Ankle and Foot Disorders

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						wearing AirHeel. Data suggest no difference.

EXTRACORPOREAL SHOCKWAVE THERAPY (ESWT)

Extracorporeal shockwave therapy (ESWT), or "shockwave therapy," has been utilized for treatment of multiple chronic soft tissue disorders including Achilles tendinopathy, plantar fasciitis, and lateral epicondylitis. The mechanism of action is unknown.(28) (Rompe 09)

1. *Recommendation: Extracorporeal Shockwave Therapy for Chronic Mid-portion Achilles Tendinopathy*
   Extracorporeal shockwave therapy is recommended as an adjunct to an eccentric exercise for chronic, recalcitrant Achilles tendinopathy.

   Indications – Moderate to severe, recalcitrant Achilles tendinopathy. Patients should have failed NSAIDs, eccentric exercises, physical or occupational therapy, and local injection(s).(28, 50) (Rompe J Bone Joint Surg Am 08, Rompe 09)

   Frequency/Duration – Three to 4 weekly sessions over 3 to 4 consecutive weeks, using 2,000 shocks at 0.1 to 0.2 J/mm^2 administered in conjunction with an eccentric exercise program.(28, 50, 61, 62) (Rasmussen 08; Rompe 07; Rompe J Bone Joint Sur Am 08; Rompe 09)

   Indications for Discontinuation – Completion of course, resolution of symptoms, adverse effects, intolerance, non-compliance.

   Strength of Evidence – **Recommended, Evidence (C)**
   Level of Confidence –Low

2. *Recommendation: Extracorporeal Shockwave Therapy for Acute, Subacute, or Post-operative Achilles Tendinopathy*
   Extracorporeal shockwave therapy is not recommended for treatment of acute, subacute, or post-operative Achilles tendinopathy.

   Indications – Moderate to severe recalcitrant Achilles tendinopathy. Patients should have failed NSAIDs, eccentric exercises, physical or occupational therapy, and local injection(s).(28, 50) (Rompe J Bone Joint Surg Am 08, Rompe 09)

   Frequency/Duration – Three to 4 weekly sessions over 3 to 4 consecutive weeks, using 2,000 shocks at 0.1 to 0.2 J/mm^2 administered in conjunction with an eccentric exercise program.

   Indications for Discontinuation – Completion of course, resolution of symptoms, adverse effects, intolerance, non-compliance.

   Strength of Evidence – **Not Recommended, Insufficient Evidence (I)**
   Level of Confidence – Moderate

Rationale for Recommendations

Evidence of efficacy for ESWT in treatment of patients with chronic Achilles tendinopathy is conflicting. There are two high-quality RCTs comparing ESWT with sham ESWT(62, 63), (Rasmussen 08; Costa 05) and one high-quality study comparing ESWT with a non-treated control group.(61) (Rompe 07) Adequacy of blinding of ESWT is unclear.(62, 63) (Rasmussen 08; Costa 05) One sham-controlled trial failed to demonstrate efficacy(63) (Costa 05) while another showed statistically significant functional improvement, but questionable clinical improvement,(62) (Rasmussen 08) raising questions of treatment effectiveness. The dosing and treatment intervals were different between the trial that failed to

demonstrate efficacy(63) (Costa 05) and those that did, which may have accounted for the variable effects. The trial with a non-treatment control group suggested ESWT was superior to non-treatment(61); (Rompe 07) however, the level of benefit was modest and there was no superiority of the ESWT to eccentric exercises.

