

Analgesic effect of photobiomodulation after placement of elastomeric separators: randomized controlled clinical trial

Efeito analgésico da fotobiomodulação após colocação de separadores elastoméricos: ensaio clínico controlado randomizado

Efecto analgésico de la fotobiomodulación tras la colocación de separadores elastoméricos: ensayo clínico controlado aleatorizado

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Abstract

Objective: Pain resulting from the positioning of elastomeric separators is a strong reason for abandoning orthodontic treatment. So, this study aims to verify the analgesic effects of photobiomodulation (PBM) in participants submitted to orthodontics with elastomeric separators. **Methods:** Participants were individuals who received separators on the mesial and distal surfaces of the first molars. They were randomly separated into two groups: an experimental group that received photobiomodulation (PBM) (n=22) and a placebo group (n=22). After the positioning of the separators, the PBM group received one application of PBM (2 J of energy applied in 20 seconds per point, adding up to 12 J per molar (6 J on the vestibular surface and 6 J on the lingual surface) over the cervical portion and the apical third of the tooth. Pain was measured one hour after placement, with the aid of a visual analog scale (VAS). Statistical analysis involved the Mann-Whitney, Fisher's Exact and chi-square tests. **Results:** Reports of severe pain only occurred in the placebo group. However, a larger percentage of the individuals in the PBM group reported feeling moderate pain compared to this same intensity in the placebo group. No significant differences among groups were found with regards to reports of mild pain and no pain. An association was found between pain and the female sex in both groups. **Conclusion:** Significant difference was found in severe pain sensitivity when PBM was applied after the positioning of elastomeric separators, favoring the irradiated participants. Thus, PBM may be a useful tool in orthodontic treatment. **Clinical Trials Reference Number** (www.ClinicalTrials.gov), NCT03939988.

Keywords: Pain; Photobiomodulation; Orthodontics; Elastomeric separators.

Resumo

Objetivo: A dor decorrente do posicionamento dos separadores elastoméricos é um forte motivo para o abandono do tratamento ortodôntico. Portanto, esse estudo pretende verificar os efeitos analgésicos da fotobiomodulação (PBM) em participantes submetidos à ortodontia com separadores elastoméricos. **Metodologia:** Os participantes foram indivíduos que receberam separadores nas superfícies mesial e distal dos primeiros molares. Eles foram separados aleatoriamente em dois grupos: um grupo experimental que recebeu fotobiomodulação (PBM) (n=22) e um grupo placebo (n=22). Após o posicionamento dos separadores, o grupo PBM recebeu uma aplicação de PBM (2 J de energia aplicada em 20 segundos por ponto, somando 12 J por molar (6 J na superfície vestibular e 6 J na superfície lingual) sobre a porção cervical e o terço apical do dente. A dor foi mensurada uma hora após a colocação, com auxílio de uma escala visual analógica (EVA). A análise estatística envolveu os testes Mann-Whitney, Exato de Fisher e Qui-quadrado. **Resultados:** Relatos de dor intensa ocorreu apenas no grupo placebo. No entanto, uma porcentagem maior dos indivíduos do grupo PBM relatou sentir dor moderada em comparação com essa mesma intensidade no grupo placebo. Não foram encontradas diferenças significativas entre os grupos em relação ao relato de dor leve e sem dor. Foi encontrada associação entre dor e sexo feminino em ambos os grupos. **Conclusão:** Foi encontrada diferença significativa na sensibilidade à dor intensa quando a PBM foi aplicada após o posicionamento dos separadores elastoméricos, favorecendo os participantes irradiados. Assim, a PBM pode ser uma ferramenta útil no tratamento ortodôntico. **Número de Referência do Ensaio no Clinical Trials** (www.ClinicalTrials.gov), NCT03939988.

Palavras-chave: Dor; Fotobiomodulação; Ortodontia; Separadores elastoméricos.

