Effects of 904-nm Low-Level Laser Therapy in the Management of Lateral Epicondylitis: A Randomized Controlled Trial

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ABSTRACT

Objective: The aim of this study was to evaluate the effectiveness of 904-nm low-level laser therapy (LLLT) in the management of lateral epicondylitis. *Background Data:* Lateral epicondylitis is characterized by pain and tenderness over the lateral elbow, which may also result in reduction in grip strength and impairment in physical function. LLLT has been shown effective in its therapeutic effects in tissue healing and pain control. *Methods:* Thirty-nine patients with lateral epicondylitis were randomly assigned to receive either active laser with an energy dose of 0.275 J per tender point (laser group) or sham irradiation (placebo group) for a total of nine sessions. The outcome measures were mechanical pain threshold, maximum grip strength, level of pain at maximum grip strength as measured by the Visual Analogue Scale (VAS) and the subjective rating of physical function with Disabilities of the Arm, Shoulder and Hand (DASH) questionnaire. *Results:* Significantly greater improvements were shown in all outcome measures with the laser group than with the placebo group (p < 0.0125), except in the two subsections of DASH. *Conclusion:* This study revealed that LLLT in addition to exercise is effective in relieving pain, and in improving the grip strength and subjective rating of physical function of patients with lateral epicondylitis.

INTRODUCTION

Lateral EPICONDYLITIS is a common condition, often described as inflammation of the common extensor. Research shows, however, that granulation tissue can be found at the origin of the extensor carpi radialis brevis (ECRB) muscle.¹ Macroscopic tearing, additionally, was associated with histological findings.² This pathology suggested a degenerative process, as no inflammatory cells were identified histologically.³ Therefore, researchers now prefer using the term "tendinosis", instead of "tendinitis".

The onset of symptoms is usually gradual and insidious, but occasionally it can be sudden. Pain is localized at the lateral epicondyle but may spread up and down the upper limb, which could be aggravated by grasping, lifting, or twisting actions. Grip is sometimes impaired due to pain and this may restrict daily activities.

Low-level laser therapy (LLLT) is a common electrophysical modality used in clinical practice for the management of lateral epicondylitis. LLLT seems to be effective in promoting tissue healing and pain control, which may involve various mechanisms.⁴ Recent clinical trials have revealed its efficacy in reducing pain and improving grip strength and the subjective rating of physical function,⁵⁻⁹ but the reported findings were controversial. A few systematic reviews have concluded that there is insufficient evidence either to demonstrate the benefit or lack of effect of laser therapy.^{10–13} In particular, there is a lack of common consensus on the choice of optimal treatment parameters. The objective of the study was to examine the effectiveness of 904-nm LLLT in the management of lateral epicondylitis with regard to mechanical pain threshold, maximum grip strength, level of pain at maximum grip strength, and the subjective rating of physical function.

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METHODS

Subjects

Thirty-nine patients were recruited from the outpatient physiotherapy department of a local hospital. The criteria for inclusion in this study were that the patient should experience pain over the lateral epicondyle in the following clinical tests: (1) palpation of the lateral epicondyle of humerus; (2) resisted extension of the wrist or middle finger; and (3) passive stretching of the extensor muscle group of the wrist and fingers. The patient should also be able to independently complete the Visual Analogue Scale (VAS) and the Disabilities of the Arm, Shoulder and Hand (DASH) questionnaire. The criteria for exclusion were patients with a history of elbow trauma, surgery, elbow osteoarthritis, rheumatoid arthritis, pain arising from cervical spine disorders, radial nerve entrapment, malignant tumors in their upper limbs, previous episode(s) of lateral elbow pain on the same side, steroid injection or other prior treatment regimes received before treatment, or injury on duty. Informed and written consent was obtained from all of the patients. No patients dropped out of the study.

Study design

The patients were randomly assigned into two treatment groups by an investigator by drawing lots using the non-replacement method. A standardized exercise program and advice on home care was prescribed to all patients in the initial session. The exercise program was derived from previous studies,^{14–16} and included exercises to stretch and strengthen the forearm muscles. A log sheet with the description of exercises was given to the patients, and their compliance with the exercise program was checked at each treatment session.

