

# Extrinsic Stain Removal Efficacy Of a Stannous-containing Sodium Fluoride Dentifrice

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## ABSTRACT

**Objectives:** Two clinical trials were independently conducted to compare the extrinsic stain removal efficacy of a stannous-containing sodium fluoride dentifrice in a formulation with high cleaning silica, relative to a positive control whitening dentifrice over a 2-week period.

**Methods:** The studies utilized a randomized, two-week, double-blind, parallel group study design. A total of 119 (61 and 58 for each study) generally healthy adults with visible extrinsic tooth stain were enrolled in the studies. At the Baseline visit, stain was assessed on the facial surfaces of the twelve anterior teeth using the Lobene Stain Index. In each study, subjects were randomized based on their Baseline Lobene stain scores to either the stannous-containing sodium fluoride toothpaste or the positive control toothpaste (Colgate Total Plus Whitening®) to use twice per day for two weeks. Tooth color was reassessed at week Two. Analysis of covariance (ANCOVA) with treatment as a factor and Baseline Lobene score as the covariate was used to assess treatment difference. All comparisons were two-sided using a 5% level of significance.

**Results:** There were no statistically significant differences in Lobene composite stain scores between the two treatment groups ( $p=0.354$  and  $p=0.343$  for each study, respectively). Both groups showed statistically significant reductions in Lobene composite stain scores at week Two ( $p < 0.0001$ ) relative to baseline.

**Conclusions:** Collectively, these two stain removal clinical trials demonstrate the statistically significant extrinsic stain removal efficacy for the stannous-containing sodium fluoride dentifrice relative to baseline. There were no statistically significant differences between the two treatment groups.

## OBJECTIVE

To evaluate the stain removal efficacy of a Stannous containing Sodium fluoride dentifrice relative to a positive control whitening dentifrice over a two week period in a subject population with pre-existing natural extrinsic stain.

## MATERIALS AND METHODS

### Study Design:

Both studies were randomized, double-blind, parallel group, controlled clinical studies. Institutional review and informed consent were obtained prior to study initiation. A total of 119 (61 for Study 1, 58 for Study 2) subjects participated in the studies.

### Clinical examinations (BL, Week 2):

Lobene Stain Index, on facial surfaces of twelve anterior teeth

### Product usage:

At least 1 minute, twice daily

- Experimental dentifrice:



- Positive control dentifrice:



### Statistical analysis:

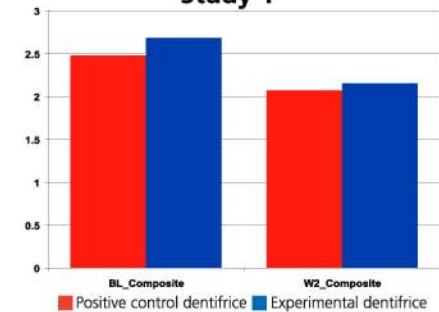
Analysis of covariance (ANCOVA) with BL Lobene score as the covariate was used to assess treatment difference. Statistical comparisons were two sided with a 5% significance level.

## RESULTS

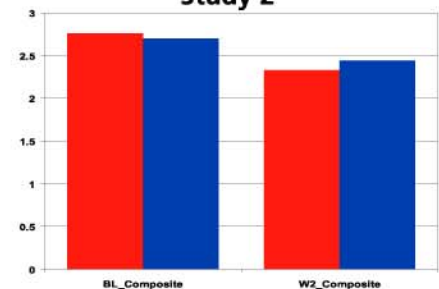
- Both the Experimental and the Positive control dentifrices resulted in statistically significant reductions in Lobene composite stain scores at week Two ( $p < 0.0001$ ) relative to baseline.
- The adjusted mean changes between treatment groups didn't differ significantly between the two dentifrice groups ( $p=0.3574$  and  $p=0.3431$  for each study, respectively).

## RESULTS

### Study 1



### Study 2



### BL Imaging



### Week 2 Imaging



## CONCLUSIONS

- Stannous-containing sodium fluoride dentifrice showed significant stain removal efficacy relative to baseline.
- No significant difference was observed between the two dentifrices.