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Effects of Laser Acupuncture Therapy for Patients With Inadequate Recovery From Bell's Palsy: Preliminary Results From Randomized, Double-Blind, Sham-Controlled Study

Gil Ton[1], Li-Wen Lee[2], Wen-Chao Ho[3], Cheng-Hao Tu[1], Yi-Hung Chen[1], Yu-Chen Lee[1,2,4*]

[1]College of Chinese medicine, Graduate Institute of Acupuncture Science, China Medical University, Taichung 40402, Taiwan
[2]Department of Acupuncture, China Medical University Hospital, Taichung 40402 Taiwan
[3]Department of Public Health, China Medical University, Taichung 40402, Taiwan
[4]Chinese Medicine Research Center, China Medical University, Taichung 40402 Taiwan

***Correspondence to**
Yu-Chen Lee, Graduate Institute of Acupuncture Science, China Medical University, No.91, Hsueh-Shih Road, Taichung, Taiwan 40402. Fax: 04-22037690; Email: d5167@mail.cmuh.org.tw

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Abstract

Introduction: Inadequate recovery from Bell's palsy exists in a third of patients and results in physical and social impairments. The controversial nature of existing medical treatment options means that novel, alternative approaches are needed. In basic and clinical studies, low-level laser therapy (LLLT) has proven successful in regenerating peripheral nerves. Laser acupuncture therapy (LAT) is a rapidly growing treatment modality; however, its effectiveness for treating chronic Bell's palsy is unknown. The feasibility of this innovative approach is the focus of this pilot study.

Methods: A two-armed, parallel, randomized, investigator-subject-assessor-blinded, sham-controlled pilot study was conducted, and 17 eligible subjects were randomly allocated to either LAT (n = 8) or sham LAT (n = 9). The LAT group received three treatments each week for six weeks (18 sessions), while the sham LAT group received the same procedure but with a sham laser device. The change from baseline to week 6 in the social subscale of the Facial Disability Index (FDI) was the primary outcome. Secondary outcomes were changes in the House-Brackmann facial paralysis scale (HB), the Sunnybrook facial grading system (SB) and a stiffness scale at weeks 3 and 6.

Results: A significant difference was shown in the HB score ($P = 0.0438$) between baseline and week 3 and borderline significance was observed in both SB and stiffness scores from baseline to week 6 ($P = 0.0598$ and $P = 0.0980$ respectively). There was no significant difference in the FDI score between baseline and week 6.

Conclusion: To the best of our knowledge, this clinical trial is the first such investigation on this topic. Our findings suggest that using LAT may have clinical effects on long-term complications of Bell's palsy and justify further large-scale studies.

Keywords: Bell's palsy sequelae; Randomized controlled trial; Laser acupuncture; Low-level laser therapy.

Introduction

Facial palsy with idiopathic and peripheral origins, also known as Bell's palsy, is the most common reason for acute, unilateral facial paralysis[1] that leads to functional impairment of the facial muscles and creates considerable social distress. On the whole, Bell's palsy prognosis is favorable. A large-scale prospective study found that more than 71% of patients recovered spontaneously and regained normal facial muscle function.[2] However, it was revealed in the same study that patients with complete paralysis had poorer recovery, and only 61% of them regained normal mimic function. Weakness of the muscles, voluntary and involuntary contractures and facial spasms are the most common complications.[3] The current medical treatment for chronic and persistent cases is insufficient compared to modalities available to treat an acute stage of palsy.[4] Physiotherapy and invasive medical treatments, such as botulinum toxin injections or surgical decompression, are considered medical options for persistent cases; however, the benefits of these options are controversial and may result in adverse effects.[3,5]

Acupuncture is a common medical option for the

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treatment of both acute and chronic stages of Bell's palsy in Asia, and different forms of acupuncture treatments have shown positive outcomes. In an observational study conducted in Taiwan, acupuncture use for nervous system diseases was ranked fourth.[6] Electro-acupuncture added to standard therapy has proven to be superior to standard therapy alone and provides improved functional recovery.[7] Manual acupuncture and adjunctive thread-embedding acupuncture have shown beneficial effects when used as treatments for Bell's palsy sequelae.[8,9] In two meta-analysis studies, acupuncture was associated with an effective response rate[10] and an increased cure rate in comparison with standard therapy.[11]