Phyaction (model 796), a gallium-arsenide (Ga-As) laser device, with a 25-W probe (model 242) was used to deliver LLLT. It was a class 3B laser. The laser probe delivered an average power of 25 mW, with a wavelength of 904 nm, a pulse duration of 200 nsec, and a beam diameter of 4.0 mm.

Prior to the application of laser irradiation, all tender points including the origin of the ECRB muscle, were identified, and the skin over the area to be treated was cleaned with warm water and soap to remove excess grease in order to reduce possible reflection or refraction on the surface of the skin. The tender points were irradiated using the direct skin contact technique with the laser probe held perpendicularly on the surface of the skin. Laser therapy was delivered with a pulse repetition frequency of 5000 Hz and an energy density of 2.4 J/cm² with an irradiation time of 11 sec at each point. The energy dose for each point was 0.275 J. The average number of tender points in the laser group was 2.4, therefore resulting in a total energy dose of 0.66 J on average delivered to each patient. The patients in the placebo group were treated with identical procedures but with sham irradiation without switching the knob on the laser probe.

The patients received three sessions of treatment per week for 3 weeks. Upon the completion of each session of laser treatment, the home exercise program was continued until the 3-week follow-up (3-wk FU) session.

Outcome evaluation

The outcome measures were assessed in the following time intervals: (1) session 1 (baseline); (2) session 5; (3) session 9

(last session); and (4) 3-wk FU session. The assessments used are described next.

Mechanical pain threshold. A pressure algometer was used to measure the pressure exerted on the skin through the rubber tip in kg/cm². During the assessment, the patients were seated comfortably with shoulder slightly abducted, elbow in 90° flexion, forearm in full pronation, and with forearm, wrist, and hand supported.¹⁷ The most sensitive point on the elbow was identified by palpation and marked for standardization for subsequent assessments. The pressure algometer was applied perpendicularly on the target point until the patients first reported of pain; it was then removed from the skin and the value was recorded.

Maximum grip strength. A grip dynamometer attached to the EVAL SoloSystem (Greenleaf Medical, Palo Alto, CA) was used. The average of three trials of grip strength and the value of coefficient of variance (CV) was recorded. The data was regarded as reliable if the value of CV was below 10%. During the assessment, patients were seated comfortably with shoulder adducted, elbow flexed to 90°, and forearm and wrist in a neutral position.¹⁸ The patients were asked to squeeze the dynamometer as hard as possible, with the grip force applied smoothly without rapid wrenching or jerky movements. Three trials were performed, with a 20-sec rest between each trial. The average value of the three trials was recorded in kilograms.

Visual Analogue Scale (VAS). This pain rating scale consists of a horizontal line 10 cm long with "No pain" and "Pain as bad as it could be" marked on the left and right end of the line, respectively.¹⁹ During assessment, the patients were asked to rate the level of pain immediately after the test for maximum grip strength. They were required to make a mark on the line and the distance from the left end to the mark on the scale was measured and recorded as the VAS score.

Disabilities of the Arm, Shoulder and Hand (DASH) questionnaire. This was developed to measure disabilities and symptoms in persons with musculoskeletal disorders of the upper limb. DASH consists of 30 questions with five response options for each item in the main section. There are two optional modules consisting of four questions, respectively, which specify the difficulties and symptoms experienced in the performance of sports or music and at work. It is scored from 0 to 100 in each of the three sections, with a higher score indicating a greater level of disabilities and symptoms. The Chinese version of the questionnaire was shown to be valid and reliable.²⁰ The patients were asked to fill in the DASH questionnaire by themselves, and the total score of each section was calculated and recorded.

Statistical analysis

The statistical analysis was performed using the Statistical Package for the Social Sciences (SPSS 12.0). A general linear model repeated measures analysis of variance (ANOVA) was used to analyze the interaction and main effects between the laser group and the placebo group in the four outcome measures across the four assessment time intervals. The level of significance (alpha) was set at 0.05, and the Bonferroni Correction was used to adjust the inflation of alpha due to multiple comparisons.

