Systematic Review of the Efficacy and Safety of Shock Wave Therapy for Lateral Elbow Pain

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ABSTRACT. ***Objective.*** To determine the efficacy and safety of extracorporeal shock wave therapy (ESWT) for lateral elbow pain.

Methods. Systematic review of randomized controlled trials using Cochrane Collaboration methodology.

Results. Nine placebo-controlled trials (1006 participants) and one trial of ESWT versus steroid injection (93 participants) were included. The 9 placebo-controlled trials reported conflicting results, although 11 of 13 pooled analyses found no significant benefit of ESWT over placebo, e.g., weighted mean difference for improvement in pain (on a 100-point scale) from baseline to 4–6 weeks (pooled analysis of 3 trials, 446 participants) was –9.42 (95% CI –20.70 to 1.86). Two pooled results favored ESWT, e.g., relative risk of treatment success (at least 50% improvement in pain with resisted wrist extension at 12 weeks) for ESWT in comparison to placebo (pooled analysis of 2 trials, 192 participants) was 2.2 (95% CI 1.55 to 3.12). However, this finding was not supported by the results of 4 other trials that were unable to be pooled. Steroid injection was more effective than ESWT at 3 months after the end of treatment assessed by a reduction of pain of 50% from baseline [21/25 (84%) vs 29/48 (60%); $p < 0.05$]. Minimal adverse effects of ESWT were reported.

Conclusion. Based upon systematic review of 9 placebo-controlled trials, there is "platinum" level evidence that ESWT provides little or no benefit in terms of pain and function in lateral elbow pain. There is "silver" level evidence based upon one trial that steroid injection may be more effective than ESWT. (J Rheumatol 2006;33:1351–63)

Key Indexing Terms:
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Lateral elbow pain (also known as tennis elbow or lateral epicondylitis) is a common condition, with a reported prevalence of 1%–3% and a peak incidence in people aged 40 to 50 years[1]. The majority of cases of lateral elbow pain are thought to be due to a musculotendinous lesion of the common extension origin at the attachment to the lateral epicondyle[2]. Focal changes such as focal hypoechoic areas of degeneration, discrete cleavage tears (both partial and complete), and involvement of the lateral collateral ligament can be identified on sonographic examination of the common extensor origin in participants with lateral elbow pain[3].

Lateral elbow pain is generally regarded as having a natural history that is self-limiting: in a general practice trial of an expectant waiting policy, 80% of the people with elbow pain of already > 6 weeks' duration had recovered after one year[4]. In a minority of people symptoms persist for 18 months to 2 years and in some cases for much longer[5]. A small proportion of people eventually undergo surgery, although reliable data on surgical rates in unselected patients are lacking. The cost is therefore high, in terms of both lost productivity and healthcare use.

High quality clinical trial evidence to either support or refute the efficacy of many commonly used treatments for lateral elbow pain and guide clinical practice is limited. From the early 1990s there have been reports from Germany of the use

of extracorporeal shock wave therapy (ESWT) as treatment for a variety of musculoskeletal disorders including both lateral and medial epicondylitis[6-8]. Shock waves are single pulsed acoustic or sonic waves that dissipate mechanical energy at the interface of 2 substances with different acoustic impedance[9]. How ESWT results in the symptomatic improvement of lateral elbow pain is not well understood. The electrophysiological pathways and molecular mechanisms of the proposed antinociceptive effect (blockage of activation of nociceptors, which are receptors in the skin, deep structures, and viscera that cause pain upon activation) of ESWT are still unknown[6]. Rompe, *et al* have hypothesized that there is an overstimulation of nerve fibers, resulting in an immediate analgesic effect (hyperstimulation analgesia)[10,11]. Physical effects on cell permeability and induction of diffusible radicals have also been postulated to cause disruption of the tendon tissue, resulting in induction of a healing process[9].

The efficacy of ESWT in the treatment of lateral elbow pain has been systematically reviewed[12-14]. Boddeker, *et al* included 20 studies, of which only one was a randomized controlled trial (RCT)[10]. The other 19 studies included were case series reporting beneficial effects of ESWT. Our original systematic review included 2 RCT[6,10], but due to their conflicting results we were unable to draw any firm conclusions about the efficacy of ESWT[13]. Stasinopoulos and Johnson have recently published another systematic review that included an additional 3 placebo-controlled trials[15-17], one trial comparing ESWT to steroid injection[18], and one trial comparing 2 different ESWT delivery techniques[19]. They performed a methodological assessment of included trials, but did not perform a metaanalysis of the available data[14]. We have found 4 additional randomized placebo-controlled trials that were not included in their review[20-23]. Our aim was to determine the efficacy and safety of ESWT for lateral elbow pain by performing an updated systematic review and metaanalysis of all currently available RCT data.

MATERIALS AND METHODS

This systematic review used the methodology proposed by the Cochrane Collaboration[24].

Literature identification. The literature was searched up to and including February 2005 according to the sensitive search strategy outlined by the Cochrane Collaboration for RCT[25]. Medline, Embase, CINAHL, Science Citation Index (Scisearch), and the Cochrane Controlled Trials Register were searched. As this was one in a series of reviews for lateral elbow pain, it was decided not to include search terms for specific interventions, but simply to identify all possible trials related to lateral elbow pain. The reference lists of all identified studies and correspondence relating to those studies were also searched. The details of the search strategy are given in the Appendix.

Eligibility criteria. Two independent reviewers (RB, JY) examined the titles and abstracts of the trials identified by the search strategy to determine whether they met the inclusion criteria. All trials classified as relevant by at least one of the reviewers were retrieved and translated where necessary. The retrieved articles were reexamined to ensure they met the inclusion criteria.

All published and unpublished randomized comparisons of ESWT versus placebo, or another modality, or of varying types and dosages of SWT were included in this review, and comparisons were established according to intervention. Trials were included if participants were adults (age > 16 years) with lateral elbow pain defined as elbow pain that is maximal over the lateral epicondyle, and increased by pressure on the lateral epicondyle and resisted dorsiflexion of the wrist and/or middle finger. Trials that included participants with a history of significant trauma or systemic inflammatory conditions such as rheumatoid arthritis were excluded. Studies of various soft tissue diseases and pain due to tendinitis at all sites were included, provided that the lateral elbow pain results were presented separately or > 90% of participants in the study had lateral elbow pain.

Methodological quality assessment. Two reviewers independently assessed the methodological quality of each trial. As in our original review[13], the methodological quality of included trials was assessed based upon whether the trials met key criteria (appropriate randomization, allocation concealment, blinding, number lost to followup, and intention-to-treat analysis). Failure to fulfil these criteria was considered to have potentially biased the overall outcome of the included trial. Allocation concealment was ranked as: A, adequate; B, unclear; or C, 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. Authors were contacted to obtain more information when needed. All outcomes reported in the trials were extracted and these included overall pain, pain at rest and with activities and resisted movements, function/disability, Roles and Maudsley score, grip strength, satisfaction with abilities to perform full activities and sport, composite endpoints of "success" of treatment, and adverse effects.

