Journal of Lasers in Medical Sciences

J Lasers Med Sci 2022;13:e30

Original Article

http://journals.sbmu.ac.ir/jlms

doi 10.34172/jlms.2022.30

Therapeutic Effect of a Low-Level Laser on Acute Pain and Post-operative Mouth Opening After Closed Reduction of Mandibular-Condylar Fracture

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Received: August 15, 2021
Accepted: June 7, 2022
Published online July 11, 2022

Abstract

Introduction: The purpose of this study was to determine the therapeutic effect of low-level laser therapy (LLLT) on acute pain and the range of mouth opening after condylar closed reduction surgery. The use of low-level lasers, especially to reduce inflammation and pain, has received more attention in recent years. The results of many studies performed in this field are contradictory, and the effectiveness of low-level lasers in the treatment of patients is still uncertain.

Methods: This study was performed as a randomized, double-blinded clinical trial on 40 patients with condylar closed reduction surgery. Patients were randomly assigned to two groups of 20 patients, including the placebo and intervention groups. In the intervention group, the patients received LLLT (100 mw, 2 J/cm^2, 20 S/point, 14 extraoral points, 7 days). The range of jaw movements after opening the intermaxillary-fixation was measured. Patients' pain was assessed using the visual analog scale (VAS). Data were analyzed using SPSS software version 21, the chi-square test, and repeated measures ANOVA.

Results: There was no significant difference between the study groups in terms of the range of jaw motions. The mean VAS score was 56.85 (SD=3.817) in the intervention group and 60.95 (SD=4.861) in the placebo group, showing a statistically significant difference between the two groups at the end of the study (P=0.007)

Conclusion: The results of this study indicated the effectiveness of low-level lasers in reducing acute pain in patients undergoing closed condylar surgery.

Iranian Registry of Clinical Trials (IRCT20200520047519N1)

Keywords: Low-level laser therapy; Mandibular condyles; Surgery; Closed reduction; Fracture.

Introduction

Joint traumas, condylar fractures, and their treatments can lead to many problems for patients, such as pain, limitation in jaw movements, and limitation in daily life activities. Mandibular deviation during mouth opening, joint resorption, ankylosis, headache, difficulty in chewing and talking, the negative effects of chronic and acute pain on sleep,[1] as well as temporomandibular joint disorders (TMDs) are common side effects after the treatment of condylar fractures.[2] These problems have adverse effects on the patient's satisfaction with the outcome of treatment and quality of life, disrupt the patient's normal daily activities, and impose economic problems due to the inability to work and losing working days. Therefore, developing effective treatment protocols to restore function and reduce pain after surgery in the shortest possible time is of great importance.[3]

About 11% to 50% of all facial fractures and 40% of mandibular fractures due to traumas are related to the condylar region.[4] Different possibilities of mandibular fractures make it difficult to choose the optimum treatment technique. The primary objective of the treatment is to reconstruct the occlusion, along with the normal jaw and temporomandibular joint function and anatomy. The therapeutic options consist of closed reduction with intermaxillary fixation (IMF) (resin-bonded orthodontic brackets, arch bars, eyelet wires, direct wires) or open reduction with internal fixation (plates, wires, hard wares placed directly across the fractured site), analgesic and muscle relaxant medications, moist heat, soft diet, and stretching exercises after surgery. The main surgical treatments are close reduction and open reduction.[5-7] Complications of both treatments include muscle spasm, limited mouth opening, deviation during mouth opening, and the occurrence of joint ankylosis. Therefore, mouth opening and restoring the function through physiotherapy are of great importance.[2,8,9] Accordingly, the patient's cooperation in performing the

Please cite this article as follows: Bahari Bandari A, Hajmohammady S, Mafi S. Therapeutic effect of a low-level laser on acute pain and post-operative mouth opening after closed reduction of mandibular-condylar fracture. *J Lasers Med Sci.* 2022;13:e30. doi:10.34172/jlms.2022.30.

exercises is very important. One of the most important factors influencing patient cooperation is the level of pain in the affected area.

