



Clinical Trial of Three 10% Carbamide Peroxide Bleaching Products

(Essai clinique de trois produits blanchissants à base de peroxyde de carbamide à 10 %)

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SOMMAIRE

Historique

Le marché d'aujourd'hui regorge de produits blanchissants commerciaux. Or, rares sont ceux qui ont fait l'objet de comparaisons cliniques.

Méthodes

Pour cette étude, trois différents produits blanchissants commerciaux à base de peroxyde de carbamide à 10 % ont été utilisés par 24 patients dans le cadre d'un protocole de nuit, durant une période de deux semaines. Chaque patient devait utiliser deux produits simultanément, pour une comparaison en parallèle.

Résultats

Effet de blanchiment des dents est apparu en moyenne après $2,4 \pm 1,7$ jours. La sensibilité des dents a été l'effet secondaire le plus souvent enregistré, 64 % des patients l'ayant signalé après $4,8 \pm 4,1$ jours, et ce, pour une durée de $5,0 \pm 3,8$ jours. Bien que des différences aient été observées entre les trois produits testés chez un même patient, aucune différence statistique ne l'a été, pour ce qui est du délai d'apparition de l'effet subjectif du blanchiment ou du délai d'apparition, de la fréquence et de la durée de la sensibilité des dents, et ce, que ces produits soient comparés par paire ou individuellement ($p < 0,05$).

Conclusion

Le choix du produit blanchissant à utiliser devrait se faire en fonction de la concentration de l'ingrédient actif, de la viscosité du produit et autres propriétés commerciales. D'autres recherches devront être effectuées pour étudier les causes de la sensibilité des dents et les méthodes susceptibles d'en réduire la gravité et la fréquence.

Mots clés MeSH : dental devices, home care; peroxides/therapeutic use; tooth bleaching/methods.

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Cet article a fait l'objet d'une révision par des pairs.

Introduction

Patients today have many options to achieve a more ideal tooth colour or appearance, including bleaching, veneers and crowns. Tooth bleaching is a relatively simple and conservative option. The most popular method of tooth bleaching is the home bleaching system wherein the

patient wears a custom-made bleaching tray containing carbamide peroxide overnight.¹⁻⁴

A profusion of commercial bleaching systems exists on the market today. Home bleaching systems commonly utilize carbamide peroxide to deliver a more stable form of hydrogen peroxide, the active bleaching agent. Most

home bleaching systems contain 10% carbamide peroxide, but different commercial brands claim superiority based on differences in the carrier of the active ingredient, which could affect material delivery, material retention in the bleaching tray (material viscosity) or patient compliance (tooth sensitivity, material taste). Although

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Fig. 1: Pre-study photo of maxillary arch. Teeth were matched to the Vita shade tab A3.



Fig. 2: Post-study photo of maxillary arch. Teeth were matched to the Vita shade tab A1.

there are a few reports that compare the different bleaching systems by listing their material and marketing contents,⁵⁻⁶ clinical comparisons of different bleaching systems are rare.

In this study, three commercial 10% carbamide peroxide bleaching systems were used by 24 patients in an overnight protocol maintained for two weeks to compare their subjective clinical effects.

Materials and Methods

The bleaching treatment was performed on 24 volunteer adult dental students, staff and patients who expressed an interest in bleaching their teeth. The indications, contraindications, risks and benefits of bleaching were written into the consent form and discussed with each subject. The bleaching treatment was performed on vital teeth with no or minimal intact restorations, no or minimal dentin exposure, and no or minimal history of tooth sensitivity. The fabrication of the bleaching trays, the dispensing of the bleaching kits and the photographing the patients were personally supervised by the author.

An irreversible hydrocolloid impression was taken of each patient's upper arch to fabricate stone study models. Reservoirs approximately 0.5 mm to 1.0 mm thick for the bleaching agent were built into the bleaching trays by first applying a photopolymerizable spacer material (LC Block-Out, Ultradent) onto the labial surfaces of the teeth to be bleached.

