Risk factors for developing tooth sensitivity and gingival irritation associated with nightguard vital bleaching

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Abstract *The purpose of this study was to determine risk factors in the development of tooth sensitivity and gingival irritation associated with the nightguard vital bleaching technique. The potential risk factors evaluated (sex, age, reported allergy, whitening solution, number of times the solution was changed daily [its usage pattern], and dental arch) were collected from the daily log form turned in by each of the 64 participants after completion of the 6-week lightening process. Also evaluated for each participant, from color slides, were tooth characteristics such as gingival recession, defective restorations, abfraction lesions, enamel-cementum abrasion, etc, and reported side effects. The generalized Mantel-Haenszel statistic was used to assess the association between the potential risk factors and the development of tooth sensitivity and/or gingival irritation. No statistical relationship existed between age, sex, allergy, tooth characteristics, or the dental arch lightened and the development of side effects. Initially, a statistically significant association existed between side effects and the whitening solution used. However, when the analysis was controlled for usage pattern, this relationship disappeared. Patients who changed the whitening solution more than once a day reported statistically significantly more side effects than did those who did not change the whitening solution during their usage time.* (Quintessence Int *1997;28:527-534.*)

Clinical relevance

Patients undergoing the nightguard vital bleaching process often experience side effects such as tooth sensitivity and gingival irritation. The main predictor for these side effects was found to be changing the whitening solution more than once a day.

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Introduction

Since its introduction by Haywood and Heymann[1] in 1989, nightguard vital bleaching (NGVB) has gained acceptance among dentists as an effective and simple method of lightening intrinsically stained or discolored teeth. Also referred to as *dentist-prescribed home-applied bleaching*,[2] the original technique involved applying a 10% carbamide peroxide whitening solution containing Carbopol (carboxypolymethylene, B. F. Goodrich) in a custom-fitted vinyl nightguard (0.02-inch) for 6 to 8 hours a night. Positive results were usually seen in 2 to 6 weeks. Modifications, improvements, and variations in the clinical technique now include the following: *(1)* wearing a softer custom-fitted guard (0.035-inch Sof-Tray, Ultradent); *(2)* using a 5%, 10%, 16%, or higher concentration of carbamide peroxide or 1% to 10% hydrogen peroxide whitening solution; *(3)* applying the solution for one or more intervals during the day; and *(4)* increasing the amount of Carbopol.[3-16]

In a previous report on NGVB, side effects (tooth sensitivity and/or gingival irritation) were reported to affect up to 67% of the patients undergoing the NGVB technique.[17] Patients experiencing side effects in that study reported them to be transient and to disappear, either spontaneously or in response to a decrease in the frequency of application, a decrease in the number of hours of usage per day, or a cessation of the procedure for a few days. In any event, all side effects ceased soon after the completion of the whitening procedure and had not recurred at the 3-year recall appointment.

The purpose of this study was to determine risk factors in the development of side effects (tooth sensitivity and gingival irritation) associated with the NGVB technique.

Method and materials

A retrospective study was conducted in which 64 charts of patients who had participated in a previous NGVB clinical study at the University of North Carolina School of Dentistry were evaluated. All nightguards were fabricated from 0.02-inch Coping material (Buffalo Dental) to extend 2 to 3 mm onto tissue, and without reservoirs. Care was taken at insertion to smooth rough edges and to reduce areas where tissue blanching or pressure occurred.

One of two products was used for a whitening solution. Proxigel (Reed and Carnrick) and Gly-Oxide (Marion Murrell Dow) were used in the bleaching study because they were the first materials reported to achieve this whitening result when used in a tray.[2] Although many new dental bleaching products were entering the market at this time, these were two commercially available for use in the mouth. Both materials are oral antiseptics from reputable companies with good quality production, consistent formulation, and predictable shelf life. Proxigel represents those bleaching agents in a glycerine base that contain Carbopol, while Gly-Oxide represents those bleaching agents that do not contain Carbopol. The patent for Proxigel[2] indicates that the addition of Carbopol makes the material thicker and stickier and slows down the oxygen release. All early 10% carbamide peroxide dental bleaching materials were rough copies of one of these two formulations.

Each subject had kept a daily log form on which they recorded the number of days and/or nights used, the number of hours of whitening per day or night, the whitening solution used (Proxigel or Gly-Oxide), how many times the whitening solution was changed in a 24-hour period (hours of usage and number of changes), and side effects (tooth sensitivity and/or gingival irritation). The log forms were collected from each subject at completion of the bleaching procedure. Demographic and medical information was collected from each patient's medical history form. Tooth characteristics (gingival recession, defective restorations, abfraction lesions, enamel-cementum abrasion, etc) were evaluated from pretreatment or posttreatment color slides. Two examiners evaluated the slides and reached a consensus on the presence or absence of the tooth characteristics.

