



OPEN Focused shock wave and ultrasound therapies in the treatment of lateral epicondylitis - a randomized control trial

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Persistent symptoms of lateral epicondylitis prompt patients to seek effective conservative treatment. The study aimed to determine the effects of focused shock wave (FSWT) and ultrasound therapies for lateral epicondylitis. Sixty patients with tennis elbow were randomly divided into three equal groups: A, B, and C. Group A received a total of 3 FSWT sessions, with 7 days between treatments; Group B received ultrasound therapy in 10 sessions over 2 weeks, while patients in Group C were treated with placebo ultrasound. All patients were also given deep friction massage. Before the start of therapy, and at 1, 3, 6, and 12 weeks after its completion, pain intensity and function of the affected upper limb were assessed in all patients. Wrist extensor and flexor strength and grip strength were measured in the affected and unaffected limb. Significant reductions in pain and significant improvements in the function of the affected limb compared to baseline values were observed in all study groups at 6 and 12 weeks after the completion of therapy. Analysis of percentage changes in these variables showed significant differences between Groups A and B in favor of Group A. The strength of wrist extensors and grip strength of the affected limb at 6 and 12 weeks after treatment completion was significantly higher in Groups A and B compared to pre-therapy values. However, there were no statistically significant differences between the groups regarding percentage changes in muscle strength in the affected limb. Pain reduction and function improvement in patients with lateral epicondylitis were significantly greater after FSWT (0.2 mJ/mm² / 4 Hz / 2000 shocks) than after sonotherapy (3 MHz / 0.5 W/cm² / 20%). Increases in wrist extensor strength and grip strength of the affected limb were comparable after both therapies. Given the greater therapeutic effect in the subjective evaluation, we recommend a combination therapy of FSWT with deep friction massage.

Trial registration The trial was prospectively registered in the ISRCTN registry (no. ISRCTN11907358 registration date 30.07.2020).

Keywords Tennis elbow, Extracorporeal shock wave therapy, Ultrasonic waves, Therapeutics

Abbreviations

RSWT	Radial shock wave
FSWT	Focused shock wave
PRTEE	Patient-Rated Tennis Elbow Evaluation
NRS	Numerical Rating Scale

Lateral epicondylitis (also referred to as tennis elbow) is a degenerative dysfunction usually affecting the tendons of the extensor carpi radialis brevis and the extensor digitorum communis at their origin at the anterior aspect of the lateral epicondyle of the humerus. The predominant symptoms are pain localized on the lateral aspect of the elbow joint and tenderness of the lateral epicondyle of the humerus, interfering with the function of the affected limb¹. As a result of long-lasting tensile overload, microinjuries are formed, which add up and chronically damage the internal structure of the tendon and its attachment at the cellular level and in the intercellular

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space². In case of complete failure of repair mechanisms, the end result of pathogenetic degenerative changes in the tendon is degenerative tendinopathy³.

Persistent symptoms of lateral epicondylitis prompt patients to seek effective conservative treatment⁴. Conservative treatments for tendinopathy include various forms of physiotherapy. One of the manual treatments used to treat tendinopathy is deep friction massage, used by 88.1% of physiotherapists⁵. Physical agents used in conservative treatment of tennis elbow include laser therapy and electrical stimulation, but also mechanical waves (ultrasound and shock wave)^{6,7}.

There is plenty of papers in the literature in which researchers have evaluated the therapeutic efficacy of ultrasound, radial and focused shock wave in patients with tennis elbow. Most often, however, the effect of only one of these mechanical stimuli was studied, or the effect of ultrasound was compared with that of radial shock wave (RSWT), or the effect of RSWT was compared with that of focused shock wave (FSWT)^{8–14}. To the best of the authors' knowledge, no published studies have compared the effect of ultrasound with that of FSWT, which prompted us to take up this issue.

Shock wave differs significantly from ultrasound wave in physical characteristics and mechanisms of interaction^{15,16}. In medical applications, all shock wave energy is focused on a tiny focal point, the shape of a reversed cigar, at an appropriate depth in tissues at the site of a lesion. Focusing is possible due to the proper contouring of the transmitter head and gel caps in the shape of truncated cones¹⁶. In contrast, ultrasound propagates as longitudinal waves. The intensity of the ultrasound wave decreases as it moves away from the ultrasound source and passes through the medium. The shock wave is a more intense mechanical stimulus than the ultrasound wave. It is characterised by high amplitude, very high speed of propagation through the medium (greater than or close to the sound speed depending on the medium) and low frequency (1–8 Hz). The strength of the ultrasonic effect depends on its intensity. The intensity determines the amount of energy emitted per unit of time by the surface of the piezoelectric transducer. Ultrasound intensities used in physiotherapy range from 0.05 to 2.0 W/cm²^{15–18}. Due to the lack of scientific reports, the present study compares the therapeutic efficacy of two mechanical stimuli with entirely different characteristics used in the physical treatment of lateral epicondylitis, i.e., ultrasound, which is commonly used in reimbursed healthcare and focused shockwave, readily offered to patients in units providing commercial services.

Since the mechanical effect of FSWT on tissues is more intense than that of ultrasound waves, we assumed that pain reduction in patients with tennis elbow would be greater after shock wave than after sonotherapy treatments. It was also assumed that the decrease in tendon pain after mechanotherapy would improve the function of the affected upper limb and that the magnitude of the therapeutic effect would depend on the type of mechanical stimulus used.

