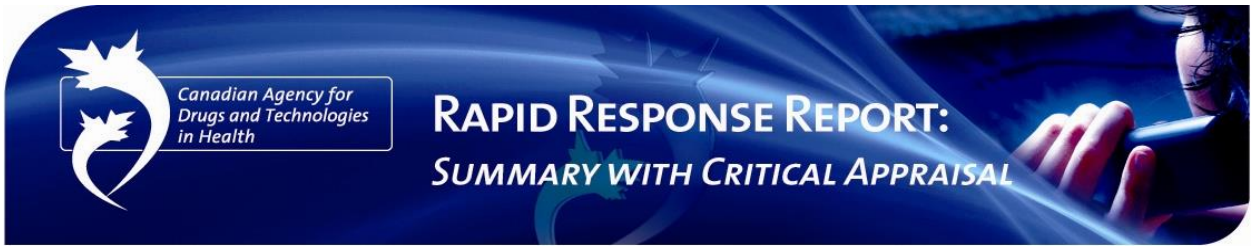

TITLE: Shockwave Therapy for Pain Associated with Upper Extremity Orthopedic Disorders: A Review of the Clinical and Cost-Effectiveness

DATE: 01 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 stimulation of tissue healing, breakdown of calcification, alteration of cell membrane permeability, and alteration of cell activity through cavitation.[6,7] Devices used for SWT vary in design, depending on the way shockwaves are generated and the level of energy that it can produce. Generally, the shockwaves are generated by electrohydraulic, electromagnetic or piezoelectric mechanisms.[6,8] 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.[8] RSWT is a low- to medium- energy shockwave that is pneumatically generated through the acceleration of a projectile inside the hand-piece of the medical device and then transmitted radially from the tip of the applicator to the target area.[8]

SWT has been used for over two decades for the treatment soft tissue and bone related

musculoskeletal disorders. There is however some debate regarding the effectiveness of SWT compared to placebo or other treatment modalities.

The purpose of this report is to review the clinical effectiveness and cost-effectiveness of shockwave therapy for pain associated with upper extremity orthopedic disorders. A separate report will 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 upper extremity orthopedic disorders?

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

KEY FINDINGS

Evidence from four systematic reviews suggests that, in comparison with placebo, shockwave therapy (SWT) using high energy is effective in reducing pain in calcific tendinitis of the shoulder. Evidence suggests that that there is no significant benefit with SWT compared to placebo or other treatments in case of non-calcific tendinitis of the shoulder. It should be noted however, that there is considerable overlap in the studies included in the four systematic reviews, hence findings are not mutually exclusive.

Findings on the effectiveness of shockwave therapy compared with placebo or control for treating lateral epicondylitis were inconsistent, hence definitive conclusions are not possible. Evidence from single studies suggests there is no significant difference between SWT and physical therapy or percutaneous tenotomy for treating lateral epicondylitis. Findings on the effectiveness of SWT compared with corticosteroid injection for treating lateral epicondylitis were inconsistent, hence definitive conclusions are not possible.

Adverse events commonly reported with SWT include pain, small bruises and hematomas, petechial bleeding, and erythema.

No studies on cost-effectiveness of SWT 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 upper 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.[9] 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[1-3,6,7,10,11] met the inclusion criteria and were included in this report. These comprised of seven systematic reviews. Appendix 1 describes the PRISMA flowchart of the study selection.

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.

Shoulder

Four relevant systematic reviews[2,3,6,7] on SWT for chronic tendinitis of the shoulder were identified. Two systematic reviews[2,7] were published from the Netherlands in 2011 and 2016, one systematic review[3] was published from USA in 2014 and one systematic review[6] was published from the UK in 2014.

The systematic review by Louwerens et al.[2] included eight RCTs and one non-randomized study that were published between 2002 and 2014, and evaluated SWT therapy for patients with chronic calcific rotator cuff tendinopathy. Only the SWT group with 346 patients was considered and data for pre- and post- treatment for this single arm were presented by the systematic review authors; data for the comparator arms were not presented. The mean ages of patients in each study ranged between 47 years to 57 years, ratios of females to males ranged between 0.7 to 8.7, and symptom durations (prior to enrollment in the study) ranged between 6 months to 5 years.

The systematic review by Huisstede et al.[7] included eight RCTs that were published between 1999 and 2008 and evaluated SWT for patients with calcific and non-calcific rotator cuff tendinosis. The mean ages of patients, proportion of females, and duration of symptoms were not reported. SWT was compared with placebo or no treatment (4 RCTs, number of patients [N]= 312), and with TENS (1 RCT, number of shoulders = 63)

The systematic review by Bannuru et al.[3] included 14 relevant RCTs that were published between 1999 and 2012 and evaluated SWT therapy for patients with chronic tendinitis of the shoulder. The mean ages of patients ranged between 52 years to 57 years, proportions of females ranged between 39% and 65%, and symptom durations ranged between three to 12 months. SWT was compared with placebo or no treatment (10 RCTs, N = 575), with exercise (1 RCT, N = 104), with radiation therapy (1 RCT, N = 60), and with TENS (1 RCT, N = 60).

The systematic review by Speed,[6] included six RCTs that were published between 2001 and 2009 and evaluated SWT for patients with calcific and non-calcific rotator cuff tendinopathy. The SWT group was compared with a control group. Details of the SWT were presented but what constituted the control treatment was not described.

All of the systematic reviews reported outcomes with respect to pain and function. Measurement scales used varied in the RCTs; the visual analog scale (VAS) and the Constant and Murley score (CMS) were used in majority of the studies. Of the four systematic reviews, two systematic reviews[2,3] reported on adverse events. The length of follow up varied between four weeks and 4 years in the included RCTs.

Elbow

Four relevant systematic reviews[1,6,10,11] on SWT for elbow pain were identified. One systematic review[1] was published from Canada in 2016, one systematic review[10] was published from the Netherlands in 2014, one systematic review[6] was published from the UK in 2014, and one systematic review was published from Australia in 2011.

The systematic review by Dion et al.[1] included five RCTs that were published between 2002 and 2014 and evaluated SWT for patients with soft tissue injury of the elbow. The ages of patients were ≥ 18 years. The proportion of females and duration of symptoms were not reported. SWT was compared with sham (4 RCTs, N = 523) and low level laser therapy (LLLT) (1 RCT, N = 60).

The systematic review by Dingemanse[10] included one systematic review published in 2005 and five RCTs published between 2005 and 2011and evaluated SWT for patients with epicondylitis. The included systematic review included 1099 patients; patient numbers for the individual RCTs were not reported. The mean ages of patients, proportion of females, and duration of symptoms were not reported. In the systematic review, SWT was compared with placebo or injection and in the individual RCTs, SWT was compared with placebo, physical therapy, or percutaneous tenotomy.

The systematic review by Speed,[6] included five RCTs that were published between 2002 and 2005 and evaluated SWT for patients with recalcitrant common extensor tendinopathy. The total number of patients was 598. The mean ages of patients, proportion of females, and duration of symptoms were not reported. The SWT group was compared with the control group (details of the control group were not presented).

The systematic review by Bisset et al[11] included two systematic reviews published in 2005 and 2006 and two individual RCTs published in 2003 and 2008, and evaluated SWT for patients with chronic tennis elbow (also referred to as lateral epicondylitis). The two included systematic reviews included 1006 and 834 patients and the two individual RCTs included 68 and 93 patients. The mean ages of patients, proportion of females, and duration of symptoms were not reported. The two systematic reviews and one RCT compared SWT with sham, and one RCT compared SWT with corticosteroid injection plus anesthetic injection.

All of the systematic reviews reported outcomes with respect to pain. One systematic review[1] reported on outcomes with respect to both pain and function using various measurement scales. Measurement scales used were not specified in three systematic reviews.[6,10,11] Of the four systematic reviews, two systematic reviews[1,11] reported on adverse events. Duration of follow-up varied between 1 week and 12 months in the included RCTs.

Summary of Critical Appraisal

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

Shoulder

Of the four included systematic reviews, three systematic reviews[2,3,7] were generally well conducted. All four systematic reviews[2,3,6,7] stated the objective and the inclusion criteria. Exclusion criteria was stated in three systematic reviews[2,3,6] and not explicitly stated in one systematic review.[7] In all four systematic reviews, a comprehensive literature search using multiple databases was undertaken, the article selection process was described, a list of included studies was provided. None of the systematic reviews provided a list of excluded studies. Article selection and data extraction was done in duplicate and quality assessment was conducted in three systematic reviews[2,3,7] and was unclear in one systematic review.[6] The quality of the studies varied from low to high but was generally of low quality. Characteristics of

the individual included studies was described in all the four systematic reviews but details regarding patient characteristics were lacking in two systematic reviews.[6,7] No pooling of data was undertaken in the systematic reviews, likely because the studies were heterogeneous. One systematic review[3] presented Forest plots of individual studies without pooling, but details of the data used were lacking. Publication bias does not appear to have been explored in any of the systematic reviews. In three systematic reviews[2,3,6] the authors stated there was no conflict of interest and in one systematic review[7] conflict of interest was not mentioned.

