RESEARCH ARTICLE

WILEY

One-year bleaching efficacy using two HP products with different pH: A double-blind randomized clinical trial

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Funding information

Conselho Nacional de Desenvolvimento Científico e Tecnológico, Grant/Award Number: 305588/2014-1; Fondo Nacional de Desarrollo Científico y Tecnológico, Grant/ Award Number: N1170575

Abstract

1-year bleaching efficacy produced by two hydrogen peroxide gels with different pHs. **Materials and Methods:** Twenty-eight patients were divided into two groups corresponding to two different products: Pola Office (pH = 2.0/SDI) and Pola Office Plus (pH = 7.0/SDI). The treatment was assessed during and after the bleaching procedure up to 12 months post-treatment. The assessment consisted of two bleaching scales shade guide units (ΔSGU) and spectrophotometric device (ΔE , ΔEOO , and Whiteness Index) of both maxillary quadrants. Results for ΔSGU s in both scales and ΔEOO and Whiteness Index were compared using Mann Whitney test and ΔE measurements through the t-Student test for paired samples in each evaluation time. The color rebound (1- vs 12-month postbleaching data) was evaluated with Wilcoxon test

Objectives: This split-mouth, double-blind, randomized clinical trial evaluated the

Results: During the different times of evaluation, the color variation was similar for both products (P > .05), both for subjective (Δ SGUs) and objective assessments (ΔE , Δ E00, and Whiteness Index). Also, both products showed a slight rebound after 12-month postbleaching (P > .05).

Conclusions: Concerning the stability of color, in-office dental whitening with two hydrogen peroxide gels of different pHs produced similar results, with no significant of regression, for 12 months postwhitening.

Clinical Significance: Bleaching using a neutral (pH = 7.0) in-office gel demonstrated similar stability and rebound effect than an acidic one (pH = 2.0).

KEYWORDS

(alpha = .05).

color stability, hydrogen peroxide, pH, randomized clinical trial, teeth bleaching

1 | INTRODUCTION

Dental whitening is a conservative, widely-used technique in today's dental practice due to its safety, efficacy, and high impact on the esthetics of patients.¹ As this technique has become a routine dental procedure, the quantification and the efficacy of tooth whitening is a

concern in esthetic dentistry. Traditionally, dentists determine the color of human teeth via visual comparison to a reference standard set called a shade guide. Alternatively, instrumental assessments generate quantitative and objective data. From these objective data, it is possible using different formulas to determine dental whiteness which is of extreme importance in these treatments. For this purpose, some

J Esthet Restor Dent. 2019;1-7. wileyonlinelibrary.com/journal/jerd © 2019 Wiley Periodicals, Inc.

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indices have been developed and widely used. The list includes the Commission Internationale de l'Eclairage (CIE) Whiteness Index WIC, the Whiteness Index according to ASTM E-313-73 WI, and the Z% index. Recently, a whiteness formula (WIO) that optimizes the original CIE whiteness formula (WIC) has been developed, rendering the best performance for the prediction of tooth whiteness.^{2,3} Whiteness Index described based on the distance between a specified color value and a nominal white, represented in the CIELAB color space as $L^* = 100$, $a^* = 0$, and $b^* = 0$.⁴ The Whiteness Index is a one-dimensional color index to quantify whiteness, the index allows a greater correlation with the visual perception of color.

Regarding the modalities of dental whitening, the in-office technique represents a good option for patients looking for a fast, safe, and effective dental bleaching treatment. A recent meta-analysis showed that there is no difference in effectiveness and sensitivity when comparing the at-home and in-office bleaching techniques.⁵

However, one of the most important concerns related to the inoffice bleaching is that the color could rebound in few days. In an in vivo evaluation, Matis et al assessed eight in-office bleaching gels based on 15% to 35% of hydrogen peroxide.⁶ Authors showed that although there was a significant whitening effect immediately after bleaching, there was a rebound effect for the eight in-office products expressed in Delta *E* values in order of 51% to 65% after 1 and 6 weeks post-treatment, respectively.⁶

One of the most likely reasons for color rebound may be related to the pH of the in-office bleaching gel. Most of older in-office bleaching gels have a low pH ranging from 2.4 to 6.2,^{7.8} primarily to increase the average life of the product, which is stabilized in acidic environments to prevent it from decomposing.⁹ However, it makes the bleaching product acidic enough to produce enamel demineralization, which some authors interpret as causing some bleaching effect¹⁰ and changes in chemical composition, morphology, and mechanical properties of the tooth structure.^{11,12}

More recently, in-office bleaching gels with alkaline/neutral pH,¹³ which are less aggressive to tooth structure have been launched in the market, in an effort of manufacturers to reduce this side effect. Recently published clinical studies have hypothesized that in-office bleaching agents with alkaline/neutral pH are as effective as the previous ones,¹⁴⁻¹⁷ which is explained by the fact that bleaching may occur independently of the pH of the bleaching gel.¹⁸ However, to the extent of our knowledge, the role of pH of in-office bleaching gel in the long-term efficacy has not been evaluated yet.

