Medical Policy Manual Medicine, Policy No. 90

Extracorporeal Shock Wave Therapy (ESWT)

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IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

Extracorporeal shock wave therapy (ESWT) uses shock waves directed at areas of pain; however, the mechanism by which ESWT has on musculoskeletal and soft tissue conditions is not well defined. The policy addresses ESWT for all musculoskeletal and soft tissue conditions.

MEDICAL POLICY CRITERIA

Extracorporeal shock wave therapy (ESWT), using either a high- or low-dose protocol, is considered **investigational** for all musculoskeletal and soft tissue indications, including but not limited to acute fracture, avascular necrosis, chronic epicondylitis (tennis elbow), delayed union and nonunion of fractures, erectile dysfunction (ED), plantar fasciitis, Peyronie's disease, soft tissue or wound repair, spasticity, and tendinopathies.

NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.

CROSS REFERENCES

None

BACKGROUND

EXTRACORPOREAL SHOCK WAVE THERAPY (ESWT)

Extracorporeal shock wave therapy (ESWT), also known as orthotripsy, has been available since the early 1980s for the treatment of renal stones, and has been widely investigated for the treatment of biliary stones. Shock waves create a transient pressure disturbance, which disrupts solid structures, breaking them into smaller fragments, allowing spontaneous passage and/or removal of stones. The mechanism by which ESWT might have an effect on musculoskeletal conditions is not well defined.

Chronic musculoskeletal conditions, such as tendinitis, can be associated with a substantial degree of scarring and calcium deposition. Calcium deposits may restrict motion and encroach on other structures such as nerves and blood vessels, causing pain and decreased function. One hypothesis is that disruption of these calcific deposits by shock waves may loosen adjacent structures and promote resorption of calcium, thereby decreasing pain and improving function. Other functions are also thought to be involved. Physical stimuli are known to activate endogenous pain control systems, and activation by shock waves may "reset" the endogenous pain receptors. Damage to endothelial tissue from ESWT may result in increased vessel wall permeability, causing increased diffusion of cytokines, which may in turn promote healing. Microtrauma induced by ESWT may promote angiogenesis and thus aid in healing. Finally, shock waves have been shown to stimulate osteogenesis and promote callous formation in animals, which is the rationale for ESWT in delayed union or non-union of bone fractures.

Both high-energy and low-energy ESWT protocols have been investigated. A high-energy protocol consists of a single treatment of high energy shock waves (1300mJ/mm^2). This painful procedure requires anesthesia. A low-energy protocol consists of multiple treatments, spaced one week to one month apart, in which a lower dose of shock waves is applied (1405mJ/ mm^2 over three sessions). This protocol does not require anesthesia.

PLANTAR FASCIITIS

Plantar fasciitis is a very common ailment characterized by deep pain in the plantar aspect of the heel, particularly on arising from bed. While the pain may subside with activity, in some patients the pain may persist, interrupting activities of daily living. On physical examination, firm pressure will elicit a tender spot over the medial tubercle of the calcaneus. The exact etiology of plantar fasciitis is unclear, although repetitive injury is suspected. Heel spurs are a common associated finding, although it has never been proven that heel spurs are the cause of the pain. It should be noted that asymptomatic heel spurs can be found in up to 10% of the population. Most cases of plantar fasciitis are treated with conservative therapy, including rest or minimization or running and jumping, heel cups, and nonsteroidal-anti-inflammatory drugs. Local steroid injection may also be used. Improvement may take up to one year in some cases.

Conservative therapy of plantar fasciitis is successful in the vast majority of cases. Rest or minimization of running or jumping is the cornerstone of therapy. Heel cups are sometimes helpful in alleviating symptoms, presumably by padding the heel and absorbing the impact of walking. Nonsteroidal anti-inflammatory drugs are also helpful in acute cases. If the above measures are ineffective, a local injection of steroids may be effective. Improvement is frustratingly slow and gradual, taking up to a year in some cases. For refractory cases, either open or endoscopic plantar fasciotomy may be considered.

TENDINOPATHIES

Tendinitis of the Shoulder

Tendinitis of the shoulder results from strain of the shoulder girdle muscles, most commonly the muscles of the rotator cuff. These small muscles control rotation of the shoulder and are prone to injury and inflammation due to their location and relative weakness.

Calcific tendinitis refers to a condition in which clinical signs and symptoms of tendinitis are accompanied by calcium deposition at the site of the affected tendon. This most commonly occurs at the origin of the supraspinatus muscle but may also involve other muscles of the rotator cuff. The cause of calcium deposition is not well understood, and there is not a clear correlation between clinical symptoms and the presence or extent of calcific deposits. Many patients with chronic tendinitis do not have calcium deposition, and less than half of patients with calcific deposition on x-ray exhibit clinical symptoms.

Initial therapy consists of rest, anti-inflammatory medications, physical therapy, and/or local corticosteroid injections. Response to conservative therapy varies, but it is common for shoulder tendinitis to become chronic, especially when the muscles of the rotator cuff are involved. When conservative treatment fails, a number of invasive techniques are available for both calcific and non-calcific tendinitis of the shoulder. For example, needle irrigation can be performed for calcific tendinitis, during which calcium deposits are localized and disrupted by needling under fluoroscopic guidance. Following disruption, irrigation and aspiration removes loose calcium particles. Approximately 10% of patients with chronic shoulder tendinitis undergo surgery, usually performed arthroscopically.

Tendinitis of the Elbow

Lateral epicondylitis is the most common form of tendinitis of the elbow, and results in lateral elbow pain and functional limitations. The disorder is caused by overuse or injury of the tendons that attach the arm muscles to the elbow, such as commonly occurs from playing tennis (“tennis elbow”). However, only a minority of cases are caused by playing tennis; the majority occur from other activities that involve repetitive extension of the wrist. Overuse of the extensor muscles lead to microtears at their insertion point, which incites an inflammatory response. Repetitive cycles of injury and inflammation lead to tendinosis, degeneration of the tendon structures, and disorganized healing.

The diagnosis of lateral epicondylitis is made by characteristic pain and tenderness at the lateral aspect of the elbow, in conjunction with typical activities or injury that accompany this condition. Radiologic imaging is not necessary for diagnosis but may be useful in ruling out other causes of lateral elbow pain, such as fracture, dislocation, degenerative joint disease, and other bony or soft tissue pathologies. Imaging is usually normal in lateral epicondylitis, although occasionally calcium deposition can be seen.

Conservative treatment consists of rest, activity modification, anti-inflammatory medications, and/or physical therapy. Corticosteroid injections and orthotic devices can also be tried as adjuncts to conservative measures. A number of surgical treatments are available for patients who do not respond to conservative treatment; approximately 5%–10% of patients with tendinitis of the elbow require surgery. Surgery may be performed as open or laparoscopic procedures. The general approach is to debride any degenerative or nonviable tissue and to repair tears or other structural abnormalities.

FRACTURE NONUNION AND DELAYED UNION

The definition of a fracture nonunion has remained controversial, particularly in the duration of time required to define a condition of nonunion. Complicated variables are present in fractures, i.e., degree of soft tissue damage, alignment of the bone fragments, vascularity, and quality of the underlying bone stock. The time period has been variously described as lack of visible signs of healing within three months, six months, or nine months. A substantial source for the disagreement regarding the clinical definition of nonunion stems from the use of heterogeneous study populations, which limit comparisons between studies. The nonunion fracture can be further defined as atrophic, in which no callus formation occurs, or hypertrophic, with callus formation at both sides of the fracture, but without fusion. Delayed union refers to a decelerating bone healing process, as identified in serial x-rays, together with a lack of clinical and radiologic evidence of union, bony continuity, or bone reaction at the fracture site for no less than three months from the index injury or the most recent intervention. (In contrast, nonunion serial x-rays show no evidence of healing.) When grouped together, delayed union and nonunion are sometimes referred to as ununited fractures.

ERECTILE DYSFUNCTION (ED)

Erectile Dysfunction can be a sign of a physical or psychological condition. It is characterized by the inability of a male to become erect, or the inability to maintain an erection. Depending on the cause of ED, treatments may include oral medications, testosterone therapy, penile injections, intraurethral medications, or surgery. One cause of ED may be related to the corpus cavernosum – the erectile tissue of the penis. This tissue fills with blood during an erection, and corpus cavernosum dysfunction may be related a variety of pathophysiologies. Treatments for corpus cavernosum dysfunctions may include surgery, steroid injections, or adrenergic receptor medicines. Another condition that may be related to ED is Peyronie’s disease or penile fibrosis. Peyronie’s disease is a condition in which fibrous scar tissue forms under the skin of the penis, resulting in an abnormally curved penile erection. This may cause pain, difficulty becoming erect, or inability to maintain an erection. Currently, the only FDA-approved treatment for Peyronie’s disease is intralesional collagenase injections.

WOUND HEALING AND OTHER NON-MUSCULOSKELETAL CONDITIONS

ESWT has been investigated to accelerate tissue repair and regeneration in various wounds including foot and pressure ulcers, burns, and scars. Specifically, ESWT may result in the upregulation of angio-active factors such as nitric oxide and vascular endothelial growth factor, resulting in induced angiogenesis. Other Musculoskeletal AND Neurologic Conditions

ESWT has been investigated for a variety of other musculoskeletal conditions, including medial tibial stress syndrome, osteonecrosis (avascular necrosis) of the femoral head, coccydynia, and painful stump neuromas. Spasticity refers to a motor disorder characterized by increased velocity-dependent stretch reflexes. It is one characteristic of upper motor neuron dysfunction, which may be due to a variety of pathologies.

