

Electric Pulp Testing Evaluation of Dental Anesthesia After 660-nm Laser-Photobiomodulation Therapy: Results of a Double-Blind Randomized, Placebo-Controlled Clinical Trial

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Abstract: *Background:* For many years, injection of chemical solutions of anesthesia are well-known conventional method in dental practice. To date, various complications have known to be caused by this injection as well as the high extent of anxiety and fear that have shown to be related with this procedure. By the most recently, introduction of photobiomodulation therapy (PBMT) in the field of laser dentistry, many efforts have been made to evaluate the state of PBMT- anesthesia on different laser parameters. *Objectives:* This double blinded randomized clinical trial aims at evaluating the efficacy of PBMT with 660nm diode laser on elevation of post-treatment electric pulp testing (EPT) scores representing as an anesthesia, in contralateral healthy premolars. *Methods and Materials:* 19 participants have included in this study according to the inclusion criteria. Each participant had two caries-free healthy contralateral maxillary first premolars, of which one was chosen randomly to be treated with sham (placebo) irradiation or laser treatment (Diode laser, 660nm, 200 mW, 12 J/cm², 30s). The EPT scores were evaluated two minutes before the laser/placebo treatment and right after the treatment. *Results:* 14 out of 19 (73.68%) sites which received laser treatment, showed more than 20% increase in EPT value, while in the placebo group 11 out of 19 (57.89%) sites that were treated with sham irradiation showed less than 20% change in EPT values after treatment. Therefore, there was a significant difference in EPT responses between the laser and placebo treatment groups (*fisher's exact*=0.106, *p-value*=0.047). Besides, the regression coefficients of post and pre-treatment EPT scores of laser and placebo treatment groups were 0.4 (*p-value*=0.008) and 0.98 (*p-value*=0.008), respectively. No gender differences were found regarding the EPT responses. *Conclusion:* The diode laser, 660nm PBMT with the given protocol can effectively induce a pulpal anesthesia, while further studies should elucidate the precise mechanism of its action and the capacity for its clinical applicability in dental practice.

Keywords: Photobiomodulation Therapy, Electric Pulp Testing, Anesthesia

1. Introduction

Injection of chemical solutions has been applying as the first choice for local anesthesia in dental practice for more than a century [1]. Although, an anesthesia obtained by chemical solutions have strictly been proven to be effective in clinical practice, in contrast, it can also cause several local and systemic complications such as syncope, hyperventilation, allergy, trismus, hematoma, facial paralysis, infection, and nerve injury [2]. In addition, the process of injection itself is

associated with anxiety, fear, phobia, and a salient reason in avoiding a dental visit [3, 4]. To this date, photobiomodulation therapy (PBMT) has introduced as an alternative or enhancing method for anesthesia in many studies [5, 6]. While since decades, PBMT has been using for the treatment of dental hypersensitivity in patients with exposed root surfaces [7]. In addition, laser therapy by various laser wavelengths (Nd:YAG, Er:YAG, CO₂, He-Ne, diode) and different pulse durations have led to the treatment of tooth hypersensitivity as well [9]. To this, studies have shown that patients suffering from dental

hypersensitivity have open dentinal tubules on their teeth's root surfaces, which make them more susceptible to experience a pain like sensation due to chemical and mechanical stimulants [8]. Besides, laser therapy can affect odontoblastic activity which subsequently may results in increased production of tertiary dentine, hence, sealing the dentinal tubules and reducing the hypersensitivity. On the other hand, reduction of neural transmission and neural suppression in nerve endings, inducing analgesic or anesthetic state, have been suggested as another justification [10]. Overall, PBMT and laser therapy are non-invasive cost-effective methods that can be effectively used in clinical setting as analgesics or anesthetics prior to dental treatment. Various studies with different laser wavelengths, pulse durations and energy densities have investigated many modalities of PBMT inhibitory effects [11, 13], however, a recent review of literature reports that further studies should elucidate the full potential therapeutic effects of PBMT in dental practice. Further studies should also be conducted on cellular and molecular mechanisms and pathways, on which PBMT affects.

