



TITLE: Extracorporeal Shock Wave Therapy (ESWT) for Musculoskeletal Disorders

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EXTRACORPOREAL SHOCK WAVE THERAPY (ESWT) FOR MUSCULOSKELETAL DISORDERS

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 tendinitis of the shoulder, lateral elbow pain, and heel pain that are 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.

Plantar fasciitis (heel pain)

Heel pain due to plantar fasciitis is common, affecting 10% of population. The most common site of heel pain is at the insertion of the plantar fascia on the medial tubercle of the calcaneous. The pain usually is present when the patient first stands up in the morning and worsens with prolonged standing, walking or running. The underlying cause is unknown. The most common theories include injury at the origin of the plantar fascia (obesity, repetitive stress) or biomechanical abnormalities of the foot (flat foot, over pronation, calcaneal tendon contracture). The clinical diagnosis is usually straightforward. A heel spur may be seen on x-ray in up to 50% of patients, but as many as 27% of people without heel pain have heel spurs (DeMaio *et al.* 1993; Prichasuk *et al.* 1994).

The goals of treatment are to alleviate pain and to restore function. However, the treatment can be difficult and frustrating. Conservative management is usually tried initially. These therapies include stretching, local ice application, physical therapy, non-steroidal anti-inflammatory drugs (NSAIDS), shoe inserts (heel cups, pads, custom orthotics), night splints, and corticosteroid injections. One cohort study of conservative treatments found that about half of patients were pain free after 6 months, one third had intermittent symptoms, and the remainder had constant pain (Miller *et al.* 1996). Steroid injections often relieve pain, but they are associated with an increase risk of rupture of the plantar fascia and often the pain recurs (Miller *et al.* 1995; Acevedo *et al.* 1998). When conservative measures fail, surgery is sometimes performed to release a portion of the plantar fascial insertion into the calcaneous (Benton-Weil *et al.* 1998; Jarde *et al.* 2003). However, the long recovery time and possible morbidity make surgical therapy a last resort.

Lateral epicondylitis (tennis elbow)

The etiology of 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. 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.

Rotator cuff tendinitis / shoulder pain (calcific and non-calcific)

Shoulder pain is most common in people between 30 and 60 years of age. It usually results from strain of the rotator cuff muscles. Usual treatment options include physical therapy, NSAIDS, and steroid injections, although evidence of efficacy is limited (Green *et al.* 1998). If calcium deposits are present within the affected tendon, surgical removal of the deposits has been reported to improve symptoms (Rochwerger *et al.* 1999; Maier *et al.* 2002).

Rotator cuff tendon calcification can be found in 2% to 20% of asymptomatic shoulder joints depending on the imaging technique (Bosworth 1941; Rupp *et al.* 2000). The supraspinatus tendon is most commonly involved (Bosworth, 1941). The prevalence in patients with shoulder pain is as high as 50% (Bosworth 1941; De Palma *et al.* 1961). These calcifications are usually classified into 3 types based on the observations of Gartner (Gartner 1993). Type I calcifications have sharp margins and homogenous structure. Type II calcifications either have sharp margins with non-homogenous structure or have no defined border, but have homogeneous structure. Type III calcifications are fluffy and indistinct. In one study, 85% of Type III calcifications disappeared spontaneously over 3 years, while only 35% of Type I and Type II calcifications disappeared over the same time period (Gartner 1993). Hence most studies of therapies for calcific rotator cuff tendonitis exclude patients with Type III calcifications.

Extracorporeal shock wave therapy (ESWT)

Extracorporeal shock wave therapy 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 in use in Europe for over a decade, Canada for 5 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, which allows for more normal tissue healing.

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

A trained orthopedic surgeon or podiatrist 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. A range of protocol 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 heel pain for one to two weeks following the treatment. Pain is usually managed with an over the counter analgesic. After treatment for plantar fasciitis, full weight bearing is allowed immediately after the procedure. However, patients are advised not to participate in any stressful activity (running, jogging, etc.) for at least 4 weeks.

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 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.

Both the Ossatron and the Dornier Epos Ultra are approved for the treatment of *Plantar fasciitis (heel pain)*

The Siemens SONOCUR Basic and the HealthTronics Ossatron are approved for the treatment of Lateral epicondylitis (tennis elbow)

Treatment of Rotator cuff tendinitis / shoulder pain (calcific and non-calcific) with any of the FDA approved devices noted here is considered an off-label use of these devices.

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 plantar fasciitis, heel spur, calcaneal spur, lateral epicondylitis, supraspinatus, shoulder, rotator cuff, musculoskeletal, tendonitis, and tendinitis. The search was performed for the period from 1966 through April 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.

The depth of literature and the strong placebo effect usually seen in clinical trials of procedures treating pain led this review to focus on randomized clinical trials (RCT). At least 5 RCTs were identified for each indication, allowing for a thorough evaluation of the technology. 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 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 RCT's was sham ESWT unless otherwise noted. The search identified nine randomized clinical trials (n=1076) of ESWT for plantar fasciitis. Two of the clinical trials encompassing the greatest number of participants (n=438) were of good quality (Tables 1 and 2). The remaining seven studies had methodological flaws due to inadequate blinding, different co-interventions, and/or loss to follow-up. The five RCTs (n=626) of ESWT for lateral epicondylitis included only one good quality trial (n=272) and one study comparing ESWT to steroid injection (Tables 4 and 5). Finally, the search identified 2 RCTs (n=114) of ESWT for non-calcific rotator cuff tendinitis and 6 RCTs (n=530) of ESWT for calcified rotator cuff tendinitis (Tables 7 and 8). Of these studies, one compared ESWT to TENS, one compared aiming ESWT at the calcification to ESWT aimed at the insertion of the tendon (usual target), and two compared high energy to low energy ESWT (one with a third sham group). Nine studies of ESWT for plantar fasciitis, 5 studies of elbow tendinitis, and 8 studies of rotator cuff 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 (6 weeks to 1 year) with most investigators asserting that follow-up of at least 3 to 6 months was needed to fully assess the efficacy of ESWT.

Adverse events were poorly reported in many of these clinical trials. Indeed, 7 of the 21 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.

Outcome measures specific to a particular musculoskeletal disorder are discussed below.

Plantar fasciitis (heel pain)

Patients treated with ESWT for plantar fasciitis are usually those with pain for more than six months who have failed to respond to conservative measures and who are considering surgical therapy. In addition to the outcome measures discussed above, some clinical trials of therapies for plantar fasciitis assess pain intensity using a dolorimeter device to put varying degrees of pressure over the painful area; activity using a 5-point clinical evaluation scale assessing the distance and time the subject was able to walk without heel pain; and the use of pain medications.

Lateral epicondylitis (tennis elbow)

The only measurement specific to lateral epicondylitis 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°.

Rotator cuff tendinitis / shoulder pain (calcific and non-calcific)

The most common outcome for studies of shoulder pain is change in the 100-point Constant and Murley Scale (CMS). The CMS is a standard method for assessing shoulder function that combines both subjective (35 points) and objective (65 points) criteria. The subjective portion asks about the degree of pain and the patient's ability to perform usual tasks of daily living. The objective portion assesses shoulder range of motion and power.

Studies of calcific tendinitis usually reported the absolute reduction in either the area or diameter of the calcification as well as the percentage of patients with partial or complete resorption of the calcification.

