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Clinical effectiveness and sensitivity with overnight use of 22% carbamide peroxide gel

Joe C. Ontiveros*, Magda S. Eldiwany, Rade Paravina

Department of Restorative Dentistry and Prosthodontics, The University of Texas School of Dentistry, Houston, TX, USA

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ABSTRACT

Objective: To evaluate clinical effectiveness, color rebound and sensitivity of 22% carbamide peroxide (CP) with 3% potassium nitrate.

Methods: Twenty-one participants were enrolled and treated overnight for 2 weeks with 22% CP (Venus White, Heraeus Kulzer). Visual color measurement was performed and expressed in shade guide units (SGU) of Vita Classical (VC) and Vita Bleachedguide 3D Master (BG) shade guides. Instrumental color measurements were performed using an intraoral spectrophotometer (Vita Easyshade Compact, EC). Color measurements were taken on a canine and central incisor at baseline, 2, 3, and 4 weeks. Participants documented sensitivity and data were analysed with Wilcoxon and Bonferroni correction at the 0.05 level of significance.

Results: Mean BG SGU difference immediately, 1 and 2 weeks postbleaching compared to baseline was 4.9 (2.1), 4.5 (2.2) and 4.6 (2.0), respectively. Corresponding VC values were 7.0 (3.5), 6.4 (3.3) and 6.5 (3.4), while corresponding ΔE^* values were 8.3 (4.1), 8.1 (4.0) and 7.9 (3.5). For visual shade evaluation there was a significant decrease in SGU from baseline and each subsequent week, $p < 0.001$. There was no difference between week 3 and week 4 using VC or BG. For instrumental color measurements, there was no difference from week 2 to week 3 for canines and generally no difference between week 3 and week 4 for incisors.

Conclusions: Visual and instrumental evaluation showed rebound occurred 1 week postbleaching with 22% carbamide peroxide and 3% potassium nitrate. In general, color was stable at 2 weeks postbleaching. Participants reported low sensitivity levels with a mean value of below 2 on a 0–10 scale.

Clinical significance: This study demonstrates efficacy with overnight usage of 22% carbamide peroxide with 3% potassium nitrate and demonstrates postbleaching color is stable at two weeks with low tooth sensitivity.

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1. Introduction

At-home bleaching is commonly carried out using a custom tray fabricated for overnight usage with low concentrations of carbamide peroxide. The use of at-home bleaching was first introduced to the dental profession by Haywood and Heymann using 10% carbamide peroxide in 1989.¹ The

effectiveness and safety of at-home bleaching with 10% carbamide peroxide has been well documented in early clinical studies^{2–4} as well as the incidence of tooth sensitivity, the most common side effect, which ranges from ‘mild’ to ‘moderate’ in severity.⁵

Higher concentrations of carbamide peroxide have been evaluated in vivo^{6–9} and in vitro.^{10,11} As concentration increases so does the concern for the increased incidence of tooth

* Corresponding author at: 7500 Cambridge St., Suite 5350, Houston, TX 77054, United States. Tel.: +1 713 486 4482; fax: +1 713 486 4353.

E-mail address: Joe.C.Ontiveros@uth.tmc.edu (J.C. Ontiveros).

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sensitivity.⁸ Tooth sensitivity associated with at-home bleaching has been shown to decrease with the addition of potassium nitrate.^{12–15} Concentrations of carbamide peroxide from 15% to 22% are typically prescribed for shorter treatment times ranging from 1 to 2 h. There have been no clinical studies investigating the short term color rebound effect of 22% carbamide peroxide or its effect on tooth sensitivity when used overnight for two weeks.

