**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 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.)

**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 ∆b* 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 (∆L*), redness (∆a*), and overall color (∆W*), 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.)

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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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**0890**

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

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