EFFECT OF HIGH INTENSITY LASER VERSUS LOW INTENSITY LASER IN TREATMENT PATIENTS WITH LATERAL EPICONDYLITIS; A RANDOMIZED CONTROL TRIAL

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Abstract

Objective: to compare the effects of high intensity laser versus low intensity laser in treating patients with lateral epicondylitis (LE).
Methods: forty participants in this randomized, single-blinded, repeated measurement study with lateral epicondylitis, their age ranged from 30 to 50. Participants were classified into two groups at random, group (A) (n = 20), which received high intensity laser therapy (HILT) and strengthing exercise, group (B) (n = 20), which received low intensity laser therapy (LILT) and strengthing exercise. Visual analog scale, hand dynamometer and disabilities of the arm, shoulder and hand questionnaire were utilized to measure pain intensity, hand grip strength and functional disability respectively, before treatment, 2 weeks and 4 weeks after treatment.
Results: there was a significant improvement ($p < 0.05$) in pain intensity, hand grip strength and functional disability in both groups after 2 weeks and after 4 weeks of treatment.
Conclusion: In conclusion, pain severity, hand grip strength, and function abilities were all enhanced with the use of both HILT and LILT in patients with LE. In contrast to LILT, the treatment impact of HILT on LE is both more rapid and more significant in less number of treatment sessions.

Keywords: high intensity laser, low intensity laser, lateral epicondylitis, pain severity, hand grip strength, functional disability

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1. Introduction

Lateral epicondylitis (LE), is a condition that impacts the common origin of the extensor muscles characterized by Pain and dysfunction, such as grip strength reduction [1, 2]. In nearly all cases, patients complain of pain at lateral elbow that radiates distally through the extensor muscle and made worse by resistive flexion of the wrist and fingers. The symptoms appear gradually and are not always associated to a single traumatizing event. Pain is made worse by lifting weights or keeping the arm in a pronated position [3]. LE is a common occupational injury, affecting 1.7% between the ages of 30 and 60, with increasing the danger to the dominant arm.Risk factors for LE include high gripping forces, heavy lifting, twisting the forearm frequently, and repeated manual work [4, 5].Reduced daily living activities and hand grip strength are linked to increase pain in LE patients [5].

Nonsteroidal anti-inflammatory drugs and physical therapy, such as extracorporeal shockwave, transcutaneous electrical nerve stimulation (TENS), pulsed electromagnetic fields, low intensity laser therapy, ultrasound, are all used to treat LE. Braces and surgery are also used as parts of the treatment plan [6].In patients with LE, laser therapy effectively lower discomfort, improves grip strength, and increases quality of life (QoL) [7].

Low intensity laser therapy (LILT) is a painless, non-invasive and simple method, used to manage pain, enhance peripheral blood flow, and hasten the healing of injured nerves [8]. The effect of LILT on tissue is photochemical rather than thermal. QoL may be enhanced by its use in the treatment of musculoskeletal pain [9].

High intensity laser treatment (HILT) is a more recent advancement in laser treatment. It delivers greater laser power in less time with more deep tissue penetration than LILT, creating more powerful bio-stimulatory and anti-inflammatory effects [10-12]. It has been utilized to treat the pain associated with musculoskeletal conditions and sports injuries, particularly those involving the muscles and tendons [11].

Recent study showed that LILT when administered according to the correct dose protocol, may be a useful tendinopathy therapy option [13-15]. Also HILT was reported more successful results than LILT for the treatment of individuals with plantar fasciitis (PF) [16].

HILT has become an essential method for pain management, but there is scant data about its usefulness in LE. So the goal of this study was to compare the effects of high intensity laser (HILT) versus low intensity laser (LILT) in treating patients with lateral epicondylitis (LE).

