Medical Coverage Policy

Effective Date 11/15/2023
Next Review Date 11/15/2024
Coverage Policy Number............. 0004

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

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Overview

This Coverage Policy addresses extracorporeal shock wave therapy (ESWT) for a variety of applications including musculoskeletal conditions and wound healing.

Coverage Policy

Coverage for extracorporeal shock wave lithotripsy (ESWL) for musculoskeletal and orthopedic conditions varies across plans. Please refer to the applicable benefit plan document to determine benefit availability and the terms, conditions and limitations of coverage.

Extracorporeal shock wave therapy (ESWT), including extracorporeal pulse activation therapy (EPAT®) and Pulsed Acoustic Cellular Expression (PACE™) therapy, is considered experimental, investigational or unproven for ANY indication, including but not limited to the treatment of musculoskeletal conditions and soft tissue wounds.

General Background

Extracorporeal shock wave therapy (ESWT), also referred to as extracorporeal shock wave lithotripsy (ESWL), is a noninvasive treatment that involves delivery of low- or high-energy shock waves via a device to a specific site within the body. These pressure waves travel through fluid and soft tissue; their effects occur at sites where there is a change in impedance, such as the bone/soft-tissue interface. Low-energy shock waves are applied in a series of treatments and do not typically cause any pain. High-energy shock wave treatments are generally given in one session and usually require some type of anesthesia (National Institute for Clinical Excellence [NICE], 2016). The most common use for shock waves has been to break kidney stones into fragments that can then be passed (i.e., renal lithotripsy).

The two types of ESWT are focused and radial. Focused ESWT directs shock waves at a targeted area with high tissue penetration where it is proposed to stimulate healing and disrupts pain signals. The shock waves may be generated using electrohydraulic, electromagnetic or piezoelectric technology. The difference between the three methods of generation is the time at which the shockwave forms (Roerdink, et al., 2017).

Radial ESWT uses pneumatic (compressed air) devices to deliver radial shock waves to a wider area than focused ESWT at a relatively low energy level (Hayes 2016b). This generates stress waves in the applicator that transmit pressure waves (radial shock waves) non-invasively into tissue. Since the waves generated by radial ESWT are not true shock waves, the technology is also referred to as radial pressure wave therapy or extracorporeal pulse activation therapy (EPAT) (Császár, et al., 2015). However, published literature continues to refer to radially generated wave therapy as radial ESWT.

ESWT is evolving as a proposed treatment option for a variety conditions, including musculoskeletal disorders and wounds/soft tissue injuries. The mechanism by which ESWT might relieve pain associated with musculoskeletal conditions is unknown. It is thought to disrupt fibrous tissue with subsequent promotion of revascularization and healing of tissue. It has also been hypothesized that the shock waves may reduce the transmission of pain signals from the sensory nerves and/or stimulate healing (Huang, et al., 2000). On that basis, ESWT has been proposed as an alternative to surgery.

ESWT has been investigated as a treatment for various musculoskeletal conditions such as medial epicondylitis (i.e., golfer's elbow); calcific tendonitis of the rotator cuff; Achilles and patellar tendonitis; avascular necrosis of the femoral head; diabetic foot ulcers and nonunion of fracture. However, ESWT devices are FDA approved for only three indications: plantar fasciitis (i.e., heel pain) lateral epicondylitis (i.e., tennis elbow) and chronic diabetic foot ulcers (DFU's).

U.S. Food and Drug Administration (FDA)
The FDA has classified external shock wave therapy products (focal and radial) as class III devices through the premarket approval program (PMA) under the product code NBN (generator, shock-wave, for pain relief). A number of focal ESWT devices are currently approved by the FDA. The OssaTron® lithotripter (HealthTronics, Marietta, GA) is an electrohydraulic, high-energy device, approved for treatment of plantar fasciitis and lateral epicondylitis that have failed conservative treatment after six months. The Epos™ Ultra high-energy device (Dornier Medical Systems, Germering, Germany), uses electromagnetic energy to generate shock waves and is approved for the treatment of chronic plantar fasciitis. The SONOCUR® Basic (Siemens, Erlangen, Germany), is a low-dose electromagnetic delivery system, and is approved for the treatment of chronic lateral epicondylitis. More recent FDA-approved devices for the treatment of plantar fasciitis include the Orthospec™ (Medispec, Ltd, Germantown, MD) and the Orbasone Pain Relief System (Orthometrix, Inc., White Plains, NY). Both are electrohydraulic devices which utilize the spark gap method to create a shock wave.

The OrthoGold 100 (Softwave Tissue Regeneration Technologies (TRT), Woodstock GA) received FDA approval on August 28, 2020. The device is indicated to "Indicated to provide acoustic pressure shockwaves in the treatment of superficial partial thickness second degree burns in adults (22 and older) Indicated for use in conjunction with standard of care burn treatments" (FDA, 2020).

The OrthoGold 100™ (Softwave Tissue Regeneration Technologies (TRT), Woodstock GA) received FDA approval on November 26, 2019. The device is indicated to "provide acoustic pressure shockwaves in the treatment of chronic, full-thickness diabetic foot ulcers with wound areas measuring no larger than 16 cm2, which extend through the epidermis, dermis, tendon, or capsule, but without bone exposure. The OrthoGold 100 is indicated for adult (22 years and older), diabetic patients presenting with diabetic foot ulcers greater than 30 days in duration and is indicated for use in conjunction with standard diabetic ulcer care" (FDA, 2019).

The Sanuwave Health dermaPACE system received FDA approval (i.e., De Novo) on December 28, 2017. Indications for use of this device are "to provide focal acoustic pressure shockwaves in the treatment of chronic, full-thickness diabetic foot ulcers with wound areas measuring no larger than 16 cm^2, which extend through the epidermis, dermis, tendon, or capsule, but without bone exposure. The dermaPACE System is indicated for adult (22 years and older), diabetic patients presenting with diabetic foot ulcers greater than 30 days in duration and is indicated for use in conjunction with standard diabetic ulcer care" (FDA, 2017).

The two radial ESWT devices that are currently approved by the FDA are the EMS Swiss Dolorclast® and the Storz Medical Duolith SD1. The EMS Swiss Dolorclast® (Electro Medical Systems [EMS], North Attleboro, MA) was granted premarket approval (PMA) by the FDA on May 8, 2007. Indications for use of this device are chronic proximal plantar fasciitis, in patients age 18 and older, with symptoms for six months or more, and a history of unsuccessful conservative therapy. The Storz Medical Duolith SD1 shock wave therapy device (Storz Medical AG; Switzerland) received FDA approval (i.e., PMA) for similar indications in January 2016.

Plantar Fasciitis
Plantar fasciitis is an overuse injury resulting in inflammation of the plantar fascia, which connects the heel to the toes. It is a common cause of heel pain in adults. Achilles tendinopathy is also a common cause of posterior heel pain. Symptoms of plantar fasciitis usually start gradually with mild pain at the heel, pain after exercise and pain with standing first thing in the morning. On physical examination, firm pressure will elicit a tender spot over the medial tubercle of the calcaneus. Heel spurs are not necessarily associated with plantar fasciitis; heel spurs may be found in asymptomatic patients. Early treatment generally results in a shorter duration of symptoms. Conservative treatment for plantar fasciitis includes rest, physical therapy, heel cushions, nonsteroidal anti-inflammatory drugs (NSAIDs), corticosteroid injections, foot orthotics, shoe modifications, night splinting, and casting. Surgery is usually considered only for intractable pain which has not responded to 6–12 months of proper conservative treatment. Surgical interventions can include removal or release of the fascia, and removal of bone spurs.

Literature Review: The safety and effectiveness of ESWT for the treatment of plantar fasciitis have been evaluated in technology assessments, meta-analyses, and randomized controlled trials (RCTs). A number of RCTs (n=45–272) have compared ESWT to placebo, conservative treatment or steroid injections for the treatment of plantar fasciitis with conflicting results. In some studies, there is a greater reduction in heel pain in patients treated with ESWT compared to placebo (Ibrahim, et al., 2017; Gollwitzer, et al., 2015; Othman and Ragab, 2010; Ibrahim, et al., 2010; Gerdesmeyer, et al., 2008), while similar improvement rates for both treatment and placebo groups have been reported in other studies (Radwan, et al., 2012). An RCT (40) by Eslamian et al. (2016) compared radial ESWT (n=20) to a single steroid injection (n=20) for plantar fasciitis and found that both interventions caused improvement in pain and functional ability two months after treatment. Inter-group differences were not significant (p=0.072), however the foot function index was improved more with ESWT and patients were more satisfied with ESWT. An RCT (n=32) by Greve et al. (2009) compared radial shockwave treatment (n=16) and conventional physiotherapy (n=16) for plantar fasciitis and found ESWT to be no more effective than conventional physiotherapy three months after treatment. An RCT (n=149) by Wang et al. (2007) found that patients who received ESWT showed significantly better pain and function scores compared to those who received conservative treatment (p<0.001). In general, these studies have limitations such as small sample sizes and short-term follow-up that limit the generalizability of their results.

Cinar et al. (2020) conducted a randomized controlled trial (RCT) that evaluated if extracorporeal shockwave therapy (ESWT) combined with usual care (exercise and orthotic support) was comparable to usual care in improving foot function and walking velocity in patient with plantar fasciitis. Patients with plantar fasciitis pain persisting for at least one month with a minimum score of 5 on the 10-point visual analog scale (VAS); pain felt in the morning at first step over the plantar fascia in the last week before enrolling the study; tenderness to palpation over medial calcaneal tuberosity or along plantar fascia; ≥ 18 years; and agreement to participate and complete treatment and follow-up assessments (without participating in any other therapies including anti-inflammatory drugs and corticosteroid medication) were randomly allocated into two groups: ESWT (n =23), and control (n =21). Both groups were instructed to wear full-length silicone insole for three months and to practice home exercise for three weeks. Patients in the

ESWT group were also treated with a radial ESWT device once a week for three weeks. The primary outcome of this study measured functional ability using the function subscale of American orthopedic foot and ankle society (AOFAS-F) score and 12 minutes walking test including walking speed and cadence. Assessments were performed at baseline, after completion of the three week courses of treatment and at the 12-week follow-up assessment. Results showed that there was a significant improvement in AOFAS-F total score and walking speed over three months in both groups ($p<0.001$, $p=0.04$ respectively). Groups were comparable with each other for both walking speed and AOFAS-F at all follow-up assessments ($p>0.05$). Author noted limitations included the small patient population, short term follow-up and the lack of a non-treatment group. Additionally, patients were in the acute phase of plantar fasciitis and the treatment effect of ESWT might not be as efficient as when in chronic condition. The authors concluded that ESWT did not have an additive benefit over usual care to improve foot function and walking performance in patient with plantar fasciitis over three months post-treatment. Future studies are needed to investigate the benefits of providing adjunctive electrotherapeutic modalities over exercises including different gait related outcomes using high quality measures.

Xu et al. (2020) conducted a block randomized controlled trial that compared the effect of extracorporeal shock wave therapy (ESWT) and local corticosteroid injection (LCI) on patients with plantar fasciitis (PF). Patients (n=96) were randomly assigned to receive ESWT or LCI. Forty-nine patients received three low-energy radial ESWT sessions once per week for three consecutive weeks and forty-seven patients received LCI using 40 mg of methylprednisolone and 1 ml of 1% lidocaine. All patients used adjuvant plantar fasciitis therapies, which included passive dorsiflexion of the toes and gastrocnemius stretching twice a day for one month. Additionally, patients were asked to avoid the use of nonsteroidal anti-inflammatory drugs (NSAIDs) and excessive activities during the intervention period. Included patients were age 18 years and older diagnosed with plantar fasciitis more than three months ago, average pain in the last week was > 3 on the visual analog scale (VAS) and plantar fascia thickness (PFT) measured > 4 mm on ultrasound. Follow-up occurred at one, three and six months. Measure outcomes included average pain, first-step pain, plantar fascia thickness, and Foot Function Index, Chinese version of the PF patients. All patients had statistically significant improvement in pain relief and function at each follow-up visit compared with baseline ($p<0.05$). Additionally, significant recovery was maintained at the final visit in the ESWT group, but it was not maintained at three and six months in the LCI group. In both groups, the FFI score showed a significant reduction when compared to baseline, but there was significantly better improvement in the ESWT group than in the LCI group at the three- and six-month follow-up visits ($p<0.05$). There was a significant improvement in the PFT in both at the three- and six-month follow-up visits compared to baseline, with significantly better improvement in the ESWT group than in the LCI group at the six-month follow-up ($p<0.05$). The side effects or complications were recorded during treatment and each follow-up visit. All patients exhibited transient reddening of the skin after shock wave therapy, and 13 patients reported transient pain during ESWT, but this pain resolved immediately. No other clinically relevant side effects were observed. Author noted limitations include the short-term follow-up and lack of placebo control group. Additionally, it may be more effective to measure PFT using an MRI and different treatment protocols or shock wave energies may produce different results.

