A Randomized Controlled Trial of Extracorporeal Shock Wave Therapy for Lateral Epicondylitis (Tennis Elbow)

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ABSTRACT. ***Objective.*** The aims of this double-blind, randomized, placebo-controlled trial were to determine whether ultrasound-guided extracorporeal shock wave therapy (ESWT) reduced pain and improved function in patients with lateral epicondylitis (tennis elbow) in the short term and intermediate term.
Methods. Sixty-eight patients from community-based referring doctors were randomized to receive 3 ESWT treatments or 3 treatments at a subtherapeutic dose given at weekly intervals. Seven outcome measures relating to pain and function were collected at followup evaluations at 6 weeks, 3 months, and 6 months after completion of the treatment. The mean changes in outcome variables from baseline to 6 weeks, 3 months, and 6 months were compared for the 2 groups.
Results. The groups did not differ on demographic or clinical characteristics at baseline and there were significant improvements in almost all outcome measures for both groups over the 6-month followup period, but there were no differences between the groups even after adjusting for duration of symptoms.
Conclusion. Our study found little evidence to support the use of ESWT for the treatment of lateral epicondylitis and is in keeping with recent systematic reviews of ESWT for lateral epicondylitis that have drawn similar conclusions. (First Release Sept 15 2008; J Rheumatol 2008;35:2038–46)

Key Indexing Terms:
TENNIS ELBOW RANDOMIZED CONTROLLED TRIAL
EXTRACORPOREAL SHOCK WAVE THERAPY

Lateral epicondylitis or tennis elbow is a common complaint estimated to have an annual incidence of 1–3%[1-3] and to account for around 7 per 1000 primary care consultations each year[4]. It is characterized by tenderness over the lateral epicondyle of the humerus and pain on resisted dorsiflexion of the wrist or middle finger[5]. Symptoms can persist for between 6 months and 2 years but usually resolve within 12 months[6].

It is generally considered to be an overload injury with a peak incidence in 40- to 50-year-olds. Despite the name "tennis elbow," tennis is a direct cause in only 5% of those with lateral epicondylitis[7], although sports, such as tennis, requiring overhead or repetitive arm actions increase risk, with up to 40% of tennis players affected at some stage[4,8]. Workers performing highly repetitive hand tasks with non-neutral postures of the hands and arms or involving the use of heavy hand-held tools and forceful work are also at increased risk[9,10].

The condition typically follows minor and often unrecognized trauma of the extensor muscles of the forearm with the force transmitted to the osteotendinous junction, where the hypovascularity in this area may predispose the tendon to hypoxic tendon degeneration[11]. Patients usually present with a history of load-related localized pain coinciding with increased activity. Pain gradually increases in intensity and duration and may be present at rest. Many patients have prolonged symptoms before presentation for treatment. There are significant economic costs, with up to 30% of those affected needing an average of around 12 weeks off work[4,11].

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Many treatments have been advocated, mainly aimed at reducing pain and increasing functional status[12]. High quality evidence evaluating the many commonly used treatments is limited[13] and there is little evidence to support one treatment over another[4,13]. The self-limiting nature of the condition means that conservative management is generally adopted. Topical or oral nonsteroidal antiinflammatory drugs (NSAID) may provide short-term pain relief[5], but these drugs are not suitable for all patients. Corticosteroid injection with local anesthetic has also shown efficacy in the short term, but may be less effective in the long term than either no treatment or physiotherapy[14]. There have been conflicting but generally negative results from trials of ultrasound[15] and consistently negative findings for laser and other physical therapies[4]. Botulinum toxin injection has shown promising results in several trials[16-18], and topical glyceryl trinitrate is a newly proposed treatment, with little information about its efficacy[19]. Further research is warranted for both these treatment modalities. Intractable cases may require surgery[13].

Extracorporeal shock wave therapy (ESWT) is a noninvasive procedure that uses single pulsed acoustic or sonic waves generated outside the body and focused at a specific site within the body. The shock waves dissipate energy at the interface of 2 substances with different acoustic impedance, such as the bone-tendon interface, resulting in the release of kinetic energy at the junctions that can cause tissue alterations. It has been hypothesized that ESWT works by stimulating nerve fibers to produce analgesia and that disruption of the tendon tissue may induce a healing process[13,20,21].

Conclusions about its efficacy for treating lateral epicondylitis could not be drawn from the small number of randomized controlled trials (RCT) available when our study was initially planned[22-24], and further research with well designed RCT was needed to establish its absolute and relative effectiveness.

The aims of our RCT were to determine whether ultrasound-guided ESWT reduces pain and improves function in patients with lateral epicondylitis at 6 weeks (the short term) and 3 or 6 months (intermediate term) after entry into the study, and to determine whether the duration of symptoms predicted outcome.

