

Oral Presentations - Research Supported by P&G

Friday, March 10

0892

Safety and Efficacy of an Experimental Tooth Whitening Strip

A.V. RITTER¹, H.O. HEYMANN¹, E.J. SWIFT¹, A.D. WILDER¹, and R.W. GERLACH²

¹ University of North Carolina, Chapel Hill, USA

² P&G, Mason, OH, USA

Objective: This randomized clinical trial tested the safety and efficacy of 10% hydrogen peroxide polyethylene whitening strips versus that of placebo strips.

Methods: Twenty-six subjects that had at least four maxillary anterior teeth of shade A2 or darker were randomized to experimental or placebo (control) treatment groups. Subjects were given 14 maxillary whitening or placebo strips, and written and illustrated instructions that called for a twice-daily 30-min application. Evaluations were performed at baseline and after treatment (one week). An oral status interview and oral examination were performed at each visit. Any adverse event involving the teeth or oral soft tissue was recorded. Images of the maxillary anterior teeth were captured at baseline and after treatment and converted to CIEL*a*b* values using a digital imaging system. Data was analyzed using analysis of covariance ($p=0.05$). **Results:** After treatment, the difference in Δb^* (yellowness) and ΔL^* (lightness) between the experimental and control groups was statistically significant ($p < 0.0001$). The mean Δb^* was -2.44 for the experimental group, and -0.39 for the control group. The mean ΔL^* for the experimental group was 2.59, and 0.55 for the control group. Changes in overall color (ΔE) and tooth whiteness (ΔW , which combines ΔL^* and Δb^*) also were significantly greater in the experimental group than in the control group. Four subjects (29%) in the experimental group and none in the control group reported oral irritation (primarily gingival irritation). Gingival irritation was observed in five subjects in each group. Two subjects (14%) in the experimental group and none in the control group reported tooth sensitivity. Nearly all of the reported gingival irritation and tooth sensitivity was considered "mild". **Conclusion: The experimental 10% hydrogen peroxide whitening strips proved effective for tooth whitening with minimal side effects.** Supported by The Procter & Gamble Company.

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Placebo-Controlled Clinical Trial Evaluating a 6% Hydrogen Peroxide Whitening Strip

J. HARRISON¹, J.F. SIMON¹, K. KING¹, M.L. BARKER², and R.W. GERLACH²

¹ University of Tennessee, Memphis, USA

² P&G, Mason, OH, USA



Objectives: A placebo-controlled clinical trial was conducted to evaluate the clinical effectiveness and tolerability of a 6% hydrogen peroxide whitening strip. **Methods:** 29 adults were randomized to Crest® Whitestrips®, a 6% hydrogen peroxide whitening strip or placebo strip. In this 2-week, double-blind clinical trial, strips were applied unsupervised to the maxillary teeth twice daily for 30 minutes. Efficacy was measured objectively as $L^*a^*b^*$ color change from digital images at Day 8 (interim) and Day 15 (end-of-treatment). **Results:** Relative to placebo, the 6% strip group experienced significant ($p < 0.001$) color improvement for all color parameters beginning at the interim (Day 8) examination. After 7-days use, the 6% strip group had adjusted means \pm standard errors of -2.1 ± 0.15 for Δb^* and 1.6 ± 0.20 for ΔL^* . At the end-of-treatment, the adjusted Δb^* means \pm standard errors were -2.8 ± 0.18 and -0.4 ± 0.18 for the peroxide and placebo groups, respectively. Similar results were noted for ΔL^* , with adjusted means \pm standard errors of 1.9 ± 0.26 in the 6% strip group versus 0.2 ± 0.27 in placebo. Between group comparisons demonstrated highly significant ($p < 0.001$) color improvement for the 6% strip versus placebo for all color parameters measured in the study. Oral irritation (29% vs. 13%) and mild tooth sensitivity (21% vs. 13%) were the most common side effects in the peroxide strip and placebo groups, respectively. **Conclusion: This double blind, placebo-controlled clinical trial demonstrated that twice daily use of a 6% hydrogen peroxide strip yielded significant tooth whitening after 7-days, and continued whitening improvement after 14 days.**