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Drugs and Technologies
in Health

RAPID RESPONSE REPORT: SUMMARY WITH CRITICAL APPRAISAL



TITLE: Shockwave Therapy for Pain Associated with Lower Extremity Orthopedic Disorders: A Review of the Clinical and Cost-Effectiveness

DATE: 16 September 2016

CONTEXT AND POLICY ISSUES

Orthopedic disorders encompass a variety of conditions including rotator cuff tendinopathy (shoulder disorder), epicondylitis (elbow disorder), patellar tendinosis (knee disorder) and plantar fasciitis (foot disorder) and are often associated with pain. Disorders such as these may be associated with decreased productivity or disability that may last several months resulting in a financial burden to society.¹ Conventional therapies used in general practice to manage pain include rest, ice, nonsteroidal anti-inflammatory drugs, physical therapy, and subacromial corticosteroid injections.^{2,3} Patients unresponsive to such therapies may need to undergo surgical procedures.^{3,4} Shockwave therapy (SWT) may be an alternative to surgical procedures which can be expensive and associated with risk. Other therapeutic modalities include laser therapy, radiation therapy, and transcutaneous electric nerve stimulation (TENS).

SWT involves acoustic waves which carry energy to painful spots and musculoskeletal tissues with subacute, subchronic and chronic conditions.⁵ This energy assists in regeneration and repair of bones, tendons and other soft tissues.⁵ The exact mechanism of action is not clear. The interaction of shockwaves with tissue is thought to cause analgesia by over stimulation of the treated site resulting in reduced signal transmission to the brainstem, stimulation of tissue healing, breakdown of calcification, alteration of cell membrane permeability, and alteration of cell activity through cavitation.⁶⁻⁸ Devices used for SWT vary in design, depending on the way shockwaves are generated and the level of energy that they can produce. SWT includes focused shockwave therapy (FSWT) and radial shockwave therapy (RSWT). FSWT is based on shockwaves of single pressure pulses of a microsecond duration, which are focused on a specific target using ultrasound or radiography guidance.⁹ The methods to generate focused shockwaves include electrohydraulic, electromagnetic, or piezoelectric mechanisms.^{6,8,9} The focused shockwaves are generated in water (inside the applicator) and, as the acoustic impedance of water and biological tissue is comparable, this results in limited reflection and better transmission of the waves into the body.⁸ The radial shockwaves for RSWT are generated by acceleration of a projectile, using compressed air, through a tube at the end of which is the applicator.⁸ The applicator transmits the generated pressure waves into the body.

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SWT has been used for over two decades for the treatment soft tissue and bone related musculoskeletal disorders.^{6,10} There is however some debate regarding the effectiveness of SWT compared to placebo or other treatment modalities.

A previous CADTH report¹¹ reviewed the clinical effectiveness and cost-effectiveness of shockwave therapy for pain associated with upper extremity orthopedic disorders. It reported that compared with placebo, high energy SWT was effective in reducing pain in calcific but not in non-calcific tendinitis of the shoulder. Findings on the effectiveness of SWT compared with placebo for treating epicondylitis were inconsistent and no relevant cost-effectiveness studies were identified. The purpose of this report is to review the clinical effectiveness and cost-effectiveness of shockwave therapy for pain associated with lower extremity orthopedic disorders.

RESEARCH QUESTIONS

1. What is the clinical effectiveness of shockwave therapy for chronic pain associated with lower extremity orthopedic disorders?
2. What is the cost-effectiveness of shockwave therapy for chronic pain associated with lower extremity orthopedic disorders?

KEY FINDINGS

For plantar fasciitis, overall there is some suggestion that, in comparison with placebo, shockwave therapy (SWT) is an effective treatment option. Limited evidence suggests that for plantar fasciitis, the effectiveness of SWT is comparable with platelet rich plasma injection, corticosteroid injection or surgery. Adverse events were sparsely reported. Adverse effects reported with SWT included skin reddening, bruising at the site of application, and local swelling and pain.

For greater trochanteric pain syndrome, a case control study showed that SWT was statistically significantly more effective than conservative treatment, and findings from a quasi-randomized controlled trial (RCT) comparing SWT with corticosteroid injection or home training were inconsistent.

For patellar tendinopathy, a case control study and a quasi-RCT showed that SWT was statistically significantly more effective than conservative treatment. One retrospective study showed that effectiveness of SWT and surgery was comparable. Findings from studies comparing SWT with placebo or corticosteroid injection were inconsistent.

For medial tibial stress syndrome, addition of SWT to either conservative treatment or to a running program had added benefit.

No studies on the cost-effectiveness of SWT for chronic pain associated with lower extremity orthopedic disorders were identified.

METHODS

Literature Search Methods

A limited literature search was conducted on key resources including PubMed, The Cochrane Library, University of York Centre for Reviews and Dissemination (CRD) databases, Canadian and major international health technology agencies, as well as a focused Internet search. Filters were applied to limit the retrieval to health technology assessments, systematic reviews, and meta analyses, randomized controlled trials, non-randomized studies, and economic studies. Where possible, retrieval was limited to the human population. The search was also limited to English language documents published between January 1, 2011 and August 5, 2016.

Rapid Response reports are organized so that the evidence for each research question is presented separately.

Selection Criteria and Methods

One reviewer screened citations and selected studies. In the first level of screening, titles and abstracts were reviewed and potentially relevant articles were retrieved. Two reviewers assessed the potentially relevant articles for inclusion. The final selection of full-text articles was based on the inclusion criteria presented in Table 1.

Table 1: Selection Criteria	
Population	Adults with chronic pain associated with lower extremity orthopedic disorders
Intervention	Shockwave Therapy
Comparator	Any
Outcomes	Pain reduction, reduced need for opioids, harms, cost-effectiveness
Study Designs	Health technology assessments (HTA), systematic reviews (SR), meta-analyses (MA), randomized controlled trials (RCT), observational studies, and economic studies.

Exclusion Criteria

Articles were excluded if they did not meet the selection criteria outlined in Table 1, they were duplicate publications, or were published prior to 2011. Because a large number of systematic reviews were identified, randomized controlled trials and observational studies were not considered. Articles comparing different types of SWT without a non-SWT arm were excluded. Studies on fracture, cancer pain, arthritis pain, and back pain were excluded. Systematic reviews with studies that were already included in other included systematic reviews were excluded unless they provided additional information.

Critical Appraisal of Individual Studies

The included systematic reviews were critically appraised using the AMSTAR checklist.¹² Summary scores were not calculated for the included studies; rather, a review of the strengths and limitations of each included study were described narratively.

SUMMARY OF EVIDENCE

Quantity of Research Available

A total of 570 citations were identified in the literature search. Following screening of titles and abstracts, 548 citations were excluded and 22 potentially relevant reports from the electronic search were retrieved for full-text review. No potentially relevant publications were retrieved from the grey literature search. Of these potentially relevant articles, 15 publications were excluded for various reasons, while seven publications^{10,13-18} met the inclusion criteria and were included in this report. These comprised seven systematic reviews of which four systematic reviews^{13,14,18,19} were on foot and ankle related disorders, two systematic reviews^{15,17} were on thigh, knee and tibia related disorders, and one systematic review¹⁶ included several disorders of the lower extremity.

Additional references of potential interest are provided in Appendix 5.

Summary of Study Characteristics

Characteristics of the included systematic reviews are summarized below and details are available in Appendix 2, Table A1.

Foot and ankle related disorders

Five relevant systematic reviews^{10,13,14,16,18} were identified. One systematic review¹⁶ was published in 2015 from the UK, two systematic reviews were from Taiwan in 2015¹⁴ and 2012,¹⁸ one systematic review¹³ was published in 2014 from Australia, and one systematic review¹⁰ was published in 2013 from the Philippines.

The systematic review by Mani-babu et al.¹⁶ that assessed the efficacy of SWT for lower limb tendinopathy, included 11 relevant studies on patients with Achilles tendinopathy, published between 2004 and 2011. These 11 studies comprised five RCTs, four prospective pre- and post-treatment studies and two retrospective case control studies. These studies include a total of 629 patients of mean age in the range 39 to 59 years, and symptom duration ranging from at least three months to six months. The proportion of females to males was not reported. SWT was compared with placebo in two RCTs; eccentric loading (exercise) (Ec) was compared with Ec plus SWT in one RCT; Ec was compared with SWT in one RCT; Ec was compared with SWT and with wait-and-see in one RCT; four studies compared pre- and post SWT; and SWT was compared with control in two studies. The outcomes reported included pain, function, and success rate; and follow-up varied between 3 months and 24 months. Outcomes were assessed using a visual analog scale (VAS), the American orthopedic foot and ankle society (AOFAS) scale, the Euro quality of life (EQoL), functional index of lower limb activity (FIL), Roles and Maudsley scale (RMS), and Victorian institute of sport assessment questionnaire-Achilles (VISA-A).

The systematic review by Hsiao et al.¹⁴ that assessed the efficacy of SWT, autologous blood products (ABP including platelet-rich plasma [PRP]), and corticosteroids (CS) for adults with chronic plantar fasciitis, included four RCTs on SWT which were published between 2005 and 2013. One RCT compared SWT with PRP and included 38 patients with a mean age of 46 years. The proportion of females was 45% and mean duration of symptoms was between 12 and 18 months. Outcomes assessed included pain and treatment success and follow-up was up

to six months. Three RCTs compared CS with SWT. These RCTs included a total of 245 patients of mean ages in the range 34 years to 45 years. The proportion of females ranged between 53% and 70%, and symptom duration was between 12 weeks to 39 weeks. Outcomes assessed included pain and treatment success and follow-up was up to 12 months. The authors mentioned that definitions of treatment success in the included RCTs varied but most considered a decrease in VAS score or in heel tenderness of >50% from baseline as treatment success.

The systematic review by Landorf¹³ that assessed the efficacy of SWT for patients with plantar fasciitis, included three systematic reviews published between 2005 to 2013, and six individual RCTs published between 2006 and 2012. The three systematic reviews compared SWT with placebo. The number of patients was 790 in one systematic review, 881 in one systematic review, and was not reported in one systematic review. The age and the proportion of females to males were not reported in any of the systematic reviews. The duration of symptoms was 3 months in one systematic review, six months in one systematic review and not reported in one systematic review. Of the six individual RCTs, two RCTs compared SWT with placebo, two RCTs compared SWT plus local anesthetic with corticosteroid (CS) plus local anesthetic; one RCT compared SWT with CS plus local anesthetic; and one RCT compared SWT with surgery. In four RCTs the number of patients ranged between 64 and 120, and in two RCTs the patient number was not reported. The proportion of females to males was not reported for any of the RCTs. The duration of symptoms varied between 6 weeks and at least eight weeks in two RCTs, and was not reported for four RCTs. The outcomes reported in this systematic review included pain, function, and adverse events. The follow up was 12 weeks in three systematic reviews, ranged between six weeks to 24 weeks in three RCTs, and was not reported for three RCTs.

The systematic review by Dizon et al.¹⁰ included 11 RCTs published between 2002 and 2010 and included a total of 1384 patients with chronic plantar fasciitis, who were unresponsive to conservative care with medication and/or physical therapy. Of these 11 RCTs, 10 RCTs compared SWT with placebo and included 1352 patients of ages in the range 26 years to 87 years. The proportion of females ranged between 48% and 73%, and symptom duration prior to treatment ranged between six weeks and six months. The remaining RCT comparing SWT with physical therapy (ultrasound) included 32 patients, age ranged between 25 years and 68 years. The proportion of females was 81%, and the duration of symptoms was six months. Outcomes reported included pain, function and adverse events; and follow up ranged between six weeks to 12 months.

