









Impact of Photobiomodulation during Root Canal Treatment on Oral Health-Related Quality of Life: A Randomized Clinical Trial

Vania Gomes Moraes¹, Wayne Martins Nascimento², Marcelo Levin Cidade D'Amato Tavares³,
Ludmila da Silva Guimarães¹, Erlange Andrade Borges Silva¹, Fernanda Garcias Hespanhol²,
Livia Azeredo Alves Antunes^{1,2,3}, Leonardo dos Santos Antunes^{1,2,3}

¹Postgraduate Program in Dentistry of Health Institute of Nova Friburgo, Fluminense Federal University, Nova Friburgo, RJ, Brazil.
²Postgraduate Program, School of Dentistry, Fluminense Federal University, Niterói, RJ, Brazil.
³Department of Specific Formation, School of Dentistry, Fluminense Federal University, Nova Friburgo, RJ, Brazil.

Corresponding author: Leonardo dos Santos Antunes

E-mail: leonardoantunes@id.uff.br

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ABSTRACT

Objective: To evaluate the impact of endodontic treatment with photobiomodulation on oral health-related quality of life (HRQoL). **Material and Methods:** Seventy participants with single-rooted teeth and a diagnosis of asymptomatic apical periodontitis were selected and randomized into two groups: control group (CG, n = 35), root canal treatment without additional treatment, and experimental group (EG, n = 35), root canal treatment associated with antimicrobial photodynamic therapy and low-level laser therapy. OHRQoL was assessed using the Oral Health Impact Profile Questionnaire (OHIP-14) at baseline and 7 and 30 days after treatment. Data were subjected to Wilcoxon, Mann-Whitney tests, and linear regression using the generalized estimating equation model, using the Statistical Package for Social Science software with a significance level of 5%. **Results:** No statistically significant differences were found between groups regarding sociodemographic and clinical characteristics ($p > 0.05$). There was also no difference in the OHRQoL between the CG and EG ($p > 0.05$). However, there was a statistical difference in OHIP-14 scores between baseline and the 7- and 30-day follow-up intervals in both groups for all domains ($p < 0.05$). **Conclusion:** Root canal treatment, with or without photobiomodulation, significantly improved the OHRQoL of participants after 7 and 30 days of treatment.

Keywords: Quality of Life; Oral Health; Photochemotherapy; Low-Level Light Therapy; Endodontics.

Introduction

Quality of life is an individual's perception of their position in life in the context of the culture and value systems in which they live and about their goals, expectations, standards, and concerns [1]. Oral health is related to the individual's general health, implying the ability to perform daily activities such as eating, talking, smiling, and contributing creatively to society [2]. Many instruments for assessing oral health-related quality of life (OHRQoL) have been used to evaluate oral diseases' functional and psychosocial impacts [3]. The Oral Health Impact Profile-14 (OHIP-14) is a questionnaire that has been proposed for use in clinical trials, epidemiological research, and evaluation of the outcome of treatment for the health of the population [4], and can be considered effective in OHRQoL [3].

The success of endodontic therapy depends on reducing microorganisms and their by-products in the root canal system [5]. The apical third is a critical zone because of ramifications and lateral canals with a high prevalence of bacterial biofilms [6]. Failure to properly clean this region is a potential cause of persistent infection, compromising treatment outcomes [7].

Post-endodontic pain, also called flare-up, is a side effect that significantly affects the quality of life and is reported in 3-58% of patients [8,9]. Non-pharmacological strategies, such as antimicrobial photodynamic therapy (aPDT) and low-level laser therapy (LLLT), have been suggested to minimize these complications [10,11]. Antimicrobial photodynamic therapy can be used in PEP on teeth with necrotic pulps [11,12] and in reducing microorganisms in the root canal system without affecting cell viability [13], promoting periradicular healing. LLLT is associated with reduced PEP after root canal retreatment [9,10] and after root canal treatment of mandibular molars with symptomatic apical periodontitis [14]. In addition, photobiomodulation enhances the healing process and has efficacy in inflammatory parameters [15]. At the cellular level, it alters cellular functions such as adenosine triphosphate (ATP) production, protein and prostaglandin synthesis, release of neurotransmitters, growth, cell differentiation, and phagocytosis [16].