Tooth whitening and whitening research have undergone significant advancements recently: new and effective products have been introduced; the same is true for the first shade guide designed specifically for whitening monitoring, Vita Bleachedguide 3D Master (BG, Vita Zahnfabrik, Bad Säckingen, Germany, Fig. 1)^{16,17}; a new ISO guidance on visual and instrumental color measurement in dentistry has been published¹⁸; and a method of assuring consistent repeated measurement in whitening research has been introduced and proven effective.¹⁹

The purpose of this study was to implement all these advancements in evaluation of the effectiveness, tooth sensitivity and short-term color rebound effect of a 22% carbamide peroxide at-home whitening system with 3% potassium nitrate. The null hypotheses of the study were: (1) there would be no effect in color difference following two weeks of overnight treatment using 22% carbamide peroxide with 3% potassium nitrate measured at 1 day, 1 week, and 2 weeks post-bleaching, and (2) the bleaching formula with 3% potassium nitrate would not mitigate tooth sensitivity enough to complete 2 weeks of active overnight treatment.

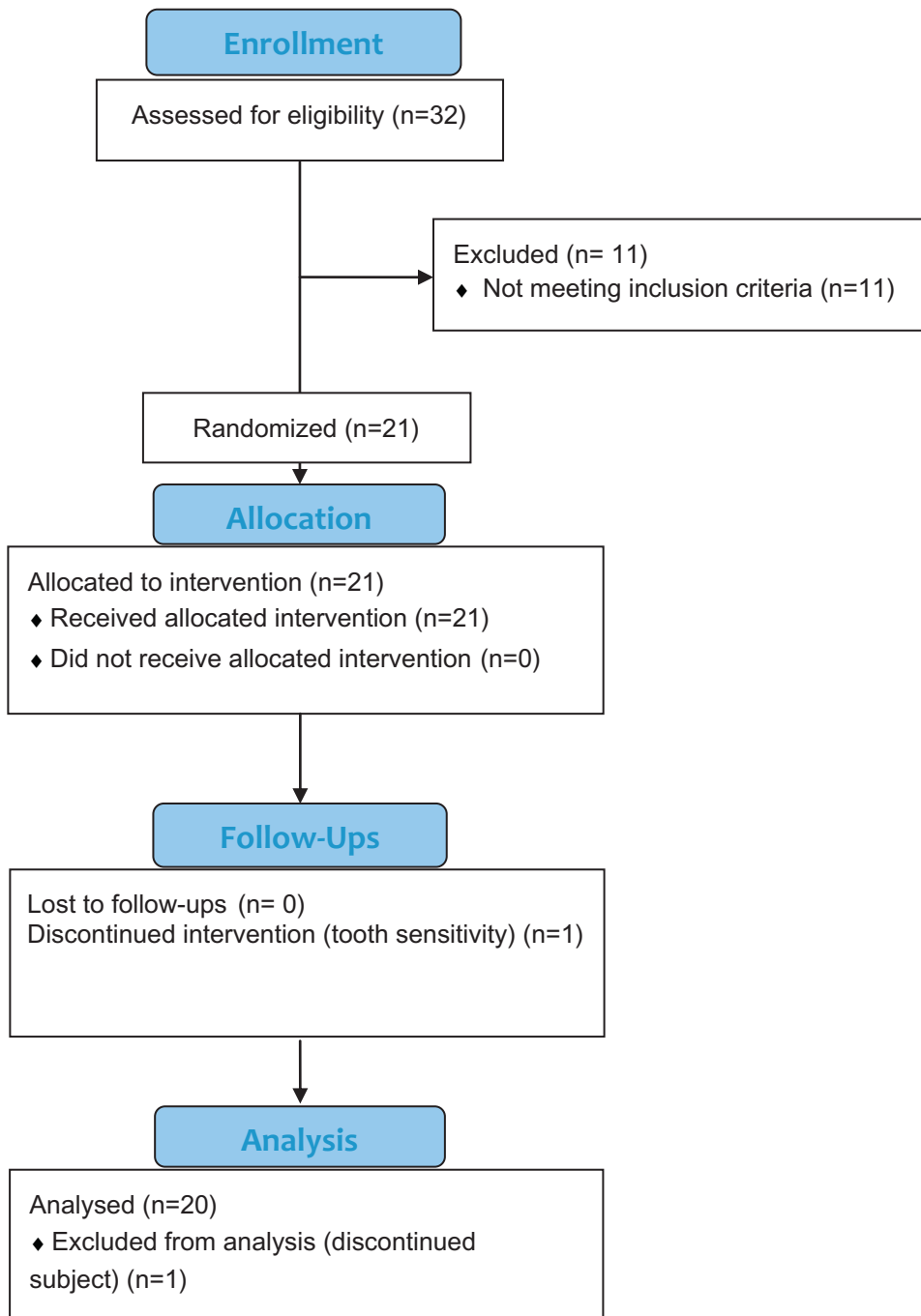
2. Methods and materials

A total of 21 participants with no history of previous tooth whitening and no tooth sensitivity were recruited for at-

