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ORIGINAL ARTICLE

Effectiveness of high-intensity laser therapy and splinting in lateral epicondylitis; a prospective, randomized, controlled study

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Abstract Lateral epicondylitis (LE) is a common disorder that causes pain on the outside of the elbow, as well as pain and weakness during gripping. In this prospective, randomized, controlled, assessor-blinded trial, we planned to investigate the effects of high-intensity laser therapy (HILT) in patients with LE and to compare these results with those of a brace and placebo HILT. Patients were randomly assigned to three treatment groups. The first group was treated with HILT. The second group (sham therapy group) received placebo HILT, while the third group (brace group) used the lateral counterforce brace for LE. The patients were assessed for grip strength, pain, disability, and quality of life. Outcome measurements and ultrasonographic examination of the patients were performed before treatment (week 0) and after treatment (after 4 and 12 weeks). HILT and brace groups showed significant improvements for most evaluation parameters (pain scores, grip strength, disability scores, and several subparts of the short-form 36 health survey (physical function, role limitations due to physical functioning, bodily pain, general health, and vitality)) after treatment (after 4 and 12 weeks). However, the improvements in evaluation parameters of the patients with LE in HILT and brace groups were not reflected to ultrasonographic findings. Furthermore, comparison of the percentage changes of the parameters after treatment relative to pretreatment values did not show a significant difference between HILT and brace groups. We conclude that HILT and splinting are effective physical therapy modalities for patients with LE in reducing pain and improving disability, quality of life, and grip strength.

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Introduction

Lateral epicondylitis (LE) or tennis elbow is a common disorder that causes pain on the outside of the elbow, as well as pain and weakness during gripping. It has been found to occur in approximately 1.3–1.7 % of people between the third and sixth decades of life in studied populations [1, 2]. Physical strain may play a part in the development of LE, as the dominant arm is significantly more often affected than the non-dominant arm. LE is usually self-limiting, and symptoms seem to resolve between 6 and 24 months in most patients [3].

To date, a standardized, universally accepted program for LE treatment has not been established. Various nonsurgical modalities have been described. In general, treatment can begin with patient education, application of commonly available treatments, physiotherapy, manual therapy, laser therapy, tennis elbow brace, exercises, massage, and local injection therapy, as well as oral or topical nonsteroidal anti-inflammatory drugs (NSAIDs) [4].

Laser treatment is a noninvasive and painless method that can be easily administered in therapy units for a wide range of conditions [5]. Effectiveness of low-level laser therapy (LLLT) in LE is controversial. One meta-analysis of LLLT for lateral epicondylitis found that LLLT was ineffective in the treatment of LE [6]. However, other two examinations of the literature based upon treatment protocol concluded a positive effect [7, 8].

Recently, the pulsed neodymium-doped yttrium aluminum garnet (Nd:YAG) laser, a form of high-intensity laser therapy (HILT), was introduced as a new treatment option. The superiority of HILT over LLLT is that HILT is able to reach and stimulate the larger and/or deeper areas; accordingly, during HILT therapy, significantly greater energy might be transferred into tissue compared to LLLT [9]. The effectiveness of HILT in LE is not yet clarified.

As a conservative treatment intervention, splinting is one of the most frequently used treatment modality for LE. Two popular methods of bracing include a forearm counterforce strap and a wrist extension splint. Although braces are commonly prescribed for lateral epicondylitis, controversy still exits regarding their effectiveness [10].

Clinical examination is generally accepted to be appropriate for the diagnosis of LE in most patients [11]. However, in patients with persistent pain and disability despite treatment, imaging methods including ultrasonography might be necessary. For this reason, ultrasonographic evaluation for injuries of the extensor tendon, nearby soft tissues, and/or the cortex of the lateral epicondyle may be valuable [12].

In this trial, we planned to investigate the effects of HILT in patients with LE and to compare (clinically and ultrasonographically) these results with those of a brace and sham HILT.

Methods

This prospective, randomized, controlled, assessor-blinded study was conducted in Physical Medicine and Rehabilitation Department of the university hospital between May 2013 and June 2014. Ninety-three patients (42 female/51 male; age range between 20 and 50 years) with the diagnosis of unilateral LE were enrolled in the study and assigned to three groups. Figure 1 summarizes the flowchart regarding patients' enrollment.

Before inclusion, all subjects were examined by one of the authors to confirm the diagnosis of LE. Patients were diagnosed based on the following criteria for LE: (1) pain in the lateral elbow region (lasting less than 3 months), (2) local tenderness on palpation over the lateral epicondyle, (3) resisted wrist and/or middle finger extension produced typical pain at the origin on the lateral epicondyle, and (4) a positive Mill's test [13]. Patients who fulfilled the above criteria were enrolled in the study.

Exclusion criteria were as follows: (1) fibromyalgia, (2) previous treatment for ipsilateral LE, (3) substantial rheumatoid arthritis, osteoarthritis, or inflammatory arthropathy affecting the elbow or wrist, (4) carpal tunnel syndrome, (5) cubital tunnel syndrome, (6) cervical radiculopathy, (7) previous elbow surgery, (8) previous radius/ulna fracture with resultant deformity of the affected extremity, (9) other elbow pathologies, (10) neurological deficit(s) in the ipsilateral upper limb, (11) systemic metabolic diseases, (12) other cervical/shoulder disorders, and (13) bilateral elbow pain.

