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POLISH JOURNAL OF PHYSIOTHERAPY

OFICJALNE PISMO POLSKIEGO TOWARZYSTWA FIZJOTERAPII

THE OFFICIAL JOURNAL OF THE POLISH SOCIETY OF PHYSIOTHERAPY

NR 3/2022 (22) DWUMIESIĘCZNIK ISSN 1642-

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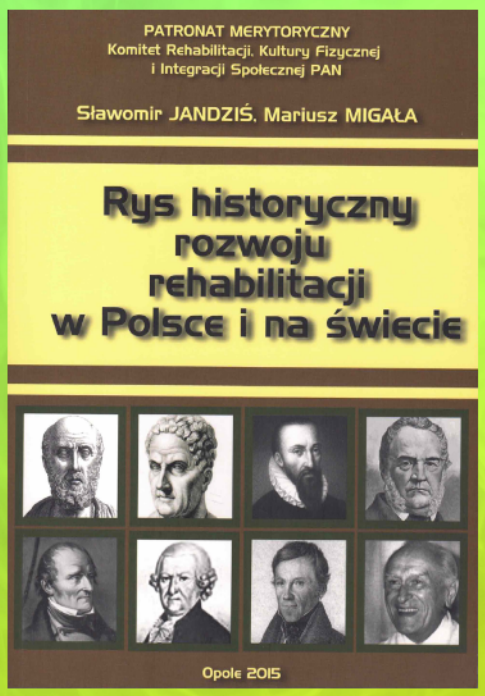

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Effect of low level laser versus electrical stimulation on facial nerve regeneration in patients with Bell's palsy: a randomized controlled trial

Wpływ laseroterapii niskiego poziomu i stymulacji elektrycznej na regenerację nerwu twarzowego u pacjentów z porażeniem Bella: randomizowane badanie kontrolowane

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Abstract

Purpose. This study was done to compare between the effect of low level laser and electrical stimulation on Bell's palsy. Methods. A randomized controlled trial was done on 45 patients of both genders with Bell's palsy; their ages ranged from 18–45 years. Patients were randomly divided into three equal groups. All groups (A, B & C) have received medical treatment. In addition, group (A) (Low level laser therapy), was treated with low level laser therapy, two sessions/ week for 6 weeks, while group (B) (ES group) was treated with electrical stimulation for the same time and group (C) (control) followed the traditional treatment, which consisted of massage and facial exercises. The primary outcome for the study was the degree of facial nerve regeneration assessed by facial nerve electromyographic sharp wave presence, while the secondary outcomes were facial motor function, assessed by House-Brackmann scale and the quality of life, measured by facial disability index. The outcomes were evaluated pre and after 6 weeks of the interventions. Results. There was a statistically significant difference (P = 0.0001) between the three groups regarding facial disability index score and House-Brackmann score in favor of laser group. Conclusion. Low level laser treatment is more effective than electrical stimulation and traditional treatment in achieving functional recovery in Bell's palsy patients.

Key words:

facial palsy, low level laser therapy, electrical stimulation therapy

Streszczenie

Cel. Niniejsze badanie przeprowadzono w celu porównania wpływu laseroterapii niskiego poziomu i stymulacji elektrycznej na porażenie Bella. Metody. Randomizowane kontrolowane badanie przeprowadzono na 45 pacjentach obu płci z porażeniem Bella; ich wiek wahał się od 18 do 45 lat. Pacjenci zostali losowo podzieleni na trzy równe grupy. Wszystkie grupy (A, B i C) zostały poddane leczeniu. Dodatkowo grupa (A) (laseroterapia niskiego poziomu) była poddawana laseroterapii niskiego poziomu, dwie sesje/tydzień przez 6 tygodni, natomiast grupa (B) (grupa ES) była poddawana stymulacji elektrycznej przez ten sam czas, a grupa (C) (kontrolna) była poddawana leczeniu tradycyjnemu, które obejmowało masaż i ćwiczenia twarzy. Najważniejszym skutkiem przeprowadzanego badania był stopień regeneracji nerwu twarzowego oceniany na podstawie obecności ostrych fal nerwu twarzowego widocznych w badaniu elektromiograficznym, natomiast drugorzędnymi skutkami były funkcje motoryczne twarzy oceniane w skali House-Brackmanna oraz jakość życia mierzona wskaźnikiem niepełnosprawności twarzy. Wyniki zostały ocenione przed i po 6 tygodniach leczenia. Wyniki. Wystąpiła statystycznie istotna różnica (P=0,0001) między trzema grupami w zakresie wskaźnika niepełnosprawności twarzy i wyniku House-Brackmann na korzyść grupy poddawanej laseroterapii. Wniosek. Laseroterapia niskiego poziomu jest skuteczniejsza niż stymulacja elektryczna i leczenie tradycyjne w osiąganiu powrotu do zdrowia u pacjentów z porażeniem Bella.

