

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:** Data from 18 different clinical trials were included in the analysis. This inclusive assessment involved study subjects who used a flexible polyethylene, whitening strip coated with an adhesive hydrogen peroxide bleaching gel. All subjects used a common regimen, wherein whitening strips were worn twice daily over a 2-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 308 subjects with complete demographic, behavioral and effectiveness data. Initial tooth color, age, tobacco use and race were significantly (p<0.05) related to the primary clinical response (Δb^* , yellowness). Subjects who regularly used tobacco experienced less whitening (0.33 Δb^*) on average compared to non-users. Coffee/tea/cola consumption was not significantly related to clinical response. Initial tooth color was the most significant (p<0.0001) factor related to whitening. For subjects having the same age, racial background and smoking habits, each 1-unit increase in baseline yellow tooth color resulted in approximately 10% more color improvement after 14 days of treatment. **Conclusion: This meta-analysis of whitening strip research demonstrates that baseline color and other factors are significant determinants of whitening effectiveness.**

OBJECTIVE

This research investigates the impact of behavioral, clinical and demographical parameters on whitening response based on an extensive clinical trials database collected as part of the development of a strip-based tooth whitening system.

MATERIALS AND METHODS

Design: Data from 18 different clinical trials were included in the analysis. All subjects used Crest Whitestrips™ twice daily over a 2-week period. (The Procter & Gamble Company, Cincinnati, OH, USA)

Efficacy Assessment: Efficacy was measured objectively using digital images of maxillary anterior teeth. The primary efficacy response of interest was tooth color change from baseline in b* (yellowness) after two weeks of bleaching. Negative Δb^* (change from baseline in b*) corresponds to reduction in yellowness.

Statistical Analyses: The impact of the behavioral, clinical and demographic parameters on day 14 whitening response was explored using general linear model. The factors examined included age, starting tooth color, gender, ethnicity, and tobacco and coffee/tea/cola usage.

RESULTS

Table 1. Summary of demographic and behavior parameters and initial tooth color

Sample Size	308
Starting tooth color in b*	18.0 (1.8)
Age	37.3 (10.9)
Gender (Female)	225 (73.1%)
Ethnicity:	
White	270 (87.7%)
Black	23 (7.5%)
Asian	8 (2.6%)
Hispanic	7 (2.3%)
Tobacco Use	34 (11%)
Coffee/Tea/Cola Use	238 (77.3%)

Table 2: Impact on Whitening Response (b*):

Factor	Impact	p-values
Intercept*	0.32	0.56
Starting tooth color in b*	-0.19	<0.0001
Age*	0.03	<0.0001
Gender (Female-Male)†	0.01	0.9199
Ethnicity*		
Black-White	-0.48	0.0119
Asian-White	0.40	0.1914
Hispanic-White	0.09	0.7951
Tobacco Use (N-Y)*	-0.33	0.0319
Coffee/Tea/Cola Use (N-Y)†	-0.05	0.6953

† Estimates were obtained from full model;
* Estimates were obtained from reduced model, which consists of significant factors only.

After 14 days of treatment with strips, for subjects with same background in other variables described above, on average,

- 1-unit increase in baseline yellow tooth color resulted in approximately 10% more color improvement;
- Subjects experienced 0.3 more whitening in b* when compared to those who were 10 years older;
- Racial differences were noted;
- Non-smokers experienced 0.33 units more reduction in yellowness when compared to smokers;
- Gender and coffee/tea/cola drinking habit were not significantly associated with whitening benefit.

CONCLUSION

Starting tooth color, age, race and smoking habits are significant determinants of whitening effectiveness.

Gender and coffee/tea/cola consumption have no significant impacts on whitening response.