



Kansas City

An Independent Licensee of the Blue Cross and Blue Shield Association

Extracorporeal Shock Wave Therapy for Plantar Fasciitis and Other Musculoskeletal Conditions

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Policy

Blue Cross and Blue Shield of Kansas City (Blue KC) will not provide coverage for Extracorporeal Shock Wave Therapy for Plantar Fasciitis and Other Musculoskeletal Conditions. This is considered investigational.

When Policy Topic is covered

Not Applicable

When Policy Topic is not covered

Extracorporeal shock wave therapy (ESWT), using either a high- or low-dose protocol or radial ESWT, is considered **investigational**, as a treatment of musculoskeletal conditions, including but not limited to plantar fasciitis; tendinopathies including tendinitis of the shoulder and elbow (epicondylitis, tennis elbow), stress fractures, delayed union, non-union and avascular necrosis of the femoral head.

Considerations

Note: High-energy ESWT requires the use of anesthesia and is performed in a hospital or ambulatory surgery center. Low-energy ESWT is usually used in the office without anesthesia.

There are no specific CPT codes for the radial ESWT (rESWT). The existing category III CPT code for low energy ESWT - 0019T - should be used

Description of Procedure or Service

Extracorporeal shock wave therapy (ESWT) is a noninvasive method being evaluated to treat pain using shock waves or sound waves. These waves are directed from outside the body onto the area to be treated, the heel in the case of plantar fasciitis. Shock waves may be generated at high or low energy intensity, and treatment protocols may include more than one treatment.

Background

Extracorporeal shockwave treatment (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, thus 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 trials of ESWT in delayed union or non-union of bone fractures.

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 cause the pain. It should be noted that asymptomatic heel spurs can be found in up to 10% of the population.

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 these 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.

Tendinitis of the Elbow (Lateral Epicondylitis)

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 is caused by playing tennis; the majority occurs from other activities that involve repetitive extension of the wrist. Overuse of the extensor muscles leads 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.

Nonunion and Delayed Union

The definition of a fracture nonunion has remained controversial, particularly in the necessary duration to define a condition of nonunion. One proposed definition is failure of progression of fracture-healing for at least 3 consecutive months (and at least 6 months following the fracture) accompanied by clinical symptoms of delayed/nonunion (pain, difficulty weight bearing). For purposes of policy development, the following criteria have been used to define nonunion:

- at least 3 months have passed since the date of fracture;
- serial radiographs have confirmed that no progressive signs of healing have occurred;
- the fracture gap is 1 cm or less; and

- the patient can be adequately immobilized and is of an age likely to comply with non-weight bearing.

Delayed union refers to a decelerating bone healing process, as identified in serial radiographs. (In contrast, nonunion serial radiographs show no evidence of healing.) Delayed union can be defined as a decelerating healing process, as determined by serial radiographs, together with a lack of clinical and radiologic evidence of union, bony continuity, or bone reaction at the fracture site for no less than 3 months from the index injury or the most recent intervention.

The original U.S. Food and Drug Administration (FDA) labeling of fracture nonunions defined nonunions as fractures that had not shown progressive healing after at least 9 months from the original injury. This timeframe is not based on physiologic principles but was included as part of the research design for FDA approval as a means of ensuring homogeneous populations of patients, many of whom were serving as their own controls. Some fractures may show no signs of healing, based on serial radiographs as early as 3 months, while a fracture nonunion may not be diagnosed in others until well after 9 months. The current policy of requiring a 3-month timeframe for lack of progression of healing is consistent with the definition of nonunion as described in the clinical literature.