Słowa kluczowe

porażenie nerwu twarzowego, laseroterapia niskiego poziomu, elektrostymulacja

Introduction

Bell's palsy, also known as idiopathic facial palsy, is regarded as the most common form of one-sided facial paralysis. It is an acute face paralysis that can occur because of facial nerve inflammation close to the stylomastoid foramen [1]. The paralysis of facial nerve is related to many various functional and cosmetic issues that could greatly impact the social and psychological state of the patients [2]. Bell's palsy is a lower motor neuron condition that is thought to cause around 60–75% of acute one-sided facial paralysis cases [1]. Bell's palsy can result into not only a disturbing facial deformity, but also an impaired capability to communicate using facial articulation and expression [3]. Physical therapy modalities that are mostly used for Bell's palsy include electrotherapy, massage, facial exercise, bio-feedback, and electrical stimulation [1, 4].

Electrical stimulation, as a therapeutic modality, has been widely accepted and commonly used for its ability to improve the performance of healthy and the diseased muscles skeletal muscles in both research studies and in clinical settings [5, 6].

Laser stands for light amplification of the stimulated emission of radiation, a form of phototherapy that includes applying monochromatic light upon biological tissues to provoke a biologically modulated response within those tissues [7].

Using laser light in therapeutic applications with low intensity is referred to as low level laser therapy (LLLT). LLLT augments cellular metabolism leading to accelerated energy production along with increased protein and collagen synthesis. Additionally, laser helps form new blood vessels, leads to vascular relaxation and enhances microcirculation of the skin [8].

Many studies have approved the efficacy of physical therapy modalities on patients with Bell's palsy, but in our knowledge, the comparison between the effect of electrical stimulation and low level laser on Bell's palsy was not studied. So, the aim of the study was to compare between the effect of low level laser and electrical stimulation on Bell's palsy.

Materials and methods

Design

A randomized control trail was conducted to compare between the effect of low level laser and electrical stimulation on Bell's palsy. Data were collected pre and post treatment from June 2018 to March 2019. The research was approved by the institutional review board at National Institute of LASER Enhanced Sciences, Cairo University [Cu-NILES/15/21), following the Declaration of Helsinki Guidelines on conducting the human research. Each patient was educated about the study assessment and treatment procedures and informed consent was obtained from each one of them.

Participants

Forty-five patients of both genders with Bell's palsy were selected from the outpatient clinic of faculty of physical therapy & the national institute of laser enhanced sciences, with their ages ranging from 18–45 years. They were randomly assigned into three equal groups (A, B & C).

Exclusion criteria included Pregnancy or breastfeeding, patients who received medical treatment or acupuncture therapy in other hospitals before this study, diabetes course ≥ 5 years, hypertension (3rd grade) / hyperlipidemia present for 3 or more years. Also, a patient with a history of malignant tumor, sexually transmitted disease, renal or hepatic disease, gastric or duodenal ulcer, or glaucoma was excluded. Moreover, acute otitis, chronic otitis on the affected side, tuberculosis, immunodeficiency syndromes, recent head injury, psychiatric disease, infectious disease, or any other condition that puts the person at risk of being influenced by the study treatment or that may affect the completion of the study (e.g., participation in other clinical trials within 3 months) were also exclusion criteria.

Randomization

The recruited patients were randomly assigned, after signing consent form, into three equal groups by using computerized randomization. Serially numbered opaque envelopes were used and opened by an investigator who has no direct contact with the participants. Following randomization, there was no dropping out of subjects from the study, figure 1.

