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

Policy Number: 2023T0269GG
Effective Date: October 1, 2023

Instructions for Use

Table of Contents **Page**

Related Commercial/Individual Exchange Policy

- Lithotripsy for Salivary Stones

Community Plan Policy

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

Application

UnitedHealthcare Commercial

This Medical Policy applies to all UnitedHealthcare Commercial benefit plans.

UnitedHealthcare Individual Exchange

This Medical Policy applies to Individual Exchange benefit plans in all states except for Colorado.

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
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)
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.

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 did observe 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.

A 2017 Health Technology Assessment , contracted by the Washington State Health Care Authority, reviewed 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).

In 2015, Mani-Babu et al. reported results of a systematic review and meta-analysis of studies evaluating ESWT for lower limb tendinopathies, including Achilles tendinopathy. The review included 11 studies which evaluated ESWT for Achilles tendinopathy. In pooled analysis, the authors reported that ESWT was associated with greater short term (< 12 months) and long-term (> 12 months) improvements in pain and function compared with nonoperative treatments. The authors noted that findings from RCT's of ESWT for Achilles tendinopathy are contradictory, but that there is at least some evidence for short-term improvements in function with ESWT.

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.

A Hayes Health Technology Assessment (2022) 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 a 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 -0.49, 95% CI −0.88 to −0.11) and functional status (standardized mean difference 0.62, 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. 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 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.

Verstraelen et al. (2014) conducted a systematic review and meta-analysis of RCTs across five electronic online databases to identify all RCTs that compared high-energy ESWT (> 0.28 mJ/mm^2) with low-energy ESWT (< 0.09 mJ/mm^2) in treating patients with calcifying rotator cuff tendinitis. The literature search originally identified 194 potentially relevant studies; 189 of which were screened out as they did not meet the criteria for the analysis. The total study population from five RCT's of low-versus high-energy ESWT consisted of 359 participants. All five RCTs showed greater improvement in functional outcome (Constant-Murley score) in patients treated with high-energy ESWT compared with patients treated with low-energy ESWT at 3 and 6 months. The 3-month mean difference was 9.88 (95% CI, 9.04–10.72, p < 0.001; 6-month data could not be pooled). Furthermore, high-energy ESWT more often resulted in complete resorption of the deposits at three months. The corresponding odds ratio was 3.40 (95% CI, 1.35–8.58) and p = 0.009 (6-month data could not be pooled). Based on the meta-analysis, the authors concluded that high-energy ESWT is more effective than low-energy ESWT in terms of functional outcome (Constant-Murley score) and radiographic resorption (chance of complete resorption) of the deposits after three months. However there is still a need for high-quality RCTs to discover the exact dose-response relation. In the authors' opinion, this future research should focus on high-energy ESWT because current available evidence indicates that high-energy ESWT is more effective than low-energy ESWT regarding the functional and radiologic outcomes in the short term and midterm.

In a 2013 systematic review and meta-analysis, Ioppolo et al. included six RCTs on ESWT compared to sham treatment or placebo for calcific shoulder tendinopathy. Greater shoulder function and pain improvements were found at six months with ESWT over placebo. However, most studies were considered to be low quality.

Huisstede et al. (2011) performed a systematic review of RCTs examining the effectiveness of ESWT as a treatment alternative for calcific and non-calcific rotator cuff tendinosis. The reviewers found that only high-ESWT (H-ESWT) is effective for treating calcific rotator cuff tendinosis. No evidence was found for the effectiveness of ESWT to treat non-calcific rotator cuff tendinosis.

Lee et al. (2011) performed a systematic review of RCTs examining the midterm effectiveness of ESWT for calcified rotator cuff tendinitis. The review found consistent evidence of midterm effectiveness of ESWT in reducing pain and improving shoulder function. However it was determined that the different outcome measures used and inadequate reporting details in the included studies did not permit a quantitative synthesis of the effectiveness of this treatment. A lack of follow up period beyond one year in the studies was also a limitation and did not allow for conclusions to be made on the longer-term effectiveness of ESWT.

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.

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 Visual Analog Scale (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 terms 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 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.