Regulatory Status

Currently, five ESWT devices are approved for marketing by the U.S. Food and Drug Administration (FDA). The OssaTron® device (HealthTronics, Marietta, GA), an electrohydraulic delivery system was approved by the FDA on July 20, 2000, for patients with chronic proximal plantar fasciitis—i.e., pain persisting more than 6 months and not responding to conservative management. It is also FDA-approved for treatment of lateral epicondylitis (tennis elbow). The Epos™ Ultra (Dornier, Germering, Germany), an electromagnetic delivery system, was approved by the FDA on January 15, 2002, for plantar fasciitis. The SONOCUR® Basic (Siemens, Erlangen, Germany) also uses an electromagnetic delivery system and was approved by the FDA for use in chronic lateral epicondylitis (symptoms unresponsive to conservative therapy for more than 6 months) on July 19, 2002. In 2005, the Orthospec™ Orthopedic ESWT (Medispec Ltd, Germantown, MD), an electrohydraulic spark-gap device, and the Orbasone™ Pain Relief System (Orthometrix, White Plains, NY), a high-energy sonic wave system, received approval for treatment of chronic proximal plantar fasciitis in patients 18 years of age or older.

Both high-dose and low-dose protocols have been investigated. A high-dose protocol consists of a single treatment of high-energy shock waves (1300 mJ/mm²). This painful procedure requires anesthesia. A low-dose protocol consists of multiple treatments, spaced 1 week to 1 month apart, in which a lower dose of shock waves is applied. This protocol does not require anesthesia. The FDA-labeled indication for the OssaTron® and Epos™ Ultra device specifically describes a high-dose protocol, while the labeled indication for the SONOCUR® device describes a low-dose protocol.

Another type of ESWT, radial ESWT (rESWT) received premarket approval (PMA) in May 2007. The FDA-approved device is the Dolorclast from EMS Electro Medical Systems, Nyon, Switzerland. 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.

Rationale

The most clinically relevant outcome measures of extracorporeal shock wave treatment (ESWT) are pain and functional limitations. Pain is a subjective, patient-reported measure. Therefore, pain outcomes require quantifiable pre- and posttreatment measures. Pain is most commonly measured with a visual analog scale (VAS). Quantifiable pre- and posttreatment measures of functional status are also used, such as Short Form (SF)-12 and SF-36. Minor adverse effects of ESWT are common but transient, including local pain, discomfort, local trauma, bleeding, and swelling. More serious adverse

outcomes of ESWT may potentially include neurologic damage causing numbness or tingling, permanent vascular damage, or rupture of a tendon or other soft tissue structure.

Because of the variable natural history of plantar fasciitis and other musculoskeletal conditions and the subjective nature of the outcome measures, randomized controlled trials (RCTs) are needed to determine whether outcomes are improved with ESWT. Trials should include a homogenous population of patients with a defined clinical condition, use standardized outcome measures whenever possible, and define *a priori* the magnitude of response that is clinically significant.

Literature Review

This policy was originally based on a 2001 TEC Assessment that concluded that ESWT met TEC criteria as a treatment for plantar fasciitis in patients who had not responded to conservative therapies.(1) Therefore, the 2001 medical policy stated that ESWT would be considered medically necessary in these patients. A 2003 TEC Assessment reviewed subsequently available literature on ESWT for musculoskeletal conditions with a focus on 3 conditions: plantar fasciitis, tendinitis of the shoulder, and tendinitis of the elbow.(2) The 2003 TEC Assessment came to different conclusions, specifically, that ESWT did not meet TEC criteria as a treatment of plantar fasciitis or other musculoskeletal conditions. Therefore, the policy statement was revised to indicate that ESWT is investigational. In October 2004, updated TEC Assessments were completed for plantar fasciitis and tendinitis of the elbow.(3,4) The 2004 TEC Assessments concluded that ESWT did not meet TEC criteria for the treatment of these conditions. Since the 2004 TEC Assessments, the policy has been updated periodically with literature searches using the MEDLINE database. The most recent literature update covered the period of December 2012 through January 20, 2014. Following is a summary of key studies to date.

