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EVALUATION OF PHOTOBIOMODULATION AS A PAIN PREVENTION ALTERNATIVE IN ORTHODONTIC MOVEMENT AFTER INSTALLATION OF ORTHODONTIC APPLIANCES: RANDOMIZED CLINICAL STUDY

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ABSTRACT

Introduction: Photobiomodulation is a promising technique for pain management, whether local and/or systemic, due to the beneficial effects generated by the application of laser. **Objective:** To evaluate the clinical application of intravascular laser irradiation of blood (ILIB) and photobiomodulation (PBM-T), as a predictor of improvements and/or pain prevention and compare its effectiveness when combined or not. **Methods:** The present study was carried out with 71 patients, selected according to the inclusion and exclusion criteria and randomly divided into 4 groups regarding the laser application procedure, namely: control group, PBMT, ILIB and PBMT + LIB. All patients were instructed and should fill out questionnaires regarding quality of life parameters and VAS scales and the Facial Pain Scale (EFD) after the procedure. **Results:** It was observed in the initial evaluation, a difference (p<0.001) regarding the limitation of food and pain when chewing, "sensitivity" in the experimental groups, as well as the values obtained for the variables EFD and VAS were different from the control group. . The statistical difference in the experimental groups was maintained in the evaluation time of 24h, (p<0.001) regarding the variables, between the groups. And in the evaluation time of 3 days, lower values were observed, being similar between the groups only in the evaluation of 7 days. **Conclusion:** It can be concluded that photobiomodulation is an effective option for pain prevention. Regarding their use, when compared in isolation, PBMT and ILIB present similar results, and when associated, the techniques have a greater analgesic and pain prevention effect when compared to the other groups.

INTRODUCTION

Orthodontic treatment was often performed in the mixed and young permanent dentition phase, thus allowing for the possible efficient correction of occlusal anomalies, during or shortly after the development of malocclusion. However, over the last decades the treatment has been increasingly adhered to by adults, aiming at an improvement in facial and smile aesthetics, (MALTAGLIATI & MONTES, 2007) which report feeling more pain when compared to adolescents and pre-teens (BROWN & MOERENHOUT, 1991;

CHOW & CIOFFI, 2018). Pain is defined as an unpleasant sensory and emotional experience associated with actual or potential tissue damage (DIDDIGE *et al*., 2020). This is one of the most important reasons why patients are discouraged from seeking orthodontic treatment. It is stated that these pains arise from the pressure process of the periodontium generated by the orthodontic device on the tooth, in which there is a change in blood flow, causing ischemia, inflammation and edema in the area, in addition to the release of cytokines that are responsible for the reabsorption of the tooth. bone in the direction of the force vector and by stimulating osteoclast formation in the opposite direction of the force.

