



TITLE: Extracorporeal Shock Wave Therapy for the Treatment of Lateral Epicondylitis

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PUBLISHER NAME: California Technology Assessment Forum

DATE OF PUBLICATION: October 20, 2004

PLACE OF PUBLICATION: San Francisco, CA



EXTRACORPOREAL SHOCK WAVE THERAPY (ESWT) FOR THE TREATMENT OF LATERAL EPICONDYLITIS

INTRODUCTION

The California Technology Assessment Forum is requested to review the scientific evidence for the use of the extracorporeal shock wave therapy for the treatment of lateral elbow pain (lateral epicondylitis) that is unresponsive to conservative treatment.

BACKGROUND

Extracorporeal shock wave therapy (ESWT) was originally used by urologists to break up kidney stones but recently has been used by orthopedic surgeons to treat tendonopathies. Most of the published literature has focused on the use of ESWT to treat three disorders: plantar fasciitis (heel pain), lateral epicondylitis (tennis elbow) and tendonopathies of the shoulder.

Lateral Epicondylitis (LE)

The etiology of LE (tennis elbow) is poorly understood. The primary symptom is pain localizing in the lateral epicondyle of the humerus and the origin of the common extensor tendon just distal to the epicondyle. The pain commonly radiates over the extensor surface of the forearm and tends to worsen with activities that use the extensor muscles (wrist extension and supination). The onset is typically acute following new activities, but can be gradual. Pain waxes and wanes over weeks to months. The primary modes of treatment include icing, NSAIDs, rest, activity modification, physical therapy, ultrasound, acupuncture and forearm bracing. If these fail, corticosteroid injections into the origin of the common extensor tendon are often successful. A systematic review of therapies for LE found that only steroid injections had proven efficacy (Labelle *et al.* 1992). Surgery is reserved for chronic cases not responding to the therapies described above.

ESWT

ESWT is well established for the treatment of kidney stones. Shock waves create a transient pressure flux that disrupts solid structures, breaking them into fragments, which facilitates their passage or removal. In the early 1990's, early reports suggested that shock wave therapy had efficacy in the treatment of chronic tendon and ligament pain (Rompe *et al.* 1996b). It has been used in Europe for over a decade, Canada for five years and recently was approved by the FDA for use in the US. It is generally divided into high energy therapy, requiring limb blocks or general anesthesia, and low energy therapy. The latter can also be divided into energy levels requiring local anesthesia or not requiring anesthesia. Additionally, ESWT can be guided by imaging, such as fluoroscopy or ultrasound, or can be directed by patient feedback. Proponents argue that ESWT for orthopedic disease can provide long lasting analgesia and stimulates the healing process.

The mechanism of action underlying the possible therapeutic benefits of ESWT is unclear (Wild *et al.* 2000). Chronic musculoskeletal conditions can be associated with significant scarring and calcification. Disruption and absorption of calcium deposited in tendons may loosen adjacent structures and promote reabsorption of the calcium (Ogden *et al.* 2001). Another hypothesis is that hyperstimulation of the painful region activates a descending inhibitory central nervous system response which suppresses overall pain sensation (Rompe *et al.* 2001). Shock waves have also been hypothesized to stimulate or reactivate healing in tendons, surrounding tissue and bone through microdisruption of avascular or minimally vascular tissues, allowing more normal tissue healing.

Contraindications to the use of ESWT include patients with soft tissue infections, osteomyelitis, local tumors, coagulopathies, pregnancy or pacemakers.

