

The Efficacy of Low-Level Laser Therapy in the Treatment of Bell's Palsy in Diabetic Patients



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Abstract

Introduction: The most common causes of the abrupt onset of unilateral facial weakness are stroke and Bell's palsy. The drug regimen together with electrical stimulation was more effective in treating Bell's palsy than conventional drug treatment alone. We aimed to evaluate more effective and safe therapies for the treatment of Bell's palsy.

Methods: This clinical interventional study was conducted on 30 diabetic patients with Bell's palsy who referred to a pain clinic for 1 year and were treated by low-level laser (LLL). The system of House-Brackmann was used for assessing the severity of nerve damage and patients were evaluated by electromyography and nerve conduction study (NCS) before and after treatment with low-level laser. These patients had not consumed any other medication for facial nerve palsy.

Results: In the present study, 30 cases with poorly controlled diabetes mellitus (18 females and 12 males) were studied. After 12 sessions of low-level laser therapy (LLLT), we could observe complete recovery in 18 patients and partial recovery in 6 patients after 3 months.

Conclusion: The recovery rate showed that LLLT is a safe, reliable and proper alternative approach for the treatment of facial nerve palsy, especially in the presence of underlying conditions such as diabetes mellitus.

Keywords: Low-level laser; Diabetic patients; Bell's palsy.

Introduction

Idiopathic facial palsy is commonly known as Bell's palsy as it was described by Dr. Charles Bell in 1821 as a sudden event without a known reason, which influences facial never palsy.¹ The stroke and Bell's palsy are the most prevalent reasons for the sudden onset of unilateral facial weakness. The central or peripheral palsy is defined by the patient's history and neurologic examination. The incidence of Bell's palsy is 10 to 40 cases per 100000 people, per year; it is known that it has caused 0.3% of all cases of bilateral facial paralysis. Genders are affected equally and the median age at the onset is 15-40 years old, but it may occur at any age. The left and right sides of the face are involved with equal frequency. The abrupt onset with facial muscle weakness progressing over hours to days could be observed. Its incidence increases in cold regions² Bell's palsy may be the first manifestation of diabetes, and in any patient manifestation with this neurological deficit, glucose tolerance should be checked.³ No persistent association was demonstrated between the onset of mononeuropathy and age, gender, diabetic treatment and duration, diabetic control, or other diabetic complications.⁴ Thus, the usual site of facial nerve lesion in

diabetics appears to be distal to the chorda tympani, while in patients whose glucose tolerance is normal, no such selectivity exists. Some cases of Bell's palsy may, in fact, be a diabetic mononeuropathy.⁵ Most patients experience a full recovery, but some have permanent disfiguring facial weakness. However, older age, hypertension, impairment of taste, pain except for the ear, and complete facial weakness are among poor prognostic factors. In the first three days, electrical studies cannot show any alterations in affected facial muscles, while a continuous impairment of electrical activity is often observed on days 4 to 10. As many as 90% of patients have complete recovery when excitability returns; in case of lack of excitability, only 20% of patients have a full recovery. Other reasons for the acquired peripheral facial weakness are less likely to cause facial weakness. One of the underlying considerable diseases is diabetes mellitus.⁶ The drug combination with electrical stimulation was more effective in the rescue treatment of Bell's palsy in relation to conventional drug treatment alone. The effectiveness of such sub-threshold, continuous, low-frequency electrical stimulation suggests a new therapeutic approach to accelerate nerve regeneration and improve functional recovery after

injury.⁷ For initiating of the patient's recovery process, the pressure on the nerve may be helpful. The surveys supposed that this can be facilitated by steroid or a steroid plus an antiviral drug (e.g. acyclovir).⁸ Short treatment duration is considered, but it can cause undesirable impacts. It may result in the induction or worsening of hyperglycemia, especially in diabetics, although patients with diabetes, malignant hypertension, hepatic and renal dysfunction may need higher doses.⁹ Results can show combined treatment with low-level laser therapy (LLLT) and exercise therapy is correlated with a remarkable recovery of facial disability index (FDI) in comparison with only exercise therapy. In the treatment of neuropathic and neurogenic pains, the proposed mechanisms of beneficial effects of lasers include (1) increasing the production of ATP in mitochondria and increasing cellular oxygen consumption leading to muscle relaxation; (2) increasing serotonin and endorphin levels; (3) producing anti-inflammatory effects (decreasing prostaglandin synthesis); (4) improvement of skin blood supply; (5) decreasing the permeability of neuron cell membranes to sodium and potassium ions (leading to the hyperpolarization of neurons); and (6) increasing lymphatic drainage and decreasing edema. It should be considered that the intensity and power of the laser have various impacts depending on the varying skin color of people.¹⁰ Accordingly, few studies were conducted about the evaluation of the effect of low-level lasers (LLs) on Bell's palsy treatment; on the other hand, conventional treatments have various adverse effects, especially in diabetic patients who suffer from diabetes mellitus. We decided to determine the effect of LLs on the treatment course of Bell's palsy.

