

Repetitive Low-Energy Shock Wave Treatment for Chronic Lateral Epicondylitis in Tennis Players

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Background: There is conflicting evidence regarding extracorporeal shock wave treatment for chronic tennis elbow.

Hypothesis: Treatment with repetitive low-energy extracorporeal shock wave treatment is superior to repetitive placebo extracorporeal shock wave treatment.

Methods: Seventy-eight patients enrolled in a placebo-controlled trial. All patients were tennis players with recalcitrant MRI-confirmed tennis elbow of at least 12 months' duration. Patients were randomly assigned to receive either active low-energy extracorporeal shock wave treatment given weekly for 3 weeks (treatment group 1) or an identical placebo extracorporeal shock wave treatment (sham group 2). Main outcome measure was pain during resisted wrist extension at 3 months; secondary measures were >50% reduction of pain and the Upper Extremity Function Scale.

Results: At 3 months, there was a significantly higher improvement in pain during resisted wrist extension in group 1 than in group 2 (mean [SD] improvement, 3.5 [2.0] and 2.0 [1.9]; $P = .001$ for between-group difference of improvement) and in the Upper Extremity Function Scale (mean [SD] improvement, 23.4 [14.8] and 10.9 [14.9]; $P < .001$ for between-group difference of improvement). In the treatment group, 65% of patients achieved at least a 50% reduction of pain, compared with 28% of patients in the sham group ($P = .001$ for between-group difference).

Conclusion: Low-energy extracorporeal shock wave treatment as applied is superior to sham treatment for tennis elbow.

Keywords: tennis elbow; shock wave treatment; ESWT; placebo-controlled trial

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 epicondylalgia or epicondylitis. It is a repetitive overuse injury producing microtears in the tendons that attach the extensor muscles to the epicondyle. In tennis players, it most often results from overload while performing a backhand stroke. Lateral epicondylalgia more likely occurs in unskilled tennis players who use a racket that is too stiff, who hit the ball late, who frequently "frame" the ball, or whose forearm muscles are weak. Those who are older than 40 appear most susceptible.³³

Recent treatment modalities of lateral elbow epicondylalgia are evaluated on the grounds of evidence-based medicine criteria. Systematic reviews have failed to identify

evidence for the use of acupuncture,^{6,7} for the effectiveness of orthotic devices,³⁰ and for the effectiveness of physiotherapy or corticosteroid injection.^{27,28} The situation is particularly frustrating regarding surgery, in which hardly any controlled trials exist.^{1,2,11,14} Concerning extracorporeal shock wave treatment (ESWT), however, variable results have been reported in several prospective studies.[†]

In 2002, Haake et al⁹ published results of a large, double-blinded, prospective, randomized, multicenter study on lateral epicondylitis which examined the effects of active ESWT under local anesthesia compared to those of placebo ESWT under local anesthesia. This study concluded that ESWT treatment did not have any added therapeutic benefit beyond placebo.

The conclusion by Haake et al was seriously debated as there were 3 major variations to a randomized-controlled trial²⁵ showing a beneficial effect of ESWT: the use of local anesthesia; 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 3 days following an ESWT.

[†] References 3-5, 12, 13, 16, 19, 20, 24, 26, 29, 34.

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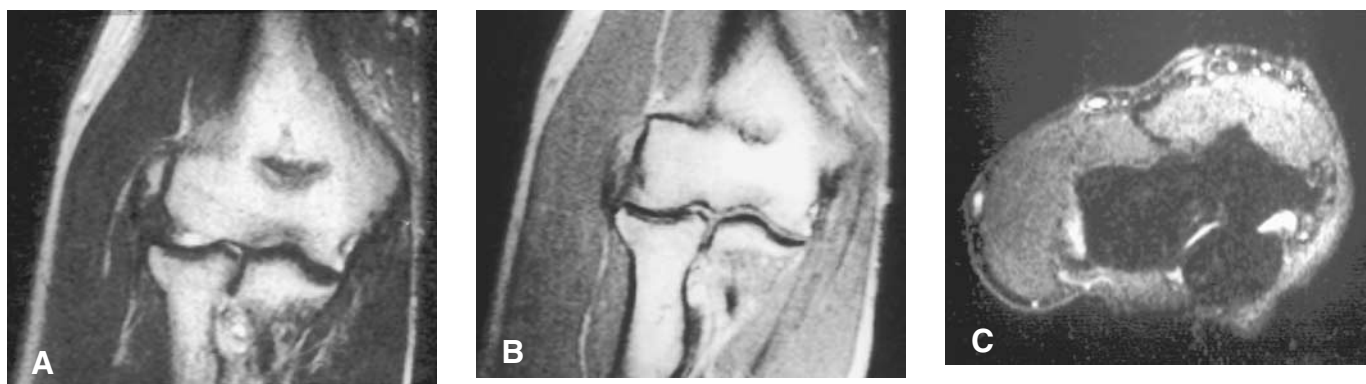


