Published Online July 11, 2007

Repetitive shock wave therapy for lateral elbow tendinopathy (tennis elbow): a systematic and qualitative analysis

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Objective: Pooled meta-analyses of statistically and clinically heterogeneous data of randomised-controlled studies are difficult to interpret. Therefore, a qualitative study-by-study assessment was thought to be of greater relevance, to physicians confronted with a therapy-resistant tennis elbow patient, to determine the effectiveness of shock wave therapy (SWT) for lateral elbow tendinopathy.

Setting: Orthopaedic clinic.

Methods: Randomized trials were identified from a current search of The Cochrane Bone, Joint and Muscle Trauma Group specialized register of trials, the Cochrane Central Register of Controlled Trials, MEDLINE and reference lists of articles and dissertations. We included 10 trials that randomized 948 participants to SWT or placebo or treatment control. For each trial, two independent reviewers assessed the methodological quality and extracted data. Methodological quality criteria included appropriate randomization, allocation concealment, blinding, number lost to follow-up and intention-to-treat analysis.

Results: Conflicting results of the 10 studies were found. There was considerable heterogeneity in terms of methodological quality; treatment regimen; patient selection and follow-up period, precluding pooled analyses. Instead, individual trial results were described in the text. Only six trials had a high-quality methodology. Two independent high-quality randomized placebo-controlled trials (196 participants) reported significant success of SWT over placebo (65 versus 28%; 61 versus 29%). Design of both trials included enrolment of chronic recalcitrant patients only; 1500–2000 shocks of low-energy flux density (0.1 mJ/mm^2) applied to the site of maximal discomfort (clinical focusing) in weekly intervals; no use of local anaesthesia and main follow-up at least 3 months after the last application. Three other independent high-quality trials (406 participants) did not find any benefit of SWT over placebo (32 versus 33%; 35 versus 34%; 39 versus 31%). In these three trials, study designs deviated from the design described earlier, enrolling acute patients or applying SWT under

Accepted: June 6, 2007
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DOI: 10.1093/bmb/ldm019
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local anaesthesia or expanding the application intervals to 4 weeks, while reducing the main follow-up to 4 weeks.

Conclusions: With current studies heterogeneous in terms of the duration of the disorder; type, frequency and total dose of SWT; period of time between SWT; type of management and control group; timing of follow-up and outcomes assessed, a pooled meta-analysis of SWT for lateral elbow tendinopathy was considered inappropriate. In a qualitative systematic per-study analysis identifying common and diverging details of 10 randomized-controlled trials, evidence was found for effectiveness of shock wave treatment for tennis elbow under well-defined, restrictive conditions only.

Keywords: lateral elbow tendinopathy/tennis elbow/shock wave treatment/qualitative analysis

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Introduction

With an incidence of ~1% per 1000 patients per year and a prevalence of 1–3% of adults per year, tennis elbow is one of the most often diagnosed pathology of the upper extremity.[1–7] New research shows that the typical histological pattern of an angiofibroblastic proliferation is more characteristic of a failed healing response rather than of an inflammatory process.[1,5,8–12]

Although tennis elbow is more prevalent, few of the treatments used rest on scientific evidence and none has been proved more effective than the others.[13–25]

Low-energy shock wave therapy (SWT) to address the failed healing response of a tendon is not widely known among the medical community. The rationale for its clinical use being stimulation of soft tissue healing and inhibition of pain receptors, and hence, SWT has been thoroughly investigated experimentally during the past decade.

To determine its clinical effectiveness and safety for lateral elbow pain in the frame of a meta-analysis, Buchbinder *et al.*[26] searched various registers. They included nine trials that randomized 1006 participants to SWT or control and one trial that randomized 93 participants to SWT or steroid injection. Results of the nine controlled trials differed, as did patient selection, treatment regimen, outcome assessment and main follow-up period. When available data from those trials were pooled, they found 'platinum' level evidence that SWT provided little or no benefit in terms of pain and function in lateral elbow pain.[3]

A meta-analysis, however, cannot improve the quality or reporting of the original studies. Other limitations come from misapplications of the method, such as when study diversity is ignored or mishandled in the analysis or when the variability of patient populations, the quality of the

data and the potential for underlying biases are not addressed. If relevant valid data are statistically and clinically too heterogeneous, a meta-analysis should be avoided and reviewers should perform a qualitative review in a systematic manner.[3,27] Following the QUOROM recommendations,[28] a checklist organized into 21 headings and subheadings was used to gather information on items such as search methodology, study selection, data abstraction, study characteristics and data analysis.

Methods

Search strategy

As described by Buchbinder *et al.*,[26] randomized trials were identified from a current search of The Cochrane Bone, Joint and Muscle Trauma Group specialized register of trials (December 2006), the Cochrane Central Register of Controlled Trials (The Cochrane Library, 2006), MEDLINE (from 1966 to December 2006) and reference lists of articles and dissertations. Only English, French and German language publications were considered. Further citations were sought from the reference sections of papers retrieved and from contacting experts in the field to identify studies 'in the pipeline'.

The following search strategy was used to search. It was decided to include search terms for specific interventions. The reference lists of all identified studies and correspondence relating to those studies were also searched:

- Shock wave therapy or shockwave therapy or shock wave treatment;
- AND tennis elbow or elbow pain or epicondylitis;
- AND random* (Table 1).

Table 1 Summary of the search strategy used and the number of hits for each item and total.