Plantar Fasciitis

Eight studies met the inclusion criteria for the 2004 TEC Assessment.(3) Five double-blind RCTs, reporting on 992 patients, were considered to be of high quality. Overall, evidence included in the 2004 TEC Assessment showed a statistically significant effect on between-group difference in morning pain measured on a 0 to 10 VAS score. Uncertain was the clinical significance of the change. The absolute value and effect size were small. The most complete information on the number needed to treat to achieve 50% to 60% reduction in morning pain was from 2 studies of high-energy ESWT (and including confidential data provided by Dornier), combined number needed to treat=7 (95% confidence interval [CI], 4 to 15). Improvements in pain measures were not clearly associated with improvements in function. Effect size for improvement in pain with activity was nonsignificant, based on reporting for 81% of patients in all studies and 73% of patients in high-energy ESWT studies. Success in improvement in Roles and Maudsley (RM) score was reported for fewer than half the patients: although statistically significant, confidence intervals were wide. Where reported, improvement in morning pain was not accompanied by significant difference in quality-of-life measurement (SF-12, physical and mental scales) or use in pain medication.

Systematic reviews and meta-analyses of RCTs have reported that ESWT for plantar fasciitis is better than or comparable to placebo in reducing pain(5-7) and improving functional status in the short-term.(5,6) 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, eg, dose intensities, type of shockwaves and frequency of treatments, also often lacked uniformity. Additionally, given 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.

In 2005, results were reported from FDA-regulated trials delivering ESWT with the Orthospec™, and Orbasone™ Pain Relief System.(8,9) Orthospec™ examined efficacy in a multicenter, double-blind,

sham-controlled trial randomizing 172 participants with chronic proximal plantar fasciitis failing conservative therapy to ESWT or sham treatments in a 2 to 1 ratio.(9) At 3 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). However, there was no difference in improvement in patient-assessed activity and function between ESWT and sham groups. Orbasone™ conducted a multicenter, randomized, sham-controlled, double-blind trial in which 179 participants with chronic proximal plantar fasciitis were randomized to active or sham treatment. (8) At 3 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 3 months of 2.3; 95% CI, 1.5 to 3.3). While ESWT was associated with more rapid improvement (and statistically significant) in a mixed-effects regression model, insufficient details were provided to evaluate the analyses.

Gerdesmeyer et al reported a multicenter double-blind RCT of radial rESWT conducted for FDA PMA of the Dolorclast from EMS Electro Medical Systems in 2008.(10) In this study, 252 patients were randomized, 129 to rESWT and 122 to sham treatment. The patients had heel pain for at least 6 months and failure of at least 2 nonpharmacologic and 2 pharmacologic treatments before entry into the study. Three treatments at weekly intervals were planned, and more than 90% of patients in each group had all 3 treatments. Outcome measures were composite heel pain (pain on first steps of the day, with activity and as measured with Dolormeter), change in individual VAS scores, and RM score measured at 12 weeks and 12 months. Success was defined as at least 60% improvement in 2 of 3 VAS scores or, if less pain reduction, then 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 at 12 weeks included changes in RM 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 the 12-week follow-up, rESWT was followed by a decrease of the composite VAS score of heel pain by 72.1% versus 44.7% after placebo ($p=0.022$). The success rate for the composite score was 61% versus 42% ($p=0.002$). Statistically significant differences were noted on all secondary measures. A number of limitations concerning this published study prevent definite conclusions from being reached, including the following: the limited data concerning specific outcomes (eg, 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 from this publication. There are also questions about the adequacy of patient blinding regarding treatment.

Several smaller trials (50 patients or less) show inconsistent results.(11-13)

One RCT compared ESWT with an active alternative, endoscopic plantar fasciotomy.(14) This study included 65 patients with refractory plantar fasciitis who had failed at least 3 lines of treatment in the preceding 6 months. Outcome measures were a 0 to 100 VAS of morning pain, the American Orthopaedic Foot and Ankle (AOFAS) Ankle-Hindfoot Scale, and patient subjective assessment using the 4-item RM score. Over the course of 1-year follow-up, both groups improved significantly on each outcome parameter, and there were no significant differences between groups. The percent of patients achieving a least a 50% reduction in the AOFAS score was reported in 74% (25/34) of patients in the ESWT group compared with 68% (21/31) patients in the surgery group ($p=0.79$). Success rates at 1 year, defined as a patient-reported good or excellent outcome per the RM score, were reached in 70.6% (24/34) patients in the ESWT group compared with 77.4% (24/31) in the surgery group. At 2 years of follow-up, the percent reporting success was higher in the surgery group, with 80% (20/25) reporting a successful outcome versus 50% (13/26, $p=0.03$) in the ESWT group. Similarly, at 3-years follow-up, the percent reporting success was 80% (20/25) in the surgery group compared with 48% (11/23) in the ESWT group ($p=0.021$).