Therefore, this study evaluated the color stability of teeth after being subjected to bleaching treatment with two products of different pH values (acidic 2.0 vs neutral 7.0), in a follow-up of 12 months. The null hypotheses were that (a) no significant difference would be detected in terms of bleaching results between in-office bleaching gels with different pHs and (b) no color rebound will be detected in both groups of participants when 1-month postbleaching were compared to 12-month postbleaching results.

2 | MATERIALS AND METHODS

This study is the 12-month follow-up of an earlier study¹⁷ registered at rebec.gov.br under the identification number RBR-3h6n6c. All 12-month recall measurements were performed in the clinic of Dental School of the local University from June 2016 to June 2017.

This study was a randomized, split-mouth, double-blind, controlled clinical trial with an equal allocation rate. The experimental design following the recommendations of the international group Consolidated Standards of Reporting Trials, ¹⁹ and respecting the principles of the Declaration of Helsinki. The participants signed an informed consent form and 2 weeks before the bleaching procedures, all of the volunteers received a dental screening, dental prophylaxis with pumice and water with a rubber cup. This research was carried out in accordance with the current country laws relating to human experiments.

2.1 | Eligibility criteria

The subjects included in this clinical trial should be over 18 years old and in good general and oral health condition. The participants were required to have six maxillary and mandibular anterior teeth without caries lesions or restorations. All upper incisor should be shade A2 or darker, as judged by comparison with a value-oriented shade guide (VITA Classical Shade Guide, Vita Zahnfabrik, Bad Säckingen, Germany). Also, all patients should agree to return monthly for postwhitening evaluation.

Pregnant or lactating women and smokers were not included in this trial. Participants with anterior restorations, orthodontic appliances, bruxism, severe internal tooth discoloration (tetracycline stains, fluorosis, pulpless teeth), and exposed dentine were also excluded. Additionally, participants who took anti-inflammatories, analgesics, or antioxidants were not included in the study.

2.2 | Sample calculation

Using the program G-Power 3.1, a .2 beta error, and an alpha error of .05, a sample calculation of 25 patients per group was obtained. Considering the dropout rate reported in other published trials (5%), it was decided to increase the sample to 28 patients per group, in agreement with the ΔE of the color of recent studies of our group.²⁰⁻²²

2.3 | Randomization and allocation concealment

Twenty-eight patients who previously had participated in the study of bleaching with two 35% hydrogen peroxide gels with different pH values were selected for this study. ¹⁷ A split-mouth model was used for tooth whitening. The allocation of the sides was conducted randomly, using a sample randomizing method (computer-generated tables, www. sealedenvelope.com). After the application of a light-cured gingival barrier; sealed envelopes, consecutively numbered, containing the identification of the groups were opened and one of the in-office bleaching products was assigned (Pola Office and Pola Office+, both from SDI, Bayswater, Victoria, Australia) and applied in their respective upper hemi-arch, according to the manufacturer's instructions.

The operator was not blinded to the procedure, as both in-office bleaching gels had different commercial presentations. However, the participants and the examiners who evaluated the color changes were not aware of the allocation of the participants within the study groups.

2.4 | Bleaching procedure

This study employed the acid gel 35% HP Pola Office (SDI, Bayswater, Victoria, Australia) and the neutral gel 37.5% HP Pola Office+ (SDI, Bayswater, Victoria, Australia). After isolated the gingival tissue of the teeth, the HP gels were applied in three opportunities of 8 minutes each on both groups. The products were renewed every 8 minutes during the 24-minutes application period, according to the manufacturer's directions. Two bleaching sessions were performed with a 1-week interval between them. All of the participants were instructed to brush their teeth regularly (ie, four times a day) with fluoridated toothpaste without whitening components that were provided by the investigators.