Search number	Search term	Number of hits
#1	Shock wave therapy	3930
#2	Shockwave therapy	915
#3	Shock wave treatment	4004
#4	Tennis elbow	941
#5	Elbow pain	1968
#6	Epicondylitis	665
#7	Random*	469741
#8	#1 or #2 or #3	4763
#9	#4 or #5 or #6	2806
#10	#7 and #8	409
#11	#7 and #9	304
#12	#10 and #11	40

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Two reviewers independently reviewed the identified trials to determine those that met the inclusion criteria. Full articles describing trials were obtained and the same two reviewers independently applied the selection criteria to the studies. Only trials reporting repetitive SWT were included. There was complete consensus concerning the final inclusion of randomized controlled trial (RCTs).

Methodological quality assessment

The methodological quality of each RCT was independently assessed by two reviewers. It was planned to use consensus to resolve disagreements with a third reviewer to be consulted if disagreements persisted; however, there were no disagreements.

As proposed by Buchbinder *et al.*,[26] the methodological quality of included trials was assessed on the basis of whether the trials met key criteria (appropriate randomization, allocation concealment, blinding, number lost to follow-up and intention-to-treat analysis). Allocation concealment was ranked adequate, unclear or inadequate.

Data extraction

Two reviewers independently extracted the data on the study characteristics including source of funding, study population, intervention, analyses and outcomes using standardized data extraction forms.[26,28]

In order to assess efficacy, raw data for outcomes of interest (mean values and standard deviations for continuous outcomes and number of events for binary outcomes) were extracted where available in the published reports.

Data analysis

The studies were first assessed for clinical heterogeneity with respect to the disease severity of participants (acute versus chronic); type of SWT device (electromagnetic versus radial versus multiple); dose or intensity of the intervention (energy flux density: low energy versus high energy, number of impulses of SWT, number of applications: single versus repetitive, application intervals: weekly versus monthly, SWT with versus without local anaesthesia); definition of outcome and assessment; control group and main follow-up (1 month versus >3 months).

All studies differed in various variables. The decision not to combine the studies in a meta-analysis was based on the setting, participants, interventions and outcomes of the included trials (great clinical diversity) and on the methods used to perform the trial varying in a way

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that was likely to overly influence the results (great methodological diversity). The studies were therefore not combined in a pooled analysis, but described separately.

Results

Description of studies

This review identified six placebo-controlled trials involving 60, 271, 74, 114, 78 and 75 participants, respectively.[29–34] Two trials involving 100 and 62 patients compared a standard SWT concept with a low-number application.[35,36] One trial, involving 93 participants, of SWT versus steroid injection was found.[37] One trial compared a lateral versus dorsal tangential SWT application technique in 41 patients.[38] The trials were performed in Germany,[33,35] Germany and Austria,[30] the UK,[31,34,37] Canada,[29] the USA[32] and Italy.[36,38]

One article was excluded for not reporting exclusively data of SWT for lateral elbow tendinopathy in less than 30 participants,[39] one article reported single-session SWT[19] and one was a long-time follow-up report[8] (Fig. 1).

Interventions

Devices

A variety of devices were used to generate shock waves in the different trials with heterogeneous sets of shock wave parameters. Seven trials generated shock waves electromagnetically[29,31–35,38]; in one trial, the type of shock waves was not specified[37] and one trial used eight different shock wave devices at different sites.[30] Spacca *et al.*[36] used a radial shock wave device.

Use of local anaesthesia

Nine of 10 trials were performed without local anaesthesia and only one trial administered local anaesthetics (LAs).[30]

Intervals of application

In all 10 trials, SWT was administered repetitively. In eight trials, the interval between treatments was weekly.[29,31–33,35–38] Only in one trial, the interval was monthly.[34] The interval between treatments was not provided for one trial.[31]

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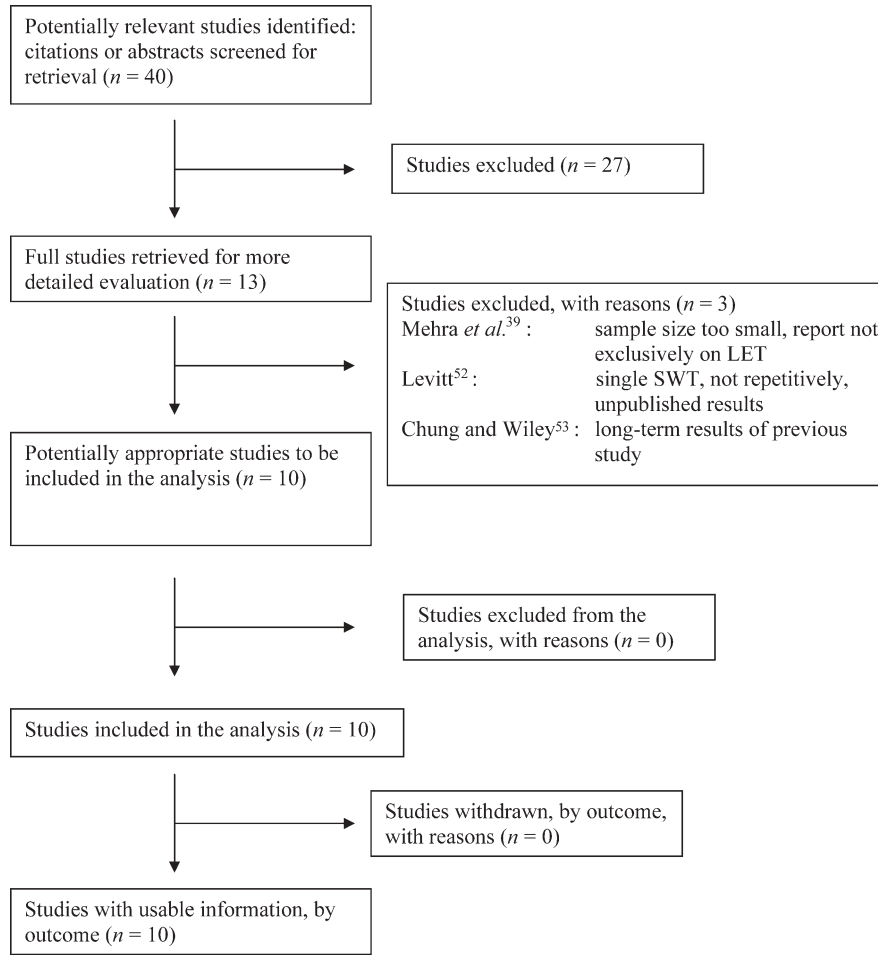

Fig. 1 QUOROM statement diagram flow.

