

Extracorporeal shock-wave treatment for tennis elbow

A RANDOMISED DOUBLE-BLIND STUDY

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The efficacy of extracorporeal shock-wave therapy for tennis elbow was investigated using a single fractionated dosage in a randomised, double-blind study. Outcomes were assessed using the Disabilities of Arm, Shoulder and Hand questionnaire, measurements of grip strength, levels of pain, analgesic usage and the rate of progression to surgery. Informed consent was obtained before patients were randomised to either the treatment or placebo group. In the final assessment, 74 patients (31 men and 43 women) with a mean age of 43.4 years (35 to 71), were included.

None of the outcome measures showed a statistically significant difference between the treatment and control groups ($p > 0.05$). All patients improved significantly over time, regardless of treatment. Our study showed no evidence that extracorporeal shock-wave therapy for tennis elbow is better than placebo.

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Tennis elbow (lateral epicondylitis) is a condition whose aetiology is poorly understood. The principal symptom is pain located at the lateral epicondyle of the humerus and the common extensor origin just distal to it. The pain quite commonly radiates distally over the extensor surface of the forearm and tends to worsen with activities which require action of the extensor muscles. The onset of symptoms is usually abrupt after an unaccustomed activity, but it may

also be gradual. It usually follows a protracted course, with the degree of pain increasing and decreasing. The principal methods of treatment include splinting, physiotherapy, ultrasound and functional bracing, as with a tennis elbow clasp. If these measures fail, injection of corticosteroids into the common extensor origin is usually given. Surgery is reserved for persistent cases. The commonly used term 'lateral epicondylitis' implies inflammation, but it has not been possible to demonstrate inflammation in pathological specimens, either in the acute or chronic form, because most patients had previously received local injections.¹

Although extracorporeal shock wave therapy (ESWT) has been used extensively for a variety of orthopaedic conditions, the mechanism of its effect on bone and soft tissues remains controversial. Its effect on tennis elbow and on other orthopaedic conditions is unproven because of the lack of randomised, double-blind studies with adequate power. We have attempted to address this deficiency in this study.

Patients and Methods

We recruited 158 patients (70 men and 88 women) into the study all of whom had received extensive conservative treatment and were awaiting surgery. They were sent information about the planned study by post and 141 (63 men and 78 women) who responded were invited to an initial screening clinic. The senior author (LCB) examined each patient to apply the inclusion and exclusion criteria (Table I). He excluded 55 patients (28 men and 27 women), either because it was not possible to make a firm diagnosis of tennis elbow, or because they had a criterion for exclusion. An in-depth discussion of the design of the study and the proposed form of treatment was conducted with the patients. Assurance was given that all patients would remain on the waiting list of the original surgeon unless they were relieved of symptoms at follow-up of 12 months. The end-point of the study was defined as either surgery for tennis elbow, as originally planned, or a request to be removed from the surgical waiting list.

At the start of the study, 86 patients (35 men and 51 women) were randomly selected to either the treatment or placebo group. The full course of therapy was followed by 75 patients (31 men and 44 women), but one did not attend

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Table 1. The inclusion and exclusion criteria applied at the initial visit to ascertain the diagnosis of tennis elbow, unresponsive to conservative treatment, and to exclude patients with concurrent conditions and contraindications

Inclusion criteria

- Pain localised to the lateral epicondyle
- Tenderness over the lateral epicondyle, the supracondylar ridge and the first 2 cm of the extensor muscle mass
- Previous conservative treatment (physiotherapy or steroid injection)
- Increased pain on resisted wrist extension
- Increased pain on elbow extension with full wrist flexion

For inclusion the first three and at least one of the last two criteria must be fulfilled

Exclusion criteria

- Pain over the radial and posterior interosseous nerve
- Positive resisted supination test
- Pain and tenderness located over the radiohumeral joint
- Exacerbation of pain on movement of the neck
- Sensory disturbance in the affected arm but not a previous carpal or cubital tunnel syndrome with complete resolution of symptoms
- Previous surgery for lateral epicondylitis or radial nerve entrapment
- A history of fracture of the affected elbow
- Age below 18 years
- Coagulation disorders
- Untreated infections of the involved arm
- Apparent hyperthyroid state
- Tumours of the limb
- Pregnancy

Any of the above calls for exclusion

any of the follow-up appointments. Hence, 74 patients (31 men and 43 women) with a mean age of 43.4 years (35 to 71), of which 37 were in the treatment and 37 in the control group, were included in the final assessment.

