Effectiveness of and tooth sensitivity with at-home bleaching in smokers

A multicenter clinical trial

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ABSTRACT

Background. The authors conducted a 2-center controlled clinical study to show the equivalence of at-home bleaching in smokers and nonsmokers at 1 week and 1 month and evaluate tooth sensitivity (TS).

Methods. The authors selected 60 smokers and 60 nonsmokers with central incisors of shade A2 or darker. The participants performed bleaching with 10% carbamide peroxide for 3 hours daily for 3 weeks. The authors evaluated the color by using a shade guide and a spectrophotometer before, during, and after bleaching (1 week and 1 month). Patients recorded TS by using a 0-4 scale and a visual analog scale. The authors used multivariable regression analysis to test factors associated with color change and TS ($\alpha = .05$).

Results. Smokers and nonsmokers showed significant color change statistically equivalent to within $\pm$ 2.0 units at 1 week after bleaching. Overall, color shade improved by 4.1 shade guide units (95% confidence interval [CI], 3.7-4.5) and 7.8 units of color change measured with the spectrophotometer (95% CI, 7.1-8.5) at 1 month. None of the factors affected the TS risk. TS absolute risk and intensity were similar between groups ($P > .05$), with an overall estimate of 47% (95% CI, 38-56%).

Conclusions. The immediate effectiveness of whitening- and bleaching-related TS were not affected by smoking.

Practical Implications. Smoking did not affect the immediate color change (1 week). Effective whitening was achieved regardless of whether the patient was a smoker. However, this equivalence was not apparent 1 month after bleaching, with smokers having slightly darker teeth.

Key Words. Tooth bleaching; smoking; dentin sensitivity.

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Public demand for aesthetic dentistry, including dental bleaching, has increased in recent years.[1] Results from several clinical studies have reported the effectiveness of at-home bleaching with 10% carbamide peroxide (CP).[2-6]

Despite the effectiveness of dental bleaching, tooth sensitivity (TS) is a common adverse effect,[7] which occurs in 37%-90% of patients, even with use of low-concentrate, at-home bleaching gels.[4,6,8-13] In the literature, investigators have reported other detrimental effects

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of bleaching on the enamel surface,[14-16] as well as increased enamel permeability.[17]

These difficulties are probably why professionals usually request that their patients avoid smoking during the bleaching treatment or even refuse this procedure to smokers. Cigarette smoke contains water, air, carbon monoxide, carbon dioxide, and tar. During burning, cigarette components such as tar, sugar, and cocoa are transferred to the smoke.[18] These components cause dental discoloration because of their dark hue and ability to adhere to dental surfaces.[19] The concern about bleaching in smokers also is highlighted by the eligibility criteria of several clinical trials on bleaching, which exclude smokers,[2-4,6,10,13,20-22] without scientific support that smoking can jeopardize the bleaching outcome.

Considering that the prevalence of self-assessed tooth discoloration in smokers is almost twice that reported by nonsmokers,[23] smokers are probably the main candidates for bleaching procedures. However, to our knowledge, no study investigators so far have evaluated whether smoking can affect bleaching effectiveness and TS. Therefore, our aim in this 2-center controlled clinical trial was to show the therapeutic equivalence of at-home bleaching in smokers and nonsmokers at 1 month (primary outcome) and 1 week (secondary outcome). In addition, we evaluated the absolute risk and intensity of TS.

METHODS

The State University of Ponta Grossa (protocol 16457/2012) and the University of Chile (protocol 2013/41) Ethics Committees approved this equivalence clinical trial. The ClinicalTrials.gov identification number was NCT02017873. The study took place within the dental clinics of both universities from February to December 2013.

Inclusion and exclusion criteria. We evaluated participants in a dental chair and after dental prophylaxis with pumice and water to check whether they met the study's eligibility criteria. Participants included in this clinical trial were aged between 18 and 54 years and had good general and oral health. Each participant had at least 1 central incisor of shade A2 or darker as assessed by means of comparison with a value-oriented shade guide (VITA classical, VITA Zahnfabrik). We did not include participants who had undergone previous dental bleaching procedures during orthodontic treatment or those who were pregnant or lactating or had bruxism habits. In addition, we excluded participants with restorations on the labial surfaces of their anterior teeth and noncarious cervical lesions; with veneers or full crowns; with gingival recession, spontaneous tooth pain, or internal tooth discoloration; and with teeth that had been treated endodontically or had fluorosis.

During screening, we measured the patients' baseline TS with vertical and horizontal percussion and with an air jet at the cervical area. We did not include patients with a TS higher than mild on a 5-point verbal numeric rating scale.

Sample size calculation. We based the sample size calculation on the color change measured with the spectrophotometer (ΔE), the primary outcome of the study. One hundred eighteen participants were required to exclude a difference of means of 2.0 units of ΔE at 1 week and 1 month (equivalence limit) with a power of 90% and α of 5%. With these calculations, we took into consideration a standard deviation of 3.3 in the ΔE. The equivalence limit we chose was lower than the ΔE threshold of 3.0, above which color differences become clinically perceptible.[24-26]

Study design. We asked the participants who met the inclusion criteria about their daily smoking habits. Those who did not smoke were part of the group of nonsmokers, and those who smoked at least 10 cigarettes per day belonged to the group of smokers. We included 60 participants in each group—30 from Brazil and 30 from Chile.

We made alginate impressions of each participant's maxillary and mandibular arch and filled the impressions with dental stone. We did not apply block-out material to the labial surfaces of the teeth.[27] We used a 1-millimeter–thick soft vinyl material provided by the manufacturer (Whiteness, FGM Dental Products) to fabricate the custom-fitted tray to hold the bleaching gel. We trimmed the bleaching tray 1 mm beyond the marginal gingiva and delivered the tray and the 10% CP gel (Whiteness Perfect, FGM Dental Products) to each participant with oral instructions for use. We instructed all participants to wear the tray with the bleaching agent for 3 hours daily for 3 weeks.

We instructed the participants to remove the tray after the daily bleaching period, wash it with water, and brush their teeth as usual. We also provided verbal instructions about oral hygiene, encouraging participants to brush their teeth regularly with fluoridated toothpastes without whitening components.

Shade evaluation. We evaluated the color with objective and subjective methods. For both devices, we checked the color at the middle one-third area of the labial surface of the anterior central incisor according to the American Dental Association guidelines.[28]

For the objective shade evaluation, we used a digital spectrophotometer (VITA Easyshade, VITA

ABBREVIATION KEY. **a*:** Color along the red-green axis. **b*:** Color along the yellow-blue axis. **CP:** Carbamide peroxide. **ΔE:** Color change measured with the spectrophotometer. **L*:** Luminosity. **NS:** Not significant. **ΔSGU:** Change in shade guide units. **TS:** Tooth sensitivity.