Evaluation of Side Effects and Patients' Perceptions during Tooth Bleaching

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ABSTRACT

Objective: The objective of this nightguard vital bleaching (NGVB) study was to compare tooth sensitivity (TS), gingival irritation (GIr), and other side effects, as well as patients' perceptions during tooth bleaching, from treatment with experimental 5 and 7% hydrogen peroxide (HP) bleaching solutions with those of a commercially available 10% carbamide peroxide (CP) product.

Materials and Methods: Sixty-one participants completed the study wearing a scalloped maxillary treatment tray without reservoirs with the different concentrations of bleaching gels for 30 minutes twice a day for 7 days. Parameters evaluated were changes in gingival index (GI), nonmarginal gingival index, nongingival oral mucosal index, and tooth vitality. Participants were seen pretreatment, after 7 treatment days, and 1 week post-treatment. A daily log form to record TS and GIr was completed by each participant as well as a sensitivity questionnaire at each appointment. Additionally, at 10 months post-treatment, a questionnaire was sent to the participants concerning TS and GIr relative to the treatment process.

Results: Data from end-of-treatment questionnaires, daily log forms, and clinical examination revealed a statistical difference ($p \leq 0.05$) in the patients' ranking of and days of TS and GIr between group S (7% HP) and group T (10% CP, control group) at the end of active treatment. There also existed a statistical clinical change in the GI levels for groups R and S compared with the control group T. There was no statistical difference ($p > 0.05$) in any of the parameters evaluated among the three products at 7 days or 10 months post-treatment.

Conclusions: Participants in group S reported significantly more TS, GIr, and days of each compared with the control. There also existed a significant clinical change in the GI levels for groups R and S compared with the control group T. There was no significant difference among the three products at 7 days post-treatment. After ending treatment, TS/GIr was resolved in 2 to 3 days and did not recur during the 10 months post-treatment.

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CLINICAL SIGNIFICANCE

The experimental HP bleaching solutions, as described in this study, can be used in NGVB with no long-term side effects as evaluated in this study for up to 10 months post-treatment.

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INTRODUCTION

The desire for whiter teeth has made tooth bleaching one of the most sought-after cosmetic procedures in dentistry. Available bleaching modalities include dentist-supervised in-office bleaching, dentist-prescribed home-applied bleaching or nightguard vital bleaching (NGVB), and over-the-counter consumer-available systems. The majority of active bleaching agents are various concentrations of either carbamide peroxide (CP) or hydrogen peroxide (HP). With respect to NGVB when using a 10% CP bleaching solution, its efficacy and safety has been well documented and accepted by both patients and dental practitioners.[1–13] Accordingly, the ADA has given the seal of approval to several 10% CP bleaching solutions for use as at-home bleaching products.

CP breaks down into HP and urea. Bleaching solutions of 10% CP contain the equivalent of 3.3% HP. Manufacturers have introduced into the marketplace various concentrations of HP bleaching solutions delivered via a bleaching tray, whitening strip, or as a paint-on whitening solution. HP solutions are used 30 to 60 minutes per treatment period one to two times a day.

Numerous articles exist in the literature comparing the efficacy of various concentrations of CP and HP solutions when delivered via whitening strips or paint-on solutions.[14–26] Only one peer-reviewed article could be found in the literature comparing equivalent concentrations of CP and HP.[15] One needs to be cognizant of the concentrations being compared when evaluating studies using HP and CP. For the most part, the concentration of HP reported in the literature is 5 to 14% HP. This equates to 16 to 46% CP. From these studies, it can be concluded that teeth can be successfully bleached with CP and HP bleaching solutions. Shade stability of the HP bleaching solutions post-treatment was found to be comparable with that achieved with 10% CP.[15] Additionally, the higher the bleaching solution concentration, the quicker a shade change will occur.