Evidence has shown that conventional root canal treatment improves patients' OHRQoL [17,18]. However, the results are limited, and new controlled clinical studies with standardized assessment approaches are needed [18]. To date, no randomized controlled clinical trial has evaluated the impact of this adjuvant therapy on the OHRQoL. Therefore, this study aimed to assess the effect of photobiomodulation on the OHRQoL of endodontically treated teeth. The null hypothesis is that photobiomodulation does not influence OHRQoL.

Material and Methods

Ethical Clearance and Protocol Register

The local Research Ethics Committee approved this randomized controlled clinical trial (no 2.353.996). All participants signed an informed consent form. The study report followed PRIRATE 2020 statements [19], and the study protocol was recorded in the www.clinicaltrials.gov (NCT03704857) database.

Sample Calculation

G*Power software (version 3.1., Dusseldorf, Germany) was used to determine the sample size, with an alpha error of 0.05, a beta error (power) of 0.8, and an intermediate effect size of 0.657 (psychometrica.de/effect_size). The mean baseline OHIP-14 score of 15.1 (standard deviation [SD]=10.2) and a mean 1-month post-treatment score of 8.9 (SD = 8.6) were used, according to Liu et al. [20]. Consequently, 30 individuals in each group were required to detect clinically significant differences. Fifteen percent were added

to compensate for any loss, totaling 35 patients in each group who were randomly selected, ensuring representativeness to the original population.

Recruitment and Eligibility Criteria

This study was performed between July 2019 and February 2020 at the Faculty of Dentistry of the Fluminense Federal University/Health Institute of Nova Friburgo, Rio de Janeiro, Brazil. Patients with deep carious lesions and deteriorated coronary structures who indicated a need for root canal treatment were selected.

The inclusion criteria were as follows: participants over 18 years of age, with the presence of single-rooted teeth diagnosed with pulp necrosis determined using tests of sensitivity to cold and heat and radiographic evidence of apical periodontitis. Only teeth with negative sensitivity and non-vitality responses were selected, as confirmed by the absence of bleeding in the access to the pulp chamber.

Patients with preoperative pain and edema, treatment with antibiotics in the previous month, and use of analgesics/anti-inflammatory drugs 24 hours prior or needing antibiotic premedication for dental treatment were excluded. Participants with pre-existing health conditions that would put them at risk during clinical care (i.e., myocardial infarction in the last six months, uncontrolled hypertension, or uncontrolled diabetes), as well as those with generalized periodontal disease, pregnancy, lactation, or allergy to sodium hypochlorite (NaOCl), were also excluded. Details are presented in the PRIRATE flowchart [19].

Randomization of Interventions

Seventy participants were divided into two treatment groups: 35 in the control group (CG), who received root canal treatment without additional treatment, and 35 in the experimental group (EG), who received root canal treatment associated with aPDT and LLLT.

A random list was created on the website www.random.org, with an allocation ratio 1:1. The patients were randomly assigned to one of the two treatment groups mentioned above. The sequentially numbered allocation list was placed in opaque and sealed envelopes opened before the operator's intervention. Before the envelope was opened, participants responded to the OHIP-14 questionnaire to measure the OHRQoL at baseline.

Owing to the type of intervention, the operator (L.S.G) was not blinded to the execution of the procedures. However, the patients and outcome examiners were blinded to the allocation of information. In the CG, the exit end of the laser was covered with aluminum foil without the patient's knowledge, and both the patient and operator used safety glasses to simulate photobiomodulation. All sounds from the device also remained functional.

Study Interventions

Clinical procedures were performed in a single session using a standardized protocol [21], and by a single endodontist with eight years of experience (LSG).