All enrolled patients were instructed not to take any analgesic and/or NSAIDs during the treatment and control periods. All patients were informed about the study procedure, and they have given written consent to participate. This study was approved by the local ethical committee of the university.

Treatment groups

Patients were randomly assigned to three treatment groups (HILT group vs sham therapy group vs brace group). Randomization was allocated by using numbered envelopes method. HILT group (group 1) was treated with HILT. Sham therapy group (group 2) received placebo HILT. Patients in the brace group (group 3) used the lateral counterforce brace for LE. All enrolled patients were not treated with HILT before for any other disorders. The treatment modalities in all groups (HILT, placebo HILT, or brace) were started 1 day after initial assessment.

HILT (pulsed Nd:YAG laser therapy)

Patients received pulsed Nd:YAG laser treatment, produced by a HIRO 3 device (ASA Laser, Arcugnano, Italy). The apparatus provided pulsed emission (1064 nm), very high peak power (3 kW), a high level of fluency (energy density; 360–1780 mJ/cm^2), a short duration (120–150 μs), a mean power of 10.5 W, a low frequency (10–40 Hz), a duty cycle of about 0.1 %, a probe diameter of 0.5 cm, and a spot size of 0.2 cm^2 [9].

A standard handpiece endowed with fixed spacers was used to provide the same distance to the skin and perpendicularly to the zone to be treated with a laser beam diameter of 5 mm. Three phases of treatment were performed for every session. The total energy delivered to the patient during one session was 1275 J through three phases of treatment. The first phase involved fast manual scanning (100 cm^2 per 30 s) of common extensor tendon (CET), soft tissues near the lateral epicondyle, and extensor muscles extending over forearm from lateral epicondyle (extensor carpi radialis longus and brevis, extensor carpi ulnaris, and extensor digitorum communis). Scanning was performed in both transverse and longitudinal directions. In this phase, a total energy dose of 625 J was administered. In the first phase, the laser fluency was set to three subphases of 510 mJ/cm^2 (208 J), 810 mJ/cm^2 (208 J), and 970 mJ/cm^2 (209 J), for a total of 625 J. The second phase involved applying the handpiece with fixed spacers vertically to 90° on CET near the lateral epicondyle (trigger point inactivation phase). The second phase was carried out on CET with a fluency of 360 mJ/cm^2 (6 J), 510 mJ/cm^2 (9 J), and 610 mJ/cm^2 (10 J) and a time of 6 s at each time, for a total of 25 J. The third phase involved slow manual scanning (100 cm^2 per 60 s) of the same

