

# A Randomized Clinical Trial Evaluating the Anti-Gingivitis Efficacy of an Oral Hygiene Routine including a Novel Stabilized Stannous Fluoride Dentifrice, Oscillating-Rotating Electric Toothbrush and Floss

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## KEY CLINICAL FINDINGS

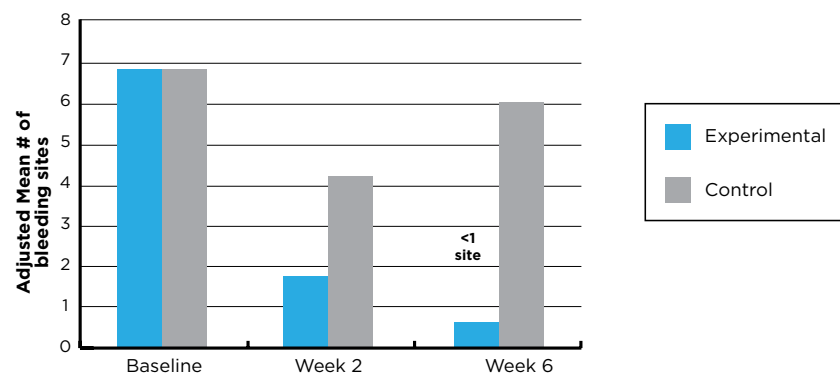
After 6 weeks of using a stabilized stannous fluoride dentifrice, oscillating-rotating electric toothbrush and floss, the experimental oral hygiene group was nearly free of gingivitis with less than one bleeding site (0.85).

The experimental group showed greater reductions in gingival bleeding after 6 weeks than the control group, which had a dental prophylaxis followed by use of a regular anti-cavity dentifrice and soft manual toothbrush.

- The experimental group had 86% fewer bleeding sites compared to the control group at Week 6. See Figures 1 & 2.
- 68% of subjects in the experimental group had no bleeding at Week 6 compared to 0% in the control group. See Figure 3.

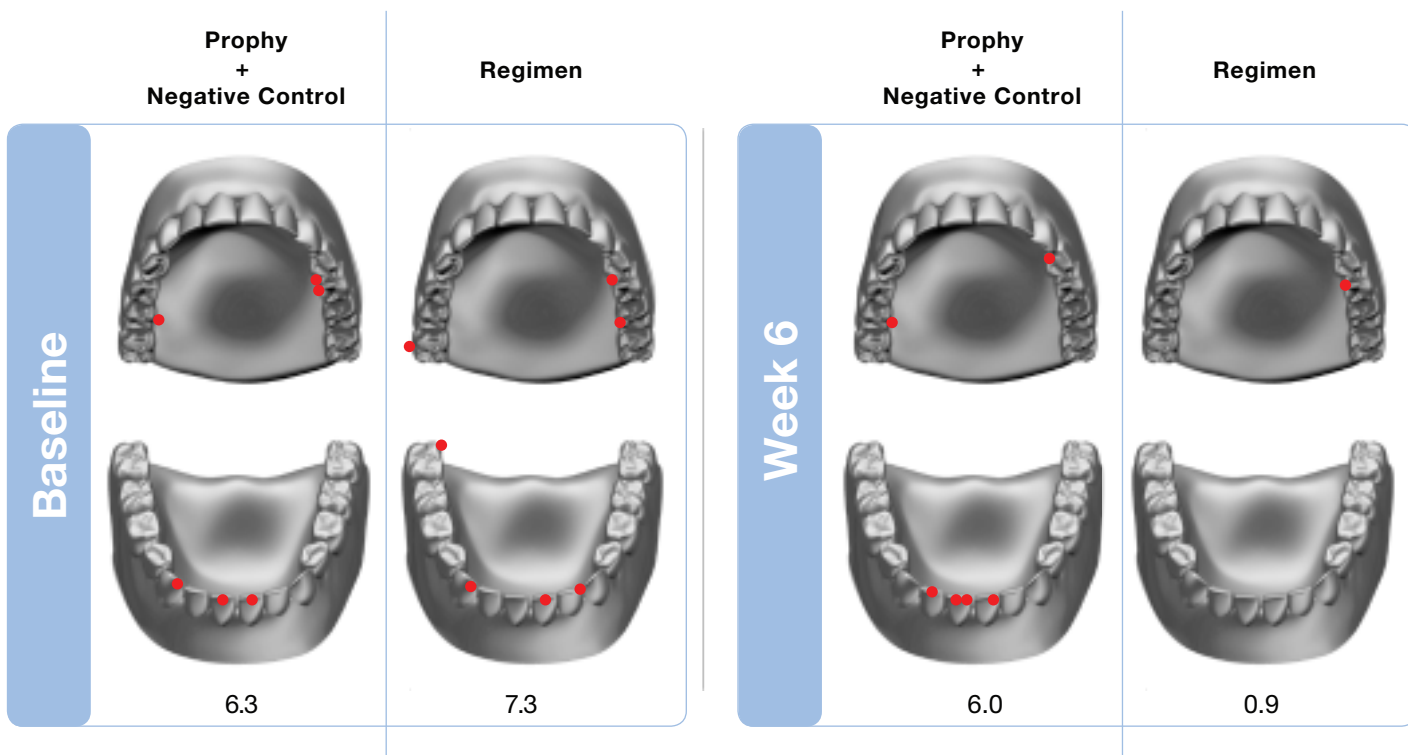
There were no Adverse Events in this study. All treatments were well tolerated.