MATERIALS AND METHODS

Study design. A double-blind, randomized, placebo-controlled trial was conducted between October 1998 and October 2001. Patients fulfilling the inclusion criteria and who provided written informed consent were randomized in blocks of 4 to receive either experimental or placebo regimens according to a computer-generated random-number list created by the study biostatistician. Patients and the single outcome assessor were blinded to the therapy received.

Patients. Patients were recruited from community-based general practitioners, rheumatologists, and orthopedic surgeons between October 1998 and September 2001. Eligible patients were at least 18 years old, with lateral elbow pain of at least 6 weeks' duration, normal anteroposterior and lateral radiographs of the elbow, and reproducibility of pain by 2 or more of the following tests: palpation of the lateral epicondyle and/or the common extensor origin of the elbow; resisted wrist extension (dorsiflexion) and pronation with the elbow in extension; and pain reproduced by static stretching of the pronated wrist in palmar flexion with the elbow in extension.

Patients were excluded if they had bilateral epicondylitis, generalized inflammatory arthritis such as rheumatoid arthritis, concurrent shoulder and/or neck pain and/or pain proximal to the elbow on the affected side, any wound or skin lesion on the lateral side of the affected elbow, neurological symptoms or abnormal neurological findings in the affected arm, pregnancy, severe infection, known malignancy, bleeding disorder, pacemaker, previous surgery to the elbow, oral and/or topical NSAID in the previous 2 weeks, local corticosteroid injection in the previous month, oral glucocorticosteroids within the previous 6 weeks, lack of informed consent, or any other reason thought likely to result in inability to complete the trial.

Description of interventions. All treatments were given by a single ESW therapist who telephoned the study center immediately prior to the treatment being administered and was informed of the treatment allocation, according to the patient's identification number. Participants waited in separate waiting rooms prior to their treatment to ensure that treatment allocation blindness was maintained. The ESW therapist interacted with the patient in a standardized way and was not involved in any other part of the study. Stringent efforts were made to ensure that participants were treated in a uniform manner.

Treatments were given according to a standardized protocol using the Dornier MedTech Epos (Extracorporeal Pain therapy and Orthopaedic System). Patients were positioned in a chair with a foam arm support resting on their lap. Ultrasound gel was placed on a water cushion and the ultrasound transducer. The water cushion and transducer were placed over the lateral epicondyle and positioned so that the common extensor tendon was visible. The crosshair used to indicate the position of the shock wave focus was positioned within the tendon adjacent to the head of the humerus. Patients were asked to help direct the shock wave to the area of maximal tenderness, which may have resulted in moving the crosshair by a few millimeters within the origin of the common extensor tendon.

Each patient received a total of 3 treatments given at weekly intervals. The placebo group received a subtherapeutic dose of 100 shock waves per week (i.e., a maximum total of 300 shock waves given over 3 wks). The energy used did not exceed 0.03 mJ/mm^2 (Level 1) and the frequency of pulses was set at 90 per min. The experimental group received 2000 shock waves per week (i.e., a total of 6000 shock waves given over 3 wks), with the energy level set at the maximum level tolerated by the patient. The frequency of pulses was set at 240 per min.

Patients were instructed in standard stretching exercises and could wear braces or splints if they desired. All patients were asked to cease NSAID 2 weeks prior to the commencement of the study. Apart from paracetamol, no other forms of therapy (including massage, chiropractic, laser acupuncture, oral, topical or local injected corticosteroids) were allowed during the first 6 weeks of the study. At each visit information about any cointerventions, medications, and alternate therapies used by patients since the last visit was recorded.

Ethical approval for the study was obtained from the Epworth Hospital Ethics Committee.

Baseline and outcome assessment. Baseline information included date of birth, sex, years of formal education, marital status, employment and type of work, duration of symptoms, history of trauma to the elbow and previous episodes of elbow pain, medication, previous treatments, and whether compensation was being received or sought.

Followup evaluations were performed at 6 weeks, 3 months, and 6 months after completion of the 3-week treatment course. Seven outcome measures were collected: (1) Overall Pain was measured on a 100 mm vertical visual analog scale (VAS) with descriptors at each end (scale range 0 "No pain" to 100 "Pain as bad as it can be"). (2) Overall Function level of the upper limb was measured on a 100 mm vertical VAS (scale range 0 "No