Therefore, this study aimed at evaluating the anesthetic efficacy of PBMT therapy with a 660 nm diode laser (200mW, CW, contact mode, 12 J/cm², 30s).

2. Materials and Methods

2.1. Study Design

This double-blinded randomized clinical trial was approved by the Ethics Committee of Guilan University of Medical Sciences, Iran (IR. GUMS. REC. 1397. 439). A total of 25 participants have participated in this study, which were fully informed about the procedures prior to taking a written informed consent.

2.2. Inclusion Criteria

Inclusion criteria were available in Table 1. All participants had contralateral first maxillary caries free first premolars with no restorations and vital based on thermal vitality tests and radiographs.

Table 1. Summary of EPT difference before and after placebo or laser treatment.

type of treatment	> 20% increase	> 20% decrease	< 20% change	Total
Laser	14 (73.68%)	2 (10.53%)	3 (15.79%)	19 (100%)
Placebo	7 (36.84%)	1 (5.26%)	11 (57.89%)	19 (100%)

2.3. Exclusion Criteria

The participants with fixed orthodontic treatment, pregnancy, blood-related disorders, light sensitivity, suffering from dentinal hypersensitivity or epilepsy, taking analgesic medications, using pacemakers and who had arrhythmias were considered to be excluded from the study. Finally based on the criteria mentioned above, 19 individuals were included in this study.

2.4. Randomization

The randomization process was in accordance with Consolidated Standards of Reporting Trials (CONSORT) [14]. The randomization process was double-blinded in which neither the participants nor the operator was aware of the laser or the placebo. We used a split mouth design in which all participants received both laser therapy and placebo while, proper protective equipment was worn by both the participant s and the operators.

2.5. PMB/ Plasebo Therapy

The 660nm diode laser (Al, Ga, In, P- Konftec, Malaysia) 200 mW, 12 J/cm², 30s was used in this study, which included two parts; a sham laser probe (placebo) in which the active medium was dissembled from the laser unit and an active laser probe which was equipped with a medium of 660-nm wavelength producer (Figures 1, 2). The maxillary first premolars were randomly chosen for the laser treatment or placebo, according to controlled double-blinded clinical trial's study design. The laser /placebo irradiation was

performed on the buccal surface of the maxillary first premolars for the duration of 30 seconds (Figure 3).

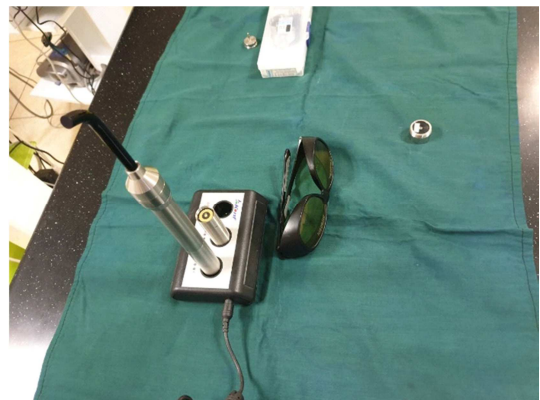


Figure 1. Assembled 660nm laser apparatus.



Figure 2. Detached 660nm low level diode laser.

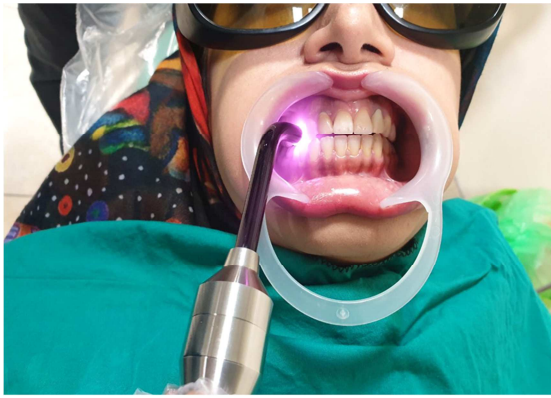


Figure 3. PBMT procedure.



