

POSITION PAPER ON USE OF EXTRACORPOREAL SHOCK WAVE THERAPY (ESWT) FOR MUSCULOSKELETAL PROBLEMS

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I. PURPOSE

The purpose of this document is to review the available literature concerning the use of Extracorporeal Shock Wave Therapy (ESWT) for the treatment of a variety of musculoskeletal conditions. It is focused to the rationale, outcomes to date, indications, complications, and criteria to be considered for authorization of the study. This information should assist MCOs and providers in authorization decisions for this service.

II. BACKGROUND

In the 1980's shock wave therapy was introduced to treat renal calculi. In the mid-late 1980's shock wave therapy was expanded to include treatment of stones in other organs such as the gall bladder, bile duct, pancreas, and salivary glands. Since 1990 several studies have been performed to assess the outcome of ESWT on a variety of orthopedic conditions including treatment of pseudoarthrosis, calcaneal spurs and/or plantar fasciitis, calcific tendonitis of the shoulder, and lateral epicondylitis.¹

Shock waves are single pulse sound waves that propagate rapidly and cause a sudden rise in pressure at the wave front. The waves are generated through a fluid medium such as water and a coupling gel to facilitate transmission into biologic tissues. The wave front dissipates mechanical energy at the interface of two structures with different acoustic impedance. While the exact mechanism of treatment is unknown, Varelein et.al. found no pathological changes in joint cartilage of rabbits administered 2000 shock waves of 1.2 mJ/mm² when analyzed at 0, 3, 12, and 24 weeks post intervention.² In another study, Hammer et. al. found that in 22 individuals with unilateral plantar fasciitis, the plantar fascia was thickened on the symptomatic side compared to the asymptomatic side when measured by ultrasound. Six months after administration of a course of ESWT, individuals noting improvement in symptoms were found to have a decrease in the thickness of the plantar fascia compared to pre-treatment thickness as measured by ultrasound. The decrease in the thickness of the fascia was not noted in those individuals that remained symptomatic.³

III. CLINICAL STUDIES

A. Plantar Fasciitis

Rompe et. al. performed a randomized, single-blinded study to determine the effectiveness of three applications of 2100 impulses of low-energy shock waves to long distance runners who had heel pain for more than 12 months and who had at least three attempts of non-operative treatment.

Non-operative treatment included physical therapy, orthotic devices, or prior course of pharmacologic treatment. Forty-five patients met the criteria and were randomized to receive either ESWT or a sham procedure. The treatment group received 2100 shocks at an energy flux density of 0.16 mJ/mm^2 at a frequency of 4 Hz without local anesthesia at one week intervals for three weeks. The control group received similar treatment except a sound reflecting pad was interposed between the coupling membrane of the treatment head and heel to absorb the shock waves. Patients were reevaluated at 6 and 12 months after last application of ESWT by another independent physician. The primary outcome was defined as a reduction of the subject's self assessment of pain on first walking in the morning using a 10 point visual analog scale. Secondary outcome measures were defined as $\geq 50\%$ reduction of a subject's self-assessment of pain on first walking in the morning, VAS rating of less than 4, and improvement from a baseline in the American Orthopaedic Foot and Ankle Society's Ankle-Hindfoot Scale. Sixteen patients of the treatment group and 19 patients in the control group were evaluated at 12 months. Results were as follows:

<u>Group</u>	<u>Measure</u>	<u>Initial</u>	<u>6-months</u>	<u>1-year</u>
Treatment	VAS in morning	6.9 \pm 1.3	2.1 \pm 2.0	1.5 \pm 1.7
Control	VAS in morning	7.0 \pm 1.3	4.7 \pm 1.9	4.4 \pm 1.7
Treatment	Ankle-Hndft Scale	52.7 \pm 10	89.9 \pm 8.6	90.4 \pm 8.3
Control	Ankle-Hndft Scale	49.7 \pm 10.1	69.1 \pm 20.1	75.4 \pm 17
Treatment	Subjective Scale	4.0 \pm 0.0	2.1 \pm 0.8	1.9 \pm 0.6
Control	Subjective Scale	4.0 \pm 0.0	3.0 \pm 1.0	2.7 \pm 1.1

At twelve months, 72% (13 of 18) of patients in the treatment group and 35% (7 of 20) of patients in the control group reported more than 50% improvement in pain on first walking in the morning. Those patients who refused to complete clinical evaluation were rated as treatment failures. The treatment was considered unpleasant but not as unpleasant as local infiltration received in prior treatment. No adverse side effects were noted.⁴

Buchbinder et.al. performed another randomized, double-blind, placebo controlled study of ESWT in individuals considered to have plantar fasciitis. Patient inclusion criteria consisted of plantar pain for at least six weeks and an ultrasound confirmed lesion defined as thickening of the origin of the plantar fascia greater than or equal to 4 mm as well as hypoechogenicity and alteration in the normal fibrillary pattern of the fascia. Patients were randomly assigned to the placebo group or treatment group. The placebo group (N = 85) received 100 shock waves per treatment with energy of 0.02 mJ/mm^2 at a frequency of 60 per minute. There were a total of three treatments given at weekly intervals. The total dose received by the placebo group was 6.0 mJ/mm^2 . The treatment group (N = 81) received 2000 or 2500 shock waves per treatment with energy varying between 0.02 and 0.33 mJ/mm^2 . The frequency of the impulse was gradually increased to 240 per minute. The treatment goal was a total dose of 1000 mJ/mm^2 . The mean dose in the experimental group was 1406 mJ/mm^2 . Outcome measures were performed at 6 and 12 weeks after completion of the three week treatment course. Measures included morning and activity pain measured on a 100 mm Visual Analog Scale, walking ability without need to rest due to a painful heel, The Maryland Foot Score, questioning using the Problem Elicitation Technique, and Short Form-36 Health Survey (SF-36). According to the authors, they could find no benefit of ESWT over placebo for this study. Both groups improved with respect to pain with a 20 mm improvement on the VAS at 6 weeks and 25 mm improvement at 12 weeks. There are

several limitations to this study including the short duration of symptoms for inclusion, short duration of follow-up post intervention, the placebo group received ESWT rather than sham therapy, and variable dosing for the intervention group.⁵

Rompe et. al. performed another randomized, double blind clinical trial in which 100 individuals were randomly assigned to receive 1000 impulses or 10 impulses of low-energy shock waves with weekly application over three weeks. Outcomes were measured at six months and five years by a blinded observer. Outcomes were based on a four step score of excellent (no pain, patient satisfaction with treatment outcome, and unlimited walking without pain); good (symptoms substantially decreased, patient satisfaction with treatment outcome, and ability to walk without pain for more than one hour); acceptable (symptoms somewhat decreased, pain more tolerable than before treatment, and slight patient satisfaction with treatment); and poor (symptoms identical or worse and patient dissatisfaction with treatment). At six months the rate of excellent and good outcomes was significantly better in the group receiving 1000 impulses by 47 percent over the group receiving 10 impulses per treatment. After five years the differences in scores decreased to 11 percent due to the high rate of good results from subsequent surgery in the group who received 10 impulses per treatment. Fifty-eight percent of patients receiving 10 impulses per treatment had undergone surgery compared to 13 percent of those who received 1000 impulses per treatment. No adverse side effects were noted. The authors concluded that three treatments of 1000 impulses of low-energy seemed to be a useful noninvasive treatment for plantar fasciitis and allowed patients to avoid surgery for chronic heel pain.⁶ This study prompted the American Academy of Orthopaedic Surgeons to post a “News Release” citing that ESWT effectively treats plantar fasciitis.⁷

