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Placebo-controlled Six-month Clinical Trial of 6% Hydrogen Peroxide Whitening Strips

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Objective: A randomized, double blind, placebo-controlled clinical trial was conducted to evaluate clinical response following 2-week use of whitening strips. **Methods:** Balancing for baseline shade, 53 healthy adults were treated with 6% hydrogen peroxide whitening strips or placebo. Strip treatment was twice daily for two weeks. Subjects were evaluated at end-of-treatment, and 3 and 6 months post-treatment. Standard tooth shade measurements were collected from the maxillary anterior teeth by 2 independent examiners. Periodontal health was assessed using standard methods for measuring gingivitis (GI) and plaque (PII). **Results:** Between-group comparisons using the Vita Lumin guide demonstrated a highly significant ($p < 0.0001$), 4.7 shade improvement 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 ($p < 0.0001$) 4.5 shade and 4.3 shade improvements relative to placebo at the Month 3 and Month 6 examinations. Except for a modest GI reduction at Month 6 favoring the strips, there were no significant between-group differences in GI or PII at any time point. Both treatments were well tolerated. Only 4% of whitening strip users had tooth sensitivity and 4% had oral irritation. **Conclusion:** Two weeks use of 6% hydrogen peroxide whitening strips yielded significant mean shade improvement at end-of-treatment and post-treatment, with a safety profile that was similar to placebo



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Clinical Trial of Two 6% Hydrogen Peroxide Equivalent Whitening Systems: Strips Versus Paint-On

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Objective: The new, peroxide-containing tooth whitening systems use various devices to deliver peroxide to the tooth surface. This 14-day clinical trial was conducted to evaluate the clinical effectiveness of a new paint-on system relative to a marketed control having a similar pre-treatment peroxide concentration. **Methods:** A total of 30 healthy adults were randomized to Colgate® Simply White™, an 18% carbamide peroxide paint-on liquid in an applicator bottle, or Crest® Whitestrips®, a 6.0% hydrogen peroxide gel on a whitening strip. Study participants were supplied with the manufacturers' written instructions for use, treatment was twice daily for 30 minutes, and all usage was unsupervised. Efficacy was measured as $L^*a^*b^*$ color change using digital images of the anterior dentition. **Results:** Adjusting for baseline, the Day 14 estimated means and standard errors for Δb^* (yellowness) were $-0.20 (0.29)$ for the paint-on group compared to $-2.57 (0.31)$ for the strip group. Response was similar for lightness/brightness (ΔL^*), with the adjusted mean (SD) of $0.12 (0.26)$ and $1.71 (0.27)$ in the paint-on and strip groups, respectively. Only the strip group differed significantly ($p < 0.0001$) from baseline for Δb^* or ΔL^* . Between-group comparisons showed highly significant ($p < 0.001$) greater color improvement for the strip group for all of the individual parameters (Δb^* , ΔL^* , Δa^*), as well as composite color (ΔE^*) and overall whiteness (ΔW^*). Both treatments were well tolerated, and no subjects discontinued treatment early due to an adverse event. **Conclusion:** Use of the 6.0% whitening strips resulted in more than ten-fold superior whitening to the 18% carbamide peroxide paint-on liquid, the latter of which failed to exhibit any significant $L^*a^*b^*$ color change from baseline.

Whitestrips relative to ADA requirements