(FURSTMAN & BERNICK, 1972; SANDY*et al.*, 1993; ERTAN *et al.*, 2004; MOTYL*et al.*, 2009) The perception of pain reported by the patient related to the installation of the orthodontic appliance occurs mainly after 6, 24 and 48 hours, with the apex being after 24 hours, and can last for up to 7 days. (ERTAN *et al.*, 2004) In order to measure pain, there are several scales, some of which are the Visual Analogue Scale (VAS) (BIJUR*et al.*, 2001), and the Facial Scale of Pain (EFD) (Face Pain Scale - FPS)(SILVA & THULER, 2008). The VAS scale is reliable, and can be used to measure chronic and acute pain in several areas of health, and consists of a 10 cm line with the ends written "least possible pain" and the other "worst possible pain", in which the patient must indicate where he believes it is equivalent to his own sensitivity (BIJUR *et al.*,2001). FPS, on the other hand, originally consists of seven faces, presented on an increasing scale, in which the left does not express any pain, followed by faces that show more and more pain, until the right that expresses a lot of pain (SILVA & THULER, 2008). Thus, in order to measure pain related to different orthodontic appliances on the market, some studies were carried out, based on questionnaires completed by the patients themselves, in which they answered the VAS scale and reported the severity of pain, as well as the frequency of ingestion of each food , and if they had difficulty chewing, talking, if any analgesic medication was used, if they had sensitivity to ice cream and cold, taste alteration, and difficulty sleeping, continue daily activities (SCOTT *et al.,* 2008; DIDDIGE *et al.,* 2020). In order to minimize pain-related complaints, orthodontists routinely use pharmacological methods, through the prescription of analgesics (ASHKENAZI & LEVIN, 2012). However, a technique for non-pharmacological pain management has been reported in the literature, which is an aspect of laser therapy, known as photobiomodulation (photodynamic therapy - PBMT). The PBMT technique consists of applying the laser to certain local points, presenting several benefits in different areas of medicine (RKEIN & OZOG, 2014) and also in the treatment of dental diseases (PRAZMO *et al.*, 2016), being also used in orthodontics. due to its effects of improving tissue growth, accelerating bone and nerve regeneration, as well as reducing pain after orthodontic installation and adjustments, it is currently considered a supportive measure (CRONSHAW *et al.*, 2019). Another aspect of photobiomodulation is the irradiation of laser in the blood (ILIB, English Intravascular Laser Irradiation of Blood) which consists of the application of the laser in a systemic way, due to the possible realization it can be done in the forearm, hand and ankle, as well as transmucosally and transcutaneous (WIRZ-RIDOLFI, 2013). And the technique has an aspect known as modified ILIB, which consists of continuous irradiation with red laser (660 nm) in the region of the radial artery, with the aid of a wristband for positioning the laser tip. The technique has the advantages of anti-inflammatory power and analgesic effects, in addition to numerous other factors that make ILIB efficient in the treatment of various vascular, cardiac and systemic diseases, and in the reduction of postoperative complications (KHOO *et al.,* 2013). Currently, there are already scientific data that support the use of PBMT in orthodontics (CRONSHAW *et al.,* 2019). However, despite the advantages and promising results in relation to the use of ILIB, there are no studies carried out to verify the effects of its use on pain control in orthodontic treatments. Thus, it was intended to study the application and effectiveness of PBMT and modified ILIB separately and together to prevent pain related to the installation of orthodontic appliances.

MATERIAL AND METHODS

After the project was approved by the ethics committee (CAAE 37476520.1.0000.5481), 71 patients were selected from a private clinic, who, after meeting the inclusion and exclusion criteria and agreeing to fill in and sign the Informed Consent Form, were randomly divided into random drawing, in which they were directed to one of the four different groups, regarding the laser application protocol. For this selection, the following criteria were adopted:

Inclusion criteria: Patients who agreed to participate in the research; aged between 18 and 50 years old; light/moderate crowding; with a contact telephone, to obtain the data and to have all the teeth in the arch.

Exclusion criteria: Patients who did not agree to participate in the research, pregnant women, allergic to paracetamol or who were continuously using analgesic or anti-inflammatory medication. Those who: had severe crowding were also excluded; absence of one or more teeth; with indication for orthognathic surgery; indication of extractions; they did not have a telephone number; patients undergoing cancer treatment; those who had already undergone previous orthodontic treatment; and patients with tattoos in the wrist region.

Clinical Procedures: The 71 patients selected at the dental office were randomly divided through a random draw carried out by the patient, in which there was a dark box with cards of four different colors (red, yellow, blue and green) and when a card was removed, it was targeted to one of four different groups with regard to laser application protocol. All patients received standard orthodontic guidelines, namely: 1) regarding food; 2) regarding oral hygiene; 3) adaptation guidance with the device; and finally 4) in case of pain or sensitivity, you could use Paracetamol 200 mg orally (35 drops) every 4 hours. They were also instructed on how to fill out the questionnaires regarding the parameters of quality of life and the VAS scales and the Facial Pain Scale. Postoperative follow-up was performed by telephone by a third person, a dental assistant, who was blind to which group the patient was allocated to, and was performed after 4 and 24 hours and on the 3rd and 7th day after installation. Regarding the clinical procedure, orthodontic accessories from the commercial brand Morelliltda, prescription Roth Light, were glued to all patients, and only after the use of the laser, regardless of which group they were allocated to, the leveling arches and elastic ligatures were installed. , adopting the 0.12" NiTi round leveling arc of the commercial brand Morelli ltda. Regarding the laser application protocol in each group, described in Table 1: In the CONTROL group (n=18 – red) the simulation of local and systemic application was performed, but in both situations the device was not activated. In the PBMT group (n= 18 - yellow) only one application was performed, right after the installation of the orthodontic appliance and prior to the installation of the leveling arch. In the ILIB group (n=18 - blue) only a single application was performed, during the installation of the orthodontic appliance and prior to the installation of the leveling arch. In the ILIB + PBMT group (n=17 - green) as well as in the PBMT group and ILIB group, an association of the protocols described above was performed.