REGULATORY STATUS

ESWT devices approved by the U.S. Food and Drug Administration (FDA) include the following:

Device Name	Type	FDA Approved Indication(s)
OssaTron® device (HealthTronics)	High-dose - Electrohydraulic delivery system	Chronic proximal plantar fasciitis for patients with symptoms of plantar fasciitis for 6 months or more that has failed to respond to conservative management. Chronic lateral epicondylitis (tennis elbow) that has failed to respond to conservative treatment.
Epos™ Ultra (Dornier)	High-dose - Electromagnetic delivery system	Treatment of chronic plantar fasciitis for patients with symptoms of plantar fasciitis for 6 months or more and a history of unsuccessful conservative therapy.
SONOCUR® Basic (Seimens)	Low-dose - Electromagnetic delivery system	Treatment of chronic lateral epicondylitis (commonly referred to as tennis elbow) for patients with symptoms of chronic lateral epicondylitis unresponsive to conservative treatments for more than 6 months.
Orthospec™ Extracorporeal Shock Wave Therapy Device (Medispec Ltd.,)	High-energy – Electrohydraulic/Spark Gap	Treatment of chronic proximal plantar fasciitis with or without heel spur in patients 18 years of age or older who have had symptoms for 6 months or more and a history of unsuccessful conservative therapies to relieve heel pain.
Orbasone™ Pain Relief System (Orthometrix)	High-energy – sonic wave	Treatment of chronic proximal plantar fasciitis in patients 18 years of age or older that has failed to respond to conservative therapy. Chronic proximal plantar fasciitis is defined as heel pain in the area of the insertion of the plantar fascia on the medial calcaneal tuberosity that has persisted for 6 months or more.
Dolorclast® (EMS - Electro Medical Systems)	Radial ESWT (rESWT)	Radial ESWT is generated ballistically by accelerating a bullet to hit an applicator, which transforms the kinetic energy into radially expanding shock waves. Other types of ESWT produce focused shock waves that show deeper tissue penetration with significantly higher energies concentrated to a small focus. Radial ESWT is described as an alternative to focused ESWT and is said to address larger treatment areas, thus providing potential advantages in superficial applications like tendinopathies.
Duolith® SD1 Shock Wave Therapy Device (Storz Medical AG)	Electromagnetic delivery	Treatment of chronic proximal plantar fasciitis in patients 18 years of age or older with a history of failed alternative conservative therapies for at least 6 months.
Dermapace System (SANUWAVE Health, Inc.)	High-energy electro-hydraulic	Provide 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. Indicated for adults (>22 years old), diabetic patients presenting with diabetic foot ulcers >30 days in duration and is indicated for us in conjunction with standard diabetic ulcer care.

EVIDENCE SUMMARY

The most clinically relevant outcomes of ESWT used for these conditions are improvements in pain and/or function. Both of these outcomes can be influenced by nonspecific effects, placebo response, natural history of the disease, and regression to the mean; therefore, they need to be evaluated in randomized, controlled trials that maintain satisfactory blinding of the treatment assignment. Pain outcomes require quantifiable pre- and post-treatment measures, which are most commonly measured with a visual analogue scale (VAS). Collectively, the pain measurement literature cautions against using only statistical significance of difference in mean change in scores to determine clinical significance. More meaningful to patients and clinicians is the correlation of improvement in pain scores with improvement in function and quality of life. Thus, quantifiable pre- and post-treatment measures of functional status are also necessary. Although there is a lack of validated instruments for many indications, in some cases the SF12 and SF36 (instruments for measuring health status and outcomes from the patient's point of view) may be employed for this purpose. Also, some studies were the Roles and Maudsley score, the Maryland Foot score, and the American Orthopedic Foot and Ankle Society (AOFAS) Ankle-Hindfoot scale.

ALL INDICATIONS

Technology Assessment

In 2017, a Healthy Technology Assessment (HTA) was conducted reviewing the evidence for the efficacy of ESWT for several musculoskeletal indications including plantar fasciitis, tendinopathies (shoulder, elbow), and knee osteoarthritis[1]. The HTA covered electronic databases such as PubMed, Cochrane, and the National Guideline Clearinghouse, from their inception to November 2016 to identify any relevant literature. The HTA included a total of 72 RCTs looking at the efficacy and safety of ESWT for several musculoskeletal indications. Outcomes were stratified by the duration of follow up including short term (<3 months), intermediate (3-12 months), and long term (>12 months). The primary outcomes that were assessed were a variety of pain outcomes and functional outcomes. The HTA concluded that there is not consistent, high quality evidence to support the use of ESWT for any indication. Specific results from the HTA are reported in their respective sections below.

PLANTAR FASCIITIS

Systematic Reviews and Technology Assessment

In their systematic review and meta-analysis, Li (2018) assessed RCTs to determine whether ESWT or corticosteroid injections (CSIs) are more effective in plantar fasciitis pain reduction (measured using VAS), treatment success, recurrence rate, function scores, and adverse events.[2] The review included 9 RCTs with a total of 658 cases in which 330 participants received ESWT and 328 received CSI. Meta-analyses showed that CSI is more effective than low-intensity ESWT at VAS reduction (3 months post-treatment: MD, -1.67; 95% CI -3.31 to -0.04; P=0.04; I2=85%). However, high-intensity ESWT is more effective than CSI (2–3 months posttreatment: MD, 1.12; 95% CI, 0.52–1.72; P=0.0003; I2=59%). One study followed patients for 12 months posttreatment and found no significant different in pain outcomes, and no significant difference was found in recurrence rates or functional scores between ESWT and CSI. Four ESWT recipients in one trial reported severe headache or migraine following the procedure; no severe adverse effects were reported for CSI. Though CSI is more readily available than ESWT, the authors reported that ESWT recipients have a faster return to full activities after the procedure. One limitation of this systematic review is the inclusion of only nine trials with 658 cases, only 2 of which followed up for as long as one year. Also, the doses of CSI varied across studies, which may affect heterogeneity.

A 2017 Health Technology Assessment (HTA) reviewed the evidence for the efficacy of ESWT for treating plantar fasciitis[1]. A pooled analysis was completed with five high quality studies which showed that short-term pain outcomes were significantly better in the ESWT group compared to a sham group (RR=1.38, 95% CI: 1.15.1-66). There were inconclusive results in intermediate and long-term pain outcomes. One study found no difference between groups for functional outcomes and one low quality study showed that ESWT had greater improvement in function compared to sham. The HTA reported insufficient and low quality evidence across the studies comparing ESWT to active control groups for both pain and functional outcomes.

A 2017 meta-analysis by Sun that included nine RCTs and 935 patients looked at pain outcomes in patients with plantar fasciitis[3]. When compared to a placebo, ESWT had better improvements in pain outcomes (OR 2.58, 95% CI 1.97-3.39). Focused shock (OR 2.17, 95% CI 1.49-3.16) and radial shock (OR 4.63, 95% CI 1.30-16.46) also showed significant improvements in pain outcomes when compared to placebo. The authors conclude that focused shock waves may be an alternative treatment and no conclusions can be drawn about the effectiveness of general ESWT and radial shock wave therapy due to significant variations in the including studies.

A 2017 meta-analysis by Lou that included nine RCTs looked at several pain outcomes in patients with recalcitrant plantar fasciitis[4]. The analysis compared patients without local anesthesia to a placebo with primary outcomes being assessed at 12 weeks. When compared to placebo, ESWT significantly improved overall heel pain, improving visual analog scale scores (VAS) by 60% at the first step in the morning as well as during daily activities, improving the Roles and Maudsley score, and reducing pain after applying a force meter. The authors conclude that ESWT may be considered when standard treatments have failed.

In 2014, Yin conducted a systematic review and meta-analysis, that included seven randomized or quasi-randomized studies (n=550) regarding the efficacy of ESWT for chronic recalcitrant plantar fasciitis.[5] For the primary outcome of treatment success rate, which was defined differently across the included studies, pooled analysis of the five trials (N=448 subjects) that evaluated low-intensity ESWT showed that ESWT was more likely than control to lead to treatment success (pooled risk ratio [RR] 1.69; 95% CI 1.37 to 2.07; P<0.001). In pooled analysis of the two trials (N=105 subjects) that evaluated high-intensity ESWT, there was no difference between ESWT and control in treatment success. A strength of this analysis is restricting the population to patients with at least six months of symptoms, since this is a clinical population that is more difficult to treat and less likely to respond to interventions. However, a weakness of this study is the heterogeneity in the definition of “treatment success”, which makes interpreting the pooled analysis challenging.

Randomized Controlled Trials

A RCT by Zhao (2023) examined the outcomes of ESWT, kinesio tape, and ESWT + kinesio tape or control among 91 patients [6]. Patients were randomly assigned to one of the four groups and were examined at baseline and 4-weeks. Study investigators assessed pain (VAS), plantar fascia thickness, and the American Orthopaedic Foot and Ankle Society (AOFAS) score. Results indicated that the ESWT + kinesio tape group had significantly smaller VAS scores compared to the kinesio tape only group (p<0.0001). AOFAS score of ESWT only and ESWT + kinesio tape was significantly greater than the control group, but not kinesio tape only. These results indicate that ESWT may not provide additional improvements in functionality compared to kinesio tape.

