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Longevity, Esthetic Perception, and Psychosocial Impact of Teeth Bleaching by Low (6%) Hydrogen Peroxide Concentration for In-office Treatment: A Randomized Clinical Trial

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Clinical Relevance

In office bleaching with 6% hydrogen peroxide catalyzed by titanium dioxide that is activated with a hybrid light (blue LED/infrared laser) achieves clinical effectiveness at nine months and has a positive dental confidence and psychosocial impact on patients.

SUMMARY

Objective: The aim was to evaluate the color longevity after nine months of in-office bleaching with gel (6% hydrogen peroxide), to compare this to a control concentration of 35% in a split-mouth study model, and to assess the dental confidence and psychosocial impact on patients.

Methods and Materials: Twenty-seven patients were assessed at the nine-month recall. The bleaching procedure with 6% or 35% hydrogen

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peroxide gel was performed randomly in the upper hemi-arch of each patient. The color was measured at baseline and at one week, one month, and nine months after the procedure, using the Vita Easyshade spectrophotometer, the Vita classical shade guide organized by value, and Vita Bleach Guide 3DMaster. Moreover, two surveys, OHIP-Esthetics and PIDAQ, were used to assess the esthetic self-perception and psychosocial impact of the bleaching procedure. During the nine-month recall, the color was assessed before and after dental prophylaxis.

Results: Twenty-seven patients participated in the nine-month recall. There was a significant difference in ΔE between the two groups at all times assessed ($p<0.011$). The ΔL, Δa, and Δb showed a difference between the two groups at all times assessed ($p<0.038$), except for ΔL from the baseline vs nine-month after prophylaxis value ($p>0.20$). There was no significant difference in ΔSGU at all times ($p>0.05$). There was a significant difference in OHIP-Esthetics and PIDAQ sums compared with baseline scores ($p<0.03$).

Conclusion: The two compounds remained effective at nine months, with a slight rebound of color, and maintained their objective color difference but not the subjective color difference. Patients were satisfied with the bleaching procedure, and this had a positive impact on esthetic perception and a positive psychosocial impact at the nine-month recall.

INTRODUCTION

Dental bleaching is currently the treatment of choice for extrinsic discoloration pigmentation because it is quick, minimally invasive, and relatively inexpensive.[1] Recently, several studies have reported the effectiveness of bleaching gels with lower concentrations,[2] and there are *in vitro* studies that support lower cell damage at these low concentrations of peroxide.[3] There has been some research into bleaching gels catalyzed by agents such as titanium dioxide nanoparticles activated by hybrid light (laser/LED) with different concentrations (15%).[4] These concentrations show similar effectiveness, and in some cases, much lower adverse post-procedure effects.[4]

Information about the longevity of bleaching in the literature is somewhat controversial. Some studies have shown a marked rebound of color; others show only a slight difference.[5-7] Moreover, the regression continues with the passage of time. All of these reports are related to concentrations of gels higher than 10% hydrogen peroxide, with only one report[8] at 6%. This report by Vano and others indicates that the patients did not achieve a change of at least five units of ΔE intially and showed a color rebound near 50% at nine months.[8] It is important for clinicians to know about the new in-office concentrations and to correlate these with patients.

Patient expectations regarding dental bleaching are very important and poorly described in the literature. This is specifically true for effects on esthetic perception and other factors such as the psychosocial impact. A recent study by Martin and others indicated a positive effect on esthetic perception and psychosocial discomfort factors by the Oral Health Impact Profile (OHIP-Esthetics) at the one-month recall after bleaching.[9] It would be interesting for clinicians to know whether this effect is stable over time.

The objective of this trial was to show the longevity and effect on esthetic perception and psychosocial impact of bleaching by 6% hydrogen peroxide gel catalyzed by titanium dioxide nanoparticles and activated by hybrid light. The longevity of the color change was compared with that of a control concentration of 35% in a split-mouth study model. The first null hypothesis of this study was that the longevity of the color compared before and after dental prophylaxis at nine months after tooth bleaching is the same between the two gel methods. The second null hypothesis was that there is no effect on the esthetic perception or psychosocial impact on patients at nine months vs baseline.

METHODS AND MATERIALS

This clinical study was approved by the Ethics Committee of the local Faculty of Dentistry where the study took place between July 2014 and September 2015. It is registered on the site of the Clinical Trials Registry (NCT02353611) and was conducted according to the Consolidated Standards of Reporting Trials Statement and Helsinki Declaration of 1975 revised in 2000.

Thirty-two volunteers were selected and received a dental prophylaxis and oral hygiene instructions one week prior to the beginning of this study to achieve similar oral conditions. They also freely signed an informed consent.