Follow-up: Patients were followed up by phone for contact by a third person, a dental assistant who was blind to the allocated group, being carried out after 4 and 24 hours and on the 3rd and 7th day after installation, in order to collect information about the research and in order to minimize possible complications with pain related to the installation of the device.

Data analysis: The data obtained were analyzed by descriptive and inferential statistics using the IBM SPSS Software and the experimental groups (GC; PBMT; ILIB; PBMT+ILIB) were compared at each of the evaluation times (4hs; 24hs; 3 days and 7 days) for the variables of interest. For the quantitative variables, the Shapiro-Wilk normality test was performed, verifying that the age variable presented a normal distribution ($p>0.05$) and the EFD and VAS variables presented a non-normal distribution.Thus, the values for the age of the participants were compared between the experimental groups using the One-way ANOVA test and the scores obtained for the EFD and VAS variables were compared using the Kruskal-Wallis test, with the Mann-Whitney post-test. Frequencies were compared using the chi-square test with Yates correction. For all tests, a significance level of 5% was adopted.

RESULTS

The distribution of participants of each gender between the experimental groups did not show a significant difference ($p=0.323$), as well as the average age of the participants were similar between the experimental groups ($p=0.551$) (Table 2), indicating that the experimental groups are comparable for other variables of interest, without the influence of gender or age.

Table 1. Protocol used for the use of laser in each of the groups

	GC	PBMT	ILIB	PBMT + ILIB
Wavelength (nm)	Simulation	808 nm	660 nm	808nm / 660nm
Application points	4 points per tooth: cervical buccal apical buccal lingual / cervical palatine lingual/apical palatine	4 points per tooth: cervical buccal apical buccal lingual / cervical palatine lingual/apical palatine	Onlyone point onthe radial artery	Associationof PBMT and ILIB protocols
Joules	0 J	2 J per point (960 J)	3.000 J/ cm2	2 J per point (960 J) and 3.000 J/cm2
Application time	46 min	16 min	30 min	46 min

Note: CG = Control group; PBMT = Irradiation with photobiomodulation; ILIB = Intravascular blood irradiation; PBMT + ILIB = Association of irradiation with photobiomodulation and intravascular irradiation of blood; nm= nanometers; J= Joules.

Table 2. Distribution of study participants according to sex and age in each of the experimental groups

Variables	Category	Group				p
		GC	PBMT	ILIB	PBMT + ILIB	
Genre	Female	12 (32,4%) [a]	10 (27,0%) [a]	9 (24,4%) [a]	6 (16,2%) [a]	0,323 *
	Male	6 (17,6%) [a]	8 (23,5%) [a]	9 (26,5%) [a]	11 (32,4%) [a]	
Age	Average (DP)	28,33 (7,06) [a]	25,50 (5,83) [a]	25,50 (5,54) [a]	27,06 (8,82) [a]	0,551 **

Note: CG = Control group; PBMT = Irradiation with photobiomodulation; ILIB = Intravascular blood irradiation; PBMT + ILIB = Association of irradiation with photobiomodulation and intravascular irradiation of blood; DP = Standard Deviation. * Chi-Square test with Yates correction. ** One-way ANOVA test. Comparisons are on the same line. Equal letters indicate that there is no statistically significant difference between the groups. Significance level = 5%.