With respect to safety issues and sensitivity for HP solutions, the literature is less clear and limited in scope. Documentation exists for patients' perception of tooth sensitivity (TS) and gingival irritation (GIr) or clinical soft and hard tissue parameters, but usually not both.[14–20] Some studies report that GIr is the most common side effect,[14,16] although Mokhlis and colleagues cite no difference at all in side effects when comparing CP and HP bleaching solutions.[15] Some studies report that no statistically significant differences exist between comparative bleaching solutions without reporting the percentage of participants with side effects or the type of side effects.[15,18]

Most bleaching studies, whether CP or HP, report side effects occurring within each studied population without giving consideration to the participants' preexisting TS/GIr or potential for developing such during bleaching. In a pilot study conducted by Smith and colleagues, participants using a desensitizing agent prior to bleaching experienced less TS, although this improvement was not statistically significant.[27] Interestingly, they did find that those participants who presented with preexisting TS, consumed citrus drinks or colas on a daily basis, or used toothpaste,

fluoride, or a dental restoration to treat sensitivity were more likely to develop sensitivity during bleaching than those who did not and would benefit from a desensitizing agent (form 1).

The objective of this study was to evaluate TS, GIr, and other side effects, as well as patients' perceptions of tooth bleaching from treatment with experimental 5 and 7% HP tooth bleaching formulas, and to compare the results with those of a commercially available 10% CP formula with the ADA seal.

MATERIALS AND METHODS

Sixty-one participants took part in this double-blind, parallel NGVB study. The protocol was reviewed and approved by the University of North Carolina School of Dentistry's Institutional Review Board prior to the start of the study. The initial screening procedure included an oral soft tissue assessment to determine the eligibility of each potential participant to enter the study. All participants completed an approved human informed consent form, medical history form, and a questionnaire to establish his or her baseline assessment for TS and GIr (form 1).

An alginate impression (Jeltrate Plus, Dentsply/Caulk Milford, DE, USA) of the maxillary arch was made and poured in dental stone. Custom maxillary 0.035-inch bleaching trays were fabricated for each participant using the material and design (scalloped and trimmed just short of the gingival margin and without facial reservoirs) as recommended by the manufacturer (Colgate Oral Pharmaceuticals, Inc., Canton, MA, USA). Participants began a 7-day study phase with two 30-minute daily sessions using one of the two test HP products, 5% HP (group R, equivalent to 16% CP), 7% HP (group S, equivalent to 22% CP), or the control group, (group T, Colgate Platinum Professional Daytime 10% CP). Colgate Platinum Professional Daytime 10% is an ADA-accepted peroxide-containing oral hygiene product. The test HP products also contained 5% potassium nitrate (PN), a tooth-desensitizing agent. The twice-a-day regimen represented exaggerated use, as recommended by the manufacturer, for the experimental HP solutions used in this study, but was done to keep the participants and examiners blinded as to the various treatment solutions because the 10% CP bleaching solution is to be used twice a day. The manufacturer-recommended treatment time for groups R and S is 30 minutes once a day. Treatment products (R, S, or T) were assigned using a blocked randomized design. There was no attempt to block participants according to their risk of developing sensitivity. Participants were asked to follow a standard oral hygiene regimen throughout the study and were given a new Colgate Plus toothbrush and Colgate Total toothpaste (Colgate Oral Pharmaceuticals, Inc., Canton, MA, USA). Clinical objective outcomes evaluated were the changes in gingival index (GI), nonmarginal gingival index (NMGI), nongingival oral mucosal index (NGOMI), and tooth vitality (TV). Also evaluated were the patients' perceptions of TS and GIr and days of occurrence during the study.

To assess the gingival conditions of each patient, the Loe GI was employed on teeth #4 to 13.[28] Each quadrant was isolated with cotton rolls, air-dried, and visibly and tactically inspected using a mouth mirror and probe. Four gingival areas (distal, facial, mesial, and lingual) were examined systematically for each tooth. To evaluate soft tissue changes occurring in the oral cavity (ulcers, abrasion, etc.), the NMGI and NGOMI were used as developed and described by Curtis and colleagues.[11]

TV was assessed using coolant-saturated (Hygienic Green Endo Ice, The Hygienic Corporation, Akron, OH, USA) cotton-tip applicators applied to the facial surfaces of teeth #6 to 11. A response to the coolant within 10 seconds was recorded as a positive response. If there was no response to the coolant within 10 seconds, then a negative response was recorded. There was no attempt on the

part of the evaluators to quantify the response.