On October 12, 2000, the Food and Drug Administration approved the marketing of the OssaTron – P990086 for the treatment of chronic plantar fasciitis for adult patients who have had symptoms for a minimum of six months and have tried other standard treatment.⁸

Plantar Fasciitis (2005 Update)

A study was performed by Speed et. al. to assess the effectiveness of moderate dose shock wave therapy in treating plantar fasciitis. The study included 46 patients randomly assigned to receive ESWT and 42 patients assigned to receive placebo. Inclusion criteria were three months of heel pain that failed to respond to conservative treatment and tenderness near the medial calcaneal insertion of the plantar fascia. Subjects received ESWT consisting of 1500 pulses at 0.12 mJ/mm² or sham ESWT once per month for three months. Symptoms were assessed at one and three months following completion of the ESWT. A response was considered positive with a 50% reduction from the baseline pain. At three months 37% of the ESWT group and 24% of the sham group showed a positive response. The authors concluded the study found no treatment effect of moderate dose ESWT over placebo. However, this study included patients with only three months of conservative treatment and the ESWT energy transmitted was less than that used in most other studies.⁹

Hammer et.al. reported on their two year results of a randomized cross-over study in which patients with a diagnosis of plantar fasciitis who had failed a minimum of six months of conservative treatment were randomized to one of two groups. Patients randomized to the first group (24 patients) were given three weekly treatments of ESWT (3000 shock waves/session at 0.2 mJ/mm²). Patients in the second group (23 patients) were treated with iontophoresis with diclofenac and oral NSAID. After twelve weeks, patients in the second group were allowed to receive ESWT using the same protocol as the first group. Clinical evaluations were performed at six, twelve, and 24 weeks and at two years following the completion of the ESWT. Outcome

measures included patient assessment using a Visual Analog Scale regarding different situations such as rest, activities of daily living, and one leg stance, and estimate of the duration of comfortable walking time. The second group showed no significant improvement with treatment after the first twelve weeks (iontophoresis) as described by the various activities using the Visual Analog Scale or duration of comfortable walking time. After receiving ESWT both groups noted improvement which was found to be 94% in the first group and 90% in the second group when assessed two years after completion of ESWT.¹⁰

Wilner and Strash¹¹ reported on their experience of treating 264 patients diagnosed with chronic proximal plantar fasciopathy who had symptoms for more than six months and failed conservative treatment. Using general anesthesia individuals underwent treatment with 1800 shocks at 18 kilovolts to the heel. Outcome measures included physician assessment of heel pain, patient's assessment of heel pain, patient assessment of activity level prior to developing pain, and patient's use of pain medications. Two years after treatment 87% of patients rated the outcome as good to excellent and only 2% showed no improvement. The authors were also using ESWT to treat other foot conditions such as Achilles tendonopathy and non-union of fractures with reported success.

Another study by Theodore et. al., randomly allocated 150 patients to receive one treatment of either ESWT or sham ESWT. All patients had symptoms for at least six months, failed conservative treatment, VAS score > 5, and Roles and Maudsley Score of 3 or 4 (fair, poor). The active group received 3800 shocks (3500 at 0.36 mJ/mm²) for a total of 1300 mJ/mm². Patients were evaluated at three months and those who received sham ESWT were offered one treatment of ESWT. Outcomes were assessed at three months and 12 months post treatment. Primary outcome measurement was reduction in pain while walking for the first few minutes in the morning as measured by the Visual Analog Scale score. The authors report a 57% success at three months and 94% success at 12 months post treatment in the active group. The crossover group (those who were provided ESWT three months after receiving sham ESWT) had a 78% good to excellent response at three months and 93% good response at 12 months. The control group had a 47% improvement in VAS from baseline with the sham ESWT. This was attributed to an expected 30% placebo improvement in chronic conditions and the self-limited nature of the condition.¹²

A study by Porter and Shadbolt¹³ compared treatment with ESWT to corticosteroid injection (CSI). Inclusion criteria were symptoms of heel pain for at least six weeks duration, site of maximal tenderness at the calcaneal attachment of the plantar fascia, and pain aggravated by hopping on the foot and relieved by tie-beam taping. All patients were instructed on a stretching exercise program. Sixty-four patients were randomly assigned to receive a single corticosteroid injection and 61 patients were randomly assigned to receive low-energy ESWT delivered as three applications at weekly intervals of 1000 pulses with an energy flux density of 0.08 mJ/mm². Nineteen patients who elected not to participate served as a control group performing only stretching exercises. Patients were assessed before treatment and three and twelve months post treatment. Outcome measures were the rating of pain on a Visual Analogue Scale (VAS) and a measurement of a tenderness threshold (TT) using a pressure algometer. Results are summarized in the following table:

	<u>Pre-Treatment</u>		<u>3 Mo. Post Treatment</u>		<u>12 Mo. Post Treatment</u>	
	<u>VAS</u>	<u>(TT)</u>	<u>VAS</u>	<u>(TT)</u>	<u>VAS</u>	<u>(TT)</u>
CSI	5.47 (2-8)	5.3 (1-11)	1.48 (0-7)	9.42 (7-11)	0.84 (0-7)	9.6 (7-11)
ESWT	5.52 (3-8)	5.2 (1-11)	3.69 (0-8)	6.72 (4-11)	0.84 (0-4)	9.54 (5-11)
Control	5.47 (3-7)	5.7 (4-7)	3.58 (2-5)	7.63 (6-9)	2.42 (1-4)	9.84 (8-11)

The authors concluded that at three months corticosteroid injection was more effective than ESWT in regard to pain and tenderness and at twelve months there was not difference. However, this study provided treatment in the first six weeks whereas most other studies waited until there was failed treatment for six months. Several patients in each group may have improved regardless of treatment due to the natural course of plantar fasciitis. Additionally, the dose of ESWT administered was below that generally recommended in more recent studies.

Ogden et. al. published a study that included non-randomized patients that were used to develop criteria for a randomized study and a randomized cross-over study. Inclusion criteria was failure to respond to at least three attempts at conservative treatment, assessment of pain over the plantar fascia by an examiner using a dolorimeter that was ≥ 5 cm on a 10 cm visual analog scale, and the patient self-assessment of pain after first five minutes of walking in the morning that was ≥ 5 cm on a 10 cm visual analog scale. Active treatment consisted of 100 graded shocks from 0.12 to 0.22 mJ/mm² to assess effectiveness of anesthesia followed by 1400 shocks at 0.22 mJ/mm². Placebo treatment was delivered with a Styrofoam block and fluid-filled intravenous bag between the treatment head and subject's heel. Patients were assessed at one, two, three, six, nine, and twelve months. Outcomes were assessed at three months and twelve months. Required positive outcome criteria included an improvement of at least 50% in the dolorimeter-induced baseline pain score, 50% improvement on the patient self-assessment of pain on first walking in the morning compared to baseline, an improvement by one point on a five point scale of the assessment of distance and time the patient could walk without pain, and no need to use pain medication between ten and twelve weeks after treatment. Patients who failed to improve at three months and those who received the placebo treatment were allowed to receive active treatment using the same protocol. The authors state that for the 289 patients who had one or more treatments, 76.8% had a good or excellent result.¹⁴