Figure 4. Electric Pulp Testing procedure.

2.6. Electric Pulp Testing (EPT)

We applied the same EPT usage methodology as previous studies [12, 15] while, the device (Parkell pulp vitality tester Farmingdale, NY, USA) have used in many previous similar studies as well [16, 17]. All the participants have given proper instruction on how the test works (Figure 4). Firstly, a non-experimental tooth was chosen and the participants were instructed to release the metal handle at the moment of any light pain- like or tingling sensation. Secondly, to start the procedure, all experimental teeth were cleaned and dried then, isolated before applying the EPT device. In continue, there were two EPT attempts with a gap of two minutes before laser or placebo treatment and instantly after the treatment, finally, the number at the point of cessation was recorded. For more explanation, the EPT number before and after the treatment were subtracted while, negative differences indicated excitatory effect and positive differences

considered as anesthetic effect.

2.7. Data Analysis

All data was analyzed via R version 4.0.2, R Foundation for Statistical Computing, Vienna, Austria provided that P-values below 0.05 were considered as statistically significant. Fisher's exact test, linear regression, and descriptive. The EPT scores were classified into 6 categories based on the placebo treatment, laser treatment, more than 20% increase in EPT value after placebo or laser treatment, more than 20% decrease in EPT value after placebo or laser treatment, or less than 20% difference in EPT value after placebo or laser treatment. Also, Gender difference was analyzed in the laser treatment group. Furthermore, a scatterplot was used to visualize point-data analysis and linear regression for EPT values before and after laser or placebo treatment.

3. Results

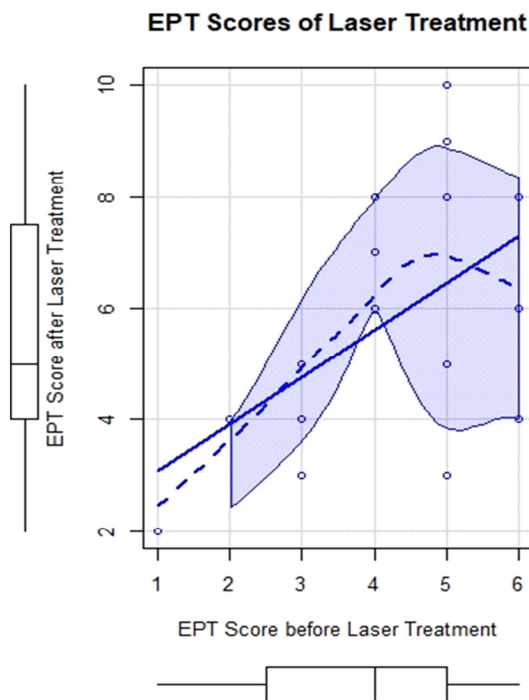
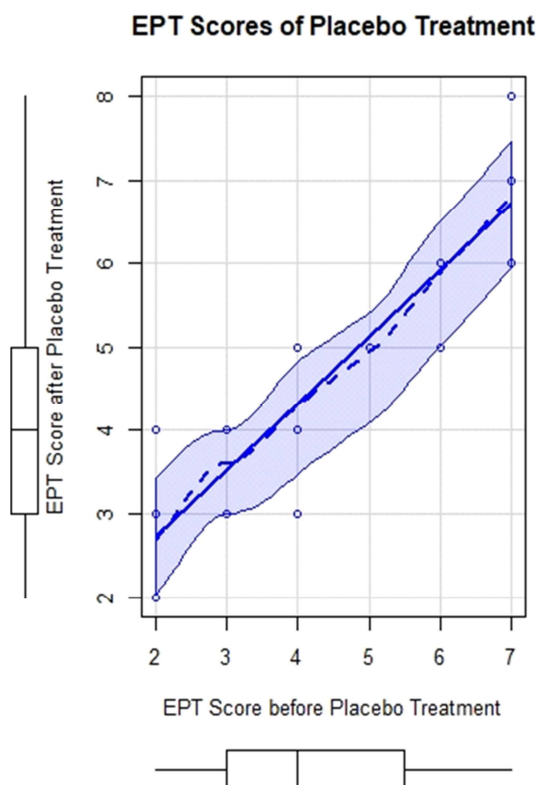
Overall, 19 participants (14 females and 5 males) with an informed consent have undergone placebo or laser treatments. The mean (\pm SE) age was 30.78 (\pm 2.76) among the participants. No adverse effects were found regarding laser treatment in any of the participants. Also, none of the participants experienced painful or irritating sensation, lingering pain, or other symptoms during the procedures. The response patterns regarding the EPT values in both laser and placebo treatment groups were available in Table 1. Taking it into account, 14 out of 19 (73.68%) sites, which received laser treatment, showed more than 20% increase in EPT value, while in the placebo group 11 out of 19 (57.89%) sites which were treated with a sham irradiation showed less than 20% change in EPT values after treatment. No significant difference was found between male and female participants regarding the EPT change after both treatment (Table 2), Nevertheless, according to Fisher's exact test, there were a significant difference in EPT responses between the laser and placebo treatment groups ($FE=0.106$, $p\text{-value}=0.047$). In addition, the scatter plot of pre/post-treatment comparison of EPT values in placebo group, showed a linear correlation near 1.0 (0.98) that indicates minute effect of placebo treatment on EPT values. More information is available in Figures 5 and 6, where the same plot for the comparison of pre/post-treatment EPT values in laser treatment group, resulted in a regression coefficient of 0.4, showing both excitatory (decreased scores) and anesthetic effects (increased scores). The summary of the regression coefficients of pre/post-treatment EPT values are presented in Table 3.