Materials and Methods

After being approved by the research and ethical committees of Tabriz University of Medical Sciences (5/D/973180), this clinical interventional study (identifier: IRCT2017011128545N2; <https://www.irct.ir/trial/23144>) was conducted on all patients with Bell's palsy, who had a history of diabetes and referred to pain clinic of Imam Reza teaching hospital over one year. The exclusion criteria were patients aged under 18 years old, pregnancy, having (no) electromyography and nerve conduction tests, seizures, cancer, coagulopathies or pacemakers. All diabetic patients aged more than 18 years old were selected by a consecutive method over one year. Along with the recording of demographic data and consumption of corticosteroids or other drugs, all patients were visited and the severity of facial nerve damage was classified as complete, moderate and mild:

1. Total palsy: No identifiable motion on the affected side of the face
2. Moderate palsy: Significant motion with asymmetry in rest and activity

3. Mild palsy: Symmetric in rest and asymmetric in motion

Then, basic electrodiagnostic tests (including electromyography and nerve conduction study [NCS]) were performed for all patients, and bilateral compound motor action potential (CMAP) was assessed through the tests. CMAP is the result of the stimulation of nerve files and it monitors muscle response for the evaluation of the function of the motor unit. Electromyography (EMG) was performed by the Viking Quest device in the physiotherapy clinic and the severity of the axonal injury of the facial nerve was assessed by the electromyography method and compared CMAP amplitude (peak to peak) of two sides. For the recording of CMAP, the anterior portion of the ear tragus was stimulated for 0.2–0.5 millisecond and with the frequency of 1 Hz. The potentials were recorded of branches of frontalis, orbicularis oris and orbicularis oculi nerves on two sides. In this study, the percentage of amplitude decline of the CMAP wave of the affected side in relation to the healthy side was considered the severity index of the axonal injury and classified as follows: unimpaired, mildly impaired, moderately impaired, and severely impaired.

Then, the rate of muscle activity was assessed by the electromyography of muscles (i.e., frontalis, orbicularis oris and orbicularis oculi) on 2 sides of the face and compared two-sided EMG findings with together. Finally, the results were classified as follows:

1. No voluntary motor unit potential
2. Single voluntary motor unit potential
3. Discrete activity pattern
4. Reduced interference pattern
5. Complete recovery

After electrodiagnosis was conducted, the patients underwent 12 sessions of laser therapy by the LLL (3 times in a week). Laser therapy was provided by the low-level machine (model BLT-4000; power: 334 mW, dose: 16 J/cm², frequency: 100 Hz, area: 1 cm², accessory: 830 nm). The diode of the LLL (the wavelength of 980 nm and frequency of 100 Hz, energy density of 5 J per every point of direct contact with the skin of the face) was taken at 9 points for a period of one minute. Contact sites in the affected side were located near the mastoid process in the stylomastoid foramen and two points in every pathway of facial nerve branches (these points were selected based on previous studies), including the area of the temporal branch in forehead, the branch of zygomatic nerve along the zygomatic arc, the buccal nerve in the middle portion of cheeks over buccal muscles, and the mandibular branches in the chin area.

After 12 sessions of laser therapy, the clinical severity of motor palsy of the facial nerve was determined and the recovery rate of patients was clinically evaluated:

1. Complete recovery: the complete return of voluntary motion without any asymmetry in rest or activity or contraction

2. Good recovery: incomplete recovery without paresis in motion
3. Moderate recovery: incomplete recovery with mild paresis in motion
4. Poor recovery: incomplete recovery without paresis (i.e., normal motion and contraction).