The reputation of acupuncture as a safe treatment with minimal side effects,[12] along with its clinical efficacy for a myriad of conditions, has made it one of the most frequently used complementary treatments in Western countries.[13] This growing interest has cultivated rapid growth and development of acupuncture research and the practice of alternate forms of acupuncture, such as laser acupuncture therapy (LAT).[14] Notably, low-level laser therapy (LLLT) has been shown to be effective in regenerating peripheral nerves in preclinical studies.[15] It also demonstrated clinical efficacy in pediatric paralysis,[16] adults with acute Bell's palsy[17,18] and a series of individual case reports of chronic Bell's palsy.[19] While LLLT is the photonic stimulation of areas to initiate therapeutic effects in the body, LAT is defined as the photonic stimulation of acupuncture points with low-intensity, non-thermal laser irradiation.[20] The human face plays a significant role in social interactions, and damage to its underlying muscle structure can cause considerable physical and social disabilities. Since LAT therapeutic effects on persistent and long-term Bell's palsy are unknown, this feasibility pilot clinical investigation was therefore designed.

Materials and Methods

The protocol for this study was published in detail beforehand.[21]

Recruitment of Subjects

This trial was conducted in the Acupuncture Department of China Medical University Hospital in Taichung, Taiwan. Posters in the clinics of the Acupuncture and Neurology departments of the hospital were used to recruit patients experiencing inadequate recovery from Bell's palsy. The recruitment period was from May 2018 to July 2020.

Inclusion and Exclusion Criteria

Patients who met all of the following inclusion criteria were enrolled in the study: males or females older than 20 years; confirmed Bell's palsy diagnosis (ICD-9-CM 351.0) with more than three months prior to entering the study; scores of less than 80 on both of the Facial Disability Index (FDI) and social and physical subscales; ability to comply with the study procedure; and provision of written informed consent. The subjects were not restricted from using any prescribed drugs or Chinese herbal medicine while participating in the trial. The patients with at least one of the following conditions were excluded from the study: recurrence of Bell's palsy or contracture and spasm with unknown reason; other neurological disorders or multiple cranial nerve palsies; uncontrolled hypertension or diabetes mellitus; pregnancy or active breastfeeding; facial nerve palsy within three months of study enrollment that was treated with steroids, antiviral drugs or surgery; any condition for which the patient received acupuncture or any other type of rehabilitation therapy within one month of study enrollment.

Design

After the screening procedure, eligible subjects were randomized to either the LAT group or the sham LAT group and received the same laser treatment three times per week for six weeks, for a total of 18 sessions. Treatment was administered by a trained, fourth-year, Chinese medicine resident doctor. The normal laser device consisted of a visible but harmless red light beam, which was used to direct the infrared laser beam precisely onto the skin, and acoustic signaling to indicate when irradiation began and ended. The sham laser device used in this study was deactivated by the manufacturer (Reimers and Janssen GmbH, Waldkirch, Germany). The laser irradiation was set to 0 mW of infrared light; however, its visual red light beam and acoustic signaling were retained, which made this sham laser procedure valid and reliable[22] because both the investigator and the subjects were blinded to the procedure. The study followed the Consolidated Standards of Reporting Trials (CONSORT)[23] and the 2010 checklist detailed in the Standards for Reporting Interventions in Clinical Trials of Acupuncture (STRICTA).[24]

Primary and Secondary Outcomes

The primary outcome measurement was the FDI social subscale score change between baseline measurements and those taken at 6 weeks[25] The secondary outcomes were the score changes between baseline and six weeks for the FDI physical subscale, the House-Brackmann facial paralysis scale (HB), the Sunnybrook facial grading system (SB) and the stiffness scale.

The FDI scoring system consists of two sections: a social score and a physical score. Each section consists of five multiple-choice questions relating to either physical or social issues that occurred in the previous month. The FDI, HB and SB systems have shown good reliability and validity[25,26] and are commonly used in Bell's palsy studies. FDI, HB and SB measurements were performed on the first visit, the 9th visit and the18th visit, and those scores were compared with baseline scores. The stiffness scale

was applied in each session and compared with baseline values. On a scale of 1–5, the subject was asked to select the number that best represented the current level of stiffness (where 1 = no stiffness and 5 = very stiff).[27] As far as we know, no traditional Chinese version of the FDI exists; therefore, a native Chinese professional translator translated the English version into traditional Chinese.[25] We used the translated version beforehand in our acupuncture department and decided that these questionnaires are clear and comprehensible to use in our study.