Çağlar Okur and Aydın (2019) conducted a prospective randomized controlled trial (RCT) that investigated the effectiveness of extracorporeal shock wave therapy (ESWT) and custom foot orthotics (CFO) in patients with plantar fasciitis. The patients (n=83) were randomized into two groups. Group I (n=40) received three sessions of ESWT once a week and group II (n=43) received a custom foot orthotic. The study included patients aged 30–60 years diagnosed with plantar fasciitis that experienced persistent heel pain while walking, had pain and sensitivity in the sole and showed abnormal foot pronation due to pain. Patients were assessed in terms of pain at rest, pain during walking (morning and evening), foot functions and foot health using the visual analogue scale (VAS), the Foot Function Index Revised (FFI-R), and the Foot Health Status

Questionnaire (FHSQ). The data were obtained prior to treatment (0) and at four, 12, 24 and 48 weeks after treatment. Three patients were lost to follow-up and were excluded from the study data. There were no significant differences in the ESWT and CFO groups between week 0 and week four (p>0.05). At post-treatment week 12, the physical activity sub-parameter of FHSQ was significantly different in favor of the CFO group (p<0.05). At week post-treatment 24, there was a significant difference in evening VAS and FHSQ sub-parameters foot pain, foot function, general foot health and physical activity in favor of the CFO group (p<0.05). At week post-treatment 48, there was a significant difference in evening walking VAS scores; FFI and FHSQ sub-parameters foot pain, foot function and physical activity in favor of the CFO group (p<0.001). Author noted limitations included the lack of a control group, pain was completely resolved and the use of subjective evaluation measures. The authors concluded that ESWT and CFO are both effective modalities but neither method was superior in the treatment of PF.

Mishra et al. (2019) conducted a prospective comparative nonrandomized trial that investigated and compared the effectiveness of methylprednisolone injections (DMP) and extra-corporeal shock wave therapy (ESWT) in treating plantar fasciitis. Patients (n=60) were divided into two groups based on the patients preference. Group 1 (n=30) received a methylprednisolone injection at the point of maximal tenderness (PMT) and group 2 (n=30) received ESWT. The primary outcome was reduced pain which was measured using the Visual Analogue Pain Scale (VAS). Follow ups of both groups occurred at six weeks, three months and six months. Results at six weeks and six months revealed a significant VAS score improvement with patients in the ESWT group compared to patients of the DMP group (p=0.005; p=0.02, respectively). Author noted limitations included the small sample size, non-randomized design with possible selection bias, heterogeneous patient population, lack of functional scoring and a short term follow up. The authors concluded that future research with long term follow-up is needed to consolidate the preliminary observations made in this study.

Lai et al. (2018) published the results of a prospective randomized controlled trial which evaluated and compared the therapeutic effects of ESWT and corticosteroid injections (CSI) in patients with chronic plantar fasciitis. 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 (n=110) were randomly assigned to receive ESWT (n=55) or CSI (n=55). The outcomes measured were a decrease in pain over a 12-week period and an increase in plantar fascia thickness. Outcomes were measured before treatment and at the fourth and 12th week following treatment using the visual analog scale (VAS), 100-points scoring system and ultrasound. Thirteen subjects were lost to follow-up and the outcomes were reported on the patients (n=97) that completed the study (n=47/ESWT group; n=50/CSI group). The VAS of patients that received ESWT was lower than those who received corticosteroid injection at the fourth and 12th week (p=0.001 and p<0.001 respectively). The 100-points scoring system indicated that the pain level of patients with ESWT was significantly lower than those with CSI at the 12th week (p<0.001). The analysis performed comparing changes in plantar fascia thickness to clinical outcomes found that the increase in the thickness of the plantar fascia at the fourth week was positively correlated with the VAS score at 12th week (p=0.039) indicating that pain decreased as the plantar fascia thickness increased. At the fourth week, the plantar fascia was thicker in the ESWT group compared to the CSI group (p=0.048). However, the thickness decreased in both groups at the12th week. The author noted limitations of the study included: plantar fascia thickness was not measured on the normal foot, patients lost to follow-up, small patient population, and short-term follow-up. The authors summarized that extracorporeal shockwave therapy (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.

Dedes et al. (2018) conducted a nonrandomized controlled trial to evaluate the effectiveness and safety of shockwave therapy in treating tendinopathies. Patients were excluded if they were under the age of 18. The sample consisted of 384 patients suffering from elbow tendinopathy, plantar fasciitis, Achilles tendinopathy or rotator cuff tendinopathy. Three-hundred twenty-six patients received shockwave therapy and 58 patients received conservative treatment making up the control group The purpose of the study was to investigate the pain reduction, the improvement in the patient's functionality and quality of life both immediately and four weeks after therapeutic intervention using anonymous questionnaires. Additionally, comparisons were performed between the shockwave intervention group and control group. The shockwave therapy group in patients suffering from plantar fasciitis, elbow tendinopathy, Achilles tendinopathy and rotator cuff tendinopathy reported significant improvements in all parameters measured post-treatment and at the four-week follow-up ($p<0.001$). The control group also reported significant improvement post-treatment for each type of tendinopathy ($p<0.001$). However, in the four-week follow-up, the results in the shockwave group were significantly better compared to control group. Significant pain reduction and improvement in functionality and quality of life were observed in both groups of each tendinopathy, but these findings were less pronounced in the control group than those in the shock wave group. Author acknowledged limitation was that direct comparison to other studies was difficult due to the lack of consistent shockwave therapy guidelines. Further research and clinical trials are necessary to clarify the ideal parameters on the efficacy of shockwave therapy.

A number of systematic reviews and meta-analysis (n=6–11 studies/550–1287 patients) have evaluated the effectiveness of ESWT in treating chronic plantar fasciitis. These studies have been limited by short-term follow-up of 3–12 months, and have yielded conflicting results (Xiong, et al., 2019; Li, et al., 2018a; Li, et al., 2018b).

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 plantar fasciitis. RCTs were included that investigated ESWT without anesthesia with sham therapy as control. Therapeutic success in studies was defined as a decrease in visual analogue scale (VAS) score from baseline larger than 50% or 60%, or VAS score of less than 4cm after intervention. Overall, ESWT was found to have higher improvement or success rates than placebo ($p<0.00001$). A subgroup analysis of FSW and RSW therapies indicated that FSW therapy had greater improvement or success rates than placebo ($p<0.0001$). Data regarding reduction in pain scale was reported in 4/9 trials. Of these trials, three compared FSW therapy to placebo, and one assessed RSW therapy compared to placebo. Significant heterogeneity was observed in the comparisons of reduction in pain scale. ESWT was found to have greater reduction in pain scale than placebo ($p=0.05$). No serious adverse events were reported. Limitations of the analysis included 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 plantar fasciitis 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.

Yin et al. (2014) reviewed low intensity and high intensity ESWT. The authors noted that the pooled data for pain relief in the low-intensity group showed a significant difference between the ESWT and control groups ($p<0.001$) in favor of ESWT. The high-intensity group was found to have superior pain relief relative to the control group in one trial only. However, with analysis of short-term function, only low-intensity ESWT was significantly superior over the control treatment. Study results in this review indicated that low-intensity ESWT for the treatment of refractory plantar fasciitis may be more effective than sham treatment. Study limitations of heterogeneity and short-term follow-up made it difficult to draw conclusions regarding efficacy. Dizon et al.

(2013) review concluded that when ESWT was compared to placebo, ESWT was more effective in reducing morning pain (p=0.004), but no differences were seen in decreasing overall pain or activity pain (p=0.06 and p=0.07 respectively). In a subgroup analysis, moderate-intensity ESWT was more effective in decreasing overall pain and activity pain (p<0.00001 and p=0.001 respectively). Both moderate- and high-intensity ESWT were more effective in improving functional outcome (p=0.0001). Acknowledged study limitations included the lack of consistency in outcome measures, specified dose intensities (low, medium, high ESWT) and short-term follow-up. Aqil et al. (2013) reported at the 12-week follow-up, patients who received ESWT had better composite pain scores (p=0.02), and greater reduction in their VAS pain scores (p<0.001) compared to placebo. However, there was no significant difference in overall success rate of heel pain improvement between ESWT and placebo (p=0.10). This study also noted limitations which included short-term follow-up and inconsistency of dose intensity.

Carpal Tunnel Syndrome
Carpal tunnel syndrome (CTS) is a clinical syndrome caused by compression of the median nerve at the wrist. It is the most common entrapment neuropathy in adults. The pathophysiology of CTS is not fully understood, it is thought that ischemic injury due to increased carpal tunnel pressure is considered to be the most crucial factor. Risk factors include repetitive wrist movements, obesity, rheumatoid arthritis, diabetes mellitus, and menopause. Clinical symptoms include nocturnal pain, numbness and a tingling sensation in the median nerve dermatome. The diagnosis of CTS is confirmed by these typical clinical symptoms, along with electrodiagnostic studies. Treatment options consist of wrist splints, physical modalities, local corticosteroid injections, and surgical treatments. The effects of a wrist splint, local corticosteroid injection, and surgical treatment have been demonstrated in multiple studies (Kim, et al., 2019).

Literature Review: Gholipour et al. (2023) conducted a prospective randomized controlled trial that assessed the efficacy of using radial extracorporeal shock wave therapy (R-ESWT) with LCI (local corticosteroid injection) in treating carpal tunnel syndrome (CTS). Patients (n=40) with mild to moderate CTS were randomized into either the sham R-ESWT (n=20) group or the active R-ESWT group. Both groups had a LCI (local corticosteroid injection). The first group received four sessions of sham-ESWT weekly, which involved sound but no energy; the second group received R-ESWT at equal intervals. Patients were assessed at baseline, one month, three months and six months for pain using the visual analogue scale (VAS) and symptoms using the global symptom score (GSS) The GSS questionnaire measured pain, numbness, paresthesia, weakness/clumsiness, and nocturnal waking. At the end of the 6th month, patients with exacerbation of paresthesia, finger tingling, and decreased strength were referred for surgery after being confirmed by the EMG-NCV. Significant improvement was observed in both groups for pain (p<0.05) and symptoms (p<0.05) at three-months. The second group revealed more significant symptom improvement at (p<0.05) at six months. At the end of the study period, significantly more patients were referred for carpal tunnel release from the sham-ESWT group (n=15/75%) compared to (n=8/40%) to the ESWT group (p=0.025). Author noted limitations included the small patient population and short-term follow-up period. Another important limitation was the gender had a high count of females and cannot be generalizable to everyone. Accordingly, evaluation of the components that would indicate the possible mechanisms of ESWT and corticosteroids' simultaneous action in future studies are of primary concern.

Öztürk Durmaz et al. (2022) conducted a randomized controlled trial (RCT) that compared the effectiveness of radial extracorporeal shock wave therapy to local corticosteroid injection (LCI) on pain, function and nerve conduction studies in the treatment of idiopathic carpal tunnel syndrome (CTS). Adults (n=72) aged 18–65 years diagnosed with mild and moderate CTS through clinical parameters and nerve conduction studies (NCSs) were included in the study. Patients were randomized into three groups. Patients (n=33) in the rESWT/splint group received a splint and one session of rESWT per week, a total of three sessions (frequency of 5 Hz and 2000 shock pulses). Patients in the LCI/splint group (n=28) received a splint and an injection of methylprednisolone (Depo-Medrol). Patients (n=31) in the splint only group, received a splint and were instructed to use it for two months while sleeping at night and resting during the day. Primary outcomes measured symptom severity and functional status using the Boston Symptom Severity Subscale (Boston-SSS) and functional status using the Boston Functional Severity Subscale (Boston-FSS). Secondary outcomes measured pain and numbness using the Visual Analog Scale (VAS) along with hand grip strength. One week after treatment, pain, numbness and symptom severity showed significant improvement compared with pretreatment values in all three groups. In the intergroup comparison, there was a significant improvement in pain, numbness, symptom severity and functional severity in the LCI group compared to the ESWT and control groups. Twelve weeks after treatment the pain, numbness, symptom severity and functional severity showed significant improvement in all three groups. Pain and functional severity differed significantly between groups with the difference in pain was in favor of the LCI group and the difference in functional severity was in favor of the LCI and control groups. The numbness, symptom severity, and handgrip strength did not differ significantly between the groups in the 12^{th} week after the treatment. Author noted limitations included the unblinded study design, small patient population, short term follow-up and imaging (e.g., ultrasonography) was not used to determine the treatment site before both injections and rESWT. An additional limitation is that the study was conducted in Turkey and the results may not be applicable to other races or ethnic groups. The authors concluded that ESWT, splint, and local corticosteroid injection were effective for the treatment of CTS, but symptom relief was greater in the first week and 12th week with local corticosteroid injection. No health disparities were identified by the investigators.