Low-level laser therapy (LLLT) uses electromagnetic radiation in the spectrum of red or infrared light waves and is used to treat various pathological problems such as wounds, pain, and inflammation.[10-12] Also, the therapeutic effect of LLLT on reducing pain and improving the condition of patients with chronic musculoskeletal disorders, such as osteoarthritis in the knee and spine, has been reported in review articles and various studies.[11,13-16] The use of LLLT, as an adjunct therapy during the closed reduction of a fracture, third molar surgery, and orthognathic surgery to reduce pain during treatment and restore proper function afterwards, has been considered in few studies.[13,17-19] The exact mechanism of LLLT has not been explained yet, but according to recent studies, there are a few hypotheses. The effect is photochemical, not thermal. Photobiomodulation starts biochemical changes within cells, and the photons are absorbed by cellular photoreceptors and induce chains of reactions. According to Cotler et al, "The main hypothesis is that the photons separate inhibitory nitric oxide from the enzyme, leading to an intensification in mitochondrial membrane potential and stimulation of ATP production. Another hypothesis suggests light-sensitive ion channels that can be activated, letting calcium enter the cell. Also, several signaling pathways are activated via reactive oxygen species, NO, $Ca^{2+}$and cyclic AMP causing the activation of transcription factors."[11-13,20-23]

In maxillofacial surgeries, the use of low-level lasers, especially to reduce inflammation and pain, has received more attention in recent years. Previous researches have focused on the effect of LLLT on the treatment of TMDs, stimulation of ossification after oral surgeries, pain relief after oral surgery (such as third molar surgery), and improvement of mouth opening after orthognathic surgery.[10,11,14,17,24-27] The use of LLLT seems to be in line with the philosophy of accepted adjuvant therapies for the treatment of closed joint fractures due to its non-invasiveness, reversible nature, and safety.[28] Undeniably, there are reports of noteworthy outcomes by using LLLT as compared to placebo groups, while others could not find any significant differences using LLLT. There is no established protocol (energy intensity, power, exposure time, and the number of applications) currently recommended for TMDs or post-surgical management pain, edema or range of movement.[10,11,29-32] By trying to eliminate the drawbacks and shortcomings of other studies, we aimed to evaluate the therapeutic effectiveness of LLLT in reducing pain and improving jaw movements in patients undergoing condylar fracture surgery.

Materials and Methods

This research was a randomized, double-blinded clinical trial that was approved by the ethics committee of Kerman University of Medical Sciences (IR.KMU.REC.1399.148) and the Iranian Registry of Clinical Trials (identifier: IRCT20200520047519N1). Male and female patients referred to the Oral and Maxillofacial Surgery Ward, Bahonar Hospital, Kerman, were examined by a trained resident, and they underwent a CT scan to diagnose temporomandibular joint fracture according to standard diagnostic criteria.[5] The final diagnosis was confirmed by the oromaxillofascial surgeon attendant. After the diagnosis of a condylar neck fracture and sub-condylar fracture (extra-capsular), the need for closed fracture surgery as a treatment was confirmed.[33] Men and women with a previously described fracture, who needed to be treated by the arch bar and IMF or maxillomandibular fixation (MMF), were included in the study. The exclusion criteria were as follows: patients consuming psychotherapy medications, drugs, and alcohol, patients with a history of previous fractures, surgery, dislocation, and locking of the jaw, and those with absolute contraindications for MMF treatment (such as patients with mental retardation). In addition, people who had little cooperation or were at risk for seizures were excluded from the study.[2,9,33] The patients who did not attend the treatment and follow-up sessions and could not tolerate the MMF course were also excluded from the study. Further, patients with craniofacial anomalies or incomplete eruption of permanent teeth (presence of deciduous teeth), those with periodontal problems, pregnant women, individuals with pathological problems in the head and face and with pathological fractures, and patients who were unable to respond to questions were excluded from the study. For all patients, the standard treatment protocol, including arch bar placement and proper occlusion, was performed under general anesthesia, and after the patient's condition became more stable in the ward, elastic and wire IMF was performed on the day of surgery. After seven days, the MMF was opened, and the patient was trained by active physiotherapy. To control pain on the first day after surgery, ibuprofen 400 mg was prescribed to the patients every six hours.[2,9]

Patients were given the necessary explanations about the study's aims and methodology. After signing a consent form, 40 patients who desired to take part in the study were randomly separated into two groups of 20 cases. Randomization was done using the www.randomizer.org (A: LLLT recipient, B: Placebo group) and a lottery method of sampling.

