



EXTRACORPOREAL SHOCK WAVE THERAPY (ESWT) FOR PLANTAR FASCIITIS NOT RESPONDING TO CONSERVATIVE THERAPY

A Technology Assessment

INTRODUCTION

The California Technology Assessment Forum is requested to review the scientific evidence for the use of extracorporeal shock wave therapy for the treatment of heel pain that has not responded to conservative treatment. Since the topic was last reviewed in June 2004, additional data has been published on the previously reported trials and five new randomized trials have been identified.

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 up to ten percent of the population. The most common site of heel pain is at the insertion of the plantar fascia on the medial tubercle of the calcaneus. 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.^{1, 2} Thus, the presence or absence of a heel spur is not useful in diagnosing plantar fasciitis.

The goals of treatment are to alleviate pain and to restore function. Most patients recover without specific therapy, though they may experience activity-limiting symptoms for months. Conservative management is usually tried initially, although the data supporting the efficacy of these interventions is sparse.³ These therapies include avoidance of activities with significant impact on the heel (running, jumping, walking in bare feet), stretching, local ice application, physical therapy, non-steroidal anti-inflammatory drugs (NSAIDs), shoe inserts (heel cups, pads, custom orthotics), night splints, low-Dye taping, and corticosteroid injections. One cohort study of conservative treatments found that about half of patients were pain free after six months, one third had intermittent symptoms, and the remainder had constant pain.⁴ Steroid injections often relieve pain, but they may cause heel pad atrophy and an increase risk of



rupture of the plantar fascia.^{5, 6} When conservative measures fail, surgery is sometimes performed to release a portion of the plantar fascia that inserts into the medial tubercle.^{7, 8} However, the long recovery time and possible morbidity of the procedure make surgical therapy a last resort.

Extracorporeal shock wave therapy (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. It has been in use in Europe for over a decade, Canada for eight years, and recently was approved by the Food and Drug Administration (FDA) for use in the US. It is generally divided into high energy therapy, requiring 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. Contraindications to the use of extracorporeal shock wave therapy include patients with soft tissue infections, osteomyelitis, local tumors, coagulopathies, pregnancy, or pacemakers. Proponents argue that ESWT for orthopedic disease can provide long lasting analgesia and stimulates the healing process.⁹

The mechanism of action underlying the possible therapeutic benefits of ESWT is unclear.¹⁰ 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.⁹ Another hypothesis is that hyperstimulation of the painful region activates a descending inhibitory central nervous system response which suppresses overall pain sensation.¹¹ 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.⁹

A trained orthopedic surgeon or podiatrist usually performs ESWT for musculoskeletal disorders as an outpatient procedure. Since the therapy is painful, particularly at higher energy levels, some protocols involve the use of local or regional anesthesia, but others call for no anesthesia.¹² The location and depth of treatment is sometimes guided by fluoroscopy or by an ultrasound device coupled to the shock wave generator and in other protocols by the patient's report regarding the most painful location. A range of protocol have been used in studies with energy per impulse varying ten 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 four weeks.

TECHNOLOGY ASSESSMENT (TA)

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

Several devices have been approved through the FDA Premarket approval process. They include 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; the Orthospec Orthopedic ESWT (Medispec Ltd, Germantown, MD) received approval on April 1, 2005, the Orbasone Pain Relief System (Orthometrix, Inc., White Plains, NY) received FDA premarket approval on August 10, 2005, and the Siemens SONOCUR® Basic (Siemens, Iselin, New Jersey) which received FDA PMA approval on July 19, 2002.

All devices are approved for use in the treatment of plantar fasciitis except the Siemens SONOCURE which is approved for the treatment of lateral epicondylitis.

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, musculoskeletal, tendonitis, and tendinitis. The search was performed for the period from 1966 through May 2007. 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.

This review will focus on the results of the randomized clinical trials (RCT) because of the large number of randomized trials that have been performed and because intervention trials with subjective reports of pain as the primary outcome usually exhibit a large placebo effect. This bias is accentuated in the uncontrolled studies and



unblinded studies. For example, the improvement in pain in the placebo group of the randomized trials of ESWT for plantar fasciitis was 0% to 4% in the single blind trials, but 34% to 47% in the double blind trials. 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 review also focuses primarily on the use of ESWT in patients who have failed conservative therapy for at least six months as this is the primary indication for the therapy.

The search identified multiple publications for at least 14 randomized trials comparing ESWT to conservative therapy,^{9, 13-32} allowing a thorough evaluation of the technology. Several additional randomized trials compared different approaches to the delivery of ESWT³³ or compared ESWT to steroid injections earlier in the course of the disease.³⁴

The quality of the trials was assessed based on the approach used by the US Preventive Services Task force.³⁵ 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. Three of the clinical trials (n=610 participants) were of good quality (Tables 1 and 2). The remaining eleven studies had methodological flaws due to inadequate blinding, different co-interventions, and/or loss to follow-up.

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. More commonly, investigators consider an absolute change of 2.0 points or greater on the VAS pain scale to be clinically significant. 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, four of the 14 randomized clinical trials summarized in the tables made no mention of adverse events at all and the remaining reports were cursory. No serious adverse events were reported to be associated with ESWT. The main side effects were pain, local bleeding (petechiae, bruising, hematoma), and paresthesias.