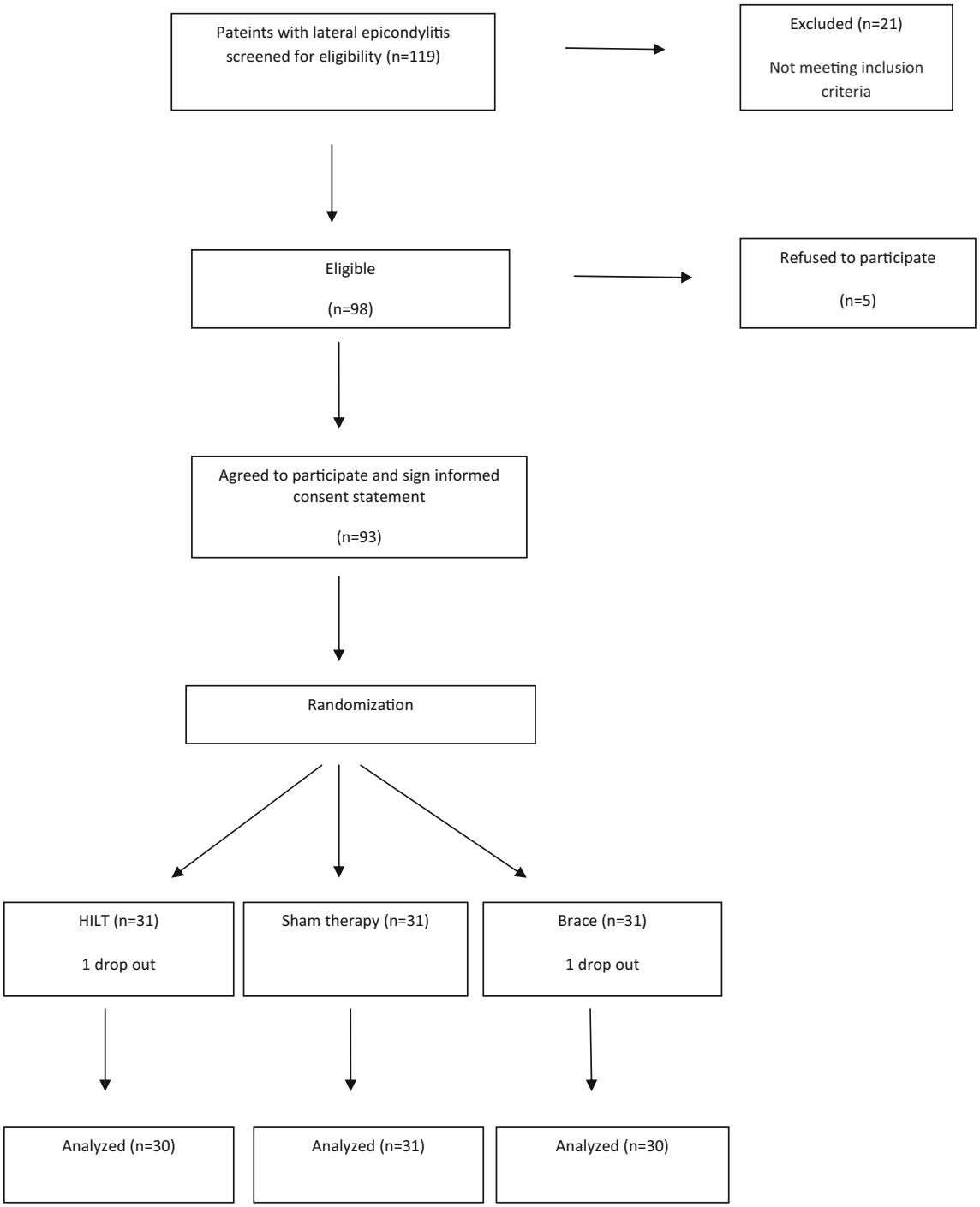

Fig. 1 Flowchart diagram for the participants who were randomized into three groups as receiving HILT, sham therapy, and brace

areas treated in the first phase until a total energy dose of 625 J was achieved (Table 1). The application time for one session was approximately 15 min with the total energy delivered to the patient during one session of 1275 J. The energy received in each phase and the total energy delivered to the patient during the treatment session were calculated by the device. HILT was applied once a day for 15 days during a period of 3 weeks. In group 2 (sham therapy group), the same treatment protocol was given, but the laser instrument was switched off during applications. All laser applications were performed by the same physiotherapist.

Brace

Patients in the brace group (group 3) used the lateral counterforce brace for LE (Aurafix, Turkey) during the daytime for

Table 1 HILT therapy phases and applied frequency, fluency, and energy dose

HILT therapy phases	Frequency (Hz)	Fluency (energy density; mJ/cm^2)	Applied HILT energy dose (J)
Phase 1 fast manual scanning (100 cm^2 per 30 s)	25	510	208
	20	810	208
	15	970	209
Phase 2 (trigger point inactivation phase)	15	360	6
	15	510	9
	14	610	10
Phase 3 slow manual scanning (100 cm^2 per 60 s)	25	510	208
	20	810	208
	15	970	209
Total applied HILT energy dose	1275		

HILT high-intensity laser therapy

4 weeks (Fig. 2). Brace removal was allowed only for bathing and sleeping.

Outcome measurements

The patients were assessed for grip strength, pain, disability, and quality of life. The same physician blinded to the randomization evaluated all the patients before treatment (week 0) and after treatment (after 4 and 12 weeks). Ninety-one patients completed the study. One male patient in HILT group and one male patient in brace group failed to complete the follow-up and dropped out of the study.

Outcome measures

We measured grip strength at 90° elbow flexion with a hand dynamometer (baseline hydraulic hand dynamometer, Irvington, NY, USA) and used the mean of three measurements [14].

Pain was assessed at rest and under strain by using a 10-cm-long visual analog scale (VAS) (0 means no pain while 10 means worst pain).

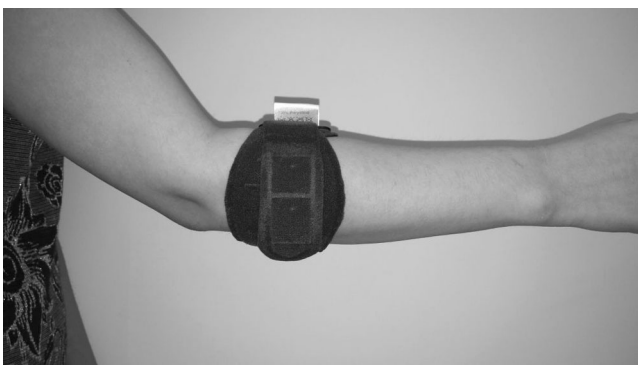

Fig. 2 The lateral counterforce brace that was used

The Patient-Rated Tennis Elbow Evaluation (PRTEE) questionnaire was used to measure the changes in functional disability. The PRTEE questionnaire is a 15-item questionnaire specifically designed for patients with LE. The items investigate pain (five items) and the degree of difficulty in performing various activities (six specific and four usual activity items) due to the elbow problem over the preceding week. Each item has one response option (0=no difficulty, 10=unable to perform). The scores for the various items are used to calculate an overall scale score ranging from 0 (best score) to 100 (worst score) [15].

Quality of life was assessed by short-form 36 health survey (SF-36) [16].

