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ORIGINAL ARTICLE

Efficacy of high and low level laser therapy in the treatment of Bell's palsy: A randomized double blind placebo-controlled trial

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Abstract The aim of the present study was to investigate and compare the effects of high intensity laser therapy (HILT) and low level laser therapy (LLLT) on the treatment of patients with Bell's palsy. Forty-eight patients participated in and completed this study. The mean age was 43 ± 9.8 years. They were randomly assigned into three groups: HILT group, LLLT group, and exercise group. All patients were treated with facial massage and exercises, but the HILT and LLLT groups received the respective laser therapy. The grade of facial recovery was assessed by the facial disability scale (FDI) and the House–Brackmann scale (HBS). Evaluation was carried out 3 and 6 weeks after treatment for all patients. Laser treatments included eight points on the affected side of the face three times a week for 6 successive weeks. FDI and HBS were used to assess the grade of recovery. The scores of both FDI and HBS were taken before as well as 3 and 6 weeks after treatment. The Friedman test and Wilcoxon signed ranks test were used to compare the FDI and HBS scores within each group. The result showed that both HILT and LLLT significantly improved the recovery of patients with Bell's palsy. Moreover, HILT was the most effective treatment modality compared to LLLT and massage with exercises. Thus, both HILT and LLLT are effective physical therapy modalities for the recovery of patients with Bell's palsy, with HILT showing a slightly greater improvement than LLLT.

Keywords Bell's palsy · HILT · LLLT · FDI · HBS

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Introduction

The face is considered to be psychologically the most important part of the body and an important component of self-concept [1]. Facial nerve paralysis is a common problem that affects facial appearance and involves the paralysis of any structures innervated by the facial nerve [2]. Lesions of the facial nerve can result in partial or full paralysis of one side of the face with impaired facial movement [3] and diminished facial expression, which interferes with the interaction with others and face-to-face communications [2]. In addition, patients with unilateral or bilateral facial paralysis have difficulties in eating, drinking, and speaking, which subsequently leads to impairment in the activities of daily living as well as social and psychological difficulties, including decreased self-esteem, anxiety, depression, and social isolation [1].

Facial paralysis can result from congenital, idiopathic, neoplastic, iatrogenic, infection, trauma, herpes zoster, tumors, diabetes mellitus, polyneuropathy, and other inflammatory causes [4]. The most common unilateral facial paralysis is Bell's palsy, also known as idiopathic facial paralysis, which is an acute paralysis of the face due to a nonsuppurative inflammation of the facial nerve near the stylomastoid foramen [5]. Bell's palsy is differentiated from other causes of facial paralysis by the absence of trauma and its rapid onset over several hours [6]. It is thought to account for approximately 60–75 % of cases of acute unilateral facial paralysis and has an annual incidence ranging from

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23 to 35 cases for 100,000 people in both sexes, mostly between the ages of 30 and 50 years [5]. Upon physical examination, the patient is unable to raise the eyebrow or tightly close the eyelid on the affected side. Moreover, the nasolabial fold is typically absent, and the mouth may be drawn toward the unaffected side. Patients may drool from the affected side because of an inability to keep the mouth closed [7].

Electrotherapy, massage, facial exercises, and biofeedback are different physical therapy modalities that have been used for the treatment of Bell's palsy with a concentration on the role of exercise therapy more than other interventions [5]. The aim of these modalities is to increase muscle and nerve function either through exercise or electrotherapy. Furthermore, thermal methods and massage work can decrease swelling and increase blood flow to the affected tissues, thereby increasing the amount of oxygen available to damaged hypoxic tissues with the aim of promoting recovery [8].

Laser therapy is a modality that can be used in the treatment of Bell's palsy. It is considered a non-invasive and painless therapeutic modality that can be used for any type of patient, including those who cannot use corticosteroids, such as diabetic and hypertensive patients [9].

Laser therapy has a favourable prognosis in the regeneration of peripheral nerves in both neurosensory and neuromotor deficits [10], such as trigeminal neuralgia, neuropathy, lower back pain with sciatica, and herpes zoster [11]. Application of a laser produces both local and systemic effects that can enhance the nerve regeneration process [11]. Moreover, laser improves the recovery of the injured peripheral nerve and decreases post-traumatic retrograde degeneration of the neurons in the corresponding segments of the spinal cord [12].