Level of Evidence: 1, 3, 4, 5

TA Criterion 2 is met



CALIFORNIA TECHNOLOGY ASSESSMENT FORUM®

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
Consentino 2001 Siena, Italy	Yes	NR	No	Yes	No	Yes	Yes	Yes	Poor (no double blinding)
Ogden 2001, 2004 7 US sites	Yes	Yes	Yes	Yes	Yes	Yes, unclear how effective.	No, different methods of anesthesia	Yes	Fair (different anesthesia could affect outcome)
Abt 2002 Berlin, Germany	Yes	No	Yes	Yes	Yes	Yes	No, repeat treatment in some at 6 weeks	No	Fair (small, possible unblinding)
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)
Haake 2003 10 sites Bad Abbach, Germany	Yes	Yes.	Yes	Yes 6%	Yes	Yes	Yes	Yes	Good
Mehra 2003 South Wales, UK	Yes	Poor	Unclear	Unclear	No	No	No, anesthesia vs. none	Yes	Poor
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)
Theodore 2004 6 US sites	Yes	Yes	No P<0.02 sex and height	Yes	Yes	Yes, but possible unblinding	Yes	Yes	Fair (partial unblinding, not comparable at baseline)
Kudo 2006 4 Canadian sites	Yes	Yes	Yes	Yes	Yes	Yes, but 59% vs. 23% (p=0.007) thought in active.	Yes	Yes	Fair (incomplete blinding)
Malay 2006 Multiple US Centers	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Good
Wang 2006 Taiwan	Pseudo-randomization	No	No	No	No	No	No	No	Poor

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
Consentino 2001 Siena, Italy Orthima Direx Med Sys LTD	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, 2004 7 US sites Ossatron High Medical Technology	Single treatment 1500 pulses 0.22 mJ/mm ² High energy Regional block for ESWT, local anesthesia for sham.	293	DB RCT	12 weeks	48.6 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).
Abt 2002 Berlin, Germany Ossatron High Medical Technology	1000 pulses 0.08 mJ/mm ² Low energy Repeated in 12 cases Local anesthesia	32	DB RCT	48 weeks	57.0 62%	5.4	≥18 years old Heel pain Failed ≥ 5 months treatments Heel spur on x-ray	Arthritis Neurologic dz. Dermatologic dz. Pregnancy. Tumor. Infection.	Translated from German.
Buchbinder 2002 6 sites Melbourne, Australia Epos Ultra Dornier Medical Systems	3 treatments Once/week 2000 or 2500 pulses 0.02 to 0.33 mJ/mm ² Variable energy 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 Piezoston 300	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.



CALIFORNIA TECHNOLOGY ASSESSMENT FORUM®

Study	Procedure	N	Design	Follow-up	Age, yrs Sex, %F	Pain 10 pt VAS	Inclusion criteria	Exclusion criteria	Comment
Rompe 2002 Mainz Germany Osteostar Siemens	3 treatments Once/week 1000 pulses 0.08mJ/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	
Haake 2003 10 sites Bad Abbach, Germany Epos Ultra Dornier Medical Systems	3 treatments Once/ 2 weeks 4000 pulses 0.08 mJ/mm2) Low energy 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.
Mehra 2003 South Wales, UK Swiss Dolorclast System, EMS	3 treatments Once/ 2 weeks 2000 pulses 0.06 mJ/mm2 Low energy Local anesthesia.	23	Unblinded RCT	24 weeks	NR	NR	NR	NR	Minimal data in report
Rompe 2003 Mainz Germany Sonocur Plus Siemens	3 treatments Once/week 2100 pulses 0.16 mJ/mm2 Intermediate energy No anesthesia.	45	DB RCT	12 months	42 51%	7.0	Age ≥ 18 years. Run ≥ 30 miles/week before sx 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 Sonocur Plus Siemens	3 treatments Once/month 1500 pulses 0.12 mJ/mm2 Intermediate energy. 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.