Resumen

Objetivo: El dolor resultante de la colocación de separadores elastoméricos es un motivo de peso para abandonar el tratamiento de ortodoncia. Así, este estudio tiene como objetivo verificar los efectos analgésicos de la fotobiomodulación (PBM) en participantes sometidos a ortodoncia con separadores elastoméricos. **Métodos:** Los participantes fueron individuos que recibieron separadores en las superficies mesial y distal de los primeros molares. Fueron separados aleatoriamente en dos grupos: un grupo experimental que recibió fotobiomodulación (PBM) (n=22) y un grupo simulado (n=22). Después de la colocación de los separadores, el grupo PBM recibió una aplicación de PBM (2 J de energía aplicada en 20 segundos por punto, sumando 12 J por molar (6 J en la superficie vestibular y 6 J en la superficie lingual) sobre la porción cervical y el tercio apical del diente. El dolor se midió una hora después de la colocación, con la ayuda de una escala analógica visual (EVA). El análisis estadístico involucró las pruebas de Mann-Whitney, Exacto de Fisher y chi-cuadrado. **Resultados:** Informes sin embargo, un mayor porcentaje de los individuos del grupo PBM reportaron sentir dolor moderado en comparación con esta misma intensidad en el grupo simulado. Se encontró una asociación entre el dolor y el sexo femenino en ambos grupos. **Conclusión:** Se encontró diferencia significativa en la sensibilidad al dolor severo. Cuando se aplicó PBM después del posicionamiento de los separadores elastoméricos, favoreciendo los participantes irradiados. Por lo tanto, PBM puede ser una herramienta útil en el tratamiento de ortodoncia. **Número de referencia de ensayos clínicos** (www.ClinicalTrials.gov), NCT03939988.

Palabras clave: Dolor; Fotobiomodulación; Ortodoncia; Separadores elastoméricos.

1. Introduction

The main complaints of orthodontic patients are the prolonged treatment time and pain, which is often underestimated by orthodontists (Sousa, 2014; Marini, 2015; Dalaie, 2015). Despite recent advances, about 90% of patients connect

orthodontics with pain and this is the most frequent factor in the avoidance of treatment (Artés-Ribas, 2013; Eslamian, 2013; Sobouti, 2015). Pain is subjective and its intensity varies depending on one's personal history, sex, age and external factors (Artés-Ribas, 2013).

The sensation of pain originated by the positioning of elastomeric separators during orthodontic treatment is very usual and acute in the first couple of days (Kim, 2013; Almallah, 2016). Forces create zones of compression and tension in the periodontal ligament, followed by inflammatory reactions inducing a cascade of reactions, such as a change in bloodstream and the liberation of chemical mediators, like histamine, serotonin, dopamine, glycine, prostaglandins, substance P and cytokines, resulting in hyperalgesia (Ren, 2015; Almallah, 2016; Farias, 2016). Prostaglandins, substance P, enkephalin, leukotrienes, bradykinins and histaminas are the major mediators in this process, as these substances sensitize nerve endings, increasing inflammation and pain (Marini, 2015; Ren, 2015; Bayani, 2016).

Patients with a high pain index tend to use pharmacological agents, such as analgesics and anti-inflammatories. However, such medications have systemic side effects, such as allergy, peptic ulcer and congestive heart problems, and can also interfere in orthodontic movement by affecting the mechanism of action of osteoclasts, thereby further extending treatment (Artés-Ribas, 2013; Sobouti, 2015; Ren, 2015; Mohammad-Hoseyni, 2015; Almallah, 2016; de Sousa, 2018).

Novel hypothesis are being researched and low-level laser therapy has been proven effective because of the therapeutic effects of photobiomodulation (PBM). According to studies, this is an effective, easy-to-administer, simple, painless therapeutic modality with no side effects and few contraindications (Kim, 2013; Sousa, 2014). Besides reductions in pain and inflammation, the biological responses of PBM include the induction of cell proliferation, acceleration of the healing process, assistance in neurological regeneration, the promotion of vascular and lymphatic microcirculation and modulation of the immune system (Huany, 2013; Basso, 2016; Nadhreen, 2019).