After a detailed anamnesis, radiographic and clinical examinations were performed. The teeth were isolated with cotton rolls, and thermal tests were performed with the application of a heated gutta percha stick (Dentsply Sirona, Charlotte, NC, USA) for hot and Endo Ice (Coltene/Whaledent Inc., Cuyahoga Falls, OH, USA) for cold stimuli, in addition to palpation and percussion.

After administration of local anesthesia with 2% lidocaine and 1:100,000 epinephrine (Alphacaine; DFL Indústria e Comércio Ltda, Taquara, Rio de Janeiro, RJ, Brazil), carious lesions were removed, and access cavities

were prepared after placement of the rubber dam. The treatments were then performed according to the following randomized procedures:

CG: After trephining the pulp chamber, the canal root was irrigated continuously with 5 mL 2.5% NaOCl (Fórmula & Ação, São Paulo, SP, Brazil) [22]. Odontometry was established with an electronic apex locator RomiApex A-15 (Romidan LTD, Kiryat Ono, Israel), with a size 15 K-file (Dentsply Sirona, Charlotte, NC, USA), and the working length (WL) was established at "00" mark [22,23]. Patency was maintained using a size 10 K-file (Dentsply Sirona, Charlotte, NC, USA) throughout the instrumentation stage.

According to the anatomical diameter of the root canal and the initial instrumentation using K files of sizes 10, 15, 20, 25, and 30 (Dentsply Sirona, Charlotte, NC, USA), Reciproc 40 or 50 files (VDW GmbH, Munich, Germany) were selected, coupled to the 6:1 contra-angle handpiece, operated in the "Reciproc" function, in VDW Silver engine (VDW). In cases where a size 30 K-file did not passively go to WL, R40 was selected, and these cases were classified as medium. In cases where a size 30 K-file passed passively to the WL, R50 was selected, and these cases were classified as large, according to the manufacturer's protocol. Reciproc instrument was introduced into the root canal with a slow in-and-out pecking motion that did not exceed 3-4 mm in amplitude. After three in-and-out movements, the file was removed and cleaned using sterile gauze. Mechanical preparation was performed up to the "00" mark, as determined by odontometry. The files were discarded after being used for a single purpose.

Each canal was irrigated with 15 mL 2.5% NaOCl (Fórmula & Ação, São Paulo, SP, Brazil) [24] using a 30-G irrigation needle (Max-i-Probe; Dentsply Sirona, York, PA, USA) up to 2 mm short of the WL [23]. After instrumentation, 17% EDTA was stirred for 5 min, and the final irrigation with 2.5% NaOCl and saline solution was performed.

The roots were dried with sterile paper tips standardized for the Reciproc System (VDW). The gutta-percha cones R40 or R50 (VDW) and MTA Fillapex (Angelus Indústria, Londrina, PR, Brazil) were used for the filling, applying the lateral condensation technique. Finally, Coltosol F (Vigodent; Coltene/Whaledent Inc., Cuyahoga Falls, Ohio, USA) was used as an intra-orifice barrier, and a definitive restoration was performed. Occlusion was checked and adjusted. Throughout the process, the application of photobiomodulation was simulated to maintain blinding.

EG: After performing the operative steps described in the CG, aPDT was performed. Initially, 0.01% methylene blue solution was inserted into the root canal until the pulp chamber was completely filled (Chimiolux, DMC Equipamentos, São Carlos, SP, Brazil) and was maintained in place for 5 min. After this pre-irradiation period, excess photosensitizer was removed using a sterile paper cone. The root canal was irradiated through a 55 mm optical fiber (MMOptics, São Carlos, SP, Brazil) coupled to a red laser source of indium gallium aluminum (InGaAlP) with a wavelength of 660 ± 10 nm (Laser Duo; MMOptics, São Carlos, SP, Brazil). The optical fiber was chemically sterilized by immersion in 1% peracetic acid for ten hours. Irradiation was performed by inserting the optical fiber in the root canal in the WL for 90 s with an output energy of 9 J, fluence of 300 J/cm^2 , output power of 100 mW, and irradiance of 3.33 W/cm^2 , with helical movements from the apical to the cervical extremity, promoting the homogeneous diffusion of light within the canal.