In 2022, a RCT by Timurtas examined the effects of ESWT and low-level laser therapy on plantar fasciitis [7]. 47 participants were randomly assigned to either ESWT or low-level laser therapy. ESWT was administered once a week and low-level laser therapy was administered three times a week for a total duration of three weeks. Primary study outcomes included foot function index including pain, disability, and activity limitations. Low-level laser therapy was found to be more effective at decreasing pain, disability, and activity limitation compared to ESWT.

In 2022, a RCT was conducted by Pisirici examining the effects of stretching exercises, stretching exercises with Graston Technique, and stretching exercises with ESWT on 69 patients with plantar fasciitis [8]. Participants were randomly assigned to one of the three groups and completed treatment for 8-weeks. Primary outcomes included pain (VAS), Foot Function Index, 12-Item Short-Form Health Survey, and the Tampa Scale for Kinesiophobia. Outcomes were assessed at pretreatment, posttreatment, and at 8-week and 6-month follow-up. The authors concluded that while VAS and Foot Function Index improved in all treatment groups, stretching exercises with ESWT and stretching exercises with Graston Technique improved more than stretching alone. Additionally, while ESWT with stretching had similar effects to Graston Technique with stretching at 8-weeks, Graston Technique with stretching was found to be more effective at improving functional status at 6-months.

A 2018 RCT by Lai compared ESWT and corticosteroid injection (CSI) as treatment options for 97 patients with plantar fasciitis.[9] The primary outcomes in the study were pain, function, and plantar fascia thickness and were assessed at baseline, four weeks, and 12 weeks. The authors concluded that ESWT is more efficacious than CSI in the treatment of plantar fasciitis in the 12-weeks assessment of VAS and 100-point score.

In 2015, Gollwitzer reported results of a sham-controlled RCT, with patients and outcome assessments blinded, evaluating ESWT for plantar fasciitis present for at least 6 months and refractory to at least two nonpharmacologic and two pharmacologic treatments.[10] A total of 250 subjects were enrolled and treated (126 in the ESWT group, 124 in the placebo group). For the study’s primary outcome, overall reduction of heel pain, measured by percentage change of the VAS composite score 12 weeks after the last intervention compared with baseline, the median decrease was greater for the ESWT group (-69.2%) than for the placebo group (-34.5%; Mann-Whitney effect size, 0.6026; p=0.003). Secondary outcomes included success rates (defined as decrease of heel pain of at least 60% from baseline for at least two of three heel pain VAS measurements) for a variety of heel pain measurements. Secondary outcomes generally favored ESWT group. For example, 54.4% of ESWT patients had reduced overall heel pain compared with 37.2% of placebo patients (odds ratio [OR], 2.015; p=0.004, 1-sided). Most patients reported satisfaction with the procedure. Strengths of this study included intention-to-treat analysis, use of validated outcome measures, and at least some reporting of changes in success rates (rather than percent decrease in pain) for groups. There was some potential for bias because treating physicians were unblinded.

Results have been reported to the FDA from multicenter, double-blind, sham-controlled trials delivering ESWT with the Orthospec™, Orthopedic ESWT, and Orbasone™ Pain Relief System. Efficacy of the Orthospec™[11] was examined in 172 participants with chronic proximal plantar fasciitis failing conservative therapy. Patients were randomized to ESWT or sham treatments in a two to one ratio. At three months, the ESWT arm had less investigator-assessed pain with application of a pressure sensor (0.94 points lower on a 10-point VAS, 95% CI: 0.02 to 1.87), but there was no difference in patient-assessed activity improvement and function between ESWT and sham groups. The Orbasone™[12, 13] trial included 179 participants with chronic proximal plantar fasciitis randomized to active or sham treatment. At three months, both active and sham groups improved in patient-assessed pain on awakening (by 4.6 and 2.3 points, respectively, on a 10-point VAS; crude difference between groups at three months of 2.3, 95% CI: 1.5 to 3.3). While this trial reported that ESWT was associated with significantly faster improvement in a mixed-effects regression model, insufficient details were provided to evaluate the analyses. Although these devices are approved by the FDA for treatment of chronic plantar fasciitis and examined for efficacy in apparently well-designed, double-blind RCTs, definitive, clinically meaningful treatment benefits at three months were not apparent, nor was it evident that the longer-term disease natural history was altered.

The systematic reviews described previously included several RCTs that are detailed below.

Gerdesmeyer reported on a multicenter double-blind RCT of radial ESWT (rESWT) conducted for FDA premarket approval (PMA) of the Dolorclast (EMS Electro Medical Systems) that included 251 patients with heel pain for at least six months and failure of at least two nonpharmacological and two pharmacological treatments.[14] Outcomes were composite heel pain (pain on first steps of the day, with activity, and as measured with Dolormeter), change in VAS scores, and Roles and Maudsley score measured at 12 weeks and 12 months. Success was defined as at least 60% improvement in two of three VAS scores OR the patient had to be able to work and complete activities of daily living, had to be satisfied with the outcome of the treatment, and must not have required any other treatment to control heel pain. Secondary outcomes measured at 12 weeks including changes in Roles and Maudsley score, SF-36 physical percent changes, SF-36 mental percent changes, investigator's judgment of effectiveness, patient's judgment of therapy satisfaction, and patient recommendation of therapy to a friend. At 12-week follow-up rESWT was followed by a statistically significant decrease of the composite VAS score of heel pain by (72.1% vs 44.7% after sham), but the final VAS scores were not provided. Significant reductions in individual VAS scores with ESRT compared to sham were found for heel pain during daily activities (60% vs 40.68%) and heel pain after application of Dolormeter (52.85% vs. 39.66%), with no difference in heel pain when taking first steps in the morning. The success rate for the composite score was 61% vs. 42% (P=0.002). Statistically significant differences favoring ESWT were noted on all secondary measures at 12 months. The limitations of this study prevent definite conclusions from being reached. These include the limited data concerning specific outcomes (e.g., presenting percent changes rather than actual results of measures); inadequate description of prior treatment (or intensity of treatment) provided before referral to the study; use of the composite outcome measure; and no data on the use of rescue medication. In addition, the clinical significance of changes (and relative changes) in outcome measures is uncertain, and there are questions about the adequacy of patient blinding.

Kudo reported a statistically significant difference in improvement in mean pain score on first walking in the morning between the active treatment and placebo, three months after treatment.[15] There were no significant differences in other measures. It should be noted that the placebo group also reported significant improvement in pain from baseline. Intention-to-treat analysis was not reported in this study, and there was a significant difference between groups in blinding verification, with more active treatment patients reporting that they believed they received the active treatment, thus potentially biasing results.

Malay (2006) randomized 172 patients at a 2:1 ratio to either active ESWT (n=115) or sham (n=57).[16] Subjects and assessors were blinded, while non-blinded investigators administered the single treatment session. Follow-up was three months. Both groups reported improvement from baseline, with significantly more responders (decrease from baseline of 50% or more with a visual analog scale (VAS) score =4) in the active ESWT group than in the sham group (42.9% and 19.6%, respectively; p=.003). Between-group differences in reduction in heel pain reached statistical significance for both blind assessor's objective and participants' subjective assessment (p=.045 and p<.001, respectively). The reduction in pain was statistically significantly greater in the treatment group than in the sham group in the absence of heel spur (p=.012) but not when heel spur was present (p=.96). The reduction in the use of pain medication was also significantly greater in the treatment group (p<.001). It is interesting to note that despite the report of greater reduction in pain in the treatment group there was no significant between-group difference in self-assessment of activity and functional levels. This study adds to the number of randomized controlled clinical trials reporting significantly greater symptom improvement with active treatment compared with sham. However, conclusions related to health outcomes cannot be reached due to the short-term follow-up period, the 2:1 patient ratio and the administration of treatment by non-blinded investigators. In addition, it is difficult to compare these results with other studies due to differences in treatment protocol and patient selection methods.

Additional randomized controlled trials have reported similar or improved pain reduction with ESWT in patients with plantar fasciitis compared to placebo.[10, 17-24] In addition, improvement in short-term functional status was also reported.[23, 24] However, there are many limitations in interpreting these findings. Individual RCTs included in the reviews and meta-analyses reported inconsistent results and heterogeneity in the studies sometimes precluded meta-analysis of pooled data. Outcomes measured and study protocols, e.g., dose intensities, type of shockwaves and frequency of treatments, also often lacked uniformity. Additionally, because plantar fasciitis often resolves within a 6-month period, longer follow-up studies are needed to compare ESWT results with the natural resolution of the condition. The clinical significance of results reported at shorter follow-up, such as 3 months, is uncertain. As such, these trials and a pooling of their outcomes do not make a significant impact on the interpretation of the findings reached in the larger, higher-quality trials described above.

Several recent smaller randomized studies have compared ESWT with other treatments, including corticosteroid injections. One of these, by Eslamian randomized 20 patients with chronic plantar fasciitis each to ESWT and corticosteroid injections. The authors reported that both interventions led to improvements in pain and functional ability after two months, but the treatment outcomes were not significantly different between groups.[25] Another study by Mardani-Kavi comparing these two treatments in 68 patients reported greater pain reduction in the corticosteroid injection group than in the ESWT group.[26] Additionally, ESWT was compared with botulinum toxin type A injection in a trial with 72 patients described by Roca et al., which found that ESWT was superior for pain relief.[27]

Nonrandomized Studies

Nonrandomized studies[28, 29] have also reported outcomes after ESWT for plantar fasciitis, but given the lack of randomized trial design, these studies do not provide additional evidence regarding ESWT's efficacy compared with alternative therapies.