Table 3. Comparison of frequencies and scores assigned to variables of interest by participants in each of the study groups in the 4-hour assessment

Time	Variable	Category	Group				p
			GC	PBMT	ILIB	PBMT + ILIB	
4h	Limitation when eating	Yes	11 (73,4%) [a]	2 (13,3%) [b]	2 (13,3%) [b]	0 (0,0%) [b]	<0,001
		No	7 (12,5%) [a]	16 (28,6%) [b]	16 (28,6%) [b]	17 (30,3%) [b]	
	Pain when chewing	Yes	14 (66,6%) [a]	1 (4,8%) [b]	5 (23,8%) [b]	1 (4,8%) [b]	<0,001
		No	4 (8,0%) [a]	17 (34,0%) [b]	13 (26,0%) [b]	16 (32,0%) [b]	
	Difficulty speaking	Yes	-	-	-	-	-
		No	18 (25,4%)	18 (25,4%)	18 (25,4%)	17 (23,8%)	
	Pain medication	Yes	-	-	-	-	-
		No	18 (25,4%)	18 (25,4%)	18 (25,4%)	17 (23,8%)	
	Sensitivity	Yes	13 (56,5%) [a]	2 (8,7%) [b]	6 (26,1%) [a,b]	2 (8,7%) [b]	<0,001
		No	5 (10,4%) [a]	16 (33,3%) [b]	12 (25,0%) [a,b]	15 (31,3%) [b]	
	Difficulty sleeping	Yes	-	-	-	-	-
		No	18 (25,4%)	18 (25,4%)	18 (25,4%)	17 (23,8%)	
	EFD	Median(p25; p75)	1,50 [a] (1,00; 2,00)	1,00 [b] (1,00; 1,00)	1,00 [b] (1,00; 1,00)	1,00 [b] (1,00; 1,00)	<0,001
	VAS	Median(p25; p75)	1,50 [a] (0,00; 3,00)	0,00 [b] (0,00; 1,00)	0,00 [b] (0,00; 1,25)	0,00 [b] (0,00; 0,50)	0,012

Note: CG = Control group; PBMT = Irradiation with photobiomodulation; ILIB = Intravascular blood irradiation; PBMT + ILIB = Association of irradiation with photobiomodulation and intravascular irradiation of blood. EFD = Facial Pain Scale. VAS = Visual Analogue Scale. DP = Standard Deviation. Frequency Comparisons = Chi-Square Test with Yates correction. Comparison of quantitative data (EFD/VAS) = Kruskal-Wallis test with Mann-Whitney post-test. Comparisons are on the same line. Equal letters indicate that there is no statistically significant difference between the groups. Significance level = 5%.

Table 4. Comparison of frequencies and scores assigned to variables of interest by participants in each of the study groups in the 24-hour assessment

Time	Variable	Category	Group				p
			GC	PBMT	ILIB	PBMT + ILIB	
	Limitation when eating	Yes	18 (54,5%) [a]	8 (24,2%) [b]	5 (15,2%) [b]	2 (6,1%) [b]	<0,001
		No	0 (0,0%) [a]	10 (26,3%) [b]	13 (34,2%) [b]	15 (39,5%) [b]	
	Pain when chewing	Yes	17 (41,5%) [a]	11 (26,8%) [a,b]	7 (17,1%) [b]	6 (14,6%) [b]	0,001
		No	1 (3,3%) [a]	7 (23,3%) [a,b]	11 (36,7%) [b]	11 (36,7%) [b]	
	Difficulty speaking	Yes	0 (0,0%) [a]	2 (100,0%) [a]	0 (0,0%) [a]	0 (0,0%) [a]	0,239
		No	18 (26,1%) [a]	16 (23,2%) [a]	18 (26,1%) [a]	17 (24,6%) [a]	
	Pain medication	Yes	9 (69,2%) [a]	1 (7,7%) [b]	3 (23,1%) [a,b]	0 (0,0%) [b]	<0,001
		No	9 (15,5%) [a]	17 (29,3%) [b]	15 (25,9%) [a,b]	17 (29,3%) [b]	
	Sensitivity	Yes	17 (30,8%) [a]	14 (25,5%) [a]	14 (25,5%) [a]	10 (18,2%) [a]	0,096
		No	1 (6,2%) [a]	4 (25,0%) [a]	4 (25,0%) [a]	7 (43,8%) [a]	
	Difficulty sleeping	Yes	6 (75,0%) [a]	0 (0,0%) [b]	2 (25,0%) [a,b]	0 (0,0%) [b]	0,005
24hrs		No	12 (19,0%) [a]	18 (28,6%) [b]	16 (25,4%) [a,b]	17 (27,0%) [a,b]	
	EFD	Median(p25; p75)	2,00 [a] (2,00; 4,00)	2,00 [b] (1,00; 2,00)	1,50 [c] (1,00; 2,00)	1,00 [d] (1,00; 2,00)	0,001
	VAS	Median(p25; p75)	4,00 [a] (2,00; 5,25)	2,00 [b] (1,75; 3,25)	2,00 [b] (0,00; 3,00)	1,00 [c] (0,00; 2,00)	<0,001