Study Design

This was a randomized, double-blind (patients and evaluator), and split-mouth design (half of the dental arch, either left or right). One site was treated by compound 1 and the other by compound 2: these were randomly assigned. The patients were invited to participate in the study through posters put up around the city or recruited from participants in other studies in the same department who were contacted by email or phone.

A total of 131 patients were screened according to the inclusion and exclusion criteria. All subjects were over 18 years of age. Participants received a dental prophylaxis with pumice and water to determine whether they met the eligibility criteria: two central incisors with at least shade A2 or darker assessed by comparison with a value-oriented shade guide (Vita classical, Vita Zahnfabrik, Bad Sackingen, Germany), as well as anterior teeth without restorations, previous bleaching procedures, cervical lesions, or dental pain. Patients were excluded if they were pregnant or lactating; had moderate or severe fluorosis, tetracycline stains, orthodontic treatment, periodontal disease, orofacial tumors, trauma, or tooth malformation; or were taking analgesic, anti-inflammatory, or antibiotic drugs. There were 31 patients; one patient was excluded from the analysis due to missed appointments. Twenty-seven patients were assessed at nine months (Figure 1).

Two trained operators (restorative dentistry professors) administered the bleaching treatments. A third participant who did not have contact with the patients was responsible for conducting the randomization. The allocation of the groups was performed by random drawing using Microsoft Excel 2010 (Microsoft) from codes assigned to each participant.

There were two experimental groups: group A was the experimental group treated with a 6% hydrogen peroxide compound (HP6) catalyzed by titanium oxide nanoparticles that were activated with a blue hybrid light with an infrared laser. Group B acted as a control, and a 35% hydrogen peroxide bleaching compound was applied to the maxillary group of teeth. (The design of the lamp [whole mouth] did not isolate the radiation of each group.)

The following procedures were adopted to ensure double blinding: 1) labels, logos, packaging, and any other factors that could identify the products were removed, and procedures and instruments were standardized; 2) the bleaching protocol was performed in a different room from where the evaluator examined the patients; 3) the randomization was alpha-numerically coded to ensure blinding of the research team; and 4) a statistician received data tabulated in code that did not allow for identification of the treatment applied to each group.

Sample Size Calculation

The primary outcome of this study was the efficacy determined by color alteration (ΔE). Previous studies showed that the use of in-office bleaching agents containing 35% hydrogen peroxide (HP35) with or without LED/laser light leads to a ΔE value of 2.0-7.0 after two bleaching sessions.[2,4,10] At least 28 subjects were needed for 80% power in detecting significance at the 5% level and a (1-β) of 0.90, and considering a change in the primary outcome measure from seven in the control group to five in the experimental group. Due to a higher dropout rate in the last two clinical studies of our research group (5% and 10%), we decided to add more patients for a total of 31 subjects.

Bleaching Protocol

In each session, volunteers received prophylaxis with pumice powder and water. Next, gingival tissue was protected using a light-cured resin gum barrier applied according to the manufacturer's instructions (Lase Protect, DMC, São Carlos, SP, Brazil). Both bleaching agents (Lase Peroxide Flex 6% and Lase Peroxide Sensy 35%, DMC) were prepared by mixing hydrogen peroxide and thickening compounds according to the manufacturer's instructions (with three peroxide drops to one drop of thickener). The resulting gels (high viscosity allowing excellent control and avoiding contact with the neighboring tooth) were distributed uniformly on the surfaces of the teeth. Eight teeth between the second premolars were bleached for each patient. In each bleaching session, the bleaching gels were applied twice for 12 minutes each. In each application, the surface of the gel was light activated with continuous irradiance for 12 minutes using a LED/laser hybrid cold-light with a total power of 1500 mW (Bleaching Lase Plus, DMC). Three bleaching sessions were completed for the patients; the interval between sessions was seven days. The total contact time was 72 minutes for the bleaching treatments.

Objective Evaluation

Two evaluators measured the tooth color at baseline and again at one week, one month, and nine months. The color evaluation was obtained from an area of 6 mm located in the middle third of the labial surface