The main objective of this randomized controlled trial was to evaluate the effects of focused shock wave and ultrasound therapies on pain intensity, upper limb function, and muscle strength in patients with lateral epicondylitis.

Methods

The research was conducted at the Osteopathy and Physiotherapy Center in Zywiec, Poland, from August 2020 to February 2022 and was approved by the Bioethics Committee at the Jerzy Kukuczka Academy of Physical Education in Katowice on 17/01/2019 (Resolution No. 2/2019). The trial was prospectively registered in the ISRCTN registry (no. ISRCTN11907358), and processed according to Consolidated Standards of Reporting Trials (CONSORT)¹⁹. This research was conducted following the relevant guidelines and regulations including the Declaration of Helsinki.

Patients

The disease was diagnosed by an orthopedic surgeon based on subjective and objective examinations, X-ray pictures, and ultrasound scans.

The inclusion criteria were: (1) pain in the lateral epicondyle persisting for ≥ 3 months; (2) pain on palpation in the lateral epicondyle; (3) a positive Thompson's test (the patient reports pain when performing resisted extension of a slightly extended wrist, with the fingers clenched into a fist, the elbow extended, and the forearm in a pronated position); (4) a positive Mill's test (the patient reports pain when performing resisted supination of the forearm with the elbow joint slightly flexed, the forearm in a pronated position, the wrist slightly extended, and the fingers clenched into a fist); (5) pain during resisted extension of the middle finger; (6) age 18 to 65 years. Recreationally active patients were included in our study.

The exclusion criteria were as follows: local infection, pregnancy, malignancy, bilateral tennis elbow, carpal tunnel syndrome, medial epicondylitis, elbow arthritis or instability, generalized polyarthritis, ipsilateral shoulder dysfunction, neurological abnormalities, radial-nerve entrapment, cardiac arrhythmia or a pacemaker, diabetes, physical therapy and/or a corticosteroid injection administered within the previous six weeks. A detailed description of the inclusion and exclusion criteria was provided in the ISRCTN registry (no. ISRCTN11907358).

Initially, 67 patients with lateral epicondylitis were invited to participate in the experiment, with 4 patients not giving written consent to participate in the study, and 3 patients were excluded as they did not meet the inclusion criteria (Fig. 1). Ultimately, 60 patients were included in the study and randomly assigned to one of three comparison groups (1:1:1 ratio) in which participants received treatment with either FSWT (Group A), ultrasound therapy (Group B), or sham ultrasound therapy (Group C). The orthopaedic surgeon qualifying patients for the study did not know what type of therapy would be used in groups A, B and C. All participants gave their informed consent to participate in the study.

In Group A, FSWT was delivered using the Richard Wolf Piezowave without local or general anesthesia. A special cone-like cap focusing shock waves 5 mm from its top was deployed. The site to be treated was prepared by applying a special conductive gel. Patients were treated sitting, with the affected arm abducted, the elbow