The potential risk factors evaluated for the development of tooth sensitivity and/or gingival irritation were sex, age, reported allergy, dental arch, whitening solution, tooth characteristics, and the number of times the solution was changed (usage pattern). The generalized Mantel-Haenszel statistic was used to assess the association between the potential risk factors and development of tooth sensitivity and/or gingival irritation from 2 × 2 tables and to control for potential confounders in association with the presence of side effects. The level of significance was set at .05.

Results

Descriptive statistics

Of the participants, 73% (47) were female and 27% (17) were male (Fig 1). The mean age for the group was 36.5 years (SD = 14.3; median age of 34 years) with a range of 10 to 68 years. Existing allergies were reported in 42% (27) of the participants. Maxillary arches were whitened 80% (51 of 64) of the time and the mandibular arch 20% (13 of 64). All 13 mandibular arches and 32 of the maxillary arches were whitened with Proxigel. Gly-Oxide was used in 19 maxillary arches. Seventy percent (45) of the participants used Proxigel as the whitening agent, and 30% (19) used Gly-Oxide.

The usage pattern (Table 1) was either *(1)* day only or night only, with no changing of the solution during the participant's wear time, or *(2)* day only with at least one solution change during the day, or day and night use with at least one solution change. The mean number of hours worn by each group was similar (300 versus 305 hours, range of 30 to 818 hours) because all participants were asked to wear the guard for 6 to 8 hours per day. The main difference between the two groups was the change of the solution during the usage time. Thus, the members of the group that changed the

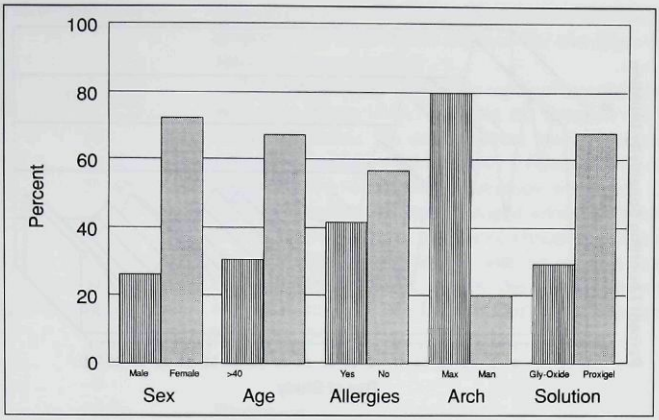

Fig 1 Demographics of study participants (n = 64)

solution more than once per day exposed their teeth and soft tissues to fresh, undiluted whitening solution more often than did participants in the day only/night only group. The group that changed the whitening solution did so at a rate of 45 minutes to 4 hours between changes and up to four changes per day. The mean number of days the guard was worn by each participant was 34.8 (SD = 7.8 days; median of 37 days) with a range of 6 to 42 days.

Tooth sensitivity and/or gingival irritation was reported by 55% of the participants, for a mean of 6.7 days (SD = 8.1 days) with a range of 1 to 39 days. In the day- or night-only group, which did not change the solution during the wear time, the mean number of days of tooth sensitivity or gingival irritation reported was 5.2 days (SD = 5.9 days; range of 1 to 26). In the two groups that reported changing the solution, the mean was 8.0 days (SD = 9.4 days; range of 1 to 39). Figure 2 shows the percentage of patients reporting side effects on a given day during the 6-week study.

Two thirds of the patients demonstrating tooth characteristics such as gingival recession, defective restorations, enamel-cementum abrasion, etc, had tooth sensitivity. Forty-two percent of the patients with no relevant tooth characteristics reported tooth sensitivity and/or gingival irritation. Figures 3a and 3b are examples of the tooth characteristics evaluated.

Table 1 Usage pattern of participants and bleaching solution used in a 6-week clinical study of nightguard vital bleaching (n = 64)

	No solution change		Solution change*		
Solution	Day only	Night only	Day use with changes	Day and night use	Total
Gly-oxide	2	2	6	9	19
Proxigel	0	33	0	12	45
Total	2	35	6	21	64

* Participants who changed the whitening solution more than once a day reported statistically significantly more side effects ($P < .02$) than did those who did not change the whitening solution during their usage time.