Ultrasonographic evaluation

Ultrasonographic examination of the patients was performed before treatment (week 0) and after treatment (after 4 and 12 weeks) by a clinician with 4 years of experience in musculoskeletal ultrasonography, who was blind to the patients' clinical data. Ultrasonographic examination was performed by using an Esoate Mylab 70 ultrasound machine with an 18–6-MHz linear array transducer. The ultrasonographic technique used in a previous study evaluating lateral epicondylitis with ultrasonography was accepted as reference [17]. The thickness/echogenicity of the CET and bony cortex of the lateral epicondyle were assessed during sonographic imaging (while patients were seated, elbows flexed and pronated). For measurement of the thickness of the CET, two lines were drawn; the first line was drawn between the peak point and lowermost point of lateral epicondyle. Then, the second line was drawn 90° perpendicular to the lower end of first line. The second line gave the thickness of the CET. The measurements were performed three times and the mean of these measurements was used for analysis (Fig. 3).

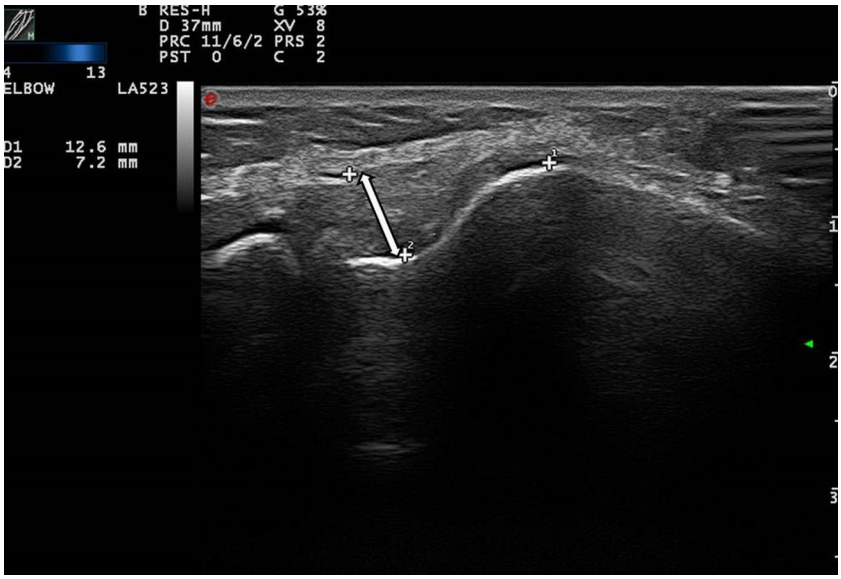

Fig. 3 Measurement of common extensor tendon thickness (*arrow* indicates the measured area of common extensor tendon)

Statistical analysis

Descriptive statistics were expressed with mean±standard deviation. A level of significance of $P<0.05$ (two-tailed) was accepted for this study. Chi-square test was used to compare categorical variables (sex, occupation, side of involvement, dominant hand, CET echogenicity, bony cortex of the lateral epicondyle). Shapiro–Wilk test was used to analyze normality of the distribution of the data. Groups were compared with one-way ANOVA (for normally distributed data (pain at rest, pain under strain, CET thickness, all subgroups of SF-36); the Tukey test was used as a post hoc test) and Kruskal–Wallis (the data without normal distribution (grip strength, PRTE EQ); Mann–Whitney *U* test was used as a post hoc test). Cochran Q test (for categorical data), Wilcoxon (the data without normal distribution), and paired *t* test (for normally distributed data) were used to compare repeated measures/evaluations within each group. The mean values of the percentage changes calculated for the groups were compared by using the independent sample *t* test (for normally distributed data) and Mann–Whitney *U* test (the data without normal distribution). The correlations were evaluated with Spearman correlation tests. All analyses were performed using the SPSS for Windows 18.0 software program.

Results

No adverse event was observed during HILT, sham therapy, and/or brace therapy in the study. There were no statistically significant differences in the demographic features and pretreatment evaluation parameters of the patients between groups. Demographic features of HILT group, sham therapy group, and brace group are given in Table 2. Pretreatment values for evaluation parameters of the groups are shown in Table 3.

The occupation of the patients were as follows: eight office workers, seven sales/marketing personnel, two heavy work workers, three unemployed, five full-time homemakers, one part-time worker, and four farmers in HILT group; nine office workers, six sales/marketing personnel, two heavy work workers, three unemployed, six full-time homemakers, two part-time workers, and three farmers in sham therapy group; and seven office workers, seven sales/marketing personnel,

Table 2 Demographic features of HILT group, sham therapy group and brace group

	HILT group (n=30)	Sham therapy group (n=31)	Brace group (n=30)	*P*
Age (years)	32.6±10.9	33.4±11.2	33.6±9.8	0.427
Sex (F/M)	13/17	14/17	15/15	0.866
Disease duration (days)	28.7±12.4	29.5±16.8	27.9±17.3	0.621
Body mass index	27.1±4.5	26.9±3.9	27.9±4.8	0.353
Side of involvement (R/L)	24/6	23/8	25/5	0.673
Dominant hand (R/L)	29/1	29/2	28/2	0.817

HILT high-intensity laser therapy, *F* female, *M* male, *R* right, *L* left

Table 3 Pretreatment values for evaluation parameters of HILT group, sham therapy group, and brace group