The systematic review by Chang et al.¹⁸ included 12 RCTs published between 2002 and 2010 and included a total of 1431 adult patients with plantar fasciitis. The ages of the patients ranged from 25 years to 87 years, the proportion of females to males was not reported, and the duration of symptoms prior to initiation of treatment ranged from six months to 312 months. Eleven RCTs compared SWT with placebo and one RCT compared high intensity SWT with medium intensity SWT. Outcomes reported included pain reduction and success rate, and the follow-up ranged between 3 months and five years. The authors mentioned that definitions of success rates in the included RCTs varied but most considered success as pain relief >50% or >60% compared to baseline, or significant improvement in foot functional scores.

Thigh, knee and tibia related disorders

Three relevant systematic reviews¹⁵⁻¹⁷ were identified. One systematic review¹⁵ was published from Australia in 2015, one systematic review¹⁶ was published from the USA in 2015, and one systematic review¹⁷ was published from the Netherlands in 2013. All three systematic reviews had a different focus so are described separately.

The systematic review by Balasubramaniam et al.¹⁵ that assessed the efficacy of platelet-rich plasma (PRP) injections for chronic tendinopathy included one relevant RCT comparing PRP injection with SWT. The RCT was published in 2013, and included 46 patients with patellar tendinopathy. The age of the patients, proportions of females and males, and duration of symptoms were not reported. Pain was assessed using a VAS, the Victorian Institute of Sport assessment questionnaire-patellar (VISA-P), and Blazina scores, and follow up was up to 12 months.

The systematic review by Mani-babu et al.¹⁶ that assessed the efficacy of SWT for lower limb tendinopathy included nine relevant studies published between 2003 and 2013. Of these nine studies, two studies were on greater trochanteric pain syndrome (GTPS) and seven were on patellar tendinopathy (PT). The two GTPS studies, comprised one quasi-RCT and one case control study, and included a total of 295 patients in the age range 46 to 51 years, with a duration of symptoms of at least six months; the proportion of females or males was not reported. In these two studies SWT was compared with control or corticosteroid injection or home training, efficacy was assessed using a VAS, RMS, Likert scale, and Harris hip score, and duration of follow up varied between 12 and 15 months. The seven studies on patellar tendinopathy, comprised two RCTs, one quasi-RCT, two prospective studies, one case control study, and one retrospective analysis, and included 317 patients of age ranges between 20 and 58 years in four studies, between 15 and 69 years in two studies; ages were not reported in one study. Of these seven studies, five studies compared SWT with sham, conservative treatment or surgery; and two studies were pre- and post- SWT treatment studies, efficacy was assessed using a VAS, VISA-P, and RMS, and duration of follow up varied between 12 and 24 months.

The systematic review by Winters et al.¹⁷ that assessed treatments for medial tibial stress syndrome (MTSS) included two relevant non-randomized studies published in 2010 and 2012. One study compared SWT plus a 6-phase running program with the 6-phase running program alone and included 42 patients (athletes) of mean age 26 years. The proportion of females was 47%. The ages and proportions of females were not comparable in the two groups and the mean duration of complaints was 189 days in the group on the running program alone and 629 days in the group on SWT plus the running program. Follow up duration was not specified. Efficacy was assessed using the length of time to complete the running program. The second study compared RSWT with and without a 12-week home training program, rest, and ice, and included 78 patients (athletes) of mean age 42 years. The proportion of females was 69% and duration of complaints ranging between 6 to 30 months. Patients were followed up to 15 months.

Summary of Critical Appraisal

Critical appraisal of the included systematic review, is summarized below and details are available in Appendix 3, Tables A2

Foot and ankle related disorders

In all five systematic reviews^{10,13,14,16,18} the objective was clearly stated, a comprehensive literature search using multiple databases was conducted, the study selection was described and list of included studies was presented. None of the systematic reviews presented a list of excluded studies. Article selection was done in duplicate in three systematic reviews^{14,16,18} and was unclear in two systematic reviews.^{10,13} Data extraction was done in duplicate in two systematic reviews,^{14,18} appears to have been done in duplicate in two systematic reviews,^{10,16} as quality assessment was done in duplicate, and was unclear in one systematic review.¹³ Quality assessment was conducted in all five systematic reviews. The tools used for quality assessment varied. In two systematic reviews,^{10,18} low quality (Jadad score < 3 or PEDro score < 7) studies were not considered, in one systematic review¹⁶ the quality of the included studies varied between moderate to high, and in two systematic reviews^{13,14} the included studies were generally of low quality. The characteristics of the individual studies were described in all the systematic reviews but details were lacking in two systematic reviews.^{13,18} Studies were pooled in three systematic reviews^{10,14,18} however in some instances the heterogeneity was high and the appropriateness of pooling is debatable. In two systematic reviews^{13,16} there was no pooling, likely due to heterogeneity. Publication bias was explored in one systematic review¹⁴ and stated to be not significant, and was not explored in four systematic reviews.^{10,13,16,18} In all the systematic reviews it was stated that the authors had no conflicts of interest. However, in one systematic review¹⁶ the authors had received industry funding though not for work on this particular project.

Thigh, knee and tibia related disorders

In all three systematic reviews,¹⁵⁻¹⁷ the objective was clearly stated, a comprehensive literature search using multiple databases was conducted, the study selection was described, and list of included studies was presented. None of the systematic reviews presented a list of excluded studies. Article selection was done in duplicate in two systematic reviews,^{16,17} and was unclear in one systematic review.¹⁵ Data extraction was done in duplicate in two systematic reviews,^{15,17} and was unclear in one systematic review.¹⁶ Quality assessment was conducted in all three systematic reviews. In one systematic review¹⁵ low quality (based on Cochrane criteria) studies were not included, in one systematic review¹⁶ the included studies varied between moderate and high quality, and in one systematic review¹⁷ the included studies were of low quality. Characteristics of the included studies were described in all three systematic reviews but lacked details in one systematic review.¹⁵ Studies were not pooled as the studies were heterogeneous. Publication bias was explored in one systematic review¹⁷ and seemed unlikely, and in two systematic reviews publication bias appears not to have been explored. In all three systematic reviews the authors stated there were no conflicts of interest, however in one systematic review¹⁶ the authors had received industry funding though for not this particular project.

Summary of Findings

What is the clinical effectiveness of shockwave therapy for chronic pain associated with lower extremity orthopedic disorders?

Findings are summarized below and details are provided in Appendix 4, Tables A3. Placebo and sham appear to be used interchangeably in the systematic reviews.

Foot and ankle related disorders

Five relevant systematic reviews^{10,13,14,16,18} were identified. Findings are summarized below and details are provided in Appendix 4, Tables A3.

The systematic review by Mani-babu et al.¹⁶ assessed the efficacy of SWT in lower limb tendinopathy and included 11 studies (RCTs, prospective pre- and post- studies and case control studies) on patients with Achilles tendinopathy. Two RCTs showed that overall for a mixed population of patients with mid-portion tendinopathy or insertional tendinopathy, there were no statistically significant differences in outcomes with SWT compared with sham, as assessed using VAS, EQoL, or AOFAS. One RCT showed that for patients with insertional tendinopathy there was statistically significant greater efficacy with SWT compared with Ec, as assessed using VAS, VISA-A and the Likert scale. One case control study showed that overall, for patients with insertional tendinopathy there was statistically significant greater efficacy with SWT compared with conservative treatment, as assessed using VAS and RMS. One RCT showed that, for patients with mid-portion tendinopathy, there was statistically significant greater efficacy with SWT plus Ec compared with Ec alone, as assessed using VAS, VISA-A, and Likert scale. One RCT showed that, for patients with mid-portion tendinopathy, there was no statistically significant difference in outcomes with SWT compared with Ec, as assessed using VAS, VISA-A, and Likert scale. This RCT also showed that, for patients with mid-portion tendinopathy, there was statistically significant greater efficacy with SWT compared to wait-and-see, as assessed by VAS, VISA-A and Likert scale, however the results with the Likert scale were statistically non-significant. One case control study showed that for patients with insertional tendinopathy there was statistically significant greater efficacy with SWT compared with conservative treatment (specifics not described), as assessed using VAS and RMS. Four prospective pre- and post- treatment studies reported that for patients with Achilles tendinopathy there was significant improvement after SWT compared to pre-treatment status, as assessed using AOFAS, VAS, VISA-A or RMS. In summary, overall SWT appears to be an effective treatment option for insertional tendinopathy and mid-portion tendinopathy, however the evidence is limited and the evidence for mid-portion tendinopathy had some inconsistencies.

The systematic review by Hsiao et al.¹⁴ that assessed the effectiveness of SWT, ABP (including PRP) and CS for adults with chronic plantar fasciitis, included four RCTs on SWT. Two meta-analyses including two RCTs each, showed there was no statistically significant difference in effectiveness with SWT compared with CS, as assessed using VAS or treatment success. One RCT showed there was no statistically significant difference in effectiveness with SWT compared with ABP (PRP), as assessed using VAS. The authors also conducted network meta-analyses for different outcomes and reported probabilities for best treatments. This systematic review also included six studies (three RCTs and three quasi-RCTs) comparing ABP with CS, which were likely included in the network meta-analyses, a network diagram however was not presented. The probability of being the best treatment with respect to pain reduction at three months was 4.8% for SWT, 78.3% for ABP, and 16.8% for CS. The probability of being the best treatment, with respect to pain reduction at six months, was 49.6% for SWT, 41.0% for ABP, and 9.3% for CS. The probability of being the best treatment, with respect to successful treatment rate, was 53.0% with for SWT, 19.6% with ABP, and 27.3% for CS. In summary, SWT appears to be an effective treatment option for plantar fasciitis under certain conditions however there are inconsistencies in findings from pair-wise meta-analyses and network meta-analyses.

The systematic review by Landorf¹³ assessed the effectiveness and safety of treatments for plantar heel pain and plantar fasciitis and included three systematic reviews and six RCTs assessing SWT. One systematic review including five RCTs showed that there was no statistically significant difference in pain reduction with SWT compared with placebo as assessed using VAS; however, there was a statistically significant between group difference with respect to proportion of patients with a decrease in limitation of activity, favoring SWT over placebo (effect sizes are reported in Appendix 4, Table A3). A second systematic review including two RCTs showed that there was a statistically significant greater improvement in pain with SWT (FSWT or RSWT) compared with placebo, as assessed using a VAS. A third systematic review including six RCTs showed that there was statistically significant greater reduction in morning pain with SWT compared with placebo, as assessed using a VAS. This systematic review also reported that adverse effects were statistically significantly higher with SWT compared with placebo, with data taken from one RCT. Adverse effects included skin reddening, pain and local swelling and less frequently dizziness, sleep disturbance, hematoma, nausea, and hair loss. One RCT showed that there was a statistically significantly greater proportion of patients experiencing pain during the procedure for SWT compared with placebo. One RCT comparing SWT with placebo, showed that there was bruising in 2% of the patients undergoing SWT, but the significance was not assessed. One RCT comparing SWT with CS injection plus local anesthetic (A) injection (CS+A), showed that the proportion of patients with clinical improvement in heel pain (assessed using a VAS) was numerically lower for patients with plantar fasciitis and perifascial edema and numerically higher for patients with plantar fasciitis and without perifascial edema for SWT compared with CS+A; statistical significance was not assessed. This RCT reported that there were no complications in any of the groups. One RCT compared SWT+A with CS+A, and reported no statistically significant difference between the groups with respect to pain relief, as assessed using a VAS. One RCT compared SWT+A with CS+A, and reported no statistically significant difference between the groups with respect to functional improvement, as assessed using the Mayo clinic scoring. One RCT compared SWT with surgery (endoscopic plantar fasciotomy [partial release]) for patients with plantar fasciopathy and found no statistically significant difference between the groups with respect to pain relief (assessed using a VAS) or functional improvement (assessed using AOFAS). In summary, limited evidence shows that SWT may be more effective than placebo for reducing pain in patients with plantar heel pain and is comparable to surgery for the treatment of plantar fasciopathy. Evidence for SWT compared to CS is also limited. Improvement with SWT compared to CS+A, appears to be lesser for patients with plantar fasciitis and perifascial edema, and greater for patients with plantar fasciitis and without perifascial edema. Improvements achieved with SWT+A or CS+A for plantar fasciitis appear to be comparable.