Interventions

Patients with Bell's palsy were assigned into three equal groups. Group (A) involved 15 patients, treated by LLLT in addition to medical treatment, while group (B) involved 15 patients, treated by electrical stimulation in addition to the same to medical treatment and group (C) involved 15 patients who received the traditional facial palsy treatment that consisted of facial massage, facial muscles' exercises and the same medical treatment. All patients received the interventions for 6 weeks.

Medical treatment in all groups involved administration of a daily dose of 60 mg of corticosteroids (prednisolone) for 10 days, with a tapered course, in addition to 400 mg of antiviral (acyclovir), five times a day for a week [9]. Also, topical ocular lubricant was applied to prevent corneal drying.

Group (A) (Low level laser therapy)

In addition to the medical treatment, group (A) received LLLT using Galium AL. Arsenide diode laser (chattanooga intellect mobile laser, USA), with a wavelength of 850 nm, and power density of 1 W/cm2. The treatment was given twice a week for 6 weeks for a total of 12 sessions. Each session involved applying laser on 8 points (1 min/ point). Using direct skin contact, facial nerve upper, middle, and lower branches as well as the nerve trunk, orbicularis oris muscle, muscles of the nose, levators of the upper lip and depressors of the lower lip were irradiated [10].

Group (B) (electrical stimulation group)

In addition to the traditional treatment, group (B) received electrical stimulation using electrical stimulator unit (faradic current- Glopus multicurrent, Italy), with a pulse duration ranging from 0.1ms to 1 ms and a frequency of 50 HZ. Intensity level was increased till having a visible muscle contraction. Electrical stimulation was applied by placing one electrode in front of the ear where the nerve trunk is present, while the other electrode was placed on the stimulated muscle. Stimulation was applied on eleven facial muscles, each for 10 min, achieving 30 minimal muscle contractions divided to 3 sets, 5 times/ week for 6 weeks [11].