In another study Haake and others performed a randomized, blinded study that included 272 patients who had failed conservative treatment for plantar fasciitis for at least six months. The active treatment group (135 patients) was provided ESWT comprised of 4000 impulses at 0.08 mJ/mm² every two weeks for a total of three sessions. The placebo group (137 patients) received the same treatment except a polyethylene foil filled with air was fixed in front of the coupling cushion to reflect the shock waves. Outcomes were measured at six and twelve weeks and one year after the last treatment. Positive outcome was measured by a Roles and Maudsley score of 1 or 2 and if the patient received no additional treatment. At one year follow up, 81% of patients in the active group and 76% of patients in the placebo group reported a Roles and Maudsley score of 1 or 2. They concluded that they could not identify any improvement with the use of ESWT. It should be noted that the ESWT used is considered low energy ESWT.¹⁵

Thompson and Crawford performed a meta-analysis of published randomized controlled trials using ESWT from 1966 until September 2004. The study included six trials totaling 897 patients. They found statistical significance that was small in favor of ESWT for the treatment of plantar heel pain. When the two poorest quality trials were excluded which they state were the greatest source of bias, the results were not statistically significant. Therefore, their review did not support the use of ESWT for plantar heel pain.¹⁶

B. Calcific Tendonitis of Rotator Cuff (Shoulder)

Wang et. al. reported on a two year follow-up of ESWT used to treat calcific tendonitis of the shoulder. The treatment group consisted of 37 patients (39 shoulders) and the control group consisted of 6 patients (6 shoulders). Inclusion criteria included shoulder pain attributable to calcific tendonitis that failed to respond to 6 months of conservative treatment which may have included NSAIDs, physical therapy, corticosteroid injection, or immobilization. For the treatment group, ESWT was performed with application of 1000 impulses of shock waves at 0.18 mJ/mm² energy flux density after they received 2% xylocaine injection over the subacromial bursa. If initial treatment was inadequate, a repeat treatment was offered at 30 and 60 days. Control group received the same treatment except a dummy electrode was used so no shock wave was created. Outcomes were assessed by a 100 point Constant score system which includes marks for pain, activities of daily living, shoulder motion, and power or strength. X-rays were obtained with follow-up visits at 2 and 4 weeks and 3, 6, and 12 months and every year thereafter to assess presence and size of calcium deposits. Of the 31 patients (33 shoulders) completing the study, 24 patients (24 shoulders) received one treatment, 6 patients (7 shoulders) had two treatments, and 1 patient (2 shoulders) had three treatments. All six patients in the control group were followed for 5 to 8 months when they decided to obtain alternative treatment for their symptoms. Patients who did not respond adequately after the first treatment showed improvement after the second or third treatment. Results are:

<u>Group</u>	<u>Measure</u>	<u>Pre-Treatment</u>	<u>Post-Treatment</u>
Study Group	Pain Intensity*	3.17 ± 1.32	8.83 ± 1.82
Control Group	Pain Intensity	3.75 ± 1.04	3.92 ± 1.24
Study Group	Pain Score*	2.98 ± 1.02	6.98 ± 0.98
Control Group	Pain Score	3.08 ± 0.66	3.25 ± 0.82
Study Group	Power	7.06 ± 3.25	22.39 ± 4.66
Control Group	Power	5.33 ± 1.63	5.83 ± 1.94
Study Group	Activities	8.30 ± 4.11	18.58 ± 2.69
Control Group	Activities	6.50 ± 2.07	7.17 ± 2.48
Study Group	Motion	23.79 ± 9.69	38.18 ± 3.48
Control Group	Motion	28.00 ± 10.88	28.00 ± 10.88

*Pain Intensity and Pain Score is represented as a reverse Visual Analog Scale. Higher value means less pain.

The study group had a statistically significant reduction in the average size of the calcium deposit after treatment. Nineteen cases (57.6%) showed complete elimination of the calcium deposit, partial elimination was found in 5 cases (15.1%), and the deposit was unchanged in 9 (27.3%). The length of time for the elimination was 2 weeks to 3 months. In the control group one patient had fragmentation of the calcium deposits and the deposits remained unchanged in five patients. The authors report that there was no recurrence of calcium deposits at two years after ESWT. The authors theorized that the calcium deposits were eliminated through a molecular mechanism of absorption associated with improved circulation at the tendon-bone junction after ESWT. The authors described no adverse effect requiring special treatment.¹⁷

Another study to determine the benefit of ESWT on calcific tendonitis of the shoulder was performed by Gerdesmeyer et. al.¹⁸ The study was a double-blind, randomized, controlled trial to determine the effectiveness of high-energy ESWT, low-energy ESWT, or sham treatment for calcific tendonitis of the shoulder. Inclusion criteria were radiographic determination of calcific deposits of 5 mm or larger, symptoms for at least 6 months, prior treatment that included physical therapy, local anesthetic or corticosteroid injection, and a trial of NSAIDs. Forty-eight patients were randomly assigned to each group to receive high-energy ESWT, low-energy ESWT, or sham. Patients and follow-up evaluators were blinded to the treatment assignments. The high-energy ESWT group received 1500 shock waves at 0.32 mJ/mm² while the low-energy ESWT group received 6000 shock waves of 0.08 mJ/mm². The impulses were administered at 120 impulses per minute. All patients received a second session 12 to 16 days later. The cumulative energy dose for all treatment individuals was 0.960 J/mm². The sham group had a similar set-up except there was no coupling gel and an air-chambered polyethylene foil was placed between the patient and the ESWT device. This prevented the patient from receiving the dose though 1500 shock waves at 120 impulses per minute were administered. After intervention, patients in all three groups received 10 physical therapy sessions. Outcomes were assessed using the Constant and Murley Scale comparing baseline to the 6 month evaluation after completion of ESWT. This scale assesses degree of pain perception, ability to perform activities of daily living, measurements of active range of motion, and shoulder power. Clinical relevant improvement was considered as a 30% increase from baseline. The presence and size of calcium deposit was also determined at 3, 6, and 12 months by radiography using a standardized technique. Mean change for each group at six months from baseline values are as follows:

<u>Measurement</u>	<u>High-Energy</u>	<u>Low-Energy</u>	<u>Sham</u>
Number of patients	47	46	41
Pain Intensity*	8.7	3.7	1.1
Daily Activities	7.5	3.0	0.3
Range of motion	10.2	5.3	1.4
Power	5.9	3.2	1.1
Composite CMS	31	15	6.6
Prop with 30% improvement	.89	.41	.17

*Inverse visual analog score. Higher number means less pain.

Complete disappearance of calcium deposit was found in 60% of the high-energy group after 6 months and 86% of members after 12 months. In the low energy group, complete calcium deposit disappearance was found in 21% at 6 months and 25% after 12 months. Immediately after the procedure 20 patients in the high-energy group reported moderate pain and 16 reported severe pain. In the low-energy group, 22 reported moderate pain and 5 reported severe pain. Four patients in the sham group reported severe pain. Petechiae, bleeding, hematoma, or erythema were found directly after treatment in 36 patients in the high-energy group, 32 in the low-energy group, and 8 patients in the sham treatment group. No significant adverse effects were observed involving the tendon, bone, muscle, or neurological system. The authors concluded that high-energy ESWT was more effective than low energy ESWT but the threshold energy is not yet defined.

