

Methodological Analysis of Randomised Controlled Trials Focusing on Shock Wave Therapy for Lateral Elbow Tendinopathy (Tennis Elbow)

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Introduction

Tennis elbow is a painful condition on and around the bony prominence on the lateral side of the elbow. This location gives tennis elbow its technical name: lateral epicondylitis. With an incidence of about 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, 14, 36, 38, 40, 41). New research shows that the histologic pattern is more characteristic of a degenerative condition rather than an inflammatory process (1, 10, 16, 23, 28, 29, 36).

Although tennis elbow is so prevalent few of the treatments used rest on scientific evidence and none has been proven more effective than the others (2, 4, 11–13, 22, 30, 31, 35, 37).

To determine the effectiveness and safety of extracorporeal shock wave therapy (ESWT) for lateral elbow pain in the frame of a meta-

analysis *Buchbinder et al.* (3) searched various registers. They included 9 trials that randomised 1006 participants to ESWT or placebo and one trial that randomised 93 participants to ESWT or steroid injection. Results of the 9 placebo-controlled trials differed tremendously. Three trials reported significant differences in favour of ESWT for all or most measured endpoints (25–27), whereas 4 trials reported no benefits of ESWT over placebo for any of the measured endpoints (6, 15, 20, 33).

Under "characteristics of included studies" *Buchbinder et al.* (3) stated considerable limitations for pooling of those 4 studies: *Chung and Wiley* (6) declined the request to provide further data. Therefore the study was included in the review but only the proportion of participants with treatment success could be included in the meta-analysis. The authors reported no significant difference between the two treatment groups for any of the measu-

red outcomes at any time-point and hence the results were considered consistent with the conclusion of the review by *Buchbinder et al.* (3). *Haake et al.* (15) used different shock wave devices for repetitive low-energy ESWT which was performed under local anaesthesia. The primary end point was the success rate after 12 weeks defined as subjective pain scale of 1 or of 2 described by *Roles and Maudsley*. To enable pooling with *Rompe* trial data, *Buchbinder et al.* (3) extracted 'failure' defined as *Roles and Maudsley* score of 4. *Melikyan et al.* (20) applied low-energy ESWT repetitively without local anaesthesia. However, mean values were presented in graphical format but without any measure of variance. Therefore the study was included in the review but only the proportion of participants eventually requiring surgery could be included in the meta-analysis. The authors reported no significant difference between the two treatment groups



Zusammenfassung/Summary

Schlüsselwörter: qualitative Analyse – Stoßwellentherapie – Tennisellenbogen – Fragebogen

Key words: qualitative review – shock wave treatment – tennis elbow – patient-rated tennis elbow evaluation (PRTEE) questionnaire

Methodologische Analyse von randomisierten, kontrollierten Studien zur Stoßwellentherapie bei lateraler Epikondylopathie (Tennisellenbogen)

In einer aktuellen Cochrane Meta-Analyse von 9 placebo-kontrollierten Studien (814 Teilnehmer) konnte in 7 Studien kein Vorteil der ESWT bei chronischer lateraler Epikondylopathie nachgewiesen werden. Zwei Studien (192 Teilnehmer) mit vergleichbaren Einschlusskriterien, vergleichbarer Durchführung der ESWT und vergleichbarer Nachbeobachtungszeit zeigten hingegen eine Wirksamkeit der ESWT. Das Gesamturteil ergab somit „Platin“-Evidenz für eine Unwirksamkeit der ESWT nach Cochrane-Kriterien. Die von uns durchgeführte qualitative Analyse identifizierte folgende Kriterien für eine erfolgreiche Durchführung einer ESWT bei lateraler Epikondylopathie: Auswahl chronisch-therapieresistenter Patienten; Applikation von 1500 bis 2000 niedrig-energetischen Impulsen (0,08-0,15 mJ/mm²); klinisches Fokussieren; wöchentliche Intervalle (3–4 Applikationen); keine Lokalanästhesie; mindestens 3-monatiges Follow-up. Eine ESWT ist also nur unter ganz bestimmten Voraussetzungen wirksam. Es ist erforderlich, dass diese definierten Voraussetzungen endlich durch die Stoßwellengesellschaften implementiert werden. Die ESWT bei Epikondylopathie ist weiterhin als vorletzte Therapiestufe zu sehen, unmittelbar vor Indikationsstellung zur operativen Revision.

