

Randomized Clinical Trial on the Efficacy and Safety of Four Professional At-home Tooth Whitening Gels

V Alonso de la Peña • M López Ratón

Clinical Relevance

Based on the results obtained in this study, in which no statistical differences in the degree of whitening with the different gels were found, we would recommend the use of gels at a lower concentration.

SUMMARY

Objective: This randomized clinical trial evaluated the efficacy and safety of four gels of differing concentrations used for at-home vital bleaching.

Materials and Methods: Ninety-six volunteers participated in the study and were divided into four groups of 24 individuals. A gel of differing concentration was used for each group: 10% and 15% carbamide peroxide and 7.5% and 9.5% hydrogen peroxide. The patients used the whitening agent in a tray without reservoirs for one hour per day for two weeks. **The measurement of the change in tooth color**

*Victor Alonso de la Peña, MD, DDS, PhD, School of Dentistry, Faculty of Medicine and Dentistry, Santiago de Compostela, Spain

Mónica López Ratón, PhD, Unit of Biostatistics, Department of Statistics and Operations Research, Faculty of Medicine, Santiago de Compostela, Spain

*Corresponding author: C./Dr. Teijeiro, No. 11, 4 ° derecha, 15701, Santiago de Compostela, La Coruña, Spain; e-mail: victorap@mun-do-r.com

DOI: 10.2341/12-402-C

was made by two observers in the maxillary right central incisor and with a colorimeter in both upper central incisors and canines, using the CIE L*a*b* and CIE L*C*h* values. Sensitivity was evaluated by the participants on a scale with values as follows: 0 = absent, 1 = minor, 2 = moderate, 3 = considerable, 4 = severe.

Results: At the baseline, the observers noted darker colors than the colorimeter ($p < 0.01$), and there were differences between incisors and canines in all the CIE L*a*b* and CIE L*C*h* values ($p < 0.001$). In all of the groups and for all of the CIE L*a*b* and CIE L*C*h* parameters, there were color changes in the assessments made in the four maxillary teeth after treatment ($p < 0.001$). There were no differences in ΔL^* and ΔE^* between the groups. The number of patients who experienced sensitivity and the intensity of the sensitivity were not significant.

Conclusions: There were no differences in the degree of whitening among the different products. With all of the products there was an increase in L*, a decrease in chromatic inten-

sity (C^*), and an increase in the value (tone) or hue (h^*).

INTRODUCTION

Ever since Haywood and Heymann¹ described night-guard vital bleaching in 1989, there have been various concentrations of hydrogen peroxide (HP) and carbamide peroxide (CP) used for at-home vital bleaching.^{2,3} The American Dental Association only considers 10% CP to be a safe whitener.⁴ The Scientific Committee on Consumer Products of the European Commission states that those whitening products with a HP concentration higher than 6% cannot be considered safe for the consumer.⁵

The principal compound responsible for dental whitening is HP (H_2O_2).⁶ A 10% CP gel is composed of approximately 3.5% H_2O_2 and 6.5% urea.⁷ Therefore, a 3.5% HP concentration should have a whitening effect similar to a 10% CP.⁸ A 25% CP gel is composed of 8.7% H_2O_2 and thus would be the equivalent of a 7.5% HP gel.⁹

There are different protocols in the daily application time for gels applied with a tray: 30 minutes, one hour, two hours, and up to eight hours overnight.¹⁰ Dental sensitivity and gingival irritation are well-known side effects.¹¹⁻¹³ Numerous clinical studies demonstrate the effectiveness of at-home vital bleaching.¹⁴ The evaluation of the whitening effectiveness is made through observation and color guides, in particular the Vitapan Classical guide (Vita Zahnfabrik, Bad Säckingen, Germany)¹⁵⁻¹⁸; the colorimeter^{10,19-21}; image digitalization; and software evaluation.²²⁻²⁵

The Commission Internationale d'Eclairage developed the CIE $L^*a^*b^*$ system.²⁶ It is a tridimensional grid in which all colors visible to the human eye are located. Colorimeters or digital spectrophotometers measure color based on the following parameters: the lightness of the color, L^* (0 being black and 100 being white); a^* , in which negative values indicate green and positive values indicate red; and b^* , in which negative values indicate blue and positive values indicate yellow. The difference between colors is given by the formula $\Delta E = \sqrt{\Delta L^{*2} + \Delta a^{*2} + \Delta b^{*2}}$, which does not express the direction in which the color deviation is oriented. Based on the CIE $L^*a^*b^*$, CIE $L^*C^*h^*$ can be determined, whereby $C^* = \sqrt{a^{*2} + b^{*2}}$ and represents chroma or saturation. This ranges from 0, which represents no saturation (ie, a neutral gray, black, or white), to 100 or more for very high chroma (saturation) or "color purity." The hue, $h^* = b/\sqrt{a^{*2} + b^{*2}}$, indicates the tone and is expressed in

degrees and thus the position of the color within a sphere. On converting the $L^*a^*b^*$ coordinates to $L^*C^*h^*$, positive numbers are produced, and since each value represents a characteristic of the color (lightness, saturation, and tone), it is easier to interpret the data. The differences between two values are determined as $\Delta L^* = L^*_1 - L^*_0$, $\Delta a^* = a^*_1 - a^*_0$, $\Delta b^* = b^*_1 - b^*_0$, $\Delta C^*_{ab} = C^*_{ab,1} - C^*_{ab,0}$, and $\Delta h^*_{ab} = h^*_{ab,1} - h^*_{ab,0}$.