The analgesic and anti-inflammatory properties of PBM are related to the reactivation of enzymes directed at pain-inducing factors, the inhibition of nerve depolarization (C fibers), cyclooxygenase 2 (COX-2), the production of ATP, the degradation of bradykinin as well as reductions in inflammatory cytokines and prostaglandins. PBM also promotes an increase in the activity of cell receptors responsible for the induction of the production of endorphins and the action potential of neurons (Sobouti, 2015; Mohammad-Hoseyni, 2015).

According to the literature, both red and infrared lasers have analgesic action. However, there are no clear, well-defined parameters due to the heterogeneity found in literature, with the use of different light sources, irradiation parameters and methods. It is therefore of considerable importance to establish a clinical protocol that supports the analgesic effects of PBM (Ren, 2015).

The objective of the present study was to verify the analgesic effects of one of PBM in orthodontic patients submitted to the positioning of elastomeric separators.

2. Methodology

Type of study

The present randomized and controlled, clinical trial was reported following guidelines of the Consolidated Standards of Reporting Trials (CONSORT) and was conducted with patients at the dentistry clinic of Universidade Nove de Julho, São Paulo, Brazil. The project was submitted to Universidade Nove de Julho's ethics committee, in accordance with Resolution 466/2012 of the National Board of Health. The trial was conducted in accordance with the 1964 Declaration of Helsinki and its later amendments. All participants (or their guardians) who were included in the study signed a free informed consent term.

Registration of study

This study received approval from the ethics committee of Universidade Nove de Julho (certificate number: 13694419.1.0000.5511) and was registered with ClinicalTrials.gov at <https://clinicaltrials.gov/ct2/show/NCT03939988>.

Sample calculation

The sample size calculation was determined, based on the results of a preceding study by Qamruddin, 2016 and using the G*Power program, version 3.1.9.2. For a test power higher than 80%, considering a 5% significance level and size effect higher than 0.60, 36 individuals would be necessary, per group (total: 72), to detect a difference between groups.

$$d = \frac{\text{largest-smallest}}{\left(\frac{\sigma}{\sqrt{n}}\right)^2} = \frac{5.04 - 1.86}{\left(\frac{3.24}{\sqrt{2}}\right)^2} = 0.60$$

However, we were only able to include 42 individuals. The participants were male and female, with at least 11 years of age, who were being submitted to orthodontic treatment at the dentistry clinic of Universidade Nove de Julho, São Paulo. The volunteers were randomly separated in two groups: an experimental group with 22 individuals and a placebo group with 22 individuals.

Randomization of participants

Randomization was performed using a computer-generated sequence (Excel 2007). Sealed envelopes contained either the letter “A” (PBM group) or “B” (placebo group). The participants who received the letter “A” were irradiated with infrared laser immediately after the positioning of the elastomeric separators. Participants who received the letter “B” were submitted to the same procedure, but the emission of irradiation was simulated.¹⁰ The participants were not aware of the group to which they belonged.

Inclusion criteria

Individuals of either sex with at least 11 years of age beginning orthodontic treatment for the first time were included in the study. We confirmed normal periodontal status in a previous exam, involving probing of the gingival sulcus. Patients with sound first molars, that presented interproximal contacts between the second molar and the second premolar, in permanent dentition, and who had not used anti-inflammatory and/or analgesic agents in the preceding four days (Farias, 2016) were included.

Exclusion criteria

Individuals with systemic diseases, periodontal disease, gingival disease, pregnant women, and individuals who habitually took medications for pain or inflammation were excluded from the study.

Operational plan

Participants received explanations regarding the aims of the trial and signed an informed consent term (those over 18 years of age and guardians of those under 18 years of age) and/or a statement of assent (minors) (Farias, 2016).

The individuals were randomly allocated to two groups by choosing between two envelopes (one with the letter “A” [PBM] and one with the letter “B” [placebo]). The participants were blind to the correspondence of the letters. The PBM group was submitted to active infrared laser irradiation and the placebo group had simulated irradiation with the laser device

switched off but emitting a sound to give the appearance of being activated. The researcher inserted the elastomeric separators (4.0 mm in diameter, reference 60.04.200, Morelli Ortodontia) with the aid of dental floss. The separators were placed at the interproximal contacts between the second premolar and the first molar, and between the first molar and the second molar. The participants then received a single session of PBM (active or placebo). The placement of the separators and administration of PBM were performed by the same researcher. The researcher and the participants wore protective goggles during the irradiation procedure (Farias, 2016).