The number of teeth to be bleached depended on the patient's smile line. Generally, teeth 14 to 24 or 15 to 25 were prepared for bleaching on the study model. The spacer was kept away (approximately 0.25 mm to 0.50 mm) from the gingival margin, the interproximal contacts and the incisal and occlusal edges. A flexible 0.9-mm-thick ethyl vinyl acetate bleaching tray was then vacuum formed and trimmed in a scalloped fashion to avoid all soft tissue contact.

The proprietary bleaching systems under investigation were Nite White Excel (peppermint cream flavour, Discus Dental), Platinum Professional Toothwhitening System (Colgate) and Opalescence Whitening Gel (regular flavour, Ultradent). For each patient, two bleaching systems were randomly selected and randomly designated "left" or "right". The patient was to use one bleaching system for the left side and another for the right side, thus using the two agents simultaneously. A preliminary trial using disclosing agents in one of the bleaching materials showed no significant crossover of bleaching material to the other side when the bleaching tray was fabricated as described. Furthermore, mild crossover of two bleaching materials was not a serious concern, because other teeth in addition to the central incisors were to be used for comparing the bleaching effect.

Each patient received a daily log form, which clearly labelled which material was to be used for

which side. The log was also to record the patient's smoking habits, the patient's coffee and tea intake, the presence or absence of restorations on the teeth to be bleached, and the presence or absence of subjective tooth sensitivity before bleaching. Patients were instructed how to place the bleaching agents into the bleaching trays. Each patient was to wear the tray for approximately 14 consecutive nights (after brushing and during sleep). Each patient was asked to record daily the duration of bleaching and any subjective evaluations or effects of each bleaching agent. Patients were advised that if they experienced tooth sensitivity or other side effects, they could reduce their exposure to the agents by reducing either the duration or the frequency of bleaching. The patients were free to discontinue the treatment at any time.

A pre-study photograph of the teeth was taken under standardized lighting conditions using the same camera and dental operatory light, with and without a matching Vita shade guide tab of the teeth to be bleached (**Fig. 1**). After the bleaching treatment, a post-study photograph of each patient was taken (**Fig. 2**) and the daily logs were collected. Data on the onset of tooth whitening (first patient record of subjective tooth whitening) and the onset, frequency and duration of tooth sensitivity for each bleaching agent were analyzed by ANOVA ($p < 0.05$). Paired *t*-tests were also performed

to compare the two bleaching agents used side-by-side on the same patient ($p < 0.05$).

The protocol for this study was approved by the University of Toronto Office of Research Services Human Subjects Review Committee.

Results

Fifteen women and nine men participated. Their mean age was 28.5 years (range 17 to 51). They did not exhibit tooth sensitivity or recession in the subject teeth before the bleaching treatment. The patients bleached their teeth for 13.5 ± 2.9 nights. Three-quarters of the patients (18 of 24) complied with the daily regimen. The other patients skipped a day or more during the treatment for sensitivity reasons. The recorded time of onset of subjective tooth whitening and the onset, frequency and duration of tooth sensitivity are listed in **Table I**.

Side effects of the bleaching treatment presented minimal problems to the patients. Six patients (25%) reported gum tingling, tenderness or mild sensitivity for one or two days. One patient reported a scratchy throat for one day. One patient reported sleep interruption and a sore jaw for a couple of days toward the end of treatment. Another patient reported some bruxism as a response to wearing the tray. Three patients did not like the consistency of one of the bleaching products compared with the other.

Inpatient differences in whitening effect and tooth sensitivity by the two commercial bleaching systems used by each patient were occasionally reported; however, there was no clear trend for the inpatient differences for the bleaching agents. No inpatient differences in tooth whitening were noted between the left and right halves. There were no statistical differences in the time of onset of subjective tooth whitening and the onset, frequency and duration of tooth sensitivity among the three commercial bleaching systems when compared pairwise (paired *t*-test) or independently (ANOVA).

