ORIGINAL ARTICLE



Teeth whitening with 6% hydrogen peroxide and its impact on quality of life: 2 years of follow-up

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Abstract

This study aimed to evaluate color longevity after 2 years of whitening gel (6% hydrogen peroxide (HP), blue LED/infrared laser activation system) in comparison to a control 35% concentration in a split-mouth study and investigate the long-term effect on quality of life (QOL). Thirty-one patients were treated. Whitening using 6% or 35% HP gel was performed on half of the upper jaw in each patient. The color was measured at baseline and 1 week, 1 month, 1 and 2 years after treatment using the Easyshade Vita spectrophotometer and the Vita Bleached and Vita Classical Shade Guides organized by value. During 2 years of follow-up, color was evaluated before and after dental prophylaxis. Oral Health of Impact Profile (OHIP 14) and Psychosocial Impact Dental Aesthetics Questionnaire (PIDAQ) surveys measured QOL. Nineteen patients were evaluated at the 2-year follow-up. Significant differences in ΔE were measured between the two groups at all time points (p < 0.05). No significant differences in ΔSGU were observed at any time point (p > 0.05). The positive effect of bleaching on QOL was maintained in patients treated with a low concentration of the whitening gel. The two compounds remained effective after 2 years. An objective color difference was found between the groups, but no difference was observed in subjective reports. The positive effect on QOL remained after 2 years of follow-up in this cohort of patients. *ClinicalTrials.gov identifier* NCT02353611.

Keywords Tooth bleaching · Laser · Quality of life · OHIP · PIDAQ

Introduction

Teeth whitening is currently the treatment of choice for extrinsic pigmentation discoloration because it is relatively inexpensive, quick, and minimally invasive [1]. There is a high degree of satisfaction among patients, including personality styles related to the pursuit of this treatment [2]. Several studies have recently reported the efficacy of gels with concentrations lower than the in-office technique for whitening; some of these gels were assisted by laser or LED lamps, with catalysis systems achieving similar effectiveness under adverse conditions (lower sensitivity) [3–5]. Most of

those studies used blue or violet LED lamps at half intensity (<1500 mW in total) in combination with low-intensity infrared lasers to achieve an effect similar to bleach with less intensity and without the high prevalence of sensitivity induced by bleaching [6].

Studies performed in vitro have shown fewer damaged cells (pulpar cells) at these low concentrations of peroxide [7]. Whitening gels are also catalyzed by other agents, such as nanoparticles of titanium dioxide, and are activated by hybrid light (laser/LED) with different concentrations (15%) [8]. The photons emitted by blue light have an activating role for the chemical reaction, and the blue wavelength $(450 \pm 10 \text{ nm})$ acts as a catalyst on the nitrogen dioxide Ti, making the oxidation reduction reaction more efficient and leading to the degradation of the pigments. The chemical reaction was boosted by approximately 20 times in comparison to a gel of the same concentration that lacked the activation system [4].

Information about the longevity of color post-whitening is inconclusive and controversial. Some studies have shown

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a marked rebound of color, while others reported a slight difference in the medium term [9, 10]. Clearly, the regression continues over time. It is important for clinicians to have knowledge about new treatments that involve in-office bleaching with an LED/laser system that catalyzes the redox chemical reaction in less time and exhibits longevity in the long term. The future of bleaching gels will involve low concentrations of hydrogen peroxide, particularly in light of new European regulations.

The psychological factors associated with this type of treatment are poorly explored in the literature. However, recent reports show positive effects on patients' quality of life, specifically esthetic self-perception and psychosocial impact; however, there are no reports of prospective studies with a long-term emphasis [11].

Therefore, the objective of this randomized clinical trial was to demonstrate the longevity of a tooth whitening gel (6% hydrogen peroxide) with titanium dioxide nanoparticles that act as a catalyst after activation with a hybrid (LED blue/infrared laser) light. The longevity of color after 2 years was compared with the control 35% concentration in a splitmouth study, and the effects on QoL were investigated. The first null hypothesis is that the longevity of color throughout the follow-up period is the same for both gels before and after dental prophylaxis. The second null hypothesis is that the bleaching procedure has no effect on QoL (self-perception esthetics and psychosocial impact) in this cohort of patients.