A trained orthopedic surgeon usually performs ESWT for musculoskeletal disorders in an outpatient setting. Since the therapy is painful, some protocols involve the use of local or regional anesthesia (ankle or shoulder block), but others call for no anesthesia (Thiel 2001). The location and depth of treatment is sometimes guided by fluoroscopy or by an ultrasound device coupled to the shock wave generator. Other protocols require patients to direct the focus of sound waves to the region of maximal pain. A range of protocols have been used in studies with energy per impulse varying 10-fold with different numbers of impulses and therapy sessions. Different authors use different cutoffs, but low energy ESWT usually involves impulses delivering between 0.05 and 0.1 mJ/mm². High energy therapy delivers impulses over 0.2 mJ/mm². Despite extensive use of ESWT for musculoskeletal disorders, there are no established treatment parameters. Immediately after treatment, the treated area is checked for discoloration, swelling and bruising. The patient is then discharged with an ice pack. Patients may experience some discomfort after the anesthesia wears off. They may also continue to experience their typical elbow pain for one to two weeks following the treatment. Pain is usually managed with an over the counter analgesic.

TECHNOLOGY ASSESSMENT (TA)

TA Criterion 1: The technology must have final approval from the appropriate government regulatory bodies.

There are three primary ESWT devices. They are: the Ossatron® (HealthTronics, Marietta, Georgia) which received FDA premarket approval (PMA) on October 12, 2000; the Dornier Epos™Ultra (Dornier Medical Systems, Inc., Kennesaw, Georgia) which received FDA PMA approval on January 15, 2002; and the Siemens SONOCUR®Basic (Siemens, Iselin, New Jersey) which received FDA PMA approval on July 19, 2002.

The Siemens SONOCUR Basic and the HealthTronics Ossatron are approved for the treatment of LE.

TA Criterion 1 is met.

TA Criterion 2: The scientific evidence must permit conclusions concerning the effectiveness of the technology regarding health outcomes.

The Medline database, Cochrane clinical trials database, Cochrane reviews database and the Database of Abstracts of Reviews of Effects (DARE) were searched using the key words ESWT, shock waves, or extracorporeal shock wave therapy. These were cross-referenced with the keywords lateral epicondylitis, musculoskeletal, tendonitis and tendinitis. The search was performed for the period from 1966 through August 2004. The bibliographies of systematic reviews and key articles were manually searched for additional references. The abstracts of citations were reviewed for relevance and all potentially relevant articles were reviewed in full.

Because of the depth of literature and the strong placebo effect usually seen in clinical trials of procedures treating pain, this review will focus primarily on evidence from randomized clinical trials (RCT). Indeed, when comparing the improvement in pain in the placebo group of the randomized trials of ESWT for plantar fasciitis, pain improved 0% to 4% in the single blind trials, but 34% to 47% in the double blind trials. This bias is accentuated in the uncontrolled studies. For this reason, conclusions will mainly be drawn from the results of the double-blind studies. Non-randomized studies will be reviewed only when needed for additional details. The quality of the trials will be assessed based on the approach used by the US Preventive Services Task force (Harris *et al.* 2001). The randomization should generate comparable groups with similar loss to follow-up, and both groups should be treated the same except for the randomized intervention. Both the participants and staff performing outcome assessments should be blinded. Finally, the analysis should be intention-to-treat. Unfortunately, many investigators consider excluding protocol violators from the analysis part of intention-to-treat. The overall quality is considered good when all indicators are met. Study quality is considered poor if the groups are not close to comparable at baseline, if there is large differential loss to follow-up, if there is inadequate blinding or if there is no appropriate intent-to-treat analysis. Studies without "fatal flaws," but having some inadequacies, are considered to be of fair quality.

The comparison group in all of the RCTs was sham ESWT unless otherwise noted. The search identified six RCTs (n=704) of ESWT for LE including one good quality trial (n=272) and one study comparing ESWT to steroid injection (Tables 4 and 5). At least one additional RCT supporting the use of ESWT for LE has been presented at conferences (Pettrone *et al.* 2002), but the results have not been published in a peer reviewed journal. Five studies of elbow tendinitis were not included in this review because they lacked control groups or were not randomized.