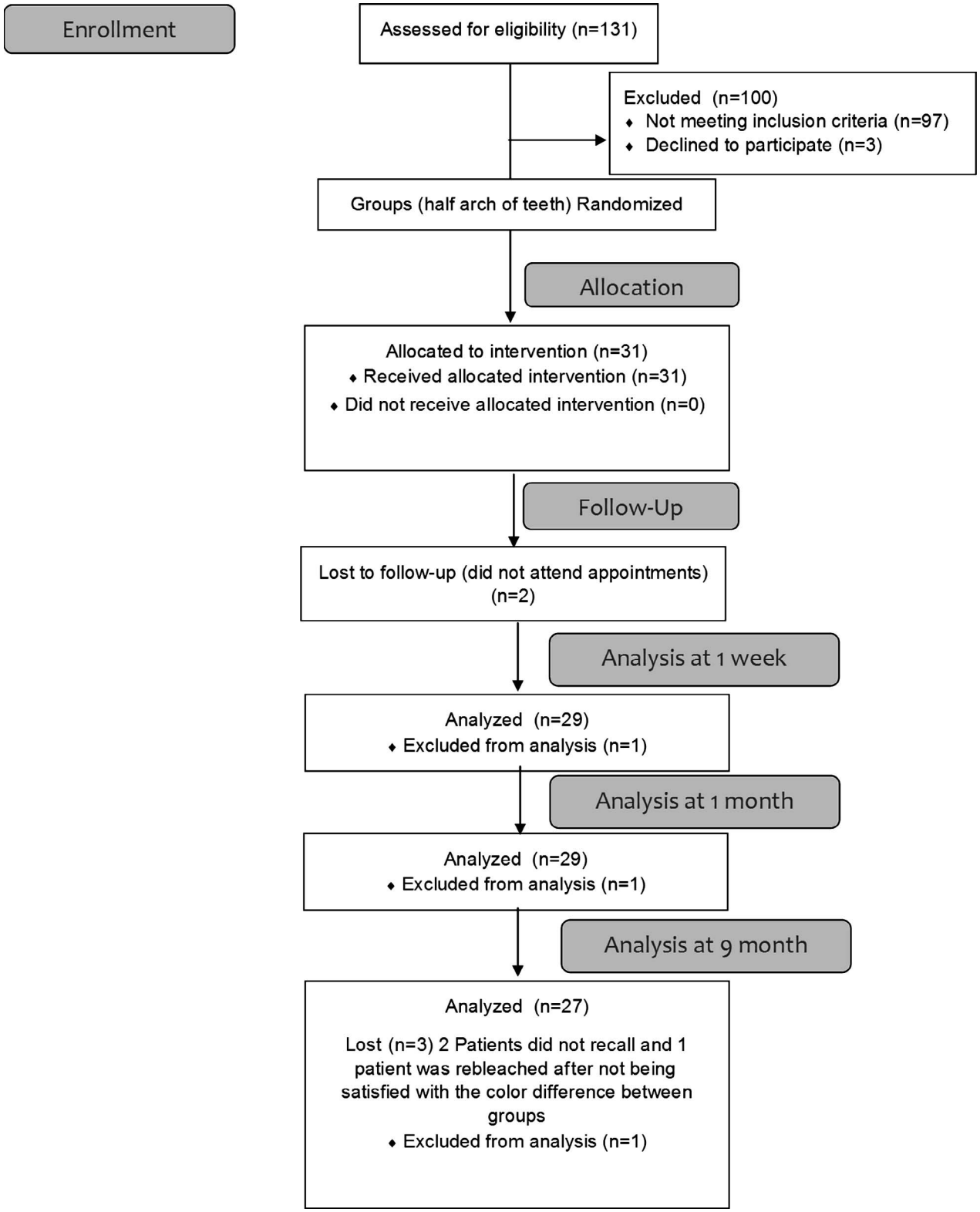

Figure 1. *CONSORT flow diagram.*

of the left and right central incisors. To standardize this evaluation, an impression of the maxillary arch was taken to make a guide using high-viscosity silicone putty (Zetaplus, Zhermack, Badia Polesine, Rovigo, Italy). A window was created on the labial surface in the middle third of the central incisor using a device with well-formed borders and a 3-mm radius corresponding to the diameter of the active part of the spectrophotometer (Vita EasyShade Compact, Vita Zahnfabrik). This device has 96% reliability.[11] The shade was determined using L*, a*, and b*. The color alteration after each session was given by the differences between the values obtained at the session and baseline. The ΔE was calculated using the following formula: $\Delta E = [(\Delta L^*)^2 + (\Delta a^*)^2 + (\Delta b^*)^2]^{1/2}$.

Subjective Evaluation

For the subjective evaluation, two calibrated evaluators (κ=0.85) under standardized light conditions (same place, hour, patient position, natural light source, assessed between 10 am and 3 pm) used the 16 tabs of the Vita classical shade guide (Vita Zahnfabrik) and 15 tabs of the Vita Bleach shade guide (Vita Zahnfabrik). Although the Vita classical scale is not linear in the truest sense, we treated the changes as continuous with a linear ranking. This was done similar to several previous clinical trials on dental bleaching.[12] The evaluators recorded the shade of the maxillary left and right central incisors at baseline during the same period as the objective evaluation.