CALIFORNIA TECHNOLOGY ASSESSMENT FORUM®

Study	Procedure	N	Design	Follow-up	Age, yrs Sex, %F	Pain 10 pt VAS	Inclusion criteria	Exclusion criteria	Comment
Theodore 2004 6 US sites Epos Ultra Dornier Medical Systems	Single treatment 3800 pulses 0.36 mJ/mm ² High energy Calcaneal nerve block in both.	150	DB RCT	12 weeks	52 73%	7.7	≥18 years old ≥ 6 months heel pain Unilateral Failed ≥ 3 prior treatments Heel pain > 5 on 10 pt VAS	Arthritis Neurologic dz. Coagulopathy. Diabetes. Pregnancy. Tumor. Infection. Prior PF surgery. PF rupture. Steroid injection in past month. Pacemaker.	Multivariable analysis of primary outcome did not account for baseline differences in sex and height.
Kudo 2006 4 Canadian sites Epos Ultra Dornier Medical Systems	Single treatment 3500 pulses 0.36 mJ/mm ² (positive energy) = 0.64 mJ/mm ² total. High energy Calcaneal nerve block in both.	114	DB RCT	12 weeks	50 64%	7.7	≥18 years old ≥ 6 months heel pain Unilateral Failed ≥ 3 prior treatments Heel pain > 5 on 10 pt VAS	Arthritis Neurologic dz. Diabetes. Pregnancy. Tumor. Infection. Prior PF surgery. PF rupture. Steroid injection in past month. Pacemaker. Worker's comp or litigation.	Partial unblinding likely due to significantly more pain in active group (p<0.0001).
Malay 2006 Multiple US Centers Orthospec Medispec LTD	Single treatment 3800 pulses "Level 7" High energy No anesthesia.	172	DB RCT	12 weeks	51 67%	NR	≥18 years old ≥ 6 months heel pain Unilateral Failed ≥ 3 prior treatments Heel pain ≥ 5 on 10 pt VAS	Neurologic dz. Pregnancy. Tumor. Infection. Coagulopathy. Prior PF surgery. PF rupture. Steroid injection in past 6 weeks.	Dose-response with those tolerating highest energy level having best response.
Wang 2006 Taiwan Ossatron High Medical Technology	1 - 3 treatments 1500 pulses each 0.32 mJ/mm ² High energy Local anesthesia for ESWT, none for control.	149	Pseudo-RCT	3.5-5 years	52 65%	4.0	≥18 years old ≥ 6 months heel pain	Peripheral vascular dz. Diabetes. Pregnancy. Tumor. Infection.	No sham. Differential co- interventions. Large potential for bias.

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
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	-0.2				
Ogden 2001, 2004 7 US sites	ESWT	148	12 weeks	-	-4.6	-	-4.6	Primary outcome composite "success" 47% vs. 30%, p=0.008 Identical use of pain medications.	18 active, 13 placebos. Pain, numbness, tingling after treatment. Resolved in 3 months.
	Sham ESWT	145			-3.9		-3.5, p 0.002 Pain with pressure		
Abt 2002 Berlin, Germany	ESWT	17	48 weeks	-4.3	-3.9	88%	-	-	-
	Sham ESWT	15		-1.9	-0.7	33%			
				p=.016 at 19 wks	p=.01 at 19 weeks	p<0.005			
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	-2.4				
				p=0.99	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			-0.0 (pain with pressure)		
				No p calculated				No p calculated	
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		10%	-0.2		
				p<0.001		p<0.001	p = 0.0001	p=0.002 Ankle-hindfoot scale	
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	-3.2	30%, p=0.59*			
				p NS	p NS	81% vs. 76% at 1 year			



