



Effectiveness and effect of non-vital bleaching on the quality of life of patients up to 6 months post-treatment: a randomized clinical trial

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Abstract

Objectives The aim of this study was to evaluate the esthetic perception of patients at 6 months after bleaching of non-vital teeth with 35% of hydrogen peroxide and 37% of carbamide peroxide using a walking bleach technique. We also assessed psychosocial impacts as well as the clinical effectiveness and stability of the color change.

Materials and methods The teeth bleaching treatment was randomly assigned to two groups according to the bleaching agent used: G1 HP = 35% of hydrogen peroxide ($n = 25$) and G2 CP = 37% of carbamide peroxide ($n = 25$). The non-vital bleaching was performed in four sessions using the walking bleach technique. The color was objectively (ΔE) and subjectively (ΔSGU) evaluated. The esthetic perception and psychosocial factors were evaluated before treatment as well as one and 6 months post-treatment using Oral Health Impact Profile (OHIP) esthetics and Psychosocial Impact of Dental Esthetics Questionnaire (PIDAQ).

Results The color change (ΔE) at 6 months ($G1 = 14.53 \pm 5.07$ and $G2 = 14.09 \pm 6.61$) for both color groups remained stable until the 6-month post-treatment ($p > 0.05$). There was a decrease in the values of OHIP esthetics and PIDAQ after treatment compared to the baseline ($p < 0.05$), and this effect was maintained 6 months post-treatment.

Conclusions Both agents were highly effective and maintained the color stability at 6 months; this positively affected the esthetic perception and psychosocial impact of patients who also remained stable over time.

Clinical relevance Non-vital bleaching produces a positive and stable impact on the esthetic perception and psychosocial factors at medium-term follow-ups.

Keywords Non-vital bleaching · Carbamide peroxide · Hydrogen peroxide · Randomized clinical trial

Introduction

One of the most important aspects of an esthetically pleasing smile is teeth color. When the color of a single tooth changes,

the negative effect may be greater than a generalized color change of all the teeth, because it is more evident that the color does not match the rest of the teeth. Intracoronary whitening is widely used as a minimally invasive alternative treatment to

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resolve esthetic discoloration of non-vital teeth [1]. In addition, it has a high satisfaction rate among patients [2]. In spite of this, there are no studies on the evaluation of the real impact of these procedures on the esthetic perception of patients. However, recent studies have shown a positive effect for patients undergoing extracoronary whitening on vital teeth [3, 4].

Today, the most common dental bleaching agents are hydrogen peroxide and carbamide peroxide, which are used in high concentrations for non-vital teeth, but the mechanism of action remains the same in all cases—that is, oxidation occurs with organic pigments and the products of decomposition of the chemical agent used [5].

The main objective of this study was to evaluate the psychosocial effects regarding esthetic self-esteem of patients undergoing non-vital tooth whitening and the stability of color change with hydrogen peroxide (35% conc.) and carbamide peroxide (37% conc.). The study used the walking bleach technique and focused on results 6 months after treatment.

The null hypotheses are the following: (1) there is no difference between the psychosocial impact and the esthetic perception of patients undergoing non-vital bleaching using the walking bleach technique with 35% of hydrogen peroxide (HP group) or 37% of carbamide peroxide (CP group) at 6 months after bleaching and (2) there is no difference in the color change of non-vital bleached teeth with 35% of hydrogen peroxide or 37% of carbamide peroxide 6 months after treatment.

Materials and methods

This randomized clinical study was approved by the Ethics Committee of the Faculty of Dentistry of the University of Chile (2016/04) and was conducted in accordance with the Consolidated Reporting Standards and the Helsinki Declaration.

A double-blind randomized study (patients and evaluator) was designed, and the randomization was performed using Excel 2013 software (Microsoft, Washington, USA). Patients were recruited through flyers in the dental school and through social networks (e.g., Facebook, Twitter).

Sample size

The sample size was determined using the GPower 3.1 software with a significance level of 5%, 90% statistical power, and a dropout of 25% based on a previous study [6]. This study corresponds to a type of therapeutic equivalence, in which a color variation of ΔE tones in the range of 7–10 or more based on the original color was considered significant.

We aimed at a sample size of 20, but to compensate for the dropout rate reported in previous studies, we used a sample size of 25 per group.