After the root canal filling stage, LT was performed according to the protocol previously described for the CG. An infrared laser source of gallium and aluminum arsenide (GaAlAs) with a wavelength of 808 ± 10 nm (Laser Duo, MMOptics, São Carlos, SP, Brazil) was used. Irradiation was performed for 40 s with an output energy of 4 J, fluence of 133 J/cm^2 , output power of 100 mW, irradiance of 3.33 W/cm^2 , and spot of 3 mm^2 , in contact and continuous wave mode in the vestibular and palatal/lingual gingiva located in the periapical region.

It is important to note that the output power of the red and infrared laser equipment was measured using a laser check (MMOptics, São Carlos, SP, Brazil) before each irradiation.

Outcome Variable

The OHIP-14 questionnaire was given to patients who participated in this study to assess each individual's OHRQoL. OHIP-14 was given before root canal treatment and on the 7th and 30th day after treatment. The primary function of this questionnaire is to evaluate the individual from the age of 14 and determine the extent of problems related to oral health that can influence their quality of life.

The OHIP version with 14 questions [25], validated in Portuguese [26], was used through an interview. The interviewer did not participate in the treatment. The OHIP has seven dimensions with two items for each area: functional limitation, physical pain, psychological discomfort, physical disability, psychological disability, social disability, and handicaps. A trained researcher administered the questionnaire, and patients' responses were scored on a Likert scale with the following answer options: never, 0; almost never, 1; sometimes, 2; almost always, 3; and always, 4. The scores were calculated by adding the 14 items answered, obtaining the final value of the OHIP-14 questionnaire, which can vary between 0 and 56, in which a higher score indicates a more significant impact on the participant's oral condition, presenting low OHRQoL.

Predictor Variables

The following predictor variables were collected and associated with the OHRQoL: age, sex (male or female), ethnicity (white/brown/black), tooth groups (anterior or posterior), tooth position in the arch (maxilla or mandible), coronary destruction (small [less than 1/3] or extensive [greater than 1/3]), and pre-existing health problems (absent or present).

After root canal treatment, postoperative pain, edema, and analgesic use were evaluated. Postoperative pain assessment was performed using the visual analogue scale (VAS), which was applied to all patients in the CG and EG for seven days and on the 14th and 30th days after the procedure. The VAS consists of a horizontal ruler with two endpoints, with 0 indicating no pain and 10 indicating severe pain. Pain levels were classified as follows: no pain, 0; mild pain, 1–3; moderate pain, 4–6; and severe pain, 7–10 [27]. Edema was clinically evaluated according to the criteria of Morse et al. [28] in the periods of 48 hours, 72 hours, and seven days by comparing the initial photograph by two independent ($K = 0.90$) and blind authors, as follows:

1. Mild: no distortion of the face, but slight edema of the gums, cheeks, or chin;
2. Moderate: superficial distortion of the cheek or chin;
3. Severe: severe distortion of the involved party.

In cases where the patient presented symptoms or some other complication, they were instructed to contact the research coordinator (LSA). Thus, the pre-established protocol was followed when necessary, in which ibuprofen (400 mg) was prescribed every six hours for five days [23,27].

Statistical Analysis

Data were analyzed using the Statistical Package for Social Sciences (version 23.0; IBM Corp., Armonk, NY, USA). The level of significance was set at 5%. The participants' sociodemographic and clinical characteristics were evaluated using the chi-squared test. The data from the OHIP-14 scores were subjected to the Wilcoxon test in comparison with the baseline, and the Mann-Whitney test was used to compare the treatment protocols at the 7- and 30-day follow-up intervals. Finally, linear regression using the generalized estimation equation model (GEE) was used to determine the magnitude of improvement in OHRQoL after treatment.

