Tray delivery of potassium nitrate–fluoride to reduce bleaching sensitivity

Van B. Haywood, DMD[1]/W. Frank Caughman, DMD, MEd[1]/
Kevin B. Frazier, DMD[1]/Michael L. Myers, DMD[1]

Objective: Tooth sensitivity is a common side effect associated with tooth whitening. The purpose of this study was to determine if bleaching tray delivery of potassium nitrate–fluoride reduces bleaching sensitivity enough to allow continuation of whitening treatment. **Method and materials:** Thirty patients were enrolled in a university-approved clinical study and had their teeth bleached at night with 10% carbamide peroxide in a custom-fitted tray. The bleaching tray was a rigid experimental design for which sensitivity was expected. If tooth sensitivity was experienced, the patient applied a gel containing 5% potassium nitrate and 1,000 ppm sodium fluoride in the bleaching tray for various time periods. Log forms were collected upon completion of bleaching, and patient interviews were used to compare effects of the gel before and after sensitivity treatment. **Results:** Sixteen out of 30 patients experienced tooth sensitivity. Of those 16 patients, 12 used the gel, and 11 of the 12 reported a reduction in sensitivity. Treatment times ranged from 10 minutes before bleaching to 30 minutes before and after. The number of applications ranged from one to continuous use. Some patients were able to continue bleaching after one gel application with no subsequent sensitivity. Other patients were unable to continue bleaching unless they continued using the gel. The incidence of tooth sensitivity (53%) reported in this study is consistent with sensitivity reported in studies using semi-rigid custom-fitted trays made from stone casts with a nonscalloped, nonreservoir design. **Conclusion:** The use of a 5% potassium nitrate–fluoride gel applied in the tray as needed for tooth sensitivity associated with nightguard vital bleaching can reduce sensitivity in a majority of patients and allow most patients to continue bleaching to completion. *(Quintessence Int 2001;32:105–109)*

Key words: bleaching, carbamide peroxide, potassium nitrate, sensitivity

CLINICAL RELEVANCE: The use of bleaching trays to deliver potassium nitrate–fluoride can reduce bleaching sensitivity and allow continuation of bleaching treatment for most patients.

Nightguard vital bleaching with 10% carbamide peroxide has enjoyed great success since it was first introduced to the dental profession in 1989.[1] This peroxide bleaching material is usually applied to the teeth in a custom fitted tray.[2] Treatment is ideally accomplished while wearing the bleaching tray overnight, but comparable results can be achieved by bleaching anytime during the day for several consecutive hours.[3,4]

[1]Department of Oral Rehabilitation, Medical College of Georgia, School of Dentistry, Augusta, Georgia 30912-1260.

Reprint requests: Van B. Haywood, School of Dentistry, AD3144, Medical College of Georgia, Augusta, Georgia 30912-1260. Email: vhaywood@mail.mcg.edu

Presented before the International Association for Dental Research, Washington DC, March 2000.

The most common side effect associated with carbamide peroxide bleaching is tooth sensitivity.[5] This sensitivity is thought to be due to the finding that the byproducts of 10% carbamide peroxide (3% hydrogen peroxide and 7% urea) readily pass through the enamel and dentin into the pulp in a matter of minutes.[6] Sensitivity is in the form of a reversible pulpitis caused from the dentinal fluid flow and pulpal contact of the material without apparent harm to the pulp.[7] These chemicals may change the osmolarity of the fluids in the pulp and dentin, producing a reversible pulpitis.

Claims have been made that some nightguard bleaching products do not cause sensitivity. However, double-blind clinical studies have shown that sensitivity occurs in 55% to 75% of treatment groups.[8–19] The placebo groups also experienced between 20% and 30% sensitivity. One study even reported tooth sensitivity of about 15% in subjects wearing only the bleaching tray. Therefore, it appears that sensitivity is a multifactorial event that cannot be totally avoided, because it is not exclusively related to the peroxide whitening material.

