

Clinical Trial Comparing Whitening Strips to a Carbamide Peroxide Potassium Nitrate Tray System

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ABSTRACT

Objective: Several factors may impact on bleaching-related sensitivity, including peroxide concentration, contact time, delivery system, use of desensitizing agents and others. This randomized clinical trial was conducted to evaluate the clinical response of a low peroxide bleaching system with a desensitizing agent relative to a marketed control.

Methods: Balancing for baseline color and age, 34 healthy adult volunteers were randomized to one of two marketed bleaching systems. Subjects received either 5% carbamide peroxide bleaching gel + potassium nitrate in a custom tray or 6.0% hydrogen peroxide bleaching strips. Daily contact time was 6-8 hours for the tray system compared to 1 hour for the strip system, following manufacturers instructions. Whitening was measured objectively using digital image analysis to assess $L^*a^*b^*$ after 7 days.

Results: The predominantly female (85%) and non-smoking (91%) study population ranged from 20-47 years of age. Both treatments yielded a statistically significant ($p < 0.01$) whitening benefit with respect to reduction in yellowness (Δb^*), as well as secondary endpoints (ΔL^* and ΔE^*). The strip group experienced greater color improvement on average for all color parameters in the study. After 7 days treatment, mean Δb^* was -1.20 in the strip group and -0.68 in the tray group, with these groups differing significantly ($p = 0.03$). Tooth sensitivity was reported by 13% of subjects using the hydrogen peroxide strips, compared to 22% of subjects using the carbamide peroxide potassium nitrate tray system. No subjects discontinued treatment early due to an adverse event. **Conclusion: The 6.0% hydrogen peroxide whitening strip system had greater whitening and less tooth sensitivity compared to the 5% carbamide peroxide potassium nitrate tray system.**

OBJECTIVE

This randomized clinical trial was conducted to evaluate the safety and efficacy responses of a low peroxide bleaching system with a desensitizing agent relative to a marketed control.

MATERIALS AND METHODS

Study Design: Balancing for baseline color and age, 34 healthy adult volunteers were randomized to one of following two marketed bleaching systems.

- Crest Whitestrips™ *: 30 minutes BID (7 hours total use).
- Colgate® Platinum™ Gentle Plus™†: 6-8 hours per day (42-56 hours total use).

* The Procter & Gamble Company, Cincinnati, OH, USA

† Colgate Oral Pharmaceutical Inc, Canton, MA, USA

Efficacy and Safety Assessment: The color of six maxillary anterior teeth was measured objectively at baseline and Day 7 visits using digital image analysis. Tooth color change from baseline in b^* (yellowness) was of primary interest. Safety evaluations included the examination of oral soft and hard tissue and adverse events at each study visit.

Statistical Analyses: Analysis of covariance was conducted to determine the mean shade change from baseline and treatment differences. Baseline tooth color was used as the covariate in the model.

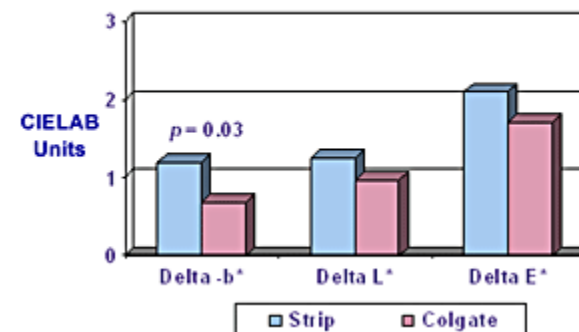
RESULTS

Baseline, tooth color, behavioral parameters and demographic characteristics:†

Sample Size	34
Starting tooth color in b^*	17 (1.6)
Age	34.1 (8.8)
Gender (Female)	29 (85.3%)
Ethnicity (Non-white)	5 (14.7%)
Tobacco Use	3 (8.8%)
Coffee/Tea/Cola Use	25 (73.5%)

†Treatment groups were balanced with respect to these demographic characteristics, behavioral parameters and baseline tooth colors.

Whitening Benefit at Day 7



Safety and Efficacy:

- Thirteen percent of the subjects in the Strip group reported tooth sensitivity compared to 22% in the Tray group.
- The mean color improvements from baseline were statistically significant ($p < 0.05$) for all color parameters in both treatment groups.
- The Strip group experienced 24-75% more whitening benefit compared to the Tray group.
- The difference with respect to the primary endpoint (reduction in yellowness, b^*) was statistically significant ($p = 0.03$).

CONCLUSION

The 6.0% hydrogen peroxide whitening strip system had greater whitening and less tooth sensitivity compared to the 5% carbamide peroxide potassium nitrate tray system.