While approved by FDA for treatment of chronic plantar fasciitis and examined for efficacy in apparently well-designed, double-blind RCTs, the weight of evidence remains consistent with the conclusions of

the 2004 TEC Assessment.(3) Definitive, clinically meaningful treatment benefits at 3 months are not apparent, nor is it evident that the longer-term disease natural history is altered with ESWT.

Section Summary

There are numerous RCTs performed that evaluate ESWT for treatment of plantar fasciitis. The evidence is mixed, with some studies reporting a benefit and others not reporting a benefit. The reasons for this variability in the literature are not clear. In studies that report a benefit, the magnitude of effect on some or all of the outcomes is of uncertain clinical significance. As a result of these insufficiencies in the literature, it is not possible to determine whether ESWT improves outcomes for patients with plantar fasciitis.

Tendinitis of the Elbow (Epicondylitis)

Six randomized, double-blinded, placebo-controlled trials enrolling 808 patients with lateral epicondylitis met the inclusion criteria for the 2004 TEC Assessment.(4) Four trials were rated “good” quality and are summarized next. Three trials utilized low-energy ESWT, and one used high-energy ESWT. Two trials reported positive effects on pain, one trial had mixed results, and another large sham-controlled study reported negative results with ESWT.

- In the SONOCUR trial, 114 patients were randomized to low-energy ESWT or sham ESWT for 3 treatment sessions administered in 1-week intervals.(15) The main outcome measures were percent response on self-reported pain scale (at least 50% improvement on 0-100 VAS) and change in the Upper Extremity Function Scale (UEFS). Results of the 2 main outcome measures at 3 months showed greater improvement in the ESWT group. Response rate was 60% in the active treatment group and 29% in the placebo group ($p<0.001$). There was a 51% improvement in the UEFS score for the active treatment group, compared with a 30% improvement in the placebo group ($p<0.05$).
- The Rompe et al trial randomized 78 tennis players to 3 treatments at week intervals of low-energy or sham ESWT.(16) Outcomes included pain ratings during wrist extension and the Thomsen Provocation Test, the RM score, the UEFS score, grip strength, and satisfaction with return to activities. At 3 months’ follow-up, the ESWT group, compared with placebo, significantly improved on all outcomes except grip strength. Treatment success (at least a 50% decrease in pain) was 65% for the ESWT group and 28% for the placebo group ($p<0.01$) and 65% of the ESWT group, compared with 35% of the placebo group, were satisfied with their return to activities ($p=0.01$).
- The OssaTron trial randomized 183 patients to a single session of high-energy or sham ESWT.(17) Treatment success was a 50% improvement on investigator and self-assessment of pain on a 0 to 10 VAS and no or rare use of pain medication. At the 8-week follow-up, the ESWT group had a greater rate of treatment success than the placebo group (35% vs 22%, respectively $p<0.05$). Mainly responsible for group differences in treatment success was the investigator assessment of pain (48% vs 29%, respectively $p<0.01$); the improvements in self-assessment of pain (81% vs 70%, respectively; $p=0.06$) and nonuse of pain medication (81% vs 70%, respectively; $p=0.09$) were only marginal.
- In the Haake et al trial, 272 patients were randomized to 3 sessions of low-energy or sham ESWT. Treatment success was defined as achieving an RM score of 1 or 2 with no additional treatments.(18) At 12 weeks, the ESWT success rate was 25.8%, and the placebo success rate was 25.4%. The percentage of RM scores below 3 did not differ between groups at either 12 weeks (31.7% ESWT vs 33.1% placebo) or at 1 year (65.7% ESWT vs 65.3% placebo) of follow-up. Furthermore, the groups did not differ along any of 5 pain assessment measures or on grip strength.

