Regence Oregon and Utah | Regence Idaho and select counties of Washington

Medical Policy Manual

Topic: Extracorporeal Shock Wave Treatment for Plantar Fasciitis and Other Musculoskeletal Conditions

Date of Origin: April 2001

Section: Medicine

Last Reviewed Date: September 2013

Policy No: 90

Effective Date: December 1, 2013

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 Treatment (ESWT)

Extracorporeal shock wave 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, 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-dose and low-dose protocols have been investigated. A high-dose protocol consists of a single treatment of high energy shock waves (1300mJ/mm^2). This painful procedure requires anesthesia. A low-dose 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.

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, Marietta, GA)	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, Germering, Germany)	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, Erlangen, Germany)	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 six months.
Orthospec™ Extracorporeal Shock Wave Therapy Device	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	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 six months or more.

Dolorclast® (EMS - Electro Medical Systems, Nyon, Switzerland)	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.

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 proved 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.

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.

Nonunion and Delayed Union

The definition of a fracture nonunion has remained controversial, particularly in the necessary duration 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 3 months, 6 months, or 9 months. The significance of disagreement on the clinical definition of nonunion is that study populations have been heterogeneous and comparisons between studies are difficult. 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 3 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.

Note: ESWT for Peyronie's disease is addressed in a separate medical policy, Medicine No. 109.

MEDICAL POLICY CRITERIA

Extracorporeal shock wave treatment, using either a high- or low-dose protocol, is considered **investigational** for all musculoskeletal indications, including but not limited to:

A. Acute fracture

B. Avascular necrosis (osteonecrosis) of the femoral head

C. Delayed union and nonunion of fractures

D. Plantar fasciitis

E. Tendinopathies, including but not limited to:

1. Achilles tendinopathy
2. Medial tibial stress syndrome (MTSS) ("shin splits")
3. Tendinitis of the elbow (including lateral epicondylitis, also known as tennis elbow)
4. Tendinitis of the shoulder (including calcific tendinitis of the shoulder)

SCIENTIFIC EVIDENCE

This policy is primarily based in part on 2003 and updated 2004 BlueCross BlueShield Association Technology Evaluation Center (TEC) Assessments[1-3], which evaluated the cumulative literature on extracorporeal shock wave treatment (ESWT) for musculoskeletal conditions, and focused on plantar fasciitis, tendinitis of the shoulder, and tendinitis of the elbow.

The most clinically relevant outcomes of ESWT 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. Both the 2003 and 2004 TEC Assessments focused on double-blind studies, as the observed placebo effect in double-blinded trials of ESWT for plantar fasciitis was substantially greater than in single-blind trials. 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 used in some studies were the Roles and Maudsley score, the Maryland Foot score, and the American Orthopedic Foot and Ankle Society (AOFAS) Ankle-Hindfoot scale.

Plantar Fasciitis

Technology Assessments

The 2004 TEC Assessment on ESWT for the treatment of chronic plantar fasciitis[2] focused on five randomized, double-blind studies reporting on 878 patients, all of which were judged to be of high quality based on specific criteria:[4-10]

- HealthTronics Surgical Services, Inc/Ogden et al.[4,5]

  293 patients with symptoms for at least 6 months' duration and failure to respond to at least three prior treatment interventions were enrolled in this trial. Patients were randomized to either sham or active treatment, and both groups demonstrated improvement at 12 weeks post-treatment. Two outcomes met statistical significance: patient reported improvement in pain on first walking in the morning and improvement in the investigator assessment of pain caused by applying pressure to the heel. However, the percent of patients who had a 50% improvement in pain was not statistically significant (60% vs. 48%, p=0.13). There was no significant difference between ESWT and placebo in the patients' self-assessments of the distance and time they were able to walk without heel pain, and pain medication use was similar in both groups. The HealthTronics report notes "none of the primary or secondary outcome measurements demonstrated differences as pronounced as the [blinded] investigator assessment."[4]

  It should be noted that Ogden and colleagues subsequently reported additional follow-up data from the above 12-week results[11], however, randomization was not preserved after 12 weeks, making the ability to draw conclusions from the data problematic.

- Buchbinder et al.[6]

  This trial enrolled 166 patients, who were randomized to either active or sham ESWT. Three treatment sessions of low-energy ESWT were given at weekly intervals. Study measures included overall, morning, and activity pain measured on a VAS scale, the Maryland Foot Score, and quality of life using SF36. Outcomes were assessed at 6 and 12 weeks. Improvements of a similar magnitude were reported for both groups on measures of pain and functioning. There were no significant group differences for any of the outcome measures.

- Haake et al.[7]

  In this trial, 272 patients with a 6-month history of plantar fasciitis were randomized to three treatments of medium-energy ESWT or sham ESWT, with treatment scheduled every two weeks. The primary outcome measure was the percentage success rate after 12 weeks based on the Roles and Maudsley score, where success was defined as a score of 1 or 2. Although both groups improved at 12 and 52 weeks, the differences between the two groups were not statistically significant for either primary or secondary outcomes. The success rate at 12 weeks was 34% in the ESWT group and 30% in the placebo group, and differences remained nonsignificant at the 1-year follow-up.

