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ORIGINAL ARTICLE

Extracorporeal Shockwave Therapy for Foot and Ankle Disorders: A Systematic Review and Meta-Analysis

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Background: Extracorporeal shockwave therapy (ESWT) was first introduced into clinical practice in 1982 and has been a beneficial inclusion to the non-invasive treatment option of numerous orthopaedic pathologies. However, clinical evidence of the use of ESWT for various foot and ankle disorders has been limited with a consensus on its efficacy yet available. Therefore, the purpose

Online Early
DOI: 10.7547/18-191

Journal of the American Podiatric Medical Association

of this study is to systematically review the literature, to provide a critical evaluation and meta-analysis for the use of ESWT in foot and ankle disorders.

Methods: The PubMed and Embase databases were systematically reviewed and clinical studies that reported ESWT use for various foot and ankle disorders included.

Results: A total of 24 clinical studies that included 12 randomized controlled trials and 12 case series were identified. Analysis of the evidence has indicated that ESWT can help manage plantar fasciitis, calcaneal spur, Achilles tendinopathy and Morton's neuroma. Meta-analysis of the change in pre- to post-VAS overall scores for plantar fasciitis significantly favored ESWT compared to placebo/conservative treatment with a MD -3.10 (95% CI, -4.36 to -1.83; I^2 = 68%; P < 0.00001).

Conclusions: The current evidence has suggested that ESWT can provide symptomatic benefit to plantar fasciitis treatment, with minimal and unremarkable side effects. Overall, ESWT has been demonstrated to be a safe treatment option with a favorable complication profile. Further well-designed studies of ESWT for the treatment of calcaneal spurs, Achilles tendinopathy and Morton's neuroma are warranted to more soundly and safely support its current use. Future studies are suggested to investigate the optimization of ESWT treatment protocols.

Online Early
DOI: 10.7547/18-191

apma Advancing foot and ankle medicine and surgery | Journal of the American Podiatric Medical Association

Extracorporeal shockwave therapy (ESWT) is a noninvasive treatment option for musculoskeletal healing. In vitro and animal studies have demonstrated that ESWT can promote cellular reparative effects by breaking down scar tissue,[1] increasing the bloody supply,[2-4] and stimulating the release of growth factors at injured sites.[5,6] The exact mechanism of how ESWT exerts these effects remains uncertain.[7] However, postulations have included mechanotransduction, whereby a mechanical load on the cellular cytoskeleton can induce signals for cellular repair.[8,9] Another postulation is that shockwaves can produce microfractures that subsequently stimulate the migration of a mesenchymal clot for healing at the injured site.[10,11]

Two types of shockwaves can be emitted from ESWT: focused and radial.[9] Focused ESWT applies a converging pressure field, whereas radial ESWT produces a diverging pressure field. Focused ESWT allows an adjustable focus at a selected depth of tissue, enabling it to penetrate deeper tissues compared to radial ESWT. In contrast, the diverging pressure field generated with radial ESWT is limited in tissue penetration despite being placed at the injured site with maximum pressure. Their differences in therapeutic effects, if any, are currently unclear. Nonetheless,

Online Early
DOI: 10.7547/18-191

Journal of the American Podiatric Medical Association

ESWT can be a useful addition or alternative in the treatment of potentially many disorders, given its healing effects coupled with the currently limited capabilities of many conservative treatments.

Albeit the promising effects of ESWT indicated in in vitro and animal studies, the extent of clinical success has been inconsistent with no overview present for the musculoskeletal applications of ESWT for foot and ankle disorders. There has also been no consensus on the optimal protocol for ESWT (focused vs. radial, energy-flux density, number of pulses administered and how often). Therefore, the purpose of this study is to systematically review the literature, to provide a critical evaluation and meta-analysis for the use of ESWT in foot and ankle disorders.