In a current Cochrane review based upon systematic review of nine placebo-controlled trials "Platinum" level evidence was found that shock wave therapy provided little or no benefit in terms of pain and function in lateral elbow pain. With the relevant data of those studies statistically and clinically too heterogeneous, the conclusion of this pooled meta-analysis was considered misleading, and a qualitative analysis was performed.

Ten relevant trials were retrieved (984 participants), 5 of which had high-quality methodology (585 Participants). Conflicting results of those studies were probably due to variations in treatment regimen (use of local anaesthesia) and patient selection (chronic vs. acute cases). Three high-quality randomised controlled

trials (255 participants) homogeneously reported the following requirements for successful shock wave treatment: Strict selection of chronic patients (symptoms > 6 months, recalcitrant to conventional treatment); application of 1500-2000 shocks of low energy flux density (0.08-0.15 mJ/mm²); application to the site of maximal discomfort (clinical focusing); weekly intervals (3-4 applications); no local anaesthesia; at least 3 months follow-up after the last application.

Shock wave treatment for tennis elbow is effective only under well-defined conditions. These conditions, together with a uniformly used outcome measurement, must be made the central and obligatory part of guidelines for shock wave treatment of tennis elbow immediately.

for any of the measured outcomes at any timepoint and hence the results were considered consistent with the conclusion of the review by Buchbinder et al. (3). Speed and co-workers (33) applied ESWT repetitively without local anaesthesia at monthly intervals. Outcome was assessed at 1 month after completion of therapy.

After a single application of low-energy ESWT in local anaesthesia or Bier block, a fifth (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 significant and benefit was only demonstrated for investigator assessed pain at 8 weeks. An additional small trial of 24 participants reported benefit but this could not be verified from the data presented (18).

When available data from those trials with different types of treatment, different types of comparison groups, or different clinical characteristics of patients were pooled by Buchbinder et al., they found "Platinum" level evidence that shock wave therapy provided little or no benefit in terms of pain and function in lateral elbow pain (3).

There is consensus, however, even among the Editorial Board of the Cochrane Review Group that, if relevant valid data are statistically and clinically too heterogeneous, a meta-analysis should be avoided and reviewers should perform a qualitative review (34, 39).

The aim of this invited review article, therefore, was to gather results from randomised controlled trials in a qualitative review to fairly assess the effectiveness of ESWT in the management of tennis elbow.

Methods

Computerised searches were performed using Medline (from 1996 to December 2005), and Center for Devices and Radiological Health (US Food and Drug Administration) databases. Only English language publications were considered. Further citations were sought from the reference sections of papers retrieved, and from contacting experts in the field.

Studies had to fulfil the following conditions: Randomised controlled trial; patients treated for tennis elbow; treatment of at least one group consisted of any type of ESWT.

Articles were analysed for pain (scales or descriptive words), and a global measure (overall improvement, proportions of patients recovered) as primary outcome measures.

Methodological quality

Eleven papers were retrieved (6, 7, 9, 15, 20, 25-27, 32, 33) the methodological quality of which was examined according to *Chalmers* et al. (5) with two evaluation forms which include 29 individually scored items, allowing a maximum score of 100 (Tables I and II). An arbitrary 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 low qua-

lity, and, if it is 40-69 %, it is satisfactory (34).

Results

Pain was the primary outcome measure for all studies. Pain was measured in all studies either by visual analogue scales, ordinal scales from 3 to 9 points, or descriptive words.

A great variety of outcome measures were used to describe global improvement or patient satisfaction. *Crowther* (9) and *Speed* (33) did not give details on global improvement or patient satisfaction.

Nine studies had used a proper method of randomization (6, 7, 9, 15, 19, 25-27, 32). *Chung* et al. reported twice on the identical cohort of patients (6, 7). Not all studies reported dropouts and the reasons adequately (9). Side effects were reported in all studies.

Table III gives our evaluation for the 11 clinical trials, expressing the results as percentages of the maximum possible score and allowing for items which were not applicable to every study and were therefore excluded from the calculations. The average score for the 10 trials was 62.5 %, with a minimum of 47 % for the weakest study design (20) and a maximum of 75 % for the strongest ones (14, 24). All studies had a satisfactory quality design.