Note: CG = Control group; PBMT = Irradiation with photobiomodulation; ILIB = Intravascular blood irradiation; PBMT + ILIB = Association of irradiation with photobiomodulation and intravascular irradiation of blood. EFD = Facial Pain Scale. VAS = Visual Analogue Scale. DP = Standard Deviation. Frequency Comparisons = Chi-Square Test with Yates correction. Comparison of quantitative data (EFD/VAS) = Kruskal-Wallis test with Mann-Whitney post-test. Comparisons are on the same line. Equal letters indicate that there is no statistically significant difference between the groups. Significance level = 5%.

Table 5. Comparison of frequencies and scores assigned to variables of interest by participants in each of the study groups in the 3-day evaluation

Time	Variable	Category	Group				p
			GC	PBMT	ILIB	PBMT + ILIB	
3-day	Limitation when eating	Yes	5 (55,6%) [a]	3 (33,3%) [a,b]	1 (11,1%) [b]	0 (0,0%) [b]	0,009
		No	13 (21,0%) [a]	15 (24,2%) [a]	17 (27,4%) [a]	17 (27,4%) [a]	
	Pain when chewing	Yes	9 (60,0%) [a]	3 (20,0%) [a,b]	3 (20,0%) [a,b]	0 (0,0%) [b]	0,003
		No	9 (16,0%) [a]	15 (26,8%) [a,b]	15 (26,8%) [a,b]	17 (30,4%) [b]	
	Difficulty speaking	Yes	-	-	-	-	-
		No	18 (25,4%)	18 (25,4%)	18 (25,4%)	17 (23,8%)	
	Pain medication	Yes	-	-	-	-	-
		No	18 (25,4%)	18 (25,4%)	18 (25,4%)	17 (23,8%)	
	Sensitivity	Yes	10 (55,6%) [a]	3 (16,7%) [a,b]	3 (16,7%) [a,b]	2 (11,0%) [b]	0,008
		No	8 (15,1%) [a]	15 (28,3%) [a,b]	15 (28,3%) [a,b]	15 (28,3%) [b]	
	Difficulty sleeping	Yes	-	-	-	-	-
		No	18 (25,4%)	18 (25,4%)	18 (25,4%)	17 (23,8%)	
	EFD	Median(p25; p75)	1,00 [a] (1,00; 2,00)	1,00 [a] (1,00; 1,25)	1,00 [a] (1,00; 1,00)	1,00 [a] (1,00; 1,00)	0,154
	VAS	Median(p25; p75)	1,00 [a] (0,00; 2,00)	0,00 [b] (0,00; 0,25)	0,00 [c] (0,00; 0,00)	0,00 [c] (0,00; 0,00)	0,002

Note: CG = Control group; PBMT = Irradiation with photobiomodulation; ILIB = Intravascular blood irradiation; PBMT + ILIB = Association of irradiation with photobiomodulation and intravascular irradiation of blood. EFD = Facial Pain Scale. VAS = Visual Analogue Scale. DP = Standard Deviation. Frequency Comparisons = Chi-Square Test with Yates correction. Comparison of quantitative data (EFD/VAS) = Kruskal-Wallis test with Mann-Whitney post-test. Comparisons are on the same line. Equal letters indicate that there is no statistically significant difference between the groups. Significance level = 5%.