We selected 50 patients with at least one non-vital tooth with discoloration of A2 or higher, according to the Vita Classic (Vita Zahnfabrik, Bad Säckingen, Germany) scale. All patients accepted and provided their informed consent.

Selection criteria

Inclusion criteria: Patients older than 18 years with one or more non-vital teeth discoloration that exhibited a tooth color of A2 or higher according to the classic vita scale were included in the study. Further inclusion criteria stipulated that the restoration did not include the vestibular surface of the tooth, the endodontic treatment was in good condition with adequate amplitude and length (asymptomatic), and the treated teeth had no prior bleaching experience.

Exclusion criteria: Patients who were pregnant or breastfeeding, patients with periodontal disease, teeth with caries lesions or periapical pathology, dental resorption (external or internal) in patients with periodontal disease, teeth with caries lesions or periapical pathology, and patients with enamel defects (hypoplasia or fluorosis of the enamel), dental staining with tetracycline, or amalgam of metallic pigment derivatives) were excluded from this study.

Patients with pathology were referred to appropriate clinical treatments in the dental school.

Patients who met the study's inclusion criteria and agreed to participate were randomly selected and divided into two study groups according to the bleaching agent used:

G1 HP = 35% conc. of hydrogen peroxide (Opalescence Endo-Ultracent, South Jordan, Utah, United States).

G2 PC = 37% conc. of carbamide peroxide (Whiteness Superendo, FGM, Joinville, Santa Catarina, Brazil).

Bleaching protocol

An ambulatory technique (walking bleach) was used. The bleaching agent was applied to the pulp chamber followed by sealing the cavity; The agent was changed weekly until after 4 weeks of treatment.

Preparation The root canal was prepared with absolute isolation (rubber gypsum, Dentsply, Brazil, SP), and the endodontic filler was removed 3 mm below the cement-enamel junction and then mechanically sealed with resin-reinforced glass ionomer (Riva light cure, SDI, Bayswater, Victoria, Australia) with a thickness of 2 mm. It was cured for 60 s at a distance of

1 cm with the Raddi Cal lamp (SDI, Bayswater, Victoria, Australia). Radiographic control was performed to confirm proper sealing of the root canal.

Four bleaching sessions Application of the bleaching agent was performed according to the manufacturer's instructions. The gel was left in the humid pulp chamber (using the walking bleaching technique). The cavity was sealed between sessions with temporary cement (Fermin, Detax, Baden-Württemberg, Germany). The gel replacement was done every 7 days. At the end of the fourth week of bleaching, the access cavity was washed with water and temporarily sealed for 7 days.

Final restoration At 1-week post-bleaching control, the final restoration was performed with Brilliant NG composite (Coltène-Whaledent AG, Switzerland) using a multilayer technique.

Color measurements were made (objective and subjective) before the start of treatment (baseline), immediately after each bleaching session, 1 week after treatment (before and after restoration), and 1 and 6 months after bleaching, respectively.

Color evaluation

Objective evaluation Two evaluators measured the color of the tooth in the middle third of the vestibular surface of the tooth using the Vita Easyshade Compact (VITA Zahnfabrik, Bad Säckingen, Germany) spectrophotometer. To standardize this evaluation, a silicone matrix (Zetaplus, Zhermack, Rovigo, Italy) was made with a window on the buccal surface 6 mm in diameter to the tip of the spectrophotometer. The color change was determined using the CIELab system with L^* , a^* , and b^* parameters. The color difference of each control was calculated with respect to the baseline. The ΔE was calculated using the following formula: $\Delta E = [(\Delta L^*)^2 + (\Delta a^*)^2 + (\Delta b^*)^2]^{1/2}$.

Subjective evaluation Two calibrated evaluators ($\kappa = 0.85$) were used to measure the color of the tooth on the middle third of the labial surface, according to the guidelines of the American Dental Association [7], in which 16 tablets of color were sorted by value from the highest (B1) to the lowest (C4). Although the Vita Classic scale is not exactly linear, the researchers treated the changes as continuous using a linear classification, as was previously done in other clinical teeth whitening trials. Color changes were recorded as the difference between the baseline and the different evaluation times, and they were expressed in the number of shade guide units (Δ SGU). If the results of the two evaluators did not match, the two evaluators discussed until a consensus on the color was reached. The color of the counterpart tooth was also recorded subjectively and compared to that of the treated tooth.