Calcific Tendonitis of Rotator Cuff (Shoulder) (2005 Update)

Moretti et. al., reported on 54 patients diagnosed with calcific tendonitis of the shoulder who underwent ESWT. Inclusion criteria were the presence of persistent shoulder pain that was refractory to conservative treatment for at least three months duration. Radiographs and

sonography were used to confirm calcium deposits and size. Patients received 2500 shock waves at 0.11 mJ/mm^2 per session. Four sessions were provided occurring every three days. Patients were assessed at one and six months following completion of the treatment sessions. Outcomes were graded based on the amount of pain relief (VAS), a Constant score, and resumption of working activity without limitations. On follow-up at six months 44% were considered excellent results, 26% good results, 23% fair and 7% poor. Work activity reportedly resumed to normal by the twelve day on average and the mean Constant score at one month follow-up was 68.2 compared to 24.5 initially. Radiographic and ultrasound evaluation at 1 month showed disappearance of calcium in 54% of the patients and reduction by more than half in 35% of the patients. In all four patients with poor results the calcium deposits were unchanged.¹⁹

Another study by Peters et. al. randomly assigned 90 patients with radiographically confirmed calcific tendonitis to receive either ESWT at 0.15 mJ/mm^2 , 0.44 mJ/mm^2 , or sham treatment. Treatment was provided at intervals of 6 weeks until symptoms resolved, five treatments were provided, or the patient dropped out of the program. Outcomes measured included assessment of pain during ESWT, side effects of treatment, number of ESWT sessions required to resolve pain and restore mobility, resolution of calcifications as identified by radiographs, and status of symptoms six months after the last treatment. Patients receiving the lower energy ESWT had less pain and fewer hematomas than patients receiving the higher energy ESWT. Only six of 31 patients in the high energy ESWT group required two treatments. At six month follow-up residual calcifications were seen in 28 of 29 sham ESWT patients, 30 of 30 lower ESWT treatment patients, and none of the 31 patients who received higher energy ESWT. In terms of pain, no patient receiving high energy complained of continued pain whereas 26 of 30 patients (87%) who received the low energy and all 29 of the 29 control (sham ESWT) patients continued to experience pain. The authors concluded that the higher energy ESWT was effective, required fewer treatments, and did not have significant side effects.²⁰

A systematic review of the medical literature published prior to May 2003 was performed by Harniman et. al. to assess the effectiveness of ESWT in treating calcific and noncalcific tendonitis of the shoulder.²¹ The authors identified 87 published reports in which the study design was a case series, cohort, case control, controlled clinical trial, or randomized controlled trial involving more than 20 subjects. Sixteen articles met inclusion criteria and were included in the review. The authors concluded that there was moderate evidence that high energy ESWT provided effective long-term improvement in pain, disability, motion and strength in patients with chronic calcific rotator cuff tendonitis when ESWT was directed at the calcific deposit. There was also moderate evidence that low-energy ESWT does not provide effective short-term improvement in pain, disability, motion, or strength in patients with chronic noncalcific rotator cuff tendonitis. However, the latter conclusion is based on only one high-quality study.

C. Non-Calcific Tendonitis of the Shoulder

Speed et. al., performed a double-blind placebo-controlled study to determine the effect of ESWT on non-calcific tendonitis of the shoulder. Participants had at least three months with clinical signs of tendonitis of the rotator cuff including a painful arc and/or an impingement sign and pain without weakness. Plain radiographs and ultrasound were used to exclude calcific tendonitis. Patients were randomly selected to receive either ESWT pulses at 0.12 mJ/mm^2 or sham treatment. Since the machine produces a noise with the delivery of each shock wave, minimal energy pulses (0.04 mJ/mm^2) were generated for the sham treatment. However, the treatment head was deflated, no coupling gel was applied and standard contact with the skin was avoided. Pre and post treatment measurements were obtained using a visual analogue scale for night pain

and the Shoulder Pain and Disability Index. The primary endpoint was taken as one month after the completion of treatment. A positive response was considered as an improvement of 50% at three months. Measurement in the Shoulder Pain and Disability Index (SPADI) and night pain are as follows:

<u>Time Interval</u>	<u>SPADI ESWT</u>	<u>SPADI Sham</u>	<u>Night Pain ESWT</u>	<u>Night Pain Sham</u>
Baseline	53.6±20.2	59.5±16.1	60.9±24.6	67.7±25.7
1 month	48.7±21.0	58.5±19.7	47.8±28.0	57.7±28.9
2 months	46.1±22.4	48.6±23.8	48.3±28.1	46.4±27.0
3 months	34.7±26.6	39.7±27.7	38.1±28.3	39.3±31.8
6 months	24.1±22.9	34.9±31.7	27.3±26.9	33.3±32.3

The authors concluded that there was no significant difference between ESWT and sham treatment for this condition. They attributed most of the improvement to placebo effect and found no evidence of added benefit from ESWT.²²

Schmitt et.al., also performed a controlled, randomised study to determine the effects ESWT on function and pain in tendonitis of the supraspinatus tendon without calcification. Twenty patients were randomly assigned to a control group and twenty to the treatment group. Inclusion criteria included an absence of calcification, duration of typical symptoms for at least six months, and failed conservative treatment. Patients received local anesthesia followed by 2000 impulses for three sessions at one week intervals. The control group received local anesthesia followed by sham impulses for three sessions at one week intervals. Foil was placed between the patients in the control group and the water cushion to prevent the shock wave from reaching the patient. Patients were evaluated at six and twelve weeks following completion of treatment. Evaluation consisted of a questionnaire that includes the Constant and Murley score and an assessment of pain on a VAS during activity and at rest. At six and twelve week follow-up no statistical difference between the two groups were found. The authors concluded that low-energy ESWT in the treatment of tendonitis was time-consuming, expensive, and had no benefit over subacromial injections.²³

D. Chronic Lateral Epicondylitis

Several articles have been written describing a limited series or anecdotal evidence of success using ESWT to treat chronic lateral epicondylitis (CLE). Wang and Chen²⁴ reported on a case series of 57 patients treated by ESWT for CLE comparing these to a control group of six patients who did not receive ESWT. Inclusion criteria were an established diagnosis of lateral epicondylitis for at least 6 months that failed to improve with nonoperative treatment. Treatment group received local anesthesia consisting of 2% lidocaine followed by 1000 impulses of ESWT at 0.18 mJ/mm² energy flux density. Nine of the 57 patients in the treatment group who had an inadequate response to the treatment were given a second treatment 30 to 45 days later. Two patients also received a third treatment. The control group underwent the same protocol except a dummy electrode was used in the ESWT machine so the machine did not generate a shock wave. Outcomes were measured using a 100 point scoring system that assessed pain, function, strength, and elbow range of motion. The intensity of pain for all evaluations was assessed using a reverse Visual Analog Scale. Of those patients receiving one treatment, 22 patients (67%) were free of complaints, 9 patients (27.3%) were significantly better, 2 patients (6.1%) were slightly better, and none were unchanged. Of the patients receiving two treatments, 4 patients (44.4%) were free of complaints, 4 patients (44.4%) were significantly better, and one patient (11.1%) was slightly

better. Of the two patients who received three treatments, one was free of complaints and the other was unchanged. There was no change in symptoms in the control group.