Level of Evidence: 1, 3, 4, 5

TA Criterion 2 is met

Table 1: Quality of the randomized clinical trials – heel pain/plantar fasciitis

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
Haake 2003 10 sites Bad Abbach, Germany	Yes	Yes.	Yes	Yes 6%	Yes	Yes	Yes	Yes	Good
Rompe 2003 Mainz Germany	Yes	Yes	Yes	Yes 13% 6 mo 24% 12 mo	Yes	Yes	Yes	No	Fair (small n, large loss to follow-up)
Speed 2003 Cambridge, UK	Yes	Yes	Yes	No 4/46 (8.7%) ESWT 8/42 (19%) sham	Yes	Yes	Yes	Yes	Fair (unequal loss to follow-up)
Buchbinder 2002 6 sites Melbourne, Australia	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Good
Hammer 2002 Homburg, Germany	Yes	No	Yes	Yes	No	No	No	Yes	Poor (no blinding)
Rompe 2002 Mainz Germany	Yes	Yes	Yes	No, differential dropout from protocol violations	No	Yes	No	No	Poor (no double blinding)
Consentino 2001 Siena, Italy	Yes	NR	No	Yes	No	Yes	Yes	Yes	Poor (no double blinding)
Ogden 2001 7 sites Atlanta, GA	Yes	Yes	Yes	Yes	Yes	Yes, unclear how effective.	No, different methods of anesthesia	Yes	Fair (different anesthesia could affect outcome)
Rompe 1996 Mainz Germany	Yes	NR	Yes	Unclear	No	Yes	Yes	No	Poor (No double blinding or ITT)

Table 2: Description of study procedures and participants – heel pain / plantar fasciitis

Study	Procedure	N	Design	Follow-up	Age, yrs Sex, %F	Pain 10 pt VAS	Inclusion criteria	Exclusion criteria	Comment
Haake 2003 10 sites Bad Abbach, Germany	3 treatments Once/ 2 weeks 4000 pulses 0.08 mJ/mm ²) Local anesthesia	272	DB RCT	12 weeks	53.0 75%	NR	Heel pain with RM score 3 or 4. Failed 6 months conservative therapy.	Bilateral heel pain. Local infections. Local tumors. Clotting disorders Pregnancy. Arthritis. Prior surgery.	Evaluated blinding efficacy: good.
Rompe 2003 Mainz Germany	3 treatments Once/week 2100 pulses 0.16 mJ/mm ² No anesthesia.	45	DB RCT	12 months	42 51%	7.0	Age ≥ 18 years. Run ≥ 30 miles/week before six started. Pain ≥ 12 months Failed 6 months conservative therapy.	Arthritis Nerve entrapment Prior PF surgery Ruptured PF Pregnancy Infection Tumor	Large loss to f/u due to procedure ineffective.
Speed 2003 Cambridge, UK	3 treatments Once/month 1500 pulses 0.12 mJ/mm ² No anesthesia.	88	DB RCT	6 months	52.1 58%	7.2	Age ≥ 18 years. Unilateral heel pain ≥ 3 mo. Tenderness at medial calcaneal insertion.	Arthritis. Foot/ankle pathology. Neurologic abnormalities. Local dermatologic disease. Diabetes. Pregnancy. Malignancy. Anticoagulant therapy.	Large unexplained loss to f/u in placebo arm.
Buchbinder 2002 6 sites Melbourne, Australia	3 treatments Once/week 2000 or 2500 pulses 0.02 to 0.33 mJ/mm ² No anesthesia	166	DB RCT	12 weeks	53.2 58%	7.0	≥18 years old ≥ 6 weeks heel pain U/S confirmed diagnosis	NSAIDS for 2 weeks Injections 4 weeks Oral steroids 6 weeks Arthritis Neurologic dz. Dermatologic dz. Diabetes. Pregnancy. Tumor. Prior surgery Bleeding disorder Prior ESWT.	Evaluated blinding efficacy Could continue Tylenol, orthotics, splints
Hammer 2002 Homburg, Germany	3 treatments Once/week 3000 pulses 0.2 mJ/mm ² No anesthesia mentioned	47	Unblinded RCT	12 weeks	50 68%	7.4	Heel pain not responding to conservative treatment ≥ 6 months. Heel spur present.	Neurologic dz. Pregnancy. Tumor. Local infections. Bleeding disorder	Not concurrent. Controls had to wait 12 weeks before procedure done.

Study	Procedure	N	Design	Follow-up	Age, yrs	Pain	Inclusion criteria	Exclusion criteria	Comment
					Sex, %F	10 pt VAS			
Rompe 2002 Mainz Germany	3 treatments Once/week 1000 pulses 0.8mJ/mm2 No anesthesia	112	SB RCT	6 months	49.0 43%	7.8	≥18 years old ≥ 6 months heel pain Failed ≥ 6 months treatments Heel spur on x-ray	Arthritis Neurologic dz. Dermatologic dz. Diabetes. Pregnancy. Tumor. Infection. Prior PF surgery	
Consentino 2001 Siena, Italy	6 treatments Once/7-10 days 1200 pulses 0.03-0.4 mJ/mm No anesthesia	60	SB RCT	12 weeks	55.6 yrs 72%	8.3	≥18 years old Heel pain Failed ≥ 6 months treatments Heel spur on x-ray	Arthritis Neurologic dz. Dermatologic dz. Pregnancy. Tumor. Infection.	No patients lost to f/u
Ogden 2001 7 sites Atlanta, GA	Single treatment 1500 pulses 18 kV High energy Regional block for ESWT, local anesthesia for sham.	260	DB RCT	12 weeks	49.6 yrs 66%	8.1	≥18 years old ≥ 6 months heel pain Failed ≥ 3 prior treatments Heel pain ≥ 5 on 10 pt VAS	Arthritis Neurologic dz. Dermatologic dz. Diabetes. Pregnancy. Tumor. Infection. Prior PF surgery. PF rupture.	Not ITT analysis, different co-interventions (local anesthesia for ESWT, not for sham).
Rompe 1996 Mainz Germany	3 treatments Once/week 1000 pulses 0.06 mJ/mm2 No anesthesia reported.	36	SB RCT	6 weeks	49 37%	7.8	≥18 years old ≥ 12 months heel pain Failed ≥ 6 months treatments Positive bone scan	Arthritis Neurologic dz. Dermatologic dz. Diabetes. Pregnancy. Tumor. Infection. Prior PF surgery	6 randomized patients not accounted for (unclear which arm, etc.)

Table 3: Outcomes and adverse events – heel pain / plantar fasciitis

Study	Procedure	N	Follow-up*	Change in overall or resting pain (10 pt VAS)	Morning pain (10 pt VAS)	Roles-Maudsley (% good / excellent)	VAS (other pain)	Other	Adverse events
Haake 2003 10 sites Bad Abbach, Germany	ESWT	135	12 weeks	-1.5	-3.6	34%		-	18% vs. 9% Erythema 12% Pain 5% Swelling 2%
	Sham ESWT	137		-1.34 p NS	-3.2 p NS	30%, p=0.59* 81% vs. 76% at 1 yr			
Rompe 2003 Mainz Germany	ESWT	22	6 months		-4.8	-	-1.9	-	NR
	Sham ESWT	23			-2.3 p = 0.0004		-1.0 p = 0.01		
Speed 2003 Cambridge, UK	ESWT	46	3 months	37% vs. 24% reporting ≥ 50% improvement. p=0.25*		-	-3.3	-	1 episode syncope due to pain during ESWT. Patient withdrew from study.
	Sham ESWT	42					-3.7 p NS		
Buchbinder 2002 6 sites Melbourne, Australia	ESWT	81	12 weeks	-2.6	-2.4	4 other measures p > 0.38	-	p>0.45 on all 8 measures	Mild and same in the two groups.
	Sham ESWT	85		-2.6 p=0.99	-2.4 p=0.92				
Hammer 2002 Homburg, Germany	ESWT	24	12 weeks	-4.9	-	-	-4.2	+4.9 hours	NR
	Wait 12 weeks	24		+0.02 No p calculated			-0.0 (pain with pressure) No p calculated	+0.0 hours	
Rompe 2002 Mainz Germany	ESWT	54	24 weeks	-2.0		57%	-5.8	+37	Modest pain, none severe. No infections, hematomas.
	Sham ESWT	58		-0.1 p<0.001		10% p<0.001	-0.2 p = 0.0001	+19 p=0.002 Ankle-hind foot scale	
Consentino 2001 Siena, Italy	ESWT	30	12 weeks	-5.2	-4.4	-		Sonographic reduction in inflammation 57% vs. 40%	Transient erythema, pain. "No side effects."
	Sham ESWT	30		-0.6 p<0.0001	-0.2 p<0.0001				
Ogden 2001 7 sites Atlanta, GA	ESWT	130	12 weeks	-	-4.5	-	-4.6	Primary outcome composite "success" 47% vs. 30%, p=0.008	18 active, 13 placebos. Pain, numbness, tingling after treatment.
	Sham ESWT	130			-3.9 p NR		-3.5, p NR Pain with pressure		
Rompe 1996 Mainz Germany	ESWT	15	6 weeks	-1.7	-	-	Pain with pressure 67% improvement vs. 8%, p<0.0001	Improved or pain free: 67% vs. 27%, p<0.005.	NR.
	Sham ESWT	15		-0.75 p<0.01					