function — arm in a sling" to 100 "Full function"). (3) The presence or absence of discomfort in normal daily activities was measured using an 8-item pain-free function index that has been validated and used in lateral epicondylitis studies[25,26]. (4) Upper extremity disability and symptoms were assessed using the fixed-item upper arm-specific Disabilities of the Arm, Shoulder and Hand (DASH) questionnaire[27] that has been validated for use in shoulder trials[28]. The instrument has been used in lateral epicondylitis studies but has not been validated for this purpose[29-31]. People not engaging in sport or work did not answer the optional DASH sport and work modules. (5) General quality of life was assessed using the Medical Outcomes Study Short Form-36 Health Survey (SF-36)[32], a self-administered 36-item generic indicator of health status consisting of 8 subscales representing 8 dimensions of quality of life: physical function, role limitation due to physical problems, bodily pain, general health, vitality, social functioning, role limitations due to emotional problems, and general mental health. (6) Maximum pain-free grip strength (MPFGS) in the involved arm and maximum grip strengths (MGS) in the uninvolved and involved arm were measured using a squeeze dynamometer (Jamar, TEC, Clifton, NJ, USA) with the elbow at 90° of flexion. The mean strength (in kg) of 3 trials for each measure, conducted at 20-s intervals, was used to calculate the ratios of the MPFGS and the MGS in the involved arm to the MGS in the uninvolved arm[33]. (7) The Problem Elicitation Technique (PET) is an interviewer-administered patient-preference disability questionnaire[34], modified from the McMaster Toronto Arthritis Patient Preference Disability Questionnaire (MACTAR)[35], in which patients are asked to identify problems they would most like to see improve as a result of treatment. The PET was originally developed and validated for use in studies of rheumatoid arthritis[34]. Patients are asked to rate the importance of the problem on a 10-point scale (0 "least important" to 10 "most important") and to identify the level of difficulty, severity, or frequency they experience with each problem on a 7-point scale (0 "lowest level of difficulty/severity/frequency" to 7 "highest level"). Each problem is scored by multiplying the magnitude of the problem by its importance and the total PET score derived by summing the scores for the 5 most important problems. The PET also assesses patient overall global health by use of a 10-point scale (1 "worst possible health" to 10 "perfect health"). It has been successfully used in clinical trials of plantar heel pain and adhesive capsulitis[36,37].

At the 3-month followup visit patients were asked what treatment they thought they had received. Their responses were used to determine the success of blinding.

Sample size. The sample size calculation was based on the comparison of average post-baseline pain for the ESWT and placebo groups with respect to overall pain measured on the 100 mm VAS. A sample size of 65 patients per group would have 80% power at a significance level of 5% to detect a 10-mm difference between the 2 groups with a between-subject standard deviation of 20 mm. This sample size would also provide 80% power to detect a difference of 12 mm at individual timepoints using an adjusted significance level of 1%.

Data analysis. Analyses were conducted on an intention-to-treat (ITT) basis and included all randomized patients who provided post-baseline data. The characteristics of the 2 groups at baseline and the mean changes in outcome variables from baseline to 6 weeks, 3 months, and 6 months were compared using t-tests or Wilcoxon rank-sum tests as appropriate. Improvements in outcome variables are shown as positive changes in the table; negative changes indicate a worsening of the outcome measure. Analyses were repeated with missing values for the 6-week, 3-month, and 6-month followup points imputed using switching regression, an iterative multivariable regression technique[38].

The effect of duration of symptoms on outcome measures was examined using generalized estimating equations regression adjusted for the baseline values of the outcome variables. Additional analyses to test the effect of time, treatment, and the interaction between time and treatment were conducted using analysis of variance for repeated measures. Success of blinding was assessed using the James Blinding Index[39]. The Blinding Index ranges from 0, representing total lack of blinding, to 1 for complete blinding. A value of 0.5 indicates random guessing. The study is regarded as lacking blinding if the upper bound of the confidence interval (CI) is less than 0.5. If the lower bound of the CI is greater than 0.5 there is no evidence of unblinding. All analyses were performed using Stata v9 (Stata Corp., College Station, TX, USA, 2006).

RESULTS

A total of 68 patients were randomized (36 ESWT group, 32 placebo group) and all patients received their randomized treatment (Figure 1). Two patients from the ESWT group withdrew after the treatment but before the 6-week followup visit for reasons unrelated to the trial. Three (1 ESWT and 2 placebo) completed treatment but did not attend the 6-week followup. A further 3 (1 ESWT and 2 placebo) did not attend the 3-month followup. Five patients (4 ESWT and 1 placebo) did not attend the 6-month followup (Figure 1). A change in management of the company performing the ESWT and a lack of funding to secure an alternative treatment provider meant the recruitment target of 65 per group could not be met.

The average energy level of the shock waves received by the ESWT group was 0.56 mJ/mm^2 (SD 0.27, range 0.10–1.22). The median total dose for this group was 1062 mJ/mm^2. The total dose received by the placebo group was 6.0 mJ/mm^2. The Blinding Index was 0.70 (95% CI 0.58-0.82), indicating no evidence of unblinding.

The demographic and clinical characteristics of the 63 patients who provided baseline data are given in Table 1. At baseline, the ESWT group had significantly lower PET global health scores ($p = 0.025$) than the placebo group, but there were no differences between the 2 treatment groups on any other measure. The 5 participants who withdrew from the study before the 6-week followup (3 active group, 2 placebo group) had significantly lower baseline scores for role limitation (physical), vitality, social functioning, and mental health dimensions of the SF-36 ($p = 0.004$, $p = 0.0004$, $p = 0.019$, and $p = 0.0002$, respectively) than those who remained in the study.

