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Effect of Low-Level Laser on the Healing of Neurosensory Disturbance Following Sagittal Split Ramus Osteotomy: A Double-Blind, Randomized Clinical Trial

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Abstract

Background: Neurosensory disturbances following orthognathic surgery, especially sagittal split ramus osteotomy are quite common. Furthermore improving the injuries to the inferior alveolar nerve following ramus osteotomy is still a challenge.
Objectives: This study aims to evaluate the influence of low-level laser therapy (LLLT) on the improvement of neurosensory disturbance following sagittal split ramus osteotomy.
Methods: This randomized, double- blinded clinical study was executed in a university-affiliated hospital, Tehran, Iran, during January 2017 and March 2018. Patients underwent sagittal split ramus osteotomy (SSRO) divided into case and control groups. Ten sessions of laser irradiation of 810 nanometers wavelength and power of 70 mW were rendered for eight minutes in the case group, while the patients in the control group were not irradiated. Thermal test, mechanoreceptor sensory tests, and satisfaction of the patients were evaluated during follow up examinations. Mapping of the affected skin area was marked to assess the healing process of the nerve damage.
Results: A total of 40 patients were included in the current study followed for a 12-month period. Statistical analysis of extracted data from the two-point discrimination test showed the significant better response of mechanoreceptors among the case group patients rather than the control ones (P value = 0.035). Marking the hyposthetic skin area in the patients that experienced laser therapy demonstrated that almost all of them manifested less sense on the vermilion area (85% in the case group versus 15% in the control group). Despite the control group patients whom on the mental foramen area significantly more paresthesia was experienced.
Conclusions: In conclusion, low-level laser therapy following sagittal split osteotomy may be helpful in faster recovery of nerve injuries and higher satisfaction of the patients.

Keywords: Irradiation, Laser, Nerve, Osteotomy, Orthognathic Surgery, Paresthesia, Sagittal Split Ramus

1. Background

Facial nerve injury following surgical processes (iatrogenic causes) and maxillofacial traumas is common. Neural problems could happen in 3.9% and 15.96% following wisdom tooth surgical extraction and mandibular fractures respectively (1, 2). Sagittal split ramus osteotomy (SSRO) during orthognathic surgery is a frequent iatrogenic cause of nerve injury. Nerve paresthesia in the lower lip region is the most common finding following SSRO (3). Neuropraxia is the most frequent injury following SSRO (4). Neurosensory disturbance is seen up to 74% after sagittal split osteotomy (5). In some cases, hypoesthesia remains for more than one year where it is considered permanent (6, 7). Permanent hypoesthesia is an important complication of sagittal split osteotomy and leads to significant morbidity (6).

Symptoms of neural injuries are a spectrum from complete anesthesia, following neurotmesis, to mild hypoesthesia, following neuropraxia. Irritation resulted from altered sense makes the patient look forward to a treatment (8). Although low level laser therapy (LLLT) and some other treatments are suggested as a treatment protocol for neuropraxia, there is no consensus on the best treatment plan for recovery of neurosensory disturbance following sagittal split osteotomy (8, 9).

LLLT is used as a treatment modality for different diseases in the oral and maxillofacial field. This modality has been described in the literature presents cytokine releasing effect such as endothelial growth factor and fibroblast growth factor (10, 11). Considering the molecular effects of

LLLT has led the researchers to achieve some benefits in the treatment of oral and maxillofacial patients. The positive effects of LLLT on reducing maxillofacial pain, accelerating oral ulcer repair, and faster healing of bone defects have been presented in various investigations (12, 13).

Various investigations are executed on evaluating the influence of LLLT on the healing process of damaged nerves (14, 15). Some studies like Gigo-Benato et al. yielded the influence of LLLT on the promotion of the nerve regeneration (16). These researches have indicated the positive effects of LLLT on the healing process of inferior alveolar nerve, and lingual nerve resulted from wisdom tooth surgical extraction (17). LLLT has been also used in accelerating the repair process of damaged nerve following orthognathic surgery (9), although some of the articles declined the results of the other ones (18).