In 2014, Yin and colleagues published a systematic review and meta-analysis of studies involving ESWT for PF. The authors included a total of seven studies that were either RCTs or quasi-RCTs involving subjects with PF of at least 6 months duration. The primary outcome was treatment success rate. Among the five studies included in the pooled analysis for low energy devices, the result indicated that low energy ESWT was more likely to lead to treatment success than control treatment.

However, the authors noted significant heterogeneity in the definitions for treatment success across studies. The pooled analysis for high energy ESWT devices involved two studies, and no difference between the ESWT and control treatments was reported. This study is hampered by the heterogeneity of the definition of treatment success across studies, as well as the basic issues of the base studies themselves, which are addressed above.

Dizon et al. (2013) conducted a systematic review and meta-analysis of clinical trials (2002-2010) to evaluate the effectiveness of ESWT in treating chronic PF. Eleven studies were included in this review. The primary outcome measure of interest was overall pain in the morning and during activity. Compared to placebo control, ESWT was more effective in reducing morning pain. There was no difference between ESWT and control in decreasing overall pain; however moderate-intensity ESWT was more effective in decreasing overall activity pain. There was no significant difference in the effectiveness of decreasing activity pain. Both moderate-and high-intensity ESWT were more effective in improving functional outcome. Acknowledged study limitation include the lack of consistency in outcome measure, specified dose intensities and follow-up.

A 2009 guidance statement from NICE states that the current evidence on the efficacy of ESWT for refractory PF raises no major safety concerns; however, current evidence on its efficacy is inconsistent. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research. NICE encourages further research into ESWT for refractory PF in the form of clinical studies with clearly described patient selection and treatment protocols, including a description of local anesthesia use and the type of energy applied (NICE, 2009b).

Gerdesmeyer et al. (2008) conducted a multi-center, RCT of 245 patients comparing radial ESWT (which works on the superficial skin layers) and placebo in the treatment of chronic PF. All patients underwent three interventions. Primary endpoints were changes in VAS composite score from baseline to 12 weeks' follow-up, overall success rates, and success rates of the single VAS scores (heel pain at first steps in the morning, during daily activities, during standardized pressure force). Secondary endpoints were single changes in VAS scores, success rates, Roles and Maudsley score, SF-36, and patients' and investigators' global judgment of effectiveness 12 weeks and 12 months after extracorporeal shock wave therapy. Radial ESWT proved significantly superior to placebo with a reduction of the VAS composite score of 72.1% compared with 44.7%, and an overall success rate of 61.0% compared with 42.2% in the placebo group at 12 weeks. Superiority was even more pronounced at 12 months, and all secondary outcome measures supported radial ESWT to be significantly superior to placebo. The authors concluded that radial ESWT significantly improves pain (based on VAS and self-report), function, and quality of life compared with placebo in patients with recalcitrant PF. While the results of this study are promising, the results are not statistically significant when compared to chance; therefore, additional studies with long term follow-up and objective evaluation are needed.

While studies of high energy-ESWT appear to have more positive and more robust results, none of the reviewed studies directly tested the comparative efficacy of high energy-ESWT versus typical low energy-ESWT, and a meta-analysis by Thomson et al. (2005) questions the clinical significance of the treatment effect. The meta-analysis evaluated the data from 897 patients and resulted in a pooled estimate of a mean 0.42-point reduction (confidence interval 0.02-0.82) on a zero to ten VAS in morning pain at three months. This mean difference was statistically significant. However, the authors question its clinical relevance because after the removal of the biggest source of bias (the two poorest quality studies), the results were not significant. Furthermore, the authors tested for heterogeneity of effect in terms of VAS pain scores among six studies. They found no evidence of heterogeneity, which suggests that the effectiveness of ESWT does not depend on energy level.

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).

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 lower extremity orthopedic disorders including PF. It was concluded that more evidence is needed to determine whether ESWT is more clinically effective than surgery for pain associated with lower extremity orthopedic disorders (CADTH, 2016).

