

ABSTRACT

Topical application of hydrogen peroxide (HP) is widely recognized as a safe and effective method for vital tooth bleaching. With the professionally-administered tray systems, increasing peroxide concentration increases whitening efficacy, but decreases tolerability. Since this relationship has not been established for the polyethylene strip-based bleaching systems, a double-blind clinical trial was conducted among 22 adults to assess the impact of increasing peroxide concentration on clinical response. Subjects were randomized to flexible strip bleaching systems containing 5.3% or 6.5% HP, with treatment 30 minutes per arch, twice daily for 14 days. Digital images of tooth color were analyzed to determine color change in CIELab units, while tolerability was assessed by both examination and subject report. Using digital image analysis at Day 15 (one day post-treatment), both groups experienced a significant ($p < 0.05$) overall color benefit ΔE^* . For the primary efficacy variable, the Day 15 mean Δb^* in the 5.3% group was -1.8 CIELab units for maxillary teeth and -1.3 for mandibular teeth, while the 6.5% group experienced an additional 28-31% reductions in yellow. A total of 5 subjects (2 in the 5.3% group and 3 in the 6.5% group) reported tooth sensitivity. For oral irritation, there was no evidence of concentration relationship relating to incidence, severity or duration, and all sensitivity/irritation was transient. **This clinical research demonstrates that a modest increase in peroxide concentration on a flexible bleaching strip results in increased whitening effectiveness, without adversely impacting on overall tolerability.**

INTRODUCTION

Tooth whitening, using carbamide or hydrogen peroxide in a professionally administered tray system is a very effective and popular dental office procedure. The primary adverse events reported during this treatment are tooth sensitivity and local oral mucosal irritation, usually transient in nature and mild in severity. And, it is well established that increasing tray peroxide concentration increases whitening efficacy but decreases tolerability. This clinical study was designed to determine if this same dose-response relationship, for safety and efficacy, also occurs with the polyethylene strip-based bleaching system.

STUDY DESIGN

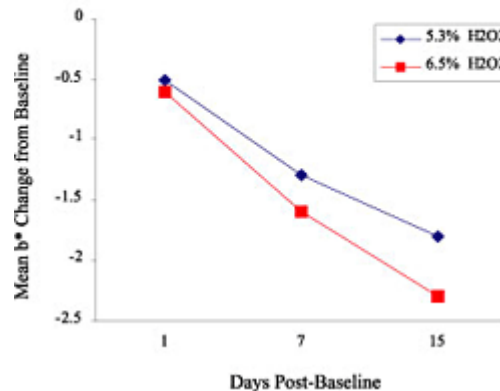
This was a single center, randomized, examiner blind study to evaluate the effects of a polyethylene film with a hydrogen peroxide tooth bleaching gel (at two concentrations used 30 minutes twice a day) during a 14 day usage period. Subjects were randomized to one of two treatment groups:

1. polyethylene film with a 5.3% HP tooth bleaching gel
2. polyethylene film with a 6.5% HP tooth bleaching gel

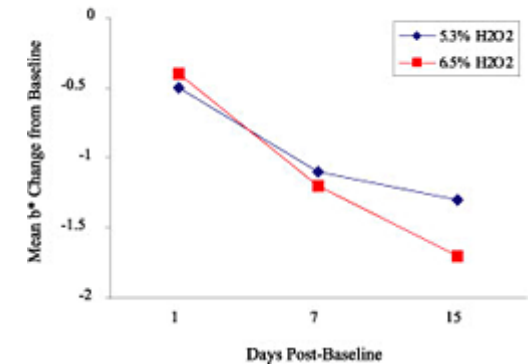
At Baseline (Day 0), subjects received an oral status interview, oral soft tissue (OST) exam, oral hard tissue (OHT) exam and digital images were captured. On Day 1, first product use was supervised and OST & OHT exams were done immediately after product removal. At Days 1, 7 and 15, subjects received an oral status interview, OST examination and digital images were captured.

RESULTS

Mean b^* Change from Baseline
Maxillary Anterior Teeth



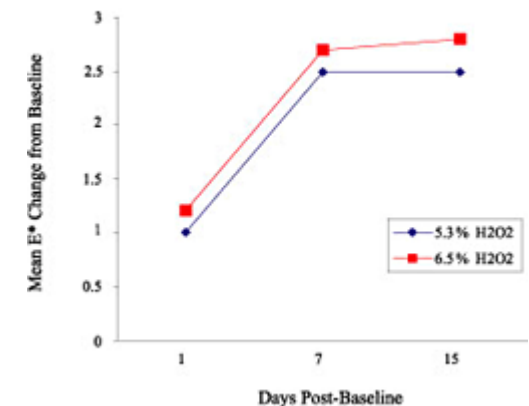
Mean b^* Change from Baseline
Mandibular Anterior Teeth

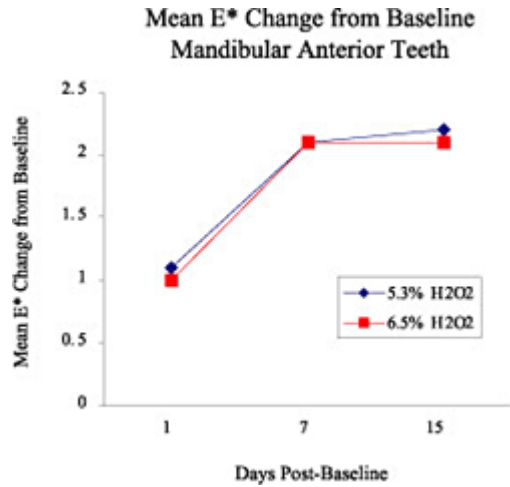


-Teeth in the 6.5% HP group were generally less yellow (smaller Δb^*), on average, after 7 or more days of treatment than teeth in the 5.3% HP group. Increased treatment time generally resulted in greater reduction of yellow (Δb^*).

-Maxillary teeth experienced a greater reduction in b^* on average than mandibular teeth.

Mean E^* Change from Baseline
Maxillary Anterior Teeth





CONCLUSION

-Test product was generally well tolerated, and there were no meaningful dose-relationships associated with event frequency, onset, severity or duration, and no meaningful differences between groups in terms of tolerability.
-A modest increase in hydrogen peroxide concentration on a flexible bleaching strip results in increasing whitening effectiveness, without adversely impacting overall tolerability.

ΔE^* ($\Delta E^* = \sqrt{\Delta b^*2 + \Delta L^*2 + \Delta a^*2}$) was consistently higher in the 6.5% HP group for maxillary teeth.

Both groups experienced a significant ($p < 0.05$) overall color benefit, ΔE^* .

Table 1. Adverse Events

	5.3% HP STRIP	6.5% HP STRIP
Dropouts "For Cause"	0	1
Tooth Sensitivity	2	3
OST Irritation	7	3

Number of subjects

Overall mean severity for both tooth sensitivity and OST irritation AEs was slight to moderate.