* Follow-up for primary endpoint

Table 4: Quality of the randomized clinical trials – tennis elbow / lateral epicondylitis

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
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 5: Description of study procedures and participants – tennis elbow / lateral epicondylitis

Study	Procedure	N	Design	Follow-up for primary outcome	Age, yrs Sex, %F	Pain 10 pt VAS	Inclusion criteria	Exclusion criteria	Comment
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 2000 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 2000 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 1500 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 1000 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 6: Outcomes and adverse events – tennis elbow / lateral epicondylitis

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
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

Table 7: Quality of the randomized clinical trials – shoulder pain

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
Consentino 2003 Siena, Italy	Yes	NR	Yes	Unclear	No	Yes	Yes	Unclear	Poor
Gerdesmeyer 2003 7 sites Munich, Germany	Yes	Yes	Yes	No: more in placebo arm excluded from analysis due to use of other therapies	Yes	Yes	Yes	No	Fair: for placebo comparisons. Good for comparing high to low energy.
Pan 2003 Taipei, Taiwan	Yes	Yes	Yes	Yes	No	No	No	Yes	Poor (not blinded)
Perlick 2003 Bad Abbach, Germany	Yes	NR	NR	Yes	Unclear	Yes	Yes	Yes	Poor-fair (unable to assess blinding of outcome assessment, scant details reported)
Haake 2002b Marburg, Germany	Yes	Yes	NR	Yes	Yes	Yes	Yes	Yes	Good
Speed 2002 Cambridge, UK	Yes	NR	Yes	No 20% lost to f/u at 6 months	Yes	Yes	Yes	Yes, for primary outcome at 1 month	Fair-good
Schmitt 2001 Marburg, Germany	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Good
Rompe 1998 Mainz, Germany	Yes	Yes	Yes	Unclear, 26/126 dropped. Unclear if before or after randomization.	Unclear	Inadequate	No. Regional anesthesia in one arm vs. no anesthesia in other.	No	Poor (large loss to follow-up, poor blinding)

Table 8: Description of study procedures and participants – shoulder pain

Study	Procedure	N	Design	Follow-up	Age, yrs	Pain	Inclusion criteria	Exclusion criteria	Comment
					Sex, %F	10 pt VAS			
Consentino 2003 Siena, Italy	4 treatments Every 4-7 days 1200 pulses up to 0.28 mJ/mm ² No anesthesia	70	SB RCT	1 month Large loss to f/u at 6 months	51.8 61%	-	Calcified rotator cuff tendon. Shoulder pain ≥ 10 months. Failed conservative therapy ≥ 6 months.	Arthritis Neurologic dz. Dermatologic dz. Pregnancy. Tumor. Infection Rotator cuff tear.	Unusual lack of placebo response in control group. Small study. Incomplete reporting of follow- up and outcomes.
Gerdesmeyer 2003 7 sites Munich, Germany	2 treatments Every 2 weeks High energy: 1500 pulses 0.32 mJ/mm ² Low energy 6000 pulses 0.08 mJ/mm ² Regional anesthesia	144	DB RCT	6 mo	62.3 60%	5.9	Calcified supraspinatus tendon. Shoulder pain ≥ 6 months. Failed conservative therapy. Age ≥ 18 years.	Arthritis Neurologic dz. Pregnancy. Tumor. Infection Coagulopathy. Diabetes. Rotator cuff tear. Shoulder bursitis. Prior surgery. Type III calcification.	Excellent methods except exclusion of protocol violators from ITT analysis.
Pan 2003 Taipei, Taiwan	2 treatments Every 2 weeks 2000 pulses 0.26-0.32 mJ/mm ² No anesthesia reported.	60	Unblinded RCT	12 weeks	57 65%	6.6	Calcified rotator cuff tendon. Shoulder pain ≥ 6 months or pain ≥ 4/10 on VAS.	Arthritis Neurologic dz. Pregnancy. Tumor. Infection Coagulopathy. Pacemaker. Rotator cuff tear.	
Perlick 2003 Bad Abbach, Germany	2 treatments Every 3 weeks 2000 pulses High energy 0.42 mJ/mm ² Low energy 0.23 mJ/mm ² Local anesthesia for both	80	Unclear if SB or DB RCT	1 year	48.4 55%	7.5	Calcified rotator cuff tendon. Shoulder pain ≥ 12 months. Failed conservative therapy. Type I or II calcification that is ≥ 10 mm diameter.	Arthritis Neurologic dz. Pregnancy. Tumor. Infection. Rotator cuff tear. Prior surgery.	
Haake 2002b Marburg, Germany	2 treatments Every 1 week 2000 pulses 0.35 mJ/mm ² Local anesthesia	50	DB RCT	1 year	50 70%	6.5	Calcified rotator cuff tendon. Shoulder pain ≥ 6 months. Failed conservative therapy. Type I or II calcification that is ≥ 5 mm diameter	Arthritis Neurologic dz. Pregnancy. Tumor. Infection. Rotator cuff tear. Prior surgery. < 18 years old.	

Study	Procedure	N	Design	Follow-up	Age, yrs	Pain	Inclusion criteria	Exclusion criteria	Comment
					Sex, %F	10 pt VAS			
Speed 2002 Cambridge, UK	3 treatments Every month 1500 pulses 0.12 mJ/mm ² No anesthesia	74	DB RCT	1 month	52.6 58%	-	No calcification. Age ≥ 18 years. Shoulder pain ≥ 3 months.	Arthritis Neurologic dz. Dermatologic dz. Pregnancy. Tumor. Infection Coagulopathy.	
Schmitt 2001 Marburg, Germany	3 treatments Every 1 week 2000 pulses 0.11 mJ/mm ² Local anesthesia	40	DB RCT	12 weeks	52 50%	8.0	No calcification. Age ≥ 18 years. Shoulder pain ≥ 6 months. Failed conservative therapy.	Arthritis Neurologic dz. Tumor. Infection Rotator cuff tear. Prior surgery.	
Rompe 1998 Mainz, Germany	1 treatment 1500 pulses 0.28 mJ/mm ² Regional anesthesia	126	Unclear if SB or DB RCT	24 weeks	48 56%	-	Calcified rotator cuff tendon. Shoulder pain ≥ 12 months. Failed conservative therapy ≥ 6 months. Type I or II calcification that is ≥ 5 mm diameter	Arthritis Neurologic dz. Pregnancy. Tumor. Infection Rotator cuff tear. Frozen shoulder	