A technology assessment of RCTs evaluating the safety and efficacy of ESWT for the treatment of chronic PF was performed for the CADTH. Ho (2007) concluded "the lack of convergent findings from these randomized trials of ESWT for PF suggests uncertainty about its effectiveness. The evidence reviewed does not support the use of this technology for this condition."

Delayed or Nonunion Fractures

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

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 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, highlighting the need for a 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.

Elster, et al. (2010) conducted a study with one hundred ninety-two patients were treated with ESWT at a single referral trauma center for treatment for tibia nonunion. Nonunion was determined by radiographic or CT analysis at least six months following operative or nonoperative treatment, with at least three months of no radiographic changes. Fracture healing was determined by radiographic or CT analysis. At the time of last follow up, 138 of 172 (80.2%) patients demonstrated complete fracture healing. Mean time from first shock wave therapy to complete healing of the tibia nonunion was 4.8 months. Associated factors influencing fracture healing included number of orthopedic operations shock wave treatments and pulses delivered. Patients requiring multiple (more than one) shock wave treatments versus a single treatment had a significantly lower likelihood of fracture healing. This study concludes that high energy ESWT may be used successfully in the treatment of tibia nonunions. The reported healing rate of 80% and the large sample size gives this study relevance; however, limitations include retrospective design and lack of a control group using immobilization alone. Although this study evaluated nonunion of tibia fractures, there is potential for future investigation of ESWT in the treatment of fracture and arthrodesis nonunion in the foot and ankle.

Zelle et al. (2010) conducted a systematic review to evaluate the results of ESWT in the treatment of fractures and delayed unions/nonunions. Ten studies were included and involved 924 patients who underwent one to three treatment sessions. The overall union rate in patients with delayed union/nonunion was 76% and ranged from 41% to 85%. The authors concluded that while promising, ESWT for the treatment of fractures and delayed unions/nonunions requires further studies. Additional studies need to investigate how shock wave therapy compares with other treatment approaches and if different anatomic fracture locations demonstrate different success rates. In addition, the optimal treatment dose needs to be identified in further investigations.

A RCT by Cacchio et al. (2009) compared ESWT with surgical treatment in 126 patients with long-bone non-unions. Outcomes were measured using x-rays. Each group showed the same amount of healing at six, 12 and 24 months. The authors concluded that ESWT is as effective as surgery in stimulating union of long-bone hypertrophic non-unions. The study is limited by lack of blinding and a control group. Additional studies are needed to further validate the results.

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 in the form of RCT regarding the efficacy of ESWT for LE is conflicting and inconsistent.

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 -.02]) 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 3 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 8 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) thicknesses 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 visual analogue scale (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.

A 2017 Health Technology Assessment (HTA) reviewed the evidence for the efficacy of ESWT for treating LE. In two studies patients receiving ESWT were two times as likely to achieve ≥ 50% improvement over baseline in the short-term compared with those receiving sham. There is no evidence for intermediate or long-term wrist extension pain outcomes. Further, there is not enough evidence from three small studies to determine the effect of ESWT vs. sham on other non-specified pain outcomes over any timeframe. There was significant improvement in short-term function in two studies however there was no difference after 12 months of follow-up.

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 mos. after treatment using a VAS for pain and 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 1- and 3-mo 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 mos. after treatment when compared with sham radial ESWT.

A National Institute for Health and Care Excellence (NICE*)* guidance on the use of ESWT for refractory tennis elbow states that the evidence on ESWT for refractory tennis elbow raises no major safety concerns; however, current evidence on its efficacy is inconsistent. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research (NICE, 2009a).

Staples et al. (2008) conducted a double-blind, RCT on 68 patients to determine whether ultrasound-guided ESWT reduced pain and improved function in patients with LE (tennis elbow) in the short term and intermediate term. Patients were randomized to receive three ESWT treatments or three treatments at a subtherapeutic dose given at weekly intervals. Seven outcome measures relating to pain and function were collected at follow-up evaluations at six weeks, three months, and six months after completion of the treatment with mean changes compared for the two groups. The groups did not differ on demographic or clinical characteristics at baseline and there were significant improvements in almost all outcome measures for both groups over the 6-month follow-up period, but there were no differences between the groups even after adjusting for duration of symptoms. The authors concluded that there was little evidence to support the use of ESWT at a therapeutic or subtherapeutic dose for the treatment of LE.