Figure 1. An MRI of a 54-year-old male tennis player with chronic lateral epicondylalgia. A, increased signal intensity in a T2-weighted sequence (coronal plane). B, increased signal intensity in a proton density sequence (coronal plane). C, increased signal intensity in a short inversion time inversion recovery sequence (transversal plane).

The current study addressed these 3 problems: it was a randomized, placebo-controlled trial of ESWT for chronic lateral epicondylitis in recreational tennis players, with patients and observers blinded toward the treatment regimen. No local anesthesia was applied, a single shock wave device and standardized application parameters were used, and any pain medication between ESWT and 3-month follow-up was prohibited.

PATIENTS AND METHODS

The presenting authors, with the assistance from the Department of Orthopaedic Surgery, Johannes Gutenberg University School of Medicine, performed a randomized trial with a parallel-group design over 5 years. Patients were blinded to the way of treatment, as were the independent observers.

The objective of the study was to evaluate the efficiency of repetitive, active low-energy ESWT versus placebo ESWT for recreational tennis players suffering from chronic tennis elbow.

Inclusion criteria were playing recreational tennis (at least 1 hour per week before symptoms occurred; mean, 3.4 hours per week; range, 1-14 hours per week), having a history of epicondylalgia of the radial humerus (at least 2 positive clinical tests) for at least 1 year, having a positive MRI (increased signal intensity of extensors) (Figure 1),^{10,18} experiencing pain unresponsive (before entering study) to rest, reviewing of stroke technique and equipment by a tennis professional, having undergone at least 3 conventional conservative therapy programs (including at least 3 local injections, at least 10 individual treatments of physical forms of treatment, at least 3 weeks of nonsteroidal anti-inflammatory drug [NSAID] medication), having passed at least a 2-month interval since the last conservative treatment, and experiencing baseline pain of at least 4 points on a 0 to 10 visual analog scale (VAS) during resisted wrist extension (Thomsen Provocation Test).

Patients with the following conditions were excluded from the study: local arthrosis/arthritis, rheumatoid arthritis, cervical compression syndrome; pathologic neurological findings of the extremity to be treated; previous operation on the epicondyle to be treated; previous ESWT to any site (because of risk of unblinding); pregnancy; thrombopathy; anticoagulant therapy or manifest hyperthyroidosis; infection of the upper extremity to be treated; suffering from tumor of the upper extremity to be treated; use of local anesthesia during ESWT; and any additional treatment between ESWT and 3-month follow-up, with the exception of already-used braces.

Patients

Ninety-three patients were assessed for eligibility until a total of 78 cases were enrolled. Six patients did not meet the inclusion criteria, and 9 patients refused to participate. Seventy-eight patients agreed to participate and were treated according to the study protocol (Figure 2).

All patients gave informed consent to participate in the study. The trial was approved by an institutional review board. Patients were assigned, with use of concealed randomization, to receive ESWT or placebo treatment. Randomization was performed according to a computer-generated random numbers list.

Treatment Group (Group 1)

Thirty-eight patients were allocated to the active ESWT treatment (group 1), 18 women and 20 men, with a mean age of 45 years (range, 23-69 years). Twenty-nine patients were right handed, and 9 were left handed. Duration of symptoms averaged 24.0 months (range, 12-120 months).

Sham Group (Group 2)

Forty patients were allocated to the placebo ESWT treatment (group 2), 20 women and 20 men, with a mean age of



Figure 3. Extracorporeal shock wave treatment of the lateral elbow.

treatment group were recommended to stop playing tennis until 1 week after the last ESWT.

Sham Group (Group 2)

As a control for a possible placebo effect, patients were blinded as to which treatment they were assigned to. The setup in both groups was identical. In the placebo group, a polyethylene foil filled with air and fixed with ultrasound gel in front of the coupling cushion completely reflected the shock waves.⁹ The typical sound created by the lithotripter remained constant. Only the person performing the intervention knew the treatment allocation. All patients of the placebo group were recommended to stop playing tennis until 1 week after the last ESWT.