Results

Table 1 presents the sociodemographic and clinical characteristics of participants in the CG and EG. No statistically significant differences were found concerning sex, ethnicity, health problems, arch position, tooth groups, coronary destruction, edema, pain, or medication use ($p > 0.05$).

Table 1. Sociodemographic and clinical characteristics of individuals, comparing the control versus experimental groups.

Variables	Total		Control Group		Experimental Group		p-value
	N	%	N	%	N	%	
Sex							
Female	43	61.4	21	60.0	22	62.9	0.806
Male	27	38.6	14	40.0	13	37.1	
Ethnicity							
White	38	54.3	20	57.1	18	51.4	0.704
Black	15	21.4	8	22.9	7	20.0	
Brown	17	24.3	7	20.0	10	28.6	
Health Problems							
Yes	37	52.9	18	51.4	19	54.3	0.811
No	33	47.1	17	48.6	16	45.7	
Arch Position							
Maxilla	45	64.3	24	68.6	21	60.0	0.454
Mandible	25	35.7	11	31.4	14	40.0	
Tooth Groups							
Anterior	59	84.3	29	82.9	30	85.7	0.743
Posterior	11	15.7	6	17.1	5	14.3	
Coronary Destruction							
Small	41	58.6	23	65.7	18	51.4	0.225
Extensive	29	41.4	12	34.3	17	48.6	
Edema							
Yes	4	5.7	3	8.6	1	2.9	0.303
No	66	94.3	32	91.4	34	97.1	
Pain							
No	49	70.0	21	60.0	28	80.0	0.080
Mild	13	18.6	10	28.6	3	8.6	
Moderate	4	5.7	1	2.9	3	8.6	
Severe	4	5.7	3	8.6	1	2.9	
Use of Medication							
Yes	11	15.7	7	20.0	4	11.4	0.324
No	59	84.3	28	80.0	31	88.6	

Table 2 shows the impact of these different endodontic protocols on OHRQoL scores using the OHIP-14 questionnaire. No significant difference was observed between the treatment protocols ($p > 0.05$). There were no significant differences between the two groups' total OHIP or domain scores at baseline ($p > 0.05$). However, there was a substantial difference in OHIP-14 scores between baseline and the 7- and 30-day follow-up intervals in both groups for all questionnaire domains ($p < 0.05$).

Table 2. Comparative analysis of the impact of different endodontic protocols on Oral Health-Related Quality of Life (OHRQoL) scores of the OHIP-14.

OHIP-14 Domains		Control Group		Experimental Group		p-value**
		Mean	SD	Mean	SD	
Functional Limitation	Baseline	1.43	1.88	1.17	2.18	0.203
	7 days	0.06	0.34	0.31	0.90	0.090
	p-value*	<0.001		0.003		
	30 days	0.09	0.51	0.11	0.47	0.581
	p-value*	0.003		0.003		

Physical Pain	Baseline	3.34	2.53	2.86	2.03	0.490
	7 days	1.40	2.17	0.83	1.60	0.257
	p-value*	0.001		<0.001		
	30 days	0.54	1.09	0.34	1.14	0.158
Psychological Discomfort	Baseline	3.86	2.57	4.86	2.56	0.113
	7 days	0.97	1.93	1.09	1.48	0.263
	p-value*	<0.001		<0.001		
	30 days	0.86	1.38	0.46	0.95	0.173
Physical Disability	Baseline	2.37	2.46	1.97	2.36	0.484
	7 days	0.74	1.58	0.51	1.46	0.368
	p-value*	<0.001		<0.001		
	30 days	0.11	0.40	0.17	0.57	0.942
Psychological Disability	Baseline	3.80	2.64	3.31	2.56	0.383
	7 days	0.54	1.56	0.69	1.94	0.824
	p-value*	<0.001		<0.001		
	30 days	0.34	1.00	0.31	0.87	>0.999
Social Disability	Baseline	1.54	2.55	1.66	2.20	0.540
	7 days	0.26	0.82	0.49	1.69	0.787
	p-value*	0.002		0.004		
	30 days	0.14	0.49	0.40	1.46	0.652
Handicapped	Baseline	1.83	2.55	2.43	2.33	0.203
	7 days	0.14	0.69	0.46	1.36	0.364
	p-value*	<0.001		<0.001		
	30 days	0.00	0.00	0.17	1.01	0.317
Total	Baseline	18.17	12.71	18.26	11.97	0.837
	7 days	4.11	5.96	4.40	8.65	0.705
	p-value*	<0.001		<0.001		
	30 days	2.09	3.07	1.97	5.20	0.355
	p-value*	<0.001		<0.001		