The results presented here are for the ITT analysis and the analysis using imputed data gave similar results (data not shown).

Pain and function. More than half the participants had experienced elbow symptoms for at least 10 months. Both groups showed significant improvement at the 6-month followup in the principal outcome measures of pain and function, but there were no statistically significant differences between the groups in the degree of improvement and no consistent advantage of the treatment group over the placebo group (Table 2). Outcome measures not showing improvement at 6 months were PET global health score and the SF-36 dimensions of general health, vitality, social functioning, and mental health. The SF-36 dimensions general health, vitality, and mental health were comparable with the Australian population values[40] at baseline. All other dimen-

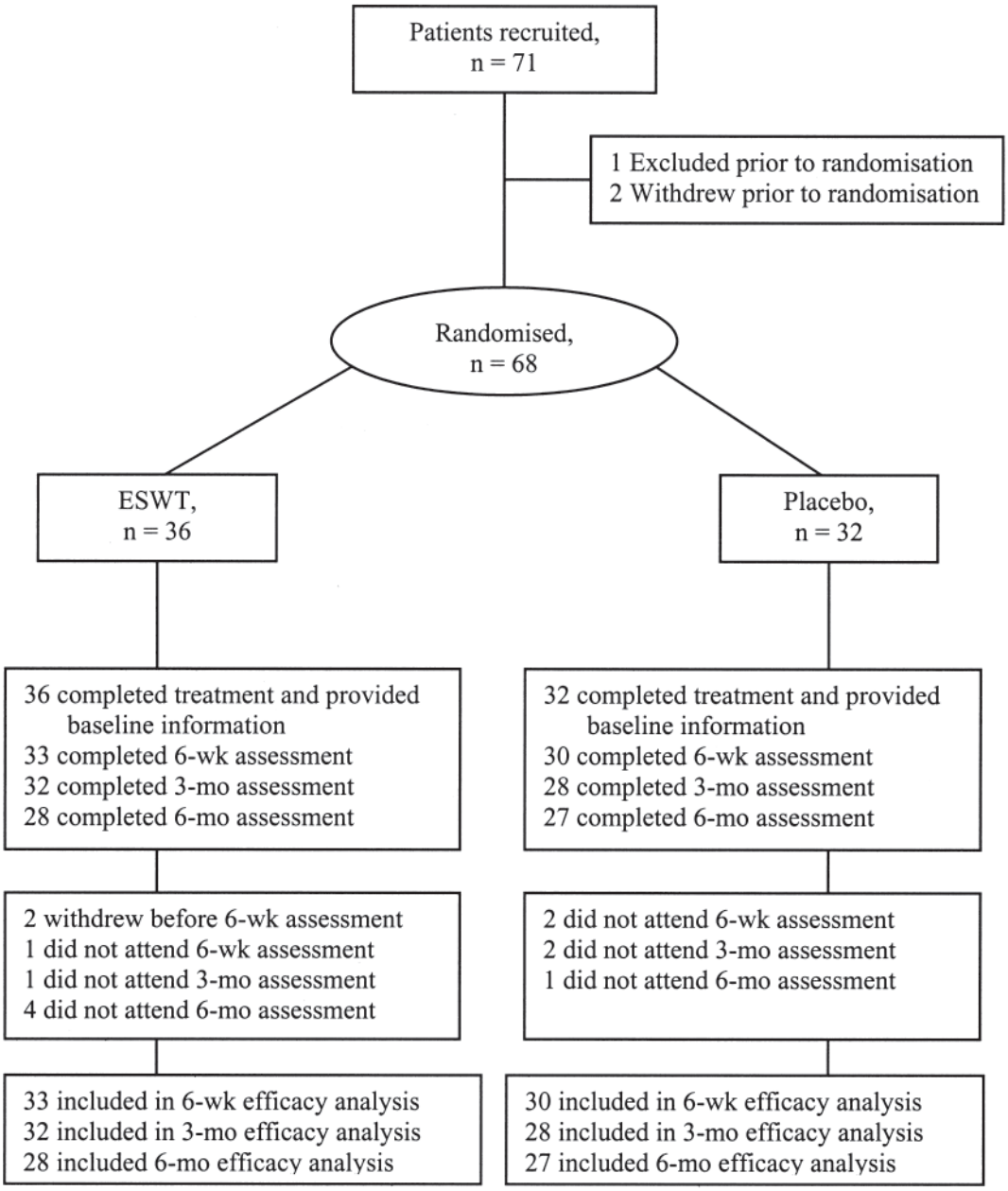

Figure 1. The progress of participants in the trial.

sion scores were below the population average. At the 6-month followup, despite showing significant improvements from baseline, role limitation due to physical problems and bodily pain remained below the population levels. All other dimension scores at 6 months were similar to those for the population.

