Effectiveness of Extracorporeal Shock Wave Therapy in the Treatment of Previously Untreated Lateral Epicondylitis

A Randomized Controlled Trial

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Background: Extracorporeal shock wave therapy is a relatively new therapy used in the treatment of chronic tendon-related pain. Few randomized controlled trials have been performed on it, and no studies have examined the effectiveness of extracorporeal shock wave therapy as a frontline therapy for tendon-related pain.

Hypothesis: Subjects treated with active extracorporeal shock wave therapy will have higher rates of treatment success than subjects treated with sham extracorporeal shock wave therapy.

Design: Double-blind randomized controlled trial.

Methods: Sixty subjects who had previously untreated lateral epicondylitis for less than 1 year and more than 3 weeks were included in this study. Subjects were randomly allocated to receive 1 session per week for 3 weeks of either sham or active extracorporeal shock wave therapy. Subjects in the active therapy group received 2000 pulses (energy flux density, 0.03-0.17 mJ/mm^2). All subjects were provided with a forearm-stretching program. After 8 weeks of therapy, subjects were classified as either treatment successes or treatment failures according to fulfillment of all 3 criteria: (1) at least a 50% reduction in the overall pain visual analog scale score, (2) a maximum allowable overall pain visual analog scale score of 4.0 cm, and (3) no use of pain medication for elbow pain for 2 weeks before the 8 week follow-up. Visual analog scale scores were also collected for pain at rest, during sleep, during activity, at its worst, and at its least, as well as for quality of life (using the EuroQoL questionnaire) and grip strength.

Results: Success rates in the sham and active therapy groups were 31% and 39%, respectively. No significant difference was detected between groups ($\chi^2_1 = 0.3880$, $P = .533$). Mean change in quality of life over 8 weeks was an increase of 1.3 and 3.3 for sham and active therapy groups, respectively, and mean change in grip strength over 8 weeks was an increase of 7.4 kg and 6.8 kg for sham and active therapy groups, respectively.

Conclusions: Despite improvement in pain scores and pain-free maximum grip strength within groups, there does not appear to be a meaningful difference between treating lateral epicondylitis with extracorporeal shock wave therapy combined with forearm-stretching program and treating with forearm-stretching program alone, with respect to resolving pain within an 8-week period of commencing treatment.

Keywords: lateral epicondylitis; randomized controlled trial; extracorporeal shock wave therapy (ESWT)

Lateral epicondylitis (LE) is a common condition that affects between 1% and 3% of the population.[28] It is defined as a degenerative process, characterized by the presence of dense populations of fibroblasts, vascular hyperplasia, and disorganized collagen.[21] Clinically, affected patients complain of persistent pain and tenderness at the extensor origin of the elbow during palpation, hand grip, and resisted extension of the wrist.

There is little evidence to support one therapy over another for the treatment of LE. A systematic review of 185 articles published from 1966 to 1992 revealed that only one study met the predetermined criteria for scientific validity for a clinical trial, and it concluded that "the poor

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quality and contradictory results of the randomised and controlled trials reported so far in the literature means that there is not enough scientific evidence to favour any particular type of treatment for acute lateral epicondylitis."[17] This conclusion is supported by one other review on the treatment of LE[2] and by a randomized controlled trial comparing the effectiveness of physical therapy, corticosteroid injection, and a "wait-and-see" policy in the treatment of "acute" LE, which failed to detect a clinically relevant difference between the 3 therapies.[24]

Over the past 10 years, low-energy extracorporeal shock wave therapy (ESWT) has been used to treat a variety of orthopaedic diseases, including LE. The mechanisms by which ESWT acts are not well understood. Recent animal studies have postulated that ESWT may stimulate the production of angiogenic markers and neovessels, as well as reduce calcitonin gene-related peptide expression in dorsal root ganglions.[27,29] However, these studies have only been performed in either healthy animals or animals with artificially created tendinopathy. The evidence for these mechanisms is also conflicting.[9-11] Although there have been numerous studies investigating the effects of ESWT on LE,[5,8,12,14-16,18,22,23,25] only 4 can be considered randomized controlled trials.[5,8,23,25] These trials possess fundamental methodological differences (various follow-up periods, study populations, and outcomes) that affect the ability to come to a consensus about the role of ESWT in the treatment of LE. In addition, the vast majority of ESWT studies have been restricted to patients who have had failed nonoperative therapy for LE. No study has specifically addressed the effectiveness of low-energy ESWT as a primary treatment for LE.