Table 9: Outcomes and adverse events – shoulder pain

Study	Procedure	N	Follow-up	Change in overall or resting pain	Constant and Murley scale	Radiographic change	Other	Adverse events
Consentino 2003 Siena, Italy	ESWT	35	1 month	-	+29	71%	-	"Self limiting initial pain." No other AE's.
	Sham ESWT	35			-2 p<0.001	0% Partial or complete resorption.		
Gerdesmeyer 2003 7 sites Munich, Germany	High ESWT	48	6 months	-5.4	+31	-153 mm ²	60%	Severe pain 33% vs. 10% vs. 8%. Petechiae / bruising 75% vs. 67% vs. 17%. High vs. low vs. sham respectively
	Low ESWT	48		-2.4, p<0.001	+15, p<0.001	-78, p=0.03	21%	
	Sham ESWT	48		-1.1, p<0.001	+7, p<0.001	-41, P<0.001	11% Complete resorption	
Pan 2003 Taipei, Taiwan	ESWT	32	12 weeks	-4.1	+28	-4.4 mm	-	15% sore arm in ESWT.
	TENS	28			-1.7 p<0.001	+12 p<0.001		
Perlick 2003 Bad Abbach, Germany	High ESWT	40	1 year	-4.2	+25	55%	-	"Most found it painful." 100% vs. 38% petechiae. 20% vs. 3% hematoma.
	Low ESWT	40			-3.9 p NS	+22 p NS		
Haake 2002b Marburg, Germany	ESWT at calcification	25	1 year	-5.1	+66	58%	-	"No severe side effects."
	ESWT at insertion of tendon	25			-3.1 p<0.05	+36 p<0.05		
Speed 2002 Cambridge, UK	ESWT	34	1 month	-2.3	-	-19	-	NR
	Sham ESWT	40			-2.8 p NS, night pain			
Schmitt 2001 Marburg, Germany	ESWT	20	12 weeks	-3.0	+26	NA	-	NR
	Sham ESWT	20			-2.2 β p NS	+22 p NS		
Rompe 1998 Mainz, Germany	ESWT	50	24 weeks	-	+35	64%	68%	NR
	Sham ESWT	50				+24 p<0.01	50%, p<0.01 Partial or complete resorption	

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

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

Plantar fasciitis (heel pain)

The literature search identified nine randomized clinical trials of ESWT for plantar fasciitis (Rompe *et al.* 1996b; Cosentino *et al.* 2001; Ogden *et al.* 2001; Buchbinder *et al.* 2002; Hammer *et al.* 2002; Rompe *et al.* 2002; Haake *et al.* 2003; Rompe *et al.* 2003; Speed *et al.* 2003). Table 1 summarizes the quality assessment of the trials, Table 2 summarizes the study design, interventions and patient characteristics, and Table 3 summarizes the results of each study. In general, the quality of the trials was poor, mainly due to poor blinding.

Lack of blinding is a fatal flaw for randomized clinical trials with pain as an outcome. Most studies with good blinding demonstrate a significant 30-50% reduction in symptoms for the control group over 3 months. Participants in the control group for the study of Hammer *et al.* (2002) were aware that they would receive ESWT if they did not improve. They had absolutely no benefit from 12 weeks of therapy with heel cups, NSAIDS, and iontophoresis. There were no changes in VAS pain scores at rest (43.1 to 43.1), in daily life (70.2 to 70.4), standing on one leg (74.6 to 74.8) or with firm thumb pressure (84.2 to 84.2). In contrast, the blinded control groups who received sham ESWT in the studies of Haake *et al.* (2003) and Ogden *et al.* (2001) had dramatic reductions in pain ($p < 0.001$) and improvements in function ($p < 0.001$) after 12 weeks of follow-up. Similar findings of minimal improvement in the sham ESWT group are seen when outcome assessment is not blinded (Rompe *et al.* 1996b; Cosentino *et al.* 2001; Rompe *et al.* 2002)

The significant variability in the ESWT technique used (Table 2) highlights the lack of an accepted approach to ESWT for plantar fasciitis. One investigator (Rompe) who has published extensively on ESWT and popularized its use for orthopedic applications has three separate randomized clinical trials using the technique to treat plantar fasciitis. Initially he used 1000 impulses at 0.06 mJ/mm² (Rompe *et al.* 1996b) with great success (improved or pain free 67% vs. 27%, $p < 0.005$). In his next study, however, he increased the energy to 0.08 mJ/mm² (Rompe *et al.* 2002), and in his most recent publication, the energy was doubled to 0.16 mJ/mm² and the number of impulses per session was also more than doubled to 2100. This investigator consistently studied treatment regimens of three sessions done at weekly intervals, but other investigators studied as few as one session (Ogden *et al.* 2001) or as many as six sessions (Cosentino *et al.* 2001). Most investigators did not use any anesthesia, but one used local anesthesia (Haake *et al.* 2003) and one used regional anesthesia (Ogden *et al.* 2001). The lack of consensus on the appropriate number of sessions, impulses per session, and strength of the shock wave casts doubt on the efficacy of any one regimen.

Patient selection was relatively uniform across studies (Table 2). They were adults averaging 50 years old with a slightly higher proportion of women than men. Patients with diseases that might contribute to heel pain were excluded, as were patients who might suffer complications. Patients had average pain scores of 7 to 8 on a 10 point VAS and suffered from chronic pain not responding to usual conservative measures.

As noted above, the majority of the studies had significant methodological flaws. However, two of the largest studies met all criteria and are considered to be of good quality (Buchbinder *et al.* 2002; Haake *et al.* 2003). The two studies are discussed in greater detail below.

Buchbinder et al (2002) studied whether ultrasound-guided ESWT reduced pain and improved function in patients with plantar fasciitis. They conducted a double-blind, randomized, placebo-controlled trial between April 1999 and June 2001. Participants were recruited from community-based referring physicians (primary care physicians, rheumatologists, orthopedic surgeons, and sports physicians) in Melbourne, Australia. They screened 178 patients and enrolled 166; 160 completed the 15-week protocol. Entry criteria included age of at least 18 years with plantar fasciitis, defined as heel pain maximal over the plantar aspect of the foot of at least six weeks duration, and an ultrasound-confirmed lesion, defined as thickening of the origin of the plantar fascia of at least 4 mm, hypoechogenicity, and alterations in the normal fibrillary pattern. Patients were randomly assigned to receive either ultrasound-guided ESWT given weekly for three weeks to a total dose of at least 1000 mJ/mm² (n = 81), or identical placebo to a total dose of 6.0 mJ/mm² (n = 85). Treatment consisted of 2000 or 2500 impulses with energy settings increasing from 0.02 to 0.33 mJ/mm² as tolerated by the patient. The mean energy per shock is estimated to be approximately 0.16 mJ/mm². Outcomes included overall, morning, and activity pain which were measured on a visual analog scale, Maryland Foot Score, walking ability, Short-Form-36 Health Survey (SF-36) score, and Problem Elicitation Technique score which were measured at six and 12 weeks after treatment completion. At six and 12 weeks, there were significant improvements in overall pain in both the active group and placebo group (mean [SD] improvement, 18.1 [30.6] and 19.8 [33.7] at six weeks [P =.74 for between-group difference], and 26.3 [34.8] and 25.7 [34.9] at 12 weeks [P =.99], respectively). Similar improvements in both groups were also observed for morning and activity pain, walking ability, Maryland Foot Score, Problem Elicitation Technique, and SF-36. There were no statistically significant differences in the degree of improvement between treatment groups for any measured outcomes. Interestingly, this was the only study to assess the efficacy of participant blinding. They found that they achieved a moderate to high degree of blinding (blinding index =0.68). Side effects were mild and similar in the two groups. The investigators concluded that the study found no evidence to support a beneficial effect on pain, function, and quality of life of ultrasound-guided ESWT over placebo in patients with ultrasound-proven plantar fasciitis six and 12 weeks following treatment. The study suggests that ESWT does not have a significant role to play in the early treatment of plantar fasciitis. The study has been criticized for including patients with symptoms less than 6 months as many of those patients improve with conservative therapy.