home whitening clinical study using 22% carbamide peroxide (Venus White, Heraeus Kulzer, South Bend, IN), 20 of which completed the study. Prior to being enrolled in the study, participants completed a health history form and received an oral exam to screen for caries and confirm teeth to be evaluated were shade A2 or darker. Exclusion criteria included participants who have previously bleached, self-reported sensitivity, intrinsic staining (tetracycline, fluorosis), and existing restorations on teeth to be analysed, currently using chlorhexidine, or other oral mouth rinses, pregnant, and any pre-existing medical or dental conditions considered by the investigators to place participants at increased health risk. A written informed consent was obtained from each subject that included agreement to return for scheduled visits and follow ups and avoid any non-study dentifrices and tooth whitening products for the duration of the study. The written consent and protocol were approved by the Committee for Protection of Human Subjects at the University of Texas Health Science Centre at Houston. A prophylaxis was provided to remove superficial stains, and an impression was made with polyvinyl siloxane for the fabrication of maxillary and mandibular custom bleach trays. Models were poured in microstone, and base was trimmed parallel to the occlusal surface approximately 10 mm from gingival margin. A light cure resin material (LC Block-Out, Ultradent, South Jordan, UT) was applied on the models to the labial surfaces extending 1.5 mm from the gingival line and short of the incisal edges or occlusal surfaces. The resin material was polymerized for 2 min in a light curing unit (Triad 2000, Dentsply International). Custom bleach trays were fabricated by heating 0.9 mm (0.035"), 5 × 5 vinyl sheet material (Sof-Tray Classic, Ultradent, South Jordan, UT) with a vacuum former unit and trimmed upon cooling 0.3 mm from gingiva and scalloped around the labial inter-dental papillas.



Fig. 1 – Shade guide designed for monitoring dental whitening used in the current study.

CONSORT Flow Diagram

At the second appointment each subject had a custom positioning jig made of clear silicone bite registration material (Discus Dental/Philips Oral Health Care, Culver City, CA) to provide a repeatable area for the placement of the instrument tip during measurements before and after tooth whitening. An instrumental baseline color measurement was taken on the middle third of the central incisor and canine using a contact intraoral spectrophotometer (Vita Easyshade, Vita Zahnfabrik, Germany). Visual color assessment was performed by three evaluators with superior color matching competency.¹⁸ All evaluators took visual shade measurements independently

and were blinded to selections recorded at prior visits. A consensus on visual shade selection was reached when needed. Results were expressed in shade guide units (SGU – difference in SGU was denoted Δ SGU.) of Vita Classical (VC, Vita Zahnfabrik, Bad Säckingen, Germany) and Vita Bleached-guide 3D Master (BG) shade guides. Color corrected light (Rite lite, AdDent, Inc., Danbury, CT), having a correlated color temperature (CCT) of 5500 K and color rendering index (CRI) > 92, circumferential 45/0 optical geometry, and illuminance of ~1000 lux at the distance of 5 cm, was used for visual color matching. The shade matching distance was 25 cm. The