Conclusion

There are numerous RCTs identified, including several well-designed double-blinded RCTs, which have evaluated ESWT for treatment of plantar fasciitis. The evidence is mixed, with some studies reporting a benefit and others reporting no benefit. The reasons for this variability in the literature are not clear. Definitive, clinically meaningful treatment benefits at three months are not apparent, nor is it evident that the long-term natural course of disease is altered with ESWT. Therefore, no reliable conclusions can be reached concerning ESWT for the treatment of plantar fasciitis.

TENDINITIS OF THE SHOULDER

Systematic Reviews and Technology Assessment

A systematic review and meta-analysis was conducted by Angileri in 2023 examining the outcomes and complications of nonoperative and operative chronic calcific tendinitis with ESWT, ultrasonography-guided needling, and surgery [30]. A total of 27 RCT studies were included including 2,212 nonoperative patients and 140 operative patients. Study outcomes included pain (VAS) Constant-Murley Shoulder Outcome Score, and resolution of calcific deposits. The pooled mean difference in VAS was -3.83 for ESWT, -4.83 for ultrasonography-guided needling and -4.65 for surgery. The pooled mean difference in the Constant-Murley Shoulder Outcome Score was 18.30 for ESWT, 22.01 for ultrasonography-guided needling, and 38.35 for surgery. Complete resolution of calcified deposits occurred in 27.3% of ESWT patients, 66.7% of ultrasonography-guided needling patients, and 85% of surgical patients. These results show that ESWT improved outcomes the least compared to ultrasonography-guided needling and surgery. Additionally, surgery was found to result in the greatest improvements in functional outcome scores, resolution of calcified deposits, and pain.

A 2017 Health Technology Assessment (HTA) reviewed the evidence for the efficacy of ESWT for treating shoulder tendinopathies[1]. Two trials showed that treatment with ESWT showed greater improvement in pain outcomes when compared to sham over all time frames (low and moderate quality studies). Several other studies indicated no significant improvements in pain outcomes across all timeframes. Results for functional outcomes were inconsistent with low and moderate quality studies showing improvement in function with ESWT compared to sham or active control with the majority of studies showing no difference between groups.

A systematic review and network meta-analysis published in 2016 by Arirachakaran compared clinical outcomes between ESWT, ultrasound-guided percutaneous lavage (barbotage), subacromial corticosteroid injection, and combined treatment for rotator cuff calcific tendinopathy.[31] The clinical outcomes in this study were pain (VAS), shoulder function (Constant Murley score) and size of calcium deposit. The authors identified seven relevant studies, including six with ESWT: four that compared ESWT to placebo, and one each comparing ESWT to corticosteroid injection plus barbotage and ESWT plus barbotage. The results of the network meta-analysis, which allows indirect comparisons between active treatments, indicated that while ESWT significantly improved pain and function compared with placebo, barbotage plus corticosteroid injections significantly improved pain (VAS) and calcium deposit size compared to the other treatments. The authors noted that the majority of the studies were unclear regarding randomization sequence generation and allocation concealment, which could lead to selection bias or confounding.

A 2015 systematic review by Yu assessed the effectiveness of various passive physical modalities for shoulder pain and included 11 studies considered to be at low risk of bias, with five studies that reported on ESWT.[32] Three, published from 2003 to 2011, were for calcific shoulder tendinopathy, including 1 RCT comparing high-energy ESWT with low-energy ESWT (N=80), one RCT comparing rESWT with sham ESWT (N=90), and one RCT comparing high-energy ESWT with low-energy ESWT and sham ESWT (N=144). All three trials reported statistically significant differences between groups, favoring ESWT, for change in shoulder pain VAS score.

In 2014, Verstraelen conducted a systematic review of RCTs evaluating the efficacy of high versus low energy ESWT as a treatment for calcifying tendinitis of the shoulder in five RCTs (n=359).[33] Eligible for inclusion were all RCTs that compared high-energy ESWT (> 0.28 mJ/mm^2) with low-energy ESWT (< 0.08 mJ/mm^2). All five trials indicated greater improvement in functional outcome in patients treated with high-energy ESWT when compared to low-energy ESWT at three and six month follow-up. The three month mean difference in outcomes, measured by the Constant-Murley score, was 9.88 (95% CI, 9.04-10.72, p<0.001); however, the six month data could not be pooled.

In 2014, Bannuru published a systematic review of RCTs comparing high-energy ESWT with placebo or low-energy ESWT for the treatment of patients with calcific and noncalcific shoulder tendinitis.[34] Twenty-eight studies were included in the review. In seven studies comparing ESWT with placebo for calcific tendinitis, all studies reported significant improvements in pain or functional outcomes associated with ESWT. Only high-energy ESWT was consistently associated with significant improvements in both pain and functional outcomes. In eight studies comparing high- with low- energy ESWT for calcific tendinitis, studies did not demonstrate significant improvements in pain outcomes, although shoulder function was improved with high-energy ESWT. Authors indicated that all included RCTs were limited by small sample size and heterogeneous design, and in general, trials were low quality and associated with a high risk of bias.

In a 2013 systematic review and meta-analyses, Ioppolo included six RCTs on ESWT compared with sham treatment or placebo for calcific shoulder tendinopathy.[35] Greater shoulder function and pain improvements were found at six months with ESWT over placebo. Most studies were considered to be low quality.

In 2011, Huisstede published a systematic review that included 17 RCTs of calcific (RCTs=11) and non-calcific (RCTs=6) tendinopathy of the rotator cuff.[36] Moderate quality evidence was found for the efficacy of ESWT versus placebo for calcific tendinopathy, but not for noncalcific tendinopathy. High-frequency ESWT was found to be more efficacious than low-frequency ESWT for calcific tendinopathy. Authors reported the most prevalent methodological limitations were a lack of care-giver blinding (65%) and a lack of intention-to-treat analysis (35%). Due to the heterogeneity of the included studies, results could not be pooled for analysis.

Randomized Controlled TrialsRCTs not represented in the systematic reviews described above are included below.

In 2022, Lee examined the impact of ESWT and ultrasound-guided shoulder injections in patients with supraspinatus tendinitis [37]. A total of 26 patients randomly assigned to either ultrasound-guided injection or ESWT. Primary study outcomes included pain (VAS), American Should and Elbow Society (ASES) score, and Constant score at baseline, 1-month post and 3-months post procedure. At 1-month, VAS, ASES, and Constant score improved the most among patients receiving ESWT. At 3-months, both groups clinically improved, however no statistical significance existed between groups.

In 2009, Schofer compared the effects of high-energy versus low-energy ESWT in 40 patients with rotator cuff tendinopathy.[38] An increase in function and reduction of pain were found in both groups (p<0.001). Although improvement in Constant score was greater in the high-energy group, there were no statistically significant differences in any outcomes studied (Constant score, pain, subjective improvement) at 12 weeks and 1 year after treatment.

Several other trials have been published; however, these studies have similar methodological limitations, such as small study population, short duration of follow-up, and/or lack of double-blinding.[39-43]

Conclusion

In summary, a number of RCTs have evaluated the use of ESWT to treat shoulder tendinopathy, which have been summarized in several systematic reviews and meta-analyses. Although some trials have reported a benefit in terms of pain and functional outcomes, particularly for high-energy ESWT for calcific tendinopathy, many available trials are considered poor quality. As a result, there is insufficient evidence to permit conclusions concerning whether ESWT improves outcomes for patients with tendinitis of the shoulder.

TENDINITIS OF THE ELBOW (LATERAL EPICONDYLITIS)

Systematic Reviews and Technology Assessment

A 2023 meta-analysis by Chen examined the long-term effects of treatments for lateral epicondylitis [44]. 16 studies were included with a total of 867 participants that examined pain (VAS/pain score), grip strength, pain-free function questionnaire (PFFQ), or Disabilities of the Arm, Shoulder, and Hand (DASH) score. ESWT significantly relieved long-term pain, however, there was no significant difference between ESWT and control groups in long-term functional outcomes.

A 2022 systematic review and meta-analysis reviewed the efficacy of ESWT for treating lateral epicondylitis [45]. The study included 40 RCTs that examined the use of ESWT to injection therapies including corticosteroids, autologous whole blood, platelet-rich plasma, botulinum toxin A, and dextrose prolotherapy. The authors concluded that dextrose prolotherapy, botulinum toxin A, and ESWT outperformed placebo for short-term pain relief and that ESWT outperformed placebo for medium-term pain relieve. Additionally, ESWT improved short-term and medium-term grip strength recovery compared to other treatments.

A 2017 Health Technology Assessment (HTA) reviewed the evidence for the efficacy of ESWT for treating lateral epicondylitis[1]. In two studies patients receiving ESWT were two times as likely to achieve ≥50% improvement over baseline in the short-term compared with those receiving sham (RR 2.2; 95% CI 1.6-3.1). There is no evidence for intermediate or long term wrist extension pain outcomes. Further, there is not enough evidence from three small studies to determine the effect of ESWT vs. sham on other non-specified pain outcomes over any timeframe. There was significant improvement in short-term function in two studies however there was no difference after 12 months of follow-up.

