Effectiveness of Nightguard Vital Bleaching with 10% Carbamide Peroxide — A Clinical Study

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ABSTRACT

Objective: To use the criteria set by the American Dental Association to evaluate the effectiveness of nightguard vital bleaching with 10% carbamide peroxide through a controlled randomized clinical trial.

Materials and Methods: Fifty volunteers allocated to either an experimental group (Opalescence PF 10%; OPA) or a control group (placebo; PLA) used a gel for 21 days. Observations of tooth colour were recorded at baseline, immediately after 3 weeks of use (day 21), and 30 days (day 30) and 6 months (day 180) after the treatment was finished. Colour was evaluated with the Vitapan classical shade guide and from the volunteers' degree of satisfaction. Tooth sensitivity and gingival bleeding were also assessed.

Results: The median increase in the lightness of the teeth in the OPA group was 3 units, based on the value-ordered Vitapan shade guide. This improvement in lightness was maintained for 6 months in 88% of this group. In the PLA group, 8% had a 2-unit reduction in tooth colour at day 21. Tooth sensitivity occurred in the OPA (36%) and PLA (8%) groups. Gingival bleeding was not associated with gel use. Volunteers' satisfaction was 92% for the OPA and 8% for the PLA group.

Conclusions: With the protocol used, nightguard vital bleaching was an effective technique that had minimal and transient side effects that disappeared after treatment without causing sequelae or complications.

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Tooth discolouration, regardless of its origin, is the most important factor in the esthetics of a smile because discolouration is more rapidly perceived than other esthetic abnormalities.[1] To solve this problem, tooth-bleaching techniques involving oxidizing substances have been used since the 19th century.[2] In esthetic dentistry, nightguard vital bleaching (NGVB) is the most widely used technique because of its easy application, low cost and wide acceptance by patients.[3] The technique, introduced by Haywood and Haymann[4] in 1989, involves self-application of a 10% carbamide peroxide solution in a custom-fitted soft plastic nightguard that is used at night for about 6 to 8 hours for up to 6 weeks.

With the increasing popularity of this technique and the development of several commercial products, questions about their

effectiveness, longevity and effect on oral tissues have been the focus of several reports. Clinical studies[5–15] have shown that an at-home application of 10% carbamide-peroxide-based products effectively whiten teeth. Haywood and others[15] assessed the effectiveness of NGVB after 6 weeks of treatment and found a 97% success rate in teeth darkened by age or smoking, or in teeth with brown spots, inherent stains, or in single dark teeth. Other studies[16,17] have shown that the NGVB technique is more effective and more accepted than techniques done in the dental office, which use 35% hydrogen peroxide. Recently, based on a systematic review of home-based chemically induced whitening of teeth in adults, Hasson and others[18] reaffirmed the effectiveness of this technique. However, they pointed out the need for independent clinical studies because the majority of the studies they reviewed were either sponsored or conducted by the manufacturer.

Some studies[19,20] conducted extensive follow-ups that indicated that NGVB had high longevity. Leonard[21] showed that the colour change resulting from NGVB remained satisfactory with no re-bleaching in 43% of patients 10 years after the initial treatment.

Most clinical studies[11,15,17,19] showed that tooth sensitivity was the most prevalent side effect associated with this technique, followed by gingival irritation. However, these effects were transient and disappeared at the end of treatment.[19]

Since NGVB is a therapeutic intervention, the best scientific evidence of the effectiveness of this treatment is obtained from controlled, randomized trials, as recommended by American Dental Association (ADA) clinical guidelines.[22,23] According to these guidelines, the clinical effectiveness of bleaching can be shown by a 2-unit decrease on a colour scale arranged by value (lightness), according to manufacturer's specifications. Moreover, this change must be maintained for up to 6 months in at least half of the sample analyzed and the results compared with those for a control group.

The purpose of the current in vivo study was to use the criteria set out in the ADA guidelines to evaluate the effectiveness of NGVB with 10% carbamide peroxide and the possible side effects (gingival bleeding and tooth sensitivity) associated with this procedure in a double-blinded controlled randomized clinical trial. This independent study is an integral part of a wider investigation that evaluates changes in the microstructure of dental enamel after bleaching.

