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Effectiveness of 6% hydrogen peroxide concentration for tooth bleaching—A double-blind, randomized clinical trial

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ABSTRACT

Objective: The aim of this clinical randomized double-blind split-mouth study was to assess the effectiveness of a 6% hydrogen peroxide with nitrogen-doped titanium dioxide light activated bleaching agent.

Method: 31 patients were treated with: one upper hemiarcade with a 35% hydrogen peroxide bleaching agent and the other hemiarcade with a 6% hydrogen peroxide. Two applications were completed each treatment session and three sessions were appointed, with one week interval between them. Tooth colour was registered each session and 1 week and 1 months after completing the treatment by spectrophotometer, registering parameters L^*, a^* and b^*, and subjectively using VITA Classic guide. Tooth sensitivity was registered by VAS and patient satisfaction and self-perception result was determined using OHIP-14. Tooth colour variation and sensitivity were compared between both bleaching agents.

Results: Both treatment showed a change between baseline colour and all check-points with a $\Delta E = 5.57$ for 6% and of $\Delta E = 7.98$ for the 35% one month after completing the ($p < 0.05$). No statistical differences were seen when subjective evaluations were compared. Also, no differences were seen in tooth sensitivity between bleaching agents. OHIP-14 questionnaire demonstrated a significant change for all patients after bleaching.

Conclusions: A 6% hydrogen peroxide with nitrogen-doped titanium dioxide light activated agent is effective for tooth bleaching, reaching a ΔE of 5.57 one month after completing the treatment, with no clinical differences to a 35% agent neither in colour change or in tooth sensitivity.

Clinical significance: A low concentration hydrogen peroxide bleaching agent may reach good clinical results with less adverse effects.

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1. Introduction

In treatments for most teeth colour alterations, bleaching is the procedure of choice, because (1) it is minimally invasive, (2) it is quick and effective, and (3) it does not wear down tissue, as is the case with fixed prostheses. Patients are becoming more demanding and want effective treatment. The effectiveness of bleaching is defined as a change of at least 5 units of ΔE, which represents an increase in luminosity, mainly with an increase of the value in the colour of the bleached tooth.[1,2]

There are reports of cellular damage (to pulp cells) caused by typical concentrations of bleaching gel (38%), which has alarmed authorities, who have taken regulatory measures.[3] For example, the European Community banned concentrations above 6% for teeth bleaching procedures. Despite the restrictions, patients will continue consulting for bleaching, and therefore, dentists will have to search for and provide solutions.[2,4]

In general, in-office bleaching, with higher concentrations of hydrogen peroxide at 35%, are effective. Manufacturers recommend at least 2 sessions with applications of contact gel for 20 min or more to achieve the result.[5] The at home bleaching or similar systems, i.e., over the counter, such as whitening strips, use much lower concentrations of peroxide (6–10%),[5,6] but the contact time is much greater, even up to 20 h for effective bleaching. The challenge is to achieve effectiveness with low concentrations of peroxide to reduce adverse effects and the time in contact with the bleaching gel.

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%).[7–9] These concentrations show similar effectiveness, and in some cases, much lower adverse post-procedure effects. However, only one report[10] have used a concentration permitted by the European Community.[4,11] In this report by Vano et al. the patients do not achieve a change of at least 5 units ΔE, which was considered ineffective.[10]

Soares et al. recently reported on low-concentration (17.5%) and short-duration applications and found significantly reduced cellular damage under in vitro conditions.[12–14] There is interest in RCTs to assess compounds with lower concentration that would comply with standards such as those of the European Community. The objective of this work is to show the effectiveness of a bleaching gel (6%) catalyzed by titanium dioxide nanoparticles and activated by hybrid light. The effectiveness of the concentration was compared with that of a control concentration of 35% in a split-mouth study model. The null hypothesis of this study is that the effectiveness as a main outcome along the different times will be the same between the two gel methods.