Methods

Search Strategy and Study Identification

Two separate authors (T.N.B.T.Y and D.S.) systematically reviewed the PubMed and Embase databases according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines in April 28, 2016.[12] The search terms employed were: (Extracorporeal

Online Early
DOI: 10.7547/18-191

Journal of the American Podiatric Medical Association

shockwave therapy OR extracorporeal shockwave treatment) AND (orthopaedic OR bone OR soft tissue OR muscle OR ligament OR tendon OR fascia OR musculoskeletal). No time limit was given for the publication date. The titles, abstracts and full-texts of the studies were reviewed using the eligibility criteria illustrated in Table 1. In addition, all citations of included studies were manually assessed for any possible inclusion. Studies were included based on the agreement between the two authors with any discrepancies resolved by mutual consensus.

Assessment of Evidence

The level of evidence (LoE) published in all reviewed studies was assessed using previously published criteria from *The Journal of Bone and Joint Surgery*.[13] The quality of evidence (QoE) was assessed using the Newcastle-Ottawa Scale,[14] a nine-point scale, with studies having six or more points being defined as as low risk of bias and studies with fewer than six points defined as having a high risk of bias.[15]

Data Categorization and Evaluation

Predetermined data of the included studies were collected and categorized into the following: 1) plantar fasciitis, 2) calcaneal spur, 3) Achilles tendinopathy, and 4) Morton's neuroma. The

Online Early
DOI: 10.7547/18-191

Journal of the American Podiatric Medical Association

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extent of clinical success was measured by the "relative change" of collected outcome scores from baseline to final follow-up using the following formula: ([pretreatment outcome score – posttreatment outcome score]/[pretreatment outcome score]) × 100. A positive score indicated an improvement in outcomes, whereas a score of zero was no improvement in outcomes and a negative score was a deterioration in outcomes.

Statistical Analysis

Statistical analysis was performed using RevMan version 5.3 (The Nordic Cochrane Centre, Copenhagen, Denmark). Meta-analysis for the results was performed if two or more studies employed the same outcome scores. I^2 values expressed heterogeneity with <25% being considered low heterogeneity, ≥25% of moderate to high heterogeneity.[16] Continuous outcomes were expressed as mean difference (MD) and dichotomous outcomes as risk ratio (RR). Fixed-effects models were used if the calculated heterogeneity was low, while random-effects models were used if the calculated heterogeneity was moderate to high.[17] Methods described by Wan et al. were used to estimate the mean and standard deviation if other measures of averages were reported.[18] Standard deviation of pre- and post-treatment outcome

Online Early
DOI: 10.7547/18-191

Journal of the American Podiatric Medical Association

scores were standardized according to the law of cosines by the following formula: $\sqrt{(S_x^2 + S_y^2)}$ where *x* and *y* represent the standard deviation of a specific pre- and post-treatment outcome score respectively. Values of $P < .05$ were considered statistically significant.

Results

The search strategy identified 24 studies for inclusion after applying specific eligibility criteria (Figure 1).[7,19-41] This included 13 studies that assessed the efficacy of ESWT for plantar fasciitis[19-31], two studies for calcaneal spur[32,33], seven studies for Achilles tendinopathy[7, 34-39] and two studies for Morton's neuroma[40,41]. The included studies were published between 2002 and 2016, with 12 studies being of LoE I (50%) and 12 studies of LoE IV (50%). The mean QoE of 5.08 ± 8.24, with 12 studies having a good QoE of ≥ 6 points on the Newcastle-Ottawa Scale. The characteristics of the included studies are summarized in Table 2.

Plantar Fasciitis

The application of ESWT for plantar fasciitis was reported in 7 RCTs[19-25] and 6 case series.[26-31] The RCTs compared the efficacy of ESWT against a placebo, conservative treatment (physiotherapy, iontophoresis and NSAIDs), injections (corticosteroid and autologous conditioned plasma