2. Materials and Methods

Participants: Forty subjects (17 male and 23 female), their age ranged from 35 to 55 years old diagnosed with unilateral epicondylitis, and referred by their orthopedic physician. Individuals who met the inclusion criteria (pain located outside of the elbow, localized tenderness on palpating the lateral epicondyle, pain with resisted wrist and/or middle finger extension, as well as a positive Cozen test) were considered to have LE. Less than four weeks of LE, fibromyalgia, prior management for ipsilateral LE, osteoarthritis ,rheumatoid arthritis, or inflammatory arthropathy impacting the wrist or elbow, carpal and cubital tunnel syndrome, after elbow surgery ,cervical radiculopathy, after radius/ulna fracture with subsequent deformity of the involved limb, other elbow pathologies, neurological problems were excluded from the study[17]. Using a flowchart, we were able to summarize the entire recruitment procedure (Figure 1)

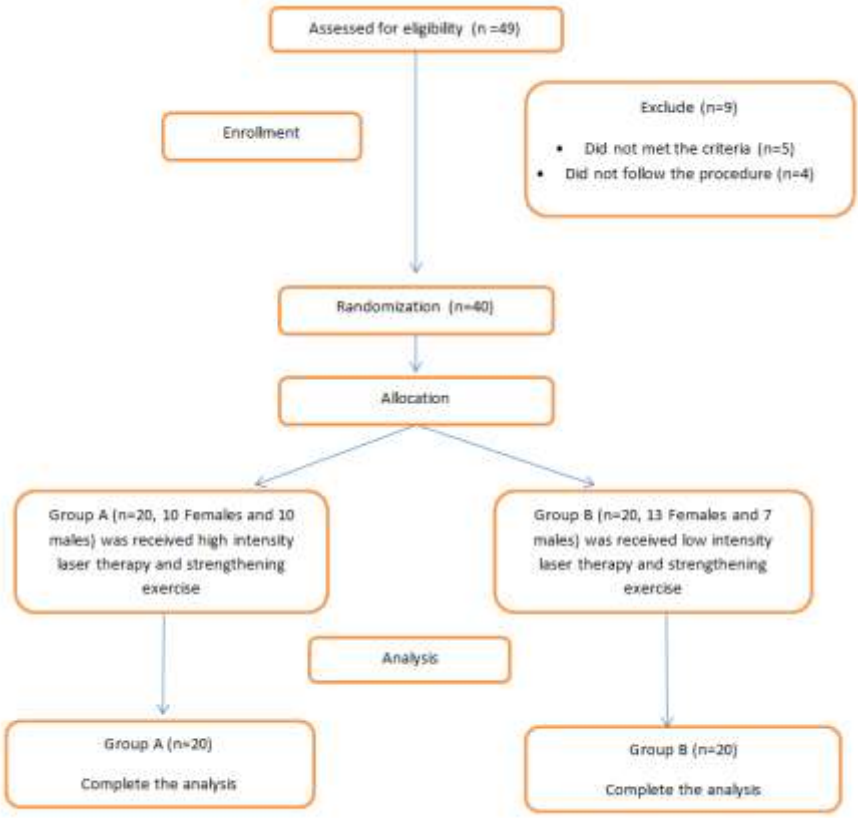

Figure (1): Flow chart for participants in the study.

Study design and randomization

A randomized, single-blind, repeated measurements trial was used in this research , from the periods between Januarys to March 2023. The included participants were assigned randomly into group A or B by using computer-generated random number tables.The participants in the current investigation were kept blind until the study end.

Ethical considerations

This study has been given the approval by the faculty of Physical Therapy's Research Ethics Committee at Egypt's Modern University for Technology and Information (REC/2111/MTI.PT/2212273). Before the study began, each participant had to read about the experiment's procedures and sign a consent form.

Procedure :

The same strengthening exercises program was given to both groups. Group (A), which got HILT, included 2o Participants with LE. There were 20 Participants with LE in group (B), which received LILT. Participants in each group completed 3 sessions per week for 4 weeks.

