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How should we use corticosteroids in lateral epicondylitis? Local injection or phonophoresis?

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Abstract

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DOI: 10.5455/annalsmedres.2023.08.220 costeroid injection and corticosteroid phonophoresis on grip strength, functional status, pain, and quality of life in lateral epicondylitis. **Materials and Methods:** Patients with a diagnosis of lateral epicondylitis who underwent corticosteroid phonophoresis or local corticosteroid injection were included in the study. Patients were grouped according to the treatment they received. In the first group, corticosteroid phonophoresis was applied to the lateral epicondyle region using a continuous mode ultrasonic at 1.0 W/cm^2 and 1mHz dose with 0.1% betamethasone valerate cream as a conductive agent. In the second group, corticosteroid and local anesthetic injections were applied to the lateral epicondyle region. Two groups received the supervised exercise program. Before treatment and two weeks after treatment, visual analog scale, muscle strength, grip strength, Quick Disabilities of the Arm, Shoulder, and Hand scores,

Aim: This study, it was aimed to compare and evaluate the effectiveness of local corti-

Results: A total of 43 patients (23 phonophoresis, 20 corticosteroid injections) were enrolled. Although pain, function, and quality of life of patients improved significantly with both groups, no significant difference was recorded between the groups. Grip and palmar pinch strength significantly increased in only the phonophoresis group. In addition, changing of grip and palmar pinch strength was significantly better in the phonophoresis group than in the corticosteroid injection group.

and Nothingom Health Profile results for both groups were recorded from patient files and

Conclusion: It was determined that corticosteroid administration via phonophoresis instead of injection was more beneficial in terms of grip and palmar pinch strength.

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Introduction

Lateral epicondylitis (LE) is the most common musculoskeletal problem of the elbow joint and affecting 1-3% of the general population [1-3]. LE occurs equally in male and female, the dominant arm is more frequently affected and usually affects adults between the ages of 40 and 50 [4,5].

The extensor carpi radialis brevis is the most affected muscle, but the extensor carpi radialis longus, extensor digiti minimi, extensor digitorum, extensor carpi ulnaris, and supinator muscles may also be involved. Any occupational or sports-related activity that involves excessive and repetitive use of these muscles (e.g., writing, typing, tennis, playing an instrument, handicraft) can cause LE [6-8]. Overuse can lead to inflammation, immature repair, tendinosis, and micro- ruptures. The continuation of this cycle of injury and immature repair cause more significant ruptures and ultimately result in altered muscle-tendon biomechanics and worsening of symptoms [9].

In most cases, LE is diagnosed clinically. The main complaints of patients are pain and decreased grip strength during daily activities [10,11]. The diagnosis can be confirmed by pain-inducing tests such as resistant wrist extension, passive wrist flexion, resistant middle finger extension, and tenderness on palpation [12].

Treatment of LE should be focused on pain management, improvement in grip strength and endurance, return to normal function, maintenance of movement, and prevention of further clinical impairment [13]. Many treatments have already been described in the literature. These include immobilization and splinting, ice applications, nonsteroidal anti-inflammatory drug (NSAID), corticosteroid injection (CI), platelet-rich plasma, stem cell therapy,

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acupuncture, thermotherapy, ultrasound, phonophoresis (PH), iontophoresis, laser therapy, electrotherapy modalities, manipulation, stretching and strengthening exercises [3, 14-18]. Despite all these treatment methods, there is no consensus on the most effective treatment method for improving function and quality of life and reducing disability [19]. Also, when LE becomes chronic, treatment may become more difficult. That is why it's crucial to find the best treatment method.

Gastrointestinal diseases and bleeding diathesis; may limit the use of oral NSAIDs or corticosteroid injections as treatment for LE. In these cases, transdermal administration of anti-inflammatory drugs with PH may be more suitable. The use of ultrasound for the transdermal delivery of drugs such as corticosteroids, local anesthetics and salicylates is known as PH [20]. Most drugs are absorbed very slowly through the skin; high-frequency sonic vibration can accelerate this process [21]. In addition, it has been stated that the heat produced by ultrasound is an important factor in PH and may be effective in treating soft tissue damage, accelerating healing, and reducing pain by resolving inflammation [22].

There are limited studies on the application of PH in LE [21-23]. In addition, there is no recent study comparing the effectiveness of corticosteroid injection and corticosteroid PH, and there is no consensus on which treatment is more effective.