Based on the lack of evidence for any particular treatment for LE and the lack of studies involving people who have not received any therapy for LE, the purpose of this study was to determine the effectiveness of low-energy ESWT in the treatment of previously untreated LE in subjects affected for more than 3 weeks and less than 1 year. It was hypothesized that subjects treated with active ESWT would have higher rates of treatment success than those treated with sham ESWT.

METHODS

Ethical approval for this study was obtained from the Conjoint Health Research Ethics Board at the University of Calgary. Subjects were recruited by poster advertisements in physicians' offices, gyms, fitness centers, golf clubs, tennis clubs, racquet sport clubs, universities, and colleges, as well as through e-mail campaigns to faculty and staff at the University of Calgary and Mount Royal College. Potential subjects were screened by phone. Eligible subjects reported to the University of Calgary Sport Medicine Centre for initial assessment and were examined by one physician (JPW). Inclusion and exclusion criteria are listed in Table 1. Subjects who met all of these criteria were serially accepted into the study until the a priori estimated sample size was attained.

Sample size was calculated using the PS Power and Sample Size Calculations statistical package[7] and was based on a test of proportions in which $\alpha = .05$ and $1 - \beta = .8$. The expected proportion of treatment successes in the sham group was 0.2. Although the reported success rate in Rompe et al[23] was 80%, the investigators considered a 60% success rate to be a clinically relevant and successful result. The expected proportion of treatment successes in the active group was therefore 0.6. To allow for a 20% dropout/loss to follow-up rate, a sample size of 60 subjects was selected.

Subjects were not informed as to whether there was a sham protocol involved in the study but were informed that the purpose of the study was to compare 2 different therapy protocols. This deception was performed to preserve subject blinding, as there is widespread accessibility of information on ESWT protocols, in particular informa-

TABLE 1
Inclusion and Exclusion Criteria

Inclusion Criteria	Exclusion Criteria
Lateral elbow pain	History of active treatment for lateral epicondylitis (past or present)
18 years of age or older	Posterior interosseous nerve compression
Less than 1 year since onset of symptoms	Traumatic injury to the affected elbow
More than 3 weeks since onset of symptoms	Workers' Compensation Board claimants
Tenderness over lateral epicondyle and common extensor origin tendons	Elite athletes
Pain worsened with resisted wrist extension and hand grip	Systemic rheumatologic condition (eg, rheumatoid arthritis, Reiter's syndrome)
Pain worsened with elbow extension, forearm pronation, wrist palmar flexion	Contraindications for extracorporeal shock wave therapy:
Willing to discontinue bracing	Evidence of nerve or nerve root irritation
Informed consent form signed	Pregnancy
	Blood coagulation disorder
	Presence of bony or articular lesions in the elbow (radiographically determined; calcific tendinitis acceptable)
	Malignant disease
	Subjects with pacemakers

tion regarding discomfort during therapy. Because the sham therapy was not painful, subjects would have been able to unblind themselves to their allocation by whether their therapy was uncomfortable or not.

The sequence of random allocation to either active ESWT or sham ESWT was determined using block randomization with random block sizes of 2, 4, and 6. Sequence generation and concealment were performed by a person who was not involved in any other way in the study. Randomization was stratified between unilaterally affected subjects and bilaterally affected subjects. Allocation concealment was achieved with the use of numbered opaque envelopes. Subjects were allocated to either active ESWT or sham ESWT after their screening visits, once inclusion and exclusion criteria were confirmed. To determine the treatment protocol, the ESWT technician opened the envelope during the subject's first treatment visit. The study coordinator did not have access to subject treatment records, including subject allocation or the allocation sequence, until the 60th subject had completed the 8-week follow-up evaluation.