After the completion of the 1-month treatment, the patients were evaluated by electromyography and NCS. In addition to the comparison of the recovery rate of the patients, their findings were compared with basic electromyographic results. After coding, data were collected and analyzed by SPSS version 16. The categorical and discrete data including gender, consumption of corticosteroids or other drugs, the severity of the axonal injury of the facial nerve, the pattern of muscle activity and the recovery rate or clinical recovery grade were assessed and compared by proper method (e.g. chi-square by the Monte Carlo's method, Mann-Whitney U test). The p-value of less than 0.05 was considered statistically significant. The cost of basic electrodiagnostic tests was provided by the research project. Here we summarized House-Brackmann grading in Table 1.

But we have one question: what are lasers (light amplification by stimulated emission of radiation) are devices that typically generate electromagnetic radiation with a relatively uniform wavelength, phase, and polarization, originally described by Theodore Maiman in 1960 in the form of a ruby laser. The LLL is a particular type of laser which affects biologic systems through non-thermal means.¹¹

Results

Our study was conducted on 30 patients with diabetes who were selected by the consecutive method. The patients did not receive other medications for the treatment of palsy, particularly corticosteroids due to their underlying disease (based on their endocrinologist's diagnosis) and after confirmation of diagnosis, we treated them by

12 sessions of LLL. All demographic data are shown in Table 2.

On the basis of the findings, any cases didn't involve in grade II the facial nerve palsy. Three cases (16.7%) were affected by grade IV of Bell's palsy and 12 cases had grade V of Bell's palsy. In addition, fifteen cases had grade VI of Bell's palsy. After 12 sessions of LLLT, we observed that these patients had treatment contraindications with corticosteroids, while they did not receive any other treatment. The House-Brackmann grading scales improved to grade I (18 cases), grade II (6 cases), and grade IV (6 cases) (Table 3). Then, basic electrodiagnostic tests (including electromyography and NCS) were performed and the degree of axonal injury in NCS was determined based on our mentioned standard scales. The severity of axonal injury based on the study of nerve conduction amplitude showed that 21 cases had moderately impaired amplitude and 9 patients had a severe disorder. Of course, the patterns of nerve conduction velocity (NCV) showed that 6 patients had a severe impaired function and 18 cases had a moderate one. Twenty-one cases showed no voluntary potential of motor unit, 6 cases had a single voluntary motor potential unit, and 3 patients had a reduced interference pattern. We followed up all the patients by EMG and NCS after 3 months. Finally, we observed that 18 (60%) patients experienced recovery. There was a statistically significant association between laser therapy and the pattern of recovery in EMG (*P* value <0.001). Here, we summarized the distribution of EMG patterns before and after the treatment by the LLL in Table 4.

Here, we evaluated the patterns of NCV after one month and 3 months of treatment by laser. There was no significant association between the recovery pattern and laser therapy (*P* = 0.754). However, after 3 months, we could observe a significant association between the recovery pattern and laser therapy (*P*<0.001). In the present study, the results showed that females experienced

Table 1. House-Brackmann Grading

Grading	Function	Gross	At Rest	Motion
Grade I	Normal	Normal	Normal	Normal
Grade II	Slight dysfunction	Slight noticeable weakness on close inspection; may have very slight synkinesis	Normal symmetry and tone	Forehead - moderate to good function; eye - complete closure with minimum effort; mouth - slight asymmetry.
Grade III	Moderate dysfunction	Obvious but not disfiguring difference between two sides; noticeable but not severe synkinesis, contracture, and/or hemifacial spasm	Normal symmetry and tone, Motion: forehead - slight to moderate movement; eye - complete closure with effort; mouth - slightly weak with maximum effort.	
Grade IV	Moderate to severe dysfunction	Obvious weakness and/or disfiguring asymmetry	Normal symmetry and tone	Forehead - none; eye - incomplete closure; mouth - asymmetric with maximum effort.
Grade V	Severe dysfunction	Only rare perceptible motion	Asymmetry	Forehead - none; eye - incomplete closure; mouth - slight movement.
Grade VI	Total paresis, no movement	-	-	-

Table 2. The Demographic Data

Variables	Age (Mean ±SD)	Weight (kg)	Height (cm)
Female (n=18)	40.66±11.74	55.5±6.28	163. 83±9.49
Male (n=12)	42.25±13.67	74±69.5	179±8.28

a higher grade of recovery but 6 males had a complete recovery. These results were confirmed by EMG and NCV studies after completing 12 sessions of treatment.

