Efficacy of Photobiomodulation Therapy for Orthodontic Pain Control Following the Placement of Elastomeric Separators: A Randomized Clinical Trial

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Abstract

Introduction: Controlling pain in orthodontic patients has gained special attention. This study assessed the efficacy of photobiomodulation therapy (PBMT) for pain control following the placement of elastomeric separators.

Methods: This split-mouth single-blind randomized clinical trial evaluated 30 orthodontic patients who required posterior elastomeric separators. The two maxillary quadrants were randomized into the laser and control groups. In the laser quadrant, an 808 nm diode laser (400 mW, 15.60 J/cm², 11 seconds, continuous-wave, contact mode) was irradiated to the cervical third of the maxillary first molar roots 24 hours prior to the placement of separators. The control quadrant received placebo radiation by a light-curing unit. The patients received the second laser cycle right before the placement of separators 24 hours later. The level of self-perceived pain was recorded at 0, 2, 6, 24, and 72 hours and 5 days after the intervention in the laser and control quadrants using a visual analog scale (VAS). Data were analyzed using the analysis of variance (ANOVA) and paired-samples t test.

Results: The trend of change in the pain score was similar in both groups. The pain score was significantly lower in the laser group than the control group at all-time points (P<0.05) except at time 0. The pain score increased in the first 6 hours and reached its maximum level in 24 hours in both groups.

Conclusion: PBMT by an 808 nm diode laser can effectively decrease pain following the placement of elastic separators.

Keywords: Orthodontics; Pain; Separator; Photobiomodulation therapy; Diode; Low-level laser therapy.

Introduction

Orthodontic treatment is required for some patients to enhance their masticatory function and smile esthetics. Orthodontic pain is an unwanted side effect of orthodontic treatment that causes some concerns for patients.1 Orthodontic forces cause orthodontic tooth movement and bone remodeling around the roots, which can generate pain. Evidence shows that 70% to 95% of orthodontic patients complain of pain due to orthodontic appliances.2 Also, 8% to 30% of orthodontic patients discontinue treatment due to pain.1,3-7 Around 90% of patients experience pain in the initial stages of orthodontic treatment, which decreases their cooperation, impairs their treatment course, speech, and mastication, and can adversely affect their oral health-related quality of life.8 A high percentage of orthodontic patients complain of sleep disturbances due to pain in the first week following the placement of orthodontic archwires.9 Orthodontic pain is often described as a sense of pressure, tension, or soreness.10 The pain is continuous in the first 1-2 days and then becomes interrupted after 2 days.10

Elastomeric separators are among the most commonly used orthodontic appliances that can cause pain.11 Separators are used to create a space between the banded
teeth, which is a painful procedure. Pain starts around 2 hours after the placement of orthodontic separators and reaches its maximum level at 24 hours. The pain gradually subsides from day 3 and reaches its minimum level on days 5 and 7.

Pain due to orthodontic treatment has an inflammatory origin. Pain with inflammatory origin is often managed by the use of non-steroidal anti-inflammatory drugs, which are the gold standard for this purpose. However, non-steroidal anti-inflammatory drugs decelerate orthodontic tooth movement and have many contraindications. Also, they have systemic side effects such as allergic reactions, thrombocytopenia, skin rash, hypertension, headache, nephrotoxicity, hepatic toxicity, gastrointestinal problems, and an increase in the risk of heart disease.

Recently, photobiomodulation therapy (PBMT) formerly known as low-level laser therapy was suggested as an alternative to pharmaceutical therapy. Evidence shows that PBMT has no adverse systemic effects. The analgesic efficacy of PBMT in dentistry has previously been documented. A previous study demonstrated higher analgesic efficacy of PBMT than ibuprofen, infrared laser, and bite wafer. Another group of researchers refuted the optimal analogic efficacy of PBMT for pain control following the placement of separators. Considering the existing controversy and variations in laser parameters and protocols, this topic is still in need of further investigation. The purpose of this study was to test the hypothesis whether an 808 nm diode laser can decrease orthodontic pain following the placement of elastomeric separators.

