Nightguard Vital Bleaching: Side Effects and Patient Satisfaction 10 to 17 Years Post-Treatment

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ABSTRACT

Statement of the Problem: The long-term patient satisfaction and safety of nightguard vital bleaching (NGVB) requires further evaluation.

Purpose of the Study: The purpose of this study was to evaluate patients' satisfaction and identify side effects of NGVB up to 17 years post-treatment.

Materials and Methods: Thirty-one participants who had completed previous NGVB studies using 10% carbamide peroxide were contacted at least 10 years post-treatment (range 10–17 years, average 12.3 years). Participants reported shade satisfaction (very satisfied [VS], partially satisfied [PS], or not satisfied [NS]) as well as potential complications. Participants had teeth # 6 to 11 examined for tooth vitality, gingival inflammation (Löe's Gingival Index [GI]), and radiographically for external cervical resorption (ECR).

Results: All of the participants had successful lightening of their teeth. Sixty-one percent (19) had not retreated their teeth. Of those who had not retreated their teeth and who responded to the question of whitening satisfaction, 31% (4/13) were VS, 54% (7/13) were PS, and 15% (2/13) were NS with their current shade. Of those who had retreated their teeth, all were VS or PS. Ninety-one percent of the examined teeth had GI = 0 (normal), 7% had GI = 1 (mild inflammation), and 2% had GI = 2 (moderate inflammation). Sixty-nine percent of teeth tested responded to a cold stimulus. Radiographs did not detect ECR or apical lesions. No participant reported having a gingival biopsy post-treatment, and 87% would whiten again.

Conclusions: Patient satisfaction with NGVB may last as long as 12.3 years in average (range 10–17 years) post-treatment. GI and ECR findings were considered within the normal expectations for the sample studied, suggesting minimal clinical post-NGVB side effects up to 17 years.

CLINICAL SIGNIFICANCE

Nightguard vital bleaching provides patient satisfaction with minimal side effects up to 17 years post-treatment.

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INTRODUCTION

Use of peroxide-based whitening techniques as a conservative option for in-office professional esthetic treatment of discolored teeth was reported in the late 1800s.[1,2] Home-based tooth whitening, commonly referred to as nightguard vital bleaching (NGVB), became available approximately a century later and has

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been found to be an effective, relatively easy, and inexpensive means of lightening the dentition.[3–5] Short-term clinical and laboratory studies that have evaluated potential adverse side effects, such as damage to or compromised bonding with tooth structure, pulpal pathology, external cervical root resorption, gingival irritation, and carcinogenic activity, suggest that NGVB (using 10% carbamide peroxide [CP]) is safe.[6–15]

One medium-term study, which evaluated patients up to 10 years post-treatment, found that NGVB safely provided stable whitening of the dentition.[16] However, because NGVB with 10% CP is one of the methods of tooth whitening accomplished with limited professional supervision, there is a legitimate need to demonstrate long-term acceptable levels of patient satisfaction and safety.[17]

The objectives of this long-term retrospective longitudinal case series were to determine patients' satisfaction and to identify side effects of a NGVB technique. The hypothesis advanced is that NGVB with 10% CP results in patient satisfaction with very limited side effects up to 17 years post-treatment.

MATERIALS AND METHODS

The protocol and a consent form for this study were reviewed and approved by the Institutional Review Board at the University of North Carolina (UNC). Inclusion/exclusion criteria required that the patients had completed one of the UNC School of Dentistry (UNCSOD) NGVB trials that were conducted between 1989 and 1996. There was no compensation for participating in the study. Thirty-one out of approximately 150 subjects participated in the study (22 females [71%] and 9 males [29%]). The UNCSOD NGVB studies in this time period utilized various formulations of 10% CP solution in custom vacuum-formed trays 8 to 10 hours per night for treatment times that ranged from 2 weeks (NiteWhite®, Discus Dental, Culver City, CA, USA) to 6 weeks (Proxigel®, Reed & Carnrick, Jersey City, NJ, USA) to 6 months (Opalescence®, Ultradent Products, Inc., South Jordan, UT, USA).

Participants where afforded an opportunity to answer a questionnaire designed to identify their level of satisfaction (very satisfied [VS], partially satisfied [PS], not satisfied [NS]), if they had additional tooth whitening (retreatment), and if they perceived that there were any complications related to the original treatment (Table 1). Teeth #6 to 11 (Fédération Dentaire Internationale [FDI] #13–23) of each subject were isolated with cotton rolls and immediately evaluated for Löe's gingival index (GI)[18,19] and tooth vitality (TV) by tetrafluorethane according to manufacturer's instructions (Endo-Ice®, Coltene Whaledent, Cuyahoga Falls, OH, USA). Three periapical photo-stimulable phosphor digital radiographic images (VixWin 2000, Gendex Dental Systems, Des Plaines, IL, USA) were obtained and evaluated for external cervical resorption (ECR) by two licensed dentists participating in the UNC dental faculty practice and a third-year UNC oral radiology resident. Table 2 shows the ranking scale for the GI and ECR findings.