Care was taken to ensure that study participants did not meet, and individual study participants were asked to wait in separate waiting areas. Patients were informed that it was usual to have soreness after treatment and that the pain might be worse for a few days after ESWT. In addition, it was emphasized that healing might take several weeks to occur and that the patient should not expect max-

imum improvement until 12 weeks after the last treatment. Participants were able to continue wearing braces already used for the treatment of the epicondylitis. Apart from using a brace, no other therapies (including massage, chiropractic, laser, splint, acupuncture, any pain medication, or oral, topical, or locally injected corticosteroids) were allowed until 3-month follow-up.

METHOD OF EVALUATION

Patients were assessed prior to treatment, at 3 months, and at 12 months after the last application of low-energy ESWT by an independent treatment-blinded observer. The actual study procedure was done by a second physician who was aware of the treatment. However, this physician did not play any role in assessing the patients before and after treatment.

Primary Outcome Measure

The primary efficacy end point was defined as reduction from baseline to month 3 posttreatment in the pain VAS during resisted wrist extension (Thomsen Test), without any additional conservative or operative treatment in the observed time interval besides already-used braces. The 3-month interval was selected because it was expected that the healing process would likely be evident (although not necessarily be complete) at this point in time. A relevant clinical improvement was defined as >30% decrease of pain ratings.

Thomsen Provocation Test. With the shoulder flexed to 60°, the elbow extended, the forearm pronated, and the wrist extended about 30°, pressure is applied to the dorsum of the second and third metacarpal bones in the direction of flexion and ulnar deviation to stress the extensor carpi radialis brevis and longus.

Secondary Outcome Measures

Pain Reduction. The first secondary efficacy end point was defined as the number of patients achieving at least a 50% reduction from baseline to month 3 posttreatment and to month 12 posttreatment in the pain VAS during resisted wrist extension.

Roles and Maudsley Score. The second secondary efficacy end point was defined as improvement of outcomes according to the 4-step (1-4) score of Roles and Maudsley²³ at 3-month follow-up and at 12-month follow-up: excellent (1 point): no pain, patient satisfied with treatment outcome; good (2 points): symptoms significantly improved, patient satisfied with treatment outcome; acceptable (3 points): symptoms somewhat improved, pain at a more tolerable level than before treatment, patient slightly satisfied with treatment outcome; poor (4 points): symptoms identical or deteriorated, patient not satisfied with treatment outcome.

Upper Extremity Function Scale. The third secondary outcome measure was functional assessment with the Upper Extremity Function Scale,²² which was performed

at all examinations. This is a self-administered 8-item questionnaire that can be used to measure the impact of upper extremity disorders on a person's ability to perform physical tasks. The rating of each task ranges from 1 to 10 points. One point indicates no problem with completing the task, and 10 points indicate a major problem or inability to complete. The physical tasks rated are sleeping, writing, opening jars, picking up small objects with fingers, driving a car more than 30 minutes, opening a door, carrying a milk jug from the refrigerator, and washing dishes. The minimum score is 8 points, and the maximum score is 80 points.

Grip Strength. The fourth secondary outcome measure was grip strength as assessed with the Jamar dynamometer (Preston Healthcare, Jackson, Miss), the pressure being registered in kg/cm². After the dynamometer was adjusted for hand size, the patient held the dynamometer in one hand in line with the forearm and hanging by the thigh. Maximum grip strength was then determined. The best of 2 trials for each patient was recorded.

Overall Satisfaction. In addition, all patients were asked whether they were able to perform activities at the desired level and to continue playing recreational tennis.

STATISTICS

The primary aim of this study was to compare the clinical outcome after repetitive low-energy ESWT without local anesthesia with the clinical outcome after repetitive low-energy placebo ESWT without local anesthesia. Based on a previous study,²⁵ a difference of 2 points of average pain rating, on a VAS ranging from 0 to 10 points, was assumed between both groups, with a common SD of 2 points. Average pain ratings were assumed to be 3 ± 2 points in the active group and 5 ± 2 points in the placebo group at 3-month follow-up. A sample size of 35 patients per treatment group would have >80% of the power in detecting the treatment difference, with a 2-sided significance level of .01. A dropout of 10% was expected. To test this hypothesis, a 2-sided unpaired *t* test, Welch corrected, was carried out to compare the pain scores of patients receiving active ESWT with those of patients receiving placebo ESWT at 3-month follow-up. Missing responses were imputed as the last observation carried forward. Absolute differences for the success rates and 95% confidence intervals (CI) were calculated (Graphstat, Graphpad Inc, San Diego, Calif). To evaluate the secondary outcome measures, either a *t* test or a Fisher exact test was performed when comparing both groups. Data analysis was planned on an intention-to-treat principle using all randomized patients who provided any postbaseline data.