Proxigel

Proxigel (a moderately low pH (4.8), Carbopol-containing, anhydrous-based solution) was used in 45 participants (Table 2). Twenty-one (47%) of the 45 participants reported having side effects with Proxigel. Six reported tooth sensitivity, seven reported gingival irritation, and eight reported both side effects. Only three of the 21 participants experiencing side effects quit at some point during the whitening procedures. As the side effects subsided, all three resumed the NGVB process.

Gly-Oxide

Gly-Oxide (a neutral pH (7.0), non-Carbopol-containing solution) was used in 19 participants (Table 2). Fourteen (74%) of the 19 participants experienced side effects with Gly-Oxide. Three reported tooth

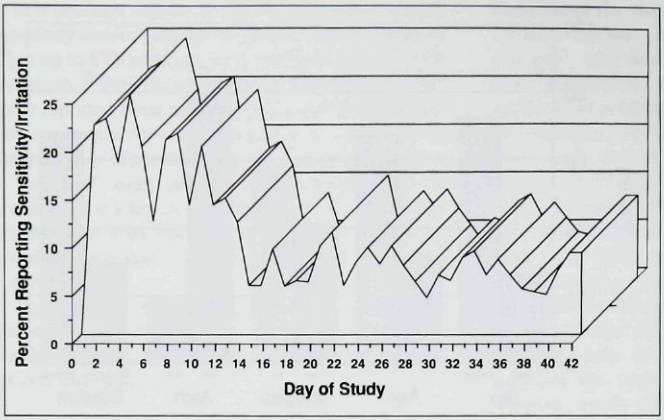

Fig 2 Percent of patients reporting tooth sensitivity and/or gingival irritation on a given day during nightguard vital bleaching.

Figs 3a and 3b Examples of tooth characteristics evaluated in the study.

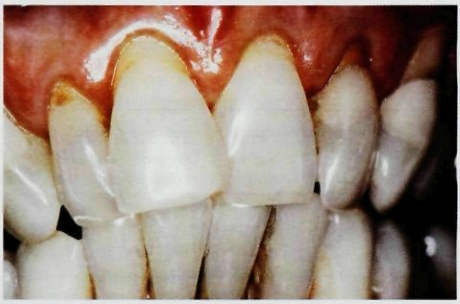

Fig 3a *(Above)* Gingival recession and defective restorations.

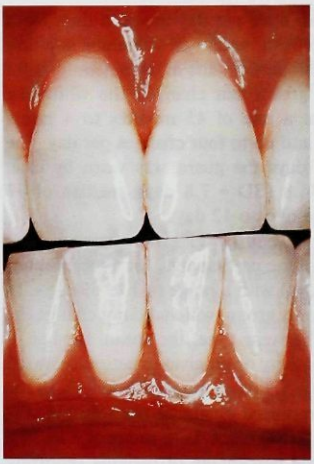

Fig 3b *(Right)* Gingival recession.

sensitivity, seven reported gingival irritation, and four reported both. Only four of the 14 participants experiencing side effects quit at some point during the whitening procedure. As the side effects subsided, all four resumed the NGVB process.

As a group, only seven patients (11%) experiencing side effects quit at some point during the NGVB process. The average length of time participants discontinued the whitening process was 3.3 days (SD = 3.0), with a range of 1 to 10 days. Four of the seven reported having side effects again after resuming the NGVB process.

Statistical analysis

Side effects (tooth sensitivity and/or gingival irritation) were reported in 55% of the participants (47% of the Proxigel users and 74% of Gly-Oxide users). The presence of a side effect was not significantly associated with any of the demographic risk factors or with

Table 2 Comparison of bleaching solutions* used in the study

	Proxigel	Gly-Oxide
Participants (n)	45	19
Age (y)	35.1	39.5
Range	10-66	25-68
Sex (n)		
Male	10	7
Female	35	12
Length of use (d)	34.9	34.7
Range	6-42	18-42
Sensitivity		
Yes	21	14
No	24	5
Sensitivity (d)	6.7	6.7
pH	4.8	7.0
Thickening agent	Carbopol	None

* Both 10% carbamide peroxide.

any type of tooth characteristic. Side effects were reported in about the same percentage of females and males, 55% and 53%, respectively. The percentage of patients younger than 40 years of age reporting side effects (59%) was higher, but not significantly higher, than that in older patients (45%).

Existing allergies were reported in 42% of the participants. Of these, 10 used Gly-Oxide and 17 used Proxigel as the whitening agent. Fifty-two percent of the participants who reported an existing allergy experienced side effects, while 57% of those not reporting an existing allergy experienced side effects.

The maxillary arch was bleached 80% of the time. There was no statistically significant difference in the occurrence of side effects when the maxillary arch or when the mandibular arch was bleached (57% and 40%, respectively), nor was there an association between tooth characteristics and side effects.