All subjects, regardless of allocation, were educated on a simple stretching program at their initial visits as part of their treatment protocols. The program consisted of a single forearm extensor stretch.[20] Subjects were instructed to perform 4 repetitions, holding the stretch for 20 seconds, 4 times a day. This was instituted to address potential for flexion contractures.

Subjects allocated to active ESWT received 3 treatment sessions for each affected arm—1 a week for 3 weeks. Treatments were applied using a low-energy shock wave machine, the Sonocur Basic (Siemens AG, Erlangen, Germany). Conducting gel was applied to the site of pain, and the treatment head of the machine was placed on the point of maximum pain as identified by the subject. Subjects received 2000 pulses of 0.03 to 0.17 mJ/mm^2 per affected arm in each treatment session. The energy flux density used to treat each subject was determined by the subject's own pain tolerance, as per the manufacturer's protocol. All treatments were administered at the University of Calgary Sport Medicine Centre. The treatment technician was not involved in any of the data collection or follow-up process, with the exception of adverse events detection.

Subjects allocated to the sham ESWT group received 3 treatment sessions for each affected arm—1 a week for 3 weeks. Before administration of the therapy, an air buffer pad was placed between the head of the machine and the skin of the subject's elbow. Conducting gel was applied to the elbow, and the head of the machine was placed on the lateral epicondyle. The treatment technician administered 2000 pulses of 0.03 mJ/mm^2, none of which was transmitted to the subject's tissues owing to the air buffer pad.

Demographic data were collected from all subjects. All subjects were assessed at time of inclusion in the study for pain, quality of life, and pain-free maximum grip strength. Pain was measured for each affected elbow using a series of 10-cm visual analog scale (VAS) scores to evaluate overall elbow pain, resting pain, pain during sleep, pain during the subject's main activity, pain at its worst, and pain at its least. The left-hand anchors were labeled "no pain," and the right-hand anchors were labeled "worst pain imaginable." Quality of life was assessed using the thermometer subsection of the EuroQol 5D (EQ5D) quality-of-life instrument.[3] Pain-free maximum grip strength was measured for each affected elbow using a dynamometer (Jamar, Bolingbrook, Ill). Subjects were tested in a standing position, with the elbow at 90° of flexion.[6,19] They were instructed to squeeze the dynamometer until discomfort was felt at the lateral epicondyle. Each subject performed the grip test 3 times on each arm. The mean score for the affected arm was calculated and used for analysis.

The primary outcome of this study was treatment success or failure. A treatment success was defined a priori as (1) at least a 50% reduction in overall elbow pain as measured by the overall pain VAS, (2) a maximum allowable overall elbow pain score of 4.0 cm, and (3) no use of pain medication for LE for 2 weeks before the 8-week evaluation. A treatment failure was defined as a lack of a treatment success. Fulfillment of all 3 success criteria was required for classification as a treatment success. In bilaterally affected subjects, fulfillment of all 3 success criteria in both arms was required for classification as a treatment success.

All tools and measures were administered at baseline, 4 weeks, and 8 weeks after initiation of therapy. The evaluator was not aware of subject allocation. Subjects were also given a log form to record their use of pain medication and were instructed to record the medication taken, the dosage, the date it was taken, and why it was taken (eg, for a headache, for elbow pain). Detected adverse events were classified as mild, moderate, or severe.[26] All subjects were unblinded to the true nature of the study and to their allocation immediately after the completion of the 8-week follow-up.

Statistcs

An intention-to-treat analysis was performed on the data. As per the approach in which the last observation is carried forward, values for the most recent visit were carried forward to complete missing outcome values from subjects who were lost to follow-up or missed follow-ups.[4] The primary outcome of treatment success or failure was analyzed using a χ^2 test. The null hypothesis for this test was that there would be no difference between the 2 treatment groups with respect to the proportion of subjects classified as treatment failures. Confidence intervals were calculated by treatment group for VAS scores, quality of life, and maximum pain-free grip strength.

