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ORIGINAL ARTICLE

Effectiveness of multiwave locked system laser on the treatment of patients with idiopathic Bell's palsy: a randomized double-blind placebo controlled trial

Mohamed Salaheldien Alayat[1] · **Ahmed Mohamed Elsodany**[2] · **Nahla Ahmad AlMatrafi**[1] · **Amir Abdel Raouf El Fiky**[3]

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Abstract

The objective of this study is to investigate the effect of scanning and point application of multiwave locked system (MLS) laser therapy on the recovery of patients with idiopathic Bell's palsy (IBP). A randomized double-blind placebo-controlled trial was carried out on 60 patients with subacute BP. Patients were randomly assigned into three groups of 20 patients each. Facial massage and facial exercises were applied to all patients. Group one received MLS laser as a manual scanning technique (10 J/cm^2, area 50cm^2, total energy 500 J). Group two received MLS laser using point application technique (10 J/point, 8 points, total 80 J). Group three received placebo laser. House–Brackmann scale (HBS) and facial disability index (FDI) were used to evaluate the facial recovery. Assessment was performed at baseline and after 3 and 6 weeks of treatment. Comparison within and between groups was performed statistically with significance level $p < 0.05$. Results showed significant improvement in the FDI and HBS after treatment in all groups. Both scanning and point application significantly improved the score of FDI and HBS more than placebo group. Scanning technique combined with facial massage and exercises had a more significant effect than the point application group or the placebo group in improving FDI and HBS scores after 3 and 6 weeks of treatment. The MLS laser is an effective physiotherapy method used for the treatment of patients with IBP. MLS laser in scanning or point application techniques was more effective than exercise alone with greater effect of scanning technique than point application technique.

Keywords Bell's palsy · Multiwave locked system · Facial disability index · House–Brackmann scale

Introduction

The face forms the main essential segment of the body regarding one's appearance and it is a critical part of self-impression [1]. Facial nerve palsy means paralysis of one facial muscles innervated by the seventh cranial nerve (facial nerve) [2]. It may be caused as a result of stroke and to a lesser extent from diabetes mellitus, hypertension, herpes zoster, Lyme disease, Ramsay Hunt syndrome, amyloidosis, eclampsia, sarcoidosis, and parotid nerve tumors [2]. Facial palsy results in impaired facial expressions and psychological affection which lead to affect social communication and connections markedly [2].

Idiopathic Bell's palsy (IBP) is sudden onset unilateral paralysis of the facial muscles, which cannot be recognized as any disease of the central nervous system or ear [3]. The absence of trauma and the sudden onset may distinguish the IBP from other causes of facial paralysis [4]. Several estimations arise in the literature regarding

✉ Mohamed Salaheldien Alayat
mohsalahpt@hotmail.com; msatyiat@uqu.edu.sa

Ahmed Mohamed Elsodany
ahmed_sodonay@hotmail.com

Nahla Ahmad AlMatrafi
s44285499@st.uqu.edu.sa

Amir Abdel Raouf El Fiky
aafiky@uqu.edu.sa

[1] Physiotherapy and Rehabilitation Department, Faculty of Applied Medical Science, Umm Al-Qura University, Makkah, Saudi Arabia

[2] Department of Basic Science, Faculty of Physical Therapy, Cairo University, Giza, Egypt

[3] Department of Physical Therapy for Neurological Disorders and Its Surgery, Faculty of Physical Therapy, Cairo University, Giza, Egypt

the incidence of BP to be 20–25 cases [5], 23–35 cases [6], 13–34 cases [7], and 15–30 cases [8] per 100,000.

About 71% of IBP cases resolved spontaneously and 84% of patients returned to their normal function [9], while the rest will continue with facial motor dysfunction, which involves moderate to severe weakness of the facial muscles, synkinesis, or facial contracture. Pain behind the ear is a common symptom present in some cases, but it is unusual and the etiopathogenesis unclear [10]. The degree of weakness at onset may predict the recovery. With partial paralysis, complete recovery occurs to about 94% of patients within 4 months while in severe nerve dysfunction, complete recovery occurs only 61% of cases [9]. A recently published prospective study reported that the degree of weakness after 1 week of onset is the prediction factor for recovery for IBP [11].