Habibzadeh et al. (2022) conducted a randomized controlled trial (RCT) that evaluated the short-term effect of radial shockwave on the median nerve pathway as a new method in patients with mild-to-moderate carpal tunnel syndrome (CTS). Patients with CTS (n=60) were randomized into three groups: the point shockwave group (n=20), the sweep shockwave group (n=20) and the control group (n=20). The point shockwave group had ten sessions of conventional physiotherapy and four sessions of rESWT on the carpal tunnel. The sweep shockwave group had ten sessions of conventional physiotherapy and four sessions of rESWT on the carpal tunnel and median nerve pathway. The control group received ten sessions of conventional physiotherapy. Follow-up occurred at one and four weeks after the end of treatment. Pain and paresthesia intensity and symptom severity significantly decreased in all three groups at one and four weeks, but significantly greater improvement was noted in shockwave groups. In terms of clinical and electrophysiological parameters, two groups of shockwaves showed similar results. There were no differences observed between utilizing radial shockwave on the carpal tunnel or median nerve pathways on the palmar surface of the hand, in terms of clinical and electrophysiological measurements. Author noted limitations included the lack of long-term follow-up and failure to re-evaluate the electrophysiological parameters of the median nerve four weeks after the end of the treatment. An additional limitation is that the study was conducted in Iran and the results may not be applicable to other races or ethnic groups. The authors concluded that radial shockwave combined with conventional physiotherapy is an effective noninvasive treatment for mild-to-moderate carpal tunnel syndrome that produces greater and longer-lasting results than conventional physiotherapy alone. Randomized controlled studies with large patient populations and long-term follow-up are needed to validate the outcomes of this study. No health disparities were identified by the investigators.

Turgut et al. (2021) conducted a double-blind, randomized controlled trial that evaluated the efficacy of extracorporeal shock wave therapy for pillar pain after open carpal tunnel release. Patients (n=60; 50 women and 10 men) were included that presented with a visual analogue scale (VAS) score of ≥ 5, pillar pain after CTRS and hyperemic and edematous scar tissue. Patients were allocated into two groups: the experimental ESWT group (n=30) and the control group (n=30). The ESWT group received three sessions of ESWT (Storz Medical AG, Tägerwilen, Switzerland), one session per week. The control group received three sessions of sham ESWT, one session per week. Pre- and post-treatment scores were assessed by an orthopedist blinded to the group assignment. Outcomes measured pain using the VAS and hand functions using the Michigan hand outcomes questionnaire (MHQ) before treatment, three weeks, three months, and six months after treatment. Six months after the treatment, the results indicated a significant difference in VAS scores and MHQ scores between the groups ($p<0.001$; $p<0.001$, respectively) in favor of the ESWT group. Limitations of the study included the small patient population and disproportionate amount of males and females enrolled. The authors noted that future studies should include larger samples to better understand the etiology of pillar pain and the effectiveness of ESWT in its management. No health disparities were identified by the investigators.

Koçak Ulucaköy et al. (2020) conducted a double-blind, prospective, randomized, placebo-controlled trial that assessed the efficacy of extracorporeal shock wave therapy (ESWT) in carpal tunnel syndrome (CTS) compared to wrist splint treatment. The study enrolled patients (n=189; 22 males and 167 females) diagnosed with mild-to-moderate CTS. Patients (n=295 wrists) were randomized into four groups: group 1 (n=47) received a splint, group 2 (n=47) received splint and rESWT, group 3 (n=45) received rESWT and group 4 (n=50) received splint and placebo rESWT. All patients were assessed at baseline and at one- and three-months following treatment. Pain and functionality were assessed using the Visual Analog Scale (VAS), finger pinch strength, Boston Carpal Tunnel Questionnaire (BCTQ), Leeds Assessment of Neuropathic Symptoms and Signs (LANSS), and electrophysiological examination. Twenty-one patients were lost to follow-up at the end of the third month. All the assessments except for the finger pinch and LANSS showed a significant improvement in all four groups at one and three months, compared to baseline ($p<0.05$). The pinch strength showed a significant improvement in each measurement in Groups 2, 3, and 4 compared to baseline, while Group 1 did not significantly differ from the baseline at one month, at three months the scores significantly improved. Pain and functionality significantly improved in all groups ($p<0.05$). In the group with ESWT and using wrist splint combined, a greater improvement of the hand function and electrophysiological measures was observed. The authors noted that the main limitation of study is the lack of a treatment group receiving only placebo rESWT. An additional limitation is the disproportionate amount of males and females enrolled. No health disparities were identified by the investigators.

Sweilam et al. (2019) conducted a randomized controlled trial that evaluated the efficacy of extracorporeal shock wave therapy (ESWT) in the management of carpal tunnel syndrome (CTS) and compared it with local steroid injection. Patients (n=53) were randomized into two groups: a steroid injection control group (n=28) and an ESWT study group (n=25). The measured outcome was the improvement of symptoms using the visual analog scale (VAS) and the Boston's carpal tunnel questionnaire (BCTQ) symptoms severity score. Also, electrophysiological studies were done on both median and ulnar nerves through comparing their distal terminal motor latencies (DML) at baseline and on each visit. Patients were assessed at baseline then after two- and four-weeks using VAS score, electrophysiological studies and Boston Carpal tunnel questionnaire (BCTQ) score. There was a significant improvement of symptoms assessed by pain VAS score and BCTQ score in both groups during follow-up. Nerve conduction studies of median nerves showed significant decrease of distal motor latencies and increase of amplitude in both groups after two and four weeks. Comparing both groups, there was no difference in pain VAS and BCTQ scores, distal motor latency and nerve conduction velocity of median nerves between both groups on the second and third visits. The authors concluded ESWT is as effective as local steroids injection for management of CTS but ESWT is better being noninvasive. However, larger long-term studies are needed to confirm these results.

Haghighat et al. (2019) conducted a prospective randomized controlled trial to evaluate the effect of extracorporeal shockwave therapy (ESWT) on pillar pain after carpal tunnel release. Patients (n=34) with pillar pain for at least one month following carpal tunnel release surgery and visual analog scale > 5 were randomly assigned into the ESWT group (n=17) or the control group (n=17). Both groups received four sessions of ESWT weekly, with the sham group receiving sound but no energy. Outcomes measured hand function using Brief-Michigan Hand Outcome Questionnaire (Brief-MHQ) and pain score using visual analog scale (VAS). The MHQ score and pain score were measured at baseline, one month, and three months. At baseline, hand function and pain score were similar in both groups. Hand function and pain score improved in both groups during the study period. Hand function at one month and three months was significantly better in the ESWT group than the control group (p=0.032, p<0.0001; respectively). The pain score after one month was not clinically significant between the groups (p=0.066). However, after three months the pain score in the ESWT group was significantly lower than the control group (p<0.0001). The authors concluded that hand function and pain scores in patients with pillar pain after carpal tunnel release improved faster in those who received ESWT compared to sham. Future studies with larger sample size are needed to validate the results.

Kim et al. (2019) conducted a systematic review and meta-analysis of the evidence (n=6 RCTs/281 subjects) evaluating whether extracorporeal shock wave therapy (ESWT) can improve symptoms, functional outcomes, and electrophysiologic parameters in carpal tunnel syndrome (CTS). RCTs were eligible for inclusion if there was at least three months of follow-up that described the effect of ESWT on CTS. The primary outcome measured symptoms which included pain, numbness, tingling sensation, or weakness with follow-up ranging from 12–24 weeks. The ESWT showed significant overall effect size compared to the control (p=0.005). Symptoms, functional outcomes, and electrophysiologic parameters all improved with ESWT. However, there was no obvious difference between the efficacies of ESWT and local corticosteroid injection (p=0.135). The author noted limitations were the small sample size and the patient population was limited to those with mild to moderate CTS, as no studies attempted to investigate the effect of ESWT on severe CTS. The authors concluded that that data on the long-term effects of ESWT are lacking and further research is needed to confirm the long-term effects and the optimal ESWT protocol for CTS.

Atthakomol et al. (2018) conducted a prospective randomized controlled trial that compared the efficacy in relieving pain and improving clinical function between single-dose radial extracorporeal shock wave therapy (rESWT) and local corticosteroid injection (LCsI) in the treatment of carpal tunnel syndrome (CTS) over the mid-term (24 weeks). Twenty-five patients > 18 years with mild to moderately severe CTS were randomized to receive either single dose rESWT (n=13) or LCsI (n=12). Primary outcomes measured the improvement of clinical symptoms and functional recovery using the Boston self-assessment questionnaire (BQ), while secondary outcomes measured the intensity of pain at rest using the used the Visual analogue scale (VAS) and electrodiagnostic parameters. Evaluations were performed at baseline and at one, four, 12 and 24 weeks after treatment. There was a significant reduction of VAS and functional scores in the rESWT group at weeks 12 (p=0.022 and p=0.0075, respectively) and 24 (p=0.0065 and p=0.0073, respectively) compared to baseline while there was no significant change for the LCsI group. There were also significant reductions in symptom severity score and Boston questionnaire score at weeks four (p=0.031 and p=0.0082, respectively) 12 (p=0.0059 and p=0.032, respectively) and 24 (0.0040 and 0.0037, respectively) in the rESWT group compared to baseline. In the LCsI group, there was significant reduction in terms of symptom severity score at weeks one and four as well as in the Boston questionnaire score at week one compared to the baseline (p=0.0047, p=0.011 and p=0.037, respectively). As to electrodiagnostic parameters, the rESWT and LCsI group showed significant reduction in peak sensory distal latency at week 12 compared to the baseline (p=0.0047 and p=0.026, respectively).There were no significant changes from baseline in the other electrodiagnostic parameters in either group at week 12. Author noted limitations included the small patient population and the different dose intensity of rESWT might affect the results of treatment and long-term results, beyond 24 weeks, were not measured.

In a randomized controlled trial, Raissi et al. (2017) examined the effectiveness of radial extracorporeal shock wave (rESW) therapy in the treatment of carpal tunnel syndrome (CTS). Forty patients with mild to moderate CTS were allocated into two groups: shock wave and wrist splint intervention group (n=20) and the wrist splint only control group (n=20). Primary outcomes measured pain and tingling within the last week using the visual analog scale (VAS). Secondary outcomes measured the severity, frequency and duration of symptoms and the amount of disturbance during daily activities using the Quick Disabilities of the Arm, Shoulder, and Hand Questionnaire (Quick DASH). Additionally, electrophysiological examinations were conducted to measure median sensory and motor distal latencies and amplitudes. All measurements occurred pretreatment, three weeks, eight weeks and 12 weeks post-treatment. There were significant improvements in post-treatment values of VAS, QuickDASH score, SNAP distal latency and CMAP distal latency in both groups. A comparison of the two groups indicated a statistically significant decrease in the post-treatment values of SNAP distal latency in the interventional group at three week (p=0.050), eight week (p=0.005) and 12 week after treatment. (p=0.012). Although a greater improvement in VAS and the QuickDASH score was noted in the intervention group compared with that in the control group, the differences were not significant. There were not any serious side effects in any of the patients, except one patient who complained of transient wrist pain after 12 weeks. Author noted limitations included that the majority of the participants were female, the routine nerve conduction study can only evaluate large diameter fibers, and the use of sham ESW therapy would be better in the control group. Finally, the most effective intensity and the appropriate number of ESW therapy shots and sessions remain unclear, and further studies are needed with a larger number of patients with alternative protocols (such as the use of more sessions, different shock intensity or combined ESW therapy with other therapeutic modalities). The authors concluded that low-energy shock waves may represent an effective and non-invasive treatment in cases of nerve compression where fiber regeneration is necessary. Future studies are needed to explore the parameters for optimizing the efficacy of rESW therapy.

Lateral Epicondylitis
Lateral epicondylitis is caused by repetitive motion that exerts stress on the grasping muscles of the forearm, which originate at the lateral epicondyle of the elbow. Conservative treatment involves rest, ice, stretching, strengthening, avoiding activity that hurts, and, as healing occurs, strengthening exercises. While the majority of cases of fasciitis, tendonitis and epicondylitis resolve spontaneously with rest and discontinuation of the provoking activity over time, surgical treatment may be indicated for patients who fail conservative treatment.

Literature Review: A number of RCTs (n=32–114) and systematic reviews with meta-analysis have evaluated the safety and effectiveness of ESWT versus sham for the treatment of lateral epicondylitis. These studies have been limited by short-term follow-up of 6–12 months and have yielded conflicting results. Some studies have demonstrated significant improvement of pain and/or function for patients in the treatment group (Pettrone and McCall, 2005; Rompe, et al., 2004). Other study results have indicated that ESWT for tennis elbow was no better than placebo, corticosteroid injections or surgery (Chen, et al.2023; Karanasios, et al., 2021; Defoort, et al., 2021; Capan, et al., 2016; Staples, et al., 2008; Radwan, et al., 2008).