Discussion

Conflicting results were found in this qualitative review of randomised controlled trials on the effectiveness of ESWT for lateral elbow tendinopathy. However, when focusing on 5 trials with the highest

methodological quality (6, 15, 25, 27, 32) a clearer picture unfolds.

A large trial by *Haake* et al. (15) had failed to show any efficiency of ESWT. This was a multicentre, randomised, placebo-controlled study 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. All patients were treated *under local anaesthesia*. Overall, therapeutic success rate 12 weeks after intervention (primary end point) was 26 % in the ESWT and 25 % in the placebo group. The authors concluded that this treatment did not have any added therapeutic benefit beyond placebo.

This conclusion was seriously debated among the various centers participating in the trial because there were three major differences to a previously published randomised controlled trial (26) showing a beneficial effect of ESWT: the use of local anaesthesia; the use of various shock wave devices with various application parameters, meaning that each patient received a different dose; and the use of anti-inflammatory drugs immediately during and after the three days following an ESWT.

Two studies (25, 27) independently addressed these problems and improved the study design accordingly: they were randomized, placebo-controlled trials with blinded patients and observers. No local anaesthesia was applied, and a single shock wave device and standardized application parameters were used. These

Tab. I: Evaluation form A, adapted from Chalmers et al. [5] showing the 15 items scored to evaluate the study design of a clinical trial. The total possible score is 60.

Items	Possible Points
Dates of study description	0-2
Results of randomisation	0-2
Post type 2 estimate	0-3
Confidence limits	0-3
Time series analysis	0-2
Timing of events	0-4
Correlation	0-2
Statistical analysis	0-4
p Value	0-2
Withdrawals	0-4
Handling withdrawals	0-4
Side effects	0-2
Retrospective evaluation	0-3
Presentation of results	0-3
Measure of outcome of active therapy was made	0-2

Tab. II: Evaluation form B, adapted from Chalmers et al. [5] showing the 14 items scored to evaluate the data analysis of a clinical trial. The total possible score is 40.

Items	Possible Points
Description of selection of subject was adequate	0-3
Description of patients screened was provided	0-3
Inclusion criteria for study included	0-2
Exclusion criteria for study included	0-2
Withdrawals and reason for withdrawal were described	0-3
Therapeutic regimen definition	0-3
Control appearance	0-2
Randomisation was blinded	0-10
Patients were blinded to treatment group	0-8
Investigators were blinded to treatment group	0-8
Power calculation (sample size requirements)	0-4
Adequacy of randomisation was evaluated	0-4
Adequacy of blinding was evaluated	0-3
Compliance with treatment was assessed	0-3
Measure of outcome of active therapy was made	0-2

changes of the study design compared with the *Haake* trial (15) resulted in a significantly higher improvement in pain. In the *Rompe* study (27) at 3 months 65 % of patients achieved at least a 50 % reduction of pain, compared with 28 % of patients in the sham group. Their results were investigated by a current randomised, placebo controlled trial by *Pettrone* and *McCall* (25). Using exactly the treatment regimen

described by *Rompe* et al. (27) they found a statistically significant difference in pain reduction at 12 weeks. 61 % of active treated patients showed at least 50 % improvement in pain, compared to 29 % in the placebo group. This was found to persist for one year. Hence, in combination, both trials provided additional weight of evidence to the conclusion, that ESWT as utilized, repetitively, low-energy, without

the use of local anaesthesia, was a safe and effective treatment of chronic lateral epicondylitis.

Most recently, by applying virtually the identical treatment regimen *Spacca* et al. (32) observed a 84 % success rate in the treatment group compared to 10 % in the control group at 6-month follow-up.

Chung and *Wiley* (6, 7) also adopted the treatment regimen proposed by *Rompe* et al (27). However, they changed the selection of patients from chronic, recalcitrant to acute, previously untreated cases. At 8 weeks, success rates in the sham and active therapy groups were 31 % and 39 %, respectively. No significant difference was detected between groups.

Taking into account these 4 trials with a virtually identical treatment regimen (6, 25, 27, 32), two points become obvious:

Unsatisfactory results can be expected when a local anaesthetic is used during repetitive low-energy ESWT, and when acute instead of chronic cases are selected for treatment.

