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Original Research Article

Effects of High-Intensity Laser Therapy on Pain Sensitivity and Motor Performance in Patients with Thumb Carpometacarpal Joint Osteoarthritis: A Randomized Controlled Trial

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Abstract

Objective. To examine the effects of high-intensity laser therapy (HILT) on pain sensitivity and motor performance in patients with thumb carpometacarpal (CMC) osteoarthritis (OA). **Design**. Prospective, triple-blinded, randomized, placebo-controlled trial. **Setting**. Private practice, Malaga, Spain. **Subjects**. Forty-three patients (mean ± SD age = 71 ± 12 years) with a diagnosis of thumb CMC OA grade 1–2 were randomized to the control group (N = 21) or experimental group (N = 22). **Methods**. The experimental group (ExpG) received high-intensity laser therapy (HILT), and the control group (ConG) received a placebo treatment. The outcome measures were pain intensity (visual analog scale) and key pinch strength measurements (dynamometer). All outcome measures were collected at baseline, immediately following the intervention, at four weeks, and at 12 weeks following the intervention. **Results**. Analysis of variance revealed a group × time interaction ($F = 40.8$, $P < 0.001$) for pain intensity, with those patients receiving LT experiencing a greater reduction in pain compared with those receiving placebo therapy at the end of the intervention ($P < 0.001$), as well as at 12 weeks after the intervention. Although mean values in the ExpG were higher than in the ConG for key pinch at assessment, these differences were not statistically significant. **Conclusions**. HILT effectively diminishes pain intensity when used as an isolated treatment for patients with thumb CMC OA, but the effect of treatment decreases after 12 weeks.

Key Words: Pain; Thumb; Osteoarthritis; Laser Therapy

Introduction

With the aging population, patients who present with thumb carpometacarpal (CMC) osteoarthritis (OA) are commonly seen in hand therapy departments [1]. Basal thumb pain is common in people over the age of 55 and can cause deformity and limitations in activities of daily living (ADL) [2]. This disorder is identified by degeneration of cartilage, which produces symptoms that worsen over time [3]. Symptoms related to thumb CMC OA include thumb pain during activity, decreased strength, decreased thumb motion, and limitations in functional performance that include difficulty writing, manipulating small objects, and carrying a 10-pound bundle [4–6].

The main goals of thumb CMC OA treatment are to improve functional performance, improve hand function,

and decrease pain and stiffness. To achieve these goals, patients are often referred to rehabilitation services, including occupational and physical therapy [7,8].

Systematic reviews have demonstrated that different conservative approaches, such as the use of an orthosis, strengthening exercises, and educational programs, are effective for the management of thumb CMC OA, but only modest treatment effects have been reported for the application of individual interventions [9–11].

Clinical application of low-level laser therapy (LLLT), also known as photobiomodulation (PBM), is the use of red and near-infrared light to stimulate healing, relieve pain, and reduce inflammation. The use of LLLT has been increasing in recent years due to its positive clinical effects [12]. Although laser therapy (LT) is considered an effective nonsurgical intervention for reducing pain and improving function in subjects with knee OA, fewer studies support their use for patients with hand conditions [13–17]. LT intervention in patients with median nerve lesions had a positive effect on nerve growth parameters, as concluded Seyed et al. [18]. Burger et al. described favorable outcomes for pain, symptom severity, functional ability, and grip strength at the end of LT treatment and short-term follow-up in adults with carpal tunnel syndrome (CTS) [19]. Positive effects of LLLT were also demonstrated by Li et al. in subjects with mild to moderate CTS, with improved hand grip, reduced visual analog scale (VAS) pain intensity scores, and improved sensory nerve action potentials at three-month follow-up [20].