CONSORT 2010 Flow Diagram

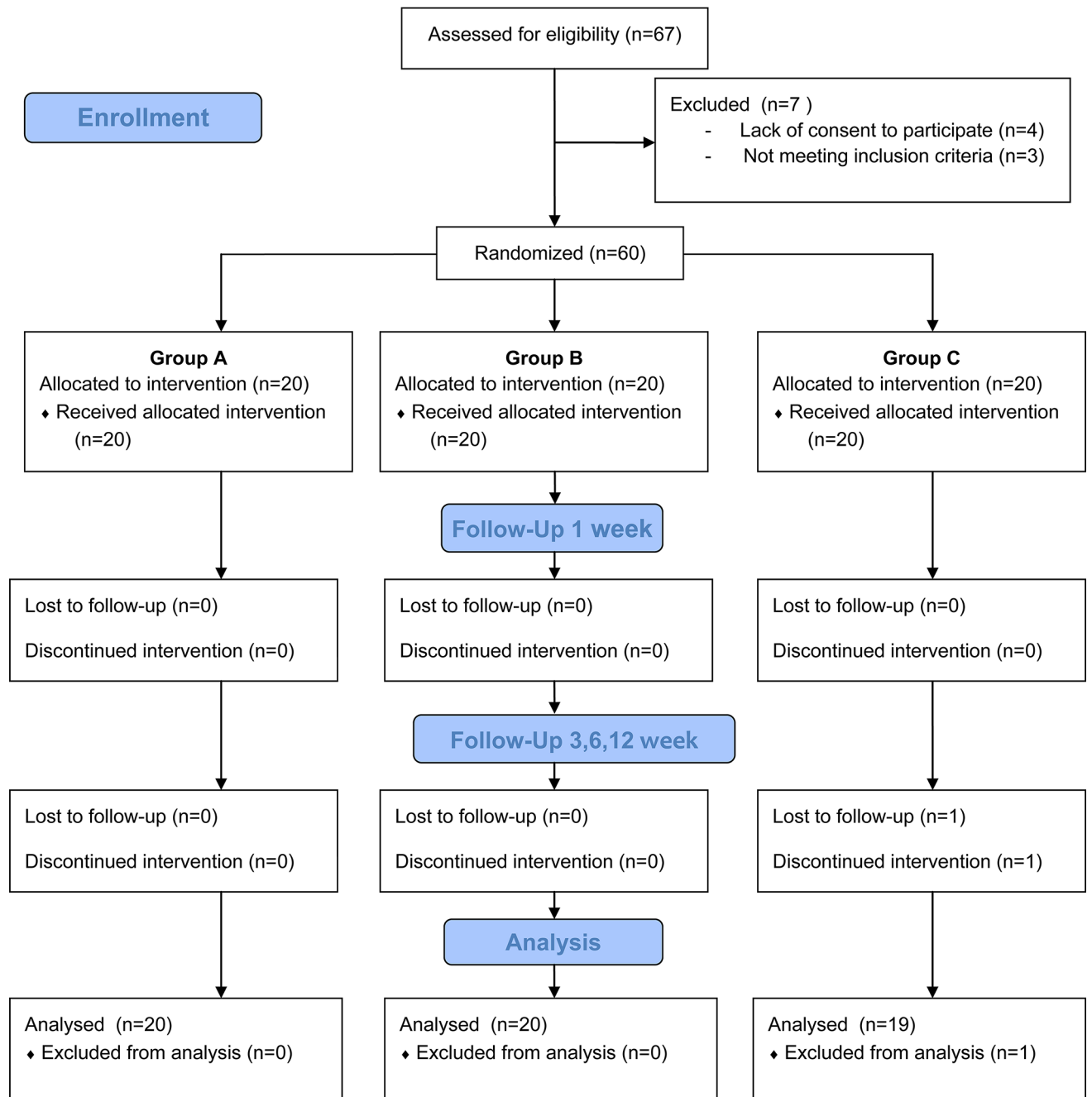


Fig. 1. Flowchart of the trial from the baseline.

joint flexed at approximately 60 degrees, and the forearm pronated and rested on the therapeutic table. Energy flux density was set at 0.2 mJ/mm^2 and shock wave frequency at 4 Hz. During each procedure, 2000 pulses were applied to the most painful point of the lateral epicondyle. Patients received a total of three procedures separated by one-week intervals. The methodology of the FSWT procedure was established based on previous work by Król et al.²⁰

Patients in Group B were treated with ultrasounds generated by the Cosmogamma US13 EVO provided with a 5 cm^2 ultrasound applicator. A special conductive gel was applied to the treatment site before the procedure. Patients were treated sitting, with the affected arm abducted, the elbow joint flexed at approximately 60 degrees, and the forearm pronated and rested on the therapeutic table. Ultrasound frequency was set at 3 MHz. Pulsed ultrasonic waves (with 20% duty cycle) and 0.5 W/cm^2 spatial average temporal peak (SATP) were used as described in a study by Białek et al.¹⁰. During each procedure, the most painful point of the lateral epicondyle

was treated with ultrasound for 5 min in a semi-stationary manner (the applicator's movements were minimal). Patients received a total of 10 procedures on weekdays over two consecutive weeks.

Patients in Group C were also treated using the Cosmogamma US13 EVO unit. The treatment position and unit's settings were also the same as in Group B. The only difference was that the applicator did not generate ultrasounds. Patients received a total of 10 procedures on weekdays over two consecutive weeks.

In all three groups, shockwave and ultrasound therapies were combined with a deep friction massage. The massage procedures lasted 12 min and was held every second day during the treatment period (excluding the weekend), so each patient received a total of 7 procedures. A transverse friction technique was used.

Blinding included patients treated with ultrasound and placebo ultrasound, the physician qualifying patients for the experiment, the person collecting data and taking measurements, and the statistician. Blinding did not include patients undergoing FSWT, the physiotherapist performing the treatments, and the study supervisor.

Outcome assessment

All patients were assessed for pain intensity, upper limb function, and muscle strength before the intervention and at 1, 3, 6, and 12 weeks of therapy completion.

A numerical scale of 0–10 was used to assess pain intensity during activity, with 0 representing no pain and 10 representing the worst pain the patient could imagine.

The Patient-Rated Tennis Elbow Evaluation (PRTEE) questionnaire²¹ was used to assess the disability of the affected limb. This questionnaire consists of 3 subscales. In the first, patients assessed pain while performing certain activities in the affected limb over the past week. Each of the 5 questions in this section was rated on a scale of 0 to 10, with 0 representing no pain and 10 representing the worst conceivable pain. In the second and third parts, patients rated the degree of difficulty when performing 10 different activities during the past week. Each of the 10 questions included in this part was also rated on a scale of 0 to 10; in this case, 0 meant no difficulty in performing the activity, and 10 represented the inability to act. The overall PRTEE score is the sum of the scores from the pain subscale and half of the sum of the scores from the second and third functional subscales.

An SH5001 dynamometer (SAEHAN Corporation) was used to measure wrist extensor and flexor muscle strength and grip strength ([kG]). Each measurement was conducted in a sitting position. When measuring the wrist extensor strength, the patient's arm was adducted, the elbow was bent to 90°, the forearm was supinated, the wrist was flexed, and the fingers were straightened. The patient's forearm was stabilized on the table with two straps. The patient's starting position during the measurement of wrist flexor strength was similar, with the patient's forearm pronated and the wrist positioned in extension. Each patient performed 3 consecutive attempts of maximal wrist extension (when measuring wrist extensor strength) and flexion (when measuring wrist flexor strength), separated by 30-second intervals. During the grip strength measurement, the patient's arm was adducted, the elbow was bent to 90°, and the forearm was placed in an intermediate position between supination and pronation. The patient performed 3 consecutive maximal grip tests on the dynamometer, which were separated by 30-second intervals. The mean value of the three measurements was used for statistical calculations²⁰.

