Journal of Photochemistry and Photobiology 8 (2021) 100062

Contents lists available at ScienceDirect

Journal of Photochemistry and Photobiology

journal homepage: www.sciencedirect.com/journal/journal-of-photochemistry-and-photobiology

Efficacy of photo bio-modulation therapy for pain relief and soft tissue wound healing after dental implant surgery: A double-blind randomized clinical trial

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ARTICLE INFO

Keywords:
Low-level Laser Therapy
Pain Relief
Photo bio-modulation Therapy
Wound Healing

ABSTRACT

Objective: This study aimed to investigate the effect of photo bio-modulation therapy (PBMT) on pain relief and wound healing after dental implant surgery.
Background data: Photo bio-modulation (PBM) has been used as a therapeutic method for the healing of wounds and controlling pain and inflammation.
Materials and methods: In this clinical trial, 21 patients including 12 men and 9 women were selected based on inclusion criteria. Forty-two implants were placed in the posterior regions of both sides of the mandible. Immediately after the surgery, 660 nm and 810 nm diode laser beams with an energy density of 6 J/cm^2 were concurrently irradiated on three sides of the implant regions, buccal, occlusal, and lingual sides. After 48 h both two lasers were applied to patients without irradiation, as placebo devices in the control side. The severity of patients' pain was examined after 12, 24, 48, and 72 h based on a visual analog scale (VAS). Wound healing score was also determined at 3, 7, and 14 days postoperatively using the Likert scale from 0 to 4. The data were analyzed with SPSS. Statistical significance was set at $\alpha = 0.05$.
Results: The laser side exhibited a significant improvement in wound healing and pain relief at all the intervals compared to baseline ($p < 0.05$). Wilcoxon test showed that the wound healing score on the laser side at 3 ($p < 0.001$), 7 ($p < 0.001$), and 14 ($p = 0.03$) days was significantly better than that on the placebo side. Paired t-test showed that at all the intervals of 12 h ($p < 0.008$), 24 h ($p < 0.04$), 48 h ($p < 0.008$), and 72 h ($p < 0.02$), the mean pain score on the laser side was significantly lower than that on the placebo side.
Conclusion: Given the limitations of this study, the results showed that PBM enhanced wound healing and decreased pain after dental implant surgery.

Introduction

The goal of novel dental treatments is to restore the patient's oral status to normal in terms of function, convenience, aesthetics, speech, and tissue health [1]. One of the novel methods of regenerating patients' dentition is the use of dental implants to replace the root of the lost teeth, which fulfills the functioning and aesthetics of the patient with a high confidence level. Since the prerequisite of implant placement is making an incision and creating a wound in the soft tissue, followed by drilling the jaw bone, as with any other surgery, the procedure might have complications, including swelling, pain, improper healing of soft and hard tissue, bleeding and hematoma, and eventually failure in the implant–bone osseo integration [2]. Various techniques have been suggested or clinically assessed, including pharmacotherapy by steroid and non-steroidal analgesics to manage and minimize the complications resulting from dental implants. The application of different types of laser

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https://doi.org/10.1016/j.jpap.2021.100062
Received 26 February 2021; Received in revised form 16 August 2021; Accepted 25 August 2021
Available online 5 September 2021

in various dental treatments has attracted a great deal of attention for several decades. These lasers have been evaluated as a primary method of treatment or an adjunctive method alongside the mainstream treatments [3–6].

Lasers are categorized into high-intensity and low-intensity types.

