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CLINICAL ARTICLE

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Teeth bleaching with low concentrations of hydrogen peroxide (6%) and catalyzed by LED blue (450 ± 10 nm) and laser infrared (808 ± 10 nm) light for in-office treatment: Randomized clinical trial 1-year follow-up

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Abstract

Objectives: The aim of this study was to evaluate color longevity after a year of in-office bleaching with gel (6% hydrogen peroxide HP, LED blue/laser infrared activation system) compared to a 35% control concentration in a split-mouth study model.

Materials and Methods: Thirty-one patients were initially treated. The bleaching procedure with 6% or 35% gel HP was performed randomly in the upper half arcade of each patient. The color was measured at baseline and at 1 week, 1 month, and 1 year using the spectrophotometer Vita Easyshade, Vita Bleached, and Vita classical Shade guide organized by value. During the 1-year recall, the color was assessed before and after dental prophylaxis.

Results: Only 27 patients were assessed in the 1-year recall. There was a significant difference in the ΔE between the two groups at all times assessed ($P < .011$). The ΔL, Δa, and Δb showed significant difference between both groups at all assessed times ($P < .038$). There was no significant difference between the ΔSGU at all times ($P > .05$) except for the Vita bleachedguide postprophylaxis comparison ($P < .05$).

Conclusion: The two compounds remained effective at 1 year. When objectively evaluated, color difference between groups was found, not seen when subjectively determined.

CLINICAL SIGNIFICANCE

A low concentration hydrogen peroxide bleaching agent can reach good clinical results at 1 year of follow-up.

KEYWORDS
infrared laser, low concentration, teeth bleaching

1 | INTRODUCTION

Tooth bleaching is currently the treatment of choice for extrinsic discoloration pigmentation because it is a quick, minimally invasive, and relatively inexpensive practice.[1] There is a high degree of patient satisfaction[2] including personality styles related to the search for this treatment.[3] Several studies have recently reported the effectiveness of bleaching gels with lower concentrations for in-office technique; some of these were assisted by laser or LED lamps with catalyzing systems[4–6] achieving similar effectiveness as low adverse effects (lower sensitivity). Most studies use blue or violet LED lamps of medium intensity (<1500 mW in total) in combination with low level infrared laser to attain similar bleaching effect with less intensity and prevalence of sensitivity induced by bleaching.[4]

Some in vitro studies have shown lower cell damage (similar to human dental fibroblast) at these low concentrations of peroxide.[7]

Bleaching gels are also catalyzed by agents such as titanium dioxide nanoparticles and are activated by hybrid light (laser/LED) with different concentrations (15%).[8] However, this prior study only reports on the first few months postbleaching. There are lingering questions about the long-term fate of color and brightness.

Information about the longevity of bleaching in literature is controversial. Some studies have shown a marked rebound of color, while others reported a slight difference.[9,10] Clearly, the regression continues with time. All reports are related to the concentrations of gels higher than 10% hydrogen peroxide; only one report[11] used a 6% concentration. In a recent study was reported that patients did not experience an initial change of at least 5 units of ΔE, and showed an approximately 50% color rebound at nine months. It is important for clinicians to have knowledge about the new in-office bleaching treatment. The LED/laser system catalyzed the redox chemical reaction in less time via an acceleration effect.[4]

Therefore, the aim of this randomized clinical trial was to show the longevity of bleaching teeth using gel (6% hydrogen peroxide) with titanium dioxide nanoparticles as a catalyst that was activated with a hybrid light (LED blue/laser infrared); the longevity at 1-year follow-up of color was compared with 35% control concentration in a split-mouth study model. The first null hypothesis is that the longevity of color along the different times will be the same between the two gel methods before and after dental prophylaxis.

