Medical Coverage Policy

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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. Refer to the customer’s benefit plan document for coverage details.

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], 2009b; 2012c). 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 (Hayes 2016a; reviewed 2018 a). 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; reviewed 2018b). 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 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 cm², 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.”
The two radial ESWT devices that are currently approved by the FDA are the EMS Swiss Dolorclast® and the Storz Medical Duolith SD1 (Hayes 2016b; reviewed 2017). 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; Kudo, et al., 2006; Malay, et al., 2006; Theodore, et al., 2004; Rompe, et al., 2003), while similar improvement rates for both treatment and placebo groups have been reported in other studies (Radwan, et al., 2012; Haake, et al., 2003; Buchbinder, et al., 2002). 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.

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 non randomized 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. 326 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 the 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 Directory Report published by Hayes reviewed the available literature on focused ESWT for Chronic Plantar Fasciitis. The review included randomized controlled trials (RCTs) (n=17 studies), with studies comparing ESWT to sham treatment (10 RCTs), or to other active treatments (six RCTs), and one RCT comparing full-dose ESWT to low-dose ESWT. Sample sizes ranged from 54–293 patients. Outcome measured in studies were patient-rated pain on visual analog scale (VAS), pain threshold, functional measures, quality of life (QOL), overall treatment success, and complications. Follow-up occurred through five years. Some evidence was found suggesting that ESWT may decrease patient-reported pain and increase functional outcomes in the short term for patients with plantar fasciitis, however study results were conflicting. Most of the complications reported were transient and consisted of swelling, bruising, and pain or discomfort associated with treatment. The overall body of evidence evaluating ESWT for plantar fasciitis was described as large in size and moderate in quality. The authors noted that despite some positive findings, placebo-controlled trials did not consistently demonstrate statistically significant differences in outcomes between ESWT and sham treatment. It was concluded that additional controlled, blinded long-term safety data from well-designed trials on ESWT for plantar fasciitis are needed further evaluate the technology (Hayes 2016a; reviewed 2018a).

Another published Hayes Directory Report reviewed the available literature on radial ESWT for chronic plantar fasciitis. The review included RCTs (n=10 studies), with studies comparing radial ESWT to sham treatment (four RCTs), or to other active treatments (five RCTs), and one RCT comparing radial ESWT with focused ESWT. Sample sizes ranged from 25–252 patients. Outcomes measured were patient-rated pain on VAS, pain threshold, functional measures, QOL, overall treatment success, and complications. Follow-up ranged from two months to 24 months. Although some of the moderate-size body of evidence suggested that radial ESWT may decrease patient-reported pain and increase functional outcomes in the short term for patients with plantar fasciitis, results were conflicting. When reported, complications were primarily transient and consisted of swelling, bruising, and pain or discomfort associated with treatment. The overall quality of the evidence was low with a small amount of long-term safety data available. Limitations of the evidence includes methodological weaknesses of individual studies such as lack of long-term follow-up, confounding due to secondary treatments, and high loss to follow-up. Similar to the findings with focused ESWT for the treatment of plantar fasciitis, it was concluded that additional controlled, blinded long-term studies are needed to assess the safety and effectiveness of radial ESWT (Hayes 2016b; reviewed 2018b).

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 (Li, et al., 2018a; Li, et al., 2018b; Xiong, et al., 2018). 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 (Sun, et al., 2017).

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 that 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: 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.

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 (BO), while secondary outcomes measured the intensity of pain at rest using 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=56–114) 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
Aydin 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 epicondylitis (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=7–10 studies/712–1099 patients) have evaluated the effectiveness of ESWT in treating chronic lateral epicondylitis. These studies have yielded conflicting results (Buchbinder, et al., 2006; Stasinopoulos and Johnson, 2005).

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; Gerdesmeyer, et al., 2003). 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.
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.

