint. The primary outcomes measured were the effectiveness of ESWT compared to 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 four, 12, and 24. In both groups there were significant improvements in decreasing pain, increasing grip strength, and improving quality of life at four, 12, and 24 weeks compared to pretreatment values. However, there was no statistically significant difference between the two groups at the three time points. The authors noted limitations of the study were the small patient population and use of the patient-reported questionnaires.

Capan et al. (2016) conducted a double-blind, randomized, placebo-controlled trial in outpatient clinics of a medical faculty hospital. Fifty-six patients with LE were randomized to radial ESWT or sham radial ESWT groups. Both the patients 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 at the same area. Study patients were assessed at baseline and at one and three 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 radial ESWT and sham radial ESWT groups showed a significant improvement in all outcome measures at post treatment follow-up points. Favorable absolute and percentage changes in assessments at one- and three-months post treatment did not show any significant difference between groups. The authors concluded radial ESWT does not seem to be more effective either in reducing pain or improving function or grip strength in patients with LE at least at three months after treatment when compared with sham radial ESWT.

Refractory Greater Trochanteric Pain Syndrome (GTPS)

There is insufficient quality evidence to conclude ESWT is effective for GTPS therefore, additional research involving larger, well-designed studies is needed to establish its safety and efficacy.

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 randomized controlled trials (RCTs) of medium or high quality, and low risk of bias, that measured pain and function in adults with clinically diagnosed gluteal tendinopathy. PEDro scale and Cochrane Risk of Bias Tool 2.0 were used to assess internal validity and risk of bias. A total of 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 standardized mean differences (SMD) and 95% confidence intervals (95% CI) 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. Corticosteroid 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 to corticosteroid injection for function [SMD = 0.46; 95% CI (0.00, 0.91)]. For pain, focused shockwave therapy (f-ESWT) demonstrated superiority in the long term [SMD = 5.77; 95% CI (4.84, 6.71)] compared to corticosteroid injection. The authors concluded that exercise and education can be cautiously recommended as the core approach for pain management and function, potentially supplemented by corticosteroid or f-ESWT, while definitive trials of promising interventions are needed to derive robust practice recommendations. This systematic review has limitations, being a single study with large confidence intervals and short-term results only. The findings of this systematic review need to be validated by well-designed studies. Further investigation is needed before clinical usefulness of ESWT is proven.

Harding et al. (2024) conducted a systematic review and meta-analysis to investigate the efficacy of shock wave therapy (SWT) on pain and function in the management of GTPS compared to alternative treatment interventions. The study included a total of 1221 participants of which 849 underwent SWT and post treatment follow-up ranged from one week to two years. The results demonstrated within RCTs, large treatment effects were identified across all follow-up timepoints for pain in SWT groups. Following SWT in non-RCTs, a large treatment effect for pain was consistently seen across all timepoints. Moderate-large functional treatment effects of SWT in RCTs were seen at all follow-up timepoints. Within non-RCTs SWT resulted in moderate treatments effects in all time points. The authors concluded although moderate strength evidence was found, SWT was not significantly beneficial compared to control for pain or function over time. Further robust RCTs investigating the impact of optimal treatment protocols of SWT on acute versus chronic would be beneficial for optimizing patient care. Limitations in the study include methodological heterogeneity, risk of bias, and lack of standardization.

The ECRI Institute 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 physical therapy, pain medication, and other non-surgical 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 limited data available and the high risk of bias from the studies reviewed because of lack of randomization or complete blinding, small size, high attrition, and 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 patients per treatment. The ECRI Institute recommended large, multi-centered studies to validate available data and to assess long term outcomes related to pain recurrence and retreatment (ECRI 2020).

Ramon et al (2020) completed a randomized, multicenter clinical trial with 103 participants with chronic GTPS. The participates were divided into two groups, both of which were treated with three weekly sessions of focused extracorporeal shockwave treatment (F-ESWT) with the test group (n = 53) receiving an energy flux density (EFD) of 0.20 mJ/mm^2 and the control group (n = 50) receiving the lowest EFD of the device (0.01 mJ/mm^2) using the same brand of device. Each participant was assessed at baseline and one, two, three, and six months after the last session by clinicians blinded to the group allocation. The authors concluded that F-ESWT and a specific home exercise program is safe and effective for GTPS, with a success rate of 86.8% at two months after treatment that was maintained until the end of the six month follow up. Limitations identified by the authors included a lack of follow-up beyond six months, a lack of exact data on participants' compliance with the home exercise protocol, the 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 and that the control group received some albeit the lowest dose of ESWT so it could be considered a quasi-placebo group. The authors recommend 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 Tendonitis