RESULTS

Follow-up

Treatment Group (Group 1). Three months after active ESWT without local anesthesia, 34 of 38 patients of the

active ESWT group were evaluated (Table 1). Two more patients reported a good outcome on the phone but cancelled clinical examination because of lack of time. Two patients were lost to follow-up. All patients were unblinded at this point in time, and restrictions of treatment were lifted.

Twelve months after active ESWT without local anesthesia, 31 of 38 patients of the active ESWT group were examined; 1 additional patient refused follow-up, and 2 others were lost to follow-up (Figure 2).

Sham Group (Group 2). Three months after placebo ESWT without local anesthesia, 36 of 40 patients of the placebo group were evaluated (Table 1). Four patients were disqualified because of additional treatment (3 had taken NSAIDs, and 1 had been given an injection). All patients were unblinded at this point in time, and in case of persisting symptoms, patients were offered to receive crossover, that is, active ESWT. Twenty-four patients agreed to have active ESWT.

Twelve months after placebo ESWT without local anesthesia, 33 of 40 patients of the placebo group were evaluated. One additional patient had gone abroad, and 2 others refused follow-up (Figure 2). All 24 patients who received active ESWT were included in this follow-up.

Blinding

Assessment of patients' blindness was performed immediately after the last ESWT treatment by the caregiver. In the placebo group, the number of patients who guessed that they had been assigned to receive ESWT was approximately equal to the number who guessed that they had been assigned to the placebo group (18 of 40 patients vs 22 of 40 patients, respectively). However, nearly 3 out of 4 patients receiving active ESWT correctly guessed their assignment (29 of 38 patients vs 9 of 38 patients, respectively).

Primary Outcome Measure

The primary efficacy end point was defined as reduction from baseline to month 3 posttreatment in the pain VAS during resisted wrist extension, without any additional conservative or operative treatment in the observed time interval. Missing responses were imputed as the last observation carried forward.

The average pain score for patients who received the active treatment (group 1) was 7.1 ± 1.4 points at baseline, 3.6 ± 2.1 points at 3 months, and 3.1 ± 2.4 points at 12 months. The average score for the placebo patients (group 2) was 7.1 ± 1.6 points at baseline, 5.1 ± 2.1 points at 3 months, and 4.3 ± 2.3 points at 12 months. At 3 months, the mean between-group difference was 1.6 points (95% CI: 0.6-2.5; $P = .0001$). At 12 months, the between-group difference was 1.3 points (95% CI: 0.2-2.3; $P = .019$).

Both groups improved over time. Mean changes in pain measures from baseline at 3 and 12 months are given in Table 2.

TABLE 1
Demographic and Clinical Characteristics and Baseline Outcome Measurements
of Trial Participants Who Completed 3-Month Assessments^a

Characteristic	Group 1: Active ESWT (n = 34)	Group 2: Placebo (n = 36)	Dropouts (n = 8)
Age, mean (SD), y	45.9 (12.3)	46.2 (11.2)	45.9 (14.6)
Women (%)	16 (47.1)	18 (50.0)	4 (50.0)
Height, mean (SD), cm	178.4 (10.1)	181.3 (10.4)	177.1 (8.9)
Weight, mean (SD), kg	72.4 (18.5)	69.4 (14.3)	68.7 (20.3)
Duration of symptoms, mean (range), kg	23.3 (12-120)	25.1 (12-132)	28.1 (12-72)
Positive MRI, months	34 (100)	36 (100)	8 (100)
Treatments during previous 12 months (%)			
NSAIDs	33 (97.1)	34 (94.4)	8 (100)
Physical therapy	34 (100)	36 (100)	8 (100)
Orthotics	34 (100)	36 (100)	8 (100)
Cortisone injections	33 (97.1)	34 (94.4)	8 (100)
≤ 2	2 (5.8)	1 (2.7)	0 (0)
> 2	31 (91.2)	33 (91.7)	8 (100)
Injection of anesthetic			
≤ 2	0 (0)	5 (13.9)	2 (25)
>2	34 (100)	31 (86.1)	6 (75)
Massage	30 (88.2)	29 (80.5)	4 (50)
Pain during Thomsen test 0-10, mean (SD)	7.1 (1.4)	7.1 (1.6)	6.8 (1.9)
Roles and Maudsley score 1-4, mean (SD)	3.8 (0.4)	3.6 (0.5)	3.5 (0.5)
Upper Extremity Function Scale 10-100, mean (SD)	5.0 (1.9)	4.9 (1.8)	5.1 (1.6)
Dynamometer test kg/cm ² , mean (SD)	44.2 (21.3)	39.4 (22.8)	42.1 (12.6)

^a Data are according to treatment group. ESWT, extracorporeal shock wave treatment; NSAIDs, nonsteroidal anti-inflammatory drugs.