Haake et. al. performed a prospective, randomized, placebo-controlled study to evaluate the effectiveness of ESWT for the treatment of epicondylitis.²⁵ Inclusion criteria included diagnosis of CLE based on two or more positive clinical tests, 6 months of unsuccessful conservative therapy with three or more local injections, 10 or more physical therapy treatments, and 10 or more treatments with physical forms of therapy. Patients meeting criteria were randomly assigned to receive three treatments of low energy ESWT (134 patients) or sham treatment (137 patients). Treatments were immediately preceded by local anesthesia consisting of 3 ml of 1% mepivacaine. Treatments consisted of 2000 pulses with a positive energy flux density between 0.07 and 0.09 mJ/mm² and were provided weekly for three weeks. A polyethylene foil filled with air was placed between the ESWT machine and the coupling cushion during treatment of patients assigned to the sham treatment or placebo group. Treatment outcomes were assessed at 6 weeks, 12 weeks, and 12 months after the last treatment. The primary end point of the study was the 12 week assessment. Treatment was defined as successful if the patient score on the subjective pain scale described by Role and Maudsley was 1 or 2 (Rated “excellent” or “good”) and the patient had not received any additional treatment. Secondary end points were the Roles and Maudsley score, a Visual Analogue Scale score, and grip strength measurement. The success rate after 12 weeks for those patients completing follow up was:

<u>Measurement</u>	<u>ESWT Group</u>	<u>Placebo</u>
Success	32 (25.8%)	31 (25.4%)
Failure		
Total	92 (74.2%)	91 (74.6%)
Due to additional treatment alone	10 (8.1%)	10 (8.2%)
Due to Roles and Maudsley score of 3 or 4	53 (42.7%)	44 (36.1%)
Due to additional treatment and Roles and Maudsley score of 3 or 4	29 (23.4%)	37 (30.3%)
Total	124 (100%)	122 (100%)

There were no significant differences in the secondary end points between the ESWT and placebo groups. The authors noted that both groups were noted to have a clear improvement over the time period whether in the ESWT or placebo group. Side effects were monitored and most consisted of transitory reddening and swelling of the skin or pain following the application of shock waves. The authors concluded that there was no relevant difference in the clinical success rate of ESWT compared to placebo control group for the treatment of CLE.

Speed et. al. performed another randomized clinical study to determine the effectiveness of ESWT.²⁶ Inclusion criteria was unilateral lateral elbow pain for at least three months with point tenderness at or near the common extensor tendon insertion at the lateral epicondyle and pain reproduced with resisted extension of the middle finger distal to the proximal interphalangeal joint. Patients were randomly assigned to receive three ESWT treatments consisting of 1500 pulses at 0.18 mJ/mm² or sham (control) treatments consisting of 1500 pulses at 0.04 mJ/mm² without coupling gel. A total of three treatments were given to each individual one month apart. No local anesthesia was used. The primary end point was a 50% improvement from baseline at three months (1 month after completion of treatment). Forty patients were assigned to the treatment group and 35 patients to the placebo group. Two patients withdrew from the treatment group due to worsening of symptoms and two withdrew from the placebo group for unknown reasons. At three months 14 (35%) of patients in the treatment group and 12 (34%) in the placebo group showed a 50% improvement from baseline with respect to pain. The authors

concluded that ESWT was associated with a significant and sustained placebo effect and no evidence of added benefit of treatment when compared to sham therapy. This study had several limitations including short duration of symptoms without failure of other forms of treatment, short follow-up post treatment, and the control group perhaps received a small amount of ESWT.

Crowther et. al., reported on a comparison of one group of patients diagnosed with lateral epicondylitis receiving a single injection of 20 mg of triamcinolone with lignocaine versus a second group that received a series of 2000 shock waves (maximum 0.1 mJ/mm^2) to the area weekly for three weeks. Inclusion criteria consisted of a history of tennis elbow for more than four months without history of surgical intervention or injection in the previous year. Clinical findings to support the diagnosis included tenderness over the lateral epicondyle of the humerus and reproducible pain with resisted wrist or finger extension. Of the fifty-one patients randomized to receive ESWT, 48 completed the treatments. Of the forty-two patients randomized to receive the injection, 17 refused after the randomization. Twenty-five patients received the injection and completed the study. The visual analogue scale in those receiving the injection fell from a pretreatment value of 67 to 21 by six weeks after the injection and to 12 at three months post injection. The means score for the ESWT fell from a pretreatment value of 61 to 35 at six weeks and to 31 at three months post completion of treatment. Using a reduction of pain by 50% as a criteria for success, 21 (84%) of those receiving the injection were considered successful versus 29 (60%) of the ESWT group. The authors concluded that while both treatments relieved symptoms, the injection of steroid and local anesthetic was more effective. The authors also indicated that the cost of ESWT treatment was 100 times the cost of the injection.²⁷

The U. S. Food and Drug Administration has approved the SONOCUR Basic System manufactured by Siemens Medical Solutions, Inc. for treatment of tennis elbow whose pain remain despite six months of standard treatment.²⁸

Lateral Epicondylitis (2005 Update)

Rompe et. al. performed a study designed to determine the effectiveness of low-energy ESWT to placebo ESWT in recreational tennis players. All participants played tennis at least one hour per week and had MRI confirmation of the diagnosis of lateral epicondylitis. Study participants were randomly allocated to receive either three treatments at one week intervals of 2000 pulses with an energy flux density of 0.09 mJ/mm^2 in the active treatment group or similar treatment except for the insertion of a polyethylene foil filled with air to reflect the shock waves. Outcomes were measured at three and twelve months. Primary outcome was a reduction from baseline in the pain experienced during resisted wrist extension with a positive outcome defined as >30% decrease in pain rating. Secondary outcomes were the number of patients achieving a 50% reduction in baseline pain on resisted wrist extension, improvement of the 4-step Roles and Maudsley Score, improvement in the Upper Extremity Function Scale, grip strength, and overall satisfaction. For the group receiving ESWT, the average pain score was 7.1 ± 1.4 points at baseline, 3.6 ± 2.1 at 3 months, and 3.1 ± 2.4 points at 12 months. For the placebo group the average score was 7.1 ± 1.6 points at baseline, 5.1 ± 2.1 points at three months, and 4.3 ± 2.3 points at 12 months. Therefore both groups improved over time. At twelve months 61% of patients receiving ESWT and 38% of patients in the placebo group reported at least a 50% reduction in pain. Using the Roles and Maudsley Score, 63% in the ESWT group and 43% in the placebo group showed improvement. While grip strength improved in both groups, there was no significant statistical difference between the two groups. One flaw of the study was that after conclusion of the treatment, over 50% (22 of 40) of the placebo group believed they had been assigned to the placebo group whereas 29 of 38 patients receiving ESWT believed they were receiving ESWT. The authors

concluded that low-energy ESWT compared to placebo ESWT led to significantly better results in the treatment group.²⁹

Chung and Wiley reported on their study which was designed to determine the effectiveness of low-energy ESWT in individuals who had lateral epicondylitis for more than three weeks but less than one year and who have not had any prior treatment. Participants were randomly assigned to receive low-energy ESWT or sham ESWT. All were provided a stretching program consisting of a single forearm extensor stretch to be performed as 4 repetitions for 20 seconds four times per day. Individuals receiving low-energy ESWT (31 individuals) were given 2000 pulses of 0.03 to 0.17 mJ/mm² energy flux to the area of most tenderness weekly for three weeks. Level of energy flux density used was determined by the subject's pain tolerance. Those (29 individuals) receiving the sham ESWT were administered 2000 pulses at 0.03 mJ/mm² with an air buffer pad between the head of the machine and the subject's elbow. Treatment success was defined by at least a 50% reduction in pain measured by a Visual Analog Scale, a maximum allowable overall elbow pain score of 4.0 and no use of pain medication for lateral epicondylitis for 2 weeks before the 8 week evaluation. All measurements were performed at baseline and at four weeks and 8 weeks after initiation of therapy. Therefore, the final evaluation was performed only five weeks after the completion of the last ESWT. The proportion of treatment successes in the sham group was 0.31 and in the low-energy ESWT the success proportion was 0.30. The authors concluded that the study suggested that ESWT is not an effective therapy for lateral epicondylitis as assessed at 5 weeks after therapy. This study is limited by the variable amount of energy flux administered in the treatment and the short duration of follow-up. Individuals in this study reportedly had no prior treatment for lateral epicondylitis.³⁰