RESULTS

Evaluation of data collected from the patient questionnaire and clinical/radiographic examinations revealed overall patient satisfaction with minimal clinical post-NGVB side effects up to 17 years post-treatment in this retrospective case series study (10–17 years post-treatment, mean of 12.3 years). Results are summarized in Table 1.

Questionnaire

Participant response rate was 100% for all questions except for question 2 (Table 1). Sixty-one percent (19) of the study participants had not retreated their teeth. Eleven of these patients reported that they were currently VS or PS with the shade of their teeth, which represents 35% of all study participants. Thirty-nine percent (12) of the study participants had retreated

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TABLE 1. Questionnaire results summary

Question			Responses *N* (%)	Participants responding *N* (%)
(1) Since completion of whitening, have you had your teeth retreated?				
NO			19 (61)	31 (100)
YES			12 (39)	
If YES, for what reason: to improve esthetics				
(2) Check the item that that best describes your satisfaction with the original treatment. *				
Immediately after treatment	**No retreatment (19)**	**Yes retreatment (12)**		
Very satisfied	12/18	5/12	17 (57)	30 (97)
Partially satisfied	6/18	7/12	13 (43)	
Not satisfied	0/18	0/12	0 (0)	
Currently				
Very satisfied	4/13	4/11	8 (33.3)	24 (77)
Partially satisfied	7/13	7/11	14 (58.3)	
Not satisfied	2/13	0/11	2 (8.3)	
(3) Did you experience any kind of problems during treatment?				
NO			16 (52)	31 (100)
YES (tooth sensitivity—10 [32], gingival sensitivity—5 [16], both—2 [6])			15 (48)	
(4) Did you experience any kind of problems immediately after treatment that you felt was treatment-related?				
NO			30 (97)	31 (100)
YES (tooth sensitivity—1 [3])			1 (3)	
(5) Compared to the nontreated teeth, have you experienced any of the following problems on your treated teeth that you think might be related to the treatment?				
Staining			1 (3)	31 (100)
Decay			0 (0)	
Gum (periodontal) problems			0 (0)	
Other problems or concerns			0 (0)	
(6) Have you had any of the treated teeth veneered or crowned?				
NO			25 (81)	31 (100)
YES (Reason: broken tooth[†]—4 [13], esthetic concerns—2 [6])			6 (19)	

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TABLE 1. *Continued.*

Question	Responses *N* (%)	Participants responding *N* (%)
(7) Have you had to have a root canal on any of the treated teeth?		
NO	29 (94)	31 (100)
YES	2 (6)	
(8) Have you had any gum surgery (biopsy) done after ending the whitening treatment that may be treatment related?		
NO	31 (100)	31 (100)
YES	0 (0)	
(9) Would you have your teeth treated (whitened) again?		
YES	27 (87)	31 (100)
NO	4 (13)	

*Not all participants responded to various aspects of this question.

†The broken teeth reported were posterior teeth.

TABLE 2. Ranking scales of clinical and radiographical measurements for gingival/soft tissue* and external cervical resorption examinations

Ranking	Gingival index	External cervical resorption
0	Normal gingiva; no evidence of abnormality	No evidence of abnormality
1	Mild inflammation Slight change in color Slight edema No evidence of ulceration	Slight external root resorption
2	Moderate inflammation Redness Edema Glazing Mild ulceration	Moderate external root resorption
3	Severe inflammation Marked redness Edema Glazing Ulceration Tendency to bleed spontaneously	Severe external root resorption

*Modified from Loe H.[18] and Curtis JW et al.[19]

their teeth, all of which were VS or PS with whitening results immediately after treatment.

All of those who responded to the question of whitening satisfaction immediately after treatment indicated that they were either VS or PS (Figures 1–3). Seventy-seven percent (24) of all study participants reported their current levels of treatment satisfaction. Of these, 92% (22/24) indicated that they were VS or PS with the shade of their teeth. Two participants were NS with their shade.

Approximately one-half of the study participants reported complications of tooth and/or gingival sensitivity during their original whitening treatment. Only one participant reported any type of immediate post-treatment complication (tooth sensitivity) that he/she felt was treatment-related. One participant reported tooth staining secondary to the whitening procedure. No participant reported that they had experienced dental caries (decay) as a result of the whitening treatment.