One option for addressing the sensitivity associated with tooth bleaching is to try to predict which patients will become sensitive. However, the only significant predictors determined thus far are a previous history of sensitive teeth and/or a regimen of more than one application of the bleaching solution per day. No other indicators are apparent at this time.[20]

Since tooth sensitivity during bleaching is so common, yet unpredictable, it must be addressed clinically when it occurs. Often the sensitivity experienced is "mild," little more than an occasional annoyance to the patient requiring no alteration in the treatment protocol. Some patients experience sensitivity that cannot be ignored and in these cases, the dentist may have to instruct the patient to decrease the frequency and duration of treatments.[21] Typical advice in these cases would be to have the patient bleach every other day or for less time. When this protocol fails, some practitioners advocate the use of topical fluorides in conjunction with the bleaching treatments. In severe cases of sensitivity, some patients may have to stop bleaching either completely or for a few weeks.

In 1995, Jerome published a case study describing a technique for treating tooth sensitivity in post-periodontal surgery patients.[22] Instead of having the patient brush with a dentifrice containing potassium nitrate, he placed the potassium nitrate dentifrice in a custom-made soft tray. The use of the tray delivery system increased the efficacy of the potassium nitrate dentifrice, because the medicament-tooth contact time was increased as compared to toothbrushing.

The purpose of this paper is to present the results of a clinical study that evaluated the use of a tray-delivered potassium nitrate and fluoride solution to treat sensitivity occurring during nightguard tooth whitening procedures.

METHOD AND MATERIALS

Thirty patients were enrolled in a university-approved clinical study to evaluate tooth whitening using an experimental, directly fabricated bleaching tray. Patients included in this study had both normally discolored teeth and tetracycline-stained teeth. An ADA approved 10% carbamide peroxide,[23] Colgate Platinum (original formula, Colgate Oral Pharmaceuticals), was used as the whitening agent. Patients were fitted with a custom-fabricated experimental design tray that has been previously described.[24] The tray extended onto the gingival tissue in a nonscalloped fashion and contained no reservoirs or spacers.

Because of previous whitening studies using carbamide peroxide, as well as experience with a rigid tray, sensitivity was expected. All patients were given a syringe with an experimental gel containing 5% potassium nitrate and 1,000 ppm sodium fluoride. Each patient scored pre-treatment (baseline) sensitivity from 1 to 10 on an analog scale. Patients were instructed to record on an identical analog scale any episodes of sensitivity that occurred during whitening treatment. If sensitivity occurred, the patients were instructed to apply the experimental gel in their bleaching tray for 10 minutes following bleaching treatment. After this treatment period, they were required to rescore their sensitivity level on another analog scale. If a 10-minute application time of the desensitizing gel following bleaching treatment proved unsuccessful in reducing sensitivity, the patient was instructed to increase the gel application time to 20 minutes. If this protocol was unsuccessful, the time was increased to 30 minutes. If sensitivity persisted, the patients were instructed to apply the sensitivity gel before and after bleaching for 10 minutes, and then increasing to 20 and then 30 minutes if necessary. After each application, patients were asked to record their sensitivity scores.

The patients were recalled monthly until the bleaching treatment was complete. At completion, patients were interviewed and their sensitivity-scoring forms were collected.

RESULTS

The outcomes of the clinical whitening trial were as follows. Sixteen of 30 patients (53%) experienced some sensitivity. Of the 16 experiencing sensitivity, 12 used the gel to continue bleaching. Of the 12 using the gel, 11 reported a reduction in sensitivity and the ability to continue bleaching to a successful outcome. Patient 12 was also able to continue, but lost the data sheets, so they were not counted in the results. The other 4 patients who had sensitivity were able to continue treatment to completion without the use of gel.