Materials and Methods

Fifty dentistry students from the Universidade Federal do Rio Grande do Norte, Brazil, who wanted to lighten their teeth volunteered for the study. All these students met the inclusion criteria set out in the ADA clinical guidelines[22,23]: they had central and lateral upper incisors and had no fillings, tooth sensitivity, endodontic treatment or previous tooth bleaching. The subjects were periodontally healthy, enjoyed good general health and were nonsmokers.

Each volunteer was informed of the objectives, benefits and possible risks involved in the experiment and participated in the study only after giving written informed consent. The study was approved by the Research Ethics Committee of the university.

Calibration of the Evaluator

Before the clinical phase, the evaluator's ability to evaluate the colour of teeth was calibrated. To do this, the evaluator assessed the colour of the upper incisors of 30 randomly selected dentistry students using the Vitapan classical shade guide (Vita Zahnfabrik, Bad Sackingen, Germany). Two evaluations were done 15 days apart. The selected students' teeth were evaluated without lipstick in the same place and at the same hour of day to standardize lighting conditions. When intra-rater values were calculated, Kappa weighted values were 0.696 for the central incisors and 0.624 for lateral incisors.

Randomization

In a simple raffle, the 50 volunteers were randomly allocated to 1 of 2 groups, for a total of 25 people in each group. The experimental (OPA) group used Opalescence PF 10%, pH 6.5 (Ultradent Products Inc., South Jordan, Utah), a gel with a pH of 6.5, and the control (PLA) group used a placebo gel (Ao Pharmacêutico, Natal, RN, Brazil), a carbopol gel with a pH of 7.0. The placebo gel had the same physical characteristics as the experimental gel, except for the active agent. The placebo was placed in empty Opalescence PF packaging so that neither the volunteer nor the examiner knew which gel was being used.

Clinical Phase

After personal information (sex and age) was collected, volunteers underwent pumice stone and water prophylaxis. Alginate impressions (Jeltrate Regular, Dentsply Caulk, Milford, Del.) of the volunteers' teeth were taken to obtain dental stone models (Durone, Dentsply). In the moulds, vestibular reservoirs with 3 coatings of colorless nail varnish (Risqué, Niasi, São Paulo, Brazil) were prepared for the incisors and premolars. The trays were fabricated from a 0.035-inch soft tray (Sof-Tray, Ultradent) and trimmed just short of the gingival margin.

Baseline values for the initial tooth colour were recorded about 2 weeks after prophylaxis during the calibration phase with the use of the Vitapan classical shade guide, which assigns a value to the colour in units in descending order from lightest to darkest as set out by the manufacturer (**Table 1**). Gingival bleeding was assessed with the gingival bleeding index modified by Lang[24] and recorded as present or absent. Gingival bleeding was considered present if bleeding occurred within 10 to

Table 1 Vitapan classical shade guide arranged from lightest to darkest value

Colour	B1	A1	B2	D2	A2	C1	C2	D4	A3	D3	B3	A3.5	B4	C3	A4	C4
Rank	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16

15 seconds of a periodontal probe being passed across the gingival margin of the upper incisors, the dental elements of interest in this study. This index was favoured over the recommended Loe-Silness Gingival Index,[23] which is highly subjective.

Volunteers were given the tray and gel corresponding to the group to which they were allocated. They were also given a toothbrush (Sanifill 29 soft bristles; Sanifill, Paraná, Brazil) and toothpaste (Colgate with calcium; Colgate-Palmolive, São Paulo, Brazil) to standardize the abrasive effects and fluoride levels for all the volunteers, and a diary to record changes in tooth sensitivity. All instructions about the use of the product were given orally and in writing. All volunteers used the assigned gel (Opalescence PF 10% or placebo) overnight for 21 days.