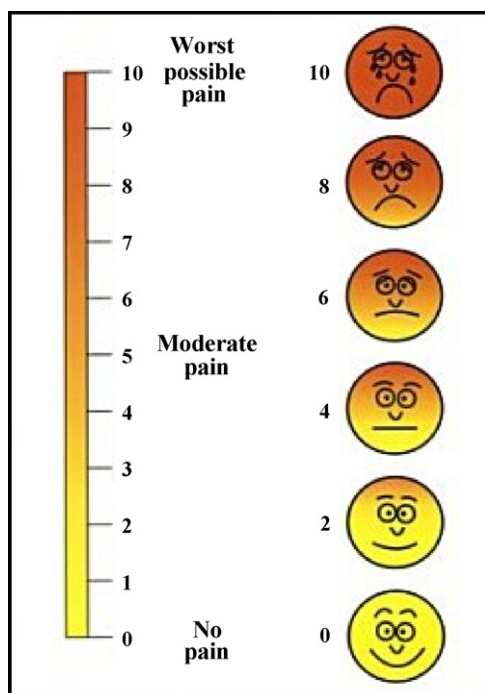


Fig. 2 – Wong-Baker Faces rating scale used to measure tooth sensitivity.

maxillary custom bleach tray was tried in the participants' mouth for accuracy and fit. The maxillary tray, bleaching agent, sensitivity log, oral and written instructions were provided to the participants along with clinical demonstrations on applying the gel in the trays. Participants were asked to enter daily logs for tooth sensitivity using the Wong-Baker Faces rating scale from 0 to 10, with zero representing no pain and 10 representing worst possible pain (Fig. 2).²⁰

Participants were asked to bleach overnight during normal sleep hours for 14 nights and cautioned of the risk of tooth sensitivity. The participants were provided with the option to discontinue treatment or return to clinic for further desensitizing treatment. They were encouraged to continue with bleaching and daily log if treatment was tolerable. Color measurement and visual assessment was repeated after 1 and 2 weeks following the end of treatment. Representative clinical images before and after treatment are shown in Fig. 3. Participants that returned to the clinic complaining of sensitivity were provided with 3% potassium nitrate gel

(Venus Comfort Gel, Venus White, Heraeus Kulzer, South Bend, IN), and were instructed to use it in the custom tray for up to 30 min a day as needed.

At the end of treating the maxillary arch, the participants were provided with a custom tray and bleaching kit to complete the mandibular arch independent of the investigation. Wilcoxon matched-paired signed-rank test and Bonferroni correction for multiple comparisons were used at the 0.05 level of significance. The following color difference thresholds were also used in result interpretation: a ΔE^* = 1.7 as the 50:50% perceptibility threshold, and a ΔE^* = 3.5 as the 50:50% acceptability threshold.²¹

3. Results

3.1. Color

Means (sd) for visual and instrumental color changes for incisors, canines and both teeth combined for three time periods are given in Table 1.

For visual shade evaluation with VC and BG, there was a statistically significant decrease in SGU from baseline and each subsequent week among all measurements, $p < 0.001$. There was no significant difference in SGU among the evaluated time intervals and teeth (incisors, canines and both teeth combined), using either BG or VC.

Statistically significant color difference (ΔE^*) relative to baseline tooth shade was recorded in all evaluated time periods ($p < 0.05$). However, there was no significant difference in ΔE^* values among the evaluated time intervals and teeth (incisors, canines and both teeth combined).

One shade guide unit using VC and BG corresponded to ΔE^* of 1.3 and 1.8, respectively. Overall, SGU for canines was 1.6 and 1.5 times for incisors using VC and BG, respectively; ΔE^* for canines was 1.4 times that of incisors.

Means (sd) for changes in lightness, chroma and hue for incisors, canines and both teeth combined for three time periods are listed in Table 2.

There was no significant difference in ΔL^* , ΔC^* and Δh° values (rebound) among the evaluated time intervals and teeth (incisors, canines and both teeth combined), except for ΔC^* comparison between T2 and T3 for incisors ($p = 0.003$) and for ΔL^* comparison for canines (0.002). Overall, changes in lightness, chroma and hue for canines were 1.9, 1.6 and 1.7 times corresponding changes for incisors, respectively.

Table 1 – Means (sd) for visual and instrumental color changes for incisors, canines and both teeth combined. Δ SGU = shade guide units, visual difference for Bleachedguide (BG) and Classical (VC); ΔE^* = total color difference, obtained using Easyshade Compact (EC); T1 = difference between immediately after whitening minus baseline, T2 = difference between one week after whitening minus baseline, T3 = difference between 2 weeks after whitening minus baseline.