This clinical study was approved by the Ethics Committee of the Faculty of Dentistry at the Universidad de Chile (PRI-ODO 15/01) and was conducted according to the Consolidated Standards of Reporting Trials Statement and Helsinki Declaration of 1975 revised in 2000. All subjects gave their informed consent before their inclusion in the study. Details that might disclose the identity of the subjects under study were omitted. Informed consent was obtained from all individual participants included in the study.

Materials and methods

This study was conducted between July 2014 and November 2016. A group of 131 participants were recruited using print and electronic ads. The participants were evaluated, and their teeth were cleaned with a pumice stone and water. Only participants who complied with the following criteria were included in the study: age of 18 years or more, two incisors with a central color of A2 or darker in comparison with the Vita Classical Color Guide (Vita Zahnfabrik, Bad Säckingen, Germany) ordered by value, no restorations or cervical lesions, and no previous bleach treatment. The study excluded pregnant or breastfeeding women, patients reporting dental pain, patients with moderate or severe fluorosis spots from tetracycline treatment, orthodontic concerns, periodontal disease, oral-facial tumors, trauma or tooth malformation, and patients taking analgesics, nonsteroidal anti-inflammatory drugs or antibiotics.

Thirty-one patients who met the criteria were initially included. All of those patients read and signed an informed consent form 1 week before beginning the study. Those patients also received dental prophylaxis and training in oral hygiene techniques. Only 19 patients (Fig. 1) were evaluated at all time points and at the 2-year follow-up.

Study design

The participants were treated with two bleaching compounds: a hemiarcade (half of the dental arch) was treated with 6% hydrogen peroxide catalyzed by titanium oxide nanoparticles and activated by a hybrid blue light with an infrared laser (experimental group), while the other hemiarch was treated with 35% hydrogen peroxide (control group). The allocation was performed via randomization using Microsoft Excel 2010 (Microsoft, Redmond, Washington, USA), with coding of each participant. All bleaching treatments were performed by one of two restorative dentistry professors who were blinded to successful treatment. In addition, the patients did not know which compound was applied to each hemiarch. To ensure blinding, any labels and logos that could serve to identify the product were removed from the package; laundering protocols were standardized and carried out in a room in which patients were evaluated; patients were codified with a number to ensure the blinding of the researchers; and the statistician received coded data, without knowing which treatment was assigned to each code.

Calculation of size displays

Previous studies showed a ΔE value of 7.0–2.0 after 2 sessions of in-office bleaching with 35% hydrogen peroxide [12, 13]. The sample size was calculated considering a difference of $\Delta E = 2$ between the treatment and control groups and taking into account an 80% chance of detecting significance at the 5% level and a value of 0.90 $(1 - \beta)$. Based on these parameters, the study required a minimum of 28 participants. As studies from our research group had patient dropout rates of 5 to 10%, we decided to include three more patients [14, 15].

Whitening protocol

Treatment is performed in three clinical sessions with 7 days between sessions. Prophylaxis with a pumice stone and water was completed at the beginning of each session. Later, the soft tissues were protected with a curing light barrier (Lase Protect—DMC, São Carlos, SP, Brazil) according to

Fig. 1 CONSORT flow chart of clinical trial



the manufacturer's instructions. Both whitening agents were prepared by mixing the peroxide (6 or 35%) with a thickening compound at a 3:1 ratio. The resulting gel was applied evenly on the surfaces of the corresponding teeth, from the central incisor to the first premolar. One hemiarcade (4 teeth) was treated with the experimental bleach compound, and the other hemiarcade was treated with the control compound. Whitening gels were kept on the teeth for 12 min during light activation via continuous irradiation with a hybrid light (blue LED/cold infrared laser) with a total capacity of 1500 mW (LED) and 300 mW (Whitening Lase Plus-DMC Equipamentos, São Carlos, SP, Brazil) (laser). Later, the gels were cleaned, and a new application was carried out according to the same specifications. In each session, a total contact time of 24 min with the whitening gel was achieved, with a total of 72 min of contact after three treatment sessions.

Objective evaluation

The color of both central incisors was measured at the beginning of the study and 1 week, 1, 12 and 24 months after treatment. To standardize this evaluation, a high viscosity silicone Putty Guide (Zetaplus Zhermack, Badia Polesine, Rovigo, Italy) was prepared with a window radius of 3 mm in the middle third of the labial surface of each tooth, and the spectrophotometer (Vita EasyShade Compact, VITA Zahnfabrik, Bad Säckingen, Germany) was inserted at the tip. L^* , a^* and b^* parameters were recorded. The color variation between baseline and each checkpoint was determined as the ΔE using the following formula:

$$\Delta E = [(\Delta L *)^2 + (\Delta a *)^2 + (\Delta b *)^2]^{1/2}$$

Subjective evaluation

For this evaluation, we used the Vita Bleached Guide (Classic Vita, Vita Zahnfabrik) and the Vita Classical Guide, arranged from the lightest (B1) to darkest (C4) color value. Although the classic Vita scale is not linear in the literal sense, we considered changes to continue with a linear graduation, as in previous clinical trials for tooth whitening [16].