The systematic review by Dizon et al.¹⁰ assessed the effectiveness of SWT for plantar fasciitis and included 11 RCTs. The number of RCTs included in the meta-analyses for the various comparisons and the various outcomes, ranged between two and three. Morning pain reduction (assessed using a VAS), and functional improvement (assessed using RMS) were statistically significantly greater with high energy SWT (H-SWT) compared to placebo. However single RCTs showed that there were no statistically significant differences between H-SWT and placebo with respect to overall pain and activity pain (assessed using a VAS). Overall pain reduction and activity pain reduction (assessed using a VAS), and functional improvement (assessed using RMS) were statistically significantly greater with medium energy SWT (M-SWT) compared to placebo. Overall pain reduction and morning pain reduction (assessed using a VAS), and functional improvement (assessed using RMS) were not statistically significantly different with low energy SWT (L-SWT) compared with placebo. One RCT showed that there was a statistically significant reduction in heel pain with H-SWT compared with placebo.

Adverse effects were statistically significantly higher with SWT compared with control (specifics not described) with respect to calcaneal pain and erythema on the calcaneal area, and there were no statistically significant differences between the two groups with respect to local edema, local paresthesia, and local bruising. One RCT showed that there was no statistically significant differences with respect to morning pain, activity pain or orthostatic pain (assessed by VAS) for treatments with H-SWT compared with physical therapy. In summary, overall it appears that compared with placebo, both H-SWT and M-SWT are effective in reducing pain and improving function, though a few inconsistencies exist.

The systematic review by Chang et al.¹⁸ assessed the effectiveness of SWT for plantar fasciitis and included 12 RCTs. Eleven RCTs compared SWT with placebo and one RCT compared high intensity SWT with medium intensity SWT. The number of RCTs included in the meta-analyses for the various comparisons and the various outcomes, ranged between two and five. Pain reduction (assessed using a VAS) and success rate (the proportion of patients achieving improvement assessed using various measures) were statistically significantly greater with both high energy focused SWT (H-FSWT) and medium energy focused SWT (M-FSWT) compared with placebo. There were no statistically significant differences with either low energy focused SWT (L-FSWT) or RSWT compared with placebo with respect to pain reduction or success rate. The authors also conducted a network meta-analysis and showed that the probability of having the best treatment success or greatest pain relief was highest for RSWT followed sequentially by L-FSWT, M-FSWT, and H-FSWT. The network meta-analysis included the RCT comparing the two SWTs of different intensities. A network diagram was provided with the thickness of the lines connecting comparators being proportional to the number of studies, however the actual number of studies used for each comparison was not explicitly stated. There were discrepancies in the results of traditional meta-analysis and network meta-analysis likely due to the heterogeneity of the included studies and wide credible intervals, as mentioned by the authors. Meta-regression analyses with different energy levels of FSWT suggested that success rate of treatment was not related to elevated energy efflux density, however elevated energy efflux density may have a slight tendency to provide greater reduction pain scores. In summary, both H-SWT and M-SWT appear to be more effective than placebo for treating plantar fasciitis.

Thigh, knee and tibia related disorders

Three relevant systematic reviews¹⁵⁻¹⁷ were identified. Findings are summarized below and details are provided in Appendix 4, Tables A3.

The systematic review by Balasubramaniam et al.¹⁵ focused on PRP injections for treatment of chronic tendinopathy and included one relevant study comparing PRP injection with SWT in patients with patellar tendinopathy. Compared to SWT, PRP injection was found to be statistically significantly better in terms of improvement in pain and function as assessed by VAS, VISA-P and Blazina scores, at 6 and 12 months. Also patient satisfaction at 12 months was significantly better with PRP compared to SWT. In summary, evidence from a single study suggested that compared with SWT, PRP injection provided greater improvement for patellar tendinopathy

The systematic review by Mani-babu et al. assessed the efficacy of SWT in lower limb tendinopathy and included two studies (quasi-RCT and case control) on GTPS and seven studies (RCT, quasi-RCT, case control, retrospective cross-sectional, and prospective pre- and post- treatment studies) on PT.

GTPS: One case control study showed that for GTPS, SWT was statistically significantly better than conservative treatment (specifics not described) at 1 month, 3 months and 12 months as assessed by VAS, Harris hip score and RMS in one study. One quasi-RCT showed that for GTPS, SWT was statistically significantly better than corticosteroid injection at 4 months and 15 months as assessed by VAS and Likert scale; however at one month, results were in favor of corticosteroid injection in comparison to SWT. This quasi-RCT also showed that for GTPS, considering VAS and Likert scale scores, at one month and 15 months, there was no statistically significant difference between SWT and home training; and at four months SWT was statistically significantly better than home training. In summary, overall SWT appears to be an effective treatment option for GTPS, however its comparative effectiveness with other treatment modalities is limited and unclear.

PT: One quasi-RCT and one case control study showed that, for PT, there was statistically significant greater efficacy with SWT compared with conservative treatment, as assessed using a VAS, VISA-P, and RMS. One RCT showed that for PT, there was no statistically significant difference in outcomes with SWT compared to placebo, as assessed using a VAS and VISA-P, whereas one RCT showed that for PT there was statistically significant improvement with SWT compared to placebo, as assessed using VISA-P and vertical jump test. One retrospective cross-sectional study showed that for PT, there was no statistically significant difference in outcomes with SWT compared with surgery, as assessed using a VAS, VISA-P, and RMS. Two prospective pre- and post- treatment studies showed that there was significant improvement with SWT compared with pre-treatment status, as assessed using a VAS, VISA-P or subjective clinical evaluation range. In summary, overall SWT appears to be an effective treatment option for PT, however its comparative effectiveness with other treatment modalities is limited and unclear.

The systematic review by Winters et al.¹⁷ assessed treatments for MTSS, and included two non-randomized studies on SWT. One study compared FSWT plus a running program with the running program alone, and found that the group on FSWT was able to complete the running program in a statistically significantly shorter duration than the group not receiving FSWT. The second study compared RSWT plus conservative treatment (home training + rest + ice) with conservative treatment alone and showed that there were statistically significant between group differences with respect to both success rate and pain severity, favoring RSWT. In summary, addition of SWT to a running program or conservative treatment enhances improvement in MTSS.

What is the cost-effectiveness of shockwave therapy for chronic pain associated with lower extremity orthopedic disorders?

No relevant studies were identified on cost-effectiveness of shock-wave therapy for chronic pain associated with lower extremity orthopedic disorders.

Limitations

Most of the studies compared SWT to placebo or sham. Studies comparing SWT with other active treatment modalities were scarce. The terms placebo and sham were used interchangeably. There appears to be some inconsistency in the definitions of placebo or sham in the included studies. There appears to be no standard definition for low, medium and high energy SWT. In the studies, it was unclear if the efficacy was entirely due to SWT as there was no reporting of co-interventions if used. Reporting of adverse effects were sparse.

There was considerable overlap in the studies included in the systematic reviews on foot and ankle disorders, hence findings from these systematic reviews are not mutually exclusive.

The quality of the included studies was variable. Comparison between studies was difficult, as the type of SWT used varied considerably with respect to intensity, number of pulses, and number of sessions. Details of placebo treatments were lacking. It was unclear if the patients were self-treating for pain, which could impact results. In some systematic reviews details of patient characteristics in the included RCTs were lacking. The minimal clinically important difference for the outcome measures were not known or presented so clinical significance of the findings were unclear.

Findings need to be interpreted in the light of these limitations.

No studies on the cost effectiveness of SWT for chronic pain associated with lower extremity orthopedic disorders were identified.

CONCLUSIONS AND IMPLICATIONS FOR DECISION OR POLICY MAKING

Seven relevant systematic reviews^{10,13-18} were identified. These comprised four systematic reviews^{13,14,18,19} on foot and ankle related disorders, two systematic reviews^{15,17} on thigh, knee and tibia related disorders, and one systematic review¹⁶ including several orthopedic disorders of the lower extremity.

For plantar fasciitis, overall there is some suggestion that, in comparison with placebo, shockwave therapy (SWT) is an effective treatment option. Limited evidence suggests that for plantar fasciitis, the effectiveness of SWT is comparable with platelet rich plasma injection, corticosteroid injection and surgery. Adverse events were sparsely reported. Adverse effects reported with SWT included skin reddening, bruising at the site of application, and local swelling and pain.

For greater trochanteric pain syndrome, a case control study showed that SWT was statistically significantly more effective than conservative treatment, and findings from a quasi-randomized controlled trial (RCT) comparing SWT with corticosteroid injection or home training were inconsistent.

For patellar tendinopathy, a case control study and a quasi RCT showed that SWT was statistically significantly more effective than conservative treatment. Findings from two RCTs comparing SWT with placebo were inconsistent. Findings from one quasi RCT comparing SWT with corticosteroid injection were inconsistent. One retrospective study showed that effectiveness of SWT and surgery was comparable.

For medial tibial stress syndrome, one non-RCT showed that addition of SWT to conservative treatment was statistically significantly more effective than conservative treatment alone; and one non-RCT showed that addition of SWT to a running program was statistically significantly more effective than the running program alone.

No studies on the cost-effectiveness of SWT for chronic pain associated with lower extremity orthopedic disorders were identified.