Many physiotherapy interventions are utilized for the treatment of IBP including facial exercises, facial massage, heat application, electrical stimulation, and biofeedback [12, 13]. Over the last three decades, low-level laser therapy (LLLT) has been broadly investigated as a method of intervention in the treatment of affected nerves [14–17]. The effect of LLLT may differ depending on different properties of laser including laser source, power, fluency, wavelength, and the mode of application which can be either in continuous or in pulsed mode [18].

Class IV lasers are high-power lasers (> 0.5 W) that can emit a high fluency level, scan large areas, and encourage repair process [19]. This type of laser is considered as an effective and safe treatment method used for modulation of localized pain in hyperirritable points such like the trigger point in patients with the myofascial pain syndrome [20–23].

Recent articles represent the multiwave locked system (MLS) laser therapy as a recent therapeutic tool used in the rehabilitation due to its specific features. MLS laser is a Class IV laser with a high peak power, which is characterized by a synchronized emission of continuous 808 nm and pulsed 905 nm waveforms [24]. MLS was used recently in researches and showed a significant modulation of musculoskeletal pain and associated disability [20, 25] with an estimate that such synchronization of the dual laser wavelengths has better efficacy [26].

Previous studies proved the positive effect of both LLLT [27] and high-intensity laser therapy (HILT) [28] in the management of IBP. However, there was no study—for the available literature—that investigated the effect of MLS in cases of IBP till now. Therefore, the aim of the current study was to investigate the efficacy of both scanning and point application of MLS laser therapy on the recovery of patients with idiopathic Bell's palsy (IBP).

Materials and methods

Trial design

This study was performed in double-blind controlled trial design after being approved by the biomedical research ethics committee at Umm Al-Qura University, Mecca, Saudi Arabia, with an approval number (HAPO-02-K-012–2022-01–911).

Individuals with BP were evaluated and referred by independent physicians from neurology department at Makkah hospitals. The first author conducted the processes of participant enrollment and allocation. Randomization was performed using online GraphPad and creating a random number for each patient. The allocation concealment was performed by an opaque, sealed envelope for each individual containing which group the patient belonged. Neither the assessor nor the laser applicant was oriented about the randomization process. This trial was carried out at the Physical Therapy Department, Umm Al-Qura University. Patients who participated in the current study were randomly assigned into three treatment groups. The same therapist treated the patients, and the study variables were measured by the same assessor. Study was registered in ClinicalTrials.gov with a registration number NCT05270187 and conducted in accordance with the Consolidated Standards of Reporting Trials (CONSORT) checklist [29].

Participants

Power analysis was performed to calculate the proper sample size by G-power software (for windows) with power (1-β error) = 0.90 and average effect size = 0.25, for three groups, three measurement intervals, and using a repeated measure analysis of variance (ANOVA), within and between interaction, to calculate the *F*-test. It revealed a total of 45 patients. The total number was increased to 60 for possible patient withdrawal. The effect size was based on our previous study with HILT on facial palsy [28].

Sixty subjects participated in the current study. All participants were eligible to participate in the study if they had BP and after referral from independent physicians. The inclusion criteria were (1) patient who had unilateral IBP either on the right or left side; (2) patient participated after 3–5 days after the acute onset subsided; and (3) able to communicate and answer questions. Patients were excluded if they had (1) central nervous system pathology; (2) sensory loss over the face; (3) recurrence or chronic BP; (4) upper motor facial nerve palsy; and (5) any infant or child (≤ 18 years) with IBP. A sufficient explanation

about the nature of the study and the intervention protocol was given to all patients. Each patient signed a consent form indicating their approval to participate in the study and publish their results. Patient's identities as well as the group randomization were kept anonymous.

Interventions

MLS laser therapy

MLS laser therapy was applied by using M6 laser equipment (ASA, Arcugnano, Italy). MLS laser therapy is a Ga-Al-Ar laser which has synchronized emission of continuous wavelength of 808 nm, a peak power of 1000 mW, mean power of 500 mW and pulsed wavelength of 905 nm, peak power of 25 W, mean power of 54 mW, and frequency of 1500 Hz. The dual wavelengths are emitted in a single handpiece with 2-cm diameter and 3.14-cm^2 spot area. Laser dose was calculated based on a previous study that considered 10 J/cm^2 as a safe therapeutic dose [28].