2. Objectives

This study aims to evaluate the effects of LLLT on the healing process of neurosensory disturbance following sagittal split ramus osteotomy in patients required orthognathic surgery.

3. Methods

3.1. Patient Selection

This prospective clinical trial was executed between January 2017 and March 2018 in Taleghani Hospital, Tehran, Iran. The current study was designed as a three-phase protocol. In phase one, 40 patients referred to the department of oral and maxillofacial surgery candidate for orthognathic surgery were randomly selected, and clinical examination was performed to rule out the existence of neurosensory disturbance. Patients were selected for the present study according to the following inclusion criteria:

- Patients required sagittal split osteotomy to correct the maxillofacial deformity
- Neuropraxia damage occurred following sagittal split osteotomy
- Routine sagittal split osteotomy with no inappropriate split occurrence
- No previous surgery
- No previous nerve damage
- No medical disease
- No anticonvulsants and antidepressants drugs consumption

The exclusion criteria were:

- History of previous orthognathic surgery
- History of neurosensory disturbance in the facial area
- Inappropriate surgical technique or complication occurrence
- Neurotmesis or axonotmesis happening
- Medically compromised patients
- Uncooperative patients

The patients were randomly divided into the groups of case and control in a simple manner. Twenty patients were included in the case group and laser therapy was performed according to the protocol, in addition, 20 patients were included in the control group, which no laser therapy was executed (the probe was used whilst the laser unit is off).

3.2. Patient Assessment

Clinical examinations, according to the Sunderland classification (19), to evaluate the presence of neurological problems of inferior alveolar nerve were as follows:

- Two-point discrimination test; which was defined as the patient's ability to detect the two nearby objects contacting the face skin truly two distinct points, not one. A calibrated drawing compass was used with minimum error (reproducibility more than 95%).
- Thermal test; which was defined as the patient's ability to discern either the heat or cool probe. Small glass tubes containing water at 15°C and 50°C were used. The perception of either cold or hot stimulus was recorded.
- Contact direction test; was defined as the patient's ability to indicate the direction of fine brush stroked across the affected area.
- Pinprick test; was defined as the patient's ability to identify the sharp needle touching the affected skin. Dental probe (Dental explorer, Medesy srl, Italy) was used for this test, and the reproducibility was about 97% with the constant force.
- Patient's satisfaction; was defined as the comfortable sense of the patient scored between zero to ten.

Included patients underwent the orthognathic surgical procedure. All orthognathic surgeries were performed by one maxillofacial surgeon blinded to the groups in one hospital. In phase two, clinical examinations mentioned above were performed immediately after transferring the patient to the surgery ward following the surgery, three months, six months, and one year after the surgery. Data extracted from the clinical assessment established in the pre-prepared chart and the area of neurological problem was mapped into four main zones (Figure 1). All the examinations were performed by one trained maxillofacial surgeon blinded to the groups with high reproducibility (more than 98).

In order to make unification, the assessment all the patients were examined in a quiet and dark room after explaining the examination procedure to the patients. It was

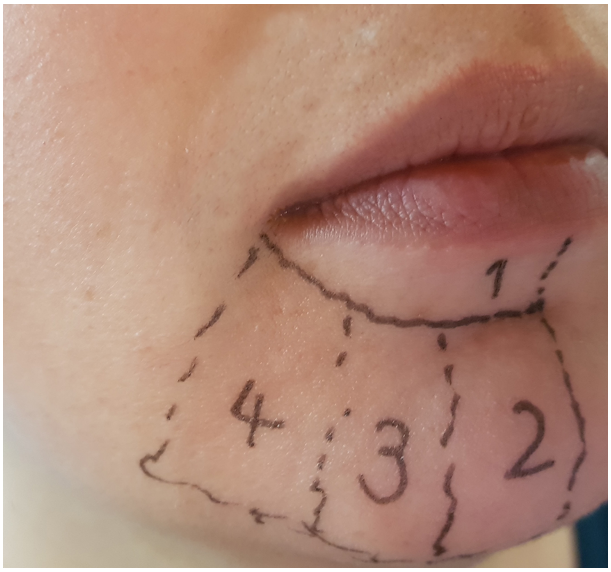

Figure 1. The affected areas of changed sense were divided into four sites of vermilion, median chin area, paramedian chin area, and mental foramen area

important to keep both the patient and the assessor blind to the treatment groups.

