Prediction of Subjective Response from Objective Color Change in a Bleaching Clinical Trial

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1037

ABSTRACT

Objective: This research was conducted to evaluate whether objectively measured color change following vital bleaching predicted subjective, first-person color perception at the end-of-treatment. **Methods:** A randomized clinical trial (N = 53) compared the objective and subjective response of two self-directed bleaching systems. Subjects used either 6.0% hydrogen peroxide whitening strips or 10% carbamide peroxide gel/dentifrice/rinse combination tray system over a 14-day period. At the end-of-treatment, efficacy was measured objectively as L*a*b* color change from digital images of the anterior dentition. Subjects rated whitening response ("whitening satisfaction") using a 5-point scale from "0" (not at all satisfied) to "5" (extremely satisfied). A cumulative multinomial probability model was used to predict the rank-ordered subjective responses from objectively measured tooth color. **Results:** Color change was evident after 14 days treatment. The adjusted mean reduction in yellowness (Δb^*) was –2.5 and –0.8 in the strip and combination groups, respectively, with these groups differing significantly ($p < 0.0001$). The subjective response was generally similar, as strip users reported greater whitening satisfaction, differing significantly ($p = 0.0033$) from the tray system. When Δb^* was included in the cumulative multinomial probability model, ΔL^*, Δa^*, and treatment were not significant predictors of subjective response. For every 1-unit decrease in Δb^*, a subject had 2.7 times greater odds of indicating more whitening satisfaction with their assigned product. At –2.5 Δb^*, the model predicted a 70% chance that users would report whiteness satisfaction at a level of 4 or 5 with only a 30% chance when Δb^* is –0.8. **Conclusion:** Objectively measured yellowness, Δb^*, was the most significant and highly predictive variable related to subjective whitening response.

OBJECTIVE

This research was conducted to evaluate whether objectively measured tooth color following vital bleaching predicted subjective, first person color perception at the end-of-treatment.

STUDY DESIGN

In this parallel group, examiner-blind, clinical trial, healthy adult volunteers (N = 53) were randomized to one of two self-directed bleaching systems:

- 6.0% hydrogen peroxide (12 mg) whitening strips (Crest® Whitestrips™ [i]) or a
- 10% carbamide peroxide gel with "boil and bite" stock tray/dentifrice/ rinse combination system (Rembrandt® Plus™ Superior Bleaching System[ii]).

Subjects used their assigned product following the labeled instructions; up to 30 minutes twice daily for a total of 14 days. Product use was unsupervised and subjects treated only the maxillary arch.

i   *The Procter & Gamble Company, Cincinnati, OH, USA.*
ii *Den-Mat Corporation, Santa Maria, CA, USA.*

METHODS

Tooth color was measured objectively using L* (lightness), a* (red – green), and b* (yellow – blue) color change from digital images of the anterior dentition taken at Baseline and Day 14. After treatment completion, study participants rated their satisfaction of the whitening response using a 6-point scale "0" (not at all satisfied) to "5" (extremely satisfied).

Adjusted mean response for objectively measured L*a*b* color change was calculated using analysis of covariance adjusting for baseline color and age. Subjective whitening satisfaction was compared between the treatments using the Wilcoxon rank-sum test. A cumulative multinomial logit probability model (more specifically, proportional-odds modeling) was used to predict the rank-ordered subjective response from objectively measured tooth color (ΔL^*, Δa^*, Δb^*) as well as the treatment. To assess the predictor significance, Type 1 and Type 3 analyses were performed. Type 1 analysis sequentially included effects into the model, while the Type 3 analysis adjusted each effect for all other effects in the model. Both the Type 1 and Type 3 methods used likelihood ratio statistics that have an asymptotic $\chi 2$ distribution.

RESULTS

Groups were well balanced at baseline with respect to tooth color L*a*b* and age. Color change was evident after 14 days of treatment. Adjusted mean reduction in yellowness (Δb^*) was –2.5 and –0.8 for the strip and tray groups, respectively, with these groups differing significantly ($p < 0.0001$). In addition, the strip product provided superior efficacy relative to the combination tray system with respect to ΔL^* and Δa^* ($p < 0.002$). Subjects from each group indicated whitening satisfaction ranging from "1" (slightly satisfied) to "5" (extremely satisfied). Median scores were "4" (very satisfied) and "3" (quite satisfied) for the strip and tray groups, respectively. In addition, the strip and tray groups differed significantly ($p < 0.0033$) with respect to subjective, first person whitening satisfaction.

Type 1 results indicated that the Δb^* effect accounted for a significant ($p < 0.0001$) amount of the deviance associated with whiteness satisfaction. Treatment, ΔL^*, and Δa^* were not significant ($p > 0.35$). Type 3 results indicated that even when all effects were accounted for, Δb^* was the most significant effect ($p < 0.1414$). Removing variables one by one until only statistically significant variables remained at the 0.1 significance level yielded a model containing only Δb^* ($p < 0.0001$).

The odds ratio for $\Delta b^* \pm$ se was 0.37 ± 0.092 demonstrating that a subject had 2.7 times (1/0.37=2.7) greater odds of choosing a higher whiteness rating when the value of Δb^* decreased by 1.0 unit (less yellowness). In the figure, for a Δb^* of –2.5 the model predicts a 70% chance that users would report whiteness satisfaction at a level of "4" or "5" (very or extremely satisfied) with only a 30% chance when Δb^* is –0.8. These predicted probabilities are directly applicable only under common color measurement conditions.

Predicted Cumulative Probability of Whiteness Satisfaction vs. Δb^*

← Yellowness Reduction (Δb^*)
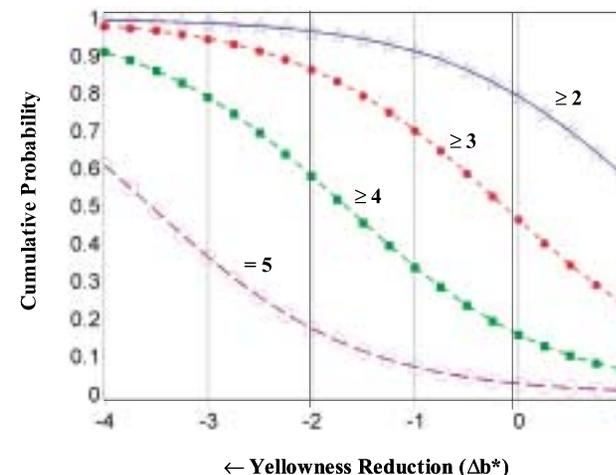
Whitening Satisfaction: 2 = Somewhat, 3 = Quite, 4 = Very, 5 = Extremely

CONCLUSIONS

❖ Objectively measured yellowness parameter, Δb^*, was highly predictive of subjective whitening response.

❖ Superior Δb^* demonstrated by the strip-based product translates into meaningfully superior first-person, perceived whitening satisfaction relative to the tray based system.