Previous research with low-energy helium neon LT of thumb OA, at 0.9 mW, demonstrated no therapeutic effects on thumb OA [21]. Other studies, however, have not been clear with their conclusions regarding the use of LT in degenerative conditions of the hand. Meireles et al. concluded that low-level aluminum gallium arsenide LT at a wavelength of 785 nm, dose of 3 J/cm^2, and mean power of 70 mW had no effect for the improvement of pain and function in subjects with rheumatoid arthritis [22]. Brosseau et al. examined the intervention with LLLT in subjects with hand OA. They concluded that participants had improvements in grip and thumb opposition range of motion; however, they also concluded that LLLT was no better than placebo for decreasing hand pain or stiffness or improving hand function [23]. Instead, positive effects on other joints with OA, such as temporomandibular and knee joints, with a lower daily consumption of rescue analgesics in the LLLT group have been demonstrated [13,24]. Although LLLT has been used in physical therapy investigations and has been demonstrated to be an effective nonsurgical intervention method for reducing pain and improving both performance of daily routines in patients with chronic back pain [25,26] and functional outcomes and pain parameters in patients with knee OA [13,14,27], recently high-intensity laser therapy (HILT) was introduced to the field of physical therapy [28]. Over LLLT, HILT is able to reach and stimulate large joints and has been proven to effectively reduce pain intensity. Nevertheless, the effects of HILT as a sole treatment have not been previously described on thumb CMC joint OA and have not been compared with a control group. Therefore, our purpose in this study was to examine the effects of HILT as a sole treatment on reducing pain sensitivity and increasing motor performance in patients with thumb CMC OA. We hypothesized that application of 12 sessions of local laser during four consecutive weeks would reduce pain in thumb CMC OA grade 1–2 patients and subsequently improve pinch force. We further expected that there would be significant differences between the two groups after the 12-week follow-up, in terms of perceived pain at the base of the thumb and pinch strength.

Methods

Study Design

We conducted a randomized (triple-blind) controlled trial. Informed consent was obtained from all participants, and the procedures were conducted following institutional ethics board clearances and according to the Declaration of Helsinki (ClinicalTrials.gov Registration Number: NCT03270488).

Participants

Patients with thumb CMC OA were consecutively recruited from February 2017 to June 2017 from the waiting lists of different local hospitals. Participants were blinded to the trial's hypothesis and to the interventions received. Inclusion criteria for this study were women >18 with a diagnosis of thumb CMC OA in their dominant hand with a radiographic stage of 1–2 according to the American College of Rheumatology [29], a reported pain intensity during activities of daily living (ADLs) of least 4/10 on the VAS, the ability to read or understand the patient information sheets, and the ability to sign a consent form to be included in the study.

Participants were excluded from the study if they had a neurologic disorder affecting the upper limb; had received previous treatment for their hand problem in the last six months, including an intraarticular joint injection to wrist, fingers, or thumb; had fractures or a significant hand injury or previous surgery to the wrist, thumb, or hand; had hand or finger tenosynovitis and/or Dupuytren disease; or were undergoing psychological or medical treatment. Also excluded were participants who suffered a disease where laser treatment is contraindicated (cancer, uncontrolled diabetes mellitus, hypertension) and those whose current medications might interfere with LT treatment (e.g., corticosteroid injections).

Procedure

The recommendations of the Osteoarthritis Research Society International (OARSI) for the design and conduct of clinical trials on hand OA [30] were followed for this

study, along with Consolidated Standards of Reporting Trials (CONSORT) Statement guidelines [31], to allow greater transparency and enhance the quality of the findings.

The randomization sequence was computer-generated and took place after consent, eligibility, and baseline assessments. Subjects were randomly allocated for treatment in control group (ConG; sham laser) or experimental group (ExpG; high-level laser). For equal distribution of subjects between both therapies, a software program randomly assigned subject numbers to a treatment group. The complete sequence has been published elsewhere [32].

An assessor blinded to treatment allocation collected basic demographic data and conducted all clinical measurements (pain intensity measurement with VAS scale line and upper limb motor performance with key pinch strength) at baseline, four weeks or after treatment completion, and 12 weeks post-treatment. Neither the investigator nor the participants were aware whether a placebo or active treatment was being administered. The same laser device was used for both groups. All conditions, including indicator lights and sounds in the laser application of verum and sham, were identical, except the laser irradiation, which was not visible for the ConG. According to the level of power output utilized, no sensation was generated. The statistician involved in the main statistical analyses was blinded to group allocation. Only the research assistant had the identifying code to determine which treatment was given.