2. Materials and methods

This clinical study was approved by the Ethics Committee of the Faculty of Dentistry at the University of Chile (PRI-ODO 15/01 and FIOUCH 13/18), where the study took place between July 2014 and December 2014. 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 Helsinsky Declaration of 1975 revised in 2000.

31 volunteers were selected and received a dental prophylaxis and oral hygiene instructions one week prior to the beginning of this study in order to achieve similar oral conditions. They also signed a term of free and informed consent.

2.1. Study design

This was a randomized, double-blinded (patients and evaluator), and split-mouth design (one hemiarcade [half of the dental arch, it can be left or right] was treated by compound 1 and the other by compound 2, which were randomly assigned) the simple randomization was performed (Excel 2000, Seattle, WA,USA). The patients were invited to participate in the study through posters posted 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 examined to check if they met the inclusion and exclusion criteria. The patients included in this study were over 18 years old. Participants were evaluated in a dental chair and after teeth prophylaxis with pumice and water to check if they met the following eligibility criteria of the study: 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. 31 patients were selected, and 1 patient was excluded from the analyses due to missed appointments (Fig. 1).

Two trained operators (restorative dentistry professors) performed the bleaching treatments. A third participant that did not have contact with the patients was responsible for

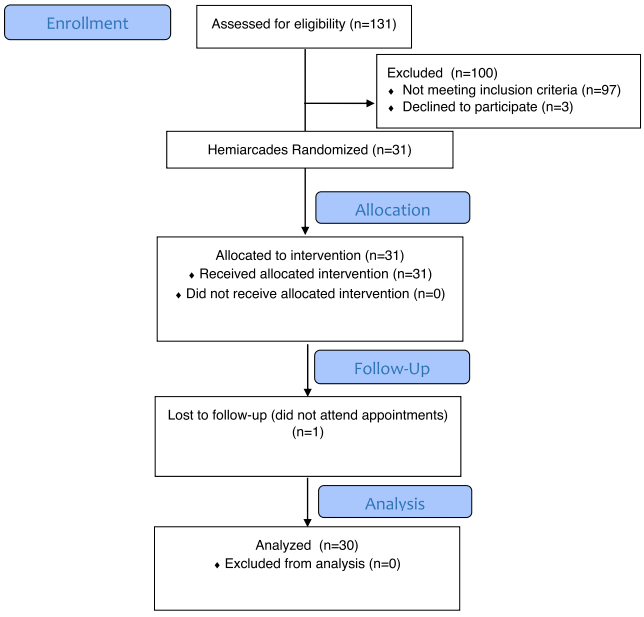

Fig. 1 – CONSORT flow diagram.

conducting the randomization. The allocation of the hemiarcades in the groups was performed by random drawing using Microsoft Excel 2010 (Microsoft, Redmond, Washington, USA) from coding assigned to each participant. There were two experimental groups: Group A acted as a control, and hydrogen peroxide bleaching compound was applied at a concentration of 35% to the upper hemiarcade. Group B was the experimental group, in which the other upper hemiarcade was treated with 6% compound (HP6) catalyzed by titanium oxide nanoparticles and activated by blue hybrid light with an infrared laser.

To ensure double blinding, the following procedures were adopted: (1) labels, logos, packaging, and any other aspect 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.

2.2. Sample size calculation

The primary outcome of this study was the efficacy determined by colour alteration (ΔE). Previous studies showed that the use of in-office bleaching agent containing 35% hydrogen peroxide (HP35) with or without LED/Laser light leads to a ΔE value of 7.0–2.0 after two bleaching sessions.[9,15,16] In order to have an 80% chance of detecting significance at the level of 5% and a $(1-\beta)$ of 0.90, and considering a change in the primary outcome measure from 7 in the control group to 5 in the experimental group, a minimum of 28 participants would be required. 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, which led to 31 patients.