Calibration was performed by two evaluators, with a recorded Kappa value of 0.85. The shadows of both central incisors were evaluated at the beginning of the study and 1 week, 1, 12 and 24 months after treatment. The threshold of perceptibility that was considered to be acceptable for this trial was a ΔE value of 2.7 tones [17].

The color was recorded on the middle third of the labial surface, as established by the guidelines of the American

Dental Association [18]. The color difference was calculated as the number of units on the guide by which the shadow of the tooth changed after treatment (Δ SGU—Shade Guide Unit). During the 2-year study period, the assessment was performed before and after dental prophylaxis, waiting 15 min for the rehydration of the teeth before the color evaluation.

Habits and diet survey

A brief survey of habits was conducted. This review included questions about the use of toothpastes with whitening agents, beverages that could generate stains, and smoking behavior.

Self-perception and psychosocial impact assessment

Before the tooth whitening and at all time points (1 week, 1 month, 1 and 2 years post-procedure), the participants completed two questionnaires: (1) the Psychosocial Impact Dental Aesthetics Questionnaire (PIDAQ) [19] and (2) the Oral Health Impact Profile (OHIP-14) [20].

The questionnaires were completed under the supervision of an examiner who was available to answer any questions from the participants.

Psychosocial Impact Dental Aesthetics Questionnaire is a psychometric test that is used to measure the psychosocial consequences of dental esthetics. The questionnaire consists of 23 items on a five-point Likert-type scale, from 0 for total disagreement to 4 for complete agreement. A patient may receive a total score of 0–72 points. The evaluation is also divided into four subscales: one positive scale [dental confidence (six questions)] and three negative scales [psychological impact (eight questions), esthetic concern (three questions), and social impact (eight questions)]. A more positive subscale score indicates greater self-confidence, while higher scores on the negative subscales indicate adverse effects of cosmetic dentistry.

Oral Health of Impact Profile-14 is an assessment that is used to evaluate esthetic perception. The survey is scored on a five-point Likert-type scale, with each option assigned a score, as follows: very often (4), often (3), from time to time (2), almost never (1), or never or not (0). A higher score indicates poor patient self-perception concerning the completed cosmetic dentistry. To calculate the OHIP-14 score for each patient, we added the scores from 14 questions, generating a total score between 0 and 56 points.

Statistical analysis

The data were tabulated, and the Shapiro–Wilk test was performed to analyze the distribution of data. The Mann–Whitney test was used to compare the efficiency and sensitivity of the results in each group. The efficacy of the treatments was evaluated with respect to ΔE and Δ SGU and then analyzed using the Wilcoxon test for within group comparisons and the Mann–Whitney test for between group comparisons. Descriptive statistics of esthetic PIDAQ and OHIP-14 test scores were determined, and the results for each time point were compared using the Wilcoxon test. With the exception of the population variables, such as age and sex, the data were coded and treated anonymously. The data were analyzed statistically using SPSS 23.0 (Lead Technologies Inc., Charlotte, NC, USA). The results were considered to be statistically significant when p < 0.05.

Results

Baseline features of the patients

Thirty-one patients were initially selected from the evaluated 131. Eleven patients did not continue, and one patient was excluded from the analysis during the 2-year followup. The sample consisted of 7 women (36.9%) and 12 men (63.1%), with an average age of 25.7 ± 3.9 years for the men and 24.1 ± 3.8 years for the women. The color characteristics at the beginning of the study are presented in Table 1.

Analysis by intention-to-treat vs. per protocol

All statistical analyses were performed via the imputation of data for outcomes that are missing (intention-to-treat) and without attribution of facts (per protocol). The same general conclusions (data not shown) were obtained in all analyses. To avoid the repetition of data, only the results obtained via the per protocol analysis are described.