Elbow

Of the four included systematic reviews, two systematic reviews[1,10] were generally well conducted. All four systematic reviews[1,6,10,11] stated the objective, and the inclusion criteria. Exclusion criteria was stated in one systematic review[6] and not explicitly stated in three systematic reviews.[1,10,11] In all four systematic reviews, a comprehensive literature search using multiple databases was undertaken, and a list of included studies was provided. None of the systematic reviews provided a list of excluded studies. The study selection process was described in three systematic reviews[1,6,10] and was not described in one systematic review.[11] Article selection and data extraction was done in duplicate in two systematic reviews[1,10] and was unclear in two systematic reviews.[6,11] Quality assessment of the included studies was undertaken in three systematic reviews[1,10,11] and not in one systematic review.[6] The quality of the evidence was variable. Description of characteristics of patients in the individual studies was lacking in all the systematic reviews. Publication bias does not appear to have been explored in any of the systematic reviews. In three systematic reviews[1,6,10]the authors stated there was no conflict of interest and in one systematic review[11] two of the three authors were involved with some of the included RCTs, and the third author was stated to have no conflict of interest.

Summary of Findings

What is the clinical effectiveness of shockwave therapy for chronic pain?

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.

Shoulder

Four relevant systematic reviews[2,3,6,7] comparing SWT with sham or active treatment for chronic tendinitis of the shoulder were identified. Findings are summarized below and details are provided in Appendix 4, Tables A3.

The systematic review by Bannuru et al.[3] compared SWT with placebo for chronic calcific and non-calcific tendinitis of the shoulder. Two RCTs (Gerdesmeyer 2003, and Hsu 2008) and four RCTs (Loew 1999, Cosentino 2003, Gerdesmeyer 2003, and Hsu 2008) on patients with calcific tendinitis, comparing high energy SWT (H-SWT) with placebo showed statistically significant between group differences favoring H-SWT for pain reduction and function improvement, respectively. For patients with calcific tendinitis, two RCTs (Gerdesmeyer 2003, and Cacchio 2006) and two RCTs (Loew 1999, and Gerdesmeyer 2003) comparing low energy SWT (L-SWT) with placebo showed a statistically significant between group difference favoring L-SWT for pain reduction and function improvement, respectively. For non-calcifc tendinitis the between group differences were not statistically significant for pain reduction (from two RCTs: Schmitt 2002 and Speed 2002). Also, for non-calcifc tendinitis, with respect to function improvement, the

between group difference was not statistically significant in one RCT (Schmitt 2002) and statistically significant favoring L-SWT in one RCT (Glasso 2012). Adverse events were reported in eight RCTs. Commonly reported adverse events associated with SWT treatment, included small bruises and hematomas, petechiae, erythema, and acute pain. More adverse events were reported for H-SWT or medium SWT compared to L-SWT or placebo. In summary, in comparison to placebo there was a statistically significant improvement with H-SWT for calcific tendinitis of the shoulder but not for non-calcific tendinitis of the shoulder.

The systematic review by Bannuru et al.[3] also compared SWT with other modalities for treating chronic tendinitis of the shoulder. One study (Engebretsen 2011) comparing SWT with exercise showed that in the short term (18 weeks) SWT was less effective than supervised exercise, but in the long term (12 months) there was no significant difference between the two groups. Also, concomitant drug use at 18 weeks or 12 months was not statistically significantly different between the two groups. Two studies (Gross 2001, Gross 2002) comparing SWT with radiation therapy showed no statistically significant differences in outcomes with treatment with SWT or radiation therapy. One study (Pan 2003) comparing SWT with TENS showed that SWT was more effective than TENS with respect to pain and Constant score outcomes.

The systematic review by Huisstede et al.[7] investigated the effects of SWT for calcific and non-calcific rotator cuff tendinosis. Two RCTs (Gerdesmeyer 2003, and Hsu 2008) on calcific rotator cuff tendinosis comparing H-SWT with placebo showed that there were statistically significant between group differences favoring SWT for pain reduction and Constant score at three, six, and 12 months follow-up. One RCT (Loew 1999) on calcific rotator cuff tendinitis showed that Constant scores were statistically significantly higher at 3 months follow-up for H-SWT compared with no treatment. One RCT (Cacchio 2006) on calcific rotator cuff tendinosis comparing RSWT with placebo showed that pain reduction and patient satisfaction were significantly better with RSWT but for function there was no statistically significant difference between the groups. Two RCTs (Schmitt 2002 and Schmitt 2001) on non-calcific rotator cuff tendinosis comparing SWT (H-SWT in one RCT and L-SWT in one RCT) with placebo showed there were no statistically significant between group differences for pain and Constant score. In summary, in comparison to placebo there is a statistically significant improvement with SWT for calcific tendinitis of the shoulder but not for non-calcific tendinitis of the shoulder. One RCT (Pan 2003) on calcific rotator cuff tendinosis comparing H-SWT with TENS showed there were statistically significant between group differences favoring H-SWT for pain and Constant score. One RCT (Gross 2002) on non-calcific rotator cuff tendinosis comparing-SWT with radiotherapy showed there were no statistically significant between group differences for pain at 12 or 52 weeks follow up.

The systematic review by Louwerens et al.[2] investigated the effects of H-SWT for the management of chronic calcific rotator cuff tendinopathy. This systematic review presented data from the SWT arms of nine trials (eight RCTs and one non-randomized trial) and compared pre- and post-treatment data. Seven trials showed H-SWT significantly improved shoulder function at six months follow up and five trials showed the improvement in shoulder remained up to one year. One trial (Kim 2014) reported a significant increase in American Shoulder and Elbow Surgeons (ASES) score and Simple Shoulder Test score after 2 years. One prospective non-randomized trial (Daecke 2002) reported promising results with H-SWT for CMS after 4 years. Frequently reported peri-treatment side effects with H-SWT included pain, erythema, local intracutaneous petechial bleeding, subcutaneous hematomas. However, these side effects affected a small number of patients and were resolved within a few days after treatment. No post-treatment complications were reported. In summary, this systematic review showed that

there was improvement with SWT compared to baseline status, in patients with calcific tendinitis of the shoulder.

The systematic review by Speed[6] examined shockwave therapies for several soft tissue conditions, including calcific and non-calcific rotator cuff tendinopathy. Three RCTs (Albert 2007, Cosentino 2003, and Gerdesmeyer 2003) showed significant benefit with FSWT compared with control at 12 weeks for calcific rotator cuff tendinopathy. Three RCTs (Schofer 2009, Speed 2002, and Schmitt 2001) showed no significant benefit with FSWT compared with control at 12 weeks for non-calcific rotator cuff tendinopathy. In summary, in comparison to control there was a statistically significant improvement with SWT for calcific tendinitis of the shoulder but not for non-calcific tendinitis of the shoulder.

Elbow

Four relevant systematic reviews[1,6,10,11] on SWT for soft tissue conditions (such as lateral epicondylitis, tennis elbow) were identified. Findings are summarized below and details are provided in Appendix 4, Tables A3.

One systematic review by Bisset et al.[11] included two systematic reviews and one RCT. It concluded that compared to sham, SWT may not be more effective for pain reduction at 4 to 6 weeks, or for pain reduction during resisted wrist extension at 12 weeks (low quality evidence). Also, compared with corticosteroid injection plus local anesthetic injection, SWT may be less effective for pain reduction at six weeks and three months (low quality evidence). Compared with placebo, SWT appears to be no more effective for improving function or pain-free grip at six weeks to six months (moderate quality evidence). The two systematic reviews presented no information on adverse effects. The RCT reported similar low rates of adverse effects in both the SWT and sham groups. Adverse effects included isolated cases of increased pain, bruising or lumps after treatment, and burning sensation. Statistical significance for the difference between the two groups was not determined. In summary, for lateral epicondylitis SWT did not appear to be any more effective than placebo and may be less effective than corticosteroid injection.

One systematic review by Dion et al.[1] on the management of common soft tissue injuries of the elbow compared SWT with sham treatment or an active treatment in patients with persistent lateral epicondylitis. This systematic review included five RCTs of which four RCTs compared SWT with sham and one RCT compared SWT with low level laser therapy (LLLT). One RCT (Spacca 2005), comparing RSWT with sham (sub therapeutic RSWT), showed statistically significant between group differences favoring RSWT for pain intensity, pain-free grip strength, and disability immediately after treatment and at six months follow up. However, the clinical significance of these outcomes could not be determined as minimal clinically important differences (MCIDs) were not known. A second RCT (Pettrone 2005) comparing SWT with sham showed statistically significant between group differences favoring SWT for pain intensity, function, activity score, and overall impression of disease status at 12 weeks; the difference was also considered clinically significant for pain intensity. However, for the clinical significance of the other outcomes could not be determined as MCIDs were not known. A third RCT (Haake 2002) comparing SWT with sham found no statistically or clinically significant between group differences for pain or grip strength at 6 weeks, 12 weeks, and 12 months. A fourth RCT (Speed 2002) comparing SWT with sham found no statistically or clinically significant between group differences for pain at one, two, or three months. In summary, there was inconclusive evidence regarding the effectiveness of SWT for persistent lateral epicondylitis. A study (Devrimsel 2014)

comparing SWT with LLLT showed statistically significant between group differences favoring SWT for pain intensity, hand grip strength, and some subscales of the short-form McGill Pain Questionnaire at one or four weeks. The authors mentioned that clinical importance could not be judged as results were presented graphically; raw data was not available.