Research studies have shown that low level laser therapy (LLLT) increases the functional activity of the injured peripheral nerve, prevents or decreases degeneration in corresponding motor neurons of the spinal cord, and improves the axonal growth and myelinisation [13]. Recently, high intensity laser therapy (HILT) was introduced to the field of physical therapy and approved by the Food and Drug Administration (FDA) in 2004. The recent development of a high-power pulsed neodymium-doped yttrium aluminum garnet (Nd-YAG) laser (wavelength, 1,064 nm), which works with high peak power, has been shown to induce a non-invasive regenerative therapy capable of reaching and stimulating organs that are difficult to reach with classical lasers, such as large and/or deep areas [14]. Recent studies have described the anti-inflammatory, anti-oedemigenic, and antalgic effects of Nd:YAG laser, justifying its use as therapy for pain and inflammation [15].

As mentioned above, laser affects tissues differently depending on the wavelength, pulse duration, pulse/energy, energy density, and delivery system. Studies of laser dose response suggest that different wavelengths have specific penetration abilities and subsequently different effects on tissue [16, 17]. Based on the limited number of studies to date that have investigated the effect of laser therapy (HILT or LLLT) on the treatment of Bell's palsy as well as the existence of new treatment modalities, such as HILT, there is still a need for further investigation of laser therapy in the treatment of acute and chronic Bell's palsy. Therefore, the aim of the present study was to investigate and compare the effects of HILT and LLLT on the treatment of patients with Bell's palsy.

Subjects and methods

Subjects

Patients with Bell's palsy who participated in this study were recruited from Al-Noor Hospital, Makkah, Saudi Arabia. The mean age of the patients was 43±9.8 years. The inclusion criteria for patient selection were any patient who had unilateral Bell's palsy either on the right or left side [18]. Treatment began in the sub-acute stage of illness 3–5 days after the acute onset subsided. We excluded patients who had central nervous system pathology, sensory loss over the face, or recurrence of Bell's palsy [19].

Power analysis

In a nonparametric test, no assumptions need to be made regarding the distribution of the values, as non-parametric tests are based on ranking values from low to high and we did not know the shape of the underlying distribution. In order to compute the sample size, a rule-of-thumb was used whereby all measured variables were non-parametric. This required calculating the sample size as in a parametric test and then adding 15 % [20]. A preliminary power analysis was applied using a power = 0.80, α=0.05, and expected effect size = 0.40, which resulted in a total sample size of 40 patients. The high effect size was recommended in order to only observe major differences between groups, which yielded a realistic sample size that allowed for the observation of major differences in the variables measured [21].

Randomization

Patients were randomized into three groups consisting of 17 patients each. Randomization was performed simply by assigning a specific identification number for each patient. These numbers were randomized into three groups using the SPSS program (IBM, Inc., USA). A randomized trial was used so the patients did not know to which group they were assigned and which treatment would be given. The therapists were

blinded to the group assignment as well, and therefore neither patients nor the therapist knew who was in which group.

Group one (HILT group) received HILT, facial massage, and facial expression exercises, group two (LLLT group) was treated with LLLT, facial massage, and facial expression exercises, and group three (exercise group) was treated with facial massage and facial expression exercises plus a sham laser (Fig. 1). All patients were given a full explanation of the treatment protocol and written informed consent was provided for their participation in the study and publication of the results. The study was approved by the departmental council of the Physical Therapy Department, Faculty of Applied Medical Science, Umm Al-Qura University, Makkah, Saudi Arabia.

Evaluation of facial recovery

To assess the grade of recovery, the facial disability scale (FDI) and the House–Brackmann Scale (HBS) were used. The FDI was developed by Van Swearingen and Brach [22] to enhance the assessment of facial neuromuscular dysfunction. Beyond the impairment domain, this index provides a reliable measurement with construct validity for evaluating patients with facial nerve disorders. This questionnaire has ten items that evaluate patients' physical and social aspects (mastication, deglutition, communication, labial mobility, emotional alterations, and social integration) and uses a 100-point scale, where a higher score indicates less impairment and handicap [3].