**Figure 1. Number of bleeding sites per group**

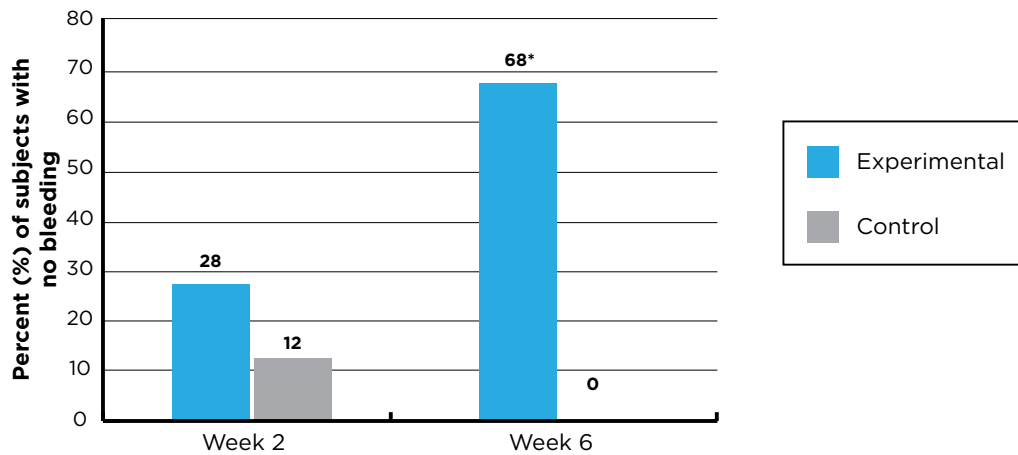


\*Statistically significant difference between groups in favor of the experimental group,  $p \leq 0.0006$ .  $n=51$ .

**Fig 2. Depiction of average number of gingival bleeding sites.**



**Figure 3. Percent of subjects with no bleeding**



\*Statistically significant difference between groups in favor of the experimental group,  $p < 0.0001$ .  $n = 51$ .

## OBJECTIVE

To evaluate the anti-gingivitis efficacy of an experimental oral hygiene routine (stabilized stannous fluoride dentifrice, oscillating-rotating electric toothbrush and floss) versus a control (dental prophylaxis, standard anti-cavity dentifrice and soft manual toothbrush) over a 6-week period.

## METHODS

This was a randomized, controlled, examiner-blind, 6-week clinical trial involving subjects with mild-to-moderate gingivitis. 52 qualifying subjects were randomized to one of two treatment groups:

### Experimental group

- Crest® Gum Detoxify dentifrice with 0.454% stabilized stannous fluoride dentifrice
- Oral-B® Professional Exclusive Genius Electric Toothbrush (D701) with oscillating-rotating technology and the Oral-B® CrossAction® brush head with angled bristles (EB50)
- Oral-B® Glide® Pro-Health Advanced floss

There was no dental prophylaxis in the experimental group.

### Control

- Dental prophylaxis
- Crest® Cavity Protection toothpaste with 0.243% sodium fluoride
- Oral-B® Indicator soft, manual toothbrush.

All products are manufactured by Procter & Gamble.

Subjects in the experimental group were instructed to brush twice daily with the dentifrice and electric toothbrush, brushing for 2 minutes each time in “daily clean” mode, and to floss their entire mouth once daily. Subjects in the control group were instructed to brush twice daily according to their normal oral hygiene habits and to refrain from flossing.

Gingival bleeding and gingivitis were assessed at Baseline, Week 2 and 6 using the Loe-Silness Gingivitis Index. An oral soft tissue examination was also conducted at each visit. 51 subjects completed the trial.

## CLINICAL COMMENT

Gingival bleeding is a common symptom of gingivitis often noticed by patients when they brush. Research indicates the absence of bleeding (on probing) is a reliable indicator for sustained periodontal health,\* so reducing gingival bleeding should be an important goal of gingivitis treatment. This study showed use of a novel stabilized stannous fluoride dentifrice, oscillating-rotating electric toothbrush and floss was highly effective at reducing gingival bleeding. After 6 weeks, subjects using these products had less than one bleeding site, significantly lower than the control group which had approximately 6 bleeding sites. Sixty-eight percent of subjects using the experimental products had no bleeding at Week 6 compared to 0% in the control group. Dental professionals should consider the stabilized stannous fluoride dentifrice, oscillating-rotating electric toothbrush and floss for patients to reduce gingival bleeding and protect their periodontal health.

\*Lang NP, Adler R, Joss A, Nyman S. *J Clin Periodontol*. 1990 Nov;17(10):714-21.