A single large RCT on ESWT for lateral epicondylitis has been published since the 2004 TEC Assessment. In 2005, Pettrone and McCall reported results from a randomized double-blind trial conducted in 3 large orthopedic practices for 114 patients receiving either ESWT in a “focused” manner (2000 impulses at 0.06 mJ/mm^2 without local anesthesia) weekly for 3 weeks or placebo.(19)

Randomization was maintained through 12 weeks, and benefit demonstrated with respect to a number of outcomes: pain, functional scale, and activity score. Pain assessed on the VAS (scaled here to 10 points) declined at 12 weeks in the treated group from 7.4 to 3.8; among placebo patients from 7.6 to 5.1. A reduction in Thomsen test pain of at least 50% was demonstrated in 60.7% of those treated compared with 29.3% in the placebo group. Mean improvement on a 10-point UEFS activity score was 2.4 for ESWT-treated patients compared with 1.4 in the placebo group—difference at 12 weeks of 0.9 (95% CI, 0.18 to 1.6). Although this study found benefit of ESWT for lateral epicondylitis over 12 weeks, the placebo group also improved significantly; whether the natural history of disease was altered is unclear. A 2005 Cochrane review, which included the Pettrone and McCall trial, 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.”(20)

In 2008, Staples et al reported a double-blind controlled trial of ultrasound-guided ESWT for epicondylitis in 68 patients.(21) Patients were randomized to receive 3 ESWT treatments or 3 treatments at a subtherapeutic dose at weekly intervals. There were significant improvements in most of the 7 outcome measures for both groups over 6 months of follow-up and no between-group differences. The authors found little evidence to support use of ESWT for this indication.

At least 2 RCTs have compared ESWT with active comparators. Jeon et al compared ESWT with steroid injection in 22 patients who presented with newly diagnosed epicondylitis.(22) Outcomes were assessed at 8 weeks posttreatment with the RM score, as well as the Nirschl score. Both groups showed significant improvement on each outcome measure at 8 weeks. The steroid injection group improved to a greater extent on the Nirschl score within the first 2 weeks, but changes were similar at longer time points. There were no differences between groups on the RM score. A second RCT compared ESWT with 2 active comparators.(23) This trial randomized 59 patients with lateral epicondylitis to ESWT, physical therapy or a single corticosteroid injection. Outcome measures were a VAS for pain, grip strength and pinch strength by dynamometer, and ultrasound. The authors reported that the VAS pain scale improved significantly in all 3 groups at 6 months’ follow-up, but no between-group differences were recorded. There were no consistent changes reported on grip strength or on ultrasonography.

A 2013 systematic review of electrophysical therapies for epicondylitis concluded that the evidence is conflicting on the short-term benefits of ESWT.(24) No evidence was found demonstrating any long-term benefits with ESWT over placebo for epicondylitis treatment.

Section Summary

Current evidence does not support the use of ESWT to treat lateral epicondylitis. Clinical trials have not been consistent in showing a benefit. The highest quality trials have tended to show no benefit, and systematic reviews have generally concluded that the evidence does not support a treatment benefit.

Shoulder Tendinopathy

There are numerous small RCTs that have evaluated ESWT for shoulder tendinopathy, primarily calcific and noncalcific tendinopathy of the rotator cuff. In a 2013 systematic review and meta-analyses, Ioppolo et al included 6 RCTs on ESWT compared with sham treatment or placebo for calcific shoulder tendinopathy.(25) Greater shoulder function and pain improvements were found at 6 months with ESWT over placebo. Most studies were considered to be low quality. Huisstede et al published a systematic review of RCTs in 2011 that included 17 RCTs of calcific (n=11) and noncalcific tendinopathy of the rotator cuff.(26) 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.

An example of an individual RCT is a study by Hsu et al. This trial randomized 33 patients to receive 2 courses of ESWT and 13 patients to sham treatment and measured radiographic outcomes, Constant

score and pain scale.(27) ESWT results were good to excellent in 87.9% of shoulders and fair in 12.1%. In the controls, 69.2% had fair and 30.1% had poor results. Calcium deposits were completely eliminated in 7 and partially eliminated in 11 of ESWT patients and partially eliminated in 2 control patients.