The purpose of this study was to evaluate the changes in color, by means of visual evaluation and use of a colorimeter, of four whitening agents used at home with customized trays for one hour per day over the course of 14 days to show which concentration is the most effective and to evaluate the sensitivity produced.

MATERIALS AND METHODS

This was a controlled, parallel, randomized, one-center clinical study undertaken at the Faculty of Medicine and Dentistry in Santiago de Compostela (Spain) that was approved by the faculty's ethics committee. Ninety-six volunteers participated, 68 women and 28 men, with an average age of 25.9 years (± 5.6 years), selected consecutively according to the inclusion and exclusion criteria described in Table 1. Before beginning the treatment, all of the participants signed an informed consent in which the treatment they were going to receive, as well as its side effects, were explained in detail. They were randomly divided into four study groups of 24 individuals by alphabetical order. Each of the groups used the following outpatient whitening gels: 10% CP (Opalescence PF 10%, Ultradent, South Jordan, UT, USA); 15% CP (Illuminé Home, Dentsply, Konstanz, Germany); 7.5% HP (Poladay, SDI, Melbourne, Australia); and 9.5% HP (Poladay, SDI).

At the first visit, personal information was recorded and a dental prophylaxis (Kerr Hawe Cleanic, Kerr Hawe SA, Bioggio, Switzerland) was performed for all patients in order to facilitate extrinsic stain removal. Immediately, alginate impressions (Cavex, Fast Set, Dust Free, Keur & Sneltsjes, The Netherlands) were made of both arches. After obtaining models cut in a horseshoe shape, customized trays without reservoirs were made using 1-mm-thick soft trays (Clear-Mouth-guard Henry Schein Inc, Melville, NY, USA) with an Econo-Vac machine (Buffalo Dental Manufacturing, Syosset, NY, USA). The splints were then trimmed to within 1 mm of the gingival margin, taking care not to cover the interdental papillae. A positioner for the colorimeter was also made using 4-mm-thick

| Inclusion Criteria | Exclusion Criteria |
|---|---|
| 18 y of age or older A minimum of 24 natural teeth, including incisors, canines, and premolars in both arches Good oral hygiene Absence of periodontal disease Sillness and L oe index ≤ 1 Absence of gingival recession Availability in the area of the study for a minimum of 4 wk | Systematic illness; persons undergoing medical treatment Requirement of antibiotic prophylaxis for dental treatment Patients under analgesic and/or anti-inflammatory therapy Pregnant or breast-feeding women Tumors of the soft or hard tissues of the oral cavity Xerostomia; alterations of the oral mucosa Smokers The presence of restorations in the six anterior teeth of either arch Active caries Periapical pathology Staining due to tetracycline or fluorosis Structural alteration of the tooth structure; Amelogenesis Exposed dentin in anterior incisors; general hypersensitivity Bruxism The use of fluoride supplementation or desensitizing agent The use of stain-inducing medications for oral use Removable prosthesis Currently undergoing orthodontic treatment Having undergone any other previous whitening treatment |

clear plates. Four orifices were made in the middle third of the maxillary central incisors and canines of the same diameter at the point of the colorimeter's probe with a 6-mm external diameter trephine in order to ensure that the color was always recorded in the same place on the tooth (Figure 1).

The colorimeter used was a Vita Easy Shade (Vita Zahnfabrik, Bad Sackingen, Germany). It is designed for dental use and has a 6-mm-diameter sensor. This colorimeter registers the colors of the Vita Classical Guide and shows the L^* , a^* , b^* , C^* , and h^* coordinates of the chromatic space of the measurement taken.

Two examiners received training through color evaluation of 42 dental students. Measurements were taken in the middle third of the maxillary right central incisor. The room in which the



Figure 1. Positioner for the digital spectrophotometer.

evaluations were made had an illumination of 6,500 Kelvin. A shade guide (Vitapan Classical, Vita Zahnfabrik) was used and ordered by lightness according to the manufacturer's recommendations. The training was completed when an 80% concordance between both observers was reached by means of the kappa test.