Control groups

The placebo control group generally comprised a physical block to the shock waves (i.e. sound-reflecting polyethylene foil filled with air to reject the shock waves, or no skin contact of the treatment head). Unlike in Buchbinder's Cochrane analysis, a subtherapeutic dose of SWT (i.e. 10 or 20 low-energy impulses)[35,36] was not regarded as sham treatment.

One trial compared SWT with 20 mg triamcinolone made up to 1.5 ml with 1% lignocaine injected into the point of maximal tenderness at the extensor origin of the lateral epicondyle of the humerus.[37] One trial compared lateral tangential focusing with dorsal tangential focusing.[38]

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Study population

Nearly all trials recruited similar study populations. All participants had lateral elbow pain with most studies also requiring evidence of localized tenderness at or near the common extensor tendon insertion at the lateral epicondyle and reproduction of pain with resisted movements. Six trials specified that participants had to have had a varying number and/or duration of unsuccessful conservative treatment(s) prior to trial inclusion,[30,31–33,35,36] whereas one trial specifically included only participants who had not previously received any treatment.[29] One trial only included recreational tennis players defined as playing recreational tennis for at least 1 h per week before symptoms occurred, with chronic symptoms of at least a year, and highly resistant to other forms of treatment.[33]

Period of symptoms

Period of symptoms required for inclusion in the studies differed largely. Trials required that study participants have a minimum of 3 months,[34] 4 months,[37] 6 months,[30,32,35] 10 months[36] or 12 months[33] duration of symptoms prior to inclusion in the trial.

Two trials did not specify a minimum duration of symptoms.[31,38] One trial specified that symptoms had to have been present for more than 3 weeks and less than a year.[29]

Accordingly, the symptoms of study participants varied between 20 and 30 months. The mean duration of symptoms was much shorter in one trial (5 months).[29] The duration of symptoms of study participants was not reported in two trials.[31,37]

Timing of follow-up

Follow-up assessments were performed at varying time points across the trials, from during treatment to 12 months after the final treatment. Haake *et al.*[30] performed follow-up assessments at 6 and 12 weeks and 12 months after the final treatment. Melikyan *et al.*[31] performed assessments at 1, 3 and 12 months after the final treatment. Rompe *et al.*[35] performed assessments immediately after completion of treatment and at 3, 6 and 24 weeks after completion of treatment. Speed *et al.*[34] performed assessments prior to the second and third treatments (at 1 and 2 months, respectively) and at 1 month after the final treatment. Crowther *et al.*[37] performed assessments at 6 weeks and 3 months after either steroid injection or at the end of completion of 3 weekly treatments of SWT. Chung and Wiley[29] performed

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assessments at 1 and 5 weeks after the completion of treatment. Rompe *et al.*[33] performed assessments at 3 and 12 months after completion of treatment, although participants and assessors were unblinded at 3 months. Pettrone and McCall[32] performed assessments at 1, 4, 8 and 12 weeks and 6 months and 12 months after the completion of treatment, although participants and assessors could be unblinded at 12 weeks if participants had not achieved at least a 50% reduction in pain, compared with baseline. Spacca *et al.*[36] performed three assessments: before therapy, after therapy and at 6 months after the final SWT.

Primary endpoint

Outcome assessment was very heterogeneous. Six trials specified a primary endpoint.[29,30,32–34,36] Haake *et al.*[30] specified the primary endpoint as success rate after 12 weeks, defined as subjective pain score of 1 or 2 on the Roles and Maudsley scale [1 = excellent (no pain, full movement and activity) and 2 = good (occasional discomfort, full movement, full activity and no additional conservative or surgical treatment)]. Another trial[35] also used the Roles and Maudsley scale and determined failure of treatment at 12 weeks, defined as a score of 4 = poor (pain limiting activities). Speed *et al.*[34] specified the primary endpoint to be a 50% improvement in pain from baseline at 1 month after the end of treatment. Chung and Wiley[29] specified the primary endpoint as treatment success at 8 weeks (5 weeks after the completion of treatment), defined as fulfilment of all of the following three criteria: (i) at least a 50% reduction in overall elbow pain as measured by overall pain visual analog scale (VAS); (ii) maximum allowable overall elbow pain score of 4.0 cm and (iii) no use of pain medications for lateral elbow pain for 2 weeks before the 8-week evaluation. Pettrone and McCall[32] and Rompe *et al.*[33] specified the primary endpoint as reduction in pain elicited by provocative Thomsen testing recorded on VAS at 12 weeks following completion of treatment, compared with baseline. Spacca *et al.*[36] defined the primary endpoint as a reduction of 3 points during resisted wrist extension.

Outcome assessment

Pain scales included in the trials were heterogeneous. Three studies used validated measures of function—the Disabilities of Arm, Shoulder and Hand (DASH)[31,36] or the upper extremity functional scale (UEFS).[32,33]

Three trials[30,33,35] used the Roles and Maudsley scale that combines assessment of pain and satisfaction with treatment into a 4-point categorical scale.