Participants were given a diary to record the number of hours of treatment, days of occurrence, and their perception of TS and GIr during the study. Instructions were also given to each participant to cease using the treatment solutions if TS/GIr was perceived as too great to tolerate the continued application of solutions.

Three clinical evaluations were conducted: baseline (insertion), after 1 week of treatment, and 1 week post-treatment. Each participant's baseline maxillary GI, NMGI, and NGOMI were determined as well as TV of teeth #6 to 11. At the insertion appointment, the bleaching tray was delivered and adjusted intraorally according to the guidelines prescribed by the manufacturer. Information about the bleaching process and written instructions were given to each patient as well as a daily log form to record TS, GIr, and other comments or concerns.

Participants were seen after 7 days of treatment to evaluate GI, NMGI, NGOMI, and TV and to complete a questionnaire on their perception of TS and GIr of the NGVB procedure (form 2). Treatment was discontinued at which time the log form was collected. Participants were seen 1 week post-treatment to evaluate GI, NMGI, NGOMI, and TV and to complete a questionnaire on their perception of TS and GIr of the NGVB procedure (form 3). Additionally, at 10 months post-treatment, a questionnaire was sent to the participants concerning TS and GIr relative to the treatment process (form 4).

Statistical Analysis

Data were analyzed from two sources: the patient questionnaires/log forms and the evaluators' assessment of clinical issues. To compare the products with one another, a one-way analysis of variance was performed for groups R, S, and T after 7 days of treatment and 1 week post-treatment. Multiple comparison *t*-tests and Dunnett's comparisons were performed to compare groups R and S with the control group T. Statistically significant differences were declared if the *p* value was 0.05 or less, unless otherwise noted. A Chi-square analysis was used to determine the statistical significance for the number of participants reporting tooth or gum sensitivity for each product group.

RESULTS

All 61 participants completed the NGVB clinical study (54 women and 7 men), wearing their bleaching tray approximately 7 hours total treatment time for each participant over the 1-week study period. No one quit the study for sensitivity reasons. The average age for participants was 28.4 years (see Table 1 for the demographics and time usage for each group). Except for GI, there were no statistically significant differences for the changes in any of the clinical parameters measured during treatment (GI, NMGI, NGOMI, and TV) (Table 2). There were no statistically significant differences for the changes in any of the clinical parameters pretreatment from 7 days post-treatment, or at 10 months post-treatment.

TABLE 1. DEMOGRAPHICS AND TIME USAGE ASSOCIATED WITH PROFESSIONAL TOOTH BLEACHING.

Group	*N*	% of Participants	% Presenting with Preoperative Sensitivity*	Gender	Mean Age (years)	Total Hours Usage Time
R	21	34	47	100% F	30.7 ± 12.8	6.4 ± 1.9†
S	20	33	60	80% F	27.6 ± 9.7	6.8 ± 3.0†
T	20	33	40	85% F	26.9 ± 8.5	7.5 ± 2.7

Sixty-one participants completed the study, 88% were female (F).
*Answered positive to question 1 on the first-visit patient questionnaire (form 1).
†No significant statistical difference from control group T ($p \geq 0.05$).

TABLE 2. TOOTH RESPONSES TO ENDO ICE AND THE CHANGES IN THE GINGIVAL INDICES FROM PRETREATMENT TO POST-TREATMENT ASSOCIATED WITH PROFESSIONAL TOOTH BLEACHING.

Group	*N*	Positive Response to Endo Ice (% pre/% post)	Gingival Index Score Change	Nonmarginal Gingival Index Change	Nongingival Oral Mucosal Index Change
R	21	96/97*	0.12 ± 0.23†	0.0*	0.0*
S	20	93/94*	0.13 ± 0.18†	0.0*	0.0*
T	20	94/96	–0.01 ± 0.14	0.0	0.0

*No significant statistical difference from control group T ($p \geq 0.05$).
†Significant statistical difference from control group T ($p < 0.05$).