3.3. Laser Protocol

Laser irradiation, carried out with a diode laser unit (Litemedics, Brendola, Italy), was applied to the total surface mental nerve pathway intraorally (one point) and extraorally (three points) with 810-nm wavelength (Figure 2). The irradiation was performed at energy densities of 8.4 J/cm^2, output power of 70 mW, power density of 140 mW/cm^2, and 0.8 cm diameter spot size of the laser used on days 0 (immediately after the surgery), 1, 2, 3, and every other day for the next two weeks (total 10 sessions). Irradiation was executed for 60 seconds for each point (totally 4 minutes for each side of the patient). The irradiation duration was 8 minutes in every episode, and the total energy density each patient received was 67.2 J. The output of the laser was controlled by a calibrated power meter made by the Iranian Atomic Energy Agency, Tehran, Iran.

3.4. Ethical Considerations

Participants were informed of the purpose and design of the investigation and signed an appropriate consent form. The procedures followed were in accordance with the ethical Medical Sciences (ethical code 95-01-000082) and with the Helsinki Declaration of 1975, which was revised in 2000. The trial is also registered in the Iranian Registry of Clinical Trials (IRCT) with the ID of "IRCT20180930041179N1".

Figure 2. Extraoral site to render the laser irradiation

3.5. Statistical Analysis

All calculations have been processed using the IBM SPSS Statistical for Windows, version 20.0 (IBM Corp, Armork, N.Y., USA). Descriptive statistics including tables and graphs have been applied to show the information. Normal assumption was checked at first. Chi-square test and Wilcoxon signed ranks were used to determine the significant differences variables. Mixed ANOVA was used to measure the significance of nerve recovery during the time between two groups. A P value of less than 0.05 has been considered statistically significant. The sample size was estimated by using PASS, version 13.0 (NCSS statistical software; Utah; USA), considering the power of study 95% and 0.05 margin of error (20). The patients who met the inclusion criteria were included in the study in an available sampling strategy until it reached 40 patients.

4. Results

At first, 54 patients were selected for this study, and according to the inclusion/exclusion criteria, 40 patients were included finally (Figure 3). A total of 40 patients (18 male and 22 female patients) were included in the current study with the mean age of 26.52 $\pm$ 3.78. Twenty patients were included in the case group (nine male and 11 female patients) with the mean age of 25.7 $\pm$ 4.06. On the other hand, 11 female and nine male patients were in the control group (20 patients), and the mean age of the control group was 27.35 $\pm$ 3.35. The neurosenensory disturbance was evaluated in a 12-month follow-up period. The mandibular setback was performed in 34 cases (85%), and the other six patients (15%) underwent mandibular advancement procedures. Mean mandibular movement during the orthognathic surgery was 3.25 ± 0.89.

Data extracted of the two-point discrimination test were divided into three groups of least distance (less than 5 mm), intermediate distance (5 to 10 mm), and large distance (more than 10 mm) (Figure 4). These data are shown in Table 1. Statistical analysis indicated significant better distinct of two separate sharp points in the case group rather than the control one after one year (P = 0.035).

Contact direction test was significantly positive among the patients who underwent laser therapy versus the control group after one year follow-up (P = 0.002). All the patients were able to identify a sharp needle that touching the affected skin, except for three patients of the control group who did not notice the contact of the needle on the vermilion border. This difference was statistically significant (P = 0.003). The patients of both groups were able to detect the heat and cool after one year. These data are categorized in Table 2.