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Rompe *et al.*[33] measured overall satisfaction by asking participants whether they were able to perform activities at the desired level and to continue to play recreational tennis.

One study used the thermometer subsection of the EuroQol 5D (EQ5D) quality-of-life instrument to assess quality of life.[29]

Pettrone and McCall[32] also used a 'patient-specific activity score' by asking participants to identify two activities from the UEFS that they found particularly difficult to perform and rate their difficulty from 1 (no difficulty) to 10 (cannot perform) and an overall participant evaluation of their disease status on a 100 mm VAS.

Melegati *et al.*[38] collected subjective data before the treatment and after 6 months using the Total Elbow Scoring System.

Two studies measured analgesic use[29,31] and one study recorded the number of participants who proceeded to surgery.[31]

Overall, the studies were clinically heterogeneous with respect to the duration of the disorder; type, frequency and total dose of SWT; period of time between SWT; type of management and control group; timing of follow-up and outcomes assessed.

Randomization

Although all 10 trials were described as randomized, only four trials described their method of randomization.[29,30,33,37]

Concealment

Concealment of treatment allocation was adequate in two trials[29,30] and adequate to 12 weeks following completion of treatment in two trials.[32,33] Concealment was considered unclear in the remaining six trials.[31,34–38]

Blinding

Participants were reported to be blinded in six trials,[29,30–34] and the assessment of outcome was blinded in eight trials.[29,30–36]

The trial comparing steroid injection with SWT was not patient-blinded,[37] as were both trials comparing SWT with low-number SWT.[35,39]

One trial unblinded all participants and outcome assessors at 12 weeks after the completion of treatment.[33] Restrictions of treatment were lifted at this time and participants in the placebo group with persisting symptoms were offered active treatment. One trial also unblinded participants at 12 weeks after the completion of treatment if

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there had not been at least a 50% improvement in pain elicited by the Thomsen test, compared with baseline.[32] Participants in the placebo group were also offered the active treatment at this time and outcome assessors were unblinded if participants received cross-over treatment. It is not known whether unimproved participants in the active group (who were unblinded at 12 weeks) could receive additional treatment.

Intention-to-treat

Six trials reported that the analysis was performed on the basis of intention to treat.[29,30,32–34,36] This could not be verified for two trials.[34,36] Three trials performed a completers analysis only.[31,35,37]

Sample size calculation

Four trials reported a sample size calculation.[29,30,32,33] Haake *et al.*[30] had sufficient power to demonstrate a 20% difference in outcome of the primary endpoint (success rate at 12 weeks), and Chung and Wiley[29] calculated that a sample size of 30 participants per group would have sufficient power to detect a 2-fold difference in the proportion of treatment successes at 8 weeks (5 weeks after the completion of treatment), assuming that 20% of the placebo group would have a treatment success (i.e. 60% success rate in the active group), allowing for a 20% dropout/loss to follow-up rate. They considered that treatment successes in 60% of the SWT group would constitute a clinically relevant and successful result. Rompe *et al.*[33] reported that a sample size of 35 patients per group would have 80% power in detecting a difference of 2 points in average pain rating to resisted wrist extension at the 3-month assessment (i.e. assuming pain is 5 ± 2 points in the placebo group and will be 3 ± 2 in the active group) with a two-sided significance level of 0.01. Pettrone and McCall[32] calculated that a sample size of 45 participants per group would provide sufficient power to demonstrate a 30% difference between the proportion of participants who improved by at least 50% from baseline to 12 weeks after the completion of treatment assuming a 50% success in placebo (80% success in active SWT) and number was increased to 114 assuming a retention rate of at least 80%.

Per-study methodological quality assessment

Rompe *et al.*[35] have published a randomized-controlled trial investigating SWT for lateral elbow pain performed at a single centre in

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Germany. They report the results of 115 chronic recalcitrant participants treated over a 3-year period.

The treatment group received 3×1000 low-energy impulses without local anaesthesia at weekly intervals and the control group received 3×10 identical impulses at weekly intervals. Main follow-up was 6 months.

Fifteen participants were reported to discontinue treatment during the first 6 weeks and were not subsequently included in the analysis (dropouts $15/115 = 13\%$). Follow-up was reported at 3, 6, 24 and 52 weeks. The trial was reported to be randomized, but the method of randomization was not described and therefore it is unclear whether allocation concealment was adequate. Both the participants and the outcome assessors were reported to be blinded to treatment allocation. The analysis was performed for completers of the trial only ($n = 100$) and the treatment allocation for the 15 participants (13%) who dropped out was not reported.

Crowther *et al.*[37] performed a randomized controlled trial in the UK including 93 chronic recalcitrant participants.

The treatment group received 3×2000 low-energy impulses without local anaesthesia at weekly intervals and the control group received an injection of 20 mg of triamcinolone made up to 1.5 ml with 1% lidocaine. Main follow-up was 3 months.

Patients in the trial were randomized using closed unmarked envelopes. It is unclear whether allocation concealment was adequate. It appears that the patients were not blinded and it is not stated whether outcome assessment was blinded. Three of 51 (5.9%) participants randomized to SWT withdrew prior to completion of treatment and 17 of 52 (32.7%) participants randomized to steroid injection refused participation after randomization. Patients who had been included in the study and withdrew after randomization were not followed on-intention-to-treat.

Haake *et al.*[30] performed a multicentre randomized placebo-controlled study in Germany and Austria including 271 participants.

The treatment group received 3×2000 low-energy impulses at weekly intervals under local anaesthesia and the control group received 3×2000 sham impulses at weekly intervals under local anaesthesia. Main follow-up was 3 months.