Randomization and Blinding

The randomization sequence was performed by a research assistant before the commencement of the study using the block randomization method[28] created by using a Microsoft Excel spreadsheet (Microsoft Corporation, 2016; Redmond, WA, USA). After undergoing the screening criteria and baseline assessments, the subjects were randomized to either the experimental group (real laser) or the control group (sham laser). The balanced sample size was ensured by grouping the subjects into even blocks of two, four, six, or eight. The randomization was conducted independently within each block and divided into four blocks using a 1:1 ratio, irrespective of gender. Only the research assistant for the trial, who was responsible for this procedure and not involved in the treatment, assessment or data analysis, knew the randomization sequence. The subjects, investigators, assessor and biostatistician were blinded to the allocation throughout the study period, and the researchers remained blinded to treatment allocation until the data were analyzed.

Laser Parameters and Acupuncture Points

We used the Handylaser Trion laser device (Reimers and Janssen GmbH, Waldkirch, Germany) in this study. Seven acupuncture points (SJ17, ST7, ST6, GB14, BL2, SI18, ST4) only on the affected side of the face were stimulated for 40 seconds, for delivery of 3J of energy with a pulsed wave (Noiger E). Two acupuncture points (LI4 and ST36) were stimulated bilaterally for 80 seconds, for delivery of 6J of energy with a pulsed wave (Noiger B). The selection of these points was based on previous studies on this topic [5] and it was done by a traditional Chinese medicine specialist who had more than 20 years of clinical experience. For a detailed description of laser parameters, see Table 1. LLLT is documented as a safe treatment and represents a non-invasive, pain-free method of treatment. From the available literature of previous studies, there is no record of any adverse effect caused by using the laser[17,18,29] to provide LAT to subjects with Bell's palsy or other conditions.[30] Nevertheless, protective goggles were used by both the investigator and the subject as a form of protection from possible laser damage to the eyes during irradiation, and any adverse events during this trial were recorded and monitored by the research investigator. Our study followed the World Association of Laser Therapy (WALT) guidelines for LLLT intervention.[31]

Power Analysis

The sample size for this pilot study was calculated using G*Power 3.0.10 for Microsoft Windows based on FDI data from a previous Bell's palsy study. The mean FDI score in the intervention group before the treatment was 68.6 with a standard deviation of 14.1, and the mean FDI score after the treatment was 80.7 with a standard deviation of 12.2.[27] The sample size was based on a power of 80% (beta 0.2), statistical significance of 95% (alpha 0.05) ($P = 0.05$), and a dropout rate of 20%. This study required 32 subjects. However, due to limited research resources and the coronavirus disease 2019 (COVID-19) worldwide pandemic, which significantly affected the study's subject recruitment and responsiveness in Taiwan, we decided to end the recruitment procedure at the original end date and use the current sample size (n = 17) as preliminary results.

Statistical Analysis

Table 1. Parameters of the Laser Device and Acupuncture Points in Our Study

Laser device	Gallium-aluminum-arsenide (GaAlAs) infrared laser (Reimers and Janssen GmbH: Waldkirch, Germany)		
Wavelength	810 nm		
Power density	150 mW/cm^2		
Probe aperture	0.03 cm^2		
Output power	maximum 150 mW		
Treatment dose	3/6 Joules per local/distal acupuncture points. 45 J/cm^2 in total per session		
Application type	Contact		
Pulsed light	Nogier E for local acupuncture points (4672 Hz), Noiger B for distal acupuncture points (584 Hz)		
Time	40/80 seconds for local/distal acupuncture points		
Acupuncture points	Chinese name[a]	Pin-yin name[b]	Alphanumeric code[c]
	翳風	yi-feng	SJ17
	下關	xia-guan	ST7
	頰車	jia-che	ST6
	陽白	yang-bai	GB14
	攢竹	zan-zhu	BL2
	顴髎	quan-liao	SI18
	地倉	di-cang	ST4
	合谷	he-gu	LI4
	足三里	zu-san-li	ST36

