

Efficacy of Multiwave Locked System Laser on Pain and Function in Patients with Chronic Neck Pain: A Randomized Placebo-Controlled Trial

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Abstract

Background: Multiwave locked system (MLS) laser therapy utilizes the synchronized emission of an 808 nm continuous laser and a 905 nm pulsed laser. It is postulated that MLS enables greater penetration and therapeutic benefit than single-wavelength low-level laser therapy (LLLT). **Objective:** The aim of this research was to evaluate the efficacies of MLS laser therapy and the 830 nm laser in the treatment of patients with chronic neck pain (CNP). **Materials and methods:** Seventy-five patients with CNP (mean age 46.28 ± 5.89 , weight 83.78 ± 5.65 kg, height 1.72 ± 4.96 m, and duration of illness of 5.98 ± 1.44 months). They were randomized into three groups. Group I received MLS laser therapy and exercises, Group II received LLLT and exercises, and Group III received placebo laser therapy plus exercises (PL + EX). Neck pain levels and neck function were measured using the visual analogue scale (VAS) and neck disability index (NDI), respectively. **Results:** Both VAS and NDI were significantly reduced post-treatment for all treatment groups. After 6 weeks of treatment, MLS plus exercise showed a significantly greater decrease in pain and disability scores (Δ VAS (6.68) and Δ NDI (39.84)) compared to both LLLT plus exercise group (Δ VAS (5.72) and Δ NDI (37.88)) and PL + EX (Δ VAS (4.84) and Δ NDI (36.68)). **Conclusions:** MLS laser therapy in conjunction with exercises decreased pain and increased functional activity following 6 months of therapy. MLS laser therapy in combination with exercises is a more effective therapy for CNP compared to exercise plus LLLT or exercise alone.

Keywords: chronic neck pain, MLS laser therapy, neck disability index

Introduction

SPINAL PAIN IS a frequent problem experienced by many people. The lumbar and cervical regions are most commonly affected,¹ with an average prevalence of nearly 23%, although a value of over 86% has been reported.² The symptoms may be localized in the posterior scapular, occipital, or cervical areas³ accompanied with the presence of tender points and limiting cervical range of movement.⁴

The most common causes of neck pain include muscular, mechanical, or postural neck pain. In one-third of patients, the pain is brief and infrequent with complete resolution of symptoms, but for other patients, the pain persists and is chronic.⁵ Chronic neck pain (CNP) is common and disabling as it results in inducing muscle spasm, limitation in the neck's range of motion, and reduction in functional status resulting in significant workday absenteeism and reduction in quality of life and cost-effective treatments.^{6,7}

Many conservative treatment approaches are available for patients with CNP, including medications, manual therapy, electrotherapy, and patient education.⁸ Low-level laser therapy (LLLT) is considered one of the effective physical therapy treatment modalities used for the treatment of CNP. LLLT provides a noninvasive treatment approach used in reducing pain in chronic painful conditions as in CNP.^{9,10} Experimental and clinical studies reported that LLLT has a photobiomodulation effect, which can reduce pain by increasing the pain threshold in the tissue level, in addition to increasing the release of β -endorphine.¹¹ Indirectly, LLLT alters the prostaglandin level in tissues¹² with the production of vasodilatation by increasing nitric oxide production.¹³

The photobiomodulation effect may depend on several factors, including laser material, power, wavelength, and application mode as either pulsed or continuous. Semiconductor Ga-As or Ga-Al-As laser emits infrared laser that is located in a band of 730–905 nm with the variable level of

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penetration reaching up to 5 cm.¹⁴ Class IV, high-power (<0.5 watt) lasers can deliver high level of energy density, which can cover large areas and is sufficient to stimulate physiological responses.¹⁵ High-power laser, which is approved by Food and Drug Administration, is considered a safe therapeutic tool in treating pain, in addition to stimulating a specific point as the trigger point in the myofascial pain syndrome.^{16,17}

Recently, multiwave locked system (MLS) laser therapy had been introduced in the field of rehabilitation and gained interests of many researchers due to its unique characteristics. MLS laser is a Class IV, high-power laser, which is characterized by a combination of dual waveforms of continuous emissions of an 808 nm wavelength and a pulsed 905 nm emitted in synchrony.¹⁸ Although both continuous 830 nm^{19–22} and pulsed 905 nm^{23,24} lasers showed significant reduction in pain and neck disability in patients with CNP, there are a number of studies that showed limited²⁵ or even no effect.^{16,26} It was postulated that the combination of these two laser waveforms provides better penetrability and effect.²⁷ In the literature, there is no study yet that has investigated the effect of this combination on chronic painful conditions such as in CNP. Therefore, the objective of this research was to evaluate the efficacies of the MLS laser therapy and the 830 nm laser in the treatment of patients with CNP.