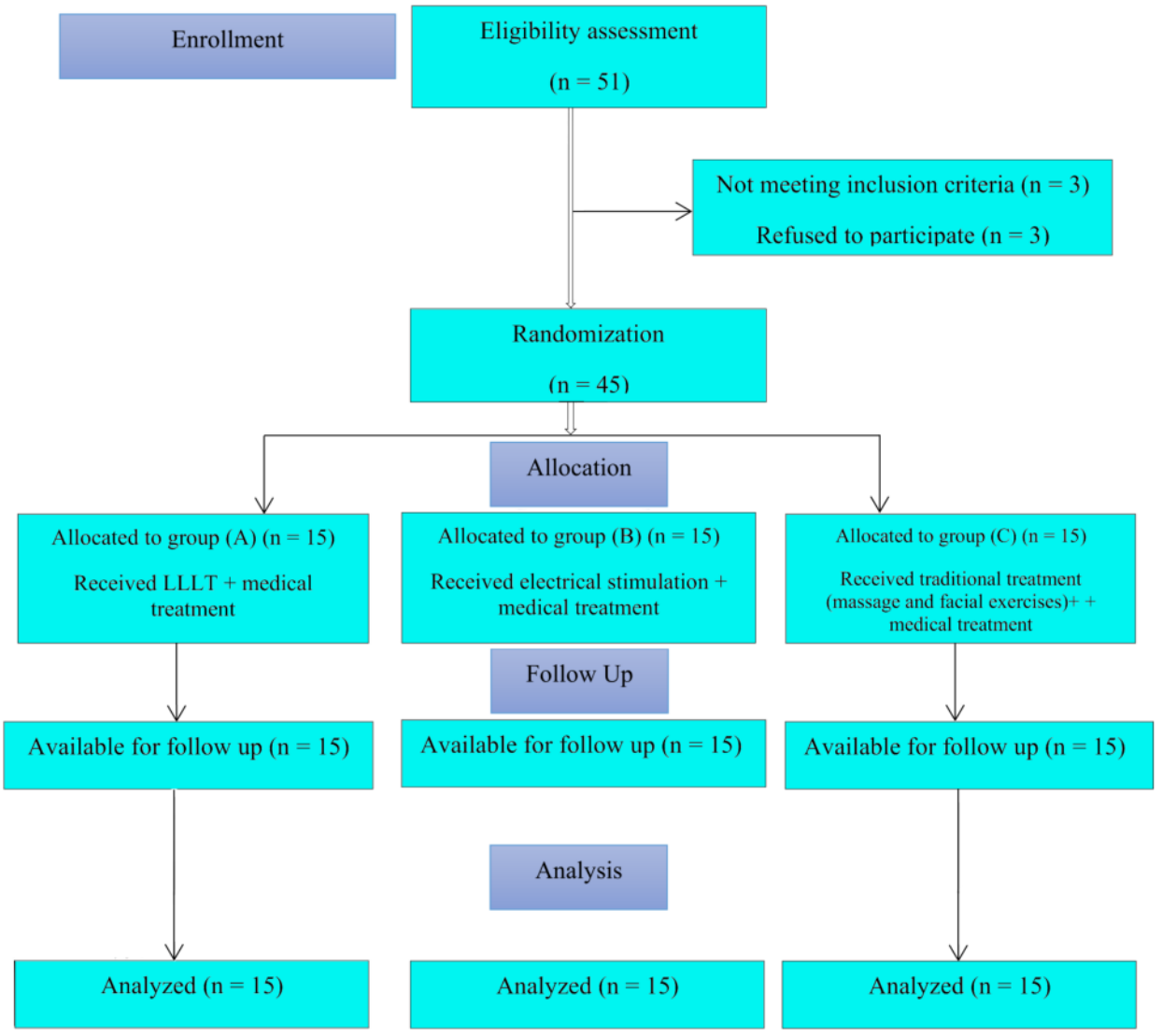

Figure 1. Flow chart of participants

Group (C) (control)

This group was treated with medical treatment added to massage and facial muscles' exercises, as the traditional facial palsy treatment. Patients in group (C) were taught to perform massage and facial exercises correctly by a physiotherapist and they were instructed to do the massage and exercises three times a day throughout treatment period for 6 weeks. Patients were also recommended to blow a balloon and to chew a gum on the paralyzed side. The given face and neck massage were done to relax the facial musculature and promote circulation. Also, they performed active assistive resistive exercises in front of a mirror and underwent proprioceptive neuromuscular facilitation [8].

Outcome measures

Electromyography (EMG) for facial nerve

Using EMG in monitoring facial nerve regeneration is helpful in predicting forthcoming recovery, as identifying muscle reinnervation using EMG can precede obvious clinical movements by 2–3 months [12]. Before application, the face was washed with water and soap to remove sweat or any other interference. According to Schumann et., [13] the electrode placement for specific muscle movement recording followed a typical pattern, where the stimulating electrode was put on facial nerve trunk on the stylomastoid foramen, and the recording electrodes were put on the facial muscles. Comparison between the unaffected and affected side was done to calculate the percentage of degeneration. This test was done pre and post treatment program for all groups.

Facial disability index (FDI)

The FDI is a widely used tool that aims to evaluate specific features related to quality of life, which can be affected due to the alterations in facial impression. It is a brief, self-reported questionnaire that involves ten questions assigned to physical impairment and psychosocial subscales, where having a higher score indicated a better quality of life. It has an internal consistency (Cronbach's alpha coefficient) of 0.83 for the whole scale, making it an effective and reliable assessment tool [14].

House-Brackmann scale (HB)

The House-Brackmann scale is a universally-validated simple grading method that can be utilized to assess the function of facial nerve [15], monitor its regeneration, and evaluates its recovery post treatment. The scale categorizes the paresis degree into six levels, where the first level represents no paresis and the sixth represents total paresis. The net score for the scale is attained by including the score for each of the facial nerve branches, thus the total scale values range from 6 up to 36 [14].

Statistical analysis

The study statistical analysis was carried out using the statistical Package program SPSS, version 25 for Windows (SPSS, Inc., Chicago, IL). Patients' descriptive statistics, involving demographic data and other study variables (EMG findings, FDI, and House- Brackmann scale) were represented by the mean and standard deviation or the median and range whenever applicable. To compare the study variables, a multivariate analysis of variance (MANOVA) 3 x 2 – mixed design was utilized, where the first independent variable was represented by the three tested groups and the second independent variable was before and after treatment assessment periods. Paired t-test was utilized to compare results before and after treatment within each group of the three groups for facial EMG positive sharp wave presence, FDI, and House- Brackmann scale, while unpaired t-test was utilized to compare the results between LLLT group, electrical stimulation group and the control group for the same variables. Significant results were indicated when the level of probability was at 0.05 ($P \leq 0.05$).