RESULTS

Figure 1 presents the flow of subjects through the study. Demographic data for the study population are presented in Table 2. Subjects were recruited between February 2002 and September 2002. A total of 60 subjects were recruited; 29 subjects were randomly allocated to the sham ESWT group, and 31 subjects were randomly allocated to the

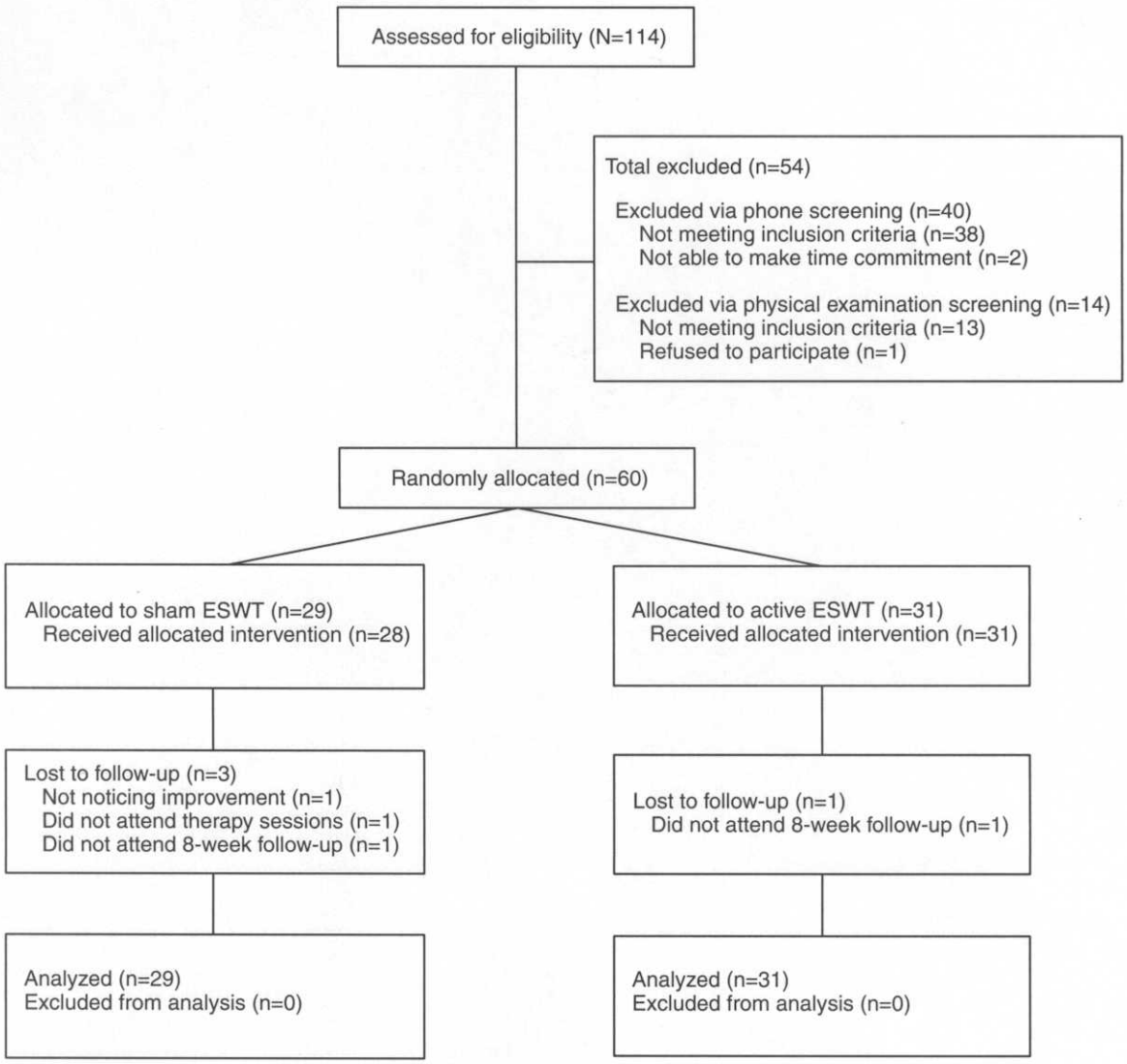

Figure 1. Subject flow diagram. ESWT, extracorporeal shock wave therapy.

active ESWT group. Four subjects in the sham group and 1 subject in the active group were lost to follow-up (Figure 1).