2.5 | Color evaluation

Color was assessed visually under standardized light conditions (same place, time, natural light source, all assessments were between 10:00 AM and 3:00 PM) by two previously calibrated operators, who showed a previous agreement (Visual Scales) of at least 85% as determined using weighted *k*-statistics. The viewing geometry, object-observer distance, visual angle, and background color were held constant. Each operator measured three times each tooth, intercalary, if there was a coincidence between the last measurements between both operators, the determined value remained as definitive, if there was any discrepancy, a calibrated third operator (professor of restorative dentistry) defined between both colors.

The shade of the maxillary right and left central incisor was assessed using the Vita Classical (Vita Zahnfabrik, Bad Sackingen, Germany) and Vita Bleachedguide (Vita Zahnfabrik) shade tabs following a protocol previously described. 17 The color variation from the beginning of the active phase through the recall sessions was estimated by the change in shade guide units (Δ SGU) that occurred when compared with the value-oriented scale of shade tabs.

After assessing with both visual scales, the teeth were objectively measured using the Vita Easyshade Compact spectrophotometer (Vita Zahnfabrik), which determines the characteristics of color according to the quantitative CIELAB system of the Commission International de L'eclairage, breaking up the color into a combination of three coordinates in a three-dimensional space. The positioning of the tip of the spectrophotometer was achieved using a silicone matrix, specially made for each patient, with a perforation in the middle face of the central incisor to be measured. Measurements were taken in three opportunities. A Delta of the total change of color was calculated using the following formula: $\Delta E * = [(\Delta L^*) \ 2 + (\Delta a *) \ 2 + (\Delta b *) \ 2]^{1/2}$. The color difference was calculated using the CIEDE 2000 formula proposed by Luo in 2001²⁴ and Whiteness Index proposed by Gerlach in 2002.

The shade measurement was performed on the maxillary right and left central incisor at the baseline and 1 and 2 weeks, 1 month, and 12 months after finishing the bleaching protocol. At 12 months, the evaluation was performed before and after dental prophylaxis with a rotating brush and prophylaxis paste (Herjos, Vigodent Coltene AS Ind. Com, RJ, Brazil). After dental prophylaxis, teeth were allowed to rehydrate for 15 minutes before color assessment. This precaution was taken because teeth become lighter as they dehydrate, ²⁶ and this situation could affect the reliability of the collected data.

2.6 | Statistical analysis

The analysis followed the intention-to-treat protocol and involved all of the participants who were randomly assigned. ¹⁹ The statistician was blinded to the study groups. Five different $\Delta E/\Delta SGU$ were calculated, as follow: $\Delta E/\Delta SGU1$ = baseline—1 session; $\Delta E/\Delta SGU2$ = baseline—2 session; $\Delta E/\Delta SGU3$ = baseline—1 week; $\Delta E/\Delta SGU4$ = baseline—1 month and $\Delta E/\Delta SGU5$ = baseline—1 year. For $\Delta SGUs$ in both scales, the distribution was non-normal, as assessed by a test of normality (Shapiro-Wilk), therefore, the data were compared via Mann Whitney. For ΔE measurements, the distribution was normal, and the data were compared via Student t-test for paired samples. The analysis was performed at different time points between groups in each ΔE evaluation. The color rebound was calculated by a comparison between 1-month and 12-month postbleaching data through Wilcoxon test. In all of the statistical tests, the alpha was preset at .05.

3 | RESULTS

3.1 | Patient flow diagram

There was a total of 28 previously bleached patients in one of the two centers (Figure 1),¹⁷ and 26 of them attended to control monitoring after 12 months. Two patients were missed. One due to the incompatibility of schedules, and another for having fixed orthodontic appliances, preventing the correct evaluation of the tooth in question.

All statistical analyses were performed with data imputation for missing outcomes (intention-to-treat) and without data imputation (per-protocol). In all analyses, the same overall conclusions were reached (data not shown). To avoid data repetition, we opted to describe only the results and statistics obtained in the intention-to-treat analysis because a lower percentage of patients (2 out of 28 [7%]) could not be evaluated in the 12-month recall.

The results for both Vita Classical shade guide and Vita Bleachedguide 3D-MASTER (Table 1), as well as for spectrophotometer evaluations (Table 2) showed a nonsignificant difference between the two groups in all assessment time evaluated (P > .05). The color rebound was also evaluated for three scales, and no significant difference was found when 1-month was compared with 12-month postbleaching (Tables 1 and 2; P > .05). The results in Δ E00 (CIEDE2000 formula; Table 3) and Whiteness Index (Table 4) showed a nonsignificant difference between both groups (P > .05).