Oral Health Impact Profile Esthetics

To evaluate esthetic perception, the OHIP-esthetic questionnaire in Chilean Spanish was validated [8]. The questionnaire was applied at baseline as well as 1 week, 1 month, and 6 months after bleaching. Each statement was a response to a Likert scale, which generates a score of 4 to 0 (very often = 4, quite often = 3, occasionally = 2, almost never = 1, never = 0).

Psychosocial impact of the dental esthetics questionnaire

The PIDAQ [9] questionnaire consisted of 23 items that were divided into four subscales (one positive and one negative), corresponding to the dimensions assessed: (1) self-confidence for dental appearance, (2) social impact, (3) psychosocial impact, and (4) esthetic concern (14). Self-confidence for the appearance of the teeth consists of six elements of self-confidence scale. The second dimension (i.e., social impact) contains eight items on the social aspects of the quality-of-life questionnaire. The third dimension (i.e., psychosocial impact) has six items related mainly to the psychosocial impact of dental esthetics. The fourth dimension deals with esthetics with three elements. The questionnaire was administered at the beginning of the session, and each participant answered the questions individually. The questionnaire used a five-point Likert scale ranging from 0 (no impact of dental esthetics on the quality of life) to 4 (maximum impact of dental esthetics on the quality of life) for each item. Answers included the following: nothing = 0, a little = 1, something = 2, strong = 3, and very strong = 4. The questionnaire was validated in Spanish. Cronbach's alpha was 0.90 [9]. The questionnaire was administered at baseline as well as at 1 week, 1 month, and 3 months after bleaching.