Table 3 shows the number of subjects scored as treatment successes and treatment failures in each group. The proportions of treatment successes in the sham ESWT and active ESWT groups were 0.31 and 0.39, respectively. No significant difference was detected ($\chi^2_1 = 0.3880$, $P = .533$) between active and sham groups.

Because of the skewed distributions of some outcome variables, median VAS scores, EQ5D thermometer ratings, and maximum pain-free grip strength scores for each group at baseline and 8 weeks are displayed in Table 4. Mean VAS, EQ5D, and maximum pain-free grip strength scores at baseline, 4 weeks, and 8 weeks are graphically shown in Figure 2.

No severe or moderate adverse events were observed. Adverse events are summarized in Table 5.

DISCUSSION

This study is the first to examine the effectiveness of ESWT in a population not previously treated for tendon-related pain. Contrary to the study of Rompe et al,[23] which was a trial performed with a similar ESWT protocol—Siemens Osteostar (Siemens AG), 3 weekly sessions, 1000 pulses of 0.08 mJ/mm^2, no ultrasound focusing, and 6-week follow-up—but with subjects who had received and failed conservative nonoperative therapy, a significant difference between sham and active ESWT was not detected at the 8-week follow-up period in this study.

It is difficult to compare the results of this trial with the remaining 3 randomized controlled trials in the literature because of the chronic nature of the LE studied (prolonged periods of LE; repeated, failed nonoperative therapy)—although the findings of the 3 latest trials are in agreement with the results of our study.[5,8,25]

TABLE 2
Demographic Data for Sham and Active ESWT Groups[a]

Characteristic	Sham ESWT Group (n = 29)	Active ESWT Group (n = 31)
Age, y	45.5 (6.6)	46.8 (9.2)
Gender	9 female, 20 male	14 female, 17 male
Weight, kg	81.5 (15.6)	76.6 (13.7)
Height, cm	176.5 (12.1)	170.1 (11.3)
Dominant hand	24 right, 5 left	29 right, 2 left
Duration of symptoms, wk	22.1 (15.7)	19.3 (13.2)

[a]Standard deviations provided in parentheses. ESWT, extracorporeal shock wave therapy.

TABLE 3
Treatment Successes and Failures

	Treatment Success		Treatment Failure	
Group	n	Within-Group Proportion	n	Within-Group Proportion
Sham ESWT[a]	9	0.31	20	0.69
Active ESWT	12	0.39	19	0.61

[a]ESWT, extracorporeal shock wave therapy.

TABLE 4
Median VAS, EQ5D, and Maximum Pain-Free Grip Strength Scores for Sham and Active ESWT Groups at 0 and 8 Weeks[a]