The HBS was classified as a universal scale by the American Academy of Otolaryngology, Committee of Disorders of the Facial Nerve. It was proposed and modified by House and Brackmann in 1985 [3]. Since then, the HBS has been extended to be the most accepted scale for assessing facial nerve palsy because of its ease of use and clinical sensitivity [23]. This scale analyzed the symmetry, synkinesis, stiffness, and global mobility of the face [3]. It is divided into six categories (normal, mild dysfunction, moderate dysfunction,

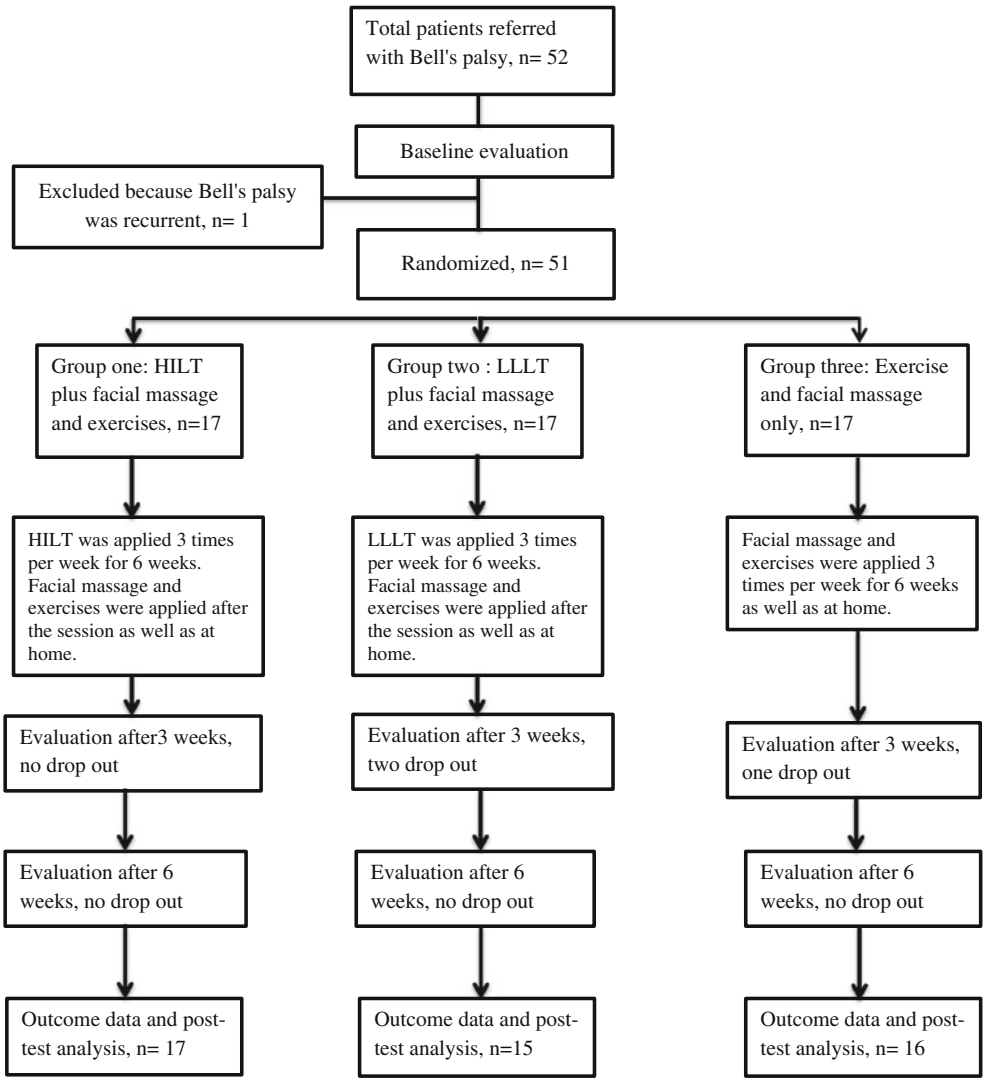

Fig. 1 Patient's flow chart

moderately severe dysfunction, severe dysfunction, and total paralysis) with grade one representing a normal facial function in all areas and grade six representing total paralysis [3]. Patients' evaluation scores of FDI and HBS were collected from all patients before treatment as well as after 3 and 6 weeks of the treatment.