For both group the strengthening exercise was in form of eccentric muscle strengnth which was performed with free weights , decided by the 10 Repetition Maximum (RM) , sitting participants with maximal wrist extension, forearm pronation, and full elbow extension. From here, the patient progressively lowers the wrist into flexion for a count of 30, then raises the wrist to its fullest extension by the assisst of opposite hand. Participants were instructed to continue exercising even if they felt slight discomfort and to cease if the pain increased and became incapacitating. Each treatment consisted of three sets of ten repetitions with a 1 minute of resting between each set. Start treatment with wrist movement without any load for 2-3 minutes as a warming up [18].

For group A,the participants received high intensity laser, the equipment used was HIRO TT (Helterapia device, ASA Laser, made in Italy). The device delivered pulsed emission 1064 nm, Nd:YAG laser with a cooling system called smart cooler which lowers the skin and the underlying tissues temperature.

Handpiece with fixed spacers was used to place a 5 mm laser beam at the identical distance from the skin and perpendicularly to the treatment area. Each session consisted of three stages of treatment. Via these three stages, 1250j of energy were provided to the patient in a single treatment

session[19]. Pulsed Nd:YAG laser treatment was given to the participants.

In first stage, we used a quick manual scan (100 cm2 per 30 s) at the common extensor tendon (CET) ,the surrounding soft tissues, as well as the extensor muscles (extensor carpi radialis longus as well as brevis, extensor digitorum communis, as well as extensor carpi ulnaris). Either transverse and longitudinal scanning were carried out. An energy dose of 624 J was given during this stage. laser fluency settings were 510 mJ/cm2 (208 J), 810 mJ/cm2 (208 J), and 970 mJ/cm2 (208 J) for a grand total of 624 J[19].

In following stage, we positioned the handpiece with constant spacers vertically to 90 degrees on CET around the lateral epicondyle (trigger point deactivation phase). Phase two was performed on CET, with fluences of 360 mJ/cm2 (6.3 J), 510 mJ/cm2 (9 J), as well as 610 mJ/cm2 (10.1 J) for 6 second for each , with overall of 25 J.

In the final stage, an overall energy dose of 624 J was delivered by manually scanning slowly (100 cm2 per 60 s) across the same locations as in the 1st phase . The patient received 1250 J of energy throughout the session which last 15 minutes The device counted up the patient's energy intake at each stage and the session's overall energy output[19].

For group B, participants were treated with low intensity laser therapy. The device used was (Mphi 5 - MLS® Laser Therapy – Asa laser -made in italy) , which used Gallium arsenide infrared diode lasers, 904 nm wavelength, 240 MW of maximum output, as well as a frequency of 5,000. LILT irradiation was applied to the most painful points, Six points were treated over the lateral epicondyle area , using a laser spot size of around 0.5 cm^2 and a power density of 2.4 J/cm^2 for 30 seconds at each area [20].

Outcome measures:

All test procedures were explained for each participant before their participation. Participants with unilateral epicondylitis were assessed by visual analog scale (VAS), hand dynamometer and the disorder of arm, shoulder and hand (DASH) questionnaire. Measurements for all subjects were made before treatment, after 2 weeks (6 sessions) and after 4 weeks (12 sessions) of interventions.

Pain intenisity : Using VAS to evaluate, it is a reliable and valid tool, utilising a 10 cm line, where the numbers 0 and 10 on either end represent no pain and extreme pain, respectively., which enables continuous data processing. To indicate how much pain they are experiencing, participants were instructed to mark along the line [21].

Grip strength: Using hand dynamometer (Jamar plus digital hand dynamometer,made in the USA by Sammons Preston) to take the readings, with the individual seated comfortably with his arm at a right angle to the body, and the elbow resting by the side. The dynamometer's base rested on the first1st metacarpal, and also the handle rested in the center of the individual's 4 fingers. The individual then exerts maximal isometric effort on the dynamometer for at least 5 second. The patient is not allowed to move any other bodily parts. The measurements were repeated 3 times and 2 minutes resting time was provided between each measurement. Then take the average of these 3 measurements [22].