Table I

Time of Onset of Subjective Tooth Whitening and Time of Onset, Frequency and Duration of Tooth Sensitivity as Reported by Patients After Bleaching Treatment

Product	Number of patients	Onset of whitening (days)	Frequency of sensitivity (%)	Onset of sensitivity (days)	Duration of sensitivity (days)
Platinum	17 halves	2.6 ± 1.6	65	6.2 ± 4.8	4.4 ± 3.4
Opalescence	15 halves	2.1 ± 1.4	60	4.0 ± 3.7	6.2 ± 4.9
Nite White	16 halves	2.4 ± 2.0	62	3.9 ± 3.6	4.5 ± 3.0
Totals	24	2.4 ± 1.7	64	4.8 ± 4.1	5.0 ± 3.8

Discussion

A placebo gel was not included in this study because it is well known that carbamide peroxide and hydrogen peroxide bleaching materials will lighten teeth significantly more than placebo materials.⁷⁻¹¹ The patients were aware which bleaching agents they were using. It was thought that potential bias by the patients toward a particular agent would be minimal given that the agents had the same 10% carbamide peroxide concentration, the patients had no previous bleaching experience or affiliations with any of the agents, and no marketing or extraneous packaging materials were given to the patients.

No attempt was made to quantify the degree of whitening achieved. Other studies have attempted to quantify tooth colour changes by using the Vita shade tab system or a colorimeter.⁷⁻¹¹ The Vita shade tab system requires subjective shade matching, and the colorimeter has been criticized because of its technique sensitivity and need for a flat surface. In addition, small increments of change that could perhaps be measured by instruments such as a colorimeter would not necessarily indicate a clinically significant result. A clinically significant bleaching result necessitates a clear perception by the patient of a difference in tooth colour. In this study, therefore, a notation by the patient that the teeth became whiter was accepted as a clinically significant colour change.

Every patient reported some degree of tooth whitening. The colour changes ranged widely from very slight to dramatic. The average onset for apparent tooth colour change was 2.5 days. An early onset of bleaching effect is desirable to encourage compliance. Four patients reported the onset of tooth whitening as occurring in localized areas of their teeth, resulting in white spots. This response to bleaching has been attributed to variations in enamel concentration.¹² The visibility of the white spots diminishes over time as the dentin and the rest of the enamel become whiter and perhaps as some of the early enamel whitening regresses. Patients should be advised of the likelihood of initial white spots as a result of the bleaching treatment.

The advantages of overnight wear include greater patient convenience and improved material retention due to less salivation and less interference with the bleaching tray by the patient. Disadvantages are that overnight wear generally leads to longer contact times and does not allow the patient to monitor the side effects, such as tooth sensitivity.

Tooth sensitivity was the most significant side effect of this study. Its frequency was relatively high compared to other reported problems. Other clinical studies using 10% carbamide peroxide for overnight wear over a period of several weeks have reported a 9% to 100% incidence of tooth sensitivity.^{7,13-16} Leonard and col-

leagues¹⁷ suggested that the only predictors for tooth sensitivity during home bleaching were frequency of application and whether the patient had sensitive teeth before bleaching. Sex, age, day or night wear pattern, dental arch, and absence or presence of abrasion, defective restorations or gingival recession had no significant effect on the development of tooth sensitivity in their study.

In the present study, most reports of sensitivity were mild, transient, sporadic or continuous over a few days, and were elicited by a cold stimulus. When specific teeth were indicated, they were usually the incisors and canines; the premolars were never indicated as specifically sensitive. Two patients reported episodes of spontaneous sensitivity. Two patients reported sensitivity to heat. Five patients reported one to three days of "acute," "very," "extreme," "high" or "severe" tooth sensitivity. The mean number of days of sensitivity was 5.0 ± 3.8 days. All patients should be advised of the likelihood of tooth sensitivity as part of their informed consent. They should also be told that sensitivity could be severe enough to prevent or at least delay the completion of treatment. In other studies, 2 of 17, 4 of 10 and 4 of 28 patients discontinued their bleaching treatment as a result of tooth sensitivity.^{7,18} In the present study, 25% of the patients skipped at least one day of bleaching for tooth sensitivity reasons but continued to bleach their teeth thereafter. One patient stopped treatment after 12 days because of sensitivity.