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

Analysis. The results of each trial were plotted as point estimates, i.e., relative risks (RR) with corresponding 95% confidence intervals for dichotomous outcomes, and mean and standard deviation for continuous outcomes. For continuous measures, preference was given to analyze the results with weighted mean differences, because these results are easier to interpret for clinicians/readers. If this was not possible (due to different trials using different scales and/or inability to convert data into the same scale), then standardized mean differences (SMD) or effect sizes were used. The studies were first assessed for clinical homogeneity with respect to the duration of the disorder, type, frequency and total dose of ESWT, control group, and the outcomes. Clinically heterogeneous studies were not combined in the analysis, but were described separately. For studies judged as clinically homogeneous, statistical heterogeneity was tested by Q test (chi-square) and I^2. Clinically and statistically homogeneous studies were pooled using the fixed-effects model. Clinically homogeneous and statistically heterogeneous studies were pooled using the random-effects model.

For the purposes of comparison and pooling data, the timing of followup has been described in this review by time from completion of treatment irrespective of when and how many treatments were given. Where appropriate, results were grouped according to the timing of followup from the completion of treatment as one of the following: (1) immediately after the end of treatment up to 1 week after the end of treatment; (2) short-term followup (4 to 6 weeks after the end of treatment); (3) intermediate followup (12 to 24 weeks after the end of treatment); or (4) longterm followup (1 year or longer, after the end of treatment).

Grading the strength of the evidence. To rank the evidence included in this review, we used the system of grading the strength of scientific evidence for a therapeutic agent that is described in the Cochrane Musculoskeletal Group scope and in *Evidence-based Rheumatology*[26]. Four categories are used to rank the evidence from research studies from highest to lowest quality as follows: (1) Platinum: A published systematic review that has at least 2 individual controlled trials, each satisfying the following: sample sizes of at least 50 per group — if these do not find a statistically significant difference, they are adequately powered for a 20% relative difference in the relevant outcome; blinding of patients and assessors for outcomes; followup is > 80% (and if not

imputations based on methods such as last observation carried forward (LOCF) are acceptable); and concealment of treatment allocation. (2) Gold: At least one randomized clinical trial meeting all the above criteria for the major outcome(s) as reported. (3) Silver: A systematic review or randomized trial that does not meet the above criteria. Silver ranking would also include evidence from at least one study of nonrandomized cohorts that did and did not receive the therapy, or evidence from at least one high quality case-control study. A randomized trial with a "head-to-head" comparison of agents would be considered silver-level ranking unless a reference were provided to a comparison of one of the agents to placebo showing at least a 20% relative difference. (4) Bronze: The bronze ranking is given to evidence if at least one high quality case series without controls is included (including simple before/after studies in which patients act as their own control) or if the conclusion is derived from expert opinion based on clinical experience without reference to any of the foregoing (for example, argument from physiology, bench research, or first principles).

RESULTS

Description of included trials. Our review published in 2002 included 2 placebo-controlled trials involving 115 and 271 participants, respectively[10,6]. This updated review includes an additional 7 placebo-controlled trials involving 75, 24, 86, 60, 78, 114, and 183 participants, respectively (total 1006 participants)[15,23,16,20,17,21,27], and one trial of ESWT versus steroid injection involving 93 participants[18]. A description of each trial is provided in Table 1. Two trials were published in abstract form[27,28], but were available from the US Food and Drug Administration (FDA) website[22,29] at the time of this review, and one of these has subsequently been published[21]. All trials were published in English and one was also published in German[7]. The trials were performed in Germany[10,17], Germany and Austria[6], the United Kingdom[15,16,18,23], Canada[20], and the United States[21,22]. We excluded one RCT that compared 2 ultrasound localization techniques to focus the ESWT because it provided no information regarding efficacy of ESWT[19].

Overall, the studies were clinically homogeneous with respect to the type, frequency, and total dose of ESWT. A variety of devices were used to generate shock waves in the different trials, although most appeared to use similar sets of shock wave parameters (Table 1). Six trials generated shock waves electromagnetically[10,15-17,20,21]; one trial used electrohydraulic shock waves[22]; in 2 trials the type of shock waves were not specified[18,23]; and one trial used 8 different shock wave devices at different sites but all were comparable with respect to shock wave parameters as determined by a consensus report by the technical working group of the German Association for Shock Wave Lithotripsy[6]. Three trials administered local anesthetic (3 ml of 1% mepivacaine[6]; 3–5 ml 1% lignocaine[23] or local anesthetic or a bier block[22]). Nine of the 10 trials administered 3 treatments, but the interval between treatments varied from 7 ± 1 days[6], weekly[10,17,18,20,21], fortnightly[23], and monthly[15]. The interval between treatments was not provided for one trial[16]. One trial administered a single treatment[22].

The placebo control group comprised a physical block to the shock waves[6,16,17,20-23]; or a subtherapeutic dose of ESWT (i.e., 10 impulses of 0.08 mJ/mm^2 [10]; or minimal energy pulses of 0.04 mJ/mm^2 in order to create the same sound with the treatment head deflated, no coupling gel, and avoidance of skin contact[15]. One trial compared ESWT to 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[18].

Description of trial participants. Nearly all trials recruited similar study populations. Participants all had lateral elbow pain, with most studies also requiring evidence of localized tenderness at or near the common extensor tendon origin at the lateral epicondyle and reproduction of pain with resisted movements (e.g., resisted wrist or middle-finger extension). Seven trials specified that participants had to have had a varying number and/or duration of unsuccessful conservative treatments prior to trial inclusion[6,10,16,17,21-23], whereas one trial included only participants who had not previously received any treatment[20]. One trial included only recreational tennis players[17]. The mean duration of pain was generally long in 7 trials, with some trials including participants with symptoms for over 10 years (Table 1). The mean duration of symptoms was much shorter in one trial, 19.8 weeks (SD 13.2) and 22.1 weeks (SD 15.7) in the ESWT and placebo groups, respectively[20]; and the duration of symptoms of study participants was not reported in 2 trials[16,18].

Timing of followup and outcome assessment. There was no uniformity in the timing of followup assessments, which varied from during treatment to 12 months after the final treatment (Table 1). A primary endpoint was prespecified in 6 trials[6,15,17,20-22]. All trials included pain scales, but these varied between studies. Three studies[16,17,21] used validated measures of function — the Disabilities of Arm, Shoulder and Hand (DASH)[30] or the Upper Extremity Functional Scale (UEFS)[31]. Three trials[6,10,17] used the Roles and Maudsley scale, which combines assessment of pain and satisfaction with treatment into a 4-point categorical scale[32]. Rompe, *et al* measured overall satisfaction by asking participants whether they were able to perform activities at the desired level and to continue to play recreational tennis[17]. One study used the thermometer subsection of the EuroQol 5D (EQ5D) quality of life instrument to assess quality of life[20]. Pettrone, *et al* also used a "patient-specific activity score" by asking participants to identify 2 activities from the UEFS that they found particularly difficult to perform and rating their difficulty from 1 (no difficulty) to 10 (cannot perform); and an overall participant evaluation of their disease status on a 100 mm visual analog scale[21].