2 | MATERIALS AND METHODS

This clinical study was carried out between July 2014 and November 2015. It was approved by the Faculty of Dentistry's Ethics Committee, registered on the website of Clinical Trials Registry (NCT02353611) and conducted as described on the Consort statement and according to the declaration of Helsinki of ethical principles for medical research involving human subjects

A group of 131 participants were recruited by printed and electronic advertisements. They were evaluated and their teeth cleaned with pumice and water. Only were included in the study patients meeting the following criteria: 18 years old or older, with both central incisors color A2 or darker compared with Vita Classical shade guide (Vita Zahnfabrik, Bad Sackingen, Germany) ordered by value, without restorations or cervical lesions, without previously received bleaching treatment. Were exclude pregnant or breastfeeding women, patients reporting dental pain and those with moderate or severe fluorosis, tetracycline stains orthodontic treatment, periodontal disease, orofacial tumors, trauma or tooth malformation or that were taking analgesic, anti-inflammatory or antibiotic drugs

Included were 31 patients that met those criteria. All of them read and signed and informed consent form 1 week before starting the study. Also they received a dental prophylaxis and were instructed on oral hygiene techniques. At 12-month recall, only 27 patients were evaluated (Figure 1).

2.1 | Study design

Participants were treated with 2 bleaching compounds: one hemiarch (half of the dental arch) was treated with 6% hydrogen peroxide catalyzed by titanium oxide nanoparticles and activated by blue hybrid light with an infrared laser (experimental group) while the other hemiarch with a 35% hydrogen peroxide (control group). The allocation was done by randomization using Microsoft Excel 2010 (Microsoft, Redmond, Washington, USA), coding each participant. All bleaching treatments were performed by one of two restorative dentistry professors that were blind to the treatment achieved. Also patients did not knew what compound was applied in each hemiarch. To assure the blinding: any label, logo, package that may serve to identify the product was removed; bleaching protocols were standardized and performed in a separate room from where patients were evaluated; patients were coded by a number to ensure blinding of the research team, and the statician received coded data, without knowing what treatment was each code.

2.2 | Sample size calculation

Previous studies showed a ΔE of 7.0–2.0 after 2 in-office bleaching sessions with a 35% hydrogen peroxide.[4,8] Sample size was calculated considering a difference of $\Delta E = 2$ between treatment and control group, and considering an 80% chance of detecting significance at the 5% level and a $(1 - \beta)$ of 0.90. With this, a minimum of 28 participants were required. As in previous studies of our research group we had a dropout of about 5% to 10%, we decided to included 3 more patients, completing.[12]

2.3 | Bleaching protocol

Bleaching treatment was performed in 3 clinical sessions with 7 days between them. At each session prophylaxis with pumice and water was completed at the beginning. After, soft tissues were protected with a light cured barrier (Lase Protect - DMC, São Carlos, SP, Brazil) set according to manufacturer's indications. Both bleaching agents were prepared mixing the peroxide (6% or 35%) with the thickening compound in a 3:1 proportion. The resulting gel was applied uniformly over the surfaces of the corresponding teeth, from the central incisor to the first premolar, bleaching one hemiarch (4 teeth) with the experimental compound and the other with the control compound. Bleaching gels were kept over the teeth for 12 minutes while light activated with continuous irradiance using LED blue/laser infrared hybrid cold-light with a total power of 1500 mW (LED) and 300 mW (laser) (Bleaching Lase Plus – DMC Equipamentos, São Carlos, SP, Brazil). After, gels were cleaned and a new application was conducted following the same specifications. Each session a total contact time of the bleaching gel of 24 minutes was achieved, completing 72 minutes of contact after the three sessions of treatment.

2.4 | Objective evaluation

Color of both central incisors was measured at baseline and 1 week, 1 month, and 1 year after completing the treatment. To standardize this evaluation, a high-viscosity silicone putty guide (Zetaplus, Zhermack, Badia Polesine, Rovigo, Italy) was prepared with a 3-mm-radius window over the middle third of the labial surface of each tooth, were the