The outcome measurements of the study were collected at each visit, namely the pretreatment and follow-up visits at one, three and 12 months after the final session of treatment. They included the Disabilities of Arm, Shoulder and Hand (DASH) function/symptom score, levels of pain, grip strength and analgesic requirement. The pen-and-paper version of the original DASH questionnaire, as devised by the American Academy of Orthopaedic Surgeons, was used.² The function/symptom score was calculated according to the following formula:

$$\text{DASH function/symptom score} = \text{Raw score} - 30/1.2$$

Levels of pain were assessed using a visual analogue scale (VAS). The grip strength on the involved side was measured by a JAMAR dynamometer (JAMAR, Jackson, Michigan). The measurements were taken in two positions: 1) with the arm adducted, the elbow flexed to 90°, and the forearm in neutral rotation, and 2) with the shoulder flexed to 90°, the elbow in full extension and the forearm in neutral rotation. Three measurements were made in each position and the mean was calculated. A comparison of the progression towards surgery was made to determine whether ESWT affected its need or urgency.

Treatment protocol. An orthopaedic extracorporeal shock-wave generator was used with an out-of-line ultrasound probe for navigation (Dornier Epos Ultra; Dornier MedTech GmbH, Wessling, Germany). All patients were subjected to the same routine regardless of the group to which they had

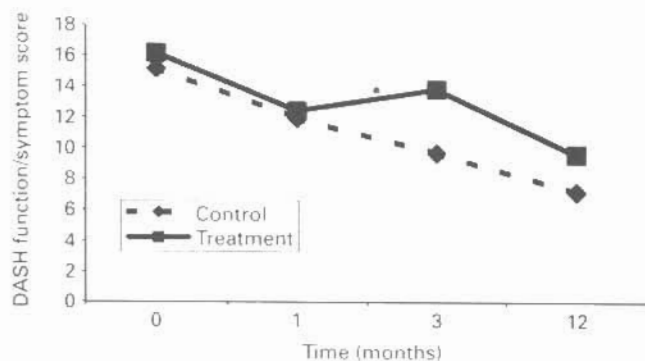


Fig. 1

Change in mean DASH function/symptom scores over time for 37 patients who received ESWT and 37 who received placebo treatment for tennis elbow.

been allocated. They were seated on a moveable chair and the affected elbow was positioned on the treatment head with the forearm supinated to allow a tangential application of the shock waves to the common extensor origin under ultrasound guidance. Ultrasound gel was used as a conductive medium between the skin and the treatment head.

All treatment sessions were started at a low energy level (1 to 3) and the intensity was gradually increased according to each patient's tolerance, not exceeding level 6. A fixed amount of energy (333 mJ/mm²) was delivered at each session amounting to 1000 mJ/mm² at the end of three sessions. An inconspicuous foam pad, which acted as a reflective medium by virtue of its air bubbles, was placed between the treatment head and the skin for the control group of patients. All aspects of the treatment, including seating of the patient, positioning of the arm with imaging on the ultrasound screen and operation of the shockwave generator were identical for both groups. No restrictions were placed on the activities of the patients after the treatment.

Statistical analysis. We used a growth-curve analysis to model the data. The chi-squared test was used for nominal data. A p value < 0.05 was considered to be statistically significant. All observers were blinded with regards to patient allocation into the treatment and control groups.

Results

The decrease in the mean DASH function/symptom score, which reflects an increase in functional level, is illustrated in Figure 1 and was highly significant for both groups ($p < 0.001$). There was, however, no significant difference between the groups at any point, including the baseline values ($p = 0.32$), neither was there a difference in the rate of improvement of the score ($p = 0.87$).

As shown in Figure 2, the mean pain experienced on lifting a 5 kg dumbbell decreased significantly over time in both groups ($p < 0.001$). There was no difference between

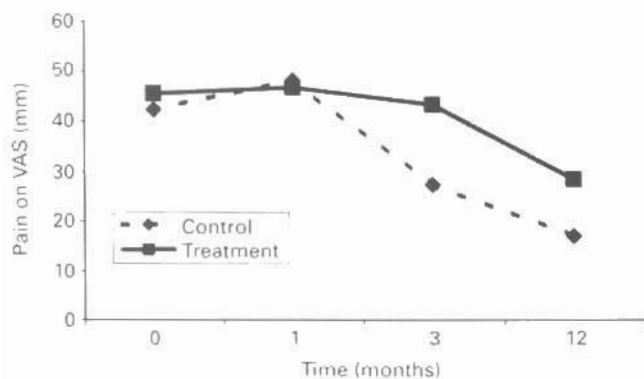


Fig. 2

The mean levels of pain on lifting a 5 kg dumbbell over time for 37 patients who received ESWT and 37 who received placebo treatment for tennis elbow.