Experimental Intervention

Following the National Standard for Safe Use of Lasers in Health Care, the ExpG received the application of LT on a painful, affected joint. A high-level, Class IV K-Laser, Mod. K1200 (Eltech K-Laser S.r.l., Treviso, Italy), was employed for the local LT and placebo treatment. Delivery parameters were established according to the acknowledged guidelines [33] and were peak power 3.0 W (duty cycle of 50%, mean power 1.5 W), with intense super pulse mode, combined wavelength of 800 + 970 nM, pulse frequency 2 Hz, energy dose 75 J per session, spot size 5 cm^2, and treatment frequency three times per week. The phase time was 15 seconds, with a total treatment time of 45 seconds. The procedure was performed by a physical therapist with experience in laser application in a reserved, noise-free room. LT was applied three times a week for four weeks. The participants were positioned in a seated position. Both the operator and subject wore protective glasses. The skin at the site to be irradiated was cleaned with 70% alcohol. LT was the only treatment intervention received by the participants. The functioning of the laser was verified before the treatment of each patient, and energy source, application points, and energy measurement were checked each time. The laser probe (head size: 4 cm^2) was applied in a circular motion from the center toward the outside over both the volar and dorsal aspects of the thumb CMC joint, with skin contact and no pressure. No therapeutic exercises, modalities, or other complementary treatments were provided in order to not interfere with assessment of the individual effectiveness of LT.

Placebo Treatment

The same equipment was used with a pen emitting a red guide light and a warning sound, but without the emission of a laser beam. All conditions including indicator lights and sounds in the laser application were therefore identical in both groups, except the laser irradiation, which was not visible. Participants of the ConG were offered the active treatment at the end of the experiment.

Outcome Measures

The primary outcome measure was pain experienced, measured by change in VAS score. This scale has been shown to be a reliable and valid instrument for the assessment of pain, being frequently employed in clinical and research contexts. It consists of a 10-cm line anchored at each end. The left-hand anchor reads "no pain," and the right-hand anchor reads "worst possible pain"; the participants mark the line to represent their pain level.

Key pinch strength, measured with a pinch dynamometer, was as a secondary outcome. Pinch positions were defined using the American Society for Hand Therapists guidelines [34]. Key pinch was defined as holding the sensor between the pad of the thumb and the radial aspect of the index finger, located approximately near the proximal interphalangeal joint. Participants were seated on an adjustable chair, with back support, with their feet on the floor, and elbows flexed at 90° with neutral position of the forearm at the front of a table. All participants were asked to not move out of the test position during testing. They were instructed to compress the pinch dynamometer with the fingers as hard as possible for three seconds. Three trials were completed. To avoid inconsistency due to fatigue, there was a one-minute rest period between each measurement. Pinch strength was reported in kg. The reported pinch strength value was the average of three trials measured.

Subjects were evaluated preintervention and at four and 12 weeks post-treatment. Key evaluation for the primary outcome will be conducted at the end of trial (week 12).

Statistical Analysis

Statistical analyses were conducted with SPSS, version 22.0 (IBM Corp., New York, NY, USA), using an intention-to-treat analysis using the last-value-carried-forward method. Group data were summarized using means and standard deviations. The Kolmogorov-Smirnov test was used to confirm the normality of the distribution of the data. Comparison of baseline