	HILT group (n=30)	Sham therapy group (n=31)	Brace group (n=30)	*P*
Pain at rest (VAS) (cm)	4.3±1.3	4.4±1.2	4.2±1.5	0.683
Pain under strain (VAS) (cm)	6.2±2.3	6.3±1.9	6.2±2.6	0.809
Grip strength (kg)	46.5±17.1	45.7±15.8	46.1±13.4	0.729
PRTEEQ	56.8±21.2	58.1±24.3	55.9±19.7	0.492
CET thickness (mm)	52.7±7.7	53.8±9.6	54.1±9.7	0.596
CET echogenicity (hyperechohenic/hypoechogenic)	25/5	25/6	26/4	0.818
PEBCLE/AEBCLE	8/22	8/23	9/21	0.832
SF-36, PF	52.1±11.1	50.7±10.9	51.8±13.2	0.724
SF-36, RL	50.9±17.8	51.2±15.2	52.2±18.7	0.647
SF-36, BP	47.2±13.1	45.9±12.9	46.8±14.5	0.611
SF-36, GH	61.3±17.5	60.9±18.4	62.9±19.5	0.489
SF-36, V	48.3±14.8	49.4±11.6	49.1±9.9	0.714
SF-36, SF	67.3±17.9	69.1±25.2	69.9±31.7	0.326
SF-36, RLEP	68.3±29.7	69.3±28.8	68.7±24.6	0.650
SF-36, GMH	59.1±19.5	60.3±21.7	61.2±23.7	0.505

HILT high-intensity laser therapy, *VAS* visual analog scale, *PRTEEQ* Patient-Rated Tennis Elbow Evaluation Questionnaire, *CET* common extensor tendon, *PEBCLE* presence of erosion in bony cortex of the lateral epicondyle, *AEBCLE* absence of erosion in bony cortex of the lateral epicondyle, *SF-36* short-form 36 health survey, *PF* physical function, *RL* role limitations due to physical functioning, *BP* bodily pain, *GH* general health, *V* vitality, *SF* social functioning, *RLEP* role limitations due to emotional problems, *GMH* general mental health

three heavy work workers, two unemployed, five full-time homemakers, two part-time workers, and four farmers in brace group. Distribution of the patients according to occupation did not show a significant difference between the groups ($P>0.05$).

HILT group and brace group showed significant improvements for pain (VAS) scores, grip strength, PRTEEQ scores and physical function, role limitations due to physical functioning, bodily pain, general health, and vitality subparts of SF-36 at the evaluations 4 and 12 weeks after treatment (Tables 4 and 6). However, there were no statistically significant improvements in any evaluation parameter in sham therapy group after treatment (Table 5). Since HILT group and brace group showed significant improvements for most evaluation parameters (for brace group, see Table 6), we compared

Table 4 The results and statistical comparisons of the pretreatment (week 0) and posttreatment (after 4 and 12 weeks) evaluation parameters in HILT group

n=30	Baseline (week 0)	After 4 weeks	After 12 weeks	P (week 0 to week 4)	*P* (week 0 to week 12)
Pain at rest (VAS) (cm)	4.3±1.3	3.1±1.1	3.1±1.2	**<0.001**	**<0.001**
Pain under strain (VAS) (cm)	6.2±2.3	3.6±1.5	3.4±1.2	**<0.001**	**<0.001**
Grip strength (kg)	46.5±17.1	53.8±18.3	53.9±17.6	**<0.001**	**<0.001**
PRTEEQ	56.8±21.2	41.3±15.4	39.8±12.2	**<0.001**	**<0.001**
CET thickness (mm)	52.7±7.7	49.6±8.1	49.4±9.2	0.546	0.543
SF-36, PF	52.1±11.1	64.5±13.2	65.9±14.1	**<0.001**	**<0.001**
SF-36, RL	50.9±17.8	63.8±16.7	64.5±17.8	**<0.001**	**<0.001**
SF-36, BP	47.2±13.1	61.2±13.7	60.8±14.7	**<0.001**	**<0.001**
SF-36, GH	61.3±17.5	69.3±11.9	69.8±12.9	**<0.001**	**<0.001**
SF-36, V	48.3±14.8	55.3±15.7	55.7±16.4	**<0.001**	**<0.001**
SF-36, SF	67.3±17.9	68.8±15.6	69.6±18.3	0.716	0.523
SF-36, RLEP	68.3±29.7	68.9±26.2	69.3±27.6	0.612	0.578
SF-36, GMH	59.1±19.5	61.7±19.2	60.7±18.4	0.432	0.624

Bold shows statistically significant difference

HILT high-intensity laser therapy, *VAS* visual analog scale, *PRTEEQ* Patient-Rated Tennis Elbow Evaluation Questionnaire, *CET* common extensor tendon, *PEBCLE* presence of erosion in bony cortex of the lateral epicondyle, *AEBCLE* absence of erosion in bony cortex of the lateral epicondyle, *SF-36* short-form 36 health survey, *PF* physical function, *RL* role limitations due to physical functioning, *BP* bodily pain, *GH* general health, *V* vitality, *SF* social functioning, *RLEP* role limitations due to emotional problems, *GMH* general mental health