An example of a high-energy versus low-energy trial is a study by Schofer et al. This trial compared the effects of high-energy versus low-energy ESWT in 40 patients with rotator cuff tendinopathy in 2009.(28) 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.

At least 1 RCT evaluated patients with bicipital tendinitis of the shoulder.(29) This trial enrolled 79 patients with tenosynovitis to ESWT or sham treatment. ESWT was given for 4 sessions once per week. Outcomes were measured at up to 12 months by a VAS for pain and the L'Insalata Shoulder Questionnaire. The mean decrease in the VAS score at 12 months was greater for the ESWT group compared with sham (4.24 vs 0.47 units, $p < 0.001$). There were similar changes in the L'Insalata Shoulder Questionnaire, with an improvement in scores for the ESWT group of 22.8 points.

Current evidence is insufficient to permit conclusions concerning the effect of this technology on shoulder tendinopathy.

Achilles Tendinopathy

Al-Abbad and Simon reported on a systematic review of 6 studies on ESWT for Achilles tendinopathy.(30) Included in the review were 4 small RCTs and 2 cohort studies. Satisfactory evidence was found demonstrating ESWT effectiveness in the treatment of Achilles tendinopathy at 3 months in 4 studies. However, 2 of the RCTs reviewed found no significant difference between ESWT and placebo in the treatment of Achilles tendinopathy.(31,32)

Costa et al reported a randomized double-blind, placebo-controlled trial of ESWT for chronic Achilles tendon pain treated monthly for 3 months in 2005.(31) 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 1 year. Two older ESWT-treated participants experienced tendon ruptures.

In 2008, Rasmussen et al reported a single-center double-blind controlled trial with 48 patients, half of them randomized after 4 weeks of conservative treatment to 4 sessions of active rESWT and half to sham ESWT.(32) Primary end point was AOFAS score measuring function, pain, and alignment and pain on VAS. The AOFAS score after treatment increased from 70 to 88 in the ESWT group and from 74 to 81 in the control ($p = 0.05$). Pain was reduced in both groups with no statistically significant difference between groups. The authors note that the AOFAS score may not be appropriate for the evaluation of treatment of Achilles tendinopathy. They conclude that ESWT appears to be a clinically relevant supplement to conservative treatment of tendinopathy; however, there is no convincing evidence for recommendation of the treatment.

Patellar Tendinopathy

A literature review to study the effectiveness of ESWT for patellar tendinopathy and to draft a treatment protocol resulted in review of 7 articles.(33) The authors found that most studies had methodologic 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 6 and 12 months, respectively. (34)

Medial Tibial Stress Syndrome

In 2009, Rompe et al published a report on the use of ESWT in medial tibial stress syndrome (MTSS), commonly known as “shin splints”.(35) In this nonrandomized cohort study, 47 patients with MTSS for at least 6 months received 3 weekly sessions of rESWT and were compared with 47 age-matched controls at 4 months. Mild adverse events were noted in 10 patients: skin reddening in 2 patients and pain during the procedure in 8 patients. Patients rated their condition on a 6-point Likert scale. Successful treatment was defined as self-rating “completely recovered” or “much improved.” The authors reported a significant success rate of 64% (30/47) in the treatment group compared with 30% (14/47) in the control group. This study represents another potential use for ESWT. In a letter to the editor, Barnes raised several limitations of this nonrandomized study, including the possibility of selection bias.(36) Larger randomized trials are needed.

Spasticity

Efficacy and safety of radial ESWT in the treatment of spasticity in patients with cerebral palsy was examined in a small RCT from Europe in 2011.(37) The 15 patients in this study were divided into 3 groups (ESWT in a spastic muscle, ESWT in both spastic and antagonistic muscle, placebo ESWT) and treated in 3 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 [not spasticity] to 4 [severe spasticity]) at 1, 2, and 3 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 the spastic muscle only was treated, there was an improvement of 1 point on the Ashworth Scale ($p = 0.05$ in comparison with placebo); for the group in which both 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 2 months after treatment, but not at 3 months.

