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Comparison of Traditional and Low Sensitivity Whiteners

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Clinical Relevance

The results of this double-blind, placebo-controlled clinical trial have direct relevance to clinical practice and provide evidence that the addition of low levels of potassium nitrate and/or potassium nitrate and fluoride significantly reduce postoperative sensitivity relative to products that do not contain either agent.

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SUMMARY

This placebo-controlled, double-blind randomized clinical trial compared five 10% carbamide peroxide tooth whitening formulations. Three products contained varying concentrations of potassium nitrate as desensitizers. One contained no desensitizers and one was a placebo. During the two weeks of active bleaching, participants used a daily diary to record the number of days of sensitivity from hot, cold, gums, tongue and/or throat. The total number of days of sensitivity experienced by the participants in each group was compared. Participants using the agent with no desensitizers did not experience any more sensitivity than those using the agent containing 3% potassium nitrate. The products that included 0.5% potassium nitrate and 0.5% potassium nitrate and 0.25% sodium fluoride were not associated with any more sensitivity than the placebo group.

In addition, the shade tab change from baseline to 11 weeks following cessation of bleaching was compared. Using an active bleaching agent, no difference in color change was noted among the four groups. All four groups were associated with significantly higher color change than the placebo.

The addition of a small percentage of potassium nitrate to a 10% carbamide peroxide tooth whitener was shown to significantly reduce post-operative sensitivity without reducing efficacy.

INTRODUCTION

Reports of sensitivity related to the use of traditional night guard vital bleaching agents are numerous. The percentage of participants reporting sensitivity has been reported to vary from 0 to 100%.[1-2] More typical is the report by Haywood and others[3] that, 52% of participants experienced tooth sensitivity and 31% experienced gingival sensitivity. A review of the literature estimated that sensitivity was a problem for two out of three people participating in clinical trials of night guard vital bleaching.[4] While more studies report the incidence of sensitivity in clinical trials, some have reported severity. Schulte and others[5] reported that sensitivity related to tooth whitening was severe enough to force participants to withdraw from their study. While 14% of participants discontinued bleaching due to sensitivity, 86% finished the study.

More recently, products with ingredients reputed to reduce or eliminate sensitivity have been marketed. Nathoo and others[6] studied two low-sensitivity bleaching agents, Colgate Gentle Plus, 5% (Colgate-Palmolive Co, Piscataway, NJ, USA) and Nite White Excel 2Z, 10% (Discus Dental, Culver City, CA, USA). In that study, 20% and 53% of participants, respectively, experienced tooth sensitivity. Gingival, throat and tongue sensitivity were not studied. Twenty percent tooth sensitivity among participants is lower than that typically reported for products without desensitizing agents but 53% is not. As noted above, sensitivity levels vary widely from study to study in the published literature. Accordingly, it is difficult to compare the sensitivity levels reported for these two agents to levels reported for traditional whitening agents in the literature and conclude that they are clearly lower. Comparing Nathoo's results to historical data is also complicated by these factors: the study did not include a more traditional bleaching product or a placebo. The percentage of carbamide peroxide for the Colgate product was 5%, which is less than that typically reported in previous studies.

In addition, another study, including Nite White Excel 2Z, reported 41% of participants experienced sensitivity, including gingival, tongue and throat sensitivity.[7] Again, this study included only products with specific ingredients added to reduce sensitivity levels. However, this study[7] also reported the percentage of days spent actively whitening, which resulted in sensitivity. As a group, participants using Excel 2Z experienced few days of sensitivity from any source. Sixteen percent of days spent bleaching resulted in sensitivity: 3% tooth and 13% soft tissue. These results can be compared to a placebo-controlled trial using the same study design, which was conducted by the same group of researchers. In that study, 7% of subjects receiving the placebo, a gel without the active ingredient, reported sensitivity. Of the total number of days this group actively wore their trays, the percentage of days resulting in sensitivity was 2.3%: 1.8% tooth and 0.5% soft tissue.[8] Even between studies with the same design, comparisons are risky, and it is important to recall that neither study involved a direct comparison between a low-sensitivity tooth whitening product and a more traditional product.