In the systematic review by Dion et al.,[1] no serious adverse events were reported in four RCTs (Pettrone 2005, Spacca 2005, Haake 2002, Speed 2002). One RCT (Haake 2002) showed that adverse events were four times more likely to be reported in the SWT group compared to the sham group (odds ratio [OR] 4.3, 95% confidence interval [CI] 2.9 to 6.3) Commonly reported adverse events included reddening of the skin, pain, and petechiae/ bleeding/ hematoma and were generally higher in the SWT group compared to the placebo group. In one RCT (Speed 2002), 5% in the SWT group withdrew due to worsening of symptoms and 6% in the sham group withdrew for unknown reasons. In one RCT (Pettrone 2005), 50% in the SWT group and 22% in the sham group experienced moderate transient pain related to treatment. In one RCT (Spacca 2005) no adverse events were reported.

One systematic review by Dingemanse et al.[10] presented findings with SWT in comparison with placebo or other active treatments in patients with epicondylitis. This systematic review included one systematic review and seven additional RCTs. The included systematic review demonstrated that there was no significant difference in outcomes between SWT and placebo groups at 1, 3, 6, and 12 months follow-up (evidence from two RCTs); no significant difference in > 50% pain reduction at 4 to 6 weeks (evidence from four RCTs); no significant difference in pain reduction at 4 to 6 months follow-up (evidence from pooled results with three RCTs); no significant difference in pain or grip strength at 12 weeks (evidence from pooled results with three RCTs); and a significant between group difference favoring SWT for 50% pain reduction at 12 months (relative risk [RR] 2.21 [95% CI 1.55 to 3.12], evidence from pooled results of two RCTs). Of the five additional RCTs comparing SWT with placebo, two RCTs showed no significant between group differences and three RCTs showed a significant between group difference favoring SWT with respect to pain at 8 to 12 weeks. One RCT comparing SWT with percutaneous tenotomy showed there was no significant between group difference and one RCT comparing SWT with physical therapy showed there was no significant between group difference. However, one RCT comparing SWT with corticosteroid injection showed a significant between group difference favoring corticosteroid injection with respect to success rate (> 50% reduction in pain) at three months follow-up but this did not remain significant at six months. In summary, there was conflicting evidence for the effectiveness of SWT compared with placebo.

One systematic review by Speed[6] on shockwave therapies for soft tissue conditions reported on findings in chronic common extensor tendinopathy (lateral epicondylitis) for low dose FSWT compared with a control. The evidence found was conflicting. Of the five RCTs included, three RCTs showed no significant between group differences with respect to pain reduction and two RCTs showed significant between group differences with respect to pain reduction, favoring FSWT. The evidence on the effectiveness of SWT for lateral epicondylitis was conflicting and the author concluded that further research regarding treatment regimens was needed.

What is the cost-effectiveness of shockwave therapy for chronic pain?

No relevant studies were identified on cost-effectiveness of shock-wave therapy for chronic pain.

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.

There was considerable overlap in the RCTs included in the systematic reviews, hence findings from these systematic reviews are not mutually exclusive.

The authors used various tools for assessing study quality, and there were some inconsistencies in quality assessment results of the included individual studies in the systematic reviews. Also, 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. In some systematic reviews details of patient characteristics in the included RCTs were lacking. The MCIDs 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 were identified.

CONCLUSIONS AND IMPLICATIONS FOR DECISION OR POLICY MAKING

Seven relevant systematic reviews[1-3,6,7,10,11] on SWT were identified. These comprised three systematic reviews[1,10,11] evaluating studies on shoulder pain, three systematic[2,3,7] evaluating studies on patients with chronic elbow pain and one systematic review[6] evaluating studies on a variety of conditions, included studies on chronic shoulder pain and chronic elbow pain.

Evidence from four systematic reviews[1,6,10,11] suggests that in comparison with placebo, H-SWT is effective for reducing pain in calcific tendinitis of the shoulder. Evidence suggests that that there is no significant benefit with SWT compared to placebo or other treatments in case of non-calcific tendinitis of the shoulder. It should be noted however, that there is considerable overlap in the studies included in these systematic reviews, hence findings are not mutually exclusive. Evidence from single RCTs on tendinitis of the shoulder suggests that there is no significant difference between SWT and treatment with exercise or radiotherapy. Evidence from a single RCT on tendinitis of the shoulder suggests SWT is more effective than TENS. Commonly reported adverse events included pain, small bruises and hematomas, petechial bleeding and erythema. More adverse events were reported for high energy SWT compared with low energy SWT or placebo. Adverse events were not reported in all the systematic reviews.

Findings on the effectiveness of SWT compared with placebo or control for treating lateral epicondylitis were inconsistent, hence definitive conclusions are not possible. Evidence from single studies suggests there is no significant difference between SWT and physical therapy or percutaneous tenotomy. Findings on the effectiveness of SWT compared with corticosteroid injection for treating lateral epicondylitis were inconsistent, hence definitive conclusions are not possible. Commonly reported adverse events included reddening of the skin, pain, petechial bleeding, and hematoma, and were generally higher in the SWT group compared to placebo group. Adverse events were not reported in all the systematic reviews.

It appears that techniques for using SWT for orthopedic disorders still need to be standardized.[12] 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.[12]

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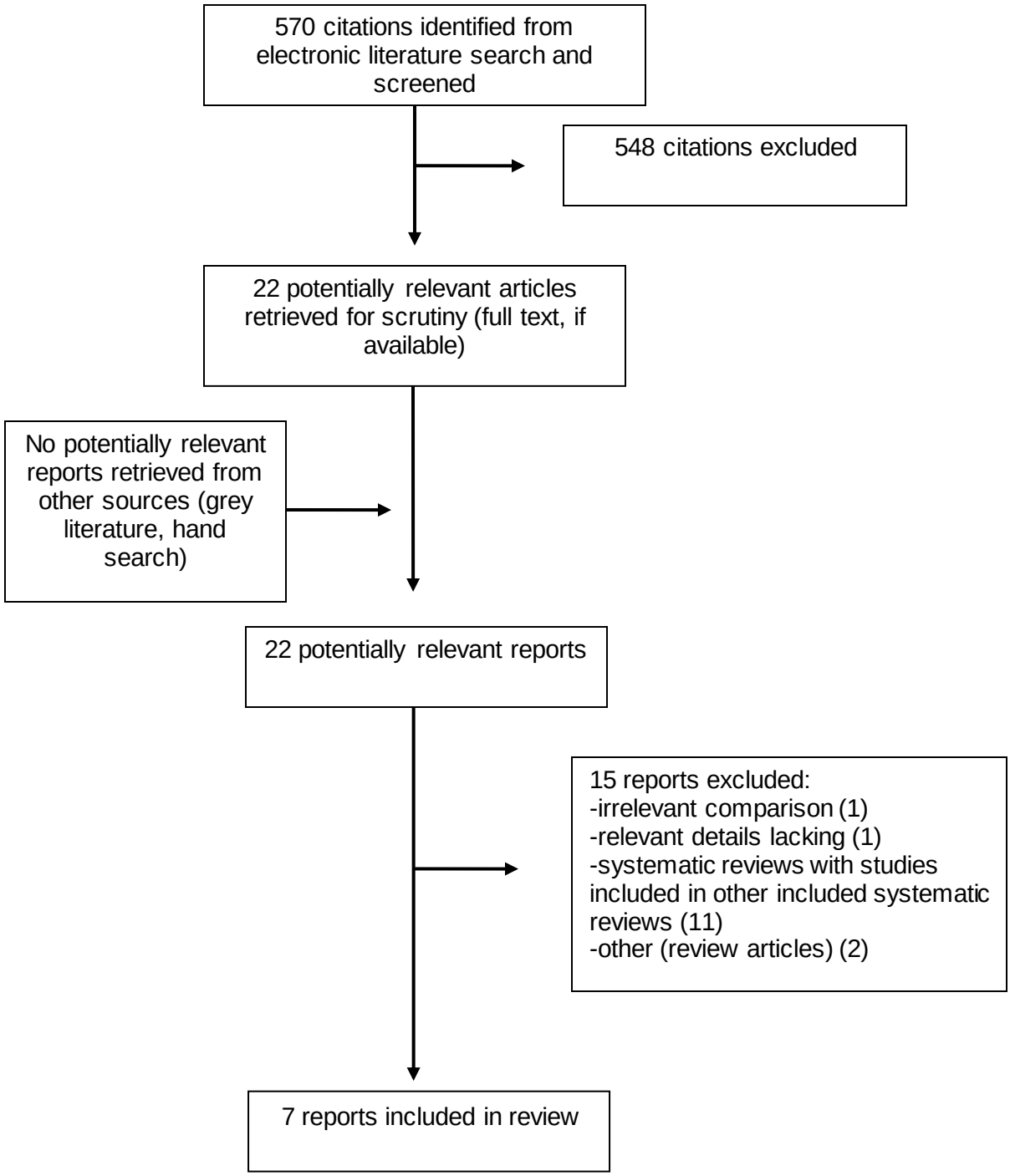
ABBREVIATIONS