On the other hand, 3 level I therapeutic studies with 255 participants have provided evidence for a distinct treatment effect of ESWT for lateral epicondylitis under the following circumstances (25, 27, 32): (1) application of 1500–2000 shocks of low-energy flux density (0.08–0.15 mJ/mm²); (2) application to the site of maximal discomfort (patient guidance); (3) no local anaesthesia; (4) weekly intervals (3–4 applications); and (5) at least 3 months follow-up after the last application.

Tab. III: Results for 11 papers on treatment by shock wave therapy (SWT). Bold: Most important differences in study design..

Reference	Number	Method of Treatment	Primary Outcome Measure	Conclusions	Quality Score
Rompe et al. [26]	100	Repetitive (3x) low-energy SWT vs. Sham, period between applications: 1 week No LA Chronic patients	Pain	SWT was more effective than sham therapy at the end of treatment and at the follow-ups	54 %
Speed et al. [33]	75	Repetitive (3x) low-energy SWT vs. Sham, period between applications: 4 weeks No LA Chronic patients	Pain	No difference after the end of treatment and at the follow-ups	51 %
Haake et al. [15]	271	Repetitive (3x) low-energy SWT vs. Sham, period between applications: 1 week LA Chronic patients	Pain	No difference after the end of treatment and at the follow-ups	75 %
Crowther et al. [9]	73	Repetitive (3x) low-energy SWT vs. Corticosteroids, period between applications: 1 week No LA Chronic patients	Pain	No difference after the end of treatment and at the follow-ups	51 %
Melikyan et al. [20]	74	Repetitive (3x) SWT vs. Sham, variable energy per shock applied, period between applications unknown No LA Chronic patients	Pain	No difference after the end of treatment and at the follow-ups	57 %
Rompe et al. [27]	78	Repetitive (3x) low-energy SWT vs. Sham, period between applications: 1 week No LA Chronic patients	Pain	SWT was more effective than sham therapy at the end of treatment and at the follow-ups	74 %
Melegati et al. [19]	41	Repetitive (3x) low-energy lateral SWT technique vs. Repetitive (3x) low-energy back SWT technique, period between applications: 1 week No LA Subchronic patients	Pain	No differences between the two techniques at the end of the treatment and at the follow-up	47 %
Chung, Wiley [6, 7]	60	Repetitive (3x) SWT vs. Sham, variable energy per shock applied, period between applications: 1 week No LA Acute patients	Pain	No difference after the end of treatment and at the follow-ups	72 %
Pettrone, McCall [25]	114	Repetitive (3x) low-energy SWT vs. Sham, period between applications: 1 week No LA Chronic patients	Pain	ESWT was more effective than sham therapy at the end of treatment and at the follow-ups	75 %
Spacca et al. [32]	62	Repetitive (3x) low-energy SWT vs. Sham, period between applications: 1 week No LA Chronic patients	Pain	ESWT was more effective than sham therapy at the end of treatment and at the follow-ups	70 %

Considering this result of this qualitative review, *Buchbinder* et al. (3) conclusions were too general when reporting "Platinum" level evidence against a benefit of shock wave treatment in terms of pain and function in lateral elbow pain.

Buchbinder's (3) report was also inappropriate when stating limited evidence of steroid injection being more effective than ESWT. This conclusion was based upon a single trial (8) of 93 participants with its methodological quality being poor, with data analysis not on-intention-to-treat, and with withdrawals of 40 % in the injection group not taken into account when calculating the outcome. In a current review article, *Cole* et al. (8) found few controlled clinical trial data of uses of corticosteroids on which to base treatment decisions. In a systematic review by *Smidt* et al. (30, 31) 13 randomised controlled trials were identified in which corticosteroid injections were used in patients with lateral epicondylitis. All but one of the studies had poor internal validity scores, thus limiting the conclusions that could be drawn from pooled data. Comparisons with placebo were made in only 2 studies, and the data were inconsistent. Of the 6 studies that examined intermediate (6 weeks to 6 months) or long-term (>6 months) outcomes, none found significant differences in favour of corticosteroid injections.

Recommendations

For the future, a homogenous concept of treatment and reporting is needed.

(1) Given the current high cost of shock wave treatment the following regimen of shock wave treatment for lateral elbow tendinopathy is recommended:

- Strict selection of chronic patients (symptoms > 6 months, recalcitrant to treatment)
- Application of 1500–2000 shocks of low-energy flux density (0.08–0.15 mJ/mm²)
- Application to the site of maximal discomfort (patient guidance)
- Weekly intervals (3–4 applications)
- No local anaesthesia
- At least 3 months follow-up after the last application.