Table 2. Gender difference of laser treatment and EPT findings.

type of treatment	> 20% increase	> 20% decrease	< 20% change	Total
Male	4 (80%)	1 (20%)	0	5 (100%)
Female	10 (71.42%)	1 (7.14%)	3 (21.42%)	14 (100%)

Table 3. Comparison of more than 20% response change between laser and placebo teeth.

Laser Placebo	> 20% increase	< 20% increase	Total
> 20% increase	7 (100%)	7 (58.33%)	14 (73.68%)
< 20% increase	0 (0%)	5 (41.67%)	5 (26.32%)
Total	7 (100%)	12 (100%)	19 (100%)
Fisher's exact = 0.106		p-value = 0.047	

**Figure 5.** Scatterplot of EPT values before and after laser treatment.**Figure 6.** Scatterplot of EPT values before and after placebo treatment.

4. Discussion

This randomized clinical trial investigated the aesthetic effect of PBMT with a 660nm laser (200mW, CW, contact mode, 12 J/cm², 30s) under a double-blinded clinical trial on the contralateral healthy first premolars dental pulp. According to the analysis, the laser treatment group experienced a significant elevation of post-treatment EPT scores indicating an anesthetic effect of PMBT on healthy dental pulps. While the placebo treatment (sham irradiation) did not cause a significant elevation of post-treatment EPT scores, however seemingly, a variation in responses exist in both placebo and laser treatment group that have also previously reported by other studies and is a common feature in PBMT studies [12, 15]. This variation in treatment responses might be in accordance with the Arndt-Schulz Law, which are in accordance to the fluencies less than 10 J/cm² hence, can be stimulative to the tissue and evoking the cellular activity whilst, higher energy densities can suppress it. Taking it into account, the energy density chosen for this study (12 J/cm²) was extremely close to the therapeutic window limit described by Arndt-Schulz Law therefore, this could be considered as normal while the given energy density can decrease a response in many people, nevertheless, it might stimulate or even enhance that response in a few subjects. To support this idea, many studies have suggested that other factors can influence the tissue response such as color or thickness of the tissues [12, 18, 19]. This may suggest that the kind of tissue may affect the suppressive response to a laser PBMT which is close to therapeutic window therefore, maybe higher fluencies of laser PBMT are needed to maintain a sufficient anesthesia for a dental practice. To this, further studies are needed to work on this issue with different parameters to investigate the best laser protocol for anesthesia in dentistry.

