Placebo-Controlled Clinical Trial Evaluating 6% Hydrogen Peroxide Whitening Strips

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ABSTRACT

Objective: This randomized, double-blind, placebo-controlled clinical trial was conducted to evaluate clinical response (safety and efficacy) following 2-week use of whitening strips. **Methods:** A total of 51 adults were treated with 6% hydrogen peroxide whitening strips or placebo strips twice daily for two weeks. Standard tooth shade measurements were collected from the maxillary anterior teeth by 2 independent examiners, while periodontal health was assessed using standard methods for measuring gingivitis (GI) and plaque (PℓI). **Results:** Subjects averaged 39 years of age (26-49), with males and females equally represented. Relative to baseline, the whitening strip group experienced a highly significant ($p < 0.0001$), greater than 5 shade improvement. Between-group comparisons using the Vita Classic guide demonstrated a highly significant ($p < 0.0001$), 4.3 ± 0.57 shade improvement for the whitening strips. There were no significant between-group differences with respect to either gingivitis or plaque scores after treatment. Both treatments were well tolerated, with only 12% of whitening strip users reporting tooth sensitivity, and 8% reporting oral irritation. None of the study subjects in either group discontinued treatment early due to an adverse event. **Conclusion:** Two weeks use of 6% hydrogen peroxide whitening strips yielded significant mean shade improvement without significant adverse events.

INTRODUCTION

Crest® Whitestrips®* consist of a polyethylene backing coated with a gel that contains 6% hydrogen peroxide (9-12 mg H_2O_2 depending on the arch). The backing strip holds the whitening gel against the subjects' teeth, maintaining it in place for the full 30 minute treatment period.

PURPOSE

This two leg, randomized, double blind clinical trial was conducted to evaluate the whitening efficacy and safety of whitening strips vs. placebo used twice daily for two weeks.

** The Procter & Gamble Company, Cincinnati, Ohio, USA.*

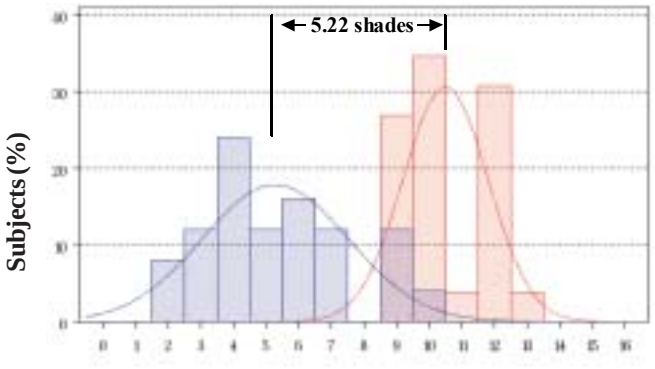
MATERIALS AND METHODS

After balancing for baseline shade, 51 healthy adults were treated with either 6% hydrogen peroxide whitening strips or placebo for 30 minutes twice daily for two weeks. The target population consisted of healthy adults who had undergone routine dental care and had a desire to have their teeth whitened. Tooth colour and safety assessments were conducted at baseline and Day 14 (end of treatment). Tooth colour change was assessed using the Vita shade (Vita Lumin®), while safety evaluations included the examination of OST, OHT, dentinal hypersensitivity and Löe and Silness GI and Silness and Löe PℓI.

RESULTS

Demographic characteristics were balanced across the treatment groups. The study population average age was 39 years; 51 % were female.

Vita Shade Scores
6% hydrogen peroxide whitening strips group



Blue: Week 2 (N=25) **Red: Baseline (N=26)**

- Relative to baseline, the whitening strip group experienced a highly significant ($p < 0.0001$), greater than 5 shade improvement and 4.3 shades improvement relative to placebo.

DATA

Mean GI/PℓI Scores			
	Baseline	**Day 14**	**p-value**
GI			
Strips	0.56	0.45	0.3548
Placebo	0.41	0.46	0.5920
PℓI			
Strips	0.44	0.28	0.0012
Placebo	0.36	0.28	0.0014

- No statistically significant between-group differences in GI and PℓI scores were found at the end of treatment period ($p > 0.05$).
- No subject AEs occurred in the placebo group. Two (8%) subjects in the active strip group reported oral irritation and three (12%) reported tooth sensitivity.

CONCLUSION

Two weeks use of 6% hydrogen peroxide whitening strips yielded significant mean shade improvement without significant adverse events using both GI and PℓI measures.

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