High-intensity or warm laser can be used for the incision and surgery of soft or hard tissue: these lasers lie within the wavelength ranges of 450–532 nm and 800–2940 nm, both in visible, near and far infra-red portions of the electromagnetic spectrum [7]. Treatment by low-intensity lasers, also known as cold or soft lasers, is referred to as low-level laser therapy (LLLT), or more precisely, photo bio-modulation therapy (PBMT). The team "LLLT" indicates the use of low-power radiation, which is between 5 and 500 mw and its non-thermal effects are used for different purposes, such as healing, pain relief, and reducing inflammation [6,8]. Mester was the first to report the effect of LLLT in medicine. He used LLLT (1 J/cm^2) to enhance wound healing [9]. It has been shown that "in vitro" PBMT increases the proliferation of epithelial cells and fibroblasts, consequently increasing collagen deposition, which is an important prerequisite for wound healing [10]. Some studies indicated that low-intensity visible lasers, such as He-Ne, drive the cellular mitosis through mitochondrial stimulation and increase the energy of metabolic cycles and enhance protein synthesis. Eventually, an improvement in wound healing in response to this type of laser is the result of increased cell proliferation [11]. In addition, low-intensity lasers have analgesic effects on both acute and chronic pains, the reason for which is still unknown; however, some principles have been known to be involved in the process [12]. However, in some studies, the analgesic effects, along with diminished inflammation and improved healing, have been reported following the delivery of low-intensity lasers following tooth extraction or tooth surgery [13–16]. Nevertheless, some studies have reported an obvious positive effect of LLLT on stimulation of healing and reduction of inflammation around periodontal and peri-implant soft and hard tissues. They have reported that there is still a great deal of heterogeneity in terms of study designs and most importantly, in light irradiation devices and the parameters used. [17]

Therefore, this double-blind, randomized clinical trial aimed to determine whether PBMT can decrease the severity of pain or enhance wound healing after dental implant surgery.

Materials and Methods

The present study was designed as a randomized clinical trial and recorded in the Iranian clinical trials website under the code of IRICT201506132269. This clinical trial was approved by Iran national committee for ethics in biomedical research (IR.MUI.REC) under the code of 1395, 3,842. In this study, patients were selected by simple sampling. First, after obtaining consent from the patients, if they met the inclusion criteria, their anxiety level was measured through a modified dental anxiety scale. Based on this test, the patients with an anxiety score <19 were selected [18]. Accordingly, 23 patients with a mean age of 46.81 years (range: 24–61 years), including 14 males and 9 females, were studied. Of 23 patients, two were excluded since they required guided bone regeneration. Forty-six Snucone implants (SNUCONE.CO, LTD, Daegu, Korea) with standard SLA (sandblasted, large-grit, acid--etched) surface were placed as submerged in the oral cavity of 23 patients through a split-mouth method (Twenty three implants in experimental side (implant surgery and PBMT group) and 23 implants in the placebo)(implant surgery and simulated PBMT group). Two implants were placed in each patient in the posterior region of both sides of mandible at the same time by an implantologist with more than 20 years of experience (First author). Since the severity of pain in the maxilla and mandible is not the same, for maximum matching, all the implants were placed on both sides of the mandible.

Exclusion criteria

The exclusion criteria consisted of age <18 years, smoking, pregnancy, the use of some medications, such as antibiotics, insulin, and corticosteroids, systemic diseases such as diabetes, cardiovascular disease, convulsions, and endocrine gland disorders, cancer, light sensitivity (5), inadequate bone volume, a history of implant failure at the site of the new implant surgery (1), nervous states or anxiety, and phobia of dentistry based on Modified Dental Anxiety Scale (MDAS) rapid assessment [18].

Surgical technique

Each of the two regions of implant placement was selected randomly based on radiographic and clinical examinations. Fifteen minutes before surgery, the patients used a 0.2% chlorhexidine solution (Behsa Pharmaceuticals Company, Tehran, Iran) as a mouthwash for 60 s. Then, the anesthetic agent was injected, comprising the infiltration of 2% lidocaine with 1:100000 epinephrine (Exir Pharma-ceuticals Company, Tehran, Iran). A crestal incision was made in the region, and a muco periosteal flap was elevated, followed by drilling steps based on the implant manufacturer's protocol. To match the samples studied, all the implants were of the submerged type (Abiding fixture), with a diameter of 4.3 and a length of 10 mm. All the implants were placed by an experienced surgeon in each patient (both implants were placed in one session in a blinded scheme). Furthermore, all the implants were placed at bone level, and the edges of both flaps were sutured as primary intention using 0–4 Vicryl suture (Supabon, Supa Co., Tehran, Iran). At the end of the surgery, systemic medications, including amoxicillin, 500 mg, and ibuprofen, 400 mg, were prescribed for each patient for seven days. The instructions were provided for each patient on how to use 0.2% chlorhexidine mouthwash for two weeks twice every day, along with other hygienic and nutritional instructions at home.