Materials and Methods
This split-mouth randomized single-blind clinical trial evaluated 30 patients (11 males and 19 females). The minimum sample size was calculated to be 25 according to a study by Furquim et al., assuming alpha=0.05, beta=0.2, mean visual analog scale (VAS) score difference of 1 unit between the right and left quadrants, and standard deviation of 1.7, using paired means power analysis feature of PASS II software.

Patient Selection
The patients were selected among orthodontic patients (aged from 13 to 37 years-old) referred to a private orthodontic clinic whose treatment plan included the use of separators (Orthotechnology, USA) with 1.3 mm thickness. The patients were selected using randomized sampling. The patients were briefed about the study and signed informed consent forms prior to their participation. Informed consent was also obtained from the parents of patients under 18 years of age.

The Inclusion Criteria
The inclusion criteria included absence of systemic diseases, periodontal or periapical diseases, having sound maxillary first molars bilaterally with sound and firm proximal contacts, absence of a posterior open bite, completely erupted second premolars and second molars bilaterally, no history of previous orthodontic treatment, absence of severe tilting of teeth, absence of ankylosis, good oral hygiene, and willingness for participation in the study.

The Exclusion Criteria
The exclusion criteria included intake of analgesics, anti-inflammatory medications, contraceptives, antidepressants, anticonvulsants, steroids, or bisphosphonates prior to the study or during the course of the study, chronic pain, facial neuralgia, psychological disorders, several root canal treatments in the posterior region, gingival inflammation, presence of gingival pigmentation in the area, spacing between molar and premolar teeth, several missing teeth, any local or systemic condition that could affect pain perception, pregnancy or nursing, and dental or periodontal problems. Also, the patients who had dental or gingival pain prior to the treatment onset were excluded. The patients who did not completely fill out the VAS questionnaire, those who took analgesics during the course of treatment, and the patients who had discontinued the treatment were also excluded. The patients were free to quit at any time.

Study Design and Random Allocation Procedure
This study had a split-mouth design. In each patient, the maxillary right and left quadrants were randomly allocated to the laser (test) and placebo (control) groups. For the random allocation of quadrants to the test and control groups, each patient was requested to pick either 0 or 1; 0 indicated laser irradiation of the left quadrant and placebo irradiation of the right quadrant while 1 indicated laser irradiation of the right quadrant and placebo irradiation of the left quadrant. The patients were assessed by someone other than the laser operator. Furthermore, the patients were blinded to the group allocation of their quadrants because the eyes were masked during laser irradiation. Thus, the study had a double-blind design.

Intervention
The laser quadrant received the first dose of 808 nm diode laser irradiation with 400 mW power and 15.60 J/cm² energy density 24 hours prior to the placement of separators. The laser-irradiated area had a surface area of 0.282 cm² and the duration of radiation was 11 seconds. The laser was irradiated in a continuous wave and contact mode perpendicular to the longitudinal axis of the tooth (Figure 1). A point in the cervical third of the buccal surface of the mesial and distal roots of the maxillary first molar was irradiated in the laser quadrant. The control quadrant underwent placebo irradiation for the same duration using a light-curing unit (L600A, Westcode,
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China). The patients were visited again 24 hours after the first round of laser irradiation and received the second round of laser therapy right before the placement of separators on the maxillary first molars. The separators were then placed.

**Pain Assessment**
The patients were provided with a VAS questionnaire to record their self-perceived level of pain. The VAS scores ranged from 0 to 10; 0 indicated no pain while 10 indicated most severe pain. The patients were requested to record their level of pain at 0, 2, 6, 24 and 72 hours and 5 days after the placement of separators for the right and left quadrants. Also, the patients were contacted at the respective time points to remind them to record their level of pain.

**Statistical Analysis**
Data were statistically analyzed using SPSS version 25. The normal distribution of the data was checked by the Kolmogorov-Smirnov test. All data had normal distribution. Thus, the level of pain was compared in each group over time using repeated measures analysis of variance (ANOVA). The pain score was compared at each time point between the laser and control quadrants using a paired-samples t-test.