Irradiation was applied to three points on the vestibular face and three points on the lingual face of the first molar: interproximal papillae of mesial and distal cervical thirds and apical third of the roots.

Photobiomodulation

A Ga-Al-As laser (Therapy XT, DMC, São Carlos, Brazil) was used, with 100 mW power, tip diameter of 600 μm . The laser had two optical fibers – each with a continuous wavelength of 808 nm (infrared) and 660 nm (red). Participants in the PBM group received the infrared laser (wavelength: 808 nm) in continuous mode.

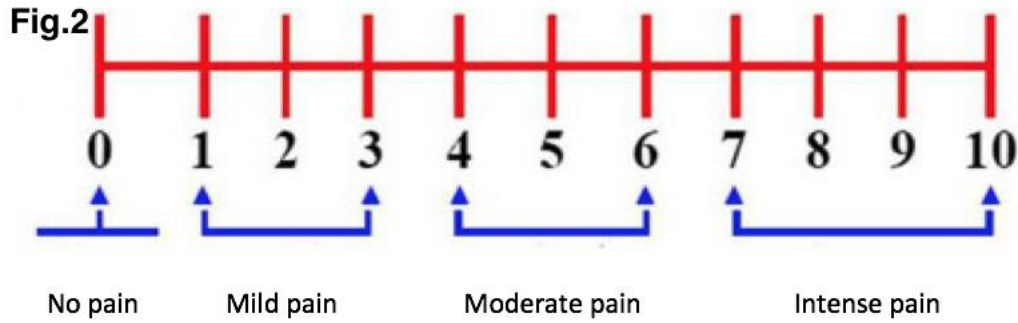
The tip of the device was positioned perpendicularly to the mucosa (without pressing) for the application in the active group and simulated laser in the placebo group (Figure 1). The parameters in the active PBM group were of 2 J of energy applied in 20 seconds per point, adding up to 12 J per molar (6 J on the vestibular surface and 6 J on the lingual surface). The parameters, described in Table 1, were selected based on a previous study (Sousa, 2014). An hour after the positioning of the orthodontic separators and application of PBM (active or placebo), the patients reported their perceptions of pain on a numeric visual analog scale (VAS) (Figure 2) at predetermined intervals. The 11-point scale ranges from 0 (absence of pain) to 10 (intolerable pain). Participants were instructed not to take any medications during the trial.

Figure 1: Application of infrared laser.



Source: personal archive.

Figure 2: Numeric Visual Analog Scale.



Source: personal archive.

Table 1: Dosimetric parameters.

Wavelength	808 nm
Spectral width (FWHM)	2 nm
Operating mode	Continuous
Polarization	Random
Beam profile	Multimodal
Area at target	0.002826 cm ²
Irradiance at target	35385 mW/cm ²
Radiant exposure	707.4 J/cm ²
Irradiated area	0.01695 cm ²
Radiant power	100 mW
Exposure time	20 s per point
Aperture diameter	600 µm
Irradiance at aperture	35385 mW/cm ²
Radiant energy	2 J per point
Number of points irradiated	6-3 points on vestibular face and 3 points on lingual face
Application method	Contact
Number of sessions	Single session
Total energy irradiated	12 J per tooth

Source: personal archive.

Analysis of cytokine profile of crevicular gingival fluid

Collection of gingival crevicular fluid was conducted for the evaluation of cytokines. Before and one hour after the positioning of the separators, absorbent paper cones were inserted in the cervical middle third of the vestibular surface of each tooth. Supragingival plaque was removed before this procedure. The teeth were isolated with relative isolation. The insertion was performed until encountering mild resistance and the cones were kept in position for 30 seconds. The volume of the gingival crevicular fluid was calculated by the difference in the weight of the paper cone before and after the placement of the separators, at a proportion of 1 g/ml. The samples were put in sterile tubes with 2 ml of phosphate buffer solution (pH 7.4) and stored at 70° C for the posterior analysis of IL-1 β . Cytokine levels were determined by a single researcher, using ELISA interleukin kits and strictly following the manufacturer's instructions (Murakami-Malaquias-Silva, 2020).