Outcomes assessed in the various clinical trials summarized below include subjects' self-assessment of pain, usually measured with a visual analog scale (VAS) from 0 to 10. Pain may be measured at rest, at night or with provocative maneuvers. If the VAS reported in a study was based on another metric (0 to 100 for example), the results were adjusted to reflect a 10-point scale. Some researchers defined an improvement of 50% or greater on VAS for pain as a clinically significant response. Another scale commonly used to assess functional improvement in musculoskeletal disease is the Roles-Maudsley scale:

Roles-Maudsley subjective pain scale

- | | |
|---------------|---|
| 1. Excellent: | no pain, full movement, full activity |
| 2. Good: | occasional discomfort, full movement, full activity |
| 3. Fair: | some discomfort after prolonged activity |
| 4. Poor: | pain, limiting activities |

The most commonly reported statistic for the Roles-Maudsley scale is the percentage of participants achieving a score of excellent or good results. The length of follow-up in the studies varied greatly (six weeks to one year) with most investigators asserting that follow-up of at least three to six months was needed to fully assess the efficacy of ESWT.

Adverse events were poorly reported in many of these clinical trials. Indeed, three of the six randomized clinical trials summarized in the tables made no mention of adverse events at all. No serious adverse events were reported to be associated with ESWT. The main side effects were pain, local bleeding (petechiae, bruising, hematoma) and paresthesia.

The only measurement specific to LE that was used in more than one study was grip strength, usually measured by a dynamometer either with the elbow flexed at 90° or straightened at 180°.

Level of Evidence: 1, 3, 4, 5

TA Criterion 2 is met

TA Criterion 3: The technology must improve the net health outcomes.

LE

The literature search identified six randomized trials of ESWT for LE (Rompe *et al.* 1996a; Crowther *et al.* 2002; Haake *et al.* 2002b; Speed *et al.* 2002; Melikyan *et al.* 2003; Rompe *et al.* 2004). Table 1 summarizes the quality assessment of the trials; Table 2 summarizes the study design, interventions and patient characteristics; Table 3 summarizes the results of each study. Only one study was judged to be of good quality (Haake *et al.* 2002b). A second publication from this same study focused solely on adverse effects of ESWT (Haake *et al.* 2002a), a topic which has been either ignored or minimally reported in most of the studies of ESWT. The primary quality deficits were inadequate allocation concealment and blinding, large and differential loss to follow-up and incorrect intention-to-treat analyses (excluding protocol violators).

The ESWT technique was different across studies. One of the five studies (Haake *et al.* 2002b) used local anesthesia, while the others did not. All used three treatment sessions: one study used one month intervals between

treatments (Speed *et al.* 2002a) while the rest treated at weekly intervals. The number of impulses per treatment ranged from 1,000 to 2,000 and the energy settings ranged from 0.07 mJ/mm² to 0.18 mJ/mm² (low to moderate). This indicates a lack of consensus in the field about how to use ESWT to treat chronic LE.

The highest quality study (Haake *et al.* 2002b) of LE was also the largest (n=272), with almost three times the number of participants as were randomized in the next largest study. The objective of the study was to investigate whether ESWT in combination with local anesthesia was superior to placebo therapy in combination with local anesthesia. Following administration of local anesthesia, either ESWT with three treatments of 2,000 pulses each and a positive energy flux density (ED+) of 0.07 to 0.09 mJ/mm² or placebo therapy was given on an outpatient basis. Treatment allocation was blinded for patients and for observers. The primary end point was based on the rate of success, as determined with the Roles and Maudsley score and whether additional treatment was required, twelve weeks after the intervention. Crossover was possible after assessment of the primary end point. Secondary end points were the Roles and Maudsley score, subjective pain rating and grip strength after six and twelve weeks and then after twelve months. The primary end point could be assessed for 90.8% of the patients. The success rate was 25.8% in the group treated with ESWT and 25.4% in the placebo group, a difference of 0.4% with a 95% confidence interval of -10.5% to 11.3%. Similarly, there was no relevant difference between groups with regard to the secondary end points. Improvement was observed in two-thirds of the patients, from both groups, twelve months after the intervention. Few side effects were reported. This was particularly surprising given that more participants randomized to ESWT than sham ESWT thought they received active therapy (71% vs. 54%). The authors concluded that ESWT, as applied in this study, was ineffective in the treatment of LE. The previously reported success of this therapy appears to be attributable to inappropriate study designs. Different ESWT application protocols might improve clinical outcome. They recommended that ESWT be applied only in high-quality clinical trials until it is proven to be effective.