Statistical analysis

The effect size was calculated based on the means and standard deviations of the primary outcomes of the pilot study (i.e., activity-related pain and grip strength). We assumed that at the probability of a type I error $\alpha = 0.05$, target power of $1 - \beta = 0.80$, and a 25% minimum significant difference between the means of the primary outcome measures, the minimum sample size in each group should be 19 participants. The target sample size was 57; three additional patients were recruited to account for dropouts.

The Kruskal-Wallis one-way ANOVA on ranks was used to test the homogeneity of the distribution of patient characteristics in terms of age, weight, height, disease duration, and all parameters assessed in Groups A, B, and C. The distribution of the other characteristics, i.e., BMI, gender, disease location in the right or left limb, and location of the disease in the dominant or non-dominant limb, was tested using the highest reliability version of the chi-square test of independence.

The following variables were analyzed in Groups A, B, and C:

- changes in pain intensity during activity,
- changes in the strength of the wrist extensors in the affected limb,
- changes in the strength of the wrist extensors in the unaffected limb,
- changes in the ratio of the wrist extensor strength in the affected limb to wrist extensor strength in the unaffected limb,
- changes in the strength of the wrist flexors in the affected limb,
- changes in the strength of the wrist flexors in the unaffected limb,
- changes in the ratio of the wrist flexor strength in the affected limb to wrist flexor strength in the unaffected limb,
- changes in the grip strength of the affected limb,
- changes in the grip strength of the unaffected limb,
- changes in the ratio of the grip strength in the affected limb to the grip strength in the unaffected limb,
- changes in the PRTEE questionnaire scores.

Percentage change in muscle strength was derived from the following formula:

$$X [\%] = \frac{(X_{pt} - X_{bt})}{X_{bt}} \times 100 [\%]$$

where: X = percentage change, X_{bt} = average strength before treatment, X_{pt} = average strength at 1, 3, 6 and 12 weeks of therapy completion.

Percentage changes were also calculated for pain during activity and for total scores on the PRTEE questionnaire:

$$Y [\%] = \frac{(Y_{bt} - Y_{pt})}{Y_{bt}} \times 100 [\%]$$

where: Y = percentage change, Y_{bt} = intensity of pain during activity before the start of treatment / total score on the PRTEE questionnaire before the start of treatment; Y_{pt} = intensity of pain during activity at 1, 3, 6 and 12 weeks of therapy completion / total score on the PRTEE questionnaire at 1, 3, 6 and 12 weeks of therapy completion.

The Shapiro-Wilk test was used to check the data for normal distribution. The Friedman ANOVA by ranks and post hoc test for Friedman ANOVA by ranks were used to analyze changes within groups. The Kruskal-Wallis one-way ANOVA on ranks and post hoc test for Kruskal-Wallis were used to analyze intergroup changes at 1, 3, 6, and 12 weeks after treatment.

The level of statistical significance differences was set at $p \leq 0.05$.

Results

The baseline characteristics of patients in all groups are presented in Table 1. The study population was homogeneous concerning participant characteristics ($p > 0.05$).

The intensity of pain experienced during activity decreased gradually, i.e., at each consecutive assessment, but only in Group A. It should be noted, though, that statistically significant changes were observed 6 and 12 weeks after the end of treatment in all three groups ($p \leq 0.05$) (Table 2). A gradual reduction in the total score obtained on the PRTEE questionnaire was also observed only in Group A. However, at 6 and 12 weeks of treatment completion, the score was significantly lower than before treatment in all three groups ($p \leq 0.05$) (Table 2). The percentage changes in pain intensity and PRTEE scores at 6 and 12 weeks post-treatment differed significantly between Groups A and B ($p \leq 0.05$) in favor of Group A, where the percentage changes were the most pronounced (Table 3). At 3, 6, and 12 weeks after therapy, the strength of the affected limb's wrist extensors and flexors in Group A was significantly higher than baseline values ($p \leq 0.05$). These changes were associated with a statistically significant increase in the ratio of the wrist extensor strength in the affected limb to the wrist extensor strength in the unaffected limb and a statistically significant increase in the ratio of the wrist flexor strength in the affected limb to the wrist flexor strength in the unaffected limb at 12 weeks after the end of treatment ($p \leq 0.05$).

In Group B, the strength of the wrist extensors of the affected limb was significantly higher in all consecutive control measurements compared to baseline ($p \leq 0.05$) (Table 4). Gradual increase in grip strength was only found in Groups A and B, with the change being statistically significant ($p \leq 0.05$) in Group A at 6 and 12 weeks after the end of treatment and in Group B at 3, 6, and 12 weeks after therapy completion (Table 4). Percentage changes in variables related to muscle strength were comparable in all groups ($p > 0.05$) (Table 3).