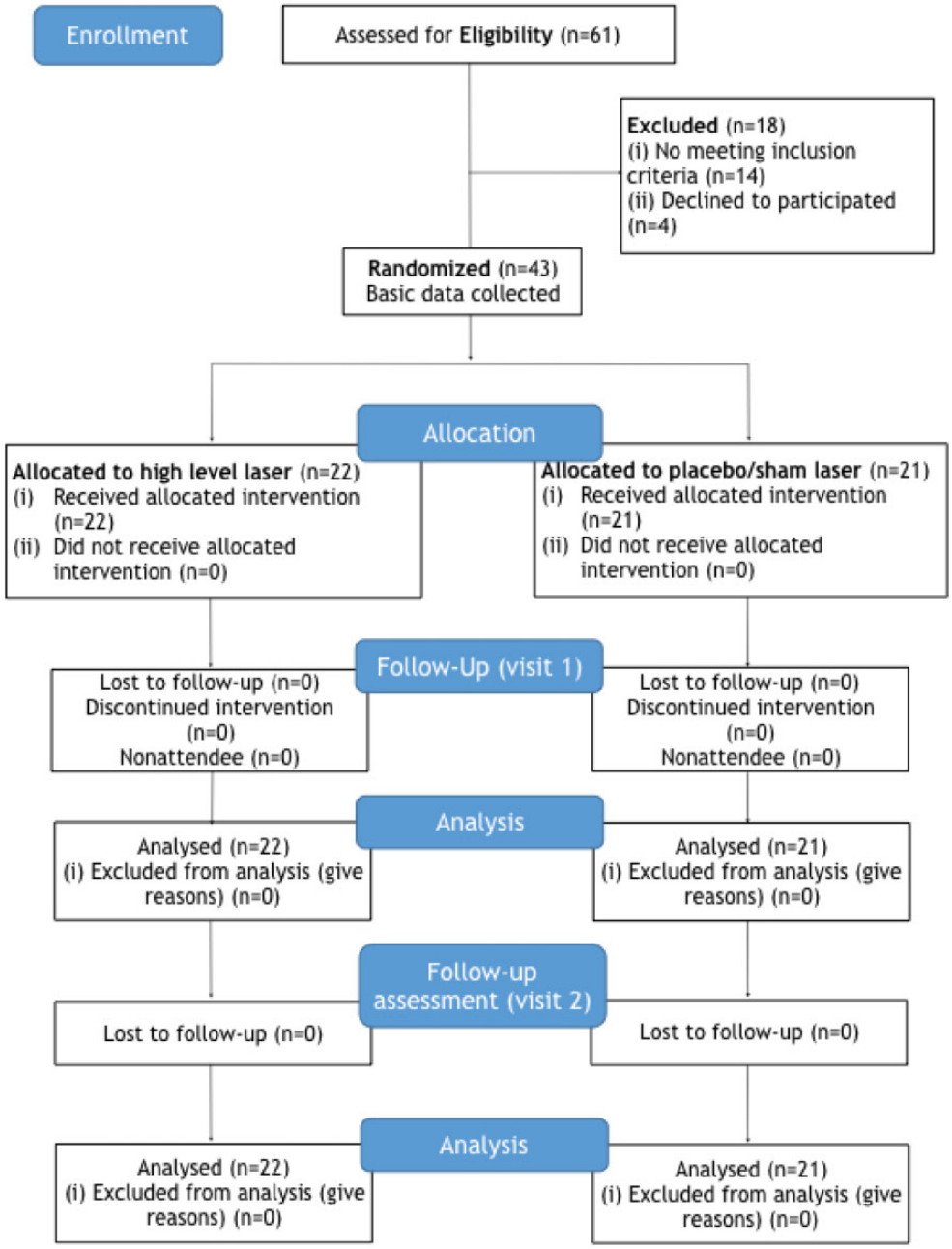

Figure 1. Consolidated Standards of Reporting Trials statement flow diagram of participants through the trial (Consolidated Standards of Reporting Trials transparent reporting of trails, Schultz et al. 2010) [35].

characteristics and outcome variables was performed with use of a two-tailed independent Student *t* test for continuous variables of age and baseline scores. Paired Student *t* tests were used to determine differences between the pre- and post-treatment measurements of the individual groups. A 2×3 repeated-measures analysis of variance (ANOVA) was used to determine the differences in time (pretreatment, post-treatment, and follow-up) as the within-subjects factor and group (experimental or control) as the between-subjects factor. The main hypothesis of interest was the group × time interaction. Between-group differences were expressed as mean differences with 95% CIs. Between-groups effect sizes were calculated using Cohen's *d* coefficient. If change scores demonstrated an effect size >0.8, it was considered large, 0.5 moderate, and <0.2 small. In all analyses, $P < 0.05$ was considered statistically significant.