[a] Name of acupuncture point according to Traditional Chinese language, [b] Name of acupuncture point according to han-yu-pin-yin romanization system, [c] World Health Organization alphanumeric code of acupuncture point

Data analysis for this study was generated using SAS software, version 9.4 of the SAS System for Microsoft Windows. Frequency and distribution were assessed for categorical and numerical variables respectively. The Wilcoxon-signed rank test and Friedman test were used to do a non-parametric analysis of the FDI, HB, SB and stiffness scale scores within each group. A paired *t* test and analysis of covariance (ANCOVA) were used to compare the differences between correlated measurements when distribution assumption fit. A generalized estimating equation was applied to compare measurements taken on the first visit (baseline), the 9th visit and the 18th visit for both groups, and further multiple variable regressions were used to control related risk factors.

Results

Subjects Enrollment and Baseline Characteristics

A total of 40 patients were screened for eligibility to join the study, 23 of whom were excluded for the following reasons: the FDI total score was higher than 80 (n = 16); duration of palsy was less than three months (n = 4); no known Bell's palsy diagnosis (n = 2); declination to participate (n = 1). These exclusions resulted in 17 eligible subjects who were randomly assigned to the LAT or sham LAT groups. Of the 17 initially randomized subjects, two subjects from the LAT group and one subject from the sham LAT group dropped out during the study period. In the LAT group, one subject failed to return and one subject withdrew consent; in the sham LA group, one subject violated the selection criteria. For the study flow chart, see Figure 1. The baseline characteristics of the LAT and sham LAT groups were similar and can be seen in Table 2. There were no significant differences in age, mean duration of palsy and FDI, SB and stiffness outcome scores between the two groups.

Analysis of Outcome Variables

Table 3 displays the mean change in SB, HB and stiffness scores from baseline to week 3 and week 6. At week 6, there was a borderline significance ($P < 0.1$) in the SB and stiffness scores for the LAT group compared with the sham LAT group ($P = 0.0598$ and $P = 0.0980$, respectively). At week 3, there was a significant change in the scores on the HB for the LAT group compared with the sham LAT group ($P = 0.0438$). Overall, at week 6 there was not a significant difference between the two groups; however, the LAT group showed a higher response rate as compared to the sham LAT group (3.05 (1.05) -2.5 (0.55), $P = 0.1156$; 22.25 (0.71-2.25 (0.46), $P = 0.9316$). At baseline, HB grades in the LAT group were as follows: one subject with severe, two subjects with moderate-severe, two subjects with moderate and one subject with mild grade facial dysfunction. At week 6, HB grades in the LAT group were as follows: three subjects (patients)