We checked the color in the middle third area of the labial surface of the central incisors according to the American Dental Association guidelines.[13] We calculated the color changes from the beginning of the active phase through the individual recall times by changing the number of shade guide units (ΔSGU) that occurred toward the lighter end of the value-oriented list of shade tabs. In the event that the operators disagreed on color matching, a consensus was reached prior to dismissing the patient. At nine months, the evaluation was performed before and after dental prophylaxis with a Robinson brush and prophylaxis paste (Herjos, Vigodent Coltene SA Indústria e Comércio, Rio de Janeiro, Brazil). After dental prophylaxis, the treated teeth were rehydrated in the patient's mouth for 15 minutes before color assessment.

Oral Health Impact Profile (OHIP-Esthetics) Questionnaire

Satisfaction was measured using the OHIP-Esthetics questionnaire validated in Chilean Spanish (Table 1).[14] The questionnaire was administered by a research operator at baseline, at one week, one month, and nine months (before prophylaxis) after bleaching. Each statement was accompanied by a Likert-type scale that generated a score ranging from 0 to 4 (never = 0, hardly ever = 1, occasionally = 2, fairly often = 3, and very often = 4). These individual scores were added to give a summary score ranging from 0 (minimum) to 56 (maximum). The outcomes were defined as the sum of the OHIP-Esthetics and dimension scores. The internal consistency was evaluated using the Cronbach α test.

The Psychosocial Impact of Dental Esthetics Questionnaire (PIDAQ)

The questionnaire consisted of 23 items (Table 1) grouped into four components using factor analysis: 1) dental self-confidence; 2) social impact; 3) psychosocial impact; and 4) esthetic concern.[15] The first factor, dental self-confidence, consisted of six items from the self-confidence scale. The second factor, social impact, contained eight items from the social aspects scale of the quality-of-life questionnaire. The third factor, psychosocial impact, was derived from six formulated items relating mainly to the psychosocial impact of dental esthetics. The fourth factor was the esthetics. The patient was asked to evaluate the items using a five-point Likert scale with numerical values 0 = not at all, 1 = a little, 2 = somewhat, 3 = strongly, and 4 = very strongly. The questionnaire was administered by a research operator at baseline, one week, one month, and nine months (before prophylaxis) after bleaching. This was validated in Spanish, with a confidence reported by a Cronbach α of 0.90.[16] The outcomes were defined as the sum of the PIDAQ questionnaire and factor scores; the internal consistency was evaluated using the Cronbach α test.

Habits and Dietary Survey

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

Statistical Analysis

After verifying the normality of the data distribution and the homogeneity of the variance-covariance matrix, the efficacy of the treatments was evaluated with respect to color alteration (ΔE and ΔSGU) and analyzed by the Wilcoxon test for within-group comparisons and the Mann-Whitney test for be-

Table 1: *OHIP-Esthetics and PIDAQ Questionnaires*

	OHIP-Esthetics Questionnaire
Q1	Have you noticed a tooth which doesn't look right?[1]
Q2	Have you felt that your appearance has been affected by problems with your teeth?[1]
Q3	Have you had sensitive teeth for example to heat or to cold food or drinks?[2]
Q4	Have you had painful areas in your mouth?[2]
Q5	Have you been self-conscious because of your teeth?[3]
Q6	Have you felt uncomfortable about the appearance of your teeth?[3]
Q7	Have you felt that your food is less tasty because of problems with your teeth?[4]
Q8	Have you avoided smiling because of problems with your teeth?[4]
Q9	Have you found it difficult to relax because of problems with your teeth?[5]
Q10	Have you been a bit embarrassed because of problems with your teeth?[5]
Q11	Have you been less tolerant of your spouse or family because of problems with your teeth?[6]
Q12	Have you had difficulties doing your usual job because of problems with your teeth?[6]
Q13	Have you been unable to enjoy the company of other people very much because of problems with your teeth?[7]
Q14	Have you felt that life in general was less satisfying because of problems with your teeth?[7]
	PIDAQ Questionnaire
	Dental Self-Confidence
1	I am proud of my teeth.
2	I like to show my teeth when I smile.
3	I am pleased when I see my teeth in the mirror.
4	My teeth are attractive to others.
5	I am satisfied with the appearance of my teeth.
6	I find my tooth position to be very nice.
	Social Impact
7	I hold myself back when I smile so my teeth don't show so much.
8	If I don't know people well I am sometimes concerned what they might think about my teeth.
9	I'm afraid other people could make offensive remarks about my teeth.
10	I am somewhat inhibited in social contacts because of my teeth.
11	I sometimes catch myself holding my hand in front of my mouth to hide my teeth.
12	Sometimes I think people are staring at my teeth.
13	Remarks about my teeth irritate me even when they are meant jokingly.
14	I sometimes worry about what members of the opposite sex think about my teeth.
	Psychological Impact
15	I envy the nice teeth of other people.
16	I am somewhat distressed when I see other people's teeth.
17	Sometimes I am somewhat unhappy about the appearance of my teeth.
18	I think most people I know have nicer teeth than I do.
18	I feel bad when I think about what my teeth look like.
20	I wish my teeth looked better.
	Aesthetic Concern
21	I don't like to see my teeth in the mirror.
22	I don't like to see my teeth in photographs.
23	I don't like to see my teeth when I look at a video of myself.