Six percent of the study participants (2) reported that they had treated teeth veneered for esthetic reasons.

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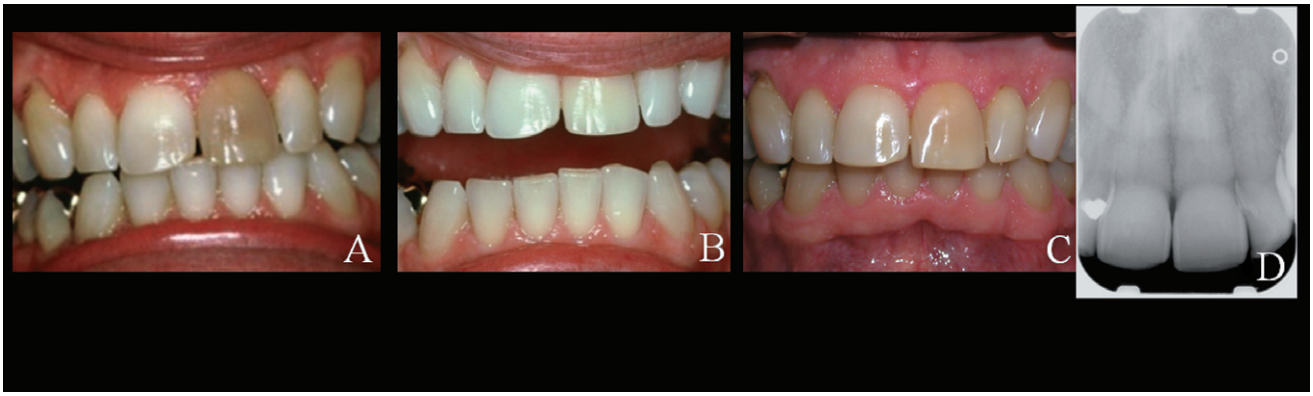

FIGURE 1. Subject #2 as presented pretreatment (A); 0 months post-treatment (B); 15 years and 11 months post-treatment (C). D, Radiographic images of the teeth examined (6–11) at 15 years and 11 months post-treatment.

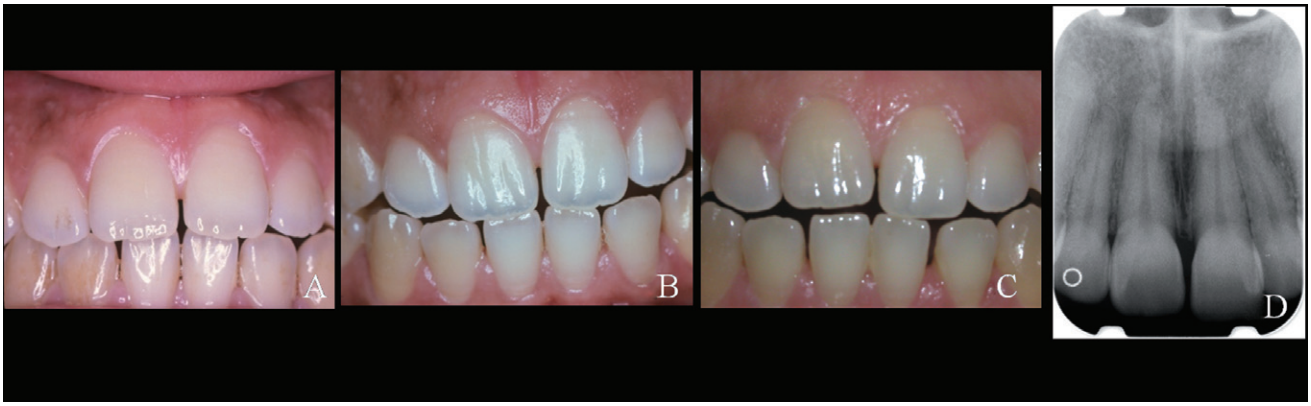

FIGURE 2. Subject #9 as presented pretreatment (A); 0 months post-treatment (B); 16 years and 4 months post-treatment (C). D, Radiographic images of the teeth examined (6–11) at 16 years and 4 months post-treatment.