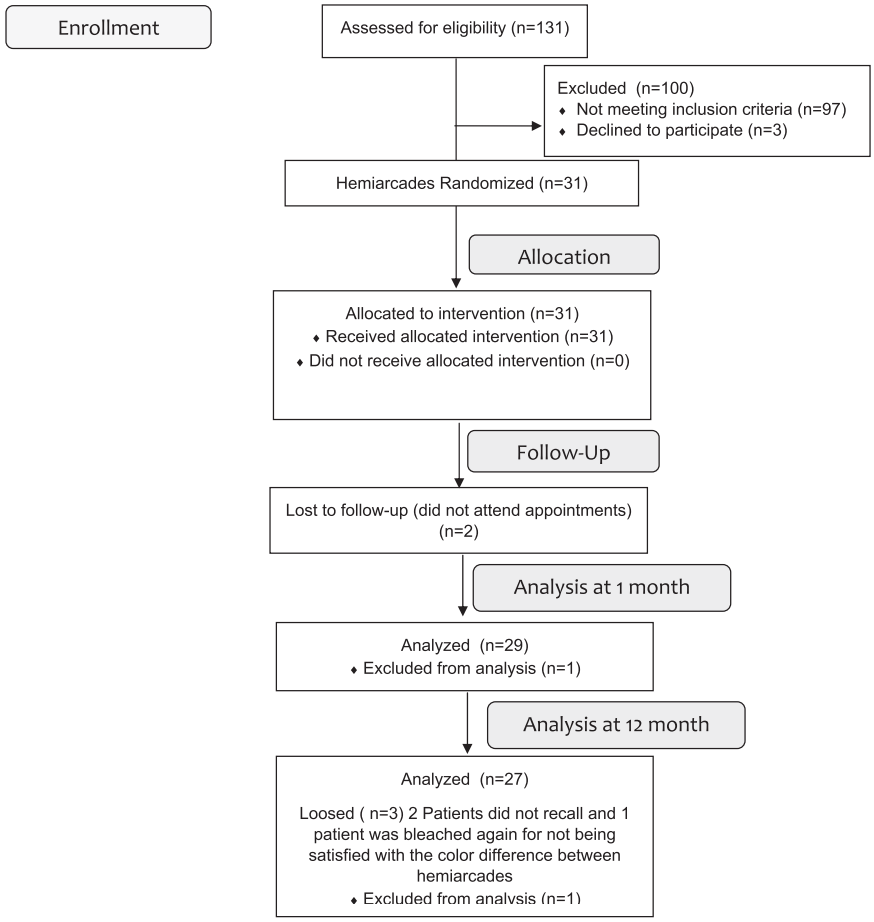

FIGURE 1 CONSORT flow chart of clinical trial

spectrophotometer (Vita EasyShade Compact, VITA Zahnfabrik, Bad Säckingen, Germany) tip was inserted. L^*, a^*, and b^* parameters were registered. Color variation between baseline and each checkpoint was determined as ΔE using the following formula:

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

2.5 | Subjective evaluation

For this, Vita Bleachedguide (Vita Classic, Vita Zahnfabrik) and the Vita Classical shade guide arranged from lightest (B1) to darkest (C4) color according to value were used. Although The Vita Classical scale is not linear in the truest sense, we treated the changes as continuous with a linear ranking as in previous clinical trials of dental bleaching.[13]

Two calibrated evaluators, with a Kappa value of 0.85 recorded the shade of both central incisors at baseline and 1 week, 1 month, and 1 year after treatment. The perceptibility threshold was 2.7 ΔE tones.[14]

Color was registered over the middle third of the labial surface as established by the American Dental Association guidelines. Color difference was calculated as the number of shade guide units that the tooth changed toward the lighter end of the shade guide (ΔSGU). At 1-year control, the evaluation was done prior and after dental prophylaxis, waiting 15 minutes for teeth rehydration before color assessment.