Patients and Methodology

Patients

Seventy-five patients with CNP were recruited to participate in the study. Their mean age was 50.61 ± 6.04 years. Patients were included in the study if they were 18 years of age or older and had unilateral or bilateral CNP that lasted for more than one month with or without limitation in the range of motion. The patient did not feel radicular pain or pain in the shoulders or upper limbs. They were also able to receive a full course of 12 treatments administered twice a week. The exclusion criteria were spinal root compression, cervical spine surgery or stenosis, or associated pathology of the upper cervical region or upper limb that may cause overlap in the clinical findings for pain from rotator cuff tendonitis, or cervical rib syndrome.²⁸

Study design

The study used a randomized, placebo-controlled design. The GPower 3.1 program (Universitat Kiel, Germany) for windows, version 3.1, was used to estimate the sample size required. The significance level was set at $\alpha=0.05$, the power, $1-\beta$ error probability=0.85, and estimated effect size=0.20. It was determined that a sample size of 72 patients was required to detect changes in three treatment groups and two measurement intervals, at baseline and at post-treatment (after 6 weeks). To account for potential subject dropout, the number of patients included in the study was increased to 75 (25 for each group).

The study was performed according to the 1964 Declaration of Helsinki and subsequent amendments or comparable ethical standards. It was approved by the Research Ethics Committee of the Faculty of Applied Medical Science of Umm Al-Qura University, Mecca, Saudi Arabia, and

local registry number (43409007). All patients were informed about the treatment protocol and gave written consent for their participation in the study and publication of the study results.

Randomization

Each patient was assigned a serial identification number from 1 to 75 and the numbers were randomized into three groups. This randomization was performed using the online GraphPad; thus, the patients in each group were blinded to the treatment given to them. The therapists were also blinded to the group assignment. Each therapist was responsible for the treatment using a single modality: MLS laser, LLLT, or exercise.

Group I (MLS + EX) received MLS laser and exercises, group II (LLLT + EX) received LLLT with exercises, and group III (PL + EX) received placebo laser plus exercises. Each patient was oriented about the treatment protocol. Patients signed a written consent form for study participation and their agreement for publication of the results.

Neck pain assessment

Pain was assessed using a visual analogue scale (VAS), a reliable and valid means for measuring the intensity of pain.²⁹ Patients were requested to score their pain between 0 and 10, where 0 represented “No pain at all” and 10 represented “The worst pain imaginable.”

Neck function assessment

The neck disability index (NDI) is a reliable and valid tool used for the self-assessment of neck function.^{30,31} An Arabic version of the NDI was used in this study. NDI has a 10-item structure, which evaluates the effect of cervical pain on the patients' functional activities. In each section, each patient was required to mark the statement that most closely described his problem. Each item was recorded out of 5 for a maximum total score of 50.³⁰

Exercise program

Patients in all treatment groups received the exercises. The exercise program included isometric exercises, stretching exercises, and postural exercises.^{32,33} Isometric neck exercise was performed from the first session. The isometric exercises performed were extension, flexion, and side bending. Stretching exercises were added from the fifth session and involved unilateral passive stretching for sternocleidomastoid, neck extensor, and side bending muscles. Postural exercises were added from the ninth session, including postural rotation exercise, side bending postural exercise, rotation-side bending postural exercise, and raise arm postural exercise.

MLS laser therapy

Mphi laser device (ASA, Arcugnano, Italy) was used in this study. It provides synchronized and overlapping continuous and pulsed emissions of Ga-Al-Ar laser emitted in a single hand piece. Mphi has a continuous emission of a wavelength of 808 nm with peak power of 1000 mW, mean power of 500 mW, spot diameter of 2 cm, and spot area of 3.14 cm^2 . Pulsed emission has a wavelength of 905 nm, peak

power of 25 W, and mean power of 54 mW with frequency of 1500 Hz.