Kaplan et al. (2023) conducted a randomized sham-controlled trial that evaluated and compared the effects of radial and focused types of extracorporeal shock wave therapy (ESWT) on lateral epicondylitis. Included patients have a new diagnosis of lateral epicondylitis, acute lateral epicondylitis (symptom duration < 3 months), aged ≥18 during the diagnosis, and have filled out the pre- and post-ESWT assessment process. If a case had both elbows affected, the elbow with a higher pain level was initially accepted for the analysis. Patients with acute lateral epicondylitis were randomized into focused (n=32), radial (n=32), and sham ESWT (n=33) groups. The ESWT was applied for three sessions at 2-4 days intervals. All the subjects were evaluated at baseline (week 0), week 5, and 13. Patient-rated tennis elbow evaluation (PRTEE) scores were used to measure forearm pain and disability. Nine patients were lost to follow-up with data from 87 patients reported in the statistical analyses (n=30, n=29, and n=28 from the treatment groups, respectively). Both focused and radial ESWT groups were seen as remarkably better than the sham ESWT group in all PRTEE scores (pain, function, and total) (p <0.001), for the change from first admission to interval examination times (weeks 5 and 13). Focused ESWT was superior to radial ESWT for the change of PRTEE total scores from baseline to weeks 5 (36.7±25.9 vs. 23.0±17.2; p=0.021) and 13 (34.7±24.3 *vs.* 22.4±18.5; p=0.044). Authors noted limitations to the study included that advanced radiologic tool for diagnosing the lateral epicondylitis was not used, there was a limitation with the operator-informed outcome measures and the subgroup analysis was not based on more detailed grouping according to weekly symptom duration. Also, the cost/benefit of the ESWT compared to other non-invasive methods of treating the lateral epicondylitis was not considered. An additional limitation of the study included that the population only included patients located in Turkey and the results may not be applicable to other races or ethnic groups. Further long-term studies with large patient populations are needed to validate the findings in this study.

Aldajah et al. (2022) conducted a randomized controlled trial (RCT) that assessed the effect of extracorporeal shock-wave therapy (ESWT) on pain, grip strength and upper-extremity function in lateral epicondylitis (LE). Forty patients with LE (21 males) were randomly allocated to either the ESWT experimental (n=20) or the conventional-physiotherapy control group (n=20). All patients received five sessions during the treatment program. The outcomes measured pain using the Visual Analog Scale (VAS), upper-extremity function using the Taiwan version of the Disabilities of the Arm, Shoulder, and Hand (DASH) questionnaire and maximal grip strength (MGS) using a dynamometer. Patients in both groups improved significantly after treatment in pain, upper extremity function and maximal grip strength; however, the scores were significant higher after ESWT (p<0.000). Author noted limitations included that the study was not double-blinded, small patient population and short-term follow-up. An additional limitation was that the study was conducted in Amman, Jordan and the results may not be applicable to other races or ethnic groups. The authors concluded that ESWT had a superior effect in reducing pain and improving upper-extremity function and grip strength in people with lateral epicondylitis. However, further long-term studies with large patient populations are needed to validate the findings in this study. No health disparities were identified by the investigators.

Aydın and Atiç (2018) performed a prospective randomized controlled trial comparing the efficacy of ESWT to wrist-extensor splint (WES) application in the treatment of lateral epicondylitis (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 (n=32) received ESWT four times per week using the DolorClast device and group two (n=35) 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. Four patients in the ESWT group and one in the WES group were lost to follow-up. In both groups there were significant improvements (p<0.001) 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 (p>0.05). The authors noted limitations of the study were the small patient population and use of the patient-reported questionnaires.

Guler et al. (2018) conducted a randomized, placebo-controlled, double-blind, prospective trial to investigate the efficacy of ESWT in patients with lateral epicondylitis (LE). Patients (n=40) were randomized into two groups, real ESWT (Group 1, n=20) or placebo ESWT (Group 2, n=20). The study included patients 18–65 years of age diagnosed with LE without treatment within the last three months. The outcomes measured were decreased pain and increased strength. Patients were evaluated using the Patient-Rated Tennis Elbow Evaluation-Turkish Version (PRTEE-T), visual analog scale (VAS) pain scores, and grip and pinching strengths. The evaluations were performed prior to treatment, at the end of treatment and one month following treatment. Both groups were treated with wrist splinting, ice treatment, and rest. Both groups found significant changes in themselves ($p<0.05$) and the VAS scores showed significant changes between pre-treatment and post-treatment in the real ESWT group ($p<0.05$). However, there were not significant differences between the groups in grasp and pinching strength, perception of changes in themselves using the PRTEE-T scores, and the VAS scores ($p>0.05$). Author noted limitations included the small patient population, the short-term follow-up, not using an imaging method such as ultrasound guidance or magnetic resonance imaging (MRI) to confirm the diagnosis, and not applying ESWT with ultrasound guidance. The authors concluded that although pain and functional improvement were more prominent patients treated with ESWT, no statistically significant differences were found between two groups. There is a need for additional multicenter, placebo-controlled studies investigating the efficacy of ESWT in treating LE.

Yalvaç et al. (2018) conducted a randomized controlled trial (RCT) that compared the efficacy of extracorporeal shock wave therapy (ESWT) and therapeutic ultrasound (US) in the treatment of lateral epicondylosis (LE). Patients (n=50) were randomized into two groups. Group 1 underwent therapeutic US (n=25) and Group 2 underwent ESWT (n=25). The study included patients 18–65 years of age who presented with a minimum of three months of elbow pain and were diagnosed with chronic LE. The outcomes measured were a decrease in pain, increased grip strength, improvement in functional status and quality of life. Patients were evaluated at baseline, after treatment, and one month following treatment using the visual analog scale (VAS), algometer, grip dynamometer, quick-disability of the arm, shoulder and hand score (QDASH), patient-rated tennis elbow evaluation (PRTEE), and the Short Form-36 (SF-36) health survey questionnaire. Six patients were lost to follow-up and the outcomes were reported on the patients (n=44) that completed the study (n=24/US group; n=20/ESWT group). Both groups showed significant improvements in terms of pain (all p values <0.0001), grip strength ($p=0.001$/US; $p=0.015$/ESWT), functional status (all p values <0.0001), and quality of life ($p=0.001$/US; $p=0.005$/ESWT). There was no significant difference between the two groups, except pressure-pain threshold algometer scores in favor of ESWT ($p=0.029$). It was noted that a limitation to the study included the lack of a control group. Additional limitations were small patient population and short-term follow-up. The authors concluded that ESWT and therapeutic US are equally effective in treating LE. Additional studies are required to assess long term effectiveness of ESWT and comparison of ESWT with other physical treatment methods.

Vulpiani et al. (2015) conducted a single-blinded RCT (n=80) comparing the effectiveness of ESWT (n=40) to cryoultrasound (n=40) in patients with chronic lateral epicondylitis. Inclusion criteria were adults 18 to 75 years old, diagnosis of chronic lateral epicondylitis within at least three months, intensity of pain ≥ five on the Visual Analogue Scale (VAS) and failure of previous conservative treatments. Criteria for exclusion included previous treatment with cryoultrasound, acute infection, and signs of elbow laxity or instability and neoplastic disease. The primary outcome was a difference of two points in pain recorded on the VAS during the Cozen test between the ESWT group and the cryoultrasound group. The secondary outcome was the number of patients who achieved at least 50% satisfactory results at three, six and 12 months of follow-up. Significant differences between groups for the VAS score were noted at six months ($p<0.001$) and 12 months ($p<0.001$) in favor of ESWT group. The satisfaction rate required at 50% was only achieved in the ESWT group in the follow-up at six (62.5%) and 12 (70.0%) months. Pain at the limit of tolerability was reported by all ESWT patients. No side effects or complications were reported by patients receiving ultrasound. Acknowledged limitations of this study include the lack of a placebo group to demonstrate the natural course of the condition and absence of hand grip strength and finger pinch analysis. Additional data are needed to confirm study results.

A number of systematic reviews and meta-analysis (n=7–12 studies/712–1166 patients) have evaluated the effectiveness of ESWT in treating chronic lateral epicondylitis. These studies have yielded conflicting results (Yao et al., 2020; Zheng, et al., 2020; Yoon, et al., 2020; Buchbinder, et al., 2006).

Yan et al. (2019) conducted a meta-analysis of the evidence (n=5 RCTs/233 patients) comparing the effectiveness of ESWT and US in relieving pain and restoring the functions of tennis elbow following tendinopathy. RCTs were eligible for inclusion if the study made a comparison between ESWT and US on efficacy for treating lateral epicondylitis and the outcomes measured were the efficacy of pain relief and functional restoration. Follow-ups were done at one, three- and six-months follow-ups. The results revealed a significantly lower VAS score of pain in the ESWT group at one, three and six months (p=0.0001; p<0.00001; p<0.0001, respectively) compared to US. Additionally, the grip strength was markedly higher three months after ESWT (p<0.00001) than in the US group. Although no significant difference was observed in the scores of the elbow function after three months of treatment (p=0.13), the subjective scores of elbow functions were found to be better in the ESWT group (p=0.0008) compared to the US group. Author noted limitations included the small patient population, side effects of ESWT and US (temporary reddening of the skin, pain, formation of small hematomas) were not evaluated during follow-up and the high heterogeneity among the results weakens the reliability of the results. The authors concluded that the efficacy of ESWT is superior to that of US in terms of pain relief and overall recovery in tennis elbow. However, longer studies are needed to assess the efficacy of ESWT and US on the tennis elbow function and to explore the optimal therapeutic setting of ESWT.

Tendonitis of the Shoulder

In tendonitis of the shoulder, the rotator cuff and/or biceps tendon become inflamed, usually as a result of repetitive activities that involve use of the arm in an overhead position. The injury may vary from mild inflammation to involvement of most of the rotator cuff. As the rotator cuff tendon becomes inflamed and thickened, it may get trapped under the acromion, causing pain and possibly restricted range of motion (ROM). The condition is usually self-limiting. Medical treatment includes rest, ice, and anti-inflammatory medications. Steroid injections are also a treatment option. Surgical intervention is considered if there is no improvement after 6–12 months of optimal medical management.

Literature Review: The evidence evaluating the safety and effectiveness of ESWT for tendonitis of the shoulder consists of controlled studies (n=43–144), both randomized and nonrandomized, in addition to technology assessments and systematic reviews. Clinical success has been reported in 60%–80% of patients with disintegration rates of the calcific deposit after ESWT varying from 47%—77% (Hsu, et al., 2008; Mouzopoulos, et al., 2007). Some studies have compared different energy levels of ESWT (Ioppolo, et al., 2013; Peters, et al., 2004; Pleiner, et al., 2004). In general, study results have suggested that high-energy ESWT is more effective than low energy ESWT for calcific tendonitis of the shoulder. These studies are limited by short-term follow-up of 6–12 months. In addition, optimal treatment parameters have not been established, and patient selection criteria have not been adequately defined.

Shao et al. (2023) conducted a randomized controlled trial that investigated the effect of ESWT on short-term functional and structural outcomes after rotator cuff (RC) repair. Included patients were aged 40 and 70 years, underwent unilateral shoulder surgery, the tear size < 5cm, the presence of pain or limited passive range of motion (ROM) after RC repair and tendon edema at three months post repair by MRI. Thirty-eight individuals were randomly assigned to the ESWT group (n=19) or control group (n=19) three months after RC repair. All participants followed a 3-month standard post-operative rehabilitation program for RC repair. A radial shock wave device (SwissDolor-Clast, EMS) was used at the end of each session by the same physiotherapist who performed the rehabilitation. A total of 32 participants completed all assessments. Pain and function improved in both groups. At six months post-repair, pain intensity was lower and ASES scores higher in the ESWT when compared to the control group (all p-values<0.01). The MRI reported that the signal/noise quotient (SNQ) 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. Author noted limitations included the small sample size and short-term follow-up. Also, included patients had medium to large rotator cuff tears and the conclusions cannot be generalized to people with massive or irreparable tears. Furthermore, the study did not include a control group with no treatment to ensure a balance between groups. An additional limitation of the study included that the population only included patients located in Turkey and the results may not be applicable to other races or ethnic groups. The study concluded that ESWT and exercise more effectively reduced early shoulder pain than rehabilitation alone and accelerated proximal supraspinatus tendon healing at the suture anchor site after RC repair. However, ESWT may not be more effective than advanced rehabilitation in terms of functional outcomes at the short-term follow-up.