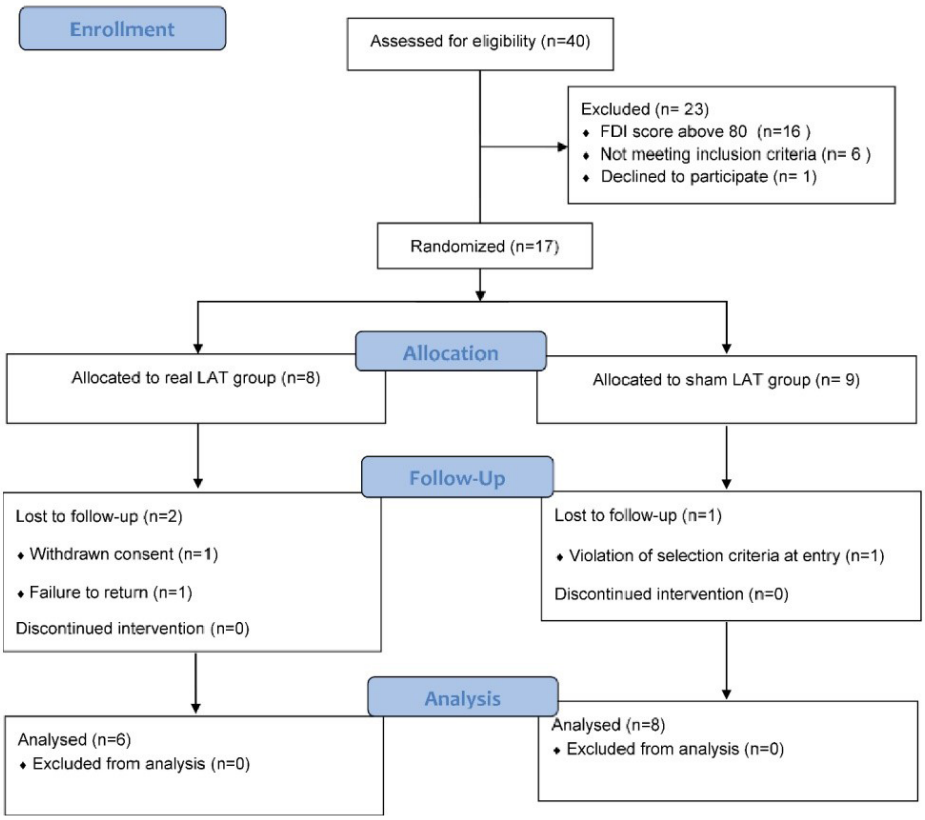

Figure 1. Study Flowchart According to CONSORT 2010.

Table 2. Baseline Characteristics of Bell's Palsy Patients According to Real LAT and Sham LAT

Variable	Chronic Bell's Palsy Patients				*P* Value
	Laser Acupuncture Therapy Used				
	Intervention (n = 6)		Sham control (n = 8)		
	No.	%	No.	%	
Gender					0.0085
Men	4	66.7%	0	0%	
Women	2	33.3%	8	100%	
Age group					0.4089
18-39	3	50%	2	25%	
40-64	3	50%	6	75%	
Mean ± SD (years)[a]	37.83 (12.72)		47.75 (13.68)		0.2195
Side of paralysis					0.0068
Left	0	0%	6	75%	
Right	6	100%	2	25%	
FDI					0.7958
Total	106.50 (28.20)		106.38 (26.06)		
Social score	49.17 (17.15)		60.00 (11.34)		
Physical score	57.33 (19.04)		46.38 (18.68)		
Sunnybrook grading score					0.0606
Total	40.67(25.61)		58.20(10.21)		
House-Brackmann grading score					0.0175
Grade II	1	16.67%	5	62.50%	
Grade III	2	33.33%	2	25%	
Grade IV	2	33.33%	1	12.75%	
Grade V	1	16.67%	0	0%	
Stiffness score	4.17 (0.75)		3.5 (0.76)		0.1307

Abbreviation: LAT, Laser acupuncture therapy; SD, standard deviation; FDI, Facial Disability Index.
[a] Wilcoxon test.

with moderate and three subjects with mild. At baseline, HB grades in the sham LAT group were as follows: one subject with moderate-severe, two subjects with moderate and five subjects with mild. At week 6, HB grades in the sham LAT group were as follows: four subjects with moderate and four subjects with mild. There were no aggravated cases in the LAT group, but one case was aggravated in the sham LAT group (Table 3). No adverse events were reported during the study. Table 4 displays the mean change in FDI scores from baseline to week 3 and week 6. There was no significant difference in the FDI score between baseline and week 6. At baseline, the FDI total score in the LAT group was 106.5 and 131.5 at week 6 as compared with 106.38 at baseline and 119 at week 6 in the sham LAT group (Table 4).

Discussion

To the best of our knowledge, this investigation is the first to evaluate LAT efficacy for the treatment of persistent, long-term chronic Bell's palsy. Previous studies of acupuncture have shown favorable effects for the treatment of chronic Bell's palsy,[8] and two LLLT clinical investigations have described positive outcomes in the treatment of acute Bell's palsy.[17,18] The preliminary results of this study show that LAT, delivered as gallium-aluminum-arsenide, 810 nm infrared wavelength, 150 mw/cm^2, applied for 40/80 seconds, 3/6 Joules in pulsed-wave per local or distal points respectively, may improve both social and physical functions in Bell's palsy patients. While Bell's palsy is not defined as severe illness, it does have a negative impact on quality of life and approximately 30% of cases are still left with complications, resulting in functional and sensory disorders which may lead to considerable social disturbance.[32] The World Health Organization published a review and analysis of reports that outline 64 conditions treatable by acupuncture with controlled clinical trials performed.[33] The list included Bell's palsy disease, but all the included studies focused on the use of acupuncture needles intervention and the acute stage of Bell's palsy. Therefore, new clinical trials using alternative approaches, such as LAT, and focusing on the chronic stage are needed. In preclinical studies, LLLT has shown tissue regenerative properties and both red and infrared wavelengths increased the functional