Six randomized, double-blinded, placebo-controlled trials enrolling 808 patients with lateral epicondylitis met the inclusion criteria for the 2004 TEC Assessment.[46] Two studies were rated as fair in quality due to 1) small sample size and group differences at baseline in duration of symptoms and prior treatment, yielding a possibility of selection bias[47]; and 2) lack of accounting for dropouts and intent-to-treat analysis.[48] Four trials were rated "good" quality. These include the SONOCUR trial, with 114 patients, which found that at 3 months the main outcome measures (Upper Extremity Function Scale and self-reported pain scale) showed greater improvement in the ESWT group, compared with the placebo group.[49] The OssaTron trial randomized 183 patients to a single session of high-energy or sham ESWT and after 8-weeks of follow-up, the ESWT group had a greater rate of treatment success than the placebo group, but self-reported pain and pain medication use was not significantly different.[50] The third trial randomized 272 patients to 3 sessions of low-energy or sham ESWT, and found no significant differences between groups for treatment success rate, pain assessment measures, or grip strength.[13] The final trial included 78 tennis players and found that the group to 3 treatments at weekly intervals of low-energy ESWT had significantly improved pain and function scores, but not grip strength at 3 months follow-up.[51] Overall, the TEC Assessment concluded that the available data did not provide strong and consistent evidence that ESWT improved outcomes of chronic lateral epicondylitis.

Other systematic reviews published since the 2004 TEC Assessment have come to similar conclusions. A 2005 Cochrane review concluded "there is 'Platinum' level evidence [the strongest level of evidence] that shock wave therapy provides little or no benefit in terms of pain and function in lateral elbow pain.[52] A 2013 systematic review of electrophysical therapies for epicondylitis concluded that the evidence conflicting on the short-term benefits of ESWT.[53] No evidence was found demonstrating any long term benefits with ESWT over placebo for epicondylitis treatment.

Randomized Controlled Trials

Aldajah (2022) compared ESWT (n=20) with conventional physiotherapy (n=20) in patients with lateral epicondylitis.[54] All patients received five sessions during the treatment program. Outcome measures included changes in VAS for pain intensity, the Disabilities of the Arm, Shoulder, and Hand (DASH) questionnaire for upper extremity function, and dynamometer for maximal grip strength. Patients in both groups improved significantly after treatment in terms of VAS, DASH scores, and maximal grip strength from baseline. However, patients in the ESWT arm performed better than those in the physiotherapy arm for all outcomes.

A 2018 RCT by Aydin compared ESWT and wrist-extensor splint application in 67 patients with lateral epicondylitis.[55] Patients in the ESWT group underwent four sessions of ESWT once every week compared with the splint group who wore a wrist splint for four weeks. Both treatments showed significantly better results compared to baseline and when compared against each other, there was no significant difference in outcomes.

A 2017 RCT by Taheri compared low-dosage (energy of 0.10 mj/mm) ESWT against high-dosage (energy of 0.25 mj/mm) ESWT in 40 patients with lateral epicondylitis[56]. Both groups showed improvements in mean pain intensity over the course of the treatment protocol. The low-dosage group showed a great reduction of pain intensity.

A double-blind RCT published in 2016 by Capan compared three weekly rESWT sessions (2000 pulses of 10Hz at a 1.8 bar of air pressure) with sham treatment in 56 patients that had not responded to previous treatments.[57] The outcomes assessed were pain and function

(VAS, Roles and Maudsley score, and Patient-Rated Tennis Elbow Evaluation), and grip strength (hand dynamometer). Both groups showed significant improvement at one and three months posttreatment, and there was no significant difference between them.

In a study published in 2015, Beyazal and Devrimsel compared ESWT with corticosteroid injection.[58] This trial randomized 64 patients, and evaluated hand grip strength and pain (VAS and short-form McGill pain questionnaire) at four and 12 weeks posttreatment. After four weeks of followup, the ESWT group showed improvement in the VAS score, but other assessments did not differ between groups. At 12 weeks posttreatment, there was a statistically significant difference in the percentages of improvements between the groups favoring ESWT for all three parameters. This study was limited by a lack of blinding, which increases the risk of bias, and reported only percentages of score improvement.

Also published in 2015, Lizis compared ESWT with therapeutic ultrasound among 50 patients with chronic tennis elbow.[59] For most pain measures assessed, pain was lower in the ESWT group immediately posttreatment and at 3 months, with the exception of pain on gripping, which was higher in the ESWT group. While trial results favored ESWT, there was a high risk of bias due to a number of factors, particularly lack of blinding of participants and outcome assessors, which make interpretation of results difficult.

Additional randomized controlled trials of ESWT for elbow tendinopathy have been published. However, these trials have significant methodological limitations (e.g. small study populations, short duration of follow-up) and as such do not warrant detailed discussion.[60, 61]

Nonrandomized Studies

Nonrandomized observational studies[62] have reported functional outcomes after ESWT for epicondylitis; however, these studies provided limited evidence about the comparative effectiveness of ESWT for lateral epicondylitis compared with other therapies.

Conclusion

In summary, the most direct evidence regarding the use of ESWT to treat lateral epicondylitis is derived from many small RCTs, which have not consistently demonstrated outcome improvements beyond those observed in control groups with ESWT. Therefore, it is not possible to reach conclusions concerning the overall effect of ESWT on health outcomes for chronic lateral epicondylitis. It is not known whether differing results are due to methodological bias or to differences in the study populations and interventions. Further, a Cochrane review, which included nine placebo-controlled trials with 1,006 participants, concluded “there is ‘Platinum’ level evidence [the strongest level of evidence] that shock wave therapy provides little or no benefit in terms of pain and function in lateral elbow pain.”[52, 63] The authors noted that when available data from the randomized trials was pooled, most benefits observed in the positive trials were no longer statistically significant.

ACHILLES TENDINOPATHY

Systematic Reviews and Technology Assessment

A 2017 Health Technology Assessment (HTA) reviewed the evidence for the efficacy of ESWT for treating Achilles tendinopathy[1]. Two small RCTs showed significant pain improvement while running or playing sports, but there was no difference between groups while working or using the stairs. One RCT reported significant improvement in function when comparing ESWT to sham. The strength of evidence for this indication was low and there was no evidence found on the intermediate or long term outcomes.

Al-Abbad and Simon published a systematic review of six studies on ESWT for Achilles tendinopathy.[64] Included in the review were four small RCTs and two cohort studies. Satisfactory evidence was found demonstrating ESWT effectiveness in the treatment of Achilles tendinopathy at three months in four studies; however, two of the RCTs reviewed found no significant difference between ESWT and placebo in the treatment of Achilles tendinopathy.[65, 66]

In 2015, Mani-Babu reported results of a systematic review and meta-analysis of studies evaluating ESWT for lower limb tendinopathies, including Achilles tendinopathy, patellar tendinopathy, and greater trochanteric pain syndrome.[67] The review included 20 studies overall, 11 of which evaluated ESWT for Achilles tendinopathy, including five RCTs, four cohort studies, and two case-control studies. In pooled analysis, the authors reported that ESWT was associated with greater short term (<12 months) and long-term (>12 months) improvements in pain and function compared with nonoperative treatments, including rest, footwear modifications, anti-inflammatory medication, and gastrocnemius-soleus stretching and strengthening. The authors noted that findings from RCTs of ESWT for Achilles tendinopathy are contradictory, but that there is at least some evidence for short-term improvements in function with ESWT.

Randomized Controlled Trials

Abdelkader (2021) performed a double-blind, randomized trial that compared ESWT (n=25) with sham control (n=25) in patient with unilateral noninsertional Achilles tendinopathy.[68] Scores were improved in both ESWT and control groups at one month on the Victorian Institute of Sports Assessment-Achilles (VISA-A) questionnaire (85 and 53.4, respectively) and the VAS (1 and 7, respectively), as well as at 16 months on the VISA-A (80 and 67, respectively) and the VAS (3 and 5.6, respectively). At both time points, scores were statistically and clinically superior with ESWT than with sham control (both p=.0001).

Stania (2023) published a RCT that compared the impacts of ESWT, ultrasound therapy, and placebo ultrasound therapy on Achilles tendinopathy [69]. A total of 39 patients were randomly assigned to one of the three groups. Primary study outcomes were posturographic measurements and subjective assessments of pain at 1-week and 6-weeks (therapy completion). Pain was significantly reduced with ESWT but not ultrasound therapy or placebo ultrasound therapy. Patients treated with ESWT had more efficient postural control at 6-weeks compared to ultrasound therapy.

A 2022 RCT examined the use of ESWT and eccentric exercises among patients with chronic tendinopathy [70]. Participants (n=63) were treated with either eccentric exercises seven days a week or ESWT four days a week for three months. Study outcomes included pain (VAS), Victorian Institute of Sports Assessment-Achilles (VISA-A) questionnaires, and ultrasonography measurements measured at pre- and post-treatment. Additionally, patient pain (VAS) was evaluated a two-years post-treatment. Eccentric exercises significantly decreased VAS scores at two-years, while ESWT had no significant changes. Additionally, eccentric exercises increased tendon thickness and stiffness, while no statistically significant differences were identified among the ESWT group.

Lynen (2016) published an RCT with 62 patients comparing peritendinous hyaluronan (HA) injections to ESWT in patients with Achilles tendinopathy[71]. The interventions included two HA injections compared with three applications of ESWT at weekly intervals. The primary outcome was change in score on the Victorian Institute of Sports Assessment-Achilles' (VISA-A) questionnaire and change in pain assessed with VAS. The results indicate that HA injections showed better improvement compared to ESWT in reducing pain outcomes (p=0.003) at three months follow-up with similar findings being seen at four weeks and six months of follow up.

Costa conducted a randomized, double-blind, placebo-controlled trial of ESWT for chronic Achilles tendon pain treated monthly for three months.[65] The study randomized 49 participants and was powered to detect a 50% reduction in VAS pain scores. No difference in pain relief at rest or during sport participation was found at one year. Two older ESWT-treated participants experienced tendon ruptures.