Lee et al. (2011) performed a systematic review of RCTs (n=9 studies) examining the midterm effectiveness of ESWT for calcified rotator cuff tendinitis. The review found consistent evidence of midterm effectiveness of ESWT in reducing pain and improving shoulder function. However it was determined that the different outcome
measures used and inadequate reporting details in the included studies did not permit a quantitative synthesis of the effectiveness of this treatment. A lack of follow up period beyond one year in the studies was also a limitation and did not allow for conclusions to be made on the longer term effectiveness of ESWT.

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 needed 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.
A prospective case series (n=208) by Schaden et al. (2007) evaluated patients with nonhealing acute and chronic soft-tissue wounds whose treatment consisted of debridement, ESWT, and moist dressings. Of the 176 patients completing the study, 156 (75%) had 100% wound epithelialization. During mean follow-up period of 44 days, there was no treatment-related toxicity, infection, or deterioration of any ESWT-treated wound. Age (p=0.01), wound size ≤ 10 cm² (p=0.01), and duration ≤ one month (p<0.001) were found to be independent predictors of complete healing. Study limitations include lack of a comparison to a control group and short-term follow-up.

**Literature Review – Diabetic Foot Ulcers:** Hayes Inc. (2019) published an emerging technology report on the dermaPACE System for diabetic foot ulcers (DFUs). The dermaPACE system delivers a proprietary type of extracorporeal shock wave therapy (ESWT) known as Pulsed Acoustic Cellular Expression (PACE) therapy. The prescription device consists of an electrohydraulic generator and wave applicator that is glided over the target ulcer. Hayes concluded that there is insufficient evidence in the published literature at this time to assess whether the addition of ESWT with the dermaPACE system significantly expedites wound healing in patients with diabetic foot ulcers.

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 cm² (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, adhesive or non-adhesive 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
ESWT significantly decreased from 1–5 years after treatment and additional studies are needed. ESWT appears effective in the treatment of chronic diabetic and nondiabetic foot ulcers. However, the effects of ESWT in 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 need 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:** 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 delayed or nonunion fractures and osteonecrosis of the femoral head, greater trochanteric pain syndrome (GTPS), low back pain, muscle spasticity, patellar tendinopathy and subacromial pain syndrome. ESWT for these indications has been evaluated in few controlled and uncontrolled studies with small patient populations ranging from 15–56 (Vidal, et al., 2011; Chen, et al., 2009; Wang, et al., 2007b; Taunton, et al., 2003) and presented in systematic reviews.

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 osteoarthritus, 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 (Seco, et al., 2011).

Zelle et al. (2010) performed a systematic review (n=11 studies/924 patients) of the literature for the use of ESWT in the treatment of fractures and delayed unions/nonunions. Studies were primarily case series (n=10) with one RCT. The overall union rate in patients with delayed union/nonunion was 76% (95% confidence interval 73%–79%) and ranged from 41% to 85%. Acknowledged limitations of the review included the lack of higher level evidence and lack of comparative data. It was noted that the natural history of these lesions remains unclear, and it may be assumed that some delayed unions may have healed using other non-operative treatment approaches.

One RCT (n=126) by Cacchio et al. (2009) compared ESWT to surgery for the treatment of long bone non-unions. At 24 months of follow-up, there were no differences found in clinical outcomes.

Alves et al. (2009) conducted a systematic review (n=5 studies) of the evidence examining the use of ESWT for osteonecrosis of the femoral head. The studies included two RCTs, an open label study, one comparative prospective study, and one case report. The lack of well-designed studies was noted, although “the non-controlled studies appeared to demonstrate some favorable result”.

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).