In fact, there was evidence in the Haake *et al.* study that ESWT caused more harm than good. Those randomized to true ESWT reported more skin erythema (21% vs. 5%), pain (5% vs. 2%) and hematomas (5% vs. 2%). Overall, the ESWT group was significantly more likely to suffer negative side effects of therapy (OR 4.3, 95% CI 2.9-6.3) (Haake *et al.* 2002a).

A second randomized trial compared ESWT to steroid injection (Crowther *et al.* 2002). This study was not blinded and thus, of poor quality. However, the results are instructive. Group 1 received a single injection of 20 mg of triamcinolone with lidocaine while Group 2 received 2,000 shock waves up to 0.1 mJ/mm² in three sessions, at weekly intervals. After six weeks there was a significant difference between the groups with the mean VAS pain score for the injection group falling 4.5 points, compared with a 2.6 point decrease in the shock-wave group (p = 0.05). After three months, 84% of patients in Group 1 were considered to have had successful treatment compared with 60% in Group 2. The investigators concluded that in the medium term, local injection of steroid is more successful and 100 times less expensive than ESWT in the treatment of tennis elbow.

The most recent study (Rompe *et al.* 2004) randomized 76 tennis players with recalcitrant MRI-confirmed tennis elbow of at least 12 months' duration. Patients were randomly assigned to receive either active low-energy extracorporeal shock wave treatment given weekly for three weeks (treatment Group 1) or an identical placebo extracorporeal shock wave treatment (sham Group 2). No anesthesia was used as the protocol required that patients direct the ESWT to the area of maximal pain during each treatment session. The primary outcome measure was pain during resisted wrist extension at three months; secondary measures included greater than 50% reduction of pain on the Upper Extremity Function Scale. Blinding was not completely successful as 76% of patients in the active group thought they had received ESWT compared with 48% of patients in the sham group. At three months, there was a significantly higher improvement in pain during resisted wrist extension in Group 1 than in Group 2 (mean [SD] improvement, 3.5 [2.0] and 2.0 [1.9]; $P = .001$ for between-group difference of improvement) and in the Upper Extremity Function Scale (mean [SD] improvement, 23.4 [14.8] and 10.9 [14.9]; $P < .001$ for between-group difference of improvement). In the treatment group, 65% of patients achieved at least a 50% reduction of pain, compared with 28% of patients in the sham group ($P = .001$ for between-group difference). There was no difference in grip strength improvement between the two groups. In this study, low-energy extracorporeal shock wave treatment appeared to be superior to sham treatment for tennis elbow. There are several differences between this study and the larger negative study of Haake *et al.* (2002). This study is a single center study under the direction of one of the earliest advocates of the therapy. Only tennis players were enrolled and MRI evidence of LE was required for enrollment. Blinding was unsuccessful, which may bias the results since the outcome measures all involve self-report of pain and function. In the Haake trial, all patients received local anesthesia and anti-inflammatory medications were recommended for the first three days following each ESWT session, while Rompe used no anesthesia and no anti-inflammatory medications were allowed during the three-month follow-up period.