HILT

The HILT group received HILT treatment with pulsed Nd: YAG laser produced by a HIRO 3 device (ASA, Arcugnano, Vicenza, Italy). The apparatus provided the following options: (Nd:YAG), with pulsed emission (1,064 nm), very high peak powers (3 kW), high levels of fluency (energy density) (810–1,780 mJ/cm), brief duration (120–150 μs), low frequency (10–40 Hz), and a duty cycle of approximately 0.1 % [14].

HILT was applied with contact and perpendicular to the superficial roots of the facial nerve of the affected side (Fig. 2). The time of application was 7 s/per point with an energy density of 10 J/cm^2. The total energy delivered to the patient during one session was 80 joules. The device calculates the number of pulses, energy received for each session, and the total energy delivered to the patient during the treatment session. HILT was applied for a total of 18 treatment sessions over a period of 6 consecutive weeks (three sessions/week). Facial massage and facial expression exercises in front of the mirror were performed after each session for all patients.

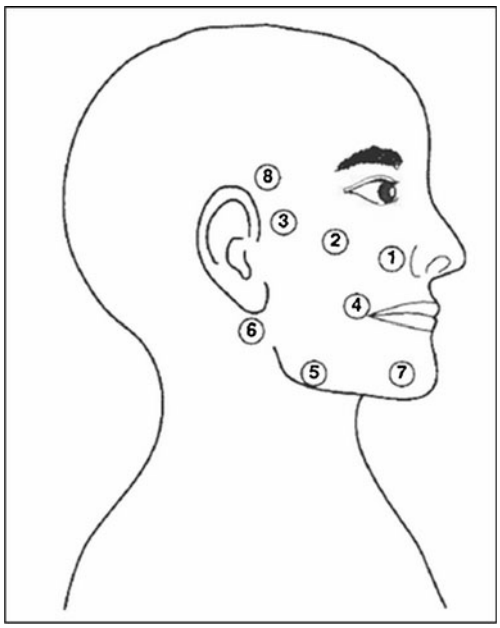

Fig. 2 Point of laser application used in the treatment of Bell's palsy (adapted from Bernal 1993)

LLLT

For LLLT, a gallium–arsenide diode (GaAs) laser (BTL-5000 laser) was used with infrared probes of 830 nm wavelength and 100 mW output power, average energy density of 10 J/cm^2, frequency of 1 KHz, and a duty cycle of 80 %. In all cases, the laser was in direct contact with the superficial roots of the facial nerve on the affected side (Fig. 2) and was applied for 2 min and 5 s per point for 8 points [24] with a total energy of 80 J. LLLT was applied for a total of 18 treatment sessions over a period of 6 consecutive weeks (three sessions/week). Facial massage and facial expression exercises in front of a mirror were performed after each session for all patients. Calibration of laser equipment was performed by the manufacturing company using a thermal power meter.

Exercises

Facial massage and facial expression exercises were carried out for all patients, including simple facial expression exercises, active graduated strengthening exercises in front of a mirror (active assisted, freedom, and resisted), proprioceptive neuromuscular facilitation exercises for facial muscles, and resisted exercises for neck muscles [19]. Participants were taught to perform massage and exercises correctly by the physiotherapist. All treatment groups were given instruction to repeat the massage and exercises two times a day for at least 6 weeks. A family member confirmed that the participant carried out the massage and exercises.

Outcome measures

To assess the grade of recovery, FDI and HBS were used. The scores of both FDI and HBS were taken before as well as 3 and 6 weeks after treatment.

Statistical analysis

Analyses of data were performed using SPSS for Windows, version 16, except for the sample size and power calculations, which were performed with G-Power 3.1 for Windows. One way analysis of variance (ANOVA) was used to compare between the patients' age in the treatment groups. Friedman test and Wilcoxon signed ranks test were used to compare the FDI and HBS scores within each group. The differences between baseline and post-treatment scale scores for each group were computed by the Friedman test. The Willcoxon signed ranks test was performed to compare between the measurements taken at pre-treatment as well as after 3 and 6 weeks of treatment. The Kruskal–Wallis test and Mann–Whitney *U*-test were used to compare the scores between the groups. The difference between treatment groups in FDI and HBS was performed by the Kruskal–

Wallis test. A Mann–Whitney test was used to compare between the same measurement interval (3 and 6 weeks) in groups in case of statistical significance. The level of statistical significance was set as $P<0.05$.