Treatment by MLS laser therapy was applied into two phases—scanning and trigger point phases. In the scanning phase, the hand piece was positioned perpendicular to the treated area. Scanning was performed to the neck extensors at the paraspinal area, sternocleidomastoid, and upper, middle, and lower fibers of the trapezius. The average treatment area was 75 cm². The energy density was 4 J/cm² with a total energy of 300 J, and the treatment time was 4 min and 16 sec.

In the trigger point phase, the hand piece was perpendicular to eight trigger points, with four points on each side of the posterior neck area. In the mid-distance between C7 and the body of the acromion, the first point was allocated. The second and third points were allocated paraspinal at the level of spine and the inferior angle of scapula. The fourth point was on the paravertebral zone, 2 cm distal to the inferior angle. MLS laser probe was perpendicular and in contact with each point. The energy density was at 4 J/cm², and the time of application was 30 sec for each point. MLS treatment was applied twice a week for 6 weeks to all patients in the MLS + EX group.

Low-level laser therapy

Patients in the LLLT + EX group received (BTL-5000 laser) Gallium-Arsenide (GaAs) diode infrared laser probes of 830 nm wavelength and a maximum of 800 mW output power. The average energy density was at 50 J/cm², frequency at 1 KHz, and duty cycle at 80%.

LLLT was applied in scanning mode. A large cluster laser probe was used with 800 mW output power, frequency of 100 Hz, and probe area of 25 cm². The treated area was the same area as that for MLS with energy density of 4 J/cm², and the time was 7 min and 49 sec to deliver 300 Jules. Treatment of trigger points was applied by a laser probe of 0.5 cm diameter and 100 mW power output. The time of application was 50 sec for each point and the application was applied to the same point as described in MLS laser treatment. LLLT was applied for 12 treatment sessions over a period of 6 consecutive weeks (2 sessions/week). Placebo laser was administered in the same way for Groups I and II, but just a light with no laser emission. Active laser power output was kept constant by a member of the Department of Laser Physics, faculty of applied science, by measuring and calibrating laser devices thrice, at the start of the study and after 2 and 4 weeks during the course of the study.

Outcome measures

The patients' neck pain level and neck function, as measured by the VAS and NDI, respectively, were collected both at baseline and at the end of treatment.

Statistical analysis

All data analysis was performed using GraphPad Software (San Diego, California). The Wilcoxon signed-ranks test was employed to perform a comparison between the values of VAS and NDI within each group before and after treatment. Significance was defined at the $p < 0.05$ level. The values of VAS and NDI in the three study groups were compared using the Kruskal–Wallis test to determine whether differences were significant. If significant differences were found between groups, the Dunn's test for multiple comparisons was performed to identify where those differences existed.

Results

A total of 75 male patients were recruited to participate in the study with their mean age (standard deviation) 46.28 (5.89), weight of 83.78 (5.65) kg, height 1.72 (4.96) m, body mass index (BMI) 28.16 (1.60) Kg/m², and duration of illness of 5.98 (1.44) months. Testing of variance homogeneity revealed a nonsignificant difference in the subjects' age ($p = 0.749$), weight ($p = 0.155$), height ($p = 0.129$), and duration of illness between the groups ($p = 0.30$). There was no significant difference ($p < 0.05$) in the patients' age, weight, height, and BMI between the treatment groups (Table 1).

The Wilcoxon signed-ranks test showed significant decreases in VAS and NDI post-treatment in all treatment groups compared to baseline values. No significant difference was found between the three groups' baseline mean NDI and VAS scores using the Kruskal–Wallis test. However, when the test was applied to the scores post-treatment, a significant difference between the treatment groups was found, as shown in Table 2. All groups exhibited significant decreases in VAS and NDI. Dunn's test for multiple comparisons showed the greatest significant improvement in both VAS and NDI post-treatment in the MLS + EX group, more than the significant reduction in the LLLT + EX group, and the least significant decrease was in the PL + EX group (Table 3). Computing the effects size of MLS plus exercises to exercises alone on pain showed Cohen's $d = 2.223$ with confidence coefficient (−1.303 to 5.748) and effect size $r = -0.74$. In LLLT + EX, the effect size r was -0.44 and Cohen's $d = 0.98$ with confidence coefficient (−1.949 to 3.922). For NDI, the effect size was calculated among

