

## ABSTRACT

Treatment with the professionally administered, tray-based peroxide bleaching systems varies widely from a few hours daily to overnight over 2-6 weeks. Development of flexible, polyethylene whitening strips allows for consistent bleaching using shorter contact times (Gerlach, *Comp Contin Educ Dent* 2000). Fixing the daily strip regimen at 30 minutes BID, a randomized, double blind, double placebo-controlled clinical study was conducted to evaluate the effects of increasing the dosing regimen on tooth shade. A total of 95 adults were randomized to one of 4 treatments: peroxide strip or placebo strip for 14 days BID or 28 days BID. Shade change and tolerability were evaluated at the end-of-treatment, and then again at 3 & 6 months post-treatment. Both the 14- & 28-day active treatment regimens were effective. At the end-of-treatment, the adjusted mean change from baseline in the 14- & 28-day active treatment groups was 6.1 and 6.8 shades respectively, with both groups differing statistically from baseline and placebo ( $p < 0.0001$ ). The 28-day BID active group experienced significant ( $p < 0.02$ ) longer term color improvement, with a 30-72% improvement in shade change at months 3 & 6 compared to the 14-day BID active group. Both active treatments were similar with respect to overall tolerability, and no subjects discontinued treatment due to causally related adverse events. **This research establishes the merit of longer duration (28 days) treatment with whitening strips to further sustain initial color improvement after bleaching.**

## OBJECTIVE

This randomized, double blind, double placebo-controlled clinical study was conducted to evaluate the effects of increasing the dosing regimen on tooth shade.

## MATERIALS AND METHODS

A total of 95 subjects were enrolled into the study. Subjects were randomly assigned to one of the following four treatment groups.

- 5.3% H<sub>2</sub>O<sub>2</sub> Strip\*: BID for 14 or 28 days;
- Placebo strip: BID for 14 or 28 days.

\*Crest Whitestrips™, The Procter & Gamble Company, Cincinnati, OH, USA

## Efficacy and Safety Assessment

Tooth color and safety assessments were conducted at baseline, 14 day, 28 day (28-day groups only), 3 and 6 month visits.

- Efficacy was assessed using Vita Shade.
- Extensive safety evaluations were performed including the examination of OST, OHT, dentinal hypersensitivity, Løe and Silness GI, and Silness and Løe PI.

## Statistical Analyses

The primary efficacy response of interest was change from baseline in Vita Shade tooth color at each respective post-treatment visit. Up to six teeth were selected from the maxillary incisors and cuspids. Analysis of covariance was conducted to determine the mean change from baseline and treatment comparisons. Baseline Vita shade score was used as the covariate in the model.

## RESULTS

### Baseline and demographic characteristics

Among the 95 subjects enrolled, 54 were female and 41 were male. Age ranged from 19 to 74, with an average of 43 years. Treatment groups were balanced with respect to these demographic characteristics, safety parameters, and average baseline Vita Shade score.

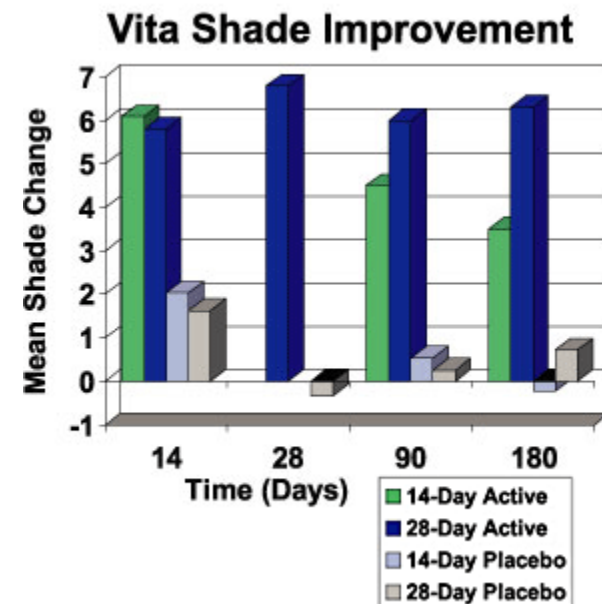
## Efficacy

-The mean color improvements from baseline in Vita Shade scores at day 14 were statistically significant ( $p < 0.0001$ ) for the two active strip groups.

-Further tooth color improvement between day 14 and day 28 was observed for the 28-day active strip group.

-Over the 6-month period, the 28-day active strip group retained an average of at least 6 shades of color improvement ( $p < 0.0001$ ) compared to 3.5 shades for the 14-day active strip group.

-The 28-day active strip group experienced significantly ( $p < 0.02$ ) greater color improvement (30-72%) at months 3 and 6, compared to the 14-day active strip group



### Safety

All treatments were generally well tolerated. Adverse event incidence and severity was directionally better in the 28 day group, particularly for tissue irritation. No subject discontinued study participation due to an AE. Periodontal health (GI and PI) improved with time overall, but was not statistically different between treatments across the 6-month study period

### CONCLUSION

- The peroxide strips were effective at day 14.
- Further color improvement was observed after an additional 14 days bleaching.
- Longer duration (28 days) of treatment further sustained the initial color improvement after bleaching.
- All treatments were generally well tolerated.

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