APS	affective pain subscale
ASES	American Shoulder and Elbow Surgeons score
CMS	Constant and Murley score
CI	confidence interval
DASH	Disability of the arm, shoulder and hand scale
ESWT	extracorporeal shock-wave therapy (used interchangeably with SWT)
FSW	focused shock-wave
FSWT	focused shock-wave therapy
FU	follow-up
H-SWT	high energy shock-wave therapy
Hz	Hertz (unit for frequency)
LLLT	low level laser therapy
L-SWT	low energy shock-wave therapy
M-SWT	medium energy shock-wave therapy
MCID	minimal clinical important difference
MD	mean difference
mJ	millijoule (unit for energy intensity)
mm	millimeter
NR	not reported
NS	not significant
OR	odds ratio
plb	placebo
PPI	present pain intensity
QA	quality assessment
RC	rotator cuff
RCT	randomized controlled trial
RR	relative risk
RSW	radial shock-wave
RSWT	radial shock-wave therapy
SD	standard deviation
SF-MPQ	short form McGill Pain Questionnaire
SMD	standardized mean difference
SPADI	shoulder pain and disability index
SPS	sensory pain subscale
SR	systematic review
SST	simple shoulder test
SWT	shock wave therapy (used interchangeably with ESWT)
T	tendinitis
TENS	transcutaneous electric nerve stimulation
TPS	total pain scale scores
tx	treatment or therapy
VAS	visual analog scale
vs	versus
WMD	weighted mean difference

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]
Shoulder				
Bannuru,[3] 2014, USA Aim: to assess efficacy of SWT for calcific or noncalcific tendinitis of the shoulder	14 RCTs (published: 1999 to 2012)	Patients with chronic tendinitis of the shoulder *SWT vs plb,or no tx:* N = 575, Age (mean) (years) = 52 to 56 (NR in 2 RCTs) % Female = 39 to 61 (NR in 2 RCTs) Symptom duration (month): 6 to 12 *SWT vs exercise:* N = 104, Age (mean) (years) = 48 % Female = 50 Symptom duration (month): 3 *SWT vs radiation tx* N = 60 Age (mean) (years) = 53 (NR in 1 RCT) % Female = 50 (NR in 1 RCT) Symptom duration (month): 6 (NR in 1 RCT) *SWT vs TENS* N = 60 Age (mean) (years) = 57 % Female = 65 Symptom duration (month): 6	SWT vs no tx (1 RCT), SWT vs plb (9 RCTs) SWT vs exercise (1 RCT), SWT vs radiation tx (2 RCTs), SWT vs TENS (1 RCT) The type of SWT used varied: energy values between 0.07 mJ/mm2 and 0.55 mJ/mm^2; number of pulses between 1500 and 6000; number of doses between 1 and 5.	Pain, function, (Scales used: VAS, CMS, SPADI, function subscale of UCLA shoulder rating scale) AE Duration of FU (month): 3 to 12
Huisstede,[7] 2011, Netherlands	8 RCTs (published: 1999 to 2008)	Patients with calcific and non-calcific rotator cuff tendinosis	ESWT vs plb, no tx, or radiotherapy The type of ESWT used	Pain level, function level, subjective improvement. (Scales used: VAS, CMS [also referred to as

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]
		N = 475 Age: NR % Female: NR Symptom duration: NR	varied: energy values between 0.1 mJ/mm^2 and 0.55 mJ/mm^2; number of pulses and sessions varied and was not reported in all cases	Constant score], UCLA shoulder rating scale) Duration of FU: 4 weeks to 12 months
Louwerens,[2] 2016, Netherlands	8 RCTs and 1 non-randomized study (published: 2002 to 2014)	Adult patients with chronic calcific rotator cuff tendinopathy N = 346 Age (mean) (year): 47 to 57 Female/Male ratio: 0.7 to 8.7 Symptom duration : 6 months to 5 years (7 RCTs) and NR (1 RCT)	H-SWT Energy varied between 0.20 mJ/mm^2 and 0.55 mJ/mm^2; number of pulses between 1,000 and 2,400; and number of sessions between 1 and 4.	Pain level, function level. (Scales used: ASES, SST, VAS, CMS) AE Duration of longest FU (months): 6 to 48
Speed,[6] 2014, UK	6 RCTs (published: 2001 to 2009)	Patients with calcific or non-calcific rotator cuff tendinopathy N = 448 Age: NR % Female: NR Symptom duration: NR	FSWT vs Sham Energy varied between 0.11 mJ/mm^2 and 0.78 mJ/mm^2; number of pulses between 1,200 and 6,000; and number of sessions between 2 and 4.	Pain level (Scales: CMS, SPADI). Duration of FU: 12 weeks to 12 months
Elbow				
Bisset, [11] 2011, Australia	2 SRs: 1 SR published in 2005, included 10 RCTs and 1 SR published in 2006 included 8 RCTs), and 2 RCTs (published in 2003 and 2008)	Patients with chronic tennis elbow *SWT vs sham:* 1SR include 9 RCTs with 1006 patients; 1 SR included 8 RCTs with 834 patients; I RCT with 68 patients *SWT vs injection:* 1 RCT with 93 patients Age: NR % Female: NR Symptom duration: NR	SWT vs Sham: 2 SRs and 1 RCT SWT vs corticosteroid injection plus anesthetic injection: 1 RCT	Pain level, function (VAS, DASH, 8 item pain-free function index, pain-free grip strength). AE Duration of FU: 4 weeks to 6 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]
Dion,[1] 2016, Canada	5 RCTs (published 2002 to 2014)	Adults with soft tissue injury of the elbow (lateral epicondyle pain) SWT vs sham N = 523 (4 RCTs) SWT vs LLLT: N = 60 (1 RCT) Age: ≥ 18 (in 3 RCTs),18 to 60 in 1 RCT, and 31 to 65 in 1 RCT. % Female: NR Symptom duration: NR	SWT vs sham or LLLT. SWT intensity: 0.06 mJ/mm^2 to 0.18 mJ/ mm^2, or 1 to 1.6 bar	Pain, tenderness, function (VAS, SF-MPQ APS, SF-MPQ PPI, SF-MPQ SPS, SF-MPQ TPS) AE Duration of FU: 1 week to 12 months
Dingemanse,[10] 2014, Netherlands	1 SR published in 2005 and including 10 RCTs; as well as 5 individual RCTs (published: 2005 to 2011)	Patients with epicondylitis N = 1099 in SR, N = NR in the included individual RCTs Age: NR % Female: NR Symptom duration: NR	SWT vs placebo or injection (in SR) SWT vs plb, physical therapy (combination of hot pack, ultrasound and friction message); or percutaneous tenotomy	Pain, grip strength, general improvement (specifics not presented) Duration of FU: 1 month to 12 months
Speed,[6] 2014, UK	5 RCTs (Lebrun 2005, Pettrone 2005, Rompe 2004, Speed 2002, and Haake 2002)	Patients with chronic recalcitrant common extensor tendinopathy (lateral epicondylitis) N = 598 Age: NR % Female: NR Symptom duration: NR	FSWT (low dose) vs control group FSWT intensity 0.03 mJ/ mm^2 to .17 mJ/mm^2, number of pulses: 1500 to 2000 and 3 sessions)	Pain, success rate (> 50 % reduction in pain) Duration of FU: 12 weeks

AE = adverse events, APS = affective pain subscale, ASES = American shoulder and elbow surgeons score, CMS = Constant and Murley score, DASH = disability of the arm, shoulder, and hand scale, ESWT = extracorporeal shockwave therapy (used interchangeably with SWT), FSWT = focused shockwave therapy, FU = follow -up, H-SWT = high energy shockwave therapy, LLLT = low energy laser therapy, NR = not reported, PPI = present pain intensity, RCT = randomized controlled trial, SF-MPQ = short form McGill pain questionnaire, SPADI = shoulder pain and disability index, SPS = sensory pain subscale, SR = systematic review , SST = simple shoulder test, SWT = shockwave therapy (used interchangeably with ESWT), TPS = total pain scale score, VAS = visual analog scale, vs = versus.