2.3. Bleaching protocol

In each session, volunteers received prophylaxis with pumice powder and water. Then, 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 were prepared by mixing hydrogen peroxide and thickening compounds according to the manufacturer's instructions (with 3 peroxide drops for 1 drop of thickener). The resultant gels were distributed uniformly on the upper hemiarcade surfaces of the teeth. A total of 8 teeth between the first premolars were bleached for each patient. In each bleaching session, the bleaching gels were applied twice for 12 min each. In each application, the surface of the gel was light activated with continuous irradiance for 12 min using LED/laser hybrid light with a total power of 1500 mW (Bleaching Lase Plus–DMC Equipamentos, São Carlos, SP, Brazil). Three bleaching sessions were completed for the patients, and the interval between sessions was 7 days. The contact total time of 72 min for the bleaching treatment.

2.4. Objective evaluation

Two evaluators measured the tooth colour for the baseline (T0), immediately after the first (T1), second (T2), and third sessions (T3), and one week (T4) and one month (T5) after the third session. The colour evaluation was obtained from an area of 6 mm located in the middle third of the labial surface 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 reflectance of the spectrophotometer (Vita EasyShade Compact, VITA Zahnfabrik, Bad Säckingen, Germany), device with a high reability, over 96%.[17] The shade was determined using the obtained parameters L^*, a^*, and b^*. The colour alteration after each session was given by the differences between the values obtained at the session and the baseline Delta E (ΔE). ΔE was calculated using the following formula: $\Delta E = [(\Delta L^*)^2 + (\Delta a^*)^2 + (\Delta b^*)^2]^{1/2}$ calculated from the baseline values.

2.5. Subjective evaluation

For the subjective evaluation, two calibrated evaluators (Kappa = 0.85) used the 16 tabs of the shade guide (Vita Classic, Vita Zahnfabrik), which were arranged from the highest (B1) to the lowest (C4) value. Although this scale is not linear in the truest sense, we treated the changes as continuous with a linear ranking, as was done in several clinical trials of dental bleaching.[18] The evaluators recorded the shade of the upper central left and right incisors at baseline with the same periods as the objective evaluation.

We checked the colour in the middle third area of the labial surface of the anterior central incisors according to the American Dental Association guidelines. We calculated the colour changes from the beginning of the active phase through the individual recall times by the change in the number of shade guide units (ΔSGU), which occurred toward the lighter end of the value-oriented list of shade tabs. In the event that the operators disagreed on colour matching, a consensus was reached prior to dismissing the patient.

2.6. Tooth sensitivity evaluation

Tooth sensitivity (TS) was characterized by the variables occurrence and intensity. These data were obtained by self-completed form and clinical evaluation during the sessions and immediately after by VAS (Visual Analogue Scale). For the VAS, we instructed the participants to place a line perpendicular to a 100-mm-long line with zero at one end indicating "no TS" and the other end indicating "unbearable TS."

The occurrence was analyzed according to whether sensitivity was reported. The intensity was calculated at four levels according to a VAS scale: 1 = none, 2 = mild, 3 = moderate, 4 = considerable, and 5 = severe. The volunteers were instructed to fill out a form for each bleaching session and for the following days between sessions in case of sensitivity in any of the bleached teeth at any time.

2.7. OHIP-14 questionnaire

Satisfaction effect was measured using the OHIP-14 questionnaire validated in Chilean Spanish (Table 1).[19] The questionnaire

Table 1 – OHIP14—aesthetics questions for patients that received dental bleaching, (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).

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]

Table 2 – Baseline demographics features of volunteers.

	n	%	Median age (±SD)
Male	19	63.33	24.1 ± 5.81
Female	11	36.67	25.2 ± 7.4
Total	30	100.00	24.5 ± 6.33

was administered by a research operator at baseline and at 1 week and 1 month after bleaching. Each statement was accompanied by a Likert-type scale, which generated a score ranging from 4 to 0 (very often = 4, fairly often = 3, occasionally = 2, hardly ever = 1, never = 0). These individual scores were added together to give a summary score ranging from 0 (minimum) to 56 (maximum). The outcomes were considered the sum of the OHIP-14 and dimension scores, the internal consistency was evaluated using the Cronbach's Alpha test; test–retest reliability ($n = 30$) using the intra-class correlation coefficient (ICC).