Methodological quality of included studies. Table 2 summarizes the methodological aspects of the included trials. Concealment of treatment allocation was adequate in 2 trials[6,20] and adequate to 12 weeks following completion of treatment in one trial[21]; was considered inadequate in one trial[23]; and was unclear in the remaining 6 trials[10,15-18,22]. One

Table 1. Summary of randomized controlled trials of extracorporeal shock wave therapy (ESWT) for lateral elbow pain.

Study	Sample Size and Design	Age, yrs, mean (SD)*: ESWT, control groups	Duration symptoms, mo*, mean (SD)*: ESWT, control groups	ESWT Treatment	Comparison Group	Outcome Timing	Outcome Measures and Primary Endpoint
Chung[20]	60, RCT, single site	46.8 (6.6) 45.5 (6.6)	19.8 wks (13.2) 22.1 wks (15.7)	3 sessions at wkly intervals; Sonocur Basic (Siemens AG, Erlangen, Germany): treatment directed to point of maximum pain; 2000 pulses of 0.03 to 0.17 mJ/mm^2 per session; no local anesthesia	Placebo: air buffer pad prevented transmission of shock waves; 2000 pulses of 0.03 mJ/mm^2	Baseline, 1, 5 wks after completion of treatment	1. Overall pain, resting pain, pain during sleep and during main activity, pain at its worst and least, 10 cm VAS 2. Thermometer subsection, EuroQol 5D 3. Pain-free maximum grip strength 4. Pain medication log 5. Adverse effects. Primary outcome: treatment success: at least 50% reduction in overall elbow pain and maximum allowable overall pain score 4.0 cm and no use of pain meds for lateral elbow pain for 2 wks before the final evaluation
Crowther[18]	93, RCT, single site	49 (range 27–69)	Not reported	3 sessions at wkly intervals; portable Storz Minilith SL1 lithotripter; 2000 shock waves (maximum 0.1 mJ/mm^2) per session; ultrasound guidance; no local anesthesia	20 mg triamcinolone (made up to 1.5 ml with 1% lignocaine) injection	ESWT: baseline baseline, 8, 14 wks. Steroid injection: 0, 6, 12 wks	1. Pain VAS (0–100) 2. Reduction of pain of 50% as criterion of success at 3 mo after end of treatment
Haake[6]	271, RCT, multicenter (n = 15)	46.9 (8.5) 46.3 (9.6)	27.6 (35.5) 22.8 (21.4)	3 sessions of 2000 pulses at ED+ = 0.07–0.09 mJ/mm^2; 6–8 days between each treatment; ultrasound used to focus the shock waves; performed under local anesthesia. Different shock wave devices used at different sites according to standard parameters	Placebo: polyethylene foil filled with air and fixed with ultrasound gel in front of the coupling cushion; same dose as active group	Baseline, 6, 12 wks and 12 mo after last intervention	Primary endpoint: success rate after 12 wks defined as subjective pain scale described by Roles and Maudsley score** was 1 or 2 and patient did not receive additional conservative or operative treatment in observed time interval. Secondary endpoints: 1. Roles = Maudsley score** 2. Intensity of pain, 11-point scale (0 = no pain, 10 = unbearable) 3. Grip strength (Bowden test) 4. Side effects and adverse reactions
Levitt[27,22]	183, RCT, multicenter (no. not specified)	44 (range 22–66) 46 (range 32–71)	22.5 (range 5.3–161.7) 4.1 (range 4.1–265.9)	Total of 1500 shocks delivered at 18 kV; under local anesthetic or bier block; affected arm draped from view of the subject	Placebo: styrofoam block to absorb shock waves; fluid-filled IV bag placed between styrofoam block and subject's elbow to mimic the feel of the coupling membrane; 1500 shocks at 18 kV	Baseline, 4 and 8 wks after treatment	1. Pain (10 cm VAS) at point of tenderness over affected lateral epicondyle by application of a pressure sensor to record amount of pressure applied, to ensure same amount of pressure was applied at each followup assessment 2. Subject self-assessment of pain during activity on 10 cm VAS 3. Frequency of pain medications use (none — chronic) Primary endpoint: success/failure after the 8-wk assessment defined as: minimum 50% improvement over baseline in investigator assessment of elbow pain, and score ≤ 4 on VAS; and minimum 50% improvement over baseline in self-assessment of elbow pain, and score ≤ 4 on VAS; and none or rare pain medication use defined as no more than 3 doses of medication during the week immediately prior to being evaluated

Table 1. Continued.

Study	Sample Size and Design	Age, yrs, mean (SD)*: ESWT, control groups	Duration symptoms, mo*, mean (SD)*: ESWT, control groups	ESWT Treatment	Comparison Group	Outcome Timing	Outcome Measures and Primary Endpoint
Mehra[23]	24, RCT, single center	No data provided	Did not specify minimum duration of symptoms	3 treatments at 2-wk intervals; 2000 shock waves at 2.5 bars of air pressure and frequency of 8–10 Hz. Electro Medical Systems (EMS) Swiss DolorClast System used. All participants received 3–5 ml 1% lignocaine at site of maximal tenderness	Placebo: clasp placed on elbow intercepted shock waves	Baseline, 3, and 6 mo after final treatment	1. Pain on VAS of 0–10. Improvement in score by 3 points considered to be significant
Melikyan[16]	86, RCT, single center	43.4 (range 35–71)	Did not specify minimum duration of symptoms	Shock waves focused on common extensor origin with ultrasound guidance; all treatments started at low energy level (1–3) and intensity gradually increased according to tolerance, not exceeding level 6.A fixed amount of energy (333 mJ/mm^2) was delivered per session (total 1000 mJ/mm^2)	Placebo: Foam pad placed between treatment head and skin acted as a reflective medium	Baseline, 1, 3, and 12 mo after end of treatment	1. DASH function/symptom score 2. Mean pain (VAS) in a typical week, and on lifting a 5 kg dumbbell 3. Grip strength (JAMAR dynamometer) 4. Analgesic requirements 5. Endpoint defined as either surgery for tennis elbow as originally planned or a request to be removed from surgical waiting list
Pettrone[21]	114, RCT, 3 centers Open trial if not improved ≥ 50%; Thomsen test at 12 wks after end of treatment and crossover permitted	47 (range 35–71) 47.3 (range 35–60)	21.3 (range 6–178) 20.8 (range 6–176)	2000 impulses at 0.06 mJ/mm^2 using Sonocur ESWT system (Siemens, USA) wkly for 3 wks; treatment head directed to point of maximal tenderness on the lateral epicondyle; shock wave focus adjusted every 200–400 impulses to the most symptomatic site; no local anesthesia	Placebo: 2000 impulses at 0.06 mJ/mm^2 using sound-reflecting pad between patient and treatment head	Baseline, 3, 6, 10, 14 wks and 6.5 and 12.5 mo from bsaeline	1. Thomsen provocation test, 100 mm VAS 2. UEFS 3. Subjective patient evaluation of disease status, 100 mm VAS 4. Patient-specific activity score: patients rated difficulty from 1 (no difficulty) to 10 (can't perform) for 2 patient-identified activities they found particularly difficult to perform (activities chosen from the UEFS). Patient-specific activity score was the average of these 2 ratings (range 1–10) 5. Grip strength (Jaymar dynamometer) 6. Adverse effects. Primary efficacy endpoint was a 50% reduction in provocation of pain by Thomsen test at 12 wks following completion of treatment compared to baseline
Rompe[10] 1996 Germany	115, RCT, single, center	43.9 (range 26–61) 41.9 (range 26–58)	24.8 (range 10 to 120) 21.9 (range 10–46)	1000 impulses of 0.08 mJ/mm^2 at wkly intervals for 3 wks. Treatment was administered at anterior aspect of lateral epicondyle and at 3 points around this site at a radius of 1.5 to 2 cm at a frequency of 3 Hz	Placebo: 10 impulses of 0.08 mJ/mm^2 at wkly intervals for 3 wks as per active group	Baseline, end of 3-wk treatment, 3, 6, and 24 wks after end of treatment	1. Pain on 100 mm VAS (night pain; pain at rest; pain with palpation over lateral epicondyle; pain with resisted wrist extension (Thomsen test); pain with resisted middle-finger extension; and pain with Chair test) 2. Overall outcome defined by level of residual pain at end of 12 wk followup, according to Roles-Maudsley score**. Failure defined by authors as Roles-Maudsley response of 4 (poor) 3. Grip strength measured by dynamometer & classified according to Mucha and Wannske criteria: 1 = equal strength on both sides; 2, 3, 4 = up to 25%, 50%, 75% reduction of grip strength compared with unaffected side