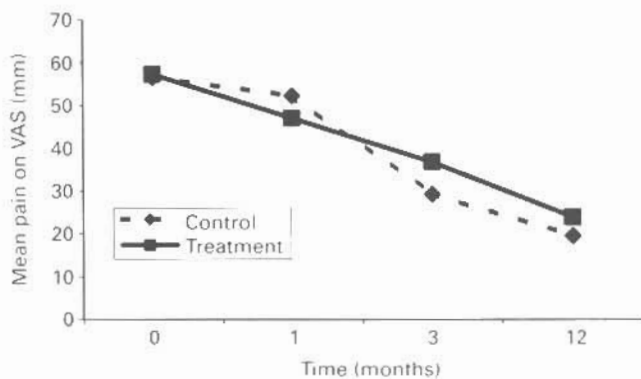


Fig. 3

The mean levels of pain perceived during a typical week before assessment for 37 patients who received ESWT and 37 who received placebo treatment for tennis elbow.

the groups in this respect at the initial measurement ($p = 0.72$), nor was the rate of improvement dissimilar ($p = 0.30$). The mean levels of pain perceived by the patient during a typical week before each assessment also decreased significantly over a period of one year (Fig. 3). In the treatment group, the mean initial VAS pain score of 57.3 mm decreased to 23.9 mm and in the control group from 56.4 mm to 19.5 mm at 12 months ($p < 0.001$). Again, no significant difference was found between the two groups at any point ($p = 0.89$).

The grip strength was measured in the two positions M_1 and M_2 . The measurement with the elbow flexed to 90° and the arm adducted (M_1) (Fig. 4a) did not improve significantly in either group (baseline, 29.5 kg; 12 months, 34.2 kg, $p = 0.22$), whereas the mean grip strength with the shoulder flexed (M_2) (Fig. 4b) did improve (baseline, 21.2 kg; 12 months, 32.4 kg, $p < 0.001$). There was no statistically significant difference between the two groups before treatment ($p = 0.77$ and $p = 0.93$, for M_1 and M_2 respectively) nor during the follow-up period ($p = 0.38$ and $p = 0.65$, for M_1 and M_2 respectively).

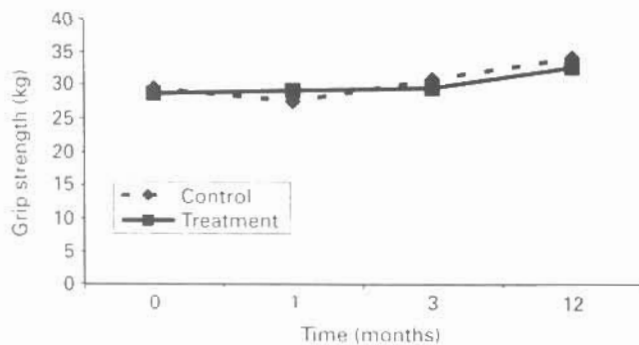


Fig. 4a

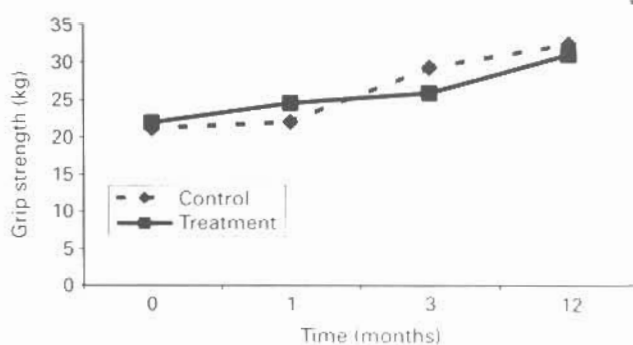


Fig. 4b

The changes in mean grip strength over time for 37 patients who received ESWT and 37 who received placebo treatment for tennis elbow. Figure 4a - Elbow flexed to 90° and the arm adducted. Figure 4b - Elbow extended and the shoulder flexed forward to 90° .

Table II. Breakdown of the number of patients (percentage) who did or did not eventually require surgery. The differences between the two groups are not significant ($p > 0.05$).