4 | DISCUSSION

The first objective of this study was to assess the possible impact of pH on the color change comparing two in-office bleaching gels with



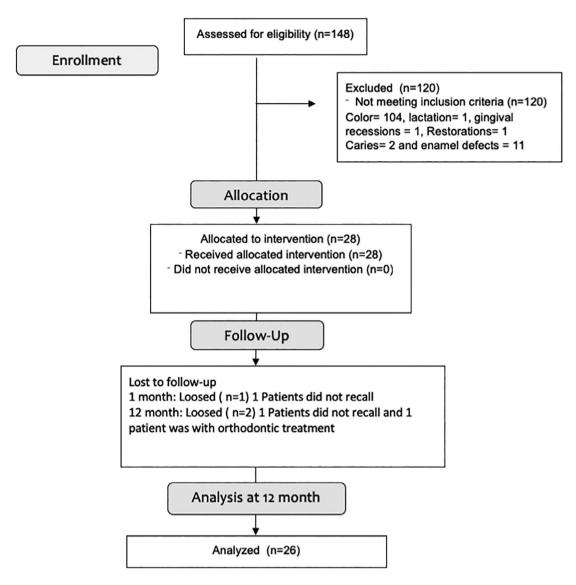


FIGURE 1 Flow diagram of the clinical trial

TABLE 1 Color change by Δ SGU (Vita Classical and Vita Bleachedguide 3D-Master) by the group in different time frames expressed by median (minimum: maximum value) and statistical significance

| | Color change by Δ SGU Vita Classic | | | Color change by Δ SGU Bleached guide 3D-Master | | |
|---------------------------------------|---|---------------------|------------------|---|---------------------|------------------|
| Assessment times | Pola Office | Pola Office Plus | Mann Whitney* | Pola Office | Pola Office Plus | Mann Whitney* |
| Baseline vs 1st bleaching session | 3 (0:7) | 4 (0:8) | 0.200 | 2 (0:4) | 2 (0:4) | 0.392 |
| Baseline vs 2nd bleaching session | 5 (2:8) | 6 (2:8) | 0.491 | 3 (1:5) | 4 (1:7) | 0.294 |
| Baseline vs 1 week after bleaching | 5 (2:8) | 6 (2:8) | 0.423 | 3.5 (1:6) | 4 (1:6) | 0.866 |
| Baseline vs 1 month after bleaching | 5.5 (2:8) | 6 (2:8) | 0.369 | 4 (1:7) | 4 (1:5) | 0.770 |
| Baseline vs 12 months after bleaching | g 5 (0:8)** | 6 (0:8)** | 0.794 | 3 (0:6)** | 3 (1:6)** | 0.574 |

Note: *For comparison between both groups in each assessment time; No significant difference was found (Wilcoxon test; P > .05); **for comparison between two assessment time (1-month vs 12-months after bleaching) in each group. No significant difference was found (Student t test for paired sample; P > .05).

Abbreviation: Δ SGU, shade guide units.

different pH values. The results showed that no significant difference in the color change was observed when both groups were evaluated at each time, as well as previously observed for immediate

evaluation.¹⁷ This observation leads us to accept the first null hypothesis. The literature is scarce regarding comparisons of inoffice bleaching gels with different pH values. However, the

TABLE 2 Color change in ΔE obtained with the Vita Easyshade spectrophotometer by the group in different time frames expressed by mean and SD, as well as, statistical analysis

| | Color change by ΔE | | Student t test for | |
|--------------------------------------|--------------------|------------------|--------------------|--|
| Assessment times | Pola Office | Pola Office Plus | paired sample* | |
| Baseline vs 1st bleaching session | 3.30 ± 2.62 | 3.60 ± 4.40 | 1.000 | |
| Baseline vs 2nd bleaching session | 6.48 ± 3.63 | 7.07 ± 4.37 | 0.592 | |
| Baseline vs 1-week after bleaching | 7.78 ± 2.92 | 9.18 ± 4.14 | 0.148 | |
| Baseline vs 1-month after bleaching | 8.15 ± 3.24 | 9.44 ± 4.84 | 0.249 | |
| Baseline vs 12-month after bleaching | 7.54 ± 3.53** | 8.76 ± 4.44** | 0.276 | |

Note: *For comparison between both groups in each assessment time; **for comparison between two assessment time (1-month vs 12-month after bleaching) in each group. No significant difference was found (Student t test for paired sample; P > .05).