In the OHIP-Esthetics questionnaire, numbers correspond to the dimensions (1 = functional limitation, 2 = physical pain, 3 = psychological discomfort, 4 = physical disability, 5 = psychological disability, 6 = social disability, 7 = handicap).

tween-group comparisons. The statistical analyses were performed using SPSS 23.0 (SPSS Inc, Chicago, IL, USA) with α=0.05. For comparison of OHIP-Esthetics and PIDAQ questionnaires scores, the Wilcoxon test was used.[17]

RESULTS

Baseline Characteristics

Of 131 patients examined, 31 patients were enrolled. Three patients did not continue, and one patient was

Table 2: *Baseline Color Features of Volunteers*

	L value (mean ± SD)	95% confidence interval		a* value (mean ± SD)	95% confidence interval		b* value (mean ± SD)	95% confidence interval		SGU value (mean ± SD)	95% confidence interval	
		Upper limit	Lower limit		Upper limit	Lower limit		Upper limit	Lower limit		Upper limit	Lower limit
Group A	84.68 ± 4.29	86.38	82.98	−0.39 ± 1.53	−0.22	−0.99	24.20 ± 4.17	25.85	22.56	6.81 ± 2.22	7.69	5.94
Group B	84.44 ± 4.59	86.25	82.62	−0.38 ± 1.26	−0.12	0.88	24.09 ± 3.69	25.56	22.64	6.93 ± 2.25	7.82	6.04

excluded from analysis in the monitoring at nine months (for not coming at the right time for evaluations). The sample consisted of 10 women (37.04%) and 17 men (62.96%), with average ages of 24.7 ± 5.86 years for men and 23.1 ± 2.81 years for women. The entire cohort was 24.1 ± 4.95 years of age. Features of color at baseline are shown in Table 2.

Per-protocol Versus Intention-to-Treat Analysis

All statistical analyses were performed with data imputation for missing outcomes (intention to treat) and without data imputation (per protocol). The same overall conclusions were reached (data not shown) in all analyses. To avoid data repetition, we describe only the results obtained per-protocol analysis.

Spectrophotometer Data

Color changes measured by units of ΔE, ΔL, Δa, and Δb from baseline are shown in Table 3. There was a significant ΔE difference according to the Mann-Whitney test between the two groups at all times assessed ($p<0.011$). There was also a color difference between the groups after one week and one month, with a noticeable difference greater than two units of ΔE suggesting a difference at the nine-month point. The ΔL, Δa, and Δb were different according to the Mann-Whitney test between the two groups at all times assessed ($p<0.038$) except for ΔL from baseline vs nine-month preprophylaxis value ($p>0.20$). To corroborate the statistical power and size effect, this

Table 3: *Changes of Color by ΔE, ΔL, Δa, and Δb (Δ Calculated From the Baseline Value) by Group in Different Periods Expressed by Mean, SD, Statistical Significance (p<0.05 in bold), Effect Size, and Statistical Power*

	Group A	Group B	Mann-Whitney (*p*)	Effect size d	Power (1 − β)
ΔE					
Baseline vs week	7.88 ± 10.49	8.19 ± 2.73	**0.004**	0.04	0.07
Baseline vs month	5.86 ± 3.79	8.24 ± 2.45	**0.000**	0.75	**0.84**
Baseline vs 9-month PrePr	6.03 ± 4.05	7.64 ± 2.64	**0.011**	0.47	0.51
Baseline vs 9-month PostPr	5.14 ± 3.49	7.81 ± 2.32	**0.000**	0.90	**0.94**
ΔL					
Baseline vs week	2.00 ± 3.51	3.75 ± 3.21	**0.016**	0.52	0.58
Baseline vs month	2.62 ± 4.06	4.10 ± 3.12	**0.033**	0.41	0.42
Baseline vs 9-month PrePr	3.06 ± 4.53	3.83 ± 3.71	0.279	0.19	0.16
Baseline vs 9-month PostPr	2.71 ± 3.16	4.50 ± 2.78	**0.010**	0.60	0.69
Δa					
Baseline vs week	−0.82 ± 1.07	−1.38 ± 0.74	**0.038**	0.61	0.70
Baseline vs month	−0.77 ± 1.10	−1.33 ± 0.81	**0.015**	0.58	0.66
Baseline vs 9-month PrePr	−0.39 ± 1.28	−1.00 ± 0.74	**0.007**	0.58	0.66
Baseline vs 9-month PostPr	−0.50 ± 1.11	−1.08 ± 0.74	**0.019**	0.62	0.70
Δb					
Baseline vs week	−1.48 ± 12.41	−6.14 ± 3.25	**0.005**	0.51	0.57
Baseline vs month	−3.48 ± 3.48	−6.14 ± 2.76	**0.001**	0.85	**0.91**
Baseline vs 9-month PrePr	−2.82 ± 3.72	−5.23 ± 2.92	**0.002**	0.72	**0.82**
Baseline vs 9-month PostPr	−2.78 ± 3.53	−5.44 ± 2.74	**0.001**	0.84	**0.91**

