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

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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  $\Delta E^*$  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.<sup>1</sup> The

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

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

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sensitivity.<sup>8</sup> Tooth sensitivity associated with at-home bleaching has been shown to decrease with the addition of potassium nitrate.<sup>12–15</sup> 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)<sup>16,17</sup>; a new ISO guidance on visual and instrumental color measurement in dentistry has been published<sup>18</sup>; and a method of assuring consistent repeated measurement in whitening research has been introduced and proven effective.<sup>19</sup>

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.

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