Online Early
DOI: 10.7547/18-191

apma Advancing foot and ankle medicine and surgery | Journal of the American Podiatric Medical Association

injections) and surgical treatment (plantar fasciotomy). The mean relative change for reported outcome scores (VAS, AOFAS, SF-12, Roles & Maudsley, Mayo scoring system) for ESWT in the 7 RCTs was 47.6%. Treatment with ESWT was noted to be superior compared to placebo or conservative treatment (33.2% mean relative change; VAS, AOFAS, SF-12, Roles & Maudsley)[19-22,24,25] but inferior compared to plantar fasciotomy (81.7% mean relative change; VAS, Roles & Maudsley)[23] and injections (63.3% mean relative change; VAS overall, AOFAS, Mayo scoring system).[22,24] The mean relative change for outcome scores was higher in the 6 case series[26-31] compared to the 7 RCTS[19-25] of ESWT in plantar fasciitis (60.9% vs. 47.6% mean relative change, respectively; outcome scores in case series were VAS, AOFAS, Roles & Maudsley, Japanese Society for Surgery of Foot (JSSF). A summary of the outcomes scores for the included RCTs and case series are illustrated in Table 3 and Table 4, respectively. Meta-analysis of the change in pre- to post-VAS overall scores significantly favored ESWT compared to placebo/conservative treatment with a MD -3.10 (95% CI, -4.36 to -1.83; I^2 = 68%; P < 0.00001).[21,23,24] This is illustrated using a random-effect model in Figure 2.

Online Early
DOI: 10.7547/18-191

Journal of the American Podiatric Medical Association

Calcaneal Spur

The application of ESWT in calcaneal spurs was reported in a single RCT[32] and one case series.[33] The RCT compared 20 patients that underwent ESWT against 20 patients that received a placebo;[32] a higher mean relative change for outcome scores were indicated in the ESWT group compared to the placebo group (63.9% vs. 40.5%, respectively; VAS, Roles & Maudsley). The case series indicated a similar mean relative change of 63.4% for the overall VAS outcome score.[33]

Achilles Tendinopathy

The application of ESWT for Achilles tendinopathies was reported in 2 RCTs[34,35] and 5 case series.[7,36-39] The RCTs compared the efficacy of ESWT versus cold air and high-energy laser therapy (CHELT) and ESWT given with oral/placebo supplementation. The mean relative change for outcome scores (VAS, Roles & Maudsley, Ankle-Hindfoot scale) of the 2 RCTs for ESWT alone was 38.0%; which is inferior compared to cold air and high-energy laser therapy (CHELT) (40.1% mean relative change)[35] but superior compared to ESWT given in combination with oral supplementation/placebo supplementation (35.9% and 23.7% mean relative changes,

Online Early
DOI: 10.7547/18-191

Journal of the American Podiatric Medical Association

respectively).[34] The oral supplementation was suggested to be implicated in tendon healing with the ingredients included to be:[34] arginine-L-alpha-ketoglutarate (500 mg), methyl-sulfonyl-methane (550 mg), hydrolyzed collagen type I (300 mg), Vinitrox™ (125 mg), bromelain (50 mg) and vitamin C (60 mg). The mean relative change for outcome scores was higher in the 5 case series[7,36-39] compared to the 2 RCTS[34,35] of ESWT in Achilles tendinopathies (75.9% vs. 38.0% mean relative change, respectively; outcome scores in case series were VAS, AOFAS, Roles & Maudsley, Victorian Institute of Sports Assessment – Achilles Questionnaire (VISA-A)).

Morton's Neuroma

The application of ESWT for Morton's neuroma was reported in two RCTs.[40,41] Both RCTs compared ESWT to a placebo. The mean relative change for outcome scores was noted superior in the ESWT group compared to the placebo group (41.0% vs. 13.3%, respectively; VAS, AOFAS).

Discussion

The National Institute for Health and Care Excellence (NICE) has published guidelines for the use of ESWT in specific foot and ankle disorders that is plantar fasciitis and Achilles tendinopathy.[42] The current systematic review has indicated that ESWT can improve symptoms for the following

Online Early
DOI: 10.7547/18-191

apma Advancing foot and ankle medicine and surgery | Journal of the American Podiatric Medical Association

foot and ankle disorders: plantar fasciitis, calcaneal spurs, Achilles tendinopathies and Morton's neuroma. However, due to the high heterogeneity and/or limited evidence, its extent of clinical success remains debatable.