- Rompe et al.[8]

  In this study, 45 patients who ran 30 or more miles per week and who had plantar fasciitis for at least 12 months were randomized to three treatments of either medium-energy or sham ESWT. Treatment

success was defined as 50% improvement in self-assessment of morning pain. At six months follow-up, the ESWT group had greater improvement on self-assessment of morning pain ($p<0.001$, the AOFAS Ankle-Hindfoot scale ($p<0.001$), and the Roles and Maudsley Scale ($p<0.01$) compared to the placebo group. Treatment success was 60% for the ESWT group and 27% for the placebo group ($p=0.06$).

- Theodore et al/Dornier Medical Systems, Inc.[9,10]

  There were 150 patients enrolled in this study. All had a six month history of moderate-to-severe heel pain and had failed at least three attempts at conservative management. Patients were randomized to a single treatment of high-energy ESWT or to placebo. Treatment success was defined as the percent of patients achieving at least 60% improvement in morning pain. At three months, treatment success was 56% in the ESWT group and 45% in the sham group ($p=0.19$), a nonsignificant difference. The ESWT group had greater improvement in the average rating of morning pain (3.4 vs. 4.1, $p=0.04$) and greater percentage of patients scoring excellent/good on the Roles and Maudsley score (62% vs. 40%, $p=0.03$). Group differences on the remaining outcomes were nonsignificant, and post-treatment scores were not reported.

Also mentioned in the 2004 TEC Assessment were several other published studies that were deemed to be of lower quality due to disproportionate dropout rates between study groups, lack of double-blinding or other limitations.[12-14]

It should be noted that although the above studies employed differing treatment protocols (high-dose versus low-dose), there are no controlled clinical trials that test the relative efficacy of differing techniques for shock wave dosage or delivery. Specifically, the effect of different dosage protocols on physiologic measures, magnitude of treatment effect, and/or adverse effects has not been determined in humans.

In summary, the evidence included in the 2004 TEC Assessment concerning ESWT for the treatment of chronic plantar fasciitis demonstrated a statistically significant effect on between-group difference in morning pain measured on a 0–10 VAS score. However, the clinical significance of the change was uncertain as the absolute value and effect size were small. The most complete information on the number needed to treat (NNT) to achieve 50%–60% reduction in morning pain was derived from the three studies of high-energy ESWT, combined NNT =7 (95% CI: 4–15). Improvements in pain measures were not clearly associated with improvements in function. Effect size for improvement in pain with activity was non-significant, 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 score was reported for fewer than half the patients and 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. Therefore, TEC concluded that the technology assessment criteria were not met.

<u>Additional Randomized Controlled Trials</u>

- Since publication of the 2004 BCBSA TEC Assessment, results were reported to the FDA from trials delivering ESWT with the Orthospec™, Orthopedic ESWT, and Orbasone™ Pain Relief System as follows:

- Orthospec™[15]

  Efficacy was examined in a multicenter, double-blind, sham-controlled trial involving 172 participants with chronic proximal plantar fasciitis failing conservative therapy. Patients were randomized to ESWT or sham treatments in a 2 to 1 ratio. 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™[16,17]

  In a multicenter, randomized, sham-controlled, double-blind trial, 179 participants with chronic proximal plantar fasciitis were randomized to active or sham treatment. 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 statistically significant more rapid improvement in a mixed-effects regression model, insufficient details were provided to evaluate the analyses.

While approved by the FDA for treatment of chronic plantar fasciitis and examined for efficacy in apparently well-designed, randomized, double-blind, controlled trials, the weight of evidence remains consistent with the conclusions of the 2004 TEC Assessment. Definitive, clinically meaningful treatment benefits at three months were not apparent, nor was it evident that the longer-term disease natural history was altered.

- Additional published large randomized, controlled, double-blind clinical trials include the following:

  - Kudo and colleagues reported a statistically significant difference in improvement in mean pain score on first walking in the morning between the active treatment and placebo.[18] 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 and colleagues randomized 172 patients at a 2:1 ratio to either active ESWT (n=115) or sham (n=57).[19] 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.

- Gerdesmeyer and colleagues reported on a multicenter double-blind randomized controlled trial (RCT) of radial ESWT (rESWT) conducted for FDA premarket approval (PMA) of the Doloclast (spelled Dolorclast in the PMA summary) from EMS Electro Medical Systems. In this study, 252 patients were randomized, 129 to rESWT and 122 to sham treatment.[20] These patients had heel pain for at least six months, and failure of at least two nonpharmacological and two pharmacological treatments prior to entry into the study. Three treatments at weekly intervals were planned, and more than 90% of patients in each group had all three treatments. One patient required local anesthesia which was allowed by the study protocol. Outcome measures were composite heel pain (pain on first steps of the day, with activity and as measured with Dolormeter), change in individual visual analog scale (VAS) scores, and Roles and Maudsley score measured at 12 weeks and 12 months. (The PMA summary indicates that VAS scores were adjusted if rescue pain medications or other treatments were used by adding two points to the VAS score at the affected visit. This was not noted in the published article; no further details on the use of analgesics were provided in the publication. Success was defined as at least 60% improvement in two of three VAS scores OR, if less pain reduction, then 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. Patients who did not achieve success at 12-weeks follow-up were allowed to withdraw and their results were carried forward for the 12-month analysis. (For this reason, results at 12 months are not discussed in this section.) A value of $P<0.025$ (1-sided) for between group difference was considered significant. A number of secondary outcomes were also 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 decrease of the composite VAS score of heel pain by 72.1% vs 44.7% after placebo ($P=.0220$); although the final VAS scores were not provided. Success rates on individual VAS scores were as follows: heel pain when taking first steps in the morning, 60.8% for ESWT vs 48.31% for placebo ($P=0.0269$ – not significant), heel pain during daily activities, 60% for ESWT vs 40.68% ($P=0.0014$), and heel pain after application of Dolormeter, 52.85% vs. 39.66% ($P=.0216$). The success rate for the composite score was 61% vs. 42% ($P=0.002$). Statistically significant differences were noted on all secondary measures. On SF-36 physical, the percent change was -44.1 for ESWT and -23.9 for placebo and on SF-36 mental the change was -22.8 vs -14.3. Just over half (58.4%) of the ESWT group and 41.52% of placebo group had good or excellent Roles and Maudsley scores. Patient global judgment of therapy satisfaction was very or moderately satisfied in 63.16% of ESWT and 46.36% of placebo patients. There are a number of limitations concerning this published study that prevent definite conclusions from being reached including the following: 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 from this publication. There are also questions about the adequacy of patient blinding regarding treatment.