National and international societies for musculoskeletal shock wave therapy are called upon to make these recommendations the central and obligatory part of their guidelines for treatment of tennis elbow immediately. Until further investigations show otherwise, shock wave treatment is to be reserved as a therapy for second-to-last resort, the last resort being surgical intervention. Shock wave therapy is to be restricted to individuals who have had chronic, treatment-resistant lateral elbow tendinopathy.

(2) New interventions for the treatment of lateral elbow pain like shock wave treatment are needed, and these should be properly evaluated in high-quality randomised controlled trials (RCTs) prior to their use in routine clinical care (3, 34). In terms of shock wave treatment only 5 trials showed such a high-quality design (6, 15, 25, 27, 32).

To improve reporting of future trials it is suggested that authors unanimously use the CONSORT statement as a model for reporting of RCTs (www.consort-statement.org). Trial reporting should include the method of randomisation and treatment allocation concealment, follow-up 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, ideally trials should include both short-term and long-term follow-up. To enable comparison and reasonable pooling of the results of RCTs, it is suggested that future trials report means with standard deviations for continuous measures or number of events and total numbers analysed for dichotomous measures.

(3) As a standard set of outcome measures would significantly enhance these research endeavours, we recommend use of the validated, simple and time-saving "Patient-rated Tennis Elbow Evaluation" (PRTEE) questionnaire as primary outcome measure (Table IV).

The PRTEE assesses the average pain and function of the affected arm during the preceding week. This time frame allows an accurate memory recall, while avoiding effects from acute fluctuations in symptoms. The questionnaire consists of two parts: part 1 deals with pain and part 2 deals with function. Each of the five items in part 1 is scored using a numeric rating scale, ranging from 0 (no pain) to 10 (worst pain imaginable). Part 2 is subdivided into Specific

Activities (6 items) and Usual Activities (4 items). The 10 items of part 2 use a scale of 0 (no difficulty) to 10 (unable to perform an activity) to rate function. The total score is the combined score which rates pain and disability of equal importance. The pain score total (out of 50 points) and the functional subscale (60 points for specific activities, plus 40 points for usual activities to give a function subscale out of 100 points which are then divided by 2 to provide the remaining 50 %) provide a total score, ranging from 0 (no pain and no functional impairment) to 100 (worst pain imaginable with a very significant function deficit) (17, 24, 38).

Rompe et al. (personal communication) examined its reliability on 2 consecutive weeks in patients who had concomitantly participated in an outcome study (26). The PRTEE results were compared with results of the Visual Analogue Scale (VAS); the Disabilities of the Arm, Shoulder, and Hand questionnaire (DASH); the Roles and Maudsley Score; and the Upper Extremity Function Scale (UEFS). Questionnaires were completed at baseline and 12 weeks. Reliability and internal consistency were excellent. Correlations were good between the PRTEE subscales and total scale and the VAS and DASH. Correlations were moderate regarding the Roles and Maudsley Score and the UEFS. Standardised response means were good in many outcome scales, being higher in the PRTEE than in the other outcome measures (personal communication). The results of Rompe's investigation reflected the ex-

perience from a paper just published by Newcomer et al. (21) from the Mayo Clinic. In their study on 94 subjects who had chronic lateral epi-

condylitis and who concomitantly participated in an outcome study, reliability was excellent, too, and correlations were moderate between

Tab. IV: Patient-rated tennis elbow evaluation..