Results

Forty-five patients, diagnosed as having facial palsy, participated in the study and they were randomly assigned into three equal groups of 15 patients each. At baseline, there were no significant differences between the three groups regarding age, gender, or side of affection ($p > 0.05$), (Table 1).

Table 1. Descriptive statistics and one-way analysis of variance (ANOVA) for age, gender, and side of affection of the three tested groups

Age (years)	Group A (N = 20)	Group B (N = 20)	Group C (N = 20)	F-value	P-value	Significance
Mean ± SD	34.66 ± 8.44	32.8 ± 8.09	32.66 ± 8.86	0.261	0.772	N.S
Gender distribution	**Group A (N = 20)**	**Group B (N = 20)**	**Group C (N = 20)**	**χ^2 –value**	**P-value**	**Significance**
Male, N (%)	10 (66.7%)	10 (66.7%)	8 (53.3%)	0.756	0.685	N.S
Female, N (%)	5 (33.3%)	5 (33.3%)	7 (46.7%)			
Side distribution	**Group A (N = 20)**	**Group B (N = 20)**	**Group C (N = 20)**	**χ^2 –value**	**P-value**	**Significance**
Left side, N (%)	8 (53.3%)	6 (40%)	6 (40%)	0.72	0.698	N.S
Right side, N (%)	7 (46.7%)	9 (60%)	9 (60%)			

N, number of cases N.S, P value > 0.05

Regarding the overall effect, statistical analysis using MANOVA 3x2 mixed design showed significant effects of the tested group (the first independent variable) on the all tested dependent variables, which are FDI (F = 12.237, P = 0.0001*).

Moreover, there were significant effects of the measuring periods (the second independent variable) on the tested dependent variables (F = 444.894, P = 0.0001*). Additionally, the interaction between the two independent variable was significant, showing that the effect of the tested groups on the dependent variables was influenced by the measuring periods (F = 61.57, P = 0.0001*), (Table 2).

Table 2. The 3x2 mixed design MANOVA for dependent variable at different measuring periods between all groups

Source of variation	F- value	P-value
Groups	12.237	0.0001*
Measuring periods	444.894	0.0001*
Interaction effect	61.57	0.0001*

*P-value: probability value * Significant at P-value < 0.05*

For the House-Brackmann scale, within group's comparison of "pre treatment" versus "post treatment" median values showed significant difference in the three groups (A, B & C). Likewise, post hoc tests indicated a significant increase in House-Brackmann scale scoring at post treatment in comparison to pre-treatment in group (A) (Z = −3.482, P = 0.0001*), group (B) (Z = −3.482, P = 0.0001*) and group (C) (Z = −3.276, P = 0.0001*), (Table 3).
Considering the effect of the tested group on House-Brackmann scale, the Kruskal-Wallis H test showed a significant difference in the post-treatment median values of House-Brackmann scale among three groups (P = 0.0001*). Using Mann-Whitney U test, results indicated significant differences between the groups (A & B) with P = 0.0001*, the groups (A & C), with P = 0.0001* and the groups (B & C), with P = 0.023*. This significant increase was in favor of group (A), compared to the groups (B & C) and in favor of group (B), compared to the group (C), (Table 4).

Table 3. Descriptive statistics and post hoc tests of the House -Brackmann scale among different groups

House-Brackmann scale	Group A, Median (IQR)	Group B, Median (IQR)	Group C, Median (IQR)
Pre treatment	2 (1)	2 (1)	2 (1)
Post treatment	6 (2)	4 (2)	3 (1)
Wilcoxon Signed Rank test	**Group A, Median (IQR)**	**Group B, Median (IQR)**	**Group C, Median (IQR)**
Z-value	−3.482	−3.482	−3.276
p-value	0.0001*	0.0001*	0.0001*

**Significant at alpha level < 0.05, IQR: Interquartile Range*

Table 4. Kruskal-Wallis H and Mann-Whitney U post hoc tests of the House -Brackmann scale among different groups

