

A double-blind randomized controlled clinical trial of 10 percent versus 16 percent carbamide peroxide tooth-bleaching agents

One-year follow-up

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At-home dentist-supervised tooth bleaching with custom trays¹ is considered the modality most frequently used to treat discolored teeth.²⁻⁵ The American Dental Association (ADA) published guidelines for the acceptance of dentist-dispensed home-use tooth-bleaching products.⁶ On the basis of the results of published clinical trials,⁷⁻⁹ these guidelines ensure the benefits, safety and effectiveness of carbamide peroxide applied in a tray at a concentration of 10 ± 1 percent (mean \pm standard deviation). However, new products and methods are available for at-home vital tooth bleaching, including gels, rinses, chewing gums, toothpastes, paint-on films and whitening strips.^{3,6,10-12}

In an attempt to increase the effectiveness and longevity

ABSTRACT

Background. The use of high-concentration tooth-bleaching agents has been associated with increased longevity of the whitening effect. The authors conducted a randomized controlled clinical trial to evaluate the longevity of the whitening effect at one year of two at-home tooth-bleaching agents.

Methods. The authors randomly assigned 92 participants with a mean shade of C1 or darker for six maxillary anterior teeth into two equal-sized groups according to carbamide peroxide concentration: 10 percent (CP10) or 16 percent (CP16). Treatment involved the use of a whitening agent in a tray for two hours daily for three weeks. The authors evaluated tooth shade with a shade guide and a spectrophotometer at baseline and one week, six months and one year after bleaching. Participants in both groups answered questions about their dietary and oral hygiene behaviors.

Results. At the one-year recall appointment, the teeth in both groups remained significantly lighter than at baseline. At this time, participants from the CP10 and CP16 groups consumed staining beverages and foods at a level as high as at the six-month recall appointment, and this consumption level was not statistically significant between groups ($P > .5$).

Conclusions. One year after bleaching, both treatment groups had the same median tooth shade, which remained lighter than at baseline.

Clinical Implications. Higher carbamide peroxide concentration does not increase the longevity of the whitening effect of at-home tooth-bleaching agents.

Key Words. Carbamide peroxide; tooth bleaching; randomized controlled clinical trials.

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of the whitening effect, manufacturers have increased the carbamide peroxide concentrations used in vital bleaching with trays.¹³⁻¹⁶ Despite this attempt, low-concentration agents can provide effects similar to those obtained with high-concentration agents.^{7,16,17}

Most studies about the longevity of the whitening effects obtained with tray-based systems for home bleaching^{8,9,18,19} have relatively short-term follow-up periods, with some having a follow-up period of less than six months.^{4,7,15,17,20} Therefore, there is a lack of randomized controlled clinical trials in the literature in which investigators study whether high-concentration agents can improve the efficacy and longevity of at-home tooth-bleaching agents. To date, investigators have not reported on possible factors associated with shade regression, such as dietary behavior (for example, consumption of staining beverages or foods).

We conducted a randomized controlled clinical trial to evaluate at one year the longevity of the whitening effect of two custom tray bleaching systems (10 percent carbamide peroxide concentration [CP10] or 16 percent carbamide peroxide concentration [CP16]). We also investigated aspects related to participants' diet and oral hygiene behaviors to evaluate their influence on the longevity of the whitening effect of the bleaching treatment.

PARTICIPANTS, MATERIALS AND METHODS

The local ethics committee at Federal University of Pelotas, Rio Grande do Sul, Brazil, approved our double-blind randomized controlled clinical trial. Before we enrolled the participants, we gave each one an informed consent form containing all of the information regarding the risks and benefits of treatment. All participants signed the consent form.

Examiners' technique calibration. Before the study began, we calibrated two examiners' techniques for determining anterior tooth shade.²¹ Working with 16 participants, the study supervisor (S.S.M.) recorded the tooth shades by using a digital spectrophotometer (Vita Easyshade, Vita Zahnfabrik, Bad Säckingen, Germany). The examiners also determined shades by using a

value-oriented shade guide (Vitapan Classical, Vita Zahnfabrik). Without communicating with each other, they selected shades in the afternoon with sunlight and under fluorescent light.

We numbered the 16 tabs in the shade guide from 1 (highest/lightest value, B1) to 16 (lowest/darkest value, C4) for statistical analysis. The examiners visually compared the shade guide tabs with the middle one-third of the six maxillary anterior teeth. We added the scores and determined the mean shade for each participant.

We chose analysis with a digital spectrophotometer as the gold standard, because it can be used to determine tooth shade by means of two methods. These methods are related to grouping shades according to the 16 shade tabs in the shade guide (B1 to C4) and the CIE $L^*a^*b^*$ color

system, which was defined by the International Commission on Illumination in 1967 and is referred to as "CIELAB." In the CIE $L^*a^*b^*$ color system, the L^* value is a measure of the lightness or darkness, the a^* value is a measure of the redness (positive a^*) or greenness (negative a^*), and the b^* value is a measure of the yellowness (positive b^*) or blueness (negative b^*). Whitening occurs mainly by increasing the lightness (higher L^*) and reducing the yellowness (lower b^*), as well as, to a lesser extent, by reducing the redness (lower a^*).^{6,22}

The examiners were trained in 13 clinical sessions across 13 days. At each session, they measured the shades of the six maxillary anterior teeth three times, with the active point of the spectrophotometer in the middle one-third of each tooth. The spectrophotometer automatically averaged the three readings for each tooth by using the CIE $L^*a^*b^*$ color system and the shade guide. We compared these readings with the visual assessment results. We calculated the total color difference or distance between two colors as

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ABBREVIATION KEY. ADA: American Dental Association. CP10: 10 percent carbamide peroxide concentration. CP16: 16 percent carbamide peroxide concentration. Δa^* : Measure of redness or greenness. Δb^* : Measure of yellowness or blueness. ΔE^* : Total color difference or distance between two colors. ΔL^* : Measure of lightness or darkness.

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