Tam[9] used a split-mouth design to compare a 10% carbamide peroxide agent to one also containing 3% potassium nitrate and 0.11% fluoride. Following the second day, the data demonstrated a trend for less sensitivity on the side with the additives. A comparison of pain scores for each group on a day-by-day basis found significantly less sensitivity on days 3, 9, 10, 11 and 13. However, making statistical comparisons between groups each day during the 14 days of active treatment creates a multiple comparisons problem. More appropriately, the groups should have been compared using an analysis that first tested for a significant difference between groups overall, then compared the groups at each evaluation using a post-hoc test. As a result, it is unclear whether the trend noted represented a significant overall difference or random variation that happened, solely by chance, to be significantly different on those five particular days.

The current study compared total sensitivity in five groups of people. One group used a whitening agent that contained no desensitizing agents, one group used a placebo and three groups used agents with varying percentages of potassium nitrate and fluoride as desensitizing agents. All active agents contained the same percentage of carbamide peroxide, and the placebo consisted of the same carrier gel used in the other products, but without any active ingredients. The number of days participants reported sensitivity relative to the number of days participants used their product was compared. The hypothesis that there were no differences between groups was tested against the hypothesis that there were significant differences between the groups. The change in color from baseline to the final evaluation was also compared. The study-wide significance level was maintained at 5%. Finally, observations regarding the percentage of participants reporting sensitivity at

any time and sensitivity from hard and soft tissue sources were also reported.

METHODS AND MATERIALS

The college's Institutional Review Board approved the study design and the informed consent procedures for the project prior to recruiting participants. Participants were recruited from the campus and the surrounding metropolitan area. Adults with no significant medical problems were sought. In addition, in order to be included, the maxillary cuspids, lateral incisors and central incisors had to be shade A3 or darker on a shade guide arranged by value (Vita Classic, Lumin Vacuum Shade Guide, Vita Zahnfabrik, H Rauter GmgH and Co KG, Germany; Table 1) and not have extensive restorative treatment.

When participants were first informed about the project, each indicated his or her willingness to participate, if eligible, and an understanding of the risks and benefits of participating by signing an informed consent document.

A dental examination was then performed to determine eligibility. Those with active caries, defective restorations and/or untreated periodontal disease were not allowed to participate unless and until the condition(s) was resolved. Upon acceptance into the study, participants were randomly assigned to one of five groups. Four groups were provided an active whitening agent: Exp 1, Exp 2, Exp 3 or Exp 4. The final group, Exp 5, received a placebo. All active groups were provided 10% carbamide peroxide products (Table 2) and used the same carrier gel. The placebo consisted of the carrier gel without carbamide peroxide, potassium nitrate or sodium fluoride. Neither the participant nor the operator was aware which material was received.

The maxillary teeth were scaled and polished and a polyvinylsiloxane (Reprosil, Dentsply Caulk, Milford, DE, USA) impression was made. The manufacturer's instructions called for a 0.5 mm layer of block-out resin (LC Block-Out, Ultradent Products, Inc) on the facial tooth surfaces to create reservoirs and fabrication of a vacuum-formed tray from soft, 0.035" stock (Sof-Tray, Ultradent Products, Inc). The tray was trimmed 0.3 mm short of the marginal crest of the gingiva.

Before the start of the project, the investigators were calibrated using the Vita Classic shade guide. One guide was arranged by value (see Table 1) and the tabs were numbered 1 to 16, darkest to lightest. Evaluators used this shade guide to match loose shade tabs from a second shade guide. The loose tabs were unidentified and randomly arranged. To be considered calibrated, the evaluator had to achieve a score of 85% or greater on two separate trials.

Participants were examined at baseline, one, two and 13 weeks. Active treatment was for the first two weeks only. At the baseline evaluation, the fit of the tray was carefully inspected to assure that it did not abrade the tissue and was well adapted. Also, participants who practiced seating the tray, were given a one-week supply of their randomly-assigned experimental product, instructed on application of the bleaching gel and told to wear the tray each night for a minimum of six hours.

Tooth color was evaluated at each appointment using the Vita Classic shade guide. Sensitivity was measured by use of a patient diary. Each day during the active whitening phase of the study, participants recorded use of their whitening agent and the presence or absence of sensitivity. Five potential sources of sensitivity were tracked: hot and cold tooth sensitivity, and gingival, tongue and throat sensitivity. To help encourage accuracy and completeness, participants brought the diary with them to the one-week evaluation and turned it in at the two-week recall.