Table 3. The Mean Change in SB, HB and Stiffness Scores

Variable	Baseline	3 Weeks	6 Weeks	P Value*
HB	2.79 (1.05)	2.54 (0.78)	2.36 (0.5)	0.3801
LAT (n=6)	3.5 (1.05)	3 (0.63)	2.5 (0.55)	0.1156
Grade II	1 (16.6%)	1 (16.6%)	3 (50%)	
Grade III	2 (33.3%)	5 (83.3%)	3 (50%)	
Grade IV	2 (33.3%)			
Grade V	1 (16.6%)			
SLAT (n=8)	2.25 (0.71)	2.14 (0.69)	2.25(0.46)	0.9316
Grade II	5 (62.5%)	5 (62.5%)	4 (50%)	
Grade III	2 (25%)	3 (37.5%)	4 (50%)	
Grade IV	1 (12.5%)			
Grade V				
P value**	0.0175	0.0438[b]	0.3519	
SB	47.93(18.86)	58.46 (14.34)	62.21 (12.81)	0.0541
LAT	37 (23.61)	51 (15.74)	64 (12.44)	0.0598
SLAT	56.13 (9.13)	64.86 (10.07)	60.88 (13.76)	0.3396
P value**	0.2343	0.1971	0.5839	
Stiffness	3.07 (1.07)	3.07 (1.07)	2.86 (1.1)	0.0470
LAT	4.17 (0.75)	3.33 (1.03)	2.83 (1.17)	0.0980[a]
SLAT	3.5 (0.76)	2.88 (1.13)	2.88 (1.13)	0.3827
P value**	0.1307	0.5459	0.7884	

Abbreviations: LAT, Laser acupuncture therapy; SLAT, Sham laser acupuncture therapy; HB, House Brackmann facial nerve grading system; SB, Sunny brook facial nerve grading system; Stiffness, Stiffness score.
*Kruskal–Wallis one-way analysis of variance (group difference from baseline to week 3 and week 6); ** Wilcoxon test (group difference from baseline); [a] border-line significance $P<0.1$; [b] $P<0.05$.

Table 4. The Mean Change in FDI Score According to Baseline, Week 3 and Week 6

Variable	Baseline	3 Weeks	6 Weeks	*P* Value*
FDI (total)	106.43±25.92	122.57±29.53	124.36±29.82	0.1447
LAT	106.5±28.2	118±23.43	131.5±29.04	0.2359
SLAT	106.38±26.06	126±34.59	119±31.18	0.3831
P value**	0.8491	0.8001	0.4902	
FDI (social)	51.07±18.95	59.71±19.37	61.14±22.38	0.2238
LAT	57.33±19.04	61.33±14.68	70.67±19.04	0.3552
SLAT	46.38±18.68	58.5±23.22	54±23.13	0.4274
P value**	0.2647	0.9489	0.2173	
FDI (physical)	55.36±14.61	62.86±15.28	63.21±12.5	0.2666
LAT	49.17±17.15	56.67±15.06	60.83±15.94	0.2675
SLAT	60±11.34	67.5±14.64	65±10	0.4550
P value **	0.1585	0.2353	0.4100	

Abbreviation: FDI, Facial Disability Index; LAT, Laser acupuncture therapy; SLAT, Sham laser acupuncture therapy.
* Kruskal–Wallis one-way analysis of variance (group difference from baseline to week 3 and week 6).
** Wilcoxon test (group difference from baseline).

activity of the injured peripheral nerve.[34] In clinical studies, LLLT has demonstrated significant functional recovery in long-term peripheral nerve injury.[29-35] In a recent systematic review[36] of the efficacy of LLLT in Bell's palsy, evidence supported six weeks of treatment, 830 nm, 100 mW output power, irradiated for 2 minutes on eight points of facial branches on the affected site. The seven acupuncture points (SJ17, ST7, ST6, GB14, BL2, SI18, ST4) (Figure 2) used for treatment were local points in the face that covered all of the nerve branches in order to promote nerve regeneration and increase blood circulation.[37] These acupuncture points are commonly used for the treatment