RESULTS

Demographic and baseline characteristics of the patients

Thirty-nine patients were recruited, with 21 patients in the laser group and 18 patients in the placebo group. The mean age of the patients was 47.4 years, with a range of 35–70 years of age. Their history of symptoms ranged from 1 to 12 months, with a mean of 3.3 months. There was no significant difference in any of the demographic data of the patients between the two groups (all p > 0.05; Table 1).

Outcome measures

In the laser group, significant improvements were detected in mechanical pain threshold, maximum grip strength, and the scores of VAS and DASH (Work) at session 5, session 9, and the 3-wk FU session as compared to the baseline (p < 0.01). Significant improvements were also detected in the scores of DASH (Main Section) and DASH (Sports/Music) in session 9 and the 3-wk FU session as compared to the baseline (p < 0.01). In the placebo group, significant improvements were detected in mechanical pain threshold, maximum grip strength, and the scores of VAS and DASH (Main Section) only in the 3-wk FU session as compared to the baseline (p < 0.01).

TABLE 1. DEMOGRAPHIC AND BASELINE CHARACTERISTICS OF PATIENTS

	Laser group $(n = 21)$	Placebo group (n = 18)
Gender		
Male	9	7
Female	12	11
Age (years)	46.1 ± 9.2	48.9 ± 8.7
Occupation ^a		
Sedentary work	7	5
Light work	6	7
Medium work	7	6
Heavy work	1	0
History of symptoms (months)	3.2 ± 2.4	3.3 ± 2.6
Affected side		
Dominant side	12	12
Non-dominant side	9	6
Current analgesics used	2	3
Use of tennis elbow band	3	4

^aThe job classifications are based on the classifications stated in the National Occupational Classification Career Handbook (NOC-CH) from the U.S. Department of Labor's *Dictionary of Occupational Titles*.

Data are expressed as mean \pm standard deviation.

improvement was detected in the score of DASH (Work) in session 9 and in the 3-wk FU session as compared to the base-line (p < 0.01; Table 2).

From session 5 onward through the 3-wk FU session, there was a significantly greater improvement in mechanical pain threshold in the laser group compared with the placebo group (p < 0.0125). From session 9 onwards, there was also a significantly greater improvement in the score of VAS in the laser group compared with the placebo group (p < 0.0125). By the 3-wk FU session, the laser group demonstrated significantly greater improvement in maximum grip strength and score of DASH (Main Section) than did the placebo group (p < 0.0125; Fig. 1).

DISCUSSION

LLLT demonstrated significantly greater analgesic effects than did placebo irradiation in terms of mechanical pain threshold and VAS. These findings concerning LLLT on pain threshold and pain relief are consistent with those of previous studies. Trigger points are commonly found around the elbow region in patients with lateral epicondylitis. They usually demonstrate lower skin resistance as compared to the surrounding tissue.²¹ A significant increase in skin resistance with pain reduction was noted in subjects who received laser therapy over muscular trigger points.^{22,23} It was also found that 904-nm infrared laser irradiation significantly increased pain thresholds over trigger points.²⁴ Various researchers have reported that LLLT significantly increased pain thresholds on myofascial pain. It was reported that 3-4 weeks of direct laser irradiation on trigger points, muscle origins, and insertions significantly increased the mechanical pain threshold and that the treatment was most effective on acute tendinitis.25 A significant increase in algometric measures was also revealed on the trigger points in myofascial pain syndrome.26 The analgesic effects produced by laser on trigger points could be due to the improvement in tissue oxygenation and local microcirculation, therefore preventing hypoxia and muscular fatigue.27-29 Laser therapy can also increase the formation of ATP to normalize the metabolic rate of the tissues with diminished energy levels. By these mechanisms, laser can interrupt the vicious cycle of the origin and development of pain.³⁰

Our positive findings were consistent with those reported in previous studies.⁵⁻⁹ It is suggested that LLLT produces pain relief by a combination of postulated mechanisms. Increased fibroblast activity and the laying down of collagen in damaged ligaments were demonstrated with the use of laser therapy.³¹ Anti-inflammatory effects were also demonstrated in a histochemical study. Prostaglandin E_2 was significantly reduced after laser irradiation, an effect that inhibited vasodilatation and platelet aggregation.^{32–34} It has also been demonstrated in animal studies that laser therapy results in a selective reduction of Aδ- and C-fiber activity.³⁵ In addition, LLLT significantly increased the latency of the superficial radial nerve with a corresponding decrease in sensory nerve conduction.³⁶