2.6 | Habits and diet survey

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

2.7 | 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 ΔE and ΔSGU and then analyzed using the Wilcoxon test for within group comparisons and the Mann-Whitney test for between group comparisons. The statistical analyses were performed using SPSS 23.0 (SPSS Inc., Chicago, IL, USA) with $\alpha = 0.05$.[15]

3 | RESULTS

3.1 | Baseline characteristics

Thirty-one patients were initially selected of the 131 evaluated. Three patients did not continue, and 1 patient was excluded from analysis during monitoring at 1 year. The sample consisted of 10 women (37.0%) and 17 men (63.0%) with average ages of 24.7 ± 5.9 years for

TABLE 1 Baseline color features of volunteers

		Confidence Interval at 95%			Confidence interval at 95%			Confidence interval at 95%		SGU value	Confidence interval at 95%	
	L value (mean ± SD)	Upper limit	Lower limit	*a** value (mean ± SD)	Upper limit	Lower limit	*b** value (mean ± SD)	Upper limit	Lower limit	Vita classic (mean ± SD)	Upper limit	Lower limit
Group A	84.7 ± 4.3	86.4	83.0	−0.4 ± 1.5	−0.2	−1.0	24.2 ± 4.2	25.9	22.6	6.8 ± 2.2	7.7	5.9
Group B	84.4 ± 4.6	86.3	82.6	−0.4 ± 1.3	−0.1	0.9	24.1 ± 3.7	25.6	22.6	6.9 ± 2.3	7.8	6.0

men and 23.1 ± 2.8 years for women. The sample was 24.1 ± 5.0 years. Features of color at baseline are presented in Table 1.

3.2 | 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 obtained (data not shown) in all the analyses. To avoid data repetition, we describe only the results obtained by per-protocol analysis.

3.3 | Spectrophotometer data

Color changes measured by units of ΔE, ΔL, Δa, and Δb from the baseline are presented in Table 2. There was a significant difference in ΔE according to the Mann-Whitney test between the two groups at all assessed times ($P < .03$). There was also a color difference between the groups after 1 week and 1 month with a noticeable difference >2 units of ΔE maintaining the difference at a 1-year recall. The ΔL, Δa, and Δb showed a difference according to the Mann-Whitney test between the two groups at all times assessed ($P \leq .05$) except for Δa from baseline versus 1-year preprophylaxis value ($P > .17$). To corroborate the statistical power and size effect, this outcome was calculated post-hoc with the ΔE values by G-Power software.[16] All values showed statistical significant differences compared to baseline ($P < .05$) via the Wilcoxon test.

3.4 | Shade guide data

The subjective color changes as evaluated by ΔSGU units are presented in Table 3. There was no significant difference between the different evaluations ($P > .1$) except for the Vita Bleachedguide post prophylaxis comparison (<0.03).

3.5 | Habits and diet survey

Of the 27 patients, 11 (40.7%) were light smokers (<10 cigarettes per day) and 22 patients (81.5%) were consumers of tea, coffee, or cola drinks (media of 2.0 times per day). Ten used whitening toothpastes with abrasive effects. This did not considering peroxide carbamide because it is not available in the local market; median = 2.80 times per day.

TABLE 2 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, effect size, and statistical power (%[a] = percentage of rebound refer to month value)