Table 1. Continued.

Study	Sample Size and Design	Age, yrs, mean (SD)*: ESWT, control groups	Duration symptoms, mo*, mean (SD)*: ESWT, control groups	ESWT Treatment	Comparison Group	Outcome Timing	Outcome Measures and Primary Endpoint
Rompe[17]	78, RCT, single center, recreational tennis players. open trial from 12 wks and crossover permitted	45.9 (12.3) 46.2 (11.2)	23.3 (range 12–120) 25.1 (range 12–132)	3 treatments at wkly intervals of low energy ESWT with 3 × 2000 pulses applied using device-dependent energy flux density of 0.09 mJ/mm^2. Repetition frequency of shock wave pulses was 4 Hz. Total dose 0.54 mJ/mm^2. Initially shockwaves delivered at lowest energy level and increased to 0.09 mJ/mm^2 within 100 pulses	Polyethylene foil filled with air and fixed with ultrasound gel in front of the coupling cushion completely reflected shock waves. Typical sound created by the litho-tripter remained constant	Baseline, 3 and 12 mo after last treatment	1. Pain on 10 cm VAS during resisted wrist extention (Thomsen test) 2. No. of participants with ≥ 50% improvement in pain with resisted wrist extension 3. Roles-Maudsley score** 4. UEFS 5. Maximum grip strength (Jamar dynamometer) 6. Overall satisfaction: ability to perform activities at desired level and to continue playing recreational tennis 7. Adverse effects Primary efficacy endpoint: pain elicited during resisted wrist extension (Thomsen test) at 12 wks following completion of treatment compared to baseline. Relevant clinical improvement defined as > 30% decrease of pain ratings
Speed[15]	75, RCT, single center	46.5 (range 26–70) 48.2 (range 31–65)	15.9 (range 3–42) 12 (range 3–40)	3 treatments at monthly intervals of 1500 pulses at 0.18 mJ/mm^2. Ultrasound used to localize area of maximal pain; no local anesthetic	Placebo: minimal energy pulses 0.04 mJ/mm^2; treatment head deflated, no coupling gel applied and no contact with skin	Baseline, 1, 2, and 3 mo (1 mo after completion of therapy)	1. Pain (10 cm VAS) during day and at night. 50% improvement from baseline considered a positive response Primary endpoint: final followup at 3 mo from baseline

* Unless otherwise specified. ** Roles-Maudsley score: 1 = excellent, no pain, patient satisfied with treatment outcome; 2 = good, symptoms significantly improved, patient satisfied with treatment outcome; 3 = acceptable, symptoms somewhat improved, pain at a more tolerable level than before treatment, patient slightly satisfied with treatment outcome; 4 = poor, symptoms identical or deteriorated, patient not satisfied with treatment outcome. VAS: visual analog scale; RCT: randomized controlled trial; DASH: Disabilities of Arm, Shoulder, and Hand[30]; UEFS: Upper Extremity Functional Scale[31] : self-administered 8-item questionnaire used to measure the impact of upper extremity disorders on a person's ability to perform physical tasks. Rating of each task ranges from 1 to 10 points, where 1 indicates no problems with completing the task and 10 indicates a major problem or inability to complete. The physical tasks rated are sleeping, writing, opening jars, picking up small objects with fingers, driving car more than 30 minutes, opening a door, carrying a milk jug from refrigerator, washing dishes. UEFS score is the sum of all responses (range 8–80). EDt: positive energy flux density.

trial unblinded all participants and outcome assessors at 12 weeks after the completion of treatment[17]. 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 there had not been at least a 50% improvement in pain elicited by the Thomsen test compared to baseline[21]. Participants in the placebo group were also offered the active treatment at this time, and outcome assessors were unblinded if participants received crossover treatment. It is not known whether unimproved participants in the active group (who were unblinded at 12 weeks) could receive additional treatment. Results after 12 weeks for both trials therefore need to be interpreted cautiously and are not presented in this review.

Efficacy of ESWT

ESWT versus placebo. The 9 placebo-controlled trials included in this updated review reported conflicting results. Three trials reported significant differences in favor of ESWT for all or most measured endpoints[10,17,21], whereas 4 trials reported no benefit of ESWT over placebo for any measured endpoint[6,15,16,20]. Another (unpublished) trial reported a statistically significant difference in the primary composite endpoint of significant improvement in investigator and subject-assessed pain and rare use of pain medications; however, this appeared to be a completers-only analysis, and when an intention-to-treat analysis was performed this result was no longer statistically significant: 33/93 (35.5%) and 20/90 (22.2%) in the ESWT and placebo groups, respectively (p = 0.07); and benefit was only demonstrated for investigator-assessed pain

Table 2. Methodological quality of randomized controlled trials of extracorporeal shock wave therapy (ESWT) for lateral elbow pain.

