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The Effect of Single Versus Double Application of Photobiomodulation Therapy on Pain Reduction Caused by Orthodontic Elastomeric Separators: A Randomized Clinical Study.

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ABSTRACT:

Background Periodontal ligament (PDL) pain, associated with the insertion of elastomeric separators, is one of the most annoying experiences at the beginning of orthodontic treatment. Photobiomodulation has recently been suggested as a method of controlling this pain.

Objectives The aim of this study was to evaluate the efficacy of photobiomodulation in controlling the pain caused by elastomeric separators and to compare a single irradiation dose 1 h before the insertion of elastomeric separators vs double irradiation, conducted 1 h before and immediately after the insertion, in terms of pain reduction.

Material and methods This randomized controlled trial was conducted at the Department of orthodontics at Bharti Vidyapeeth (Deemed to be university) Dental College and Hospital, Sangli. The sample population was comprised of 24 patients, aged between 12 and 25 years, and the patients were randomly divided into 2 groups. A split-mouth design was employed. One group received 1 dose of photobiomodulation 1 h before the insertion of elastomeric separators, whereas the other one received 2 doses of photobiomodulation 1 h before and immediately after the insertion of elastomeric separators. Eight points will be irradiated: mesial and distal of the first molar, distal of the second premolar, and mesial of the second molar, on both the buccal and lingual sides. A diode laser with a wavelength of 810 nm, an energy density of 6 J/cm2 and a power output of 300 mW will be used for an automated duration of 20 s per point. The pain levels were recorded using the Visual Analog Scale (VAS) after 1, 6, 24, 48, and 96 h. Student's t-test and the repeated measures analysis of variance (ANOVA) were employed to detect significant differences.

Results Photobiomodulation significantly reduced post-separation pain when the experimental side was compared to the placebo side in the single-irradiation group (p 0.05).

Conclusions Photobiomodulation had a positive effect on reducing the pain associated with elastomeric separation, whether it was applied as a single dose before elastomeric separation or as a double dose before and after this procedure.

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INTRODUCTION

In dentistry, orthodontics has been a significantly growing specialization to solve problems related to tooth and maxillomandibular positioning. Although orthodontics has developed significantly in several areas in the last decades, pain has been a constant worry for professionals and patients undergoing orthodontic treatment.[1]

Pain is a collateral effect that follows orthodontic treatment, caused by application of forces to promote tooth movement.[2] When mechanical forces are applied to the teeth, the resultant alterations of the blood flow start an inflammatory reaction in the periodontal tissue.[3] Periodontal ligament plays a key role in the physiological and orthodontic movements of the tooth.[4] When the tooth moves, tensile strain occurs in PDL, which is then transferred to and received by the receptors in the alveolar bone.[5]

Elastomeric separators are widely used due to their durability and ease of use with children and adolescents.6,7 The application of elastomeric separators is usually accompanied by pain.8 This pain typically starts within 24 h of insertion, increases over the next 24–48 h and subsides within 5–7 days.8 The patient may need an analgesic to relieve it. Therefore, distinct nonpharmacological and pharmacological methods have been indicated and used for controlling pain during orthodontic treatment.

Among the pharmacological methods, non-steroidal anti-inflammatory drugs have been indicated and used for controlling pain during orthodontic treatment. 9 Non-steroidal anti-inflammatory drugs should be avoided during orthodontic treatment, as they may affect the tooth movement process negatively by inhibiting the bone resorption and is contraindicated in patients suffering from allergic reactions.

Among non-pharmacological methods, photobiomodulation has been suggested to reduce pain, and is globally considered to be a safe and effective method for pain management. photobiomodulation stimulates cells to produce enkephalins and endorphins, and blocks nervous impulses in the slow-conduction velocity peripheral nerves.10

Therefore, the objectives of this clinical study are to evaluate the efficacy of photobiomodulation in controlling the pain caused by elastomeric separators and to compare a single irradiation dose 1 h before the insertion of elastomeric separators vs double irradiation, conducted 1 h before and immediately after the insertion, in terms of pain reduction.

MATERIAL AND METHODS

Ethical approval: The institutional ethics committee of Bharati Vidyapeeth (Deemed to be University) medical college and hospital, Sangli (BV(DU)MC & H/Sangli/ IEC/ D-66) has approved the present study.

Source of data: Twenty-four participants were provided for this study by the Outpatient Department (OPD) at the Bharti Vidyapeeth Dental College.

Inclusion criteria:

1. Patients aged 12-525years.

2. Patients with stable periodontal and dental health status.

3. Patients undergoing orthodontic treatment with the need of molar separation before banding.

Exclusion criteria:

1. Patients with chronic disease, chronic or neural pain, periodontitis, treated or untreated apical lesions on the first molar, open mesial and distal contact points on the first molar.