2.8. 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 colour alteration (ΔE and ΔSGU) and analyzed by the Mann–Whitney test. The statistical analyses were performed using SPSS 22.0 (SPSS Inc., Chicago, IL, USA) with $\alpha = 0.05$.

Occurrence and intensity were evaluated while taking into consideration the concentration of hydrogen peroxide (HP6 and HP35). For occurrence, we used the Z test with $\alpha = 0.05$ (IBM SPSS Statistics 22.0). To describe intensity, the highest intensity for each patient during all treatments was selected. The intensity was only qualitatively evaluated. For TS, we recorded the median (VAS calculating to intensity scale) and mean (VAS scale) of the TS throughout the bleaching therapy for each participant that experienced TS. The percentage of participants who experienced TS at least once during the bleaching therapy was considered as the absolute risk of TS.

For comparison of OHIP-14 questionnaire scores, the Wilcoxon test was used.[20]

3. Results

3.1. Baseline characteristics

Of a total of 131 patients examined, 31 patients were selected, of which one did not continue in the monitoring. The sample consisted of 11 women (36.67%) and 19 men (63.33%) with average ages of 24.1 ± 5.81 years for men and 25.2 ± 7.4 years for women. There were no differences between the two groups in terms of the characteristics of the baseline colour ($p > 0.05$), as shown in Tables 2 and 3.

3.2. Objectively measured changes

Colour changes measured by units of ΔE from the baseline are shown in Fig. 2 and Table 4. There was a significant difference according to the Mann–Whitney test immediately after session 2 ($p = 0.024$) between the two groups and after one week ($p = 0$) and one month ($p = 0$). There is also a colour difference between the groups after one week and one month, with a noticeable difference greater than 2 units of ΔE (Fig. 2). To corroborate the statistical power and size effect of this

Table 3 – Baseline colour features of volunteers.

	L value (mean ± SD)	Confidence interval at 95%		a^* Value (mean ± SD)	Confidence interval at 95%		b^* Value (mean ± SD)	Confidence interval at 95%		SGU value (mean ± SD)	Confidence interval at 95%	
		Upper	Lower limit		Upper	Lower limit		Upper	Lower limit		Upper	Lower limit
Group A	84.65 ± 4.20	83.08	86.22	−0.32 ± 1.50	−0.88	−0.24	24.37 ± 4.01	22.87	25.87	7.10 ± 2.63	6.12	8.08
Group B	84.35 ± 4.61	82.63	86.07	−0.32 ± 1.24	−0.78	0.15	24.00 ± 3.52	22.69	25.31	7.20 ± 2.64	6.21	8.19