Author/ Year	Randomization Method	Treatment Allocation*	Blinding**	Loss to Followup	Sample Size	Intention-to-Treat Analysis
Chung[20]	Block randomization, random block sizes 2, 4, 6; stratified for unilateral or bilateral involvement	A. Sequence generation and concealment by person not involved in study; numbered opaque envelopes	A, B	4/60 (6.7%)	30 participants/group sufficient power ($\alpha = 0.05$, $1-\beta = 0.8$) to detect 2-fold difference in proportion of treatment successes at 8 wks assuming 20% placebo success and 20% dropout rate	Yes
Crowther[18]	Not described	B. Closed unmarked envelopes	Participants not blinded; unclear if outcome assessment blinded	Not reported	Not reported	No. treatment completers only (ESWT 48/51, steroid injection 17/42)
Haake[6]	Permuted blocks of 6 and 4; stratified by center	A	A, B	25/271 (9%) (ESWT 10; placebo 15)	20% difference in success of therapy at 12 wks	Yes
Levitt[27,22]	Not described	B	A, B	18/183 (9.8%) (ESWT 11, placebo 7)	Not reported	No
Mehra[23]	100 slips of paper marked either "T" or "P"; participants drew randomly	C	A. Outcome assessment not blinded	nil	Not reported	Yes (as far as can tell)
Melikyan[16]	Not described	B	A, B	12/86 (14%)	Not reported	No
Pettrone[21]	Not described	A. Sealed envelope containing randomization code (A or B) given to participant at entry to study but opened by ESWT operator only	A, B to 12 weeks but unblinding at 12 wks if not ≥ 50% improved on Thomsen test at 12 wks after end of treatment. Placebo offered active treatment	6/114 (6.1%) (3 from each group) prior to 12 wk assessment; 57/114 (50%) unblinded at 12 wks (ESWT 19; placebo 38 and 34 then received active treatment)	45 participants/group to provide sufficient power ($\alpha = 0.05$, $1-\beta = 0.8$) to show 30% difference in proportion of participants improved by ≥ 50% from baseline, assuming 50% success in placebo group	Yes
Rompe 1996[10]	Not described	B	A, B	15/115 (13%)	Not reported	No
Rompe 2004[17]	Computer-generated random numbers list	A. Only person performing intervention knew treatment allocation	A, B until 3 mo assessment only	8/78 (10.3%) (4 in each group) at 3 mo; 14 (18%) (7 in each group) at 12 mo	35 participants in each group would provide sufficient power ($\alpha = 0.01$, $1-\beta = 0.8$) to detect difference of 2 points in average pain at 3 mo assuming pain is 5 ± 2 in placebo group	Yes
Speed[15]	Not described	B	A, B	4/75 (5.3%)	Not reported	Yes

* A: adequate, B: unclear, C: inadequate. ** A: participant blinded; B: outcome assessor blinded.

at 8 weeks[22]. The other small trial of 24 participants reported benefit, i.e., 10/13 participants improved significantly by ≥ 3 points on a 10-point pain scale at 6 months in comparison to 1/11 participants in the placebo group[23].

While all trials were clinically homogeneous with respect to duration of symptoms (except for Chung, *et al*[20]), type, frequency and total dose of ESWT, and control group, there was no uniformity in the timing of followup and outcomes assessed, limiting the ability to pool data across studies. Data from 2 placebo-controlled trials could not be pooled: the majority of data in one trial were presented graphically with no measures of variance[16]; and one trial reported only mean data with no measures of variance[23]. When available data were pooled, most benefits observed in the positive trials were no longer statistically significant. For example, pooled analysis of 3 trials (446 participants) showed that ESWT is not

more effective than placebo with respect to pain at rest at 4 to 6 weeks after the final treatment [weighted mean difference (WMD) for pain out of 100 = –9.42 (95% CI –20.70 to 1.86); Figure 1]; pooled analysis of 3 trials (455 participants)[6,17,21] showed that ESWT is not more effective than placebo at 12 weeks after the final treatment with respect to pain provoked by resisted wrist extension (Thomsen test) [WMD for pain out of 100 = –9.04 (95% CI –19.37 to 1.28); Figure 2] and grip strength [SMD 0.05 (95% CI –0.13 to 0.24); Figure 3].

However, pooling data from 2 positive trials (192 participants)[17,21] did show a benefit for ESWT over placebo with respect to success of treatment, defined as at least a 50% improvement in pain with resisted wrist extension at 12 weeks following completion of treatment [RR 2.2 (95% CI 1.55 to 3.12); Figure 4], while 4 other individual trials with well defined criteria for success at 4 to 12 weeks, from which data could not be pooled, failed to find evidence of benefit of ESWT[6,15,20,22]. Pooling the results of the same 2 positive trials[17,21] also showed a statistically significant benefit for ESWT over placebo for function as measured by the UEFS [WMD –9.20 (95% CI –13.56 to –4.84)], although the clinical significance of this finding is not known.

Pooled analyses combining results of other trials failed to show statistically significant benefits for ESWT over placebo across a range of outcomes including mean pain with resisted middle-finger extension or resisted wrist extension at 6 weeks following completion of treatment, night pain at 3–4 weeks following completion of treatment, or failure of treatment defined by a Roles and Maudsley score of 4 at 6 weeks and 12 months following completion of treatment. Based upon the results of one small trial[16], there was no difference in the number of participants who eventually underwent surgical release of the common extensor origin following treatment [17/37 in the ESWT group and 16/37 in the placebo group; RR = 1.06 (95% CI 0.64 to 1.77)]. The timing of surgery in relation to the trial was not specified.

ESWT versus steroid injection. One trial reported that steroid injection was more effective than ESWT at 3 months after the end of treatment, assessed by a reduction of pain of 50% from baseline as the criterion of success [21/25 (84%) vs 29/48 (60%); $p < 0.05$]. Mean pain scores at 6 weeks after the end of treatment also favored steroid injection, although measures of variance were not reported [mean pain (on a 0–100 scale) at baseline and 6 weeks was 67 and 21, respectively, in the steroid-injection group and 61 and 35 in the ESWT group; $p = 0.052$]. At 3 months after the end of treatment, mean pain scores also favored steroid injection (12 and 31 in the steroid-injection and ESWT groups, respectively).

Adverse effects

Four trials reported no significant adverse effects in any treatment groups[10,15,16,18]. One trial documented significantly more side effects in the ESWT group (OR 4.3, 95% CI 2.9 to 6.3)[33]. However, there were no treatment discontinuations or dosage adjustments related to adverse effects. The most frequently reported side effects in the ESWT-treated group were transitory reddening of the skin (21.1%), pain (4.8%), and small hematomas (3.0%). Migraine occurred in 4 participants and syncope in 3 participants following ESWT. Mehra, *et al*[23] reported that 8 participants complained of increased pain and 4 participants reported localized redness during treatment, although the condition being treated (lateral epicondylitis or

