

Factors Contributing to Tooth Whitening with a Direct Application of Percarbonate Bleaching Film

K. Brennan^{1*}, M.L. Barker², X. Zhou², A.P. Barlow¹, R.W. Gerlach²

¹Procter & Gamble, Egham, UK, ²Procter & Gamble, Mason, OH, USA



1047

ABSTRACT

Objective: Previous research indicated that age and baseline tooth color were contributing factors to the bleaching response observed following use of strip-based tooth whitening system. This meta-analysis was conducted to determine whether those factors (and/or others) were significant predictors of whitening response seen following use of a different vital bleaching system. **Methods:** Subject demographics and tooth color parameters (before and after treatment) were collected from 7 randomized, parallel-group, negative controlled clinical trials that were conducted at investigative sites in Europe and North America. All subjects in the meta-analysis used a 19% percarbonate direct application bleaching film overnight for 14 days. Efficacy ($L^*a^*b^*$) measures were made at baseline and then after 14 days of treatment via digital image analysis. Relationships between baseline parameters and clinical response were analyzed in the pooled data using ANCOVA methods. **Results:** The analysis included 187 subjects with a mean age of 23.8 years. Overall, there was a highly significant ($p < 0.0001$) color improvement averaging -1.58 after two weeks. Age and baseline yellowness (b^*) were both highly significant ($p < 0.0001$) effects in modeling the whitening response Δb^* . Baseline L^* and a^* , as well as site location, were not significant factors in response. Slope estimates demonstrated that for every 10 year decrease in age, subjects would experience an additional 0.42 unit improvement in b^* following use of the percarbonate film. **Conclusion:** Age and baseline tooth color are contributing factors to the clinical response observed following use of a direct application percarbonate bleaching film for tooth whitening.

PURPOSE

This research was carried out to determine whether a subject's clinical response to a direct application percarbonate bleaching film was influenced by baseline demographic characteristics.

MATERIALS AND METHODS

Demographic and clinical response data, CIE Lab ($L^*a^*b^*$) color space measurements, were combined from 7 randomized, parallel-group, placebo controlled clinical trials that were conducted at investigative sites in Europe and North America. Efficacy measures were made at baseline and then after 14 days of treatment via digital image analysis. The change in $L^*a^*b^*$ from baseline to Day 14 was regarded as the clinical response, with change in b^* as the primary measure. The Composite DIA parameter, ΔW^* a measure of the reduction in distance from pure white, was also examined. Relationships between baseline parameters and clinical response were analyzed in the pooled data using ANCOVA methods.

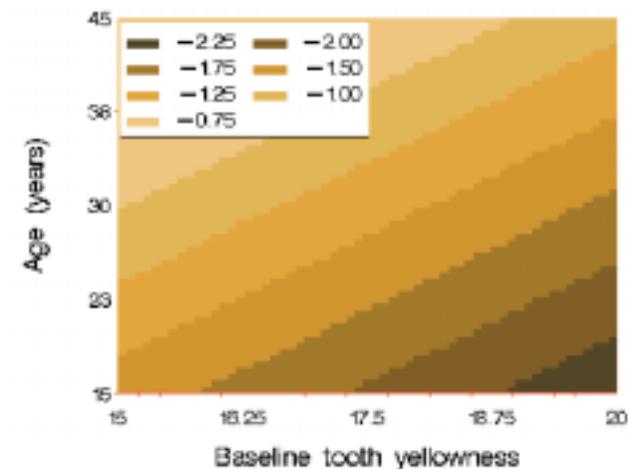
RESULTS

The analysis included 187 subjects with a mean age of 23.8 years, 112 of which were female. Overall, there was a highly significant ($p < 0.0001$) color improvement averaging -1.58 after two weeks, as measured by primary variable Δb^* . Age and baseline yellowness (b^*) were both highly significant ($p < 0.0001$) effects in modeling the whitening response Δb^* . Baseline L^* and a^* , as well as site location, were not significant factors in response. Slope estimates demonstrated that for every 10 year decrease in age, subjects would experience an additional 0.42 unit improvement in b^* following use of the percarbonate film, see Figure 1. Age and baseline tooth yellowness were also highly significant factors in efficacy response for composite parameters ΔW^* , with similar estimates for the effect of Age. Again site location was not a significant factor in response.

DATA

DIA Parameter	Demographic/baseline characteristic	Estimate (Standard Error)	P-value
Δb^*	Age	0.0427 (0.0068)	<0.0001
	Baseline b^*	-0.1650 (0.0389)	<0.0001
	Gender (Female)	-0.2521 (0.1147)	0.0293
ΔW^*	Age	0.0481 (0.0086)	<0.0001
	Baseline b^*	-0.2331 (0.0487)	<0.0001
	Baseline L^*	0.1117 (0.0475)	0.0198

Figure 1:
Relationship of Response to Age and Baseline Tooth Yellowness



CONCLUSION

Both age and baseline yellow tooth colour are contributing factors to a subject's clinical response observed following use of a direct application percarbonate bleaching film.