Table 4: *Changes of Color by ΔSGU (Vita classical and Vita Bleach Guide 3D-Master) by Group in Different Time Frames Expressed by Median (Minimum/Maximum Value), Statistical Significance, Effect Size, and Statistical Power*

	Group A	Group B	Mann-Whitney (*p*)	Effect size	Power (1 − β)
Vita Classic					
Baseline vs week	4 (Min 2/Max 9)	4 (Min 2/Max 9)	0.655	0.10	0.10
Baseline vs month	4 (Min 2/Max 9)	4 (Min 2/Max 9)	0.672	0.10	0.10
Baseline vs 9-month PrePr	3 (Min 0/Max 9)	4 (Min 2/Max 10)	0.128	0.33	0.32
Baseline vs 9-month PostPr	4 (Min 0/Max 9)	4 (Min 2/Max 10)	0.186	0.33	0.31
Vita Bleach Guide 3D-Master					
Baseline vs week	3 (Min 1/Max 6)	4 (Min 1/Max 6)	0.253	0.32	0.30
Baseline vs month	3 (Min −1/Max 5)	3 (Min 0/Max 6)	0.136	0.42	0.45
Baseline vs 9-month PrePr	2 (Min −2/Max 4)	3 (Min −1/Max 5)	0.047	0.55	0.64
Baseline vs 9-month PostPr	2 (Min −2/Max 4)	3 (Min −1/Max 5)	0.020	0.64	0.75

outcome was calculated post hoc with the ΔE values by G-Power software.[18] All values showed a statistically significant difference vs baseline ($p<0.05$) by Wilcoxon test.

Shade Guide Data

Color changes measured subjectively as expressed by ΔSGU are shown in Table 4. For Vita classical, there was no significant difference between the different evaluations ($p>0.10$). In contrast, there were significant differences by Vita Bleach Guide 3D Master ($p<0.02$) at the nine-month recall.

OHIP-Esthetics

The OHIP-Esthetics survey scores (Table 5) were significant at different times when comparing the initial baseline survey prior to the treatment and a week after bleaching ($p=0.006$). This was replicated after one and nine months ($p<0.001$) to obtain more reliable data. The results were significant ($p<0.03$). Specifically, there was a statistically significant difference after one week in dimensions. The functional limitation and psychosocial discomfort were statistically significant at one month in the psychosocial discomfort dimension. The ninth month showed statistically significant differences in all factors ($p<0.03$) except physical pain and handicap factors as shown in Table 5. There was good internal consistency as shown by the Cronbach α (0.803).

PIDAQ

The overall score on the PIDAQ was statistically significant at all times ($p<0.001$; Table 6).

Habits and Diet Survey

Of the 27 patients, 11 (40.74%) were smokers, with a mean of 4.23 cigarettes per day; 22 patients (81.48%) consumed tea, coffee, or cola (mean of 1.95 times per day); 10 patients (37.04%) used bleaching toothpastes (mean of 2.80 times per day).

Table 5: *Distribution of Scores by Dimension and for the Total OHIP-14 (Oral Health Impact Profile in Spanish) Expressed in Mean and SD, Repeatability, and Internal Consistency*

	Baseline	1 week after bleaching	1 month after bleaching	9 months after bleaching	Corrected item total correlation of sum	Cronbach α if item deleted	Cronbach α	Number of items
OHIP-EE-14	26.33 ± 7.30	24.77 ± 6.57*	24.57 ± 6.90*	23.87 ± 6,31*			0.803	7
Functional limitation	4.90 ± 1.83	4.37 ± 1.56*	4.53 ± 1.85	4.17 ± 1.78*	0.704	0.742		
Physical pain	4.27 ± 1.53	4.20 ± 1.61	4.27 ± 1.68	4.70 ± 1.62	0.098	0.859		
Psychological discomfort	5.70 ± 1.37	5.20 ± 1.37*	4.93 ± 1.53*	5.13 ± 1.38*	0.513	0.781		
Physical disability	2.83 ± 1.12	2.73 ± 0.98	2.67 ± 0.92	2.50 ± 0.86*	0.746	0.757		
Psychological disability	3.37 ± 1.85	3.20 ± 1.73	3.23 ± 1.55	2.87 ± 1.50*	0.748	0.732		
Social disability	2.60 ± 1.28	2.53 ± 1.22	2.50 ± 1.28	2.13 ± 0.43*	0.470	0.789		
Handicap	2.67 ± 1.47	2.53 ± 1.38	2.43 ± 1.07	2.37 ± 1.19	0.688	0.752		

