

2825. Safety and Efficacy of a 10% Hydrogen Peroxide Whitening Gel

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Introduction

Vital tooth whitening is an accepted over-the-counter treatment that has been transitioned from the dental office. The variety of products available for at-home tooth whitening treatments range from heat moldable trays and brush-on tooth whiteners, to tooth whitening pens and whitening strips. In this study, an experimental tooth whitening system (ETWS) (Figure 1) using a soft, flexible arch conforming tray made from an ethyl vinyl alcohol plastic was predosed with a 10% w/w hydrogen peroxide bleaching gel and was tested versus brushing only.



Figure 1. Experimental tooth whitening system.

Objectives

- To evaluate the tooth whitening efficacy on the maxillary arch of a 10% w/w hydrogen peroxide gel predosed in a flexible tray (ETWS) versus brushing alone.
- To evaluate the safety of ETWS versus brushing alone after 7 days of product use.

Methods

Clinical procedure

This was a randomized, parallel group, longitudinal, examiner-blinded study to evaluate the efficacy and safety of 10% w/w hydrogen peroxide gel predosed in a flexible tray (ETWS). A total of 74 subjects with a VITA shade of A3 or greater, based on a VITA Shade Guide value-oriented scale, were enrolled in the study.

At baseline, subjects were assigned to one of two treatments used over a 7-day period:

- ETWS to be worn once daily for 45 minutes and toothpaste
- toothpaste only.

The toothpaste used was Crest Cavity Protection. The subjects returned to the site for assessments after 5 days and 7 days of treatment. After their home application of treatment on Day 3, each subject answered a tooth whitening efficacy questionnaire regarding the appearance of their teeth. VITA shade, subject compliance, and safety were assessed at all visits. Efficacy was based on mean change from baseline in VITA shade of the facial surfaces of the maxillary incisors after 7 days of active treatment.

Statistical methods

To compare treatment using ETWS with brushing alone, a mixed-model analysis of covariance was performed on the 5-day and 7-day change in VITA shade rank, with effects of treatment group [author: text missing?], baseline shade rank as the covariate, and subject as a random effect. Within-treatment product effects were assessed by analyzing the mean changes from baseline using paired *t*-tests. All statistical tests of hypotheses were two-sided and employed a level of significance of $\alpha = 0.05$.

The response to a tooth whitening efficacy questionnaire on Day 3 ("Are your teeth whiter now?" – Yes/No) was analyzed by a CMH chi-square test to compare ETWS with brushing only, with baseline shade group (low, medium, high) as the blocking factor.

Results

- After 5 days there was statistically significantly greater whitening with ETWS compared with brushing alone (-2.50 shades vs 0.02 shades) (Figure 2). Additionally, after 7 days there was a statistically significantly greater whitening effect with the same treatment regimen compared with brushing alone (-3.45 shades vs -0.03 shades, $p < 0.0001$) (Figure 2).
- Of those subjects using ETWS, 71.4% responded that their teeth were whiter than they were before they started using the product, compared with 13.9% of those in the brushing-only group after 3 days.
- In the ETWS group, the most frequently observed and reported treatment-emergent-related oral adverse events (AEs) were desquamation, erythema, and tooth sensitivity.

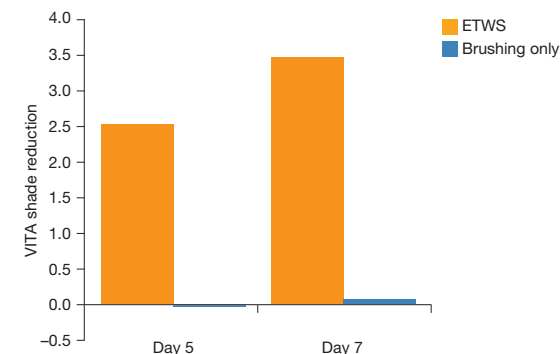


Figure 2. Summary of VITA shade reductions. ETWS, experimental tooth whitening system.

- New tooth sensitivity was reported by six subjects (16.2%) on Day 5. Among these, two subjects (5.4%) reported new tooth sensitivity on Day 7. Incidences of oral soft tissue irritation and tooth sensitivity were similar to those previously reported with the use of marketed whitening products¹.

Conclusions

- The ETWS tested produced statistically significant tooth shade reductions compared with baseline after 5 days and 7 days of treatment.
- The majority of subjects in the ETWS group observed whitening after a 3-day period.
- The AE profile of ETWS was similar to that of other marketed whitening products.

Reference

1. Bordas A, Bosma ML, Kleber CJ et al. Oral tolerability of hydrogen peroxide whitening gel formulations. Presented at the 85th International Association for Dental Research Congress, 21-24 March 2007. New Orleans, LA, USA. Abstract 2821.

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