Sensitivity varied greatly in this trial, so the gel application times were very different. The results are presented in Table 1. One patient only needed a single gel application during treatment to be able to continue successfully, while 5 patients needed 2 to 5 applications for success. Four patients used 5 to 10 applications over the course of their bleaching treatment, while one patient had to continually apply the gel to successfully complete the whitening process.

For the 11 patients who reported sensitivity, the incidence of sensitive days relative to the length of the bleaching treatment is reported in Table 2. The frequency ranged from 1% to 100% of the days of bleaching treatment.

DISCUSSION

Total treatment time for whitening teeth with night-guard bleaching techniques cannot be predicted. Treatment typically continues until the teeth are as white as the patient desires, or they have ceased changing color with continuous treatment. Because there were a variety of discolorations treated, from mild discoloration to tetracycline staining, there were a variety of treatment times used for successful whitening. The number of treatment times ranged from 12 (mild discoloration) to 330 (tetracycline staining) consecutive nights of applications in the group of patients using the gel to treat sensitivity. If the number of days of sensitivity, which were not always continuous days, are expressed as a percentage of the total number of treatment days, a better indication of the amount of sensitivity experienced can be obtained. The percentage of sensitive days relative to treatment days are presented in Table 2 and ranged from 1% to 100%, with an average of 17% of days of sensitivity. This data seems to indicate that the sensitivity was not related to bleaching duration.

When the frequency of treatment times were analyzed, the 10-minute application time after completion of the whitening treatment was used 35 times by 8 patients. The 20-minute application time after whitening was used 20 times by 5 patients. One patient used a nonprescribed treatment time of 15 minutes, which was included in the 20-minute data. The next most frequent application time was 20 minutes before bleaching.

The gel used to treat sensitivity was a combination of potassium nitrate and fluoride. Both are ingredients with a history of success in treating tooth sensitivity, but the two materials have very different mechanisms of action. Like carbamide peroxide, potassium nitrate also passes easily through the enamel and dentin to the pulp in a matter of minutes.[25,26] It has an apparent analgesic or anesthetic effect on nerve fibers by not allowing them to re-polarize after the initial depolarization in the pain signal. On the other hand, fluoride treats sensitivity peripherally by occluding the dentinal tubules and reducing the fluid flow to the pulp.[27]

Potassium nitrate has been used in desensitizing toothpastes for many years and is approved by the Food and Drug Administration at a maximum concentration of 5%.[28] Most toothpastes contain 5% potassium nitrate and fluoride. Examples include all 6 varieties of Sensodyne toothpaste (Block Drug), Crest Desensitize (the original Dequel used in the Jerome article), Colgate Desensitize, and many others. Toothpaste application generally takes 2 to 3 weeks to become effective.[29] Professionally-supplied potassium nitrate and fluoride products specifically designed for tray application include Relief (Discus Dental), Desensitize (DenMat), and UltraEZ (Ultradent Products). Some whitening systems also use potassium nitrate in the bleaching gel.

TABLE 1 Frequency of gel application for bleaching sensitivity

No. of applications	No. of patients
1	1
2–5 (not continuous)	5
5–10 (not continuous)	4
Continuous	1

TABLE 2 Relative frequency for patients experiencing sensitivity

Length of bleaching treatment (days)	Incidence of sensitivity (days)	Frequency (%)
330	5	1
150	6	4
20	1	5
80	4	5
140	7	5
144	9	6
30	4	13
22	3	14
30	6	20
29	6	21
12	12	100

Average frequency of sensitivity in total treatment: 17%.