Photographs were made at each evaluation (35 mm clinical slides, Kodak Select Elite Chrome 100 ASA, Eastman Kodak Co, Rochester, NY, USA). These slides were not used to measure shade change. Rather, they were used to document results. At the final evaluation, participants who received the placebo were provided an active agent.

The total tab change was calculated by subtracting the tab number corresponding to the baseline shade from that of the final evaluation. The data was ana-

Table 1: *Arrangement of Vita Classic Shade Guide*

Vita Shade:

B1 - A1 - B2 - D2 - A2 - C1 - C2 - D4 - A3 - D3 - B3 - A3.5 - B4 - C3 - A4 - C4

16 ◄ 1

Brightest Shade — Darkest Shade

Table 2: *Experimental Agents*

Agent	Carbamide Peroxide	Potassium Nitrate	Sodium Fluoride	Description
Exp 1	10%	0.00%	0.00%	Original Opalescence formulation
Exp 2	10%	3.00%	0.00%	Experimental
Exp 3	10%	0.50%	0.00%	Experimental
Exp 4	10%	0.50%	0.25%	Current Opalescence 10% PF
Exp 5	0%	0.00%	0.00%	Placebo

lyzed using a One-Way Analysis of Variance. Sensitivity was expressed using two measures. The percentage of participants experiencing sensitivity at any time during the active whitening phase of the trial was reported to facilitate comparison to previously published studies. This provided an estimate of the likelihood that a person using the agent would experience sensitivity.

The second measure provided an estimate of the duration of sensitivity. For each group, sensitivity was reported as the total number of days the group experienced sensitivity relative to the total number of days the group spent actively whitening. This measure provided for sensitivity from multiple sources. For example, if a participant experienced both tooth and gingival sensitivity on the same day, it was recorded as two days of sensitivity. Total sensitivity was compared among the five groups using a Chi Square test. Three additional Chi Square tests were conducted to further investigate differences between experimental groups. The significance level for each test conducted was adjusted to reflect the fact that five separate comparisons were made on data derived from one set of participants. The significance level for each test was determined by dividing the overall significance level of 5% (0.05) by the number of comparisons made and was set at 1% (0.01).

RESULTS

There was a significant association between Experimental Agent and Shade Tab Change (One-Way ANOVA; $p<0.001$). The placebo was associated with a significantly smaller shade tab change (Table 3) than all of the active agents (Holm-Sidak All Pairwise Test; $p\leq0.003$). There were no significant differences in Shade Tab Change between any pair of active agents (Holm-Sidak All Pairwise Test; $p>0.05$). The mean and standard deviation for color values at each evaluation is listed in Table 4.

For each group, the percentage of participants who experienced sensitivity at any point during active bleaching is noted in Table 5. Similarly, Table 6 lists the percentage of days participants in each group experienced sensitivity. There was a significant difference in total sensitivity between the groups (Chi Square; $p<0.001$). To further determine which products were significantly different from the others, additional tests were performed. There was no significant difference between active agents Exp 3 and 4 and the placebo—Exp 5 (Chi Square; $p=0.77$). There was a significant difference between Exp 1 and Exp 3 (Chi Square; $p<0.001$). There was no significant difference between active Exp 1 and Exp 2 (Chi Square; $p=0.071$).

Table 3: *Vita Classic: Final Shade Tab Change*

Group	Mean
Exp 1 n=19	5.4[a]
Exp 2 n=19	5.5[a]
Exp 3 n=16	7.9[a]
Exp 4 n=19	5.6[a]
Exp 5 n=18	-0.6[b]

Table 4: *Vita Classic Tab Values: Mean and Standard Deviation at Each Evaluation*

Agent	Baseline	One-Week	Two-Week	13-Week
Exp 1	8.4 (4.2)	11.5 (3.9)	13.2 (3.2)	13.8 (2.4)
Exp 2	9.0 (2.7)	13.3 (1.8)	14.8 (1.4)	14.5 (1.7)
Exp 3	6.0 (2.7)	12.6 (2.8)	14.4 (2.1)	14.1 (1.7)
Exp 4	6.5 (2.2)	12.2 (2.3)	14.1 (1.3)	12.1 (3.4)
Exp 5	7.5 (3.0)	8.7 (3.0)	9.4 (2.8)	6.9 (2.9)

As a further observation, the data was recombined into two sources: First, hot and cold sensitivity data were combined to create the category Hard Tissue Sensitivity. Second, gingival, tongue and throat data were combined to create the category Soft Tissue Sensitivity. The results for each group are listed in Table 7.