	Tooth								
	T1			T2			T3		
	Incisor	Canine	Combined	Incisor	Canine	Combined	Incisor	Canine	Combined
Δ SGU (BG)	3.9 (1.7)	5.9 (2.1)	4.9 (2.1)	3.5 (1.5)	5.5 (2.3)	4.5 (2.2)	3.7 (1.3)	5.5 (2.3)	4.6 (2.0)
Δ SGU (VC)	5.3 (2.8)	8.6 (3.4)	7.0 (3.5)	4.9 (2.4)	8.0 (3.5)	6.4 (3.3)	4.8 (2.6)	8.2 (3.4)	6.5 (3.4)
ΔE^* (EC)	6.8 (2.9)	9.8 (4.5)	8.3 (4.1)	7.1 (2.5)	9.1 (4.8)	8.1 (4.0)	6.5 (2.5)	9.4 (3.6)	7.9 (3.5)

Table 2 – Means (sd) for changes in lightness (ΔL^*), chroma (ΔC^*) and hue (Δh°), for incisors, canines and both teeth combined, obtained using Easyshade Compact (EC); T1 = immediately after whitening minus baseline, T2 = one week after whitening minus baseline, T3 = 2 weeks after whitening minus baseline.

	Tooth								
	T1			T2			T3		
	Incisor	Canine	Combined	Incisor	Canine	Combined	Incisor	Canine	Combined
ΔL^*	–3.3 (5.0)	–5.8 (3.9)	–4.6 (4.7)	–2.7 (4.9)	–5.7 (4.7)	–4.2 (5.1)	–1.4 (4.4)	–2.4 (4.8)	–1.9 (4.7)
ΔC^*	3.2 (2.8)	5.4 (3.5)	4.3 (3.4)	4.3 (2.2)	5.7 (3.7)	5.0 (3.2)	4.4 (2.0)	7.4 (3.6)	5.9 (3.3)
Δh°	–3.4 (3.5)	–7.7 (4.2)	–5.5 (4.5)	–4.5 (5.0)	–7.0 (4.2)	–5.8 (4.9)	–6.1 (6.8)	–8.2 (5.3)	–7.1 (6.2)

3.2. Sensitivity

Twenty participants were included in the analysis of the 21 participants enrolled in the study. One person complained of severe sensitivity and withdrew from the study after 1 night. The majority of patients reported mild to moderate sensitivity (scores 1–3). Twenty percent of participants experience no tooth sensitivity, 20% reported a score of 5 or greater at least one day through the course of treatment and 15% required treatment with supplemental 3% potassium nitrate gel. The mean scores for tooth sensitivity are shown in Table 3.

There were no statistically significant differences between week 1 and week 2 of active treatment ($p = 0.17$), or week 1 and week 2 post treatment ($p = 0.19$). There were statistically significant differences, after adjusting for multiple comparisons using Bonferroni correction, between weeks 1 and 3, weeks 1 and 4, weeks 2 and 3, and weeks 2 and 4; $p < 0.01$, respectively. No gingival sensitivity was reported.

4. Discussion

Clinical evaluation has been conducted on relatively high concentrations of carbamide peroxide for at-home use, such as 16–20% for 2 h^{11,22–24} or even 30% CP for 1 h²⁵, but data are lacking for higher concentrations for overnight use. Matis et al.

has looked at 15% CP compared to 10% CP overnight and demonstrated a more rapid color change with the higher concentration. However, they were not able to demonstrate a statistically significant difference over time.⁹