Table 6. Comparison of frequencies and scores assigned to variables of interest by participants in each of the study groups in the 7-day evaluation

Time	Variable	Category	Group				p
			GC	PBMT	ILIB	PBMT + ILIB	
7-day	Limitation when eating	Yes	1 (100,0%) [a]	0 (0,0%) [a]	0 (0,0%) [a]	0 (0,0%) [a]	1,000
		No	17 (24,3%) [a]	18 (25,7%) [a]	18 (25,7%) [a]	17 (24,3%) [a]	
	Pain when chewing	Yes	1 (100,0%) [a]	0 (0,0%) [a]	0 (0,0%) [a]	0 (0,0%) [a]	1,000
		No	17 (24,3%) [a]	18 (25,7%) [a]	18 (25,7%) [a]	17 (24,3%) [a]	
	Difficulty speaking	Yes	-	-	-	-	-
		No	18 (25,4%)	18 (25,4%)	18 (25,4%)	17 (23,8%)	
	Pain medication	Yes	-	-	-	-	-
		No	18 (25,4%)	18 (25,4%)	18 (25,4%)	17 (23,8%)	
	Sensitivity	Yes	4 (100,0%) [a]	0 (0,0%) [b]	0 (0,0%) [b]	0 (0,0%) [b]	0,012
		No	14 (20,9%) [a]	18 (26,9%) [a]	18 (26,9%) [a]	17 (25,3%) [a]	
	Difficulty sleeping	Yes	-	-	-	-	-
		No	18 (25,4%)	18 (25,4%)	18 (25,4%)	17 (23,8%)	
	EFD	Median(p25; p75)	1,00 [a] (1,00; 1,00)	1,00 [a] (1,00; 1,00)	1,00 [a] (1,00; 1,00)	1,00 [a] (1,00; 1,00)	0,113
	VAS	Median(p25; p75)	0,00 [a] (0,00; 1,00)	0,00 [a] (0,00; 1,00)	0,00 [b] (0,00; 0,00)	0,00 [b] (0,00; 0,00)	0,007

Note: CG = Control group; PBMT = Irradiation with photobiomodulation; ILIB = Intravascular blood irradiation; PBMT + ILIB = Association of irradiation with photobiomodulation and intravascular irradiation of blood. EFD = Facial Pain Scale. VAS = Visual Analogue Scale. DP = Standard Deviation. Frequency Comparisons = Chi-Square Test with Yates correction. Comparison of quantitative data (EFD/VAS) = Kruskal-Wallis test with Mann-Whitney post-test. Comparisons are on the same line. Equal letters indicate that there is no statistically significant difference between the groups. Significance level = 5%.

At the evaluation time of 4h, the experimental groups differed (p<0.001) in terms of food limitation and pain when chewing. The experimental groups also differed for the responses attributed to the variable "sensitivity" (p<0.001); where it was observed that the PBMT and PBMT+ILIB groups obtained similar and different frequencies of responses from the control group.

The median values obtained for the EFD and VAS variables were similar between the PBMT, ILIB and PBMT+ILIB groups and all were different from GC (Table 3).At the 24-hour evaluation time, the experimental groups differed (p<0.001) in terms of food limitation, with the frequencies of "yes" responses being similar between experimental groups and all groups differing from the control group. The scores assigned to the EFD variable were different between the groups and were lower in the PBMT+ILIB group, as well as for the VAS variable (Table 4). At the evaluation time of 3 days, the participants who had less food limitation were those in the ILIB and PBMT+ILIB groups and those who had the least pain when chewing were those in the PBMT+ILIB group. Lower values were observed for the scores attributed by the participants included in the ILIB and PBMT+ILIB groups for the VAS variable (Table 5). At the evaluation time of 7 days, the frequencies of distribution of responses in each of the groups were similar for practically all variables (Table 6).