The second good quality clinical trial (Haake *et al.* 2003) investigated the effectiveness of ESWT compared with placebo in the treatment of chronic plantar fasciitis. They conducted a randomized, double-blinded, multicenter trial using a parallel group design. Participants were recruited from nine hospitals and one outpatient clinic in Germany. The study randomized 272 patients with chronic plantar fasciitis recalcitrant to conservative therapy for at least six

months: 135 patients were allocated extracorporeal shock wave therapy and 137 were allocated placebo. Active treatment consisted of 4000 relatively low energy shocks (0.08 mJ/mm²) for 3 treatment sessions. The primary end point was the success rate 12 weeks after intervention based on the Roles and Maudsley score. Secondary end points encompassed subjective pain ratings and walking ability up to a year after the last intervention. The primary end point could be assessed in 94% (n=256) of patients. The success rate 12 weeks after intervention was 34% (n=43) in the extracorporeal shock wave therapy group and 30% (n=39) in the placebo group (absolute difference 4%, 95% CI -8.0% to 15.1%). No difference was found in the secondary end points. Few side effects were reported. The authors concluded that ESWT is ineffective in the treatment of chronic plantar fasciitis.

In summary, there was a tremendous amount of variability in the quality of the randomized trials and in the interventions studied. The two best quality studies found no evidence for benefit compared with sham ESWT. The fair to poor quality studies did demonstrate benefit compared with sham or delayed therapy, but the trials were generally small, with inadequate blinding, poor allocation concealment, and differential loss to follow-up which could bias the study results in favor of ESWT.

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

Lateral epicondylitis (tennis elbow)

The literature search identified five randomized trials of ESWT for lateral epicondylitis (Rompe *et al.* 1996a; Crowther *et al.* 2002; Haake *et al.* 2002c; Speed *et al.* 2002a; Melikyan *et al.* 2003). Table 4 summarizes the quality assessment of the trials, Table 5 summarizes the study design, interventions and patient characteristics, and Table 6 summarizes the results of each study. Only one study was judged to be of good quality (Haake *et al.* 2002C). 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).

Again, the ESWT technique was different across studies. One of the five studies (Haake *et al.* 2002c) used local anesthesia, while the others did not. All used three treatment sessions, one study used one month intervals (Speed *et al.* 2002a) while the rest treated at weekly intervals. The number of impulses per treatment ranged from 1000 to 2000 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 lateral epicondylitis.

The highest quality study (Haake *et al.* 2002c) of lateral epicondylitis 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 extracorporeal shock wave therapy in combination with local anesthesia was superior to placebo therapy in combination with local anesthesia. Following administration of local anesthesia, either extracorporeal

shock wave therapy with three treatments of 2000 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 extracorporeal shock wave therapy 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 extracorporeal shock wave therapy as applied in this study was ineffective in the treatment of lateral epicondylitis. 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 extracorporeal shock wave therapy 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 2000 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 from 6.6 to 2.1 compared with a decrease from 6.1 to 3.5 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. Ideally, the study should have performed sham ESWT on the steroid group and given a placebo injection to the ESWT group.

In summary, there is no standard ESWT treatment for lateral epicondylitis. The best quality trial showed no evidence of benefit (not even a trend) and clear evidence of harm. A randomized comparison to steroid injection (the only treatment for lateral epicondylitis that has RCT evidence of benefit), although of poor quality, found steroid injection to be superior in efficacy at a far lower cost.

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

Rotator cuff tendinitis / shoulder pain (calcific and non-calcific)

The literature for ESWT and rotator cuff tendinitis is more complex. The literature search identified eight randomized trials of ESWT for rotator cuff tendinitis (Rompe *et al.* 1998; Schmitt *et al.* 2001; Haake *et al.* 2002b; Speed *et al.* 2002b; Cosentino *et al.* 2003; Gerdesmeyer *et al.* 2003; Pan *et al.* 2003; Perlick *et al.* 2003). Table 7 summarizes the quality assessment of the trials, Table 8 summarizes the study design, interventions and patient characteristics, and Table 9 summarizes the results of each study. Four studies were judged to be of good quality (Schmitt *et al.* 2001; Haake *et al.* 2002b; Speed *et al.* 2002b; Gerdesmeyer *et al.* 2003). Two of these were studies of non-calcified tendinitis, the other two were of calcified tendinitis. In this literature, there were studies evaluating technical aspects of the procedure. Both Gerdesmeyer *et al.* (2003) and Perlick *et al.* (2003) compared high energy ESWT to low energy ESWT with a sham ESWT control group included in the Gerdesmeyer study. Haake *et al.* (2002) compared high energy ESWT aimed at the tendon insertion (the traditional target) to high energy ESWT aimed at the calcified portion of the tendon. Finally, Pan *et al.* compared ESWT to treatment with transcutaneous electric nerve stimulation (TENS).

Non-calcific rotator cuff tendinitis

The treatment approaches in the two studies of non-calcific tendinitis were similar (Schmitt *et al.* 2001; Speed *et al.* 2002b). Both study protocols used three treatment sessions with 1500 to 2000 impulses per session at energy settings of 0.11 or 0.12 mJ/mm². There was slightly greater variability in the protocols employed for calcific tendinitis, but all used relatively high energy settings (0.26 – 0.42 mJ/mm²), except for the studies comparing low to high energy settings. Almost all studies treating calcified tendinitis used some form of anesthesia.

Neither study of ESWT for treatment of rotator cuff tendinitis without calcification showed any benefit with treatment. Speed *et al.* (2003) performed a double-blind placebo-controlled trial of moderate doses of extracorporeal shock-wave therapy (ESWT) for non-calcific tendinitis of the rotator cuff. Adults (n=74) with chronic tendinitis of the rotator cuff were randomized to receive either active (1500 pulses ESWT at 0.12 mJ/mm²) or sham treatment, monthly, for three months. All were assessed before each treatment, and at one and three months after the completion of treatment. The outcome was measured with regard to pain in the shoulder, including a visual analogue score for night pain, and a disability index. There were no significant differences between the two groups before treatment. The mean duration of symptoms in both groups was 23.3 months. Both showed significant and sustained improvements from two months onwards. There was no significant difference between them with respect to change in the Shoulder Pain and Disability Index (SPADI) scores or night pain over the six-month period. A mean (+/-SD; range) change in SPADI of 16.1 +/- 27.2 (0 to 82) in the treatment group and 24.3 +/- 24.8 (-11 to 83) in the sham group was noted at three months. At six months, the mean changes were 28.4 +/- 25.9 (-24 to 69) and 30.4 +/- 31.2 (-12 to 88), respectively.

Similar results were noted for night pain. Overall, the trend was towards greater benefit in the sham group. The authors concluded that there was a significant and sustained placebo effect after moderate doses of ESWT in patients with non-calcific tendinitis of the rotator cuff, but there is no evidence of added benefit when compared with sham treatment.

Schmitt et al (2003) performed a controlled, randomized study to investigate the effects of low-energy ESWT on function and pain in tendinitis of the supraspinatus without calcification. There were 20 patients in the treatment group and 20 in the control group. The ESWT group received 6,000 impulses (energy flux density, 0.11 mJ/mm²) in three sessions after local anesthesia. The control group had 6000 impulses of sham ESWT after local anesthesia. The patients were examined at six and 12 weeks after treatment by an independent observer who evaluated the Constant and Murley score and level of pain. They found an increase in function and a reduction of pain in both groups ($p \leq 0.001$). Statistical analysis showed no difference between the groups for the Constant and Murley score or for pain. The authors concluded that ESWT was not effective for the treatment of non-calcified supraspinatus tendinitis.