During the second visit, the tray and position-finder for the colorimeter of each participant were tested for fit. Each participant was given a whitening kit. In all of the groups, the administration of the gel was for one hour per day over the course of two weeks. Before beginning the treatment, the two observers determined the initial dental color of the middle third of the upper right-hand central incisor using the Vitapan Classical shade guide, ordered by lightness. To determine the clinical result and for statistical analysis, a numeric value between 1 and 16 (shade tabs) corresponding to the sequence: B1 (1), A1 (2), B2 (3), D2 (4), A2 (5), C1 (6), C2 (7), D4 (8), A3 (9), D3 (10), B3 (11), A3.5 (12), B4 (13), C3 (14), A4 (15), C4 (16), and C4 (16) was assigned.^{10,19,21,22} For example, if after the whitening treatment the color changed from A2 to a B1, it was counted as a change of four shade tabs.

With the position-finder placed in the mouth, the Vita Easyshade colorimeter was used to measure the Vita Classical colors and L^* , a^* , b^* , C^* , h^* coordinates for the right and left maxillary central incisors and canines.

The subjects registered the sensitivity they experienced during the whitening treatment on a daily basis, filling in a questionnaire with a simplified

Table 2: The Mean (Standard Deviation, SD) of CIE L*a*b* and L*C*h* Baseline Values Measured by the Colorimeter in 96 Participants

| | Maxillary Central Incisors (n=192), Mean (SD) | Maxillary Canines (n=192), Mean (SD) | p-Value Incisors-Canines |
|----|---|--------------------------------------|--------------------------|
| L* | 83.5 (4.2) | 77.4 (4.3) | <0.001*** |
| a* | -1.1 (0.9) | 1.6 (1.2) | <0.001*** |
| b* | 18.7 (3.5) | 27.4 (3.9) | <0.001*** |
| C* | 18.8 (3.4) | 27.6 (4.0) | <0.001*** |
| h* | 93.8 (3.3) | 86.6 (3.1) | <0.001*** |

*** Statistically significant difference at 0.1% level.

scale, as follows: 0 = none; 1 = mild; 2 = moderate; 3 = considerable; and 4 = severe.^{10,19} When a participant had differing severities of sensitivity in the first or second week, the highest value was registered.

At the following visit, 14 days later, and after having completed the treatment, the color was determined both by the observers and the colorimeter, and the sensitivity survey was collected.

The assumption of normality for all variables was analyzed by means of the Kolmogorov-Smirnov test. For the study of the measurement of the observers and the colorimeter via the Classical Guide, the marginal homogeneity test was used. The study of the CIE Lab parameters was conducted by means of the Wilcoxon test. The Kruskal-Wallis and Friedman tests were utilized for the study of the sensitivity registered with the different products each day.

RESULTS

All 96 participants completed the study. The determination of color made by the observers in the middle third of the upper central incisor of the participants before beginning the treatment was, according to the Vita Classical Guide shade tabs, 5.33 (± 3.09), whereas the color registered by the

colorimeter was 4.20 (± 2.89). This difference was statistically significant ($p < 0.01$). In the measurements made with the colorimeter at the baseline in both the central incisors and upper canines, there were significant differences in all the CIE L*a*b* and CIE L*C*h* parameters ($p < 0.001$). The canines had a lower lightness and more chromatic intensity or saturation. Their positive values for a* (1.6 ± 1.2) indicate a redder color than was associated with the incisors. The value h* was superior in the incisors (93.8 ± 3.1) to that in the canines (86.6 ± 3.1), which indicates that the incisors had a more yellow color. This was also indicated by the higher positive value for b* (Table 2).

The color changes noticed by the observers and the colorimeter in the right upper central incisor after 14 days of treatment were significant in all of the groups ($p < 0.01$). If the colors noted by the observers are compared with the data from the colorimeter, there were significant differences between the two groups (Table 3). With regard to the CIE L*a*b* parameters, in all the groups, there were significant differences noted when comparing the recordings at the beginning and the end of the treatment (Table 4). In all of the gels studied, on the 14th day, when the whitening treatment was stopped, the teeth had higher luminosity (L*) and lower chromatic intensity (C*). The angle of the value for the color (h*) increased, which indicates a movement from yellow toward green. The decreases in the a* and b* values indicate movement toward green and blue, respectively. No statistically significant differences in ΔL^* and ΔE^* were detected between the groups. Once the whitening had been completed, the differences in the results obtained between incisors and canines were statistically significant in all of the groups and for all of the parameters, with the color change in the canines being most noticeable (Table 5; Figure 2).