Although numerous investigations have described the application of PBMT in dentistry and medicine, the mechanism of action has not still been precisely explained yet. However, existing theories state a photochemical basis for the reaction of laser therapy which targets cells and indicate its positive effect of cellular activity where, cytochrome c oxidase, a chromophore mostly found in mitochondria, is an important component of the respiratory chain reactions and influences the production of various intracellular molecules such as reactive oxygen species (ROS), nitric oxide, and adenosine triphosphate (ATP). The production of ATP, ROS, and glycolysis cycle are upregulated by laser therapy. High level of ROS is cytotoxic and enables apoptosis mechanisms, however, lower levels of ROS can induce apoptosis in damaged cells [20, 23]. PBMT

can also affect healing and regenerative mechanism, which makes it a viable treatment modulation in various disorders such as Parkinson's disease and temporomandibular joint disorders [24, 25]. Further studies should shed light on the precise action mechanism of PBMT which enhances its application in the field on dentistry and medicine.

While several studies have indicated the analgesic effect of PBMT in dental practice, other studies have indicated that PBMT can effectively induce anesthesia. One study has suggested the efficacy of PBMT on reducing post-operative pain in patients that underwent root canal therapy [26]. One theory suggest that PBMT can reduce the production of anti-inflammatory cytokines and inhibits neurotransmission [27]. Other studies have reported similar results regarding anesthesia and pain management in restorative, orthodontic, and endodontic surgery along with treating dental hypersensitivity [28-30]. A recent study used PBMT with a diode laser (810nm, CW, contact mode, 200mW, 84 J/cm²) as a strong alternative method for anesthesia in restorative treatment of carious teeth. This study indicated that PBMT induced-anesthesia received lower pain scores in comparison

with anesthesia due to injection. Also, 96% the patients preferred this type of anesthesia to injection of local anesthetics [11]. Another study demonstrated that the 810nm wavelength PBMT with a fluency of 106 J/cm² induces pulpal anesthesia for cavity preparation of decayed permanent teeth [31].

The result of this study is in accordance with the findings of similar studies that compared laser treatment effect on pre/post-treatment EPT scores. Liang et al performed PBMT using a 904nm GaAs diode laser where more than 60% of the laser treated sites showed reduced post-treatment EPT scores, while 30% experienced excitatory pulpal effects [12]. Another study investigated the anesthetic efficacy of PBMT on patients requiring bilateral extraction of premolars for orthodontic treatment in comparison with a topical anesthesia. A Nd: YAG laser 1064-nm was used for inducing anesthesia where the post-treatment EPT scores were significantly increased [15]. None of the aforementioned studies reported complication or adverse effect after PBM therapy. Also, no gender differences were observed in previous findings just the same as this study.

Table 4. Regression coefficients of EPT scores before and after laser or placebo treatment.

	Regression coefficient (95% CI)	R2	F-statistics
Laser Treatment	0.4 (0.11 to 0.69)	0.33	8.72 (<i>p</i> -value=0.008)
Placebo Treatment	0.98 (0.72 to 1.24)	0.78	63.06 (<i>p</i> -value<0.0001)

5. Conclusion

According to the findings of this study, laser PBMT with 660nm wavelength (200mW, CW, contact mode, 12 J/cm², 30s), effectively increases the post-treatment EPT scores in laser treatment group, indicative of anesthetic effect of PBMT, while most of the participants experienced anesthetic effect after laser treatment, some have experienced excitatory effects. Overall, this result endorses a new ascertaining laser parameter capable of induce dental anesthetic effect which could be considered as a complementary to other studies in past and future. Nevertheless, further research is still needed to investigate the precise mechanism of PBMT on anesthesia and examine the capacity of individualized treatment plan with justifying laser protocols, however it is clear that laser PBMT can play an important role in future of dentistry.

Conflict of Interest

All authors of this article declare that they have no conflicts of interest with any company or financial interest to report.

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