In summary, there is no standard ESWT treatment for LE. The best quality trial (Haake *et al.*, 2002) showed no evidence of benefit (not even a trend) and clear evidence of harm. A randomized comparison to steroid injection (the only treatment for LE that has RCT evidence of benefit), although of poor quality, found steroid injection to be superior in efficacy at a far lower cost (Crowther *et al.*, 2002). However, the most recently published trial showed evidence of benefit (Rompe *et al.*, 2004). This may be due to more stringent screening to find appropriate candidates for therapy (extensive list of conservative measures must be failed, MRI must be positive), appropriate focusing of the shock waves (to the area of maximal perceived pain) or failed blinding of participants (significantly more patients randomized to active treatment thought they received true ESWT). The use of local anesthesia in the Haake trial (2002) is unlikely to explain the different outcomes as other negative studies did not use any anesthesia (Speed *et al.*, 2002; Melikyan *et al.*, 2003).

TA Criterion 3 is not met for ESWT used to treat LE.

TA Criterion 4: The technology must be as beneficial as any established alternatives.

LE

The established alternatives to ESWT for LE are similar to those for plantar fasciitis including rest, ice, physical therapy, stretching, exercises, NSAIDS and local corticosteroid injections. Forearm bands are also sometimes used with success for LE. These measures are successful in greater than 90% of patients, although most have not been proven to alter the natural history of the disorder in randomized clinical trials (Labelle *et al.* 1992). Only steroid injections have RCT level evidence supporting efficacy. When conservative therapy fails, surgery is sometimes recommended.

Again ESWT is not being proposed as an alternative to more conservative measures. All but one of the trials required that patients have failed four to six months of conservative therapy prior to enrollment in the trials of ESWT. Speed *et al* (2003) found no benefit to early ESWT. One study without blinding (Crowther *et al.* 2002) compared ESWT to steroid injection and found steroid injections to be more effective. None of the studies compared ESWT to surgical therapy, but the goal of ESWT is to avoid surgery. More importantly, ESWT for LE has not been shown to improve net health outcomes compared to sham therapy. Thus, it cannot be said to be as beneficial as the established alternatives.

TA Criterion 4 is not met for ESWT used to treat LE.

TA Criterion 5: The improvement must be attainable outside the investigational settings.

ESWT procedures have been reported from a large number of centers around the world. There is a learning curve as documented in the multi-center clinical trial by Ogden *et al* (2001). However, the procedure is relatively simple, so with proper training and experience, health care providers outside of the investigational setting should be able to achieve results similar to those in published trials.

TA Criterion 5 is met.

Table 1: Quality of the Randomized Clinical Trials – Tennis Elbow / LE

Study	Randomization	Allocation concealment	Comparable groups at randomization	Loss to follow-up comparable?	Blinded outcome assessment	Patient blinding	Co-interventions equivalent	ITT (lost to follow-up included?)	Overall quality
Rompe 2004 Mainz, Germany	Yes	NR	Yes	Yes (8/76 in 3 months)	Yes	Yes, But unsuccessful: 76% vs. 45%, p=0.005 thought received ESWT	Yes	Yes	Fair (moderate loss to f/u, ineffective blinding)
Melikyan 2003 Southampton, UK	Yes	NR	NR	Large 12/86	Yes	Yes	Yes	No	Fair (loss to f/u, poor ITT)
Crowther 2002, Bristol, UK	Yes	Yes	NR	Large: 20 17/20 in injection group	No	No	No	No	Poor (no blinding)
Haake 2002a Marburg, Germany	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Good
Speed 2002 Cambridge, UK	Yes	NR	+/- ESWT group longer prior symptoms and more prior treatment	Yes	Yes	Yes	Yes	Yes	Fair (small n, baseline differences – possible selection bias)
Rompe 1996 Mainz, Germany	Yes	NR	Higher pain scores at rest, night and with pressure in ESWT group	Unclear	Unclear.	Yes	Yes	No	Fair (Unclear blinding, poor ITT)