With regard to the sensitivity reported by the patients, no differences were found in the numbers of patients who reported sensitivity, during the first

Table 3: Mean (Standard Deviation, SD) Changes in Color Values of the Middle One-third of the Facial Surface of the Right Upper Central Incisor After 14 Days, as Measured by Examiners (Visual Evaluation) and by Spectrophotometer; Vita Classical Shade Tabs

| | Examiners (n=96), Mean (SD) | Spectrophotometer (n=96), Mean (SD) | p-Value examiners-spectrophotometer |
|---------|-----------------------------|-------------------------------------|-------------------------------------|
| CP 10% | 3.5 (2.2) | 2.0 (1.7) | <0.05* |
| CP 15% | 1.1 (0.7) | 0.7 (0.9) | 0.230 |
| HP 7.5% | 4.9 (2.3) | 1.3 (1.9) | <0.001*** |
| HP 10% | 1.8 (1.6) | 1.0 (2.0) | 0.176 |

Abbreviations: CP, carbamide peroxide; HP, hydrogen peroxide.

*** Statistically significant difference at 0.1% level; * Statistically significant difference at 5% level.

Table 4: Mean (Standard Deviation, SD) Changes in Tooth Color Values Measured by Spectrophotometer in Both Maxillary Central Incisors and Canines After Whitening (14 Days)

| Group | Mean (SD) | P, 0-14 d |
|----------------|------------|-----------|
| CP 10% (n=24) | | |
| ΔL^* | 4.4 (2.8) | <0.001*** |
| Δa^* | -1.0 (1.2) | <0.001*** |
| Δb^* | -4.3 (2.8) | <0.001*** |
| ΔC^* | -4.4 (3.2) | <0.001*** |
| Δh^* | 1.6 (2.4) | <0.001*** |
| ΔE^* | 6.6 (3.5) | <0.001*** |
| CP 16% (n=24) | | |
| ΔL^* | 3.7 (3.8) | <0.001*** |
| Δa^* | -1.2 (1.2) | <0.001*** |
| Δb^* | -3.8 (3.6) | <0.001*** |
| ΔC^* | -3.7 (3.5) | <0.001*** |
| Δh^* | 4.3 (3.6) | <0.001*** |
| ΔE^* | 6.5 (4.0) | <0.001*** |
| HP 7.5% (n=24) | | |
| ΔL^* | 3.4 (3.7) | <0.001*** |
| Δa^* | -1.7 (1.3) | <0.001*** |
| Δb^* | -5.3 (3.3) | <0.001*** |
| ΔC^* | -5.5 (2.9) | <0.001*** |
| Δh^* | 5.9 (3.4) | <0.001*** |
| ΔE^* | 7.4 (2.6) | <0.001*** |
| HP 10% (n=24) | | |
| ΔL^* | 3.6 (3.0) | <0.001*** |
| Δa^* | -1.3 (1.4) | <0.001*** |
| Δb^* | -4.4 (4.6) | <0.001*** |
| ΔC^* | -4.4 (4.5) | <0.001*** |
| Δh^* | 4.8 (3.9) | <0.001*** |
| ΔE^* | 7.1 (4.0) | <0.001*** |

Abbreviations: CP, carbamide peroxide; HP, hydrogen peroxide.
*** Statistically significant difference at 0.1% level.

week ($p=0.381$), the second ($p=0.103$) week, or during the 14 days of treatment ($p=0.202$). There were no differences in the intensity of the sensitivity (Table 6).

DISCUSSION

The whitening trays were not made with reservoirs. Some researchers claim that the use of reservoirs does not produce improved whitening²⁸ or that they result in whitening that is only appreciable by a colorimeter and not with color guides or photographs.²⁹ Kirsten and others³⁰ affirm that the reservoirs result in an increase in inflammation in the gingival mucosa.

Table 5: Mean (Standard Deviation, SD) Differences in Color Between Central Incisors and Canines After Whitening; Measurements Taken in Both Upper Central Incisors and Canines

| Group | Maxillary Central Incisors (n=48), Mean (SD) | Maxillary Canines (n=48), Mean (SD) | p-Value Incisors-Canines |
|--------------|--|-------------------------------------|--------------------------|
| CP 10% | | | |
| ΔL^* | 2.7 (1.7) | 6.0 (2.8) | <0.001*** |
| Δa^* | -0.1 (0.8) | -2.0 (0.9) | <0.001*** |
| Δb^* | -2.5 (1.7) | -6.1 (2.5) | <0.05* |
| ΔC^* | -2.7 (3.1) | -6.1 (2.3) | <0.05* |
| Δh^* | 0.2 (2.0) | 6.5 (3.3) | <0.001*** |
| ΔE^* | 4.1 (1.8) | 9.1 (3.1) | <0.001*** |
| CP 16% | | | |
| ΔL^* | 1.9 (2.5) | 5.5 (4.0) | <0.001*** |
| Δa^* | -0.2 (0.5) | -2.1 (1.0) | <0.001*** |
| Δb^* | -1.9 (2.7) | -5.8 (3.3) | <0.001*** |
| ΔC^* | -1.9 (2.4) | -5.4 (3.5) | <0.001*** |
| Δh^* | 2.1 (2.5) | 6.5 (3.3) | <0.001*** |
| ΔE^* | 4.0 (2.3) | 9.1 (3.8) | <0.001*** |
| HP 7.5% | | | |
| ΔL^* | 1.2 (2.6) | 5.5 (3.5) | <0.001*** |
| Δa^* | -0.7 (0.5) | -2.7 (1.2) | <0.001*** |
| Δb^* | -3.9 (2.0) | -6.7 (3.7) | <0.001*** |
| ΔC^* | -4.0 (1.6) | -7.0 (3.2) | <0.001*** |
| Δh^* | 4.8 (2.5) | 7.0 (3.9) | <0.01** |
| ΔE^* | 5.0 (1.8) | 9.8 (3.5) | <0.001*** |
| HP 10% | | | |
| ΔL^* | 1.8 (1.6) | 5.5 (3.1) | <0.001*** |
| Δa^* | -0.4 (0.7) | -2.3 (1.3) | <0.001*** |
| Δb^* | -3.3 (3.0) | -5.6 (5.5) | <0.001*** |
| ΔC^* | -3.1 (3.0) | -5.7 (5.4) | <0.001*** |
| Δh^* | 3.2 (3.9) | 6.5 (3.3) | <0.001*** |
| ΔE^* | 4.6 (2.3) | 9.7 (3.8) | <0.001*** |