Patients' satisfaction of neurosensory recovery in shown in Table 3. The difference of satisfactory rate between the two groups was statistically significant (P = 0.015). Mapping of the affected sites is seen in Table 3.

5. Discussion

Damage to the inferior alveolar nerve could happen in traumatic patients and following mandibular fractures. This neurosensory problem may also occur following the sagittal split osteotomy during orthognathic surgery. Attempt to find novel methods for improving the healing process of damaged nerves are an essential challenge in the field of surgery and medical treatments. Application of low laser therapy has been proposed in helping the repair of nerves following neural injury, although it is not acceptable as a definite treatment protocol in all cases. This study was executed in a specialized governmental hospital. The Taleghani Hospital is a university-affiliated and referral hospital, and the patients were referred from the Baqiatallah hospital (also a specialized governmental hospital) too. In the current research, the influence of laser therapy on improving the neurosensory sensitivity return following sagittal split osteotomy was assessed.

Findings of the present investigation demonstrated significant mechanoreceptor sensitivity recovery among the patients underwent laser therapy. Less dysesthesia in the case group indicated laser therapy prevents deep nerve damage following surgery. Mapping of the affected skin showed a much smaller area among the patients who experienced laser therapy. In other words, the patients were significantly more comfortable after laser therapy rather than the patients of the control group. Neuropraxia is known as the axons conduction blockage while the neural sheath is intact. LLLT may be helpful in enhancing the recovery process of nerve damage. The influence of LLL on nerve healing could be assessed either subjectively or objectively. Designing the study to evaluate the nerve function both objectively and subjectively was the strength of the current study. Furthermore, the study was executed on long-term follow-up to make the results more reliable. The laser probe was used as the placebo when the unit was off to make the patients blinded to the groups. It was essential to design the study as double- blinded to reduce the possible bias.

Bruckmoser et al. evaluated the prevalence of neurosensory disturbance following sagittal split ramus osteotomy (21). They assessed the recovery of inferior alveolar nerve damage in a 12-month follow-up and evaluated the sense of lower lip skin. The neurosensory disturbance was established in 25.4% and 22.8% of the cases after six and 12 months, respectively. They concluded that the sensibility was significantly related to the age, gender, and operating time. The rate of neurosensory disturbance was significantly higher in the chin area. In the current study, after a 12-month follow up the highest rate of lack of sensibility was revealed in the vermilion of the lower lip (50% of the cases). However, in the control group, where the patients did not gain laser therapy, the lack of skin sensibility was higher in the median and paramedian chin area (40% and 25%, respectively). The present study revealed no significant relation between the age or gender and the rate of neurosensory disturbance.

Khullar et al. evaluated the efficacy of LLT on the patients who suffered from long-term nerve injury (22). They divided 13 patients into groups of case and control. They assessed the application of GaAlAs laser by the wavelength of 820 nm and the energy density of 48 J/cm^2 on the case group. The laser was irradiated on four points (one extraoral and three intraoral areas). They showed that LLT was effective in enhancing mechanoreceptor perception in the patients suffering from long-term neural damage, although it did not significantly improve the thermal sensitivity. Khullar et al. published another research evaluating the effects of LLT in the same previous protocol on sensory improvement following sagittal split osteotomy (23). They indicated that laser therapy, is effective in improving sensory response to the mechanical tests, although it had no influence on thermal perception enhancement. Similar findings were revealed in the current study. Using 810-nm diode laser irradiation following sagittal split osteotomy was significantly effective in improving sensitivity to mechanoreceptor sensory tests. The present study, similar to the Khullar et al. research showed no thermal sensitivity improvement following LLT in patients who un-