Statistical analysis

The data were organized using Microsoft Excel. Frequency and percentage were used to express qualitative data. The quantitative data presented nonparametric distribution and were therefore expressed as median + minimum and maximum. To determine normality, the Shapiro-Wilk test was used. The inferential analysis was performed with the Mann-Whitney test, Fisher’s exact test and the chi-square test. A significance level of $\alpha = 0.05$ ($p < 0.05$) was adopted.

3. Results

Table 2 displays the data of the 42 participants in the study. The PBM group had 20 patients and the placebo group had 22 patients. The samples were balanced with regards to the location of the treated tooth in the maxillary and mandibular arches. Both groups had a larger percentage of female participants.

Table 2: Data on participants of study.

	Age			Sex		Tooth treated	
	Median	Minimum	Maximum	Female	Male	Maxillary	Mandibular
				N / %	N / %	N / %	N / %
PBM group	16	11	20	12 / 60	8 / 40	10 / 50	10 / 50
Placebo group	15	11	33	18 / 90	2 / 10	12 / 55	10 / 45

Source: Personal archive.

Table 3 displays the results of the analysis of the association between groups (active or placebo) and pain level (VAS).

Table 3: Analysis of association between pain and group.

Group	PBM	n	Mild		Severe	Total	p-value
			No pain	pain	Moderate pain		
		n	12	2	6	0	20
		% in group	60.0%	10.0%	30.0%	0.0%	100.0%
		% on scale	48.0%	40.0%	85.7%	0.0%	47.6%
		% of total	28.6%	4.8%	14.3%	0.0%	47.6%
	Placebo	n	13	3	1	5	22
		% in group	59.1%	13.6%	4.5%	22.7%	100.0%
		% on scale	52.0%	60.0%	14.3%	100.0%	52.4%
		% of total	31.0%	7.1%	2.4%	11.9%	52.4%

*p <0.05 = statistically significant difference, chi-squared test. Source: Personal archive.

A significant association was found between group and pain. All participants who reported severe pain were in the placebo group, whereas none of the participants in the laser group reported this level of pain. However, a larger percentage of the participants in the laser group reported feeling moderate pain compared to this same intensity in the placebo group. Regarding reports of mild and no pain, no significant differences were found between the groups. In the analysis of the association between pain and tooth location (maxilla or mandible), no significant difference was found in either the irradiated or placebo group, as shown in Table 4.

Table 4: Analysis of association between pain level and location of tooth according to study groups.

Group	Pain scale	Region	Maxillary	Mandibular	p-value
PBM		No pain	n	6	6
	% on scale		50.0%	50.0%	100.0%
	% in region		60.0%	60.0%	60.0%
	% of total		30.0%	30.0%	60.0%
	Mild pain	n	2	0	2
		% on scale	100.0%	0.0%	100.0%
		% in region	20.0%	0.0%	10.0%
		% of total	10.0%	0.0%	10.0%
	Moderate pain	n	2	4	6
		% on scale	33.3%	66.7%	100.0%
		% in region	20.0%	40.0%	30.0%
		% of total	10.0%	20.0%	30.0%
Placebo	No pain	n	7	6	13
		% on scale	53.8%	46.2%	100.0%
		% in region	58.3%	60.0%	59.1%
		% of total	31.8%	27.3%	59.1%
	Mild pain	n	2	1	3
		% on scale	66.7%	33.3%	100.0%
		% in region	16.7%	10.0%	13.6%
		% of total	9.1%	4.5%	13.6%
	Moderate pain	n	0	1	1
		% on scale	0.0%	100.0%	100.0%
		% in region	0.0%	10.0%	4.5%
		% of total	0.0%	4.5%	4.5%
	Severe pain	n	3	2	5
		% on scale	60.0%	40.0%	100.0%
		% in region	25.0%	20.0%	22.7%
		% of total	13.6%	9.1%	22.7%

*p <0.05 = statistically significant difference, chi-squared test. Source: Personal archive

The analysis according to sex revealed a stronger association between pain and the female sex in both groups, as displayed in Table 5.

