

Research Paper: Low-level Laser Therapy Versus Electrical Stimulation for the Management of Acute Bell's Palsy: A Randomized Clinical Trial



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Citation Javath JM, D'Souza AF, Rebello SR. Low-level Laser Therapy Versus Electrical Stimulation for the Management of Acute Bell's Palsy: A Randomized Clinical Trial. *Physical Treatments*. 2021; 11(4):261-268. <http://dx.doi.org/10.32598/ptj.11.4.508.1>



Article info:

Received: 11 Jun 2021

Accepted: 23 Aug 2021

Available Online: 01 Oct 2021

Keywords:

Bell's palsy, Laser therapy, Electrical stimulation, Electrotherapy

ABSTRACT

Purpose: Electrotherapy is a common intervention for the rehabilitation of Bell's palsy. Low-level Laser Therapy (LLLT) and Electrical Stimulation (ES) are two therapeutic interventions for Bell's palsy that have been proven to be superior to conventional treatments. To date, no clinical trial has compared the effectiveness of these two interventions. This pilot study was done to compare the effectiveness of LLLT and ES in the management of acute Bell's palsy.

Methods: This randomized clinical trial was done on 25 participants with acute Bell's palsy who were randomized into two groups with 12 participants that received LLLT and 13 participants that received ES. All participants received 12 treatment sessions over two weeks. Sunnybrook Facial Grading System (SFGS) was used to assess facial symmetry and Facial Disability Index (FDI) for facial function. Outcomes were assessed at baseline and after two weeks.

Results: There was a significant improvement in SFGS and FDI scores within both groups ($P < 0.005$). There was no significant difference in SFGS and FDI scores between groups ($P = 0.164$; $P = 0.423$).

Conclusion: There is no difference between LLLT and ES in improving facial symmetry and function in acute Bell's palsy.

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Highlights

- There is no difference between Low-level Laser Therapy and electrical stimulation in improving facial symmetry and function in patients with acute Bell's palsy.

Plain Language Summary

Bell's palsy is a condition affecting the facial nerve leading to muscle weakness over one side of the face. This condition is treated using many physiotherapy techniques. Laser therapy and electrical stimulation are both more effective than the usual treatments for Bell's palsy. However, these techniques have not been compared with each other yet. This study intended to find the more effective treatment between laser therapy and electrical stimulation for improving facial appearance and function in people with early Bell's palsy.

1. Introduction

Bell's Palsy (BP) is described as an idiopathic, rapid, ipsilateral onset of facial nerve paralysis resulting in the weakness of muscles responsible for facial expression leading to facial asymmetry [1].

Higher incidence is seen in pregnancy, diabetics, hypertensives, those with viral upper respiratory tract infection, and immunocompromised patients [2]. A mean recurrence rate of 6.5% is seen among those affected previously by BP. Of all cases with primary BP, 66% show complete recovery, while those with recurrence exhibit lower recovery rates [3].

Five theories have been proposed as possible causes of BP, which include anatomical differences in the internal auditory canal width and facial nerve diameter, viral infection by herpes simplex or varicella-zoster, ischemia of facial nerve, immune response-related inflammation, and acute exposure to extreme temperatures [4]. Histopathologically, there is evidence of acute inflammation throughout the facial nerve with resultant demyelination [5]. The communication of motor, sensory and parasympathetic fibers of the facial nerve with the trigeminal nerve, vestibulocochlear nerve, glossopharyngeal nerve, and vagus nerve gives rise to its peculiar clinical manifestations [6]. In addition to facial muscle weakness, patients may present with altered facial sensation, post-auricular pain, hyperacusis, vestibular dysfunction, and pharyngeal symptoms. Some patients also exhibit disorders of lacrimation and salivation [7].

Most patients show complete spontaneous recovery within the first month, while 30% may exhibit delayed or incomplete recovery which manifests as late complications of BP, which are contractures and synkinesis [2]. Medical management of BP is focused on fast retrieval

of lost facial nerve function and to prevent the incidence of long-term complications. Commonly prescribed medications are corticosteroids, like prednisolone, for its anti-inflammatory action, and antivirals, such as acyclovir due to the probable etiology being an underlying viral infection [7]. Surgery is not a commonly utilized approach due to its cost and complications associated with the procedure [8].