* $p \leq 0.03$ *compared with baseline by Wilcoxon test.*

Table 6: *Distribution of Scores by Dimension and for the Total PIDAQ (Psychosocial Impact of Dental Aesthetics Questionnaire in Spanish) Expressed in Mean and SD*

	Baseline	1 week after bleaching	1 month after bleaching	9 months after bleaching	Cronbach α
PIDAQ	59.61 ± 12.24	56.26 ± 10.92*	56.61 ± 11.56*	54.67 ± 10.19*	0.808
Dental self-confidence	20.77 ± 5.61	23.52 ± 5.32*	23.35 ± 5.33*	24 ± 4.68*	
Social impact	16.45 ± 7.78	14.23 ± 7.10*	15.13 ± 7.23*	13.5 ± 5.36*	
Psychological impact	15.97 ± 5.57	12.77 ± 5.23*	12.55 ± 5.55*	12.25 ± 5.795*	
Esthetic concern	6.42 ± 3.38	5.74 ± 3.29*	5.58 ± 2.92*	4.92 ± 2.96*	
Dental self-confidence	20.77 ± 5.61	23.52 ± 5.32*	23.35 ± 5.33*	24 ± 4.68*	

* $p \leq 0.001$ *compared with baseline by t-test.*

DISCUSSION

This randomized clinical study used a novel treatment in an uncertain (split-mouth) design.[19,20] This was done to show the longevity and probable rebound of color of a protocol that has not been greatly explored using a low concentration of hydrogen peroxide (6%) vs a conventional high concentration peroxide control (35%). A previous report from this cohort of patients[9] showed that no patients were dissatisfied with the color difference between groups. However, after evaluating at one month, one patient requested that the research team match the colors of the groups; two patients did not attend the recall, and one was excluded for not coming at the right time for evaluations.

The results of the longevity of bleaching based on ΔE are quite interesting. There is a significant change that was maintained at nine months with a slight rebound of color. At nine months, the objective difference after prophylaxis was similar to previous controls. The color rebound was not significant vs baseline values; therefore, this accepts the first null hypothesis. The results based on ΔL, Δa, and Δb were very similar except in the preprophylaxis period. This was explained by stains that mainly affect the luminosity of the color, which occurred in both groups. A recent trial by de Geus and others[7] showed that the color had a slight change with prophylaxis. This coincides with our results. The longevity and rebound in color bleaching studies are controversial in the literature. Some studies report stable color at one year,[21,22] two years,[21,23] or longer,[24,25] but others reported stable color only for one to two years.[6,7,23,26-30] The only study with an in-office 6% hydrogen peroxide concentration technique reports 50% color rebound.[8] However, measurement methodologies in these studies are not completely standardized, and the comparison is difficult.

The blue light (cold lamp) could be a real catalyst for the chemical reaction, although there is evidence that the use of light does not improve the effectiveness of bleaching.[31] Modulating this light would be an interesting future investigation. Titanium oxide is a semiconductor under blue light and theoretically catalyzes the formation of hydroxyl radicals from hydrogen peroxide.[32] The exact role by which light or titanium oxide nanoparticles catalyze the mechanism of action remains unclear. In the literature, 6% hydrogen peroxide gels are applied for at least 120 minutes for effective whitening.[33] Here, there was a contact of 72 minutes, which assumes that this is the catalyst for the chemical reaction.

The infrared laser offers immediate control of the sensitivity produced by bleaching because it creates a temporary depolarization of nerve fibers.[4] Thus, it has no relevance to these data.

Teeth exposed to dietary coloring agents definitely have a greater potential to stain. It is important to note that diet was not considered relevant primary data because the study design was split-mouth and both sides were exposed to colorants. Smoking patients were included in this study because there is no significant difference on the effectiveness and longevity of color in patients who smoke fewer than 10 cigarettes a day according to de Geus and others.[7,34] In addition, the quantity of coffee, according to Rezende and others,[35] had no influence on the effectiveness of bleaching.