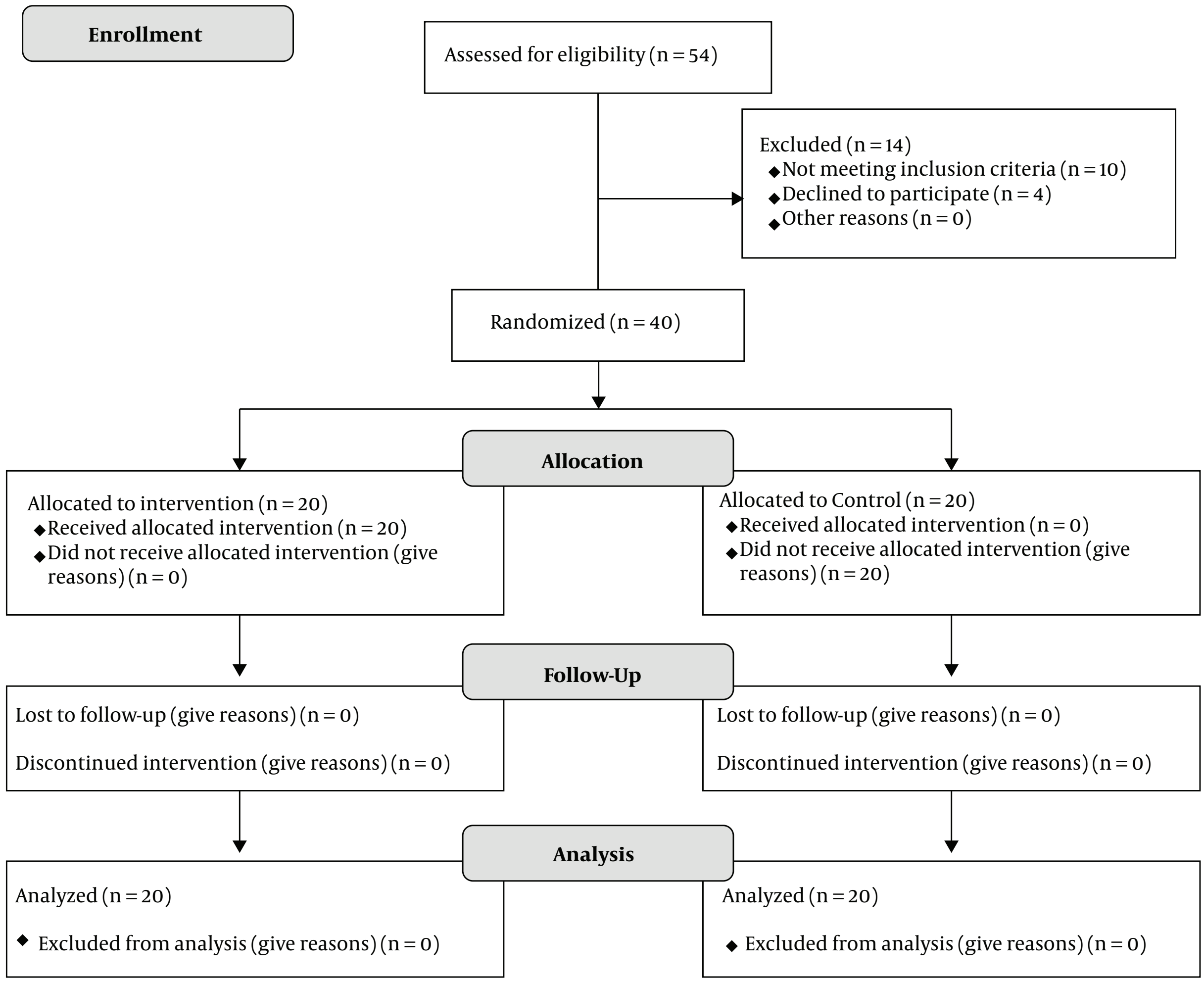

Figure 3. Consort flowchart

Table 1. Distribution of Dynamic Discrimination Test Findings in Case and Control Groups[a]

Groups	Two-Point Discrimination Test								
	Immediately After Surgery			After 6- Months			After 12- Months		
	< 5 mm	5 - 10 mm	> 10 mm	< 5 mm	5 - 10 mm	> 10 mm	< 5 mm	5 - 10 mm	> 10 mm
Case	30[b]	55	15	85	15	0	95[b]	5	0
Control	15	65	20	70	30	0	75	25	0

[a]Values are expressed as percentage.
[b]Statistically significant.

derwent orthognathic surgery. Two-point discrimination test showed the enhancement of mechanoreceptors recovery in the case group, which received laser therapy in the present study. Patients who underwent LLT could identify the two sharp points in the least distance comparing to the patients in the control group.