Table 1 Baseline features of the participants

Baseline features	Groups				
	6%	35%			
SGU baseline median (min;max) Vita Bleached Guide	8 (5;11)	8 (5;11)			
SGU baseline median (min;max) Vita Classical	5 (5;11)	5 (5;11)			
$L^* (\text{mean} \pm \text{SD})$	84.08 ± 4.64	83.46 ± 4.94			
$a^* (\text{mean} \pm \text{SD})$	-0.34 ± 1.61	-0.31 ± 1.14			
$b^* (\text{mean} \pm \text{SD})$	24.19 ± 4.37	23.89 ± 3.48			

SGU shade guide unit, SD standard deviation

Spectrophotometry data

The color changes measured in ΔE units in comparison to the baseline are presented in Table 2. There were significant differences in ΔE between the two groups at all time points, according to the Mann–Whitney test (p < 0.007). There was also a color difference between the groups after 1 week and 1 month, with a noticeable difference of more than two ΔE units at the 2-year follow-up. All values showed significant differences in comparison to the baseline values (p < 0.05) using the Wilcoxon test.

Subjective evaluation

Table 2 Comparison of ΔE values at different times, expressed as the median and the

standard deviation

The subjective color changes evaluated based on Δ SGU units using the Vita Classical and Vita Bleached Shade Guides are presented in Tables 3 and 4. There were no

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Habits and diet survey

(p > 0.1) at any time point.

Of the 19 patients, 7 patients (36.8%) were light smokers (<10 cigarettes per day) and 15 patients (78.9%) were consumers of tea, coffee or cola drinks (2.0 times per day on average). Seven patients used dentifrices with abrasive effects (2.80 times per day on average). No patient used any carbamide peroxide-containing toothpaste because it is not available at the local market.

PIDAQ

The self-confidence values increased in score, and the other three factors decreased in score. This trend was maintained

Evaluation times	Color change	Mann–Whitney	
	6%	35%	
Baseline vs. immediately after bleaching	6.15 ± 4.77	6.39 ± 2.55	0.226
Baseline vs. 1 month after bleaching	6.02 ± 4.25	8.61 ± 2.35	0.002
Baseline vs. 12 months after bleaching (pre-prophylaxis)	5.38 ± 4.15	7.99 ± 2.28	0.001
Baseline vs. 12 months after bleaching (post-prophylaxis)	5.56 ± 4.31	8.18 ± 2.38	0.001
Baseline vs. 24 months after bleaching (pre-prophylaxis)	6.15 ± 1.93	8.73 ± 2.30	0.006
Baseline vs. 24 months after bleaching (post-prophylaxis)	6.09 ± 1.74	8.81 ± 2.60	0.003

Bold values indicate statistical significance (p < 0.05)

Table 3 Comparison of \triangle SGU values at different times using the VITA Classical Shade Guide/expressed as the median and the minimum/maximum	Evaluation times	Color change vita classic	Mann–Whitney	
		6%	35%	
	Baseline vs. immediate subsequent bleaching	4 (3/10)	4 (3/9)	0.458
	Baseline vs. 1 month after bleaching	4 (2/9)	4 (2/9)	0.722
	Baseline vs. 12 months after bleaching (pre-prophylaxis)	3.5 (-2/9)	4 (1/10)	0.207
	Baseline vs. 12 months after bleaching (post-prophylaxis)	4 (-2/9)	4 (1/10)	0.261
	Baseline vs. 24 months after bleaching (pre-prophylaxis)	3 (0/8)	4 (1/9)	0.217
	Baseline vs. 24 months after bleaching (post-prophylaxis)	3 (1/8)	4 (1/9)	0.182

Table 4 Co	omparison of Δ SGU
values at d	ifferent times using
the Vita Bl	eached Shade Guide/
expressed a	as the median and the
minimum/	maximum

Evaluation times	Color change by Δ of SGU vita bleached guide			
	6%	35%	Mann-Whitney	
Baseline vs. immediate subsequent bleaching	4 (2/6)	5 (2/6)	0.067	
Baseline vs. 1 month after bleaching	3 (-1/5)	3 (0)	0.373	
Baseline vs. 12 months after bleaching (pre-prophylaxis)	2 (0/4)	3 (0/5)	0.076	
Baseline vs. 12 months after bleaching (post-prophylaxis)	2 (0/5)	3.5 (1/5)	0.054	
Baseline vs. 24 months after bleaching (pre-prophylaxis)	1 (-2/4)	2 (-2/5)	0.056	
Baseline vs. 24 months after bleaching (post-prophylaxis)	1 (-1/4)	2 (-1/5)	0.077	

after 24 months of follow-up. All PIDAQ factors were statistically significant after 24 months of follow-up (p < 0.05). Even the Social Impact factor showed a statistically significant difference in comparison to the value obtained 1 month post-treatment (p < 0.05) (Table 5).