	0 Weeks		8 Weeks		Mean Difference		
Measure	Median Score	Interquartile Range	Median Score	Interquartile Range	Pretreatment-Posttreatment	SD	CI
Sham ESWT Group							
VAS, cm							
Overall pain	3.2	2.1-5.0	2.5	1.4-4.8	0.9	0.4	0.1 to 1.8
Resting pain	1.1	0.4-2.0	0.7	0.1-2.2	0.3	0.3	–0.4 to 1.0
Night pain	0.2	0.0-0.85	0.3	0.1-0.9	–0.1	0.3	–0.6 to 0.4
Activity pain	4.9	2.6-6.3	3.3	1.5-4.9	1.1	0.5	0.0 to 2.2
Worst pain	6.0	4.6-7.4	3.9	2.3-6.2	1.7	0.5	0.7 to 2.7
Least pain	0.2	0.0-0.6	0.2	0.0-0.7	0.0	0.2	–0.3 to 0.3
EQ5D thermometer	80	70-89	80	69-89	–1.3	2.2	–5.9 to 3.2
Maximum pain-free grip strength, kg	23.4	15.6-37.9	32.0	24.0-45.8	–7.4	2.3	–12.2 to –2.7
Active ESWT Group							
VAS, cm							
Overall pain	3.9	2.1-4.9	2.0	1.0-3.2	1.5	0.5	0.5 to 2.4
Resting pain	1.2	0.6-2.1	1.0	0.1-2.1	0.5	0.4	–0.4 to 1.3
Night pain	1.3	0.1-3.5	0.4	0.0-1.5	0.8	0.4	0.0 to 1.6
Activity pain	5.2	3.3-7.4	2.4	0.8-4.1	2.6	0.5	1.6 to 3.6
Worst pain	6.9	4.9-8.5	3.6	1.5-5.7	2.7	0.5	1.7 to 3.8
Least pain	0.4	0.1-1.3	0.2	0.0-1.0	0.3	0.4	–0.5 to 1.0
EQ5D thermometer	81	70-88	84	77-90	–3.3	2.7	–8.8 to 2.2
Maximum pain-free grip strength, kg	24.7	14.7-36.0	30.0	22.0-39.5	–6.8	1.7	–10.2 to –3.3

[a]In bilaterally affected subjects, the more painful elbow (at baseline) was selected for inclusion in this analysis. VAS, visual analog scale; EQ5D, EuroQol 5D; ESWT, extracorporeal shock wave therapy; CI, 95% confidence interval (unadjusted).

Haake et al[8] did not detect a difference between sham and active ESWT but used a local anesthetic to blind subjects to their treatment allocations—varied devices, 3 weekly sessions, 2000 pulses of 0.07 to 0.09 mJ/mm^2, and ultrasound guidance. This may have been problematic and may have accounted for their low success rate in the active ESWT group, as it is the opinion of many manufacturers that patient feedback on pain/discomfort during low-energy ESWT is essential for treatment success.

Speed et al[25] also did not detect a difference between sham and active ESWT but administered treatments once a month for 3 months rather than the manufacturer-recommended course of 1 session per week for 3 weeks—Siemens Sonocur Plus (Siemens AG), 3 monthly sessions, 1500 pulses of 0.18 mJ/mm^2, and ultrasound guidance.

Although Crowther et al[5] did detect a difference between active ESWT and corticosteroid injection, no placebo/sham arm was used—Minilith SL1 (Storz Medical, Kreuzlingen, Switzerland), 3 weekly sessions, 2000 pulses of a maximum 0.1 mJ/mm^2, and ultrasound guidance. The success rate (as defined by a minimum reduction of 50% in the pain VAS) of the ESWT group was reported as 60%, which