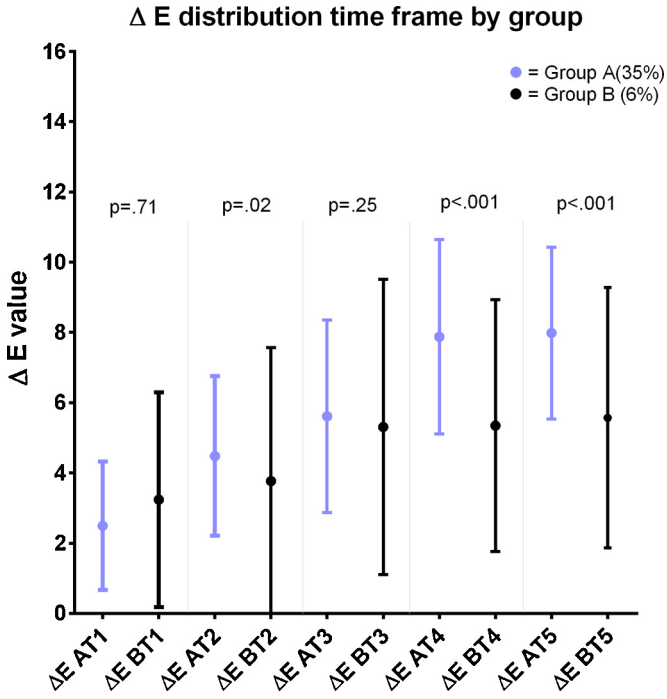

Fig. 2 – ΔE (Delta E) distribution expressed by mean and SD. The comparison was made by Mann–Whitney test ($p = 0.05$).

Table 4 – Changes of colour by ΔE (Delta E calculated from the baseline value) by group in different time frames expressed by mean, SD, statistical significance, effect size and statistical power.

ΔE	Group A	Group B	Mann–Whitney (p)	Effect size d	Power ($1 - \beta$)
T1: baseline vs. immediate S1	2.49 ± 1.83	3.24 ± 3.06	0.712	0.29	0.30
T2: baseline vs. immediate S2	4.48 ± 2.27	3.77 ± 3.80	0.024	0.22	0.21
T3: baseline vs. immediate S3	5.61 ± 2.74	5.31 ± 4.20	0.258	0.25	0.24
T4: baseline vs. week	7.87 ± 2.77	5.34 ± 3.58	0.000	0.79	0.90
T5: baseline vs. month	7.98 ± 2.45	5.57 ± 3.71	0.000	0.76	0.88

outcome was calculated post-hoc with the ΔE values by G-Power software.[21]

3.3. *Subjectively measured colour change*

Measured colour changes subjectively expressed by ΔSGU units are shown in Table 5. There is no significant difference between the different evaluations ($p > 0.3$).

3.4. *Occurrence and intensity of sensitivity*

The absolute risk of sensitivity reported for group A was 36.6% ($n = 11$), and that for group B was 50% ($n = 15$). There was no statistically significant difference when comparing the proportions of patients by the Z test ($p = 0.298$). The intensity of the sensitivity after sessions was mild, and there was no statistically significant difference between groups ($p > 0.4$). These data are shown in Table 6.

3.5. *OHIP-14*

The OHIP-14 survey scores (Table 7) at different times were significant when comparing the initial baseline survey prior to the treatment and a week after bleaching ($p = 0.006$), which was replicated after one month to obtain more reliable data. The results maintained a statistically significant difference ($p = 0.023$), specifically we had statistically significant difference a week in dimensions: functional limitation and Psychological discomfort, remaining statistically significant difference per month in Psychological discomfort dimension

Table 5 – Changes of colour by ΔSGU by group in different time frames expressed by mean and SD.

ΔSGU	Group A	Group B	Mann–Whitney (p)
T1: baseline vs. immediate S1	3.47 ± 2.13	3.67 ± 2.29	0.952
T2: baseline vs. immediate S2	5.17 ± 2.07	4.83 ± 2.21	0.414
T3: baseline vs. immediate S3	5.73 ± 2.42	5.33 ± 2.37	0.329
T4: baseline vs. week	5.30 ± 2.29	5.10 ± 2.31	0.680
T5: baseline vs. month	5.03 ± 2.30	4.83 ± 2.28	0.695

Table 6 – Sensitivity by VAS in groups by sessions ($p = 0.05$).

Sensitivity (VAS)	Group A (mean ± SD)	Group B (mean ± SD)	Mann–Whitney (p)
Baseline	0	0	1.000
T1: post first session	3.73 ± 6.52	3.53 ± 6.52	0.865
T2: post second session	3.20 ± 7.22	2.93 ± 7.77	0.759
T3: post third session	6.80 ± 17.16	3.53 ± 9.10	0.492

Table 7 – 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, * $p \leq 0.03$ compared to baseline by Wilcoxon test.