Abbreviations: CP, carbamide peroxide; HP, hydrogen peroxide.
*** Statistically significant difference at 0.1% level; ** Statistically significant difference at 1% level; * Statistically significant difference at 5% level.

The subjectivity of the evaluation of whitening by observers has already been described.^{2,31,32} Furthermore, the classic Vita guide was not designed for judging the change in color after whitening. The guide is also nonlinear in scale and lacks color uniformity, while the overlap between similar colors provides little resemblance to reality.^{10,33} One explanation for observers seeing darker colors than the colorimeter at the beginning of the study and lighter ones at the end could be because the study was not blinded. After undergoing the whitening treatment in the evaluations using the Vita Classical Guide ordered by lightness, we observed that in

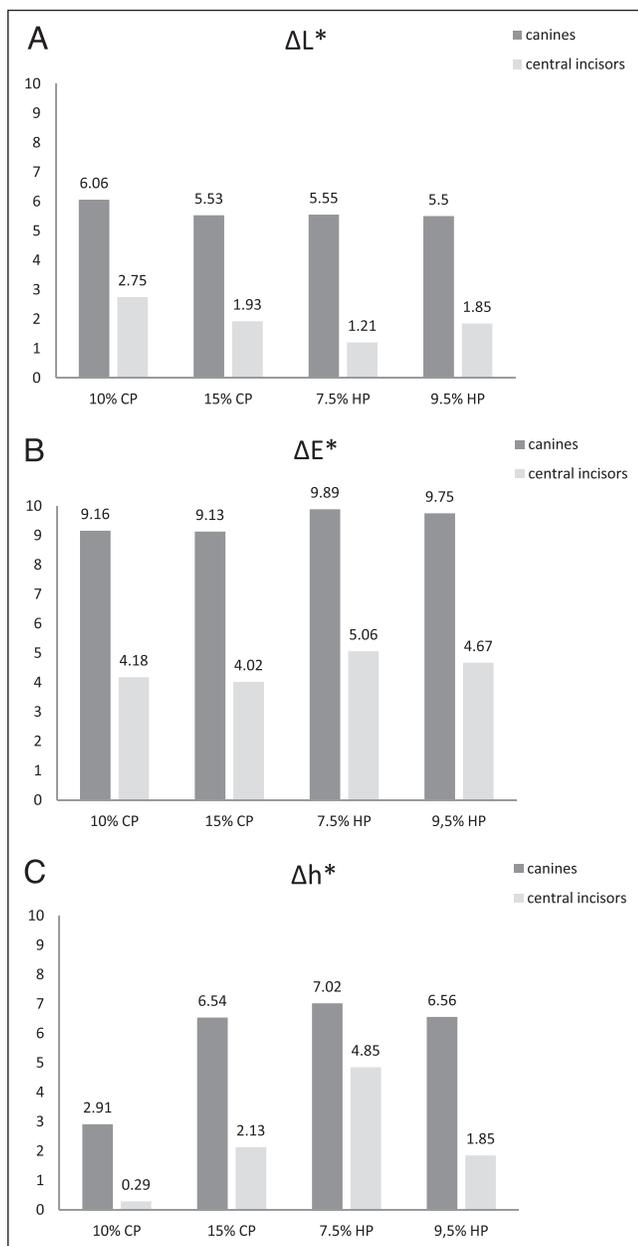


Figure 2. (A) Mean values of the changes in lightness (ΔL^*) measured with the colorimeter in upper central incisors and canines after 14 days of treatment. (B) Mean values of the changes in ΔE^* measured with the colorimeter in upper central incisors and canines after 14 days of treatment. (C) Mean values of the changes in value or tone (h^*) measured with the colorimeter in upper central incisors and canines after 14 days of treatment.

some cases, the color was considered by the observers to be even lighter than B1, a lightness score that could not be quantified. In similar studies in which 10% CP was used, observers determined with the Vita Classical Guide that there had been whitening of 5.4¹⁰ and 3.85 shade tabs.²³ In this study, the whitening measured 3.59 shade tabs.