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.

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. 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.

In 2015, Mani-Babu et al. reported results of a systematic review and meta-analysis of studies evaluating ESWT for lower limb tendinopathies, including greater trochanteric pain syndrome (GTPS). The review included 13 studies providing sufficient data to compute effect size calculations. The energy level, number of impulses, number of sessions, and use of a local anesthetic varied between studies. The authors concluded that there was limited to moderate evidence to support EWST as an effective intervention and should be considered for GTPS when other nonoperative treatments have failed.

A National Institute for Health and Care Excellence (NICE*)* guidance on the use of ESWT for refractory greater trochanteric pain syndrome states that the evidence on ESWT for refractory greater trochanteric pain syndrome is limited in quality and quantity.

Therefore this procedure should only be used with special arrangements for clinical governance, consent and audit or research (NICE, 2011).

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

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 diabetic foot ulcer (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 6 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 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 systematic review which included three RCTs, one quasi-experimental study, and one case series, Butterworth et al. (2015) found that although these studies showed improvement in wound healing following ESWT, evidence was limited. The authors concluded that further research is needed on the use of ESWT for the treatment of lower limb ulceration due to the limited evidence available.

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.

Wang et al. (2011) investigated the molecular changes of ESWT and hyperbaric oxygen therapy (HBOT) in chronic diabetic foot ulcers. The cohort study consisted of 39 patients (44 ulcers) in the ESWT group and 38 patients (40 ulcers) in the HBOT group with similar demographic characteristics. The ESWT group received shockwave therapy twice per week for total six treatments. The HBOT group received hyperbaric oxygen therapy daily for total 20 treatments. Biopsy was performed from the periphery of the ulcer before and after treatment. Significant increases in immuno-activity expression were noted after ESWT, whereas the changes after HBOT were statistically not significant. The differences of immuno-activity expressions between the two groups were comparable before treatment; however, the differences became statistically significant after treatment favoring the ESWT group. The authors concluded that ESWT showed significant increases in angiogenesis and tissue regeneration over HBOT in diabetic foot ulcers. This study is limited by a small study population. No outcomes regarding ulcer healing were reported.

Wolff et al. (2011) assessed the possible effects of comorbidities and of different wound etiologies on the success of ESWT of chronic soft tissue wounds in 258 patients. The patients underwent follow-up for a median of 31.8 months. Wound closure occurred in 191 patients (74.03%) by a median of two treatment sessions. No wound reappeared at the same location. A multivariate logistic regression model showed that pooled comorbidities and wound etiologies did not have a significant influence on success. The lack of a control group limits the validity of the conclusions of this study.

Larking et al. (2010) assessed whether ESWT increases the rate of healing in chronic decubitus ulceration in a double-blind randomized cross-over study. Ulcers were randomized into receiving either the ESWT or the placebo for a four-week period, followed by a two-week 'washout' period followed by a four-week period of the cross-over treatment/ placebo. Nine ulcers (in eight patients) were included in the study. All those with static chronic ulcers showed improved healing starting 6-8 weeks after the start of ESWT, whether treated first with the placebo or the therapy. The authors concluded that ESWT has a potential part to play in the treatment of chronic skin ulceration. This study is limited by a small study population.

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 May 31, 2023)

References

Asheghan M, Hashemi SE, Hollisaz MT, et al. Dextrose prolotherapy versus radial extracorporeal shock wave therapy in the treatment of chronic plantar fasciitis: a randomized, controlled clinical trial. Foot Ankle Surg. 2021 Aug;27(6):643-649.

Atalay SG, Gezginaslan O. Effect of neural therapy versus extracorporeal shock wave therapy for the treatment of lateral epicondylitis: a randomized-controlled trial. Eur J Integ Med. 2020 Sept;39(101210):1876-3820.

Aydın A, Atiç R. Comparison of extracorporeal shock-wave therapy and wrist-extensor splint application in the treatment of lateral epicondylitis: a prospective randomized controlled study. J Pain Res. August 2018.