DISCUSSION

There are numerous studies and systematic reviews carried out in recent years in relation to pain management in different areas of medicine and dentistry. Some of the managements to control the expectation of pain and anxiety cited in the literature are medicated or not, and some of the non-pharmacological means are virtual reality (LÓPEZ-VALVERDE *et al.,* 2020), acupuncture (GIL-MARTÍNEZ *et al.,* 2018) and laserpuncture(RANGEL & PINHEIRO, 2021), dog-assisted therapy (CRUZ-FIERRO *et al*., 2019) and photobiomodulation (SFONDRINI *et al*., 2020) as performed in the present study.Pain level assessment can be performed in several ways, as mentioned by Hjemstad (2011), but the VAS scale, numerical numeral scale (NRS) have indications that justify its use, due to the standardization in its method of administration and interpretation. with adequate significance for clinical trial statistics (HJERMSTAD *et al.,* 2011). And, as in several trials in orthodontics, there is a certain concern in the assessment and management of the level of pain in different procedures, as well as the use of different validated scales for such assessment (KILINÇ & SAYAR, 2019; ESLAMIAN *et al.,* 2019; CAMPOS *et al.,* 2019), thus justifying its use in the present research.

Another scale also used was the EFD scale, due to its ease of use with populations of different cognitive levels, and presenting clinical relevance across cultures and suitability in the pediatric population, in addition to demonstrating excellent congruent validity and strong correlation with the visual analogue scale (YOUNG *et al*., 2018), although no other studies were found with the EFD scale in orthodontics, it is widely used in clinical trials in other areas of dentistry, such as pediatric dentistry. Regarding the evaluation times performed in the study, we opted for the evaluation at different times over the course of 7 days, due to the expectation of pain that can start 2 hours after the installation of the different orthodontic accessories and can take up to 7 days. for complete resolution, as described in several clinical trials, (ERTAN *et al*., 2004; NÓBREGA *et al*., 2013; CHOW & CIOFFI, 2018; LEAL *et al.,* 2020; SFONDRINI *et al*., 2020), thus justifying the verification of pain levels at 4 different times (T1 = 4 hrs; T2 = 24 hrs; T3 = 3 days and T4 = 7 days) as performed in the present study.With regard to local photobiomodulation in orthodontics and orthodontic management, there are several trials with different objectives: in the areas of rapid maxillary expansion (GARCIA *et al.,* 2016), bone regeneration (CEPERA *et al.,* 2012) and mini-implants (MURAKAMI-MALAQUIAS-SILVA *et al.,* 2020). However, many of them aim to manage pain through non-pharmacological means (NÓBREGA *et al*., 2013; ARTÉS-RIBAS *et al*., 2013; PRASAD; PRASANNA & ABRAHAM, 2019; SFONDRINI *et al.,* 2020), but in a systematic literature review carried out in 2016, the authors concluded that there is a lack of reliable evidence on the effectiveness of a number of non-pharmacological interventions to control orthodontic pain, with a small number of studies that provide low-quality evidence that orthodontic pain can be reduced in the short term by the use of low-level laser irradiation; however, the authors highlighted the need for more research considering pain experiences during the early stages and throughout orthodontic treatment, which should be more comprehensive to assess the effectiveness of non-pharmacological interventions for orthodontic pain (FLEMING *et al.,* 2016) Regarding the ILIB, no study has been found to date correlating its use with any area of orthodontics, being a new perspective of study and management for the specialty. Considering the age and sex of all the participants, and comparing with all the variables evaluated in the different groups, there were no relevant statistical differences, as described by (ALHAIJA *et al.,* 2010), since the perception and experience of pain are relatively similar among themselves.