The sutures were removed after one week. Immediately after completion of the surgery, one of the two regions was radiated with PBMT in a random and blinded scheme by the second researcher, as follows (Fig. 1).

Photo bio-modulation therapy

In the present study, based on the consultation with laser specialist in the field of dentistry, GaAIAs diode laser with a wavelength of 810 nm in near-infrared spectrum and InGaAIP with a wavelength of 660 nm in the visible red spectrum were used, both manufactured by Polaris 2 (Astar Co., Biala, Poland). These devices generate 810 nm laser beams with 400 mW power and 660 nm beams with 40 mW power, respectively.. For laser irradiation, in the first session immediately after completion of the surgery, first, the 660 nm laser beams with an output of 40 mW power (Average power "30 mW" is 75% of peak power) and a total time of 200 s, and then 810 nm laser beams with a power of 400 mW (Average power " 300 mW" is 75% of peak power) and a total time of 20 s were irradiated to an area of 1 cm^2 with a frequency of 2 Hz and energy density of 6 J/cm^2 with pulse and contact mode on the buccal, occlusal, and lingual sides [19] Table 1. After 48 h, the laser irradiation was repeated. In the control side, the same lasers were used without irradiation as a placebo so the patients were blinded about the procedure. It should be added that the surgeon, laser therapist and examiner were different and blinded to allocation. Only the patients and the third researcher were blinded about the laser procedure

Recording the intensity of pain

The patients' pain severity was examined after 12, 24, 48, and 72 h based on a visual analog scale (VAS), ranging from zero (no pain) to 10 (the most severe pain imaginable) [20]. After discharge, the patients were trained to record their pain severity at predetermined hours after the

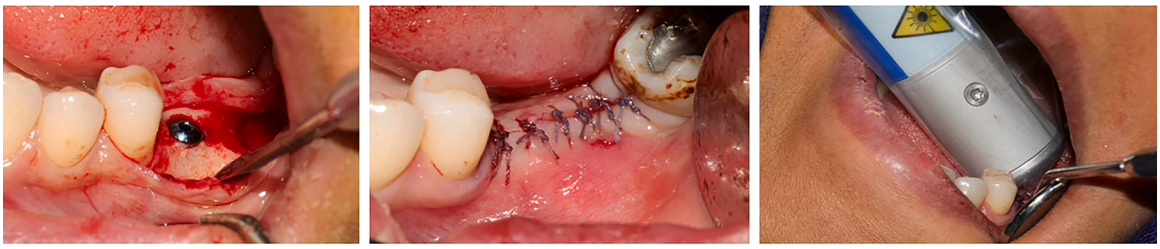

Fig. 1. Steps of surgery and Photo bio-modulation Therapy. A: Implant Insertion B: Flap suturing C: Laser Therapy from lingual side

Table 1
Table to report parameters in experimental and clinical PBM papers.

Manufacturer	Astar Co., Biala, Poland
Model Identifier	Polaris 2
Year Produced	2016
Number & Type of Emitters (laser or LED)	Laser
Wavelength and bandwidth [nm]	Red:660nm & Infra-Red: 810 nm
Pulse mode [CW or Hz, duty cycle]	2 Hz, 75%
Beam spot size at target [cm2]	1 cm^2
Irradiance at target [mW/cm2]	R:40 mw/cm^2, IR:400 mw/cm^2
If pulsed peak irradiance [mW/cm2]	R:40 mw/cm2,IR: 400 mw/cm2
Exposure duration [sec]	200 sec-red & 20 sec -IR
Radiant exposure [J/cm2]	6 J/cm^2
Radiant energy [J]	12 J
Number of points irradiated	3
Area irradiated [cm2]	1 cm^2
Application technique	Punch mode -contact
Number and frequency of treatment sessions	2
Total radiant energy over entire treatment course [J]	72J

surgery [20,21]. Furthermore, as a reminder, the patient was contacted at these intervals. These investigations were performed by the third researcher in a blinded plan. The above stages were the same in both groups (laser and control).