Rasmussen reported a single-center double-blind controlled trial with 48 patients, half of them randomized after four weeks of conservative treatment to four sessions of active rESWT and half to sham ESWT.[66] Primary endpoints were American Orthopaedic Foot and Ankle Society (AOFAS) score measuring function, pain, and alignment and pain on visual analog scale. AOFAS score after treatment increased from 70 (SD 6.8) to 88 (SD 10) in the ESWT group and from 74 (SD 12) to 81 (SD 16) in the control (p=0.05). Pain was reduced in both groups with no statistically significant difference between groups. The authors noted that the AOFAS score may not be appropriate for the evaluation of treatment of Achilles tendinopathy.

Conclusion

In summary, there is insufficient evidence to permit conclusions regarding the use of ESWT upon improved health outcomes for patients with tendinitis of the Achilles.

PATELLAR TENDINOPATHY

Systematic Reviews and Technology Assessment

A 2018 systematic review by Liao included 19 RCTs which were all classified as medium or high methodological quality[72]. The RCTs were evaluating the effect of ESWT on soft tissue disorders of the knee including tendinopathies with outcomes such as range of motion, pain reduction, and treatment success rate. The review concluded that ESWT has a significant effect on success rates, pain reduction, and range of motion restoration in patients with soft tissue disorders of the knee. The RCTs included evaluated both radial shock-wave therapy and focused shock-wave therapy while the authors concluded that type and application levels have different contributions to the overall treatment efficacy.

A 2017 Health Technology Assessment (HTA) reviewed the evidence for the efficacy of ESWT for treating patellar tendinopathy[1]. There is insufficient evidence in regards to pain and functional outcomes for ESWT when compared to sham. One small RCT showed significant improvements in long term pain and function. The quality of evidence was low for this one RCT and there was no short or intermediate term evidence.

Van Leeuwen[73] conducted a literature review to study the effectiveness of ESWT for patellar tendinopathy and to draft a treatment protocol which included resulted in a review of 7 articles. The authors found that most studies had methodological deficiencies, small numbers and/or short follow-up periods, and treatment parameters varied among studies. They concluded that ESWT appears to be safe and promising treatment but that a treatment protocol cannot be recommended and further basic and clinical research is required. In an RCT of patients with chronic patellar tendinopathy (N=46), despite at least 12 weeks of nonsurgical management, improvements in pain and functional outcomes were significantly greater (p<0.05) with plasma-rich protein injections than ESWT at six and 12 months, respectively.

In the 2015 systematic review and meta-analysis of ESWT for lower extremity tendinopathies by Mani-Babu, described above, the authors identified seven studies of ESWT for patellar tendinopathy, including two RCTs, one quasi-RCT, one retrospective cross-sectional study, two prospective cohort studies, and one case- control study.[67] Two RCTs came to different conclusions: one RCT found no difference in outcomes between ESWT and placebo at 1, 12, or 22 weeks, whereas an earlier RCT found improved outcomes on vertical jump test and Victorian Institute of Sport Assessment Questionnaire–Patellar (VISA-P) scores at 12 weeks with ESWT compared with placebo. Two studies which evaluated outcomes beyond 24 months found that ESWT was comparable with patellar tenotomy surgery and better than nonoperative treatments.

MEDIAL TIBIAL STRESS SYNDROME (MTSS) (“SHIN SPLINTS”)

Systematic Reviews

A single systematic review was identified that addressed the use of ESWT for medial tibial stress syndrome (MTSS). This review, published in 2013 by Winters evaluated the evidence for a number of treatments for MTSS, including iontophoresis, phonophoresis, ice massage, ultrasound, low-energy laser treatment, periosteal pecking (needling), stretching and strengthening exercises, sports compression stockings, lower leg braces, extracorporeal shockwave therapy, and pulsed electromagnetic field therapy.[74] There were 11 trials included in the analysis: nine RCTs and two nonrandomized trials. The authors indicated that all of the RCTs had a high risk of bias and that the nonrandomized trials were of poor quality, and for this reason, no specific treatment could be recommended.

Randomized Controlled Trials

No randomized controlled trials of ESWT for MTSS were identified.

Nonrandomized Studies

A prospective, controlled study on the use of ESWT for MTSS in 42 athletes was published in 2012 by Moen[75] One group of patients was treated with a graded running program alone, while the other group was treated with the running program and five ESWT sessions in nine weeks. The ESWT group was reported to have a significantly reduced time to recovery, defined as the ability to run 18 minutes consecutively without pain at a fixed intensity, which was reported as the main outcome measured. This study is significantly limited by the lack of blinding or randomization and the lack of validated outcome measures.

In 2010, Rompe published a report on the use of ESWT in (MTSS).[76] In this non-randomized cohort study, 47 patients with MTSS for at least six months received three weekly sessions of rESWT, and were compared to 47 age-matched controls at four months. Mild adverse events were noted in ten patients: skin reddening in two patients and pain during the procedure in eight patients. Patients rated their condition on a six-point Likert scale. Successful treatment was defined as self-rating “completely recovered” or “much improved”. The authors report a significant success rate of 64% (30/47) in the treatment group compared to 30% (14/47) in the control group. This study represents another potential use for ESWT. In a letter to the editor, Barnes has raised several limitations of this study. In a nonrandomized study, the possibility of selection bias is introduced. This is particularly problematic when outcomes are patient-reported. Larger, randomized trials are needed.

SPASTICITY

Systematic Reviews

Afzal (2023) published a systematic review and meta-analysis of 15 RCTs (389 participants) to examine the effect of EWST on lower limb function, modified Ashworth scale, walking, and quality of life among patients with lower limb post-stroke spasticity[77]. Compared to control, ESWT improved the modified Ashworth scale (p<0.01), range of motion (p<0.02), but not walking (timed up and go). These findings indicate that while ESWT may improve muscle tone and range of motion, evidence current evidence does not show improvements in functionality (walking).

Mihai (2021) performed a meta-analysis of 7 RCTs to estimate the effect of ESWT on lower limb post-stroke spasticity at long-term follow-up (≥3 weeks after treatment).[78] Compared with control, ESWT did not significantly improve Modified Ashworth Scale score at up to 12 weeks (standardized mean difference, 0.32; 95% CI, -0.01 to 0.65) or VAS score at up to 12 weeks (standardized mean difference, 0.35; 95% CI, -0.21 to 0.91), but did significantly improve passive range of motion at up to 12 weeks (standardized mean difference, 0.69; 95% CI, 0.20 to 1.19). Limitations of this meta-analysis include the small number of available studies and small sample sizes.

Lee[79] conducted a systematic review and meta-analysis of studies evaluating ESWT for patients with spasticity secondary to a brain injury. Studies were included that evaluated ESWT as sole therapy and that reported pre- and post-intervention modified Ashworth Scale scores. Five studies were included examining spasticity in the ankle plantar flexor and one examining spasticity in the wrist and finger flexors; three studies evaluated post-stroke spasticity and two evaluated spasticity associated with cerebral palsy. Immediately post-ESWT, modified Ashworth Scale scores improved significantly compared with baseline (standardized mean difference [SMD] -0.792; 95% CI -1.001 to -0.583; P<0.001). After four weeks post- ESWT, modified Ashworth Scale scores continued to demonstrate significant improvements compared with baseline (SMD -0.735; 95% CI -0.951 to -0.519; P<0.001). A strength of this meta-analysis is that it used a consistent and well-definable outcome measure. However, the modified Ashworth Scale does not account for certain clinically-important factors related to spasticity, including pain and functional impairment.

Randomized Controlled Trials

Senarath (2023) conducted a RCT examined radial ESWT (rESWT) and transcutaneous electrical nerve stimulation (TENS) in upper limb spasticity among patients with chronic post-stroke hemiplegia [80]. Patients (n=62) were randomly assigned to either rESWT to TENS over the course of four weeks. Assessments were measured at baseline, immediately after first treatment, and at the end of four weeks (post). Researchers identified that from baseline to post, rESWT reduced spasticity, improved voluntary control, and hand functioning statistically more than TENS. These results show preliminary results for ESWT, however, further research with greater sample sizes and longitudinal data is needed.

An RCT by Emara (2022) examined the use of ESWT on spasticity, gross motor function, and balance in children with unilateral cerebral policy [81]. A total of 34 patients were included and all patients completed traditional exercises for 12 weeks. The experimental group received one ESWT session one the calf muscle once per week. Primary study outcomes included the Modified Ashworth Scale, isokinetic muscle performance, Gross Motor Function Measure, Trost Selective Motor Control test, and single leg standing test. Findings indicate that ESWT treatment improved eccentric peak torque, torque threshold, gross motor function, selective motor control, and balance ($p<0.05$). The results are limited by small sample size and short duration of follow-up.

Brunelli (2022) examined the impact of radial ESWT (rESWT) conventional rehabilitation to conventional rehabilitation alone (control) among stroke patients [82]. A total of 40 patients were randomly assigned to either the experimental (rESWT) or control group. The primary study outcome was the modified Ashworth scale (MAS) at the shoulder, elbow, and wrist. This was assessed after 2 ESWT sessions had occurred, after 4 ESWT sessions, and one month post. At each time point, MAS values of the elbow and wrist but not the shoulder were significantly lower in the rESWT group compared to control. The control group increased wrist spasticity after 4 ESWT, while the rESWT group maintained constant MAS scores.