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

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

Wu et al. (2024) conducted a systematic review and meta-analysis to investigate the efficacy and safety of extracorporeal shockwave therapy (ESWT) for diabetic foot ulcers (DFUs). A total of ten randomized controlled trials (RCTs) with moderate methodological quality were included for data analysis involving 754 participants 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 participants ranged from 56.5 to 67.8 years across studies. According to the studies, the average HbA1c levels of participants 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 two weeks to as long as 20 weeks. The findings showed that ESWT was associated with complete healed ulcers [risk ratio (RR): 1.57, 95 % confidence interval (CI):1.26 to 1.95] and lower rate of unchanged ulcers (RR: 0.25, 95 %CI: 0.14 to 0.42) compared to controls. Subgroup analysis further revealed that ESWT was better than both hyperbaric oxygen therapy (HOT) and the standard of care (SOC). Moreover, ESWT also improved the average transcutaneous partial oxygen pressure (TcPO2) [mean difference (MD): 1.71, 95 %CI: 1.22 to 2.19, $p < 0.001$]. However, the rate of ≥ 50 % improved ulcers and treatment-emergent adverse events (TEAEs) 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 recommend 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 patients, the average duration of ulcers, the average follow-up duration, ulcer healing assessment time, and specific interventions vary from one to another study, 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 with a larger sample size are needed to evaluate the role of ESWT in the treatment of DFU. Finally, the studies reviewed demonstrated a critical need for stringent blood glucose control in the management of DFU, as evidenced by the participant HbA1c 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 aimed at the role of ESWT in diabetic foot ulcer (DFU) healing and the impact of different ESWT doses. In total six RCTs published between 2009 and 2019 were analyzed. The primary outcome of the study was time to healing. The results demonstrated time to ulcer healing was probably shorter in patients treated with ESWT compared to standard ulcer care alone. Patients treated with ESWT were more likely to heal at twenty weeks post-ESWT compared with those treated with standard ulcer care alone. The authors concluded ESWT remains a promising new treatment but the translation into routine clinical practice is still limited by the low certainty of evidence surrounding its effectiveness, case selection and optimum dose. 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 risk of bias, small sample size and heterogeneity.

The ECRI Institute published a Clinical Evidence Assessment on the dermaPACE System in 2020 that focused on how the device compares with standard of care and other chronic wound treatments. ECRI concluded that the evidence is somewhat favorable when comparing dermaPACE with standard of care alone as it appears to improve complete DFU healing rates at 24-week follow-up and decreases time to wound closure. ECRI based their recommendation on two low-quality RCTs (n = 206, n = 130) that were multi-centered and double blinded based on pooled data from the same study participants. ECRI also reviewed a third RCT from a single-center, open-label study (n = 77; 84 ulcers) that compared dermaPACE with hyperbaric oxygen therapy in patients 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 FDA 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 of the wound surface area, an increase of re-epithelialization and more patients 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. Patient 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 hyperbaric oxygen therapy (HBOT) in two studies. The authors also found that ESWT was more effective than HBOT for 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 that cost effectiveness was not reviewed.

In a systematic review and meta-analysis, Zhang et al. (2018) examined the effects of ESWT and conventional wound therapy (CWT) for acute and chronic soft tissue wounds. A total of ten RCTs involving 473 patients 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 to 6.04, p < 0.001) and improved wound-healing area percentage by 30.45 % (SMD = 30.45; 95 % CI: 23.79 to 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 to 0.92, p = 0.03) when 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 compared with 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 ten databases for clinical trials about ESWT in the management of chronic wound of lower extremity (CWLE). These were published between 2000 and 2016. A total of 11 studies with 925 patients were found. Expert therapists assessed the methodological qualities of the selected studies using the Physiotherapy Evidence Database (PEDro) scale and categorized each study according to Sackett's 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 with high methodological quality is required to assess the efficacy and cost-effectiveness of this relatively new physical therapy application.

In a phase II RCT, Ottomann et al. (2011) evaluated shock wave effects in burn wounds. A predefined cohort of 50 patients (6 with incomplete data or lost to follow-up) with acute second-degree burns were randomly 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. Randomization sequence was computer-generated, and patients were blinded to treatment allocation. Mean time to complete (≥ 95%) epithelialization (CE) for patients that did and 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 III 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 (ESWT) products as class III devices through the premarket approval program (PMA) 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 device name section: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed June 23, 2025)

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Policy History/Revision Information

Date	Summary of Changes
01/01/2026	**Template Update** • Created shared policy version to support application to Oxford plan membership **Supporting Information** • Archived previous policy version 2025T0269KK and SURGERY 021.35

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.

This Medical Policy may also be applied to Medicare Advantage plans in certain instances. In the absence of a Medicare National Coverage Determination (NCD), Local Coverage Determination (LCD), or other Medicare coverage guidance, CMS allows a Medicare Advantage Organization (MAO) to create its own coverage determinations, using objective evidence-based rationale relying on authoritative evidence (Medicare IOM Pub. No. 100-16, Ch. 4, §90.5).

UnitedHealthcare may also use tools developed by third parties, such as the InterQual® criteria, to assist us in administering health benefits. UnitedHealthcare Medical Policies are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.