Table 5: Analysis of association between pain level and sex according to study groups.

Group		Sex		Female	Male	Total	p-value
PBM	Pain scale	No pain	n	4	8	12	p= 0.012*
			% on scale	33.3%	66.7%	100.0%	
			% in sex	33.3%	100.0%	60.0%	
			% of total	20.0%	40.0%	60.0%	
		Mild pain	n	2	0	2	
			% on scale	100.0%	0.0%	100.0%	
			% in sex	16.7%	0.0%	10.0%	
			% of total	10.0%	0.0%	10.0%	
		Moderate pain	n	6	0	6	
			% on scale	100.0%	0.0%	100.0%	
			% in sex	50.0%	0.0%	30.0%	
			% of total	30.0%	0.0%	30.0%	
Placebo	Pain scale	No pain	n	13	0	13	p= 0.006*
			% on scale	100.0%	0.0%	100.0%	
			% in sex	65.0%	0.0%	59.1%	
			% of total	59.1%	0.0%	59.1%	
		Mild pain	n	3	0	3	
			% on scale	100.0%	0.0%	100.0%	
			% in sex	15.0%	0.0%	13.6%	
			% of total	13.6%	0.0%	13.6%	
		Moderate pain	n	0	1	1	
			% on scale	0.0%	100.0%	100.0%	
			% in sex	0.0%	50.0%	4.5%	
			% of total	0.0%	4.5%	4.5%	
		Severe pain	n	4	1	5	
			% on scale	80.0%	20.0%	100.0%	
			% in sex	20.0%	50.0%	22.7%	
			% of total	18.2%	4.5%	22.7%	

*p <0.05 = statistically significant difference, chi-squared test. Source: Personal archive.

Table 6 shows the concentrations of IL-1 β in the PBM and placebo groups. No significant difference between treatments (p = 0.971) or times (p = 0.637) and no significant interactions (p = 0.676) were revealed in the two-way repeated-measures analysis of variance.

Table 6: Concentrations of the cytokine IL-1 β in the PBM and placebo groups.

Mean IL-1B			
Immediately after placement of separators			
Group	Mean	N	Deviation
PBM	147.96	14	128.13
Placebo	97.84	10	76.43
Total	127.07	24	110.46

Source: Personal archive.

4. Discussion

The placement of elastomeric separators generates space between the teeth and banding molars is part of routine orthodontic treatment. This process causes the movement of the adjacent teeth due to close interproximal contacts as well as the release of biochemical mediators in the gingival sulcus. Average band thickness is 0.16 mm, requiring a separation of 0.25 mm. Separation methods should involve easy placement with little or no discomfort. Elastomeric separators are more efficient than other separators, but generate a higher level of pain (Qamruddin, 2016; Tripathi, 2019). Pain involved in the placement of separators affects functions such as chewing and the eating pattern and the discomfort may lead to a need for medication (Sousa, 2014; Marini, 2015; Dalaie, 2015; Tripathi, 2019).

Pain can vary with several factors, such as age, sex, pain threshold, magnitude of the applied force, emotional state, the presence of stress, cultural discrepancies and previous trauma. The feeling of pain is part of an inflammatory response resulting in the liberation of chemical mediators, like prostaglandins, histamine, bradykinins, serotonin and substance P as well as cytokines, such as interleukin-1 beta (IL-1 β), making the periodontal ligament sensitive and provoking a hyperalgesic response (Abtahi, 2013; Ren, 2015; Almallah, 2016; Farias, 2016). According to Dominguez *et al.* (2015), results from previous studies indicate that greater dental pain intensity is experienced soon after the onset of treatment and is associated with the increase in the level of these mediators.