Characteristics	Group A (n = 20) mean \pm SD or n (%)	Group B (n = 20) mean \pm SD or n (%)	Group C (n = 20) mean \pm SD or n (%)	p - value
Age (years)	47.15 \pm 8.56	46.9 \pm 8.5	45.9 \pm 11.33	> 0.05*
Sex				> 0.05**
Female	7 (35%)	9 (45%)	4 (20%)	
Male	13 (65%)	11 (55%)	16 (80%)	
Measured body height (cm)	173.3 \pm 7.31	167.85 \pm 8.22	175.2 \pm 9.73	> 0.05*
Measured body weight (kg)	80.5 \pm 16.99	78.05 \pm 12.7	84.55 \pm 18.14	> 0.05*
BMI				
<25 kg/m ²	8 (40%)	5 (25%)	7 (35%)	> 0.05**
25–29.9 kg/m ²	8 (40%)	12 (60%)	10 (50%)	
>30 kg/m ²	4 (20%)	3 (15%)	3 (15%)	
Affected limb				
Dominant	18 (90%)	12 (60%)	14 (70%)	> 0.05**
Non-dominant	2 (10%)	8 (40%)	6 (30%)	
Affected limb				> 0.05**
Left	5 (25%)	11 (55%)	6 (30%)	
Right	15 (75%)	9 (45%)	14 (70%)	
Duration of symptoms (mos)	7.1 \pm 5.25	8.1 \pm 8.25	6.8 \pm 7.7	> 0.05*

Table 1. Characteristics of study participants. *Kruskal-Wallis test, **Chi-square test.

Group	Baseline	1 week	3 weeks	6 weeks	12 weeks
Activity-related pain intensity					
A	7.2 ± 1.64	5 ± 2.27	3.35 ± 2.62*	2.2 ± 2.76*	1.75 ± 2.79*
B	7.05 ± 1.82	4.4 ± 1.67*	4.05 ± 2.31*	4.2 ± 2.63*	3.7 ± 2.54*
C	6.63 ± 1.71	4.84 ± 2.36	4.9 ± 2.23	4.05 ± 1.68*	3.47 ± 2.01*
PRTEE score					
A	58.53 ± 23.81	37.83 ± 24.7	24.85 ± 24.76*	15.65 ± 22.47*	12.93 ± 22.33*
B	55.18 ± 22.56	34.35 ± 16.56*	32.6 ± 23.25*	34.1 ± 26.17*	27.95 ± 20.65*
C	56.08 ± 23.31	44.42 ± 23.5	44.79 ± 23.53	35.45 ± 18.1*	30.87 ± 18.86*

Table 2. Change in the intensity of pain experienced during activity according to the NRS and total scores on the PRTEE questionnaire in all groups (mean ± SD). Note: post hoc test for Friedman ANOVA by ranks, against the baseline *, $p \leq 0.05$.

	Baseline	1 week	3 weeks	6 weeks	12 weeks
Strength of wrist extensors in Group A					
Affected limb	9.3 ± 3.7	11.4 ± 3.95	12.15 ± 4.03*	12.45 ± 3.98*	12.65 ± 3.98*
Ratio	0.75 ± 0.28	0.83 ± 0.26	0.9 ± 0.24	0.99 ± 0.23*	0.96 ± 0.2*
Strength of wrist extensors in Group B					
Affected limb	10.4 ± 3.15	12.35 ± 3.76*	12.55 ± 4.35*	12.9 ± 4.2*	12.8 ± 4.47*
Ratio	0.85 ± 0.16	0.93 ± 0.13	0.94 ± 0.12	0.95 ± 0.14	0.95 ± 0.18
Strength of wrist extensors in Group C					
Affected limb	9.58 ± 3.79	10.84 ± 4.3	10.95 ± 4.22	10.95 ± 3.95	10.74 ± 4.01
Ratio	0.79 ± 0.21	0.84 ± 0.18	0.84 ± 0.17	0.83 ± 0.16	0.84 ± 0.2
Strength of wrist flexors in Group A					
Affected limb	14.4 ± 4.08	17.6 ± 5.92*	18.4 ± 5.92*	19.5 ± 7.35*	19.75 ± 7.48*
Ratio	0.88 ± 0.33	1 ± 0.33	1.01 ± 0.26	1.05 ± 0.28	1.08 ± 0.27*
Strength of wrist flexors in Group B					
Affected limb	14.15 ± 4.26	16.55 ± 4.41*	15.95 ± 4.38	16.2 ± 4.69	16.5 ± 4.97*
Ratio	0.87 ± 0.19	1 ± 0.14*	0.98 ± 0.11*	0.97 ± 0.13	0.99 ± 0.14
Strength of wrist flexors in Group C					
Affected limb	14.21 ± 4.37	15.32 ± 4.18	15.95 ± 4.44	16.21 ± 4.76*	16.58 ± 5.07*
Ratio	0.86 ± 0.14	0.92 ± 0.15	0.92 ± 0.14	0.92 ± 0.13	0.92 ± 0.16
Grip strength in Group A					
Affected limb	39.3 ± 9.85	42.2 ± 9.99	43 ± 9.66	45.25 ± 10.56*	45.6 ± 10.09*
Ratio	0.92 ± 0.18	0.98 ± 0.16	0.99 ± 0.12	1.02 ± 0.11	1.03 ± 0.11*
Grip strength in Group B					
Affected limb	39 ± 12.16	42.02 ± 11.7	42.79 ± 11.83*	43.07 ± 11.85*	44.77 ± 12.17*
Ratio	0.97 ± 0.25	1.01 ± 0.19	1.01 ± 0.17	1.02 ± 0.15	1.05 ± 0.15
Grip strength in Group C					
Affected limb	40.16 ± 12.86	42.16 ± 12.65	41.05 ± 13.49	42.68 ± 12.77	43.37 ± 13.38
Ratio	0.9 ± 0.18	0.92 ± 0.19	0.91 ± 0.18	0.94 ± 0.16	0.95 ± 0.14

Table 3. Change of muscle strength in all groups (mean ± SD). Note: post hoc test for Friedman ANOVA by ranks, against the baseline. * $p \leq 0.05$.