Although our findings are promising, divergent results have been reported in other clinical trials on LLLT. The reasons for this could be differences in the methodological quality and treatment parameters used in these clinical trials. Haker and

Outcome measure	Laser group	Placebo group	p-Value (between-group)
Mechanical pain threshold (kg/cm ²)			
Session 1 (Baseline)	1.52 ± 0.89	1.34 ± 0.95	0.547
Session 5	2.09 ± 0.81^{a}	1.33 ± 0.92	0.009
Session 9	2.59 ± 0.99^{b}	1.49 ± 0.87	0.001
3-wk FU session	$3.80 \pm 1.26^{\circ}$	$1.87 \pm 0.91^{\circ}$	0.000
Maximum grip strength (kg)			
Session 1 (Baseline)	20.38 ± 8.21	18.28 ± 9.41	0.461
Session 5	22.71 ± 8.53^{a}	19.00 ± 9.82	0.214
Session 9	25.29 ± 8.26^{b}	19.56 ± 9.75	0.054
3-wk FU session	$29.57 \pm 8.96^{\circ}$	$21.61 \pm 9.70^{\circ}$	0.011
Score of Visual Analogue Scale (VAS)			
Session 1 (Baseline)	5.14 ± 1.88	5.61 ± 2.03	0.460
Session 5	4.10 ± 1.79^{a}	5.61 ± 2.00	0.017
Session 9	3.05 ± 1.77^{b}	5.39 ± 2.12	0.001
3-wk FU session	$1.48 \pm 1.36^{\circ}$	$4.28 \pm 2.11^{\circ}$	0.000
Score of Disabilities of the Arm, Shoulder			
and Hand (DASH) questionnaire			
(Main Section)			
Session 1 (Baseline)	34.73 ± 13.77	38.92 ± 18.92	0.430
Session 5	31.07 ± 15.75	37.83 ± 19.11	0.234
Session 9	23.41 ± 15.05^{b}	37.26 ± 20.45	0.020
3-wk FU session	$15.79 \pm 11.59^{\circ}$	$31.58 \pm 17.98^{\circ}$	0.002
Score of DASH (Sports / Music)			
Session 1 (Baseline)	45.61 ± 22.51	41.18 ± 22.53	0.606
Session 5	41.95 ± 23.46	36.48 ± 13.54	0.474
Session 9	32.39 ± 19.03^{b}	34.39 ± 16.96	0.773
3-wk FU session	$22.84 \pm 17.51^{\circ}$	30.23 ± 16.62	0.263
Score of DASH (Work)			
Session 1 (Baseline)	42.20 ± 22.00	41.82 ± 20.62	0.958
Session 5	33.46 ± 22.05^{a}	38.69 ± 18.86	0.457
Session 9	25.05 ± 16.99^{b}	34.79 ± 18.81^{b}	0.112
3-wk FU session	$14.74 \pm 13.04^{\circ}$	$27.36 \pm 17.22^{\circ}$	0.017

TABLE 2. COMPARISONS OF THE LASER GROUP AND PLACEBO GROUP WITH RESPECT TO OUTCOME MEASURES AT BASELINE, SESSION 5, SESSION 9, AND 3 WEEKS AFTER THE COMPLETION OF TREATMENT

^aSignificant change between the baseline and Session 5 values within the groups (p < 0.01).

^bSignificant change between the baseline and Session 9 values within the groups (p < 0.01).

^cSignificant change between the baseline and 3-weak follow-up (3-wk Fu) session values within the groups (p < 0.01).

Data are expressed as mean ± standard deviation.