Kruskal-Wallis H test	χ 2-value		P-value			
Pre treatment	0.183		0.913			
Post treatment	26.318		0.0001*			
Mann-Whitney U test	**Group (A) Vs. (B)**		**Group (A) Vs. (C)**		**Group (B) Vs. (C)**	
	U-value	**P-value**	**U-value**	**P-value**	**U-value**	**P-value**
Pre treatment	103	0.713	106.5	0.806	109.5	0.902
Post treatment	23	0.0001*	7	0.0001*	58.5	0.023*

**Significant at alpha level < 0.05*

For the FDI, within group's comparison of the "pre-treatment" versus "post treatment" mean values indicated significant increase in the three groups (A, B & C) (P = 0.0001*). On comparing the three groups, post hoc tests revealed a significant difference among the groups (A & B) and (group & C) with P = 0.0001* for both. This significant increase was in favor of group (A), compared to the group (B & C). While, there was no significant difference between (group B & C), with P = 0.078, there was a clinical difference and more improvement in favor of group B, (Table 5).

Table 5. Descriptive statistics and 3×2 mixed design MANOVA for Facial disability index at different measuring periods among different groups

FDI	Group A, (Mean ± SD)	Group B, (Mean ± SD)	Group C, (Mean ± SD)
Pre- treatment	24 ± 8.28	22.66 ± 7.03	23.33 ± 8.16
Post treatment	60 ± 11.33	40.66 ± 8.83	32.66 ± 7.98
MD	−36	−18	−9.33
% of change	150%	79.43%	39.99%

Multiple pairwise comparisons between pre and post treatment values for FDI at different groups			
Pre Vs. post	Group A	Group B	Group C
P-value	0.0001*	0.0001*	0.0001*
Multiple pairwise comparison tests (Post hoc tests) for the FDI among different groups at different measuring periods			
	Group (A) Vs. group (B)	Group (A) Vs. group (C)	Group (B) Vs. group (C)
Pre	0.99	0.98	0.97
Post	0.0001*	0.0001*	0.078

*MD, mean difference *Significant at alpha level < 0.05*

Regarding the presence of positive sharp wave in EMG, within group's comparison, using McNemar's test, showed a statistically significant increase in the reported percentage of patients having EMG positive sharp wave post treatment in the group (A), (P = 0.016*), while there was no statistically significant increase on the percentage of those patients in the groups (B) & (C) (P = 0.125 and P = 0.99) respectively, (Table 6).

On comparing the three groups pre-treatment, Chi square tests (post hoc tests) revealed that there was no significant difference (χ^2 = 0.556, P = 0.757) in the presence of EMG positive sharp wave between any of the three groups (A, B or C). Also, post hoc tests showed that there was no significant difference in the presence of EMG positive sharp wave among three groups post treatment (χ^2 = 4.2, P = 0.122), (Table 6).

Table 6. Chi-squares tests and frequency distribution of the positive sharp wave presence in EMG at different measuring periods at different groups

Frequency distribution						
	Group A		Group B		Group C	
	Absent	Present	Absent	Present	Absent	Present
Pre treatment	9 (60%)	6 (40%)	10 (66.7%)	5 (33.3%)	8 (53.3%)	7 (46.7%)
Post treatment	2 (13.3%)	13 (86.7%)	6 (40%)	9 (60%)	7 (46.7%)	8 (53.3%)
McNemar's tests						
	Group A		Group B		Group C	
P-value	0.016*		0.125		0.99	
Chi square tests (among groups)						
	χ^2-value		P-value			
Pre treatment	0.556		0.757			
Post treatment	4.2		0.122			
Chi square tests as Multiple pairwise comparison tests (post hoc tests) for the positive sharp wave presence in EMG among different groups at different measuring periods						
	Group (A) Vs. group (B)		Group (A) Vs. group (C)		Group (B) Vs. group (C)	
	χ^2-value	p-value	χ^2-value	p-value	χ^2-value	P-value
Pre treatment	0.144	0.705	0.136	0.713	0.556	0.456
Post treatment	2.727	0.099	3.968	0.051	0.136	0.713

**Significant at alpha level < 0.05*

Discussion

Bell's palsy is identified as the most frequent cause of one-sided peripheral facial nerve palsy. It commonly occurs at the ages between 15 to 45 years, with a relative high annual incident. Symptoms, involving weakness of facial muscles, retro-auricular pain pattern, abnormal noise tolerance level, and unilateral disturbed taste, are normally sudden at onset, ranging from mild to severe degree and they often peak within a day to 3 days. Symptoms include [16].