	Baseline	1 Week post-bleaching	1 Month post-bleaching	Corrected item total correlation of sum	Cronbach alpha's if item deleted
Functional limitation	4.80 ± 1.86	4.29 ± 1.59*	4.45 ± 1.87	0.867	0.714
Physical pain	4.19 ± 1.55	4.12 ± 1.62	4.19 ± 1.70	0.223	0.781
Psychological discomfort	5.58 ± 1.5	5.09 ± 1.46*	4.83 ± 1.59*	0.485	0.760
Physical disability	2.80 ± 1.10	2.70 ± 0.97	2.64± 0.91	0.779	0.749
Psychological disability	3.32 ± 1.83	3.16 ± 1.71	3.19 ±1.53	0.833	0.719
Social disability	2.58 ± 1.25	2.51 ± 1.20	2.48 ± 1.26	0.632	0.754
Handicap	2.64 ± 1.45	2.51 ± 1.36	2.41 ± 1.05	0.753	0.739
OHIP-EE-14	51 ± 25.93	49 ± 24.41*	46 ± 24.22*	1	

shown in Table 7, which shows that there was an effect perceived in the survey, and it remained for at least a month. The internal consistency by Alpha Cronbach test (0.749) and repeatability [intraclass correlation coefficient (ICC)] by total OHIP-14 was (0.749) with IC 95% (0.667 Lower/0.818 Upper Bound).

4. Discussion

In this randomized clinical study, a treatment was proposed that was thought to be a risky design (split-mouth).[22,23] This was done to demonstrate the effectiveness of a protocol that has not very explored with a very low concentration of hydrogen peroxide (6%). Since there was no certainty that the two compounds tested would have similar effectiveness, there was an explicit statement in the informed consent form indicating that if patients perceived a difference in the colour of their hemiarcades, the research team would match the colours. There were statistically significant differences in weekly and monthly checks in the results, and the research team released the analysis of the data and offered colour matching to all patients. However, none accepted, because they expressed satisfaction with the treatment.

Despite not being fully applicable to patients undergoing a bleaching procedure, the OHIP-14 questionnaire was considered adequate to assess satisfaction and aesthetic self-perception.[24] The questionnaires were applied before and after the bleaching at one week and one month to increase the reliability of the data. The aesthetic component measured by OHIP-14 probably influenced the significant difference in the scores after one week and one month for the bleaching effectiveness. The positive change was evident in the self-perception of dental aesthetics at the end of bleaching and a month later, which supports the proposal that the self-perception of dental aesthetics is modified positively by teeth bleaching. The analysis showed a temporary effect on functional limitation dimension, probably by a positive psychological effect that led to think temporarily that there was a functional improvement and over the weeks the effect concluded. And the most important effect was on the psychological discomfort dimension that showed improvement and there was a maintenance to the month post-bleaching, keeping the intervention effect. Would be interesting to know if this effect persists and associate it with the duration of the effectiveness of tooth whitening.

The results of the effectiveness of bleaching based on ΔE are quite interesting. Immediately after the third session of treatment, the colour remains without a significant difference, while after one week and one month, there is a significant change. In addition to the recovery of the tooth and the stabilization of the colour, we propose that there is a bleaching effect that continues after the treatment for group A, which is probably related to the amount of peroxide that diffuses through tissues of the tooth and stays there. In vitro studies by Mena–Serrano et al. attempted to explain this phenomenon.[25] Perhaps if the study had not used a split-mouth design, patient inter-variability factors would not have revealed this great finding related to the concentration of peroxide and the persistence of the bleaching effect.