It was reported to be single-blind on the basis that the participants were blinded to intervention, but the provider of the intervention was not blinded. However, blinded outcome assessors were used. Allocation concealment was adequate. Randomization occurred centrally by phone, using random permuted blocks of sizes six and four with separate randomization lists for each centre. Intention-to-treat analysis was used, and loss to follow-up was reported for 10 (7.5%)

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and 15 (10.9%) participants in the active and placebo groups, respectively.

Speed *et al.*[34] performed a single-centre randomized controlled trial in the UK including 75 participants. The treatment group received 3×1500 low-energy impulses without local anaesthesia at monthly intervals and the control group received 3×1500 sham impulses at monthly intervals. Main follow-up was 1 month.

The trial was reported to be randomized, but the method of randomization was not described and therefore it is unclear whether allocation concealment was adequate. Both participants and outcome assessors were reported to be blinded to treatment allocation. Four (5.3%) withdrew from the trial (two in the active group after two treatments because of worsening symptoms and two in the placebo group for reasons which were unclear). Data were reported to be analysed on an intention-to-treat basis, but it is unclear how missing data for the four participants who withdrew were handled in the analysis.

Melikyan *et al.*[31] performed a randomized-controlled trial in the UK including 86 chronic recalcitrant participants.

The treatment group received 3× a variable number of low-energy impulses without local anaesthesia at weekly intervals and the control group received sham impulses at weekly intervals. Main follow-up was 6 months.

The trial was reported to be randomized, but the method of randomization was not described and therefore it is unclear whether allocation concealment was adequate. Both participants and outcome assessors were reported to be blinded to treatment allocation. Eleven participants did not complete a full course of treatment and an additional participant did not attend for follow-up (12/86, 14%). These 12 participants were not included in the efficacy assessment and a completers-only analysis was performed.

Melegati *et al.*[38] performed a randomized-controlled trial including 41 participants. The treatment group received 3×1800 low-energy impulses without local anaesthesia at weekly intervals using tangential focusing and the control group received identical impulses using dorsal focusing. Main follow-up was 6 months.

The randomization procedure was not described. It is unclear whether allocation concealment was adequate. It appears that the patients were not blinded and it is not stated whether outcome assessment was blinded. No patient was lost to follow-up. Allocation concealment was considered unclear.

Chung and Wiley[29] performed a randomized-controlled trial in Canada including 60 subchronic previously untreated participants.

The treatment group received 3×2000 low-energy impulses of a varying intensity without local anaesthesia at weekly intervals and the

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control group received 2000 sham impulses. Main follow-up was 3 months.

Trial participants were randomized according to block randomization. All participants and outcome assessors were blinded to treatment allocation. Allocation concealment was considered adequate. Participants were not aware that there was a placebo treatment, but were informed the study was comparing two different therapy protocols. The authors stated that this deception was performed to preserve subject blinding because of widespread accessibility of information on SWT protocols, particularly information regarding discomfort during therapy. Four participants (6.7%) were lost to follow-up. Analysis was according to intention to treat with last observation used for missing outcome data.

Rompe *et al.*[33] performed a randomized-controlled trial in Germany including 78 chronic recalcitrant participants, all of whom were recreational tennis players with symptoms for at least 12 months.

The treatment group received 3×2000 low-energy impulses without local anaesthesia at weekly intervals and the control group received sham impulses at weekly intervals. Main follow-up was 3 months.

Trial participants were randomized according to a computer-generated random numbers list and only the person performing the intervention knew the treatment allocation. Both participants and outcome assessors were blinded up until the 3-month assessment, but were unblinded at this time point. Eight participants (10.3%) did not provide 3-month data. A further six participants were lost to follow-up for the 12-month assessment. Analysis was according to intention to treat with last observation used for missing outcome data. Allocation concealment was considered adequate.

Pettrone and McCall[32] performed a randomized-controlled trial in three centres in the US including 114 chronic recalcitrant participants only.

The treatment group received 3×2000 low-energy impulses without local anaesthesia at weekly intervals and the control group received sham impulses at weekly intervals. Main follow-up was 3 months.

Treatment allocation concealment was adequate as at randomization and each participant was given a unique study number and a sealed envelope with their study number on it. All participants and outcome assessors were blinded to treatment allocation up to 12 weeks following the completion of treatment. Six participants (5.3%) withdrew before the 12-week assessment. Analysis was according to intention to treat with last observation used for missing outcome data.

Spacca *et al.*[36] performed a randomized controlled trial in Italy including 62 chronic recalcitrant participants.

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The treatment group received 3×2000 low-energy impulses without local anaesthesia at weekly intervals and the control group received 3×20 low-energy impulses. Main follow-up was 6 months.

The procedure of randomization was not described. It is unclear whether allocation concealment was adequate. Patients were not blinded and it is not stated whether outcome assessment was blinded. There was no loss to follow-up until the primary endpoint at 6 months.

To allow easier understanding of the key elements of the individual studies, a summarizing assessment was performed according to Chalmers *et al.*,[40] with two evaluation forms which include 29 individually scored items, allowing a maximum score of 100. Following the recommendation from Stasinopoulos and Johnson,[3] a score of 70% is considered to be the minimum required for a high-quality design for controlled therapeutic trials. If the score is below 40% (0–39), the design of the study is of low quality, and, if it is 40–69%, it is satisfactory.

Table 2 summarizes the evaluation for the 10 included trials. The average Chalmers' score was 62.5%, with a minimum of 47% for the weakest study design[38] and a maximum of 75% for the strongest ones.[30,32] All studies had at least a satisfactory quality design.