Four dependent variables were studied: 1) the tooth colour of the upper central and lateral incisors, assessed with the Vitapan classical shade guide; 2) the presence or absence of gingival bleeding at day 21, assessed with the gingival bleeding index modified by Lang[24]; 3) tooth sensitivity occurring during treatment, recorded as yes or no in the volunteers' diaries; and 4) volunteers' satisfaction with the final colour of the teeth, recorded as satisfactory or nonsatisfactory.

The observation periods were baseline, day 21 (21 days after use of the bleaching gel), day 30 (30 days after use of the bleaching gel) and day 180 (6 months after use of the bleaching gel; for the OPA group only).

Tooth colour was analyzed at all observation periods; gingival bleeding, only at baseline and at day 21. Tooth sensitivity and the degree of volunteers' satisfaction was recorded on a questionnaire at the end of the 21-day treatment.

All analyses were done by the evaluator.

Statistical Analysis

Statistical analysis was done with SPSS software for Windows, version 10.0 (Chicago, Ill.). The colour of teeth, sex and age for each group were compared with the Mann-Whitney, χ^2 and Student's *t*-test for independent samples, respectively, at baseline.

The colour values for each group at each observation time were evaluated with Friedman's test. Data for tooth sensitivity, gingival bleeding and volunteers' satisfaction with the treatment were analyzed with Fisher's exact test. All statistical testing was carried out at a significance level of 5%.

A descriptive analysis of the score frequencies was done to evaluate the reduction in colour values for the Vitapan classical shade guide.

Results

Characteristics of the Study Population

The study's volunteers consisted of 15 men and 35 women, ranging in age from 18 to 25 years (mean age 21.6 ± 1.7 years). All volunteers completed the study. A total of 100 sets of data were collected for the OPA group and 99 for the PLA group. The data of 1 volunteer from the PLA group were lost because of upper right lateral incisor anodontia.

Statistical analysis showed no significant difference between the groups at baseline for tooth colour ($p = 0.47$), age ($p = 0.46$) or sex ($p = 0.67$).

Effectiveness of the Bleaching

Tooth Colour

The success of the bleaching for the OPA group, as assessed with the criteria set out in the ADA clinical guidelines,[22] was 96%. Bleaching resulted in an overall reduction in colour value that ranged from 1 to 8 units on the Vitapan classical shade guide, with at least 50% of the cases showing a 4-unit decrease. In the PLA group, only 8% had a reduction of more than 2 units on the scale at day 21, and none at day 30.

Colour retention, or treatment longevity, was important in the observation periods after treatment for the OPA group: only 4% had a 1-unit reduction on the Vitapan classical shade guide from day 21 to day 30, compared to 12% from day 30 to day 180.

Tooth-colour values for both groups are compared for the various observation periods in **Table 2**.

The results of the colour evaluation for the OPA group were statistically significantly different between the different observation periods (**Table 3**), except between day 21 and day 30 ($p = 0.206$). For the PLA group, a statistically significant difference in tooth colour was observed between the observation periods (**Table 4**), except between baseline and day 30 ($p = 1.000$).

Volunteers' Satisfaction

The relation between volunteers' satisfaction with the bleaching effect and the group to which they belonged was significant ($p < 0.001$). Group OPA had a satisfaction level of 92%; group PLA, 8%.

Side Effects

Tooth Sensitivity

Tooth sensitivity for the OPA group (36%) was significantly greater than that of the PLA group (8%) ($p = 0.037$).

Table 2 Median and quartiles (Q25–Q75) of tooth colour of the groups, according to the Vitapan classical shade guide, at each of the observation periods during the study

Observation periods	Groups	Median	Q_{25}–Q_{75}	*p* values
Baseline	OPA	5	5–9	0.473
	PLA	5	5–9	
Day 21	OPA	2	1–2	< 0.001
	PLA	5	5–9	
Day 30	OPA	2	1–2	< 0.001
	PLA	5	5–9	

Table 3 Median, quartiles (Q25–Q75) and mean rank for tooth colour for the OPA group at each of the observation periods during the study

Observation periods	Median	Q_{25}–Q_{75}	Mean rank	*p* values
Baseline	5	5–9	3.97	< 0.001
Day 21	2	1–2	1.89	
Day 30	2	1–2	1.98	
Day 180	2	2–2	2.15	