Discussion

The study aimed to determine the effects of FSWT and ultrasound therapies on pain intensity, upper limb function, and muscle strength in patients with lateral epicondylitis. According to the subjective assessment of patients with tennis elbow (NRS scale and PRTEE questionnaire), the treatment was effective. However, it turned out to be significantly more effective in those who received FSWT compared to sonotherapy. Patients treated with FSWT and ultrasound also showed significant increases in wrist extensor strength and grip strength of the affected limb after treatment, but these changes were comparable between the two groups.

Pain intensity has been the most frequently analyzed parameter when studying the effectiveness of therapeutic interventions in lateral epicondylitis^{14,20,22–24}. As we assumed, the greatest reduction in pain experienced during activity was achieved in the group treated with FSWT. In this group, 12 weeks after the end of treatment, pain was reduced by 76.43% compared to baseline. This change was significantly greater than that observed in the

Percentage change between trials	Group A (%±SD)	Group B (%±SD)	Group C (%±SD)	p*	Between-group analysis: A-B and B-C (post hoc**)
Activity-related pain intensity					
T ₀ -T ₁	30.01 ± 26.53	38.06 ± 19.01	26.32 ± 27.97	> 0.05	-
T ₀ -T ₂	53.57 ± 30.47	43.04 ± 26.44	26.44 ± 25.3	0.013	A-B: p > 0.05 B-C: p > 0.05
T ₀ -T ₃	69.52 ± 34.97	40.63 ± 32.42	37.16 ± 25.83	0.004	A-B: p = 0.035 B-C: p > 0.05
T ₀ -T ₄	76.43 ± 36.04	45.21 ± 37.68	49.13 ± 28.95	0.004	A-B: p = 0.015 B-C: p > 0.05
PRTEE score					
T ₀ -T ₁	35.85 ± 30.41	37.45 ± 20	18.58 ± 25.12	0.045	A-B: p > 0.05 B-C: p > 0.05
T ₀ -T ₂	59.13 ± 30.4	42.55 ± 27.28	20.7 ± 20.9	< 0.001	A-B: p > 0.05 B-C: p = 0.044
T ₀ -T ₃	74.61 ± 32.04	38.98 ± 40.66	35.23 ± 24.2	< 0.001	A-B: p = 0.005 B-C: p > 0.05
T ₀ -T ₄	80.09 ± 33.51	44.75 ± 45.92	48.77 ± 26.83	< 0.001	A-B: p = 0.005 B-C: p > 0.05
Wrist extensor strength of the affected limb					
T ₀ -T ₁	29.95 ± 44.66	20.11 ± 20.91	15.26 ± 26.21	> 0.05	-
T ₀ -T ₂	38.8 ± 43.39	20.76 ± 20.75	18.3 ± 30.87	> 0.05	-
T ₀ -T ₃	43.21 ± 48.1	24.31 ± 19.74	19.28 ± 28.69	> 0.05	-
T ₀ -T ₄	46.22 ± 51.18	22.63 ± 19.15	19.2 ± 34.93	> 0.05	-
Wrist flexor strength of the affected limb					
T ₀ -T ₁	22.71 ± 24.25	20.35 ± 26.41	10.28 ± 18.83	> 0.05	-
T ₀ -T ₂	29.76 ± 30.96	15.5 ± 23.57	15.71 ± 20.06	> 0.05	-
T ₀ -T ₃	36.88 ± 37.31	17.21 ± 26.25	18.03 ± 25.86	> 0.05	-
T ₀ -T ₄	38.65 ± 37.87	19.11 ± 27.47	19.24 ± 20.98	> 0.05	-
Extensor strength ratio (affected to unaffected)					
T ₀ -T ₁	18.36 ± 38.48	11.93 ± 24.51	10.13 ± 26.43	> 0.05	-
T ₀ -T ₂	31.65 ± 46.29	13.56 ± 24.25	11.73 ± 32.52	> 0.05	-
T ₀ -T ₃	45.19 ± 50.14	14.24 ± 21.25	9.15 ± 28.22	0.016	A-B: p > 0.05 B-C: p > 0.05
T ₀ -T ₄	44.13 ± 54.67	13.57 ± 21.52	11.84 ± 34.75	> 0.05	-
Flexor strength ratio (affected to unaffected)					
T ₀ -T ₁	18.54 ± 11.4	18.28 ± 22.58	7.08 ± 11.24	> 0.05	-
T ₀ -T ₂	21.96 ± 31.93	17.69 ± 25.44	8.02 ± 13.46	> 0.05	-
T ₀ -T ₃	29.09 ± 38.69	15.39 ± 25.99	8.26 ± 11.06	> 0.05	-
T ₀ -T ₄	33.77 ± 41.5	18.53 ± 31.6	7.81 ± 14.65	> 0.05	-
Grip strength of the affected limb					
T ₀ -T ₁	7.89 ± 8.78	9.33 ± 10.24	6.17 ± 14.99	> 0.05	-
T ₀ -T ₂	10.38 ± 10.38	12.6 ± 22.52	3.71 ± 20.17	0.013	A-B: p > 0.05 B-C: p > 0.05
T ₀ -T ₃	16.3 ± 14.51	13.61 ± 24.7	7.71 ± 16.97	0.04	A-B: p > 0.05 B-C: p > 0.05
T ₀ -T ₄	17.58 ± 15.24	18.56 ± 27.94	9.2 ± 19.64	> 0.05	-
Grip strength ratio (affected to unaffected)					
T ₀ -T ₁	7.15 ± 11.3	7.19 ± 16.59	2.32 ± 17.6	> 0.05	-
T ₀ -T ₂	9.17 ± 13.51	9.91 ± 26.29	1.58 ± 19.25	> 0.05	-
T ₀ -T ₃	13.22 ± 15.54	11.37 ± 31	5.37 ± 16.12	> 0.05	-
T ₀ -T ₄	14.54 ± 16.54	15.84 ± 33.59	7.26 ± 18.92	> 0.05	-