In the current study, both scan and point applications were used. Group one (scan group) received MLS laser in scanning mode plus massage to the facial muscles and facial expression exercises. Scanning was performed manually covering one-half of the face and scanning the affected side of the facial muscles. The average treatment area was 50 cm^2. The laser parameter was the following: 10 J/cm^2 energy density, 10 Hz frequency, time for treatment 15 min and 9 s, and 500 J total delivered energy (Table 1).

Group two (point application group) was treated with MLS applied over eight points plus massage to the facial muscles and facial expression exercises. Point application was applied with the handpiece positioned perpendicular to 8 points which are located on the branches of the affected facial nerve (Fig. 1). Each point received 10 J/point, 10 Hz frequency, and 37 s/point with total delivered energy of 80 J. Some precautions and procedures were performed such as (1) laser probe applied perpendicular over the patient skin to avoid reflection, (2) probe was not used near the eye region and both patients and therapist wore laser goggles, (3) male patients' beard was shaved, (4) dry the face before exposure, and (5) session was terminated in case of discomfortable sensation or any possible heat sensation. Group three (placebo group) received sham laser plus massage to the facial muscles and facial expression exercises and is serving as a control group. Laser was calibrated by the manufacturing company before starting the experiment and periodically during the sessions.

Exercises

Patients in all treatment groups received massage to the facial muscles and facial exercises. The facial exercises may include different facial expressions in front of mirror, applying a resistance to the sound side to reinforce the weakened side. A resisted exercise to the neck muscles was performed in all direction to encourage the movement of the facial muscles as neuromuscular facilitation exercises for facial muscles [30]. Facial massage and exercises were applied after active or placebo laser two times a week for at least 6 weeks. The same physical therapist taught all patients to perform massage and exercises at home. Patient or one of his/her family members ensured that the patients performed the massage and exercises at home.

Table 1 Laser parameters used in the current study

Item	Scan group	Point application group
Laser source	Ga-Al-Ar laser	Ga-Al-Ar laser
Wavelength	CW of 808 nm, PW of 905 nm	CW of 808 nm, PW of 905 nm
Peak power	1000 mW for 808 nm 25 W for 905 nm	1000 mW for 808 nm 25 W for 905 nm
Average power	500 mW for 808 nm 54 mW for 905 nm	500 mW for 808 nm 54 mW for 905 nm
Beam diameter	2 cm	2 cm
Beam area	3.14 cm^2	3.14 cm^2
Frequency used in the current study	10 Hz	1500 Hz
Energy density (fluence)	10 J/cm^2	10 J/point for 8 points
Area	50 cm^2	3.14 cm^2
Total energy	500 J	80 J
The duration of each treatment session	15 min and 9 s	37 s/point
The frequency of treatment	Two sessions per week for 6 weeks	Two sessions per week for 6 weeks
The cumulative dose	2 × 6 = 12 sessions	2 × 6 = 12 sessions

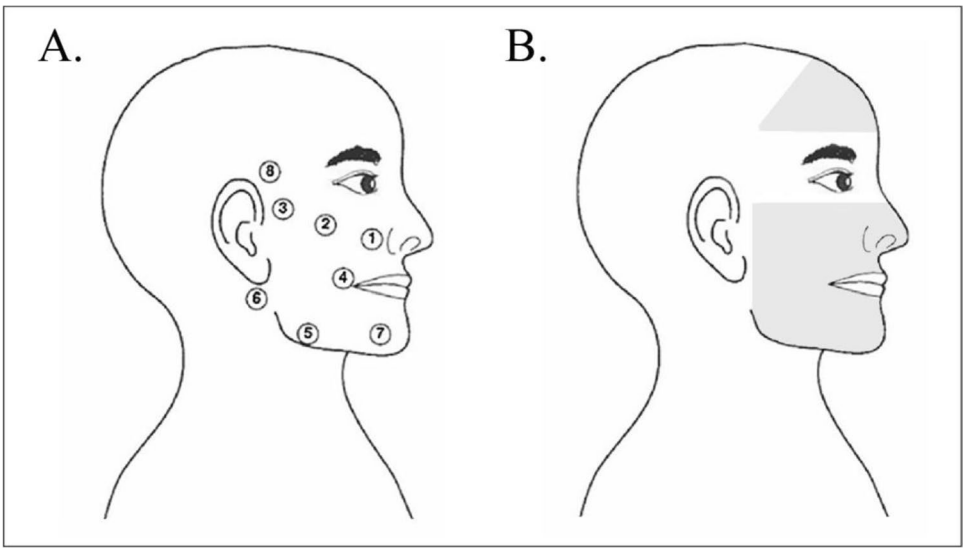

Fig. 1 **A** Eight points of laser application used in the treatment of Bell's palsy (adapted from Bernal 1993). **B** Scanned area of MLS laser on the affected facial side