Table 2: Description of Study Procedures and Participants – Tennis Elbow / LE

Study	Procedure Device	N	Design	Follow-up for primary outcome	Age, yrs Sex, %F	Pain 10 pt VAS	Inclusion criteria	Exclusion criteria	Comment
Rompe 2004 Mainz, Germany	3 treatments Once/week 2,000 pulses 0.09 mJ/mm ² No anesthesia	78	DB RCT	3 months	46 49%	7.1	Tennis > 1 hour/wk Symptoms > 12 months MRI + for LE. Failed conservative therapy VAS>4 with resisted wrist extension	Arthritis Neurologic dz, Prior surgery, Pregnancy, Tumor, Infection.,Coagulopa thy, Hyperthyroidism	10% dropout in both arms. Different reasons – additional therapy in all placebo arm. Refused follow-up all ESWT arm.
Melikyan 2003 Southampton, UK	3 treatments 333 mJ/mm ² per treatment. No anesthesia	86	DB RCT	12 months	43.4 58%	5.7	Age ≥ 18 Failed conservative therapy	Neurologic dz, Pregnancy, Tumor, Infection Coagulopathy Fracture, Prior surgery, Hyperthyroidism	
Crowther 2002 Bristol, UK	3 treatments Once/week 2,000 pulses Max 0.1 mJ/mm ² No anesthesia.	93	Unblinded RCT	3 months	49 48%	6.3	Age ≥ 18 Symptoms≥4 months Failed conservative therapy	Arthritis Neurologic dz, Dermatologic dz, Pregnancy, Tumor, Infection Coagulopathy, Pacemaker	Unblinded. Comparison group is steroid injection.
Haake 2002a Marburg, Germany	3 treatments Once/week 2,000 pulses .07-.09 mJ/mm ² Local anesthesia	272	DB RCT	12 weeks	46.7 53%	NR	Age ≥ 18 Failed conservative therapy ≥ 6 months RM score ≥ 3	Arthritis Neurologic dz. Pregnancy, Tumor, Infection Coagulopathy, Hyperthyroidism	Only study to assess blinding. Good methods but: 54% of placebo thought they received ESWT vs. 71% of active group- probably due to pain after procedure.
Speed 2002 Cambridge, UK	3 treatments Once/month 1,500 pulses 0.18 mJ/mm ² No anesthesia	75	DB RCT	3 months	47.3 56%	7.1	Age ≥ 18 Symptoms≥3 months	Arthritis Neurologic dz, Dermatologic dz, Diabetes, Pregnancy, Tumor, Infection Coagulopathy	
Rompe 1996 Mainz, Germany	3 treatments Once/week 1,000 pulses 0.08 mJ/mm ² No anesthesia	100	SB or DB RCT	24 weeks	42.9 58%	3.0	Age ≥ 18 Symptoms≥12 months Failed conservative therapy ≥ 6 months	Arthritis Neurologic dz, Pregnancy, Tumor, Infection	Unclear why 15 of 115 dropped out. Incomplete reporting. Control group worsened over time – incompatible with natural history seen in other studies.

Table 3: Outcomes and Adverse Events – Tennis Elbow / LE

Study	Procedure	N ESWT N control	Follow-up*	Change in overall or resting pain (10 pt VAS)	Grip strength	Roles-Maudsley (% good / excellent)	VAS (Other)	Other	Adverse events
Rompe 2004 Mainz, Germany	ESWT Sham ESWT	34 36	3 months	NR	Both improved. No difference between groups.	NR Average change scores: -1.4 -0.7 p=0.001	-3.5 -2.0 p=0.001 (Pain on resisted wrist extension)	23.4 10.9 p<0.001 (Upper extremity function scale)	100% erythema. Pain during procedure (95% vs. 52%) Mild symptoms. All resolved by 3 month f/u.
Melikyan 2003 Southampton, UK	ESWT Sham ESWT	37 37	12 month	-3.3 -3.6 p=0.89	Both improved. No difference between groups, p=0.93.	NR	NR	DASH function/symptom score improved for both (p<0.001) but no difference between groups (p=0.32) with trend towards better results in control.	Minimally reported. No additional pain medication needed during procedure because of pain.
Crowther 2002 Bristol, UK	ESWT Steroid injection	51 42	3 months	-3.0 -5.5 p=0.052	-	-	-	60% 84%, p<0.05 50% improvement in pain reported.	NR
Haake 2002a Marburg, Germany	ESWT Sham ESWT	135 137	12 weeks	Both improved. No difference between groups.	Both improved. No difference between groups.	32% 33%	Both improved. No difference between groups.	-	Red skin 21% vs. 5% Pain 5% vs. 2% Hematoma 5% vs. 2% More side effects in ESWT group: OR 4.3 (95% CI 2.9-6.3)
Speed 2002 Cambridge, UK	ESWT Sham ESWT	40 35	3 months	-2.5 -1.5 p NS	-	-	-	35% 34 p=.325 50% improvement in pain reported	Increase in night pain at 1 month in ESWT group, resolved by 2 months.
Rompe 1996 Mainz, Germany	ESWT Sham ESWT	50 50	24 weeks	-2.1 +0.7 p<0.001	-0.4 0 p<0.001	48% 6% p NR	-		NR