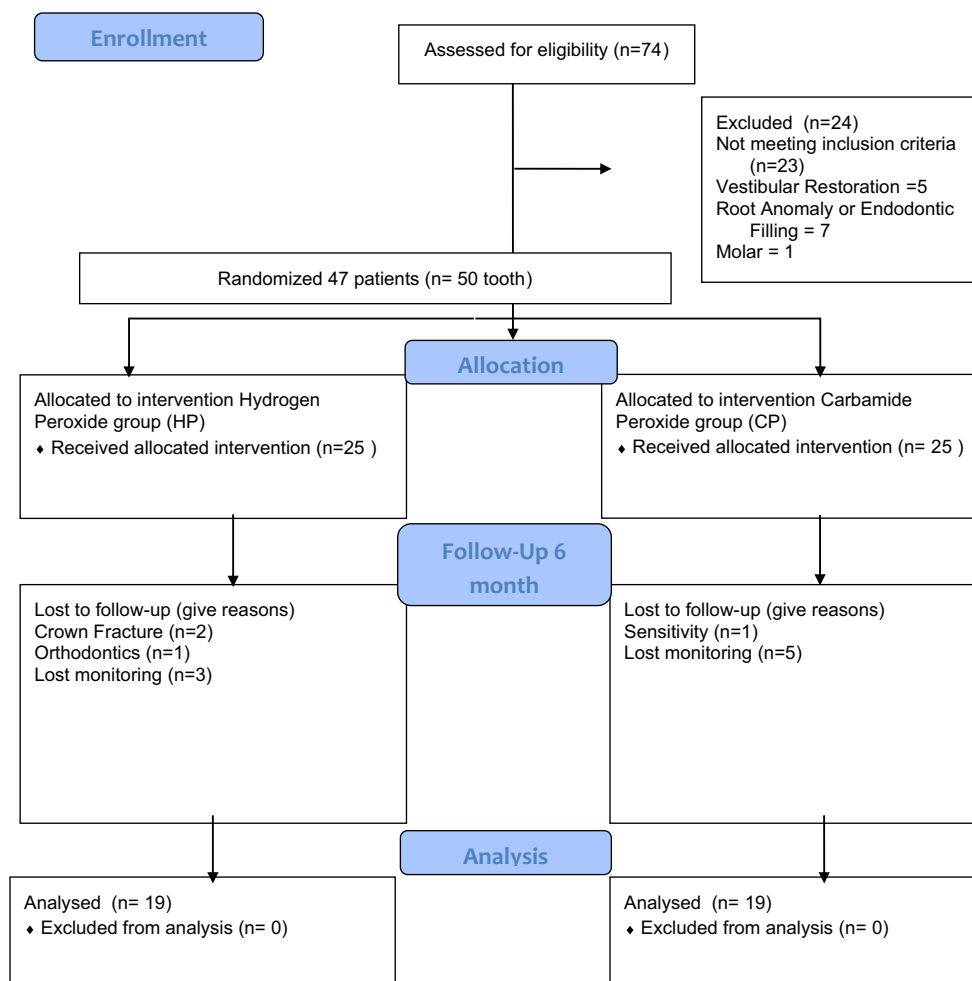
Statistical analysis

Statistical analysis was performed using SPSS 23.0 (SPSS Inc., Chicago, Illinois, USA) with $\alpha = 0.05$. For the intragroup analysis, the Wilcoxon test was used; for the between-group analyses, Mann-Whitney was used.

Results

Fifty non-vital teeth (50 patients) with discolorations were recruited from the 74 patients that were evaluated (Fig. 1). Only 38 patients were assessed at 6 months. The characteristics of the final sample are presented in Table 1.

Fig. 1 Flow diagram of the clinical trial, including detailed information on the excluded participants



Objective color evaluation

The results of ΔE obtained using the spectrophotometer are presented in Table 2. A statistically significant difference was not obtained with the Mann-Whitney test between the two groups. Table 2 shows the evolution of the color of the bleached at the 6-month follow-up. The difference of color increased significantly at baseline vs. the 4-week follow-up, and afterwards, the color remained the same (Fig. 1).

Subjective color assessment

Table 3 shows the Δ SGU vita classic scale, which shows the highest effectiveness of the hydrogen peroxide group ($p < 0.05$) in the fourth bleaching session. The increase in the color difference is more pronounced for the HP group, which showed a significant change of color at 1-week post-bleaching; the PC group only showed a color change at the 3-week treatment session.

Table 1 Baseline characteristics of the participants

Baseline features	Groups	
	G1 HP	G2 CP
Age (years; mean \pm SD)	31.37 \pm 12.59	30.84 \pm 12.10
Minimum age (years)	19	20
Maximum age (years)	65	65
Male (%)	52.6	42.1
Trauma (%)	42.1	47.4
SGU Baseline mean \pm SD	13.89 \pm 2.79	12.79 \pm 2.78
Vita Classical		
L* (mean \pm SD)	72.52 \pm 8.38	75.93 \pm 7.36
a* (mean \pm SD)	4.46 \pm 3.38	4.99 \pm 3.70
b* (mean \pm SD)	29.17 \pm 3.99	32.18 \pm 6. 88

SD standard deviation

Table 2 Color change expressed in units (ΔE ; mean and standard deviation) at all time points

Assessment times	Color change by ΔE		Mann-Whitney <i>P</i> values
	HP	CP	
Baseline vs. 1-week bleaching	8.77 ± 1.60	7.32 ± 4.75	0.146
Baseline vs. 2-week bleaching	12.87 ± 5.58*	10.93 ± 5.42*	0.271
Baseline vs. 3-week bleaching	15.58 ± 6.03*	12.33 ± 5.20*	0.130
Baseline vs. 4-week bleaching	16.65 ± 6.76*	13.01 ± 4.71*	0.075
Baseline vs. 1 week after bleaching (before restoration)	15.94 ± 7.01	13.33 ± 4.95	0.544
Baseline vs. 1 week after bleaching (after restoration)	16.31 ± 6.80	14.25 ± 5.28	0.435
Baseline vs. 1 month after bleaching	15.01 ± 5.01	13.62 ± 5.13	0.563
Baseline vs. 6 month after bleaching	14.53 ± 5.07	14.09 ± 6.61	0.954

* Statistically significant difference intragroup (Wilcoxon test, $p < 0.05$) versus previous time point

PIDAQ

Results from the PIDAQ questionnaire are presented in Table 4. The PIDAQ values were significantly different when comparing the baseline results with the results 1 month after treatment ($p < 0.05$; Wilcoxon’s test). Comparing the baseline with the 6-month follow-up, the PH group did not exhibit statistically significant values; however, in the PC group, only the psychological impact factor was not statistically significant. Between-group differences were not statistically significant ($p > 0.05$) by the Mann-Whitney test.

OHIP-esthetics

The sums of the OHIP-esthetics values of the two groups are statistically significant for the 1- and 6-month follow-ups compared to the baseline ($p < 0.05$), as calculated by the Wilcoxon test. There is no statistical difference between the two groups ($p > 0.05$); the sum and factor values are shown in Table 5.

