

The BriteSmile Procedure Safety and Efficiency Summary

A six month blind clinical study was conducted to evaluate the safety tooth whitening efficacy of the BriteSmile 2000 Tooth Whitening System. Seventy five subjects were selected to participate in this parallel, blind, three compartment, and randomized clinical study. The subjects were balanced into three groups based upon a minimal shade of D4 on the Vita Shade Guide and assigned a treatment regimen as follows:

Group 1. BriteSmile Gel alone

Group 2. Placebo Gel + BriteSmile Light

Group 3. BriteSmile Gel + Light (BriteSmile 2000 Tooth Whitening System)

Tooth whitening was performed according to the standard BriteSmile method. Basically, the soft tissues were isolated using commercial barrier materials and whitening gel was placed upon the teeth. The BriteSmile metal halide light was then placed in front of the teeth and the treatment carried out for three periods of twenty minutes each. After each 20 minute the gel was removed and a fresh layer of gel was applied.

Change in tooth color was measured by both objective and subjective methods. The objective tooth color measurement involved the use of Minolta™ CR221 chromameter. The subjective color measurements involved the use of Vita shade guide and self-reported whitening effectiveness. The objective measurements or the chromameter readings were obtained for teeth #'s 7, 8, 9 and 10 in the L*, a*, b* color space at baseline, post-treatment, 3 month recall and 6 month recall. Calculation of color change (DE) was performed using the Commission Internationale de L'Eclairage (CIE L*a*b*) color difference equation. The subjective changes in the color of teeth #7, 8, 9, and 10 were measured by using the Vita shade guide at baseline, post treatment, three month recall and six month recall. The color change was measured by arranging the tab in the order of brightness as recommended by the manufacturer. The improvement in tooth color was then calculated using the standard tab counting technique. Panelist perceptions of the improvement in tooth color were examined using questionnaires.

Product safety was evaluated by clinical examinations of the oral hard and soft tissues after treatment at three month recall and at six month recall. Data concerning dental hypersensitivity was collected by the use of panelist questionnaires.

Results from this clinical study showed a mean post-treatment DE of 7.70 ± 1.94 for BriteSmile, a mean DE of 4.04 ± 1.44 for the gel 15% hydrogen peroxide gel alone and a mean DE of 2.19 ± 0.64 for the placebo gel plus the light. Statistical analysis using the F test showed significant differences ($p < 0.01$) between the groups, indicating that the BriteSmile procedure is significantly better when compared against the controls. The shade guide measurements confirmed these results and showed a mean improvement of 8.24 ± 1.30 tabs for BriteSmile, a mean improvement of 5.4 ± 2.29 tabs for the gel alone and a mean improvement of 1.0 ± 1.98 tabs for the placebo gel plus the metal halide light. Statistical analysis by the F-test again significant differences ($p < 0.01$) between the three groups, thus indicating that the BriteSmile system has a significantly

greater tooth whitening efficacy when compared to the gel alone or the light plus the gel. The panelists also confirmed the above results; 84% of the panelists indicated that the BriteSmile group greatly whitened their teeth as compared to 16% for the gel alone and 8% for the placebo plus the light.

Color reversion was measured at the three and six month recall. The chromameter reversion at three and six months for the BriteSmile group was DE of 0.76 and DE of 1.71 respectively. Statistical analysis by the F-Test did not show significant differences ($p > 0.1$). The shade guide results confirmed the above findings and showed a mean reversion of 0.54 tabs at the three month recall and 1.06 tabs at the six month recall. Statistical analysis by the F-Test did not show significant differences ($p > 0.1$). The results were also confirmed by the panelist self assessment of color. At the three month and the six month recall approximately 95% of the panelists reported a non to slight reversion of color. All the subjects in this group had whiter teeth six months following the whitening procedure when compared to baseline.

Examination of the plaque and gingivitis indexes showed significant reductions in plaque immediately following the whitening procedure in all three groups. However, statistically significant (two tailed, type two t-test, $p < 0.05$) reduction in plaque at the three month and the six month recall was observed in the BriteSmile group and in the placebo gel plus the light group and not in the gel alone group. For the gingivitis scores, significant differences ($p < 0.05$) were only found in the BriteSmile group when the baseline GI data was compared with the 6 month recall data.

Post treatment clinical evaluations did not show significant adverse effects attributable to product usage. Subjective questionnaire concerning post-treatment hypersensitivity showed no sensitivity in 76% of the BriteSmile population, 68% in the gel alone population and 84% in the placebo gel plus the light. Slight hypersensitivity was reported in the majority of the remaining panelists.

In summary, the results of this study show that the BriteSmile procedure is significantly more effective at whitening teeth when compared to the 15% hydrogen peroxide gel alone and the placebo gel plus the light. The major adverse reaction attributable to the product is slight post-treatment hypersensitivity, the levels of which are less or comparable to the levels reported for other ADA approved tooth whitening products. The results also show a significant reduction in plaque accumulation and a significant reduction in gingivitis (six months following the whitening treatment) in the BriteSmile group. The reason for this is unclear but warrants further investigation.