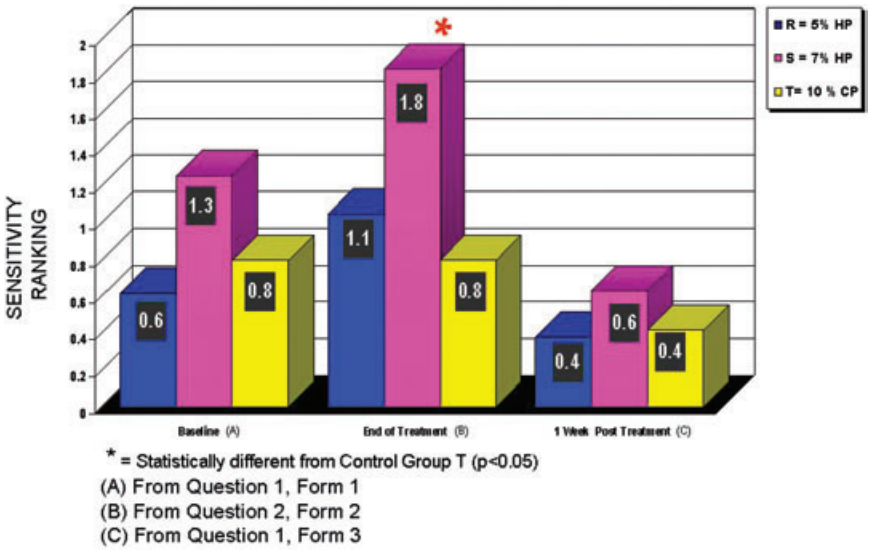

Figure 1. Tooth sensitivity ranking of participants during the nightguard vital bleaching study. CP = carbamide peroxide; HP = hydrogen peroxide.

Data from the end-of-treatment questionnaire and daily log forms revealed a statistically significant difference ($p < 0.05$) in the patients' ranking of TS and GIr experienced during active treatment for group S (7% HP) from the control group (group T, 10% CP), as well as for the number of days TS/GIr was experienced during treatment (Figures 1–3), but not for the number of participants experiencing TS/GIr (Figure 4). No statistically significant difference existed among the treatment groups ($p \geq 0.05$) in TS and GIr at 7 days post-treatment (Figures 1 and 2). Any TS/GIr above pretreatment levels reported at the end of treatment was resolved in an average of 2 to 3 days for all three products. No one reported any other type of side effect at the end of treatment or 1 week post-treatment. Forty-three percent (26/61) of the participants returned the 10th-month sensitivity questionnaire (form 4). No one reported any GIr that they felt was treatment related. One participant in the control group reported TS at the 10-month period; however, the participant had reported TS pretreatment. No one in the experimental groups reported TS/GIr or any other type of side effect.

DISCUSSION

The purpose of this study was to compare TS, GIr, and other side effects, as well as patients' perceptions from treatment with two experimental HP tooth bleaching products, with those of a commercially available 10% CP product. As mentioned earlier, the twice-a-day regimen represented exaggerated use, as recommended by the manufacturer, for the HP treatment solutions. Additionally, the equivalent bleaching concentration of the experimental products was higher than the control CP product. This would make for a worst-case scenario for the HP bleaching solutions, and possibly the reason for the increase incidence of side effects for the experimental groups as reported by the participants during treatment. Any increased incidence of side effects that was reported or noted during treatment