Physiotherapy has an important role in the management of BP. Conventional physiotherapy management usually includes moist heat application, facial expression exercises, and facial massage [9, 10]. Several physiotherapy approaches have been proved to be effective over conventional methods. These include exercise therapies, such as proprioceptive neuromuscular facilitation [11], neuromuscular re-education [9], mirror biofeedback therapy [12], mime therapy [13], and electrotherapies, such as laser therapy [14] and electrical stimulation [10].

Electrotherapy is extensively used for the treatment of BP. Commonly used modalities are Electrical Stimulation (ES), therapeutic ultrasound, electromyography-assisted biofeedback, laser therapy, and short-wave diathermy [15]. ES is usually performed using interrupted galvanic current for the facial muscles and faradic current for the nerve trunk [9]. Although the use of ES has been a topic of controversy, a randomized controlled trial found it to be effective over conventional therapy with significant improvement in outcomes after a 3-month follow-up [10]. Low-level Laser Therapy (LLLT) is a pain-free, non-invasive modality that is used to enhance tissue healing. Its effect is dependent on the parameters used for treatment [16]. LLLT and ES aid in restoration functional facial movements, decrease recovery time, and have been proven effective over conventional methods [10, 16], but they have not been compared with each other yet. Hence, this study was conducted to ascertain the more effective

modality between them for the restoration of facial symmetry and function in patients with acute BP.

2. Materials and Methods

This randomized clinical trial was conducted in a tertiary hospital. Ethical clearance was obtained from the institutional ethics committee. This study was done on 25 participants with acute BP who were diagnosed and referred by the neurology department of the hospital. All participants provided written informed consent to be included in the study. Inclusion criteria were people with acute, unilateral BP, and aged 18 and above of all genders. Exclusion criteria were sensory loss over the face, recent head and neck surgery, recent trauma to the face, recurrent facial nerve palsy, and metal implants around the head and neck area.

Participants were selected using convenience sampling and randomly allocated into two groups using the lottery method. Figure 1 illustrates the participants' flow. There was no blinding in this trial. Twelve participants received LLLT while the remaining 13 participants received ES for facial muscles. LLLT was provided using Tech Laser SS-1000 by Technomed Electronics while ES was provided using Electrostim-DT by Technomed Electronics. LLLT was provided for 5 min over eight points over the face (Figure 2), with the laser probe in direct contact with the superficial roots of the facial nerve. The parameters used were wavelength of 830nm, frequency of 1 KHz, the duty cycle of 80%, and energy density of 10 J/cm². During each session, the total energy delivered to the patient was 80 J [14]. ES was given for three sets of 30 contractions over 11 motor points of the face (frontalis, corrugator supercilii, palpebral part of orbicularis oculi, levator labii superioris alaeque nasi, levator labii superioris, levator anguli oris, risorius, orbicularis oris, depressor anguli oris, depressor labii inferioris, and levator menti) using interrupted galvanic current at a frequency of 30 Hz. The pulse duration was set at 100 msec with an interpulse interval of 0.3 sec while the intensity was kept at a level where a minimal visible contraction was obtained. Faradic current was used at 50 Hz frequency with a pulse duration of 0.7 msec to stimulate the nerve trunk for three sets of 30 contractions [10]. Each session lasted about 45 min. All participants received 12 therapy sessions over two weeks. Additionally, every participant was advised to perform facial massage and facial expression exercises at home, maintain oral hygiene, and use eye protection if needed. All participants showed good compliance throughout the treatment program, there were no dropouts during this study.

Outcome measures were administered at baseline and after two weeks. Sunnybrook Facial Grading System (SFGS) was used to assess facial symmetry. It is an observer-rated scale and measures facial symmetry at rest, on voluntary movement, and with synkinesis. The SFGS composite score ranges from 0 (complete paralysis) to 100 (normal facial function). The sensitivity, intra-rater reliability (0.94), interrater reliability (0.90) and construct validity (0.7-0.87 with House Brackmann facial grading system) have been established [17]. Facial Disability Index (FDI) was used to assess facial function. It is a patient-rated instrument with two subscales that each measures the physical function and social wellbeing of the subject. The total score of each subscale is 100 where a higher score suggests better function. The construct validity and reliability of each subscale (physical function = 0.88; social function = 0.83) have been established [18].