Results

The present study started with 52 patients. Four patients were excluded or withdrawn from the study. One patient was excluded after baseline evaluation because the facial palsy was recurrent. Two patients were withdrawn from the LLLT group and one patient from the exercise group because they did not follow the scheduled treatment sessions as shown in Fig. 1.

ANOVA was used to compare between the patients' age in the treatment groups and showed that there was no significant difference between patients' mean age in the HILT, LLLT, and exercise groups (43.82±10.36, 43.26±10.06, and 45.12± 9.35 years, respectively; $f=0.144$, $P=0.86$). For baseline scores, the Kruskal–Wallis test revealed no significant difference between the treatment groups in the HBS and FDI scores before treatment.

In the exercise group, the Friedman test was used to compare between the pre-treatment as well as 3 and 6 weeks post-treatment and revealed a statistical significant difference. In order to compare between each treatment interval in the exercise group, the Wilcoxon signed rank test was used and showed a statistical improvement after 3 and 6 weeks of the treatment in the HBS and FDI scores, with the greatest improvement found after 6 weeks (Table 1; Fig. 3).

Similar to the exercise group, the Friedman test and Wilcoxon-signed ranks test showed a statistical improvement in the HBS and FDI scores after 3 and 6 weeks of treatment in the HILT group and the LLLT group, with the greatest improvement observed after 6 weeks (Table 1; Fig. 3).

In order to compare the results between treatment groups after 3 and 6 weeks of the treatment, the Kruskal–Wallis test was used and showed a significant difference in the HBS and FDI score after 3 weeks of treatment (Table 1). The Mann–Whitney *U*-test revealed that the greatest improvement in the components of FDI scores occurred in the HILT group followed by the LLLT group. The least improvement was observed in the exercise group after 3 weeks of treatment. For the HBS, the best effect was obtained in the HILT group, but there no significant difference between the LLLT and exercise groups after 3 weeks of treatment (Fig. 3).

Analysis of the HBS and FDI scores with Mann–Whitney *U*-test after 6 weeks of treatment showed a significant difference between the treatment groups in the HBS and FDI scores (Table 1). The greatest effect was observed in the HILT group followed by the LLLT group, and the lowest effect was found in the exercise group (Fig. 3).

Table 1 Comparison of the HBS, PEFI and SFDI among treatment groups

	HBS				PFDI				SFDI			
	Mean rank				Mean rank				Mean rank			
	Pre- treatment	After 3 weeks	After 6 weeks	Chi-square	*P*-value	Pre- treatment	After 3 weeks	After 6 weeks	Chi-square	*P*-value	Pre- treatment	After 3 weeks	After 6 weeks	Chi-square	*P*-value
HILT	25.97	35.68	36.44	34	<0.01 [a]	20.06	37.41	39.74	34	<0.01[a]	21.91	39.21	38.47	34	<0.01[a]
LLLT	24.3	20.2	22.03	30	<0.01 [a]	27.06	25.53	21.8	30	<0.01[a]	28.77	22.33	25.73	30	<0.01[a]
Exercise	23.13	16.66	14.13	32	<0.01 [a]	26.84	9.81	10.84	32	<0.01[a]	23.25	10.91	8.5	32	<0.01[a]
K.W	0.40	19.18	23.06			2.72	32.47	36.28			2.15	34.72	38.26		
P-value	0.82[c]	<0.01[b]	<0.01[b]			0.26 [c]	<0.01[b]	<0.01[b]			0.34 [c]	<0.01[b]	<0.01[b]		

HBS House–Brackmann scale, *PFDI* physical facial disability index, *SFDI* social facial disability index, *HILT* high intensity laser therapy, *LLLT* low level laser therapy, *K.W* Kruskal–Wallis, *P-value* probability value

[a] Significant difference among the pre- treatment, after 3 weeks and after 6 weeks in each treatment group (Friedman test; $P<0.05$)