In this research, a gallium–aluminum–arsenide laser with a wavelength of 808 nm (86X NOVIN low-level laser, NOVIN Medical Engineering Company, Iran) was used. A trained operator who had no contact with the therapist or statistical analyst performed laser therapy. Also, the patients were assigned to the study groups by a person who was not involved in the study by handing

the patients a sealed envelope in which their assigned groups had been written. The patient was asked to use blindfolds for safety during laser treatment, and the sound of the device was exactly the same for both groups; thus, the patients were likewise unaware of their group assignments.

Due to the lack of a specific treatment protocol and the wide range of protocols that were used in previous studies (in terms of energy density, power density, duration of radiation, and the number of laser therapy sessions),[13,14,18,34] we employed a method described by de Rezende et al.[34] A gallium–aluminum–arsenide laser was used with a wavelength of 808 nm (86X NOVIN low-level laser, NOVIN Medical Engineering Company, Iran), an output power of 100 mW, and 100 J/cm^2 energy at any point for 20 Seconds (energy: 2 J/Point) while the tip of the device was 2 mm away from the skin. A total of seven therapy sessions were held right after the surgery and the following days until the opening MMF after one week. Using Rezende protocol, we performed the therapy on 14 extraoral points (two preauricular points, eight points overlying the masseter muscle, two over the submandibular lymph nodes, and two over the jugulodigastric lymph nodes) (total energy: 28 J) (Table 1).

For group B (placebo), the device was set to have no radiant power (energy density: 0). All steps were done by observing safety issues and using blindfolds for patients. The device tip was also disinfected with alcohol after each use.

Pain scores at the beginning and end of MMF treatment were recorded using the visual analog scale (VAS). For this, a 100-mm line was drawn, and the patients were asked to designate their pain severity, considering the least severe pain on the right side and the most severe pain at the left end. Using a ruler, we measured the distance from the right to the marked place in millimeters to calculate the VAS score.[35]

Then the patient was clinically examined by the clinician that was blind to grouping, and the level of jaw movement during mouth opening and lateral movements were measured and recorded using a ruler.

Table 1. The laser parameters

Parameter	Laser Group
Type of laser	Gallium–aluminum–arsenide laser
Wavelength (nm)	808
Application/point time (s)	20
No. of application points	14
Density of energy/point (J/cm^2)	100
Power (mW)	100
Energy (J/Point)	2
Total energy	28
Application technique	Non-contact

Data were analyzed using SPSS software version 21, the chi-square test, and repeated measures ANOVA.

Results

There was no significant difference between the two groups in terms of age and sex. The mean age of the LLLT group was 28.95 ± 5.23, and in the placebo group, it was 31.2 ± 5.69. The mean age of the participants showed no significant difference between the intervention and control groups according to student t-test results (P value = 0.201). According to the chi-square test, there was no significant difference between the two groups in terms of gender (P value = 1) (Table 2).

There was no significant difference between the groups in terms of the range of jaw motion. Table 3 shows the ranges of jaw movements during mouth opening (P value = 1) and lateral jaw movements (movement toward fracture side P value = 0.34, movement toward non-fractured side P value = 0.095) in the intervention and control groups (Table 3).

At the end of the study, the mean VAS scores were 56.85 (SD = 3.817) in the intervention group and 60.95 (SD = 4.861) in the placebo group, showing a statistically significant difference between the two groups at the end of the study (P = 0.007) (Table 4).

Discussion

In this study, the results showed that the severity of pain in the patients who were treated with LLLT was lower than that in the patients in the placebo group. In contrast, the ranges of jaw movements presented

Table 2. Distribution of Patients by Gender

	Laser No. (%)	Placebo No. (%)	Total No. (%)
Gender			
Man	15 (75)	15 (75)	30 (75)
Woman	5 (25)	5 (25)	10 (25)
Total	20 (100)	20 (100)	40 (100)

Table 3. Compression of the Range of Motion in 2 Groups

	Laser Mean (SD)	Placebo Mean (SD)	*P* Value[a]
Range of motion			
Maximum opening (mm)	17 (±0.026)	17 (±1.835)	1
Toward fractured side (mm)	7.9 (±2.15)	8.45 (±1.365)	0.34
Toward non-fractured side (mm)	3.8 (±1.361)	4.65 (±1.755)	0.095

Abbreviation: SD, standard deviation.
[a] P < 0.05.