Therefore, in this study, we intended to examine the shortterm effectiveness of local CI and corticosteroid PH on pain, grip strength, and functional status in LE and to compare the two treatment modalities in terms of patient satisfaction.

Materials and Methods

$Study \ design$

This study was planned as a retrospective clinical study. Approval was obtained from the Local Ethics Committee (Ankara City Hospital Clinical Research Ethics Committee, Approval number: E2-21-252) for this study and was conducted in accordance with the principles of the Declaration of Helsinki. This study consisted of a retrospective compilation of the information of patients who came to the injection outpatient clinic. A period of approximately 6 months was scanned, the sample size was not calculated because it was not created prospectively.

Participants

Participants aged 18-70 years, diagnosed with LE according to three criteria: 1) Pain in the lateral epicondyle, 2) Tenderness in the lateral epicondyle on physical examination, 3) Positive provocative tests (a: increased pain with elbow extension and dorsiflexion of the wrist against resistance, b: the presence of pain with third finger extension [elbow in extension, forearm pronation and wrist in flexion]) [24] and followed up with a diagnosis of LE for at least three months, who underwent corticosteroid PH or local CI in the physical therapy unit of our hospital between November 2020 and April 2021 included in the study. Those with rheumatic disease, metabolic disease, corticosteroid-containing drug use, cervical discopathy, elbow deformity, peripheral/central nervous system disease, bilateral symptoms, systemic musculoskeletal system disease, and corticosteroid allergy were not included in this study. Also, those who received injections or physical therapy for the elbow in the last 6 months were not included in the study.

Interventions

Type of treatment (CI or PH), complications, side, gender, age, demographic, and clinical data were obtained from medical files. (Clinical data were obtained from information noted in patient files during routine examination).

Patients were grouped according to the treatment they received. Group 1 included patients who were applied continuous mode ultrasonic at 1.0 W/cm² and steroid PH at a dose of 1 MHz to the lateral epicondyle region for two weeks, five days a week (0.1% betamethasone valerate cream was used as a conductive agent). Group 2 included patients who were injected into the lateral epicondyle region under aseptic conditions [6.43 mg betamethasone dipropionate, 2.63 mg betamethasone sodium phosphate, and 0.5 mL local anesthetic (lidocaine and epinephrine)].

Exercise programs for stretching and strengthening muscles (especially extensor carpi radialis brevis) were routinely given to all participants. In addition to treatment, all participants received training on ergonomics and activity modification to avoid provoking symptoms.

Demographic and disease characteristics

Sociodemographic characteristics such as gender, age, educational status, work and leisure activity, dominant hand, affected hand, duration of symptoms, tenderness, pain, and loss of strength were recorded from the files of the patients. Levels of tenderness, pain, and loss of strength were assessed with a 0–10 cm visual analog scale (VAS) [25]. The duration of symptoms was recorded as months.

Outcomes

Before and two weeks after treatment, muscle strength, palmar and lateral grip force, functionality, and quality of life results were recorded from patient documents for both groups. The primary output measurements of the study were pain, palmar and lateral grip force, Q-DASH, and NPH.

Muscle strength was scored on the Medical Research Council scale [26]. Elbow and wrist muscle strength were measured. Results are reported on a five-point scale. (5: Normal muscle strength, 4: Active movement against gravity and resistance, 3: Active contraction against gravity, 2: Active contraction in the absence of gravity, 1: Very slight contraction, 0: No contraction) Grip force was evaluated according to the recommendations of the American Society of Hand Therapists (forearm in neutral position, elbow flexed at 90° and wrist between 0-30° of flexion and between 0-15° of ulnar deviation) and compared with the uninjured hand [27]. Each measurement was made three times and the average of these measurements was calculated. In addition, palmar and lateral pinch force is evaluated using a pinch meter. Grip force was evaluated according to the recommendations of the American Society of Hand Therapists (forearm in neutral position, elbow flexed at 90° and wrist between 0-30° of flexion and between 0-15° of ulnar deviation) and compared with the uninjured hand [27]. Each measurement was made three times and the average of these measurements was calculated. In addition, palmar and lateral pinch force is evaluated using a pinch meter.