The effectiveness of the outcomes is evident, and there is no argument that the hemiarcades that were bleached with 35% bleaching compound had greater effectiveness. The 6% compound was considered effective, since according to Bizhang et al., bleaching is considered effective when there is at least a difference of 5 units of ΔE.[26] This is very important, since it would mean that this clinical protocol would be within the regulatory framework of the European Community standards and offer an alternative for patients seeking bleaching. In future studies, the best application time should be determined, as well as intervals between sessions to achieve better performance of the compound with minor adverse effects.[27,28]

Subjective outcomes measured by the variation of SGU units are shown to be inconsistent with the objective results. The subjective determination of tooth colour is challenged by high variability. Interference by surrounding light is a disadvantage of the subjective colour determination, as is the variability of the subjective colour impression,[26] which could explain the high bias that exists in the measurements of

two neighbouring central incisors belonging to different groups. The optical effect of the two central incisors together complicates the differentiation of colour. In addition, the human eye fails to differentiate between minor changes of units of SGU, which would explain the high patient satisfaction despite having obtained significant objective differences between both hemiarcades. Subjective assessment may not be a good tool for a split-mouth design in bleaching clinical trial.[29]

Hydrogen peroxide concentration and application duration are the two factors that determine the overall tooth-bleaching efficacy, with best results achieved with higher peroxide concentration. In this study, although bleaching agents had differences in peroxide concentration, both achieved effective results after being applied in three clinical appointments, with very low sensitivity in both groups.

To achieve the bleaching of teeth in group B (6%), nitrogen doped titanium dioxide nanoparticle semiconductors (N_TiO_2) were used. When exposed to blue light, the titanium dioxide catalyzes the formation of hydroxyl radicals from hydrogen peroxide. The combination of low-concentration hydrogen peroxide with titanium dioxide might be safer than high-concentration hydrogen peroxide due to the formation of O_2^- without OH^- radicals, which are a risk factor for bleaching. The use of N_TiO_2 permits activation by visible light. This combination is a clinically effective and safe method for discoloured teeth that causes less augmentation of pulpal sensitivity after the treatment. It is known that an infrared laser acts at a wavelength that can promote a high polarization of the nervous membrane, thus diminishing the generation of action potentials and consequently reducing the occurrence and the intensity of the generated sensitivity in both groups. This could explain the low sensitivity throughout the study for both groups.[15,30]

In relation to the absolute risk of sensitivity, data are consistent with that reported in the literature for both groups (36.66–50%).[28,31] However, the data differ from some reports that compared different concentrations like Bortolatto et al.[9] Martin et al.[16] presented results that suggest that a higher concentration of the bleach compound generates greater risk of sensitivity. The intensity of reported sensitivity was mild, which coincides with previous work by our group.[16] The result could be due to the very strict selection of patients having teeth without cracks or defects,[32] a rule required by the local ethics committee in order to avoid problems of rapid spread to the camera pulp and rear sensitivity. The second reason was exposure to the LED/laser hybrid light explains the significant drop in the intensity of group A (35%), which is important for the comfort and satisfaction of patients treated for bleaching. The design of the lamp does not isolate the irradiation of the laser/LED light to only one hemiarcade, and this drawback has a positive effect on the normal side effects of bleaching expressed in our results[16].

Methodologically, the blindness of operators, evaluators, and all of the equipment was very strict, since the DMC manufacturer and supplier of bleaching compounds prepared two formulas in bottles only labeled with letters (A or B), meaning that work was done only with codes until the end of the analysis of the project. Once completing the analysis, the company unveiled the concentrations of the product. As future work, it would certainly be interesting to follow the regression of colour in these patients and to assess whether the likely ''penetration'' of the 35% compound achieved greater effect over time.[33]

5. Conclusions

Within the limitations and protocols of this study, there was a significant difference between the objective effectiveness in the two groups. The two compounds were considered to be effective, and there were no differences in the sensitivity generated between the groups. The intensity of post-operative sensitivity was mild. Patients were satisfied with the bleaching procedure, despite objective differences between both hemiarcades.

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Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at http://dx.doi.org/10.1016/j.jdent.2015.05.011.

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