Table 4. Compression of the VAS in 2 Groups

	Laser Mean (SD)	Placebo Mean (SD)	*P* Value[a]
VAS score	56.85 (±1.38)	60.95 (±4.86)	0.007

Abbreviations: VAS, Visual Analogue scale; SD, standard deviation
[a] P < 0.05.

no significant difference between the two groups. Beak et al, in a retrospective study on the effect of LLLT on inflammation and edema in 40 patients with facial fractures, reported that LLLT effectively reduced post-traumatic edema.[18] In 2018, de Rezende et al, in a clinical trial, showed the beneficial effects of using a low-level laser on the range of mouth opening after orthognathic surgery in patients undergoing bimaxillary osteotomy.[34] In another study, 30 patients undergoing orthognathic surgery were subjected to LLLT (3 J/cm^2, 808 nm, and 100 mW) outside the oral cavity immediately and 24 and 48 hours after surgery. After mouth opening, the treatment continued inside and outside the oral cavity for 60 days, twice a week. The study groups were finally evaluated for jaw movements and pain severity (VAS). After two weeks, the range of movement was significantly higher in the intervention group compared to the control group. The severity of pain was also significantly lower in the intervention group; however, there was no significant difference in the rate of swelling reduction among the two groups. The findings of the recent report confirmed that the use of low-power lasers after orthognathic surgery not only alleviated pain but also improved jaw movements.[14] Similar to the previous two studies, our results also showed a significantly lower VAS score in the group receiving LLLT compared to the placebo group at the end of the study. One reason for the difference regarding the effect of laser therapy on jaw movements can be the longer treatment period in the study by D'ávila et al[14] compared to the present study.

Since the introduction of LLLT, it has been used for various diagnostic and therapeutic purposes. Many studies have assessed the therapeutic effects of this type of laser on inflammation and acute and chronic pain in the maxillofacial area, as well as its effectiveness in repairing soft and hard tissues.[10-13,17,26] Likewise, some studies have investigated and reported the beneficial therapeutic effects of LLLT on trauma patients and those undergoing major surgeries, such as orthognathic surgery.[13-15,18,19] These studies have reported significant impacts on pain reduction and improvements in other postoperative symptoms in the patients treated with LLLT compared to those in the placebo group. However, reviews and meta-analysis assessments in these studies could not confirm the results of these researches, so further studies are necessary to disclose the determinants of LLLT therapeutic effects.[10-12,19,25,26] Researchers declared that high heterogeneity, small sample sizes, and a high risk of bias could have deterred obtaining accurate results. Therefore, it is necessary to conduct further studies with appropriate designs to obtain more accurate results.[28] One of the drawbacks of these studies was the lack of a precise description of the randomization method, which could have affected their results. In this study, the lottery method of sampling was used for the random assignment of the patients to the intervention and placebo groups. There were not any significant differences between the groups in terms of gender, age, marital status and education, which indicated homogeneity between the groups by using the lottery method. In terms of gender, males constituted a higher ratio of the participants in both groups, which is consistent with the results of epidemiological studies on the prevalence of head and face traumas and condylar fractures in men.[4,9] On the other hand, inclusion and exclusion criteria had not been well-defined in some other studies.[7,26,29,30,32,36] In the present study, we adhered to a number of strict inclusion and exclusion criteria, which played an important role in homogeneity between the study groups.