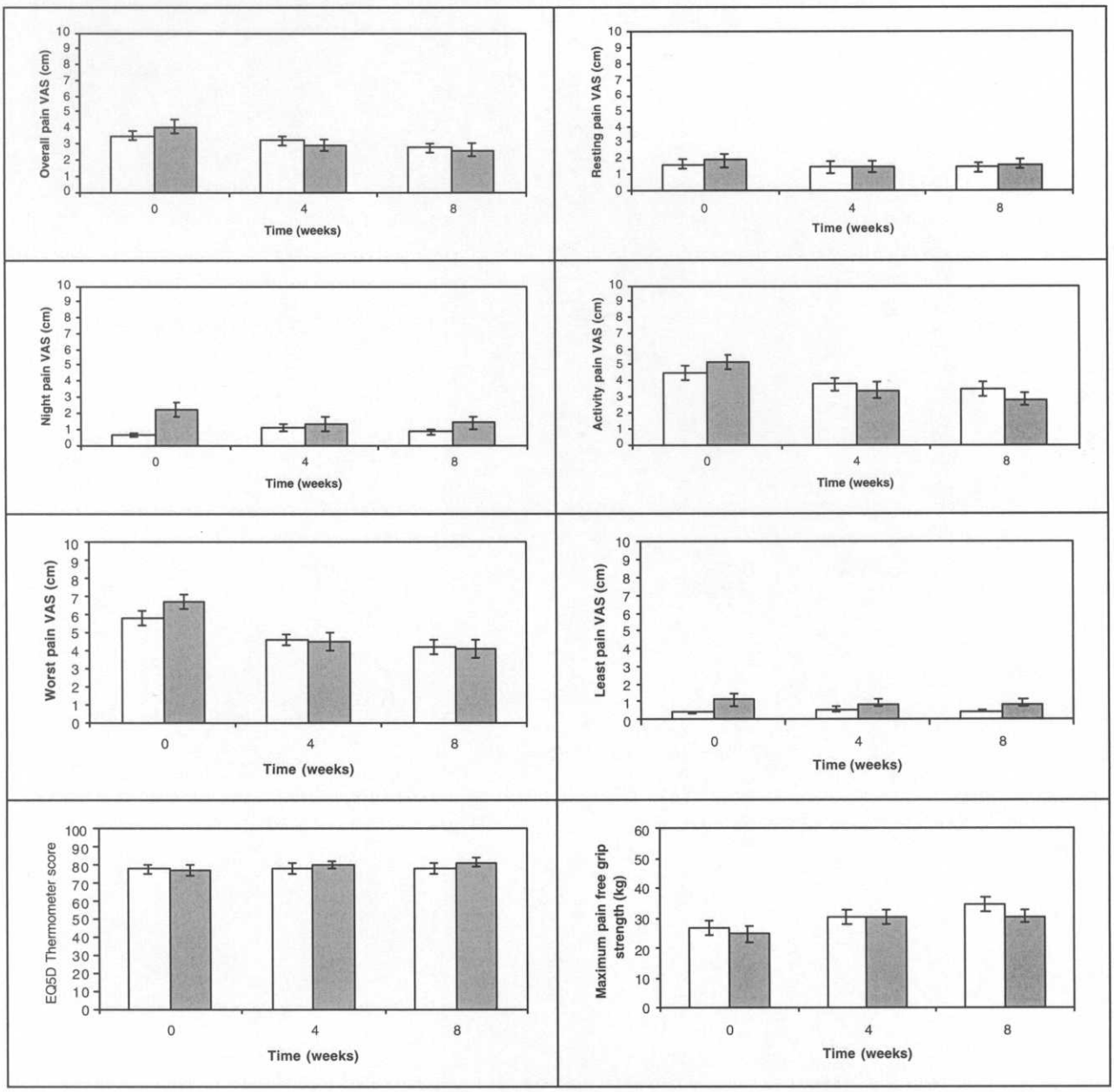

Figure 2. Mean visual analog scale (VAS), EuroQol 5D (EQ5D), and maximum pain-free grip strength scores for sham and active extracorporeal shock wave therapy (ESWT) groups at 0, 4, and 8 weeks. Unshaded bars represent sham ESWT group; shaded bars represent active ESWT group; error bars represent standard error of the mean.

was higher than that observed in this trial. Subjects were rated as treatment successes or treatment failures 3 months after the end of treatment, which was more than twice as long as the follow-up period reported in this study. It is therefore possible that a higher proportion of subjects in our trial may have been classified as treatment successes if the follow-up period had been longer than 5 weeks after the end of treatment.

Classification of individual cases as treatment success or treatment failure was necessary to preserve the unit of analysis in the primary analysis. Inclusion of bilaterally affected subjects was imperative for the purposes of generalizability, but comparison testing with the elbow as the unit of analysis would have resulted in a violation of the assumption of independence (ie, that each observation acts independently from every other observation).[1]

A sample size of 723 subjects would have been required to detect the difference in treatment success and treatment failure proportions that was observed in this study (0.31 vs 0.39, respectively). The observed difference in pro-

TABLE 5
Summary of Adverse Events Observed During or After Treatment Sessions in Active ESWT and Sham ESWT Groups[a]

Symptom	Active ESWT	Sham ESWT
Tingling during therapy	0	5
Nausea during therapy	3	0
Achiness after therapy	1	1
Soreness after therapy	3	4
Increased pain symptoms after therapy	4	3

[a]ESWT, extracorporeal shock wave therapy.

portions between groups in treatment success was not considered to be clinically significant enough to warrant a study of this size.

