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Post-treatment Safety and Color Stability Following Use of a Direct-application Percarbonate Bleaching Film for Tooth Whitening

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Objective: Extended treatment with peroxide-containing agents is recognized as an important contributor to overall safety profile of vital bleaching agents. Accordingly, a randomized, placebo-controlled clinical trial was conducted to ascertain post-treatment safety and tooth color stability following extended use of a direct application percarbonate film. **Methods:** All subjects used Crest[®] Night Effects[™], a 19% sodium percarbonate bleaching film or placebo overnight for 6-weeks, with safety and efficacy monitoring at Week 10 (one month post-treatment). Tooth brushing was standardized throughout the 10-week study. Safety evaluations included a comprehensive oral examination and subject interview to ascertain tooth sensitivity, oral irritation, and other adverse events, while efficacy was measured objectively as L*a*b* color change from digital images. Between-group comparisons were made to determine continuing (after-treatment) adverse events and color stability during the 4-week post-treatment period. **Results:** During the 6-week active treatment period, tooth sensitivity and oral irritation were the most common adverse events, affecting 28% of subjects in the active group compared to 16% in the placebo group. These events were mild in severity, and fully resolved. While side effects were transient, the color change was durable. At 4 weeks post-treatment, the active group retained 89% of the color change (Δb^*) on the maxillary teeth and 90% on the mandibular teeth, differing significantly ($p < 0.0001$) from placebo for this and all other color parameters. **Conclusion:** This clinical trial demonstrates post-treatment safety and color stability following extended daily use of a direct application percarbonate film. (This research was supported by The Procter & Gamble Co.)

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Initial and Sustained Spatial Whitening Responses with 6% Hydrogen Peroxide Whitening Strips

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Objective: Although effective, there is only limited *in vivo* evidence on the uniformity of vital bleaching across tooth surfaces. This research was conducted to evaluate the initial and sustained *in vivo* spatial whitening response profile following use of a hydrogen peroxide gel uniformly distributed across a flexible strip. **Methods:** Digital images from a randomized clinical trial (N=16) were analyzed to assess the spatial whitening response on maxillary central and lateral incisors. Subjects dosed with 6% hydrogen peroxide whitening strips, which had a uniform 12 mg/cm² peroxide density for two weeks. At Week 2 & 5 (3 weeks post-treatment), color response (L*a*b*) was determined from the proximal edges to the central region of each target tooth by mapping spatial color change, and then, by comparing the proximal and midline changes following treatment. **Results:** The whitening strips demonstrated highly significant improvement ($p < 0.001$) with respect to yellowness, with overall adjusted mean Δb^* of -2.37 overall at Week 2, and -2.33 after 3 weeks post-treatment. This improvement was evident on both the proximal (-2.15) and central (-2.41) tooth regions. Similar results were reported for lightness (ΔL^*), redness (Δa^*), and overall color (ΔW^*), with no meaningful between-region differences with respect to these color parameters. **Conclusion:** Application of a uniform 12 mg/cm² peroxide density gel to tooth surfaces via a whitening strip resulted in highly significant color improvement across proximal and midline tooth surfaces at the end-of-treatment and post-treatment. (This research was supported by The Procter & Gamble Co.)