

# Forsyth Safety and Efficacy Study

## Final Report

May 1, 2001

### Executive Summary

*Purpose and Experimental Design:* The safety and effectiveness of the BriteSmile in-office tooth whitening system was evaluated in a 6-month randomized, blinded and controlled clinical trial. Eighty-seven subjects were selected for having dark shades of anterior teeth (D4 or darker) and were randomly assigned to one of three treatment groups. The anterior teeth of the test group (the peroxide + light treatment group) were treated for one hour by the combined application of a gel containing 15% peroxide and irradiation with a high-intensity light (the standard BriteSmile treatment). One control group (the peroxide control) received only the topical application of the 15% peroxide gel. The second control group (the light control) received application of a placebo gel (no peroxide) and light irradiation. This experimental design permitted evaluation of the combined peroxide + light treatment with peroxide alone and light alone to determine the relative safety and effectiveness of the combination therapy relative to the individual components of the treatment.

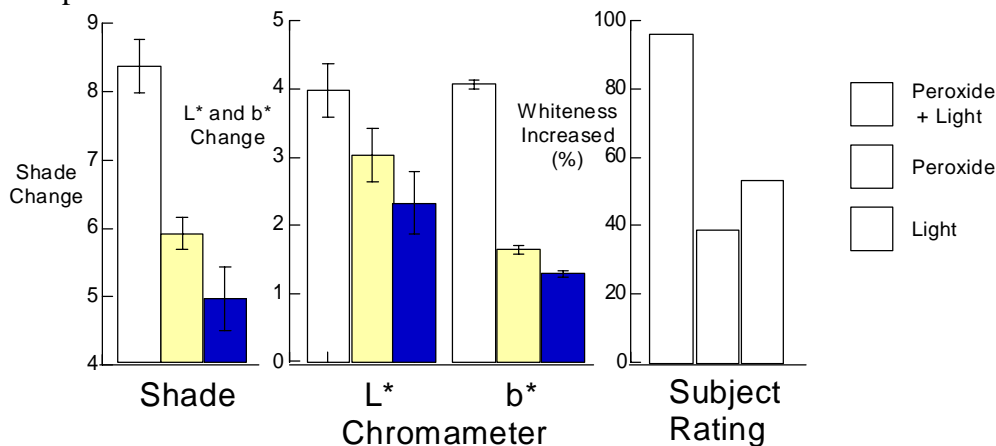


Figure 1. A comparison of changes related to tooth color following treatment by three independent measures. Results were summarized as shade (left panel), increased whiteness ( $L^*$ ) and decreased yellowness ( $b^*$ ) by chromameter measurement (middle panel) and percent of subjects rating the whiteness change to be “moderately” increased to “greatly” increased (right panel). Results in all cases were that changes in the peroxide + light treatment group were significantly greater than in the control groups.

*Effectiveness:* The peroxide + light treatment reduced the professional evaluated tooth shade by an average of 8.3 shade guide units and maintained 86.1% of this change over

the 6-month evaluation period. This change was significantly greater than that observed with either of the control treatments. Similarly, measurement of tooth color change by chromameter revealed a significant increase in whiteness ( $L^*$ ) and a significant reduction in yellowness ( $b^*$ ). Both the whiteness increase and yellowness reduction were significantly greater than that measured following either of the control treatments. The statistical significance of yellowness reduction compared to control groups was maintained for the 6-month measurement period. Subject evaluation of the treatment response by questionnaire indicated that a significantly greater percentage of subjects considered the whiteness increase to be at the highest response levels compared to subjects in either of the control groups. It was therefore concluded that efficacy superiority of the peroxide + light (BriteSmile) treatment relative to both controls was confirmed by three independent measures; the professional dentist saw it (shade change), the instrument saw it (chromameter) and the subjects saw it (questionnaire). These independent observations have been summarized in the preceding figure.

*Safety:* Safety was evaluated by professional dental evaluation of oral tissues, gingival index, plaque index and subject questionnaires. Analysis of responses from subject questionnaires indicated that a post-treatment increase in tooth sensitivity was experienced by approximately 20% of subjects treated either by the peroxide + light or peroxide alone. At the 3 and 6-month visits, no residual tooth sensitivity was reported. Analysis of data from the professional evaluation of gingiva also suggested that a transient increase in gingival redness occurred in 11.6% of the subjects. Analysis of gingival index data indicated that signs of gingival irritation were not seen at the 3 and 6-month visits. In the peroxide + light treated group, gingival index was significantly lower at 6 months than before treatment.

*Summary:* All evidence supports the conclusion that the peroxide + light treatment (BriteSmile) significantly lightens the color of teeth to a greater extent than peroxide alone or light alone. Furthermore, it is clear that the tooth lightening effect lasts for the 6-months of the study and may last for several years. The data also indicate that side effects occur at low frequency, rapidly disappear and do not compromise the health of the teeth, gingiva or oral mucosa. The results of this study support the claim that the BriteSmile treatment is both safe and effective.