In the majority of the studies on the subject, positioners were not designed to ensure that the colorimeter would always measure the color at the same place.^{19,21,34} The teeth in which the measurements were made varied according to the study, with measurements occurring in the upper central incisors,^{10,24} the upper lateral and central incisors,^{15,18} in the six anterior maxillary teeth,^{13,16,19,21,22,25} or in the upper and lower anterior teeth.²⁰ In this study and in others³⁵ it has been determined that, between nonwhitened incisors and canines, there are statistically significant differences in the CIE $L^*a^*b^*$ values. Additionally, it has been affirmed that the data obtained by different colorimeters are not comparable.³⁶⁻³⁹ When software for the analysis of images obtained by a photographic camera is used to measure the degree of whitening, it is always different.²²⁻²⁵

Meireles and colleagues¹⁹ used the same colorimeter to measure the color in the six anterior teeth after a two-hour daily application (over the course of three weeks) of 10% CP: $\Delta L^* = 3.8$, $\Delta E^* = 4.3$ and 16% CP $\Delta L^* = 3.7$, $\Delta E^* = 4.6$. For the same concentrations of whitening agent, our results, $\Delta L^* = 4.41$ and 3.73 and $\Delta E^* = 6.67$ and 6.57, were measured in central incisors and canines, respectively. Using a Vita Easyshade Compact colorimeter for a 10% CP treatment applied for one hour per day over the course of 16 days, Cardoso and colleagues¹⁰ measured $\Delta E^* = 5.8$ in the upper central incisor. Our result for 10% CP in the incisor measurements was $\Delta E^* = 4.18$.

Studies in which different concentrations of CP (10%, 15%-17%) are compared have concluded that the whitening results are similar¹⁸⁻²⁰ or, on the contrary, that higher concentrations whiten more.⁴⁰ Delgado and colleagues¹⁶ affirm that there are no differences between 9% HP and 20% CP. Comparing 7.5% HP and 20% CP, Ziebolz and colleagues²⁴ did not see differences in ΔL^* and Δa^* . This finding coincides with our results, in which no significant differences were found in ΔL^* and ΔE^* in the study groups.

The evaluation of sensitivity is reported by patients on a scale that is different in each study: "Yes" or "No,"¹⁵ from 0 (none) to 4 (severe),^{10,19,40} and from 0 to 10 (high hypersensitivity).²⁴ In those studies^{19,24,25,40} in which a scale similar to the one used in this work was used, the average intensity of the sensitivity provoked by at-home whitening, as in this study, was never "considerable" or "severe."

Table 6: Patients Experiencing Sensitivity and its Intensity; Percentages in Parentheses; Mean (Standard Deviation)^a

| | CP 10% (n=24) | CP 15% (n=24) | HP 7.5% (n=24) | HP 9.5% (n=24) |
|------------------------------------|---------------|---------------|----------------|----------------|
| Sensitivity days 1-7 | 12 (50%) | 11 (45.8%) | 13 (54.2%) | 13 (54.2%) |
| Intensity of sensitivity days 1-7 | 0.33 (0.47) | 0.38 (0.49) | 0.36 (0.50) | 0.53 (0.64) |
| Sensitivity days 8-14 | 6 (25%) | 11 (45.8%) | 10 (41.7%) | 11 (45.8%) |
| Intensity of sensitivity days 8-14 | 0.20 (0.42) | 0.29 (0.46) | 0.35 (0.48) | 0.38 (0.52) |
| Sensitivity days 1-14 | 13 (54.2%) | 13 (54.2%) | 14 (58.3%) | 14 (58.3%) |
| Intensity of sensitivity days 1-14 | 0.27 (0.46) | 0.33 (0.47) | 0.37 (0.51) | 0.44 (0.57) |

Abbreviations: CP, carbamide peroxide; HP, hydrogen peroxide.
^a Tooth sensitivity evaluation: 0 = no; 1 = mild; 2 = moderate; 3 = considerable; and 4 = severe.

In other works, the percentages of participants who had sensitivity with the 10% CP varies from 13%, with a one-hour daily application,¹⁰ to 41% and 43% for 16% CP applied for two hours per day.¹⁹ In our study, the figure was 54% for a one-hour daily application for both concentrations. With the 7.5% HP, the sensitivity was 44%²⁴ and 58% in the present study. We registered 58% of patients reporting sensitivity with the 9.5% HP, whereas in another study in which 9.5% HP was applied for 30 minutes daily over the course of nine days, it did not surpass 30%. Meireles and colleagues¹⁹ affirm that 16% CP provokes more sensitivity than does 10% CP. Ziebolz and colleagues²⁴ maintain that more sensitivity occurs with 20% CP than with 7.5% HP, whereas in another study,⁴⁰ as in the present work, there were no significant differences between these concentrations. Furthermore, the CP gels used in this study used desensitizing products in their composition.