Furia³¹ reported on a series of patients with chronic lateral epicondylitis treated with high energy ESWT. The patient population consisted of 36 patients nine of whom were receiving workers' compensation. There was no control group. All patients had symptoms of lateral epicondylitis for at least six months and had received three types of conservative treatment without success. Patients were given either local anesthesia or a regional block followed by a single ESWT session. ESWT consisted of 50 shocks at each power level 1 through 6 and 2900 shocks at power level 7. This resulted in a total energy flux density of 1085 mJ/mm². Follow-up evaluations occurred at 4 and 12 weeks after treatment. Outcome measures included a visual analog scale (VAS) score, the RAND 36-Item Health Survey score, and Roles and Maudsley scale scores. The mean VAS score for the group decreased from a pretreatment value of 8.0 to 4.0 at four weeks post treatment and 2.5 at 12 weeks post treatment. These values were statistically significant. The mean RAND Physical Functioning Score pretreatment was 65.6 and improved to 80.8 at four weeks post treatment and 88.0 at 12 weeks post treatment. These values were also statistically significant. The Roles and Maudsley Scale Score found that all patients rated the condition of their elbow as poor prior to treatment. At four weeks post treatment, 16.7% rated the condition of the elbow as excellent and 52.8% rated their elbow as good. At 12 weeks post treatment, 19.4% of the individuals rated their elbow as excellent and 58.3% rated their elbow as good. Results for workers' compensation patients were no different than those not receiving workers compensation. Two patients complained of pain during treatment and two had transitory skin reddening. All of these minor complications resolved. The author concluded that ESWT was an effective treatment for chronic lateral epicondylitis and there were no differences in outcomes between patients with and without workers' compensation claims.

Another study by Pettrone and McCall randomly assigned 114 patients who had failed conservative treatment for lateral epicondylitis and who had symptoms for at least six months to receive either ESWT or sham ESWT. ESWT treatment consisted of one session per week for three weeks with 2000 impulses at 0.06 mJ/mm². The placebo group received the same treatment

but there was a sound-reflecting pad between the patient and the application head of the machine. Treating physicians were blinded to whether the patients received ESWT or sham ESWT. Patients were assessed at one, four, eight, and twelve weeks and at six and twelve months after completion of treatment. Primary outcome was relief of pain elicited by extension of the second and third metacarpal against resistance (Thomsen test) at twelve weeks. Patients were also assessed with a functional assessment with the upper extremity functional scale, a subjective evaluation of the status by the patient, and grip strength testing. If there was not a 50% reduction in pain at 12 weeks, the patient could have their treatment group revealed to them. If they had received placebo and still met inclusion criteria, they could opt to receive active ESWT treatment. In the active ESWT group, 53 of 56 patients completed the 12 week follow-up. Fifty-five of the 58 patients in the placebo group completed the 12 week follow-up. Of the 55 who completed 12 weeks of follow-up, 34 crossed-over to receive active treatment. At twelve weeks 61% of the active ESWT group had at least 50% reduction in pain compared to 29% in the placebo group. The average pain score decreased in the treatment group from 74 to 38 compared to a 76 to 51 decrease in the placebo group. Improvement in the upper extremity functional scores in the active group was also significant when compared to the placebo group. At one year 43 of 46 patients from the treatment group (93%) reported at least a 50% reduction of pain as did all 15 patients in the placebo group who did not cross over and evaluation at one year. (It is unknown the status of the other members who did not cross over.) For the primary outcome of a reduction in pain of at least 50%, 19 of the 34 cross-over placebo patients (56%) achieved a positive outcome. There were no lasting adverse effects. The authors concluded that ESWT as administered for treatment of chronic lateral epicondylitis is safe and effective.³²

Bisset, et. al., performed a review and meta-analysis of randomized clinical trials of multiple methods used to treat lateral epicondylitis that were published prior to September 2003. They considered eight studies pertaining to ESWT but only two met the level of quality to be included for analysis. These were the studies by Haake²² and Speed²³. Using the pooled data from the studies they could not find any added benefit of ESWT over that of placebo.³³

Another review of randomized controlled trials to evaluate the effectiveness of ESWT in tennis elbow was performed by Stasinopoulos and Johnson.³⁴ This review used several databases to identify articles published prior to August 2004 in English. Required study designs were limited to randomized clinical controlled trials and that evaluated ESWT by comparing it to a placebo, no treatment, or another treatment. Seven quality reports meeting criteria were identified. However, there were several differences in the studies in terms of the duration of symptoms, amount of ESWT energy administered, and duration of follow-up. Results of the studies were conflicting. Due to variability in study designs and dose administered, the authors recommended further research with well designed randomized control trials is needed to establish the effectiveness of ESWT for lateral epicondylitis.

E. Nonunion or Delayed Osseous Union

Schaden, et. al., described their experience in treating 115 patients with either nonunion or delayed fracture healing with high energy ESWT. Their patients comprised 35 patients who had 3-6 month interval between injury or last surgical procedure (delayed healing) and 80 patients who had more than 6 months between injury or last surgical procedure (nonunion). Their patients had 72 fractures in the shaft of long bones and 43 had fractures in cancellous bones. Ninety-two had had at least one operative procedure. Contraindications for treatment included epiphyseal plate within the shock wave field; coagulopathy; acute infection; alveolar tissue, brain, or spine in the shock wave field; pregnancy; or malignant tumor in the shock wave field. All patients

received anesthesia and received one shock wave treatment. The shock wave intensity and the number of shock waves used were determined by the area of the fracture gap and the cross section of the bone to be treated. Following ESWT, the fracture site was immobilized unless there was adequate internal fixation. Radiographs were obtained at 4, 8, and 12 week intervals. Total follow-up was 3 months to 4 years. Osseous unions were identified in 74.3% of patients who had delayed fracture healing, 76.3% of patients with nonunions, and 77.3% of patients with previously infected nonunions. From review of those patients failing to develop an osseous union, it was determined that a fracture was most likely unsuitable for ESWT if the fracture gap had a width greater than 5 mm, there is a defective zone greater than 5 mm in diameter, or if the fracture could not be immobilized adequately. Localized swelling, petechial hemorrhages, and local hematomas were noted which resolved without treatment. No nerve or vascular lesions were noted. The authors concluded that ESWT should be considered as the first choice in the treatment of nonunions and delayed bone fracture healing.³⁵

Another case series reported by Wang et. al., described their results with 72 patients with nonunion who received ESWT. Their inclusion criteria were failure to show bony union 6 months after initial closed or open treatment. Exclusion criteria included pathological fractures, fractures in the epiphyseal region of the bone, a fracture gap greater than 5 mm, and active infection. Patients were given general or spinal anesthesia and from 1000 to 6000 impulses at an energy flux density between 0.47 and 0.62 mJ/mm² depending on the size of the bone. Follow-up assessments were performed at 6 weeks and 3, 6, 9, and 12 months. Nine patients were lost to follow-up and eight patients chose surgical intervention during the course of the study. Fifty-five patients completed the study. These patients showed a bony union in 50.9% at three months, 67% at 6 months, and 80% at 12 months.³⁶