Table 4 Median, quartiles (Q25–Q75) and mean rank for tooth colour for PLA group at each of the observation periods during the study

Observation periods	Median	Q_{25}–Q_{75}	Mean rank	*p* values
Baseline	5	5–9	2.04	< 0.001
Day 21	5	5–9	1.92	
Day 30	5	5–9	2.04	

Gingival Bleeding

At baseline, no gingival bleeding was observed among volunteers. At day 21, no relation between gingival bleeding and the groups analyzed was found (p = 1.00). Gingival bleeding was observed in 8% of the OPA group and 14% of the PLA group.

Discussion

Several clinical studies[5–17] have assessed the effectiveness of NGVB with 10% carbamide peroxide. However, it is difficult to compare the results of these studies because of the large differences in their sample sizes, bleach products, duration of use, use of control groups (placebo or no placebo), assessment methods, teeth considered for analysis (including or excluding canines) and duration of follow-up. Most did not follow the published ADA guidelines that set standards[22] and criteria[23] for studies of tooth bleaching with peroxide-based products.

The current double-blinded randomized controlled clinical trial adhered to the recommendations of these clinical guidelines about sample size, use of commercial product and control group treated with a placebo, follow-up, assessment of the effect of the bleaching product on oral tissues and the types of teeth evaluated.

One of the greatest difficulties of studies on tooth bleaching is measuring the bleaching effect. According to the 1994 ADA criteria,[22] the effectiveness of tooth bleaching can be evaluated by 4 methods: through the use of a colour scale, photographs, a colorimeter or computer digitization. The 2000 ADA guidelines[23] recommended only 2 methods: colour measurement devices (colorimeters and spectrophotometers) and special colour-match scales. The current study and others[6,8–10,17] used comparison with the Vitapan shade guide because it is the most widely used in daily clinical practice. However, the subjectivity of this technique may produce a measuring bias that may compromise the results. It is therefore fundamental to calibrate the examiners' ability to evaluate the colour of teeth before the study. In this clinical trial, the reproducibility of the examiner's ability to do this, although not optimal, was acceptable, given the inherent subjectivity involved in evaluating tooth colour.

Although a number of authors[5,7,12,16] used the colorimeter — a more objective method of evaluating colour — its clinical significance is unknown.[25] Moreover, the

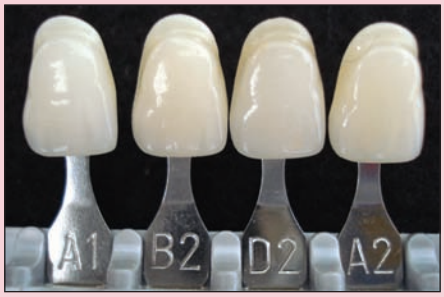

Figure 1: Vita shade guide, ordered according to value, showing baseline (A2, median = 5) and median shade change (A1, median = 2).

colorimeter must be used on a flat surface and in exacting lighting conditions to yield consistent measurements.[15]

Other studies[11,15] have used patients' perception of the bleaching effect to evaluate the effectiveness of the treatment. Although patient satisfaction is used in daily clinical practice as an indicator of successful bleaching, more precise criteria are needed. Patients' perception may be influenced by their expectations, which could compromise the results, mainly because their perceptions cannot be calibrated.

The variables of interest for the 2 groups participating in the current study were equivalent at the outset of the study. All the changes found, therefore, could be attributed to the treatments used. The median tooth colour was 5 (A2) at baseline for both groups and decreased by 3 units to 2 (A1) by day 21 and day 30 in the OPA group (**Fig. 1** and **Table 2**), demonstrating the effectiveness of the technique and the product used. When the reduction in colour value was evaluated tooth by tooth with the Vitapan classical shade guide, the median reduction was 4 units, indicating that the technique was effective for lightening teeth since it represented more than the 2 units referred to by clinical guidelines. This reduction was small compared with that reported in studies by Barnes and others[9] (7.0 units) and Niederman and others[25] (5.9 units). This is likely because our study sample was composed of young volunteers with unrestored teeth. Another factor may have been the lack of use of canines for statistical analysis, given that canines bleach more than incisors.[5,14] Studies that used canines showed a greater reduction in colour.[4,5,12,16,17]

In a meta-analysis[25] of the effectiveness of bleaching with 10% carbamide peroxide, a mean reduction of 5.9 units was found for the active agent as compared to the control group. However, measurements of central tendency such as means do not apply to scored data; it is better in these cases to use the median.