Surace et al. (2020) conducted a Cochrane review to determine the benefits and harms of shock wave therapy for rotator cuff disease, with or without calcification, and to establish its usefulness in the context of other available treatment options. The review consisted of 32 trials (n=2281/patients) which included randomized controlled trials (RCTs) and controlled clinical trials (CCTs) that used quasi-randomized methods to allocate patients, investigating patients with rotator cuff disease with or without calcific deposits. Trials comparing extracorporeal or radial shock wave therapy to any other intervention were included in the study. The outcomes measured included pain relief greater than 30%, mean pain score, function, patient-reported global assessment of treatment success, quality of life, number of participants experiencing adverse events and number of withdrawals due to adverse events. The authors found that there were very few clinically important benefits of shock wave therapy, and uncertainty regarding its safety. Due to the wide clinical diversity and varying treatment protocols it is unknown whether or not some trials tested subtherapeutic doses, possibly underestimating any potential benefits. The authors concluded that further trials of extracorporeal shock wave therapy for rotator cuff disease should be based on a strong rationale and consideration of whether or not they would alter the conclusions of this review. Additionally, a standard dose and treatment protocol should be decided before conducting further research. A core set of outcomes for trials of rotator cuff disease and other shoulder disorders would also facilitate our ability to analyze the evidence.

Wu et al. (2017) performed a systematic review and network meta-analysis (n=14 RCTs/1105 patients) to investigate the effectiveness of non-operative treatments for chronic calcific tendinitis of the shoulder. Study participants were adults diagnosed with clinical symptoms related to calcific tendinitis of the shoulder confirmed by radiologic or ultrasound examination, and unresponsive to initial conservative treatment. Studies with participants who had a history of rotator cuff partial or complete tear, general disease, or neurologic syndromes, and had previously received similar treatments (e.g., ESWT, UGN). Interventions included the following: UGN, H-FSW, RSW, L-FSW, ultrasound therapy, and TENS, and were compared to each other or a control group. The control group had to receive sham treatment or physiotherapy alone. Interventions included radial shockwave, high- and low-energy focused shockwave and ultrasound-guided needling. The outcomes evaluated were improvement in the pain severity, functional status of the shoulder, and the resolution of calcific deposits. Follow-up in studies primarily ranged from three-12 months. For outcomes of pain reduction and calcific deposit resolution, the modality that was found most likely to be ranked the best was UGN (94.2%), followed by RSW and H-FSW. For functional improvement, the treatment found most likely to be ranked the best was H-FSW (94.3%). Common adverse events of different treatments included local bruising, subcutaneous hematoma, or soreness. Acknowledged limitations of the analysis include the lack of a no-treatment group and the high heterogeneity of outcomes between studies. the authors noted that the latter could be due to differences in protocols used for treatment, number of pulses, frequency of treatment, as well as the variable range of energy levels (energy flux density), and different ultrasound-guided approaches. Individual studies were also limited by small sample sizes and short-term follow-up.

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 (n=1134) and non-calcific tendinitis (n=173). Of the 28 RCTs, 20 compared different ESWT energy levels to placebo and eight compared ESWT to other treatments. The quality of trials was reported to be variable and generally low, with numerous sources of bias and heterogeneity (e.g., diverse ESWT regimen/devices), precluding meta-analysis. RCTs were included that studied treatment of calcific or non-calcific tendinitis of the shoulder and compared different energy levels of ESWT or compared ESWT to placebo or other treatments. Nonrandomized comparative studies, single-cohort studies, and case reports were excluded. The outcome measures included of 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. Evidence suggesting a benefit of ESWT for non-calcific tendinitis was also inconclusive. Adverse effects of ESWT were reported to be dose-dependent and generally limited to a temporary increase in pain and local reactions, such as swelling, redness, or small hematomas. Limitations were heterogeneity and size of the included trials. Larger controlled randomized trials as well as standardization of energy levels and treatment protocol are needed to further define the role of ESWT for treating calcific tendinitis of the shoulder.

Ioppolo et al. (2013) conducted a systematic review (n=6 RCTs/460 subjects) to evaluate the effectiveness of ESWT for improving function and reducing pain in patients with calcific tendinitis of the shoulder, and to determine the rate of disappearance of calcifications after therapy. Studies were included that compared ESWT with placebo or no treatment and if participants were adults > 18 years of age with shoulder pain or tenderness from calcific tendonitis in patients with type I or II calcification. Exclusion criteria for subjects were history of significant trauma or systemic inflammatory conditions (e.g., rheumatoid arthritis), postoperative shoulder pain, or rotator cuff tear. Of the six RCTs, two were determined to be of methodologically high-quality. Outcome measures were clinical improvement evaluated by shoulder functional scales, and resorption of calcific deposits defined through radiographic examinations. The reduction of pain was found to be clinically significant at six months after treatment. Meta-analysis of studies evaluated the radiologic rate of resorption of calcific deposits at six months of follow-up found ESWT to be superior to no treatment or placebo for partial and total resorption. Reported results indicate that ESWT may be effective in reducing pain and facilitating the resorption of calcium deposits. However, these results are limited by the low quality and short-term follow-up of studies and lack of comparison to proven therapies.

A technology assessment of RCTs evaluating the safety and efficacy of ESWT for the treatment of chronic rotator cuff tendonitis was performed for the Canadian Agency for Drugs and Technologies in Health (CADTH). Ho (2007) found some evidence to support the use of high-energy ESWT for chronic calcific rotator cuff tendonitis. However, it was stated that more high-quality RCTs with larger sample sizes are required to provide more convincing evidence.

Wounds
ESWT has been proposed as a treatment for delayed/non-healing or chronic wounds. The mechanism by which ESWT may provide a therapeutic effect in wounds remains unclear. Potential mechanisms include durable and functional neovascularization and the reduction of pro-inflammatory effects that inhibit wound healing. ESWT is being investigated as a modality to accelerate tissue repair and regeneration in various wounds such as decubitus ulcers, burns and diabetic foot ulcers (DFUs).

Literature Review – Acute and Chronic Soft Tissue Wounds: ESWT application for wound healing has been studied in randomized controlled trials (RCTs) and case series. Zhang et al. (2017) published results of a systematic review and meta-analysis (n=7RCTs/301 subjects) to assess the effectiveness of ESWT compared to standard care treatment for the healing of chronic wounds. Studies were included in which at least 70% of participants completed the trial, and wound healing rates were recorded prospectively in terms of ESWT efficacy compared to standard wound care and monitored at least monthly during the entire trial. Follow-up occurred primarily over weeks versus months, ranging from seven weeks to 18 months. Outcomes were wound healing rate and time, percentage of the wound healing area, and adverse effects. Radial ESWT was used in 5/7 studies. The standard wound care protocol varied between studies. Compared with the control treatment, ESWT was found to significantly increase wound healing rate (p=0.0003), and the percentage of the wound healing area (p<0.00001). Wound healing time was also reduced by 19 days with ESWT treatment (p<0.00001). No serious complications or adverse effects were reported. Limitations include small sample sizes and short follow-up timeframe. Although the data suggests that ESWT as an adjunct to wound treatment could improve the healing process of chronic wounds compared to standard treatment alone, additional, larger well-designed controlled trials with long-term follow-up are need to determine the role of ESWT in chronic wound care. In 2018, Zhang et al. published an update to the previous systematic review and meta-analysis to include acute soft tissue wounds as well as chronic wounds (n=10RCTs/473 subjects) in determining the effectiveness of ESWT compared to conventional wound therapy. ESWT reduced wound-healing time by three days (p<0.001) for acute soft tissue wounds when compared to CWT alone. The conclusion remained unchanged with this addition, higher-quality and well-controlled RCTs are needed to further assess the role of ESWT for acute and chronic soft tissue wounds.

A systematic review (n=5 studies) performed by Butterworth et al. (2015) examined the effectiveness of ESWT for the treatment of lower limb ulceration. Studied included RCTs (n=3 studies/177 patients), one quasi-experimental study (n=40 patients) and one case series (n=31 patients). The majority of wounds assessed were associated with diabetes. The primary outcome was wound improvement or healing. Treatment comparators included standard care and hyperbaric oxygen. Rates of wound healing ranged from 31%–57%, with two RCTs reporting statistical significance in favor of ESWT. However, ESWT protocol varied in studies resulting in study heterogeneity and making comparison difficult. It was noted external validity of studies was poor, making it difficult to generalize study findings.

A case series (n=258) by Wolff et al, (2011) evaluated the possible effects of comorbidities and different wound etiologies on the success of ESWT treatment for of chronic soft tissue wounds were investigated. The median follow-up was 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. Pooled comorbidities and wound etiologies were not found to have a significant influence on the success of ESWT. Study conclusions are limited by the lack of a control group and relatively short-term follow-up.

Literature Review – Diabetic Foot Ulcers: Dymarek et al. (2023) conducted the SHOWN (SHOck Waves in wouNds) trial, which was a prospective, double-blinded randomized controlled

trial that aimed to assess immediate planimetric and clinical effects following a single radial ESWT session in pressure ulcers (PUs).
Patient inclusion criteria were as follows:

1. a diagnosed chronic wound of PU etiology
2. a wound duration longer than three months
3. a wound classified as grade I (full-thickness skin damage) or grade III (subcutaneous tissue damage with minor necrosis)
4. the lack of contraindications to ESWT interventions, and
5. obtaining the patient's voluntary and informed consent to participate in the study

Patients (n=40) with PUs were randomized into two groups: active ESWT (n=20), which underwent a single treatment with radial ESWT and placebo ESWT (n=20), which was exposed to sham radial ESWT. All patients continued standard wound care procedures. The planimetric assessment and clinical outcomes using Wound Bed Score (WBS) and Bates–Jansen Wound Assessment Tool (BWAT) were assessed before (M0) and after ESWT sessions (M1). After active ESWT there was a significant planimetric enhancement reported as a reduction in: wound area from 11.51 to 8.09 cm2 ($p<0.001$), wound length from 4.97 to 4.41 cm ($p<0.001$), and wound width from 3.15 to 2.49 cm ($p<0.0001$). Intergroup comparisons showed statistically significant planimetric changes and significant clinical improvement in favor of the group treated with active ESWT. The authors concluded that this preliminary RCT showed that a single session of ESWT is a promising and clinically effective modality in managing PUs. However, there is still limited data regarding the usefulness of ESWT in PUs, and further studies are in demand. The studies population only included patient in Poland and the results may not be applicable to other races or ethnic groups.

Huang et al. (2019) conducted a systematic review and meta-analysis of the evidence (n=8 RCTs/339 subjects) evaluating the efficacy of extracorporeal shock wave therapy (ESWT) for treating foot ulcers in adults with type 1 and type 2 diabetes. Randomized controlled trials (RCTs) were eligible for inclusion if patients were > 18 years of age with an active foot ulcer of neuropathic, neuroischemic or ischemic etiology (irrespective of type 1 or type 2 DM), the intervention group was treated with ESWT plus standard wound care (SWC) and the control group was treated with SWC or SWC plus HBOT. The SWC could involve blood sugar control, debridement, wound dressings, total contact casting or usual care, as long as the same concomitant treatment was used in both groups. Follow-ups ranged from five to 24 weeks. The outcomes measured were the reduction of wound surface area (WSA), percentage of re-epithelialization and population of complete cure. This study evaluated both the pooled data of the three outcomes at the end of treatment and at the end of follow up. The ESWT group and the control group presented no statistically significant difference in WSA at the end of treatment ($p=0.087$). At the end of follow-up, ESWT was found to be associated with a clinically significant reduction of WSA by 1.54 cm^2 ($p<0.001$). The meta-analysis demonstrated that ESWT can promote re-epithelialization by 18.65% at the end of treatment and 26.31% at the end of follow up and has higher effectiveness than control treatment for subjects ($p<0.001$ and $p<0.001$, respectively). ESWT significantly increased the population with complete cure at the end of treatment ($p<0.001$). However, there was no statistically significant difference at the end of follow up ($p=0.052$) between groups. Author noted limitations included the small sample size that only included patients with a DFU making it difficult to apply the result to the general population. The authors concluded that ESWT is a feasible and safe adjuvant treatment option for patients with DFU. However, because of the complicated mechanism of DFU and the insufficient number of participants in the studies, more RCTs of high quality and with good control are required to evaluate the effectiveness of ESWT in clinical practice.

Snyder et al. (2018) conducted two multicenter, prospective, controlled, double-blinded, randomized phase III clinical trials to investigate the efficacy of focused extracorporeal shockwave therapy (ESWT) as an adjunctive treatment for neuropathic diabetic foot ulcers (DFU) compared with sham treatment. Prior to randomization, eligible patients were enrolled into a two week run in period during which standard care alone was delivered. Patients who achieved > 50% wound volume reduction were ineligible for randomization. This ensured that only patients whose wounds were unresponsive to standard care were randomized. In both studies, patients were randomized to either standard care with focused ESWT active therapy (pulsed acoustic cellular expression, dermaPACE System, SANUWAVE Health Inc.), or standard care with sham therapy. Participants were randomized to receive standard care and sham ESWT (n=164, both studies combined) or standard care and active ESWT (n=172, both studies combined). Standard care included, but was not limited to, sharp debridement according to local practice, sterile saline-moistened gauze, adherent or non-adherent secondary dressings including foams and hydrocolloids, and pressure-reducing footwear. The use of antibacterial products was not permitted. Study 1 enrolled patients ≥ 18 years of age, and study 2 enrolled patients ≥ 22 years of age. Both studies included patients with at least one DFU in the ankle area or below that had persisted a minimum of 30 days prior to the screening visit. Participants could have more than one DFU, but only one was treated during this study. Both active and sham therapy were administered four times in two weeks in study one and a maximum of eight times over 12 weeks in study two. Standard care continued in both studies throughout the 12-week treatment phase and followed patients up to 24 weeks.