Quick Disabilities of the Arm, Shoulder and Hand Score (Quick DASH); is used for functional evaluation. The Quick DASH has two components: the disability/symptom division (11 items) and the optional highperformance sport/music or occupation division (4 items). Total scores range from 0-100, with higher scores representing worse functionality [28, 29].

Nottingham Health Profile (NPH); used to assess healthrelated quality of life. This scale includes Energy (3 questions), Pain (8 questions), Emotional Reactions (9 questions), Sleep (5 questions), Social Isolation (5 questions) and Physical Mobility (8 questions). It consists of 38 questions in six areas. Total scores differ from 0-100, with higher scores representing worse quality of life [30,31].

Patient satisfaction after treatment (day 15) evaluated using the Verhaar et al. clinical scoring system [24]. The Verhaar et al. clinical scoring system evaluates patient satisfaction as excellent, good, moderate, and poor. The post-treatment evaluations of the patients were compared between the groups.

Statistical analysis

Data were analyzed statistically using the Statistical Package for the Social Sciences (SPSS) 15.0 for Windows software (IBM Corporation, Chicago, IL). The Shapiro Wilk test was used to examine whether normal distributions of continuous variables showed a proper distribution. In descriptive statistics, the data were expressed as mean \pm standard deviation (SD) or median (minimum-maximum) for continuous variables, and as frequencies and percentages (%) for nominal variables. Statistically significant differences in repeated measurements within the groups were evaluated with Wilcoxon Signed Rank for continuous variables and, χ^2 and Fisher's exact test for nominal variables. Statistically significant differences between the groups were analyzed with the Independent Simple T for variables with normal distribution and Mann Whitney U test for variables with non-normal distribution. Values of p<0.05 were considered statistically significant.

Results

The mean patient age was 47.35. There were 35 (81.4%) female patients. The records of 46 patients were included in this retrospective study. The first step in selecting suitable patients was the screening of medical records. Three of them got excluded due to the loss of follow-up. According to this, twenty-three of 43 patients were classified as PH group (group 1), the other 20 were classified as CI group (group 2). There was no difference between the two groups in terms of sociodemographic characteristics such as age, gender, dominant hand, education, occupation, and duration of symptoms (p>0.05). Comparison of

 Table 1. The demographic and disease characteristics of patients.

	Group 1 (n=23)	Group 2 (n=20)	р
Age (year) mean±SD	46.78±9.17	46.20±8.12	0.859
Gender n (%)			
Female	18 (78.3%)	17 (85%)	0.578
Male	5 (21.7%)	3 (15%)	
Educational Status n (%)			
Illiterate	0	1 (5%)	
Under 5-year	2 (8.7%)	1 (5%)	
5-year	15 (65.2%)	11 (55%)	0.220
8-year	4 (17.4%)	2 (10%)	0.330
11-year	2 (8.7%)	4 (20%)	
Over 11 years	0	1 (5%)	
Work n (%)			
Housewife	18 (78.3%)	15 (65%)	
Worker	3 (13%)	2 (10%)	0.211
Teacher	0	1 (5%)	0.311
Plumber	2 (8.7%)	2 (10%)	
Leisure time activity n (%)			
Hand work	3 (13%)	3 (15%)	
Housework	0	1 (5%)	0.782
Gardening	2 (8.7%)	1 (5%)	
Dominant hand n (%)			
Right	22 (95.7%)	18 (90%)	0.761
Left	1 (4.3%)	2 (10%)	
Affected hand n (%)			
Right	20 (91.3%)	17 (85%)	0.668
Left	2 (8.7%)	3 (15%)	
Symptom duration (month) mean±SD	81.26±12.90	88.50±16.21	0.174

mean±SD: mean value ±Standard deviation.

demographic data and clinical characteristics between the groups are presented in Table 1.

There was no significant difference between the groups in terms of pre-treatment evaluation parameters (p>0.05) (Table 2).

The comparison of pain, loss of strength and tenderness levels, grip strength, Q-DASH, and NHP scores before and after treatment for group 1 and group 2 are shown in Tables 3 and Table 4.

In intragroup comparisons, pain, loss of strength, tenderness levels, Q-DASH and NHP showed significant improvement in both groups (p < 0.05), but grip strength, lateral and palmar finger pinch strength increased significantly only in the PH group (p=0.001, p=0.008, p=0.001, respectively). Verhaar clinical score was evaluated after treatment. Three patients in both groups were not satisfied with the treatment. There was no significant difference between the groups in terms of satisfaction (p=0.338). The distribution and comparison of Verhaar clinical improvement scores by groups are shown in Table 5.