Secondary Outcome Measures

Pain Reduction. One secondary efficacy end point was defined as the number of patients achieving at least a 50% reduction from baseline to month 3 posttreatment in the pain VAS during resisted wrist extension. On an intention-to-treat basis, at 3 months in the active treatment group (group 1), 25 of 38 (65%) patients achieved at least a 50% reduction of pain, compared with 11 of 40 (28%) patients in the placebo treatment group (group 2). The difference between groups was 0.4 ± 0.1 (95% CI: 0.2-0.6; $P = .001$). On intention to treat at 12 months, 23 of 38 (61%) patients in the active treatment group and 15 of 40 (38%) patients in the placebo treatment group achieved at least a 50% reduction of pain. The difference between groups was 0.2 ± 0.1 (95% CI: 0.0-0.5; $P = .0692$).

Roles and Maudsley Score. Another secondary outcome measure was defined as improvement of outcomes according to the 1 to 4 score of Roles and Maudsley.²³ Missing responses were imputed as the last observation carried forward. In the active treatment group (group 1), baseline ratings averaged 3.8 ± 0.4 points, improving to 2.4 ± 0.9 points at 3 months and to 2.3 ± 0.9 points at 12 months. In the placebo group (group 2), baseline ratings were 3.6 ± 0.5 points, improving to 2.3 ± 0.9 points at 3 months and to 2.5 ± 0.9 points at 12 months. Three months after ESWT, the mean difference between groups was 0.5 points (95% CI: 0.1-0.9; $P = .009$), with 22 of 38 patients (58%, group 1) and

13 of 40 patients (33%, group 2) achieving an excellent or good result on an intention-to-treat basis. Twelve months after ESWT, the difference between groups was 0.2 points (95% CI: -0.2-0.7; $P = .256$), with 24 of 38 patients (63%, group 1) and 16 of 40 (43%, group 2) patients achieving an excellent or good result. Both groups improved over time. Mean changes in the Roles and Maudsley score from baseline at 3 and 12 months are given in Table 2.

Upper Extremity Function Scale. Another secondary efficacy end point was an improvement from baseline to 3 months posttreatment in the patients' mean Upper Extremity Function Scale. Missing responses were imputed as the last observation carried forward. In the active treatment group (group 1), baseline ratings averaged 50.3 ± 7.9 points, improving to 26.9 ± 14.9 points at 3 months and to 25.2 ± 15.3 points at 12 months. In the placebo group (group 2), baseline ratings were 49.1 ± 8.1 points, improving to 38.2 ± 14.8 points at 3 months and to 30.6 ± 16.7 points at 12 months. Three months after ESWT, the difference between groups was 11.3 points (95% CI: 4.5-18.0; $P = .001$). Twelve months after ESWT, the difference between groups was 5.5 points (95% CI: -1.8-12.7; $P = .135$). Both groups improved over time. Mean changes in the Upper Extremity Function Scale from baseline at 3 and 12 months are given in Table 2.

Grip Strength. Results of the test are given in Figure 4. Both groups improved over time. At no time was there any statistically significant between-group difference.

TABLE 2
Comparison of Mean Changes in Pain Measures From Baseline at 3 and 12 Months^a

Outcome Measure	3 Months							12 Months						
	Group 1: Active ESWT (n = 34)		Group 2: Placebo ESWT (n = 36)		Between- Group Difference			Group 1: Active ESWT (n = 31)		Group 2: Placebo ESWT (n = 33)		Between- Group Difference		
	Mean Change ^b	SD	Mean Change ^b	SD	Mean Change ^b	95% CI ^c	P Value	Mean Change ^b	SD	Mean Change ^b	SD	Mean Change ^b	95% CI ^c	P Value
Pain (Thomsen test) (0-10)	3.5	2.0	2.0	1.9	1.5	0.6-2.4	.001	4.0	2.5	2.8	2.2	1.2	0.1-2.3	.028
Roles and Maudsley (1-4)	1.4	0.9	0.7	0.9	0.7	0.3-1.1	.001	1.5	0.9	1.1	0.9	0.4	0.0-0.8	.070
Upper Extremity Function Scale	23.4	14.8	10.9	14.9	12.4	5.7-19.1	<.001	25.1	16.2	18.5	16.9	6.7	0.8-14.1	.078

^a ESWT, extracorporeal shock wave treatment; CI, confidence interval.