* Follow-up for primary endpoint

Abbreviations:

DB RCT Double-blind, randomized controlled trial
SB RCT Single-blind, randomized controlled trial
NSAIDS Non-steroidal anti-inflammatory drugs
DASH Disabilities of Arm, Shoulder, and Hand score
ESWT Extracorporeal shock wave therapy
TENS Transcutaneous electric nerve stimulation
SPADI Shoulder pain and disability index

ITT Intention-to-treat
%F Percentage female
PF Plantar fasciitis
N Number of participants
UK United Kingdom
VAS Visual analog scale
RM Roles and Maudsley

NS Not significant
NR Not reported
NA Not applicable
F/U Follow-up
U/S Ultrasound
AE Adverse events

OPINIONS OF OTHERS

Blue Cross Blue Shield Association (BCBSA)

In October 2004, the BCBSA Technology Evaluation Center Medical Advisory Panel determined that the use of ESWT for lateral epicondylitis does not meet TEC criteria.

Centers for Medicare and Medicaid Services (CMS)

A published policy regarding the use of ESWT for LE was not found on the CMS website.

California Orthopaedic Association (COA)

The COA does not have a formal position regarding the use of this technology, however, a COA representative did provide testimony in support of the recommendation.

CONCLUSION

Pain from LE tends to resolve over extended periods of time, even for patients who have failed conservative therapy for many months. Therefore, uncontrolled studies of ESWT, while promising, may represent the natural history of the disorder abetted by a strong placebo effect. Studies with pain as the primary outcome commonly are subject to large placebo effects. Indeed, in non-blinded RCT's of ESWT, the placebo group usually reported minimal improvements while the placebo group in well-blinded studies reported 30-50% improvements in pain scores. This highlights the need for high quality, double-blinded, randomized trials as the minimum standard of evidence.

A recent German systematic review of ESWT for LE identified 20 clinical trials, all of which demonstrated successful results (Boddeker *et al.* 2000). However, each of the identified studies had methodological flaws. In contrast to these earlier reports from uncontrolled and non-randomized studies, there was no difference in the degree of improvement in pain between groups in the higher quality RCTs. Both ESWT and sham ESWT groups showed clear improvements in pain, function and grip strength over six weeks to one year of follow-up, but the between-group differences were negligible and sometimes favored the sham group (Haake *et al.* 2002; Speed *et al.* 2002; Melikyan *et al.* 2003). One recent study reported positive results (Rompe *et al.* 2004), but this may have been due to inadequate blinding. Given the small, but real harms from ESWT and minimal evidence of benefit, ESWT for LE should not be performed outside of clinical trials. There may be ESWT techniques that work for selected patient populations suffering from LE, but they have not yet been defined by the current literature.

RECOMMENDATION

It is recommended that the use of ESWT for the treatment of LE does not meet technology assessment criteria 3 or 4 for safety, effectiveness and improvement in health outcomes.

The California Technology Assessment Forum panel voted to approve the recommendation as written.

October 20, 2004

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