Medications reported to effective at controlling pain include ibuprofen, paracetamol/acetaminophen, sodium naproxen, aspirin, meloxicam, etoricoxib, piroxicam and tenoxicam, all of which have side effects. Alternative therapies without side effects are also described for pain, for instance, physiotherapeutic methods, gum and a viscoelastic plate (Farganegan, 2012; Bayani, 2016; Nadhreen, 2019; Topolski, 2018). Farzanegan *et al.* (2012), and Bayani *et al.* (2016), found that chewing gum and viscoelastic plates can replace ibuprofen.

Recent studies have shown that photobiomodulation is favorable to the reduction in pain sensitivity due to its anti-inflammatory and photobiomodulating action. Laser irradiation offers advantages, such as hemostasis, the absence of mechanical contact, regenerative capacity and a reduction in bacterial cells at the application site (Nadhreen, 2019).

A study involving rats submitted to palatal expansion reported that the PBM group continued gaining weight more easily when compared to the non-irradiated control group due to the more effective control of pain with PBM (Artés-Ribas, 2013). Kim *et al.* (2013); Eslamian *et al.* (2013); Marini *et al.* (2015); and Farias *et al.* (2016) and found that the administration of PBM after the placement of separators was effective at controlling pain in the first three days, with an accentuated difference between the treatment and control groups. Farias *et al.* (2016) and Eslamian *et al.* (2013) found positive results using infrared laser at a wavelength of 810 nm regarding the reduction in pain respectively with a single dose (three points on the vestibular face for 15 seconds each) and with 10 doses repeated after 24 hours. Almallah *et al.* (2016) checked the effect of infrared laser comparing a protocol with a single application immediately after the placement of the separators and another

protocol with two applications (immediately after placement and after 24 hours). They found that PBM was effective at pain reduction, corroborating with our results (in which no patient in the PBM presented severe pain), with no significant difference between one and two sessions.

Sobouti *et al.* (2015), also reported a positive effect on the reduction in pain using red laser during the traction of maxillary canines. However, Dalaie *et al.* (2015), and Cronshaw *et al.* (2019), found no significant differences in pain during orthodontic movement with the administration of infrared laser. Bayani *et al.* (2016), compared red and infrared PBM to bite plates and ibuprofen and concluded that infrared laser was more effective at controlling pain. Based on information compiled from previous articles, Sousa *et al.* (2014), concluded that pain is inhibited with both red and infrared wavelength applying energy between 1 to 2 J and alternating powers, points and the quantity of energy. Lee *et al.* (2018), reported the use of red laser for the regulation of pro-inflammatory cytokines, which could be of considerable use in periodontal therapy.

PBM is a quickly growing modality for stimulating healing, enhancing tissue regeneration and reducing both pain and inflammation. PBM has no reported side effects and no long-term adaptation to treatment has been shown. Infrared laser has clinical advantages for pain control, such as deeper penetration (Shi, 2015; de Sousa, 2018; Cronshaw, 2019). According to Ren *et al.* (2008), the results of studies that investigate pain reduction in orthodontics with the application of laser depend on three main factors: individual variation, the methods employed in the study and the laser parameters. A difference in IL-1 β was expected, since this cytokine is present in situations of pain and inflammation (Ren, 2015). However, no difference between groups was found. Future studies should test different collection times.

PBM is also being explored in other topics on Orthodontics. Its effect on accelerating orthodontic tooth movement (Dominguez, 2020; Li, 2021), on the prevention of enamel demineralization (Paulos, 2017), and even its capacity to enhance the efficiency of dental alignment (Caccianiga, 2017; Lo Giudice, 2020) have been researched. Our study showed its efficacy at preventing severe pain during the use of elastomeric separators. This shows that PBM is a therapy that is being more and more encouraged in this particular field of Dentistry.

5. Conclusion

A significant difference in pain sensitivity was found when PBM was administered after the positioning of elastomeric separators. During the experiment, only the placebo group reported feeling severe pain, whereas none of the individuals in the PBM group reported this degree of pain. The present findings suggest that the application of infrared laser on the dental mucosa has an analgesic, preventive, photomodulating effect on the pain experienced after placing elastomeric separators. Thus, PBM may be a useful tool in orthodontic treatment.

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