^b Positive change indicates improvement and negative change worsening.

^c Positive difference in mean change indicates ESWT group improved more than placebo group. Because of rounding, some between-group differences may differ from values obtained by subtracting mean change (placebo ESWT) from mean change (active ESWT).

Overall Satisfaction

At 3 months, 25 of 38 patients (65%) of the active treatment group reported they were able to perform activities at the desired level and to continue playing recreational tennis compared to 14 of 40 patients (35%) of the placebo group (mean between-group difference = 0.3; 95% CI: 0.1-0.5; *P* = .012). At 12 months, 27 of 38 patients (71%) of the active treatment group reported they were able to perform activities at the desired level and to continue playing recreational tennis compared to 22 of 40 patients (55%) of the placebo group (mean between-group difference = 0.2; 95% CI: -0.1-0.4; *P* = .165).

Side Effects

In all patients, temporary reddening occurred after low-energy shock wave application. Thirty-six of 38 patients receiving active ESWT (group 1) reported pain during ESWT, and 21 of 40 patients in the placebo group (group 2) reported pain. Eight patients in the active ESWT group suffered from nausea during the treatment—none vomited, however—as did 1 patient from the sham group. There were no treatment discontinuations or dosage adjustments related to adverse effects. No lasting side effects were noted. All side effects had resolved by final follow-up.

DISCUSSION

There is a very controversial discussion on the evidence to support use of ESWT in a patient with chronic tennis elbow (Table 3).

A large trial by Haake et al⁹ had failed to show any efficiency of ESWT. This was a multicenter, randomized, 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.

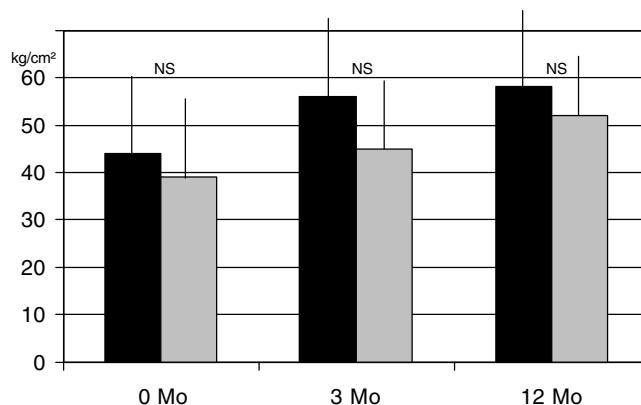


Figure 4. Mean grip strength, in kg/cm², and SD measured with the Jamar dynamometer before start of the trial and at 3 months and 12 months after intervention in the active treatment group (black bars) and the placebo group (gray bars). Mo, months; NS, not significant.

However, blinded outcome assessors were used. All patients were treated under local anesthesia. Overall, therapeutic success rate 12 weeks after intervention (primary end point) was 26% in the ESWT and 25% in the placebo group. Minor side effects were documented.⁸ 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 3 major differences to a previously published randomized-controlled trial²⁵ showing a beneficial effect of ESWT: the use of local anesthesia; 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 3 days following an ESWT. The current study addressed

TABLE 3
Prospective Studies Evaluating ESWT for the Treatment of Tennis Elbow^a

Author	Source	Study Type ^b	Number of Patients	EFD	Anes-thesia	FU After Last Inter-vention	ESWT Group		Placebo Group	
							Result	Score ^c	Result	Score ^c
Rompe et al ²⁴	<i>Z Orthop Ihre Grenzgeb</i> (1996)	D	75	L	–	6	72%	1		
Rompe et al ²⁵	<i>J Bone Joint Surg Br</i> (1996)	B	100	L	–	6	48%	1	12%	1
Perlick et al ²⁰	<i>Z Orthop Ihre Grenzgeb</i> (1999)	D	30	H	+	12	43%	1	73%	1
Krischek et al ¹³	<i>Arch Orthop Trauma Surg</i> (1999)	D	41	L	–	12	62%	2	24%	2
Maier et al ¹⁶	<i>Z Orthop Ihre Grenzgeb</i> (2000)	D	27	L	–	5	32 points	3		
Rompe et al ²⁶	<i>Arch Phys Med Rehabil</i> (2001)	C	60	L	–	12	55%	1	60%	1
Ko et al ¹²	<i>Clin Orthop</i> (2001)	D	72	H	+	3	72%	4		
Wang and Chen ³⁴	<i>Am J Sports Med</i> (2002)	D	57	H	+	24	61%	4		
Crowther et al ⁵	<i>J Bone Joint Surg Br</i> (2002)	B	98	L	–	3	60%	5	84%	5
Speed et al ²⁹	<i>J Orthop Res</i> (2002)	A	75	L	–	1	35%	5	34%	5
Haake et al ⁹	<i>J Bone Joint Surg Am</i> (2002)	A	272	L	+	3	26%	1	25%	1
Pettrone et al ^{21,32}	www.fda.gov/cdrh/pdf/p010039.html	A	114	L	–	3	61%	5	29%	5
Levitt et al ^{15,31}	www.fda.gov/cdrh/pdf/p990086s003.html	A	183	H	+	2	52%	5	31%	5
Melikyan et al ¹⁷	<i>J Bone Joint Surg Br</i> (2003)	A	74	H	–	12	24 points	3	20 points	3
Rompe et al (current study)	<i>Am J Sports Med</i> (2004)	A	78	L	–	3	65%	5	28%	5