[a]Only 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[9]

Strengths	Limitations
Shoulder	
Bannuru,[3] 2014, USA	
• The objective was clearly stated. • The inclusion and exclusion criteria were stated. • Multiple databases (Medline, Embase, Cochrane Central register of Controlled Trials, Web of Science, and Google scholar) were searched from inception to November 2013 • Study selection was described and the flow chart of the study selection process was presented • List of included studies was provided • Article selection was done by three reviewers and eligibility determined by consensus • Data extraction was done by three reviewers independently • Quality assessments of studies were conducted based on the Cochrane risk of bias tool. The quality of the studies was generally low. • Characteristics of the individual studies were provided • The authors stated that there was no conflict of interest.	• List of excluded studies was not provided • Publication bias does not appear to have been explored • Metaanalysis details were not presented • There appeared to be some inconsistencies in the results reported in the text and in the figure.
Huisstede,[7] 2011, Netherlands	
• The objective was clearly stated. • The inclusion criteria were stated, exclusion criteria was not explicitly stated. • Multiple databases (PubMed, Embase, Pedro, Cinahl, and Cochrane library) were searched up to October 2010 • Study selection was described but the flow chart of the study selection process was not presented • List of included studies was provided • Article selection was done by two reviewers and eligibility determined by consensus • Data extraction was done by two reviewers independently • Quality of the studies were assesses independently by two reviewers, using the 12 quality criteria by Furlan et al.[13] (Cochrane Back Review group). Three RCTs were of high quality and 5 RCTs were of low quality. • Characteristics of the individual studies were	• List of excluded studies was not provided • Pooling of studies was not undertaken as studies were heterogeneous • Publication bias does not appear to have been explored • There was no mention of conflict of interest

Table A2: Strengths and Limitations of Systematic Reviews and Meta-Analyses using AMSTAR checklist[9]

Strengths	Limitations
provided but lacked details on patient characteristics • Pooling of studies was not undertaken as studies were heterogeneous	
Louwerens,[2] 2016, Netherlands	
• The objective was clearly stated. • The inclusion and exclusion criteria were stated. • Multiple databases (Medline, Embase, Pedro, Cinahl, Sportdiscus, and Cochrane database of systematic reviews) were searched from 1978 to December 2014 • Study selection was described and the flow chart of the study selection process was presented • List of included studies was provided • Article selection was done by two reviewers independently and eligibility determined by consensus • Data extraction was done by two reviewers independently • Quality assessments of studies were conducted based on the criteria developed by Coleman et al. (a validated scale) The quality of the studies was generally good (Coleman score ranged between 80 and 94 in 6 RCTs, 77 in 1 RCT and 62 in 1 RCT) • Characteristics of the individual studies were provided • The authors stated that there was no conflict of interest.	• List of excluded studies was not provided • Pooling of studies was not undertaken (possibly due to heterogeneity of the studies; also the authors investigated conditions before and after H-SWT, hence considered only the active treatment arm in the RCT) • Publication bias does not appear to have been explored
Speed,[6] 2014, UK	
• The objective was clearly stated. • The inclusion and exclusion criteria were stated. • List of included studies was provided • Multiple databases (PubMed, Embase, and Cochrane database); orthopedic, rheumatology, and sports medicine journal; references in review articles and shock-wave literature; and the general internet were searched for articles published between from 1980 and 2012. • Study selection was described and the flow chart of the study selection process was presented • Characteristics of the individual studies were provided but lacked details on patient	• List of excluded studies was not provided • Unclear if article selection was done in duplicate • Unclear if data extraction was done in duplicate • Unclear if quality assessment was undertaken. However, the authors mentioned that studies with methodological deficiencies would be excluded. • Pooling of studies was not undertaken (possibly due to heterogeneity of the studies • Publication bias does not appear to have been explored

Table A2: Strengths and Limitations of Systematic Reviews and Meta-Analyses using AMSTAR checklist[9]

Strengths	Limitations
characteristics • The authors stated that there was no conflict of interest.	
Elbow	
Bisset, [11] 2011, Australia	
• The objective was clearly stated. • The inclusion criteria were stated. • Multiple databases (Medline, Embase, and Cochrane database of systematic reviews) were searched up to November 2009. Cochrane library was searched for database of abstracts of reviews of effects (DARE) and health technology assessment (HTA) • List of included studies was provided • Quality of the evidence was assessed using Grading of recommendations assessments, development and evaluation (GRADE) and was variable ranging from very low to moderate. • Characteristics of the individual studies were provided but lacked details on patient characteristics and intervention descriptions • One author was co-author of two RCTs and one SR that are included in this review. One author was co-author in several RCTs included in this review and one author had no competing interests	• The exclusion criteria was not explicitly stated • Study selection process was unclear • List of excluded studies was not provided • Unclear if article selection was done in duplicate • Unclear if data extraction was done in duplicate • Pooling of studies was not generally undertaken (possibly due to heterogeneity of the studies) • Publication bias does not appear to have been explored
Dion, [1] 2016, Canada	
• The objective was clearly stated. • The inclusion and exclusion criteria were stated. • Multiple databases (Medline, Embase, Cinahl, Psycinfo and Cochrane central register of controlled trials) were searched from January 1990 to January 2015. Reference lists of relevant systematic reviews were hand searched for additional references • Study selection was described and the flow chart of the study selection process was presented • List of included studies was provided • Article selection was done by two reviewers independently and eligibility determined by consensus • Data extraction was done by one reviewer and checked by a second reviewer and also further checked by a senior epidemiologists • Quality assessments of studies were conducted based on the Scottish Intercollegiate Guidelines Network (SIGN) criteria. The	• List of excluded studies was not provided • Pooling of studies was not undertaken (possibly due to heterogeneity of the studies) • Publication bias does not appear to have been explored

Table A2: Strengths and Limitations of Systematic Reviews and Meta-Analyses using AMSTAR checklist[9]

Strengths	Limitations
studies generally had low risk of bias. • Characteristics of the individual studies were provided but lacked details on patient characteristics. • The authors stated that there was no conflict of interest.	
Dingemanse,[10] 2014, Netherlands	
• The objective was clearly stated. • The inclusion criteria were stated. • Multiple databases (PubMed, Embase, Cinahl, Pedro and Cochrane library) were searched up to February 2010 for SRs and up to August 2012 for RCTs • Study selection was described and the flow chart of the study selection process was presented • Article selection was done by two reviewers independently and eligibility determined by consensus • Data extraction was done by two reviewers independently • Quality assessments of studies were conducted based on the criteria adapted from Furlan et al. High quality was defined as a "yes" score ≥ 50%. Of the 10 RCTs included in the included SR, QA scores were ≥ 50% for 6 RCTs, < 50% in 2 RCTs and unclear in 2 RCTs. Of the 5 individual individual RCTs the QA scores were ≥ 50% in 4 RCTs and < 50% in 1 RCT. • The authors stated that there was no conflict of interest.	• The exclusion criteria were not explicitly stated. • List of excluded studies was not provided • Description of patient characteristic and interventions were lacking. • Pooling of studies was not undertaken (possibly due to heterogeneity of the studies) • Publication bias does not appear to have been explored
Speed,[6] 2014, UK	
• Strengths and limitations of this systematic review (which includes studies on shoulder, elbow and heel) are presented above in the section on "Shoulder"	

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

Shoulder

Bannuru,[3] 2014, USA

Main Findings:

ESWT versus placebo

Comparison of ESWT with placebo for treating tendinitis (T) of the shoulder

Condition	Comparison	No. of RCTs	Outcome	Findings from meta-analysis (as shown in the figure)
Calcific T	H-ESWT vs plb	2 (Gerdesmeyer 2003, Hsu 2008)	Pain reduction	h-ESWT statistically significantly better than plb
Calcific T	L-ESWT vs plb	2 (Gerdesmeyer 2003, Cacchio 2006)	Pain reduction	L-ESWT statistically significantly better than plb
Non-calcific T	L-ESWT vs plb	2 (Schmitt 2002, Speed 2002)	Pain reduction	L-SWT and plb not statistically significantly different
Calcific T	H-ESWT vs plb	4 (Loew 1999, Cosentino 2003, Gerdesmeyer 2003, Hsu 2008)	Function improvement	H-SWT statistically significantly better than plb
Calcific T	L-ESWT vs plb	2 (Loew 1999, Gerdesmeyer 2003)	Function improvement	L-SWT statistically significantly better than plb
Non-calcific T	L-ESWT vs plb	2 (Schmitt 2002, Glasso 2012)	Function improvement	Inconsistent. L-SWT statistically significantly better than plb in l RCT and no statistically significant difference in the two treatments in 1 RCT

H-ESWT = high energy extracorporeal shock wave therapy, L-ESWT = low energy extracorporeal shock wave therapy, plb = placebo, T = tendinitis, vs = versus

Calcification: Five studies showed that H-ESWT that reduction in calcification was significantly greater with H-ESWT compared with placebo treatment and results for L-ESWT were inconclusive.

Adverse events

Adverse events were reported in eight RCTs. Commonly reported adverse events associated with ESWT treatment, included small bruises and hematomas, petechiae, erythema, and acute pain. More adverse events were reported for high- or medium- energy SWT compared to low-energy ESWT or placebo.

ESWT versus exercise

One study (Engebretsen 2011) showed that in the short term (18 weeks), ESWT was less effective than supervised exercise but in the long term (12 months) there was no significant difference between the two groups. Also concomitant drug use at 18 weeks or 12 months was not statistically significantly different between the two groups.

