Whitening efficacy of a 2.7% hydrogen peroxide gel

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Objective:

This clinical study was designed to assess the clinical tooth whitening efficacy of a once per night application of an applicator-dispensed 2.7% hydrogen peroxide gel as compared to an identical application of a matching placebo gel containing 0.0% hydrogen peroxide after 21 days of use.

Methods:

A phase III, randomized, double-blind, two-cell and parallel-group clinical study was conducted on healthy subjects (18-70 years). Subjects were required to possess a minimum average Vita Extended Bleachedguide Shade score of 17 or darker. Subjects were randomized into two groups (Test and Placebo Group) and instructed to use their assigned gel after brushing at night, before bedtime, and to leave it until morning. Oral soft and hard tissue assessments, and tooth shade evaluations were conducted at baseline, 7-days, 14-Days, and at 21-Days overnight applications.

Results:

The between treatment comparison using the Vita Extended Bleachedguide demonstrated that at the 7-day, 14-day and 21-day examinations, subjects in the 2.7% hydrogen peroxide group exhibited statistically significant whitening improvements of 2.15 ($p < 0.001$), 2.81 ($p < 0.001$) and 3.03 ($p < 0.001$), respectively, in mean tooth shade as compared to the subjects in the 0.0% hydrogen peroxide matching placebo group. Shade changes versus baseline for the 0.0% hydrogen peroxide gel were reported as 0.22, 0.28, and 0.22 at the 7, 14, and 21-day examinations.

Conclusions:

The results of this phase III, randomized, double-blind, two-cell and parallel-group clinical study supports the conclusions that a 2.7% hydrogen peroxide gel provided significant tooth shade guide improvement from baseline when applied once daily (overnight) over a 21-day period at every measured time point.