Functional disability: DASH is a valid and reliable questionnaire [23].It composed of a thirty-item disability/symptom scale that inquires on the patient's health throughout the last week The questions inquire as to how difficult it is for patient to engage in many physical tasks due to your shoulder,arm, or hand problems (21 items).Questions assess how much patients suffering from pain, activity-concerned pain, numbness, weakness, as well as stiffness (a total of 5), along with how the problem affects social interactions, job, sleep, and self-perception (4 items).There are five responses for each item. A scale score, from 0 (indicating no disability) to 100 (indicating extreme disability) [23].

Sample size:

Pilot research with ten patients was conducted due to the dearth of pertinent literature and the inherent challenges in determining the extent of the effect. The least appropriate sample size for the current investigation was determined to be 20 cases in each category using the statistical tool G*POWER (version 3.1.9.2; Franz Faul, Universitat Kiel, Germany). In order to calculate the effect size, this software was used. The calculations used the following values: $\alpha = 0.05$, $ß = 0.2$, effect size = 0.34, and allocation ratio N2/N1 = 1.

Statistical analysis:

The gender distribution was detected using Chi-square test. Measures of central tendency (means and standard deviations) were used to represent all of the study's data. We compared subject characteristics among groups using an unpaired t-test. Shapiro-Wilk test was performed to ensure data follows a normal distribution. A homogeneity of variances test (Levene's test) was performed to examine whether or not the groups were homogenous. We used the unpaired t-test to compare the variables across groups and the paired t-test to compare the variables before and after intervention within each group. Differences among the 3 times were tested using one-way ANOVA and a least-squares difference (LSD) post

hoc testing. In this analysis, a p value of less than 0.05 is considered to be significant. For all analyses, we relied on SPSS for Windows, Version 22. (IBM SPSS, Chicago, IL, USA).

3. Results

A) Patients demographic data:

Each group consisted of 20 participants; Age, weight, height, and BMI did not significantly differ between the two groups of individuals ($p > 0.05$)as in (Table 1).

Table (1): Comparison of age, weight, height and BMI between groups (A and B).

	Group (A) $\overline{X}$ **± SD**	**Group (B)** $\overline{X}$ **± SD**	**t-value**	**p-value**	**Level of significant**
Age (years)	47.9 ± 5.48	45.8 ± 7.11	1.05	0.302	N.S
Weight (kg)	75.4 ± 10.7	73.6 ± 11.6	0.51	0.613	N.S
Height (m)	1.7 ± 0.1	1.68 ± 0.09	0.61	0.543	N.S
BMI (kg/m^2)	26.19 ± 2.68	25.99 ± 2.77	0.23	0.821	N.S

$\overline{X}$: Mean. SD: Standard Deviation. t-value: Unpaired test value.

p-value: Probability value. NS: Non-Significant.

B) Gender distribution:

Gender distribution data for groups A and B indicated no statistically significant difference ($p > 0.05$) among the 2 groups (Table 2).

Table (2): Comparison of the frequency distribution and chi squared test for gender distribution between groups (A and B).

	Group (A)	**Group (B)**	**X^2-value**	**p-value**	**Level of significant**
Females	10 (50%)	13 (65%)	0.026	0.719	NS
Males	10 (50%)	7 (35%)			

$\overline{X}$: Mean. SD: Standard Deviation. X^2: Chi squared value.
p-value: Probability value. NS: Non-Significant.

C) Measured variables:

1) Pre- treatment comparison between the two groups:

After comparing the pre- treatment measures of VAS, muscle strength and Dash questionnaire between two groups, the non significant differences were shown of all measured variables between the two groups ($p > 0.05$) (Table 3).

2) Pre, post-1 and post-2 treatment comparison for group (A):

After comparing the pre, post-1 and post-2 treatment measures of VAS, Muscle strength and Dash questionnaire for group (A), the significant differences were shown of all measured variables ($p < 0.05$) (Table 3).

3) Pre and post-1 and post-2 treatment comparison for group (B):

After comparing the pre, post-1 and post-2 treatment measures of VAS, Muscle strength and Dash questionnaire for group (B), the significant differences were shown of all measured variables ($p < 0.05$) (Table 3).