Two trials evaluated patients with chronic Achilles tendon disorders who failed other treatment.(28, 50) (Rompe J Bone Joint Surg Am 08; Rompe 09) The first study compared ESWT and eccentric exercises and found statistically significant differences between the groups, with EWST patient outcomes superior.(50) (Rompe J Bone Joint Surg Am 08) The second study found a combination of eccentric exercises plus ESWT superior to exercises alone considering statistically significant differences alone.(28) (Rompe 09) However, although the groups receiving and not receiving ESWT had statistical differences, the clinical significance of the findings is uncertain because they were within the limits of reproducibility of one of the primary measurement instruments.(51) (Robinson 01) The investigators in these trials administered ESWT with timing and number of shocks similar to the authors of the successful sham ESWT study.(62) (Rasmussen 08)

The effectiveness of ESWT is unclear as the studies that showed differences between ESWT and non-ESWT groups were modest and may have reflected statistically rather than clinically significant differences. ESWT has not conclusively shown itself to be invasive in the literature cited in this section when administered as specified by the investigators.(28, 50, 61, 62) (Rasmussen 08; Rompe 07; Rompe J Bone Joint Surg Am 08; Rompe 09) Tendon rupture was reported in one study(63) (Costa 05); however, the circumstances of the ruptures cast doubt on whether ESWT was a contributing factor. There are no quality studies for treatment of acute, subacute, and post-operative Achilles tendinopathy patients, and given other treatment options, ESWT is not recommended for acute, subacute, or post-operative Achilles tendinopathy.

Evidence for the Use of Extracorporeal Shockwave Therapy for Achilles Tendinopathy
There are 5 high-quality RCTs incorporated into this analysis.

Author/Year Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments
Rasmussen 2008 RCT	9.0	N = 48 assigned to non-operative treatment of chronic Achilles tendinopathy	ESWT vs. sham ESWT (ESWT: 1 session each week for 4 weeks, 2000 shots 0.21-0.51 ml/mm^2, 50 Hz); all patients assigned eccentric exercises.	AOFAS score increased more in intervention, 70 to 88 ($p < 0.05$), than controls, 74 to 81. No difference in pain between groups.	"EWST appears to be a clinically relevant supplement to conservative treatment of tendinopathy. Currently, however, there is no convincing evidence for recommendation of ESWT."	Conservative treatment included stretching and eccentric exercise training as co-interventions. AOFAS score measures pain (40 points), function (50 points), alignment (10 points). Clinical significance set at 10 point difference. Baseline lower AOFAS scores in ESWT group than controls. Data suggest no

	High	>0.60
Kassel	Low	<0.12
	High	>0.12

The total energy delivered during an application of ESWT is a product EFD of each shock, the number of shocks, the area of the energy delivery for each shock (usually on the order of 20mm^2), and the amount of energy absorbed by the tissue. Thus, a "low energy" application with a high number of shocks may impart more energy than a "high energy" application with a low number of shocks. No classification scheme to address this aspect of ESWT could be found. In lithotripsy, highly-focused shock waves are more effective. What if any bearing the transmission area has on treatment in musculoskeletal disorders is not addressed in the medical literature. Other areas of confusion when seeking an understanding of ESWT are that energy flux density may be reported in different ways and energy is distributed in the shock waves differently at different energy levels. EFD is reported as "total energy flux density (EFD)" or "positive energy flux density (EFD_+)," the latter being the amount of energy contained in only in the initial, rapid, positive-pressure compression wave (and does not include the longer negative-pressure wave that follows). EFD_+ is always smaller than EFD, and its comparative size may be dependent on EFD and the ESWT device.(237-240) (Ogden 01, Maier 05, Thiel Intl Soc Med Shockwave, Tóth-Kischkat Intl Soc Med Shockwave) Lower-energy EFDs have comparatively small proportions of their total energy in EFD_+ than do higher-energy EFDs.(241) (Kudo 06) EFD and EFD_+ may be recorded as the energy in the portion of the wave with sonic energy twice that of baseline, with pressure over 5 MPa (50 atmospheres), or in a "focal area" of the highest energy of 5mm diameter.(238-240) (Maier 05, Thiel Intl Soc Med Shockwave, Tóth-Kischkat Intl Soc Med Shockwave) The different ways of measuring EFD may result in reporting differences of several-fold.(237, 242) (Ogden 01; Rompe 03) Lastly, the frequency of delivery of shock waves may affect secondary phenomena, such as formation of air bubble in tissue with the low-pressure portion of the energy wave that follows the high-pressure pulse, a phenomenon known as cavitation.