The low-level laser is a clinically well-accepted tool in medicine and dentistry, which is characterized by photobiological stimulation without causing any thermal damage to the body.[11] Unlike high-power lasers, these lasers have a low level of energy and are only suitable for inducing tissue excitatory responses. Low-level lasers encompass a wavelength range that can alter cellular function without causing excessive and high heat; however, the exact mechanism of action of low-level lasers in reducing pain, healing wounds, and reducing inflammation remains unclear.[11]

There are currently several hypotheses about how low-level lasers work in the treatment of headaches and facial pain and how they enhance the functional performance of tissues, cells, and organs.[23,28] One of the proposed mechanisms is the improvement of microcirculation after low-level laser irradiation, boosting oxygen delivery to the hypoxic cells associated with trigger points.[12,23] A review study strongly supported the biological effects of LLLT on damaged soft tissues, suggesting two mechanisms: (1) modulating biochemical inflammatory markers and inducing the production of local anti-inflammatory factors in soft tissues, and (2) improving angiogenesis by increasing the secretion of growth factors and forming a vascular network in the affected area.[12,16,23,27]

In the closed condyle fracture treatment, it is highly important to early intervene to activate the jaw to increase the range of jaw movements towards the normal level. In this process, patient cooperation is a key factor, and the lack of cooperation is a frequent issue that irreversibly affects the outcome of the treatment. Among important reasons for patients' lack of cooperation are pain and discomfort; thus, it seems that the use of safe pain-relieving adjunctive therapies with low side effects can play an effective role in boosting patient comfort, accelerating the healing process and preventing the high costs of open surgeries for the patient and the health system.[2,9]

The present study showed that LLLT could be used effectively to reduce acute inflammatory pain, so it is expected that the start of physiotherapy sessions after

the treatment will be easier for the patient, upgrading the patient's compliance with postoperative physiotherapy. Nevertheless, a long-term follow-up is needed to confirm a reduction in the length of the treatment.

On the other hand, the placebo effect has been proven to affect the outcomes of the studies assessing the effectiveness of new treatments. Thus, the outcomes of any therapeutic intervention can be influenced to some extent by the placebo effect, which is also true for LLLT.[37,38] The use of shamans or placebo can alter pain regulation pathways based on the patient's expectations of the treatment, and these changes can be observed in patients' MRI.[37] The World Laser Therapy Association has agreed to include the placebo group as a part of the clinical trials studying the effects of low-level lasers on joint and facial muscle pain. Therefore, because many previous studies have been conducted without using a placebo group, their results may not be (sufficiently) valid.[39] In fact, studies on pain have shown that the placebo effect plays an important role in the recovery of patients.[37,38]

According to the biopsychological model of pain, the role of the psychosocial dimension becomes highly remarkable in chronic pain and is even more effective in the persistence of pain than the biological dimension. In the case of acute pain, on the other hand, which includes inflammatory responses and chemical mediators such as inflammatory cytokines, the biological dimension is more significant in pain perception.[40] Given that acute pain was assessed in this study, the pain-reducing effects of LLLT can be interpreted with a higher certainty.

LLLT is a new therapeutic modality that is widely appraised for its effectiveness. Many studies have reported promising treatment outcomes for laser therapy in different conditions. This strategy can have a positive effect on patients' and physicians' expectations of treatment outcomes, promoting the placebo effect. Nevertheless, we here showed that LLLT was not effective in improving the limitations of jaw movements, which can be attributed to the relative diversity of fracture patterns and mechanical interferences, providing a low possibility for matching all cases. Accordingly, it seems that for a definite conclusion on the effects of laser therapy on jaw movements, there is a need for conducting long-term studies on a large number of patients with similar fracture patterns.

Conclusion

In general, it can be concluded that LLLT can reduce post-surgical pain; however, its mechanism of action is not well-understood. LLLT can be safely used as an adjuvant therapy besides standard treatments to reduce pain and inflammation after orofacial surgery, but further research is needed to better understand LLLT therapeutic mechanisms. On the other hand, we suggest large study populations and long-term follow-up periods for future studies.

Acknowledgements

This study was supported by the Dental School of Kerman University of Medical Sciences, Kerman, Iran, and Shahid Bahonar Hospital of Kerman. We would like to appreciate our colleagues in the dental school of Kerman University of Medical Sciences and Shahid Bahonar Hospital, who provided expertise that greatly assisted the study. Besides, the patients who participated in this study are appreciated.

Conflict of Interests

The authors declare that they have no conflict of interest.

Ethics Considerations

The protocol of the study was approved, under the code IR.KMU.REC.1399.148, by the Research Ethics Committee of Kerman University of Medical Sciences.

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