Nitrate is a normal component of the human diet. A typical daily intake by an adult in the United States is about 75 mg/day.[30] Mean daily intake of potassium nitrate and sodium nitrite from total diet was calculated at 215 mg and 7.7 mg, respectively.[31] Of the dietary intake of nitrate, over 85% comes from the natural nitrate content of vegetables such as beets, celery, lettuce, and spinach. While concern exists for nitrosamines, known carcinogens in experimental systems that may form nitrite and certain amines, there does not appear to be a significant problem with the use of potassium nitrate in this manner. Based on estimates of the amount of material that may be ingested during bleaching,[32,33] the normal daily dietary intake of nitrates is approximately 40 to 70 times the amount potentially ingested by this application technique (Yiming Li, personal communication, June 2000). Also, a reduction reaction is needed in order to convert nitrate (NO_3) to nitrite (NO_2), which may then interact with certain amines to form nitrosamines. Peroxides in bleaching gels are strong oxidizers, and bleaching is generally considered an oxidation reaction (Yiming Li, personal communication, June 2000).

The use of potassium nitrate in desensitizing toothpastes for many years has also demonstrated long-term clinical safety in human usage.

One shortcoming of at-home bleaching is that treatment requires patient compliance to be successful. This at-home compliance requirement also proved to be a frustration in collecting data in this study. Although the potassium nitrate–fluoride gel was helpful in allowing patients to continue whitening, the data acquisition was not as successful as originally planned. Patients lost forms or completed them incorrectly. Illness and travel schedules interrupted continuity, and varied treatment times made comparisons difficult. Since sensitivity is seldom a continuous event, strict adherence to protocol was unattainable.

On the other hand, this treatment design afforded the patient control of when and how to treat their sensitivity. They were given an active role in managing their discomfort with a technique that was simple and effective. This study indicates that 10- to 30-minute applications of the desensitizing material, used as needed when sensitivity occurs, can be very helpful. This desensitizing application may have to be continuous or alternated with bleaching treatments.

CONCLUSION

The use of a 5% potassium nitrate–fluoride gel applied in the bleaching tray as needed for tooth sensitivity from nightguard bleaching reduced tooth sensitivity in a majority of patients. This reduction in sensitivity allowed mofst patients to continue whitening to a successful completion, including those patients undergoing long-term treatment for tetracycline staining.

ACKNOWLEDGMENTS

Supported by Colgate Oral Pharmaceuticals (Grant No. 11-12-03-1260-82) and the Medical College of Georgia.