There were no differences between the groups in any outcome measures at the 6-week and 6-month followup visits (Table 2). At the 3-month followup visit there was a statistically significant difference between the groups in favor of the active group for DASH Work and Sport modules, but neither of these was completed by all patients. Similar results were obtained after adjusting for duration of symptoms or for the variables showing differences at baseline (data not shown).

The most common problems identified at baseline by the PET are shown in Table 3. Over half the participants (53%) had problems in the Mobility domain that they would most like to see improved by treatment. Limitations to role or household activities and to leisure activities also figured prominently among problems needing improvement. Feelings of frustration and depression also caused concern.

Table 1. Demographic and clinical characteristics and baseline outcome measurements for all participants by treatment group.

Variable	ESWT, n = 33 (%)	Placebo, n = 30 (%)	Dropouts, n = 5 (%)
Females, n (%)	14 (42.4)	12 (40.0)	2 (40.0)
Mean (SD) age, yrs	49.8 (7.4)	49.1 (8.8)	47.6 (9.0)
Laterality, right	25	20	5
Mean (SD) duration of elbow symptoms in weeks (range)	52.6 (64.3) (10–300)	68.0 (98.8) (6–520)	92.8 (88.0) (20–260)
History of elbow trauma	2	1	2
Previous episodes of elbow pain	9	6	8
Seeking compensation	1	—	1
Previous treatment of any type	32 (97)	27 (90)	5 (100)
Corticosteroid injections	23 (70)	18 (60)	3 (20)
NSAID	18 (55)	18 (60)	4 (68)
Stretching	16 (48)	17 (57)	4 (80)
Topical antiinflammatory drugs	16 (48)	17 (57)	1 (20)
Brace	16 (48)	18 (60)	3 (60)
Massage	9 (27)	13 (43)	1 (20)
Ultrasound	8 (24)	5 (17)	0 —
Acupuncture	3 (9)	3 (10)	1 (20)
Chiropractic	3 (9)	3 (10)	2 (40)
Outcome measures, mean (SD)			
Pain Index (Range 0–100)	67.0 (25.5)	61.3 (23.6)	71.4 (35.5)
Function Index (Range 0–100)	64.2 (27.5)	64.1 (25.7)	55.6 (44.2)
8-item pain-free function index (8IPFFI) (range 0–8)	6.7 (1.7)	6.4 (1.9)	5.4 (2.1)
Dash Function Score (range 0–100)	40.3 (14.3)	37.7 (16.8)	45.6 (25.3)
Dash Sport Score (range 0–100)	66.4 (29.1) (n = 25)	53.3 (37.5) (n = 19)	50.0 — (n = 1)
Dash Work Score (range 0–100)	44.2 (23.6) (n = 28)	38.2 (27.7) (n = 26)	39.6 (34.2) (n = 3)
Pain-Free Grip Strength (PFGS)	0.32 (0.28)	0.21 (0.21)	0.39 (0.28)
Maximum Grip Strength (MGS)	0.78 (0.53)	0.70 (0.29)	0.50 (0.36)
SF-36 score, mean (SD) (range 0–100)			
Physical function	70.5 (13.0)	73.5 (11.2)	51.0 (38.8)*
Role limitation (physical)	38.6 (39.1)	45.8 (43.6)	20.0 (44.7)
Bodily pain	38.2 (20.7)	43.7 (23.5)	29.2 (30.0)
General health	74.8 (17.1)	74.2 (16.4)	60.2 (37.2)
Vitality	59.1 (19.7)	64.4 (14.6)	30.0 (26.2)*
Social function	76.1 (21.3)	74.6 (23.3)	50.0 (31.9)*
Role functioning (emotional)	62.6 (43.1)	67.8 (40.6)	40.0 (54.8)
Mental health	73.3 (16.8)	72.7 (15.8)	41.6 (26.5)*
Health transition	3.2 (0.8)	3.1 (0.9)	2.6 (1.5)
Problem Elicitation Technique (PET) score, mean (SD)	151.9 (50.8)	140.7 (70.4)	93.1 (75.2)
PET global health assessment (SD) (range 0–10)	6.6 (1.8)	7.6 (1.3)	6.1 (3.9)

* $p < 0.05$. ESWT: extracorporeal shock wave therapy; NSAID: nonsteroidal antiinflammatory drugs; SF-36: Medical Outcomes Study Short Form-36 Health Survey.

There was greater concern about participation in leisure activities than about being unable to work for a wage. Problems in other domains were mentioned by fewer participants.

Few adverse events were reported for either group (Table 4). Participants in the ESWT group reported increased pain, bruising or red spots, or a burning sensation in the arm following treatment. For the placebo group, increased pain and lumps in the elbow area were the only reported adverse events.