Additional study with a larger number of subjects is needed to permit conclusions regarding the efficacy of this technology on spasticity.

Osteonecrosis of the Femoral Head

A systematic review of ESWT in osteonecrosis (avascular necrosis) of the femoral head was conducted by Alves et al in 2009.(38) Only 5 articles, all from non-U.S. sites, were identified: 2 RCTs, one comparative study, 1 open-label study, and 1 case report for a total of 133 patients. Several studies were from one center in Taiwan. Of the 2 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, eg, energy level and number of treatments. The authors state that more research is needed, particularly well-designed RCTs, to further elucidate the role of ESWT in treatment of osteonecrosis of the femoral head.

A comparative study not included in the Alves et al systematic review was published by Chen et al in 2009.(39) In this small study, for each of 17 patients with bilateral hip osteonecrosis, 1 side was treated with total hip arthroplasty, while the other was treated with ESWT. Each patient was evaluated at baseline and after treatment utilizing 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, which also appeared to be reduced. The authors then compared the ESWT-treated data with 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 6 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.

Based on the systematic review and this study, the impact of ESWT on net health outcome for osteonecrosis is unknown.

Nonunion, Delayed Union, Acute Fractures

In 2010, Zelle et al reviewed the English and German medical literature for studies of ESWT in the treatment of fractures and delayed union/nonunion, restricted to studies with greater than 10 patients.(40) Ten case series and 1 RCT were identified. Number of treatment sessions, energy protocols, and definitions of nonunion varied across studies; union rate after intervention was likewise heterogeneous, ranging from 40.7% to 87.5%. The authors conclude the overall quality of evidence is conflicting and of poor quality.

The RCT included in the Zelle review reported on the use of ESWT in acute long bone fractures.(41) Wang et al randomized trauma patients (n=56) with femur or tibia fractures to a single ESWT treatment following surgical fixation while still under anesthesia. Patients in the control group underwent surgical fixation but did not receive the ESWT treatment. 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 6 months, patients who had received ESWT had VAS scores of 1.19 compared with 2.47 in the control group ($p<0.001$); mean percentage of weight bearing at 6 months was 87% versus 78%, respectively ($p=0.01$). Radiographic evidence of union at each interval also favored the study group. At 6 months, 63% (17/27) of the study group achieved fracture union compared with 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.

One RCT of ESWT compared with surgery for nonunion of long bone fractures was identified. Cacchio et al enrolled 126 patients into 3 groups: low- or high-energy ESWT therapy, or surgery.(42) Patients were identified for participation in the study if referred to one of 3 Italian centers with nonunion fractures, here defined as at least 6 months without evidence of radiographic healing. The primary end point was radiographic evidence of healing. Secondary end point data of pain and functional status were collected by blinded evaluators. Neither patients nor treating physicians were blinded. At 6 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 end points 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.

The evidence does not permit conclusions about the impact of ESWT in fracture nonunion, delayed union, and acute long bone fractures.

Summary

Extracorporeal shock wave therapy (ESWT) is a noninvasive method being evaluated to treat pain using shock waves or sound waves. These waves are directed from outside the body onto the area to

be treated, eg, the heel in the case of plantar fasciitis. Shock waves may be generated at high- or low-energy intensity, and treatment protocols may include more than one treatment.

ESWT has been investigated for use in a variety of musculoskeletal conditions. Differences in treatment parameters among studies, including energy dosage, method of generating and directing shock waves, and use or absence of anesthesia, limit generalizations from results of multiple studies. The precise mechanism of action of ESWT and the impact of anesthesia on outcomes continue to be matters of discussion.

Data as to the effectiveness (impact on net health outcome) of ESWT in the treatment of musculoskeletal conditions remains inconclusive, including in the FDA-approved indications for plantar fasciitis and lateral epicondylitis. Therefore, the use of this technology in the treatment of musculoskeletal conditions, including plantar fasciitis, lateral epicondylitis, patellar tendonitis, and tendonitis of the shoulder, remains investigational. The use of ESWT is also investigational for the treatment or prevention of fracture nonunion or in the treatment of osteonecrosis of the femoral head.