- Additional randomized controlled trials and meta-analysis of these trials regarding ESWT for plantar fasciitis have been published.[21-26] However, these are small and/or short trials with significant methodological limitations and inconsistent conclusions. 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.

Clinical Practice Guidelines

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.[27] The guideline recommends ESWT as a reasonable alternative to surgery. However, the guideline references the same unreliable studies considered in this review.

In summary, the evidence consists of unreliable studies with methodological limitations. Therefore, no reliable conclusions can be reached concerning ESWT for the treatment of plantar fasciitis.

Tendinopathies

Tendinitis of the Shoulder

Technology Assessments

In the 2003 TEC Assessment[1], four studies enrolled a total of 199 patients with tendinitis of the shoulder. Two were randomized, double-blind controlled trials, comparing ESWT to sham ESWT[15,16]; and two were nonrandomized, unblinded controlled trials.[28,29] Only the study by Schmidt was rated as "good," meeting all of the quality criteria.[30] In this study, both treatment and sham groups showed similar improvements on pain and functional status measures, with no significant group differences.

The remaining three studies were rated as "poor" due to several serious methodological limitations. Two studies were nonrandomized studies and did not use blinding, which were considered fatal flaws in the TEC Assessment.[28,29] Although the study by Speed and colleagues was randomized and double-blinded, there was an unacceptably large loss to follow-up of 32% for the primary endpoint — also considered a fatal flaw.[31]

The TEC Assessment concluded there was not sufficient evidence to permit conclusions concerning whether ESWT improved outcomes for patients with tendinitis of the shoulder. The highest quality evidence, two placebo controlled trials, including one rated "good" quality, suggested that there is no benefit in health outcomes for this indication.

Additional Randomized Controlled Trials

Since completion of the 2003 BCBSA TEC Assessment, additional double-blinded, randomized studies were published:

- Gerdesmeyer and colleagues compared the effectiveness of high-energy and low-energy ESWT to sham treatment in patients with calcific tendonitis.[32] Although patients and evaluators were blinded to the treatment, all patients underwent 10 sessions of physiotherapy following ESWT, which introduced a co-intervention. This study demonstrated statistically significant improvements in VAS

scores between active and sham treatments at 6 and 12 months; however, there was a significant dropout rate at 12 months. While the findings of this study indicate there may be a treatment effect from ESWT (particularly high-energy EWST), the authors stated that their findings need to be confirmed in high-quality randomized clinical trials with different treatment protocols and treatment parameters. They also stated that further studies were necessary to analyze long-term treatment effects.

- Pleiner and colleagues randomized 43 patients with calcific tendonitis to sham or active ESWT, the latter of which consisted of two treatment sessions of high-energy ESWT, two weeks apart.[33] There was a high overall loss to follow-up of 23%; dropouts were counted as treatment non-responders in the analysis. This study reported a larger decrease in pain scores for the active ESWT group, but the difference was not statistically significant. Similarly, more patients had complete resolution of their calcific deposits, but the differences did not reach statistical significance. However, there was a statistically significant improvement in the Constant and Murley score (a measure of functional status) for the active ESWT group.

- In the third randomized, double-blinded study, Peters and colleagues randomized 90 patients to sham, low-dose, or high-dose ESWT.[34] There were large differences in reported outcomes favoring the high-dose ESWT group. For example, 82% of patients in the high-dose group were pain-free after one treatment, compared with 0% in the placebo and low-dose groups. All patients in the high-dose ESWT group had resolution of their calcific deposits and none had recurrence of pain at 6 months, whereas in the other two groups, no patients had complete resolution of calcific deposits, and nearly all reported recurrence of pain at 6 months. It should be noted that statistical analysis was poorly reported in this study, omitting some comparisons between the treatment and placebo groups. Also, this study used unusual outcome measures, including the average number of treatments required to become pain-free and the percent of patients with recurrence of pain after 6 months.

- Hsu and colleagues concluded from their single-center study that ESWT showed promise for treatment of calcifying tendonitis of the shoulder.[35] In this study, patients were randomized to receive two courses of ESWT (n=33) or sham treatment (n=13). Outcome measures included radiographic outcomes, Constant score and pain scale. 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% poor results. Calcium deposits were completely eliminated in seven and partially eliminated in 11 of ESWT patients and partially eliminated in two control patients.