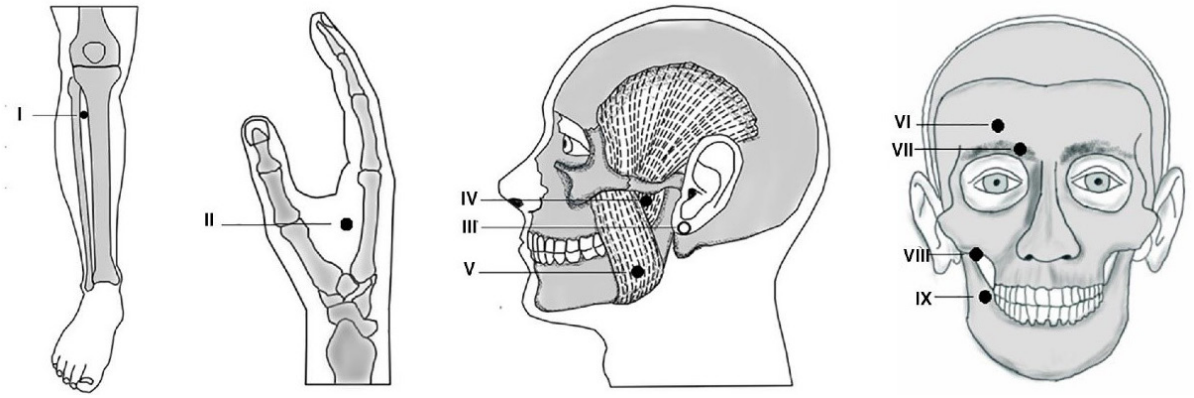

Figure 2. Acupoints Used in the Study: **(I)** ST36; **(II)** LI4; **(III)** SJ17; **(IV)** ST7; **(V)** ST6; **(VI) GB14**; **(VII)** BL2; **(VIII)** SI18; **(IX)** ST4.

of Bell's palsy.[5] Although the facial nerve has both motor and sensory fibers, its predominant function is motor,[1] and the fibers that control facial expression are located within the nerve branches. The temporal branch controls the orbicularis oculi, frontalis and corrugator supercilii muscles; the zygomatic branch controls the orbicularis oculi muscle; the buccal branch controls the buccinator, orbicularis oris and zygomaticus muscles, and the cervical branch controls the platysma muscle. We deliberately irradiated these acupuncture points for a relatively long period (40 seconds) with high output power (150 mw/cm^2) (Table 1) in order to let the photoreceptors absorb the photons slowly, thereby altering ATP synthesis and modulating cell reactions through the mitochondria.[38] Our acupuncture location and laser parameters, which included the pulsed wave and infrared wavelength, were similar to previous LLLT studies that used local points on the affected site and showed a significant improvement.[17,18] However, these were studies done with subjects in a sub-acute stage with a mean duration time of 3–5 days after the onset of symptoms. More than two-thirds of patients in this stage can recover spontaneously. In our study, all the included subjects were in the chronic stage of palsy, with a mean duration time of 12 months in the intervention group. The likelihood of regaining normal mimical function after this time period is very low.[2] The two other acupuncture points (LI4 and ST36 bilaterally) used in the study are distal points, and they are located in the upper and lower limbs (Figure 2). Both of these points are considered key points to treat Bell's palsy and are commonly used in both basic and clinical studies.[39] Moreover, in a clinical study using LAT in patients with long-term temporomandibular disorder, laser irradiation on LI4, ST6 and ST7 acupuncture points improved pain scores and maximal mouth opening.[40] In our study, we used a pulsed light treatment, and Noiger B (584 Hz) was applied to the distal points on the limbs while Noiger E (4672 Hz) was applied to points on the affected facial side (Table 1). Noiger B is being used for chronic conditions, and Noiger E is being used in diseases of the nervous system. Previously, we published a case study that demonstrated significant amelioration in severe, long-term central facial palsy, in which the same acupuncture points and laser parameters were applied.[41] While the prognosis for peripheral types of facial palsy is overall favorable, central palsy has a poorer recovery rate and the treatment is usually persistent with a slow response, if any[42]; however, using the same laser parameters and acupuncture points achieved positive outcomes and highlighted the possible effect of LAT on improving chronic cases of palsy. Likewise, in other clinical observations of LLLT for the treatment of pediatric Bell's palsy and long-term cases of paralysis, laser irradiation has shown positive therapeutic effects.[16-19]