2. Patients not willing for the study.

PROCEDURE

For the purpose of the study, patients were divided into two groups, i.e., Group A and Group B. After isolating the field using cotton rolls, on the Test side group A 12 patients will receive a single irradiation dose of photo biomodulation 1 h before the insertion of elastomeric separators in the maxillary region and in the group B 12 patients will receive double irradiation dose of photo biomodulation 1 h before and immediately after the insertion of elastomeric separators in the mandibular region. Eight points will be irradiated: mesial and distal of the first molar, distal of the second premolar, and mesial of the second molar, on both the buccal and lingual sides. A diode laser with a wavelength of 810 nm, an energy density of 6 J/cm2 and a power output of 300 mW will be used for an automated duration of 20 s

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per point. On the placebo (control) side, the same laser device will be used after the safety cover is placed so that the device produced the same sounds, but no irradiation will be done. The 8 mm biostimulation probe will be applied to the same points and for the same duration. The operator and the patient will wear laser protective goggles to prevent any harm to the eyes. To prevent any deviations due to gender, age or personal pain threshold, the patients will not be made aware of which side represented the placebo.

Pain assessment

The patients will be given questionnaires to evaluate their perception of pain at the following assessment time points: 1, 6, 24, 48, and 96 h after elastomer separation. Every patient will be given a chart to rate the level of their pain on VAS. A 10-mm line will be used, with the left side representing no pain (i.e., score 0) and the right side representing the worst pain (i.e., score 10). The patients will be asked to put a mark on the line at the point which best represented the level of pain they felt.

Post-Surgical Care:

All patients will receive oral and written postoperative instructions. All patients will be instructed not to take any analgesics during the pain assessment period. In case of severe pain, they will be allowed to take 500-mg tablets of paracetamol (acetaminophen) once or twice, but they will be asked to fill in the questionnaire page provided to them before taking any analgesics.

STATISTICAL ANALYSIS

Two-sample t-tests were employed to evaluate the efficacy of LLLT in reducing pain by comparing the single- and double-irradiation groups. The repeated measures analysis of variance (ANOVA) was employed to evaluate changes in pain perception over time in each group.

RESULTS

In the single-irradiation group, pain increased over time, then decreased, with no significant differences in the pain levels between the assessment time points, whether the comparisons were made on the experimental side or the placebo side (Table 1). In the double-irradiation group, pain increased, then decreased, with statistically significant changes in the pain levels for both the experimental and the placebo sides (Table 1).

Significant differences in the pain levels were found between the placebo and experimental sides at 1, 6, 24 and 48 h after separation in the single-irradiation group (Table 2). Significant differences in the pain levels were also found between the 2 sides at all assessment time points (at 1, 6, 24, 48, and 96 h) in the double-irradiation group (Table 2).

Table 1. Descriptive statistics of the pain levels in the study groups at the different assessment time points, with the p-values of the repeated measures analysis of variance (ANOVA) test.

Group	Side	T1	T2	T3	T4	T5	F-value	p-value
Single irradiation	Experimenatal	8.50±14.29	13.44±19.9	22.61±28.6	19.28±24.59	17.06±2540	1.772	0.171
Single irradiation	placebo	14.94±23.99	27.17±26.99	33.28±31.70	31.22±29.60	23.39±29.77	2.618	0.071
Double irradiation	experimental	9.56 ±15.77	19.94±27.21	30.28±28.22	22.61±25.74	15.17±23.83	3.499	0.027*
Double irradiation	placebo	20.17 ±18.10	36.95±28.69	42.06±26.57	37.61±28.66	21.50±23.44	4.602	0.006**

T1 – 1 h after separation; T2 – 6 h after separation; T3 – 24 h after separation; T4 – 48 h after separation; T5 – 96 h after separation; * significant difference at $p < 0.05$; ** significant difference at $p < 0.01$. Data for T1–T5 presented as mean ±SD.

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Table 2. Descriptive statistics of the differences between the experimental and placebo sides in each group at each assessment time point, with the p-values of the paired t-test.