Discussion

This randomized clinical study shows the esthetic perception and psychosocial impact of internal bleaching and the effectiveness of intracoronary whitening with two bleaching agents (35% of hydrogen peroxide (HP group) and 37% of carbamide peroxide (CP group)). Moreover, this study demonstrates behavior up to 6 months post-bleach treatment. Both gels were highly effective using the walking technique on non-vital teeth. Also, the color reached was stable 6 months after treatment. To date, the positive effect on esthetic perception and the psychosocial impact of patients has remained, but there was a tendency to decrease the effect. Therefore, both null hypotheses are accepted, since the two gels were widely effective according to objective and subjective measurements at the 6-month follow-up and had similar positive effects on the esthetic perception and psychosocial impact of the patients in this clinical trial.

Whitening non-vital teeth is a minimally invasive treatment, and it has good efficacy and stability over time. Our results demonstrate the stability of the treatment results with two more common gels for at least 6 months post-treatment using an

Table 3 Color change expressed in units (ΔSGU using the Vita Classical Scale; mean and standard deviation) at all time points

Assessment times	Color change by ΔSGU		Mann-Whitney <i>P</i> values
	HP	CP	
Baseline vs. 1-week bleaching	2.89 ± 2.56	2.84 ± 2.93	0.863
Baseline vs. 2-week bleaching	6.68 ± 4.27*	4.53 ± 3.75*	0.154
Baseline vs. 3-week bleaching	8.21 ± 4.37*	5.95 ± 3.78*	0.085
Baseline vs. 4-week bleaching	9.26 ± 4.01*	6.89 ± 3.57	0.046
Baseline vs. 1 week after bleaching (before restoration)	8.53 ± 4.13*	6.79 ± 3.72	0.130
Baseline vs. 1 week after bleaching (after restoration)	8.74 ± 3.90	6.89 ± 3.56	0.116
Baseline vs. 1 month after bleaching	8.16 ± 3.75	6.58 ± 3.75	0.201
Baseline vs. 6 month after bleaching	8.21 ± 3.66	6.58 ± 3.72	0.191

* Statistically significant difference intragroup (Wilcoxon test, $p < 0.05$) versus previous time point

Table 4 PIDAQ results at different time points

Dimension	Time points					
	Baseline		1 month after bleaching		6 months after bleaching	
	PH	PC	PH	PC	PH	PC
Dental self-confidence	17 (6:26)	14 (12:26)	19 (10:30) ^a	21 (6:26) ^a	20 (10:27)	21 (7:27) ^a
Social impact	19 (8:40)	23 (8:34)	15 (8:31) ^a	19 (8:32) ^a	12 (8:37)	18 (8:26) ^a
Psychological impact	18 (8:26)	19 (8:24)	14 (6:24) ^a	14 (6:24) ^a	15 (6:24)	14 (6:20)
Esthetic concern	9 (3:14)	10 (3:14)	5 (3:12) ^a	6 (3:12) ^a	6 (3:15)	6 (3:12) ^a

PH peroxide hydrogen group, PC peroxide carbamide group

^a Statistically significant difference (Wilcoxon test, $p < 0.05$) versus baseline

^b Statistically significant difference (Wilcoxon test, $p < 0.05$) versus 1 month. Expressed in median values (minimum/maximum)

objective methodology. A change of about 14 ΔE after the treatment was obtained and remained stable with the control for at least 6 months. This is also because non-vital teeth can have extreme discoloration [5]. The subjective measurements coincide with the objective values that show a pronounced effectiveness at 6 months post-treatment ($> 6.5 \Delta SGU$ values).

The purpose of non-vital teeth whitening is to achieve a tooth color that is similar to the color of adjacent teeth. A huge change of color is achieved, although the discoloration is quite intense. This will also depend on the original color and etiology of the teeth, since the stains of organic origin have a better prognosis than the inorganic origin [10].

Being a randomized clinical trial, the protocol was normalized in four bleaching sessions with a walking bleaching technique. The color of adjacent teeth should be considered to customize treatments that meet this goal. Therefore, depending on the specific factors of the teeth with discoloration, the patient's preferences should be considered during bleaching and

the number of sessions or repetitions. For the clinician, it is important to evaluate the success of the treatment based on the opinion of the patients, but success should not necessarily be evaluated through comparisons with neighboring teeth [11].