DISCUSSION

There was overall improvement in pain and function measures in the short term (3 mo) and intermediate term (6 mo), but there were no clinically meaningful differences between the ESWT and placebo groups at any of the followup timepoints for any of the measured outcome variables. At no followup point did the differences between the groups, for pain or function, consistently favor the treatment group. After 6 months, the improvements were somewhat better in the

Table 2. Mean differences in outcome measures from baseline at 6 weeks, 3 months, and 6 months.

Outcome Measure	6 Weeks Mean (SE) Change				3 Months Mean (SE) Change				6 Months Mean (SE) Change			
	ESWT, n = 33	Placebo, n = 30	Between-Group Difference (95% CI)	p	ESWT, n = 32	Placebo, n = 28	Between-Group Difference (95% CI)	p	ESWT, n = 28	Placebo, n = 27	Between-Group Difference (95% CI)	p
Pain Index	27.7 (5.7)	26.0 (6.4)	1.7 (–18.8 to 15.3)	0.84	26.1 (6.5)	26.7 (6.0)	–0.6 (–18.4 to 17.3)	0.95	31.7 (6.5)	40.7 (5.9)	–9.0 (–26.6 to 8.6)	0.31
Function Index	8.3 (5.1)	11.2 (5.4)	–2.9 (–17.2 to 11.9)	0.70	9.0 (6.1)	1.7 (5.0)	7.3 (–8.7 to 23.3)	0.36	9.2 (5.8)	19.0 (5.1)	–9.8 (–25.2 to 5.7)	0.21
8-item pain-free function index	2.3 (0.4)	2.2 (0.5)	0.1 (–1.2 to 1.3)	0.91	2.5 (0.5)	2.4 (0.4)	0.1 (–1.3 to 1.2)	0.91	3.2 (0.5)	4.0 (0.5)	–0.8 (–2.2 to 0.6)	0.25
Dash Function	15.3 (2.4)	9.0 (3.8)	6.3) (–2.5 to 15.1)	0.16	18.9 (2.7)	10.9 (3.4)	8.1 (–0.5 to 16.7)	0.07	21.0 (3.2)	21.3 (3.9)	–0.3 (–10.3 to 9.8)	0.96
Dash Sport	24.6 (6.4)	8.3 (7.5)	16.6 (–3.9 to 37.0)	0.11	26.5 (5.7)	6.3 (5.6)	20.2 (–2.2 to 38.3)	0.03	34.9 (7.2)	24.7 (8.5)	–10.2 (–33.0 to 12.5)	0.37
Dash Work	19.9 (3.6)	14.3 (4.1)	5.6 (–5.3 to 16.5)	0.31	24.2 (4.0)	6.8 (5.5)	17.4 (–4.0 to 30.8)	0.01	27.9 (5.1)	17.0 (5.9)	10.8 (–4.8 to 26.5)	0.17
Pain-free Grip	0.17 (0.06)	0.22 (0.07)	–0.05 (–0.22 to 0.12)	0.57	0.35 (0.06)	0.31 (0.06)	0.04 (–0.13 to 0.20)	0.68	0.43 (0.09)	0.48 (0.06)	–0.05 (–0.15 to 0.26)	0.58
Maximum Grip Strength	0.10 (0.09)	0.08 (0.05)	0.02 (–0.19 to 0.24)	0.83	0.19 (0.09)	0.10 (0.04)	0.09 (–0.12 to 0.31)	0.40	0.23 (0.11)	0.21 (0.05)	0.02 (–0.22 to 0.27)	0.85
SF–36												
Physical function	14.1 (11.4)	25.5 (23.1)	–11.4 (–61.5 to 38.7)	0.65	6.6 (3.7)	0.9 (3.7)	5.7 (–4.8 to 16.1)	0.28	5.4 (2.9)	6.7 (5.0)	–1.3 (–12.7 to 10.1)	0.82
Role limitation (physical)	9.1 (6.7)	12.5 (8.8)	–3.4 (–25.5 to 18.4)	0.76	14.8 (8.3)	13.4 (9.0)	1.5 (–23.1 to 26.0)	0.91	18.8 (9.8)	23.1 (8.8)	–4.4 (–30.9 to 22.1)	0.74
Bodily pain	11.3 (4.2)	13.2 (4.4)	–1.9 (–14.1 to 10.2)	0.75	14.4 (4.6)	13.3 (5.0)	1.1 (–12.4 to 14.5)	0.88	14.6 (4.5)	17.6 (4.6)	–2.9 (–15.9 to 10.0)	0.65
General health	–3.3 (2.4)	–0.7 (2.5)	–2.4 (–9.4 to 4.6)	0.50	–6.9 (3.3)	–6.0 (2.8)	–0.9 (–9.8 to 7.9)	0.83	–2.1 (3.0)	–3.8 (3.3)	1.7 (–7.2 to 10.7)	0.70
Vitality	1.1 (3.0)	–0.6 (3.6)	1.7 (–7.6 to 10.9)	0.72	2.0 (3.6)	1.1 (4.2)	0.9 (–10.1 to 11.9)	0.87	5.4 (3.4)	1.2 (3.6)	4.2 (–5.8 to 14.1)	0.40
Social function	2.7 (3.4)	2.5 (5.6)	0.2 (–12.7 to 13.0)	0.98	7.8 (5.5)	2.7 (6.9)	5.1 (–12.4 to 22.7)	0.56	8.0 (4.2)	3.2 (6.1)	4.8 (–9.9 to 19.5)	0.52
Role limitation (emotional)	13.1 (7.5)	10.0 (7.9)	3.1 (–18.6 to 25.0)	0.77	16.7 (9.7)	13.1 (8.6)	3.6 (–22.7 to 29.9)	0.79	19.0 (9.5)	22.2 (8.5)	–3.2 (–28.7 to 22.4)	0.80
Mental health	0.7 (3.0)	3.7 (3.6)	–3.0 (–12.3 to 6.3)	0.52	–0.5 (4.3)	0.9 (4.9)	–1.4 (–14.4 to 11.6)	0.84	4.7 (2.7)	2.2 (3.2)	2.5 (–5.9 to 10.9)	0.56
Health transition	–0.06 (0.11)	–0.13 (0.20)	0.07 (–0.36 to 0.51)	0.74	0.16 (0.13)	0.39 (0.20)	–0.23 (–0.71 to 0.24)	0.32	–0.43 (1.7)	–0.63 (0.19)	0.20 (–0.31 to 0.71)	0.43
Problem Elicitation Technique (PET)	44.0 (13.6)	44.6 (12.4)	–0.6 (–37.8 to 36.7)	0.98	72.4 (15.0)	43.8 (15.5)	28.6 (–14.4 to 71.6)	0.17	92.6 (14.3)	100.6 (15.1)	–8.0 (–50.0 to 33.9)	0.70
PET global health	0.43 (0.29)	0.10 (0.21)	0.34 (–0.42 to 1.10)	0.39	0.58 (0.44)	0.30 (0.33)	0.28 (–0.88 to 1.44)	0.63	–0.24 (0.54)	0.23 (0.66)	0.48 (–1.23 to 2.19)	0.58