Two placebo-controlled trials reported significant differences in favour of SWT for all or most measured endpoints.[32,33] Involving 196 participants, both studies observed the following principles: (i) chronic recalcitrant cases; (ii) 2000 low-energy impulses; (iii) 3× in weekly intervals; (iv) clinical focusing, no local anaesthesia and (v) main follow-up of 3 months. In the study by Rompe *et al.*,[33] at 3 months 65% of patients achieved at least a 50% reduction in pain, compared with 28% of patients in the sham group. Using exactly the treatment regimen of Pettrone and McCall,[32] they found a statistically significant difference in pain reduction at 12 weeks. Sixty-one per cent of active-treated patients showed at least 50% improvement in pain, compared with 29% in the placebo group. This was found to persist for 1 year.

Success rates of SWT groups, undergoing a comparable treatment regimen in three treatment-controlled trials, were 48,[35] 60[37] and 84%.[36]

Three trials did not find any benefit of SWT over placebo.[29,30,34] All deviated from the concept of application outlined earlier.

Haake *et al.*[30] reported a multicentre, randomized, placebo-controlled study on chronic recalcitrant participants. The treatment group received 3×2000 low-energy impulses at weekly intervals under local anaesthesia and the control group received 3×2000 sham impulses under local anaesthesia at weekly intervals. Main follow-up was 3 months. Overall, therapeutic success rate 12 weeks after intervention (primary endpoint) was 32% in the SWT and 33% in the

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Table 2 Studies included.

Reference	Quality score[5] (%)	Subgroup	Number of patients	Method of treatment	Primary outcome measure	Follow-up	Success rates	Effect of SWT?
Rompe *et al.*[35]	54	No LA; chronic patients	100	Repetitive (3×) low-energy SWT versus low-number SWT, period between applications: 1 week	Number of patients with Roles and Maudsley score 1 or 2, of 4	6 months	SWT: 48% Sham: 6%	**Positive** SWT was more effective than sham therapy at the end of treatment and at the follow-ups
Rompe *et al.*[33]	74	No LA; chronic patients	78	Repetitive (3×) low-energy SWT versus Sham, period between applications: 1 week	Number of patients with pain reduction on VAS by 50%	3 months	SWT: 65% Sham: 28%	**Positive** SWT was more effective than sham therapy at the end of treatment and at the follow-ups
Pettrone and McCall[32]	75	No LA; chronic patients	114	Repetitive (3×) low-energy SWT versus Sham, period between applications: 1 week	Number of patients with pain reduction on VAS by 50%	3 months	SWT: 61% Sham: 29%	**Positive** SWT was more effective than sham therapy at the end of treatment and at the follow-ups
Spacca *et al.*[36]	70	No LA; chronic patients	62	Repetitive (3×) low-energy SWT versus Sham, period between applications: 1 week	Pain reduction on VAS (0–10)	6 months	SWT: 4.0% Sham: −1.5%	**Positive** SWT was more effective than sham therapy at the end of treatment and at the follow-ups
Crowther *et al.*[37]	51	No LA; chronic patients	93	Repetitive (3×) low-energy SWT versus corticosteroids, period between applications: 1 week, **Analysis not on-intention-to-treat**	Number of patients with pain reduction on VAS by 50%	3 months	SWT: 60% Steroids: 84%	**Positive** Steroids were more effective than SWT at the end of treatment and at the follow-ups
Melikyan *et al.*[31]	57	No LA; chronic patients	74	Repetitive (3×) SWT versus sham, **variable energy per shock applied, period between applications unknown**	Number of patients with surgery required	3 months	SWT: 46% Sham: 43%	**None** No difference at the end of treatment and at the follow-ups
Speed *et al.*[34]	51	No LA; chronic patients	75	Repetitive (3×) low-energy SWT versus sham, **period between applications: 4 weeks**	Number of patients with pain reduction on VAS by 50%	**1 month**	SWT: 35% Sham: 34%	**None** No difference at the end of treatment and at the follow-ups

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Table 2. *Continued*

Reference	Quality score[5] (%)	Subgroup	Number of patients	Method of treatment	Primary outcome measure	Follow-up	Success rates	Effect of SWT?
Moher *et al.*[28]	47	No LA; **sub-chronic patients**	41	Repetitive (3×) low-energy lateral SWT technique versus repetitive (3×) low-energy back SWT technique, period between applications: 1 week **No sham group**	Pain reduction on VAS (0–10)	6 months	SWT: 4.6% Sham: 4.5%	**Positive** No differences between the two techniques at the end of the treatment and at the follow-up
Chung and Wiley[29]	72	No LA; **acute patients**	60	Repetitive (3×) SWT versus sham, **variable energy per shock applied**, period between applications: 1 week	Number of patients with pain reduction on VAS by 50	**1 and 3 months**	SWT: 39% Sham: 31%	**None** No difference at the end of the treatment and at the follow-ups
Haake *et al.*[30]	75	**LA**; chronic patients	271	Repetitive (3×) low-energy SWT versus sham, period between applications: 1 week	Number of patients with roles and Maudsley score 1 or 2, of 4	3 months	SWT: 32% Sham: 33%	**None** No difference at the end of treatment and at the follow-ups

Bold: most important differences in the study design. SWT, shock wave treatment.

placebo group. The authors concluded that this treatment did not have any added therapeutic benefit beyond placebo.

Speed *et al.*[34] performed a single-centre, randomized-controlled trial in the UK including 75 participants. The treatment group received 3×1500 low-energy impulses without local anaesthesia at monthly intervals and the control group received 3×1500 sham impulses at monthly intervals. Main follow-up was 1 month.