Lundeberg⁵ reported no difference in subjective outcomes but only significant improvement in some objective outcomes favoring laser therapy on lateral epicondylitis; while other authors generally reported significant improvement in subjective outcomes. The subjective outcome measure was not reported clearly in the study and the authors suggested that a five-point scale might not be sensitive enough to detect minor changes. The study also did not exclude subjects with previous injection of steroid, which have been shown recently to inhibit the anti-inflammatory effects from LLLT.³⁷ They also conducted studies with LLLT on acupuncture points, but reported negative findings.^{38–40} This controversy may be related to the indirect exposure of irradiation to the ELBR tendon as the acupuncture points selected were not exactly over the tendon. Bjordal et al.⁴¹ suggested the significance of direct exposure to the tendon to be one of the key success factors for the effectiveness of LLLT. Besides, the dose applied in the study in 1987 was relatively low (only 0.004 J per point for Ga-As laser and 0.093 J per point for He-Ne laser).³⁸ They also did not exclude subjects with previous injection of steroid in the study in 1990.³⁹ The laser unit used in the study in 1991 was not a single-wavelength laser, which consisted of two different wavelengths in one system.⁴⁰

The rationale behind the selection of optimal treatment parameters is therefore vital. Concerning the type of laser that was employed in this study, the 904-nm Ga-As laser is an infrared laser that has a short and strong energy delivery in the pulsed mode, but a low average output. One *in vitro* study has shown



FIG. 1. Mechanical pain threshold, maximum grip strength, Visual Analogue Scale (VAS), and Disabilities of the Arm, Shoulder and Hand (DASH) questionnaire (Main Section) across sessions for the two groups.

that an infrared laser penetrates more deeply with the same incident energy loss than a visible red laser.⁴² Penetration is also better with pulsed lasers than with continuous lasers as the former seems to overcome the skin barrier at lower doses than the latter.⁴³ Therefore, a 904-nm pulsed infrared laser seems to be appropriate for treating superficially situated ECRB tendon over the lateral epicondyle.

Besides the penetration and wavelength of the laser, the effects of LLLT are dose-dependent. Bjordal et al.⁴¹ reviewed 10 laboratory trials and found that too low or too high a power density and dose was ineffective. They suggested that the clinical treatment parameters for lateral epicondylitis with a 904-nm infrared laser are a dose of 0.3–3 J/cm² and a power density of 2–100 mW/cm². The choice of dose of 2.4 J/cm² in the present study lies within this suggested range.

Bjordal et al.⁴¹ recommended a frequency of treatment of three to five times per week. However, the derivative was based on laboratory trials only. Based on clinical experience, Simunovic et al.⁸ suggested that the expected improvement could slow down if treatment was interrupted for longer than 1 week, especially in the initial stage of laser therapy. They adopted a treatment regime of daily sessions (five times) per week for acute cases and reduced the frequency to every second day, and subsequently to one or two times per week. In chronic cases, after the initial three consecutive sessions, the frequency can be reduced to every second day. They reported that repeated irradiation in optimal weekly intervals promotes the cumulative effects of LLLT. The patients recruited in the present study were more or less in the subacute stage, with a mean history of symptoms of 3.3 months; therefore, the frequency of treatment was standardized at three times per week.

In the present study, LLLT or sham irradiation was given in addition to an exercise program. Therefore, the net placebo effect of laser could not be estimated. Our findings showed that a significant analgesic effect was demonstrated in the laser group from session 5 onwards. As the outcome measures were not assessed in each session, it was possible that the analgesic effects actually reached a significant level earlier than session 5. In addition, significant betweengroup differences were found in all outcomes at the 3-week FU session. It was possible that the effects of laser therapy might extend beyond a 3-week period. Long-term followups, including information on relapse rates, may be included in future studies.

The results of this study may shed light on similar applications of LLLT in other musculoskeletal conditions with similar etiology. Shoulder impingement syndrome, Dequervain's disease, and trigger finger all share similar etiologic factors as lateral epicondylitis. LLLT can be considered as one of the physical strategies that can be used to reduce this kind of tendinopathy pain.

CONCLUSION

In conclusion, nine sessions of LLLT in addition to exercise is effective in relieving pain, increasing grip strength, and improving subjective rating of physical function in the short term, and the effect can be maintained for at least 3 weeks.

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LLLT in the Management of Lateral Epicondylitis

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