Recording wound healing scores

The third researcher clinically examined the wounds at 3, 7-, and 14-days postoperative intervals and recorded the wound healing score in the questionnaire. The wound healing scores were determined using the Likert scale from 0 to 4 [22]. The examinations were the same in both the laser and placebo groups.

The following scoring system was adopted:

1 complete wound healing
2 wound healing and the presence of a line of fibrin membrane
3 wound healing and the presence of a wide layer of fibrin
4 incomplete wound closure (dehiscence)
5 no wound closure and necrosis of the wound margins

Twenty-three patients with a mean age of 46.81 years (range: 24–61 years), including 14 males and 9 females, were studied. Each patient received two bone-level implants in the posterior mandible, bilaterally. Of 23 patients, two were excluded since they required guided bone regeneration. The patients did not develop an infection or any complication during the follow-up period. Wound healing, pain severity, and the correlation between anxiety level and pain intensity were analyzed.

Data analysis

The data were analyzed with SPSS 22 (IBM SPSS Statistics. IBM Corporation, USA) using the Wilcoxon test, paired t-test, and Pearson's correlation coefficient. Statistical significance was set at $\alpha = 0.05$. Wilcoxon test used since one of the variables in the present study was an ordinal one (healing scores) and was compared between two sides of mandible. The reason of using paired t- test was to compare quantitative VAS score (range of 0 to 20) between two sides of mandible and also the reason of using Pearson correlation coefficient was to evaluate the correlation between mean of anxiety before surgery based on MDAS index (ranged between 5 to 20) and mean of patient's pain (VAS score)

Results

Based on the results presented in Table 2, the Wilcoxon test showed that wound healing at 3 ($p < 0.023$), 7 ($p < 0.011$), and 14 days ($p = 0.002$) on the laser side was significantly better than that on the placebo side. There were also significant differences about healing score between different intervals in each group ($p < 0.05$).

As shown in Table 3, the frequency of higher wound healing scores was more significant in the laser group compared to the placebo group. Paired t-test showed that at 12 ($p < 0.008$), 24 ($p < 0.04$), 48 ($p < 0.008$), and 72 h ($p < 0.02$), the mean pain score based on the VAS on the laser side was significantly lower than that on the placebo side (Fig. 2). The Pearson's correlation coefficient showed a correlation between the mean score of anxiety based on MDAS and the mean score of pain based on VAS on the laser side at 12, 24, and 72 h, but no such a correlation was noted at 48 h Table 4.

Discussion

In this split-mouth study, the same conditions (as much as possible) were considered in terms of the surgical technique and site, type and sizes of implants, and medications prescribed after the surgery. In order to reduce the effect of confounding factors on the measurement of these

Table 2
Frequency distribution of wound healing score in the laser and placebo sites at different time points

Time (day)	Healing scores	laser (%) n	Placebo (%) n
Third	0	(0)0	(0)0
	1	(57.1)12	(8.4)1
	2	(38.1)8	(76.2)16
	3	1(4.8)	4(19)
seventh	0	(42.9)9	(4.8)1
	1	(47.6)10	(61.9)13
	2	(9.5)2	(28.6)6
	3	0(0)	1(4.8)
Fourteenth	0	(81)17	(.42)9
	1	(14.3)3	(57)12
	2	(4.8)1	(0)0
	3	0(0)	0(0)
P.V	Third- seventh	PV<0.001	PV<0.001
	Third- Fourteenth	PV < 0.001	PV < 0.001
	seventh - Fourteenth	pv = 0.003	PV < 0.001

Table 3
Mean VAS scores of pain at different time points between two groups

Time(hours)	Laser group Mean ± SD	Placebo group Mean ± SD	*p*-value
12	3.14±1.1	3.48±1.12	0.008
24	1.9±1	2.2±1	0.04
48	0.9±0.8	1.2±0.9	0.008
72	0.3±0.1	0.6±0.2	0.02

parameters for evaluating the effect of PBMT on postoperative pain and healing time

PBMT has been suggested to decrease surgical complications due to its bio-stimulatory effects [6–9]. The results showed that 660- and 810 nm lasers enhanced wound healing at 3, 7, and 14 days postoperatively. In addition, pain reduction on the laser sides was considerable compared to the placebo side. In addition, the mean pain score on the laser side was significantly lower than that on the placebo side. These results are consistent with some previous studies, although they used different laser wavelengths and methodologies[13–16,23–27].

