

# **0654 Clinical Evaluation of a Light Activated Tooth Whitening System**

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**Objective:** A six-month clinical study was conducted to evaluate the safety and efficacy of the BriteSmile Tooth Whitening System. **Methods:** Seventy five subjects participated in this parallel, blind, three compartment, and randomized trial. The subjects were balanced into three groups of Vita D4 or darker. The treatment regimens were: BriteSmile Gel alone; Placebo Gel + BriteSmile Light; BriteSmile Gel + Light (BriteSmile System). Tooth whitening was performed according to the BriteSmile method and product safety was evaluated by clinical examinations. Change in tooth color was measured by the Minolta™ chroma-meter and the Vita Shade guide. Color measurements were obtained for teeth #'s 7, 8, 9 and 10 at baseline, post-treatment, 3 month post-treatment and 6 month post-treatment. Color change calculations were performed using the CIE L\*a\*b\* equation and the standard tab counting technique. **Results:** Mean post-treatment deltaE's were  $7.70 \pm 1.94$  for BriteSmile System;  $4.04 \pm 1.44$  for gel alone and  $2.19 \pm 0.64$  for placebo gel+light. The mean shade improvements were  $8.24 \pm 1.30$  tabs for BriteSmile System;  $5.4 \pm 2.29$  tabs for gel alone and  $1.0 \pm 1.98$  tabs for the placebo gel+light. Statistical analysis showed significant differences (F test,  $p < 0.01$ ), indicating that the BriteSmile System is significantly better versus the controls. The chroma meter color reversion at three and six months for the BriteSmile group was deltaE of 0.76 and 1.71 respectively. The shade guide showed mean reversions of 0.54 and 1.06 tabs at three and six month post-treatment. Statistical analysis by the F-Test showed no significant differences ( $p > 0.1$ ). Post treatment clinical evaluations did not show significant adverse effects attributable to product usage. **Conclusions:** The results of this study show that the BriteSmile System is significantly more effective at whitening teeth when compared to the controls and color reversion is minimal.