OHIP-14

The sum of the OHIP values decreased, and this trend continued after 24 months. In addition, the factors physical limitation, physical pain and physical incapacity exhibited statistically significant differences in comparison to the baseline (p < 0.05) (Table 6).

Discussion

In this randomized clinical study, a treatment design was used that made it possible to compare the control and the experimental groups under the same conditions (splitmouth) [21]. This approach was used to show the longevity at long-term follow-up and the likely color rebound after an unexplored treatment protocol, which employs a low concentration of hydrogen peroxide (6%) catalyzed by a hybrid light (laser/LED), in comparison with a control treatment of conventional peroxide at a high concentration (35%). The patients were not satisfied with the color difference between the two hemiarcades in an earlier report on this cohort [4].

There is no consensus in the literature concerning the real efficacy of the low concentration of hydrogen peroxide in over-the-counter (OTC) products. A previous study concluded that there is evidence that OTC bleaching products have low effectiveness and strongly recommended that dentists provide timely information to patients [22]. That study also concluded that the effectiveness of these products is low in comparison with other traditional whitening approaches. In 2009, a study of OTC whitening products that focused on hydrogen peroxide concentrations similar to those used in the experimental group (6%) was published [23]. The analysis demonstrated that these products whiten effectively, but the bleaching required 2 h per day (1680 min) for 2 weeks to achieve this effect. In ours and another recently published study [15], there were only 72 min of contact with a 6% peroxide gel. This approach resulted in a ΔE of 6 at the month

Table 5PIDAQ values by timepoint, expressed as the medianand the minimum/maximum

Dimension	Time points							
	Baseline	Immediately post-bleach- ing	1 month after bleaching	12 months after bleach- ing	24 months after bleach- ing			
Dental self-confidence	20 (7/30)	24 A (8/30)	24 A (11/30)	23 A (8/30)	24 A (8/30)			
Social impact	16 (8/38)	14 A (8/40)	12 (8/33)	11 A (8/39)	9 AB (8/38)			
Psychological impact	18 (6/25)	13 A (6/24)	13 A (6/22)	14 A (6/24)	12 A (6/22)			
Esthetic concern	6 (3/14)	5 (3/12)	3 (3/12)	6 (3/15)	3 A (3/15)			

A=statistically significant difference (Wilcoxon test, p < 0.05) versus baseline, B=statistically significant difference (Wilcoxon test, p < 0.05) versus 1 month after bleaching

Table 6 O	OHIP esthetics	values by tin	e point,	expressed a	is the n	nedian a	and the	minimum/	maximum
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Dimension	Time points									
	Baseline	1 week after bleaching	1 month after bleaching	12 months after bleaching	24 months after bleach- ing					
Functional limitation	5 (2/10)	4 (2/8) A	4 (2/9)	4 (2/9) A	4 (2/7) A					
Physical pain	4 (2/7)	4 (2/8)	4 (2/8)	4 (2/6)	5 (2/7) ABC					
Psychological discomfort	6 (2/8)	6 (2/7)	5.5 (2/8)	5 (2/8)	5 (2/7)					
Physical disability	2 (2/6)	2.5 (2/6)	3 (2/6)	3 (2/6)	2 (2/5) A					
Psychological disability	3 (2/10)	3 (2/9)	3 (2/9)	2 (2/8)	2 (2/6)					
Social disability	2 (2/7)	2 (2/7)	2 (2/7)	2 (2/4)	2 (2/3)					
Handicap	2 (2/9)	2 (2/9)	2 (2/7)	2 (2/8)	2 (2/5)					
Sum	27 (14/51)	24.5 (14/49) A	25.5 (14/46) A	23.5 (14/48) A	23 (17/37) A					

A=statistically significant difference (Wilcoxon test, p < 0.05) versus baseline, B=statistically significant difference (Wilcoxon test, p < 0.05) versus 1 week after bleaching, C=statistically significant difference (Wilcoxon test, p < 0.05) versus 1 month after bleaching

post-bleaching, with a very low rebound in the second year of follow-up.