DISCUSSION

These results indicate that the addition of potassium nitrate and sodium fluoride did not have a negative effect on the bleaching efficacy of the active agents test-

Table 5: *Participants Experiencing Sensitivity*

Product	Sensitivity
Exp 1	62%
Exp 2	77%
Exp 3	36%
Exp 4	45%
Exp 5	25%

Table 6: *Days of Active Bleaching Resulting in Sensitivity*

Product	Sensitivity		No Sensitivity
	# of Days	Percentage	# of Days
Exp 1	89	32.5%[a]	185
Exp 2	118	40.1%[a]	176
Exp 3	41	13.7%[b]	259
Exp 4	31	11.7%[b]	235
Exp 5	28	12.4%[b]	197

Table 7: *Comparison of Hard and Soft Tissue Sensitivity*

Group	Hard Tissue Sensitivity		Soft Tissue Sensitivity		No Sensitivity
	# of Days	Percentage of Days	# of Days	Percentage of Days	
Exp 1	44	16.1%	45	16.4%	185
Exp 2	51	17.3%	67	22.8%	176
Exp 3	35	11.7%	6	2.0%	259
Exp 4	19	7.1%	12	4.5%	235
Exp 5	23	10.2%	5	2.2%	197

ed. They also support the conclusion that wearing the stent with the carrier gel was associated with some sensitivity. Relative to the traditional product (Exp 1) without any added desensitizing agents and the agent with 3% potassium nitrate (Exp 2), the addition of a small percentage of potassium nitrate reduced participants' sensitivity to levels equivalent to the placebo (Table 6). In critiquing the results of a study testing a whitening agent containing ACP as a desensitizer, Kanca[10] noted that the generation of ACP, by combining calcium nitrate and potassium phosphate, generated potassium nitrate in addition to ACP. The authors responded[10] that this criticism was misleading, because the potassium nitrate generated was only 0.25%, which was so far below the usual 3% to 5% as to be clinically irrelevant. The current study provides evidence supporting Dr Kanca's questioning of the study's conclusion. With the current study in mind, it seems unclear as to whether the reduction in sensitivity noted was related to the addition of ACP, as the authors concluded,[11] or whether the low level of potassium nitrate generated as a byproduct was, in fact, clinically relevant.

Examination of the data in Table 7 seems to suggest that the addition of 0.25% fluoride resulted in reduced tooth sensitivity and increased soft tissue sensitivity. However, this was not one of the hypotheses tested in this study and was only noted following examination of the study results. Accordingly, further study is required to determine whether this is a significant trend or just random variation between groups.

The addition of potassium nitrate to Exp 3 and potassium nitrate and fluoride to Exp 4 was associated with a reduction in sensitivity. The method by which the addition of potassium nitrate to the agents resulted in reduced sensitivity currently is not fully understood. Initially, it had been hypothesized that potassium nitrate in desensitizing toothpastes acted by occluding the dentinal tubules. However, a study by Pashley and others[12] demonstrated that potassium nitrate did not significantly decrease dentin permeability, as would be expected if this were the case.

Using an animal model, Markowitz and Kim[13] tested the hypothesis that either the anion or the cation of potassium nitrate had a desensitizing effect on pulp. A deep cavity preparation was made to allow the application of various hypertonic solutions for testing. Next, one of the test agents was introduced, a stimulus applied and sensory nerve activity levels recorded. Once testing of the agent was complete, the area was cleansed with a neutral solution and a new stimulus was applied. Potassium ion was found to reduce sensory nerve activity levels. Levels were found to return to normal following cleansing of the potassium ion solution. The authors concluded that the rise in potassium ion concentrations in the extracellular fluid did not allow the nerve endings to repolarize. As a result, following the application of potassium ions, the nerve endings could not respond to new stimuli. The authors also noted a brief period of high-frequency sensory nerve responses immediately following application of potassium nitrate. In humans, this type of sensory nerve activity is interpreted as pain. In a study investigating the effect of potassium ions on dentin sensitivity in humans,[14] most subjects reported pain as the initial response to the application of potassium ions but not sodium ions in a cavity preparation. Since this study delivered the 5% KCl hypertonic solutions under a fluid pressure of 150 Hg, the authors concluded that potassium caused the initial pain response. That is, 5% potassium nitrate caused VAS scores of 40 during the first 60 seconds, while 5% NaCl only produced VAS scores of <10. Yet, the response was similar to the study by Markowitz and Kim[13] that delivered the solutions tested only at atmospheric pressure.