The results of the primary analysis are supported by the lack of differences observed between groups in all of the secondary outcomes (resting pain, night pain, activity pain, pain at its worst, pain at its least, EQ5D thermometer score, maximum pain-free grip strength). Although the median VAS scores decreased over time in the active ESWT group, median scores decreased similarly in the sham ESWT group.

Mean values for pain-free grip strength were consistent with previously reported values for LE-affected patients Although the typical grip strength protocol involves selecting the best of 2 or 3 trials for analysis, the mean of 3 trials was used to more accurately reflect the clinical picture of the subjects. Normally, the maximum value is selected because of warm-up effects that may render a mean score to be an inaccurate reflection of grip strength. Pain-free maximum grip strength was chosen as the grip strength outcome in this study because it is a better indicator of the impact that LE has on gripping motions (testing absolute maximum grip strength is essentially a test of both strength and pain tolerance). Because subjects were asked to squeeze the dynamometer to the point of onset of pain, there is a possibility that the values obtained from subsequent trials may have been affected by previous trials (eg, an analgesic effect from previous painful stimulus), thus possibly artificially inflating the grip strength score. There have been no studies to compare the validity of selecting the mean or maximum value for grip strength in subjects with LE. The mean of 3 trials was chosen as the outcome to allow the inclusion of possible higher strength values (as a result of warm-up effects) as well as the lower values (as a result of not having been affected by possible analgesic effects of previous trials).

Quality of life as measured by the EQ5D thermometer score did not change significantly over time within or between groups. Values for the EQ5D thermometer were consistent with those reported by people in Alberta who had no medical problems,[13] suggesting that although patients who are affected by LE are somewhat impaired in their activities, LE does not seem to have a large impact on their evaluation of their overall state of health. Further research is warranted to determine the usefulness of gathering quality-of-life data on this population when conducting efficacy trials.

Compliance with the stretching program was neither confirmed nor controlled. This did not have any bearing on the findings of this study for 3 primary reasons: (1) Compliance to stretching protocols is seldom confirmed in the clinical setting—often, patients are given a set of home exercises (for a variety of conditions), instructed in their use, and left to perform their home programs at their own discretion. Mimicking the clinical setting as closely as possible was considered an important factor in evaluating the use of ESWT for untreated LE, as it is the setting in which ESWT is and will be performed. (2) Not controlling for compliance did not affect the comparability of the 2 treatment groups. Subjects more prone to comply and those less prone to comply would have been distributed comparably between the 2 groups because of the random nature of their treatment allocation. (3) For this study, the usefulness of tracking compliance by conventional methods was questionable. In our experience, stretching logs have usually had poor return rates and poor compliance rates in terms of subjects' failing to complete information in their logs on a day-to-day basis. This can result in subjects' filling in missing dates long after the actual dates have passed and therefore biasing the log in such a way that it is not possible to assess the direction of recall bias.

The aim of this study was to examine the effectiveness of low-energy ESWT in a setting that was close to those used in other centers in North America. The ESWT protocol recommended by the manufacturer of the ESWT machine was preserved. Subject blinding was performed using an alternative to anesthesia. Assessment of blinding was not possible, as subjects were not informed that a sham therapy group was a possible allocation until their 8-week follow-ups were completed.

CONCLUSION

The results of this study suggested that ESWT is not an effective therapy for LE in subjects from a previously untreated population with pain for less than 1 year, as assessed at 5 weeks after therapy. The stability of this result over a longer period of time is not yet known. Further research involving longer follow-up periods is warranted to confirm the results presented in this article.

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