Bannuru RR, Flavin NE, Vaysbrot E, et al. High-energy extracorporeal shock-wave therapy for treating chronic calcific tendinitis of the shoulder: a systematic review. Ann Intern Med. 2014.

Butterworth PA, Walsh TP et al. The effectiveness of extracorporeal shock wave therapy for the treatment of lower limb ulceration: a systematic review. Foot Ankle Res. 2015; 8:3.

Cacchio A, Giordano L, Colafarina O, et al. Extracorporeal shock-wave therapy compared with surgery for hypertrophic long-bone nonunions. J Bone Joint Surg Am. 2009 Nov;91(11):2589-97.

Canadian Agency for Drugs and Technologies in Health (CADTH). CADTH Rapid Response Reports. Shockwave therapy for pain associated with lower extremity orthopedic disorders: a review of the clinical and cost-effectiveness. Ottawa (ON): Canadian Agency for Drugs and Technologies in Health; 2016 Sep.

Canadian Agency for Drugs and Technologies in Health (CADTH). CADTH Rapid Response Reports. Shockwave therapy for pain associated with upper extremity orthopedic disorders: a review of the clinical and cost-effectiveness. Ottawa (ON): Canadian Agency for Drugs and Technologies in Health; 2016 Sep.

Capan N, Esmaeilzadeh S, Oral a, et al. Radial extracorporeal shock wave therapy is not more effective than placebo in the management of lateral epicondylitis: a double-blind, randomized, placebo-controlled trial. Am J Phys Med Rehabil. July 2016.

Cinar E, Saxena S, Akkurt HE, et al. Extracorporeal shockwave therapy in the management of plantar fasciitis: a randomized controlled trial. Foot (Edinb). 2020 Sep;44:101679.

Dizon JN, Gonzalez-Suarez C, Zamora MT, et al. Effectiveness of extracorporeal shock wave therapy in chronic plantar fasciitis; a meta-analysis. Am, J Phys Med Rehabil. 2013 Jul;92(7):606-20.

ECRI. dermaPACE System (Sanuwave Health, Inc.) for treating chronic wounds. October 2020. (Clinical Evidence Assessment).

ECRI. Extracorporeal shock wave therapy for chronic lateral hip pain. November 2020. (Executive Summary).

Elster EA, Stojadinovic A, Forsberg J, Shawen S, Andersen RC, Schaden W. (2010). Extracorporeal shock wave therapy for nonunion of the tibia. J Orthop Trauma, 24, 133-141.

Feeney KM. The effectiveness of extracorporeal shockwave therapy for midportion Achilles tendinopathy: a systematic review. Cureus. 2022 Jul 18;14(7):e26960.

Gerdesmeyer L, Frey C, Vester J, et al. Radial extracorporeal shock wave therapy is safe and effective in the treatment of chronic recalcitrant plantar fasciitis: results of a confirmatory randomized placebo-controlled multicenter study. Am J Sports Med. 2008 Nov;36(11):2100-9.

Gezginaslan Ö, Başar G. Comparison of effectiveness of density and number of sessions of extracorporeal shock wave therapy in plantar fasciitis patients: a double-blind, randomized-controlled study. J Foot Ankle Surg. 2021 Mar-Apr;60(2):262-268.

Gollwitzer H, Saxena A, DiDomenico LA, et al. Clinically relevant effectiveness of focused extracorporeal shock wave therapy in the treatment of chronic plantar fasciitis: a randomized, controlled multicenter study. J Bone Joint Surg Am. 2015; 97(9):701-708.

Hayes, Inc. Health Technology Assessment. Extracorporeal shock wave therapy for calcific tendonitis of the shoulder. Hayes, Inc.; August 5, 2022.

Ho C. Extracorporeal shock wave treatment for chronic plantar fasciitis (heel pain). Issues Emerg Health Technol. January 2007.

Huang Q, Yan P, Xiong H, et al. Extracorporeal shock wave therapy for treating foot ulcers in adults with Type 1 and Type 2 diabetes: A systematic review and meta-analysis of randomized controlled trials. Can J Diabetes. 2020 Mar;44(2):196-204.e3.