- Schofer and colleagues compared the effects of high-energy versus low-energy ESWT in 40 patients with rotator cuff tendinopathy.[36] 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.[37-41]

In summary, there is insufficient evidence to permit conclusions concerning whether ESWT improves outcomes for patients with tendinitis of the shoulder without calcification. Results of the two small trials enrolling patients with this indication do not suggest a benefit from ESWT. In contrast, data from trials enrolling patients with calcific tendinitis are promising; however, a confirmatory trial mirroring the good quality of the Gerdesmeyer trial with longer follow-up is needed. Evidence from the currently available

trials is suggestive of a treatment benefit but is not sufficient to permit conclusions concerning health outcomes.

Tendinitis of the Elbow

Technology Assessments

Six randomized, double-blinded, placebo-controlled trials enrolling 808 patients with lateral epicondylitis met the inclusion criteria for the 2004 TEC Assessment.[3] 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[42]; and 2) lack of accounting for dropouts and intent-to-treat analysis.[43] Four trials were rated "good" quality and are summarized below:

- In the SONOCUR trial, 114 patients were randomized to low-energy ESWT or sham ESWT for 3 treatment sessions administered in 1-week intervals.[44] 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 OssaTron trial randomized 183 patients to a single session of high-energy or sham ESWT.[45] Treatment success was defined as a 50% improvement in investigator and self-assessment of pain on a 0–10 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%, $p <0.05$). Mainly responsible for group differences in treatment success was the investigator assessment of pain (48% vs. 29%, $p <0.01$); the improvements in self-assessment of pain (81% vs. 70%, $p =0.06$) and non-use of pain medication (81% vs. 70%, $p =0.09$) were not statistically significant.

- Haake and colleagues reported on a trial that randomized 272 patients to 3 sessions of low-energy or sham ESWT.[17] Treatment success was defined as achieving a Roles and Maudsley score of 1 or 2 with no additional treatments. At 12 weeks, the ESWT success rate was 25.8%, and the placebo success rate was 25.4%. The percentage of Roles and Maudsley 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 on any of 5 pain assessment measures or on grip strength.

- Rompe and colleagues randomized 78 tennis players to 3 treatments at weekly intervals of low-energy or sham ESWT.[46] Outcomes included pain ratings during wrist extension and the Thomsen Provocation Test, the Roles and Maudsley score, the Upper Extremity Function score, grip strength, and satisfaction with return to activities. At 3 months follow-up, the ESWT group, compared to 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 to 35% of the placebo group were satisfied with their return to activities ($p=0.01$).

Overall, the TEC Assessment concluded that the available data did not provide strong and consistent evidence that ESWT improved outcomes of chronic lateral epicondylitis.

Additional Randomized Controlled Trials

Since publication of the 2004 BCBSA TEC Assessment, additional randomized trials were published:

- In the first, sixty subjects were randomly allocated to receive one session per week for three weeks of either sham or active ESWT.[47] All subjects were provided with a forearm-stretching program. After eight weeks of therapy, subjects were classified as either treatment successes or treatment failures according to fulfillment of all three criteria: 1) at least a 50% reduction in the overall pain visual analog scale score; 2) a maximum allowable overall pain visual analog scale score of 4.0 cm; and 3) no use of pain medication for elbow pain for two weeks before the eight week follow-up. Success rates in the sham and active therapy groups were not significantly different (31% and 39%, respectively, p=0.533).

- In the second study, Pettrone and McCall reported results from a randomized double-blind trial conducted in three large orthopedic practices.[48] This study enrolled 114 patients who received either placebo or ESWT weekly for three weeks in a "focused" manner (2,000 impulses at 0.06 mJ/mm-2 without local anesthesia). Randomization was maintained through 12 weeks, and benefit was demonstrated with respect to a number of outcomes, namely 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 (mean 3.6, 95% CI: 2.8 to 4.5) and among placebo patients, from 7.6 to 5.1 (mean 2.4, 95% CI: 1.6 to 3.3). A reduction in Thomsen test pain of at least 50% was demonstrated in 60.7% of those treated compared to 29.3% in the placebo group (ARR 31.4%, 95% CI: 13.2 to 46.9). Mean improvement on a 10-point upper extremity functional activity score was 2.4 for ESWT-treated patients compared to 1.4 in the placebo group — a difference at 12 weeks of 0.9 (95% CI .18 to 1.6). This study found benefit of ESWT for lateral epicondylitis over 12 weeks. However, the placebo group also improved significantly. Whether the natural history of disease was altered is unclear.

- Staples and colleagues conducted a double-blind controlled trial of ultrasound-guided ESWT for epicondylitis.[49] Sixty-eight patients were randomized to receive three ESWT treatments or three treatments at a subtherapeutic dose at weekly intervals. There were significant improvements in most of the seven outcome measures for both groups over six months of follow-up and no between-group differences. The authors found little evidence to support use of ESWT for this indication.

- Radwan and colleagues randomly assigned 56 patients with persistent tennis elbow to ESWT without anesthesia (29 patients) or percutaneous tenotomy (27 patients).[50] Both groups improved at all time points through 12-months follow-up. At three months, the success rates, defined as Roles and Maudsley score: excellent and good, were 74.1% of patients in the tenotomy group and 65.5% of ESWT patients.