Rezende et al[24] reported a significant difference in wound closure between diode laser with 1.3 J/cm^2 dose and a control group seven days postoperatively. They suggested that the shortening of the inflammatory phase resulted in faster initiation of the proliferative phase.

Ozcelik et al[13] evaluated the effects of 588 nm diode laser with 4 J/cm^2 energy in the continuous mode in a split-mouth design after gingivectomy and gingivoplasty. They showed that the application of PBMT might increase epithelialization and wound healing.

Kreisler et al[25] showed that irradiation of 809 nm GaAlAs laser with 1.96, 3.92, and 7.84 J/cm^2 energy significantly increased the proliferation of gingival fibroblasts at 24 h; however, the proliferation of gingival fibroblasts decreased after 48 and 72 h. They reported a limited laser effect and recommended the repetition of treatment to obtain favorable effects of laser in clinical applications. Accordingly, laser irradiation was repeated for two sessions in the present study.

Recently, Caccianiga et. al[27] in a similar study have assessed the effect of PBMT after implant surgery by using the ATP38 device. This system is a spectral technology emitting cold polychromatic lights with a combination of wavelength from 450 to 835 nm depending on the field of action. They have concluded that PBMT is an effective method in reduction of severity/duration of pain and swelling after dental implant surgery.

On the other hand, the results of the present study do not coincide with some other studies [28–31]. Schlager et al[32] used red diode laser with 670 nm wavelength, 250 mW/cm^2 power and 2 J/cm^2 dose in continuous mode for the treatment of burns in rats in three groups for 10, 20, and 30 consecutive days and reported no positive effect for laser therapy, which is different from the results of the present study. Such discrepancy in the results might be attributed to differences in laser energy [31], wavelength and frequency of the laser, its systemic effect [26], and type of wound [11,32]. These factors might affect the outcome of PBMT and give rise to controversial results [11,18,26,32]. Regarding the systemic effects of PBMT, Karu et al and Calin et al believe that PBMT can stimulate the release of growth factors and other materials into the blood stream. These substances can reach distant areas in the body and cause systemic effects [33,34]. However, this theory is contradicted by some split-mouth studies showing better results on the laser side [35,36]. Moreover, irradiated areas absorb all the laser energy, and the mediators and growth factors released in these areas have local, not systemic, effects [34].

In implant surgery, postoperative pain usually originates from the surface region (soft tissue incision) and deep region (bone preparation). Accordingly, in this clinical study, we used a red laser with a wavelength of 660 nm with low penetration depth and infrared laser with a wavelength of 810 with a higher penetration depth to relieve pain (both superficial and deep origins) [19,37]. In addition to considering the depth of laser penetration, studies have shown that the red and infrared

Table 4
Pearson's correlation coefficient between anxiety score and pain score according to the VAS in the two sides at different time points

Time(hours)	Laser		placebo	
	r	*p*-value	r	*p*-value
12	0.549	0.005	541	0.006
24	0.331	0.036	472	0.015
48	0.253	0.134	0.558	0.004
72	0.311	0.042	0.352	0.03