Table A3: Summary of Findings of the Systematic Review

Main Study Findings and Author's Conclusions

ESWT versus radiation therapy

Two studies (Gross 2001, Gross2002) showed that, no statistically significant differences in outcome with treatment with ESWT or radiation therapy

ESWT versus TENS

One study (Pan 2003) showed that ESWT was more effective than TENS with respect to pain, Constant score, and calcification resolution outcomes

Authors' Conclusions:

"High-energy ESWT is effective for improving pain and shoulder function in chronic calcific shoulder tendinitis and can result in complete resolution of calcifications." Page 542

Huisstede,[7] 2011, Netherlands

Main Findings:

Calcific RC-tendinosis

Study, patient number, comparison	Outcome measure	Time point	SWT	Placebo, no tx, or active tx	*P*-value
Gerdesmeyer[a] 2003, N = 96, H-SWT vs plb	Pain (VAS), mean (SD) or MD (95% CI)	Baseline	6.5 (1.3)	5.6 (1.6)	NR
		12 months	-5.6 (-6.3 to -4.9)	-1.9 (-2.7 to -1.2)	<0.001
	CMS, Mean (SD) or MD (95% CI)	Baseline	60 (11.0)	64.2 (12.8)	NR
		12 months	31.6 (27.3 to 36.0)	13.7 (8.4 t0 19.0)	0.001
Hsu[b] 2008, N = 46, H-SWT vs plb	Pain (VAS),	Baseline	7.2	NR	>0.05 (but stated as comparable)
		12 months	1.3	NR	<0.005
	Constant score	Baseline	57.3	56.2	<0.05
		12 months	88	NR	<0.05
Loew[c] 1999, N = 80, H-SWT1 (I session) vs no tx; H-SWT2 (2 sessions) vs no tx	Constant score, mean (SD), H-SWT1 vs no tx;	Baseline	39.0 (11.8)	44.5 (8.3)	NS
		12 months	63.7 (14.6)	47.8 (11.4)	<0.0001
	Constant score, mean (SD), H-SWT1 vs no tx;	Baseline	43.5 (13.1)	44.5 (8.3)	NS
		12 months	68.5 (13.1)	47.8 (11.4)	<0.0001
Cacchio[d] 2006,	Pain, mean (SD)	Baseline	1.39 90.97)	1.04 (1.03)	0.897

Table A3: Summary of Findings of the Systematic Review

Main Study Findings and Author's Conclusions

N = 90, RSWT vs plb		6 months	7.95 (0.92)	2.64 (1.14)	0.002
	Function, mean (SD)	Baseline	2.10 (0.33)	2.18 (0.45)	0.474
		6 months	4.50 (0.82)	2.45 (1.61)	0.163
	Patient satisfaction, mean (SD)	Baseline	0.80 (0.50)	0.84 (0.45)	0.749
		6 months	4.60 (1.03)	1.05 (0.95)	0.001
Pan[e] 2003, Number of shoulders = 63, H-SWT vs TENS	Pain (VAS), MD (95% CI)	12 weeks	-4.08 (-8.00 to 3.00)	-1.74 (-5.50 to 2.00)	0.000
	Constant score, MD (95% CI)	12 weeks	28.31 (-4.00 to 51.00)	11.86 (-6.00 to 54.00)	0.000

CI = confidence interval ,CMS = Constant and Murley score, H-SWT = high energy shockwave therapy, MD = mean difference, NR = not reported, NS = not significant, plb = placebo, RSWT = radial shockwave therapy, SD = standard deviation, TENS = transcutaneous electric nerve stimulation, VAS = visual analog scale, vs = versus

Note:

[a] In Gerdesmeyer 2003, for H-SWT vs plb, the between group differences with respect to pain and CMS were statistically significant also at 3 and 6 months, favoring H-SWT

[b] In Hsu 2008, for H-SWT vs plb , the between group differences with respect to pain and Constant score` were statistically significant also at 3 and 6 months, favoring H-SWT

[c] In Loew 1999, for L-SWT vs plb, the between group differences with respect to pain and Constant score were not significant at 3 months. H-SWT1 and H-SWT2 indicate one session and two sessions respectively.

[d] In Cacchio 2006, for RSWT vs plb, the between group differences with respect to pain, and patient satisfaction were statistically significant and for function not statistically significant, at 4 weeks. The UCLA Shoulder rating scale was used for each item (pain, function, and patient satisfaction).

[e] In Pan 2003, for H-SWT vs TENS, the between group differences with respect to pain and CMS were statistically significant also at 2 and 4 weeks, favoring H-SWT

Non-calcific RC-tendinosis

Study, patient number, comparison	Outcome measure	Time point	SWT	Placebo, or active tx	*P*-value
Schmitt[a] 2002, N = 40, H-SWT vs plb	Pain during rest (VAS), mean (SD)	Baseline	5.58 (1.9)	6.00 (3.1)	>0.05
		1 year	0.50 (1.7)	0.44 (1.3)	>0.05
	Constant score, mean (SD)	Baseline	41.27 (13.2)	44.68 (13.5)	>0.05
		1 year	106.36 (32.6)	109.52 (18.7)	>0.05
Schmitt[b] 2001, N = 40, L-SWT vs plb	Pain during rest (VAS), mean (SD)	Baseline	5.35 (2.54)	5.40 (3.00)	>0.05
		12 weeks	2.30 (3.03)	3.22 (2.82)	>0.05
	Constant score, mean (SD)	Baseline	40.70 ()13.29)	42.20 (13.04)	>0.05
		12 weeks	66.50 (37.92)	64.39 (32.68)	>0.05
Gross[c] 2002, N = 30, L-SWT vs radiotherapy	Pain during rest (VAS), mean (SD)	Baseline	5.3 (2.0)	4.9 (2.3)	NS
		52 weeks	1.5 (1.4)	3.1 (3.2)	NS
	Constant	Baseline	50.1 (12.1)	47.6 (8.7)	NS

Table A3: Summary of Findings of the Systematic Review

Main Study Findings and Author's Conclusions

	score, mean (SD)	52 weeks	97.8 (21.3)	87.4 (38.9)	NS

H-SWT = high energy shockwave therapy, L-SWT = low energy shockwave therapy, plb = placebo, SD = standard deviation, VAS = visual analog scale, vs = versus

Additional notes:
[a]In Schmitt 2002, for H-SWT vs plb, the between group differences with respect to pain during activity and subjective improvement were not significant at 1 year.
[b]In Schmitt 2001, for L-SWT vs plb, the between group differences with respect to pain during activity and subjective improvement were not significant at 1 year.
[c]In Gross 2002, for L-SWT vs radiotherapy, the between group differences with respect to pain during rest, pain during activity, Constant score, and subjective improvement were not significant at 12 weeks or 52 weeks.

Authors' Conclusions:

"In conclusion, high-ESWT is effective (strong and moderate evidence) to treat calcific RC-tendinosis in the short, mid and long term.[…….] For non-calcific RC-tendinosis, […..] no evidence in favour of low, mid or high-ESWT compared to placebo, each other, or other treatment was found for non-calcific RC-tendinosis. Therefore, this review presents evidence for effectiveness of high-ESWT for calcific RC-tendinosis, but no evidence for effectiveness of ESWT to treat non-calcific RC-tendinosis."p424

(ESWT = extracorporeal shockwave therapy)

Louwerens,[2] 2016, Netherlands

Main Findings:

Results before and after H-SWT in management of rotator cuff tendinopathy

Study	Patient number	Outcome measure	Baseline, Mean (SD)	After H-SWT[a], Mean (SD)
Kim 2014	29	ASES	49.9	78.3 at 2 year FU
		SST	34%	78.6% at 2 year FU
Ioppolo 2012	23	CMS	49.26 (8.6)	79.4 (0.33) at 6 month FU
Hsu 2008	33	CMS	57.3	88 at 1 year FU
Perlick 2003	40	CMS	48.4	73.2 at 1 year FU
Pleiner 2004	23	CMS	46 (21)	70 at 6 month FU
Gerdesmeyer 2003	48	CMS	60	91.6 (95% CI, 86.7 to 95.3) at 1 year FU
Cosentino 2003	35	CMS	45 (18)	76 (16) at 6 month FU
Daecke 2002	56 (Group 1)	CMS	49 (13)	88 (8) at >2 year FU
	59 (Group 2)	CMS	69 (19)	85 (8) at >2 year FU
Rompe 1998	50	CMS	53 (13.1)	88 (11.5) at 6 month FU

ASES = American shoulder and elbow surgeons score, CMS = Constant and Murley score,, FU = follow -up, H-SWT = high energy shockwave therapy, SD = standard deviation

[a]Only data at the follow up time of maximum duration are reported here when data at multiple follow up times were available, follow up times varied from 6 months to 4 years.

Adverse effects

Frequently reported peri-treatment side effects with H-SWT include pain, erythema. Local intracutaneous petechial bleeding, subcutaneous hematomas. However, these side effects were resolved within a few days after treatment. No post-treatment complications were reported

Authors' Conclusions:

Table A3: Summary of Findings of the Systematic Review

Main Study Findings and Author's Conclusions

"Patients can achieve good to excellent clinical outcomes after high-energy ESWT, US-guided needling, and arthroscopy for calcific tendinopathy of the shoulder. Side effects and posttreatment complications should be taken into account when a decision is being made for each individual patient. Physicians should consider high-energy ESWT and US-guided needling as minimally invasive treatment options when primary conservative treatment fails." p165

Speed,[6] 2014, UK

Main Findings:

This systematic review included five relevant RCTs of which four RCTs (Cosentino 2003, Gerdesmeyer 2003, Speed 2002 and Schmitt 2001) were discussed in an already included systematic review so are not presented here again. Findings from one RCT (Albert 2003) comparing FSWT with sham treatment are presented here.