TABLE 1. PATIENTS DEMOGRAPHIC DATA

	MLS + EX Mean ± SD	LLLT + EX Mean ± SD	PL + EX Mean ± SD	p
Age (years)	46.6 ± 6.10	45.20 ± 6.10	47.04 ± 5.54	0.521 ^a
Weight (Kg)	83.64 ± 7.175	83.60 ± 4.36	84.12 ± 5.27	0.938 ^a
Height (m)	1.74 ± 4.71	1.71 ± 3.91	1.71 ± 5.83	0.112 ^a
BMI (kg/m ²)	27.57 ± 2.13	28.45 ± 1.06	28.47 ± 1.29	0.076 ^a
Duration of illness (months)	6.0 ± 1.22	5.68 ± 1.49	6.28 ± 1.568	0.341 ^a

^aNonsignificant difference in pre-treatment mean values (ANOVA; $p < 0.05$).

BMI, body mass index; MLS, multiwave locked laser system; LLLT, low-level laser therapy; PL, placebo laser; EX, exercises; SD, standard deviation; p , probability value.

TABLE 2. CHANGES IN THE VISUAL ANALOGUE SCALE AND NECK DISABILITY INDEX AMONG TREATMENT GROUPS

	VAS			NDI		
	Pre-treatment	Post-treatment	p	Pre-treatment	Post-treatment	p
MLS + EX	39.76	19.58	<0.0001 ^a	37.80	17.82	<0.0001 ^a
LLLT + EX	37.88	38.90	<0.0001 ^a	36.08	37.18	<0.0001 ^a
PL + EX	36.36	55.52	<0.0001 ^a	40.12	59.00	<0.0001 ^a
Qi-square	0.35	37.4		0.43	46.35	
p	0.839 ^b	<0.0001 ^c		0.803 ^b	<0.0001 ^c	

^aSignificant difference in the same treatment group (Wilcoxon signed-ranks test; $p < 0.05$).

^bNonsignificant difference in pretreatment mean values (Kruskal–Wallis test; $p < 0.05$).

^cSignificant difference between treatment groups (Kruskal–Wallis test; $p < 0.05$).

VAS, visual analogue scale; NDI, neck disability index; MLS, multiwave locked laser system; EX, exercises; LLLT, low-level laser therapy; PL, placebo laser; p, probability value.

treatment groups and showed effect size $r = -0.79$ and Cohen's $d = 2.63$ (-1.155 to 6.416) for MLS + EX, while $r = -0.635$ and Cohen's $d = 1.646$ (-1.561 to 4.853) in LLLT + EX compared to PL + EX.

Discussion

CNP is a common patient complaint. Despite its prevalence and causes, so many treatment approaches exist in the literature, varying from nonsteroidal anti-inflammatory drugs, modification of work environment, use of neck support, passive interventions such as massage, electrotherapy, mechanical traction, and mobilization, and manipulation to surgery in advanced cases.³⁴ Laser therapy is a safe treatment intervention that has been widely used in the treatment of patients with both acute and CNP.³⁵

A relatively new form of laser therapy is MLS laser therapy, in which one pulsed laser beam and one continuous laser beam are combined into a synchronized, dual-wavelength emission. When applied to tissue, MLS can have analgesic, anti-edematous, and anti-inflammatory effects. The physiological effects of MLS therapy are believed to be maximized by combining the individual benefits from the two modes of operation of the constituent beams within the laser. The pulsed component has an immediate pain relieving effect by reducing the velocity of nerve transmission.²³ The continuous component is less effective at relieving pain, rather it acts upon inflammation and edema, which the pulsed component does not. It is thought that the action of this mode is achieved by encouraging adenosine triphosphate production, stimulating blood and lymphatic circulation, and the subsequent faster reabsorption of fluid.³⁶

Laser penetration into tissue is dependent on the wavelength of the laser light, longer wavelengths being more penetrating.