It appears that techniques for using SWT for orthopedic disorders still need to be standardized.²⁰ There appears to be a lack of consensus regarding the definitions for high and low energy SWT. Other issues include determination of precise doses and optimal frequency of application, whether the shockwaves should be directed to the target area by radiological or ultrasound imaging, and whether local anesthetic injections should be used in the target area prior treatment to reduce pain.²⁰

PREPARED BY:

Canadian Agency for Drugs and Technologies in Health

Tel: 1-866-898-8439

www.cadth.ca

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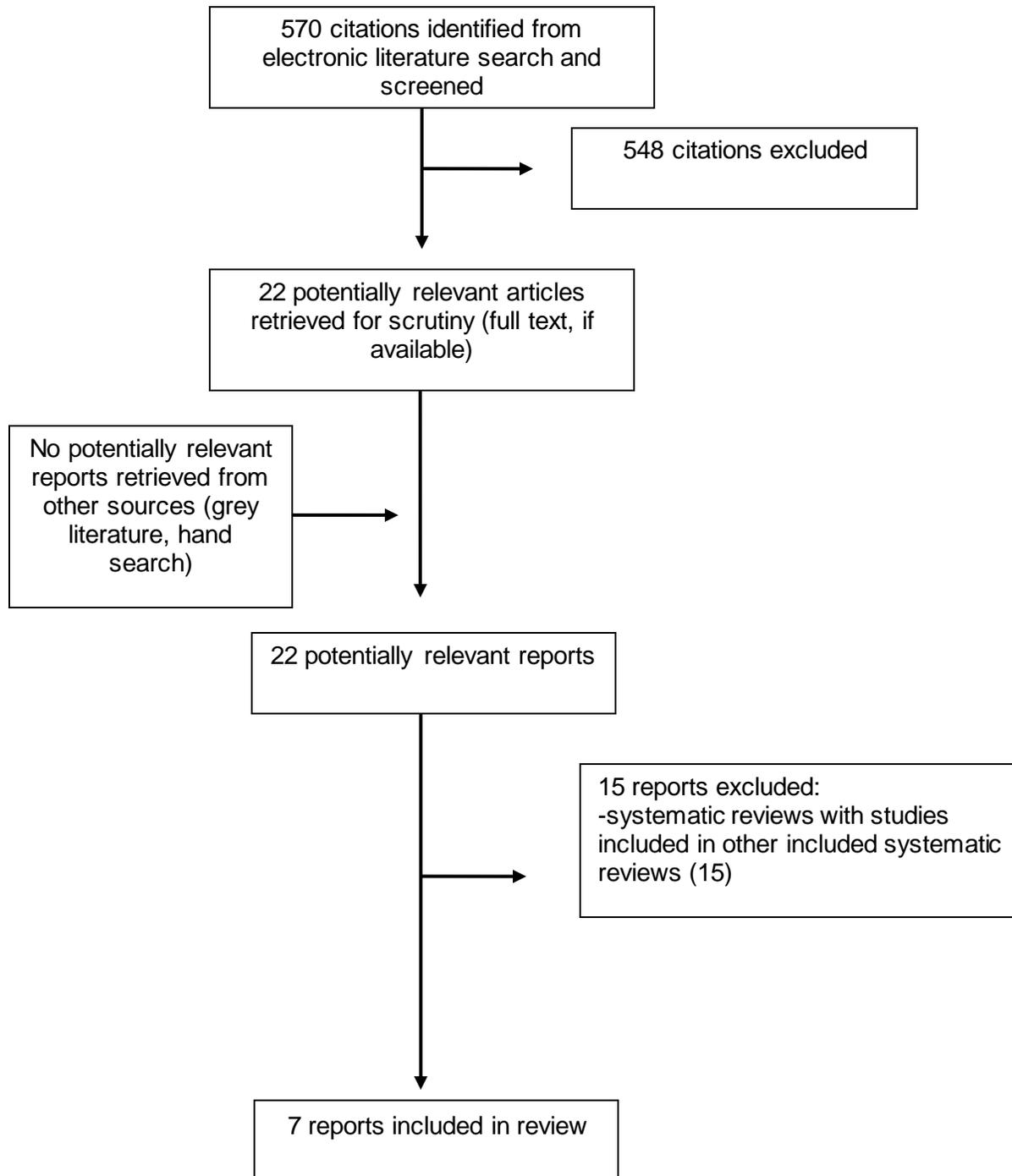
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ABBREVIATIONS

A	anesthetic
ABP	autologous blood product
AE	adverse events
AOFAS	American Orthopaedic Foot and Ankle Society
CI	confidence interval
Con	conservative treatment
CS	corticosteroid
Ec	eccentric loading
EQoL	Euro Quality of Life
ESWT	extracorporeal shock-wave therapy
FSWT	focused shock-wave therapy
FIL	functional index of lower limb activity
FU	follow up
GTPS	greater trochanteric pain syndrome
H-FSWT	high energy focused shock-wave therapy
H-SWT	high energy shockwave therapy
HT	home training
Hz	Hertz (unit for frequency)
L-FSWT	low energy focused shockwave therapy
L-SWT	low energy shockwave therapy
MCID	minimal clinical important difference
MD	mean difference
M-FSWT	medium energy focused shockwave therapy
M-SWT	medium energy shockwave therapy
mJ	millijoule (unit for energy intensity)
mm	millimeter
MTSS	medial tibial stress syndrome
NR	not reported
NS	not significant
OR	odds ratio
plb	placebo
PRP	platelet-rich plasma
PT	patella tendinopathy
QA	quality assessment
RCT	randomized controlled trial
RMS	Roles and Maudsley score
RR	relative risk
RSWT	radial shock-wave therapy
SD	standard deviation
SMD	standardized mean difference
SR	systematic review
SW	shockwave
SWT	shock wave therapy
VAS	visual analog scale
VISA-A	Victorian Institute of Sport Assessment Questionnaire–Achilles
VISA-P	Victorian Institute of Sport Assessment Questionnaire – Patellar

APPENDIX 1: Selection of Included Studies



APPENDIX 2: Characteristics of Included Publications

Table A1: Characteristics of Included Systematic Reviews and Meta-Analyses				
First Author, Publication Year, Country	Types and numbers of primary studies included^a	Population Characteristics^a	Comparisons^a	Clinical Outcomes, Length of Follow-Up^a
Foot and ankle related disorders				
Chang, ¹⁸ 2012, Taiwan Aim: To compare the effectiveness of FSWT of different intensity levels and RSWT for managing plantar fasciitis	12 RCTs (published: 2002 to 2010)	Adults with plantar fasciitis N = 1431 Age range (years): 25 to 87 % Female: NR Symptom duration (months): 6 to 312	SWT (low, medium, and high intensity FSWT; and RSWT) vs plb (1 RCT compared high intensity SWT with medium intensity SWT) SWT intensity: 0.08 mJ/mm ² to 0.64 mJ/mm ²	Pain level, clinical success rate. (VAS) Duration of FU: 3 months to 5 years
Dizon, ¹⁰ 2013, Philippines Aim: To evaluate the effectiveness of SWT in treating chronic plantar fasciitis	11 RCTs (published: 2002 to 2010)	Adults with chronic plantar fasciitis who were unresponsive to conservative care. N = 1384 <i>SWT vs plb (10 RCTs)</i> N= 1352 Age range (years): 26 to 87 % Female: 48 to 73 Symptom duration: 6 weeks (1RCT), 3 months (1RCT), 6 months (8 RCTs) <i>SWT vs physical therapy (1 RCT)</i> N= 32 Age (range) (years): 25 to 68 %Female = 81 Symptom duration: 6 months	<i>SWT (low, moderate, and high intensity) vs plb (10 RCTs)</i> SWT: intensity: 0.02 mJmm ² to 0.64 mJ/mm ² , (1 RCT: energy level 1 to 7); pulses between: 1000 to 4000; number of sessions: 1-3. <i>SWT vs physical therapy (1 RCT)</i> SWT: intensity 0.14 mJ/mm ² , 2000 pulses	Overall pain reduction, morning pain, activity pain, function, adverse events (VAS, RMS) Duration of FU: 6 weeks to 12 months
Hsiao, ¹⁴ 2015, Taiwan Aim: To compare the efficacy of autologous blood-derived	4 RCTs (published: 2005 to 2013)	Adults with recalcitrant plantar fasciitis. <i>SWT vs platelet-rich plasma (1 RCT)</i> N= 38 Age (mean) (years): 46	<i>PRP vs SWT (1RCT):</i> SWT: intensity 0.02 to 0.42 mJmm ² , pulses 20000, 2 sessions <i>CS vs SWT (3 RCTs):</i> Intensity 0.08 mJ/mm ² to 0.28 mJ/mm ² ; pulses	Pain reduction, treatment success (VAS) <i>PRP vs SWT (1RCT):</i> Follow up at 3 and 6 months (time

Table A1: Characteristics of Included Systematic Reviews and Meta-Analyses

First Author, Publication Year, Country	Types and numbers of primary studies included ^a	Population Characteristics ^a	Comparisons ^a	Clinical Outcomes, Length of Follow-Up ^a
products, corticosteroids and SWT for plantar fasciitis		<p>% Female: 45 Symptom duration (mean) (months): 12 to 18</p> <p><i>SWT vs corticosteroids (3 RCTs)</i> N=245 Mean age (years): 34 to 45 % Female: 53 to 70 Symptom duration (mean) (weeks): 12 to 39 (not reported for 1 RCT)</p>	1000 to 3000; sessions 1 to 3 (intensity not reported in 1 RCT)	<p>points used for metaanalysis)</p> <p><i>CS vs SWT (3 RCTs):</i> Follow up at 3 and 6 months (time points used for metaanalysis)</p> <p>Duration of FU: up to 12months</p>
Landorf, ¹³ 2014, Australia Aim: To evaluate effectiveness of conservative and non-conservative treatments for plantar heel pain.	<p>3 SRs (published: 1 SR in 2005 and 2SRs in 2013 [search dates: 2004, 2010, 2013], including 19 RCTs)</p> <p>6 RCTs (published: 2006 to 2012)</p>	<p>Patients with plantar fasciitis (mentioned as adults in 3 SRs and 2 RCTs, and as people in 4 RCTs)</p> <p><i>SWT vs plb (3 SRs)</i> N = 790 in 1 SR, 881 in 1 SR and NR in 1 SR. Age: NR % Female: NR Symptom duration: 3 months in 1 SRT, 6 months in 1 SR and NR in 1 SR.</p> <p><i>SWT vs plb (2 RCTs):</i> N = 114 in 1 RCT and NR in 1 RCT, Age: NR, % Female: NR, Symptom duration: NR</p> <p><i>SWT vs CS + local anesthetic injection (1 RCT)</i> N = 64 Age: NR % Female: NR Symptom duration: at least 8 weeks</p>	<p>SWT compared with placebo</p> <p>SWT compared with corticosteroid injection plus local anesthetic injection</p> <p>SWT plus local anesthetic injection compared with corticosteroid injection plus local anesthetic injection</p> <p>SWT compared with surgery</p> <p>The type of SWT used varied. In one SR, the intensity was between 0.16 mJ/mm² and 0.25 mJ/mm², and sessions were between 1 and 3. In one RCT the intensity was 0.03 mJ/mm², 2000 pulses, 4 sessions. SWT details were not reported in the other included SRs or RCTs.</p>	<p>Pain relief, functional improvement, (VAS) Adverse effects.</p> <p>Duration of FU: 12 weeks in 3 SRs; 6 weeks to 24 weeks in 3 RCTs and NR for 3 RCTs.</p>

Table A1: Characteristics of Included Systematic Reviews and Meta-Analyses

First Author, Publication Year, Country	Types and numbers of primary studies included ^a	Population Characteristics ^a	Comparisons ^a	Clinical Outcomes, Length of Follow-Up ^a
		<p><i>SWT + local anesthetic injection vs CS + local anesthetic (2 RCTs)</i> N = 120 Age: NR % Female: NR Symptom duration: > 6 months</p> <p><i>SWT vs surgery (partial release endoscopic plantar fasciotomy (1 RCT))</i> N = 65 Age: NR % Female: NR Symptom duration: NR</p>		
Mani-babu, ¹⁶ 2015, UK Aim: To evaluate the effectiveness of SWT for lower limb tendinopathies	11 (5 RCTs, 4 prospective studies, 2 case control) published: 2004 to 2011	<p>Patients with Achilles tendinopathy</p> <p>N = 629, Mean age (years) = 39 to 59 (age NR for 1 RCT) % Female = NR Symptom duration (month): at least 3 to 6</p>	<p>SWT vs plb (2 RCTs), Ec vs SWT vs wait-and-see (1 RCT), Ec vs SWT (1 RCT), Ec vs Ec+SWT (1 RCT), SWT (4 pre- & post-prospective studies), SWT vs control (2 case-control studies)</p> <p>SWT: Intensity between 0.1 mJ/mm² to 0.51 mJ/mm², pulses 1500 to 3000, sessions 1 to 4 (8 studies); 2000 pulses at 2.5 bar at 6 to 10 Hz, 3 sessions (1 study); 2000 pulses 21 kV at 2Hz, 1 session (1 study); and 2500 pulses at 2.4 bar at 11 to 13 Hz, 3 sessions (1 study)</p>	<p>Pain, function, success (VAS, VISA-A, RMS, Likert scale, FIL, EQoL, AOFAS)</p> <p>Duration of FU (months): 3 to 24</p>
Thigh, knee and tibia related disorders				
Balasubramaniam, ¹⁵ 2015, Australia.	1 RCT (published: 2013)	<p>Patients with patellar tendinopathy</p> <p>N = 46</p>	<p>PRP injection vs SWT</p> <p>2 PRP injections over 2 weeks</p>	(VISA-P, VAS, Blazina score)