Thus, analyzing the results obtained at T = 4 hours, it can be seen that there was a statistical difference (p<0.001) with regard to the main complaints related to the orthodontic appliance soon after installation, namely: sensitivity, limitation for food and pain when chewing, and it can be seen that, as in photobiomodulation research, such as that of Pinheiro*et al.* (2015) and Sfondrini *et al.* (2020) there was an analgesic/anti-inflammatory effect generated due to photobiomodulation, whether local and/or systemic, leading to a prevention and/or decrease in pain expectancy and improvement in quality of life parameters in the initial hours in the experimental groups. . Based on the results, it is also verified that the PBMT+ILIB group presented low percentages in the variables "pain to chew" (4.8%), "limitation to food" (0.0%) and "sensitivity" (8.7 %), thus demonstrating that the association of photobiomodulation and ILIB techniques can provide in the initial hours a better analgesia and anti-inflammatory power of the supporting periodontium of the teeth involved in orthodontic treatment, when compared to the techniques in isolation, despite of both experimental and study groups showed no statistical difference with regard to EFD and VAS and other variables, as illustrated in table 2. Regarding the results obtained at T=24 hours, it can be seen that the expectation of pain and the main complaints related to the installation of the orthodontic appliance, which are already expected as at the peak in this period, were higher in the variables in all groups, with higher percentages being the variables "pain to chew", "limitation to food" and "sensitivity", as well as in T=4, but there were significant differences in relation to the experimental groups and control, especially when comparing the GC with the ILIB + PBMT, with 69.2% of the patients in the GC required the use of prescribed analgesic medication, against 0.0% of the

patients in the ILIB + PBMT group, and a difference in the median of VAS scale, being 4.00 for the GC and 1.00, and p<0.001 for the ILIB + PBMT group. In relation to the ILIB and PBMT groups, there were no relevant statistical differences regarding all variables, as shown in table 2. Regarding the assessments at T = 3 days, the variants "food limitation", "pain when chewing" and "sensitivity" were still statistically different between the groups, especially when comparing the CG with the PBMT + ILIB group, however, as reported by Sfondrini*et al.* (2020), the need to use analgesic medication was no longer verified in any of the groups, as well as no statistical difference was observed in relation to the EFD and VAS scales. Thus, it can be associated with spontaneous pain resolution in the CG within the expected time, as well as in the other experimental groups, and as described by Chow and Cioffi (2018). And in relation to T = 7 days, the state of normality was observed, with no statistical differences between the groups and no more complaints regarding the variables still present at T = 3 days.

Finally, in this way, the null hypothesis is rejected, since there were statistical differences between the groups, with the technique performed in the ILIB + PBMT group being predominantly observed to be more effective. Regarding the technique, the present research focused on orthodontic treatment with fixed accessories, due to the wide usability in the daily life of orthodontists, presenting an accessibility of execution in the dental office, being necessary to acquire the low power laser device and the qualification professional. Regarding the applicability of photobiomodulation and ILIB, in isolation and when associated, in relation to the protocols used, the PBMT group had a duration of 16 minutes, these minutes being consumed in performing the irradiation at different points on all teeth, after bonding, thus adding to the procedure time. In addition, the technique also showed a slight superiority to the ILIB group, when related to the evaluation of quality of life parameters, being statistically more effective in the initial hours. In the ILIB group, despite having duration of 30 minutes for irradiation, the same was performed concomitantly with the bonding of the orthodontic accessories, which has a similar duration to the time used in the irradiation, thus not requiring extra time of care. However, when associated with the techniques, as performed in the PBMT+ILIB group, they lasted 46 minutes only with regard to the use of the laser, and the ILIB could be performed during bonding, and the PBMT after finishing the clinical procedure, as performed in the research, but the duration can be an obstacle when performed in an outpatient environment in the daily life of the orthodontist, since to be carried out, it demands a long time of application, and patient waits, and the cost/benefit of using the technique.

CONCLUSION

Our results suggest that photobiomodulation is a viable option for pain prevention/control when applied in a punctual and/or systemic way, in the bonding of the orthodontic appliance, and can be safely used in dental offices, especially in orthodontic management. Regarding its use, when compared in isolation, the local PBMT and the ILIB present similar results, and the professional can choose which technique is easier to use, but the PBMT proves to be more efficient in the initial hours, despite to have a difference in terms of duration. And when associated, the techniques have a greater analgesic and pain prevention effect when compared to other groups, and only the estimated duration should be taken into account by professionals.

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