

ABSTRACT

Objective: In traditional tray-based bleaching systems, increasing peroxide concentration is reported to impact on both whitening effectiveness and tolerability. This research summarizes the clinical response following use of a higher concentration whitening strip system. **Methods:** Data from three single center, parallel group, randomized clinical trials were pooled to assess the clinical response following extended use of a 6.5% hydrogen peroxide whitening strip. The study population consisted of teens and adults who underwent tooth bleaching (maxilla and mandible) twice daily for up to a 4-week period. Digital images of the 12 maxillary and mandibular anterior teeth were collected at baseline, and again throughout the study period to measure L*a*b* color change. Repeated measures analysis was used to estimate response over the treatment period. **Results:** The 101 study subjects exhibited considerable diversity with respect to age (11-56 years), ethnicity (49% non-white) and gender (59% female). For the primary response variable, change in yellowness (Δb^*), color improvement was evident after 1 week and continued through week 4. Mean changes in b^* (SE) were -1.78 (0.13), -2.43 (0.16), -2.72 (0.28) and -3.12 (0.17) at Weeks 1, 2, 3 & 4 respectively. At each time point, color improvement differed significantly from baseline ($p < 0.0001$). The higher concentration strips were generally well-tolerated, with minor tooth sensitivity (33%) and oral irritation (31%) representing the most commonly reported events associated with treatment. **Conclusion: This research involving a diverse population demonstrates that use of a 6.5% hydrogen peroxide whitening strip results in significant color improvement over a 4-week period.**

OBJECTIVE

A 5.3% hydrogen peroxide bleaching strip system has been shown to be well tolerated with whitening results similar to some traditional tray-based bleaching systems. Increasing peroxide concentration is reported to impact both whitening effectiveness and tolerability in tray-based systems. The purpose of this research was to assess the clinical safety and efficacy of a 6.5% hydrogen peroxide bleaching strip system, where whitening efficacy was assessed from both the maxillary and mandibular dentition.

MATERIALS AND METHODS

Three clinical studies comprising a total of 101 subjects were conducted at three US centers to assess the safety and efficacy of a 6.5% hydrogen peroxide whitening strip system. Each study followed a parallel groups, randomized design in which the maxillary and mandibular anterior dentition was treated with the whitening strips for a period of up to four weeks.

In these trials, digital image analysis was used to objectively measure pre- and post-treatment anterior (maxillary and mandibular) tooth color in CIELAB color space as b^* (yellowish-bluish), L^* (lightness) and a^* (greenish-reddish). The primary efficacy endpoint in each study was b^* . The data from all three studies were pooled to assess the overall clinical response following extended use of the 6.5% hydrogen peroxide whitening strip. The tooth color data were statistically modeled with a linear mixed model with compound symmetry correlation structure. The model included study and visit (Weeks 1-4) as class variables and baseline color as a covariate.

RESULTS

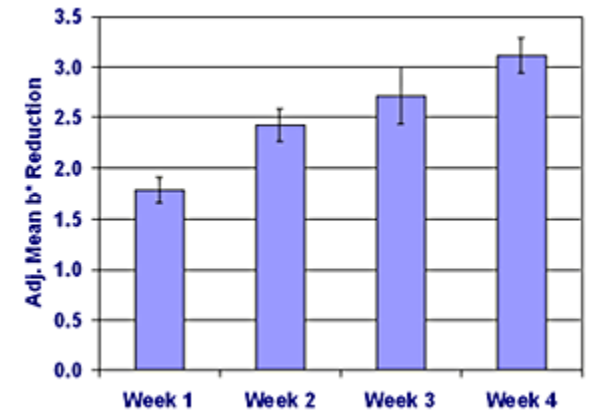
The study population exhibited considerable demographic diversity (Table 1). Most subjects were female (59%) and white (51%), ranging in age from 11-56 years. Mean b^* at baseline was similar across the studies, ranging from 14.2-21.7.

Table 1. Demographics Summary

Study	Number of Subjects	Age Mean (SD)	% Female	% Non-White	Mean Baseline b^* (SD)
A	21	38.0 (8.3)	81%	14%	17.9 (1.77)
B	9	29.0 (3.2)	44%	0%	18.1 (1.05)
C	71	14.7 (1.7)	55%	65%	17.9 (1.55)

The adjusted mean changes in b^* (SE) at Weeks 1-4 were -1.78 (0.13), -2.43 (0.16), -2.72 (0.28) and -3.12 (0.17), respectively (Figure 1). Each represents a highly statistically significant ($p < 0.0001$) reduction from baseline in average tooth yellowness. The greatest incremental whitening benefit was achieved at Week 1 where 57% of the overall benefit at Week 4 was realized. 78% and 87% of the final whitening benefit was achieved by Week 2 and Week 3, respectively.

Though the incremental improvement from successive weeks of bleaching generally decreased over time, the mean whitening benefit achieved at Week 1 was nearly doubled by Week 4.



The 6.5% hydrogen peroxide strips were generally well tolerated. The most commonly reported adverse events were minor tooth sensitivity (33%) and oral irritation (31%). These results are similar to those reported for 5.3% hydrogen peroxide strips.

CONCLUSION

A 6.5% hydrogen peroxide strip system was effective whitening both the maxillary and mandibular dentition of a diverse population from three clinical trials.

Over a four week treatment period, average tooth color improved with each week of treatment.

Tolerability of the strips was similar to that reported for lower concentration bleaching systems used over shorter treatment periods.