Table A1: Characteristics of Included Systematic Reviews and Meta-Analyses

First Author, Publication Year, Country	Types and numbers of primary studies included ^a	Population Characteristics ^a	Comparisons ^a	Clinical Outcomes, Length of Follow-Up ^a
Aim: To systematically review the literature regarding PRP therapy for chronic tendinopathy		Age: NR % Female: NR Symptom duration: NR	SWT: no details reported	Duration of FU: 2 to 12 months
Mani-babu, ¹⁶ 2015, UK Aim: To evaluate the effectiveness of SWT for lower limb tendinopathy.	<i>2 studies on GTPS</i> published in 2009 (1 quasi RCT and 1 case-control study) and <i>7 studies on PT</i> published: 2003 to 2013 (2 RCTs, 1 quasi-RCT, 2 prospective studies, 1 case control study, and 1 retrospective cross-sectional outcome analysis)	Patients with lower limb tendinopathy. <i>GTPS (2 studies):</i> N = 295, Age (mean) (years): 46 to 51, % Female: NR Symptom duration: 6 months, and at least 6 months <i>PT (7 studies):</i> N = 317, Age (years): ranges within 20 and 58 in 4 studies, ranges within 15 and 69 in 2 studies, and NR in 1 study, % Female: NR Symptom duration: 3 to 6 months in 4 studies, 12 months in 1 study, and just mentioned as chronic in 2 studies	SWT vs control or other modalities <i>GTPS (2 studies; SWT vs control, home training or corticosteroid injection):</i> SWT: intensity 0.12 mJ/mm ² , 2000 impulses, 3 sessions in 1 study; and 0.18 mJ/mm ² , 2000 impulses, 1 session in 1 study. <i>PT (7 studies; SWT vs placebo SWT, conservative treatment or surgery; or pre- and post-treatment studies):</i> SWT: intensity 0.08 mJ/mm ² to 0.58 mJ/mm ² , 1000 to 2000 impulses, and 1 to 5 sessions	<i>GTPS (2 studies):</i> Likert scale, VAS, Harris hip score, and RMS Duration of FU: 12 months to 15 months <i>PT (7 studies):</i> VAS, VISA-P, and RMS Duration of FU: 12 weeks to 24 months
Winters, ¹⁷ 2013, Netherlands. Aim: To assess the effectiveness of conservative and surgical interventions in patients with medial	2 non-randomized studies (published in 2010, and 2012)	Athletes with medial tibial stress syndrome <i>Study 1 (Moen 2012)</i> N = 42 (22 in Group 1 and 20 in Group 2) Group 1: Age (mean [SD]) (years): 22.7 (7.2), % Female: 65, Duration of complaints (mean [SD]) (days):	SWT vs other treatment modality <i>Study 1 (Moen 2012)</i> (SWT + 6-phase graded running program) vs (6-phase graded running program) SWT: intensity 0.10 mJ/mm ² to 0.30 mJ/mm ² , 1000 to 1500 shocks per session, 5	<i>Study 1:</i> Days to completion of running program. Duration of FU: NR <i>Study 2:</i> Pain level, success rate. Duration of FU: 1 to 15 months

Table A1: Characteristics of Included Systematic Reviews and Meta-Analyses

First Author, Publication Year, Country	Types and numbers of primary studies included ^a	Population Characteristics ^a	Comparisons ^a	Clinical Outcomes, Length of Follow-Up ^a
tibial stress syndrome		189.3 (339.8) Group 2: Age (mean [SD]) (years): 30.0 (12.5), % Female: 27, Duration of complaints (mean [SD]) (days): 629.2 (761.1) <i>Study 2 (Rompe 2010)</i> N = 78 Age(mean [range]) (years): 42 (18 to 56), % Female: 69, Duration of symptoms (months): 15.4 in one group and 13.7 in another group	sessions <i>Study 2 (Rompe 2010)</i> (SWT + [12-week home training program, relative rest, and ice]) vs (12-week home training program, relative rest, and ice) SWT: low energy, pressure of 2.5 bars, 2000 shocks per session, 3 sessions. Pain killers were provided to patients in both groups, if requested	

AOFAS = American orthopedic foot and ankle society, CI = confidence interval, CS = corticosteroid, EQoL = Euro quality of life, FIL = functional index of low er limb activity, FU = follow -up, GTPS = greater trochanteric pain syndrome, NR = not reported, plb = placebo, PRP = platelet-rich plasma, PT = patellar tendinopathy, RCT = randomized controlled trial, RMS = Roles and Maudsley score, SD= standard deviation, SR = systematic review, SWT shockwave therapy, VAS= visual analog scale, VISA-A = Victorian Institute of Sport Assessment questionnaire –Achilles , VISA-P= Victorian Institute of Sport Assessment questionnaire – patellar, vs = versus
^aOnly information relevant for this report are presented here

APPENDIX 3: Critical Appraisal of Included Publications

Table A2: Strengths and Limitations of Systematic Reviews and Meta-Analyses using AMSTAR checklist ¹²	
Strengths	Limitations
Foot and ankle related disorders	
Chang, ¹⁰ 2012, Taiwan	
<ul style="list-style-type: none"> • The objective was clearly stated. • The inclusion and exclusion criteria were stated. • Multiple databases (Medline, PubMed) were searched from 1996 to June 2011. Also, Cochrane Central register of Controlled Trials, Cochrane systematic reviews, ClinicalTrials.gov, and reference list of included trials and metaanalyses were manually searched. • Study selection was described and a flow chart for study selection was presented • List of included studies was provided • Article selection was done in duplicate • Data extraction was done in duplicate • Quality assessment was conducted using the Jadad scale (0 to 5) and studies scoring less than 3 were considered to be of low quality and were not considered for meta-analysis • Characteristics of the individual studies were provided, but lacked details of patient characteristics • Meta-analyses were conducted. However, in some instances the pooling of RCTs with high heterogeneity may be debatable • The authors stated that there was no conflict of interest. 	<ul style="list-style-type: none"> • List of excluded studies was not provided • Publication bias does not appear to have been explored
Dizon, ¹⁰ 2013, Philippines	
<ul style="list-style-type: none"> • The objective was clearly stated. • The inclusion and exclusion criteria were stated. • Multiple databases were searched (including but not limited to: PubMed Central, Ovid, Cochrane Library, BioMed Central Google Scholar, EBSCO) from 1990 to 2010. Also reference list of the relevant articles were manually searched. • Study selection was described and a flow chart for study selection was provided was presented • List of included studies was provided • Data extraction was done independently and appears to have been done in duplicate, however not explicitly mentioned that it was done in duplicate • Quality assessments of studies were 	<ul style="list-style-type: none"> • List of excluded studies not provided • Unclear if article selection was done in duplicate • Publication bias does not appear to have been explored

Table A2: Strengths and Limitations of Systematic Reviews and Meta-Analyses using AMSTAR checklist¹²

Strengths	Limitations
<p>conducted using PEDro scale (11 items). Studies scoring less than 7 were considered to of low quality and were not considered for analysis. The scores for the included studies was between 7 and 10 on the 11 point scale.</p> <ul style="list-style-type: none"> • Characteristics of the individual studies were provided • Metaanalysis were conducted and appear to be appropriate. • The authors stated that there was no conflict of interest. 	
<p>Hsiao,¹⁴ 2015, Taiwan</p>	
<ul style="list-style-type: none"> • The objective was clearly stated. • The inclusion and exclusion criteria were stated. • Multiple databases were searched (PubMed and Scopus) from inception to 2014. Grey literature search was conducted. Also reference list of the relevant articles were manually searched. • Study selection was described and a flow chart for study selection was provided was presented • List of included was provided • Article selection was done in duplicate • Data extraction was done in duplicate • Quality assessment was conducted using the Jadad scale (0 to 5) and studies scoring less than 3 were considered to be of low quality. Majority of the included studies were of low quality • Characteristics of the individual studies were provided. • Publication bias was assessed using the Begg's test and the Funnel plot and the authors concluded there was no significant publication bias. • Meta-analyses were conducted. However, in some instances the pooling of RCTs with high heterogeneity may be debatable. • The authors stated that there was no conflict of interest. 	<ul style="list-style-type: none"> • List of excluded studies not provided
<p>Landorf,¹³ 2014, Australia</p>	
<ul style="list-style-type: none"> • The objective was clearly stated. • The inclusion and exclusion criteria were stated. • Multiple databases (Medline [1966 onwards], Embase [1980 onwards], Cochrane database of systematic reviews, Database of abstracts 	<ul style="list-style-type: none"> • List of excluded studies was not provided • Unclear if article selection was done in duplicate • Unclear if data extraction was done in duplicate • Publication bias does not appear to have been explored

Table A2: Strengths and Limitations of Systematic Reviews and Meta-Analyses using AMSTAR checklist¹²

Strengths	Limitations
<p>and of reviews of effects [DARE] and HTA database) were searched up to November 2013.</p> <ul style="list-style-type: none"> • Study selection was described but a flow chart was not presented • List of included studies was provided • Quality assessment was conducted. The quality of evidence was evaluated using GRADE and the level of evidence was judged to be low or weak. • Characteristics of the individual studies were provided, but lacked details of patient characteristics • Meta-analyses results from included SRs were presented. Meta-analysis of included studies were not included individual studies was not done, likely due to heterogeneity. • The author provided disclosure and there does not appear to be any conflict of interest 	
<p>Mani-babu,^{1b} 2015, UK</p>	
<ul style="list-style-type: none"> • The objective was clearly stated. • Multiple databases (PubMed [Medline], Embase, Web of knowledge, Cochrane, and Cinahl) were searched (search conducted in February 2013). Article reference lists were also searched. • Study selection was described and a flow chart for study selection was presented • List of included studies was provided • Article selection was done in duplicate • Quality of the studies was assessed using a modified Downs and Black checklist (max score = 28). The score varied between 23 and 26 in 3 studies and between 15 and 19 in 5 studies. • Characteristics of the individual studies were provided. • Meta-analyses were conducted but results were not pooled (likely due to heterogeneity of the studies) • The authors stated that there was no conflict of interest. However, the authors have received funding from industry, though not for work on this particular systematic review. 	<ul style="list-style-type: none"> • The inclusion and exclusion criteria were not explicitly stated • List of excluded studies was not provided • Unclear if data extraction was done in duplicate, however quality of studies was assessed independently by two reviewers. • Publication bias does not appear to have been explored
<p>Thigh, knee and tibia related disorders</p>	
<p>Balasubramaniam,^{1b} 2015, Australia</p>	
<ul style="list-style-type: none"> • The objective was clearly stated. • Multiple databases (Medline, Embase, EBSCO, 	<ul style="list-style-type: none"> • The inclusion and exclusion criteria were not explicitly stated.