ESWT may have an energy flux density–responsive treatment efficacy. The optimal energy flux density required for various disorders has yet been determined. The inconsistent use of outcome scores for ESWT assessment has limited specific subgroup meta-analysis. In an animal study on 42 rabbits with Achilles tendinopathy, Rompe et al[43] suggested that an energy flux density of no more than 0.28 mJ/mm^2**Q4** should be clinically used, as tissue damage can occur if not adhered to. Rompe et al[43] added that permanent tissue damage was observed with the use of high-energy ESWT (0.60 mJ/mm^2) was used. In plantar fasciitis, Lee et al. reported superior results in medium energy ESWT (0.16 mJ/mm^2) when compared to low energy ESWT (0.08 mJ/mm^2). Specifically, medium energy ESWT was more effective in reducing pain, with this having incorporated the absence of side effects associated with high energy shockwaves.[44] A 2-point reduction of a 10-point VAS pain scale has been accepted to be clinically significant in reducing pain and improving patient satisfaction.[45,46] With this, the current study has

Online Early
DOI: 10.7547/18-191

apma Advancing foot and ankle medicine and surgery | Journal of the American Podiatric Medical Association

demonstrated that ESWT can clinically mitigate the pain for plantar fasciitis, calcaneal spurs, Achilles tendinopathy and Morton's neuroma.

ESWT has demonstrated unremarkable complications for the treatment of plantar fasciitis, calcaneal spurs, Achilles tendinopathy and Morton's neuroma. Complications have included local pain during treatment, residual pain, mild edema and erythema at the site of ESWT application. Low energy ESWT (<0.2 mJ/mm^2) has generally been reported to be a well-tolerated treatment with minimal complications. In contrast, high energy ESWT (>0.2 mJ/mm^2) has been reported to have required local anesthesia due to pain and discomfort during the procedure.[47] Two studies included in the current systematic review reported similar experiences with high energy ESWT (0.36 mJ/mm^2), with these studies having added local anesthesia for pain control.[20,26] Kudo et al. reported that in 53 plantar fasciitis treated with high energy ESWT (0.36 mJ/mm^2), 79.3% of patients complained of pain during the procedure while 14% of patients had residual pain at three months follow-up after ESWT application; attributing this to the insufficient amount of local anesthesia given and also the lower pain threshold of selected patients.[20] Chuckpaiwong et al. also noted complications of pain during high energy ESWT (0.36 mJ/mm^2) in

Online Early
DOI: 10.7547/18-191

Journal of the American Podiatric Medical Association

7.1% of 225 patients treated for plantar fasciitis.[26] Interestingly, several studies have found superior treatment outcomes in patients given ESWT without local anesthesia. It has been postulated that anesthesia may affect the inflammatory mediated processes and alters the biological effects of ESWT.[48] Therefore, medium-energy ESWT (0.08 to 0.28 mJ/mm^2) without anesthesia may be the optimal balance of least complications (most commonly, pain during ESWT) and outcomes.

Comparing the alternative non-surgical treatment options, ESWT has had inferior results of RCTs for plantar fasciitis when compared to Autologous Conditioned Plasma (ACP), whilst being less invasive (47.6% vs. 55% mean relative change, respectively; VAS, AOFAS).[19-22,24,25] Although superior treatment outcomes have been demonstrated in patients that underwent plantar fasciotomy compared to ESWT (47.6% vs. 81.7% mean relative change, respectively; VAS, AOFAS, Roles & Maudsley), it appears sound that ESWT should be trialled before more invasive measures are considered, for example injections. Importantly, ESWT has demonstrated minimal complication rates, a lessened painful recovery and that hospitalization not required.[23] Interestingly, Notarnicola et al. reported that in patients with Achilles tendinopathy, cold air and

Online Early
DOI: 10.7547/18-191

Journal of the American Podiatric Medical Association

high energy laser therapy (CHELT) produced a faster and more efficacious pain relief compared to ESWT.[35]

There were several limitations of this study. Studies were only screen within the PubMed and Embase that were written in English. Therefore, potentially predisposing selection bias. The RCTs included in this review were also of small sample sizes, with the results may not truly be representative of the general population. The extensive range and inconsistent use of treatment regimens (energy-flux density, number of pulses and sessions administered), treatment types (focused vs. radial) and outcome measures (16 various outcome measures) may have predisposed elements of procedural and reporting bias respectively.