Miloro and Repasky evaluated the LLT influence on the lower lip sensitivity recovery following sagittal split ramus osteotomy (24). Six patients underwent LLT following orthognathic surgery and neurosensory tests performed to assess the degree of nerve damage. They revealed that rapid progression in the improvement of nerve healing

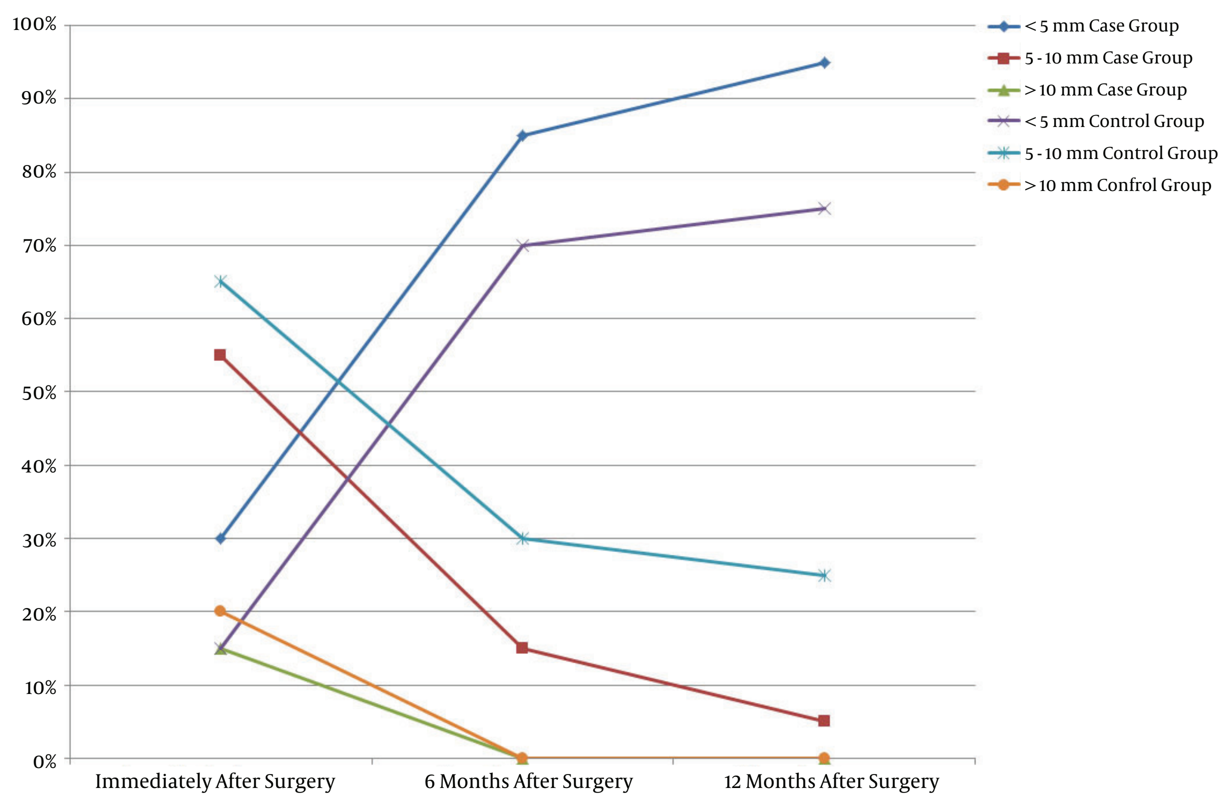

Figure 4. Diagram of the two-point discrimination test in each group and each time

Table 2. The Positive Response to Mechanical and Thermal Tests in Case and Control Groups 12- Months After Surgery[a]

Groups	Thermal Test	Pinprick Test	Contact Direction Test
Case	100	100[b]	85[b]
Control	100	85	70

[a]Values are expressed as percentage.
[b]Statistically significant.

might occur by application of laser therapy. However small sample size, considering no control group, and short follow up period (two months) made the results less reliable.