Calcific rotator cuff tendonitis

The evidence for ESWT treating rotator cuff tendinitis with calcification is more robust. In addition to sham controlled trials, there are dose ranging studies, studies comparing where to focus the shock waves, and comparisons with other investigational approaches like TENS. Both studies comparing low to high energy ESWT suggested more benefit with high energy therapy. The study of Perlick et al (2003) used relatively high energy ESWT for the low energy group (0.23 mJ/mm²) . High energy therapy (0.42 mJ/mm²) was consistently, but non-significantly more effective in pain relief, improvements on the Constant-Murley score, and in decreasing the degree of calcification. Evaluation of this study was limited by the minimal reporting of study methods and results in the manuscript.

The other study comparing high to low energy ESWT also had a sham ESWT control group and had more complete reporting of methods and results (Gerdesmeyer *et al.* 2003). The investigators studied whether fluoroscopy-guided ESWT improves function, reduces pain, and diminishes the size of calcific deposits in patients with chronic calcific tendinitis of the shoulder. They conducted a double-blind, randomized, placebo-controlled trial between February 1997 and March 2001 among 144 patients (of 164 screened) recruited from referring primary care physicians, orthopedic surgeons, and sports physicians in seven orthopedic departments in Germany and Austria. The two ESWT groups received the same cumulative energy dose. Patients in all three groups received two treatment sessions approximately two weeks apart, followed by physical therapy. The primary end point was the change in the mean Constant and Murley Scale (CMS) score from baseline to six months after the intervention. Secondary end points were changes in the mean CMS scores at three and 12 months, as well as changes in self-rated pain and radiographic change in size of calcific deposits at three, six, and 12 months. Of 144 patients enrolled, all completed treatment as randomized and 134 completed the six-month follow-up. Both high-energy and low-energy ESWT

resulted in significant improvement in the six-month mean (95% confidence interval [CI]) CMS score compared with sham treatment (high-energy ESWT: 31.0 [26.7-35.3] points; low-energy ESWT: 15.0 [10.2-19.8] points; sham treatment: 6.6 [1.4-11.8] points; $p < 0.001$ for both comparisons). Patients who received high-energy ESWT also had significant six-month CMS improvements compared with those who received low-energy ESWT ($p < 0.001$). The results were similar for both the three-month and 12-month CMS comparisons, as well as for self-rated pain and radiographic changes at three, six, and 12 months. Of note, the area of calcification decreased 153 mm² in the high energy group, 78 mm² in the low energy group, and only 41 mm² in the sham ESWT group ($p < 0.05$ for high energy compared to each of the other groups). The authors concluded that both high-energy and low-energy ESWT appeared to provide a beneficial effect on shoulder function, as well as on self-rated pain and that they both diminished size of calcifications, compared with placebo. Furthermore, high-energy ESWT appeared to be superior to low-energy ESWT.

Of note, the authors excluded several patients from the “intention-to-treat” analysis who received other therapies like NSAIDs or steroid injections. This was primarily a problem in the sham ESWT arm. Only one patient in the high energy group and two patients in the low energy group were excluded from the analysis for this reason. Thus, it was unlikely to have a significant impact when comparing the results of high and low energy ESWT. However, a much higher proportion ($6/48 = 12\%$) of the participants in the sham ESWT group were excluded for this reason, calling into question the internal validity of any comparisons with the sham ESWT group. It is worth noting that these protocol violators were most likely patients who had the least resolution of their symptoms over time. Thus, the bias due to inappropriate exclusion of these patients would most likely be against efficacy of ESWT.

The study of Haake et al (2002) is a good quality study comparing ESWT directed at the calcification to ESWT directed at the tendon insertion. Fifty patients were included in the study. The first group of patients received 4000 impulses at 0.35 mJ/mm² in two treatment sessions after receiving local anesthesia at the origin of the supraspinatus tendon. Patients in the second group received extracorporeal shock wave therapy at the calcified area. Follow-up examinations were done 12 weeks and one year after treatment, by an independent observer. An increase of function and a reduction of pain occurred in both groups. Statistical analyses showed a significant superiority of extracorporeal shock wave application at the calcified area in the primary end point (Constant and Murley score), which increased 66 points in the “aim at calcium” group compared with 36 points in the “aim at insertion” group ($p < 0.05$). There was also a higher percentage of participants who cleared the calcium deposit completely (55% vs. 36%, p NS). The authors concluded that focusing of extracorporeal shock wave therapy at the calcific deposit for treatment of calcifying tendinopathy of the supraspinatus muscle is superior to focusing the therapy at the insertion of the tendon.

Harms were poorly reported in the majority of these studies even though higher energy settings were generally used for rotator cuff tendinitis than for plantar fasciitis or lateral epicondylitis. Three of the studies did not mention any

adverse effects of the therapy (Rompe *et al.* 2001; Schmitt *et al.* 2001; Speed *et al.* 2002b), while two others simply noted “no severe side effects” (Haake *et al.* 2002b) or “self-limiting initial pain” (Cosentino *et al.* 2003). Gerdsmeyer *et al.* (2003) had the most complete reporting of adverse events. Comparing high energy to low energy and sham ESWT, they noted patient reports of severe pain (33%, 10% and 8% respectively) and petechiae or bruising (75%, 67%, and 17% respectively). Perlick *et al.* also reported that most participants found it painful (100% high energy vs. 38% low energy). All of the reported adverse events were due to local trauma from the shock waves and resolved within several days.

In summary, there are two good quality studies of ESWT for non-calcified rotator cuff tendinitis. Neither study found significant benefits for ESWT and in one study (Speed *et al.* 2002b) there was a trend towards better results in the sham ESWT group. The randomized studies of ESWT for calcific tendinitis were uniformly positive. There were further studies indicating that high energy settings produce better results than low energy settings (Gerdsmeyer *et al.* 2003; Perlick *et al.* 2003) and one study indicating better efficacy if the shock wave is aimed at the calcification, not at the insertion of the tendon (Haake *et al.* 2002b). The adverse effects are primarily local pain and bruising which resolve within several days. These are more than offset by the relief of pain and improvements in function achieved with ESWT.

TA Criterion 3 is not met for ESWT used to treat chronic rotator cuff tendinitis without calcification.

TA Criterion 3 is met for ESWT used to treat chronic rotator cuff tendinitis with calcification of the tendon.

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

Plantar fasciitis (heel pain)

The established alternatives to extracorporeal shock wave therapy for plantar fasciitis include rest, ice, physical therapy, stretching, exercises, shoe inserts, orthotics, night splints, NSAIDs, and local corticosteroid injections. These are successful in greater than 95% of patients, although most have not been proven to alter the natural history of the disorder in randomized clinical trials (Crawford *et al.* 2003). When conservative therapy fails, either open or endoscopic release of the plantar fascia is sometimes recommended. The long recovery time, potential for scarring with chronic pain, and other surgical complications make surgery the choice of last resort.

ESWT is not being proposed as an alternative to more conservative measures. All but one of the trials required that patients have failed three to six months of conservative therapy prior to enrollment in the trials of ESWT. Speed *et al.* (2003) found no benefit to early ESWT. ESWT would be used only in patients failing conservative measures who are being considered for surgery. None of the studies compared ESWT to surgical therapy, but the goal of ESWT is to

avoid surgery. More importantly, ESWT for plantar fasciitis has not been shown 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 plantar fasciitis.

Lateral epicondylitis (tennis elbow)

The established alternatives to extracorporeal shock wave therapy for lateral epicondylitis 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 lateral epicondylitis. 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 lateral epicondylitis 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 lateral epicondylitis.