Group	Time point	Difference between the experimental and placebo sides mean ±SD	T-value	p-value
Single irradiation	T1	6.44 ±15.88	0.103	1.72
Single irradiation	T2	13.72 ±18.21	0.005**	3.20
Single irradiation	T3	10.67 ±20.80	0.044*	2.18
Single irradiation	T4	11.94 ±21.19	0.029*	2.39
Single irradiation	T5	6.33 ±15.31	0.097	1.75
Double irradiation	T1	10.61 ±16.10	0.012*	2.80
Double irradiation	T2	17.00 ±21.84	0.004**	3.30
Double irradiation	T3	11.78 ±17.69	0.012*	2.82
Double irradiation	T4	15.00 ±17.14	0.002**	3.71
Double irradiation	T5	6.33 ±10.36	0.019*	2.59

DISCUSSION

The pain caused by elastomeric separation is inflammatory in nature. That is why it is important to use a laser that has an anti-inflammatory effect, one which does not cause any thermal changes in the irradiated area. This feature can be found in lasers with a wavelength of 600–1,000 nm.[11] In this study, a diode laser with an 810-nm wavelength was used. It has been shown to have excellent tissue penetration and to be highly effective in reducing pain in comparison with other lasers.[12] Kim et al. used an AlGaInP laser with a wavelength of 635 nm.[13] They used multiple irradiations and found significant differences in pain reduction only on the 1st day, not on the following days.[13] Different outcomes might be due to the use of different types of lasers with different wavelengths.

In the present study, a diode laser was applied to Eight points will be irradiated: mesial and distal of the first molar, distal of the second premolar, and mesial of the second molar, on both the buccal and lingual sides. A diode laser with a wavelength of 810 nm, an energy density of 6 J/cm2 and a power output of 300 mW will be used for an automated duration of 20 s per point. This was similar to what Eslamian et al. used in their study.[8] It has also been documented that low doses of photobiomodulation would achieve the desired effect, whereas higher doses (exceeding 5 J/cm2 per point and 20 J/cm2 per tooth) could eliminate the analgesic and anti-inflammatory effect.7,37,38 Furquim et al. used a high dose of 80 J/cm2 and found no significant differences between the treatment and placebo sides.[14]

Eslamian et al. used a double-irradiation method, immediately and 24 h after separation, and found positive results on the side of double irradiation.[8] Abtahi et al. used a GaAr laser with a wavelength of 904 nm, 6 J of energy and a 7mm tip diameter,[15] whereas Kim et al. used an AlGaInP laser with a wavelength of 635 nm, 10 J of energy and a 5.6mm tip diameter.[13]Both studies found that laser application was useful in reducing the peak of pain perception, which generally occurs 24 h after separation, but at the same time they found no statistically significant differences between the laser and control groups at other observation time points.[13]

The time of pain perception differed between the patients studied, starting after 1 h in 63.89% of the sample, after 6 h in 13.89% of the sample and after 24 h in 11.11% of the study population. Thus, the majority of patients perceived pain within 1–24 h after dental separation. These results were similar to what Shetty et al. and Artés-Rebas et al. found in their research.[12] They found that pain started within 2–24 h of the insertion of elastomeric separators.[12]

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Eslamian et al. found that pain appeared immediately and up to 24 h after separation, and Ngan et al. reported that pain perception began 4–24 h after separation.[16,17]

In the current study, the maximum pain perception was recorded 24 h after the insertion of elastomeric separators, which is in agreement with the findings of Eslamian et al. and Fujiyama et al.,[16] whereas Abtahi et al. recorded the maximum pain perception 48 h after separation.[15] This delay might be attributed to the different number of laser applications. Abtahi et al. applied the laser daily for 5 days,[15] whereas Eslamian et al. performed double irradiation[16] and Fujiyama et al. administered a single irradiating dose.[18]

In the current study, no significant differences were found between the experimental sides in the singleand double-irradiation groups, indicating that double irradiation had a similar action to a single application of a laser.

Previously published work has shown that elastomeric separation pain usually decreases within 48–72 h[19] and subsides after 5–7 days.[20] Therefore, any assessment after 96 h (i.e., 4 days) would be of great benefit in evaluating the pain levels at later stages, before pain disappears. However, it should be noted that one of the shortcomings of the current study is that the last assessment time was 4 days after separation, and the assessment of the pain levels should have been taken 5, 6 or 7days after the insertion of separators.

The present study found photobiomodulation to be of significant benefit in pain reduction. This effect was similar to the ones reported in different studies when pharmaceutical analgesics were used at the same time points as those used in the current study for laser irradiation.[21] Low et al.[21] and Minor et al.[22] used an analgesic 1 h before separation. Bernhardt et al. administered an analgesic 1 h before separation and 5 h after separation.[23] The results of these studies were similar to those of the current study, indicating the possibility of replacing medication with photobiomodulation when the use of separators is planned.

CONCLUSION

The application of photobiomodulation significantly reduced the pain induced by elastomeric separation. Photobiomodulation was beneficial in pain reduction, whether applied in a single dose or a double dose, with no significant differences between the 2 methods.

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