Table A2: Strengths and Limitations of Systematic Reviews and Meta-Analyses using AMSTAR checklist¹²

Strengths	Limitations
<p>and Cochrane library) were searched (search dates not reported)</p> <ul style="list-style-type: none"> • Study selection was described and a flow chart for study selection was presented • List of included studies was provided • Data extraction was done in duplicate • Quality assessment was conducted using the Cochrane criteria checklist by Furlan et al.²¹ Quality assessment results were not presented but the authors mentioned that low quality studies were excluded. • Pooling not applicable as only one relevant study. • The authors stated that there was no conflict of interest. 	<ul style="list-style-type: none"> • Unclear if article selection was done in duplicate • List of excluded studies was not provided • Description of study characteristics lacked details regarding patient characteristics and interventions. • Publication bias does not appear to have been explored
<p>Mani-babu,¹⁶ 2015, UK</p>	
<ul style="list-style-type: none"> • Discussed above in “Achilles tendinopathy and plantar fasciitis” section 	<ul style="list-style-type: none"> • Discussed above in “Achilles tendinopathy and plantar fasciitis” section
<p>Winters,¹⁷ 2013, Netherlands</p>	
<ul style="list-style-type: none"> • The objective was clearly stated. • The inclusion and exclusion criteria were stated. • Multiple databases (Medline, PubMed, Cochrane central register of controlled trials, Embase, Cinahl, Pedro, SportDiscus) were searched from inception to June 2012. Also, ClinicalTrials.gov, conference abstracts, British Library Inside, Web of Science and Biosis previews were searched. Reference list of included studies and existing reviews were manually searched. • Study selection was described and a flow chart for study selection was presented • List of included studies was provided • Article selection was done in duplicate • Data extraction was done in duplicate • Quality assessment was conducted using the Cochrane risk of bias tool for RCTs and the Newcastle Ottawa scale for non-randomized studies. The two relevant included studies were judged to be of low quality. In addition “levels of evidence” of the Oxford center of evidence-based medicine were used to evaluate methodological quality. Level of evidence was considered to be 4 (low, high numbers indicate low level of evidence) • Characteristics of the individual studies were provided • Publication bias was explored. The authors 	<ul style="list-style-type: none"> • List of excluded studies was not provided • Pooling was not performed as studies were heterogeneous. It was however stated a priori that meta-analyses would not be conducted in case of heterogeneous studies

Table A2: Strengths and Limitations of Systematic Reviews and Meta-Analyses using AMSTAR checklist¹²

Strengths	Limitations
<p>stated that publication bias seemed unlikely considering the symmetrical distribution of studies in the Funnel plot</p> <ul style="list-style-type: none"> • The authors stated that there was no conflict of interest 	

APPENDIX 4: Main Study Findings and Author’s Conclusions

Table A3: Summary of Findings of the Systematic Review

Main Study Findings and Author’s Conclusions				
Foot and ankle related disorders				
Chang, ¹⁰ 2012, Taiwan				
Main Findings:				
Pain reduction (assessed using VAS) with SWT compared to placebo, for plantar fasciitis				
Comparison	No of studies	No of patients or heels	SMD (95% CI)	Heterogeneity, I ² (%)
L-FSWT vs plb	2 (Haake 2003, Rompe 2002)	353	-1.59 (-4.33 to 1.15)	98.7
M-FSWT vs plb	2 (Marks 2008, Rompe 2003)	353	-1.21 (-1.76 to -0.67)	37.5
H-FSWT vs plb	2 (Kudo 2006, Theodore 2004)	255	-0.33 (-0.58 to -0.08)	0
RSWT vs plb	2 (Ibrahim 2010, Gerdsmeyer 2008)	293	-10.32 (-30.17 to 9.53)	93.9
Clinical success rate^a with SWT compared to placebo, for plantar fasciitis				
Comparison	No of studies	No of patients or heels	OR (95% CI)	Heterogeneity, I ² (%)
L-FSWT vs plb	2 (Haake 2003, Rompe 2002)	353	2.36 (0.50 to 11.14)	91.0
M-FSWT vs plb	5 studies (Marks 2008, Golwitzer 2007, Ogden 2004, Rompe 2003, Speed 2003)	477	1.56 (1.23 to 1.96)	0
H-FSWT vs plb	2 (Kudo 2006, Theodore 2004)	255	1.43 (1.07 to 1.91)	60.0
RSWT vs plb	2 (Ibrahim 2010, Gerdsmeyer 2008)	293	2.72 (0.74 to 10.07)	88.6
^a Success rate assessed as proportion of patients achieving improvement assessed by various measures (Roles and Maudsley sores, VAS or not specified)				
Results of network meta-analysis with placebo and various SWTs				
Intervention	Treatment effect assessed using VAS MD (95% CrI)			
Placebo	0.062 (-0.373 to 0.502)			
L-FSWT	-2.376 (-5.443 to 0.811)			
M-FSWT	-2.181 (-6.15 to 1.864)			
H-FSWT	-1.141 (-5.44 to 3.248)			
RSWT	-6.088 (-8.295 to -3.415)			
CI = confidence interval, CrI = credible interval, FSWT = focused shockwave therapy, H-FSWT = high energy FSWT, L-FSWT = low energy FSWT, M-FSWT = medium energy FSWT, MD = mean difference, OR = odds ratio, plb = placebo, SMD = standardized mean difference, SWT = shockwave therapy, vs = versus				
Authors’ Conclusions:				
“The present meta-analysis provides quantitative evidence to support the use of shock wave therapy for plantar fasciitis. The success rates of treatment were not related to energy levels, while the magnitudes of pain reduction might disclose a slight dose-response relationship. Therefore, the investigators who				

Table A3: Summary of Findings of the Systematic Review

Main Study Findings and Author's Conclusions

already own an FSW modality, setting the highest and mostly tolerable energy efflux densities without anesthesia in the range of medium intensity is the preferable option. However, for those who attempt to choose between FSW therapy and RSW therapy for treating plantar fasciitis, we recommend RSW therapy because of its lower price and likely better effectiveness in clinical practice." Page 1267

Dizon,¹⁰ 2013, Philippines

Main Findings:

Chronic Plantar Fasciitis

Overall pain reduction (assessed using VAS) with SWT compared to placebo

Comparison	No of studies	No of patients	MD (95% CI)	Heterogeneity, I ² (%)
L-SWT vs plb	1 (Buchbinder 2002)	161	0.60 (-10.15 to 11.35)	n/a
M-SWT vs plb	3 (Gerdesmeyer 2008, Ibrahim 2010, Speed 2003)	369	-6.60 (-6.74 to -6.46)	0
H-SWT vs plb	1 (Theodore 2004)	150	-0.70 (-1.63 to 0.23)	n/a
All	5	680	-4.39 (-9.05 to 0.27)	97

Morning pain reduction (assessed using VAS) with SWT compared to placebo

Comparison	No of studies	No of patients	SMD (95% CI)	Heterogeneity, I ² (%)
L-SWT vs plb	2 (Buchbinder 2002, Haake 2003)	433	-0.50 (-1.28 to 0.29)	0
H-SWT vs plb	2 (Kudo 2004, Theodore 2004)	264	-1.00 (-1.70 to -0.29)	0
All	4	597	-0.77 (-1.30 to -0.25)	0

Morning pain reduction (assessed using VAS) with SWT compared to placebo

Comparison	No of studies	No of patients	OR (95% CI)	Heterogeneity, I ² (%)
M-SWT vs plb	2 (Gerdesmeyer 2008, Speed 2003)	331	0.65 (0.42 to 1.00)	0

Activity pain reduction (assessed using VAS) with SWT compared to placebo

Comparison	No of studies	No of patients	OR (95% CI)	Heterogeneity, I ² (%)
M-SWT vs plb	2 (Gerdesmeyer 2008, Speed 2003)	331	0.47 (0.30 to 0.74)	0
H-SWT vs plb	1 (Gollwitzer 2007)	40	1.50 (0.43 to 5.25)	n/a
Total	3	371	0.59 (0.33 to 1.05)	32

Functional outcome (assessed using RM score) with SWT compared to placebo

Comparison	No of studies	No of patients	OR (95% CI)	Heterogeneity, I ² (%)
L-SWT vs plb	1 (Haake 2003)	256	0.80 (0.49 to 1.32)	n/a
M-SWT vs plb	1 (Gerdesmeyer 2008)	243	0.51 (0.30 to 0.84)	n/a
H-SWT vs plb	3 (Gollwitzer 2007, Kudo 2005, Theodore 2004)	291	0.47 (0.29 to 0.75)	0
Total	5	790	0.57 (0.43 to 0.76)	0

Table A3: Summary of Findings of the Systematic Review

Main Study Findings and Author's Conclusions

Findings from RCTs not included in meta-analysis

Study	Comparison	Outcomes	Results
Chow, 2005 N=57	M-SWT (fixed or increasing intensity) vs plb	Max tolerable walking/standing duration	Fixed energy density group: mean ± SD 1.40 ± 0.40 P-value <0.001 Maximum tolerable energy density group: Mean ± SD of 2.32 ± 0.39 P<0.001
Malay, 2006 N=172	H-SWT vs plb	Heel pain (baseline to 3 months)	Favors H-SWT group MD = -3.95 P-value <0.001
Greve, 2009 N=32	H-SWT vs physical therapy	Morning pain (VAS) Activity pain (VAS) Orthostatic pain (VAS) Pain at pressure	No statistically significant different between the groups in any of the outcomes. However, faster effects seen in the SWT group.

Adverse events with SWT compared with control

Adverse Event	OR (95% CI)
Calcaneal pain	8.19 (3.05 to 22.2)
Erythema on calcaneal area	3.06 (1.18 to 7.93)
Local edema	0.74 (0.31 to 1.76)
Local paresthesia	0.86 (0.27 to 2.70)
Local bruising	0.63 (0.20 to 1.95)

Authors' Conclusions:

"The results of this review provide evidence for the effectiveness of ESWT using moderate and high intensity, in reducing pain and improving function in patients with chronic plantar fasciitis." Page. 617

Hsiao,¹⁴ 2015, Taiwan

Main Findings:

Pain Reduction (assessed using VAS)

Comparison	No of studies	No of patients	Time point (months)	MD (95% CI)	Heterogeneity, I ² (%)
SWT vs CS	2 (Porter 2005, Yucel 2010)	185	3	-0.87 (-4.15 to 2.40)	72.2
ABP (PRP) vs SWT	1 (Chew 2013)	38	3	0.00 (-2.55 to 2.55)	NA
			6	1.00 (-2.10 to 4.10)	NA

ABP = autologous blood product, CI = confidence interval, CS = corticosteroid, MD = mean difference, NA not applicable, PRP = platelet-rich plasma, SWT = shockwave therapy, VAS = visual analog scale

Treatment Success

Comparison	No of studies	No of patients	OR (95% CI)	Heterogeneity, I ² (%)
SWT vs CS	2 (Yucel 2010,	120	1.34 (0.62 to 2.88)	79.3

Table A3: Summary of Findings of the Systematic Review

Main Study Findings and Author's Conclusions

Saber 2012)			
CI = confidence interval, CS = corticosteroid, OR = odds ratio, SWT = shockwave therapy			

Authors' Conclusions:

"The present meta-analysis compared the efficacy of ABPs, CSs and SW therapy in the treatment of plantar fasciitis. The results demonstrated that ABPs, followed by CSs, were best in providing early pain relief. However, SW therapy and ABPs provided better pain reduction than CSs at 6 months." (p. 1742)

(ABP = autologous blood product, CS = corticosteroid, SW = shockwave)

Landorf,¹³ 2014, Australia

Main Findings:

Pain relief: SWT compared with placebo (assessed using VAS) at 12 weeks

SR, patient number	Comparison	Outcome measure	Findings
Dizon 2013, 5 RCTs used N = 680, (heel pain)	SWT vs plb	Overall pain reduction (VAS)	MD (95% CI): -4.39 (-9.05 to 0.27), (Heterogeneity, I ² =97%) Difference: NS
Aquil 2013, 2 RCTs used N=NR (plantar fasciitis)	(FSWT or RSWT) vs plb	Overall % improvement in mean VAS composite scores	SMD (95% CI): 0.38 (0.05 to 0.72), Favors RSWT or FSWT
Aquil 2013, 2 RCTs used N=NR (plantar fasciitis)	RSWT vs plb	Reduction in overall mean heel pain (VAS)	SMD (95% CI): 0.60 (0.34 to 0.85), Favors RSWT
Thomson 2005, 6 RCTs used N=881 (plantar heel pain)	SWT vs plb	Morning pain (10 cm VAS scores)	WMD (95% CI): 0.42 (0.02 to 0.83) Favors SWT

Functional Improvement: SWT compared with placebo

SR, patient number	Comparison	Outcome measure	Findings
Dizon 2013, 5 RCTs used N = 790, (heel pain)	SWT (low to high) vs plb	Proportion of people with a decrease in limitation of activity duration (4 point patient self-assessment)	OR (95% CI): 0.57 (0.43 to 0.76), Favors low to high intensity SWT

Adverse Effects: SWT compared with placebo

Study	Comparison	Adverse Effects
SR: Thomson	SWT vs plb,	Skin reddening, pain and local swelling,

Table A3: Summary of Findings of the Systematic Review

Main Study Findings and Author's Conclusions		
2005, data from 1 RCT, (plantar heel pain)	sham, or low dose treatment	and, less frequently, dizziness, sleep disturbance, hematoma, nausea, and hair loss. OR (95% CI): 2.26 (1.02 to 5.18), Favors plb
SR: Thomson 2005, data from 1 RCT, (plantar heel pain)	SWT vs plb, sham, or low dose treatment	SWT: sensation of heat and numbness or bruising (N=2), Plb: a burning sensation in the heel and ankle (N=1), Significance not assessed
RCT: Kudo 2006, (plantar fasciitis)	SWT vs plb	Pain during procedure SWT: 46/58 (79%) Plb: 6/56 (9%), <i>P</i> < 0.0001, favors plb
RCT: Malay 2006, (plantar fasciitis)	SWT vs plb	SWT: Bruising at site of application (N=2, 2%), Significance not assessed

SWT versus corticosteroid (CS) injection plus local anaesthetic (A) injection

RCT, patient number	Findings
Sorrentino, 2008 N=64 (plantar fasciitis)	Subgroup analysis of 32 people with plantar fasciitis and perifascial edema Proportion of people with clinical improvement in heel pain (VAS score) SWT: 6/16 (38%) (CS + A): 14/16 (88%) Significance not assessed
	Subgroup analysis of 30 people with plantar fasciitis and without perifascial edema Proportion of people with clinical improvement in heel pain (VAS score) SWT: 13/15 (93%) (CS + A): 5/15 (36%) Significance not assessed
	Adverse effects: It was reported that there were no complications in any of the groups.

SWT plus local anaesthetic (A) injection versus corticosteroid (CS) injection plus local anaesthetic (A) injection

RCT, patient number	Outcome measure
Yucel, 2010 N=60 (plantar fasciitis)	Pain relief Change from baseline in mean pain score (assessed using 100 mm VAS) at 3 months SWT + A: -5.3 CS + A: -4.0

Table A3: Summary of Findings of the Systematic Review

Main Study Findings and Author's Conclusions	
	<p>$P > 0.05$</p> <p>Pain relief Change from baseline in mean heel tenderness on palpation (assessed using physician score ranging from 0 = no pain, to 3 = painful, winces, and withdraws) at 3 months SWT + A: -0.9 CS + A: -0.8 $P > 0.05$</p> <p>Adverse effects Treatment-related pain: SWT + A: 0/27 (0%), CS + A: 33/33 (100%);</p> <p>SWT+ A: 2 patients reported a mild throbbing sensation lasting on average 5 days (range 3-7 days) but not requiring analgesia CS + A: patients receiving CS injection had pain lasting on average 5 days (range 2-9 days) after administration of intervention</p>
Saber, 2012 N=60 (plantar fasciitis)	<p>Functional improvement Mean change from baseline in functional status (assessed using Mayo Clinic scoring ; total 100 points, where 90-100 = excellent results, 80-89 = good, 70-79 = fair, and <70 = poor) , up to 24 weeks SWT + A: 46.83 to 85.83, CS + A: 46.66 to 84.00 $P = 0.296$</p>
SWT versus surgery (endoscopic plantar fasciotomy)[(partial release)]	
RCT, patient number	Findings
Radwan, 2012 ^a N=65 (plantar fasciopathy)	<p>Pain relief Median change from baseline in morning pain scores (assessed using 100 mm VAS ranging from 0 = no pain, to 100 = maximal pain) at 1 year SWT: 71 to 15, Surgery: 68 to 16; No significant difference ($P = 0.20$)</p> <p>Functional improvement Median change from baseline in functional score (assessed using AOFAS, total score) at 1 year SWT: 71 to 15, Surgery: 68 to 16; No significant difference ($P = 0.27$)</p>
<p>AOFAS=American Orthopedic Foot and Ankle-Hindfoot Scale; Intention-to-treat analysis with last observation carried forward; 3 participants from the ESWT group and 2 participants from the fasciotomy group did not complete the 1 year assessment" (p. 39)</p>	
Authors' Conclusions:	
<p>"Extracorporeal shock wave therapy (ESWT) may be more effective than placebo at reducing pain at 12 weeks in people with chronic plantar heel pain, but this is based on limited evidence.</p> <p>ESWT may be equally effective as endoscopic plantar fasciotomy (partial release) at reducing pain and</p>	

Table A3: Summary of Findings of the Systematic Review

Main Study Findings and Author's Conclusions

improving function at 1 year in adults with recalcitrant plantar fasciopathy, but this is based on weak evidence.

We don't know how low-dose ESWT compares with high-dose ESWT, or how ESWT (with or without local anaesthetic injections) compares with corticosteroid injection plus local anaesthetic injection, as the evidence is weak." Page 29

Mani-babu,¹⁰ 2015, UK

Main Findings:

Achilles tendinopathy

Comparison of SWT with placebo or other treatment for pain and function

Study, design, patient number, comparison	Outcome measure	SMD (95% CI)
Mid-portion or insertional tendinopathy		
Costa, 2005, RCT, N = 49, SWT vs plb	3 month pain (VAS)	-0.44 (-1.01 to 0.13)
	Function (FIL)	-1.05 (-1.65 to -0.45)
	EQoL	-0.21 (-0.77 to 0.36)
Rasmussen 2008, RCT, N = 48, SWT vs plb	AOFAS	-0.52 (-1.09 to 0.06)
Mid-portion tendinopathy		
Furia, 2008, case control, N=68, SWT vs conservative treatment	1 month pain (VAS)	-2.97 (-3.67 to -2.27)
	3 month pain (VAS)	-3.75 (-4.56 to -2.95)
	12 month pain (VAS)	-3.42 (-4.18 to -2.66)
Rompe, 2007, RCT, N=50, SWT vs Ec	4 month pain (VAS)	0.17 (-0.38 to 0.73)
Rompe, 2007, RCT, N=50, SWT vs wait-and-see		-0.93 (-1.52 to -0.34)
Rompe, 2009, RCT, N=68, (SWT + Ec) vs Ec		-0.53 (-1.01 to -0.05)
Rompe, 2007, RCT, N=50, SWT vs eccentric loading		0.29 (-0.27 to 0.85)
Rompe, 2007, RCT, N=50, SWT vs wait-and-see	VISA-A	-1.03 (-1.62 to -0.44)
Rompe, 2009, RCT, N=68, (SWT + Ec) vs Ec		-0.76 (-1.25, -0.27)
Insertional tendinopathy		
Furia, 2006, case control, N=68, SWT vs conservative treatment	1 month pain (VAS)	-2.10 (-2.70 to -1.50)
	3 month pain (VAS)	-2.42 (-3.05 to -1.78)
	12 month pain (VAS)	-2.39 (-3.02 to -1.76)
Rompe, 2008, RCT, N=50 SWT vs eccentric loading	4 month pain (VAS)	-0.86 (-1.44 to -0.27)
	VISA-A	-1.54 (-2.18 to -0.91)

AOFAS= American Orthopaedic Foot and Ankle Society; Ec = eccentric loading, EQoL= Euro Quality of Life, FIL = Functional Index of Lower Limb Activity, VISA-A = Victorian Institute of Sport Assessment Questionnaire–Achilles (questionnaire assessing severity of Achilles tendinopathy)

Comparison of SWT with placebo or other treatment for success

Study patient number, comparison	Outcome measure	Risk Ratio (95% CI)
Mid-Portion Tendinopathy		

Table A3: Summary of Findings of the Systematic Review

Main Study Findings and Author's Conclusions		
Furia, 2008, case control, N=68, SWT vs conservative treatment	1 month RMS	0.37 (0.21 to 0.64)
	3 month RMS	0.20 (0.09 to 0.46)
	12 month RMS	0.37 (0.21 to 0.64)
Rompe, 2007, RCT, N=50, SWT vs Ec	Likert Scale (1-6)	1.20 (0.64 to 2.25)
Rompe, 2007, RCT, N=50, SWT vs wait-and-see		0.63 (0.40 to 1.00)
Rompe, 2009, RCT, N=68, (SWT + Ec) vs Ec		0.40 (0.18 to 0.91)
Insertional Tendinopathy		
Furia 2006, case control, N=68, SWT vs conservative treatment	1 month RMS	0.99 (0.69 to 1.42)
	3 month RMS	0.28 (0.13 to 0.62)
	12 month RMS	0.28 (0.13 to 0.62)
Romp, 2008, RCT, N=50, SWT vs Ec	Likert Scale (1-6)	0.50 (0.28 to 0.89)
CI = confidence interval, Ec = eccentric loading,, RMS = Roles and Maudsley score		

Additional results from SWT prospective pre- and post- treatment follow-up studies

Study	Outcome	Results
Lakshmana 2004,	VISA-A, AOFAS	"Significant difference in both scores after treatment" Page 754
Fridman 2008	VAS	"Significant reduction in VAS score for morning pain as well as activity pain 4 mo after ESWT" Page 755
Vulpiani, 2009	VAS	"Significant improvement in outcome measures over short (2 mo) and medium term (6-12 mo)" Page 755
Saxena, 2011	RMS	"Significant improvement in score for proximal insertional, and paratendinosis" Page 755
AOFAS= American Orthopaedic Foot and Ankle Society, RM = Roles and Maudsley, VISA-A = Victorian Institute of Sport Assessment Questionnaire–Achilles (questionnaire assessing severity of Achilles tendinopathy)		

Authors' Conclusions:

"Extracorporeal shock wave therapy appears to be an effective intervention for lower limb tendinopathies, with moderate-level evidence of efficacy for all 3 tendinopathies reviewed... For AT, the results suggest that ESWT is superior to eccentric loading in the short term for insertional tendinopathy, effective when combined with eccentric loading in midportion tendinopathy, and superior to various alternative nonoperative treatments, particularly in recalcitrant presentations." Page 759-760

Thigh, knee and tibia related disorders

Balasubramaniam,¹⁵ 2015, Australia

Main Findings:

Outcomes with PRP compared with SWT in patients with patellar tendinopathy

Study, number of patients	Comparison	Outcomes
Vetrano 2013, RCT, N = 46	PRP injection vs SWT	Statistically significant between group difference, favoring PRP (mean difference from baseline in VISA-P scores, 36.0 for PRP and 21.5 for SWT). No statistically significant difference in VISA-P, VAS and Blazian scores at 2 months. Statistically significant improvement with PRP compared with SWT in VISA-P plus VAS scores at 6 and 12 months, and