Chung and Wiley[29] did not deviate from the treatment regimen outlined earlier. However, they changed the selection of patients from chronic recalcitrant to acute, previously untreated cases. Main follow-up was 2 months, and success rates in the sham and active therapy groups were 31 and 39%, respectively.

Discussion

Low-energy SWT for tendinopathies is not widely known among the medical community. The rationale for its clinical use being stimulation of soft tissue healing and inhibition of pain receptors, and hence, it has been thoroughly investigated experimentally during the past decade. Ohtori *et al.*[41] demonstrated that after low-energy shock wave application, the number of sensory fibres in the epidermis decreased significantly as indicated by the loss of immunoreactivity for calcitonin gene-related peptide. Re-innervation of the epidermis started 2 weeks after treatment. When repeating shock wave application after 14 days in another experiment, Takahashi *et al.*[42] described the delay of re-innervation for as long as 42 days, significantly longer than after single shock wave application. Wang *et al.*[43] found that low-energy SWT positively influenced neovascularization at the tendon–bone junction in rabbits, producing a significantly higher number of neo-vessels and angiogenesis-related markers, including endothelial nitric oxide synthase, vessel endothelial growth factor and proliferating cell nuclear antigen. Chen *et al.*[44] reported that low-energy SWT promoted healing of Achilles tendinopathy. Proliferation of tenocytes adjunct to hypertrophied cell aggregate and newly formed tendon tissue coincided with intensive TGF-beta1 and IGF-I expression. The effect of shock waves appeared to be time-dependent.

Although experimentally positive effects of SWT on tendon healing and pain modulation have become undebatable, conflicting results were found in this qualitative review of randomized controlled trials on the effectiveness of SWT for lateral elbow tendinopathy.

Ten controlled trials including 948 participants, reporting conflicting results, were included in this systematic review. Overall, the studies were clinically heterogeneous with respect to the duration of the

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disorder; type, frequency and total dose of SWT; period of time between SWT; type of management and control group; timing of follow-up and outcomes assessed.

Confronted with clinical and methodological heterogeneity, the statisticians involved thought it would be better to present this systematic review using a more qualitative approach instead of combining results. A systematic descriptive analysis was given preference.

Two placebo-controlled trials[32,33] reported highly significant differences in favour of SWT and three did not.[29,30,34] Three more treatment-controlled trials reported effectiveness of SWT[35,36,38] and two did not.[31,37]

The discrepancy in the results between the positive and negative trials in our review may be explainable on the basis of differing trial quality. The largest negative trial (271 participants) was of high quality with a valid randomization method, adequate concealment of treatment allocation, blinding of participants and outcome assessors and intention-to-treat analysis. It reported both a prespecified primary endpoint and sample size calculation.[30] The second negative trial (75 participants) did not report its method of randomization, but did blind both participants and outcome assessors, reported a prespecified primary endpoint and performed an intention-to-treat analysis, although it is not clear whether it was adequately powered to detect a clinically important difference between groups as no sample size calculation was reported.[34] Owing to inadequate reporting of results, one placebo-controlled trial published in 2003 did not provide conclusive data, but supported the ineffectiveness of SWT.[31] The two positive trials[32,33] allowed either all patients to be unblinded at 12 weeks[33] or unblinding at 12 weeks for those without an adequate response.[32] In both trials, placebo patients were also offered cross-over into the active group at 12 weeks and unblinded patients were allowed additional therapy. Restriction on other treatments was also lifted at this time, although additional treatments received by unimproved participants in the active group were not reported. Owing to a diminished number of blinded participants, and the possibility of confounding of any treatment effects, it was impossible to interpret the long-term results of these trials.

This review also included one trial comparing steroid injection with SWT, which demonstrated a benefit of steroid injection over SWT at 3 months with respect to 50% reduction in pain.[37] However, following randomization, a considerable number of patients allocated to injection therapy withdrew from the study, making interpretation of the results difficult.

We found a lack of uniformity in both the timing of follow-up and the outcomes that were measured. All studies measured pain, with

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some including varying aspects of pain. Three trials used the Roles and Maudsley scale which incorporates both pain and an assessment of whether pain limits activities into a 4-point categorical scale,[30,33,35] although Rompe *et al.*[33] analysed the results as a continuous rather than categorical data. Three trials included an upper-arm-specific disability measure (the DASH)[31,36] or the UEFS,[32,33] and no trial included a generic quality-of-life instrument. An international consensus for the use of a standard set of outcome measures in clinical trials for lateral elbow pain that are valid, reliable and sensitive to change would improve our ability to interpret and compare the results of different studies.[19,20,45,46] These might include overall pain with or without provocation, a measure of upper extremity function (such as the UEFS), ability to carry out usual activities, work and/or sport and possibly also a measure of quality of life.

There continues to be considerable debate relating to the use of SWT in soft tissue musculoskeletal complaints: the optimal shock wave treatment regimes; dosing intervals and whether focusing of SWT to the site of pathology can be improved by fluoroscopy or ultrasound. Some experts argue that the shock waves should be focused on the site of maximal tenderness as determined by the patient and imaging may result in errors in localization of the pathology; whereas the contrary view is that imaging, together with clinical input from the patient, may improve the accuracy and therefore the efficacy of SWT.[26]

One of the most interesting questions is whether application of an LA has a negative effect on the outcome of tendinopathies after SWT.[47] These interventions are sometimes used as the treatment, which is uncomfortable and sometimes painful. Recently, two interesting papers were published, comparing the use of SWT with and without local anaesthesia in patients with chronic plantar fasciopathy.