Practice Guidelines and Position Statements

In 2010, Thomas et al published a revised practice guideline on the treatment of heel pain on behalf of the American College of Foot and Ankle Surgeons.(43) This guideline identifies ESWT as a third tier treatment modality in patients who have failed other interventions, including steroid injection. The guideline recommends ESWT as a reasonable alternative to surgery.

The National Institute for Clinical Excellence has published guidance on ESWT for a number of applications.

- Guidance issued in November 2003 states that current evidence on safety and efficacy for treatment of calcific tendonitis of the shoulder “appears adequate to support the use of the procedure, provided that normal arrangements are in place for consent, audit and clinical governance.”(44)
- Guidance issued in August 2009 states that current evidence on the efficacy of ESWT for refractory tennis elbow, Achilles tendinopathy, and plantar fasciitis “is inconsistent and the procedure should only be used with special arrangements for clinical governance, consent and audit or research.”(45-47)
- Guidance issued in January 2011 states that evidence on the efficacy and safety of extracorporeal shockwave therapy (ESWT) for refractory greater trochanteric pain syndrome “is limited in quality and quantity. Therefore this procedure should only be used with special arrangements for clinical governance, consent, and audit or research.”(48)

A 2007 summary by the Canadian Agency for Drugs and Technologies in Health noted that results from randomized trials of ESWT for plantar fasciitis have been conflicting.(49) The report notes that the “lack of convergent findings from randomized trials of ESWT for chronic plantar fasciitis suggests uncertainty about its effectiveness. The evidence reviewed in this bulletin does not support the use of this technology for this condition.” Similarly, a 2007 report by CADTH on ESWT for chronic lateral epicondylitis notes that the results from randomized trials have been conflicting and half of the studies showed no benefit over placebo for any outcome measures.(50) The report notes that “the lack of convincing evidence regarding its effectiveness does not support the use of ESWT for CLE (chronic lateral epicondylitis).” A third 2007 summary by the CADTH concludes that “the current evidence supports the use of high-energy ESWT for chronic calcific rotator cuff tendonitis that is recalcitrant to conventional conservative treatment, although more high-quality RCTs with larger sample sizes are required to provide more convincing evidence.”(51)

Medicare National Coverage

No national coverage determination (NCD) was identified. In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

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Billing Coding/Physician Documentation Information

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| 28890 | Extracorporeal shock wave, high energy, performed by a physician, requiring anesthesia other than local, including ultrasound guidance, involving the plantar fascia |
| 28899 | Unlisted procedure, foot or toes |
| 0019T | Extracorporeal shock wave involving musculoskeletal system, not otherwise specified, low energy |
| 0101T | Extracorporeal shock wave therapy; involving musculoskeletal system, not otherwise specified; high energy |
| 0102T | Extracorporeal shock wave therapy; high energy, performed by a physician, requiring anesthesia other than local, involving lateral humeral epicondyle |

Additional Policy Key Words

N/A

Policy Implementation/Update Information

- | | |
|--------|---|
| 5/1/01 | New policy added to the Medical section. Prior authorization required; medically necessary with criteria. |
| 3/1/02 | No policy statement changes. Prior authorization is not require; predetermination is recommended. |
| 3/1/03 | No policy statement changes. |
| 6/1/04 | Policy statement revised to indicate ESWT is considered investigational. Predetermination recommendation removed. |
| 3/1/05 | No policy statement changes. |
| 9/1/05 | No policy statement changes. |
| 3/1/06 | Description section expanded, rationale updated. |
| 9/1/06 | No policy statement changes. |
| 3/1/07 | No policy statement changes. |
| 9/1/07 | No policy statement changes. |
| 9/1/08 | No policy statement changes. |
| 9/1/09 | Policy statement updated to include radial ESWT. |
| 9/1/10 | No policy statement changes. |
| 9/1/11 | No policy statement changes. |
| 9/1/12 | No policy statement changes. |
| 9/1/13 | No policy statement changes. |
| 9/1/14 | No policy statement changes. |

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