Table 1. Baseline characteristics

	Experimental (N = 22)	Control (N = 21)	*P* Value
Age	63.1 ± 7.5	64.3 ± 8.6	0.5
Gender, female	22 (100)	21 (100)	
VAS	6.3 ± 1.2	5.9 ± 1.1	0.6
Key pinch strength	5.5 ± 1.2	5.9 ± 1.0	0.6

Data are expressed as mean ± standard deviation or No. (%).
VAS = visual analog scale.

Sample Size Determination

The appropriate sample size was calculated in order to achieve a power of 80% and to detect a mean difference of three points between the groups in the score on the VAS with a two-sided 5% significance level. Based on results from a previous study, a clinically significant difference reduction in VAS score was defined as 3 cm [36], with a standard deviation of 3.49 [37], a probability of a type I error of 0.05, and a power of 80%, which resulted in an estimated sample size of 21 for each group [38].

Results

Demographic and Clinical Data of Patients

Sixty-one consecutive participants (N = 61) with CMC OA were screened for eligibility criteria. Forty-three participants (mean ± SD age = 71 ± 12 years) satisfied all eligibility criteria, agreed to participate, and were randomized to the control (N = 21) or experimental (N = 22) group. Subjects were excluded or withdrawn from the study because they did not agree to participate in the study (N = 4), suffered from concomitant carpal tunnel syndrome (N = 8), or had received previous treatment (N = 6). Figure 1 provides a flow diagram of subject recruitment and retention through the study. Baseline features of both groups were not different for all variables (Table 1). No adverse effects were detected during or after the application of the treatment, and none of the participants started drug therapy during the study.

Response to Treatment

Pain Intensity

The mean pain score of the ExpG decreased from 6.3 ± 1.2 to 4.2 ± 1.1 after the four-week treatment, whereas the mean pain score of the ConG decreased 0.7 points from 5.9 ± 1.1 to 5.2 ± 1.1. The between-groups effect size was large at post-treatment ($d = 1.9$), in favor of the ExpG. The VAS demonstrated a significant time factor (F[2.0] = 40.8, $P < 0.001$, partial eta = 0.6) and group × time interaction (F[1.0] = 9.7, $P < 0.001$, partial eta = 0.2). The ExpG showed a statistically significant decrease in pain after treatment ($P = 0.001$), and a statistically significant difference between groups emerged ($P = 0.01$). At follow-up, a significant effect of treatment was found in the ExpG ($P = 0.002$) and a slight tendency

Table 2. Mean (SD) for outcome at all study visits for each group, mean (SD) difference within groups, and mean (95% CI) difference between groups.

Outcome	Groups						Difference Within Groups				Difference Between Groups			
	Pre		Post		FU		Post Minus Pre		FU Minus Pre		Post		FU	
	ExpG (N = 22)	ConG (N = 21)	ExpG (N = 22)	ConG (N = 21)	ExpG (N = 18)	ConG (N = 17)	ExpG	ConG	ExpG	ConG	ExpG Minus ConG		ExpG Minus ConG	
VAS	6.3 (1.2)	5.9 (1.1)	4.2 (1.1)	5.2 (1.1)	5.6 (1.0)	5.8 (1.1)	−2.1* (0.2)	−0.7 (0.2)	−0.7* (0.3)	−0.1 (0.2)	−1.0 (0.3 to 1.8)		−0.2 (−0.8 to 0.6)	
Pinch (kg)	5.5 (1.2)	5.9 (1.0)	6.4 (1.0)	6.1 (0.7)	5.5 (1.0)	5.9 (0.9)	0.9 (0.1)	0.2 (0.1)	0.0 (0.1)	0.0 (0.2)	0.3 (−0.9 to 0.3)		−0.4 (−0.3 to 1.0)	

ConG = control group; ExpG = experimental group; FU = follow-up; Pre = pretreatment; Post = post-treatment; VAS = visual analog scale.
*Significant between-groups difference, $P < 0.05$.