Vidal (2020) performed a randomized, controlled, crossover trial that compared radial ESWT with botulinum toxin type A in reducing plantar flexor muscle spasticity in 68 patients with cerebral palsy.[83] After six months, patients crossed over to the alternative treatment. Spasticity was evaluated using the Tardieu scale, which measures resistance to passive movement at slow and fast velocities measured with a goniometer. Treatment success was defined as improvement in dorsiflexion by ≥10° of the gastrocnemius muscle or the soleus muscle at two months after each intervention. In the first phase, success rates were similar between radial ESWT and botulinum toxin type A (45.7% and 36.4%, p=.469). Following crossover, significantly more patients achieved response with radial ESWT (39.4% vs. 11.4%; p=.011), which the authors attributed to a carry-over effect of radial ESWT from the first phase of treatment.

Two single-blind RCTs were published in 2016, assessing the effects of rESWT on upper limp spasticity in patients with chronic stroke. One of these, reported by Li randomized 60 patients into three equal groups with the following treatments: 1) one session of rESWT per week for three weeks, 2) one single session of rESWT, and 3) one session of sham rESWT per week for three weeks.[84] The primary outcome of the study was the Modified Ashworth Scale (MAS) score for the hand and wrist, and the secondary outcome was the Fugl-Meyer Assessment score. The authors reported that groups receiving rESTW had significant reductions in spasticity, with the reductions lasting for 8-12 weeks for the single session group and at least 16 weeks for the three session group.

The second study, by Dymarek, randomized 60 patients to two either rESWT or placebo.[85] The outcomes assessed in this study were the MAS score for three joint (fingers, elbow, and radiocarpal), surface electromyography (sEMG) of two forearm muscles, and infrared thermal imaging. Patients in the rESWT group had a reduced MAS score for the finger joints, a decrease in sEMG activity in the two muscles, and increases in IRT detection.

A small, 2011 RCT examined the efficacy and safety of rESWT in the treatment of spasticity in patients with cerebral palsy.[86] The 15 patients in this study were divided into three groups (ESWT in a spastic muscle, ESWT in both spastic and antagonistic muscle, and placebo

ESWT) and treated in three weekly sessions. Spasticity was evaluated in the lower limbs by passive range of motion with a goniometer and in the upper limbs with the Ashworth scale (0-4, no spasticity to severe spasticity) at one, two, and three months after treatment. Blinded evaluation showed significant differences between the ESWT and placebo groups for range of motion and Ashworth scale. For the group in which only the spastic muscle was treated, there was an improvement of one point on the Ashworth scale (p=0.05 in comparison with placebo); for the group in both which the spastic and antagonistic muscle was treated, there was an improvement of 0.5 points (not statistically significant in comparison with placebo); and for the placebo group there was no change The significant improvements were maintained at two months after treatment, but not at three months.

Additional RCTs with large sample sizes are needed to permit conclusions regarding the efficacy of this technology on spasticity.

Nonrandomized Studies

Several nonrandomized studies have evaluated the efficacy of ESWT for spasticity treatment. A prospective case-control study by Wang assessed rESWT for spastic plantar flexor muscles in 66 children, aged one to five years, with cerebral palsy.[87] Treatment consisted of one ESWT session per week for three months, in combination with traditional conservative therapy. The control group had conservative therapy alone. Conservative therapy in this study included physical therapy, Chinese massage, meridian mediation, and muscle stimulation. The parents of the patients elected which treatment the patients received, with 34 children in the rESWT group and 32 in the traditional conservative therapy. Improvements in the Modified Ashworth Scale grade, passive range of motion, and Gross Motor Function Measure-88 were reported for the rESWT group, relative to the control group. However, the lack of randomization and blinding in this study are serious limitations.

Daliri evaluated the efficacy of a single session of ESWT for treatment of post-stroke wrist flexor spasticity in a single-blinded trial in which each patient received both sham control and active stimulation.[88] Fifteen patients with post-stroke spasticity at a mean 30 months post-stroke were included, each of whom received one sham stimulation followed one week later by one active ESWT treatment. Investigators were not blinded. Outcomes evaluated included the modified Ashworth Scale to evaluate spasticity intensity, the Brunnstrom recovery stage tool to assess motor recovery, and the neurophysiological measure of H_{max}/M_{max} to measure alpha motor neuron excitability. Ashworth scores and Brunnstrom recovery stage scores did not improve after sham treatment. Ashworth Scale scores improved significantly from baseline (mean 3) to after active ESWT treatment (mean score 2, 2, and 2 immediately post-therapy, 1 week post-therapy, and 5 weeks post-therapy, respectively; P<0.05). H-max/Mmax ratio improved from 2.30 before therapy to one week after active ESWT (P=0.047). Brunnstrom recovery stage scores did not significantly improve after active ESWT. Given the lack of a comparison with a control group, this study provides limited evidence about the efficacy of ESWT for post-stroke spasticity

In 2014, Santamato evaluated ESWT for the treatment of post-stroke lower limb spasticity in 23 patients. Authors concluded that ESWT was a safe and effective treatment for of poststroke plantar-flexor muscles spasticity, reducing muscle tone and improving passive ankle dorsiflexion motion; however, this study was limited by a lack of randomization, small sample size and short-term follow-up.[89]

Summary

In summary, a relatively small body of evidence, with limited RCT evidence, is available to evaluate the use of ESWT for spasticity. Several studies have demonstrated improvements in spasticity measures after ESWT. Further controlled trials are needed to determine whether ESWT leads to clinically meaningful improvements in pain and/or functional outcomes for spasticity.

AVASCULAR NECROSIS (OSTEONECROSIS) OF THE FEMORAL HEAD

Systematic Reviews

A systematic review of ESWT in osteonecrosis (avascular necrosis) of the femoral head was conducted by Alves in 2009.[90] Only five articles, all from non-U.S. sites, were identified: two RCTs, one comparative study, one open-label study, and one case report for a total of 133 patients. Several studies were from one center in Taiwan. Of the two RCTs, one (n=48) was randomized to the use of concomitant alendronate; ESWT treatments were in both arms of the study and ESWT was therefore not the comparator. The other RCT compared ESWT with a standard surgical procedure. All results noted a reduction in pain over the time of the study, which was attributed by each of the study's authors to a positive effect of ESWT. However, the authors of this review noted the limitations of the available evidence: lack of double-blind design, small numbers of patients included, short duration of follow-up, and nonstandard intervention (e.g. energy level and number of treatments).

Nonrandomized Studies

A comparative study reported on the experiences of 17 patients with bilateral hip osteonecrosis who were treated with total hip arthroplasty on one and ESWT on the other side.[91] Each patient was evaluated at baseline and after treatment utilizing the visual analog scale (VAS) for pain and Harris hip score, a composite measure of pain and hip function. There was a significant reduction in scores before and after treatment in both treatment groups. Hips treated with ESWT were also evaluated for radiographic reduction of bone marrow edema on magnetic resonance imaging (MRI), which also appeared to be reduced. The authors then compared the ESWT-treated data to the total hip arthroplasty results, stating that the magnitude of improvement was greater for the ESWT-treated hips. However, hips were not randomized to treatment intervention; the side with the greater degree of disease was treated with surgery in each case. Moreover, time between hip interventions within the same patient averaged 17.3 months, with a range of six to 36 months; in all but one case, surgery preceded ESWT. Therefore, conclusions about the superiority of one intervention over the other cannot be made.

Summary

A limited body of evidence addresses ESWT for osteonecrosis of the femoral head. Hence, the available evidence is insufficient to allow conclusions about the efficacy of ESWT for osteonecrosis.

NONUNION, DELAYED UNION, AND ACUTE FRACTURES

Systematic Reviews

Sansone (2022) published a systematic review and meta-analysis involving 23 studies that evaluated the effectiveness of ESWT in the treatment of nonunion fracture in long bones.[92] The review included 2 RCTs, a single non-randomized controlled trial, and 20 observational studies (14 retrospective; 6 prospective), with a total of 1838 cases of delayed union or nonunion. Only data for 1200 of the 1838 cases were included in the meta-analysis since several studies did not separate results from long bones from those of other bones. Healing occurred in 876 (73%) of the 1200 total long bones after ESWT. Hypertrophic cases were associated with a 3-fold higher healing rate as compared to oligotrophic or atrophic cases ($p=.003$). Bones in the metatarsal region were the most receptive to ESWT with a healing rate of 90%, followed by the tibiae (75.5%), femurs (66.9%), and humeri (63.9%). Increased healing rates were observed among patients who had shorter periods between the injury and ESWT ($p<.02$). Six months of follow-up was generally too brief to fully evaluate the healing potential of ESWT with several studies demonstrating increasing healing rates at follow-ups beyond six months after the last ESWT. Limitations included that the authors in seven included studies did not distinguish between delayed union and nonunion when describing the patient population. In several other studies, the patient population was described clearly; however, data from delayed unions and nonunions were reported together. Incomplete data reporting also contributed to a lack of identifying and differentiating treatment protocols for ESWT.

Randomized Controlled Trials

Cacchio compared surgery to low- and high-energy ESWT in 126 patients.[93] Patients were identified for participation in the study if referred to one of three Italian centers with nonunion fractures, here defined as at least six months without evidence of radiographic healing. The primary endpoint was radiographic evidence of healing. Secondary endpoint data of pain and functional status were collected by blinded evaluators. Neither patients nor treating physicians were blinded. At six months, rates in the lower energy ESWT, higher energy ESWT and surgical arms had similar healing rates (70%, 71% and 73%, respectively). There was no significant difference among the groups at this stage. All groups healing rates improved at further follow-up at 12 and 24 months without significant between-group differences. Secondary endpoints of pain and disability were also examined and were similar. The authors believe this to be the first RCT of its kind and encourage additional study. Lack of blinding may have led to differing levels of participation in other aspects of the treatment protocol.