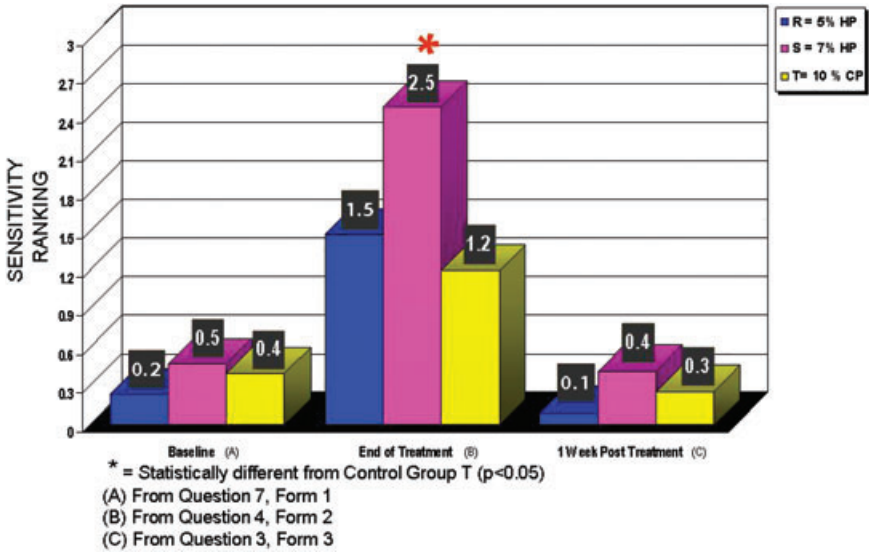

Figure 2. Gingival irritation ranking of participants during the nightguard vital bleaching study. CP = carbamide peroxide; HP = hydrogen peroxide.

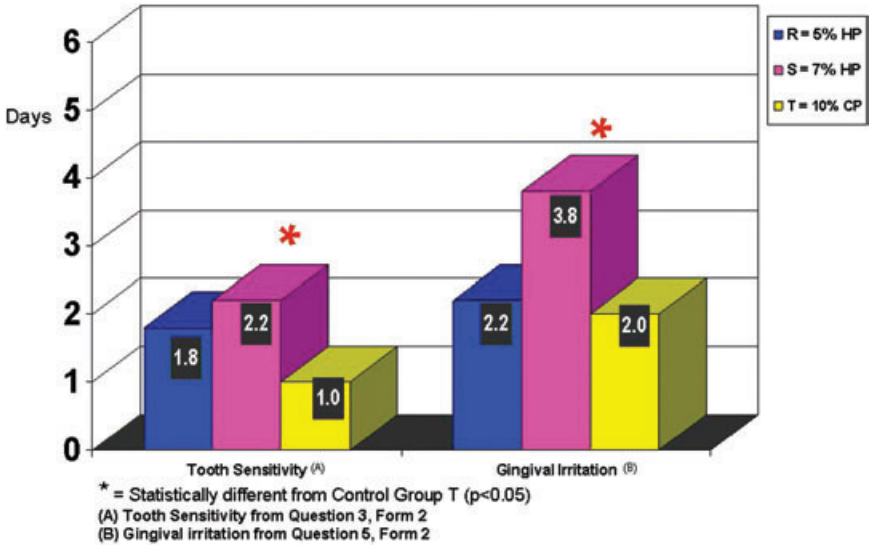

Figure 3. Days participants reported tooth sensitivity/gingival irritation during the nightguard vital bleaching study. CP = carbamide peroxide; HP = hydrogen peroxide.

subsided during the 1-week post-treatment phase. All sensitivity was recorded at a moderate level or less, with no one dropping out of the study because of sensitivity.

Ten months post-treatment, no one in the experimental HP groups reported any type of side effect that they felt was treatment related.

