10% Hydrogen Peroxide Whitening Strips: Evidence from 8 Clinical Trials

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ABSTRACT

Objective: This research summarizes an extensive clinical trials database collected as part of the development of a strip-based tooth whitening system in order to ascertain factors that contribute to clinical effectiveness. **Methods:** There were 8 different clinical trials in the inclusive analysis. In all these studies, subjects used a flexible polyethylene, whitening strip coated with a thin 10% hydrogen peroxide bleaching gel twice daily for 30 minutes over a 1-week period. Efficacy was measured in a common fashion using digital images of maxillary anterior teeth to objectively determine tooth color change in CIELAB units (b* yellowness, L* lightness, and a* redness). **Results:** The analysis included 175 subjects with demographic, effectiveness and safety data. Age and baseline tooth color were positively-correlated. The regression of age on tooth color demonstrated a slope (SE) of 0.043 (0.0091) b* units per year. Tooth color improved over the 7-day usage period. After adjusting for random study effects, the overall mean (SE) Δb* and ΔL* were –2.0 (0.15) and 1.9 (0.10), respectively, with each differing significantly ($p < 0.0001$) from baseline. Age and baseline tooth color were significantly ($p < 0.002$) related to the primary clinical response (Δb*, yellowness). Minor tooth sensitivity (21%) and oral irritation (21%) represented the most common adverse events. Across 8 clinical trials, only 1 subject (0.6%) discontinued use early due to a treatment-related adverse event.

Conclusion: This meta-analysis of 8 randomized clinical trials showed the 10% hydrogen peroxide whitening strips to be safe and effective, with baseline color and age representing significant determinants of whitening effectiveness.

OBJECTIVE

This research summarizes an extensive clinical trials database collected as part of the development of a strip-based tooth whitening system in order to ascertain factors that contribute to clinical effectiveness.

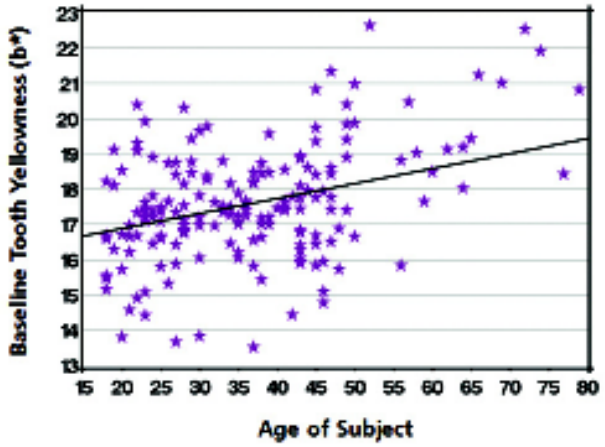
MATERIALS AND METHODS

There were 8 different clinical trials in the inclusive analysis. In all these studies, subjects used a flexible polyethylene, whitening strip coated with a thin 10% hydrogen peroxide bleaching gel twice daily for 30 minutes over a 1-week period. Efficacy was measured in a common fashion using digital images of maxillary anterior teeth to objectively determine tooth color change in CIELAB units (b* yellowness, L* lightness, and a* redness). Adjusting for random study effects, regression analysis was used to fit the linear relationship between baseline tooth yellowness (b*) and age. The overall mean color response was estimated using an mixed model adjusting for random study effects, age, and starting color.

RESULTS

The analysis included 175 subjects with demographic, effectiveness and safety data. Age and baseline tooth color were positively-correlated. The regression of age on tooth color demonstrated a slope (SE) of 0.043 (0.0091) b* units per year.

Baseline b*	Estimate (SE)	P-value
Intercept	16.033 (0.391)	< 0.0001
Age Slope	0.043 (0.009)	< 0.0001



RESULTS (Cont.)

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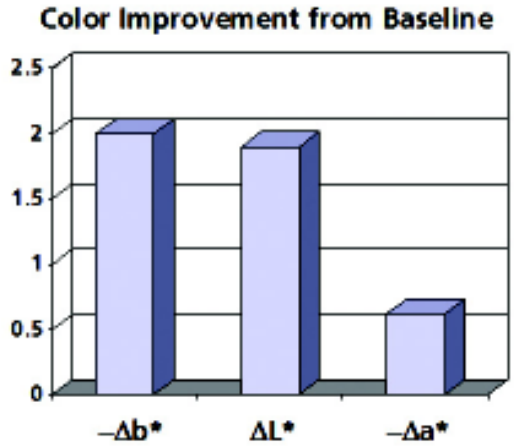

CONCLUSION

This meta-analysis of 8 randomized clinical trials showed the 10% hydrogen peroxide whitening strips to be safe and effective, with baseline color and age representing significant determinants of whitening effectiveness.