TABLE 3 Color change in Δ E00 by the group in different times expressed by mean and SD, as well as, statistical analysis

| | ΔΕ00 | | |
|--------------------------------------|-------------|------------------|--------------------|
| Assessment times | Pola Office | Pola Office Plus | Mann-Whitney test* |
| Baseline vs 1st bleaching session | 2.3 ± 1.8** | 2.3 ± 1.4** | 0.793 |
| Baseline vs 2nd bleaching session | 3.6 ± 1.5 | 3.9 ± 2.0** | 0.662 |
| Baseline vs 1-week after bleaching | 4.6 ± 1.8 | 5.3 ± 2.0 | 0.190 |
| Baseline vs 1-month after bleaching | 4.6 ± 1.8 | 5.3 ± 2.4 | 0.528 |
| Baseline vs 12-month after bleaching | 4.2 ± 1.7 | 4.7 ± 1.8 | 0.377 |

Note: *For comparison between both groups in each assessment time; **for comparison between assessment time vs 12-month after bleaching in each group with significant difference (Wilcoxon test; P < .05).

TABLE 4 ΔE values of Whiteness Indexes for dentistry obtained with the Vita Easyshade spectrophotometer by the group in different times expressed by mean and SD, as well as, statistical analysis

| | Whiteness Ind | ex | | |
|--------------------------------------|---------------|------------------|--------------------|--|
| Assessment times | Pola Office | Pola Office Plus | Mann-Whitney test* | |
| Baseline vs 1st bleaching session | 0.29 ± 1.93 | 1.03 ± 2.40 | 0.272 | |
| Baseline vs 2nd bleaching session | 3.95 ± 1.83* | 4.63 ± 1.75* | 0.382 | |
| Baseline vs 1-week after bleaching | 5.59 ± 2.24* | 6.26 ± 3.35* | 0.223 | |
| Baseline vs 1-month after bleaching | 5.17 ± 2.41 | 6.15 ± 3.64 | 0.473 | |
| Baseline vs 12-month after bleaching | 5.26 ± 2.04 | 6.02 ± 2.55 | 0.265 | |

Note: *For comparison between both groups in each assessment time; No significant difference was found (Mann-Whitney test; P > .05) **for comparison between two assessment time in each group; Significant difference was found with previous time in each group (Wilcoxon test; P < .05).

aforementioned is in agreement with at least two recently published clinical trials. 14,15

For instance, Basting et al¹⁴ showed that color change measured after 3-week of bleaching had no difference when one acidic in-office bleaching gel (Pola Office, SDI, Bayswater, Victoria, Australia) were compared with a more neutral in-office bleaching gel (Opalescence Boost PF, Ultradent, South Jordan, Utah). In the same line, Kossatz et al¹⁵ showed that after two bleaching sessions the same results in terms of color change were observed when one acidic in-office gel (Whiteness HP, FGM, Joinville, SC, Brazil) were compared with an one more neutral in-office gel (Whiteness HP Blue, FGM, Joinville, SC, Brazil).

Both groups showed one difference greater than 5 ΔE after 1-month postbleaching, which, according to the literature represents an effective bleaching.^{5,27} Also, according to the subjective assessment, the difference of color between the two groups is not enough for the human eye to be discriminated, and therefore both bleaching

systems maintained an acceptable whitening during all period of evaluation.²⁸ The subjective evaluation coincided with the spectrophotometric. The whitening indexes show a good stability of both bleaching at the 1-year control, which according to the literature, reflect more precisely the rebound of whitening treatments and have a good correlation with the visual perception of color.⁴

However, the most interesting result of the present study was that no significant color change assessed by different formulas and methods was seen when 1-month postbleaching results were compared with 12-month post-treatment, for either of the HP gel evaluated. It was seen an average ΔE of less than 1 for either the acidic bleaching gel product (Pola Office; pH = 2), or for the neutral one (Pola Office Plus; pH = 7.0).