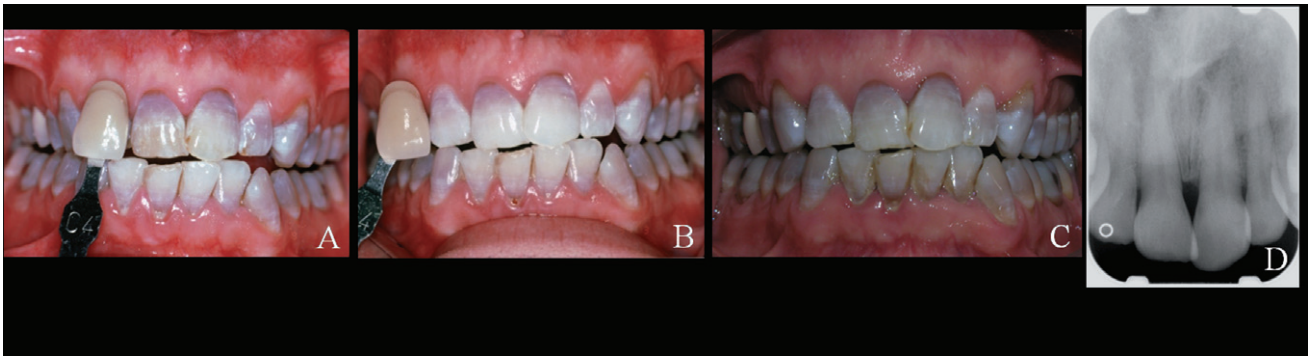

FIGURE 3. Subject #14 as presented pretreatment (A); 0 months post-treatment (B); 12 years and 7 months post-treatment (C). D, Radiographic images of the teeth examined (6–11) at 12 years and 7 months post-treatment.

Sixteen percent of the study participants (4) reported that they had required a crown at some point after the whitening procedures were accomplished. Subsequent review of the participants' dental records revealed that the teeth requiring crowns were posterior teeth that were included in the full-arch custom vacuum-formed trays utilized during the whitening studies.

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Six percent of the study participants (2) reported a need for endodontic treatment at some point after the original NGVB study was accomplished. No participant reported having a gingival biopsy post-treatment that may have been treatment-related, and 87% of the study participants would have their teeth whitened again.

Clinical/Radiographic Examination

Ninety-one percent of the examined teeth had GI = 0 (normal), 7% had GI = 1 (mild inflammation), and 2% had GI = 2 (moderate inflammation). Upon independent qualified observation of the radiographs, no evidence of ECR was detected, and no apical lesions were observed in the teeth examined. Sixty-nine percent of the teeth tested responded positive to the TV test.

DISCUSSION

The finding that 35% of the patients who underwent NGVB without additional retreatment that were VS with results up to 17 years post-treatment is consistent with overall long-term trends in levels of patient satisfaction.[16,20] This indicates that approximately one-third of the patients who utilize NGVB will likely experience lasting satisfactory results. Question 2 on the survey may have been confusing for some participants, as indicated by the lower response rate when queried about current levels of satisfaction (77%). It may be that the level of satisfaction had not changed over time, and therefore, patients probably felt that no further answer was needed to be given. This represents an area where the questionnaire clarity can be improved.

The purpose of this study was not to examine this group of patients for evidence of tooth structure damage that may have resulted from exposure to CP. However, the questionnaire did provide opportunity for the participants to report their dental experience after the whitening treatment was accomplished. It is interesting to note that only one study participant reported staining, which potentially could be related to modification or compromise of tooth surface alteration as a complication. Staining of the dentition is common and not associated with any pathologic process. In addition to potential CP-induced surface alterations, increased tendency to develop dental fractures over time may be a sign of compromised tooth structure secondary to CP exposure. None of the anterior teeth exposed to NGVB were reported to be fractured/broken. It may be that the posterior teeth in full-arch whitening trays were also exposed to CP. Sixteen percent of the study participants reported that they had experienced a broken posterior tooth since the original NGVB was accomplished (at some point in the last 10–17 years). This is well below the overall posterior tooth fracture incidence of ~80 fractured teeth/1,000 person years.[21] Therefore, even though it is likely that the NGVB exposed the posterior teeth to CP, there is no evidence in this small sample to suggest structural compromise of dentition, which has been exposed to 10% CP through NGVB. It is important to note that the specific timing and tooth number of the reported broken teeth were not verified in this study, which limits the interpretive value of these particular findings.

Failure or loss of anterior or posterior composite resin restorations after NGVB might indicate that restoration bonds to tooth structure had been compromised as a result of exposure to CP. However, none of the study participants reported the need for restoration replacement or loss of restorations as a problem or concern. This is consistent with recent in vitro studies that found that bond strengths of composite resin to bovine enamel and dentin did not change significantly after the restored samples had been exposed to 10% CP.[22] It is important to note, however, that bond strengths of the restored samples were found to decrease with increasing CP concentration (15% and 20% CP) and that the bond to enamel was impacted more than the bond to dentin.[22] Long-term studies that evaluate the effect of higher concentrations of CP on composite restorations should be accomplished. It is important to note that the questionnaire does not specifically ask about restoration replacement or loss, which reveals a limitation in the questionnaire design and the interpretative value of the study findings.