Prazeres et al. investigated the LLT efficacy on the healing process of damaged inferior alveolar nerve in the patients who underwent orthognathic surgery (25). Six patients were divided into groups of case and control. Laser therapy by the wavelength of 830 nm was performed on four patients. Mechanoreceptor sensory and thermal tests showed that the level of paresthesia was reduced significantly in the patients who experienced laser therapy. They concluded that laser therapy might accelerate the recovery of neurosensory sensitivity. Similar findings of the current study indicated that the patients who received laser therapies were more comfortable and the deep paresthesia was not experienced by any of the patients in the case group. The neurosensory return was more rapidly achieved in the case group compared to the control one.

Fuhrer-Valdivia et al. executed a study on the LLT among the patients who underwent sagittal split osteotomy of the ramus (26). A total of 31 patients were divided into groups of case and control. An 810-nm diode laser was used by the energy density of 32 J/cm^2 in the case group. Findings of their study demonstrated that the healing period of injured nerve was shorter in the case group besides the degree of neurosensory return was much higher compared to the control group. The present study showed a faster healing process and a higher magnitude of neurosensory return following LLT, although no significant difference in thermal sensitivity was seen between groups of case and control.

The advantage of the current study was designing a double-blinded study. Both the assessor and the patients were blinded to the groups. The laser probe was used in the control group while the device was off to blind the pa-

Table 3. Types of Neurosensory Disturbance and Mapping of the Affected Skin in Case and Control Groups[a]

Groups	Types of Disturbance (12- Months After Surgery)			Affected Skin Area (Following Surgery)				Affected Skin Area (12- Months After Surgery)				Median	IQR
	Hypoesthesia	Paresthesia	Dysesthesia	Vermilion	Median Chin Area	Para Median Chin Area	Mental Foramen Region	Vermilion	Median Chin Area	Para Median Chin Area	Mental Foramen Region		
Case	95	5	0	10	40	30	20	85	15	0	0	2.5	1.75
Control	65	15	20[b]	15	40	25	20	15[b]	40	30[b]	15[b]	1	0

Abbreviation: IQR, interquartile range.
[a]Values are expressed as percentage.
[b]Statistically significant.

tients included in this group. Actually, the patients were not aware of which group they were in. The observer who examined the tests was also blinded to the groups. Long-term follow-up was another strength of the present investigation. Not all studies reported in the literature were designed to follow the patients for one year.

5.1. Conclusion

The current study revealed that application of laser therapy in 10 sessions by the energy density of 40 J/cm^2 on the patients with neurosensory disturbance following sagittal split osteotomy might be useful in the rapid progression of the nerve healing process. LLT also may improve patients' sensory comfortably consisting dysesthesia following orthognathic surgery.

Footnotes

Authors' Contribution: Conception and design of the study were made by Mohammad Hossein Kalantar Motamedi, in addition, he approved the final draft of the manuscript Mohammad Esmaeelinejad performed the clinical part of the study and wrote the manuscript.

Conflict of Interests: The authors declare that they have no conflict of interests.

Clinical Trial Registration: The trial is registered in Iranian Registry of Clinical Trials (IRCT) with the ID of IRCT20180930041179N1.

Ethical Considerations: The procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation of Baqiatallah University of Medical Sciences (ethical code 95-01-000082) and with the Helsinki Declaration of 1975 that was revised in 2000.

Funding/Support: The study was self-funded.

Patient Consent: Participants were informed of the purpose and design of the investigation and signed an appropriate consent form.

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