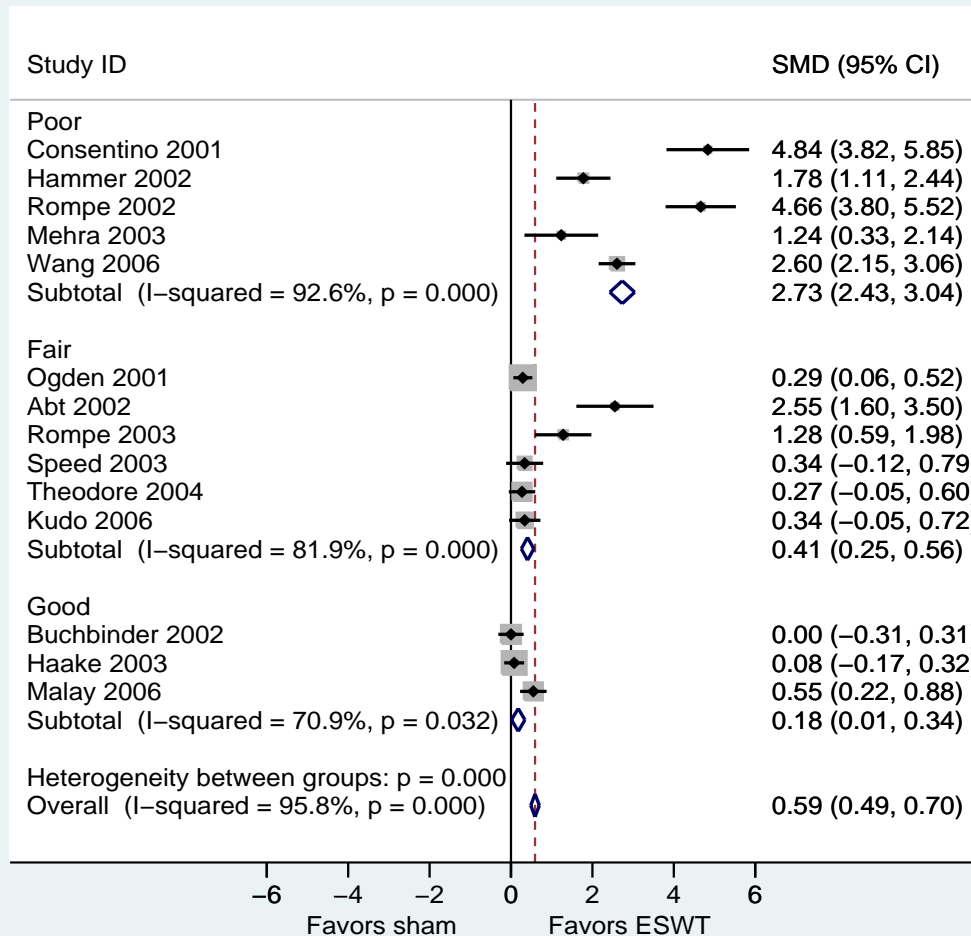
CALIFORNIA TECHNOLOGY ASSESSMENT FORUM®

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
Mehra 2003	ESWT	13	24 weeks	-4.0	NR	NR	NR	NR	NR
South Wales, UK	Sham ESWT	10		-0.4					
				p < 0.05					
Rompe 2003	ESWT	22	6 months		-4.8	-	-1.9	-	NR
Mainz Germany	Sham ESWT	23			-2.3		-1.0		
					p = 0.0004		p = 0.01		
Speed 2003	ESWT	46	3 months	37% vs. 24% reporting ≥ 50% improvement.		-	-3.3	-	1 episode syncope due to pain during ESWT. Patient withdrew from study.
Cambridge, UK	Sham ESWT	42		p=0.25*			-3.7		
							p NS		
Theodore 2004	ESWT	76	12 weeks		-4.3	62%	56%	-	Minimal except transient pain during treatment sessions.
6 US sites	Sham ESWT	74			-3.6	40%	45%		
					p 0.0435	p 0.033	p 0.19 for >60% improvement		
Kudo 2006	ESWT	58	12 weeks	-2.5	-3.6	43%	47%	43%	Pain during treatment 79% vs. 9%, p<0.0001.
4 Canadian sites	Sham ESWT	56		-1.6	-2.6	31%	23%	35%	
				p 0.052	p<0.001	p 0.012	p 0.01 for >60% improvement	p 0.09 for success by AOFAS	
Malay 2006	ESWT	115	12 weeks	-3.4	NR	NR	-2.5	53%	"None significant"
Multiple US Centers	Sham ESWT	57		-1.8			-1.6	29%	2 bruises, 1 edema: all in active ESWT group.
				P<0.001			p 0.045	p 0.003 for >50% improvement	
Wang 2006	ESWT	79	64 months	-3.8	NR	83%	-	-	"None"
Taiwan	Conservative	70	40 months	+0.1		55%			
				p<0.001		P<0.001			

* Follow-up for primary endpoint

Figure 1: Meta-analysis of Visual Analog Scale (VAS) for Pain at 3 Months* Grouped by Overall Quality of the Randomized Trial

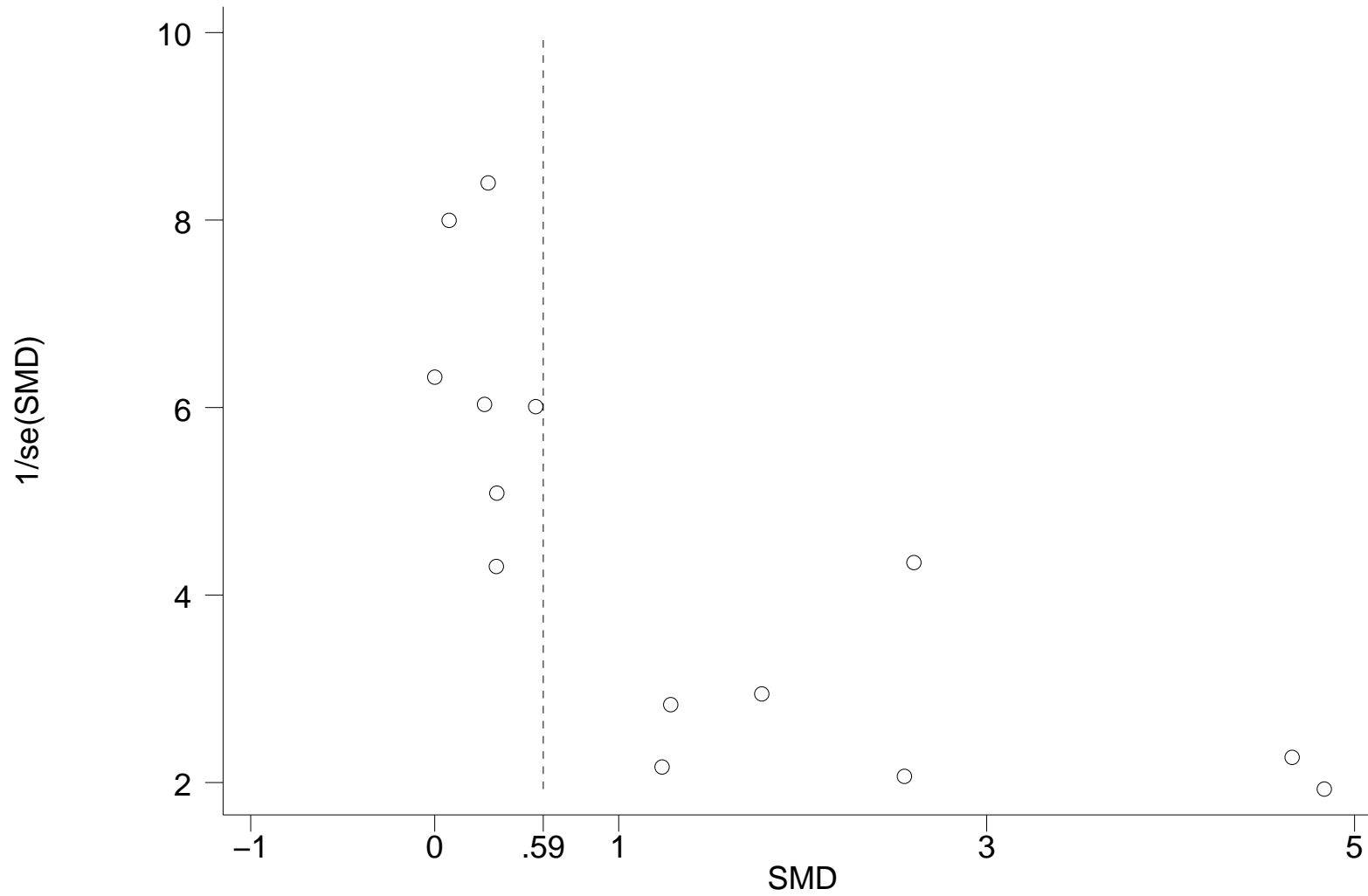
Change in VAS pain three months after treatment