There are no reports on how paste with no bleaching agents may affect the bleaching in the medium or long term. Hopefully, this report will shed some light on that subject and may have some influence on future studies. However, the use of a prophylaxis protocol reported by de Geus and others[7] showed a difference—particularly in the light parameter specified in Table 3. This shows that the presence of accumulated pigments and/or plaque could be a factor that slightly influences color changes. This

could be solved with a prophylaxis. Therefore, evaluation of the longevity of color outcomes in long-term recalls requires color assessment before and after removal of extrinsic staining by mechanical cleaning and dental prophylaxis.[36] Many clinical studies assessed the color rebound of at-home bleaching and did not report the dietary habits during and after tooth bleaching. Only a few studies have associated diet with the longevity of at-home bleaching; the findings were inconclusive.[5,21,28]

The 6% compound was effective at nine months. According to Bizhang and others, bleaching is considered effective when there is at least a difference of five units of ΔE.[37] Subjective outcomes measured by the variation of SGU by Vita classical and Vita Bleach scales units remain inconsistent with the objective results. The data at nine months by the Vita Bleach scale are nearest to objective data, which could be because it is a more symmetrical and appropriate scale to measure color changes in bleaching;[38] however, the immediate results by Vita Bleach (Table 4) are also inconsistent with the objective measurement. This may be explained by the high bias that exists in the measurements of two neighboring central incisors belonging to different groups because the human eye cannot discriminate between color changes below two units. Subjective scales are only complementary aides and might guide the clinician regarding the effectiveness of whitening.[39] The effect of subjective similarity could be a key point in explaining the effect on esthetics perception and psychosocial impact on patients. The two study groups had stable color at nine months. This means that the color stability is not dependent on the concentration, unlike effectiveness that is directly related to the concentration of the gel.[40]

The OHIP-Esthetics questionnaire results at the nine-month point are controversial. The questionnaires were administered before and after bleaching at one week, one month, and nine months of recall to increase the reliability of the data. The esthetic component measured by OHIP-Esthetics probably influenced the significant difference in the scores after one week, one month, and nine months for bleaching effectiveness. The positive change was evident in the self-perception of dental esthetics at the end of bleaching and one month later. This supports the notion that self-perception of dental esthetics is positively modified by teeth bleaching. The results of OHIP-Esthetics in the ninth month are striking because they show a positive effect vs baseline in terms of functional limitation factors, psychosocial discomfort, physical disability, psychosocial disability, and social disability. This might indicate that the medium-term effect of bleaching generates an esthetic perception that is sharper and deeper than a period of one month. This documents that the psychosocial effects are not immediate and interventions could have an effect in the medium term.[41,42] This might be captured by our OHIP-Esthetics results.

The PIDAQ questionnaire was originally developed to be applied in patients receiving orthodontic treatment;[15] however, isolated factors can also be applied to a patient who experiences dental esthetics through bleaching. In the first factor, "auto dental confidence," there was a positive effect of bleaching in this group of patients until nine months. This impacted dental esthetics on the emotional state of individuals, and maintaining the effect correlated with the maintenance of color. The second factor (social impact) also showed a positive effect at nine months, referring to potential problems in social situations due to a subjective perception of an unfavorable dental appearance. The effects persisted throughout the month. The third factor of psychosocial impact is composed of items dealing with feelings of inferiority and unhappiness when the affected individual compares him/herself with others who have superior dental esthetics. This was positively influenced at nine months of recall. It is known that comparison processes play an important role in psychosocial well-being and that upward comparisons might provoke dysphoric moods.[43]

There was a positive impact of bleaching in patients until the ninth month, similar to what was reported by Martin and others.[9] Clearly the PIDAQ questionnaire is a good tool to substantiate the effects of bleaching. This has been poorly reported in the literature, and additional tools are needed for successful clinical treatments.

According to our results, the second null hypothesis was rejected because there was a positive effect on esthetic perception and psychosocial impact measured by OHIP-Esthetic and PIDAQ by the bleaching procedure.

Methodologically, the blinded nature of the operators, evaluators, and all of the equipment was very strict. Two new evaluators were included to avoid the "probable recognition" bias, and thus all aspects of the study were completely blind. To assess the esthetic perception and psychosocial impact, it would have been appropriate to have a nonbleached group. However, both surveys were designed and validated to measure perception in

patients. Another limitation mentioned in the literature is problems that arise from answering the questionnaire, ie, the alertness of the patient or simply their interest in answering something that may not be pleasing. However, instruments such as the OHIP-Esthetics and PIDAQ are widely used and have been validated by the scientific community. These assessments have been used in many medical studies and could be a beneficial tool for future research in dentistry.

CONCLUSIONS

Within the limitations and protocols of this study it can be concluded that there was a significant difference between the objective color. Both groups had a similar longevity of color. The two compounds maintained effectiveness at nine months with a slight rebound in color. Patients had a positive impact on their dental confidence and psychosocial well-being at nine months post teeth bleaching.

Regulatory Statement

This study was conducted in accordance with all the provisions of the local human subjects oversight committee guidelines and policies of the Faculty of Dentistry of the University of Chile PRI-ODO 15/01. The approval code for this study is: FIOUCH 13/18.

Conflict of Interest

The authors of this manuscript certify that they have no proprietary, financial, or other personal interest of any nature or kind in any product, service, and/or company that is presented in this article.

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