Discussion

The results of the present study showed that diabetic patients had a higher grade of Bell's palsy, which was confirmed by EMG and NCV results. After LLLT, we observed that 6 cases had a complete recovery and 4 patients experienced mild sequelae after the treatment such as mild facial asymmetry and mild drooping of the brow. In the follow-up period after 3 months, we could not find any symptoms of recurrence and 6 cases of patients who had an incomplete recovery reached a complete recovery based on objective, EMG and NCV monitoring. According to clinical training and new literature, management of Bell's palsy is evolving.¹² Zhao et al stated that the peak age of Bell's palsy is in the fourth decade of life, 55.1% being men. These results are similar to our demographic values and gender distribution. The highest prevalence of Bell's palsy is seen during spring and summer. Zohrevandi et al showed that men and women are equally affected with similar occupational distribution with the peak age

of the fourth decade of life and it occurs more in summer and autumn. The most common comorbid disease is diabetes mellitus.¹³ The high grade of nerve damage (V and VI) is observed in diabetic patients.¹⁴ Pourmomeny et al stated that the incidence of Bell's palsy is 23 to 35 in 100 000 cases. The reason for facial nerve palsy in half of the cases is idiopathic and incomplete recovery correlates with facial muscle weakness, contracture, hyperkinesis, atrophy, and synkinesis.¹⁵ Electrophysical assessment is commonly performed for the prediction of prognosis and NCS can evaluate the severity of facial nerve about 48 hours after the onset of symptoms.¹⁶ Diabetes mellitus (DM) has been reported to be unrelated to the prognosis of Bell's palsy, whereas the studies by Kang et al have found that DM worsens prognosis. Various types of therapeutic approaches are available, but the effectiveness of definitive treatments are unknown.¹⁷ The traditional systemic corticosteroid therapy in acute peripheral Bell's palsy in patients with DM type 2 can cause hyperglycemia, and local therapy is required as an alternative treatment approach.^{18,19} Palsy could be treated by corticosteroids up to the rate of 17% in a complete recovery by treatment difference.²⁰

The LLL can relieve pain, inflammation, and edema and help in healing wounds and preventing tissue injury; these effects were accepted many years before the invention of lasers. Lasers (light amplification by stimulated emission of radiation) are devices that typically generate electromagnetic radiation with a relatively uniform wavelength, phase, and polarization, originally described

Table 3. House-Brackmann Grading Scale Before and After the Treatment by the Low-Level Laser on Third Month

		House-Brackmann Scaling Grades					
		Grade I	Grade II	Grade III	Grade IV	Grade V	Grade VI
Pre	Female	0 (0.0)	0 (0.0)	0 (0.0)	3 (16.7)	6 (33.3)	9 (50)
	Male	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	6 (50)	6 (50)
Post (3 months)	Female	12 (66.7)	6 (33.3)	0 (0.0)	0 (0)	0 (0)	0 (0.0)
	Male	6 (50)	0 (0.0)	0 (0.0)	6 (50)	0 (0)	0 (0.0)

Data are shown as No. (%).

Table 4. The Finding of NCV Study Before and After the Treatment by the Low-Level Laser in the First and Third Months

		Pre	Post (1 month)	P Value	Post (3 months)	P Value
NCV study	Severely impaired	9 (30)	6 (20)	0.754	0 (0.0)	<0.001
	Moderately impaired	21 (70)	18 (60)		6 (2.0)	
	Mildly impaired	0 (0.0)	6 (20)		6 (20)	
	Unimpaired	0 (0.0)	0 (0.0)		18 (70)	
EMG study	No voluntary motor unit potential	21 (70)	12 (40)	0.648	0 (0.0)	<0.001
	Single voluntary motor unit potential	9 (30)	6 (20)		0 (0.0)	
	Discrete activity pattern	0 (0.0)	6 (20.0)		6 (20.0)	
	Reduced interference pattern	0 (0)	6 (20)		6 (20)	
	Complete recovery	0 (0.0)	0 (0.0)		18 (60)	

Data are shown as No. (%).

