

# Clinical Trial Comparing Strip and Wrap Tooth Whitening

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## ABSTRACT

**Objectives:** Direct-to-consumer tooth whitening systems use various devices and treatment regimens to deliver peroxide to the tooth surface. This 14-day clinical trial was conducted to evaluate the clinical response of a new “wrap-around” delivery relative to a marketed strip control.

**Methods:** A total of 39 healthy adults were randomized to Rite Aid Whitening Wraparounds™, a hydrogen peroxide tooth “wrap”, or Crest® Whitestrips®, a 6% hydrogen peroxide gel on a whitening strip. Following the manufacturers written instructions for use, the wrap was applied once daily, and the strips were applied twice daily, each for 30 minutes over a 14-day period. Efficacy was measured as L\*a\*b\* color change using digital images of the anterior dentition on Day 15. Subjects were also questioned regarding personal color perception using a linear scale.

**Results:** Adjusting for baseline and age, the Day 15 estimated means (SE) for Δb\* (yellowness) were -1.08 (0.15) for the wrap group compared to -1.73 (0.15) for the strip group. Between-group comparisons showed highly significant ( $p < 0.005$ ) improvement favoring the strip group. Groups also differed significantly with respect to the perceptual parameters relating to whitening improvement ( $p = 0.030$ ), satisfaction with whitening ( $p = 0.029$ ), and overall treatment impression ( $p = 0.027$ ). Oral irritation was the most common adverse event in both the wrap (37%) and strip (20%) groups.

**Conclusion:** Use of 6% whitening strips resulted in significant objective and subjective whitening versus a hydrogen peroxide wrap.

## OBJECTIVE

This study was designed to evaluate objective and subjective whitening efficacy and safety of two marketed tooth-whitening systems.

## MATERIALS AND METHODS

This was a randomized, double-blind, parallel group clinical trial with a total of 39 healthy adult volunteers. The maxillary anterior teeth were treated for 14 days for 30 minutes per manufacture's instructions. For the objective measurement of Δb\*, treatment groups were compared using ANCOVA with baseline and age as covariates.

At the completion of the Day 15 visit, subjects were asked to rate how much whiter their teeth looked after using their assigned product on a 1-9 scale. Subjects were then asked to rate their whitening satisfaction of the assigned product from 0 (not at all satisfied) to 5 (extremely satisfied). In addition, overall impression of the products was measured by asking the subjects to indicate their preference on a scale from -4 (dislike the most possible) to 0 (neutral) to +4 (like the most possible) for the assigned product. For the subjective assessments, the Wilcoxon rank-sum test was used to compare treatment groups.

## RESULTS

BASELINE DEMOGRAPHICS		
	Strip	Wrap
<b>Subjects: N</b>	20	19
<b>Age: Mean (S D)</b>	40.5 (12.49)	41.5 (9.97)
<b>Min — Max</b>	18-62	22-58
<b>Female: N (%)</b>	14 (70.0%)	16 (84.2%)
<b>Tobacco Users: N (%)</b>	3 (15.0%)	3 (15.8%)

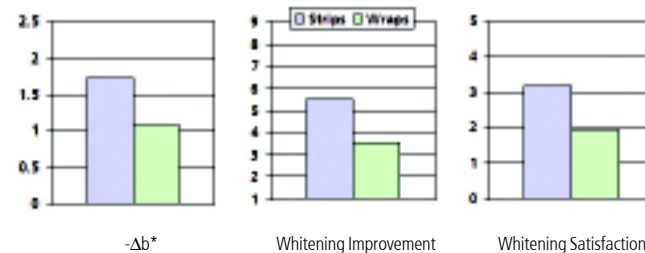
**Safety:** Both treatments were generally well-tolerated. There were a total of 13 subjects with 18 adverse events (all determined to be possibly or probably related to treatment). With the exception of 1 event in the wrap group classified as moderate in severity, 94% of events were classified as “mild”. No subject discontinued treatment or withdrew early because of a product-related adverse event.

## RESULTS (Cont.)

**Efficacy:** At the Day 15 visit, the strip group provided greater reduction in yellowness (Δb\*) when compared to the wrap group with adjusted means and standard errors of  $-1.73 \pm 0.15$  and  $-1.08 \pm 0.147$ , respectively. The treatment comparison for Δb\* was statistically significant ( $p$ -value = 0.0042).

**Questionnaire:** The mean scores for whitening improvement and whitening satisfaction for each treatment group are displayed below. For overall impression, the mean score was 2.00 for the strip group and 0.95 for the wrap group. For all three assessments, the strip group provided statistically significant improvement relative to the wrap group ( $p < 0.05$ ).

Day 15 Objective and Subjective Mean Responses



## CONCLUSION

Use of 6% whitening strips resulted in significant objective and subjective whitening versus a hydrogen peroxide wrap.