*If 3-month data were not available, then used closest time point available.

The size of the box for each study represents the weight of the study in the meta-analysis. The lines around the point estimate represent the 95% confidence interval for the individual studies. The diamonds represent summary estimates from the meta-analysis; the width of the diamond is the 95% confidence interval. SMD: standardized mean difference.

Figure 2: Funnel Plot Demonstrating Evidence for Publication Bias



SMD: Standardized mean difference. SMD=0 indicates no difference in response between sham and active ESWT. SMD 0.59 is the summary estimate from the meta-analysis.



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

The literature search identified fourteen randomized clinical trials of ESWT for plantar fasciitis. 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 more recent trials was fair to good. Earlier studies suffered from inadequate 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% to 50% reduction in symptoms for the control group over three months. Participants in the control group for the study of Hammer et al.¹⁹ 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.¹⁷ and Ogden et al.⁹ 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^{16, 26, 28}

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/mm²²⁶ 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/mm²²⁸, and in his most recent publication³³, 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 session⁹ or as many as six sessions¹⁶. Most investigators did not use any anesthesia, but one used local anesthesia¹⁷ and one used regional anesthesia⁹. 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, many of the studies had significant methodological flaws. However, three of the larger studies met

all criteria and are considered to be of good quality ^{15, 17}. These studies are discussed in greater detail below.

Buchbinder et al ¹⁵ 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 (96%) 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 VAS, 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 six months as many of those patients improve with conservative therapy.

The second good quality clinical trial ¹⁷ 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 three 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.

Finally, Malay et al. published the results of a double-blind, multicenter trial in the United States that randomized 172 patients using a two to one randomization scheme to either ESWT or sham ESWT. Patients were followed for three months for the efficacy outcomes and 12 months for safety.²² Follow-up for efficacy endpoints at three months was 88% (101/115) in the ESWT group and 89% (51/57) in the sham group. Patients were required to be symptomatic for at least six months with at least four months of treatment by a physician and their pain scores on a ten point VAS for pain on initial weight bearing in the morning had to be at least five. No anesthesia was used during treatment. Patients were started at the lowest energy level and it was increased every 3.5 minutes until the highest energy level was reached (Level 7). If a patient was unable to tolerate a particular energy level, the operator decreased the level. Patients received 3500 shocks over 25 minutes. At 12 weeks, pain as assessed by a blinded investigator decreased by 2.5 points in the ESWT group and by 1.6 points in the sham group ($p=0.045$). More importantly, the patients' self-assessment of pain decreased by 3.4 points in the ESWT group and by 1.8 points in the sham group ($p<0.001$). More patients responded (defined by at least a 50% reduction in pain) in the ESWT group than in the sham group (53% vs. 29%). A greater proportion of patients in the ESWT group decreased their use of pain medications (34% vs. 14%, $p<0.001$), although there were not significant differences in patient's self-assessment of activity and function. Treatment response appeared to correlate with the maximum shock wave energy tolerated by the patient: those reaching level 6 or 7 had an average decrease in pain of 2.9 points, while those reaching 4.5 to 5.9 decreased only 1.7 points. The average decrease in the placebo arm was only 1.5 points. No significant adverse events were reported and only three patients reported minor adverse events (bruising or local swelling), all in the ESWT group.

It is not clear why the results in the Malay trial differ from the prior two trials. The variable energy delivery scheme, up to the tolerated level, was similar to that used by Buchbinder et al. The two to one randomization scheme suggests that recruitment involved advertising to patients that they had a two thirds chance of being randomized to the active group, and thus created an expectation of benefit with ESWT. Since no anesthesia was used and the energy delivered increased to the limit of tolerance, it is likely that there was some degree of unblinding, with more patients in the active group experiencing pain, and thus validation that they were randomized into the active ESWT study group. Similarly, patients randomized to the sham group may have guessed that they were in the sham group and thus setting up an expectation for no improvement. The authors did not report either the patients' experience of pain

during treatment or the patients' assessment of randomization status.