Additional randomized controlled trials of ESWT for elbow tendinopathy have been published. However, these trials have significant methodological limitations as well (e.g., small study populations, short duration of follow-up) and as such do not warrant detailed discussion.[51,52]

In summary, the available data are inconsistent; 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 the different results are due to methodological bias or to differences in the study populations and interventions. In the context of mixed results from previous studies, only exceedingly convincing differential outcomes provide sufficient evidence to alter the conclusions of the 2004 TEC

Assessment. 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."[53,54] 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.

Chronic Achilles Tendon Pain

Randomized Controlled Trials

- Costa and colleagues conducted a randomized, double-blind, placebo-controlled trial of ESWT for chronic Achilles tendon pain treated monthly for three months.[55] 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.

- Rasmussen and colleagues 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 radial ESWT and half to sham ESWT.[56] 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. They concluded 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.

Medial Tibial Stress Syndrome (MTSS) ("shin splints")

Randomized Controlled Trials

No randomized controlled trials of ESWT for MTSS were identified.

Non-randomized Studies

In 2009, Rompe and colleagues published a report on the use of ESWT in medial tibial stress syndrome (MTSS).[57] In this non-randomized cohort study, 47 patients with MTSS for at least 6 months received 3 weekly sessions of radial ESWT, and were compared to 47 age-matched controls at four months. Mild adverse events were noted in ten patients: skin reddening in 2 patients and pain during the procedure in 8 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

Randomized Controlled Trials (RCTs)

A small RCT examined the efficacy and safety of radial ESWT in the treatment of spasticity in patients with cerebral palsy.[58] The 15 patients in this study were divided into 3 groups (ESWT in a spastic muscle, ESWT in both spastic and antagonistic muscle, and 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 (0-4, no spasticity to 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 only the spastic muscle was treated, there was an improvement of 1 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 2 months after treatment, but not at 3 months.

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

Avascular Necrosis (Osteonecrosis) of the Femoral Head

Comparative Studies

Chen and colleagues 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.[59] 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 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.

Nonunion, Delayed Union and Acute Fractures

Randomized Controlled Trials

- Cacchio and colleagues compared surgery to low- and high-energy ESWT in 126 patients.[60] 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 and colleagues randomized 56 trauma patients with femur or tibia fractures to a surgical fixation with or without subsequent single ESWT treatment.[61] 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 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 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.

Other

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, and dystonia.[62]

Summary

In summary, studies continue to provide weak or contradictory evidence of efficacy for extracorporeal shock wave treatment (ESWT) as a treatment of any musculoskeletal condition. Differences in treatment parameters among studies including energy dosage, method of generating and directing shock waves, and use or absence of anesthesia preclude making 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. Given these findings, high-quality randomized trials with large numbers of patients are needed to demonstrate a clear and substantial benefit for ESWT in these musculoskeletal conditions. Therefore, ESWT is considered investigational for all musculoskeletal indications.

REFERENCES

1. TEC Assessment 2003. "Extracorporeal Shock Wave Treatment (ESWT) for Musculoskeletal Condition." BlueCross BlueShield Association Technology Evaluation Center, Vol. 18, Tab 5.
2. TEC Assessment 2004. "Extracorporeal Shock Wave Treatment for Chronic Plantar Fasciitis." BlueCross BlueShield Association Technology Evaluation Center, Vol. 19, Tab 18.
3. TEC Assessment 2004. "Extracorporeal Shock Wave Treatment for Chronic Tendinitis of the Elbow (Lateral Epicondylitis)." BlueCross BlueShield Association Technology Evaluation Center, Vol. 19, Tab 16.