The primary outcome measured for both studies was the incidence of complete wound closure within 12 weeks. The secondary outcomes measured: target ulcer area, volume, depth and perimeter; rate of wound closure; mean wound area reduction; percentage of patients with an increase in wound area; rate of treatment emergent AEs, treatment emergent SAEs and device-related treatment emergent AEs; recurrence and amputation rate; rate of ESWT malfunctions; and changes in baseline values in wound pain assessed by VAS. The safety outcome was conducted on the pooled dataset and measured the rate of adverse events (AEs) at 24 weeks after initial application, including serious adverse events (SAEs), device-related AEs, and active therapy malfunctions throughout the application, treatment, and follow-up periods. The primary outcome was not met in Study 1 or Study 2, nor was it met in the pooled analysis. However, statistically significantly more DFU healed at 20 (35.5% versus 24.4%; p=0.027) and 24 weeks (37.8% versus 26.2%; p=0.023) in the active treatment arm compared with the sham-controlled arm.

Galiano et al. (2019) published the secondary safety and efficacy outcomes from two studies on the efficacy of focused extracorporeal shockwave therapy (ESWT) as an adjunctive treatment for neuropathic diabetic foot ulcers (DFU) compared with sham treatment. Wound area reduction (48.6% versus 10.7%, p=0.015), and perimeter reduction (46.4% versus 25.0%, p=0.022,) were significantly greater in the active therapy group compared with the sham-treated group, respectively. The difference in time to wound closure in the pooled population was significantly in favor of the active therapy group (84 days versus 112 days, respectively; p=0.0346). The proportion of subjects who achieved wound area reduction (WAR) from baseline at week 12 of ≥ 90% was significantly higher in the active therapy group. The incidence and nature of infection were consistent with previously published studies, and pain was not increased in the active therapy group. Amputation was insignificantly higher in the sham-treated group and recurrence did not differ. The incidence of all AEs at 24 weeks was 73.2% in the ESWT group and 68.9% in the sham group; the difference was not significant (p=0.338). Incidence of serious AEs was 32.0% in the ESWT group and 43.3% in the sham group (p=0.042). Author noted limitations included not knowing the outcomes in patients who were not eligible for the study and the subjective nature of patient self-managing their wound care during the run in period.

Omar et al. (2014) published the results of a single blinded randomized controlled clinic trial that evaluated the efficacy of extracorporeal shock wave therapy on the healing rate, wound surface area and wound bed preparation in chronic diabetic foot ulcers (DFUs). Thirty-eight patients with 45 chronic DFUs were randomly assigned to the ESWT group (n=19 patients/24 ulcers) and the control group (n=19 patients/21 ulcers). Patients with the following criteria were included in the study: diagnosis of type I and II diabetes; grades 1A, and 2A, ulcers that had not responded to ≥ 3 months of conservative treatment; ulcer measured ≥ 0.5 cm and ≤ 5 cm at any dimension; and patient had peripheral neuropathy was willing to participate in the study and comply with the follow-up. The outcome measured was the percentage of decrease in wound surface area (WSA) and wound bed preparation. These measurements were taken at baseline, after the end of the interventions (week eight), and at the 20-week follow-up. A total of six patients were lost to follow-up. At baseline, the wound bed preparation scores had no significant differences between both groups (p>0.05). After eight weeks, the rate of ulcers that reported complete healing was 33.3% and 14.28% in the ESWT and control groups, respectively. At the twenty-week follow-up, both groups maintained significantly higher rates of complete healing, 13 ulcers (54%) in ESWT-group and 6 ulcers (28.5%) in the control-group. For the ulcers that healed within 20-week, the average healing time was significantly lower in ESWT-group (64.5 ± 8.06 days) compared to the control group (81.17 ± 4.35 days). There were significant differences (p<0.05) among nonhealed ulcers in both groups. The ≥ 50% reduction of WSA of nonhealed ulcers was 33.5% in the ESWT group and 19% in the control group. The unchanged ulcers were 12.5%, and 52.5%, in the ESWT and the control group, respectively. Author acknowledged limitations included the small sample size, grade of ulcers (1A and 2A) and short-term follow-up.

Wang et al. (2014) published the results of a cohort study which evaluated the long-term outcomes of extracorporeal shockwave therapy for chronic foot ulcers. The cohort consisted of 67 patients (n=72 ulcers) with 38 patients (n=40 ulcers) in the diabetes mellitus (DM) group and 29 patients (n=32 ulcers) in the non-diabetes mellitus (non-DM) group. The inclusion criteria included patients with recurrent or persistent nonhealing diabetic or nondiabetic ulcers of the foot for > 3 months. All patients received ESWT to the diseased foot using dermaPACE device (Sanuwave, Alpharetta, GA) twice per week for three weeks for a total of six treatments. The outcomes evaluated healing of chronic foot ulcers using clinical assessment and tissue viability measured by local blood flow perfusion scan preoperatively and postoperatively at six weeks, one year and five years. Other outcome measures were mortality and morbidity. There were tens patients lost to follow-up (n=9 DM group, n=1 non-DM group). The clinical results of the non-DM group were significantly better than those of the DM group at three months (p=0.006), one year (p=0.027), and five years (p=0.022), respectively. The blood flow perfusion rates significantly improved in both DM and non-DM groups (p=0.011 and p=0.033) respectively. The improvements of blood flow perfusion rate began at six weeks and lasted for up to one year following ESWT. However, from 1–5 years the blood flow perfusion rate decreased in both groups. The non-DM group showed significantly better blood flow perfusion than the DM group at five years (p=0.04). The mortality rate was 15% in total series, 24% in the DM group, and 3% in the non-DM group from 1–5 years after treatment. The rate of amputation was 11% in total series, 17% in DM group, and 3.6% in non-DM group (p=0.194), not significant. There were no systemic/neurovascular or device related complications during the study. The authors concluded ESWT appears effective in the treatment of chronic diabetic and nondiabetic foot ulcers. However, the effects of ESWT significantly decreased from 1–5 years after treatment and additional studies are needed.

Wang et al. (2011) conducted a prospective open-label, randomized study that compared the effectiveness of extracorporeal shockwave therapy (ESWT) using the dermaPACE device (Sanuwave, Alpharetta, GA, USA) and hyperbaric oxygen therapy (HBOT) in chronic diabetic foot ulcers. Patients (n=87) were randomized to either the ESWT group (n=39 patients/44 feet) or the HBOT group (n=38 patients/40 feet).This study included patients with chronic non-healing diabetic foot ulcers for greater than three months duration. The healing of the ulcers was evaluated using clinical assessment, blood flow perfusion scan and histopathological examination. Clinical assessment of the ulcer status was performed by physical examination at three and six weeks, then once every three months and included visual observation and photo-documentation. Blood flow perfusion scan and histopathological examination were performed prior to the initiation of the treatment protocol and as part of the last examination. The clinical results after one treatment course showed completely healed ulcers in 57% and 25% ($p=0.003$); ≥ 50% improved ulcers in 32% and 15% ($p=0.071$); unchanged ulcers in 11% and 60% ($p<0.001$) for the ESWT group and the HBOT group, respectively. Twenty-seven patients also received a second course of treatment due to improved but incomplete healing of the ulcers 4–6 weeks from the first treatment. The results after a second course of treatment showed completely healed ulcers in 50% and 6% ($p=0.005$); ≥ 50% improved ulcers in 43% and 47% ($p=0.815$); unchanged ulcers in 7% and 47% ($p=0.015$) for the ESWT group and the HBOT group, respectively. Prior to the initiation of treatment, the blood flow perfusion rates were comparable between the two groups ($p=0.245$). The blood flow perfusion rates were significantly increased after ESWT ($p<0.001$), whereas, the changes after HBOT were not statistically significant ($p=0.916$). Following the treatment protocol, the difference in blood flow perfusion rate between the two groups became statistically significant favoring the ESWT group ($p=0.002$). In histopathological examination, the ESWT group showed considerable increases in cell proliferation, cell concentration and cell activity, and a decrease in cell apoptosis as compared to the HBOT group. Adverse events included four patients in the HBOT group developed middle ear barotraumas and sinus pain. The symptoms resolved spontaneously upon the release of the chamber air pressure. No other adverse events were related to neurovascular complications or device related problems. Author acknowledged limitations included: the small patient population, unblinding of patients and providers, different grades of ulcers, lack of long-term follow-up and use of only one type of shockwave device. Although the results of the current study demonstrated that ESWT is more effective than HBOT in chronic diabetic foot ulcers, additional, larger well-designed controlled trials with long-term follow-up are needed to determine the role of ESWT in chronic non-healing diabetic foot ulcers.

Moretti et al. (2009) conducted an RCT (n=30) of patients with neuropathic diabetic foot ulcers treated with standard care and ESWT or standard care alone. The healing of the ulcers was evaluated over 20 weeks by the rate of re-epithelization. After 20 weeks of treatment, 53.33% of the ESWT-treated patients had complete wound closure compared with 33.33% of the control patients, and the healing times were 60.8 and 82.2 days, respectively ($p<0.001$). Significant differences in the index of the re-epithelization were observed between the two groups ($p<0.001$).

Literature Review – Burns: Aguilera-Sáez et al. (2022) conducted a prospective, randomized, controlled trial that evaluated the efficacy of using extracorporeal shock wave therapy (ESWT) in the treatment of burn scars. Adult patients (n=40) with burn scars were randomized into two groups: the ESWT group (n=20) and the control group (n=20). The ESWT group received the ESWT (DermaPACE1 System, SANUWAVE Health Inc., USA) twice per week for four weeks and the control group received the standard treatment for burn scars. Outcomes measured the appearance of scar with the Vancouver Scar Scale (VSS), pruritus and pain with Visual Analog Scale (VAS) before the start of the treatment and at two weeks and five months after the treatment. Both groups showed improvements in all measured outcomes through the study. At six months, the improvements were statistically significant for the appearance of the scars in the control group and pain and pruritus in the ESWT group. There were not any statistically significant differences between the ESWT and the control group at two weeks after treatment or at five months after treatment. A limitation of the study included that the study was conducted in Spain and the results may not be applicable to other races or ethnic groups. The authors concluded that the efficacy of ESWT as adjunctive treatment for burn scars as far as outward appearance, pain and pruritus as end-results is questionable. However, further studies with large patient populations are needed to validate the findings in this study. No health disparities were identified by the investigators.

Lee et al. (2020) conducted a double-blinded, randomized, controlled trial to investigate the regeneration effect of extracorporeal shock wave therapy (ESWT) on hypertrophic scar regeneration using objective measurements. The study included Korean burn patients who had complete epithelialization on scars following autologous split-thickness skin grafting (STSG) using Matriderm. Patients (n=48) were randomized to either the ESWT group (n=25) or control group (n=23) group. Both groups received standard treatment for burn scars, which included occupational therapy, physical therapy, stretching exercises, pruritus/scar pain medication, pressure therapy, moisturizing cream and silicone gel application. Efficacy outcomes were measured by comparing the skin test results (thickness, melanin, erythema, thickness, elasticity, transepidermal water loss [TEWL], sebum, and skin elasticity levels) between the ESWT and control groups. The interval between treatments was one week and skin characteristics were measured before treatment and after six weeks of treatment for both groups. The improved changes from pre-treatment to post-treatment showed significant changes in scar thickness, erythema and sebum in favor of the ESWT group compared to the control group (p=0.03, p=0.03, p=0.02; respectively). There were no significant differences between the two groups for melanin levels, transepidermal water loss (TEWL), skin distensibility, biological skin elasticity, gross skin elasticity, and skin viscoelasticity (p=0.62, p=0.94, p=0.87, p=0.32, p=0.37, and p=0.29; respectively). Study limitations included possibly generalizability due to the high number of men in the study and small sample size. The authors concluded that ESWT has objective beneficial effects on burn-associated scar characteristics, however further study is required to observe the changes of scar characteristics over a longer time frame, and psychometrics measurements. Additionally, studies regarding ESWT protocols (intensity, frequency, and interval) are necessary. The authors noted that in order to confirm the mechanisms of the effects on the scar characteristics observed in this study, future cellular and molecular studies are essential.