**Results**
Of 30 patients, 4 were excluded due to incomplete questionnaires. Thus, the data of 26 patients including 16 females and 10 males with a mean age of 20.4±5 years (range 13 to 37 years) were statistically analyzed.

Table 1 shows the mean pain score in the laser and control quadrants at different time points. Minimum pain was noted on day 5 in the laser group (3.91) while maximum pain was noted at 24 h in the control group (7.92). A paired-samples t-test was applied for a pairwise comparison of the pain score between the laser and control quadrants at different time points. As shown in Table 1, the difference in the pain score between the two groups was not significant at time 0 (P=0.052). However, at all other time points, the pain score was significantly lower in the laser group (P<0.05). The mean difference in the pain score between the laser and control quadrants was minimum at time zero (0.28) and maximum at 72 hours (0.74).

As shown in Figure 2, the pain score in the placebo group increased from time zero to 6 hours and reached its maximum level at 24 hours. At 72 hours, the pain score was almost similar to time 0. On day 5, the pain score was even lower than that at time 0.

In the laser group, the trend of change in the pain score was almost similar to that in the placebo group; however, the pain score was generally lower than that in the placebo group at all time points. In both groups, the pain score at 72 hours was almost similar to that at time 0.

**Discussion**
This clinical trial assessed the effect of an 808 nm diode laser on pain following the placement of orthodontic elastomeric separators. The results showed that PBMT decreased the severity and duration of pain.

Following the application of orthodontic forces, bone resorption is induced at the pressure site by RANKL signaling in osteoclast precursors. The RANKL is specifically expressed by the osteoblasts. In vitro investigations have shown that the 810 nm laser can increase the expression of both RANKL and RANK in the tissue, which are two necessary components for the induction of tooth movement and osteoclastogenesis. Also, evidence shows that PBMT stimulates osteoblasts and induces the differentiation of osteoclasts during orthodontic tooth movement, and accelerates bone remodeling as such.

A recent study on rats showed that irradiation of the 810 nm low-level laser decreased the expression of the COXII gene, and subsequently

<table>
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<th>Time/Quadrant</th>
<th>Mean</th>
<th>Std. Deviation</th>
<th>Sig. (2-tailed)</th>
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<td>0 h-(control side)</td>
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<td>3.91</td>
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Figure 1. Laser Irradiation Prior to the Placement of Separators.

Table 1. Mean Pain Score in the Laser and Control Quadrants at Different Time Points.
enhanced healing, vasodilation, and decreased edema and reactions, and oxygen transfer. The secondary effects of PBMT are related to intracellular signals.

Laser irradiation also induces the production of ATP, from the area, and cellular activity increases as such. Also, the laser was irradiated to each point for 11 seconds required for analgesic effects of laser and has minimal energy density. The mode of application in a continuous or chopped mode is another controversial topic. Previous studies have reported a single dose, double dose, and multiple-dose laser irradiation. In this study, double dose laser irradiation was performed. Also, the laser was irradiated to each point for 11 seconds (a total of 22 seconds for the mesial and distal roots) since evidence shows that it is the minimum duration required for analgesic effects of laser and has minimal complications. The laser was irradiated in a continuous mode, similar to many previous studies.

Our methodology in this study had some major differences with previous studies on this topic. The main difference was the irradiation of the first dose of laser 24 hours prior to the placement of separators, which decreased the severity and duration of pain in the laser quadrant at all time points.

One limitation of this study was difficulty in blinding the patients since both the laser and placebo light were irradiated in the same session. However, the eyes were masked and the patients were requested to wear dark protective glasses to ensure blinding.

Further studies are required to assess the analgesic efficacy of different laser types with different parameters. Moreover, considering the role of stress in the perceived decreased the production of prostaglandin E2 and edema, which all led to pain reduction. Another study showed the acceleration of tooth movement in rats by PBMT.