4. HealthTronics Surgical Services Inc. Supplementary data including Final report G960232 for HealthTronics Ossatron™ indicated for ESWL treatment of chronic proximal plantar fasciitis, submitted to FDA on April 6, 2001.
5. Ogden, JA, Alvarez, R, Levitt, R, Cross, GL, Marlow, M. Shock wave therapy for chronic proximal plantar fasciitis. *Clin Orthop Relat Res*. 2001 Jun(387):47-59. PMID: 11400894
6. Buchbinder, R, Ptasznik, R, Gordon, J, Buchanan, J, Prabaharan, V, Forbes, A. Ultrasound-guided extracorporeal shock wave therapy for plantar fasciitis: a randomized controlled trial. *JAMA*. 2002 Sep 18;288(11):1364-72. PMID: 12234230
7. Haake, M, Buch, M, Schoellner, C, et al. Extracorporeal shock wave therapy for plantar fasciitis: randomised controlled multicentre trial. *BMJ*. 2003 Jul 12;327(7406):75. PMID: 12855524
8. Rompe, JD, Decking, J, Schoellner, C, Nafe, B. Shock wave application for chronic plantar fasciitis in running athletes. A prospective, randomized, placebo-controlled trial. *Am J Sports Med*. 2003 Mar-Apr;31(2):268-75. PMID: 12642264
9. Theodore, GH, Buch, M, Amendola, A, Bachmann, C, Fleming, LL, Zingas, C. Extracorporeal shock wave therapy for the treatment of plantar fasciitis. *Foot Ankle Int*. 2004 May;25(5):290-7. PMID: 15134608
10. Dornier Medical Systems Inc. Dornier Epos™ Ultra Summary of Safety and Effectiveness, PMA #P000048. [cited 12/15/2008]; Available from: http://www.fda.gov/cdrh/pdf/p000048.html
11. Ogden, JA, Alvarez, RG, Levitt, RL, Johnson, JE, Marlow, ME. Electrohydraulic high-energy shock-wave treatment for chronic plantar fasciitis. *J Bone Joint Surg Am*. 2004 Oct;86-A(10):2216-28. PMID: 15466731
12. Speed, CA, Nichols, D, Wies, J, et al. Extracorporeal shock wave therapy for plantar fasciitis. A double blind randomised controlled trial. *J Orthop Res*. 2003 Sep;21(5):937-40. PMID: 12919884
13. Rompe, JD, Schoellner, C, Nafe, B. Evaluation of low-energy extracorporeal shock-wave application for treatment of chronic plantar fasciitis. *J Bone Joint Surg Am*. 2002 Mar;84-A(3):335-41. PMID: 11886900
14. Cosentino, R, Falsetti, P, Manca, S, et al. Efficacy of extracorporeal shock wave treatment in calcaneal enthesophytosis. *Ann Rheum Dis*. 2001 Nov;60(11):1064-7. PMID: 11602481
15. U.S.Food and Drug Administration (FDA) Center for Devices and Radiological Health. Orthospec™ Summary of Safety and Effectiveness. [cited 12/15/2008]; Available from: http://www.fda.gov/cdrh/pdf4/p040026b.pdf
16. US. Food and Drug Administration (FDA) Center for Devices and Radiological Health. Orbasone™ Summary of Safety and Effectiveness. [cited 01/2012]; Available from: http://www.fda.gov/cdrh/PDF4/p040039b.pdf
17. Haake, M, Konig, IR, Decker, T, Riedel, C, Buch, M, Muller, HH. Extracorporeal shock wave therapy in the treatment of lateral epicondylitis : a randomized multicenter trial. *J Bone Joint Surg Am*. 2002 Nov;84-A(11):1982-91. PMID: 12429759
18. Kudo, P, Dainty, K, Clarfield, M, Coughlin, L, Lavoie, P, Lebrun, C. Randomized, placebo-controlled, double-blind clinical trial evaluating the treatment of plantar fasciitis with an extracoporeal shockwave therapy (ESWT) device: a North American confirmatory study. *J Orthop Res*. 2006 Feb;24(2):115-23. PMID: 16435344
19. Malay, DS, Pressman, MM, Assili, A, et al. Extracorporeal shockwave therapy versus placebo for the treatment of chronic proximal plantar fasciitis: results of a randomized, placebo-controlled, double-blinded, multicenter intervention trial. *J Foot Ankle Surg*. 2006 Jul-Aug;45(4):196-210. PMID: 16818146
20. Gerdesmeyer, L, Frey, C, Vester, J, et al. Radial extracorporeal shock wave therapy is safe and effective in the treatment of chronic recalcitrant plantar fasciitis: results of a confirmatory