Positive values for the mean change scores indicate improvement, negative values indicate worsening; positive values for between-group difference scores favor the treatment group. ESWT: extracorporeal shock wave therapy; SE: standard error of the mean; SF-36: Short Form-36 Health Survey.

placebo group than the ESWT group for both pain and function. These results were not modified after adjusting for the duration of painful symptoms. The most likely explanation of the improvements in both groups is the self-limiting natural history of the condition, whereby most patients with lateral epicondylitis recover within 1 year[13,14].

Recent systematic reviews of ESWT for lateral epicondylitis have concluded there was little evidence that it provided greater benefit than placebo in terms of improvement in pain or function and that it was less effective than steroid injections[12,13].

The strengths of our study lie in the effective blinding of patients to their treatment and the precise localization of the ESWT. Patients in the placebo group received a small shock wave dose to simulate treatment and we believe this helped minimize the likelihood of unblinding. To maximize the potential for successful treatment, patients helped direct the shock waves to the most tender site rather than relying only on the operator to localize the treatment.

As a result of funding problems, our study failed to meet its recruitment target of 65 per group, leaving it with insufficient power to detect the specified difference of 10 mm in

Table 3. Number of patients reporting specified problem at baseline and the ranked score for each problem (importance by severity/difficulty/frequency) (total n = 56).

Problem	N	Total Score	Problem	N	Total Score
Mobility	36	2718	Do the laundry	2	41
Carry or lift heavy parcel/object	9	424.5	Peel vegetables	1	40
Lifting light parcel — dinner plates	10	307.5	Pour kettle	1	14
Drive a car	9	293.25	Leisure activities/Going out	24	1210.50
Open large jars	5	205	Participate in sport or athletic activities	20	900.75
Open a jar	6	204.75	Participate in leisure outings	2	90
Reach overhead and get down a 5 lb bag	5	190	Participate in nonathletic activities	2	77
Turn on/off tap	5	156	Craft; knitting	2	75
Open small jars	6	135.25	Cut fabric	1	61.75
Squeeze salt container; squeezing/pumping action	3	125	Participate in clubs, organizations, religious activities	1	6
Straighten arm	3	120	Feelings	14	691.25
Pick up small items	2	110	Frustrated	8	409.25
Open a door	3	110	Depressed	5	266
Push/pull	2	78	Anxious, stressed	1	16
Use computer mouse	2	76.25	Self-care/Grooming	13	636.75
Grasping object	2	71	Take a shower	2	80
Carry or lift light parcel/object	1	70	Put on socks	2	78.25
Bend and straighten elbow	2	66	Dry self after bath or shower	2	62.25
Wring out a cloth	1	60	Back fastenings	1	60
Any contact directly on elbow	1	50	Put on trousers	1	60
Lack of mobility	1	50	Put on shirt/jacket	1	50
Open car door/locks	1	50	Pull clothes overhead	1	50
Turn a key in lock	1	45	Manage the toilet	1	50
Lift a 5-10 lb bag	2	18	Dry hair	1	40
Open cans or tins	1	10	Apply deodorant	1	38.5
Role activities/Household activities/Housework	33	2158.25	Put on stockings/pantyhose	1	31.5
Work for wage outside home	11	447	Tie boots and shoes	2	18.25
Minor home maintenance outside; gardening	7	295.5	Shave	2	18
Do vacuuming	4	155	Sleep and rest	8	381.5
Major home maintenance inside	3	148	Sleep through night	6	286.5
Light housecleaning	3	142.5	Lie comfortably in bed	2	95
Do heavy cleaning	3	136.25	Social interaction	3	127.25
Lift full pots off stove	3	106	Shake hands	3	127.25
Do grocery shopping	3	77	Communication	3	170.75
Look after children/family	2	76	Write	2	83.25
Do ironing	2	75	Use a dictaphone	1	47.5
Minor home maintenance inside	1	50	Type	1	40
Chop/cut vegetables	1	47.5			