Rotator cuff tendinitis / shoulder pain (calcific and non-calcific)

The established alternatives to extracorporeal shock wave therapy for rotator cuff tendinitis include rest, ice, physical therapy, stretching, exercises, NSAIDs, and local corticosteroid injections. Response varies, but the majority of patients recover completely. Most of the conservative therapies have not been proven to alter the natural history of the disorder in randomized clinical trials (Green *et al.* 1998). Only steroid injections have RCT level evidence supporting efficacy. When conservative therapy fails, surgery is sometimes recommended. There is good evidence supporting efficacy of both endoscopic and open surgical procedures, although there are significant risks including nerve injury (Rubenthaler *et al.* 2003).

Again ESWT is not being proposed as an alternative to conservative therapy. Most of the trials required that patients have failed six to twelve months of conservative therapy prior to enrollment in the trials of ESWT. None of the studies compared ESWT to surgical therapy, but the goal of ESWT is to avoid surgery. ESWT for non-calcified rotator cuff tendinitis 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. However, ESWT for calcified rotator cuff tendinitis reduced pain and improved function compared to sham ESWT, with only short-term pain and bruising as side effects. ESWT also

clearly reduces the size of the calcification and promotes clearance of the calcification, which has been associated with resolution of symptoms.

TA Criterion 4 is not met for ESWT used to treat chronic rotator cuff tendinitis without calcification.

TA Criterion 4 is met for ESWT used to treat chronic rotator cuff tendinitis with calcification of the tendon.

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 for all 3 indications for ESWT.

OPINIONS OF OTHERS

Blue Cross Blue Shield Association (BCBSA)

The BCBSA Technology Evaluation Center Medical Advisory Panel last reviewed the use of Extracorporeal Shock Wave Therapy for musculoskeletal conditions in June 2003 and determined that the use of this technology did not meet TEC criteria.

California Orthopaedic Association (COA)

The COA was not able to provide representation at the meeting. They do not have a formal opinion or position on the use of this technology.

California Podiatric Medical Association (CPMA)

The CPMA was not able to provide representation at the meeting.

CONCLUSION

All three of these musculoskeletal disorders tend to improve over extended periods of time, even for patients who have failed conservative therapy for several months. Therefore, uncontrolled studies of ESWT for all three disorders were promising, but may represent mainly the natural history of the disorders abetted by a strong placebo effect. Studies with pain as the primary outcome commonly are subject to large placebo effects. Indeed, in the non-blinded RCT's of ESWT, the placebo group usually reported minimal improvements while the placebo group in the 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.

The nine RCT's of ESWT for plantar fasciitis illustrate this quite clearly. There was a tremendous amount of variability in the quality of the randomized trials and in the interventions studied. The fair to poor quality studies demonstrated benefit compared with sham or delayed therapy, but the trials were generally small, with inadequate blinding, poor allocation concealment, and differential loss to follow-up, which could have biased the study results in favor of ESWT. In contrast, the two good quality studies found no evidence for benefit compared with sham ESWT. Indeed, a recent New England Journal of Medicine review of therapies for plantar fasciitis (Buchbinder, 2004) concluded "the available data do not provide substantive support for its use." Many different variations of ESWT were tried in these trials. There may still be an effective treatment using ESWT for plantar fasciitis, but it remains to be defined.

Similar findings are noted in a recent German systematic review of ESWT for lateral epicondylitis that identified 20 clinical trials, all of which demonstrated successful results (Boddeker *et al.* 2000). However, each of the identified studies had methodological flaws, again demonstrating the importance of high quality double blinded, randomized trials when assessing the efficacy of therapies for musculoskeletal pain. 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.* 2002c; Speed *et al.* 2002a; Melikyan *et al.* 2003). Given the small, but real harms from ESWT and no evidence of benefit, ESWT for lateral epicondylitis should not be performed outside of clinical trials. There may be ESWT techniques that work for selected patient populations suffering from lateral epicondylitis, but they have not yet been defined by the current literature.

The quality of evidence for ESWT to treat shoulder pain is somewhat better. There were two good quality studies of ESWT for non-calcified rotator cuff tendinitis. Neither study found significant benefits for ESWT and in one study (Speed *et al.* 2002b) there was a trend towards better results in the sham ESWT group.

The randomized studies of ESWT for calcific tendinitis were uniformly positive. There were further studies indicating that high energy settings produce better results than low energy settings (Gerdesmeyer *et al.* 2003; Perlick *et al.* 2003) and one study indicating better efficacy if the shock wave is aimed at the calcification, not at the insertion of the tendon (Haake *et al.* 2002b). The adverse effects are primarily local pain and bruising which resolve within several days. These are more than offset by the relief of pain and improvements in function achieved with ESWT. The good quality, double-blinded RCTs support these findings.

RECOMMENDATION

Plantar fasciitis (heel pain)

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

Lateral epicondylitis (tennis elbow)

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

Rotator cuff tendinitis / shoulder pain (calcific and non-calcific)

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

It is recommended that the use of ESWT for the treatment of calcific rotator cuff tendinitis does meet technology assessment criteria 1 through 5 for safety, effectiveness, and improvement in health outcomes when used for patients meeting the following criteria:

- Age \geq 18 years old
- Shoulder pain lasting \geq 6 months
- Shoulder pain not responding to conservative therapy with rest, NSAIDS, and physical therapy for at least three months
- Gartner Type I or II calcification of at least 5 mm diameter documented in the affected tendon
- High energy ESWT of at least 0.26 mJ/mm² for at least two sessions of 2000 impulses per session
- Local or regional anesthesia strongly encouraged
- No bleeding disorder and not taking oral anticoagulants

The California Technology Assessment Forum approved the recommendations as presented for plantar fasciitis and calcific tendonitis of the shoulder. The Forum tabled a decision on the recommendation for lateral epicondylitis until new studies could be considered. Review is scheduled for a future meeting.

June 9, 2004

REFERENCES

- Acevedo, J. I. and J. L. Beskin (1998). "Complications of plantar fascia rupture associated with corticosteroid injection." *Foot Ankle Int* 19(2): 91-7.
- Benton-Weil, W., A. H. Borrelli, L. S. Weil, Jr., *et al.* (1998). "Percutaneous plantar fasciotomy: a minimally invasive procedure for recalcitrant plantar fasciitis." *J Foot Ankle Surg* 37(4): 269-72.
- Boddeker, I. and M. Haake (2000). "[Extracorporeal shockwave therapy in treatment of epicondylitis humeri radialis. A current overview]." *Orthopade* 29(5): 463-9.
- Bosworth, B. (1941). "Calcium deposits in the shoulder and subacromial bursitis: a survey of 12122 shoulders." *Jama* 116: 2477-2489.
- Buchbinder, R., R. Ptasznik, J. Gordon, *et al.* (2002). "Ultrasound-guided extracorporeal shock wave therapy for plantar fasciitis: a randomized controlled trial." *Jama* 288(11): 1364-72.
- Buchbinder, R. (2004). "Clinical practice. Plantar fasciitis." *N Engl J Med* 350(21): 2159-66.
- Cosentino, R., R. De Stefano, E. Selvi, *et al.* (2003). "Extracorporeal shock wave therapy for chronic calcific tendinitis of the shoulder: single blind study." *Ann Rheum Dis* 62(3): 248-50.
- Cosentino, R., P. Falsetti, S. Manca, *et al.* (2001). "Efficacy of extracorporeal shock wave treatment in calcaneal enthesophytosis." *Ann Rheum Dis* 60(11): 1064-7.
- Crawford, F. and C. Thomson (2003). "Interventions for treating plantar heel pain." *Cochrane Database Syst Rev*(3): CD000416.
- Crowther, M. A., G. C. Bannister, H. Huma, *et al.* (2002). "A prospective, randomised study to compare extracorporeal shock-wave therapy and injection of steroid for the treatment of tennis elbow." *J Bone Joint Surg Br* 84(5): 678-9.
- De Palma, A. F. and J. S. Kruper (1961). "Long term study of shoulder joints afflicted with and treated for calcific tendinitis." *Clin Orthop* 20: 61-72.
- DeMaio, M., R. Paine, R. E. Mangine, *et al.* (1993). "Plantar fasciitis." *Orthopedics* 16(10): 1153-63.
- Gartner, J. (1993). "[Tendinosis calcarea--results of treatment with needling]." *Z Orthop Ihre Grenzgeb* 131(5): 461-9.