by Theodore Maiman in 1960 in the form of a ruby laser. The LLL is a particular type of laser which affects biologic systems through non-thermal means. Leal-Junior et al in 1967 reported non-thermal effects of lasers on mouse hair growth. According to Leal-Junior et al, the characteristic of LLLs are as follows: power output of lasers = 0.001-0.1 W and in the range = 300-10 600 nm; and pulse rate beginning from 0.¹¹ Bernal et al presented their 6-year practice in treatment by a laser for the rehabilitation of Bell's palsy, but they used a 904 nm diode GaAs and 632.8 (HeNe) laser. Laser Irradiation was conducted on the region of the facial nerve in 8 points for 5 minutes and 4 sessions over 1 week. The patients who received treatment within 2 weeks were recovered 100% and this recovery was obtained without additional medication. They concluded that LLLT is a safe, noninvasive, easy-to-apply and comparatively side-effect-free modality offering a complementary and effective tool in the treatment of facial paralysis.²¹ Another study was on the systematic evaluation of the LLLT effect on the regeneration of nerves in children with facial nerve palsy. A total of 31 patients were divided into 2 groups. Group 1 received LLLT and group 2 was treated with the conventional method. Two diode lasers were used (i.e., 670 and 830 nm wavelengths & 100 mW respectively 300 mW max of output power). The results indicated the validity of this method in that 87.5% of the patients treated with the laser compared to only 60.0% of the patients in the control group displayed a complete recovery.²² Another survey evaluated the effect of LLLT plus exercise treatment on functional outcome during recovery time in facial palsy. In this study, 46% (mean age 41 ± 9.7 years; 40 women and 6 men) were divided into 2 groups. One group received laser treatment at a wavelength of 830 nm, power output of 100 mW, and a frequency of 1 kHz using a gallium-aluminum-arsenide (GaAlAs, infrared laser) diode laser. Laser treatment (mean energy density of 10 J/cm^2) was administered to 8 points on the affected side of the face 3 times per week, for a total of 6 weeks. In the laser group, significant improvement in FDI scores was observed relative to the baseline in weeks 3 and 6 ($P < 0.001$). Good FDI scores were remarkably higher in weeks 3 and 6 in the laser group than the exercise group ($P < 0.05$).²³ In 1 case report, the House-Brackmann grading system was applied for the assessment of facial nerve recovery. A 3-year-old boy with facial nerve palsy experienced full recovery after 11 sessions of LLLT after a total of 3 weeks. The 660-nm laser with low (10 J/cm^2) or moderate (60 J/cm^2) energy density can help to accelerate the neural recovery. For these reasons, from the sixth session onward, the energy density progressively decreased based on the patient's report as well as clinical observations. The output power of 60, 50, and 40 mW was administered for sessions 6, 7, and 8.²⁴ The some evidence for LLLT efficacy in individuals with Bell's palsy were obtained by volunteers who participated in an randomized controlled trial. Associated outcomes are

alterations in disease status, functional outcomes, quality of life, and treatment-related morbidity. Bell's palsy may be completely treated over several months, so it is difficult to determine improvements from laser therapy over the natural resolution of disease. The available randomized controlled trial did not include a sham treatment; LLLT was associated with better results in this study. In another study, patients were treated with physiotherapy. They suggested a statistical improvement after 6 weeks of the treatment based on the House-Brackmann scale and FDI scores, with the highest cure rate after this period.²⁵ The prognosis of Bell's palsy is correlated with the onset of recovery. Early recovery is associated with a desirable prognosis. Recovery within 1 week, 1 to 2 weeks and 2 to 3 weeks are an indication of 88%, 83%, and 61% complete recovery respectively. Other factors that show a poor prognosis are as follows: hypertension and DM.²⁶ Sham-controlled surveys and additional studies are required for the comparison of LLLT with other alternative palsy treatments. The evidence is insufficient to determine the effects of technology on the health outcome.¹⁶ In the present study, we could show a rate of 70% recovery after 12 weeks of LLLT.

Conclusion

We applied LLLT for the treatment of 30 patients with Bell's palsy. LLLT was effective in these cases. The recovery rate showed that LLLT is a safe, reliable and proper alternative approach to the treatment of facial nerve palsy, especially in conditions such as diabetes where we cannot use conventional medications such as corticosteroids due to their complications (e.g. hyperglycemia).

Conflict of Interests

The authors declare no conflict of interest.

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