1 PATIENT-RATED TENNIS ELBOW EVALUATION	
Name _____	Date _____
<p><i>The questions below will help us understand the amount of difficulty you have had with your arm in the past week. You will be describing your average arm symptoms over the past week on a scale 0-10. Please provide an answer for all questions. If you did not recently perform an activity listed, please estimate the pain or difficulty you would expect if you did perform that activity. If you never perform the activity or cannot estimate, draw a line completely through the question.</i></p>	
1. PAIN in your affected arm	
<p><i>Rate the average amount of pain in your arm over the past week by circling the number that best describes your pain on a scale from 0-10. A zero (0) means that you did not have any pain and a ten (10) means that you had the worst pain imaginable.</i></p>	
Sample scale	0 1 2 3 4 5 6 7 8 9 10 No Pain Worst Imaginable
RATE YOUR PAIN:	
When you are at rest	0 1 2 3 4 5 6 7 8 9 10
When doing a task with repeated arm movement	0 1 2 3 4 5 6 7 8 9 10
When carrying a plastic bag of groceries	0 1 2 3 4 5 6 7 8 9 10
When your pain was at its least	0 1 2 3 4 5 6 7 8 9 10
When your pain was at its worst	0 1 2 3 4 5 6 7 8 9 10
2. FUNCTIONAL DISABILITY	
A. SPECIFIC ACTIVITIES	
<p><i>Rate the amount of difficulty you experienced performing each of the items listed below, over the past week, by circling the number that best describes your difficulty on a scale of 0-10. A zero (0) means you did not experience any difficulty and a ten (10) means it was so difficult you were unable to do it at all.</i></p>	
Sample scale	0 1 2 3 4 5 6 7 8 9 10 No Difficulty Unable To Do
Turn a doorknob	0 1 2 3 4 5 6 7 8 9 10
Carrying a plastic bag of groceries	0 1 2 3 4 5 6 7 8 9 10
Lifting a full coffee cup or glass of milk to your mouth	0 1 2 3 4 5 6 7 8 9 10
Opening a jar	0 1 2 3 4 5 6 7 8 9 10
Pulling up pants	0 1 2 3 4 5 6 7 8 9 10
Wringing out a washcloth or wet towel	0 1 2 3 4 5 6 7 8 9 10
B. USUAL ACTIVITIES	
<p><i>Rate the amount of difficulty you experienced performing your usual activities in each of the areas listed below, over the past week, by circling the number that best describes your difficulty on a scale of 0-10. By "usual activities", we mean the activities that you performed before you started having a problem with your arm. A zero (0) means you did not experience any difficulty and a ten (10) means it was so difficult you were unable to do any of your usual activities.</i></p>	
1. Personal activities (dressing, washing)	0 1 2 3 4 5 6 7 8 9 10
2. Household work (cleaning, maintenance)	0 1 2 3 4 5 6 7 8 9 10
3. Work (your job or everyday work)	0 1 2 3 4 5 6 7 8 9 10
4. Recreational or sporting activities	0 1 2 3 4 5 6 7 8 9 10
Comments:	

the PRTEE subscales and total scale and the other outcome scales. Standardised response mean was good in many outcome scales, being slightly higher in the PRTEE than in the other outcome measures. So, the PRTEE is a reliable, reproducible, and sensitive instrument for assessment of lateral elbow tendinopathy. It was at least as sensitive to change as the other outcome tools tested. The PRTEE should be a standard primary outcome measure in research on tennis elbow.

(4)

Though the best concept we have today to assess various treatment regimens, the role of meta-analysis, as conducted currently, has to be challenged.

The protocol for a Cochrane review, for instance, requires collection of data of all randomised controlled trials available. Outcome measures, considered to be the most important to the authoring research group, are chosen for the systematic review. Measures of variance are derived from the paper, and, where not available, from p-values given. When data are available for a pooled estimate of the impact of intervention it is intended that meta-analyses are conducted for direct comparisons. In terms of shock wave treatment, if one compares apples (a disorder of various intensity and of various duration) to oranges (various shock wave therapy regimens in terms of number of sessions, number of shocks applied per session, various energy flux density per shock, various periods between applications) to peaches (various outcome measures, various periods of

follow-up), it is to be expected that one will find inconclusive evidence not supporting a benefit of shock wave treatment. This applies for any other treatment concept as well.

Therefore it is a key point for credibility of the scientific community to analyse critically the method of those review processes:

It must be stated more clearly from the reviewers, how problematic it is to combine the results of a group of studies in a meta-analysis – for example, studies of patients with different types of treatment, different types of comparison groups, or different clinical characteristics.

Any conclusions drawn from these analyses should be reported in a differentiated manner, to avoid being deliberately misinterpreted by the medical community and by health insurance providers in order to refuse new effective interventions to their patients.

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Statement

The authors draw the attention of the reader to the point that this paper is an extended up-to-date report of an original article published in German in 2005 (Rompe JD et al. *Stoßwellentherapie bei Tennisellenbogen*. *Orthopaede* 2005; 34:567-570). Now presented in English this invited review article contains essentially similar datasets, conclusions, and references. Although this is an invited review article, and although the editor was informed, the current article likely falls within the framework of redundant publication.

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