Outcomes (assessed by CMS)

Study, patient number, comparison	RC tendinopathy	Findings
Albert 2007	Calcific	Significant benefit (as assessed using CMS) with FSWT at mean FU 110 days (41 days to 225 days). FSWT: 50.7 (33.7 to 70.2) to 63.2 (23.8 to 90), *P* < 0.0001; Sham (control): 50.3 (28.2 to 83.8) to 54.8 (19.9 to 86.8), *P* = 0.061

CMS = Constant and Murley score, FSWT = focused shockwave therapy, FU = follow -up

Authors' Conclusions:

"Where benefit is seen in F-ESWT, it appears to be dose dependent, with greater success seen with higher dose regimes. There is low level evidence for lack of benefit of low-dose F-ESWT and RPT in non-calcific rotator cuff disease [.....]" p1
(F-ESWT = focused extracorporeal shock-wave therapy, RPT = radial pulse therapy)

Elbow

Bisset, [11] 2011, Australia

Main Findings:

SWT vs sham

This systematic review comparing SWT with sham in patients with tennis elbow, included 2 systematic reviews (Buchbinder 2006, Rompe 2007) and one RCT (Staples 2008).

The systematic review by Buchbinder et al. had a search date up to 2005 and included 9 RCTs with 1006 patients and comparing SWT (with or without local anesthetic) with sham treatment. The RCTs were of variable quality; 5 RCTs were considered to be of moderate to high quality. Of these 9 RCTs, pooled results were obtained using 6 RCTs on patients with chronic unresponsive tennis elbow and 3 RCTs were not included in the pooling as 2 RCTs did not provide variance measures and 1 RCT included patients with short term symptoms with no previous treatment. However, it was mentioned that inclusion of these RCTs in the pooled analysis would not have altered the overall findings of the review.

Findings from the systematic review by Buchbinder et al.

Study	Findings
3 RCTs pooled, N = 446	No significant between group difference in pain reduction (measured using a scale 0 to 100) at 4 to 6 weeks. WMD = -9.42 (95% CI, -20.70 to 1.86)
3 RCTs pooled, N = 455	No significant between group difference in improvement in pain in resisted

Table A3: Summary of Findings of the Systematic Review

Main Study Findings and Author's Conclusions	
	wrist extension (using Thomsen test) at 12 weeks. WMD = -9.04 (95% CI, -19.37 to 1.28)
1 RCT (Melikyan 2003), N = 24	Greater pain reduction (assessed with VAS) with SWT compared with sham at 6 months FU: 6.6 at baseline to 3.0 for SWT 6.6 at baseline to 6.2 for sham However, it was mentioned that these results need to be interpreted with caution, as treatment allocation concealment was inadequate
1 RCT (Mehra 2003), N = 86	No significant between group difference for any measured outcome at any time point
1 RCT (Chung 2004), N = 60 (previously untreated	No significant between group difference in treatment success at 5 weeks (39% with SWT and 31% with sham); RR 1.65 (95% CI, 0.62 to 2.51)
2 RCTs N = 192	Significantly greater level of treatment success (at least 50% improvement in pain with resisted wrist extension) at 12 weeks with SWT compared with sham. RR = 2.20 (95% CI, 1.55 to 3.12)
4 RCTs	No significant between group difference in treatment success at 4 to 12 weeks

CI = confidence interval, RCT = randomized controlled trial, RR = relative risk, SWT = shockwave therapy, WMD = weighted mean difference

The systematic review by Rompe et al. had a search date of 2006, and included 8 RCTs with 834 patients. This systematic review included 7 RCTs that were included in the systematic review by Buchbinder et al. plus an additional RCT. The authors of this systematic review did not pool studies as they considered the studies to be too heterogeneous. Three RCTs were not considered; one RCT because of small sample size, one RCT because a single application of SWT was used, and one RCT because of lack of appropriate long term data. Four RCTs reported positive findings for pain reduction, but the significance level was not reported. One RCT (Spacca 2005) reported that RSWT was more effective than sham at reducing pain, both after treatment and at 6 months FU.

The RCT by Staples et al. with 68 patients found no significant difference in outcomes with SWT compared with sham in patients with chronic tennis elbow.

Outcomes with SWT versus sham

Outcome	Findings, MD (95% CI)	
	At 6 weeks FU	At 6 months FU
Pain (VAS)	1.7 (-18.8 to 15.3)	-9.0 (-26.6 to 8.6)
Function (VAS)	-2.9 (-17.2 to 11.9	-9.8 (-25.2 to 5.7)
8-item pain-free function index	0.1 (-1.2 to 1.3)	-0.8 (-2.2 to 0.6)
DASH scale function	6.3 (-2.5 to 1 5.1)	-0.3 (-10.3 to 9.8)
Pain-free grip strength	-0.05 (-0.22 to 0.12)	-0.05 (-0.15 to 0.26)

CI = confidence interval, DASH = disability of the arm, shoulder, and hand scale, FU = follow-up, MD = mean difference, VAS = visual analog scale

Adverse effects

The two systematic reviews presented no information on adverse effects. The RCT reported low rates of adverse effects in both the SWT and sham groups. Adverse effects included isolated cases of increased pain, bruising or lumps after treatment and burning sensation. Level of significance for difference between the two groups was not determined.

SWT versus corticosteroid injection

One RCT (Crowther 2002) with 93 patients compared single corticosteroid injection plus anesthetic injection

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versus SWT (2000 shock waves, three sessions weekly). Treatment success rate (success assessed as > 50% reduction in pain from baseline) was significantly better at reducing pain at 6 weeks and at 3 months (success rate: 84% with corticosteroid injection plus anesthetic injection and 60% with SWT, *P* <0.05)

Authors' Conclusions:

"Extracorporeal shock wave therapy is unlikely to be more effective than placebo at improving pain, and may be less effective than injected corticosteroids." p2

Dion,[1] 2016, Canada

Main Findings:

This systematic review on management strategies for soft tissue injuries of the elbow included 5 RCTs relevant for our review. Of the 5 RCTs, four RCTs (Pettrone 2005, Spacca 2005, Haake 2002, and Speed 2002) compared SWT with sham, and one RCT (Devrimsel, 2014) compared RSWT with low level laser therapy (LLLT).

Findings from the RCTs

Study, number of patients	Intervention	Comparison	Findings
Devrimsel 2014, N = 60	RSWT (2000 shock-waves of intensity 1.6 bar and frequency 16 Hz; 1 session per week for 3 weeks)	LLLT (intensity of 3.6 joule, frequency of 500 Hz, and wavelength of 850 nm	Statistically significant between group differences in hand grip strength, VAS, SF-MPQ APS, and SF-MPQ PPI, favoring RSWT at 1 and 9 weeks FU. No statistically significant between group differences in SF-MPQ SPS, and SF-MPQ TPS at any time point. Presence of tenderness: RR 0.73 (95% CI, 0.41 to 1.32) at 1 week RR 0.50 (95% CI, 0.10 to 2.53) at 9 weeks
Haake 2002, N = 272	SWT (low energy, 2000 pulses) with anesthetic, 3 visits every 18 to 24 days	Placebo SWT	Roles and Maudsley scores of 1 or 2: 27.2%, 31.7%, and 65.7% at 6 weeks, 12 weeks, and 12 months respectively for SWT; 23.2%, 33.1%, and 65.3% at 6 weeks, 12 weeks, and 12 months respectively for placebo. No between group differences in pain reduction or grip strength at any FU point Adverse events (frequency)
Pettrone 2005, N = 114	SWT (intensity 0.06 mJ/mm^{2,} 2000 pulses) once a week for 3 weeks	Sham	Differences in mean change (95% CI) for (SWT – sham) at 12 weeks FU Pain: 12.1 (5.03 to 19.17) Functional scale: 1 (0.56 to 1.44) Activity score: 1.8 (1.20 to 2.40) Grip strength: 7.1 (-0.15 to 14.35)
Speed 2002, N = 75	SWT (intensity 0.18 mJ/mm^{2,} 1500 pulses) once a month for 3 months	Sham	Differences in mean change (95% CI) for (SWT – sham) VAS (transformed into 0 to 100) for pain during the day: 1.4 (-5.12 to 7.92) at 1 month, 5.8 (-2.26 to 13.86) at 2 months, 9.8 (0.19 to 10.41) at 3 months.

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			VAS (transformed into 0 to 100) for night pain: -19.3 (-28.11 to -10.49) at 1 month, -6.9 (-15.85 to 2.04) at 2 months, -7.4 (-16.62 to 1.82)
Spacca 2005, N = 62	RSWT (4 sessions, 2000 pulses per session [1.2 bar and 4 Hz for 500 pulses and 1 bar, 10 Hz for 1500 pulses])	Control (subtherapeutic RSWT)	Differences in median change for (RSWT – control) immediately after intervention: Pain at rest: 4.5, Pain provoked by palpation: 9, Pain at Thomsen test: 5, Pain-free grip strength: 11, DASH: 23.5 Differences in median change for (RSWT – control) at 6 months FU: Pain at rest: 6, Pain provoked by palpation: 8, Pain at Thomsen test: 6, Pain-free grip strength: 9, DASH: 25. The between group differences were statistically significant differences favouring RSWT for pain at rest, pain provoked by palpation, pain during Thomsen test, pain-free grip strength test, and DASH, immediately after intervention and at 6 months .