According to ADA clinical guidelines,[22,23] to verify the longevity of bleaching, at least 50% of the sample must continue to have a visible colour change at the 6-month recall appointment. In the current study, results of the recall showed that the treatment used was effective: the median value for the tooth colour of the OPA group was 2 at day 30 and at day 180 (**Table 3**), although 4% of the teeth had increased 1 unit on the Vitapan classical shade guide between day 21 and day 30 and 12% between day 30 and day 180. The small colour reversal observed at 6 months (12%) was less than that found by other authors.[8,9,15,19] Swift and others[10] reported similar results (10.4%) and observed no significant difference after 2 years (16.4%). As in our study, Swift and others[10] observed no difference in the tooth colour immediately after bleaching and after 30 days. They also observed no difference in colour immediately after bleaching and after 3 months.[10]

The effectiveness observed for our PLA group (8.0%) was less than that found by Russell and others[8] (15.4%) and Barnes and others[9] (20.0%). A systematic review[25] of the effectiveness of NGVB with 10% carbamide peroxide showed (through meta-analysis) that the placebo causes a bleaching effect of about 0.7 ± 0.6 points on the colour scale. Data that point to the effectiveness of placebo substances may be attributable to intra- and interobserver disagreement.

The degree of volunteers' satisfaction reflects the effectiveness of the bleaching technique used. The results of this study indicate a very high degree of satisfaction (92%) among the volunteers of the OPA group, compared with that (8%) for the PLA group.

The most important side effects of the NGVB technique, tooth sensitivity and gingival irritation, disappeared at the end of treatment, corroborating the findings of Haywood.[3] The incidence of tooth sensitivity (36% for the OPA group and 8% for the PLA group) was smaller than that found in other studies,[11,15,19] possibly because of the presence of desensitizing agents such as potassium nitrate (0.5%) and fluoride (0.11%) in the bleaching gel. Gingival irritation, as determined by the presence of gingival bleeding, was not significant in either group and was likely a result of the mechanical irritation of the tray.[3]

Conclusions

NGVB with 10% carbamide peroxide, when used according to the clinical protocol of the current study, was effective for lightening tooth colour, both for the period immediately after treatment and for the 6-month follow-up period. Of the 2 main side effects assessed, tooth sensitivity was more prevalent than gingival irritation, and both were transient and disappeared at the end of treatment.

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References

1. Baratieri LN, Junior SM, Andrada MAC, Vieira LCC, Ritter AV, Cardoso AC. Clareamento de dentes. In: Odontologia Restauradora-Fundamentos e Possibilidades. São Paulo: Quintessence; 2002. p. 675–722.

2. Haywood VB. History, safety, and effectiveness of current bleaching techniques and applications of the nightguard vital bleaching technique. *Quintessence Int* 1992; 23(7):471–88.

3. Haywood VB. Current status of nightguard vital bleaching. *Compend Contin Educ Dent* 2000; 21(Suppl 28):S10–S17.

4. Haywood VB, Heymann HO. Nightguard vital bleaching. *Quintessence Int* 1989; 20(3):173–6.

5. Gegauff AG, Rosenstiel SF, Langhout KJ, Johnston WM. Evaluating tooth color change from carbamide peroxide gel. *J Am Dent Assoc* 1993; 124(6):65–72.

6. Reinhard JW, Eivins SE, Swift Jr EJ, Denehy GE. A clinical study of nightguard vital bleaching. *Quintessence Int* 1993; 24(6):379–84.

7. Rosenstiel SF, Gegauff AG, Johnston WM. Randomized clinical trial of efficacy and safety of a home bleaching procedure. *Quintessence Int* 1996; 27(6):413–24.