In order to summarize data across all trials, we performed a meta-analysis using the VAS overall pain score at 12 weeks as the primary outcome. If that was not available, we used the VAS pain score on first awakening. These data are presented as the standardized mean difference (SMD) in a Forrest plot in Figure 1. The SMD is positive when the difference between the two groups favors ESWT (greater reduction in VAS pain in the ESWT group compared with the placebo or sham group) and negative when the outcome favors the sham group. The magnitude of the SMD is the number of standard deviations difference between the two groups in the randomized trial. The summary SMD for the 14 trials is 0.59 (95% CI 0.49-0.70), a highly significant result. As is evident from the Figure, there were large differences across the 14 trials (p for heterogeneity <0.001). We performed metaregression to attempt to understand the source of the heterogeneity. Possible explanations that were considered included the manufacturer of the device used, the use of and type of anesthesia (none, local, regional), the level of energy flux used in treatment (low, intermediate, high), and the quality of the trial. Only trial quality significantly predicted differences in the magnitude of the benefit across trials ($p < 0.01$). Figure 1 breaks the 14 trials into subgroups based on quality. The five poor quality trials had a summary SMD of 2.73, the six fair quality trials had a summary SMD of 0.41, and the four good quality trials had an SMD of 0.18. Thus, the higher the quality of the trial, the smaller the difference between the ESWT group and the sham group.

We also looked for evidence of publication bias using a funnel plot (Figure 2). A funnel plot, as the name implies, should have a peak around the true difference between the two groups (near the summary estimate 0.59), and gradually slope away on both sides. Studies at the base of the funnel usually represent small studies with low power. There should be a wide range of results including some studies that are very strongly positive and other studies that are negative. There should be symmetry around the peak of the funnel. If there are primarily studies to the right of the peak (positive studies), then there is likely publication bias. In other words, the small positive studies have been published and contribute to the summary estimate, but the small, negative studies have not been published. The funnel plot of randomized clinical trials of ESWT for the treatment of plantar fasciitis peaks near zero (no difference between the two groups) and is notable for the complete absence of studies to the left of the peak. This is strong evidence for publication bias.

In summary, there was a tremendous amount of variability in the quality of the randomized trials and in the interventions studied. The best quality studies found minimal 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. There was clear evidence of publication bias. Thus, the summary estimate



from the meta-analysis should be disregarded. The totality of the evidence suggests little or no benefit to ESWT for plantar fasciitis beyond the placebo effect.

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

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

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.³ 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; it is an alternative to surgical intervention. 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.²⁹ found no benefit to early ESWT. A second randomized trial compared early ESWT to corticosteroid injection³⁴ as early as six weeks after the onset of pain (average three months). VAS pain scores decreased more rapidly in the corticosteroid injection group than in the ESWT group (1.5 vs. 3.7 at 3 months, $p < 0.001$), although there were no differences between the two groups after 12 months (VAS pain score = 0.84 for both). ESWT for plantar fasciitis 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 plantar fasciitis.

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.⁹ 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. However, since improvements have not been demonstrated under TA criteria 3 and 4, TA criterion 5 cannot be met.

TA Criterion 5 is not met for ESWT.



CONCLUSION

Patients with plantar fasciitis tend to improve over extended periods of time, even patients who have failed conservative therapy for months. Therefore, the uncontrolled studies of ESWT, while promising, 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 RCTs of ESWT, the placebo group usually reported minimal improvements, while the placebo group in the well blinded studies reported 30% to 50% improvements in pain scores. This highlights the need for high quality, double-blinded, randomized trials as the minimum standard of evidence.

Meta-analysis of the fourteen RCTs of ESWT for plantar fasciitis illustrate this quite clearly. There was significant variability in the quality of the randomized trials and in the interventions studied. However, only the quality of the studies was significantly associated with the magnitude of the benefit observed in the clinical trials. 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, two of the three 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 fasciitis³⁶ concluded “the available data do not provide substantive support for its use.” Furthermore, there is strong evidence for publication bias in the available literature. The asymmetry of the funnel plot indicates that many small studies with negative results have been performed, but not published. Finally, 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. The literature does not clearly support a benefit of high energy compared with low energy ESWT nor is it clear that the use of anesthesia abrogates the analgesic benefits of ESWT. Until unequivocal benefit is demonstrated in high quality clinical trials, ESWT should remain investigational.

RECOMMENDATION

It is recommended that the use of ESWT for the treatment of plantar fasciitis does not meet technology assessment criteria 3, 4, or 5 for safety, effectiveness, and improvement in health outcomes.

The California Technology Assessment Forum panel voted in favor of this recommendation.

June 20, 2007



RECOMMENDATIONS OF OTHERS:

Blue Shield Blue Cross Association (BCBSA)

The BCBSA Technology Evaluation Center conducted a review of this technology in March 2005. The Medical Advisory Panel determined that criteria were not met for the treatment of chronic plantar fasciitis..

Centers for Medicare and Medicaid Services (CMS)

The CMS does not have a policy specific to the use of this technology. However, a HCPS code does exist for ESWT high-energy plantar fasciitis.

