

Poster Presentations - Research Supported by P&G

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Placebo-Controlled, Six-Month Clinical Trial of Strip-Based Whitening

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Objective: A placebo-controlled clinical trial was conducted to evaluate shade change, benefit duration, and safety of a 6% hydrogen peroxide whitening strips. **Methods:** Fifty healthy adults were randomized to whitening strips with 6% hydrogen peroxide or placebo. Strips were worn for 30 minutes two times a day for 4 weeks. After 2 & 4 weeks strip use, and again, at Month 3 & 6 post-treatment, standard tooth shade measurements were collected from the maxillary anterior teeth, and periodontal health was assessed using standard methods for measuring gingivitis (GI) and plaque (PII). **Results:** This Mexico City, DF study population had a mean (SD) age of 23.0 (4.2), 70% of whom were female. At Week 2, the strip group exhibited an adjusted mean (SE) shade change of -5.6 (0.45), differing significantly from placebo and baseline ($p < 0.0001$). At the Week 4 end-of-treatment visit, between group comparisons demonstrated a highly significant ($p < 0.0001$) -6.7 shade change for the whitening strips at end-of-treatment compared to placebo. This shade improvement persisted throughout the post-treatment period, with the whitening strips exhibiting highly significant ($p < 0.0001$) 6+ mean shade improvement relative to placebo at the Month 3 and Month 6 examinations. There were no significant ($p > 0.23$) between-group differences in mean GI or PII scores during the post-treatment period. Both treatments were well tolerated, with no subject discontinuing treatment early due to an adverse event. **Conclusion: Use of 6% hydrogen peroxide whitening strips yielded a significant shade improvement beginning at Week 2, and continuing through 6 months post-treatment.**

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Gingival Recession and Clinical Response with Extended Whitening Strip Use

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Objective: Previous research suggests that gingival recession may play a role in bleaching-related tooth hypersensitivity. This relationship was evaluated in a randomized clinical trial comparing extended use of two different hydrogen peroxide strip whitening systems. **Methods:** A total of 60 subjects with no history of tooth sensitivity were randomly assigned equally to Crest® Whitestrips® Premium (10% hydrogen peroxide) or Crest® Whitestrips® (6% hydrogen peroxide). Strips were applied to the maxillary teeth twice daily for 30 minutes over a 21 day period. Efficacy was evaluated using digital image analysis to assess CIELAB tooth color, while safety was measured by examination and interview. **Results:** Subjects ranged from 18-50 years of age. Treatments were balanced, with 12 subjects (6 per group) having recession on the maxillary anterior dentition. Mean age was 40.3 and 32.3 years for subjects with and without recession, respectively, with subsets differing significantly ($p = 0.0005$). Both the 10% and 6% strip treatments were effective. Adjusting for baseline and age, end-of-treatment means \pm SE for Δb^* (yellowness) were -3.14 ± 0.239 and -2.38 ± 0.247 for the 10% and 6% strips, respectively, with groups differing significantly ($p = 0.032$). Overall, 22% of the subjects reported tooth hypersensitivity: 32% in the higher concentration and 10% in the lower concentration groups. Fisher's Exact Test demonstrated no significant ($p > 0.99$) differences in tooth hypersensitivity based on recession status. Occurrence was the same (17%) among subjects with or without baseline gingival recession. No subject discontinued treatment due to an adverse event. **Conclusion: Clinical research showed both whitening strips to be effective, and gingival recession was not a factor in the occurrence of tooth hypersensitivity with extended use.**