CONCLUSIONS

Based on the results obtained in this study, in which no statistical differences in the degree of whitening with the different gels were found, we would recommend the use of gels at a lower concentration, as is recommended by the American Dental Association and the Scientific Committee on Consumer Products of the European Commission. As a result of the use of different colorimeters or photographic cameras with measurements taken on different teeth, we believe that studies evaluating the effectiveness of whitening treatments are difficult to compare results. A standardized method is needed for the evaluation of the effectiveness of whitening and the safety of gels applied at home. All of the products used produced a lowering of chroma or saturation and an increase in lightness and hue. Negative a* and b* values indicate a movement in the chromatic space toward green and blue, respectively. These changes were more noticeable in the canines.

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.

(Accepted 13 May 2013)

REFERENCES

- Haywood VB, & Heymann HO (1989) Nightguard vital bleaching *Quintessence International* **20(3)** 173-176.
- Joiner A (2006) The bleaching of teeth: A review of the literature *Journal of Dentistry* **34(7)** 412-419.
- Matis BA (2003) Tray whitening: What the evidence shows *Compendium of Continuing Education in Dentistry* **24(4A)** 354-362.
- American Dental Association. Council on Scientific Affairs (2010) Treatment considerations for dentists and their patients. Retrieved online June 8, 2012 from http://www.ada.org/sections/about/pdfs/hod_whitening_rpt.pdf
- European Commission (2007) Health & Consumer Protection. Directorate General. Scientific Committee on Consumer Products. Opinion on hydrogen peroxide, in its free form or when released, in oral hygiene products and tooth whitening products. Retrieved online June 9, 2012 from http://ec.europa.eu/health/ph_risk/committees/04_sccp/docs/sccp_o_122.pdf
- Sulieman MA (2008) An overview of tooth-bleaching techniques: Chemistry, safety and efficacy *Periodontology* **2000** **48** 148-169.
- Haywood VB (2007) Diagnosis and treatment planning for bleaching. In: *Tooth Whitening. Indications and Outcomes of Nightguard Vital Bleaching* Quintessence Publishing Co, Chicago, Ill, 1-26.
- Alonso de la Peña V, & Balboa Cabrera O (2006) Comparison of the clinical efficacy and safety of carbamide peroxide and hydrogen peroxide in at-home bleaching gels *Quintessence International* **37(7)** 551-556.
- Nathoo S, Stewart B, Petrone ME, Chaknis P, Zhang YP, & DeVizio W (2003) Comparative clinical investigation of the tooth whitening efficacy of two tooth whitening gels *Journal of Clinical Dentistry* **14(3)** 64-69.
- Cardoso PC, Reis A, Loguercio A, Vieira LC, & Baratieri LN (2010) Clinical effectiveness and tooth sensitivity associated with different bleaching times for a 10 percent