Table A3: Summary of Findings of the Systematic Review

Main Study Findings and Author's Conclusions

		Blazina scores at 12 months. Significantly better patient satisfaction with PRP compared with SWT at 12 months.
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Authors' Conclusions:

“Despite no placebo, study supports conclusion that PRP significantly better than ESWT in functional, pain, and patient satisfaction at 6 and 12 months” Page 257
 “Although the results of this review show promise for the use of PRP in chronic tendinopathy, the analysis highlighted the need for more controlled clinical trials comparing PRP with placebo.” Page 253
 (PRP = platelet-rich plasma)

Mani-babu,¹⁶ 2015, UK

Main Findings:

Greater trochanteric pain syndrome (GTPS)

Outcomes (VAS, Harris hip scores) for SWT compared with control or other modalities in patients with GTPS (data from Forest plot)

Study, design, number of patients,	Outcome measure	Time period (month)	SMD (95% CI) ^a
Furia 2009, case control, N = 66 (33 in SWT, 33 in Con)	VAS score	1	-2.60 (-3.26 to -1.93)
		3	-4.08 (-4.94 to -3.21)
		12	-3.35 (-4.12 to -2.59)
	Harris hip score	1	-2.43(-3.08 to -1.79)
		3	-3.18 (-3.92 to -2.44)
		12	-3.67 (-4.48 to -2.86)
Rompe 2009, quasi-RCT, N = 229 (78 in SWT, 75 in CS, 76 in HT)	VAS score	1	SWT vs CS: 1.3 (0.79 to 1.47) SWT vs HT: -0.09 (-0.41 to 0.23)
		4	SWT vs CS: -0.48 (-0.80 to -0.16) SWT vs HT: -0.75 (-1.08 to -0.42)
		15	SWT vs CS: -0.90 (-1.23 to -0.57) SWT vs HT: -0.10 (-0.42 to 0.21)

Con = conservative treatment, CS = corticosteroid injection, HT = home training, SWT = shockwave therapy, VAS = visual analog scale

^aNegative value indicates SWT is better

Outcomes (success rate using RMS, Likert scale) for SWT compared with control or other modalities in patients with GTPS (data from Forest plot)

Study, design, number of patients,	Outcome measure	Time period (month)	RR (95% CI) ^a
Furia 2009, case control, N = 66 (33 in SWT, 33 in Con)	RMS	1	0.64 (0.43 to 0.96)
		3	0.29 (0.15 to 0.58)
		12	0.33 (0.16 to 0.68)
Rompe 2009, quasi-RCT, N = 229 (78 in SWT, 75 in CS, 76 in HT)	Likert scale (1 to 6)	1	SWT vs CS: 3.63 (2.41 to 5.48) SWT vs HT: 0.93 (0.84 to 1.04)
		4	SWT vs CS: 0.65 (0.44 to 0.97) SWT vs HT: 0.54 (0.37 to 0.79)
		15	SWT vs CS: 0.49 (0.32 to 0.76) SWT vs HT: 1.30 (0.72 to 2.34)

Con = conservative treatment, CS = corticosteroid injection, HT = home training, RMS = Roles and Maudsley score, SWT = shockwave therapy

^aRR < 1 indicates SWT is better

Table A3: Summary of Findings of the Systematic Review

Main Study Findings and Author's Conclusions

Patella tendinopathy

Outcomes (VAS, VISA-P) for SWT compared with control or other modalities in patients with patellar tendinopathy (data from Forest plot)

Study, design, number of patients,	Outcome measure	Time period	SMD (95% CI) ^a
Furia 2013, case control, N = 66 (33 in SWT, 33 in Con)	VAS	1 month	-2.05 (-2.65 to -1.44)
		12 weeks	-2.33 (-2.96 to -1.69)
		>12 months	-2.62 (-3.29 to -1.95)
Zwerver 2011, RCT, N = 62 (31 in SWT, 31 in plb)	VAS	1 week	-0.23 (-0.73 to 0.26)
		12 week	-0.31 (-0.81 to 0.20)
		22 week	-0.09 (-0.59 to 0.41)
	VISA-P	1 week	-0.03 (-0.53 to 0.47)
		12 week	0.11 (-0.38 to 0.61)
		22 week	0.12 (-0.38 to 0.62)
Wang 2007, quasi-RCT, N = 50 (27 SWT, 23 Con)	VAS	>12 months	-3.47 (-4.34 to -2.60)
	VISA-P	>12 months	-4.77 (-5.85 to -3.69)
Peers 2003, retrospective cross-sectional, N = 27 (14 SWT, 13 surgery)	VAS	>12 months	0.38 (-0.38 to 1.15)
	VISA-P	>12 months	-0.50 (-1.27 to 0.27)

Con = conservative treatment, SWT = shockwave therapy, VAS = visual analog scale, VISA-P = Victorian Institute of Sport Assessment questionnaire – patellar
^aNegative value indicates SWT is better

Outcomes (success rate using RMS) for SWT compared with control or other modalities in patients with patellar tendinopathy (data from Forest plot)

Study, design, number of patients,	Outcome measure	Time period (month)	RR (95% CI) ^a
Wang 2007, RCT, N = 50 (27 SWT, 23 Con)	RMS	>12 months	0.20 (0.06 to 0.63)
Peers 2003, retrospective cross-sectional, N = 27 (14 SWT, 13 surgery)	RMS	>12 months	0.69 (0.24 to 1.99)

Con = conservative treatment, RMS = Roles and Maudsley score, SWT = shockwave therapy
^aRR < 1 indicates SWT is better

Results from three included studies on patients with patellar tendinopathy (not included in the Forest plots)

Study, design, number of patients,	Outcome measure	Follow up	Findings
Zwerver 2010, prospective pilot study, N = 19 (19 SWT)	VAS, VISA-P	3 months	For both outcome measures, significant improvement with SWT (no data reported)
Vulpiani 2007, prospective study, N = 73 (73 SWT)	VAS, subjective clinical	>24 months	For both outcome measures, significant differences with SWT at 1 month post-treatment as well as in the short term (<

Table A3: Summary of Findings of the Systematic Review

Main Study Findings and Author's Conclusions			
	evaluation range		12 months) and in the long term (> 24 months) but not in the medium term (between 12 and 24 months) (no data reported)
Taunton 2003, RCT, N = 20 (10 SWT, 10 placebo)	VISA-P and vertical jump test	12 week	For both outcome measures, significant improvement with SWT compared to placebo (no data reported)
SWT = shockwave therapy, VAS=visual analog scale, VISA-P= Victorian Institute of Sport Assessment questionnaire – patellar			

Authors' Conclusions:

“These results indicate that ESWT is a viable short- and long-term treatment option for GTPS and may be used as an alternative to home training and corticosteroid injections.” Page:757

“Even though these studies indicate that ESWT may be a promising short- and long-term treatment option for treating PT, the majority of evidence is limited. Further research with a more robust study design will help to identify the true effectiveness of ESWT for patients with PT.” Page 758

(ESWT = extracorporeal shockwave therapy)

Winters,¹⁷ 2013, Netherlands

Main Findings:

This systematic review had a broad objective and examined several treatment modalities. The two non-randomized studies (Rompe 2010, and Moen 2012) comparing SWT with and without conservative interventions for the treatment of medial tibial stress syndrome, that are relevant for our report are presented here.

Findings from the Moen 2012 non-randomized study

Outcome	Interventions		P value
	FSWT + (6-phase running program)	(6-phase running program)	
Days from starting running program to completing phase 6 of the program (i.e. ability to run for 18 consecutive minutes at a pace at which speech becomes difficult) (mean [SD])	59.7 (25.8)	91.6 (43.0)	0.008
Multivariate risk factor analysis showed that treatment explained 17.5% of the total variance in the number of days to full recovery and sex explained a significant% of the variance (P = 0.039)			

Findings from the Rompe 2010 non-randomized study

Outcome	Time period (months)	Interventions		P value
		RSWT + (HT+ rest + ice)	(HT + rest + ice)	
Success rate (%) (using Likert)	1	29.8	12.8	All <0.001
	4	63.8	29.8	

Table A3: Summary of Findings of the Systematic Review

Main Study Findings and Author's Conclusions				
scale: 1 – 6) ^a	15	29.8	12.8	
Severity of pain (mean [SD]) (scale 1 - 10) ^b	1	5.8 (0.9)	7.3 (2.9)	All <0.001
	4	3.8 (1.1)	6.9 (0.8)	
	15	2.7 (0.9)	5.3 (2.6)	
^a 6-point Likert scale: 1 = completely recovered, 2 = much improved, 3 = somewhat improved, 4 = same, 5 = worse, and 6 = much worse. ^b Pain scale (1 to 10), where 1 = no pain, and 10 = very severe pain				
<p>Authors' Conclusions:</p> <p>"Iontophoresis, phonophoresis, ice massage, ultrasound therapy, periosteal pecking and extracorporeal shockwave therapy (ESWT) could be effective in treating MTSS when compared with control (Level 3 to 4 of evidence)." Page 1315</p> <p>"None of the studies are sufficiently free from methodological bias to recommend any of the treatments investigated. Of those examined, ESWT appears to have the most promise." Page 1316</p>				
<p>A = anesthetic, ABP = autologous blood product, AOFAS = American orthopedic foot and ankle society, CI = confidence interval, Con = conservative treatment, CS = corticosteroid, Ec = eccentric loading, ESWT = extracorporeal shockwave therapy, EQoL = Euro quality of life, FIL = functional index of lower limb activity, FSWT = focused shockwave therapy, H-FSWT = high energy focused shockwave therapy, HT = home training, L-FSWT = low energy focused shockwave therapy, MD = mean difference, M-FSWT = medium energy focused shockwave therapy, OR = odds ratio, plb = placebo, PRP = platelet-rich plasma, RMS = Roles and Maudsleys score, RR = relative risk, RSWT = radial shockwave therapy, SD = standard deviation, SMD = standardized mean difference, SW = shockwave, SWT = shockwave therapy, VAS = visual analog scale, VISA-A = Victorian Institute of Sport Assessment questionnaire – Achilles, VISA-P = Victorian Institute of Sport Assessment questionnaire – patellar</p>				

APPENDIX 5: Additional References of Potential Interest

Systematic reviews with studies that were already included in the included systematic reviews:

Al-Abbad H, Simon JV. The effectiveness of extracorporeal shock wave therapy on chronic achilles tendinopathy: a systematic review. *Foot Ankle Int.* 2013 Jan;34(1):33-41.

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Di Matteo B, Filardo G, Kon E, Marcacci M. Platelet-rich plasma: evidence for the treatment of patellar and Achilles tendinopathy--a systematic review. *Musculoskelet Surg.* 2015 Apr;99(1):1-9.

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Larsson ME, Kall I, Nilsson-Helander K. Treatment of patellar tendinopathy--a systematic review of randomized controlled trials. *Knee Surg Sports Traumatol Arthrosc*. 2012 Aug;20(8):1632-46.

Lustenberger DP, Ng VY, Best TM, Ellis TJ. Efficacy of treatment of trochanteric bursitis: a systematic review. *Clin J Sport Med [Internet]*. 2011 Sep [cited 2016 Sep 16];21(5):447-53. Available from: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3689218>

van der Worp H, van den Akker-Scheek I, van Schie H, Zwerver J. ESWT for tendinopathy: technology and clinical implications. *Knee Surg Sports Traumatol Arthrosc [Internet]*. 2013 Jun [cited 2016 Sep 16];21(6):1451-8. Available from: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3657080>