Wang randomized 56 trauma patients with femur or tibia fractures to a surgical fixation with or without subsequent single ESWT treatment.[94] Patients were evaluated for pain and percent weight-bearing capability on the affected leg by an independent, blinded evaluator. Radiographs taken at these same intervals were evaluated by a radiologist blinded to study group for fracture healing or nonunion. Both groups showed significant improvement in pain scores and weight-bearing status. Between-group comparisons of pain by VAS, and weight bearing favored study patients at each interval. At six months, patients who had received ESWT had VAS scores of 1.19 compared to 2.47 in the control group ($p<0.001$); mean percentage of weight bearing at six months was 87% versus 78%, respectively ($p=0.01$). Radiographic evidence of union at each interval also favored the study group. At six months, 63% (17/27) of the study group achieved fracture union compared to 20% (6/30) in the control group ($p<0.001$). The authors note some limitations to the study: the small number of patients in the study, surgeries performed by multiple surgeons and questions regarding adequacy of randomization.

In summary, the methodological limitations in the evidence do not permit reliable conclusions regarding the effectiveness of ESWT for fracture nonunion, delayed union, and acute fractures.
Erectile dysfunction (ED)

Systematic Reviews

A 2023 systematic review and meta-analysis by Wang examined the use of ESWT for treatment of Peyronie's disease [95]. Four RCTs were included with a total of 151 participants who received ESWT and 150 participants who received control treatment. Compared to control, ESWT significantly reduced plaque size (p=0.02), relieved pain (p=0.0008), but had no significant effect on penile curvature or sexual function improvements. The long-term efficacy of ESWT for the treatment of ESWT is unknown.

A 2022 systematic review and meta-analysis by Rho examined the use of low-intensity ESWT (Li-ESWT) in the treatment of ED following prostatectomies [96]. A total of five RCTs were included (n=460) and the primary outcome was the International Index of Erectile Function score. At 3-4 months post, the Li-ESWT group showed statistically significantly better results compared to control (p=0.02). However, at 9-12 months, no statistically significant differences existed between Li-ESWT and control groups. These results indicate that Li-ESWT may have a significant effect on early recovery but not long-term recovery of ED following prostatectomies. These data are also limited by low-quality evidence, and additional high-quality RCTs are needed.

In 2019, Dong published a systematic review and meta-analysis examining the use of low-intensity ESWT (Li-ESWT) in the treatment of ED [97]. A total of seven RCTs involving 522 patients. Compared to sham therapy, Li – ESWT improved the International Index of Erectile Function score and the Erection Hardness Score (p<0.00001) from baseline to follow-up (p<0.00001). Compared to sham, Li-ESWT appears to improve symptoms related to ED. Further RCTs should compare the effects of Li-ESWT to standard care treatments to better determine its utility.

Randomized Controlled Trials

No additional RCTs that are not included in the systematic reviews and meta-analysis were found.

Summary

A limited body of evidence addresses ESWT for erectile dysfunction, Peyronie's Disease, or corpus cavernosum. Hence, the available evidence is insufficient to allow conclusions about the efficacy of ESWT for erectile dysfunction, Peyronie's Disease, or corpus cavernosum.

WOUND HEALING AND NON-MUSCULOSKELETAL INDICATIONS

Systematic Reviews

In 2022, Yang published a systematic review and meta-analysis examining the use of ESWT with post-burn pathological scars [98]. A total of nine RCTs with 422 patients were included in this study in which participants completed comprehensive rehabilitation with ESWT or comprehensive rehabilitation alone. Compared to comprehensive rehabilitation alone, ESWT combined with comprehensive rehabilitation was found to be more effective in relieving pain (p<0.001), itching related to the scars (p=0.004), scar appearance improvements (p=0.003), elasticity (p<0.001), decreasing scar thickness (p=0.04), and promoting the maturation status of scars (p<0.001). Further research is needed investigating the use of ESWT for post-burn scar treatments with greater sample sizes.

A systematic review by Aguilera-Saez (2020) examined the use of ESWT in the treatment of burn patients. A total of 15 articles were included, of which 7 examined the use of ESWT for acute burns, 6 examined the use of ESWT for post-burn scars, 1 examined ESWT in the treatment of heterotopic ossification following a burn, and 1 examined the use of ESWT at skin-graft donor sites. The authors concluded that the scientific evidence regarding the use of ESWT for burn patients is weak due to the paucity of information, and weak information regarding patient outcomes. More high-quality trials examining the use of ESWT in the treatment of burns is needed, both acutely and for post-burn scars.

In 2020, a systematic review and meta-analysis by Huang was published examining the use of ESWT in the treatment of foot ulcers in adults with Type 1 and Type 2 Diabetes [99]. Eight systematic reviews with a total of 339 patients were included. ESWT was found to produce a greater reduction in wound surface area and increased re-epithelialization. At end of treatment, a greater percentage of ESWT patients had a complete cure, however, at the end of follow-up, this was no longer statistically significant. Further research is needed examining the long-term effects of ESWT on foot ulcers with this specific population.

Randomized Controlled Trials

A double-blinded RCT by Lee examined the use of ESWT on hypertrophic scar regeneration among skin grafting patients [37]. A total of 25 patients received ESWT once a week while 23 patients received standard treatment for six weeks. At six weeks post, ESWT significantly decreased scar thickness (p=0.03) and erythema (p=0.03) compared to control. However, no significant differences were identified between ESWT and control groups comparing melanin, transepidermal water loss, skin distensibility, biological skin elasticity, gross skin elasticity, and skin viscoelasticity. These findings do not support the use of ESWT in the treatment of hypertrophic scar regeneration.

A RCT by Dymarek (2023) investigated the effects of ESWT on pressure ulcers [100]. Patients (n=40) were randomly assigned to either radial ESWT (rESWT) or sham ESWT. Primary study outcomes included Wound Bed Score, Bates-Jansen Wound Assessment Tool, and wound characteristics. ESWT significantly decreased wound area (p<0.001), wound length (p<0.001), and wound width (p<0.0001) compared to sham ESWT. Further, wound Bed Score statistically increased (p<0.001) and Bates-Jansen Wound Assessment Tool statistically decreased (p<0.001) among patients who were treated with ESWT. Additionally, all studied outcomes among the sham ESWT group regressed throughout the duration of treatment. This data is limited by a small sample size and additional investigations are needed.

Summary

A limited body of evidence addresses ESWT for wound healing. The available evidence is insufficient to allow conclusions about the efficacy of ESWT for wound healing.

OTHER MUSCULOSKELETAL AND NEUROLOGIC CONDITIONS

Other possible uses of ESWL noted in the literature but not supported by evidence from randomized controlled clinical trials include: osteochondritis dissecans, patellar tendinitis and other forms of chronic tendinitis, chronic low back pain, and dystonia.[67, 101, 102]

In 2023, a systematic review and meta-analysis by Liu examined the efficacy and safety of ESWT for treatment of low back pain [102]. A total of 12 RCTs (n=632) were included with study duration spanning from four weeks to 12 weeks. Primary outcomes included pain, lumbar dysfunction, and mental health. Compared to control, ESWT better improved pain relief at four weeks and 12 weeks ($p<0.001$ and $p<0.001$). ESWT significantly improved lumbar dysfunction at four weeks and 12-weeks compared to control ($p<0.001$ and p-0.03). No significant differences were identified regarding mental health between ESWT and control groups. Further research is needed to identify how ESWT compares to standard of care and longitudinal data is needed.

ESWT has been investigated for treatment of coccydynia in a small case series of two patients[103], an RCT with 34 patients[104], and painful neuromas at amputation sites in a small RCT of 30 patients.[105]

In the 2014 systematic review and meta-analysis of ESWT for lower extremity tendinopathies by Mani-Babu [67], described in previous sections, the study authors reviewed two studies of ESWT for greater trochanteric pain syndrome, including one quasi-RCT comparing ESWT with home therapy or corticosteroid injection and one case-control study comparing ESWT with placebo. ESWT was associated with some benefits compared with placebo or hone therapy.

PRACTICE GUIDELINE SUMMARY

The 2010 American College of Foot and Ankle Surgeons (ACFAS) practice guideline on the treatment of heel pain identifies ESWT as a third tier treatment modality in patients who have failed other interventions, including steroid injection.[106] The guideline recommends ESWT as a reasonable alternative to surgery. However, the guideline references the same unreliable studies considered above.

SUMMARY

There is not enough research to show that extracorporeal shock wave therapy (ESWT) as a treatment for any musculoskeletal conditions improves health outcomes. There are no clinical guidelines based on high quality evidence that recommend ESWT for any musculoskeletal or soft tissue conditions. Therefore, ESWT is considered **investigational** for all musculoskeletal indications.

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CODES

Codes	Number	Description
CPT	0101T	Extracorporeal shock wave involving musculoskeletal system, not otherwise specified
	0102T	Extracorporeal shock wave performed by a physician, requiring anesthesia other than local, and involving the lateral humeral epicondyle
	0512T	Extracorporeal shock wave for integumentary wound healing, including topical application and dressing care; initial wound
	0513T	Extracorporeal shock wave for integumentary wound healing, including topical application and dressing care; each additional wound
	0864T	Low-intensity extracorporeal shock wave therapy involving corpus cavernosum, low energy
	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
	55899	Unlisted procedure, male genital system [when specified as ESWT (for example for ED or Peyronie's disease)]
HCPCS	None	

Date of Origin: *April 2001*