It is not fully understood why some patients experience side effects during treatment and others do not. No doubt that it is multifactorial and not always related to the bleaching solution, as side effects have been documented for participants using a placebo treatment solution during bleaching.[2,10,14] The bleaching tray and/or chemical additives play a role in causing side effects during bleaching. Hard and soft tissue conditions can affect the development of side effects during NGVB such as gingival recession and pretreatment thermal and tactile sensitivity.[29] Additionally, dietary habits such as eating or drinking citrus fruits and juices or acidic drinks such as colas on a daily basis may place patients at risk for developing side effects during NGVB.[21,30]

Participants in group S reported more TS after 1 week of treatment than did those from groups R and T. However, group S had a larger percentage of participants with pre-treatment sensitivity (60% for group S, 47% for group R, and 40% for the group T; Table 1); therefore, more TS would be expected in this group. Although no attempt was made to randomly assign those at risk for developing sensitivity as per the criteria of Smith and colleagues,[27] in retrospect, this would have been an excellent idea. With respect to TS, practitioners should strive to

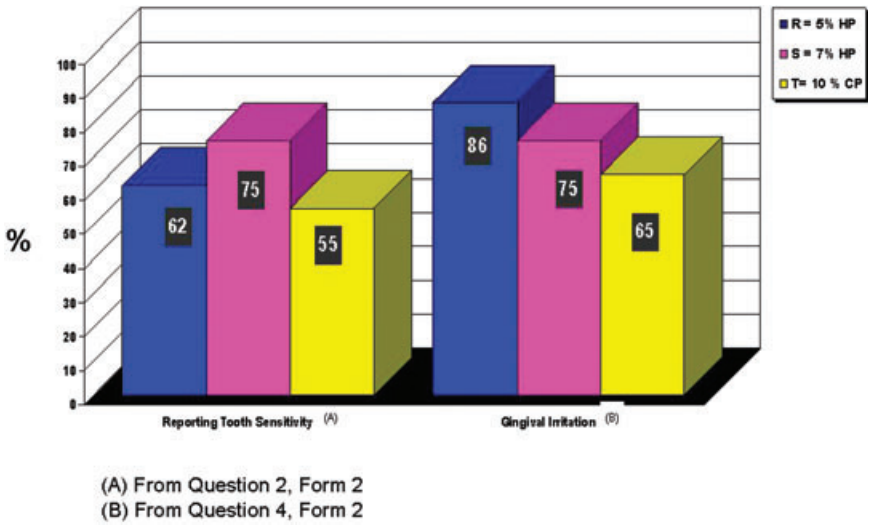

Figure 4. Percent of participants reporting tooth sensitivity/gingival irritation during the nightguard vital bleaching study. CP = carbamide peroxide; HP = hydrogen peroxide.

identify those patients at risk for developing TS in order to properly select a bleaching solution and regimen that will satisfy the patients' need with as few side effects as possible.

One week post-treatment, there was no significant difference for participants reporting TS issues among the three groups as reported by the participants on their questionnaire (form 2). Actually, the average mean ranking that the participants recorded for TS was almost half of their pretreatment value (Figure 1). One explanation for this could have been the desensitizing effect of PN that was in the 5 and 7% HP products (groups R and S, respectively). This effect was not a part of the study to be evaluated, but it is well documented that PN can aid in decreasing sensitivity.[30–33] Although PN is often prescribed after TS occurs during NGVB, PN may have a cumulative and/or residual effect and thus be prescribed for a period of time pretreatment.[30]

With respect to GIr as reported by the participants, the treatment phase was statistically higher for group S when compared with the control group T (Figure 2). The number of participants reporting GIr and the number of days of GIr was also higher for group S than for group T (Figures 3 and 4). The primary factor is most likely a result of the effective concentration of the bleaching agent in group S as well as the number of treatment times per day. The equivalent bleaching concentration for group S is two times that of group T.

Scalloping and trimming of the bleaching tray is considered very important in preventing or decreasing GIr. Additionally, participants received a new toothbrush that could have contributed to the irritation recorded. Any GIr reported on the end-of-treatment questionnaire was resolved in an average of 2 to 3 days post-treatment for all three products. No one quit the study for GIr reasons. The increase in participant-reported GIr and the resolution within a few days post-treatment is similar to what has been reported for other CP and HP bleaching solutions.[30,34] No one reported GIr that they felt was treatment related at 10 months post-treatment.

