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Consistency of Stain Formation and Removal in Induced-stain Clinical Trials

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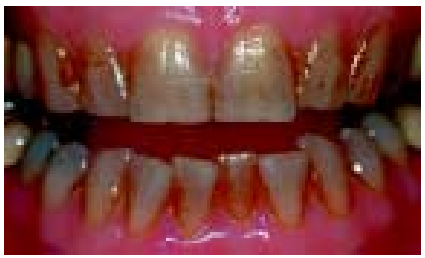
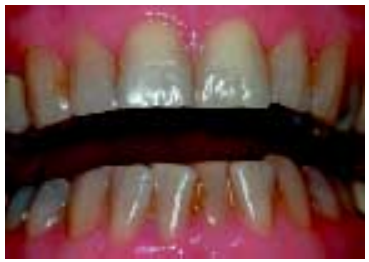
Objective: A short-term induced stain model has been successfully used to demonstrate clinical stain removal efficacy of tooth whitening dentifrices. This paper evaluates the consistency of stain formation and removal in this model. **Methods**: Two randomized, controlled stain removal trials were conducted 15 months apart at a single center using a common design and examiner. The design included a 3-week stain induction phase and a 6-week stain removal phase. At the beginning of the stain induction phase, all subjects received a prophylaxis and then were assigned to a daily rinsing regimen of one time chlorhexidine/three times tea and limited tooth brushing. After 3 weeks, subjects were assessed for the stain formation of 8 incisor teeth using the Lobene Index (Composite, Area and Intensity) and then randomly assigned to treatment groups. **Results**: At the end of the stain induction phase, a total of 459 subjects demonstrated measurable stain and met the entry stain criterion (Lobene Composite score > 0) for the treatment phase. For the 2 studies, the baseline Lobene composite scores differed by 9.0% with means and standard deviations of 1.10 ± 0.68 and 1.00 ± 0.62, respectively. ANOVA analysis shows that these means were not significantly different (p = 0.10). The baseline Lobene Area means differed statistically between the studies (p = 0.0024), while the Intensity means were not statistically different (p = 0.65). For the stain removal phase, 174 subjects were assigned to a common marketed control dentifrice (sodium fluoride/ silica base). Stain removal after 6 weeks of product use was consistent across the two studies for the Lobene measurements. The adjusted Lobene mean changes from the baseline (Composite, Area and Intensity) differed by 7-14% between the studies (p-values were not significant). **Conclusion**: These data suggest that this short-term induced stain model consistently delivers stain formation and stain removal

Stain Induction



Stain Removal



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Effects of Concentrated Hydrogen Peroxide on Enamel Surface Microhardness *in vitro*

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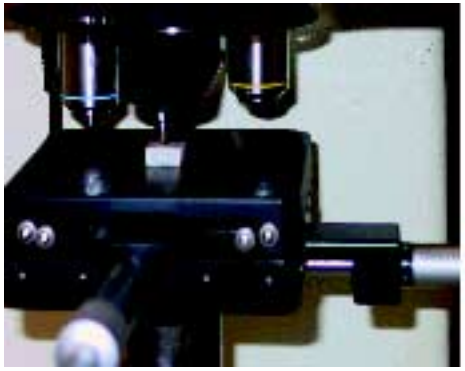
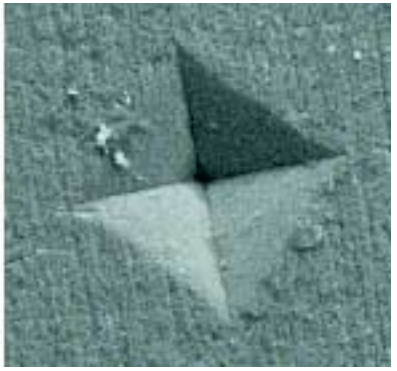
It is important that vital tooth bleaching does not produce changes in hard tissue properties which may indicate increased susceptibility of the dentition to caries or tooth wear processes. **Objectives:** This study examined the effects of concentrated hydrogen peroxide bleaching gels on tooth surface color and physical hardness *in vitro*. **Methods:** Human molars were cross-sectioned and mounted face up in methacrylate blocks. Surfaces were ground and polished and assessed for surface hardness (Beuhler, 200 gm. – Vickers Hardness – 5 indentations avg.) and color (image analysis Fuji digitized camera w/ CIELAB L*a*b*). Teeth were bleached for 28 hours (30 min. increments *bid*) with an aqueous gel base containing either 13 % H_2O_2 or 16 % H_2O_2. Bleaching was carried out in a.m./p.m. with human pooled saliva soaks in between/ overnight. Twice daily specimens were brushed with Crest® Regular dentifrice. Hardness and color were re-measured following bleaching. **Results:** Bleach effects on color were statistically significant: Non-treated $\Delta b^* = -0.54$ (ns vs. initial); 13.0 % H_2O_2 $\Delta b^* = -7.85$ (sig. vs. initial at $p < 0.05$ Students t); 16.0 % H_2O_2 $\Delta b^* = -5.18$ (sig. vs. initial at $p < 0.05$ Students t). Hardness was not changed by bleaching: Non treated $\Delta VHN = +28.3$ (ns. vs. initial); 13.0 % H_2O_2 $\Delta VHN = +15.6$ (ns. vs. initial); 16.0 % H_2O_2 $\Delta VHN = +20.7$ (ns. vs. initial). **Conclusions:** These results confirm the efficacy of commercial hydrogen peroxide in enamel bleaching with both 13 and 16 % hydrogen peroxide gels producing significant tooth whitening. Surface microhardness analysis confirmed the safety of bleaching process to enamel.





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