pain or function measured on a 100-mm VAS. Given the observed variability of outcome measures in the study, the sample size obtained would have had 40% power to detect a 10-mm advantage on the VAS pain scale or a 10-point advantage in function for the treatment group.

We chose to deliver a small shock wave dose to the placebo group rather than sham therapy to limit the likelihood that patients would determine their treatment allocation. It is possible, but unlikely, that this small dose had a therapeutic effect. In spite of the limitations, our study did not show ESWT to be consistently better than placebo in bringing about even minor improvements and there was no evidence of its providing relief more quickly than placebo.

Optimal ESWT dosages and frequency have not been studied extensively for musculoskeletal problems, but it has been suggested that low-energy treatments (energy flux density < 0.2 mJ/mm^2) produce an analgesic effect. Low-energy shock waves are generally accepted for lateral elbow pain[41], while high-energy shock waves stimulate tissue and bone regeneration[42]. Previous studies have covered the range from low to high energy levels, and no consistent benefit from a particular energy level has been apparent4[42,43]. Our study used high-energy shock waves and found no differences in pain or function between the treatment and placebo groups at any of the followup points.

It has also been suggested that patients with long duration of symptoms may respond better as they have abnormal tissue and nociceptor changes that are targeted by ESWT[44]. Many patients in this trial had experienced painful symptoms for more than a year, but our analyses incorporating duration of symptoms did not indicate any modification of the effect of ESWT by symptom duration. Given the variety

Table 4. Adverse events by followup visit and group.

Treatment Group	Followup Visit	No. with Event	Adverse Event
ESWT	3 weeks	1	Bruising after 1st treatment
	6 weeks	4	Pain or tenderness in the arm
		1	Burning sensation
	3 months	1	Burning sensation
Placebo	3 weeks	1	Lump in area
	6 weeks	1	Pain and lump
	3 months	1	Pain
	6 months	2	Pain

of ESWT energy levels that have been studied and the lack of strong evidence to support its use in general, if particular regimens are to be promoted, then these will have to be assessed with trials specifically designed to compare different energy levels in patients with short and long symptom durations.

At baseline, the trial participants had lower scores for the physical functioning, physical role limitation, bodily pain, social functioning, and emotional role functioning dimensions of the SF-36 than the general Australian population[40]. Improvements were seen in all these but role limitation (physical), and bodily pain scores remained below the national norms after the 6-month followup. Thus, despite considerable improvements in pain and function, patients still suffered some residual pain and had limitations related to functioning in their usual role. In a minimal intervention study, Haahr and Andersen[45] reported that 17% of cases recruited from general practice showed no improvement after 1 year, highlighting that for some patients the condition can remain a longterm problem.

The PET allows patients to specify the problems they would most like to be resolved by treatment and to give a weighting to these problems. The most important problems identified related to carrying or lifting objects, performing housework, participating in paid employment or sporting activities, and feelings of frustration and depression. The items related to function are adequately identified by the 8-item pain free function index and the DASH questionnaire, but problems with feelings of frustration and depression are not well identified by the fixed-item questionnaires. PET scores improved over the course of the study, highlighting the importance of incorporating measures such as this that identify patients' concerns as well as pain and function.

Given the substantial improvements in both groups over the course of the study, ESWT would have to alleviate symptoms more rapidly or be substantially better in the long run than other treatments. Our results are consistent with previous studies that have shown little evidence of a short- or longterm benefit from ESWT for lateral epicondylitis. The question arises whether it is worthwhile to conduct further studies of this treatment. If there is a benefit from ESWT it is likely to be small, not clinically significant, and would require a very large study to demonstrate an effect.

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