4) Pre, post-1 and post-2 treatment comparison between the two groups:

After comparing the post-1 and post-2 treatment measures of VAS, Muscle strength and Dash questionnaire between two groups, the significant differences were shown of all measured variables between the two groups ($p < 0.05$) (Table 3).

Table (3): Comparison of VAS, muscle strength and Dash questionnaire for the two groups.

		Pre-treatment	Post-1 treatment	Post-2 treatment	**f-value**	**p-value**
VAS	**Group (A)** $\overline{X}$ **± SD**	6.95 ± 0.99	4.4 ± 0.75	2.75 ± 0.64	136.12	0.0001^{S}
	Group (B) $\overline{X}$ **± SD**	7.3 ± 0.86	5.45 ± 1.1	3.6 ± 0.82	78.11	0.0001^{S}
	% of improvement	-	28.86%	30.9%	-	-
	t-value	1.18	3.52	3.66	-	-
	p-value	0.244^{NS}	0.001^{S}	0.001^{S}	-	-
Muscle strength	**Group (A)** $\overline{X}$ **± SD**	33.99 ± 3.04	43.69 ± 3.02	50.12 ± 2.53	159.97	0.0001^{S}
	Group (B) $\overline{X}$ **± SD**	32.3 ± 2.28	39.08 ± 2.61	44.61 ± 2.76	116.14	0.0001^{S}
	% of improvement	-	10.55%	10.99%	-	-
	t-value	2.01	5.7	6.58	-	-
	p-value	0.053^{NS}	0.0001^{S}	0.0001^{S}	-	-
Dash questionnaire	**Group (A)** $\overline{X}$ **± SD**	82.72 ± 3.4	49.29 ± 4.23	27.17 ± 3.65	197.31	0.0001^{S}
	Group (B) $\overline{X}$ **± SD**	84.47 ± 3.91	57.11 ± 5.58	34.29 ± 6.16	449.3	0.0001^{S}
	% of improvement	-	15.86%	26.21%	-	-
	t-value	1.51	5.01	4.45	-	-
	p-value	0.14^{NS}	0.0001^{S}	0.0001^{S}	-	-

$\overline{X}$: Mean. SD: Standard Deviation. % of improvement: Percentage of improvement. t-value: Unpaired t-test. f-value: ANOVA test value.
p-value: Probability value. NS: Non-Significant. S: Significant.

5) Comparison between (pre and post-1), (pre and post-2) and (post-1 and post-2) for group (A):

As presented in Table (4), when contrasting after treatment measures of VAS, Muscle strength and Dash questionnaire between (pre and post-1), (pre and post-2) and (post-1 and post-2) for group (A), significant differences were found of all measured variables ($p < 0.05$).

Table (4): Comparison of VAS, Muscle strength and Dash questionnaire between (pre and post-1), (pre and post-2) and (post-1 and post-2) for group (A).

Items	**VAS**					
	Pre-treatment	**Post-1 treatment**	**Pre-treatment**	**Post-2 treatment**	**Post-1 treatment**	**Post-2 treatment**
$\overline{X}$ **± SD**	6.95 ± 0.99	4.4 ± 0.75	6.95 ± 0.99	2.75 ± 0.64	4.4 ± 0.75	2.75 ± 0.64
% of improvement	36.69%		60.43%		37.5%	
t-value	11.42		15.7		11.01	
p-value	0.0001		0.0001		0.0001	
Level of Substantial	S		S		S	
	Muscle strength					
	Pre-treatment	**Post-1 treatment**	**Pre-treatment**	**Post-2 treatment**	**Post-1 treatment**	**Post-2 treatment**
$\overline{X}$ **± SD**	33.99 ± 3.04	43.69 ± 3.02	33.99 ± 3.04	50.12 ± 2.53	43.69 ± 3.02	50.12 ± 2.53
% of improvement	28.53%		47.71%		14.71%	
t-value	24.5		34.65		24.72	
p-value	0.0001		0.0001		0.0001	
Level of Substantial	S		S		S	
	Dash questionnaire					
	Pre-treatment	**Post-1 treatment**	**Pre-treatment**	**Post-2 treatment**	**Post-1 treatment**	**Post-2 treatment**
$\overline{X}$ **± SD**	82.72 ± 3.4	49.29 ± 4.23	82.72 ± 3.4	27.17 ± 3.65	49.29 ± 4.23	27.17 ± 3.65
% of improvement	40.41%		67.15%		4488%	
t-value	58.71		65.74		38.93	
p-value	0.0001		0.0001		0.0001	
Level of Substantial	S		S		S	