randomized placebo-controlled multicenter study. *Am J Sports Med*. 2008 Nov;36(11):2100-9. PMID: 18832341
21. Gollwitzer, H, Diehl, P, von Korff, A, Rahlfs, VW, Gerdesmeyer, L. Extracorporeal shock wave therapy for chronic painful heel syndrome: a prospective, double blind, randomized trial assessing the efficacy of a new electromagnetic shock wave device. *J Foot Ankle Surg*. 2007 Sep-Oct;46(5):348-57. PMID: 17761319
22. Marks, W, Jackiewicz, A, Witkowski, Z, Kot, J, Deja, W, Lasek, J. Extracorporeal shock-wave therapy (ESWT) with a new-generation pneumatic device in the treatment of heel pain. A double blind randomised controlled trial. *Acta Orthop Belg*. 2008 Feb;74(1):98-101. PMID: 18411608
23. Ibrahim, MI, Donatelli, RA, Schmitz, C, Hellman, MA, Buxbaum, F. Chronic plantar fasciitis treated with two sessions of radial extracorporeal shock wave therapy. *Foot Ankle Int*. 2010 May;31(5):391-7. PMID: 20460065
24. Greve, JM, Grecco, MV, Santos-Silva, PR. Comparison of radial shockwaves and conventional physiotherapy for treating plantar fasciitis. *Clinics (Sao Paulo)*. 2009;64(2):97-103. PMID: 19219314
25. Radwan, YA, Mansour, AM, Badawy, WS. Resistant plantar fasciopathy: shock wave versus endoscopic plantar fascial release. *Int Orthop*. 2012 Oct;36(10):2147-56. PMID: 22782376
26. Zhiyun, L, Tao, J, Zengwu, S. Meta-analysis of high-energy extracorporeal shock wave therapy in recalcitrant plantar fasciitis. *Swiss Med Wkly*. 2013;143:w13825. PMID: 23832373
27. Thomas, JL, Christensen, JC, Kravitz, SR, et al. The diagnosis and treatment of heel pain: a clinical practice guideline-revision 2010. *J Foot Ankle Surg*. 2010 May-Jun;49(3 Suppl):S1-19. PMID: 20439021
28. Rompe, JD, Zoellner, J, Nafe, B. Shock wave therapy versus conventional surgery in the treatment of calcifying tendinitis of the shoulder. *Clin Orthop Relat Res*. 2001 Jun(387):72-82. PMID: 11400897
29. Loew, M, Daecke, W, Kusnierczak, D, Rahmanzadeh, M, Ewerbeck, V. Shock-wave therapy is effective for chronic calcifying tendinitis of the shoulder. *J Bone Joint Surg Br*. 1999 Sep;81(5):863-7. PMID: 10530851
30. Schmitt, J, Haake, M, Tosch, A, Hildebrand, R, Deike, B, Griss, P. Low-energy extracorporeal shock-wave treatment (ESWT) for tendinitis of the supraspinatus. A prospective, randomised study. *J Bone Joint Surg Br*. 2001 Aug;83(6):873-6. PMID: 11521932
31. Speed, CA, Richards, C, Nichols, D, et al. Extracorporeal shock-wave therapy for tendonitis of the rotator cuff. A double-blind, randomised, controlled trial. *J Bone Joint Surg Br*. 2002 May;84(4):509-12. PMID: 12043769
32. Gerdesmeyer, L, Wagenpfeil, S, Haake, M, et al. Extracorporeal shock wave therapy for the treatment of chronic calcifying tendonitis of the rotator cuff: a randomized controlled trial. *JAMA*. 2003 Nov 19;290(19):2573-80. PMID: 14625334
33. Pleiner, J, Crevenna, R, Langenberger, H, et al. Extracorporeal shockwave treatment is effective in calcific tendonitis of the shoulder. A randomized controlled trial. *Wien Klin Wochenschr*. 2004 Aug 31;116(15-16):536-41. PMID: 15471181
34. Peters, J, Luboldt, W, Schwarz, W, Jacobi, V, Herzog, C, Vogl, TJ. Extracorporeal shock wave therapy in calcific tendinitis of the shoulder. *Skeletal Radiol*. 2004 Dec;33(12):712-8. PMID: 15480643
35. Hsu, CJ, Wang, DY, Tseng, KF, Fong, YC, Hsu, HC, Jim, YF. Extracorporeal shock wave therapy for calcifying tendinitis of the shoulder. *J Shoulder Elbow Surg*. 2008 Jan-Feb;17(1):55-9. PMID: 18069011
36. Schofer, MD, Hinrichs, F, Peterlein, CD, Arendt, M, Schmitt, J. High- versus low-energy extracorporeal shock wave therapy of rotator cuff tendinopathy: a prospective, randomised, controlled study. *Acta Orthop Belg*. 2009 Aug;75(4):452-8. PMID: 19774810

37. Cosentino, R, De Stefano, R, Selvi, E, et al. Extracorporeal shock wave therapy for chronic calcific tendinitis of the shoulder: single blind study. *Ann Rheum Dis*. 2003 Mar;62(3):248-50. PMID: 12594112
38. Pan, PJ, Chou, CL, Chiou, HJ, Ma, HL, Lee, HC, Chan, RC. Extracorporeal shock wave therapy for chronic calcific tendinitis of the shoulders: a functional and sonographic study. *Arch Phys Med Rehabil*. 2003 Jul;84(7):988-93. PMID: 12881822
39. Galasso, O, Amelio, E, Riccelli, DA, Gasparini, G. Short-term outcomes of extracorporeal shock wave therapy for the treatment of chronic non-calcific tendinopathy of the supraspinatus: a double-blind, randomized, placebo-controlled trial. *BMC Musculoskelet Disord*. 2012 Jun 6;13:86. PMID: 22672772
40. Liu, S, Zhai, L, Shi, Z, Jing, R, Zhao, B, Xing, G. Radial extracorporeal pressure pulse therapy for the primary long bicipital tenosynovitis a prospective randomized controlled study. *Ultrasound Med Biol*. 2012 May;38(5):727-35. PMID: 22425375
41. Kim, JY, Lee, JS, Park, CW. Extracorporeal shock wave therapy is not useful after arthroscopic rotator cuff repair. *Knee Surg Sports Traumatol Arthrosc*. 2012 Feb 21. PMID: 22349603
42. Speed, CA, Nichols, D, Richards, C, et al. Extracorporeal shock wave therapy for lateral epicondylitis--a double blind randomised controlled trial. *J Orthop Res*. 2002 Sep;20(5):895-8. PMID: 12382950
43. Melikyan, EY, Shahin, E, Miles, J, Bainbridge, LC. Extracorporeal shock-wave treatment for tennis elbow. A randomised double-blind study. *J Bone Joint Surg Br*. 2003 Aug;85(6):852-5. PMID: 12931804
44. FDA CDRH Summary of Safety and Effectiveness for SONOCUR® 2002. [cited 12/15/2008]; Available from: http://www.fda.gov/cdrh/pdf/P010039b.pdf
45. FDA CDRH Summary of Safety and Effectiveness for OssaTron® 2000. [cited 12/15/2008]; Available from: http://www.fda.gov/cdrh/pdf/p990086b.pdf
46. Rompe, JD, Decking, J, Schoellner, C, Theis, C. Repetitive low-energy shock wave treatment for chronic lateral epicondylitis in tennis players. *Am J Sports Med*. 2004 Apr-May;32(3):734-43. PMID: 15090392
47. Chung, B, Wiley, JP. Effectiveness of extracorporeal shock wave therapy in the treatment of previously untreated lateral epicondylitis: a randomized controlled trial. *Am J Sports Med*. 2004 Oct-Nov;32(7):1660-7. PMID: 15494330
48. Pettrone, FA, McCall, BR. Extracorporeal shock wave therapy without local anesthesia for chronic lateral epicondylitis. *J Bone Joint Surg Am*. 2005 Jun;87(6):1297-304. PMID: 15930540
49. Staples, MP, Forbes, A, Ptasznik, R, Gordon, J, Buchbinder, R. A randomized controlled trial of extracorporeal shock wave therapy for lateral epicondylitis (tennis elbow). *J Rheumatol*. 2008 Oct;35(10):2038-46. PMID: 18792997
50. Radwan, YA, ElSobhi, G, Badawy, WS, Reda, A, Khalid, S. Resistant tennis elbow: shock-wave therapy versus percutaneous tenotomy. *Int Orthop*. 2008 Oct;32(5):671-7. PMID: 17551726
51. Gunduz, R, Malas, FU, Borman, P, Kocaoglu, S, Ozcakar, L. Physical therapy, corticosteroid injection, and extracorporeal shock wave treatment in lateral epicondylitis. Clinical and ultrasonographical comparison. *Clin Rheumatol*. 2012 May;31(5):807-12. PMID: 22278162
52. Jeon, JH, Jung, YJ, Lee, JY, et al. The effect of extracorporeal shock wave therapy on myofascial pain syndrome. *Annals of rehabilitation medicine*. 2012 Oct;36(5):665-74. PMID: 23185731
53. Buchbinder, R, Green, SE, Youd, JM, Assendelft, WJ, Barnsley, L, Smidt, N. Shock wave therapy for lateral elbow pain. *Cochrane Database Syst Rev*. 2005(4):CD003524. PMID: 16235324