*Wilcoxon test; **Mann-Whitney test.

Table 3 shows the linear regression results using the GEE model between the CG and EG. The sociodemographic and clinical characteristics of participants (sex, age, ethnicity, health problems, arch position, tooth groups, coronary destruction, edema, pain, and medication use) did not significantly influence the score in any of the domains ($p > 0.05$), at intervals between baseline and 7 or 30 days.

Table 3. Linear Regression by Generalized Estimating Equation Model (GEE) comparing the control versus experimental groups.

Domains	T0 versus T7			T0 versus T30		
	p-value	Coefficient	Standard Error	p-value	Coefficient	Standard Error
Functional Limitation	0.838	-0.067	0.327	0.711	-0.129	0.347
Physical Pain	0.504	-0.313	0.468	0.747	-0.153	0.475
Psychological Discomfort	0.251	0.651	0.567	0.591	0.305	0.568
Physical Disability	0.573	-0.234	0.415	0.910	0.047	0.416
Psychological Disability	0.454	-0.358	0.478	0.722	-0.186	0.521
Social Disability	0.753	0.127	0.403	0.666	0.173	0.401
Handicapped	0.255	0.456	0.400	0.411	0.343	0.417
Total Score	0.726	0.843	2.408	0.877	0.401	2.589

Model adjusted by sex, age, ethnicity, health problems, tooth group, arch position, coronary destruction, edema, pain, and medication use.

Discussion

Pain is one of the main determinants of OHRQoL in individuals undergoing root canal treatment [29]. In this context, adjuvant treatments such as aPDT and LLLT have been suggested to minimize the incidence of post-endodontic treatment pain [10,11]. However, another study showed that photobiomodulation did not significantly affect postoperative pain after root canal treatment [21]. To date, no randomized controlled clinical study has evaluated the impact of this adjuvant therapy on the OHRQoL. The authors hypothesized that photobiomodulation would not influence the OHRQoL, and the null hypothesis was accepted.

Patient-centered outcome assessments are essential because they focus on how illnesses and treatment modalities affect a person's social, emotional, and physical functioning, and based on this perspective, they can help define appropriate treatment goals[30]. In the present study, OHRQoL was assessed using the OHIP-14 questionnaire, which was proposed for use in clinical trials, epidemiological research, and assessment of treatment outcomes for the population's health [4]. Furthermore, studies have demonstrated that OHIP-14 is also a valid, reliable, and responsive instrument to assess the effects of root canal treatment on OHRQoL [20,31], corroborating the present study since significant changes in OHRQoL were observed during the follow-up periods, indicating the sensitivity of OHIP-14 to root canal treatment.

No patient was re-evaluated during the entire follow-up period, which reduced the bias of loss to follow-up. This high follow-up rate is likely due to the short study period (7–30 days). These data are consistent with those of a previous study examining the effects of a 1-month vs. 12-month reference period on the OHIP-14 questionnaire. They concluded that, although a standardized 12-month reference period is recommended, using a shorter reference period in population surveys does not appear to affect responses [32].