Table 2. Comparison of evaluation parameters before treatment of groups.

	Group 1	Group 2	р
Pain score (VAS:0-10cm) median (min-max)			
Arm	5.00 (0.0-10.0)	4.5 (0.0-10.0)	0.981
Elbow	7.0 (5.0-10.0)	6.5 (0.0-10.0)	0.996
Forearm	3.5 (0.0-8.0)	2.10 (0.0-8.0)	0.724
Tenderness level (VAS:0-10cm) median (min-max)	7.0 (2.0-10.0)	7.5 (0.0-10.0)	0.862
Level of loss of strength (VAS:0-10cm) median (min-max)	5.5 (0.0-10.0)	4.5 (0.0-10.0)	0.918
Elbow Region Muscle strength (0-5) mean±SD			
Flexion	5.0±0.0	4.95±0.22	0.986
Extension	5.0 ± 0.0	5.0 ± 0.0	1.000
Pronation	5.0 ± 0.0	5.0 ± 0.0	1.000
Supination	4.91±0.28	4.90±0.30	0.994
Wrist Region Muscle strength (0-5) mean±SD			
Flexion	5.0±0.0	5.0±0.0	1.000
Extension	5.0 ± 0.0	5.0 ± 0.0	1.000
Grip force (kg) mean±SD	17.49±3.51	16.99±3.96	0.579
Lateral finger grip force(kg) mean±SD	7.67±2.87	7.31±2.15	0.611
Palmar finger grip force (kg) mean±SD	6.67±1.90	6.58±1.90	0.873
Q-DASH (0-100) mean±SD	52.54±7.16	48.60±8.95	0.566
Q-DASH work model (0-100) mean±SD	54.78±8.30	57.18±8.48	0.337
NHP (0-100) mean±SD			
Energy	65.21±15.50	65.01±11.48	0.914
Pain	55.97±16.51	49.83±9.31	0.328
Sleep	44.34±10.72	38.11±8.94	0.464
Emotional reaction	48.30±12.58	50.55±5.04	0.723
Social isolation	26.07±7.58	27.10±7.64	0.847
Physical mobilite	30.07±9.12	27.50±6.51	0.452

mean±SD: mean value ±Standard deviation, VAS: Visual Analog Scale, Q-DASH: Quick Disabilities of the Arm, Shoulder, and Hand Score, NHP: Nottingham Health Profile.

Discussion

This study examined the short-term efficacy of CI and PH in LE and compared patient satisfaction with the two treatment modalities. According to the results of our study, it has been shown that both CI and PH have positive effects on pain, loss of strength, tenderness, functionality, and quality of life. While there was an increase in grip strength and palmar strength in patients with PH, this increase was not found in the CI group.

Commonly known as tennis elbow, the most common complaints of patients with LE are pain and decreased grip strength. Many treatment methods have been used to reduce pain and increase muscle strength. Despite the diversity of treatment modalities, there is no universally accepted treatment [32].

CIs are a common treatment for patients with LE. Exactly how they work is not known; they probably help control the local inflammatory response and pain generation [33]. CI appears to be superior to NSAIDs in the first 4-week period, but no difference was observed at the later stage [15,34]. The early response of corticosteroids may be due to their analgesic and anti-inflammatory effects. A systematic review concluded that after eight weeks, CI was no more effective than placebo [35]. Although CI appears to be effective in relieving pain from LE in the short term, no long-term benefit has been identified. In addition, it has been reported that it may cause a new trauma to the degenerative tissue because it is an invasive method and has a high recurrence rate [36]. In addition, CI has been shown to have a negative effect on grip strength [19]. Although CI is widely used in the treatment of LE, its lack of long-term effect, increasing the risk of trauma and adversely affecting grip strength have led us to seek alternative treatment. However, considering the analgesic and anti-inflammatory effects of corticosteroids, we thought that non-traumatic and longer-acting corticosteroid-containing treatment alternatives could be effective.