4.1. Effectiveness

The first null hypothesis stating two weeks of overnight use would not affect color 1 day, 1 week, and 2 weeks post-bleaching, has been rejected. Both visual (SGU_{BG}) and instrumental findings exceeded the 50:50% acceptability threshold of $\Delta E^* = 3.5$ and efficacy levels listed in the ADA Guidelines for Dentist Dispensed Home-Use Tooth Bleaching Products (4 ccu = 4 SGU_{VC} = 4 ΔE^* , where ccu denotes a color change unit).²⁶ This might justify inclusion of a “very effective” category as a testing outcome in the ADA guidelines. In analogy with ISO TR 28642¹⁸, this can be defined as recommended ccu + 2 SGU or ΔE^* . As far as the SGU_{BG} is concerned, the new marking of BG tabs, with each tab marked with odd number from 1 to 29, and with “interpolated” even numbers in between, that has been introduced after this study, suggests that 2 SGU_{VC} exists between the adjacent BG tabs and 1 SGU_{VC} between the interpolated BG (BGi). When SGU and ΔE^* values were compared, 1 SGU_{VC} corresponded to 1.3 ΔE^* , while 1 SGU_{BG} corresponded to $\Delta E^* = 1.8$, i.e., which means that 1 SGU_{BGi} corresponded to 0.9 ΔE^* in new numeric

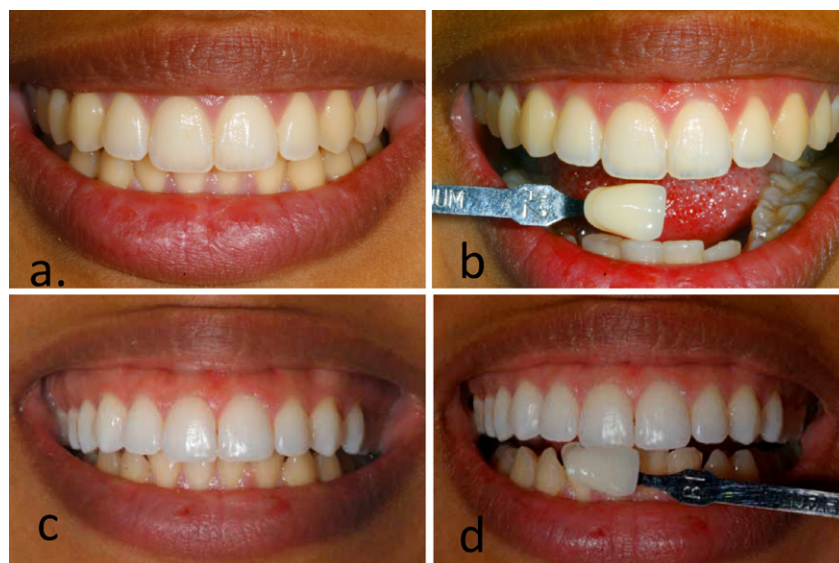


Fig. 3 – Representative clinical images (a–b) before treatment, (c–d) after treatment, using overnight 22% carbamide peroxide with 3% potassium nitrate.

Table 3 – Mean (standard deviations), median, 25%, 75% quantile for tooth sensitivity scores during and after treatment with 22% carbamide peroxide.

	Active treatment week 1	Active treatment week 2	Post-treatment week 3	Post-treatment week 4
Mean	1.2 (1.2) ^a	1.7 (2) ^a	0.2 (0.4) ^b	0.1 (0.3) ^b
Median	0.8	0.8	0	0
25%, 75% quantile	0.1, 2.1	0.1, 2.6	0, 0.1	0, 0

Different letters indicate significance, $p < 0.01$.

marking, which nicely corresponds to ADA equation that $1 \text{ ccu} = 1 \text{ SGU} = 1 \Delta E^*$. In another study, the ratio between the SGUs was $1 \text{ SGU}_{\text{VC}} = 1.6 \text{ SGU}_{\text{BG}}$ ($0.8 \text{ SGU}_{\text{BGi}}$), while $1 \text{ SGU}_{\text{VC}}$ corresponded to $\Delta E^* = 1.0^*$, and $1 \text{ SGU}_{\text{BG}}$ corresponded to $\Delta E^* = 1.6$ ($1 \text{ SGU}_{\text{BGi}}$ corresponded to $\Delta E^* = 0.8$).¹⁹ In two other studies, the color difference between the first and 15th tab of BG was divided with that of VC, and the ratio was $1 \text{ SGU}_{\text{BG}} = 1.9 \text{ SGU}_{\text{VC}}$.¹⁷ These findings provided rationale for equalizing SGU_{VC} with SGU_{BGi} (interpolated BG). Although mentioned studies provide pretty good comparison between SGU_{VC} and SGU_{BG} , and between SGUs and ΔE^* values, additional comparison with SGU_{BGi} , which is more discriminating than SGU_{BG} , might provide additional knowledge on the above listed ratios.