[b] Significant difference in the same measurement interval among treatment groups (Kruskal Wallis test; $P<0.05$)

[c] Non-significant difference in the pre-treatment scores among treatment groups

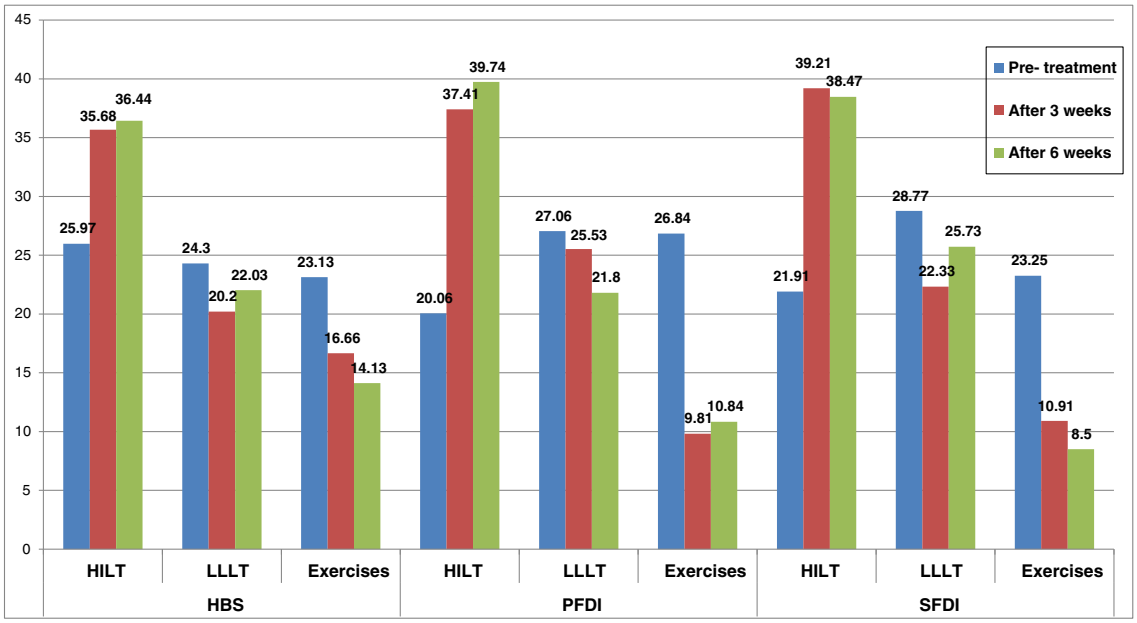

Fig. 3 Comparison of the HBS, PEFI and SFDI among treatment groups

Discussion

This study was conducted to investigate and compare the effects of HILT and LLLT on the treatment of patients with Bell's palsy. We found that both HILT and LLLT were significant treatment modalities for patients recovering from Bell's palsy. Moreover, HILT was the most effective treatment modality compared to LLLT and massage with exercises. This study assess a treatment regimen that began 3–5 days after the initial diagnosis of facial palsy during the sub-acute stage and included three sessions per week over a period of 6 consecutive weeks.

Bernal [24] previously found that LLLT is an excellent complementary medium for the recovery of facial paralysis and provides a painless therapeutic alternative without side effects that can be used on any type of patient, including those who cannot use corticosteroids, such as diabetics and hypertensive patients [24]. In addition, Ladalardo et al. [10] studied the effect of GaAs diode laser in patients with Bell's palsy and used HBS to assess the outcome. In that study, patients who received the treatment showed a functional improvement ranging between one and three grades on the HBS [10].

In spite of the many applications in humans, the biomodulative effect of LLLT has still not been completely understood. One of the possible explanations of the laser effect is through an increase in the activity of enzymes involved in the mitochondrial respiratory chain, such as cytochrome oxidase and adenosine triphosphatase (ATP) [25], thereby leading to an increase in ATP production in mitochondria [26]. In addition, it increases DNA synthesis as well as collagen and pro-collagen production [27].