Outcome measurements

Facial Disability Index (FDI) and House–Brackmann Scale (HBS) were used to evaluate the degree of facial nerve recovery. The scores of both scales were collected at the baseline and after 3 and 6 weeks of treatment.

The FDI was used to assess the dysfunction in the facial muscles [31]. The FDI index is considered as a valid and reliable measurement index for evaluating patients with facial nerve disorders [32]. It is divided into two subscales, Physical Facial Disability Index (PFDI) and Social Facial Disability Index (SFDI). The index contains 10 items with a 100-point scale, where the higher the score the less dysfunction and impairment [6].

The HBS is one of different scales used for the quantification of the facial function by providing reproductive measurable degrees the paralysis of the facial nerve [6]. The HBS has been spread out to be widely acceptable scale for evaluating facial paralysis because of its usability, reliability, accuracy, and sensitivity [33]. The HBS scale evaluates the facial symmetry, synkinesis, stiffness, and global mobility [6]. It has six grades in which the first grade indicates a normal function and sixth grade indicating complete paralysis [34].

Statistical analyses

Analyses of parametric data like the patients' age were performed using ANOVA test compared between the treatment groups. For non-parametric data, the Kruskal–Wallis test was used to compare between the HBS, PFDI, and SFDI scores among treatment groups at baseline and after 3 and 6 weeks of treatment. In case of statistical differences at measurement intervals, Mann–Whitney test was used. Friedman test was used to analyze the effect of intervention within each group. The software used for the analysis for the parametric and non-parametric data was SPSS (version 20).

Results

A total of 60 patients with a mean age ± SD (40.03 ± 8) years successfully completed their treatment sessions. No patients were dropout in the follow-up (Fig. 2). There was a non-significant difference ($p = 0.93$) among patients' mean of age in the scan, Point application, and placebo groups (40.6 ± 8, 39.8 ± 8.3, and 39.7 ± 8.8 years), respectively.

At baseline, there was a non-significant difference in the HBS, PFDI, and SFDI among treatment groups. However, at post treatment, there were statistically significant differences in all three groups. Furthermore, comparison between groups revealed significant differences in the results of HBS, PFDI, and SFDI at 3 weeks and 6 weeks after treatment with a greatest effect observed in the scan group followed by point application group with a least effect in the placebo group (Table 2, Fig. 3).

Discussion

The present study aimed to investigate the efficacy of both scanning and point application of MLS laser therapy on the recovery of patients with IBP. Results showed that MLS significantly improved the score of FDI and HBS. Moreover, MLS applied in scanning technique combined with facial massage and exercises had a more significant effect than the point application group or the placebo group.

Recently, Tanganeli et al. reported that proper use of photobiomodulation alone is an effective treatment choice for patients with BP, regardless the age of patients. Additionally,