It is clear that the objective of non-vital teeth whitening is to match the color of the tooth with the color of the other teeth, thus achieving a harmonious color. Although the results do not always achieve the exact color, patients are often satisfied with the results [12].

The PIDAQ shows that the positive effect is maintained at least 6 months in all dimensions, except for the psychological impact in the PC group; this is in contrast with the PH group, which did not exhibit statistically significant values at 6 months. This could mean that the psychosocial impact achieved by the whitening treatment is only temporary [13].

The esthetic perception assessed with the OHIP esthetic questionnaire showed a positive effect that remained stable for at least 6 months when compared with the baseline. This

Table 5 Effect of bleaching on the esthetic self-perception evaluated with the OHIP questionnaire

Dimension	Time points					
	Baseline		1 month after bleaching		6 months after bleaching	
	PH	PC	PH	PC	PH	PC
Functional limitation	4 (2:8)	5 (4:8)	2 (0:6) ^a	4 (0:8) ^a	2 (0:6) ^a	3 (0:6) ^a
Physical pain	3 (0:5)	3 (0:5)	2 (0:4) ^a	2 (0:8)	2 (0:5) ^a	3 (0:5)
Psychological discomfort	4 (2:6)	5 (0:6)	4 (0:6) ^a	4 (1:8)	4 (0:6) ^a	4 (1:6)
Physical disability	1 (0:6)	2 (0:5)	1 (0:3)	0 (0:6)	0 (0:5)	1 (0:5)
Psychological disability	1 (0:6)	4 (0:6)	1 (0:5) ^a	2 (0:6) ^a	1 (0:5) ^a	2 (0:5) ^a
Social disability	0 (0:5)	1 (0:4)	0 (0:6)	0 (0:4)	0 (0:5)	0 (0:3)
Handicap	0 (0:6)	1 (0:4)	0 (0:6)	0 (0:4)	0 (0:5) ^a	0 (0:4) ^a
Sum	14 (5:38)	20 (5:32)	12 (2:31) ^a	13 (5:41) ^a	10 (3:36) ^a	13 (4:27) ^a

PH peroxide hydrogen group, PC peroxide carbamide group

^a Statistically significant difference (Wilcoxon test, $p < 0.05$) versus baseline

^b Statistically significant difference (Wilcoxon test, $p < 0.05$) versus 1 month. Expressed in median values (minimum/maximum)

was reflected in the sum of the score and dimension of functional limitation and psychological discomfort that accompanied the color of longevity. The other dimensions showed variations in the times, which shows that quality of life is complex, and there are multiple factors that influence it. These results correlate with those reported by Meireles et al. [14]

Within the limitations of this study, we can mention that there was a high dropout (24%), which is an imminent bias within this type of clinical studies; nevertheless, the sample finally analyzed ($n = 19$) per group is not far from the one considered as original sample without overestimation to compensate this possible loss.

Conclusions

Both agents—35% of hydrogen peroxide (HP group) and 37% of carbamide peroxide (CP group)—are effective with the non-vital tooth whitening technique—that is, the color stays stable for at least 6 months. There is a positive impact on the esthetic perception and psychosocial impact of patients, and it is consistent over time.

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Compliance with ethical standards

This randomized clinical study was approved by the Ethics Committee of the Faculty of Dentistry of the University of Chile (2016/04) and was conducted in accordance with the Consolidated Reporting Standards and the Helsinki Declaration.

Conflict of interest Cristian Bersezio declares that he has no conflict of interest. Paulina Ledezma declares that she has no conflict of interest. Carla Mayer declares that she has no conflict of interest. Oriana Rivera declares that she has no conflict of interest. Osmir O Junior and Eduardo Fernández declare that they have no conflict of interest.

Ethical approval This clinical study was approved by the Ethics Committee of the Faculty of Dentistry at the University of Chile (PR-ODO 16/04) and was conducted according to the Consolidated Standards of Reporting Trials Statement and Helsinki Declaration of 1975 revised in 2000. All persons gave their informed consent prior to their inclusion in the study. Details that might disclose the identity of the subjects under study were omitted.

Informed consent Informed consent was obtained from all individual participants included in the study.

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