Table 4. Percentage change in the analysed parameters in all groups. T₀ – baseline; T₁ – after 1 week; T₂ – after 3 weeks; T₃ – after 6 weeks; T₄ – after 12 weeks; p* - Kruskal-Wallis one-way ANOVA on ranks; p** - post hoc test for Kruskal-Wallis.

ultrasound-treated group, where pain decreased by 45.21%. A significant post-FSWT reduction in pain during activity was also observed by other authors^{14,20,22,24}. In the studies by Król et al.²⁰ and Stania et al.¹⁴, pain intensity during activity in patients with lateral epicondylitis decreased by 65.73 – 84.61% after FSWT treatment.

The PRTEE questionnaire can be the standard primary outcome measure in the evaluation of tennis elbow complaints²¹, as confirmed by numerous research papers^{7,8,23,25}. Rompe et al.²¹ demonstrated that the reliability

and internal consistency of PRTEE were excellent (PRTEE pain subscale, 0.94; PRTEE specific activities subscale, 0.93; PRTEE usual activities, 0.85).

In the present experiment, the sum of PRTEE questionnaire scores obtained 12 weeks after the end of treatment in all three study groups was significantly lower than before treatment. The percentage reduction of this value in Group A (80.09%) was significantly greater than the reduction obtained in Group B (44.75%). Significant improvements in the function of the affected limb, as assessed by the PRTEE questionnaire, were also obtained in another experiment²⁵, in which a group of patients with lateral epicondylitis was treated with FSWT (as in our study). Immediately after treatment, the PRTEE score decreased significantly more than in our experimental groups, i.e., by an average of 40.4 points. It should be noted, though, that the energy density used by Erslan et al.²⁵ was significantly lower than that used in our study (0.2 mJ/mm²) and ranged from 0.06 mJ/mm² to 0.12 mJ/mm². Other studies⁸, in which ultrasound or RSWT was applied to patients with tennis elbow, also achieved improvements in the function of the affected upper limb. However, direct comparison to the results of other authors is difficult due to considerable discrepancies in shock wave and ultrasound application methodologies.

Regenerative processes within the affected tendon are long-lasting and occur gradually over time²⁶. Shockwave application does not lead to sudden resolution of tendinopathy symptoms. Still, it initiates the process of tissue healing¹⁴, which has been confirmed by the results of the present experiment. Patients in Group A showed no significant improvement in pain intensity and function of the affected limb in the first measurement after therapy.

The reduction in pain intensity achieved in patients in Group A and the resulting improvement in upper limb function was probably partly related to the complex analgesic mechanism by which FSWT affects tissues. In a histological study conducted in humans with lateral epicondylitis, increased concentrations of pain neurotransmitters, i.e., substance P and calcitonin gene-related peptide, were observed within the attachment of the short wrist extensor tendon²⁷. In numerous animal experiments, a reduction in the concentration of these neurotransmitters was obtained after FSWT application^{28–31}. The analgesic effect of the shock wave may also be due to the degeneration of free nerve endings, as observed in another experiment³⁰ in which FSWT was applied to rats. It has also been suggested that the analgesic effect may result from the activation of spinal mechanisms of pain inhibition³² and the diffuse noxious inhibitory controls response³³.

Reduced strength of the forearm and hand muscles is a characteristic symptom in patients with lateral epicondylitis³⁴. Measurement of the strength of the wrist extensors and flexors is rarely used when assessing the effectiveness of FSWT^{14,20,35}, in contrast to the measurement of grip strength, which is used relatively frequently^{7,8,14,20,22}.

In the present study, the strength of the affected limb's wrist extensor muscles at 3, 6, and 12 weeks post-treatment was significantly greater than before the intervention in the FSWT-treated and ultrasound-treated groups. Although the percentage changes in the strength of these muscles of the FSWT-treated group were more than twice as high as in the ultrasound-treated group (strength increased by 46.22% in Group A and 22.63% in Group B), the difference between the groups did not reach the level of statistical significance. The increased strength of the affected limb's wrist extensor muscles in Groups A and B was likely due to the concomitant reduction in pain following the treatments, which allowed for greater motor activity of the affected limb.