- Gerdesmeyer, L., S. Wagenpfeil, M. Haake, *et al.* (2003). "Extracorporeal shock wave therapy for the treatment of chronic calcifying tendonitis of the rotator cuff: a randomized controlled trial." *Jama* 290(19): 2573-80.
- Green, S., R. Buchbinder, R. Glazier, *et al.* (1998). "Systematic review of randomised controlled trials of interventions for painful shoulder: selection criteria, outcome assessment, and efficacy." *Bmj* 316(7128): 354-60.
- Haake, M., I. R. Boddeker, T. Decker, *et al.* (2002a). "Side-effects of extracorporeal shock wave therapy (ESWT) in the treatment of tennis elbow." *Arch Orthop Trauma Surg* 122(4): 222-8.
- Haake, M., M. Buch, C. Schoellner, *et al.* (2003). "Extracorporeal shock wave therapy for plantar fasciitis: randomised controlled multicentre trial." *Bmj* 327(7406): 75.
- Haake, M., B. Deike, A. Thon, *et al.* (2002b). "Exact focusing of extracorporeal shock wave therapy for calcifying tendinopathy." *Clin Orthop*(397): 323-31.
- Haake, M., I. R. Konig, T. Decker, *et al.* (2002c). "Extracorporeal shock wave therapy in the treatment of lateral epicondylitis : a randomized multicenter trial." *J Bone Joint Surg Am* 84-A(11): 1982-91.
- Hammer, D. S., S. Rupp, A. Kreuz, *et al.* (2002). "Extracorporeal shockwave therapy (ESWT) in patients with chronic proximal plantar fasciitis." *Foot Ankle Int* 23(4): 309-13.
- Harris, R. P., M. Helfand, S. H. Woolf, *et al.* (2001). "Current methods of the US Preventive Services Task Force: a review of the process." *Am J Prev Med* 20(3 Suppl): 21-35.
- Jarde, O., P. Diebold, E. Havet, *et al.* (2003). "Degenerative lesions of the plantar fascia: surgical treatment by fasciectomy and excision of the heel spur. A report on 38 cases." *Acta Orthop Belg* 69(3): 267-74.
- Labelle, H., R. Guibert, J. Joncas, *et al.* (1992). "Lack of scientific evidence for the treatment of lateral epicondylitis of the elbow. An attempted meta-analysis." *J Bone Joint Surg Br* 74(5): 646-51.
- Maier, M., T. Krauter, C. Pellengahr, *et al.* (2002). "[Open surgical procedures in calcifying tendinitis of the shoulder - concomitant pathologies affect clinical outcome]." *Z Orthop Ihre Grenzgeb* 140(6): 656-61.
- Melikyan, E. Y., E. Shahin, J. Miles, *et al.* (2003). "Extracorporeal shock-wave treatment for tennis elbow. A randomised double-blind study." *J Bone Joint Surg Br* 85(6): 852-5.
- Miller, R. A., J. Torres and M. McGuire (1995). "Efficacy of first-time steroid injection for painful heel syndrome." *Foot Ankle Int* 16(10): 610-2.

- Ogden, J. A., R. Alvarez, R. Levitt, *et al.* (2001). "Shock wave therapy for chronic proximal plantar fasciitis." *Clin Orthop*(387): 47-59.
- Pan, P. J., C. L. Chou, H. J. Chiou, *et al.* (2003). "Extracorporeal shock wave therapy for chronic calcific tendinitis of the shoulders: a functional and sonographic study." *Arch Phys Med Rehabil* 84(7): 988-93.
- Perlick, L., C. Luring, H. Bathis, *et al.* (2003). "Efficacy of extracorporeal shock-wave treatment for calcific tendinitis of the shoulder: experimental and clinical results." *J Orthop Sci*8(6): 777-83.
- Prichasuk, S. and T. Subhadrabandhu (1994). "The relationship of pes planus and calcaneal spur to plantar heel pain." *Clin Orthop*(306): 192-6.
- Rochwerger, A., J. P. Franceschi, J. M. Viton, *et al.* (1999). "Surgical management of calcific tendinitis of the shoulder: an analysis of 26 cases." *Clin Rheumatol* 18(4): 313-6.
- Rompe, J. D., R. Burger, C. Hopf, *et al.* (1998). "Shoulder function after extracorporeal shock wave therapy for calcific tendinitis." *J Shoulder Elbow Surg* 7(5): 505-9.
- Rompe, J. D., J. Decking, C. Schoellner, *et al.* (2003). "Shock wave application for chronic plantar fasciitis in running athletes. A prospective, randomized, placebo-controlled trial." *Am J Sports Med* 31(2): 268-75.
- Rompe, J. D., C. Hope, K. Kullmer, *et al.* (1996a). "Analgesic effect of extracorporeal shock-wave therapy on chronic tennis elbow." *J Bone Joint Surg Br* 78(2): 233-7.
- Rompe, J. D., C. Hopf, B. Nafe, *et al.* (1996b). "Low-energy extracorporeal shock wave therapy for painful heel: a prospective controlled single-blind study." *Arch Orthop Trauma Surg* 115(2): 75-9.
- Rompe, J. D., C. Schoellner and B. Nafe (2002). "Evaluation of low-energy extracorporeal shock-wave application for treatment of chronic plantar fasciitis." *J Bone Joint Surg Am* 84-A(3): 335-41.
- Rompe, J. D., J. Zoellner and B. Nafe (2001). "Shock wave therapy versus conventional surgery in the treatment of calcifying tendinitis of the shoulder." *Clin Orthop*(387): 72-82.
- Rubenthaler, F., J. Ludwig, M. Wiese, *et al.* (2003). "Prospective randomized surgical treatments for calcifying tendinopathy." *Clin Orthop*(410): 278-84.
- Rupp, S., R. Seil and D. Kohn (2000). "[Tendinosis calcarea of the rotator cuff]." *Orthopade* 29(10): 852-67.

Schmitt, J., M. Haake, A. Tosch, *et al.* (2001). "Low-energy extracorporeal shock-wave treatment (ESWT) for tendinitis of the supraspinatus. A prospective, randomised study." *J Bone Joint Surg Br* 83(6): 873-6.

Speed, C. A., D. Nichols, C. Richards, *et al.* (2002a). "Extracorporeal shock wave therapy for lateral epicondylitis--a double blind randomised controlled trial." *J Orthop Res* 20(5): 895-8.

Speed, C. A., D. Nichols, J. Wies, *et al.* (2003). "Extracorporeal shock wave therapy for plantar fasciitis. A double blind randomised controlled trial." *J Orthop Res* 21(5): 937-40.

Speed, C.A., C. Richards, D. Nichols, *et al.* (2002b). "Extracorporeal shock-wave therapy for tendonitis of the rotator cuff. A double-blind, randomised, controlled trial." *J Bone Joint Surg Br* 84(4): 509-12.

Thiel, M. (2001). "Application of shock waves in medicine." *Clin Orthop* (387): 18-21.

Wild, C., M. Khene and S. Wanke (2000). "Extracorporeal shock wave therapy in orthopedics. Assessments of an emerging health technology." *Int J Technol Assess Health Care* 16(1): 199-209.