$\overline{X}$: Mean. SD: Standard Deviation. % of improvement: Percentage of improvement. t-value: Paired t-test. p-value: Probability value.
S: significant.

6) Comparison between (pre and post-1), (pre and post-2) and (post-1 and post-2) for group (B):

As presented in Table (5), when contrasting after treatment measures of VAS, Muscle strength and Dash questionnaire between (pre and post-1), (pre and post-2) and (post-1 and post-2) for group (A), significant differences were found of all measured variables ($p < 0.05$).

Table (5): Comparison of VAS, Muscle strength and Dash questionnaire between (pre and post-1), (pre and post-2) and (post-1 and post-2) for group (B).

Items	**VAS**					
	Pre-treatment	**Post-1 treatment**	**Pre-treatment**	**Post-2 treatment**	**Post-1 treatment**	**Post-2 treatment**
$\overline{X}$ ± SD	7.3 ± 0.86	5.45 ± 1.1	7.3 ± 0.86	3.6 ± 0.82	5.45 ± 1.1	3.6 ± 0.82
% of improvement	25.34%		50.68%		33.94%	
t-value	11.1		22.58		10.18	
p-value	0.0001		0.0001		0.0001	
Level of Substantial	S		S		S	
	Muscle strength					
	Pre-treatment	**Post-1 treatment**	**Pre-treatment**	**Post-2 treatment**	**Post-1 treatment**	**Post-2 treatment**
$\overline{X}$ ± SD	32.3 ± 2.28	39.08 ± 2.61	32.3 ± 2.28	44.61 ± 2.76	39.08 ± 2.61	44.61 ± 2.76
% of improvement	20.99%		38.11%		14.15%	
t-value	29.95		33.7		20.23	
p-value	0.0001		0.0001		0.0001	
Level of Substantial	S		S		S	
	Dash questionnaire					
	Pre-treatment	**Post-1 treatment**	**Pre-treatment**	**Post-2 treatment**	**Post-1 treatment**	**Post-2 treatment**
$\overline{X}$ ± SD	84.47 ± 3.91	57.11 ± 5.58	84.47 ± 3.91	34.29 ± 6.16	57.11 ± 5.58	34.29 ± 6.16
% of improvement	32.39%		59.41%		39.96%	

t-value	29.8	48.37	34.68
p-value	0.0001	0.0001	0.0001
Level of Substantial	S	S	S

$\overline{X}$: Mean. SD: Standard Deviation. % of improvement: Percentage of improvement. t-value: Paired t-test. p-value: Probability value.
S: significant.

4. Discussion

The current academic research's main focus is to compare the effects of HILT versus LILT in treating patients with LE. According to the findings of our study, after 2 weeks of treatment program, HILT combined with strengthening exercise (group A) revealed a significant and high percentage of improvement in all outcome measures in comparison to group B. after the completion of treatment (4 weeks) both groups had significant effect in improving all outcome measures with the high percentage of improvement in group A.

HILT's efficacy in LE has only been examined in a few previous studies. Pain, hand grip strength, disability, as well as quality of life measures all improved significantly in advantage of HILT in a study by Salli et al. [24]. The long-term effects of HILT were also studied by Akkurt et al. [25], who found that the VAS (during rest and activity), DASH and grip strength, all improved significantly after treatment and increasing through six months later.

In addition, Alayat et al. [26] stated that HILT with exercise showed better outcomes than placebo laser plus exercise or exercise alone in addressing low back pain.