ESWT may induce frank tissue damage and pain at higher energy. One set of authors assert that energy flux levels of more than 0.34mJ/mm^2 require "regional nerve blocks combined with either intravenous sedation or general anesthesia."(243) (Malay 06) However, in most studies, the authors do not indicate anesthesia was administered. Other than the assertion by Malay,(243) (Malay 06) a threshold for anticipating pain or administering anesthesia is not clear.

1. Recommendation: Extracorporeal Shockwave Therapy for Chronic Plantar Fasciitis
Extracorporeal shockwave therapy (ESWT) is recommended as a treatment for chronic plantar fasciitis in select patients with chronic recalcitrant conditions.

Indications – Chronic plantar heel pain consistent with plantar fasciitis. In most studies of ESWT used for treatment of plantar fasciitis, patients often have at least 6 months of symptoms and fail physical or occupational therapy with active and passive exercises, NSAIDs, and glucocorticosteroid injection(s).(237, 241-249) (Malay 06, Kudo 06, Rompe 03, Theodore 04, Cosentino 01, Mehra 03, Ogden 04, Rompe 02 & 96, Ogden 01) The presence or absence of heel spur does not impact decision for use of ESWT.(246) (Cosentino 01)

Frequency/Duration – Treatment protocols vary; 1 to 3 treatment sessions with reported efficacy are 1,500 impulses at 0.22 mJ/mm2 to 3,800 impulses at 0.36 to 0.64mJ/mm2. (237, 241, 243, 245, 249) (Ogden 01, Ogden 04, Theodore 04, Kudo 06, Malay 06) Serial sessions of 1,000 to 2,100 impulses at 0.16 mJ/mm2 or lower repeated over 3 sessions spaced in weekly or biweekly intervals is also reported.(242, 246, 247) (Rompe 03, Cosentino 01, Mehra 03)

Indications for Discontinuation – Resolution, intolerance, non-compliance.

Strength of Evidence – **Recommended, Insufficient Evidence (I)**
Level of Confidence – Low

2. Recommendation: Extracorporeal Shockwave Therapy for Acute or Subacute Plantar Fasciitis
Extracorporeal shockwave therapy (ESWT) is not recommended for treatment of acute or subacute plantar fasciitis.

Strength of Evidence – **Not Recommended, Insufficient Evidence (I)**
Level of Confidence – Moderate

3. Recommendation: Ultrasound or Fluoroscopy Guidance for Shockwave Therapy for Plantar Fasciitis
Ultrasound or fluoroscopic guidance is not recommended over application of energy at the point of maximal tenderness for treatment of plantar fasciitis.

Strength of Evidence – **Not Recommended, Insufficient Evidence (I)**
Level of Confidence – Low

4. Recommendation: Local Anesthesia with High Shockwave Therapy for Plantar Fasciitis
Local anesthesia is recommended when used in conjunction with high-energy ESWT for the treatment of plantar fasciitis.

Strength of Evidence – **Recommended, Insufficient Evidence (I)**
Level of Confidence - Low

5. Recommendation: Local Anesthesia with Low or Medium Shockwave Therapy for Plantar Fasciitis
There is no recommendation for or against the use of local anesthesia when used in conjunction with low- or medium-energy ESWT for the treatment of plantar fasciitis.

Strength of Evidence – **No Recommendation, Insufficient Evidence (I)**
Level of Confidence – Low

6. Recommendation: Radial Extracorporeal Shockwave Therapy for Chronic Plantar Fasciitis
There is no recommendation for or against the use of radial ESWT (rESWT) for the treatment of chronic plantar fasciitis.

Indications – Same as ESWT (see above).

Strength of Evidence – **No Recommendation, Insufficient Evidence (I)**
Level of Confidence – Low

7. Recommendation: Radial Extracorporeal Shockwave Therapy for Acute or Subacute Plantar Fasciitis
Radial ESWT (rESWT) is not recommended for the treatment of acute or subacute plantar fasciitis.