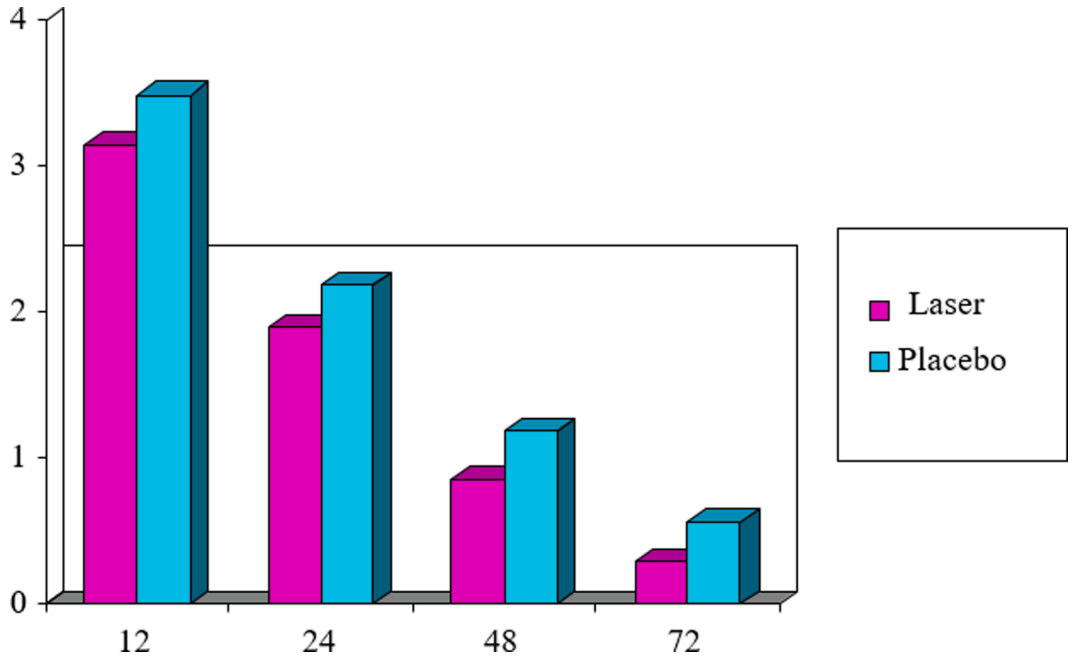

Fig. 2. Mean pain scores (VAS) in the two groups at different time intervals.

spectra potentiate each other's effect because possibly, radiation of one spectrum is followed by the activation of the photo acceptor of the other spectrum [38].

In the present study, although due to limitations, it was not possible to evaluate the effect of the two types of laser in each group, the results suggested that concurrent radiation of both lasers with a dose of 6 J/cm^2 was effective in reducing the pain resulting from implant surgery in the mandible. Pozza et al [39] investigated the analgesic effect of laser therapy and infrared (830 nm) and red (660 nm) laser types with a dose of 10 J/cm^2 on healthy tissues of mice in two separate groups. They reported that irradiation of both lasers generated analgesic effects, consistent with the results of the present study. However, they stated that the red laser yielded better results. The better effect of red laser with a lower penetration depth is possibly justified by the subcutaneous injection of formalin in the mice sole skin in that study and developing a superficial experimental pain. Also, considering the pain medication mechanisms following laser irradiation, based on previous reports [10, 12], they reported that although laser therapy results in the elevated synthesis and release of endorphins and reduced release of nociceptive receptors, such as bradykinin and serotonin, possibly these mechanisms are not implicated in pain. They believed that diminished sensory nerve conduction by laser therapy is one of the significant mechanisms of pain elimination in mice.

Such possibilities are also supported by some previous studies [40–42]. According to Iijima et al [40] and Palmgren et al [41], laser beams stabilize cellular membranes involved in regulating nerve impulse transmission. Such a regulation inhibits depolarization by increasing ATP synthesis, thereby causing a significant increase in the slow nerve function. As soon as the sensory nerve conductivity speed declines, pain reduction can be observed. Another important factor in the mitigation of pain among laboratory animals undergoing radiation, compared with the control group, is the vascular effects of laser therapy. By delivering low-intensity laser beams, especially the red wavelength, increased blood circulation occurs, which in turn enhances the oxygenation in the lymphatic drainage, the activity of neutrophils, macrophages, and fibroblasts, and metabolism of damaged cells, eventually diminishing pain at the very early minutes following irradiation [43–47].

In addition, the red laser has photochemical effects, which emerge faster, as they directly affect mitochondria. On the other hand, the infrared laser has photo-physical or photoelectrical effects, which appear later since it indirectly influences the mitochondria [39].