This Comparative study investigated effect of LLLT and electrical stimulation on 45 patients, divided into three equal groups of both genders, with Bell's palsy and their ages ranged from 18– 45 years. In the current study there was no significant difference between the groups in the age, gender distribution or side of affection.

In agreement with that result, Ordahan and Karahan [17] showed that a total of 46 patients with unilateral facial paralysis had no statistically significant difference in mean age between the groups. Similarly, a study by Abdrabou et al. [18] showed insignificant differences between study groups in the duration of paresis.

The current study findings also revealed that there was no significant difference between the three groups regarding the presence of positive sharp wave in the EMG, while within groups, there was a significant difference in only group (A) that received LLLT with medication after 6 weeks of treatment.

Results from a study by Low et al. [19] agreed with these results as it showed that LLLT has positively affected normal peripheral nerve parameters in form of both nerve excitability and action potential. Also, Abdrabou et al. [18] indicated a significant improvement in latency, amplitude, and axonal loss in patients with Bell's palsy when treated by LLLT group than those treated by electric stimulation. While, on the other hand, Quinn et al. [20] disagree as they stated no hard evidence on whether the LLLT was effective in managing twenty one patients having Bell's palsy.

The present study also found a significant improvement in all groups post treatment regarding both House-Brackmann scale, and FDI, with that improvement was in favor of LLLT group. These findings were congruent to Khullar et al., [21] who stated that LLLT had improved nerve functional recovery, possibly due to direct augmentation of the axonal regeneration process. Additionally, Ordahan and Karahan [17] stated a greater improvement in FDI scores in the group receiving LLLT at 3 and 6 weeks post treatment, compared to the exercise group. Likewise, Alayat et al. [10] used FDI to evaluate the effect of LLLT on Bell's palsy outcomes, and observed functional improvement in patients who received LLLT. Moreover, Fontana and Bagnato [22] reported a complete enhancement in a child aged 3 years having Bell's palsy following LLLT for 3 weeks. At the same time, a study of 228 children Bell's palsy, done by Prescott [23], discovered that a high-dosage steroid treatment did not significantly affect recovery times. In addition, Ladalardo et al. [24] reported that Bell's palsy patients, who were treated by gallium arsenide laser diodes, demonstrated a significant functional improvement.

Many studies [have explained the reason behind the improvement seen in patients with Bell's palsy undergoing LLLT. Generally, LLLT was found to stimulate the photoreceptors in the mitochondrial and cell membrane, resulting into enhanced cellular functions, and cell proliferation rate, as it increases DNA, and RNA synthesis as well as collagen production [25, 26]. Also, Kneebone [27] found that applying laser could enhance neuronal regeneration through both local and systematic actions. Another mechanism is that LLLT reduces neuronal retrograde degeneration in the neurons connected to the spinal cord and increases the damaged peripheral nerves healing [28].

Moreover, Chow et al. [29] determined that LLLT has a direct influence on nerve structure, leading to enhanced healing rate of communication blocks. Additional studies also researchers showed that LLLT dilates arterial and capillary blood vessels, thus it helps increase microcirculation, activate angiogenesis, and stimulate nerve regeneration [30].

Although few studies have discussed the efficacy of LLLT in the treatment of Bell's palsy cases, Bernal [31] revealed that it is a painless adjunctive treatment method, with no adverse effects for patients having facial paralysis, especially when they are contraindicated to the steroid treatments, as with diabetes and hypertension.

The current study has many strength points. First, it was randomized and involving patients of both males and females. Also, it used objective methods to assess outcomes. The study has a point of limitation, though. Further studies are needed to be conducted on patients of one gender who have Bell's palsy and to include a larger sample for more conclusive results.

Conclusion

Low level laser treatment is more effective than electrical stimulation and traditional treatment in managing Bell's palsy patients, and achieves better functional recovery and more improved quality of life.

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Acknowledgement

The authors would like to thank all individuals who participated in this study.

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