Table 5 The results and statistical comparisons of the pretreatment (week 0) and posttreatment (after 4 and 12 weeks) evaluation parameters in sham therapy group

n=31	Baseline (week 0)	After 4 weeks	After 12 weeks	P (week 0 to week 4)	*P* (week 0 to week 12)
Pain at rest (VAS) (cm)	4.4±1.2	4.1±1.9	4.0±2.3	0.754	0.712
Pain under strain (VAS) (cm)	6.3±1.9	5.9±2.7	5.9±3.1	0.542	0.585
Grip strength (kg)	45.7±15.8	47.9±14.2	48.1±17.8	0.416	0.391
PRTEEQ	58.1±24.3	55.9±25.6	56.0±27.2	0.395	0.406
CET thickness (mm)	53.8±9.6	52.4±11.1	51.7±13.2	0.723	0.561
SF-36, PF	50.7±10.9	52.5±13.5	53.1±13.9	0.692	0.463
SF-36, RL	51.2±15.2	53.3±13.4	52.7±16.7	0.522	0.617
SF-36, BP	45.9±12.9	46.6±13.4	47.8±13.5	0.812	0.672
SF-36, GH	60.9±18.4	61.8±17.9	60.4±16.9	0.724	0.921
SF-36, V	49.4±11.6	51.6±12.3	50.6±12.4	0.678	0.825
SF-36, SF	69.1±25.2	69.7±23.6	70.7±26.3	0.816	0.693
SF-36, RLEP	69.3±28.8	68.8±22.2	68.5±29.3	0.854	0.716
SF-36, GMH	60.3±21.7	59.7±23.1	60.1±25.5	0.788	0.929

HILT high-intensity laser therapy, *VAS* visual analog scale, *PRTEEQ* Patient-Rated Tennis Elbow Evaluation Questionnaire, *CET* common extensor tendon, *PEBCLE* presence of erosion in bony cortex of the lateral epicondyle, *AEBCLE* absence of erosion in bony cortex of the lateral epicondyle, *SF-36* short-form 36 health survey, *PF* physical function, *RL* role limitations due to physical functioning, *BP* bodily pain, *GH* general health, *V* vitality, *SF* social functioning, *RLEP* role limitations due to emotional problems, *GMH* general mental health

the percentage changes of parameters after 4 and 12 weeks relative to pretreatment values in both groups. Comparison of the percentage changes of all parameters both after 4 and 12 weeks relative to pretreatment values did not show a significant difference between HILT and brace groups (Table 7).

Compared to the baseline measurements, the CET thicknesses did not change significantly after treatment (after 4 and 12 weeks) in any group (Tables 3, 4, and 5). Further, the changes in CET thickness were also similar between the HILT and brace groups (Table 6). Also, cortical irregularities of the lateral epicondyle or echogenicity of the CET did not change significantly during follow-up. Comparison of the CET echogenicity and presence or absence of erosion in bony cortex of the lateral epicondyle of the three groups showed that there were no statistically significant differences between groups after treatment (data not shown). There was no

Table 6 The results and statistical comparisons of the pretreatment (week 0) and posttreatment (after 4 and 12 weeks) evaluation parameters in brace group

n=30	Baseline (week 0)	After 4 weeks	After 12 weeks	P (week 0 to week 4)	*P* (week 0 to week 12)
Pain at rest (VAS) (cm)	4.2±1.5	3.0±1.4	2.9±1.3	**<0.001**	**<0.001**
Pain under strain (VAS) (cm)	6.2±2.6	3.7±1.7	3.5±1.5	**<0.001**	**<0.001**
Grip strength (kg)	46.1±13.4	53.2±13.5	53.6±14.8	**<0.001**	**<0.001**
PRTEEQ	55.9±19.7	43.7±16.5	42.1±13.7	**<0.001**	**<0.001**
CET thickness (mm)	54.1±9.7	51.8±10.2	50.9±11.3	0.411	0.336
SF-36, PF	51.8±13.2	63.9±11.5	64.7±15.3	**<0.001**	**<0.001**
SF-36, RL	52.2±18.7	64.7±19.2	64.8±20.3	**<0.001**	**<0.001**
SF-36, BP	46.8±14.5	60.8±16.8	61.5±17.9	**<0.001**	**<0.001**
SF-36, GH	62.9±19.5	71.6±17.2	71.9±18.3	**<0.001**	**<0.001**
SF-36, V	49.1±9.9	56.9±13.5	56.5±14.4	**<0.001**	**<0.001**
SF-36, SF	69.9±31.7	71.2±24.5	71.3±26.7	0.643	0.671
SF-36, RLEP	68.7±24.6	69.2±23.4	69.5±25.8	0.722	0.635
SF-36, GMH	61.2±23.7	62.2±21.5	62.5±24.7	0.542	0.525

Bold shows statistically significant difference

HILT high-intensity laser therapy, *VAS* visual analog scale, *PRTEEQ* Patient-Rated Tennis Elbow Evaluation Questionnaire, *CET* common extensor tendon, *PEBCLE* presence of erosion in bony cortex of the lateral epicondyle, *AEBCLE* absence of erosion in bony cortex of the lateral epicondyle, *SF-36* short-form 36 health survey, *PF* physical function, *RL* role limitations due to physical functioning, *BP* bodily pain, *GH* general health, *V* vitality, *SF* social functioning, *RLEP* role limitations due to emotional problems, *GMH* general mental health

Table 7 Comparison of the HILT group and brace group on the basis of the posttreatment (after 4 and 12 weeks) percentage changes and difference scores relative to pretreatment (week 0) values