Unlike the positive results obtained from previous studies, [13-16], Lopez-Ramirez et al.[49] did not observe any effect by low-intensity irradiation in reducing the level of pain and inflammation or trismus in patients following impacted third molar surgeries. Immediately after the surgery, these researchers used GaAlAs laser with a wavelength of 810 nm and a dose of 5 J/cm^2 intraorally with a distance of 1 cm from the surgical area. The irradiation time was 32 s and was carried out only once. In their report, they mentioned limitations such as a lack of indication for precise determination of pain assessment time and irradiation in a broad area to keep the 1-cm distance, as the causes of failure in achieving positive outcomes.

Given the distance between the laser irradiating tip and the target tissue, and the emphasis on the importance of determining the effective dose in a therapeutic window when using PBMT, Grace Sun and Jan Tuner reported that, to this end, the tip of the laser probe should be as close as possible to the target tissue and even it should exert pressure to the mucosa so that the energy loss would be minimized. They recommended the contact mode for all the cases of laser use [48]. In addition, in the study by Lopez-Ramirez, although the level of the determined dose seems appropriate, and according to Arant-Schulz law [39], it lies within the range of 1–10 J/cm^2, the irradiation time or its frequency of application might have been inadequate since the inflammation resulting from a surgical wound, which is often associated with pain, is not a phenomenon that happens immediately after surgery. Instead, it occurs gradually and peaks 24–48 h after the surgery[50,51]. Therefore, considering the positive results in the present study, laser irradiation should be repeated within the first two or three days after the surgery to relieve the pain resulting from inflammation. Another essential point is the selection of the wavelength, which is one of the most important and essential parameters in PBMT; GaAlAs laser has been introduced as the selected wavelength to relieve the pain resulting from deep wounds [38].

However, in open surgical operations, such as the third molar surgery or implant placement, in addition to bone involvement, elevating the soft tissue or periosteal is associated with pain and discomfort. Therefore, since the red laser is effective at the surface, and the infrared laser is effective for deep wounds due to its great penetration depth, affecting the deep nerve terminals [16], it is suggested that both types of wavelengths be used concurrently to relieve pain or accelerate wound healing following oral surgical procedures that involve both the soft tissue (superficial wound) and bone (deep wound). Given the contradictory and discrepant results of many previous studies in this regard, it seems that no protocol has determined the type of laser, modality, and number of irradiation stations to achieve pain relief using a single wavelength.

In a review study, Fekrazad et al concluded that in human studies on PBMT, due to different types of disease and confounding variables, the effect of race or knowledge, and the practitioner's experience, the selection of patient and proper parameters of laser is very difficult. Therefore, more standardized studies should be conducted to present more precise suggestions [6]. The only point that can be added is that by benefiting from all the potentials of low-intensity lasers and increasing the frequency of laser irradiation sessions and observing a safe margin of intensity and radiation dose, one can possibly achieve significant pain relief in the clinic. Nevertheless, it is suggested that to achieve more accurate results and more proper therapeutic protocols, further studies should be conducted in this regard.

Regarding the correlation between pain severities based on VAS and the degree of anxiety in terms of MDAS scale, the present study showed a correlation between increased anxiety score from 5 to 19 and an increase in pain severity (VAS) in each patient. According to studies by Aznar-Arasa et al [52] and Appukuttan et al[53], patient anxiety before surgery causes behavioral and emotional changes, affecting pain perception. Moreover, they found a correlation between the results of VAS and MDAS, consistent with the present study.

Conclusion

According to the findings and given the limitations of this study, concurrent irradiation of 660 nm and 810 nm low-intensity lasers with a dose of 6 J/cm^2 in the primary stages of acute inflammation resulted in pain relief and improved wound healing in the implant placement area in the posterior mandible of patients. Therefore, PBMT might enhance wound healing and relieve pain after dental implant surgery.

Ethical Considerations

This study was approved by the Medical Ethics and Research Office at the Isfahan University of Medical Sciences and financially supported by this University.

Conflict of Interests

None declared.

Declaration of Competing Interests

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.jpap.2021.100062.

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