In patients with lateral epicondylitis, pain in the area of the lateral epicondyle of the humerus occurs during hand grip, limiting the ability to develop the maximum moment of force. When the activity of the wrist extensor muscles increases, the grip force also increases, as observed in our study, i.e., at 6 and 12 weeks after treatment, the grip strength of the affected limb increased significantly. However, the increase was only observed in Groups A and B and was comparable. Similar changes in the strength of the wrist extensors and flexors, as well as the grip strength of the affected limb, were observed in other studies^{14,20}, which compared the effectiveness of FSWT and RSWT in patients with tennis elbow. In an experiment conducted by Yalvac et al.⁸, significant improvement in grip strength of the affected limb was noted in both the ultrasound and RSWT groups four weeks after the end of treatment, with this experiment, like our own, showing no significant differences between the groups.

In our experiment, treatment of patients in all study groups proved effective, with the best therapeutic efficacy achieved in patients in Group A, particularly regarding analgesic effect and improvement in function. Since deep friction massage was performed during treatment in all groups, it can be speculated that it influenced, to a greater or lesser extent, the outcome of the therapy. Through manual techniques, microstructural abnormalities in the affected tendons can be acted upon mechanically. The beneficial therapeutic effect of deep friction massage is believed to be associated with increased blood flow at the site of its application, elimination of tissue adhesions between collagen fibers, improvement of their spatial organization, and stimulation of mechanoreceptors³⁶.

Since the treatment was partially successful in Group C patients (concerning the NRS scale and the PRTEE questionnaire), it is reasonable to assume that, in part, the results obtained in Group C were due to the placebo effect. The neurobiology of the placebo effect is complex and involves various psychological, neurochemical, and neurophysiological processes³⁷.

Two types of shock wave therapy are used to treat lateral epicondylitis: radial and focused^{8,9,11–14,38}. From a therapeutic point of view, radial and focused shockwave treatments differ in the volume of tissue affected by the mechanical waves and the strength of the impact. In the case of FSWT, the entire energy of the shock wave is focused on a small area of tissue¹⁷. A new line-focused ESWT has been recently introduced to apply a focused shock wave to larger areas of tendon tissue³⁹. With RSWT, the force of the mechanical wave is much smaller but also covers a larger tissue volume¹⁷. Targeting the shockwave to a small area of tissue, characteristic of traditional focused shockwave treatments, requires prior accurate localisation of the lesions by ultrasound. Radial shock wave therapy allows the treatment of the target point and more extensive lesions¹⁷.

Mechanical waves induce a mechanotransduction effect in tissues, through which the processes of repair and remodeling of pathologically altered tissues are initiated^{15,16,40,41}. Shockwave alters the morphological

characteristics and activity of fibroblasts⁴², affects macrophage function⁴³, and stimulates inflammatory and catabolic processes that are associated with the removal of damaged extracellular matrix elements⁴⁴. Shock wave-induced stimulation of repair processes is also attributed to the stimulation of tenocyte proliferation and collagen synthesis^{45,46}. In addition to mechanical effects, the biological effects of ultrasound are associated with thermal effects and physicochemical modifications¹⁵.

None of our patients reported adverse effects from ultrasound therapy. For focused shock wave treatments, two patients developed subcutaneous hematoma during the first application and one during the second treatment. There was also a slight swelling in the lateral epicondyle in three patients after the first treatment and two after the second application. All these symptoms subsided by the time patients presented for their subsequent treatment. Twelve patients each time reported slight but tolerable pain at the site of shock wave application.

The main limitation of the present study is the absence of long-term measurements. The lack of a placebo FSWT group may also be considered a weakness. However, nowadays, patients generally know that shockwave application is painful or at least intensely experienced. If such a group had been created, the lack of any sensation associated with shock wave application would undoubtedly have made the patients suspicious, and it should be assumed they would have guessed they were receiving a sham treatment.

There is a need for further randomized clinical trials of high methodological quality to evaluate the effects of mechanotherapy in patients with lateral epicondylitis at a time point distant from therapy completion. The results of such studies would help determine whether and how durable the therapeutic effects of FSWT and ultrasound are. Literature analysis also indicates the need for other objective methods to assess therapy progress.

Conclusions

Both combination therapies (FSWT with deep friction massage and ultrasound with deep friction massage) proved effective in patients with lateral epicondylitis and pain in the lateral epicondyle persisting for ≥ 3 months. Pain reduction and function improvement in patients with lateral epicondylitis were significantly greater following FSWT (0.2 mJ/mm² / 4 Hz / 2000 shocks) than after sonotherapy (3 MHz / 0.5 W/cm² / 20%) while increases in wrist extensor strength and grip strength of the affected limb were comparable for both therapies. Given the greater therapeutic effect in the subjective evaluation, we recommend a combination therapy of FSWT with deep friction massage.

Data availability

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request

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Author contributions

The authors declare that all authors were fully involved in the study and the preparation of the manuscript and that the material within has not been and will not be submitted for publication elsewhere. PK: the preparation of the research program; the interpretation of data; the statistical analysis. BŁ: the execution of research; the interpretation of data; the preparation of the manuscript. TK: the execution of research; the interpretation of data; the preparation of the manuscript. MK: the literature review; the preparation of the manuscript. MS: the execution of research; the interpretation of data; the preparation of the manuscript.

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Competing interests

The authors declare no competing interests.

Ethics approval and consent to participate

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Consent for publication

Not applicable.

Additional information

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