The effect of lasers on orthodontic pain following the placement of archwire or canine retraction has been previously studied and all such studies have confirmed the positive efficacy of lasers for pain control. However, the level of pain following canine retraction and archwire treatments is often higher than that after separator placement, which may overestimate the effects of PBMT. Thus, it is not accurate to compare the results of such studies with this study.

Several factors may affect the results of PBMT, such as the variability in patients' pain perception threshold, the methodology of studies, laser parameters, age and gender of patients, physiological status, previous pain experience, psychological conditions, the placebo effect, and the duration and intensity of orthodontic forces applied.

This study had a split-mouth design, which is a strength of this study. This design eliminates the effect of patient-related confounding factors on the results and better elucidates the pure effect of the intervention.

The analgesic effects of PBMT are attributed to several mechanisms that increase the surface temperature and subsequently the local blood flow to the area, which induces healing. Also, by an increase in blood flow, the stimulants and the pro-inflammatory mediators are eliminated faster from the area, and cellular activity increases as such. Laser irradiation also induces the production of ATP, inhibits the release of pro-inflammatory mediators and neurotransmitters in the target tissue, and decreases pain as such. It induces the release of endorphins, stimulates lymphocytes, and directly inhibits the pain signals. It also inhibits the release of arachidonic acid. The effects of PBMT depend on the laser wavelength, pulse frequency, power and duration of laser irradiation. The primary effects of PBMT are related to intracellular activities such as increasing the level of ATP, redox reactions, and oxygen transfer. The secondary effects are exerted on the target tissue and include pain relief, enhanced healing, vasodilation, and decreased edema and hyperemia in inflammatory processes.

In this study, maximum pain was noted at 24 hours in both groups. Previous studies reported maximum pain at 24 and 36 hours, 48 hours, and 6 and 30 hours. In this study, the pain score in both groups increased from time zero to 6 h and reached its maximum level at 24 hours. On day 5, the pain score was even lower than that at time 0. In the laser group, the pain score was generally lower than that in the placebo group at all time points. In both groups, the pain score at 72 hours was almost similar to that at time 0. A previous study used a CO₂ laser and reported no pain on day 4. Some other studies reported a significant reduction in pain after 24 hours. Orthodontic pain often starts within 0-2 hours after the placement of separators, increases within the next 6-24 hours, reaches its maximum level at 24 hours, and then decreases. It often disappears after 6-7 days.

In this study, a VAS was used for pain assessment due to its easy use, reliability, sensitivity and reproducibility, which is commonly used in studies on pain.

The diode laser was irradiated for pain relief in this study since the efficacy of the Ga-Al-As diode laser for pain relief has been previously confirmed. The selection of the 808 nm laser wavelength was due to the fact that orthodontic pain has an inflammatory origin. Thus, the selected wavelength for pain relief should exert anti-inflammatory effects and has higher penetration. PBMT with an 800-830 nm wavelength has shown maximum analgesic efficacy.

Controversy exists regarding the exact dose of the laser. In this study, the laser was irradiated with 15.60 J/cm² energy density. The mode of application in a continuous or chopped mode is another controversial topic. Previous studies have reported a single dose, double dose, and multiple-dose laser irradiation. In this study, double dose laser irradiation was performed. Also, the laser was irradiated to each point for 11 seconds (a total of 22 seconds for the mesial and distal roots) since evidence shows that it is the minimum duration required for analgesic effects of laser and has minimal complications. The laser was irradiated in a continuous mode, similar to many previous studies.

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Further studies are required to assess the analgesic efficacy of different laser types with different parameters. Moreover, considering the role of stress in the perceived
pain, it would be ideal to assess the stress level of patients by the STAI-S questionnaire and exclude patients with a high level of stress to obtain more accurate results.

Conclusion

PBMFT with the 808 nm diode laser can effectively decrease pain following the placement of orthodontic elastomeric separators.

Ethical Considerations

The study was approved by the Ethics Committee of Tehran University of Medical Sciences (IR.TUMS.DENTISTRY.REC.1397.167) and registered in the Iranian Registry of Clinical Trials (identifier: IRCT20190610043853N1).

Conflict of Interests

None.

References

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