Moreover Kaydok et al. [20] has been demonstrated that HILT is more efficient in pain and function for the immediate treatment of LE. However, compared to the LILT, the HILT had more of an impact on hand grip strength and DASH.

Nevertheless, Basford et al. [27] failed to show that the neodymium-doped yttrium aluminium garnet (Nd-YAG) laser proved to be more effective than a placebo after 4 weeks.

The particular mechanism of action for HILT is not revealed. In contrast to LILT, it is thought to have both photochemical and photo thermal actions by deliver powerful laser energy in a shorter period of time ,it produce an output energy more than 500 mW by using a scattering laser radiation approach, which causes deeper tissue penetration [12,28].

HILT has the therapeutic benefits of being anti-inflammatory, anti-edema and analgesic [29]. It is believed that the analgesic benefits of HILT are based on a variety of modes of action, including delaying the transmission of the pain input and raising the body's creation of morphine-mimetic chemicals [30]. Also, it might have direct effects on nervous system components, which might speed up the rate of conduction blocks or stop the transmission of pain signals through the C pain and A-delta fibers [31]. It also improves blood circulation, raises blood vessel permeability and quickens the metabolic response of cells [32] .Furthermore; HILT's photochemical and photo thermal activities may improve flow of blood and vascular permeability, induce anti-inflammatory effects, and stimulate the formation of collagen in tendons. HILT can therefore aid in repairing damaged tissues and obliterating painful stimuli [32].

The effectiveness of LILT in the treatment of LE has been reported to have conflicting findings. LILT yields better outcomes than a placebo, according to several LE trials [15] .Patients' pain as well as physical functioning improved temporarily after receiving LILT at the 904 nm wavelength, according to a meta-analysis of LILT therapies conducted by Bjordal et al. [33]. However, Bisset et al.[34] concluded from a meta-analysis they published that LILT is unsuccessful for treating LE.

The biomodulatory effects of LILT treatment are still poorly understood despite having numerous uses in humans. According to the study of Tam [35], LILT can increase microcirculation, activate angiogenesis, stimulate nerve regeneration, and improve immune function through dilatation of arterial and capillary vessels. Long-term LILT can stimulate mitosis in cultured cells, leading to increased cell proliferation, DNA/RNA production, collagen creation, and overall cell quantity. LILT increases cellular functioning and proliferation rate by stimulating the photoreceptors found on mitochondria as well as cell membranes to transform light energy into chemical energy that takes the shape of ATP inside the cell [32,36-37]. In addition, studies have demonstrated that LILT therapy can reduce inflammation by lowering levels of proinflammatory cytokines like

interleukin-1 alpha and raising levels of other cytokines as well as anti-inflammatory growth factors including fibroblast growth factor [38]. Accelerating cell proliferation, collagen production, and tissue regeneration, and possibly reducing the secretion of prostaglandins, cytokine levels, as well as cyclooxygenase are all benefits of LILT [39, 40].

Also the results of our study attributes to the fact that strengthening exercise in a form of eccentric exercise can reduce discomfort and increase muscle strength in LET patients [41]. Eccentric contraction would seem to stimulate tendon, increasing the amount of collagen and reducing the amount of neuro-vascular ingrowth, both of which appear to influence pain [42, 43].

Limitations:

The research has an age limit (35-55), absence of follow-up make challenging to predict how long these alterations could persist in the subjects. In light of this, the authors suggest future researches to incorporate a variety of follow-up times and target different age groups in their sample. Moreover, the sample size of only forty participants may have limited its generalizability. Nonetheless, the authors ran a power test to determine the absolute minimum number of participants required.

5. Conclusion

In conclusion, pain severity, hand grip strength, as well as function disability were all improved with the use of either HILT or LILT in those with LE. In contrast to LILT, the treatment impact of HILT on LE is both more rapid and more significant in less number of treatment sessions.

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Conflicts of interest

The academic work's authors have not disclosed any conflicts of interest.

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