APS = affective pain subscale, DASH = disability of the arm, shoulder, and hand scale, LLLT = low level laser therapy, PPI = present pain intensity, RR = relative risk, RSWT = radial shockwave therapy, SF-MPQ = short form McGill pain questionnaire, SPS = sensory pain subscale, SWT = shockwave therapy, TPS = total pain scale score, VAS = visual analog scale

Adverse events:

No serious adverse events were reported in 4 RCTs (Pettrone 2005, Spacca 2005, Haake 2002, and Speed 2002). Commonly reported adverse events included, reddening of the skin, pain, and petechiae/ bleeding/ hematoma and was generally higher in the SWT group compared to the placebo group. In one RCT (Haake 2002), patients receiving SWT were four times more likely to experience adverse events compared to those patients receiving sham treatment (OR 4.3 (95% CI 2.9 to 6.3). In 1 RCT (Speed 2002), 5% in the SWT group withdrew due to worsening of symptoms and 6% in the sham group withdrew for unknown reasons. In 1 RCT (Pettrone 2005), 50% in the SWT group and 22% in the sham group experienced moderate transient pain related to treatment. In 1 RCT (Spacca 2005) no adverse events were reported.

Authors' Conclusions:

"There is inconclusive evidence for the effectiveness of shockwave therapy or LLLT for persistent lateral epicondylitis." From accepted manuscript - page number NR

"We did not find any admissible studies for the management of other soft tissue injuries of the elbow, such as medial epicondylitis or olecranon bursitis." From accepted manuscript - page number NR

(LLLT = low-level laser therapy)

Dingemanse,[10] 2014, Netherlands

Main Findings:

Findings from one systematic review (Buchbinder 2005 [10 RCTs , N =1099]) comparing SWT with placebo or injection for patients with epicondylitis

Table A3: Summary of Findings of the Systematic Review

Main Study Findings and Author's Conclusions

Include studies in systematic review	Findings
Comparison: SWT vs injection	
Crowther 2004, N = 93, low quality (QA score = 33%)	Significant between group difference in favor of corticosteroid injection at 3 months FU with respect to success rate (success defined as ≥50% pain reduction from baseline). Success rate: 84% for corticosteroid injection and 60% for SWT; $P < 0.05$ However results did not remain significant at 6 months FU
Comparison: SWT vs plb	
Mehra 2003 (N = 24) (QA score = 67%), Melikyan 2003 (N = 74) (QA score = 50%), both high quality	No significant differences between SWT and plb for epicondylitis lateralis, at 1, 3, 6, and 12 months FU
Haake 2002 (N = 272) (QA score = 83%), Rompe 1996 (N = 115) (QA score = unclear), Speed 2002 (N =75) (QA score = 67%), all high quality	Pooled analysis showed no significant differences in pain between SWT and plb at 4 to 6 months FU
Haake 2002 (QA score = 83%), Rompe 2004 (QA score = unclear), Pettrone 2004 (QA score = 83%) (Total N = 455), all high quality	Pooled analysis showed no significant differences in pain and grip strength between SWT and plb at 12 weeks FU
Two studies (references unclear)	Pooled analysis showed there was a significant between group difference in favor of SWT, for 50% pain reduction at 12 weeks FU (RR 2.21 [95% CI 1.55 to 3.12])
Speed 2002 (N =75) (QA score = 67%), Haake 2002 (N = 272) (QA score = 83%), Chung 2004 (QR score = 33%) (N = 60), and Levitt 2004 (QA score = 50%), (N =183)	No significant differences between SWT and plb with respect to 50% pain reduction at 4 to 12 weeks FU. Results were not pooled as FU durations varied

CI = confidence interval, FU = follow-up, QA = quality assessment, RR = relative risk, SWT = shockwave therapy

Table A3: Summary of Findings of the Systematic Review

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Findings from individual studies comparing SWT with placebo for patients with epicondylitis

Study (QA score)[a]	Findings
Collins 2011 (QA score = 64%)	Significant difference with respect to pain during activity, in favor of SWT at 8 weeks FU (Mean values: 7.73 to 3.35 for SWT group and 7.81 to 5.50 for plb group)
Staples 2008 (QA score = 67%)	No significant differences between SWT and and plb at 4 and 6 weeks, and at 12 to 48 weeks FU
Chung 2005 (QA score = 33%)	
Pettrone 2005 (QA score = 83%)	Significant difference with respect to pain, favoring SWT at 12 weeks FU. Pain (mean [SD]): 74 (15.8) at baseline to 37.6 (28.7) for SWT, and 75.6 (16) at baseline to 51.3 (29.7) for plb. Overall impression (mean [SD]): 70.3 (16.0) at baseline to 32.8 (27.7) for SWT, and 46.2 (28.11) at baseline to 46.2 (28.11) for plb
Spacca 2005 (QA score = 67%)	Significant difference with respect to pain, favoring SWT at 12 weeks FU. Pain (mean values): 4.5 (2 to 7) at baseline to 0.5 (0 to 2) for SWT, and 4.5 (2 to 8) at baseline to 6.5 (3 to 9) for plb. Grip strength (mean values): 38 (32 to 41) at baseline to 46 (34 to 56) for SWT, and 37 (32 to 41) at baseline to 36 (32 to 44)

FU = follow-up, QA = quality assessment, RR = relative risk, SD =standard deviation, SWT = shockwave therapy

[a]Quality assessment (QA) score ≥50% considered as high quality

Findings from studies comparing SWT with active treatments in epicondylitis

Study (Patient number, QA score[a])	Comparison	Findings
Radwan (N= 56, QA score = 45%)	SWT vs percutaneous tenotomy	No significant differences between the groups with respect to pain score, grip strength, or recovery
Gunduz (N = NR, QA score = 100%)	SWT vs physical therapy (combination of hot packs, ultrasound and friction message	No significant differences between the groups with respect to pain score, or grip strength

QA = quality assessment, NR = not reported, SWT = shockwave therapy

[a]QA score ≥ 50% considered as high quality

Authors' Conclusions:

"We found conflicting evidence for the effectiveness of ESWT versus placebo, percutaneous tenotomy and physical therapy on short-term, mid-term and long-term follow-up." p8
"No studies were found studying the effectiveness of treatments for ME" p9
"To draw more valid conclusions regarding electrophysical modalities, we recommend conducting high-quality RCTs studying different intensities. Studies should also include longer follow-up periods in order to investigate the long-term effects of electrophysical modalities for the treatment of epicondylitis."

(ME = medial epicondylitis)

Table A3: Summary of Findings of the Systematic Review

Main Study Findings and Author's Conclusions

Speed,[6] 2014, UK

Main Findings:

This systematic review included five relevant RCTs on the management of chronic recalcitrant common extensor tendinopathy (lateral epicondylitis)

Findings from the included RCTs comparing SWT versus control

Study, number of patients	Treatment	Findings at 12 week FU
Haake 2002, N = 271	SWT (intensity: 0.07 mJ/mm^2 to 0.09 mJ/mm^2, 2000 pulses, 3 sessions, once weekly)	No significant between group differences. Pain (mean [SD]): 65.9 (19.4) to 38.3 for SWT, 60.25 (25.5) to 50.4 (29.4) for control
Lebrun 2005, N = 60	SWT (intensity: 0.03 mJ/mm^2 to 0.17 mJ/mm^2, 2000 pulses, 3 sessions, once weekly)	Success rate (> 50% improvement): 39% in SWT group and 31% in control group
Pettrone 2005, N = 114	SWT (intensity: 0.06 mJ/mm^2, 2000 pulses, 3 sessions, once weekly)	Significant between group differences. Improvement in pain score by > 50% observed in 61% in SWT group and 29% in control group
Rompe 2004, N = 78 (tennis players)	SWT (intensity: 0.09 mJ/mm^2, 2000 pulses, 3 sessions, once weekly)	Significant between group differences. Significantly greater improvement in pain during resisted wrist extension with SWT: 3.5 (2.0) for SWT and 2.0 (1.9) for control. Success rate (> 50% reduction in pain): 65% for SWT and 28% for control
Speed 2002, N = 75	SWT (intensity: 0.12 mJ/mm^2, 1500 pulses, 3 sessions, once monthly)	No significant between group differences "Success": 25.8% in SWT group and 25.4% in control group

FU = follow-up, SD = standard deviation, SWT = shockwave therapy

Authors' Conclusions:

"Focused extracorporeal shockwave therapy (F-ESWT) and radial pulse therapy (RPT) should be considered as different treatment modalities.
There continues to be a lack of large well-designed RCTs in general in F-ESWT and RPT.
Where benefit has been demonstrated further research into the most effective regimes is needed." Page 5 of 6

(F-ESWT = focused extracorporeal shockwave therapy, RPT = radial pulse therapy)

APPENDIX 5: Additional References of Potential Interest

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

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Systematic reviews lacking outcome details:

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11. Schmitz C, Csaszar NB, Milz S, Schieker M, Maffulli N, Rompe JD, et al. Efficacy and safety of extracorporeal shock wave therapy for orthopedic conditions: a systematic review on studies listed in the PEDro database. Br Med Bull [Internet]. 2015 [cited 2016 Aug 11];116:115-38. Available from: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4674007