	Week 4 HILT group	Week 4 Brace group	P	Week 12 HILT group	Week 12 Brace group	*P*
Pain at rest (VAS) (cm)	−0.28±0.15	−0.28±0.17	0.823	−0.28±0.16	−0.31±0.18	0.512
Pain under strain (VAS) (cm)	−0.42±0.20	−0.40±0.25	0.756	−0.45±0.24	−0.43±0.27	0.761
Grip strength (kg)	0.15±0.07	0.15±0.08	0.815	0.16±0.08	0.16±0.07	0.868
PRTEEQ	−0.27±0.12	−0.22±0.15	0.498	−0.30±0.16	−0.25±0.18	0.453
CET thickness (mm)	−0.06±0.03	−0.04±0.03	0.427	−0.06±0.04	−0.06±0.03	0.898
SF-36, PF	0.24±0.13	0.23±0.15	0.734	0.26±0.17	0.25±0.15	0.673
SF-36, RL	0.25±0.14	0.24±0.13	0.811	0.27±0.13	0.24±0.15	0.592
SF-36, BP	0.29±0.15	0.30±0.13	0.804	0.29±0.18	0.31±0.19	0.639
SF-36, GH	0.13±0.08	0.14±0.06	0.721	0.14±0.07	0.14±0.08	0.925
SF-36, V	0.14±0.07	0.16±0.09	0.562	0.15±0.08	0.15±0.09	0.891
SF-36, SF	0.02±0.01	0.02±0.01	0.845	0.03±0.02	0.02±0.01	0.721
SF-36, RLEP	0.01±0.01	0.01±0.01	0.921	0.01±0.01	0.01±0.01	0.849
SF-36, GMH	0.04±0.02	0.02±0.02	0.681	0.03±0.01	0.02±0.01	0.682

HILT high-intensity laser therapy, *VAS* visual analog scale, *PRTEEQ* Patient-Rated Tennis Elbow Evaluation Questionnaire, *CET* common extensor tendon, *PEBCLE* presence of erosion in bony cortex of the lateral epicondyle, *AEBCLE* absence of erosion in bony cortex of the lateral epicondyle, *SF-36* short-form 36 health survey, *PF* physical function, *RL* role limitations due to physical functioning, *BP* bodily pain, *GH* general health, *V* vitality, *SF* social functioning, *RLEP* role limitations due to emotional problems, *GMH* general mental health

correlation between ultrasonographic findings (CET thicknesses, echogenicity of the extensor tendon, and cortical irregularities of the lateral epicondyle) and clinical evaluations in the study (Table 8).

Discussion

The main findings of this study were as follows: (1) HILT and brace groups showed significant improvements for most evaluation parameters (pain (VAS) scores, grip strength, PRTEEQ scores and physical function, role limitations due to physical functioning, bodily pain, general health, and vitality subparts of SF-36) after treatment (both after 4 and 12 weeks). (2) Improvements in pain scores, grip strengths, and PRTEEQ scores of the patients with LE in HILT and brace groups were not reflected to ultrasonographic findings. (3) Comparison of the percentage changes of all parameters both after 4 and 12 weeks relative to pretreatment values did not show a significant difference between HILT and brace groups.

LLLT is a conservative treatment choice for patients with LE. Trials on the effectiveness of LLLT in LE have shown conflicting results. Earlier studies about the effectiveness of LLLT on LE showed that LLLT is not effective in improving pain, grip strength, and global improvement on the short term in lateral epicondylitis [6, 18–23]. However, according to the results of other studies and a meta-analysis, LLLT may have some beneficial effects on pain reduction and grip strength increase [7, 8, 24–26]. Contradictory results may be considered to be due to different treatment protocols regarding variables such as dose, duration, and frequency [27].

Table 8 Correlations between ultrasonographic findings and clinical findings

n=91		CET thicknesses	CET echogenicity	Cortical irregularities of the lateral epicondyle
Pain at rest (VAS) (cm)	r	0.104	0.157	0.075
	p	0.453	0.324	0.632
Pain under strain (VAS) (cm)	r	0.212	0.196	0.109
	p	0.175	0.286	0.542
Grip strength (kg)	r	0.067	-0.045	-0.078
	p	0.712	0.811	0.579
PRTEEQ	r	0.168	0.068	0.110
	p	0.272	0.382	0.456

VAS visual analog scale, *PRTEEQ* Patient-Rated Tennis Elbow Evaluation Questionnaire, *CET* common extensor tendon

LLLT is based on the belief that laser radiation, and possibly monochromatic light, are able to alter cellular and tissue function in a manner dependent on the characteristics of light itself [28]. Since LLLT works at low irradiation intensities (low energy doses), it is assumed that any biologic effects are secondary to the direct effects of photonic radiation and are not the result of thermal processes. However, HILT uses higher-intensity laser irradiation and causes minor and slow light's absorption by chromophores, which has been utilized. So that, some thermal processes in the target tissue may be triggered by HILT [29, 30].

A form of HILT, pulsed Nd:YAG laser therapy, has been used for a variety of diseases. Effectiveness of pulsed Nd:YAG laser therapy in pain control has been shown in ankle pain [31], subacromial impingement syndrome [32], low back pain [30, 33], and knee osteoarthritis [34, 35]. To the best of our knowledge, no study has investigated the effectiveness of HILT in patients with LE. The results of this study revealed that pulsed Nd:YAG laser therapy (HILT) is as effective as brace therapy in the treatment of these patients with respect to decreased pain and disability and improved quality of life.