^a ESWT, extracorporeal shock wave treatment; EFD, energy flux density; FU, follow-up in months; L, low energy; H, high energy.

^b A, randomized masked trial (ie, with sham ESWT); B, randomized open trial (ie, control group without placebo ESWT); C, nonrandomized trials with control group; D, nonrandomized trials without control group.

^c 1, excellent or good outcome according to the Roles and Maudsley score; 2, excellent or good outcome according to the Verhaar score; 3, visual analog scale; 4, excellent or good clinical outcome; 5, at least a 50% reduction of pain.

these 3 problems and improved the study design accordingly: it was a randomized, placebo-controlled trial with blinded patients and observers. No local anesthesia was applied, a single shock wave device and standardized application parameters were used, and no steroidal anti-inflammatory drugs between ESWT and 3-month follow-up were allowed. To improve the quality of the diagnosis, lateral epicondylitis had been confirmed by MRI in all cases.

These changes of the study design compared with the Haake et al trial⁹ resulted in a significantly higher improvement in pain during resisted wrist extension and in the Upper Extremity Function Scale in the active treatment group compared to the placebo group. At 3 months, 25 of 38 patients (65%) of the active treatment group reported they were able to perform activities at the desired level and to continue playing recreational tennis, compared to 13 of 40 patients (33%) of the placebo group.

The results of the current randomized, placebo-controlled trial with significant differences are fully confirmed by a presentation of short-term data from Pettrone et al.^{21,32} They randomized 114 patients with at least a 6-month history of lateral epicondylalgia into double-blinded active treatment and placebo groups. As in the current trial, treatment consisted of 3 weekly treatments of 2100 impulses, using clinical focusing without local anesthesia or a sham treatment without local anesthesia. An identical Sonocur shock wave device was used. Overall, 108 of 114 patients completed 12 weeks of treatment. The average

pain VAS score improved from 74 to 38 points in the active treatment group and from 76 to 51 points in the placebo group. On intention to treat, a statistically significant difference in pain reduction was observed at 12 weeks, with 34 of 56 of active treatment patients (61%) showing at least 50% improvement in pain, compared to 17 of 58 (29%) in the placebo group.

The current investigation was a randomized and placebo-controlled trial. Nevertheless, it suffers from some limitations. First, it is a monocenter study, and treatment was performed by an expert team of orthopaedic surgeons. A selection and treatment bias cannot be ruled out completely, though a standardized randomization procedure was used. Second, patients were not matched for activity level before treatment. Third, only tennis players were included in the trial. However, when comparing the current study with the study by Pettrone et al,^{21,32} it appears likely that given an identical study design, it does not matter whether a recreational tennis player or a member of the general population is treated with repetitive low-energy ESWT for chronic elbow epicondylalgia. Fourth, three fourths of the study patients were able to correctly diagnose their assignment, whereas only one half of the placebo patients were able to do so. Obviously, blinding was less successful in the treatment group and may be a possible explanation for the improved outcome of this group. On the other hand, using a local anesthesia to blind the patients during treatment does not work any better. Haake et al⁹ observed that more than two thirds of the

patients treated with active ESWT under local anesthesia correctly guessed their assignment. In the placebo group, the number of patients who guessed that they had been assigned to receive active ESWT was equal to the number who guessed that they had been assigned to the placebo group. However, they did not find any improved outcome in the active ESWT group. Fifth, the primary outcome measure focused on the 3-month follow-up. Therefore, evaluation of 12-month results in the sham group was not split between 24 patients receiving active ESWT 3 months after placebo ESWT and 9 patients not receiving active ESWT 3 months after placebo ESWT. Long-term results should be addressed in a separate trial.