ΔE	Group A	%[a]	Group B	%[a]	Mann-Whitney (*P*)	Effect size *d*	Power (1 − β)
Baseline vs week	7.9 ± 1.1		8.2 ± 2.7		**.004**	0.04	0.07
Baseline vs month	5.9 ± 3.8		8.2 ± 2.5		**.000**	0.75	**0.84**
Baseline vs 9 month PrePr	6.0 ± 4.1	None	7.6 ± 2.6	7.9%	**.011**	0.47	0.51
Baseline vs 9 month PostPr	5.1 ± 3.5	14%	7.8 ± 2.3	5.5%	**.000**	0.90	**0.94**
Baseline vs 12 month PrePr	5.0 ± 3,7	16.9%	7.2 ± 2.7	14.4%	**.001**	0.67	**0.77**
Baseline vs 12 month PostPr	5.1 ± 3,7	16.0%	7.3 ± 2.6	12.3%	**.023**	0.71	**0.81**
ΔL							
Baseline vs week	2.0 ± 3.5		3.8 ± 3.2		**.016**	0.52	0.58
Baseline vs month	2.6 ± 4.1		4.1 ± 3.1		**.033**	0.41	0.42
Baseline vs 12 month PrePr	2.9 ± 3.4		4.8 ± 3.1		.050	0.38	0.65
Baseline vs 12 month PostPr	2.7 ± 3.6		4.4 ± 3.1		**.023**	0.49	0.54
Δa							
Baseline vs week	−0.8 ± 1.1		−1.4 ± 0.7		**.038**	0.61	0.70
Baseline vs month	−0.8 ± 1.1		−1.3 ± 0.8		**.015**	0.58	0.66
Baseline vs 12 month PrePr	−0.4 ± 1.1		−0.9 ± 1.0		.171	0.46	0.48
Baseline vs 12 month PostPr	−0.4 ± 1.2		−1.1 ± 0.7		**.002**	0.76	**0.85**
Δb							
Baseline vs week	−1.5 ± 1.2		−6.1 ± 3.3		**.005**	0.51	0.57
Baseline vs month	−3.5 ± 3.5		−6.1 ± 2.8		**.001**	0.85	**0.91**
Baseline vs 12 month PrePr	−2.4 ± 3.5		−4.6 ± 3.1		**.014**	0.66	**0.75**
Baseline vs 12 month PostPr	−2.4 ± 3.4		−4.8 ± 2.8		**.002**	0.75	**0.85**

TABLE 3 Changes of color by ΔSGU (Vita Classic 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)	.655	0.10	0.10
Baseline vs Month	4 (Min 2/Max 9)	4 (Min 2/Max 9)	.672	0.10	0.10
Baseline vs 12 month PrePr	3 (Min 2/Max 9)	4 (Min 0/Max 10)	.223	0.35	0.69
Baseline vs 12 month PostPr	4 (Min 0/Max 8)	5 (Min 1/Max 8)	.210	0.35	0.68
Vita Bleach Guide 3D-Master					
Baseline vs Week	3 (Min 1/Max 6)	4 (Min 1/Max 6)	.253	0.32	0.30
Baseline vs Month	3 (Min 1/Max 5)	3 (Min 0/Max 6)	.136	0.42	0.45
Baseline vs 12 month PrePr	1 (Min 2/Max 4)	2 (Min −1/Max 5)	.063	0.53	0.64
Baseline vs 12 month PostPr	4 (Min 2/Max 9)	4 (Min 0/Max 10)	.026	0.33	0.71

4 | DISCUSSION

In this randomized clinical study, the treatment was thought an uncertain design (split-mouth).[17,18] This was conducted to show the longevity and probable rebound of the color of a protocol that has not been greatly explored using a low concentration of hydrogen peroxide (6%) catalyzed by hybrid light (LED/Laser) compared with a conventional high concentration peroxide control (35%). No patients were dissatisfied with the color difference between both hemiarcades in a previous report from this cohort of patients.[19]

There is no consensus in the literature about the actual effectiveness of low hydrogen peroxide products in over-the-counter products. However, one consistency is that products must have long contact times with the tooth surface. A previous study concluded that there is not sufficient evidence about OTC bleaching products and recommended that dentists provide timely information to patients.[20] It also concluded that the effectiveness of these products is low compared to other traditional bleaching approaches. In 2009, it was published a meta-analysis of OTC bleaching products that focused on hydrogen peroxide concentrations similar to our experimental group (6%).[21] The analysis showed effective whitening but the whitening required 2 weeks for 2 hours per day (1680 minutes) to achieve this effect. In our study and other recently published,[22] there was only 72 minutes of gel contact at 6% peroxide. This resulted in a Δ*E* of 5.9 in the postbleaching month with a 16% rebound in the follow-up year (Δ*E* of 5).