	Surgery		
	Required	Not required	Total
Treatment group	17 (46)	20 (54)	37 (50)
Control group	16 (43)	21 (57)	37 (50)
Total	33 (45)	41 (55)	74 (100)

There was no difference in the proportion of patients using analgesics at any stage when evaluated using the chi-squared test (1 month, chi-squared test = 0.104, $df = 1$, $p = 0.747$; 3 months, chi-squared test = 0.133, $df = 1$, $p = 0.715$; 12 months, chi-squared test = 0.009, $df = 1$, $p = 0.926$).

Of the 37 patients in the treatment group, 17 (46%) eventually underwent surgical release of the common extensor origin, compared with 16 (43%) in the control group (Table II). This difference does not reach significance (chi-squared test = 0.047, $df = 1$, $p = 0.829$).

Discussion

ESWT was well tolerated by most patients. There was no need to administer anaesthesia for the levels of ESWT used in this study; most patients experienced no major discomfort. The total amount of applied energy was constant (1000 mJ/mm^2) in order to ensure uniformity in the treatment group. No shock-wave energy was applied to the patients in the placebo group. This was ensured using a commercially made, disposable foam pad obtained from the manufacturers of the shock-wave equipment. The material had been tested under laboratory conditions and was known to completely obstruct shock-wave energy by virtue of the air bubbles contained within. Shock waves are reflected at interfaces created by materials of different density (e.g. solid-to-air) and require the presence of a transmission medium such as ultrasonic gel to propagate.

Previous studies of ESWT for tennis elbow have reported varying degrees of success. Rompe et al³ treated 100 patients with ESWT, half with 3000 pulses of 0.08 mJ/mm^2 (a total of 240 mJ/mm^2) and half with 30 pulses of 0.08 mJ/mm^2 (a total of 2.4 mJ/mm^2) of shock-wave energy. They found a significant alleviation of pain and improvement of function in the first group with a good or excellent outcome in 48% and an acceptable outcome in 42% at final review compared with 6% and 24%, respectively, in the second group. The follow-up period was only 24 weeks. It is not unreasonable to view their second group as a sham treatment group in practical terms, since such a small number of pulses at such a low energy level could be considered as a placebo. The dose-response relationship for ESWT has not been defined, however, and is therefore subject to future research.

Krischek et al⁴ treated 30 patients with tennis elbow and 30 with golfer's elbow, medial epicondylitis, applying 500 pulses at 0.08 mJ/mm^2 at each of three sessions. At 24 weeks 60% of the patients with tennis elbow achieved a good or excellent outcome, compared with 27% of those with golfer's elbow. Conversely, Richter, Ekkernkamp and Muhr⁵ achieved an asymptomatic period of only three months in 13 of 16 patients. The asymptomatic period lasted for more than three months in only two patients. They took a sceptical view of the use of ESWT for lateral epicondylitis, contrary to the encouraging observations of previous studies.

In a comprehensive review of the literature, Bøddeker and Haake⁶ concluded that the efficacy of ESWT for tennis elbow could be neither confirmed nor rejected. Recruitment into our study was conditional upon having exhausted conservative forms of treatment. All patients were awaiting surgery at the time of enrolment. This criterion was deliberately set because the study seeks to address whether ESWT could be an alternative for these intractable cases.

Tennis elbow generally responds well to standard forms of conservative management such as physiotherapy and injections of cortisone. It is therefore improper to suggest the use of a technically demanding and expensive modality, such as ESWT, for newly diagnosed patients who could

well benefit from simple measures. On the other hand, intractable tennis elbow constitutes a therapeutic challenge, and surgery is by no means uniformly successful. All the patients in our study had received physiotherapy in the form of splintage and exercises, and at least one injection of cortisone. There is no evidence in the literature to suggest that the duration of physiotherapy, or indeed the number of injections, makes a difference to the natural history of the condition. Similar selection criteria have been used by other authors.² The intensity of the shock waves which are applied was chosen at a higher level than that which has been shown to be effective in other studies, but was well tolerated without local anaesthesia.^{3,4} The total dosage was uniform for all patients in the treatment group.

We have not been able to show a significant difference between the treatment and the control groups in respect of any of the measured parameters at this dosage. The symptoms suffered by all patients improved steadily over the year of follow-up regardless of the group to which they had been selected. This improvement could be ascribed to the self-limiting nature of the condition. In a very similar study for supraspinatus tendonitis, Schmitt et al⁷ did not find a significant difference of outcome between the group which was treated with ESWT and the placebo group. Larger study groups will be required to increase the detection power if it is thought that the benefit of ESWT is small. This will only be achievable with multicentre studies. Orthopaedic shock-wave devices are not currently available to most clinicians who may find it increasingly difficult to acquire the equipment in the light of the findings of this and other studies.⁶⁻⁸

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