Conclusions

This systematic review has indicated that reasonable evidence is present for the use of ESWT for plantar fasciitis. Overall, ESWT appear to have favourable complication profile with minimal and unremarkable side effects. Further well-designed studies of ESWT for the treatment of calcaneal spur, Achilles tendinopathy and Morton's neuroma are required to confirm its safe and efficacious use. Future studies are suggested to maximize patient outcomes by the investigation

Online Early
DOI: 10.7547/18-191

Journal of the American Podiatric Medical Association

if an optimal ESWT type (focused vs. radial), energy flux density and/or treatment regimen is present.

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Conflict of Interest: None reported.

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Online Early
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Journal of the American Podiatric Medical Association

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Online Early
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Journal of the American Podiatric Medical Association

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Online Early
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Journal of the American Podiatric Medical Association

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Online Early
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Journal of the American Podiatric Medical Association

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Journal of the American Podiatric Medical Association

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Online Early
DOI: 10.7547/18-191

apma Advancing foot and ankle medicine and surgery | Journal of the American Podiatric Medical Association

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Figure 1. Preferred Reporting Items for Systematic Reviews and Meta-Analyses flow diagram.

Figure 2. Meta-analysis of the change in pre- to post-VAS overall scores for plantar fasciitis, random-effects model

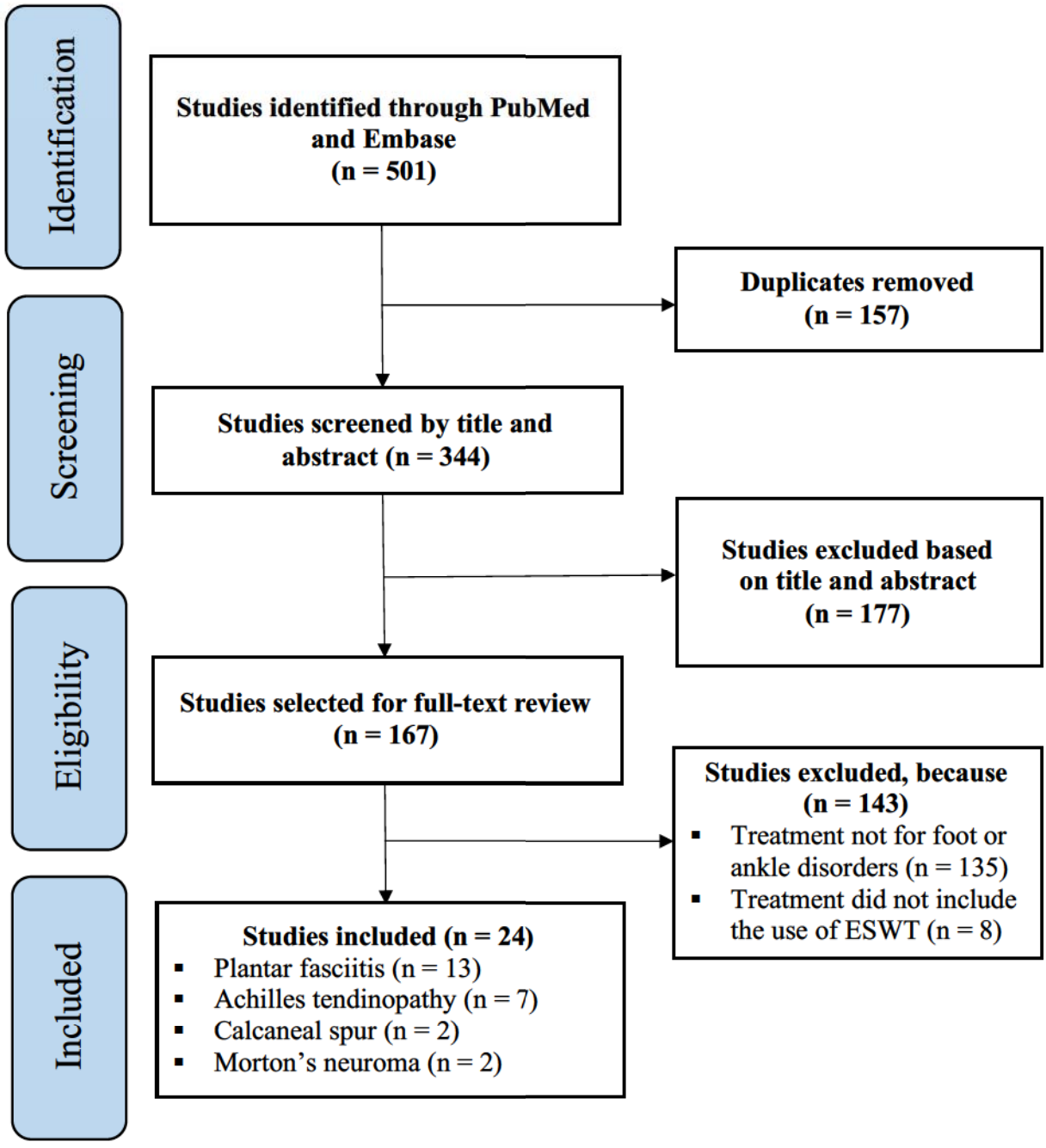
Online Early
DOI: 10.7547/18-191

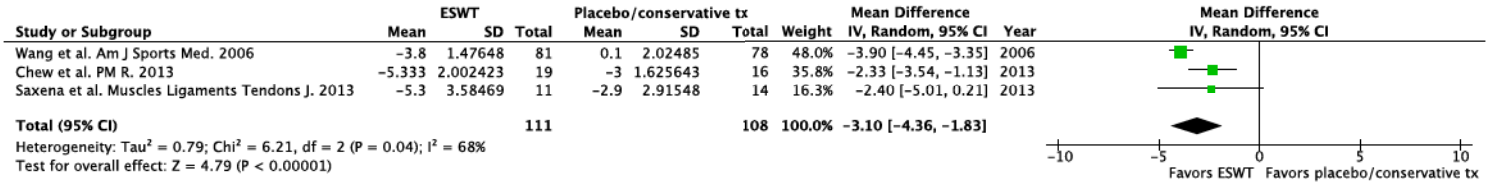
Journal of the American Podiatric Medical Association

Table 1. Eligibility Criteria

Inclusion criteria
Treatment included the use of ESWT
Treatment was for foot or ankle disorders
Clinical studies
Published in peer-reviewed journal
Written in English
Exclusion criteria
Human cadaver studies
Animal studies
In vitro studies

Abbreviation: ESWT, extracorporeal shock wave therapy.


Identification
Screening
Eligibility
Included
Studies identified through PubMed and Embase (n = 501)
Duplicates removed (n = 157)
Studies screened by title and abstract (n = 344)
Studies excluded based on title and abstract (n = 177)
Studies selected for full-text review (n = 167)
Studies excluded, because (n = 143)
Treatment not for foot or ankle disorders (n = 135)
Treatment did not include the use of ESWT (n = 8)
Studies included (n = 24)
Plantar fasciitis (n = 13)
Achilles tendinopathy (n = 7)
Calcaneal spur (n = 2)
Morton's neuroma (n = 2)


ESWT
Placebo/conservative tx
Mean Difference
Mean Difference
Study or Subgroup
Mean SD Total Mean SD Total Weight IV, Random, 95% CI Year
IV, Random, 95% CI
Wang et al. Am J Sports Med. 2006 -3.8 1.47648 81 0.1 2.02485 78 48.0% -3.90 [-4.45, -3.35] 2006
Chew et al. PM R. 2013 -5.333 2.002423 19 -3 1.625643 16 35.8% -2.33 [-3.54, -1.13] 2013
Saxena et al. Muscles Ligaments Tendons J. 2013 -5.3 3.58469 11 -2.9 2.91548 14 16.3% -2.40 [-5.01, 0.21] 2013
Total (95% CI) 111 108 100.0% -3.10 [-4.36, -1.83]
Heterogeneity: Tau² = 0.79; Chi² = 6.21, df = 2 (P = 0.04); I² = 68%
Test for overall effect: Z = 4.79 (P < 0.00001)
-10
-5
0
5
10
Favors ESWT
Favors placebo/conservative tx