Strength of Evidence – **Not Recommended, Insufficient Evidence (I)**
Level of Confidence – Moderate

Rationale for Recommendations
There are multiple quality placebo-controlled trials providing conflicting outcomes for the efficacy of ESWT for the treatment of chronic plantar heel pain. Most of the high-quality studies failed to show superiority of ESWT to placebo(250-254); (Haake 03, Buchbinder 02, Speed 03, Marks 08; Gollwitzer 07) however, there are two high-quality trials(241, 243) (Malay 06, Kudo 06) and seven moderate-quality trials(237, 242, 244-247, 249) (Rompe 03, Theodore 04, Cosentino 01, Mehra 03, Ogden 04, Rompe 96, Ogden 01) that suggested efficacy. Additionally, evidence for intermediate- and long-term harm was lacking.

Interpretation of these results is complicated by the wide variations in amount of energy delivered, treatment frequency, and use of local anesthetics. The optimal EFD for ESWT is unclear, as are the strata for energy flux delivery. Rompe used low energy (~0.08mJ/mm^2), medium energy (~0.28mJ/mm^2), and high energy (~0.60mH/mm^2), in agreement with the Mainz classification.(254) (Gollwitzer 07) Quality trials have demonstrated low- and high-energy density delivery treatment regimens to be both effective and non-effective. Comparison of outcomes with total energy delivered is also inconsistent, as quality trials demonstrated total energy (EFD multiplied by the number of pulses at that EFD) between 60 mJ/mm^2 (244) (Rompe 96) and 2330mJ/mm^2 (241) (Kudo 06) to be both effective and ineffective. This energy range presumes EFD, not EFD$_+$, reported by the study authors. Described protocols consisted of 3 treatment sessions, with varied impulse energy density (0.02 to 0.33mJ/mm^2), number of impulses applied (1,500 to 4,000 per session), and spacing of treatment sessions (every third day to every other week). Thus, the optimal energy level of treatment is not well defined. There are three quality studies that demonstrated benefit from a single high-energy treatment session.(237, 243, 245) (Malay 06, Theodore 04, Ogden 01) One trial suggested a dose effect with increased impulses.(255) (Rompe 02)

Benefit of ESWT compared to corticosteroid injection in acute patients was compared.(256) (Porter 05) Both groups improved and no recommendation is made for either as an acute treatment. In comparison to mixed conservative therapies(257) (Greve 09) one moderate-quality trial found no differences in outcomes measures, whereas two moderate-quality trials demonstrated ESWT more effective than serial conservative treatments of NSAIDs, orthotics, physiotherapy, stretching, and cortisone injections.(258-260) (Hammer 02, 03, Wang 06) These studies had multiple weaknesses limiting interpretation of results, but suggest for chronic conditions, ESWT may provide greater benefit than continuing with other non-operative treatments. ESWT may be invasive, particularly at high energy, when it may be performed with an injected anesthetic. Adverse effects from ESWT, particularly high-energy ESWT, may include erythema, pain, numbness, and tingling which are generally transient.(237, 241, 246, 249, 250) (Cosentino 01, Ogden 01, Ogden 04, Haake 03, Kudo 06) ESWT is moderate to high cost depending on numbers of treatments. However, the results of the studies are heterogenous, with more than a quarter of the high-quality studies and all seven moderate-quality studies showing efficacy. Thus, ESWT is recommended for treatment of chronic plantar fasciitis if more conservative measures have failed, particularly as if surgery is being considered.

A high-quality trial comparing radial ESWT (rESWT) with sham demonstrated efficacy in reduction of pain and improved function at 3 months and 1 year.(261) (Gerdesmeyer 08) There are no studies comparing rESWT versus ESWT. Another moderate-quality trial compared perpendicular to tangential application of energy, which demonstrated no difference in outcomes as both groups improved the same.(262) (Tornese 08) The study was missing a control group and therefore no recommendation is made for one technique over the other. Radial ESWT is similar to ESWT in other aspects, adverse effects, and cost. Based on the insufficient evidence of efficacy for ESWT, there is insufficient evidence for recommendation.