IV. COVERAGE BY OTHER PAYORS

Many payors (insurers) have provided position statements regarding ESWT. The following agencies and their position are provided as evidence of the current reimbursement for the procedure:

In January 2005 the Department of Health & Human Services (DHHS) published billing descriptors for ESWT to be covered by Medicare and Medicaid. According to DHHS, the HCPCS code for ESWT for tennis elbow is C9720 and the ESWT “long descriptor” is “High-energy (greater than 0.22 mJ/mm²) extracorporeal shock wave (ESW) treatment for chronic lateral epicondylitis (tennis elbow).” The HCPCS code for ESWT for chronic plantar fasciitis is C9721 and the “long descriptor” is “High-energy (greater than 0.22 mJ/mm²) extracorporeal shock wave (ESW) treatment for chronic plantar fasciitis”. Payment rate for both codes is \$850. Under “Coverage Determinations” it states “The fact that a drug, device, procedure, or service is assigned an HCPCS code and a payment rate under the OPPS does not imply coverage by the Medicare Program, but indicates only how the product, procedure, or service may be paid if covered by the program. Fiscal intermediaries determine whether a drug, device, procedure, or service meets all program requirements for coverage, for example, that it is reasonable and necessary to treat the beneficiary’s condition and whether it is excluded from payment.” In Ohio, ESWT is not covered according to Palmetto GBA. The procedure is covered in several other areas of the country.³⁷

Aetna® “considers extracorporeal shock-wave therapy (ESWT) experimental and investigational for epicondylitis, shoulder tendonitis, Achilles tendonitis, nonunions, or other musculoskeletal

indications because there is insufficient evidence of effectiveness of ESWT for these indications in the medical literature.”³⁸

The Regence Group in June 2005 concluded “ESWT, using either a high- or low-dose protocol, is considered investigational for all indications, including but not limited to plantar fasciitis, lateral epicondylitis, tendinopathies including calcific tendonitis of the shoulder, stress fracture, delayed union, nonunion, and avascular necrosis of the femoral head.”³⁹

The Blue Cross/Blue Shield positions are supported by published assessments by the Technology Evaluation Center. This assessment was prepared in February 2005 for the use of ESWT for chronic lateral epicondylitis⁴⁰ and in March 2005 for the use of ESWT for chronic plantar fasciitis.⁴¹ For both conditions ESWT failed to meet the established criteria for those organizations.

Washington State Department of Labor and Industries “does not cover ESWT for the treatment of musculoskeletal disorders. The studies on ESWT do not conclusively show the therapy’s effectiveness for treating plantar fasciitis or lateral epicondylitis. In addition, the FDA has not approved ESWT devices to treat calcific tendonitis or fractures.”⁴²

V. ODG Treatment in Workers’ Comp

For chronic plantar fasciitis, ODG⁴³ treatment guidelines state the following:

<p>Extracorporeal shock wave therapy (ESWT)</p>	<p>Not recommended using high energy ESWT. Under study for low energy ESWT, where the latest studies show better outcomes without the need for anesthesia. Trials in this area have yielded conflicting results. Recent evidence is less promising than early results. A recent high quality study concluded that, “Extracorporeal shock wave therapy is ineffective in the treatment of chronic plantar fasciitis”. (Haake-BMJ, 2003) (Blue Cross Blue Shield, 2003) A meta-analysis of data from six randomised-controlled trials that included a total of 897 patients was statistically significant in favor of low energy ESWT for the treatment of plantar heel pain but the effect size was very small. A sensitivity analysis including only high quality trials did not detect a statistically significant effect. (Thomson, 2005) ESWT should be done without local anesthesia (LA) in patients suffering from chronic heel pain. LA applied prior to treatment reduced the efficiency of ESWT. (Rompe, 2005) Success rates after low-energy ESWT with local anesthesia are significantly lower than after identical low-energy ESWT without local anesthesia. Higher energy levels could not balance the disadvantage of this effect. (Labeck, 2005) Corticosteroid injection is more efficacious and multiple times more cost-effective than high energy ESWT in the treatment of plantar fasciopathy. (Porter, 2005) While another study also reported that ultrasound-guided ESWT is ineffective (in line with placebo) in the treatment of plantar fasciitis (Buchbinder-JAMA, 2002), others have reported conflicting evidence for the effectiveness of low energy extracorporeal shock wave therapy in reducing night pain, resting pain and pressure pain in the short term for heel pain/plantar fasciitis. (Crawford, 2002) (Crawford-Cohrane, 2003) (Hammer, 2002) Prior to these, ESWT was reported to be a safe and effective nonsurgical method for treating chronic, recalcitrant heel pain syndrome. (Ogden, 2001) (Ogden, 2002) (Rompe, 2002) (Rompe, 1996) (Weil, 2002) Other recent studies are mixed. (Theodore, 2004) (Lee, 2003) (Hammer, 2003) (Speed, 2003) The results of various measures both within and across the above studies did not provide consistent and compelling evidence that ESWT improved health outcomes related to plantar fasciitis. The improvements seen could have been a result of the natural course of the disease. (BlueCross BlueShield, 2004) Note: See the Elbow and Shoulder chapters for other uses of ESWT.</p>
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	<p>Criteria for the use of Extracorporeal Shock Wave Therapy (ESWT): <i>If the decision is made to use this treatment despite the lack of convincing evidence.</i></p> <ol style="list-style-type: none"> 1) Patients whose heel pain from plantar fasciitis has remained despite six months of standard treatment. 2) At least three conservative treatments have been performed prior to use of ESWT. These would include: a. Rest, b. Ice, c. NSAIDs, d. Orthotics, e. Physical Therapy, e. Injections (Cortisone). 3) Contraindicated in Pregnant women; Patients younger than 18 years of age; Patients with blood clotting diseases, infections, tumors, cervical compression, arthritis of the spine or arm, or nerve damage; Patients with cardiac pacemakers; Patients who had physical or occupational therapy within the past 4 weeks; Patients who received a local steroid injection within the past 6 weeks; Patients with bilateral pain; Patients who had previous surgery for the condition. 4) Maximum of 3 therapy sessions over 3 weeks.
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For lateral epicondylitis, ODG⁴⁴ states the following:

<p>Extracorporeal shockwave therapy (ESWT)</p>	<p>Not recommended using high energy ESWT. Under study for low energy ESWT, where the latest studies show better outcomes without the need for anesthesia. Trials in this area have yielded conflicting results. The value, if any, of ESWT for lateral elbow pain, can presently be neither confirmed nor excluded. After other treatments have failed, some providers believe that shock-wave therapy may help some people with heel pain and tennis elbow. However, recent studies do not always support this, and ESWT cannot be recommended at this time for epicondylitis, although it has very few side effects. (Haake2, 2002) (Buchbinder-Cochrane, 2002) (Boddeker, 2000) (Ko, 2001) (Krischek, 1999) (Rompe, 2001) (Vogt, 2001) (Chung, 2002) (Wang, 2003) (Speed, 2002) (Crowther, 2002) (Blue Cross Blue Shield, 2003) (Chung, 2004) (Stasinopoulos2, 2005) (Blue Cross/Blue Shield, 2005) (Bisset, 2005) The results from a recent double-blind study conclude that low-dose shock wave therapy without anesthetic is a safe and effective treatment for chronic lateral epicondylitis. (Pettrone, 2005) Another high quality clinical trial concluded that high energy ESWT with anesthesia was ineffective in the treatment of lateral epicondylitis. (Haake, 2002) Outcomes may be better in chronic cases (> 12 months) treated with low energy ESWT. (Rompe, 2004) It is not possible to draw firm conclusions concerning the effect of ESWT on tendinitis of the elbow from the conflicting data reported. This data parallels that for plantar fasciitis in that it is not known whether the different results are due to methodological bias or to differences in the population and intervention. (BlueCross BlueShield, 2004) See also the Ankle & Foot Chapter, and the Shoulder Chapter.</p> <p>Criteria for the use of Extracorporeal Shock Wave Therapy (ESWT): <i>If the decision is made to use this treatment despite the lack of convincing evidence.</i></p> <ol style="list-style-type: none"> 1) Patients whose pain from lateral epicondylitis (tennis elbow) has remained despite six months of standard treatment. 2) At least three conservative treatments have been performed prior to use of ESWT. These would include: a. Rest, b. Ice, c. NSAIDs, d. Orthotics, e. Physical Therapy, e. Injections (Cortisone). 3) Contraindicated in Pregnant women; Patients younger than 18 years of age; Patients with blood clotting diseases, infections, tumors, cervical compression, arthritis of the spine or arm, or nerve damage; Patients with cardiac pacemakers; Patients who had physical or occupational therapy within the past 4 weeks; Patients who received a local steroid injection within the past 6 weeks; Patients with bilateral pain; Patients who had previous surgery for the condition. 4) Maximum of 3 therapy sessions over 3 weeks.
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For tendonitis and calcific tendonitis of the shoulder, ODG⁴⁵ provides the following information:

<p>Extracorporeal shock wave therapy (ESWT)</p>	<p>Recommended as indicated below. For patients with calcifying tendinitis of the shoulder with inhomogenous deposits, quality evidence has found extracorporeal shock wave therapy (ESWT) equivalent to or better than surgery, and it may be given priority because of its noninvasiveness. (Rompe, 2001) (Haake, 2002) (Haake, 2001) (Pan, 2003) (Wang, 2003) (Cosentino, 2003) (Lowe, 1999) (Pleiner, 2004) (Moretti, 2005) However, there is no evidence of benefit in non-calcific tendonitis of the rotator cuff, or other shoulder disorders. (Speed, 2002) (Blue Cross Blue Shield, 2003) In treating calcifying tendonitis, both high-energy and low-energy ESWT provide a beneficial effect on shoulder function, as well as on self-rated pain and diminished size of calcifications, but high-energy ESWT appears to be superior to low-energy ESWT. (Gerdesmeyer-JAMA, 2003) (Perlick, 2003) While the findings indicate there may be a treatment effect from ESWT for tendinitis of the shoulder, the findings need to be confirmed in high-quality randomized clinical trials with different treatment protocols and treatment parameters. (BlueCross BlueShield, 2004) (Trebinjac, 2005) Three-dimensional, computer-assisted navigation reveals significantly better results and is therefore recommended when extracorporeal shock wave therapy is used in the treatment of calcific tendinitis of the rotator cuff. (Sabeti-Aschraf, 2005) See also the Ankle & Foot Chapter, and the Elbow Chapter.</p> <p>Criteria for the use of Extracorporeal Shock Wave Therapy (ESWT):</p> <ol style="list-style-type: none"> 1) Patients whose pain from calcifying tendinitis of the shoulder has remained despite six months of standard treatment. 2) At least three conservative treatments have been performed prior to use of ESWT. These would include: a. Rest, b. Ice, c. NSAIDs, d. Orthotics, e. Physical Therapy, e. Injections (Cortisone). 3) Contraindicated in Pregnant women; Patients younger than 18 years of age; Patients with blood clotting diseases, infections, tumors, cervical compression, arthritis of the spine or arm, or nerve damage; Patients with cardiac pacemakers; Patients who had physical or occupational therapy within the past 4 weeks; Patients who received a local steroid injection within the past 6 weeks; Patients with bilateral pain; Patients who had previous surgery for the condition. 4) Maximum of 3 therapy sessions over 3 weeks.
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VI. DISCUSSION

ESWT appears to be safe in that other than localized pain, swelling, and perhaps bruising, no other adverse effects are commonly seen and no adverse effect is permanent. As several authors indicated, if ESWT is unsuccessful, the surgical option is still available. As indicated by Ogden et. al.,⁴⁶ comparison of study results are difficult due to the studies lacking “significant data generating parameters that would allow credible outcome analysis.” The natural history of the conditions for which the treatment has been used are frequently of limited duration or the primary symptom is pain which is subject to considerable “placebo effect” in clinical studies. There has been no standardization in the treatment as to the number of shock waves applied, the energy of the wave, the number of applications of ESWT, or the interval between applications. Many of the studies have had short duration of follow-up or inclusion criteria have included patients with short duration of symptoms (3 months) which may have improved regardless of treatment. Given these factors and that several studies have not demonstrated beneficial effect of ESWT for treatments such as plantar fasciitis, epicondylitis, and noncalcific tendonitis of the shoulder, use of ESWT to treat these conditions is debatable. Additionally, at least two studies have described the cost of ESWT as much more than more traditional treatment for similar outcomes.

For calcific tendonitis of the shoulder, the treatment reportedly has resulted in less pain and is associated with high percentage of resorption of deposited calcium. Patients who benefit usually can avoid surgical procedures and any associated rehabilitation. Favorable outcomes to date have been reported on the two case series for delayed healing or nonunion of fracture. All authors and studies have indicated that if used, ESWT should be used only after conservation (non-surgical treatment has failed), symptoms present for a minimum of six months, and for calcific tendonitis of the shoulder, that x-rays confirm the diagnosis of calcific tendonitis.

V. RECOMMENDATION

1. Studies have not demonstrated consistent results or efficacy in the treatment of plantar fasciitis, epicondylitis, and noncalcific tendonitis of the shoulder. ESWT is considered unproven and investigational for these services.
2. Use of ESWT in the treatment of x-ray confirmed calcific tendonitis of the shoulder shows preliminary good results with improvement of symptoms, resorption of the calcium deposit, improved function, and avoidance of surgery. Replication of the results in additional studies would be beneficial prior to acceptance. Authorization of ESWT could be considered on a case-by-case basis.
3. Two reports of case series have described beneficial outcomes in the treatment of nonunion of fractures with development of an osseous union in both series in 75-80% of patients in the study. Use of ESWT may avoid additional surgery and its use to date has not been associated with known adverse effects. Additional studies describing similar results would be beneficial. Authorization of ESWT could be considered on a case-by-case basis.
4. If ESWT is authorized, the following criteria should be met:
 - a. Appropriate allowed condition in the claim;
 - b. Symptoms and signs of the condition present for at least 6 months;
 - c. At least three failed non-operative treatment modalities including, but not limited to,
 - i. Activity modification/work restrictions
 - ii. Exercise Program as appropriate
 - iii. Physical Therapy as appropriate
 - iv. Splint, orthotics, or other appropriate durable medical equipment
 - v. Anti-inflammatory medications as appropriate
 - vi. Steroid injections(In cases of nonunion, appropriate medical evidence and additional allowance appropriate.)
 - d. Injured worker would otherwise be considered surgical candidate;
 - e. ESWT can only be performed with FDA approved devices;
 - f. ESWT energy per shock greater than 0.22 mJ/mm² (DHHS criteria);
 - g. Ultrasound imaging and anesthesia is included in the fee for the procedure;
 - h. Only one course (up to three treatment sessions) may be authorized.

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