4.2. Color rebound

Color differences, majority of color coordinate differences, and SGU differences one and two weeks after bleaching (compared to baseline) were not statistically significant from these recorded immediately post bleaching, indicating that there was no color rebound in evaluated periods.

According to some studies, dentists have been advised to caution participants to expect a partial rebound in lightness after 1 week or less using 10% carbamide peroxide.^{27,28} However, the evidence in the dental literature regarding color rebound is equivocal when bleach concentrations, wear times, and methods for color monitoring are considered.

One clinical study investigated bleaching with 17% and 10% carbamide peroxide for 7 days for 2 h/day. There was no difference after 1 week and the use of a low concentrated bleaching gel was more advisable to prevent tooth sensitivity. While a statistically significant difference was not detected, the higher concentration did show a faster increase in lightness initially.²³ In the current clinical trial, 22% carbamide peroxide was prescribed for overnight daily treatment for two weeks, longer time than the manufacturer's instructions of 1–2 h/day. Another study⁹ demonstrated a continued relapse in color for up to 6 weeks post-bleaching with a 15% CP formula. This is contrary Kihn et al.⁷ who reported 54% of the participants treated with 15% carbamide peroxide showed a change of 7–9 shades after two weeks of treatment and remained the same after two weeks post-bleaching. In other words, the color was stable at 2 weeks. This is in agreement with the findings of the current study where no relapse in color occurred after two weeks post-bleaching compared to one week post-bleaching.

4.3. Experiment set-up

Shade guides. Many bleaching studies have been performed using so-called value scales of different shade guides, and VC

has been the most frequently used one. VC was also listed as a reference shade guide in ADA guidelines for over the counter, dentist dispensed home-use, and professional in-office tooth bleaching products. However, credibility of color evaluation data obtained using VC value scale is to a certain extent compromised due to its severe shortcomings:

- It does not correspond to visual light to dark order.
- Inconsistent color distribution.
- Narrow color range.
- Lack of very light shadows: dictates exclusion of the a large % of population in bleaching studies.
- Poor correlation of the VC value scale with the increase in chroma.
- Color discrimination competency tools condition method, instrument selection and repositioning.
- Inconsistency with the ADA bleaching guidelines: the reported average color difference (ΔE^*) between the adjacent tabs is 4.2 and 5.4¹⁷, while the ADA guidelines specify that $1 \text{ SGU} = 1 \Delta E^*$.

BG does not exhibit any of these shortcomings and is why the ADA Council on Scientific Affairs decided to include the Bleachedguide instead of Vita Classical as an example of an appropriate shade guide for the evaluation of whitening in the guidelines for Bleaching Products (both dentist dispensed and over the counter) and for Stain Removal Products.

Observers. Observer recruitment is another important issue in bleaching study design. ISO TR 28642 specifies guidelines for the evaluation of color discrimination competency in dentistry by matching of pairs of tab from two identical shade guides, with one set of tabs being de-identified. A total of 50%, 70% and 85% of correctly matched pairs correspond to low-, average-, and superior color discrimination competency, respectively. Individuals with less than 50% of matched pairs should be considered non-competent for color matching. Visual color evaluations in whitening research should be performed by at least 3 observers having superior color discrimination competency.¹⁸ All three observers in this study were tested using this method and each of them matched all 16 pairs of two VC shade guides. It is of critical importance to comply with these guidelines as opposed to recruiting “experienced” practitioners or prosthodontics, or females for visual evaluation in whitening research. There is no sufficient evidence that experienced individuals or females are better in color matching than less experienced individuals or males, respectively. However, there is evidence of significant differences among color normal individuals within any of these categories. According to Farnsworth Munsell 100 Hue

test, 16%, 68% and 16% of individuals have superior, average and low color discrimination, respectively.²⁹