The use of ultrasound and fluoroscopy has been described to guide the location for ESWT application. The quality comparison trial found no difference in outcomes using fluoroscopy compared to palpation.(263) (Dorotka 06) Ultrasound was used in three high-quality studies that showed no benefit over sham treatment,(250-252) (Haake 03, Buchbinder 02, Speed 03) but has not been compared without ultrasound in the same study. Therefore, there is insufficient evidence that the use of ultrasound or fluoroscopy guidance provides additional benefit over application of energy at point of maximal tenderness, and is therefore not recommended.

Regarding the use of local anesthesia, a high-quality study compared the effect of local anesthesia block to no block in subjects receiving low-energy ESWT and found local block reduces the positive treatment effect of ESWT, with prolonged benefit at 3 months, suggesting pain associated with ESWT has a treatment effect.(264) (Rompe 05) However, two high-quality studies finding no effect of ESWT did not utilize a local block and still found no effect over placebo.(250, 251) (Haake 03, Buchbinder 02) Thus,

there is insufficient evidence for a recommendation for or against the use of local block with low- or medium-energy ESWT. Local anesthesia is typically used in high-energy ESWT, using the Mainz categorization, to over 0.60mJ/mm^2, and is recommended for use with high-energy ESWT.

Evidence for the Use of ESWT for Plantar Fasciitis

There are 9 high- and 14 moderate-quality RCTs (one with two reports) or quasi-RCTs incorporated into this analysis. There are 2 low-quality studies in the Appendix.(265, 266) (Furia 05, Alvarez 03)

Author/Year Study Type	Score (0-11)	Sample Size	Comparison Groups	Results	Conclusions	Comments
			ESWT vs. Sham			
Haake 2003 RCT	10.0	N = 272 chronic plantar fasciitis with symptoms >6 months and failure of conservative treatment (non-specified)	ESWT vs. sham. Active treatment: 4,000 shocks 0.08 mJ/mm^2 x 3 treatments 2 week intervals; mepivacaine local used. Energy focused on insertion of fascia guided by ultrasound; 12 week at 12-month follow-up period; 320 mJ/mm^2; low energy flux.	Primary outcome: success on Roles and Maudsley Scale (score 1-2): 12 weeks – difference in success rates 3.6% (-8.0% to 15.1; p = 0.5927), OR 1.18 (0.675 to 2.07). 12 months: 91 of 113 (81%) ESWT vs. 87 of 115 (76%) placebo p >0.05. No significant effect of ESWT.	"We cannot recommend specific applications of extracorporeal shock wave therapy to be tested in further clinical studies because all major trials, using different shockwave variable and types of lithotripters, showed negative results."	Blinding of treat-ment method shown to be effective, 75% (therapy) vs. 65% (placebo) thought they were in treatment group. Local anesthesia with 2ml mepivacaine. Data suggest no benefit from ESWT given parameters.
Buchbinder 2002 RCT	9.5	N = 166 plantar fasciitis with symptoms range 8-900 weeks, mean 36-43 weeks; 12-week follow-up period; Dx of thickened insertion of plantar fascia (>4 mm) by ultrasound required	ESWT vs. sham. Active treatment: 2,000-2,500 shocks of variable energy (0.02-0.33mJ/mm2) dictated by pain tolerance) x 3 weekly treatments. No local used. Energy focused on insertion of fascia guided by ultrasound; ≤825 mJ/mm^2; low to medium energy flux.	At 6 and 12 weeks, significant improvements in overall pain in both active group placebo group although no differences between groups (mean±SD): 17.9±30.5 and 19.8±33.7 at 6 weeks (p = .74). 26.3±34.8 and 25.7±34.9 at 12 weeks (p = .99). No significant effect of ESWT.	"We 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 6 and 12 weeks following treatment."	Use of anesthesia not noted. Focus of energy on thickest portion of plantar fascia vs. most tender point. Suggests ESWT provided no benefit given parameters of study at 6 or 12 weeks. Study included subacute and chronic conditions. No long-term follow-up.