

Poster Presentations - Research Supported by P&G

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1806

12-Month Post-Treatment Safety and Efficacy of 10% Hydrogen Peroxide Strips

R.W. GERLACH¹, M.L. BARKER¹, L.A. BOWMAN¹, **L. BENZ**², K. KARPINIA², and I. MAGNUSSON²

¹ P&G, Mason, OH, USA

² University of Florida, Gainesville, USA

Objective: Subjects in a placebo-controlled clinical trial were evaluated at end-of-treatment, and again, one year after completion of treatment to ascertain efficacy and safety of 10% hydrogen peroxide whitening strips. **Methods:** 39 subjects were randomized to Crest® Whitestrips® Premium, a 10% hydrogen peroxide whitening strip or placebo. Treatment was twice daily for 7 days, at-home and unsupervised. Subjects in the 10% strip group were re-evaluated at 12-months post-treatment to ascertain long-term color change, and clinical safety. Efficacy was measured objectively as $L^*a^*b^*$ color change from digital images at end-of-treatment and post-treatment. **Results:** For the 12-month recall subjects in the 10% strip group, end-of-treatment mean (SD) Δb^* was $-2.5 (1.02)$, and mean ΔL^* (SD) was $2.5 (0.91)$. This 10% strip group experienced significant ($p < 0.0001$) end-of-treatment color improvement (Δb^* & ΔL^*) relative to baseline and placebo. At 12-months post-treatment, the 10% strip group had mean (SD) Δb^* of $-1.9 (1.00)$, and mean ΔL^* (SD) of $2.2 (0.90)$. Treatment differed significantly ($p < 0.0001$) from baseline for both Δb^* and ΔL^* . Mild tooth sensitivity and oral irritation, the most common side effects in the study, resolved during treatment or post-treatment. No subjects discontinued treatment early due to an adverse event, and there were no post-treatment findings except for whitening. **Conclusion: This clinical trial demonstrated 12-month post-treatment safety and long-term whitening following twice daily use of a 10% hydrogen peroxide strip.**

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Clinical Trial Comparing Daytime and Overnight Tooth Whitening Systems

K. KARPINIA¹, I. MAGNUSSON¹, M.L. BARKER², and R.W. GERLACH²

¹ University of Florida, Gainesville, USA

² P&G, Mason, OH, USA

Objective: While most peroxide-containing tooth whitening systems use various devices to deliver peroxide to the tooth surface, some are barrier-free. This clinical trial was conducted to evaluate the clinical effectiveness of a barrier-free paint-on system relative to a marketed barrier control. **Methods:** A total of 40 healthy adults were randomized to Colgate® Simply White™ Night, a 8.7% hydrogen peroxide, barrier-free, paint-on liquid, or Crest® Whitestrips® Premium, a 10% hydrogen peroxide gel on a whitening strip. Following the manufacturer's instructions, the paint-on was used overnight for 14 days, while the strip was applied twice daily for 7 days. All usage was unsupervised. Efficacy was measured as $L^*a^*b^*$ color change using digital images of the anterior dentition. **Results:** Adjusting for baseline and age, the end-of-treatment estimated means (SE) for Δb^* (yellowness) were $-0.37 (0.09)$ for the paint-on group (Day 15) compared to $-2.05 (0.09)$ for the strip group (Day 8). Response similarly favored the strips for ΔL^* and Δa^* color change. Between-group comparisons showed highly significant ($p < 0.0001$) greater color improvement for the strip group for all of the individual parameters (Δb^* , ΔL^* , Δa^*), as well as overall color improvement (ΔW^*). Oral irritation was the most common adverse event overall, reported by 25% and 15% of subjects in the paint-on and strip groups, respectively. While there were no reports in the paint-on group, 6 subjects in the strip group reported transient tooth sensitivity. No subjects discontinued treatment early due to an adverse event. **Conclusion: Use of the 10% whitening strip barrier system for 7 days resulted in more than five-fold superior whitening compared to 14 nights use of a barrier-free, 8.7% hydrogen peroxide paint-on liquid**