Huisstede BM, Gebremariam L, van der Sande R, et al. Evidence for effectiveness of extracorporeal shock-wave therapy (ESWT) to treat calcific and non-calcific rotator cuff tendinosis–a systematic review. Man Ther 2011; 16:419.

Ioppolo F, Tattoli M, Di Sante L, et al. Clinical improvement, and resorption of calcifications in calcific tendinitis of the shoulder after shock wave therapy at 6 months' follow-up: a systematic review and meta-analysis. Arch Phys Med Rehabil. 2013 Sep;94(9): 1699-706.

Kwok IHY, Ieong E, Aljalahma MA, et al. Extracorporeal shock wave treatment in foot and ankle fracture non-unions - A review. Foot (Edinb). 2022 May;51:101889.

Lai TW, Ma HL, Lee MS, et al. Ultrasonography and clinical outcome comparison of extracorporeal shock wave therapy and corticosteroid injections for chronic plantar fasciitis: A randomized controlled trial. J Musculoskelet Neuronal Interact. March 2018.

Larking AM, Duport S, Clinton M, et al. Randomized control of extracorporeal shock wave therapy versus placebo for chronic decubitus ulceration. Clin Rehabil. 2010 Mar;24(3):222-9.

Lee SY, Cheng B, Grimmer-Somers K. The midterm effectiveness of extracorporeal shockwave therapy in the management of chronic calcific shoulder tendinitis. J Shoulder Elbow Surg. 2011 Jul;20(5):845-54.

Liu WC, Chen CT, Lu CC, et al. Extracorporeal shock wave therapy shows superiority over injections for pain relief and grip strength recovery in lateral epicondylitis: a systematic review and network ,eta-analysis. Arthroscopy. 2022 Jun;38(6):2018-2034.e12.

Mani-Babu S, Morrissey D, et al. The effectiveness of extracorporeal shock wave therapy in lower limb tendinopathy: a systematic review. Am J Sports Med. March 2015.

National Institute for Health and Care Excellence (NICE). IPG311. Extracorporeal shockwave therapy for refractory plantar fasciitis. August 26, 2009b.

National Institute for Health and Care Excellence (NICE). IPG313. Extracorporeal shockwave therapy for refractory tennis elbow. August 26, 2009a.

National Institute for Health and Care Excellence (NICE). IPG376. Extracorporeal shockwave therapy for refractory greater trochanteric pain syndrome. January 26, 2011.

National Institute for Health and Care Excellence (NICE). IPG571. Extracorporeal shockwave therapy for Achilles tendinopathy. December 21, 2016.

National Institute for Health and Care Excellence (NICE). IPG742. Extracorporeal shockwave therapy for calcific tendinopathy in the shoulder. November 9, 2022.

Omar MT, Gwada RF, Shaheen AA, et al. Extracorporeal shockwave therapy for the treatment of chronic wound of lower extremity: current perspective and systematic review. Int Wound J. 2017 Dec;14(6):898-908.

Ottomann C, Stojadinovic A, Lavin PT, et al. Prospective randomized phase II trial of accelerated re-epithelialization of superficial second-degree burn wounds using extracorporeal shock wave therapy. Ann Surg. 2011 Aug 17.

Özmen T, Koparal SS, Karataş Ö, et al. Comparison of the clinical and sonographic effects of ultrasound therapy, extracorporeal shock wave therapy, and kinesio taping in lateral epicondylitis. Turk J Med Sci. 2021 Feb 26;51(1):76-83.

Ramon, S, Russo, S, Santoboni, F, et al. Focused shockwave treatment for greater trochanteric pain syndrome: a multicenter, randomized, controlled clinical trial. J Bone Joint Surg Am. 2020;102(15):1305-1311.

Schneider HP, Baca J, Carpenter B, et al. American College of Foot and Ankle Surgeons Clinical Consensus Statement: diagnosis and treatment of adult acquired infracalcaneal heel pain. J Foot Ankle Surg. 2017; 57(2):370-381.