Joo et al. (2020) conducted a double-blinded, randomized, controlled trial that evaluated the efficacy of extracorporeal shock wave therapy (ESWT) compared to sham stimulation therapy on hypertrophic scars of the hand caused by burn injury. Included patients were age 18 years and older who had sustained a deep partial-thickness (second-degree) burn or a full thickness (third-degree) burn on the right hand. The burn was treated with a split-thickness skin graft (STSG) < 6 months prior to enrollment. All included patients were in the re-epithelialization phase of wound healing. Patients (n=48) were randomized to the ESWT group (n=23) or the sham group (n=25). Patients in both groups received standard rehabilitation treatment for burn injuries to the hands, including medication, scar lubrication, massage therapy to the scars, and occupational therapy to improve hand function. Occupational therapy treatment consisted of 20 sessions (30 min per day, five days a week) for four weeks. Patients received one ESWT or sham treatment session per week for four weeks. The outcomes measured the change in the severity of pain, scar thickness, and hand function between the ESWT and sham groups, from baseline measures taken immediately before the intervention and measures taken immediately after session four. The change in the score from baseline to post-treatment was compared between the two groups. ESWT significantly improved the pain score (p=0.001), scar thickness (p=0.018), scar vascularity (p=0.0015), and improved hand function (simulated card-turning, p=0.02; picking up small objects, p=0.004). The other measured outcomes were not significantly different between the two groups. Author noted limitations included the small sample size, short term follow-up period, and the absence of detailed measurement of range of motion in the affected hand. The authors concluded ESWT is effective in decreasing pain, suppressing hypertrophic scarring, and improving hand function. However, future studies with a longer time frame and more detailed assessment are needed to confirm the findings of this study. Additional research into the mechanisms underlying the clinical effects of ESWT are needed to determine optimal parameters for the clinical management of hypertrophic scars.

Samhan and Abdelhalim (2019) conducted a randomized placebo-controlled, double-blind trial that evaluated the impacts of low-energy extracorporeal shockwave therapy (low-energy ESWT) in the management of pain, pruritus and health-related quality of life (HRQOL) in patients with burns. Adults aged 18–55 years with partial to full thickness burns that were cured in a spontaneous manner without surgery or received a skin graft (split or full thickness graft) were included in the study. Patients (n=45) were randomized into the low-energy ESWT study group (n=22) or to the placebo group (n=23). The study group received low-energy ESWT once per week for four consecutive weeks and the placebo group received ESWT without energy. Both groups received the traditional physical therapy program under supervision of trained physical therapists in addition to low-energy ESWT three days per week for four weeks. Outcomes were measured before and after treatment procedures in both groups using the Numerical Rating Scale (NRS) for pain and for pruritus, Pressure Pain Threshold (PPT), 12-Item Pruritus Severity Scale (12-PSS), and Burn Specific Health Scale-Brief (BSHS-B). The Numerical Rating Scale (NRS) for was decreased significantly in the study group than in the placebo group (p<0.05). The PPT, 12-PSS, and BSHS-B scores were improved more significantly in the study group than in the placebo group (p<0.05) while body image and burn associated issues were improved at the same level in both groups (p>0.05). The authors concluded that low-energy ESWT decreased post-burn pain, increased PPT, and improved 12-PSS scale in form of decreasing post-burn pruritus recurrence, periods, influence on ADL and emotion, reaction to pruritus, severity, and extent. Simultaneously, HRQOL was improved in the study group including a total score, especially in physical capabilities domain, and psychosocial issues domain while body image and burn associated issues slightly improved at the same level within both groups because they need long time to be better. Further studies should be concerned with the long-term effects and different dosage of low-energy ESWT on post burn pain, pruritus and HRQOL.

Joo et al. (2018) conducted a prospective, single-blinded, randomized controlled trial that investigated the effect and mechanisms of extracorporeal shock wave therapy (ESWT) on burn scar pruritus. Patients (n=46) were randomized to the experimental group (n=23) or the sham stimulation group (n=23). Adults aged 18–75 years old with partial-to-full-thickness burns that had spontaneously healed or underwent skin grafting with a complaint of severe pruritus were included. The two groups received standard treatment, which included medication, scar lubrication, burn rehabilitation massage therapy, and physical therapy. The experimental group was treated with ESWT weekly for three weeks. The sham stimulation group was treated with the same shock wave equipment, but no energy was emitted. To assess the efficacy of treatment the numerical rating scale (NRS), 5D-Itch Scale, and Leuven Itch Scale were evaluated immediately before ESWT and after the third session. Laser Doppler blood perfusion imaging (LDI) was performed immediately before ESWT and after the first and third sessions. In the experimental group, NRS scores after the third ESWT were significantly decreased compared to those of the sham stimulation group (p=0.009). The duration, severity, and consequences scores of pruritus on the Leuven Itch Scale after the third ESWT were significantly decreased in the experimental group compared to the sham stimulation group (p=0.033, p=0.007, and p=0.009, respectively). The direction score on the 5-D Itch Scale after the third ESWT was significantly decreased in the experimental group compared to the sham stimulation group (p=0.033). After the first ESWT session and after three sessions, the burn area had a significant increase in perfusion according to LDI, compared with the scores before treatment in the experimental group (p=0.023 and p=0.013, respectively). Author noted limitations included that ESWT was performed in patients who had achieved re-epithelialization and the effects of ESWT for the management of acute pruritus during the inflammation and chronic remodeling phases of burn wound healing were not examined and only treatment for neuropathic pain was examined in the study.

Ottomann et al. (2012) conducted an RCT (n=44) of patients with acute second-degree burns who were assigned to receive standard therapy of debridement/topical antiseptic with (n=22), or without (n=22) ESWT. Randomization sequence was computer-generated, and patients were blinded to treatment allocation. The primary endpoint was time to complete burn wound epithelialization. Mean time to complete (≥ 95%) epithelialization for patients that did and did not undergo ESWT was 9.6 ± 1.7 and 12.5 ± 2.2 days, respectively ($p<0.0005$).

Although initial results from several RCTs and case series suggest that ESWT may promote wound healing, well-designed RCTs with larger patient populations and long-term follow-up are needed to support this wound treatment modality.

Miscellaneous Indications
ESWT has been proposed for other conditions, including but not limited to: delayed or nonunion fractures and osteonecrosis of the femoral head, greater trochanteric pain syndrome (GTPS), low back pain, neck pain, muscle spasticity, patellar tendinopathy, Achilles tendinopathy, trigger finger, chronic prostatitis/chronic pelvic pain syndrome and subacromial pain syndrome. ESWT for these indications has been evaluated in randomized controlled trials, systematic reviews and uncontrolled studies with small patient populations ranging from 15–155 with short term follow-up (Elgendy, et al., 2022; Brunelli, et al., 2022; Sakr, et al., 2022; Abdelkader, et al., 2021; Chen, et al., 2021; Gatz, et al., 2021; Pinitkwamdee, et al., 2020; Rahbar, et al., 2021; Eftekharsadat, et al., 2020; Vidal, et al., 2011; Wang, et al., 2007).

Rajfur et al. (2022) conducted a randomized controlled trial that assessed the effectiveness of focused ESWT in reducing pain intensity and improving functional efficiency in patients with chronic low back pain (LBP). Patients (n=40) with L5–S1 discopathy with chronic LBP pain were randomized into two groups: experimental group A (n=20) and control group B (n=20). Group A received fESWT at the lumbar and sacral spine. Group B received sham fESWT. Outcomes measured pain using a visual analog scale (VAS) and Laitinen Pain Scale (LPS), and functional status using the Oswestry Disability Index (ODI) before and after treatments, as well as follow-up observations at one and three months following ESWT. There was a significant analgesic effect (VAS and LPS) in both groups; however, it was significantly greater in the experimental group compared to the sham group ($p<0.05$). A more significant decrease in the perceived pain (VAS and LPS) was observed immediately after the active fESWT therapy. After one and three months, there were no significant between-group differences ($p>0.05$). Also, there was a significant effect in terms of functional state (ODI) for both groups ($p<0.05$); however, between-group comparisons revealed no statistically significant differences ($p>0.05$). Author noted limitations included the small patient population and short-term follow-up. Additionally, future research should use objective measurement methods (e.g., stabilometric platform, surface electromyography). An additional limitation of the study was that the study only included patients in Poland and the results may not be applicable to other races or ethnic groups. The authors concluded that ESWT reduces pain, although it does not seem to significantly improve a patient's functional state. Further clinical trials should be done, especially regarding patient functional evaluation after applying focused ESWT. No health disparities were identified by the investigators.

Abdelkader et al. (2021) conducted a double-blind randomized controlled trial (RCT) that compared the efficacy of conservative physical therapy treatments to ESWT with conservative physical therapy treatments for treating chronic noninsertional Achilles tendinopathy (NAT). Adult patients with unilateral NAT (n=50; n=22 men, n=28 women) who failed standard conservative treatment were randomized into two groups. Patients in the study group (n=25) received four sessions of ESWT at weekly intervals in addition to conservative physical therapy treatments. Patients in the control group (n=25) received the same conservative physical therapy treatment as well as sham ESWT. Function and pain were assessed at baseline, one month, and 16 months using the Victorian Institute of Sport Assessment–Achilles questionnaire (VISA-A) and visual analog scale (VAS), respectively. Both groups significantly improved one month posttreatment, however functional scores and pain reduction was significantly better in the study group than in the control group (both $p=0.0001$). At the 16-month follow-up, the functional and pain scores were significantly better than those at the baseline ($p=0.0001$ for both). At all-time points, both scores in the study group were significantly better than those in the control group (p=0.0001 for both). Author noted limitations included a lack of outcome data between posttreatment and the final follow-up. Additional limitations include the small patient population, short-term follow-up and that the study only included patients in Egypt and the results may not be applicable to other races or ethnic groups. The authors concluded that adding ESWT to conservative physical therapy treatment resulted in significantly greater improvements in both the short and long term. However, further long-term studies with large patient populations are needed to validate the findings in this study. No health disparities were identified by the investigators.

Mansur et al. (2021) conducted a single-center, double-blinded, randomized controlled trial that evaluated if the use of shockwave therapy in combination with eccentric exercises improves pain and function in patients with Achilles insertional tendinopathy (AIT). Patients were eligible for inclusion if they were aged 18 and 75 years, experiencing pain at the calcaneal tendon insertion for at least three months, and a diagnosis of AIT. Patients (n=109) were randomized into either the treatment group (n=58) or the control group (n=61). The treatment group (SWT group) received eccentric exercises with extracorporeal shockwave therapy and the control group received eccentric exercises with sham shockwave therapy. Patients were assessed at baseline and at two, four, six, 12, and 24 weeks after the first intervention. Three sessions of radial shockwaves (or sham treatment) were performed every two weeks and eccentric exercises were undertaken for three months. The primary outcome measured function at 24 weeks using the Victorian Institute of Sport Assessment-Achilles questionnaire (VISA-A). Secondary outcomes measured visual analogue scale (VAS) for pain, Foot and Ankle Outcome Score (FAOS), and 12-item Short Form Health Survey (SF-12). A total of 23 patients were lost to follow-up at the 24-week assessment. At the 24-week evaluation, the SWT group exhibited a mean VISA-A of 63.2 compared to 62.3 in the control group (p=0.876). Both groups showed significant improvement (all p>0.05) in all outcomes during the study but there were not significant differences between the groups in any of the outcomes. In the SWT group there was a higher rate of failure (38.3%) with a lower rate of recurrence (17.0%) compared to the control group (11.5% and 34.6%, respectively; p=0.002 and p=0.047). There were no complications reported for either group. Author noted limitations included: the recruitment took place at a single, tertiary center that limited generalizability, short term follow-up and the amount of patients lost to follow-up. Lastly, the authors noted that previous muscle quality and tendon degeneration was not evaluated. The study concluded that extracorporeal shockwave therapy does not potentiate the effects of eccentric strengthening in the management of Achilles insertional tendinopathy. No health disparities were identified by the investigators.

Walewicz et al. (2019) conducted a prospective, single-blinded randomized controlled trial that assessed the influence of radial extracorporeal shock wave therapy (rESWT) in patients with low back pain (LBP). Adult patients (n=40) with MRI confirmed discopathy of the L5-S1 spine segment, chronic pain lasting more than three months, pseudo-radicular pain syndrome not previously treated with spine surgery were included in the study. Patients were randomized into two groups, group A received rESWT (n=20) and group B received sham treatment (n=20). Patients from group A had rESWT performed twice a week for five weeks (10 sessions) and group B was treated with sham rESWT. Both groups received stabilization training. Measured outcomes assessed pain and functional efficiency using the following: Visual Analog Scale (VAS), Laitinen Pain Scale (LPS), and Oswestry Disability Index (ODI). Outcomes were measured before the start and after the end of the full cycle of ESWT treatment. Measurements were repeated as a follow-up at one and three months after the end of the study. After the end of the study, group A had a statistically significant reduction in pain over the rESWT group (p=0.039). However, at the one- and three-month follow-up, group A experienced significantly more pain relief (p>0.05, p<0.0001; respectively) and change in functional state pain sensations (p=0.033, p=0.004; respectively) than group B. An author noted limitation included the small patient population. The study concluded that the results are promising but require further verification.