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None of the study participants reported the problem or concern of current tooth sensitivity that they associated with their NGVB. This is in contrast to the finding that 32% of the study participants reported that they had originally experienced tooth sensitivity during the NGVB. This finding is consistent with a 2002 study that surveyed and examined patients from the same population of patients that had originally participated in the UNCSOD NGVB trials.[16] Tooth sensitivity is considered to result from penetration of the CP through the tooth structure and into the pulp. Decreased CP exposure time is a strategy used to limit tooth sensitivity while undergoing active tooth whitening. Increased CP concentration increases risk of developing tooth sensitivity. To limit this side effect, the recommended daily exposure time to CP should be decreased as concentration is increased. Various tooth whitening formulations utilize additional means designed to limit sensitivity, which may include incorporation of additives such as amorphous calcium phosphate, fluoride, and/or potassium nitrate. NGVB treatment protocols vary in application times based on the active agent concentration and level of tooth sensitivity experienced.[23] The development of tooth sensitivity during NGVB does not appear to be a sign of the development of pulpal pathology. Once again, it is important to note that the questionnaire does not specifically ask about current tooth sensitivity that reveals a limitation in the questionnaire design and the interpretative value of the study findings.

There was no evidence of the development of pulpal pathology at the 10- to 17-year follow-up in this study population. This is consistent with another study, which found that 10% CP NGVB did not result in an increase in pulpal inflammation, as measured by key inflammatory markers.[24] The response to the TV test utilized in this study was found to be consistent with the reliability findings of other studies.[25,26] The percentage of study participants that subsequently required root canal treatment of teeth that had been whitened is well within the normal range of individuals that require root canal treatment in general populations, which suggests no increased risk of pulp pathology.[27] There was no evidence of ECR when using 10% CP NGVB. This is in contrast to increased ECR found secondary to nonvital internal bleaching and is in support of the notion that NGVB does not increase the long-term risk of developing ECR.[17,28] In-office systems that use up to 38% hydrogen peroxide (which is greater than 2.5× the equivalent of the highest concentration of at-home CP bleaching systems) did not cause detectable pulpal injury if the whitening was accomplished without the use of high intensity light sources.[29] This suggests that the lower CP concentrations (range = 7.5%–38%) currently available for NGVB may be within safety limits. However, long-term studies of CP NGVB formulations that are greater than 10% should seek to evaluate the likelihood of developing pulpal pathology or ECR.

None of the study participants reported any current gingival sensitivity that they associated with their NGVB. This is in contrast to the finding that 16% of the study participants reported gingival sensitivity during the original NGVB. This level of gingival sensitivity is consistent with the 2002 study mentioned earlier.[16] In all cases, the sensitivity was resolved upon completion of the active phase of NGVB. Over the long term, there was minimal evidence of gingival inflammation and no reported development of malignancy. This is in support of the notion that the use of 10% CP for NGVB has minimal side effects when used as prescribed.[17] It has been found that 16% CP preparations were as clinically safe as 10% CP, with the exception of increased gingival irritation and tooth sensitivity while actively bleaching.[30] It has been recommended that current clinical studies support the use of lower dose NGVB techniques with limited exposure times.[17,28] Newer formulations with higher concentrations of CP need to be evaluated with clinical trials especially in light of current marketing and societal trends that encourage at-home bleaching at frequent intervals. Additional studies that assess the safety of NGVB in terms of frequency of use and current CP concentrations will need to be accomplished.

This study is limited in that the baseline findings for the GI, TV, and tooth shade were no longer available for comparison with current findings. In addition, analysis of the development of low-incidence conditions in a

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small sample size prevents strong conclusions from being made. However, the results of the questionnaire and clinical/radiographic examinations lend support to the notion that NGVB with 10% CP has minimum long-term clinical side effects.

CONCLUSION

Survey of patients' satisfaction with NGVB revealed that approximately one-third of patients initially treated were either VS or PS with the long-term result of this treatment and did not have their teeth retreated. Assessment of the long-term effects of NGVB on maxillary anterior teeth revealed low risk of the development of gingival inflammation, pulpal inflammation, and external cervical root resorption. Additionally, no evidence of malignancy or any other soft tissue pathology was found. NGVB with 10% CP was found to be effective with minimal side effects up to 17 years post-treatment.

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