The analgesic effect of HILT is based on multiple mechanisms of action, including its ability to slow the transmission of the pain stimulus and to increase the production of morphine-mimetic substances in the body [9]. LLLT may have a direct effect on nerve fibers, which could inhibit Aδ- and C-fiber transmission [36]. Also, LLLT may increase blood flow and cell metabolism [37]. We believe that the main difference between HILT and LLLT is the intensity of laser therapy. So, we may hypothesize that HILT may also have these therapeutics effects of LLLT more strongly. In addition, we may hypothesize that by applying HILT over LE, some photothermal energy may be transferred into tissue. Moreover, the photochemical and photothermic effects of HILT may stimulate collagen production within tendons and increase blood flow, vascular permeability, and cell metabolism and thus help to repair damaged tendon and remove the painful stimulus.

Traditional nonoperative therapy for lateral epicondylitis is directed toward control of inflammation, enhancement of microscopic and macroscopic tissue healing, reconditioning of the extremity, and alteration of abusive force patterns. Among conservative treatment interventions, splinting is one of the most frequently used modalities for treating lateral epicondylitis [38]. However, studies on the effectiveness of splinting in LE also have shown conflicting results. Cochrane database systematic review found that no definitive conclusions can be drawn concerning effectiveness of orthotic devices for the treatment of LE [39]. But, in a meta-analysis, Borkholder et al. reported one Sackett level 1b study and ten Sackett level 2b studies that offer early positive, but not conclusive, supporting the effectiveness of splinting lateral epicondylitis [38]. Lateral counterforce braces work by reducing the level of tension in the forearm extensors. Several trials have shown that elbow straps or sleeve orthoses have superior results in terms of relief of pain and grip strength compared with a placebo orthosis or wrist splints [40, 41] However, a meta-analysis did not find one type of brace to be better than the others [6]. In our study, patients in the brace group (group 3) used the lateral counterforce brace for LE. Significant improvements were obtained for pain (VAS) scores, grip strength, PRTEEQ scores and physical function, role limitations due to physical functioning, bodily pain, general health, and vitality subparts of SF-36 after treatment (both after 4 and 12 weeks) in this group. According to the results of the current study, lateral counterforce brace for LE is not superior to HILT therapy.

Ultrasonography has been usually used as a convenient imaging method for the diagnosis and follow-up of soft tissue disorders. From this point, we tried to observe whether we could quantify the changes also by using CET thickness measurements. However, there was no correlation between ultrasonographic findings (CET thicknesses, echogenicity of the extensor tendon, and cortical irregularities of the lateral epicondyle) and clinical findings (pain scores, disability, and quality of life) in the study. Previously, in three different studies, authors investigated whether ultrasonographic findings were associated with clinical findings of the patients with LE or not. Clarke et al. [42] found no correlation with clinical findings and thickness of the tendon in patients with LE. Zeisiq et al. [43] followed up the patients with LE after intertendinous injection therapy but could not indicate a relationship with ultrasonographic findings and clinical results. Gunduz et al [17] compared the therapeutic effects of physical therapy modalities, local corticosteroid injection, and extracorporeal shock wave treatment in LE. They found that ultrasonographic findings did not change in the first 6 months of these treatment methods. Also, our ultrasonographic findings were in line with the previous studies [17, 42, 43]. The absence of the correlation can be due to the shortness of evaluation period. Longer follow-up (more than 3 months up to 1 year) of the patients with ultrasonography may reveal a correlation between ultrasonographic findings and clinical findings. Therefore, the changes would be ensuing later than the third month posttreatment.

Currently, there is no a standardized, universally accepted program for LE treatment, and also, both treatment methods (HILT and brace) are noninvasive and painless and easy for use. So that, we wanted to investigate the effects of HILT in patients with LE and to compare these results with those of a brace or placebo HILT. Also, there is no universally accepted treatment protocol concerning number of session, duration, frequency, and dose for both HILT and brace therapies. Since both treatment groups used different regimens of treatment, HILT was applied once a day for 15 days (15 min daily) during a period of 3 weeks, while brace groups used lateral

counterforce brace for a longer time (4 weeks and only removed during sleep and bathing). This may also show that HILT has an advantage in treatment duration (only 15 min a day) compared to brace therapy (during all day and removed during sleeping). If we could apply both treatment modalities with the same duration (4 weeks), we might find statistically significant differences between the groups.

The main limitations of this study are the relatively small study population and the lack of long-term (>3 months up to 1 year) follow-up results. Another limitation is that there was not any group treated with both HILT and brace therapy together. If we had such a group, we could discuss the additional effect of HILT in LE.

There are conflicting results regarding the treatment (LLLT and splinting) of LE. As a result, it is concluded that pulsed Nd:YAG laser treatment (HILT) and splinting are an effective physical therapy modality for patients with LE in reducing pain and improving disability, quality of life, and grip strength. The results of the present study are encouraging, but further studies with larger samples, longer follow-up, and possible comparisons with other conservative interventions or placebo control groups are needed to make more valid conclusion.

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