There were statistically significant differences in the effectiveness of both groups with a $\Delta E \ge 2$. Nevertheless, the clinical difference was not evident for the patients, a phenomenon that could be explained by differences in perceptibility threshold that denotes human vision when comparing two similar colors [17]. However, it is important to note that although the concentration of hydrogen peroxide in the experimental group is one-sixth of the positive control group, the effectiveness is a bit lower and the stability is very high at 2 years. In consequence, it sounds logical that by increasing the contact time of a 6% gel one could achieve similar bleaching results to using a 35% gel, gaining an additional advantage in the therapeutic safety.

Currently, there is a tendency to perform minimally invasive treatments in cosmetic dentistry (MICD), which includes dental whitening therapies [14, 24, 25]. With regard to the latter, attempts have been made to reduce the concentrations of hydrogen peroxide used in bleaching gels in all kinds of techniques [26, 27], adding catalytic nanoparticles as in this case [4, 28], and modifying the times and number of sessions [15]. Despite not obtaining the same effectiveness as traditional concentrations [29], there is a consensus that biological safety will be preferred to the relative speed of the procedure.

Some reports in the literature have investigated the longevity of tooth whitening, with controversial results. It can be difficult to compare these studies due to the use of different color measurement methodologies [9, 30, 31]. Our longevity results are based on ΔE and are quite interesting. The efficacy of bleaching was maintained at 24 months, with only a slight rebound in color. This finding reinforces the idea that by catalyzing the reaction, the hybrid light produces a permanent whitening, as opposed to the results obtained in clinical work with concentrations of 6%, where a very high color rebound was reported [32]. The color rebound was not significant with respect to the baseline (p > 0.05). Recent trials showed that the color underwent a small change during prophylaxis. This finding is consistent with our results [28, 30].

The reason for the color rebound after 2 years is not clear. The teeth may be stained after exposure to food coloring agents. Importantly, we did not include diet in our study design, and this omission could influence the results [33]. However, a split-mouth design was used to help control for this factor. We included patients who smoked, because a previous study [16] found no significant differences in the effectiveness and longevity of color, especially among patients who smoked fewer than 10 cigarettes per day. Moreover, a previous study found that coffee consumption had no impact on the efficacy of bleaching [34, 35]. Finally, no study has shown an influence of toothpaste with whitening agents over the medium or long term. This report sheds some light on that question and may have some influence on future studies.

The difference observed between pre- and post-prophylaxis assessments could demonstrate that the presence of accumulated pigments is a factor that influences slight changes in color. This problem could be solved with a prophylaxis. Therefore, evaluations of the longevity of color over the long term would require an evaluation of color before and after the removal of extrinsic stains via mechanical cleaning and dental prophylaxis [28, 30]. Most clinical studies that evaluated rebound whitening at home did not report eating habits during and after the tooth whitening treatment. Only a few studies have attempted to associate eating habits with the longevity of whitening at home, and the results of those studies were inconclusive [30, 36].

The 6% compound was effective at the 2-year follow-up, according to the consensus in the literature concerning the effectiveness of tooth bleaching for achieving color changes [23]. The subjective outcomes measured based on variations of SGU units using the Vita Classic and Vita 3D-Master Bleached Guides remain incompatible with the objective findings. This outcome explains the high bias that exists in the measurements of two neighboring teeth by different groups of human evaluators and the resulting low reliability.

The impact on QoL in the second year was maintained and evidenced by the OHIP and PIDAQ results. This finding indicates that as long as the tooth whitening effect is maintained, patients will experience positive psychological, social and functional effects. Some studies reported psychosocial effects and esthetic self-perception changes related to tooth whitening; however, this is the first report of the effects after 2 years. These findings are important in relation to the fact that tooth whitening impacts the psychosocial wellbeing of patients and has recently been considered within the WHO and FDI definition of health [37].

The effect of a whitening gel catalyzed with light (blue LED 1300 mW/cm² and infrared laser) on color changes was stable until 1 year after therapy. Methodologically, the blinding of the operators, assessors, and staff was very strict. Two new referees were included to avoid the bias of "recognition of treatment". Thus, all aspects of the study were completely blind.

Within the limitations and the protocols of this study, there was a significant difference in the objective color assessment between the two groups after 1 year of follow-up. Both groups had equal color longevity, with the whitening maintained effectively for 24 months. Whitening has a positive effect on psychosocial impact scores and esthetic selfperception, and that effect is maintained after 24 months.

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Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

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