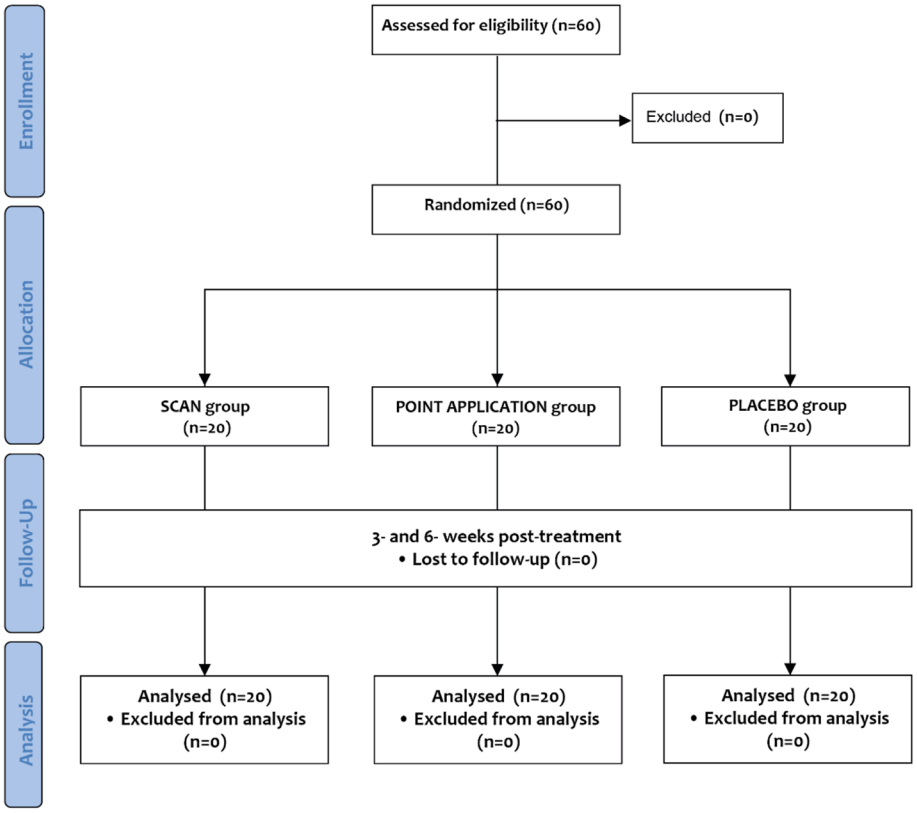

Fig. 2 Flow diagram of the study

they observed significant recovery after the 5th session with complete recovery after 10 exposures which can reduce recovery time gained with traditional modalities and prevent complications [35]. Moreover, Ladalardo et al. demonstrated functional improvement in HBS from one to three grades after treatment with GaAs diode laser in patients with BP [36]. Furthermore, Alayat et al. investigated the effect of both HILT and LLLT in the recovery BP. The results showed

Table 2 Comparison of the HBS, PFDI, and SFDI among treatment groups

Outcome			Scan group	Point application group	Placebo group	K.W	*p* value
House–Brackmann Scale (HBS)	Mean rank of K.W	Baseline	32.6	30.5	28.4	0.66	0.72
		Post-3 weeks	46.9	28.23	16.4	33.54	**< 0.01**[b]
		Post-6 weeks	47	27.9	16.6	32.52	**< 0.01**[b]
	Chi-square		40	39	38.32		
	p-value		**< 0.01**[a]	**< 0.01**[a]	**< 0.01**[a]		
Physical Facial Disability Index (PFDI)	Mean rank of K.W	Baseline	30.38	31.13	30	0.48	0.9
		Post-3 weeks	44.83	36.18	10.5	42.23	**< 0.01**[b]
		Post-6 weeks	44.78	36.23	10.5	42.27	**< 0.01**[b]
	Chi-square		40	40	39.5		
	p-value		**< 0.01**[a]	**< 0.01**[a]	**< 0.01**[a]		
Social Facial Disability Index (SFDI)	Mean rank of K.W	Baseline	27.88	32	31.63	0.72	0.7
		Post-3 weeks	47.53	32.43	11.55	43.16	**< 0.01**[b]
		Post-6 weeks	45.23	35.53	10.75	41.74	**< 0.01**[b]
	Chi-square		38.1	40	40		
	p-value		**< 0.01**[a]	**< 0.01**[a]	**< 0.01**[a]		