CONCLUSIONS

During the active treatment phase of our study, participants using the experimental 7% HP bleaching solution reported significantly more TS, GIr, and days of each compared with the control. TS and GIr as reported by the participants was mild to moderate. There also existed a significant clinical change in the GI levels for groups R and S compared with the control group T. There was no significant difference among the three products at 7 days post-treatment. No one reported any other type of side effect at the end of treatment or 1 week

post-treatment. After ending treatment, TS/GIr was resolved in 2 to 3 days and did not recur during the 10 months post-treatment. The results of our study indicate that the HP bleaching solution evaluated can be safely used to treat teeth.

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APPENDIX

FORM 1: PATIENT QUESTIONNAIRE—FIRST VISIT

Question	Response YES	Response NO
1. Do you routinely experience tooth sensitivity? If so, how much sensitivity? ❑- 5 high ❑- 4 ❑- 3 moderate ❑- 2 ❑- 1 ❑- 0 none		
2. Do your teeth normally get sensitive after a tooth cleaning?		
3. Are your teeth normally sensitive to hot and cold?		
4. Have you ever used a toothpaste or fluoride specifically to control sensitive teeth?		
5. Do you use carbonated drinks such as Coke, Pepsi, Fresca, etc. on a daily basis? If so what kind and how much?		
6. Do you eat citrus fruits or drink citrus fluids on a daily basis? If so what kind and how much?		
7. Do you routinely experience gum irritation? If so, how much irritation? ❑- 5 high ❑- 4 ❑- 3 moderate ❑- 2 ❑- 1 ❑- 0 none		
8. Have you ever had a facial Class V restoration placed to control gingival sensitivity of a tooth? If so which teeth?		

Mean ranking for questions 1 and 7 shown in Figures 1 and 2.

FORM 2: PATIENT QUESTIONNAIRE—END OF TREATMENT

1. How many **days** total did you **use** the whitening product in your mouth tray? _____ days

2. Did you experience **tooth sensitivity** during this study?

❑- 5	❑- 4	❑- 3	❑- 2	❑- 1	❑- 0
large amount of sensitivity		moderate amount of sensitivity			no sensitivity

3. How many **days, if any,** did you experience **tooth sensitivity** from the start to the end of this study? _____ Days of tooth sensitivity

4. Did you experience **gum irritation** during this study?

❑- 5	❑- 4	❑- 3	❑- 2	❑- 1	❑- 0
large amount of irritation		moderate amount of irritation			no irritation

5. How many **days, if any,** did you experience **gum irritation** from the start to the end of this study? _____ Days of gum irritation

6. Did you experience any other changes or side effects? Please describe.

Mean ranking for questions 2 and 4 shown in Figures 1 and 2.
See Figure 3 for responses to questions 3 and 5.

FORM 3: PATIENT QUESTIONNAIRE—1 WEEK FOLLOW-UP VISIT

1. Are you currently experiencing any **tooth sensitivity**?

❑- 5	❑- 4	❑- 3	❑- 2	❑- 1	❑- 0
large amount of sensitivity		moderate amount of sensitivity			no sensitivity

2. Did you experience **tooth sensitivity** during the treatment phase? Yes No (circle one)
   If yes, did the tooth sensitivity cease during this past week? Yes No (circle one)
   If yes it did cease, after how many days? _____ days

3. Are you currently experiencing any **gum irritation**?

❑- 5	❑- 4	❑- 3	❑- 2	❑- 1	❑- 0
large amount of irritation		moderate amount of irritation			no irritation

4. Did you experience **gum irritation** during the treatment phase? Yes No (circle one)
   If yes, did the gum irritation cease during this past week? Yes No (circle one)
   If yes it did cease, after how many days? _____ days

5. Did you experience any other changes or side effects? Please describe.

Mean ranking for questions 1 and 3 shown in Figures 1 and 2.
See Figure 4 for responses to questions 2 and 4.

FORM 4: PATIENT QUESTIONNAIRE—10 MONTH FOLLOW-UP VISIT

1. Are you currently experiencing any **tooth sensitivity**?

2. Are you currently experiencing any **gum irritation**?

Did you experience any other changes or side effects?