The photocatalysis effect generated by the LED/laser lamp used here is a photochemical reaction that involves the absorption of blue light and a catalyst such as nanoparticulate titanium dioxide as a semiconductor material.[23] Oxidation and reduction occur during this process. To perform the catalyst activation, appropriate photocatalysis (TiO^2) by blue radiation at wavelengths (λ) is necessary.[24] Thus, for each photon with sufficient energy that strikes the semiconductor material, an electron from the valence band is promoted to the conduction band. This technology can accelerate the tooth whitening process via the hydroxyl ion in an aqueous medium (gel) that reacts with organic contaminants to degrade carbon dioxide, water, and other salts.[6]

TiO_2 is the most common semiconductor used in photocatalysis because it is chemically and biologically inert, nontoxic, and stable with photochemical and chemical corrosion. It is also abundant and cheap and has an energy gap of 3.2 eV that can easily be excited with $\lambda < 535$ nm[25] light from the LED/laser hybrid lamp. Many researchers have selected a particular source of TiO_2 for its high photocatalytic activity.[26] Nanotechnology has been very important in the development of dental biomaterials in recent years mainly because materials on the nanoscale can achieve more efficient and rapid interactions due to the increased particle surface size.[27] The inclusion of titanium dioxide nanoparticles potentiates the semiconductor role. Consequently, the effectiveness of this nanocomposite gel is stable over time.

There are some reports in the literature about the longevity of tooth whitening with controversial results. It can be difficult to compare these due to different color measurement methodologies.[9,28] Our longevity results are based on Δ*E* and are quite interesting. The effectiveness of bleaching was maintained at 1 year with only a slight rebound in color. This reinforces the idea that catalyzing the hybrid light results in permanent whitening unlike clinical works with 6% concentrations reporting a very high rebound color.[11] The color rebound was not significant relative to baseline ($P > .05$). The results based on the Δ*L*, Δ*a*, and Δ*b* were very similar except in a preprophylaxis period that was explained by stains mainly affecting the luminosity of color of both groups. Recent trials showed that the color had a slight change during prophylaxis; this concurs with our results.[12,29]

The reason for the color rebound at 1 year is unclear. Teeth exposed to coloring agents from food can stain. Importantly, we did not include diet in our study design and this might influence the results. However, we used a split-mouth design to help control for this. Smoking patients were enrolled because a previous study[12] found no significant differences in the effectiveness and longevity of color—especially because these patients smoked fewer than 10 cigarettes a day. In addition, it was found that coffee consumption had no impact on the effectiveness of bleaching.[30] Finally, no study has shown an influence of toothpaste with bleaching agents over the medium or long term. Hopefully, this report will shed some light on the study and may have some influence on future studies. However, the use of a prophylaxis protocol as previously proposed[12] resulted in a difference—particularly for 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 outcome over the long-term recall would require a color assessment before and after the removal of extrinsic staining by mechanical cleaning and dental prophylaxis.[31] Most clinical studies that assess color rebound of at-home bleaching did not report the dietary habits during and after tooth bleaching. Only a few studies have attempted to associate dietary habits with the longevity of at-home bleaching, and their findings were inconclusive.[9,28,32]

The 6% compound was effective at 1 year, and bleaching was considered effective when there was at least a difference of 5 units in ΔE upon recall.[33] Subjective outcomes measured using the variation of SGU units by Vita Classic and Vita Bleachguide 3D-Master remain inconsistent with the objective results. This could be because of the high bias that exists in the measurements of two neighboring teeth belonging to different groups by human evaluators.

The effect of whitening gel catalyzed using light (LED blue 1300 mW/cm^2 and laser-infrared) results in effective and stable color changes even 1 year after therapy. Methodologically, the blindness of the operators, evaluators, and all 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.

5 | CONCLUSIONS

Within the limitations and protocols of this study, there was a significant difference between the objective evaluation of color between both groups at 1 year of follow-up. Both groups had equal color longevity, with maintained effectiveness at 1 year.

COMPLIANCE WITH ETHICAL STANDARDS

Ethical Standards: This research was carried out in accordance with the current Chilean laws relating to human experiments.

Conflict of Interest: The authors declare that they have no conflicts of interests and the authors do not have any financial interest in the companies or products used in this study.

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