California Orthopaedic Association (COA)

COA does not have a position/opinion specific to the use of this technology. A representative did attend the meeting to provide testimony.

California Podiatric Medical Association (CPMA)

CPMA was invited to provide a position/opinion regarding the use of this technology and testimony at the meeting.

American College of Foot & Ankle Surgeons (ACFAS)

The ACFAS was invited to provide a position/opinion regarding the use of this technology and testimony at the meeting.

Southwest American College of Sports Medicine (SWACSM)

The SWACSM chapter does not provide position/opinion regarding the validity of this technology but rather defers to the American College of Sports Medicine. The SWACSM did not provide testimony at the meeting.

A Joint Policy Statement on Extracorporeal Shock Wave Therapy issued by the APMA and ACFAC was issued in December 2003 and notes: "Based on a thorough review of the literature, ESWT appears to be an efficacious, FDA-approved non-surgical option in the treatment of chronic plantar fasciitis". The guideline is available at <http://www.acfas.org/health/privileges/eswt-statement.htm> .



ABBREVIATIONS:

ESWT: Extracorporeal shock wave therapy
NSAIDS: Non-steroidal anti-inflammatory drugs
FDA: Food & Drug Administration
PMA: Premarket approval
DARE: Database of Abstracts of Reviews of Effects
RCT: Randomized Clinical Trial
VAS: Visual analog scale
RM: Roles and Maudsley
ITT: Intention-to-treat
UK: United Kingdom
F/U: Follow up
SB RCT: Single-blind, randomized controlled trial
DB RCT: Double-blind, randomized controlled trial
U/S: Ultrasound
PF: Plantar fasciitis
TENS: Transcutaneous electric nerve stimulation
AE: Adverse events
NR: Not reported
NA: Not applicable
NS: Not significant
N: Number of participants
SMD: Standardized mean difference

REFERENCES



CALIFORNIA TECHNOLOGY ASSESSMENT FORUM®

1. DeMaio M, Paine R, Mangine RE, Drez D, Jr. Plantar fasciitis. *Orthopedics*. Oct 1993;16(10):1153-1163.
2. Prichasuk S, Subhadrabandhu T. The relationship of pes planus and calcaneal spur to plantar heel pain. *Clin Orthop*. Sep 1994(306):192-196.
3. Crawford F, Thomson C. Interventions for treating plantar heel pain. *Cochrane Database Syst Rev*. 2003(3):CD000416.
4. Wolgin M, Cook C, Graham C, Mauldin D. Conservative treatment of plantar heel pain: long-term follow-up. *Foot Ankle Int*. Mar 1994;15(3):97-102.
5. Acevedo JI, Beskin JL. Complications of plantar fascia rupture associated with corticosteroid injection. *Foot Ankle Int*. Feb 1998;19(2):91-97.
6. Miller RA, Torres J, McGuire M. Efficacy of first-time steroid injection for painful heel syndrome. *Foot Ankle Int*. Oct 1995;16(10):610-612.
7. Benton-Weil W, Borrelli AH, Weil LS, Jr., Weil LS, Sr. Percutaneous plantar fasciotomy: a minimally invasive procedure for recalcitrant plantar fasciitis. *J Foot Ankle Surg*. Jul-Aug 1998;37(4):269-272.
8. Jarde O, Diebold P, Havet E, Boulu G, Vernois J. Degenerative lesions of the plantar fascia: surgical treatment by fasciectomy and excision of the heel spur. A report on 38 cases. *Acta Orthop Belg*. Jun 2003;69(3):267-274.
9. Ogden JA, Alvarez R, Levitt R, Cross GL, Marlow M. Shock wave therapy for chronic proximal plantar fasciitis. *Clin Orthop*. Jun 2001(387):47-59.
10. Wild C, Khene M, Wanke S. Extracorporeal shock wave therapy in orthopedics. Assessment of an emerging health technology. *Int J Technol Assess Health Care*. Winter 2000;16(1):199-209.
11. Rompe JD, Riedel C, Betz U, Fink C. Chronic lateral epicondylitis of the elbow: A prospective study of low-energy shockwave therapy and low-energy shockwave therapy plus manual therapy of the cervical spine. *Arch Phys Med Rehabil*. May 2001;82(5):578-582.
12. Thiel M. Application of shock waves in medicine. *Clin Orthop*. Jun 2001(387):18-21.
13. Abt T, Hopfenmuller W, Mellerowicz H. [Shock wave therapy for recalcitrant plantar fasciitis with heel spur: a prospective randomized placebo-controlled double-blind study]. *Z Orthop Ihre Grenzgeb*. Sep-Oct 2002;140(5):548-554.
14. Buch M, Knorr U, Fleming L, et al. [Extracorporeal shockwave therapy in symptomatic heel spurs. An overview]. *Orthopade*. Jul 2002;31(7):637-644.
15. Buchbinder R, Ptasznik R, Gordon J, Buchanan J, Prabaharan V, Forbes A. Ultrasound-guided extracorporeal shock wave therapy for plantar fasciitis: a randomized controlled trial. *Jama*. Sep 18 2002;288(11):1364-1372.
16. Cosentino R, Falsetti P, Manca S, et al. Efficacy of extracorporeal shock wave treatment in calcaneal enthesophytosis. *Ann Rheum Dis*. Nov 2001;60(11):1064-1067.
17. Haake M, Buch M, Schoellner C, et al. Extracorporeal shock wave therapy for plantar fasciitis: randomised controlled multicentre trial. *Bmj*. Jul 12 2003;327(7406):75.