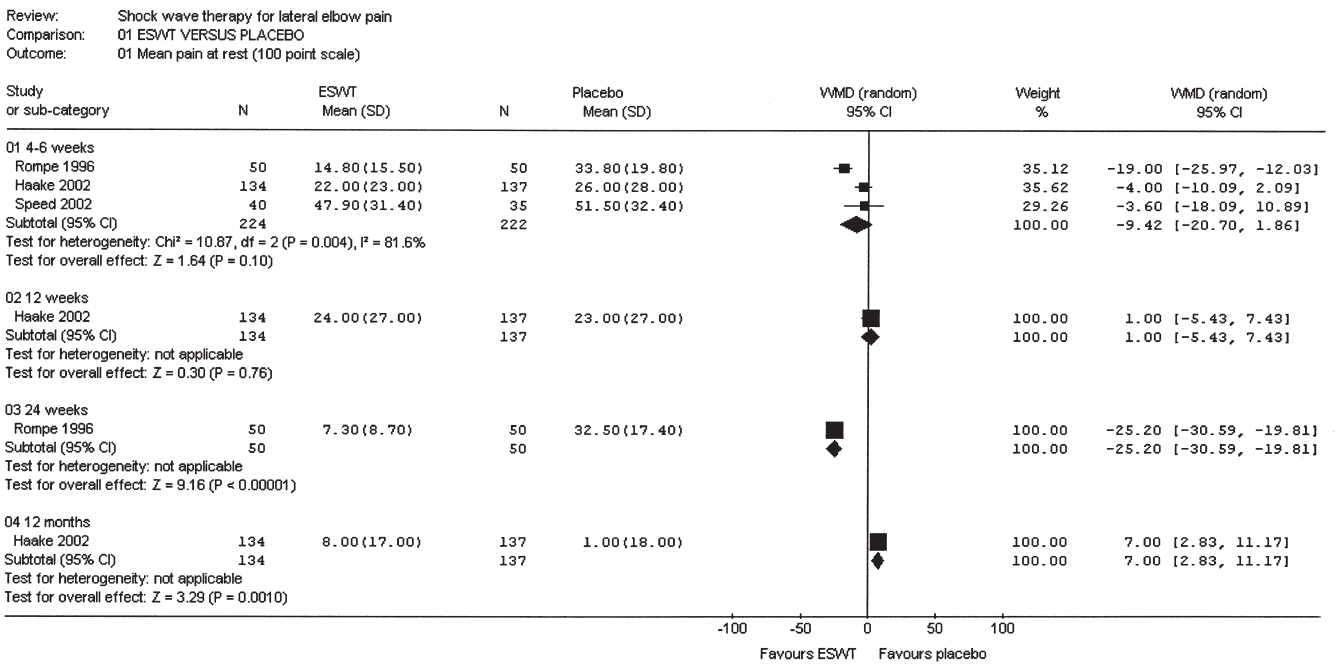

Figure 1. ESWT versus placebo: mean pain at rest (100-point scale). WMD: weighted mean difference.

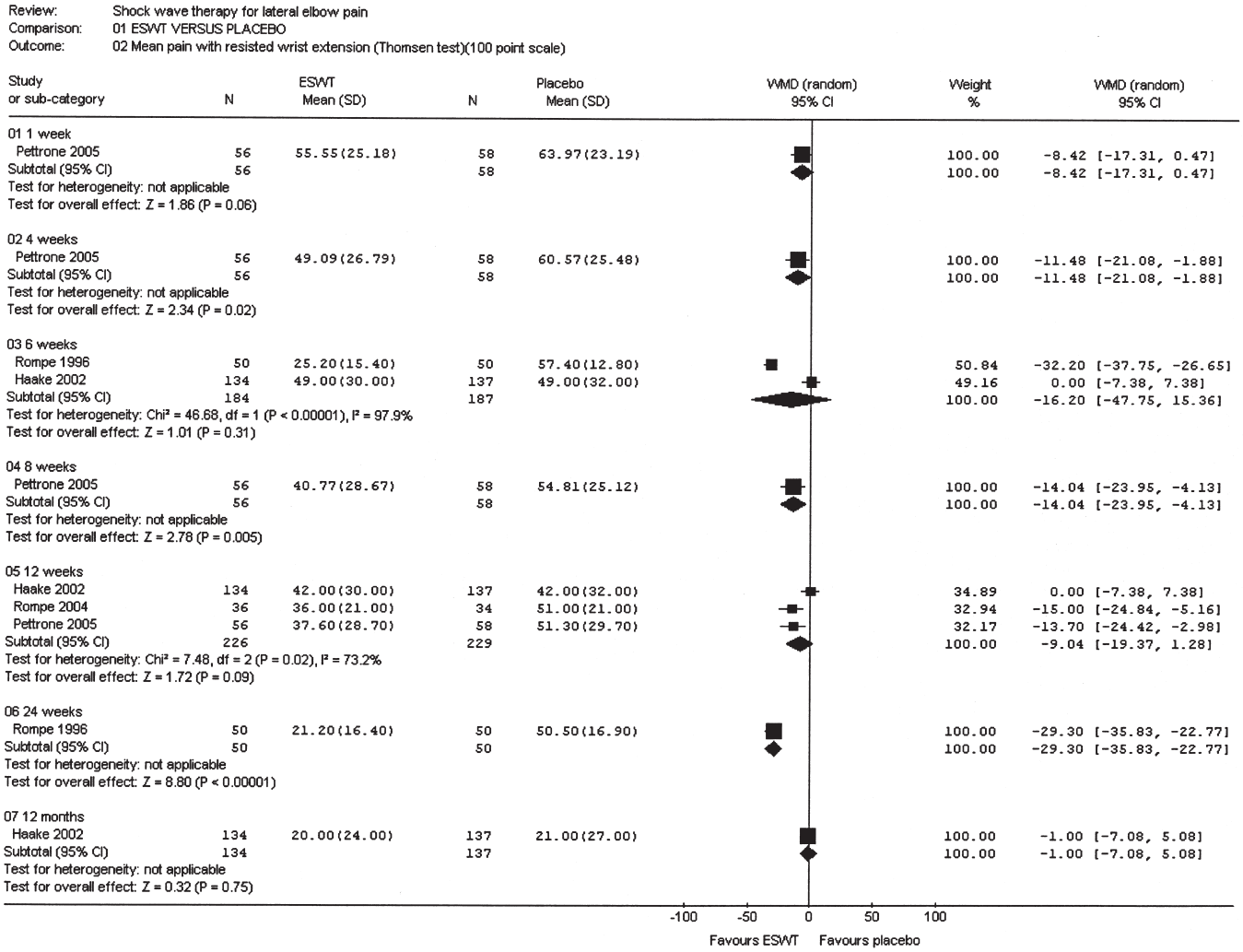

Figure 2. ESWT versus placebo: mean pain with resisted wrist extension (Thomsen test) (100-point scale). WMD: weighted mean difference.

plantar fasciitis) and the treatment group (ESWT or placebo) were not specified. Chung, *et al*[20] reported mild adverse events in 11 participants (35.5%) in the ESWT group and in 13 (46.1%) in the placebo group [tingling during therapy (5 placebo group), nausea during therapy (3 ESWT group), aching after therapy (one in each group), soreness after therapy (3 ESWT group, 4 placebo group), and increased pain symptoms after therapy (4 ESWT group, 3 placebo group)]. Pettrone and McCall[21] reported no serious adverse device effects. However, 28 (50%) and 13 (22.4%) participants in the active and placebo groups, respectively, experienced transient moderate treatment-related pain; and 10 (17.9%) participants in the active group experienced nausea during the treatment. Two participants in the active group had to stop treatment sessions prior to receiving the full 2000 impulses because of nausea: one of these participants subsequently withdrew from the study and the other was able to resume and tolerate the treatment later. An additional participant in the active group withdrew after completing the first treatment due to pain and a slight tremor in the treated arm. All side effects resolved. Rompe, *et al*[17] reported temporary reddening after low-energy shock wave application in all patients. Pain during treatment occurred in 36/38 (94.7%) and 21/40 (52.5%) of active ESWT and placebo participants, respectively; and nausea during treatment occurred in 8/38 (21.1%) and 1/40 (2.5%) active ESWT and placebo participants, respectively. All side effects had resolved by final followup. Levitt, *et al*[22] reported localized swelling, bruising, or petechiae at the treatment site (n = 19) and reactions to anesthetic agents (n = 9); however, all anesthetic reactions occurred at a single site and may have been related to the method of administering a regional block.