PH causes faster particle movement in the tissues with the effect of ultrasound and thus provides more absorption of the drug. The purpose of PH is to treat soft tissue damage and reduce pain by promoting healing and resolving inflammation [22]. One study found a statistically significant improvement in functional capacity, pain scores, and grip strength in LE patients receiving PH [21]. In a

Table 3. Pain, loss of strength and sensitivity levels, grip strengths, NHP and Q-DASH scores pre- and post-treatmentfor Group-1.

	Pre-treatment	Post-treatment	р
Pain score (VAS:0-10cm) median (min-max)			
Arm	5.00 (0.0-10.0)	1.5 (0.0-4.0)	0.001*
Elbow	7.0 (5.0-10.0)	3.5 (0.0-6.0)	0.001*
Forearm	3.5 (0.0-8.0)	1.20 (0.0-4.0)	0.017*
Sensitivity level (VAS:0-10cm) median (min-max)	7.0 (2.0-10.0)	3.30 (0.0-6.0)	0.001*
Level of loss of strength (VAS:0-10cm) median (min-max)	5.5 (0.0-10.0)	3.0 (0.0-5.5)	0.001*
Elbow Region Muscle strength (0-5) mean±SD			
Flexion	5.0 ± 0.0	5.0±0.0	1.000
Extension	5.0 ± 0.0	5.0 ± 0.0	1.000
Pronation	5.0 ± 0.0	5.0 ± 0.0	1.000
Supination	4.91±0.28	5.0 ± 0.0	0.638
Wrist Region Muscle strength (0-5) mean±SD			
Flexion	5.0±0.0	5.0±0.0	1.000
Extension	5.0 ± 0.0	5.0 ± 0.0	1.000
Grip force (kg) mean±SD	17.49±3.51	25.15±3.90	0.001*
Lateral finger grip force(kg) mean±SD	7.67±2.87	10.90±2.10	0.008*
Palmar finger grip force (kg) mean±SD	6.67±1.90	10.55±1.22	0.001*
Q-DASH (0-100) mean±SD	52.54±7.16	28.34±4.74	0.001*
Q-DASH work model (0-100) mean±SD	54.78±8.30	29.83±4.68	0.001*
NHP (0-100) mean±SD			
Energy	65.21±15.50	44.92±15.68	0.001*
Pain	55.97±16.51	32.82±11.48	0.001*
Sleep	44.34±10.72	30.43±9.19	0.001*
Emotional reaction	48.30±12.58	38.16±7.30	0.016*
Social isolation	26.07±7.58	15.65±4.32	0.004*
Physical mobilite	30.07±9.12	20.10±4.21	0.001*

mean±SD: mean value ±Standard deviation, VAS: Visual Analog Scale, Q-DASH: Quick Disabilities of the Arm, Shoulder, and Hand Score, NHP: Nottingham Health Profile, *: p<0.05.

study comparing ultrasound and PH in patients with LE, it is stated that PH treatment may be preferable to ultrasound because of its additional benefit to activities of daily living [23]. Naproxen PH was used in the treatment of LE previously and it was found to reduce pain, increase grip strength, and provide functional improvement [37]. In this study, we evaluated the data of patients who received corticosteroid PH in the treatment of LE and found that they had positive effects on pain, grip strength, sensitivity, functionality, and quality of life. We think that both the analgesic and anti-inflammatory effects of corticosteroid in the early period are utilized with corticosteroid PH, and it also contributes to the repair of soft tissue damage with PH.

Murtezani et al. compared CI with ultrasound therapy and supervised exercise [38]. Significant improvements were demonstrated for patient-rated tennis elbow evaluation (PRTEE) pain score, PRTEE function score, VAS, and grip strength in the exercise and ultrasound group compared to the CI group. As in this study, they found better grip strength in the physical therapy group. This can be explained by muscle or tendon microtrauma during the injection. In addition, studies have shown that complications such as tendon rupture, cartilage damage, subcutaneous atrophy, and loss of skin pigmentation can occur after CI [39]. The PH technique is a non-invasive, well-tolerated and risk-free method. Therefore, we support the idea that subcutaneous administration of corticosteroids via phonophoresis rather than local injection is more effective and safer in the treatment of LE.