Limitation of the Study

This study has notable limitations. First, the final number of subjects for analysis was low (n = 14) because of the influence of the COVID-19 pandemic on the Taiwanese population, which led to decreased outpatients visits and patients' unwillingness to join a 6-week study during the recruitment time. All eligible subjects in our study experienced long-term Bell's palsy and had tried both Western and Chinese medicine treatments beforehand without any success. Given this fact, we were interested in providing only one type of intervention in the study to assess the clinical effectiveness of LAT. Therefore, despite the small sample size, differences between the groups were shown and borderline significance ($P < 0.1$) in both SB and stiffness scores were observed at week 6 (Table 3). The HB score was close to a borderline significance at week 6 ($P = 0.1156$); however, at week 3, the HB score in the LAT group was significant ($P = 0.0438$). Overall, from baseline to week 6, the LAT group score was better as compared with the sham LAT group (Table 3). Both HB and SB facial nerve grading systems are commonly used in Bell's palsy studies; however, the SB scale is considered a more reliable scale than HB due to its continuous manner and wider response range.[43] Because SB, HB and stiffness were all close enough to claim statistical significance and

had a clear trend towards efficiency, we can speculate that significant results may have been achieved if the desired sample size was achieved. Thus, LAT may have clinical efficacy in the treatment of chronic Bell's palsy.

Second, there was no significant difference from baseline to week 6 in the FDI social subgroup scale, which was defined as the primary outcome measure of this study. This fact could be attributed to the low number of subjects for analysis. Moreover, very few studies have been conducted on chronic Bell's palsy, and because there were no previous LLLT studies available on this topic, our power analysis and sample size calculations were based on FDI data from the results of the mime therapy study.[27] Thus, due to the variation of treatment modalities, we speculated that the use of objective assessment techniques would be more adequate rather than a subjective, self-administrated questionnaire.[44] Third, electrodiagnostic testing was not part of the outcome measurements in this study, mainly because these diagnostic methods are used to determine the prognosis of palsy in the early stage of disease[3] while the subjects of our study were in the chronic stage. Therefore, our assessments were based on an objective evaluation of one assessor, which is an expert in his field. Nevertheless, this study offers valuable insights into the possible effect of LAT on chronic Bell's palsy and provides Chinese medicine physicians or other medical specialists who use LLLT with a reference point for how to use LAT, either as a single treatment method or as adjunctive therapy when treating peripheral facial palsy sequelae. This study is the first clinical trial to study the feasibility of LAT treatment for the complications of Bell's palsy. Apart from the fact that no adverse effects were reported and LAT has proven safe, this study provided important information on study design criteria, which can be useful for future research, whether it is a basic or clinical study. Future randomized controlled trials with a long-term follow-up of both acute and chronic Bell's palsy, which include other objective measurements like electrodiagnostic testing to assess the neurophysiological recovery of the facial nerve and muscles after LAT, are warranted. Moreover, further mechanistic studies of LAT in peripheral nerve disease are needed in order to confirm the use of acupuncture points, infrared wavelength and pulsed wave.

Conclusion

Our findings suggest that using LAT may have clinical efficacy in long-term complications of Bell's palsy. LAT is a safe treatment and should be considered for the treatment of Bell's palsy; however, our study was limited by the low sample size. Further large-scale randomized clinical studies are needed to confirm our study findings.

Ethical Considerations

The study protocol was approved by the Research Ethics Committee of the China Medical University Hospital, Taichung, Taiwan (Protocol ID: CMUH107-REC1-030) in accordance with the Declaration of Helsinki. The study is registered on ClinicalTrials.gov (Protocol ID: NCT03592797). A written informed consent form was obtained from each participant. All participants were allowed to withdraw from the study at any time.

Conflict of Interests

The authors declare that they have no conflict of interest.

Authors' Contributions

GT is the first author and YCL is the principal investigator. Drafting of the manuscript: GT. Study design: GT, CHT, YHC and YCL. Statistical analysis: WCH. Investigation: LWL. Conceptualization: GT and YCL. Data collection: GT. All authors have conducted this research and approved the final version of the manuscript.

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