It is surprising that the addition of 3% potassium nitrate to the test bleaching gel did not result in a significant reduction in the number of days participants experienced sensitivity, while the addition of 0.5% did. It appears that this difference is related to a dose-time response and is, perhaps, also related to the initial pain response following application of potassium nitrate in the *in vitro* and *in vivo* studies noted above. The 3% concentration of potassium nitrate is similar to what is found in most desensitizing toothpaste (5%), yet, pain following initial use of desensitizing toothpastes has not been reported. It is important to recall that, in the current study, 3% potassium nitrate was part of a thick gel applied to the teeth using a bleaching stent. As a result, potassium nitrate was held in close proximity to the tooth for at least six hours. This is in stark contrast to the much shorter exposure time and the dilution by saliva when potassium nitrate is applied as part of a

dentifrice. Accordingly, the total dose delivered over time is substantially greater.

Generalizing the results of *in vitro* studies to the current clinical study is somewhat problematic. There are considerable contrasts between the laboratory studies cited and the current clinical study. In both studies noted above, hypertonic solutions were applied to freshly cut dentin, that is, dentin with open tubules. The remaining dentin thickness was 20 to 50 microns in the animal model study and two millimeters in the human study. In the current study, the stents were trimmed in a manner that would cover enamel surfaces only, and all teeth were macroscopically intact. Accordingly, the ingress of potassium ions would be through microscopic defects in the enamel and through a significant remaining dentin thickness. Finally, the reduction in sensory nerve stimulation noted in the above studies lasted only as long as the exposure to potassium ions. In the current study, the reductions in pain levels were recorded at times when participants' teeth were not in contact with the bleaching agent containing potassium nitrate.

However, there is a plausible explanation as to how these laboratory studies help to explain the current results: The presence of 10% carbamide peroxide and gelling agents lower the water concentration of bleaching agents below that of dentinal fluid.[15] This osmotically increases outward seepage of dentinal fluid, which slows the inward diffusion of therapeutic agents.[16-17] The authors speculate that, when 3% KNO_3 was added to the bleaching gel, it lowered the water concentration of the gel even more, inducing more outward seepage of dentinal fluid, which slowed the inward diffusion of 3% potassium sufficiently to cancel its desensitizing effect. When 0.5% KNO_3 was added, it would produce less outward seepage of dentinal fluid, allowing more net inward diffusion of potassium ions even though its concentration was less than the 3% KNO_3-containing gel. In addition, the presence of potassium ions in the dentinal fluid acts as a reservoir of ions to supply a steady stream of potassium ions over a prolonged period of time.

These same basic concepts apply to other ingredients within the bleaching agents. The use of more concentrated solutions results in larger osmotic gradients that tend to decrease the time required for penetration of ions into tooth structures. It has been shown that products with a greater concentration of carbamide peroxide require a longer post-bleaching period to stabilize in color.[18] Relative to lower concentration products, it appears that a greater concentration of the active ingredient is built-up within the tooth over the same time period. Similarly, higher concentrations of carbamide peroxide have been associated with greater sensitivity.[18] Although higher chemical concentrates "push" ions into the tooth, they also contribute to the presence of an osmotic gradient that results in an increased outward flow of fluid through the dentinal tubules, stimulation of the mechano-receptors and pain. Again, it appears that the larger osmotic gradient created with the use of higher concentration agents may be the mechanism responsible for this increase in pain. Similarly, for the current study, it may be that, for the 3% potassium nitrate agent (Exp 2), the net effect was an increase in fluid flow outward and increased pain, rather than driving sufficient potassium ions inward to reduce pain.

CONCLUSIONS

Within the limitations of this study, it can be concluded that:

1) Participants using one of the two whiteners with 0.5% potassium nitrate had sensitivity levels equivalent to those using the placebo.
2) Relative to the whitening agent with no desensitizing agent, the addition of 0.5% potassium nitrate resulted in a significant reduction in the number of days of sensitivity experienced by participants.
3) When compared to the whitener without any potassium nitrate, the addition of 3% potassium nitrate did not result in a significant reduction in the number of days of sensitivity.
4) The addition of potassium nitrate did not result in any significant change in bleaching efficacy.

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