54. Buchbinder, R, Green, SE, Youd, JM, Assendelft, WJ, Barnsley, L, Smidt, N. Systematic review of the efficacy and safety of shock wave therapy for lateral elbow pain. *J Rheumatol*. 2006 Jul;33(7):1351-63. PMID: 16821270
55. Costa, ML, Shepstone, L, Donell, ST, Thomas, TL. Shock wave therapy for chronic Achilles tendon pain: a randomized placebo-controlled trial. *Clin Orthop Relat Res*. 2005 Nov;440:199-204. PMID: 16239807
56. Rasmussen, S, Christensen, M, Mathiesen, I, Simonson, O. Shockwave therapy for chronic Achilles tendinopathy: a double-blind, randomized clinical trial of efficacy. *Acta Orthop*. 2008 Apr;79(2):249-56. PMID: 18484252
57. Rompe, JD, Cacchio, A, Furia, JP, Maffulli, N. Low-energy extracorporeal shock wave therapy as a treatment for medial tibial stress syndrome. *Am J Sports Med*. 2010 Jan;38(1):125-32. PMID: 19776340
58. Vidal, X, Morral, A, Costa, L, Tur, M. Radial extracorporeal shock wave therapy (rESWT) in the treatment of spasticity in cerebral palsy: a randomized, placebo-controlled clinical trial. *NeuroRehabilitation*. 2011;29(4):413-9. PMID: 22207070
59. Chen, JM, Hsu, SL, Wong, T, Chou, WY, Wang, CJ, Wang, FS. Functional outcomes of bilateral hip necrosis: total hip arthroplasty versus extracorporeal shockwave. *Arch Orthop Trauma Surg*. 2009 Jun;129(6):837-41. PMID: 19165494
60. Cacchio, A, Giordano, L, Colafarina, O, et al. Extracorporeal shock-wave therapy compared with surgery for hypertrophic long-bone nonunions. *J Bone Joint Surg Am*. 2009 Nov;91(11):2589-97. PMID: 19884432
61. Wang, CJ, Liu, HC, Fu, TH. The effects of extracorporeal shockwave on acute high-energy long bone fractures of the lower extremity. *Arch Orthop Trauma Surg*. 2007 Feb;127(2):137-42. PMID: 17053946
62. Trompetto, C, Avanzino, L, Bove, M, et al. External shock waves therapy in dystonia: preliminary results. *Eur J Neurol*. 2009 Apr;16(4):517-21. PMID: 19187259
63. BlueCross BlueShield Association Medical Policy Reference Manual "Extracorporeal Shock Wave Treatment for Plantar Fasciitis and Other Musculoskeletal Conditions." Policy No. 2.01.40
64. Ho, C. Extracorporeal shock wave treatment for chronic rotator cuff tendonitis (shoulder pain). *Issues Emerg Health Technol*. 2007 Jan(96 (part 3)):1-4. PMID: 17302022

CROSS REFERENCES

None

CODES	NUMBER	DESCRIPTION
CPT	0019T	Extracorporeal shock wave involving musculoskeletal system, not otherwise specified; low energy
	0101T	Extracorporeal shock wave involving musculoskeletal system, not otherwise specified, high energy
	0102T	Extracorporeal shock wave, high energy, performed by a physician, requiring anesthesia other than local, involving lateral humeral epicondyle
	28890	Extracorporeal shock wave, high energy, performed by a physician or other

CODES	NUMBER	DESCRIPTION
		qualified health care professional, requiring anesthesia other than local, including ultrasound guidance, involving the plantar fascia
HCPCS	None	