

Thursday, June 26



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## Placebo-controlled Clinical Trial Evaluating Extended Use of a Direct-application Percarbonate Bleaching Film

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**Objective:** A placebo-controlled clinical trial was conducted to evaluate the clinical response following extended use of a novel direct application percarbonate bleaching film. **Methods:** A total of 50 healthy adults were randomized to Crest<sup>®</sup> Night Effects<sup>™</sup>, a 19% sodium percarbonate bleaching film, or placebo film without peroxide. Subjects applied the assigned product directly to the facial surfaces of the maxillary and mandibular teeth each day in the evening using an applicator brush. Efficacy was measured objectively as L\*a\*b\* color change from digital images collected every 2 weeks. **Results:** Relative to baseline, the percarbonate film group experienced significant ( $p < 0.0001$ ) color improvement for yellowness ( $\Delta b^*$ ) and lightness/brightness ( $\Delta L^*$ ) beginning as early as Week 2. After 6-weeks, the adjusted  $\Delta b^*$  means  $\pm$  standard errors on maxillary teeth were  $-2.41 \pm 0.20$  and  $-0.28 \pm 0.19$  for the active and placebo groups, respectively. Similar results were noted for  $\Delta L^*$ ,  $\Delta a^*$ , and the composite parameters  $\Delta E^*$  and  $\Delta W^*$ . In all circumstances, between group comparisons demonstrated highly significant ( $p < 0.0001$ ) color improvement in the percarbonate film group. Clinical response was similar for the mandibular teeth, as evidenced by the 6-week adjusted  $\Delta b^*$  means  $\pm$  standard errors of  $-2.02 \pm 0.19$  and  $-0.30 \pm 0.18$  for the active and placebo groups, respectively. Both treatments were generally well tolerated, with tooth sensitivity (more common with the active) and oral irritation (more common with the placebo) representing the most common side effects. **Conclusion:** Extended 6-week daily use of a direct application percarbonate film resulted in significant and meaningful tooth whitening on both maxillary and mandibular teeth without significant side effects. (This research was supported by The Procter & Gamble Co.)

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## Two-week Clinical Trial Comparing an 18% Carbamide Peroxide Paint-on Gel with Hydrogen Peroxide Whitening Strips

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**Objective:** This study evaluated the clinical response of a new, peroxide-containing paint-on gel relative to a marketed control having a similar pre-treatment peroxide concentration. **Methods:** 32 adults were randomized to Colgate<sup>®</sup> Simply White<sup>™</sup>, an 18% carbamide peroxide paint-on liquid in an applicator bottle, or Crest<sup>®</sup> Whitestrips<sup>®</sup>, a 6.0% hydrogen peroxide gel on a whitening strip. Participants were supplied with the manufacturers usage instructions specifying twice daily 30-minute treatment. Efficacy was measured objectively as L\*a\*b\* color change using digital images of the maxillary anterior teeth after 1 & 2 weeks treatment. **Results:** All subjects made all visits, and were included in the analysis. Week 1 adjusted means and standard errors for  $\Delta b^*$  (yellowness) were  $-0.3 \pm 0.12$  for the paint-on group compared to  $-1.6 \pm 0.12$  for the strip group, while lightness/brightness ( $\Delta L^*$ ) means were  $0.3 \pm 0.18$  and  $1.7 \pm 0.18$  in the paint-on and strip groups, respectively. Outcomes were consistent after 2 weeks, with 94% of strip users and 25% of paint-on users experiencing at least a 1-unit improvement in  $b^*$ . All (100%) of strip users and 19% of paint-on users had at least a 1-unit improvement in lightness at Week 2. Between-group comparisons showed highly significant ( $p < 0.0001$ ) greater color improvement for the strip group compared to the paint-on gel. For  $\Delta b^*$ ,  $\Delta L^*$  and the composite measures  $\Delta E^*$  and  $\Delta W^*$ , one week use of whitening strips resulted in significant ( $p \leq 0.0001$ ) color improvement relative to that seen following two weeks use of the paint-on gel. Both treatments were well tolerated. **Conclusion:** One week use of 6.0% whitening strips resulted in superior whitening compared to two-weeks use of an 18% carbamide peroxide paint-on liquid. (This research was sponsored by The Procter & Gamble Co.)