In the present study, the participants were considered homogeneous for all sociodemographic and clinical variables assessed between the CG and EG. The results showed that the sociodemographic and clinical characteristics of the individuals did not significantly influence the scores in any of the domains in the evaluated intervals. Furthermore, there were no significant differences at baseline between the two groups regarding the total scores or scores for any individual domain of the OHIP-14 questionnaire. This initial similarity between the groups allowed for balancing the confounding factors and an adequate comparison between the effects of the two root canal treatment protocols on OHRQoL. The randomization of individuals to different treatments also allowed for group similarity regarding individual aspects, preventing any characteristic from being unevenly distributed between the groups and influencing the results [33]. In addition, the participant's completion of the questionnaire through an interview by a blinded researcher avoided the influence on the responses, reducing measurement bias, and the performance of all treatments by a single trained endodontist made it possible to minimize differences in the performance of the techniques used.

The present findings showed similar benefits of root canal treatment associated with or without photobiomodulation on the OHRQoL of patients after 7 and 30 days of treatment for all questionnaire domains. Previous randomized clinical trials have also found a positive impact on OHRQoL after different endodontic protocols were performed at 24-hour [29] and six and 12-month [31] intervals. Another study also demonstrated that photobiomodulation accelerated the tissue healing process and postoperative pain after endodontic surgery, with favorable results in patients' quality of life in follow-up periods of 1, 3, and 7 days [34]. -Thus, a solution to the pathology in question will positively affect the patient's quality of life.

Despite the strengths already signaled in this study, such as high follow-up rate, randomization process, and sociodemographic and clinical homogeneity among participants, limitations can be pointed out. First, the presence of other oral conditions can also affect the participants' OHRQoL. Second, the low specificity of the OHIP-14 questions related to endodontic diseases makes it challenging to determine which aspects of the









endodontic treatment protocol impact each questionnaire domain. However, the OHIP-14 is a reliable instrument for assessing changes in OHRQoL after root canal treatment [20,31].

Therefore, new, well-designed randomized clinical trials must be conducted to confirm or refute this estimate and increase the precision and consistency of this scientific evidence. Furthermore, further studies should show the importance of this holistic view, the patient's response and perception of treatment, and the process of humanization between professionals and patients.

Conclusion

Root canal treatment with or without photobiomodulation significantly improved the participants' OHRQoL.

Authors' Contributions

VGM	 https://orcid.org/0000-0002-4118-9706	Conceptualization, Methodology, Data Curation, Writing - Original Draft, Writing - Review and Editing, and Funding Acquisition.
WMN	 https://orcid.org/0000-0003-4201-4710	Conceptualization, Methodology, Writing - Original Draft and Writing - Review and Editing.
MLCDT	 https://orcid.org/0000-0002-5685-8618	Methodology, Software, Investigation, and Visualization.
LSG	 https://orcid.org/0000-0002-5695-3607	Conceptualization, Methodology, Validation, Formal Analysis, Investigation, Data Curation, Writing - Review and Editing, Supervision, Project Administration, and Funding Acquisition.
EABS	 https://orcid.org/0000-0003-1308-7048	Methodology, Data Curation, Visualization, Supervision, and Project Administration.
FGH	 https://orcid.org/0000-0003-1965-2300	Conceptualization, Methodology, Validation, and Project Administration.
LAAA	 https://orcid.org/0000-0002-8432-0815	Conceptualization, Methodology, Validation, Writing - Review and Editing, Visualization, Supervision and Project Administration.
LSA	 https://orcid.org/0000-0002-2115-6958	Conceptualization, Methodology, Formal Analysis, Investigation, Data Curation, Writing - Review and Editing, Supervision, Project Administration and Funding Acquisition.

All authors declare that they contributed to a critical review of intellectual content and approval of the final version to be published.

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Conflict of Interest

The authors declare no conflicts of interest.

Data Availability

The data used to support the findings of this study can be made available upon request to the corresponding author.

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