Shao H, Zhang S, Chen J, et al. Radial extracorporeal shockwave therapy reduces pain and promotes proximal tendon healing after rotator cuff repair: Randomized clinical trial. Ann Phys Rehabil Med. 2023 Apr 5;66(4):101730.

Stania M, Juras G, Chmielewska D, et al. Extracorporeal shock wave therapy for Achilles tendinopathy. Biomed Res Int. 2019 Dec 26;2019:3086910.

Staples MP, Forbes A, Ptasznik R, et al. A randomized controlled trial of extracorporeal shock wave therapy for lateral epicondylitis (tennis elbow). J Rheumatol. 2008 Oct;35(10):2038-46.

Sun, J, Gao, F, Wang, Y, et al. Extracorporeal shock wave therapy is effective in treating chronic plantar fasciitis: A meta-analysis of RCTs. Medicine. April 2017.

Surace SJ, Deitch J, Johnston R, et al. Shock wave therapy for rotator cuff disease with or without calcification. Cochrane Database Syst Re. 2020 Mar 4;3:CD008962.

Testa G, Vescio A, Perez S, Consoli A, et al. Extracorporeal shockwave therapy treatment in upper limb diseases: a systematic review. J Clin Med. 2020 Feb 6;9(2). pii: E453.

Thomson CE, Crawford F, Murray GD. The effectiveness of extra corporeal shock wave therapy for plantar heel pain: a systematic review and meta-analysis. BMC Musculoskelet Disord. 2005 Apr 22;6:19.

Verstraelen FU, in den Kleef NJ, Jansen L, et al. High-energy versus low-energy extracorporeal shock wave therapy for calcifying tendinitis of the shoulder: which is superior? A meta-analysis. Clin Orthop Relat Res. 2014.

Wang CJ, Ko JY, Kuo YR, et al. Molecular changes in diabetic foot ulcers. Diabetes Res Clin Pract. 2011 Jul 8.

Washington State Health Care Authority Health Technology Assessment 2017. "Extracorporeal shock wave therapy (ESWT) for musculoskeletal conditions".

Willems A, van der Jagt OP, Meuffels DE. Extracorporeal shock wave treatment for delayed union and nonunion fractures: a systematic review. J Orthop Trauma. 2019 Feb;33(2):97-103.

Wolff KS, Wibmer A, Pusch M, et al. The influence of comorbidities and etiologies on the success of extracorporeal shock wave therapy for chronic soft tissue wounds: midterm results. Ultrasound Med Biol. 2011 Jul;37(7):1111-9.

Yao G, Chen J, Duan Y, Chen X. Efficacy of extracorporeal shock wave therapy for lateral epicondylitis: A systematic review and meta-analysis. Biomed Res Int. 2020:2064781.

Yin MC, Ye J, Yao M, et al. Is extracorporeal shock wave therapy clinical efficacy for relief of chronic, recalcitrant plantar fasciitis? A systematic review and meta-analysis of randomized placebo or active-treatment controlled trials. Arch Phys Med Rehabil. 2014 Aug;95(8):1585-93.

Yoon SY, Kim YW, Shin IS, et al. Does the type of extracorporeal shock therapy influence treatment effectiveness in lateral epicondylitis? A systematic review and meta-analysis. Clin Orthop Relat Res. 2020 Oct;478(10):2324-2339.

Zhang L, Fu XB, Chen S, et al. Efficacy and safety of extracorporeal shock wave therapy for acute and chronic soft tissue wounds: A systematic review and meta-analysis. Int Wound J. 2018;15(4):590-599.

Zelle BA, Gollwitzer H, Zlowodzki M, et al. Extracorporeal shock wave therapy: current evidence. J Orthop Trauma. 2010 Mar;24 Suppl 1:S66-70.

Policy History/Revision Information

Date	Summary of Changes
10/01/2023	**Application** ***Individual Exchange Plans*** • Removed language indicating this Medical Policy does not apply to Individual Exchange benefit plans in the states of Massachusetts, Nevada, and New York **Supporting Information** • Archived previous policy version 2023T0269FF

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, please 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.