8. Russell CM, Dickinson GL, Johnson MH, Curtis JW Jr, Downey MC, Haywood VB, and other. Dentist-supervised home bleaching with ten percent carbamide peroxide gel: a six-month study. *J Esthet Dent* 1996; 8(4):177–82.

9. Barnes DM, Kihn PW, Romberg E, George D, DePaola L, Medina E. Clinical evaluation of a new 10% carbamide peroxide tooth-whitening agent. *Compend Contin Educ Dent* 1998; 19(10):968–72, 977–8.

10. Swift EJ Jr, May KN Jr, Wilder AD Jr, Heymann HO, Bayne S C. Two-year clinical evaluation of tooth whitening using an at-home bleaching system. *J Esthet Dent* 1999; 11(1):36–42.

11. Tam L. Clinical trial of three 10% carbamide peroxide bleaching products. *J Can Dent Assoc* 1999; 65(4):201–5.

12. Matis BA, Mousa HN, Cochran MA, Eckert GJ. Clinical evaluation of bleaching agents of different concentrations. *Quintessence Int* 2000; 31(5):303–10.

13. Tsubura S, Yamaguchi R. Clinical evaluation of a new bleaching product "Polanight" in a Japanese population. *Odontology* 2005; 93(1):52–5.

14. Braun A, Jepsen S, Krause F. Spectrophotometric and visual evaluation of vital tooth bleaching employing different carbamide peroxide concentrations. *Dent Mater* 2007; 23(2):165–9. Epub 2006 Feb 28.

15. Haywood VB, Leonard RH, Nelson CF, Brunson WD. Effectiveness, side effects and long-term status of nightguard vital bleaching. *J Am Dent Assoc* 1994; 125(9):1219–26.

16. Zekonis R, Matis BA, Cochran MA, Al Shetri SE, Eckert GJ, Carlson TJ. Clinical evaluation of in-office and at-home bleaching treatments. *Oper Dent* 2003; 28(2):114–21.

17. Auschill TM, Hellwig E, Schmidale S, Sculean A, Arweiler NB. Efficacy, side-effects and patients' acceptance of different bleaching techniques (OTC, in-office, at-home). *Oper Dent* 2005; 30(2):156–63.

18. Hasson H, Ismail AI, Neiva G. Home-based chemically-induced whitening of teeth in adults. *Cochrane Database Syst Rev* 2006 Oct 18(4):CD006202.

19. Leonard RH Jr, Bentley C, Eagle JC, Garland GE, Knight MC, Phillips C. Nightguard vital bleaching: a long-term study on efficacy, shade retention, side effects and patients' perceptions. *J Esthet Restor Dent* 2001; 13(6):357–69.

20. Ritter AV, Leonard RH, St Georges AJ, Caplan DJ, Haywood VB. Safety and stability of nightguard vital bleaching: 9 to 12 years post-treatment. *J Esthet Restor Dent* 2002; 14(5):275–85.

21. Leonard RH Jr. Long-term treatment results with nightguard vital bleaching. *Compend Contin Educ Dent* 2003; 24(4A):364–74.

22. American Dental Association Council on Dental Therapeutics. Guidelines for the acceptance of peroxide-containing oral hygiene products. *J Am Dent Assoc* 1994; 125(8):1140–2.

23. Siew C, American Dental Association. ADA guidelines for the acceptance of tooth-whitening products. *Compend Contin Educ Dent Suppl* 2000; 28:S44–7.

24. Lang, NP. Commonly used indices to assess oral hygiene and gingival and periodontal health and diseases. In: Lang NP, Attstrom R, Loe H. Proceedings of the European workshop on mechanical plaque control: status of the art and science of dental plaque control. Chicago: Quintessence; 1998. p. 50–71.

25. Niederman R, Tantraphol MC, Slinin P, Hayes C, Conway S. Effectiveness of dentist-prescribed, home-applied tooth whitening. A meta analysis. *J Contemp Dent Pract* 2000; 1(4):20–36.