Speed et al²⁹ conducted a randomized, placebo-controlled trial on ESWT for lateral epicondylalgia with the same Sonocur device used in the current study. They included patients with symptoms for as short as 3 to 6 months. There were 75 patients treated 3 times with 1500 low-energy impulses of an energy flux density of 0.18 mJ/mm² without local anesthesia, in monthly intervals. One month after the last intervention, there was at least a 50% reduction of pain in 14 of 40 patients (35%) of the active group and in 12 of 35 patients (34%) of the placebo group. In contrast to the current trial, the follow-up time was very short (1 month after the last intervention vs 3 months after the last intervention), and the interval between the treatments was very long (1 month vs 1 week).

In March 2003, a multicenter, randomized, sham-controlled clinical trial resulted in US Food and Drug Administration approval for the Ossatron device for the treatment of chronic lateral epicondylitis.^{15,31} There were 183 subjects randomized to either active ESWT or sham treatment with the Ossatron. One hundred sixty-five patients were followed up at 4 weeks and 8 weeks after the treatment; at the 8 weeks posttreatment follow-up, a success/fail assignment was made based on 3 criteria: investigator assessment of pain, subject self-assessment of pain, and the use of pain medications. Each subject assigned to active treatment then underwent an ESWT procedure with a total of 1500 shocks delivered at a power setting of 18 kV. The average active treatment time was 20.5 minutes. For subjects assigned to sham treatment, a Styrofoam block was placed against the coupling membrane of the shock head to absorb the shock waves. A fluid-filled intravenous bag was then placed between the Styrofoam block and the subject's elbow to mimic the feel of the coupling membrane, and 1500 shocks were then delivered at 18 kV. At 8 weeks, only in the investigator's assessment of pain was there a significant difference between the active group and the placebo group. Forty-three of the 82 subjects (52%) in the active group met the success criterion of >50% improvement and VAS score of 4.0 or less compared with 26 of the 83 subjects (31%) in the placebo group. However, there was no statistically significant difference concerning the patient's self-assessment of pain (59% vs 43%) and concerning the ongoing use of pain medications (29% vs 31%).

Most recently, Melikyan et al¹⁷ investigated the efficacy of ESWT therapy for tennis elbow using a single fraction-

ated dosage in a randomized, double-blind study. A total dose of 1000 mJ/mm² was applied in 3 sessions held within a 1-week interval. The intensity of shock waves applied varied from level 1 to 6. Generally, a high-energy flux density was preferred, and no local anesthesia was used. Shock waves were applied tangentially to the common extensor origin under outline ultrasound guidance. Outcomes were assessed using the Disabilities of Arm, Shoulder, and Hand Questionnaire; measurements were of grip strength; levels of pain; analgesic usage; and the rate of progression to surgery. In the final assessment after 12 months, none of the outcome measures showed a statistically significant difference between the treatment and control groups. All patients improved significantly over time, regardless of treatment. The study showed no evidence that ESWT for tennis elbow is better than placebo.

So, many questions still remain to be answered by future prospective, randomized, controlled trials. Does local anesthetic have an adverse effect on the clinical outcome after repetitive low-energy ESWT? What about performing the treatment under regional anesthesia? Is there an adverse effect of additional pain medication on the clinical outcome after repetitive low-energy ESWT? If so, why and to what extent? Is clinical outcome after repetitive low-energy ESWT comparable with results after high-energy ESWT performed under regional anesthesia? What role does the way of focusing play for clinical success?

CONCLUSIONS

- The results of the current randomized, placebo-controlled trial contrast sharply with negative findings published previously.⁹
- After major changes in the study design, application of 2000 low-energy shock waves in 1-week intervals to the area of most pronounced tenderness over the lateral epicondyle—using an identical shock wave device in all patients and using clinical focusing without local anesthesia—led to significantly better results in the treatment group than in the placebo group in patients with recalcitrant, MRI-confirmed lateral epicondylitis. The data are consistent with those of a randomized, placebo-controlled, multicenter trial conducted in the US.^{21,32}
- There is a significant benefit of low-energy ESWT as applied when compared to sham treatment for tennis elbow 3 months after intervention. There is a considerable placebo effect of low-energy ESWT in patients with chronic lateral epicondylitis.
- Until shown otherwise in a prospective, randomized trial, no pain medication is recommended during and up to 3 months after repetitive low-energy ESWT.

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