Statistical analysis was performed using SPSS version 23, by IBM Corporation. Data were analyzed using descriptive statistics for baseline evaluation between groups. The Shapiro-Wilk test was used to ascertain normality and found that the data were not normally distributed. The comparison of pre- and post-intervention values within the groups were analyzed using the Wilcoxon signed-rank test while the comparison of pre- and post-intervention values between groups were analyzed using the Mann-Whitney U test. The significance level was set at $P < 0.05$.

3. Results

A total of 25 participants with acute BP completed the study. The descriptive data of the study participants are reported in Table 1. There were 12 subjects in the LLLT group while 13 subjects were in the ES group. There was no significant difference in the mean age between groups ($P=0.77$). Table 2 indicates a highly significant difference in pre- and post-intervention SFGS composite scores within the LLLT ($P=0.002$, $Z=-3.059$) and ES ($P=0.001$, $Z=-3.179$) groups. Table 3 indicates a highly significant difference in pre- and post-intervention FDI composite scores within the LLLT ($P=0.002$, $Z=-3.059$) and ES ($P=0.001$, $Z=-3.109$) groups. Table 4 indicates no significant difference in pre- and post-intervention SFGS composite scores between groups ($P=0.164$, $Z=-1.387$). Table 5 indicates no significant difference in pre- and post-intervention FDI composite scores between groups ($P=0.423$, $Z=-0.87$).

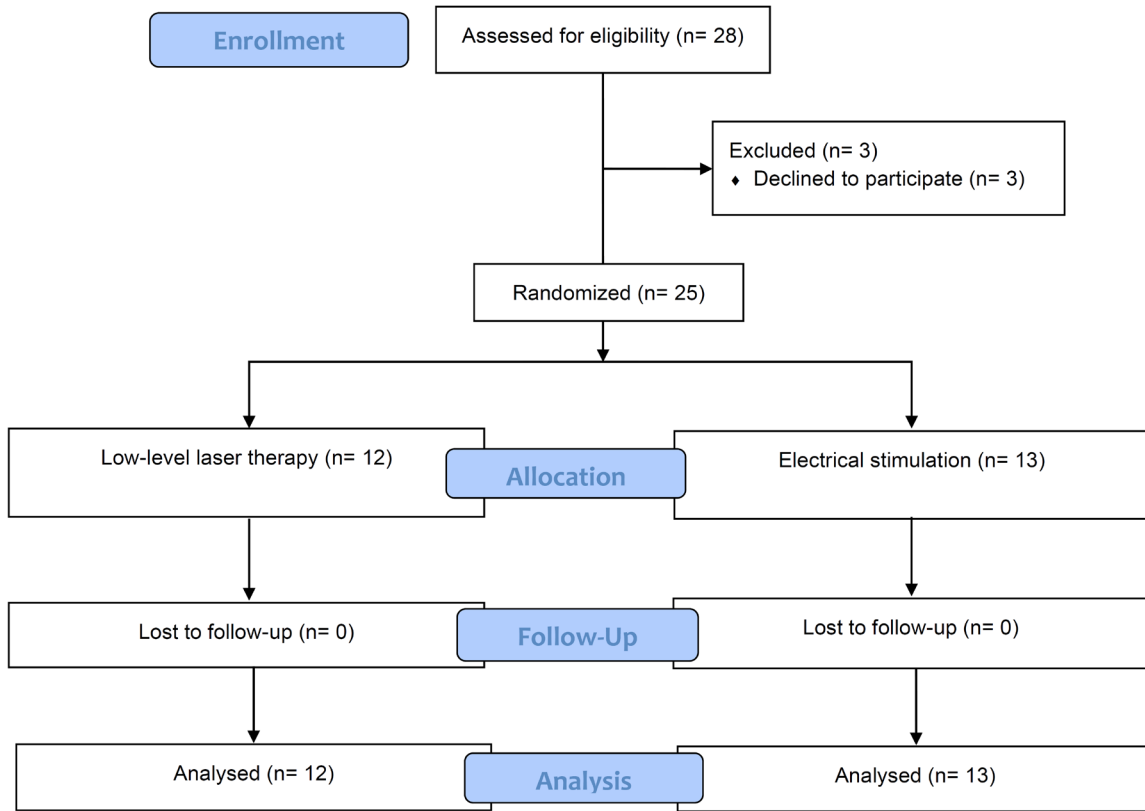
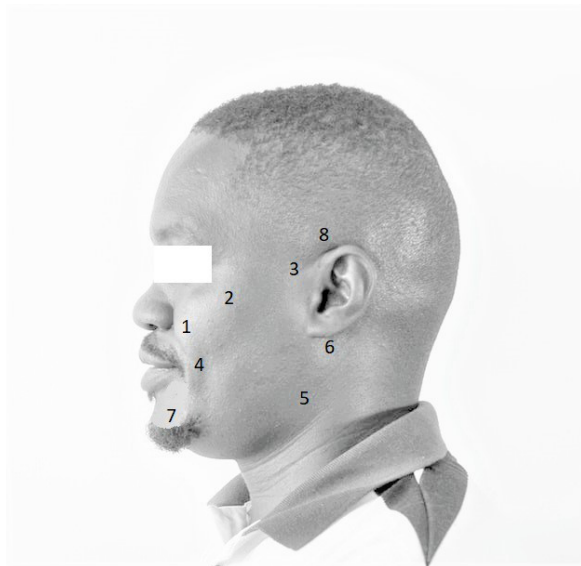