DISCUSSION

Nine placebo-controlled trials including 1006 participants, reporting conflicting results, were included in this systematic review. Data from 6 trials could be pooled, and based upon this data most of the evidence supports the conclusion that ESWT is no more effective than placebo for lateral elbow

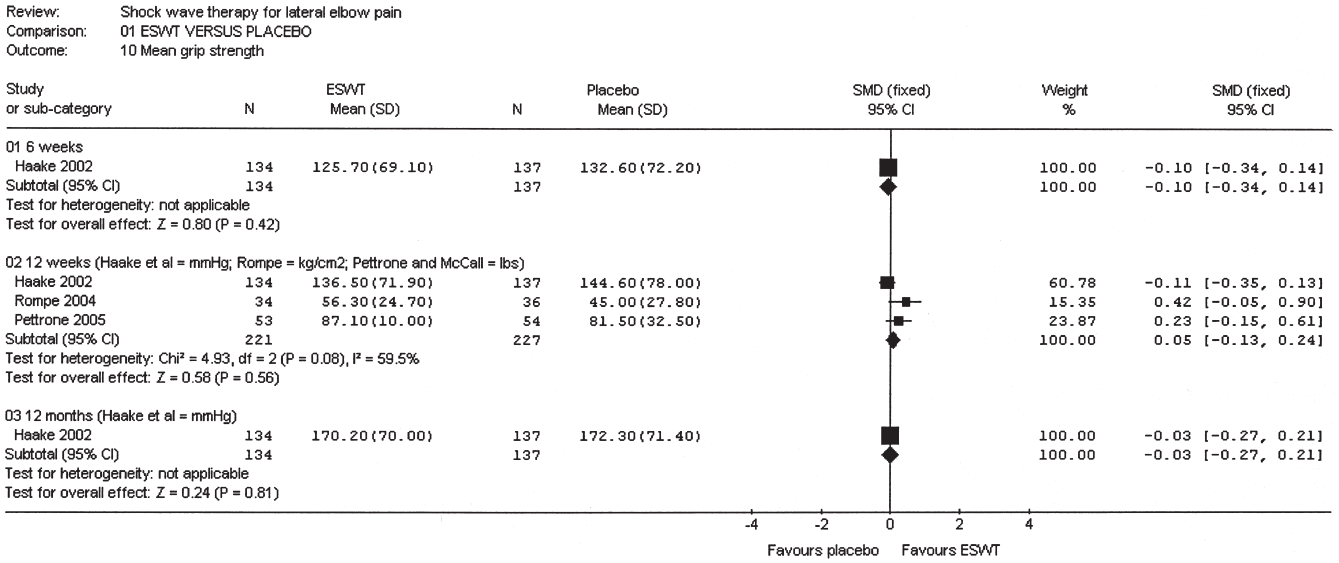

Figure 3. ESWT versus placebo: mean grip strength. SMD: standardized mean difference.

pain. While 3 trials reported highly significant differences in favor of ESWT, these results became nonsignificant when combined with the results of studies that reported no or minimal benefit of ESWT over placebo. Eleven of the 13 pooled analyses found no benefit of ESWT over placebo. The positive pooled results of 2 positive trials for treatment success were not supported by the results of 4 other individual trials that could not be pooled.

The inclusion of 2 placebo-controlled trials[16,23] that could not be included in the metaanalysis due to inadequate reporting of results would not have altered the overall findings of our review. Results of one of the 2 additional trials (86 participants) support the conclusion of the pooled analysis[16], while the second trial (24 participants) reported a significant benefit in favor of ESWT[23]. In view of the small size of the second trial, it is unlikely that it would have significantly altered the results of the metaanalysis if data were available for pooling. An additional trial[20] that studied untreated participants with lateral elbow pain also supported the findings of a lack of benefit of ESWT.

Our results are similar to the findings of a systematic review of ESWT for plantar heel pain[34]. Metaanalysis of data from the 4 high-quality RCT found no evidence of benefit of ESWT. The discrepancy in the results between the positive and negative trials in our review may also 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[6]. The second negative trial (75 participants) did not report the 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[15]. Of the 3 positive trials, one (115 participants) did not report the method of randomization and performed a completers-only analysis[10]. The other 2 positive trials allowed either all patients to be unblinded at 12 weeks[17] or unblinding at 12 weeks for those without an adequate response[21]. In both trials, placebo patients were also offered crossover into the active group at 12 weeks and unblinded patients were allowed additional therapy. Due to a diminished number of blinded participants and the possibility of confounding of any treatment effects, it was not possible to interpret the longterm results of these trials.

Our review also included one trial comparing steroid injection to ESWT, which showed a benefit of steroid injection over ESWT at 3 months with respect to 50% reduction of pain[18]. This is consistent with previous findings from one systematic review and subsequent RCT of corticosteroid injections for lateral elbow pain that found limited evidence of a short-term improvement in symptoms with steroid injections compared with placebo, a local anesthetic, orthoses (elbow strapping), physiotherapy, or oral nonsteroidal antiinflammatory drugs (NSAID)[35,36].

We found a lack of uniformity in included trials with respect to both the timing of followup and the outcomes that were measured. All studies measured pain, with some including varying aspects of pain (e.g., pain with activities and at different times). 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[6,10,17], although Rompe, *et al*[17] analyzed the results as continuous rather than categorical data. Three trials included an upper-arm-specific disability measure (the DASH)[16] or the