- carbamide peroxide gel *Journal of the American Dental Association* **141**(10) 1213-1220.
11. Jorgensen MG, & Carroll WB (2002) Incidence of tooth sensitivity after home whitening treatment *Journal of the American Dental Association* **133**(9) 1076-1082.
 12. Browning WD, Blalock JS, Frazier KB, Downey MC, & Myers ML (2007) Duration and timing of sensitivity related to bleaching *Journal of Esthetic and Restorative Dentistry* **19**(5) 256-264.
 13. Goldberg M, Grootveld M, & Lynch E (2010) Undesirable and adverse effects of tooth-whitening products: A review *Clinical Oral Investigations* **14**(1) 1-10.
 14. Hasson H, Ismail AI, & Neiva G (2006) Home-based chemically-induced whitening of teeth in adults *Cochrane Database of Systematic Reviews* 18 CD006202.
 15. Medeiros dos Santos MC, & de Lima KC (2008) Effectiveness of nightguard vital bleaching with 10% carbamide peroxide—A clinical study *Journal of the Canadian Dental Association* **74**(2) 163a-163e.
 16. Delgado E, Hernández-Cott PL, Stewart B, Collins M, & De Vizio W (2007) Tooth-whitening efficacy of custom tray-delivered 9% hydrogen peroxide and 20% carbamide peroxide during daytime use: A 14-day clinical trial *Puerto Rico Health Sciences Journal* **26**(4) 367-372.
 17. Tam L (1999) Clinical trial of three 10% carbamide peroxide bleaching products *Journal of the Canadian Dental Association* **65**(4) 201-205.
 18. Kihn PW, Barnes DM, Romberg E, & Peterson K (2000) A clinical evaluation of 10 percent vs. 15 percent carbamide peroxide tooth-whitening agents *Journal of the American Dental Association* **131**(10) 1478-1484.
 19. Meireles SS, Heckmann SS, Leida FL, Ida dos Santos S, Della Bona A, & Demarco FF (2008) Efficacy and safety of 10% and 16% carbamide peroxide tooth-whitening gels: A randomized clinical trial *Operative Dentistry* **33**(6) 606-612.
 20. Braun A, Jepsen S, & Krause F (2007) Spectrophotometric and visual evaluation of vital tooth bleaching employing different carbamide peroxide concentrations *Dental Materials* **23**(2) 165-169.
 21. Zekonis R, Matis BA, Cochran MA, Al Shetri SE, Eckert GJ, & Carlson TJ (2003) Clinical evaluation of in-office and at-home bleaching treatments *Operative Dentistry* **28**(2) 114-121.
 22. Mohan N, Westland S, & Brunton P (2008) A clinical study to evaluate the efficacy of a novel tray based tooth whitening system *Journal of Dentistry* **36**(1) 21-26.
 23. Hannig C, Lindner D, & Attin T (2007) Efficacy and tolerability of two home bleaching systems having different peroxide delivery *Clinical Oral Investigations* **11**(4) 321-329.
 24. Ziebolz D, Helms K, Hannig C, & Attin T (2007) Efficacy and oral side effects of two highly concentrated tray-based bleaching systems *Clinical Oral Investigations* **11**(3) 267-275.
 25. Gerlach RW, & Zhou X (2004) Clinical trial comparing two daytime hydrogen-peroxide professional vital-bleaching systems *Compendium of Continuing Education in Dentistry* **25**(8) 33-40.
 26. Commission Internationale de l'Eclairage (1978) Recommendations on uniform color spaces, color difference equations, psychometric color terms Supplement 2 to CIE, publication 15 Paris: CIE Central Bureau.
 27. Commission Internationale de l'Eclairage (2004) Technical report 3rd edition to CIE, publication 15.3 Austria: CIE Central Bureau.
 28. Javaheri DS, & Janis JN (2000) The efficacy of reservoirs in bleaching trays *Operative Dentistry* **25**(3) 149-151.
 29. Matis BA, Hamdan YS, Cochran MA, & Eckert GJ (2002) A clinical evaluation of a bleaching agent used with and without reservoirs *Operative Dentistry* **27**(1) 5-11.
 30. Kirsten GA, Freire A, de Lima AA, Ignácio SA, & Souza EM (2009) Effect of reservoirs on gingival inflammation after home dental bleaching *Quintessence International* **40**(3) 195-202.
 31. Oilo M (2010) Repeatability of electronic shade determination and the influence of differences in patient's sitting position *European Journal of Prosthodontics and Restorative Dentistry* **18**(4) 171-175.
 32. Della Bona A, Barrett AA, Rosa V, & Pinzetta C (2009) Visual and instrumental agreement in dental shade selection: Three distinct observer populations and shade matching protocols *Dental Materials* **25**(2) 276-281.
 33. Paravina RD, Johnston WM, & Powers JM (2007) New shade guide for evaluation of tooth whitening—Colorimetric study *Journal of Esthetic and Restorative Dentistry* **19**(5) 276-283.
 34. Tsubura S, & Yamaguchi R (2005) Clinical evaluation of a new bleaching product "Polanight" in a Japanese population *Odontology* **93**(1) 52-55.
 35. Dozic A, Kleverlaan CJ, Aartman IH, & Feilzer AJ (2005) Relations in color among maxillary incisors and canines *Dental Materials* **21**(3) 187-191.
 36. Khashayar G, Dozic A, Kleverlaan CJ, & Feilzer AJ (2012) Data comparison between two dental spectrophotometers *Operative Dentistry* **37**(1) 12-20.
 37. Lehmann KM, Devigus A, Igiel C, Wentaschek S, Azar MS, & Scheller H (2011) Repeatability of color-measuring devices *European Journal of Esthetic Dentistry* **6**(4) 428-435.
 38. Sarafianou A, Kamposiora P, Papavasiliou G, & Goula H (2012) Matching repeatability and interdevice agreement of 2 intraoral spectrophotometers *Journal of Prosthetic Dentistry* **107**(3) 178-185.
 39. Lagouvardos PE, Fougia AG, Diamantopoulou SA, & Polyzois GL (2009) Repeatability and interdevice reliability of two portable color selection devices in matching and measuring tooth color *Journal of Prosthetic Dentistry* **101**(1) 40-45.
 40. Mokhlis GR, Matis BA, Cochran MA, & Eckert GJ (2000) A clinical evaluation of carbamide peroxide and hydrogen peroxide whitening agents during daytime use *Journal of the American Dental Association* **131**(9) 1269-1277.