The anti-inflammatory effect of laser therapy can be caused by a reduction in the levels of pro-inflammatory cytokines, such as interleukin-1 alpha (IL-1α) and IL-1 beta (IL-1β) as well as an increase in the levels of anti-inflammatory growth factors and cytokines, such as basic fibroblast growth factor (bFGF), platelet-derived growth factor (PDGF), and transforming growth factor-beta (TGF-β). In addition, laser irradiation causes dilatation of blood vessels, which also leads to a reduction in swelling caused by inflammation [28]. It may also have inhibitory effects on the release of prostaglandins, cytokine levels, and cyclooxygenase (Cox) 2, and has been shown to accelerate cell proliferation, collagen synthesis, and tissue repair [29, 30].

LLLT may also have a direct effect on nerve structures, which could increase the speed of recovery of the conduction block or inhibit Aδ and C fiber transmission [31]. Moreover, it was reported that LLLT radiation significantly widens the arterial and capillary vessels, increases microcirculation, activates angiogenesis, reduces swelling caused by inflammation, and stimulates immunological processes and nerve regeneration [32–34].

The spectrum of visible to infrared light, in which the wavelength of HILT belongs, can cause stimulation as well as inhibition of various organisms [35]. HILT also quickly reduces inflammation and painful symptoms [36]. High-power pulsed Nd:YAG laser is considered a non-invasive regenerative therapy with a non-painful and non-invasive therapeutic system, which works using high peak powers (3 kW) and a particular waveform (λ=1,046 nm) with regular peaks of elevated amplitude values and low duty cycle. This prevents the laser from reaching the thermal

tissue threshold and decreases the thermal accumulation phenomena, allowing for it to penetrate the deep tissue with photothermal, photochemical, and photomechanical effects that increase blood flow, vascular permeability, and cell metabolism [14, 26].

The limited numbers of studies using HILT limits our current understanding of the therapy, and one study has previously indicated that HILT causes minor and slow light absorption by melanin and Hbo_2 chromophores [14]. This absorption increases the mitochondrial oxidative reaction as well as ATP, RNA, or DNA production (photochemistry effects), resulting in the phenomenon of tissue stimulation (photobiology effects) [37].

Some preliminary studies have shown that HILT seems to be more effective than LLLT due to its higher intensity and the depth reached by the laser [14, 38, 39]. In addition, it was mentioned that the laser effectiveness depends on factors such as wavelength, site, duration, and dose of treatment as well as depth of target tissue. Studies on the dose response profile of laser therapy suggest that different wavelengths have specific penetration abilities through human skin [16, 17].

Although many patients with facial palsy have a spontaneous clinical recovery, approximately one-fifth of the cases are left with sequelae [40]. In Bell's palsy, spontaneous complete recovery was found in approximately 69 % of the patients [41]. Therefore, approximately 31 % of Bell's palsy patients who do receive the appropriate treatment may suffer from incomplete recovery with residual facial muscle weakness with or without one or more of the commonly encountered complications (e.g., synkinesis, hyperkinesis, and/or contracture). The latter can also cause secondary psychological sequels [40].

The course of Bell's palsy is often unpredictable and spontaneous recovery should not be expected. Although the literature refers to a 75 % recovery within 2 weeks, the remaining 25 % who do not spontaneously recover with traditional medicines and therapies will retain a notable consequence of their paralysis, which may have been preventable if they had received complementary treatment with laser within 15 days of the diagnosis [24]. Therefore the laser represents an excellent physical complementary therapy that allows recovery from facial paralysis, diminishes the possibility of side effects due to corticosteroids, and reduces the consequent results of the paralysis, which can only be treated with traditional therapy. Importantly, this treatment modality can be administered to patients who cannot tolerate corticosteroids and thus allows for recovery in a noticeable manner.

Recovery in the present study was evaluated by FDI and HBS. Although these questionnaires are considered as valid and reliable measurements [22], electrophysiological measurements may be needed to support these findings in future research.

Conclusion

We found that laser therapy in an effective physical therapy modality for the recovery of patients with Bell's palsy. Both HILT and LLLT were more effective than facial massage and exercises alone, with HILT having a more significant effect than LLLT.

Recommendation

Laser therapy has been shown to be an effective treatment modality for the recovery from Bell's palsy. HILT and LLLT are effective physical therapy tools that can be used in combination with facial massage and exercises in the rehabilitation of patients with Bell's palsy.

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