Fifty-eight percent of the participants wore the guard either at night (35) or during the day (2) without changing the solution. Forty-two percent wore the guard either during the day with solution changes (6) or during the day and night with solution changes (21). Side effects were reported in 38% of the participants who did not change their solution during their usage time and in 78% of those who changed solution at least once during the day or night. There was a statistically significant difference ($P = .02$) in the proportion of side effects between the two types of usage patterns (see Table 1).

Participants using Gly-Oxide reported significantly more side effects (74%) than did the Proxigel users (47%). However, the usage pattern was associated with the type of gel used ($P = .001$). Fifteen (79%) of the Gly-Oxide users changed solutions, while only 12 (27%) of the Proxigel users changed solutions. When the association between the type of whitening solution and side effect was evaluated with an analysis that controlled for the usage pattern, the association was not significant ($P = .57$; Breslow-Day test of homogeneity, $P = .22$).

Discussion

The purpose of this project was to determine risk factors in the development of side effects (tooth sensitivity and/or gingival irritation) associated with the NGVB technique. It is not understood why some patients develop side effects while others do not because all patients are exposed to the same chemical by-products of carbamide peroxide degradation. Yarborough[18] stated that side effects may be related to the water content of the bleaching solution. Anhydrous-based whitening solutions may cause more side effects because of their drying effect on the teeth and gingiva.

The addition of Carbopol to whitening agents may also play a part in causing sensitivity or irritation.[19] Carbopol is added to whitening solutions as a thickening agent to improve tissue adherence and allow for a timed or sustained release of the whitening agent. A study that compared low-viscosity whitening solutions without Carbopol to high-viscosity solutions containing Carbopol revealed that the presence of carbamide peroxide can be demonstrated for longer periods of time in solutions with Carbopol.[20] Thus the oral tissues are exposed to the active whitening agent and its by-products for a longer period of time, and this may play a part in tooth sensitivity and gingival irritation.

Whitening solutions with a lower pH have also been implicated in the development of side effects by possibly removing minerals from the tooth at a pH below 5.5.[21] It is important to recognize the easy passage of 10% carbamide peroxide through both enamel and dentin to the pulp in 15 minutes.[22] Hence, a reversible pulpitis in patients with low pain thresh-

olds may explain tooth sensitivity, irrespective of tooth characteristics. The development of side effects during NGVB may therefore be a multifactorial phenomenon involving the interactions of the whitening solution (with formation of free radicals), the whitening tray (minor orthodontic movement of the teeth or pressure on the teeth), and patient factors such as allergies and chemical sensitivities (especially to carbamide peroxide chemistry and the chemical components of the guard).

Participants of the study were asked to record side effects, if they occurred, on the daily log form. Approximately 55% of the participants reported side effects during the study; of the reporting participants, two thirds had gingival recession, defective restorations, or enamel-cementum defects. During the postoperative appointment following the bleaching procedure, each patient was questioned about the side effects experienced. It was determined that participants could have either over-recorded or under-recorded side effects based on their perception of pain. It was evident that some patients had recorded any sensitivity or irritation, whether related to whitening or not, while others only recorded major side effects or discomfort. No attempt was made to quantify the degree of discomfort, only the presence or absence of it.

During the 6-week whitening period only 11% (7) of the participants quit at some time during the study as a result of side effects. After a mean of 3.3 days, all seven participants resumed the whitening procedure to completion. When patients were interviewed about the whitening procedure and its side effects, most stated that the benefit and personal satisfaction of having whiter teeth was worth the discomfort they had experienced and that they would continue to whiten their teeth even when having tooth sensitivity and/or gingival irritation.[23]

Possible risk factors for the development of side effects evaluated in this project were sex, age, existing allergy, dental arch, whitening solution, tooth characteristics, and usage pattern. Sex was thought to be a possible indicator for tooth sensitivity and gingival irritation because of the hormonal changes that occur in females during their menstrual cycle and the interaction of these changes with the gingiva and chemistry of the whitening solution. The time of the menstrual cycle was not recorded. Age was evaluated because pulpal changes occurring with age may make the tooth less sensitive to the whitening solution and its by-products.