K.W., Kruskal–Wallis; *p value*, probability value

[a]Significant difference among treatment intervals

[b]Significant difference among treatment groups

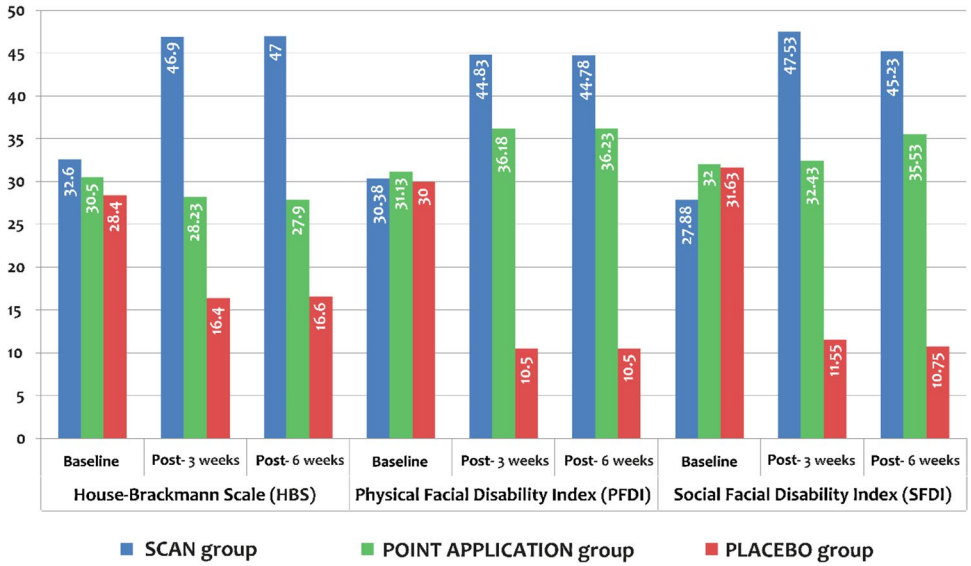

Fig. 3 Comparison of the HBS, PEFI, and SFDI among treatment groups

that both HILT and LLLT were effective treatment modalities in the recovery of patients with IBP with the HILT being superior to the LLLT [28].

MLS laser therapy is high-power laser in which pulsed and continuous laser beams are in synchronized emissions. When dual-wavelength emission is applied to tissue, it is thought to have anti-inflammatory effect. The therapeutic outcomes of MLS laser therapy are supposed to be augmented by the combination of the effects of the two laser beams [37]. The pulsed beam reduces the nerve conduction velocity causing analgesic effect [38], while continuous beam has antiedematous and anti-inflammatory effects with less effect on pain relief. It produces through increasing the production of adenosine triphosphate, increasing blood and lymphatic circulation resulting in rapid reabsorption of edema [39]. Laser therapy is believed to alter the level of pro-inflammatory cytokines and promote the anti-inflammatory growth factors resulting in blood vessel dilatation [40]. In addition, MLS laser has been found to alter the fluidity of the erythrocyte membrane causing [41].

Penetration of laser into tissue depends on its wavelength; longer wavelengths allow more penetration. Most of the lasers used nowadays depend on gallium aluminum-arsenide (Ga-Al-As) as an active medium, which produces laser in the near-infrared band. Ga-As lasers produce laser at 904 nm, which can reach about 50-mm depths [42], while 830 nm Ga-Al-As lasers can penetrate to 20–30 mm [18, 43]. Laser showed strong achievements in increasing nerve recovery rate as it enhances microcirculation, nerve electrical conductivity, and rate of axonal growth. Additionally, it enhances the regeneration of the injured nerve even with delayed application [16, 28, 44–46].

The present study showed that the scan group is the most effective technique of application followed by point application technique with the lowest effect in placebo laser after 3 and 6 weeks of application. This finding is in line with previous study by Pereira et al. who used scanning of high-power laser to enhance tissue repair of unhealed wounds [47]. Scanning laser therapy technique helps in covering the whole area of treatment and provides uniform distribution of the energy, even over large areas, contrary to point application.

On the other hand, Chen YS et al. used pulsed Ga-As 904 nm LLLT with a dose ranging from 2.23 to 3.88 J/cm^2 for one group and 8.92 to 15.5 J/cm^2 of other group and observed that laser therapy could have a double effect: it could enhance nerve regeneration, but additionally could have delay nerve recovery. Pulsed 904 nm laser could affect the sensory nerve transmission, thus improving the latency of regenerating nerves. In addition, they reported the presence of smaller myelinated axons in nerves treated by laser which could explain their findings [48].

This study has some limitations. Firstly, all included patients had first incidence of BP and in the subacute stage, thus limiting the generalization of the results to patients with chronic or recurrent BP. Secondly, facial recovery was measured with FDI and HBS; although these scales have good psychometric properties [31, 33], using of nerve conduction studies may be required to provide more objective results. Lastly, patient satisfaction with the treatment was not measured.

Conclusion

The MLS laser is an effective physical therapy method used for the treatment of patients with IBP. Addition of MLS laser in either scanning or point application techniques to facial expression exercises and facial massage was more effective

than the exercise alone. Moreover, scanning technique had a slightly greater effect than point application technique.

Declarations

Conflict of interest The authors declare no competing interests.

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