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Tooth Whitening Efficacy of 5% Hydrogen Peroxide Toothpaste

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OBJECTIVE:

To investigate the tooth whitening efficacy of a toothpaste containing 5.0% hydrogen peroxide (w/v) as compared to a matching placebo toothpaste containing 0.0% hydrogen peroxide as measured by the Vita Extended Bleachedguide Shade Guide after 4 weeks of twice a day (morning and evening) product use.

METHODS:

A phase III, randomized, double-blind, single-center, and two-cell parallel-group clinical study was conducted on healthy male and female subjects (21-70 years) from the San Juan, Puerto Rico area. Subjects with a mean Vita Extended Bleached guide shade 17 or darker were included. Study subjects were randomized into 2 groups (Test and Placebo Group) and instructed to use their assigned toothpaste for 4 weeks. Oral tissue assessments, plus tooth shade evaluations were conducted. Independent t-test was used for group comparisons with respect to baseline mean shade rank scores. A paired t-test was conducted for within-treatment comparisons with respect to baseline versus follow-up mean shade rank scores. Analysis of covariance was used for group comparisons with respect to baseline-adjusted mean delta shade changes from baseline at the follow-up examinations.

RESULTS:

Eighty (80) subjects complied with the protocol and completed the clinical study. The 3-day, 2-week and 4-week examinations demonstrated that the test group subjects experienced statistically significant ($p < 0.001$), shade improvements from baseline of 1.40, 2.58, and 4.20 units, respectively. The Test-group was significantly more effective in producing whitening after 4 weeks of product use.

CONCLUSIONS:

The results support the conclusion that brushing with a fluoridated, 5% HP toothpaste is significantly more effective than a matching placebo (non HP) toothpaste on tooth whitening after 4 weeks of product use.



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