When subjective scales are evaluated according to the ADA recommendations, effective bleaching refers to the maintenance of at least 5 Δ SGU of color difference as compared to the beginning of treatment, for at least 6 months.²⁹ Based on reports published by

Dahl and Pallesen,³⁰ there are 10% of color rebound in the first year of the bleaching, and this increases to 20% to 25% in the third year. These reports are consistent with our results since there was an increase of about 7.3% to 7.5% for both in-office gels after 12 months of clinical evaluation. However, this color rebound seems to be clinically nonrelevant, since no significant difference was observed after 12-month of clinical evaluation when evaluated by two shade guides and ΔE , ΔE 00 (CIEDE2000 formula), and Whiteness Index. All these results lead us to accept the second null hypothesis.

Unfortunately, clinical trials that focused on the stability of color for in-office bleaching gels are somewhat scarce, and there is a general notion that the greater the time of follow-up, the greater the percentage of regression of color.⁶ However, there is no consensus according to the literature.^{20,21,31-36} Several factors could be responsible for this controversy. For instance, the results observed immediately after an in-office bleaching session cannot be only attributed to the oxidative action of the HP into the dental organic substrate. But instead, It is the sum of the oxidative processes, dental dehydration, and enamel demineralization. When the immediate bleaching result is compared to the color measured some weeks later, an unrealistic color reversal is usually reported,⁶ but this does not mean ineffective bleaching since it is due to rehydration and remineralization that occurs after each bleaching session.³⁷

A recent research paper demonstrated that the application of a gum and lip guard alone, even for a short period of 10 minutes, would cause a lightening of the tooth of ΔE 7.3, without any actual bleaching having occurred. As it is known, isolation can cause the teeth to dehydrate, and it takes at least 30 minutes for teeth to rehydrate. ³⁸ Unfortunately, several clinical studies did not make clear when color was measured. ^{31,32}

Another important factor is the pH of in-office bleaching gels. Many dental whitening kits currently available on the market vary between acid and alkaline pHs. In a study conducted by Price et al, there was a range of pH values for different products, between 3.67 (acidic) and 11.13 (alkaline). Dental whitening gels that contain hydrogen peroxide usually contain an acidic medium since the compound is reduced in an acidic environment and is, therefore, more stable in storage. Alkaline products, in turn, are less stable and have earlier expiration dates; however, they are of interest now since it has been reported that decomposition of the peroxide reaction and its oxidative potential are increased in an alkaline environment, generating a more effective whitening without the associated side effects on enamel.

According to a study carried out by Young et al,³⁹ the chemistry of the hydrogen peroxide reaction depends directly on the pH of the solution in which it is contained, resulting in a more rapid reaction at pH values between 8 and 9, which leads to assume that a neutral product does not necessarily guarantee a stable or lasting whitening but only a more rapid reaction. The commercial form in a syringe of Pola Office Plus when compared to the powder-liquid presentation of Pola Office reduces the clinical time and facilitates its implementation, generating an oxidative reaction in a neutral environment, which would eliminate any deleterious effect on the surface of the enamel, such as decreasing tooth hardness. The impact of this last point is

controversial since an in vitro study carried out by Borges et al⁴⁰ verified the repair of the partially eroded enamel by the precipitation of salivary calcium and phosphate.

However, it is important to highlight the possible effect of acidic pH and high peroxide concentration gels, such as Pola Office (pH 2), on erosion, decreased enamel translucency, and opacity. While the permeability of enamel is relatively low and acts as a semipermeable membrane, allowing water and ions flow, the low-molecular weight of hydrogen peroxide facilitates its dissemination into dentin, and in high concentrations at low pH, it would have the potential to cause alterations at microstructural level that could alter the physical and optical properties of the tooth.

5 | CONCLUSION

There are no differences in the stability of color for in-office whitening using 35% hydrogen peroxide gels with different pH values 12 months post-treatment, as determined with an objective spectro-photometric measurement using color differences and Whiteness Index values as well as subjective evaluation based on shade guide measurements.

ACKNOWLEDGMENTS

This study was partially supported by the Project Fondecyt N1170575 (Chile) and National Council for Scientific and Technological Development (CNPq/Brazil) under grants number 305588/2014-1. The authors do not have any financial interest in the company whose materials are included in this article. The authors would like to thank SDI Chile (Dr. Mario Herrera) for the generous donation of the bleaching products employed in this study. The author E. Fernández dedicates this article to his two kids Elisa and Eduardo by their enormous inspiration.

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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How to cite this article: Bersezio C, Martín J, Prieto MV, et al. One-year bleaching efficacy using two HP products with different pH: A double-blind randomized clinical trial. *J Esthet Restor Dent.* 2019;1–7. https://doi.org/10.1111/jerd.12505