Conditions and method. Shade matching conditions were carefully controlled and in accordance with ISO/TR 28642 dentistry – Guidance on color measurement. When it comes to visual color matching, this includes adequate correlated color temperature, CRI and illuminance of the shade matching light utilized, appropriate optical geometry (illuminant/viewing geometry), visual angle of subtense, and shade matching distance and technique. Considerations related to instrumental color measurements include selection of the adequate instrument and measuring technique. Custom jigs enabled consistent repositioning of the spectrophotometer thereby securing a repeatable area and angulation for placement of the instrument tip in all phases of the experiment.

4.4. Sensitivity

The second null hypothesis stating 22% carbamide peroxide with 3% potassium nitrate would not mitigate tooth sensitivity enough to complete 2 weeks of active overnight treatment was partially rejected. While 95% of the participants were able to tolerate sensitivity for the duration of treatment, 1 patient chose to discontinue treatment due to sensitivity after the first day. Also, 3 participants required supplemental treatment with 3% potassium nitrate in a custom tray. The incidence of sensitivity is a common concern when prescribing at-home bleaching for any length of time. The mechanisms that causes sensitivity is not fully known, however it is believed to be associated with the passage of peroxide through enamel and dentine reaching the pulp chamber.³⁰ Higher concentrations of bleaching agent have been shown to result in a higher pulpal peroxide penetration.³¹ Kihn et al.⁷ showed no difference in tooth sensitivity between the use of 10% and 15% carbamide peroxide. They showed a mean score of 4.2 on a 20 point scale for 15% carbamide peroxide, while the current study reported a mean score of 1.7 on a 10 point scale with 22% carbamide peroxide. It has been shown that low concentrations of potassium nitrate and/or potassium nitrate and fluoride significantly reduce postoperative sensitivity compared to products without either agent.^{14,32} The bleaching agent used in the current formula included the addition of 3% potassium nitrate. All who completed treatment reported that the sensitivity ceased or decreased immediately after finishing the two-week active phase of treatment with no reports of lingering sensitivity.

It was remarkable that no participants reported gingival sensitivity. This may have been due to the careful instructions provided to each patient. The proper amount of gel to place in the tray was demonstrated to each patient with the doctor providing a demonstration, first loading the tray with the patient holding a hand mirror, making sure that the subject understood not to allow the gel to make contact with the gingival. The present study suggest that 22% concentrated bleaching agent with 3% potassium nitrate gel may be applied for overnight use and is capable of whitening teeth with major changes in lightness and chroma accompanied with low levels of tooth sensitivity. However, taking into account that no other studies are available on using such a high concentration overnight, further investigation is required to assess the long-

term safety and color stability of using high concentrations of carbamide peroxide.

5. Conclusions

1. **Whitening:** All participants exhibited statistically significant ($p < 0.05$) color change relative to baseline color after 2 weeks of overnight treatment with 22% carbamide peroxide and 4 weeks of monitoring. Visual measurements ranged from 3.7 to 10 shade guide unit changes dependent on tooth, shade guide type and time of measurement. Whitening of canines was 1.4–1.6 times more pronounced than that of incisors.
2. **Rebound:** Visual and instrumental measurements evaluation showed clinical whitening-dependent rebound occurred during the first week after bleaching compared to baseline. Overall color difference at 1 day after bleaching compared to baseline ($\Delta E^* = 8.3$), decreased very mildly 1 week and 2 weeks after bleaching ($\Delta E^* = 8.1$ and 7.9, respectively).
3. **Sensitivity:** Participants receiving nightly treatment with 22% carbamide peroxide with 3% potassium nitrate at-home bleaching agent reported low sensitivity levels with a mean value below a score of 2 on a 0–10 scale.

Conflict of interest statement

This study was funded in part by Heraeus Kulzer. Vita Bleachedguide 3D-Master was jointly developed by Dr. Rade D. Paravina and Vita Zahnfabrik. The University of Texas Health Science Center at Houston has executed a licensing agreement with Vita Zahnfabrik dealing with commercialization of this shade guide.

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