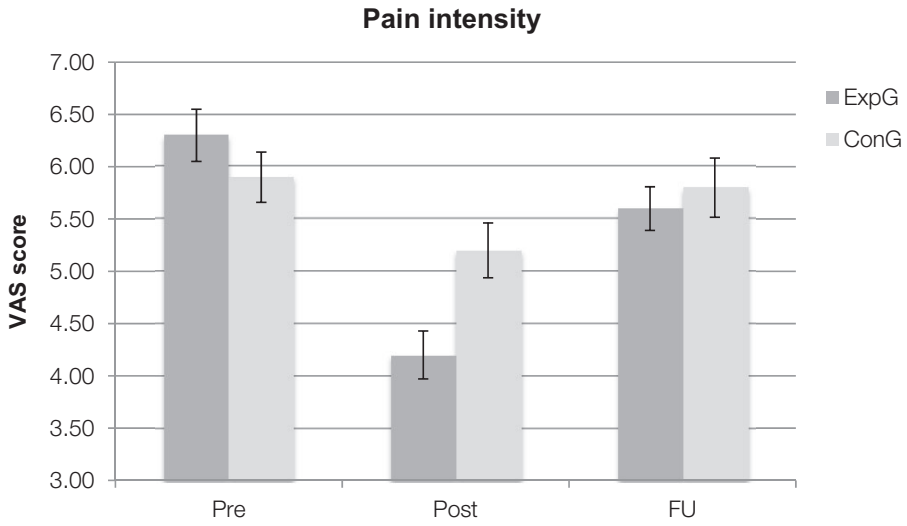

Figure 2. Effect of high-intensity laser therapy on pain intensity in the thumb carpometacarpal. ConG = control group; ExpG = experimental group; FU = follow-up; Pre = pretreatment; Post = post-treatment; VAS = visual analog scale.

of difference was observed between the groups, but it was not statistically significant ($P = 0.66$). Pain decreased from a baseline of 6.3 to 5.6 on the VAS scale for the ExpG at three-month follow-up. Between-groups effect sizes were small at follow-up ($d < 0.2$). The data are summarized in Table 2 and Figure 2.

Motor Performance

For key pinch strength, the ANOVA revealed no statistically significant group × time ($F = 2.9$, $P = 0.08$) interactions. There were also no significant main effects of time ($F = 2.8$, $P = 0.06$). The data are summarized in Table 2 and Figure 3.

Discussion

To the best of our knowledge, the present study offers a new approach to physiotherapy treatment in thumb CMC OA. This study used HILT involving direct irradiation to the painful CMC joint. Participants who received the LT protocol in this RCT benefited after a four-week treatment period with a reduction in pain intensity compared with the ConG. Although mean values in the ExpG were also higher than the ConG at four weeks for the key pinch, these differences were not statistically significant.

Previous investigations on thumb CMC OA conservative treatment found beneficial results for pain reduction using a variety of conservative interventions such as thumb immobilization [39] and manual therapy in conjunction with physiotherapy and occupational therapy [40,41]. The results of our RCT demonstrated an effective and immediate result of the LLLT on pain in thumb CMC OA, adding an additional treatment option to the armamentarium of conservative management strategies for OA. For example, LLLT could be used in the initial stages of treatment of thumb CMC OA to reduce pain and improve ability to perform ADLs.

Kjeken et al. suggested that considerable attention be devoted to improving function of the thumb as a priority because it contributes 60% to the overall function of the hand. These authors reported that hand-related activity limitations are associated with measures of hand impairment such as pain and limited joint mobility. It has been further suggested that patients with OA benefit from rehabilitation to relieve symptoms and improve function [42]. In parallel, earlier research regarding the effectiveness of HILT demonstrated benefit on pain reduction in knee OA, both in combination [28] and in isolation [16]. Our study has combined and extended those findings to support HILT to CMC joint OA as an isolated treatment at the first stages of OA.

Brosseau et al. also conducted an RCT more than a decade ago to determine the effects of LT on thumb OA, although, in contrast to our study, they used an LLLT [23]. Nevertheless, according to our results, they also found greater beneficial changes in the ExpG on pain, grip, and functional status after the application of LLLT at three and six weeks of follow-up, but their results were not statistically significantly better in the ExpG than in the ConG. Conversely, we found statistically significant differences in both pain and pinch strength after treatment with HILT and a statistically significant difference between groups in pain intensity. Discrepancies in findings between our study and Brosseau's could be due to the variability of the therapeutic application (dosage and duration), type of laser treatment received, or eligibility criteria. Our study included only participants with thumb CMC OA grade 1–2, whereas Brosseau et al. examined the efficacy of LLLT on distinct finger joints and three peripheral nerves [23].