Existing allergy was evaluated as a possible risk factor because the patient could have been sensitive to the carbamide peroxide solution and/or its by-products or to the chemical makeup of the guard. Two chemicals often contained in the whitening tray material are diethyl phthalate and vinyl acetate. Diethyl phthalate is irritating to the mucous membrane and is narcotic in high concentrations.[24] Vinyl acetate is also an irritant on contact with skin or eyes and is moderately toxic by absorption through the skin or mouth. Prolonged exposure to the skin is to be avoided.[25]

Components of whitening solutions may include hydrogen peroxide, glycerin, Carbopol, and phenacetin. Aqueous solutions of 3% hydrogen peroxide are considered to have a low toxicity and no primary systemic effects when ingested because of its decomposition in the intestines.[26] However, hydrogen peroxide can be irritating to skin and oral mucosa. Glycerin is a sweet, syrupy liquid used as a vehicle for many drugs. Glycerin can absorb water and in high concentrations is dehydrating and irritating to skin and mucous membrane.[26] Carbopol (carboxypolymethylene) is a synthetic cross-linked polymer of acrylic acid marketed as a thickener, and is believed to be nontoxic since it is stable and absorbed in the gastrointestinal tract.[26] Phenacetin (acetophenetidin) is considered very toxic and may cause skin rashes.[26] Proxigel no longer contains this element.[27] The dental arch was evaluated to see if one arch was more sensitive than the other. None of the four possible risk factors evaluated was determined to be a predictor of tooth sensitivity or gingival irritation with $P < .05$ level.

Tooth characteristics such as gingival recession, defective restorations, enamel-cementum abrasion, etc, were evaluated by color slides. Initially it was thought that these characteristics might lead to side effects during the NGVB procedure. No statistically significant correlation could be detected between patients with these tooth characteristics and side effects. From personal experience, more valid indicators would be to ask the patient if his or her teeth are normally sensitive to hot and cold and/or whether or not he or she experiences sensitivity while undergoing or after a prophylaxis. Often a gentle air blast from the air-water syringe can determine sensitivity.

Several modalities have been suggested to decrease sensitivity during the whitening process. However, the use of these modalities (desensitizing toothpaste, fluoride application, etc) has not been tested in a controlled clinical study. Although this study compared two entirely different 10% carbamide peroxide solutions with respect to pH, Carbopol and base

material, no statistically significant difference in the development of side effects could be attributed to either whitening agent after the analysis controlled for usage pattern.

The development of tooth sensitivity and gingival irritation was associated with the usage pattern of the patient ($P < .02$). Patients who changed the whitening solution more than once a day reported statistically significantly more side effects than did those who did not change the bleaching solution during their usage time. A recent report has demonstrated the presence of more than 60% of the active peroxide in new formulations in the tray after 4 hours of clinical usage.[28] Hence, to change material more frequently is to waste active solution and invite increased side effects.

Summary

The purpose of this study was to determine risk factors in the development of side effects (tooth sensitivity and/or gingival irritation) associated with the NGVB technique. The solutions used were a moderately low pH, Carbopol-containing, anhydrous-based solution (Proxigel; and a neutral pH, non-Carbopol-containing solution (Gly-Oxide). No statistical relationship existed between age, sex, allergy, whitening solution used, toth characteristics, or dental arch lightened and the development of side eects (tooth sensitivity and/or gingival irritation). Patients who changed the whitening solution more than once a day reported statistically significantly more side effects ($P < .02$) than did those who did not change the bleaching solution during their wear time.

Recommendations

The following actions are recommended to reduce the incidence of side effects (tooth sensitivity and gingival irritation) associated with NGVB:

1. A complete health history that evaluates known allergies and sensitivities to peroxides, vinyl, glycerine, etc, and especially a history of normally sensitive teeth, should be obtained.
2. A thorough oral examination of each patient should be performed, including an evaluation of gingival recession, exposed cementum, defective restorations, caries, tooth sensitivity, pulpal pathosis, or other conditions that may contribute to additional sensitivity. Sensitivity to an air blast or explorer touch may also be warning signs.[29]
3. Changing of the whitening solution during a 24-hour period should be eliminated. For initial sensitivity the patient should be instructed to do one of the following: discontinue for a day; reduce application time and then gradually increase back to ideal; reduce the frequency of application; decrease the amount of bleaching solution in the guard; or scallop the guard to reduce soft tissue contact.
4. The patient should be reevaluated if sensitivity or irritation occurs for more than 1 week after the beginning of the NGVB procedure. Insertion and removal technique should be observed to see if the patient is scraping the gingiva with fingernails or using an improper path of insertion. Guards are more easily removed from their posterior portion instead of their anterior portion. If a guard has to be remade, a new impression should be taken. Prior to fabrication of the tray, severe undercut areas should be blocked out. When the more viscous whitening agents now on the market are used, the guard should be trimmed so that it covers only enamel. The guard should be 1 mm short of the cementoenamel junction.

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