REFERENCES

1. Haywood VB, Heymann HO. Nightguard vital bleaching. Quintessence Int 1989;20:173–176.
2. Haywood VB. Nightguard vital bleaching: Current concepts and research. J Am Dent Assoc 1997;128(suppl):19–25.
3. Haywood VB. Bleaching of vital teeth: Current concepts. Quintessence Int 1997;28:424–425.
4. Haywood VB. Current status of nightguard vital bleaching. Compend Contin Educ Dent 2000;21(28, suppl):10–17.
5. Haywood VB. History, safety, and effectiveness of current bleaching techniques and applications of the nightguard vital bleaching technique. Quintessence Int 1992;23:471–488.
6. Cooper JS, Bokmeyer TJ, Bowles WH. Penetration of the pulp chamber by carbamide peroxide bleaching agents. J Endod 1992;18:315–317.
7. Schulte JR, Morrissette DB, Gasior EJ, Czajewski MV. The effects of bleaching application time on the dental pulp. J Am Dent Assoc 1994;125:1330–1335.
8. Barnes DM, Kihn PW, Romberg E, George D, DePaolo L, Medina E. Clinical evaluation of a new 10% carbamide peroxide tooth whitening agent. Compend Contin Educ Dent 1998;19:968–978.
9. Heymann HO, Swift EJ Jr, Bayne SC, May KC Jr, Wilder AD Jr, Mann GB, Peterson CA. Clinical evaluation of two carbamide peroxide tooth-whitening agents. Compend Contin Educ Dent 1998;19:359–375.
10. Reinhardt JW, Elvins SE, Swift EJ Jr, Denehy GE. A clinical study of nightguard vital bleaching. Quintessence Int 1993;24:379–384.
11. Swift EJ, May KN, Wilder AD, Heymann HO, Wilder RS, Bayne SC. Six-month clinical evaluation of a tooth whitening system using an innovative experimental design. J Esthet Dent 1997;9:265–274.
12. Haywood VB, Leonard RH, Nelson CF, Brunson WD. Effectiveness, side effects and long-term status of nightguard vital bleaching. J Am Dent Assoc 1994;125:1219–1226.
13. Leonard RH Jr. Efficacy, longevity, side effects, and patient perceptions of nightguard vital bleaching. Compend Contin Educ Dent 1998;19:766–781.
14. Leonard RH, Bentley C, Phillips C, Eagle JC, Garland GE, Gari GJ, Haywood VB. ADA Controlled clinical trial of a 10% carbamide peroxide solution [abstract 2365]. J Dent Res 1997;76:309.
15. Leonard RH, Garland GE, Eagle JC, Caplan DJ. Safety issues of 10% and 16% carbamide peroxide whitening solutions [abstract 315]. J Dent Res 1999;78:145.
16. Howard WR. Patient-applied tooth whiteners. J Am Dent Assoc 1992;123:57–60.
17. Rosenstiel SF, Gegauff AG, Johnston WM. Randomized clinical trial of the efficacy and safety of a home bleaching procedure. Quintessence Int 1996;27:413–424.
18. Small BW. Bleaching with 10 percent carbamide peroxide: An 18-month study. Gen Dent 1994;42:142–146.
19. Matis BA, Cochran MA, Eckert G, Carlson TJ. The efficacy and safety of a 10% carbamide peroxide bleaching gel. Quintessence Int 1998;29:555–563.
20. Leonard RH, Haywood VB, Phillips C. Risk factors for developing tooth sensitivity and gingival irritation associated with nightguard vital bleaching. Quintessence Int 1997;28:527–534.
21. Haywood VB. Current status and recommendations for dentist-prescribed, at-home tooth whitening. Contemp Esthet Restorative Pract 1999;3(1):2–9.
22. Jerome CE. Acute care for unusual cases of dentinal hypersensitivity. Quintessence Int 1995;26:715–716.
23. Guidelines for the acceptance of peroxide-containing oral hygiene products, American Dental Association Council on Dental Therapeutics. J Am Dent Assoc 1994;125:1140–1142.

24. Haywood VB, Caughman WF, Frazier KB, Myers ML, Bonita CY, Curtis JP, Christina-Beck L. Feasibility of immediate direct thermoplastic whitening trays [abstract 1337]. J Dent Res 1998;77:273.
25. Hodosh M. A superior desensitizer–potassium nitrate. J Am Dent Assoc 1974;88:831–832.
26. Markowitz K. Tooth sensitivity: Mechanism and management. Compend Contin Educ Dent 1992;14:1032–1046.
27. Gaffar A. Treating hypersensitivity with fluoride varnishes. Compend Contin Educ Dent 1998;19:1088–1097.
28. Tentative Final Monograph [FR56, 48302–48347]. 24 Sept 1991.
29. Silverman G, Berman E, Hanna CB, Salvato A, Fratarcangelo P, Bartizek RD, et al. Assessing the efficacy of three dentifrices in the treatment of dentinal hypersensitivity. J Am Dent Assoc 1996;127:191–201.
30. The health effects of nitrate, nitrite, and N-nitroso compounds. Washington, DC: National Academy Press, 1981.
31. Stephany RW, Schuller PL. The intake of nitrate, nitrite and volatile N-nitrosamines and the occurrence of volatile N-nitrosamines in human urine and veal calves. IARC Sci Publ 1978;19:443–460.
32. Li Y. Biological properties of peroxide-containing tooth whiteners. Food Chem Toxicol 1996;34:887–904.
33. Matis BA, Gaiao U, Blackman D, Schultz FA. Eckert GJ. In vivo degradation of bleaching gel used in whitening teeth. J Am Dent Assoc 1999;130:227–235.