Clinical Comparison of Two Direct-to-Consumer Bleaching Systems

R.W. Gerlach, X. Zhou, A.P. Barlow*
Procter & Gamble, Mason, OH, USA

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ABSTRACT

Objective: Several combination whitening systems having various peroxide sources have been introduced for direct-to-consumer whitening. A 2-week clinical trial was conducted to evaluate the clinical effectiveness of one such combination system relative to a marketed control. **Methods:** In this parallel, examiner-blind, single-center study, 24 healthy adult volunteers were randomized to Mentadent™ Tooth Whitening, a combination system consisting of a pre-rinse, 0.75% peroxide gel plus and activator paste, stock mouth tray and dosing paddle, or Crest® Whitestrips™ 6.0% hydrogen peroxide whitening strips. Study participants were supplied with the manufacturers written instructions for use, only the maxillary arch was treated, and all treatment was unsupervised. Efficacy was measured using L*a*b* color change collected from digital images of the anterior dentition. **Results:** The estimated means and standard deviations for Δb* (yellowness) were +0.18 ± 0.344 for the combination group compared to –1.81 ± 1.086 for the strip group. For the primary response variable Δb*, the strip group exhibited significant (p = 0.001) improvement from baseline, while the combination group exhibited no significant (p = 0.1137) color change. Treatments differed significantly (p < 0.0001) with respect to Δb*, and all other color parameters (ΔL*, Δa*, ΔE*, and ΔW*) measured in the study. Both treatments were similarly well tolerated, with 2 subjects reporting oral irritation and 1 subject reporting tooth sensitivity in each group. **Conclusion:** The 6.0% H_2O_2 whitening strips resulted in superior whitening, while the combination gel/rinse system failed to exhibit any significant benefit with respect to yellow tooth color.

OBJECTIVE

The primary objective of this study was to compare the efficacy of low dose (12 mg) H_2O_2 whitening strips to a marketed, tray-based combination bleaching system.

METHODS AND MATERIALS

A total of 24 generally healthy adult subjects were enrolled in this randomized, parallel group, examiner-blind, single center study. Subjects meeting the entry criteria were assigned to:

- 6% H_2O_2 (12 mg) whitening strips 30 minutes BID for 14 days (Crest Whitestrips[i])
- Pre-rinse + 0.75% H_2O_2 / activator paste combination system 10 minutes QID for 14 days (Mentadent Tooth Whitening System[ii])

METHODS AND MATERIALS (Cont.)

Subjects treated only the upper arch. Safety (oral soft tissue examinations) and efficacy (L*a*b*) measurements were obtained at baseline and Day 15.

i The Procter & Gamble Company, Cincinnati, OH, USA.
ii Unilever, Greenwich, CT, USA.

RESULTS

Efficacy:

On study completion 20 subjects aged 20-48 years were considered evaluable. For the primary response variable Δb*, the strip group exhibited significant (p = 0.0011) color improvement from baseline. The combination system group exhibited no significant (p = 0.1137) color change with respect to reduction in yellowness. The strip group experienced an average of 2.0 units additional reduction in b*, relative to the combination system group with a p-value less than 0.0001.

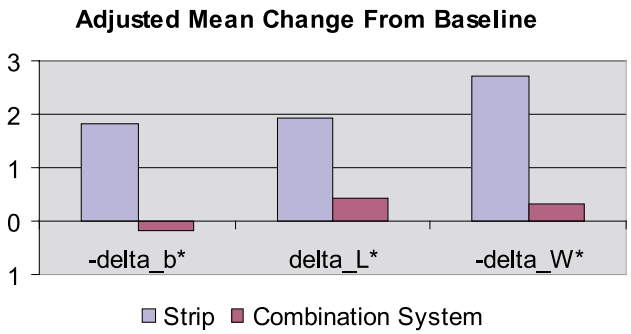
For secondary efficacy measures ΔL* (change in brightness) and ΔW*, (overall change in distance relative to pure white color) both treatment groups had statistically significant color improvement. Between-group comparison showed that the strip group experienced 1.51 units (360%) additional improvement in L* and 2.40 units (774%) additional reduction in W* compared to the combination system group.

TABLE 1

14 Day Efficacy Response				
Outcome/ Treatment	**Baseline Mean (SE)**	**Adjusted Mean (SE)**	**Changes from Baseline p-value**	**Between Treatment p-value**
Δb*				
Whitening Strips	17.192	-1.81 (0.257)	0.0011	< 0.0001
Combination System	17.292	0.18 (0.233)	0.1137	
ΔL*				
Whitening Strips	72.426	1.93 (0.206)	< 0.0001	< 0.0001
Combination System	72.421	0.42 (0.186)	0.0386	
ΔW*				
Whitening Strips	33.460	-2.71 (0.259)	0.0001	< 0.0001
Combination System	33.502	-0.31 (0.234)	0.0159	

RESULTS (Cont'd)

FIGURE 1



Safety:

Both treatments were similarly well tolerated, with 2 subjects reporting oral irritation and 1 subject reporting tooth sensitivity in each group. All adverse events were mild in nature and no subject withdrew from the study early due to adverse events.

CONCLUSION

The low dose H_2O_2 whitening strips resulted in superior whitening, while the combination gel/rinse system failed to exhibit any significant benefit with respect to yellow tooth color (Δb*).

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