**Centers for Medicare & Medicaid Services (CMS)**
- National Coverage Determinations (NCDs): No NCD found
Use Outside of the US
The Therapeutic Goods Administration (TGA) is part of the Australian Government Department of Health and Ageing, and is responsible for regulating therapeutic goods including medicines, medical devices, blood and blood products. Any product for which therapeutic claims are made must be listed, registered or included in the Australian Register of Therapeutic Goods (ARTG) before it can be supplied in Australia. The following devices are included in the ARTG listing:

1. Orthopedic extracorporeal shock wave therapy system (Dornier MedTech GmbH, Wessling, Germany) as of September 9, 2010; intended use is for treating musculoskeletal disorders (e.g., tendinopathies and soft tissue pain near bones, plantar fasciitis, epicondylopathy) and other related muscle pain syndromes
2. Electromechanical orthopaedic extracorporeal shock wave therapy system (Richard Wolf GmbH, Knittlingen, Germany) as of February 11, 2012; intended use is for the elimination of chronic pain using focused, extracorporeal shock wave therapy and trigger point shock wave therapy

The University of New South Wales (UNSW) (2013) developed guidelines for the clinical management of rotator cuff syndrome in the workplace. The stated primary objective of these guidelines is to provide evidence-based recommendations to improve clinical outcomes for workers, employers and health care providers. According to the UNSW guidelines, when non-surgical measures fail and pain continues to significantly restrict routine activities, needle aspiration, surgical removal or ESWT may be indicated. Most of the evidence supporting ESWT for calcific tendonitis originates in Europe where there is widespread use of this technique. The UNSW further states that in Australia, ESWT is only available in a limited number of sports medicine clinics (Hopman, et al., 2013).

The National Institute for Health and Clinical Excellence (NICE) issued a guidance on the use of ESWT for refractory plantar fasciitis. According to NICE, a review of the evidence raises no major safety concerns; however, current evidence on the efficacy of ESWT for this indication is inconsistent. Therefore, the procedure should only be used with special arrangements for clinical governance, consent and audit or research (NICE, 2009b; 2012b).

A NICE guidance on the use of ESWT for refractory tennis elbow stated that the evidence on ESWT for refractory tennis elbow raises no major safety concerns; however, current evidence on its efficacy is inconsistent. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research (NICE, 2009a; 2012b). According to the NICE guidance on the use ESWT for calcific tendonitis of the shoulder, current evidence on the safety and efficacy appears adequate to support the use of the procedure provided that normal arrangements are in place for consent, audit, and clinical governance (NICE, 2003; 2012a). A NICE guideline on ESWT for refractory greater trochanteric pain syndrome stated that the current evidence on the efficacy and safety is limited in quality and quantity. Therefore, ESWT for refractory greater trochanteric pain syndrome should only be used with special arrangements for clinical governance, consent and audit or research (NICE 2011; 2012c). According to the NICE guidance on ESWT for Achilles tendinopathy the evidence raises no major safety concerns. However, current evidence on efficacy of the procedure is inconsistent and limited in quality and quantity. Therefore, ESWT for Achilles tendinopathy should only be used with special arrangements for clinical governance, consent and audit or research (NICE, 2016).

Coding/Billing Information

Note: 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:
<table>
<thead>
<tr>
<th>CPT® Codes</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>20999</td>
<td>Unlisted procedure, musculoskeletal system, general</td>
</tr>
<tr>
<td>28890</td>
<td>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</td>
</tr>
<tr>
<td>28899</td>
<td>Unlisted procedure, foot or toes</td>
</tr>
<tr>
<td>0101T</td>
<td>Extracorporeal shock wave involving musculoskeletal system, not otherwise specified, high energy</td>
</tr>
<tr>
<td>0102T</td>
<td>Extracorporeal shock wave, high energy, performed by a physician, requiring anesthesia other than local, involving lateral humeral epicondyle</td>
</tr>
<tr>
<td>0512T</td>
<td>Extracorporeal shock wave for integumentary wound healing, high energy, including topical application and dressing care; initial wound</td>
</tr>
<tr>
<td>0513T</td>
<td>Extracorporeal shock wave for integumentary wound healing, high energy, including topical application and dressing care; each additional wound (List separately in addition to code for primary procedure)</td>
</tr>
</tbody>
</table>


**References**


42. Ibrahim MI, Donatelli RA, Schmitz C, Hellman MA, Buxbaum F. Chronic plantar fasciitis treated with two sessions of radial extracorporeal shock wave therapy. Foot Ankle Int. 2010 May;31(5):391-7.