Key pinch has proven to be the most robust association with OA diagnosis, and decreased pinch strength,

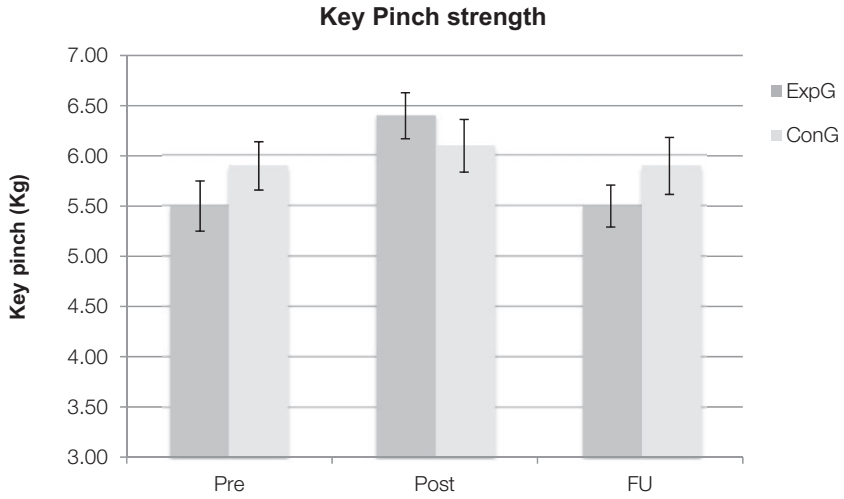

Figure 3. Effect of high-intensity laser therapy on key pinch strength in the thumb carpometacarpal joint. ConG = control group; ExpG = experimental group; FU = follow-up; Pre = pretreatment; Post = post-treatment; VAS = visual analog scale.

especially key pinch, is associated with early thumb CMC OA before the development of extensive radiographic evidence of the disease [43]. Previous studies such as that from Calder et al. suggest that episodes of pain or diminished proprioception in patients with thumb OA may impose limitations on performing activities that involve object manipulation [44]. They found that muscle fiber atrophy, motor unit loss, and sensory motor issues might be the main reasons for reduced strength and increased time to manipulate small and large objects in women with hand OA. In our results, we found no significant differences during the follow-up period of 12 weeks for either group ($P = 0.9$) for pinch strength and no differences between the groups. However, the ExpG initially experienced a gain in pinch strength from 5.5 to 6.4 kg at four weeks that returned to baseline status at 12 weeks. This is in disagreement with another study where a negative correlation between pain intensity and pinch force was found in thumb CMC OA [6]. Although our ExpG's change in pain score was clinically relevant after HLLT, our program did not include pinch strengthening or instruction in a home exercise program to be performed during the follow-up period [45]. This may explain the lack of changes in pinch strength in our study.

Limitations

There are several issues that we would like to mention as possible study limitations. First, only women were included in the study. Although the demographics of those who suffer from hand OA suggest that the highest prevalence is in women, men are also affected by hand OA [46]. Second, although previous investigations have demonstrated the effectiveness of combined conservative treatments on pain intensity, we did not apply a combination of interventions to the experimental group. Future studies should determine the effects of HILT on thumb CMC OA combined with other conservative interventions. Our assessment frequency might also have affected our findings. The results could have lasted beyond the four-week period, but as patients were not evaluated every month following treatment termination, no exact time frame over which the initial treatment benefits were reduced can be elucidated. Finally, we did not assess functional outcomes at the conclusion of the study. Future studies should assess functional status pre- and post-treatment to determine if a reduction in pain also enhances functional performance.

Conclusions

HILT is currently an effective treatment option for effective pain management in patients with thumb CMC joint OA at the dose utilized, over both the short term and medium term. However, longer-term randomized controlled trial studies with larger samples are required to verify our findings.

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