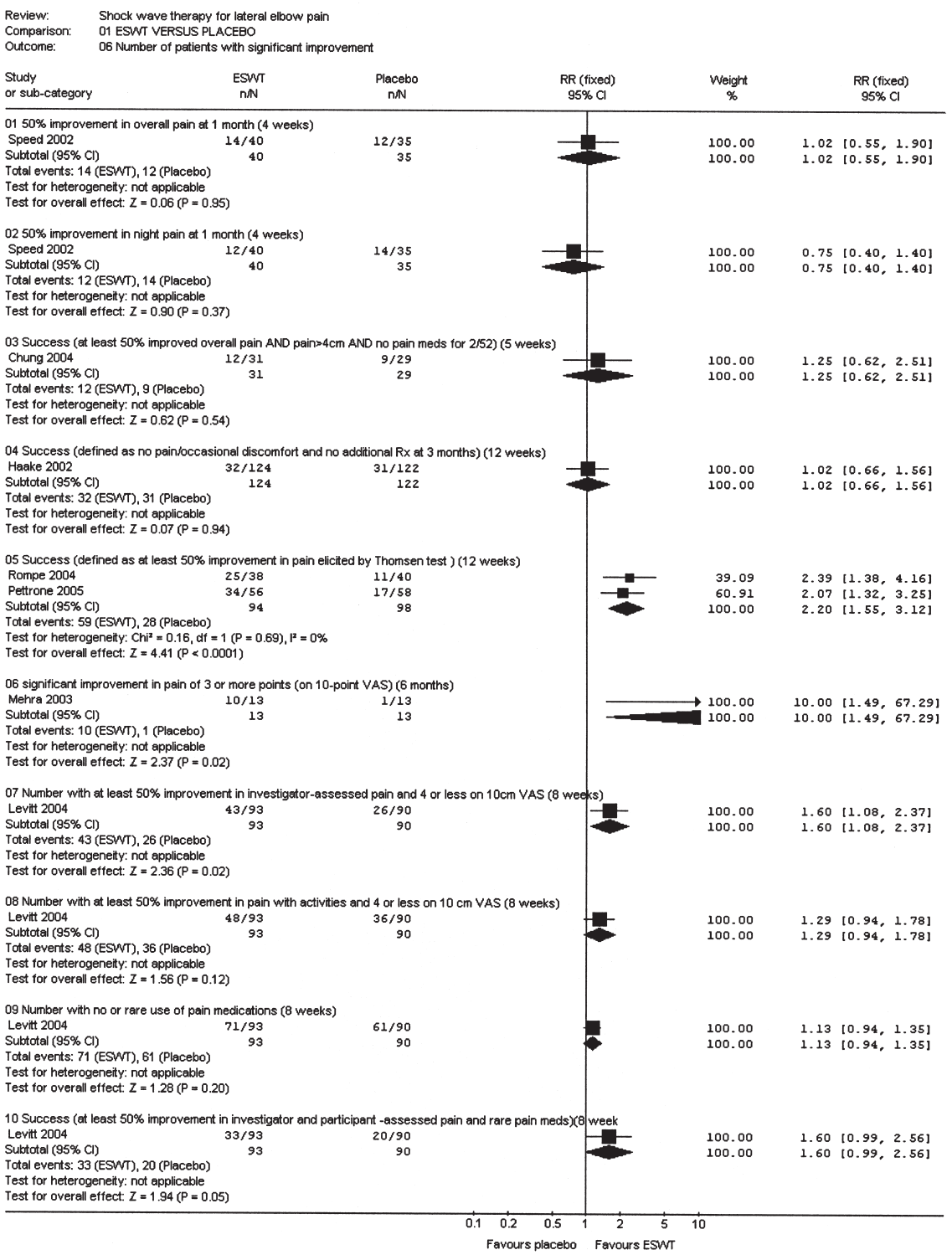

Figure 4. Number of participants with significant improvement. RR: relative risk.

UEFS[17,21], and no trial included a generic quality of life instrument (although information from the FDA report[22] of one unpublished trial suggested that the Medical Outcomes Study Short Form-36 may have been administered, although no results were given). 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. These might include overall pain with or without provocation, a measure of upper extremity function

(such as the UEFS or DASH), and ability to carry out usual activities, work and/or sport, and possibly also a measure of quality of life. To facilitate judgement about clinically important differences between treatment groups, it would also be useful to have consensus about what constitutes a clinically important improvement. Future trials could then report the proportion of participants who obtain a clinically important improvement in the groups being compared.

There continues to be considerable debate relating to the use of shock wave therapy in soft tissue musculoskeletal complaints, evident by the lively "Letters to the Editor" correspondence that seems to follow the publication of each new ESWT trial in the musculoskeletal field. Issues under contention continue to include the optimal shock wave treatment regimes; dosing intervals; and whether focusing of ESWT to the site of pathology can be improved by imaging methods such as ultrasound. Some experts argue that the shock waves should be focused to 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 ESWT. In our view, both methods are probably valid, as each would more than likely direct the focus of ESWT to the site of maximal pathology. Studies that directly compare one machine to another or compare dosing intervals, etc., may be able to determine whether there are any differences in outcome. One trial has compared 2 different ultrasound localizing techniques and reported no difference in outcome[19].

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*[17] required a positive MRI (increased signal intensity of extensors) for study inclusion. We previously used ultrasound to confirm the presence of plantar fasciitis in a trial of ESWT for plantar heel pain[37]. This may increase the homogeneity of the study population, increase the likelihood of being able to observe benefit of a new therapy if one exists, and enable valid comparisons to be made between studies. Another area of contention is the use of local anesthetic, opponents of its use arguing that local anesthetic may have detrimental effects on the outcome of ESWT, and in addition the patient is unable to verify that the correct site has been targeted when the area has been anesthetized.

All trials included in this review reported improvement in outcome in both the treated and nontreated 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 ESWT, highlighting the favorable natural history of this condition with its high rate of spontaneous improvement, 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 NSAID, corticosteroid injections, orthotics, and physiotherapeutic modalities. Yet the evidence as presented here to support this approach is limited. Furthermore, the trial by Chung and Wiley[20] failed to find any evidence of benefit of ESWT for patients with symptoms of lateral elbow pain for between 3 weeks and a year who had not been treated previously[20]. We were also previously unable to observe any differential effect of duration of symptoms on outcome from ESWT in a trial for plantar fasciitis[37]. At this time, the outcome of ESWT appears to be similar irrespective of duration of symptoms and/or receipt of prior treatment.

Summary

Based upon systematic review of 9 placebo-controlled trials, there is "Platinum" level evidence that shock wave therapy provides little or no benefit in terms of pain and function in lateral elbow pain. There is "Silver" level evidence based upon one trial that steroid injection may be more effective than ESWT.

New effective interventions for the treatment of lateral elbow pain are needed and these should be evaluated in high quality RCT prior to their routine clinical use. Their cost-effectiveness should also be assessed. Placebo effects of treatment and the fact that lateral elbow pain is a self-limiting condition also need to be taken into consideration when planning and interpreting the results of RCT. The CONSORT statement should be used as a model for reporting of RCT (available from: www.consort-statement.org; accessed March 13, 2006), including the method of randomization and treatment allocation concealment, followup of all participants who entered the trial, and an intention-to-treat analysis. Sample sizes should be reported and have adequate power to answer the research question, and for chronic pain, trials should ideally include both short-term and longterm followup. To enable comparison and pooling of the results of RCT, we suggest that future trials report means with standard deviations for continuous measures or number of events and total numbers analyzed for dichotomous measures. Development of a standard set of outcome measures, including a definition of what constitutes a clinically important improvement for lateral elbow pain, would also significantly enhance these research endeavors.

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APPENDIX

Search strategy for identification of studies.

1. exp Tennis Elbow/
2. exp Tendinitis/
3. exp Bursitis/
4. (tennis elbow or elbow pain or epicondylitis or tendonitis or tendinitis or common extensor origin).mp.
5. or/1-4
6. Clinical trial.pt.
7. random$.mp.
8. ((singl$ or doubl$) adj (blind$ or mask$)).mp.
9. placebo$.mp.
10. or/6-9
11. 5 and 10