Figure 1. Participants’ flow diagram

4. Discussion

The face is considered to be a functionally and emotionally important part of the human body due to its profound impact on self-concept and aesthetics [19]. BP is a com-

mon neurological condition that impairs facial appearance by significant alteration of facial symmetry and reduction of facial function. Unrecovered BP is known to lead to complications, like facial muscle contractures and synkinesis [2]. There is an established correlation between the severity of facial paralysis and quality of life [20]. Thus, considerable research is focused on the development of effective facial rehabilitation techniques. Early management of BP will allow the patient to recover sooner and reduce the risk of developing these complications. It must be noted that a majority of cases might exhibit spontaneous recovery but the rate of recovery differs from one individual to another based on multiple factors [2].



PHYSICAL TREATMENTS

Figure 2. Low-level Laser Therapy (LLLT) application points (in order of treatment)

Historically, physiotherapy has played a prominent role in the treatment of BP. Different approaches have been employed in the management of BP [21]. Active therapeutic approaches that include graded exercises try to improve patient independence and allow them to participate in their recovery process [9, 13]. Compliance to exercise programs is usually poor [22] and this may lead to inconsistent outcomes resulting in incomplete or delayed recovery. Passive therapeutic approaches, such as electrotherapy on the other hand allow the intervention to be tailored more easily to the status of the individual patient

Table 1. Demographic data

Parameter	Low-level Laser Therapy (n=12)	Electrical Stimulation (n=13)	P/(t-test)	
Age (y), Mean±SD	40.33±10.16	38.23±16.1	0.77	
Onset (day), %	1	8.3	15.4	-
	2	50	69.2	-
	3	41.7	15.4	-
Sex, %	Male	75	30.77	-
	Female	25	64.23	-

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Table 2. Difference in SFGS composite scores within groups using Wilcoxon signed-rank test

Groups	Number	Mean±SD		Z	P
		Pre-test	Post-test		
Low-level Laser Therapy (LLLT)	12	21.33±5.52	61.5±17.98	-3.0594	0.002
Electrical Stimulation (ES)	13	25.62±10.96	52.54±20.13	-3.1798	0.001

PHYSICAL TREATMENTS

and ensure consistency, which may allow for more reproducible and reliable results [23]. A uniform treatment program that yields reliable results may also contribute to better compliance; however, there is no evidence to support this assumption.

This study was geared towards assessing differences in facial symmetry and facial function in acute BP when treated with LLLT and ES. On comparing the outcomes at baseline, and after the treatment program, we found a significant improvement in the facial symmetry and facial function of the participants within groups (P<0.005),

which supports the findings of earlier studies [10, 14]. When comparing scores for SFGS and FDI between groups, there was no significant difference between them (P=0.164; P=0.423).

The LLLT group received the protocol used by Ordahan et al. in their randomized controlled trial. They included patients with idiopathic facial nerve palsy in the early recovery period. On comparing outcomes, the group that received LLLT showed consistently better improvement in FDI scores at multiple follow-ups [14]. A randomized double-blind placebo-controlled trial by Alayat et al.