The most common lasers are based on GaAs diodes or Gallium-Aluminum-Arsenide (GaAlAs) diodes, which emit light in the near-infrared spectrum. GaAs lasers emit light at 904 nm, which penetrate to depths of ~ 50 mm.³⁷ GaAlAs lasers emit light at 830 nm,^{38,39} which penetrate to between 20 and 30 mm.¹⁴

In this study, after 6 weeks of MLS laser therapy, patients showed marked improvement in CNP in the MLS + EX group by showing improvements in all neck functions as demonstrated by the NDI. The effect of MLS laser therapy has also been observed in Raynaud's phenomenon²⁷ and knee osteoarthritis.¹⁸ In a double-blind, randomized placebo-controlled study, significant reduction in neck pain was observed after 3 months of treatment utilizing a power of 300 mW and wavelength of 830 nm compared to sham laser.²¹ The percent of improvement in VAS Score was 44% in laser treatment group compared to 2.1% in the placebo group.²¹ Another study investigated the clinical efficacy of low-power laser therapy (LPLT) on pain and function in cervical osteoarthritis. It showed significant improvement in the group treated with LPLT, with no improvement in the placebo group.¹⁹ In this study, the percent of VAS improvement was 65.9% in the laser group compared to the placebo group (29.82%), with 66.7% improvement in neck pain after 3 months of laser treatment compared to 16.6% in the placebo group.¹⁹ Although it is difficult to compare the outcome of this study with the previously mentioned studies due to different methods of application and various therapy regimens with different doses, wavelengths, and power, the percent of VAS improvement in the two previous studies was consistent with the result of this study.

However, it has been assumed that laser therapy may do its effect through treatment of the trigger points and may assist in connective tissue healing,⁴⁰ causing anti-inflammatory effect,⁴¹ enhancing the release of endogenous opioids, and producing anti-edematous effect.³⁵ Furthermore, the frequent

TABLE 3. DUNN'S MULTIPLE COMPARISONS TEST

	VAS		NDI	
	Rank sum difference	p	Rank sum difference	p
MLS + EX vs. LLLT + EX	-20.500	<0.05 ^a	-18.50	<0.05 ^a
MLS + EX vs. PL + EX	-38.0	<0.001 ^a	-40.00	<0.001 ^a
LLLT + EX vs. PL + EX	-17.50	<0.01 ^a	-21.50	<0.01 ^a

^aSignificant difference between treatment groups (Dunn's multiple comparisons test; $p < 0.05$).

VAS, visual analogue scale; NDI, neck disability index; MLS, multiwave locked laser system; EX, exercises; LLLT, low-level laser therapy; PL, placebo laser; p, probability value.

use of laser may decrease the input of the A δ and C fibers to the dorsal horn and thus enhance reorganization of synaptic connections in the central nervous system, resulting in pain inhibition.⁴² In addition, it is known that anti-inflammatory, analgesic, and antiedematous benefits can be achieved through the use of MLS laser therapy.⁴³

In this study, MLS + EX was effective in reducing pain and neck disability more than LLLT + EX or exercises alone. Patients who were recruited in this study had non-specific chronic mechanical neck pain, which covered a broad category of patients who may suffer from neck sprain, muscular neck pain, myofascial pain syndrome, postural neck pain, cervical, or facet joint arthritis. Although patients may have different causes of CNP, the main concern of this study was their level of pain and functional impairment, which may be considered a limiting factor in this study. In further studies, the changes in muscle status (strength, activity, or trigger point tenderness) or categorization of the recruited patients to subgroups according to same definite diagnosis may be considered.

Conclusions

The MLS laser therapy is considered an effective therapeutic tool in the treatment of CNP. The use of MLS in conjunction with a suitable program of exercise was more effective in reducing neck pain and improving neck function than LLLT or exercise alone.

Recommendations

The study has shown that MLS is an effective therapy for aiding recovery from CNP, especially when used in conjunction with exercises. It is recommended that further research into the long-term effect of MLS laser therapy in the treatment of a wider range of musculoskeletal disorders be performed.

Limitation

All patients were males as they were recruited from the male section of the physiotherapy and rehabilitation department of the hospital. The treatment program included exercises in all treatment groups, at home. Although there was no report of patients not doing home exercises, we considered it as a limitation point.

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Author Disclosure Statement

No competing financial interests exist.

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