The patients were generally assessed within one week of the bleaching treatment. No patients reported the persistence of tooth sensitivity after the cessation of bleaching. This is in agreement with other reports, which conclude that no long-term irreversible pulpal effects are associated with these bleaching techniques.⁶ Electric pulp tests have indicated no significant changes in pulp response following bleaching whether the teeth were sensitive or not.^{7,16} Longer exposures to

bleaching agents do not appear to increase the level of tooth sensitivity. In this study, tooth sensitivity often diminished during the latter part of treatment. In one 6-month clinical study, the majority of tooth-sensitive days occurred near the beginning of treatment and there were only zero to 20 days of total tooth sensitivity.¹⁸

Tooth sensitivity has been attributed to the permeation of the bleaching agent into the pulp.¹⁹ Fluoride gels in the bleaching trays have been recommended for treating tooth sensitivity;³ however, fluoride's action in desensitization is unknown. It could be beneficial in reducing exposure of the pulp to the bleaching agents by simply supplanting the use of the bleaching agent for that day. Fluoride and other desensitizing pastes could also theoretically reduce the penetration of hydrogen peroxide into the pulp by reducing the permeability of dentinal tubules at their orifices. Nonetheless, the best ways to reduce the pulpal inflammation causing tooth sensitivity are probably to reduce the time of exposure to the bleaching agent and to administer anti-inflammatory analgesics.

Despite some reported intrapatient differences, there were no statistically significant differences among the three commercial bleaching systems with respect to tooth sensitivity.

According to information from the manufacturers, Opalescence uses glycerine and contains 20% water. Platinum has a water-based dentifrice formulation. Nite White Excel uses a polyglycol composition and is unique because it contains no water. The water content of the bleaching agent could conceivably affect both tooth dehydration and material stability. In the present study, the different water content of the three commercial bleaching systems did not appear to affect tooth sensitivity or tooth whitening.

The pH values of the three bleaching materials were measured at room temperature by a flat surface polymer body combination electrode with an Accumet

620 pH/mV meter (Fisher). For Platinum, the mean pH was 5.90 (± 0.03 , standard deviation); for Opalescence, 6.40 (± 0.09); and for Nite White, 7.43 (± 0.03). Scanning electron microscope investigations have shown slight changes to enamel surface morphology after exposure to bleaching material, particularly under more acidic conditions.²⁰ The clinical significance of these changes, however, is considered negligible or minimal for bleaching treatments of normal duration when the buffering and remineralization potential of the saliva are considered.²¹ Furthermore, it has been shown that the pH of a carbamide peroxide solution increases during nightguard wear as a result of urea breakdown.²² The pH of the material can affect peroxide radical liberation (and hence, bleaching effect) and material stability.²³ A sufficiently low-pH material can also open exposed dentinal tubules, resulting in increased tooth sensitivity. In the present study, the different pH values of the three commercial bleaching systems did not result in clinical differences in tooth sensitivity or tooth whitening.

The selection of a bleaching product should be based on the concentration of the active ingredient, the viscosity of the bleaching agent (higher material viscosity leads to greater material retention)²⁴ and other marketing features. It is likely that higher concentrations of carbamide peroxide will not only whiten teeth more quickly and to a greater degree, but will also lead to increased sensitivity problems. Therefore, a balance between tooth sensitivity and tooth whitening needs to be struck for each individual patient. In Canada, a concentration of 10% carbamide peroxide is significant because formulations containing greater than 10% can be used only under the supervision of dental professionals. In the United States, only 10% carbamide peroxide formulations have received the American Dental Association Seal of Acceptance from the Council on

Scientific Affairs of the American Dental Association.

Bleaching methods and materials appear to be growing by leaps and bounds. This study attempts to provide some independent clinical data for dental practitioners for the most common home bleaching method using an overnight wearing regimen in a clinical setting. Further research is needed to investigate the causes of tooth sensitivity and methods to reduce its severity and frequency. ■

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