Zhong et al. (2019) conducted a randomized controlled trial that assessed the efficacy of low-dose extracorporeal shockwave therapy on osteoarthritis knee pain, lower limb function, and cartilage alteration for patients with knee osteoarthritis. Patients (n=63) with a six-month history of knee osteoarthritis symptoms were randomly assigned to two groups. Patients in the experimental group (n=32) received low-dose ESWT for four weeks while those in the placebo group (n=31) received sham shockwave therapy. Both groups maintained a usual level of home exercise. Measured outcomes assessed knee pain and physical function using a visual analog scale (VAS), the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), and the Lequesne index at baseline, five weeks, and 12 weeks. Cartilage alteration was measured analyzing the transverse relaxation time (T2) mapping. Five patients were lost to follow-up. The VAS score, WOMAC, and Lequesne index of the ESWT group were significantly better than those of the placebo group at five and 12 weeks ($p<0.05$). Both groups showed improvement in pain and disability scores over the 12-week follow-up period ($p<0.05$). There was no significant difference in imaging results between groups during the trial, although T2 values of the ESWT group at 12 weeks significantly increased compared to those at baseline ($p=0.004$). The number and prevalence of adverse effects were similar between the two groups, and no serious side effects were found. The authors noted several limitations to the study. Patients had similar degrees of knee pain and radiographic knee OA before treatment. It is unknown whether patients with higher level of pain and more severe knee OA would benefit from ESWT. The optimal treatment protocol has not been established and high expectations and large placebo responses may influence the assessment of effect. The results may have been due to chance because of the small patient population studied. Lastly, the study was only three months, and the sustained effects for longer duration remain unknown. The authors concluded that a four-week treatment of low-dose ESWT was superior to placebo for pain easement and functional improvement in patients with mild to moderate knee osteoarthritis but had some negative effects on articular cartilage. Future studies should recruit more patients to observe the long-term effects of ESWT on knee OA and cartilage.

Gezgİnaslan and GÜmÜŞ (2019) conducted a single blind randomized-controlled trial that investigated the effects of extracorporeal shock wave therapy (ESWT) on pain, sleep, fatigue, disability, depression, and quality of life (QoL) in patients with myofascial pain syndrome (MPS). Patients with a diagnosis of MPS were included in the study if they had persistent myofascial pain at trapezius levator scapulae, supraspinatus, or infraspinatus for at least for six months and having at least three myofascial trigger points (MTrPs). The patients (n=94; 16 males and 78 females) were randomized into two groups. The treatment group (n=49) received a total of seven sessions of high-energy flux density ESWT (H-ESWT) every three days. The control group (n=45) received the following treatment: hot pack, transcutaneous electrical nerve stimulation, and ultrasound for five days for two weeks. At baseline and one month after treatment; pain, quality of life (QoL), sleep, depression, fatigue, and disability in patients with MPS were assessed and compared between the groups. After treatment, both groups reported statistically significant decreases in pain, improved QoL, sleep, depression, fatigue, and disability (all $p<0.001$). However, when the groups were compared, the ESWT group reported statistically significant decreases in pain, improved QoL, sleep, depression, fatigue, and disability (all $p<0.001$). Author reported limitation included the presence of a non-treatment group and a larger sample size would increase the power of results. Additional limitations include small patient population, disproportionate amount of males and females enrolled and short-term follow-up. The authors concluded that the study results suggest that H-ESWT is more effective than traditional physical therapy methods on pain, QoL, sleep, fatigue, depression, and disability in patients with MPS. However, they recommend further largescale, long-term studies to confirm these findings and to establish a definite conclusion. No health disparities were identified by the investigators.

Ramon et al. (2020) conducted a multicenter, randomized, controlled trial in Italy that assessed the effectiveness of electromagnetic-focused extracorporeal shockwave treatment (F-ESWT) in patients with greater trochanteric pain syndrome (GTPS). Patients (n=103) were included in the study if they were age ≥ 18 years, had unilateral pain in the greater trochanteric area for > 3 months, had pain while lying on the affected side and had local tenderness on palpation of the greater trochanteric area. Patients were randomized to the treatment group (n=53), that consisted of electromagnetic F-ESWT and a specific exercise protocol, or the control group (n=50), that received sham F-ESWT and the same exercise protocol. Both groups were treated with three weekly sessions. Patients were assessed at baseline and one, two, three and six months after treatment. The primary outcome measured pain using a visual analogue scale (VAS) score at two months. Secondary outcomes measured hip disability, lower extremity function, quality of life (QoL) and patient satisfaction. The mean VAS score significantly decreased from 6.3 at baseline to 2.0 in the F-ESWT group versus 4.7 in the control group at two months ($p<0.001$). All secondary outcomes at all follow-up intervals were significantly better in the F-ESWT group, except for the lower extremity functional score at one month after treatment ($p=0.25$). No complications were observed. Author noted limitations included the lack of follow-up of > 6 months after the intervention and the control group received 3 F-ESWT sessions at the lowest setting and it could be considered a quasiplacebo group. Thirdly, patients' compliance with the home exercise protocol was not exact. Lastly, women were more likely to be in the treatment group and a sample size of 103 patients may be not large enough to detect important differences in between the sexes. An additional limitation was the population studies only included white race and the results may not be applicable to other races or ethnic groups. The authors concluded that F-ESWT in association with a specific exercise program is safe and effective for GTPS, with a success rate of 86.8% at two months after treatment. However, further research is necessary to confirm the long-lasting effectiveness of F-ESWT for GTPS.

A randomized controlled trial (RCT) conducted by Carlisi et al (2019) investigated if focused extracorporeal shock wave therapy (f-ESWT) is an effective treatment in patients with greater trochanteric pain syndrome (GTPS). Patients (n=50) were randomized into the f-ESWT study group (n=26) or the ultrasound therapy (UST) control group (n=24). Patients in the study group were treated with focused extracorporeal shock wave therapy once a week for three consecutive weeks. Patients in the control group were treated with ultrasound therapy daily for 10 consecutive days. Patients 18–80 years of age were enrolled if they met the following inclusion criteria: unilateral hip pain persisted for six weeks or longer; physical examination showed pain to palpation in the greater trochanteric area and pain with resisted hip abduction; patient had gluteal tendinopathy, in the absence of full thickness tears; no corticosteroid injections or other conservative therapies (except pharmacological pain treatments), since the onset of the current pain episode; shock wave therapy was not contraindicated; absence of clinical signs of lumbar radiculopathy at physical examination; no hip or knee osteoarthritis, no previous fractures or surgery in the affected limb and no rheumatologic diseases. The outcomes measured hip pain and lower limb function by means of a numeric rating scale (p-NRS) and the Lower Extremity Functional Scale (LEFS scale), respectively. The first follow-up evaluation was performed two months after the first treatment session, the second was carried out six months later. The statistical analysis on the intention to treat population, showed a significant pain reduction over time for the study group and the control group, the f-ESWT proving to be significantly more effective than UST at the two-month follow-up ($p=0.020$) and at the six month follow-up ($p=0.047$). A marked improvement of the LEFS total score was observed in both groups without statistical differences between groups. Author noted limitations included the small patient population, short term follow-up and unblinding of the patients. The authors concluded that f-ESWT is effective in reducing pain, both in the short-term and in the mid-term perspective, however it is not superior to UST.

Kvalvaag et al. (2018) conducted a randomized, double-blind, sham-controlled trial to evaluate the effect of radial extracorporeal shock wave therapy (rESWT) in addition to supervised exercises in patients with subacromial pain syndrome. Patients (n=143) aged 25 to 70 years, with subacromial pain syndrome lasting at least three months were included and randomly assigned to receive either rESWT and supervised exercises (n=74) or sham rESWT and supervised exercises (n=69). Primary outcomes measured the effectiveness of treatment using The Shoulder Pain and Disability Index (SPADI) and work status. The secondary outcomes measured pain at rest, pain during activity, shoulder function, health-related quality of life and sick leave. Patients had a follow-up one year following treatment. After one year, no differences were found for the SPADI Score (p=0.89). At one year, the results for differences between groups regarding pain at rest and during activity, shoulder function, health-related quality of life and sick leave were not significant (p=0.73, p=0.80, p=0.60, 0.94, p=0.47, respectively). A prespecified subgroup analysis was performed on the patients with medium and large sized calcification which demonstrated no significant additional effect of rESWT to supervised exercises (p=0.44). Author noted limitations included the lack of a control group and the study may be underpowered for detecting a difference in the subgroup of patients with calcification in the rotator cuff. The authors concluded that radial ESWT was not superior to sham rESWT in addition to supervised exercises in the long term for patients with subacromial pain syndrome.

A 2016 report issued by the Canadian Agency for Drugs and Technologies in Health (CADTH) reviewed evidence (n=7 systematic reviews) on the effectiveness of shockwave therapy for pain associated with lower extremity orthopedic disorders. Studies included adults with chronic pain associated with lower extremity orthopedic disorders treated (e.g., plantar fasciitis or heel pain; patellar tendinopathy or knee pain; medial tibial stress syndrome, or shin pain) with shockwave therapy or a comparator. Outcomes in studies were pain reduction, reduced need for opioids, and adverse events. Articles comparing different types of SWT without a non-SWT arm were excluded, as well as studies on fracture, cancer pain, arthritis pain, and back pain. The report concluded that there is some suggestion that SWT is an effective treatment option in comparison to placebo for plantar fasciitis. Limited evidence was found to suggest that the effectiveness of SWT is comparable to platelet rich plasma injection, corticosteroid injection or surgery. Adverse effects reported with SWT included skin reddening, bruising at the site of application, and local swelling and pain. Studies demonstrated inconsistent results for SWT used to treat greater trochanteric pain syndrome, patellar tendinopathy, and medial tibial stress syndrome. It was concluded that more evidence is needed to determine whether SWT is more clinically effective than surgery for pain associated with lower extremity orthopedic disorders (CADTH, 2016).

A systematic review (n=4 RCTs/252 patients) by Seco et al. (2011) evaluated the evidence on the safety and effectiveness of ultrasound and shock wave to treat low back pain. It was summarized that the available evidence does not support the effectiveness of ultrasound or shock wave for treating LBP. High-quality RCTs are needed to assess their efficacy versus appropriate sham procedures, and their effectiveness compared to other procedures shown to be effective for LBP.

There is insufficient evidence to draw conclusions regarding the use of ESWT for the treatment of the outlined conditions.

Professional Societies/Organizations: In 2017 the Washington State Health Care Authority (WSHCA) conducted a technology assessment that evaluated the comparative efficacy, effectiveness, and safety of ESWT in adults for the treatment of various musculoskeletal and orthopedic conditions, including but not limited to plantar fasciitis, tendinopathies, adhesive capsulitis of the shoulder, and subacromial shoulder pain. As part of the technology assessment a total of 72 randomized controlled trials were included and reviewed. Limitations of the studies noted by the Committee generally included potential for risk bias, short-term follow-up, inconsistency of measured outcomes, and lack of high-quality evidence and small sample sizes. The authors concluded extracorporeal shock wave therapy was unproven for efficacy and cost-effectiveness.

A position paper by the Ohio Bureau of Workers' Compensation (BWC) assessed the literature on the use of ESWT for musculoskeletal conditions. The report concluded that studies of ESWT have not shown consistent results or efficacy in the treatment of plantar fasciitis, epicondylitis, and noncalcific tendonitis of the shoulder. Therefore, ESWT is investigational for these indications. Although the use of ESWT in the treatment of calcific tendonitis of the shoulder shows preliminary good results, replication of the results in additional studies would be beneficial. Likewise, additional studies describing beneficial outcomes in the treatment of nonunion of fractures would be valuable (Ohio BWC, 2005).

Medicare Coverage Determinations

	Contractor	Determination Name/Number	Revision Effective Date
NCD	National	No National Coverage Determination found	
LCD	Palmetto GBA	Extracorporeal Shock Wave Therapy (ESWT) L38775	2/14/2021

Note: Please review the current Medicare Policy for the most up-to-date information.
(NCD = National Coverage Determination; LCD = Local Coverage Determination)

Coding Information

Notes:
1. This list of codes may not be all-inclusive.
2. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Considered Experimental/Investigational/Unproven for any indication:

CPT®* Codes	Description
20999	Unlisted procedure, musculoskeletal system, general
28890	Extracorporeal shock wave, high energy, performed by a physician or other qualified health care professional, requiring anesthesia other than local, including ultrasound guidance, involving the plantar fascia
28899	Unlisted procedure, foot or toes
0101T	Extracorporeal shock wave involving musculoskeletal system, not otherwise specified
0102T	Extracorporeal shock wave performed by a physician, requiring anesthesia other than local, 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)

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Revision Details

Type of Revision	Summary of Changes	Date
Annual	• No policy statement changes.	11/15/2023