Table 3. Difference in SFGS composite scores between groups using Mann-Whitney U test

Groups	Number	Mean±SD	Z	P
Low-level Laser Therapy (LLLT)	12	61.5±17.98	-1.387	0.164
Electrical Stimulation (ES)	13	52.54±20.13		

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Table 4. Difference in FDI composite scores within groups using Wilcoxon signed-rank test

Groups	Number	Mean±SD		Z	P
		Pre-Test	Post-Test		
Low-level Laser Therapy (LLLT)	12	112.06±24.98	138.42±21.61	-3.059	0.002
Electrical Stimulation (ES)	13	109.42±15.97	129.83±17.07	-3.109	0.001

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Table 5. Difference in FDI composite scores between groups using Mann-Whitney U test

Groups	Number	Mean±SD	Z	P
Low-level Laser Therapy (LLLT)	12	138.42±21.61	-0.87	0.423
Electrical Stimulation (ES)	13	129.83±17.07		

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compared the efficacy of high and Low-level Laser Therapy in BP and found both interventions to be effective in improving recovery of facial function and symmetry [16]. In their study, Bernal et al. reported 100% recovery in patients who started to receive LLLT within two weeks of the onset of facial paralysis [24]. LLLT is said to produce a physiological effect in the target tissue termed photobiomodulation. Although the photobiomodulation process is poorly understood, laser therapy is known to accelerate the regeneration of damaged peripheral nerves by stimulating cellular proliferation through its interaction with mitochondria and enhancing microcirculation by activating angiogenesis [25]. There is evidence of improved muscle mass and a faster rate of myelination in the regenerated nerve fibers following exposure to LLLT [26]. Laser therapy also has an anti-inflammatory effect that reduces the level of proinflammatory cytokines and increases the level of anti-inflammatory growth factors [27]. This may alleviate the inflammation that leads to further demyelination [4, 5], which may explain the recovery seen within the LLLT group.

Participants in the ES group received the protocol provided in a randomized controlled trial by Tuncay et al., which included cases in the early stages of BP and followed them up after three months. There was a significant reduction in mean motor nerve latencies and compound muscle action potential amplitudes of the two facial muscles that were analyzed [10]. Although we did not follow up with electrophysiological measures, like the study by Tuncay et al., it might be fair to assume that these changes could have contributed to our results as well. Frigerio et al. reported improvement in outcomes after ES in acute facial nerve palsy wherein 55% of the participants reported complete eye closure [28]. Another randomized clinical trial by Kim et al. studied the effect of ES patients with acute BP and found faster recovery rates and minimal complications in the experimental group [29]. It is known that in patients with BP, the affected facial nerve exhibits inflammatory changes followed by demyelination [4, 5]. ES might contribute to recovery by the initiation of nerve sprout formation and enhancing the rate of axonal regeneration. ES prevents Wallerian degeneration and is responsible for the preservation of myelination by Schwann cells [29]. Additionally, facial nerve damage in BP leads to a gradual change in the property of the contractile element of the muscle, which results in muscle atrophy. ES for BP helps

to prevent muscle atrophy and maintain the contractile properties of facial muscles in preparation for reinnervation and gradual return to voluntary movement [29-31].

5. Conclusion

This study showed no difference between LLLT and ES in improving facial symmetry and function in patients with acute Bell's palsy. A few limitations need to be highlighted. The findings from this pilot study cannot be generalized due to the small sample size. Future studies can include larger sample size, control group, and long-term follow-up. Objective electrophysiological tests, like nerve conduction studies and electromyography, could provide more accurate and reliable results.

Ethical Considerations

Compliance with ethical guidelines

All ethical principles were considered in this article, and this study was approved by the Institutional Ethics Committee.

Funding

This research did not receive any grant from funding agencies in the public, commercial, or non-profit sectors.

Authors' contributions

All authors equally contributed to preparing this article.

Conflict of interest

The authors declared no conflict of interest.

Acknowledgments

The authors thank Dr. Raghavendra Bakke Sannegowda and Dr. Pawanraj Pullu Ishwara from the Department of Neurology, Father Muller Medical College Hospital, for referring patients to the study. The authors also thank all the participants for their co-operation during the study.

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