In this study, both PH and CI were found to be effective in the treatment of function, pain, and quality of life in LE. However, improvement in grip strength related parameters was only seen in the PH group. In PH studies using different drugs, it has been reported to be beneficial on grip strength and pain in LE patients [23,37,40]. In our study, similar results were obtained with corticosteroid PH. The point we want to draw attention to here is that considering the rapid effect of corticosteroids in reducing pain and inflammation in the early period, PH treatment should be preferred instead of CI when we are going to use corticosteroids. The average cause of LE is cumulative trauma **Table 4.** Pain, loss of strength and sensitivity levels, grip strengths, NHP and Q-DASH scores pre- and post-treatmentfor Group-2.

	Pre-treatment	Post-treatment	р
Pain score (VAS:0-10cm) median (min-max)			
Arm	4.5 (0.0-10.0)	1.25 (0.0-4.5)	0.001*
Elbow	6.5 (0.0-10.0)	3.6 (0.0-6.0)	0.001*
Forearm	2.10 (0.0-8.0)	1.0 (0.0-4.0)	0.004*
Sensitivity level (VAS:0-10cm) median (min-max)	7.5 (0.0-10.0)	4.0 (0.0-8.5)	0.001*
Level of loss of strength (VAS:0-10cm) median (min-max)	4.5 (0.0-10.0)	2.25 (0.0-6.0)	0.019*
Elbow Region Muscle strength (0-5) mean±SD			
Flexion	4.95±0.22	5.0±0.0	0.329
Extension	5.0 ± 0.0	5.0 ± 0.0	1.000
Pronation	5.0 ± 0.0	5.0 ± 0.0	1.000
Supination	4.90 ± 0.30	5.0 ± 0.0	0.162
Wrist Region Muscle strength (0-5) mean±SD			
Flexion	5.0±0.0	5.0±0.0	1.000
Extension	5.0 ± 0.0	5.0 ± 0.0	1.000
Grip force (kg) mean±SD	16.99±3.96	18.16±3.14	0.252
Lateral finger grip force(kg) mean±SD	7.31±2.15	7.97±2.17	0.697
Palmar finger grip force (kg) mean±SD	6.58±1.90	7.40±1.07	0.269
Q-DASH (0-100) mean±SD	48.60±8.95	29.63±4.09	0.001*
Q-DASH work model (0-100) mean±SD	57.18±8.48	35.42±4.92	0.001*
NHP (0-100) mean±SD			
Energy	65.01±11.48	48.33±9.19	0.005*
Pain	49.83±9.31	37.12±8.71	0.011*
Sleep	38.11±8.94	29.01±9.36	0.015*
Emotional reaction	50.55±5.04	41.66±6.01	0.008*
Social isolation	27.10±7.64	19.10±4.01	0.005*
Physical mobilite	27.50±6.51	22.51±8.70	0.022*

mean±SD: mean value ±Standard deviation, VAS: Visual Analog Scale, Q-DASH: Quick Disabilities of the Arm, Shoulder, and Hand Score, NHP: Nottingham Health Profile, *: p<0.05.

Table 5. Distribution of Verhaar healing scores amongthe groups.

n (%)	Group 1 (n=23)	Group 2 (n=20)	р
Excellent healing	1 (4.3%)	3 (15%)	
Good healing	8 (34.8%)	6 (30%)	0 220
Fair healing	11 (47.9%)	8 (40%)	0.338
Poor healing	3 (13%)	3 (15%)	

and overuse, so its recurrence is not surprising. Changing triggering and challenging activities in daily life and ergonomics training can reduce the recurrence rate.

An important limitation of our study is that it was planned retrospectively. As a retrospective study, we can not intervene in all factors, although factors that clearly influenced the results of the study were considered and excluded. The short-term evaluation of the effectiveness of treatment methods and the lack of long-term follow-up are other limitations of the study. However, well-designed follow-up studies with larger samples and longer follow-up periods are required. Prospective studies including randomized and untreated control groups are needed to better elucidate the issue.

Conclusion

There are many treatment options for LE, such as PH and CI. Patients should be informed about the advantages and disadvantages of treatment options for LE. Although PH and CI are beneficial for pain, function and quality of life, our study found that PH is a more effective treatment for handgrip strength in patients with LE. Since PH is a noninvasive treatment and has fewer side effects, it can be preferred in LE patients.

Declaration of conflicting interests

The Authors declare that there is no conflict of interest.

Ethical approval

For this study approval was obtained from the Ankara City

Hospital Clinical Research Ethics Committee (Approval number: E2-21-252).

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