CALIFORNIA TECHNOLOGY ASSESSMENT FORUM®

18. Hammer DS, Adam F, Kreutz A, Kohn D, Seil R. Extracorporeal shock wave therapy (ESWT) in patients with chronic proximal plantar fasciitis: a 2-year follow-up. *Foot Ankle Int.* Nov 2003;24(11):823-828.
19. Hammer DS, Rupp S, Kreutz A, Pape D, Kohn D, Seil R. Extracorporeal shockwave therapy (ESWT) in patients with chronic proximal plantar fasciitis. *Foot Ankle Int.* Apr 2002;23(4):309-313.
20. Krischek O, Rompe JD, Herbsthofer B, Nafe B. Symptomatic low-energy shockwave therapy in heel pain and radiologically detected plantar heel spur. *Z Orthop Ihre Grenzgeb.* 1998;136:169-174.
21. Kudo P, Dainty K, Clarfield M, Coughlin L, Lavoie P, Lebrun C. Randomized, placebo-controlled, double-blind clinical trial evaluating the treatment of plantar fasciitis with an extracorporeal shockwave therapy (ESWT) device: a North American confirmatory study. *J Orthop Res.* Feb 2006;24(2):115-123.
22. Malay DS, Pressman MM, Assili A, et al. Extracorporeal shockwave therapy versus placebo for the treatment of chronic proximal plantar fasciitis: results of a randomized, placebo-controlled, double-blinded, multicenter intervention trial. *J Foot Ankle Surg.* Jul-Aug 2006;45(4):196-210.
23. Mehra A, Zaman T, Jenkin AI. The use of a mobile lithotripter in the treatment of tennis elbow and plantar fasciitis. *Surgeon.* Oct 2003;1(5):290-292.
24. Ogden JA, Alvarez RG, Levitt RL, Johnson JE, Marlow ME. Electrohydraulic high-energy shock-wave treatment for chronic plantar fasciitis. *J Bone Joint Surg Am.* Oct 2004;86-A(10):2216-2228.
25. Rompe JD, Decking J, Schoellner C, Nafe B. Shock wave application for chronic plantar fasciitis in running athletes. A prospective, randomized, placebo-controlled trial. *Am J Sports Med.* Mar-Apr 2003;31(2):268-275.
26. Rompe JD, Hopf C, Nafe B, Burger R. Low-energy extracorporeal shock wave therapy for painful heel: a prospective controlled single-blind study. *Arch Orthop Trauma Surg.* 1996;115(2):75-79.
27. Rompe JD, Kullmer K, Riehle MH, Herbsthofer B, Eckardt A, Burger R. Effectiveness of low energy extracorporeal shock waves for chronic plantar fasciitis. *Foot Ankle Surg.* 1996;2:215-221.
28. Rompe JD, Schoellner C, Nafe B. Evaluation of low-energy extracorporeal shock-wave application for treatment of chronic plantar fasciitis. *J Bone Joint Surg Am.* Mar 2002;84-A(3):335-341.
29. Speed CA, Nichols D, Wies J, et al. Extracorporeal shock wave therapy for plantar fasciitis. A double blind randomised controlled trial. *J Orthop Res.* Sep 2003;21(5):937-940.
30. Theodore GH, Buch M, Amendola A, Bachmann C, Fleming LL, Zingas C. Extracorporeal shock wave therapy for the treatment of plantar fasciitis. *Foot Ankle Int.* May 2004;25(5):290-297.
31. Wang CJ, Chen HS, Huang TW. Shockwave therapy for patients with plantar fasciitis: a one-year follow-up study. *Foot Ankle Int.* Mar 2002;23(3):204-207.
32. Wang CJ, Wang FS, Yang KD, Weng LH, Ko JY. Long-term results of extracorporeal shockwave treatment for plantar fasciitis. *Am J Sports Med.* Apr 2006;34(4):592-596.
33. Rompe JD, Meurer A, Nafe B, Hofmann A, Gerdesmeyer L. Repetitive low-energy shock wave application without local anesthesia is more efficient than repetitive low-energy shock wave application with local anesthesia in the treatment of chronic plantar fasciitis. *J Orthop Res.* Jul 2005;23(4):931-941.



CALIFORNIA TECHNOLOGY ASSESSMENT FORUM®

34. Porter MD, Shadbolt B. Intralesional corticosteroid injection versus extracorporeal shock wave therapy for plantar fasciopathy. *Clin J Sport Med*. May 2005;15(3):119-124.
35. Harris RP, Helfand M, Woolf SH, et al. Current methods of the US Preventive Services Task Force: a review of the process. *Am J Prev Med*. Apr 2001;20(3 Suppl):21-35.
36. Buchbinder R. Clinical practice. Plantar fasciitis. *N Engl J Med*. May 20 2004;350(21):2159-2166.