Labek *et al.*[48] reported that they had enrolled 60 patients with a chronic plantar fasciitis in a triple-arm randomized trial. Patients were randomly assigned to receive repetitive low-energy SWT without local anaesthesia (group I) or repetitive SWT (energy flux density doubled) with local anaesthesia (group II) or repetitive low-energy SWT with local anaesthesia (group III). At 6 weeks, there was significant improvement in pain during first steps in the morning in all groups, by 4.2 points in group I, by 2.6 points in group II and by 2.4 points in group III. A reduction in pain of at least 50% was achieved in 60% of patients in group I, in 36% of patients in group II and in 29% of patients in group III. In conclusion, at 6 weeks, success rates after low-energy SWT with local anaesthesia were significantly lower than that after identical low-energy SWT without local anaesthesia.

A current randomized-controlled study from Germany[49] confirmed their observation. The average pain score for patients who received

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SWT without local anaesthesia (group I) was 6.9 points at baseline and 2.2 points at 3 months. The average pain score for patients who received SWT with local anaesthesia (group II) was 6.7 points at baseline and 4.1 points at 3 months. At 3 months in group I, 67% of patients achieved at least a 50% reduction in pain, compared with 29% of patients in group II.

In the only human experiment in this field so far, Klonschinski *et al.*[50] investigated whether the biological effects of SWT differ between application with and without an LA in humans. SWT was applied to the skin after local pretreatment either with lidocain cream LA or without LA to the corresponding location of the contralateral limb. Increasing energy flux density led to a significant increase of pain. LA significantly attenuated this pain and significantly inhibited C-fibre activity, with a significant reduction in local vasodilation. Reduction in vasodilation correlated positively with the amount of energy flux density applied. SWT without LA resulted in a dose-dependent lower pressure pain threshold, i.e. sensitization, than did SWT with LA. Together, SWT in a dose-dependent fashion activated and sensitized primary afferent nociceptive C-fibres in human skin. LA substantially altered the biological responses after SWT.

Obviously, accurate targeting of the pathology at the spot of maximal point tenderness, as described to the examiner by the patient, is crucial for optimal application of low-energy shock waves. This is impossible after application of local anaesthesia.

Studies that directly compare one machine with another or compare dosing intervals and so on may be able to determine whether there are any differences in outcome. In part, physical differences between the devices used for the individual trials may explain for the heterogeneity of outcomes. One trial has compared two different ultrasound localizing techniques and reported no difference in outcome.[38]

A second, related point of difference is whether imaging such as ultrasound or magnetic resonance imaging (MRI) has a role in establishing the presence of pathology at the site of tendon insertions such as the common extensor origin in patients with lateral elbow pain. For example, the recent trial by Rompe *et al.*[33] required a positive MRI (increased signal intensity of extensors) for study inclusion. This may increase the homogeneity of the study population, increase the likelihood of being able to demonstrate benefit of a new therapy if one exists and enable valid comparisons to be made between studies.[26]

As already pointed out by Buchbinder *et al.*,[26] all trials included in this review reported improvement in outcome in both the treated and non-treated populations. These observed treatment effects might be explained on the basis of placebo effects related to participating in a trial or the self-limiting natural history of the condition. Proponents of

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SWT, highlighting the favourable natural history of this condition with its high rate of spontaneous improvement,[51] have asserted that this treatment should be reserved for patients with chronic recalcitrant cases that have failed to respond to a multitude of other conservative treatments such as NSAIDs, corticosteroid injections, orthotics and physiotherapeutic modalities.[32,33,35,36] The trial by Chung and Wiley[29] who failed to find any evidence of benefit of SWT for patients with symptoms of lateral elbow pain who had not previously been treated supports this opinion.

Conclusion

The assumption that a meta-analysis routinely represents the final and accurate viewpoint in an area of research is not warranted. The authors need to determine how broadly their conclusions can be applied and to what patient groups. The addition of study protocols that are significantly different from one another can make a meta-analysis less reliable.

Because of the multiple variables inherent in the use of SWT in the management of lateral elbow tendinopathy (LET), pooled comparisons of published results appear problematic. Currently, there is no consensus on the use of repetitive low-energy SWT, which does not require local anaesthesia, and on the use of high-energy SWT, which requires local or regional anaesthesia. There is no consensus for differentiating between low-energy and high-energy shock waves as multiple physical variables are involved.

What are the implications for clinical practice?

On the basis of well-designed studies showing favourable or unfavourable results, it seems that the literature supports a therapeutic benefit of SWT for managing chronic lateral elbow tendinopathy under restricted conditions only. In this context, this qualitative review identified common variables going along with satisfying results of SWT in the range of 60%:

- chronic recalcitrant patients;
- repetitive application of 2000 low-energy SWT at weekly intervals for 3–6 weeks;
- clinical focusing;
- without local anaesthesia;
- follow-up at least 3 months after last application.

Our research has further identified components that may possibly have an adverse effect on the clinical outcome: enrolment of acute, previously untreated patients; repetitive application of low-energy SWT at

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monthly intervals; use of local anaesthesia and follow-up less than 3 months.

Accordingly, SWT is recommended only after routine therapy options have failed and when the patients are confronted with the indication of a surgical intervention.

Clearly, we are in a situation where there is still uncertainty (not enough trials of high quality and contradictory evidence from a group of trials). Clearly, there is a need for further research in order to gain sufficient evidence to assess the effects of SWT of lateral elbow tendinopathy. This further research needs to be targeted to specific issues that have arisen out of this review (homogenous intervention; identical outcome assessment; comparable participants and comparable follow-up evaluation). In the end, a large-scale high-quality controlled trial comparing repetitive low-energy SWT applied without local anaesthesia with a standard surgical approach in patients with a previously recalcitrant lateral elbow tendinopathy is the ultimate goal.

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