A Clinical Trial to Assess the Effect of a Regimen including a Novel Stannous Fluoride Dentifrice, Power Toothbrush and Floss on Gingivitis

RW Gerlach, C García-Godoy, A Walanski, M Barker, M Gabbard, J Dunavent

KEY CLINICAL RESULTS

- The test regimen group (stannous fluoride dentifrice, power toothbrush and floss) had 71% fewer bleeding sites at Week 4 and 95% fewer bleeding sites at Week 6 compared to the control group (dental prophylaxis at baseline, regular anti-cavity toothpaste and soft manual toothbrush) p < 0.001. See Figures 1 & 2.
- At Week 6, 83% of subjects in the test regimen group exhibited no bleeding at any measured site.
- The test regimen group also showed a 68% reduction in gingivitis (GI) at Week 4 and a 95% reduction in GI at Week 6 compared to the control group (p < 0.001). See Figure 3.
- Both groups showed a significant reduction in bleeding and gingivitis at Weeks 2, 4 and 6 relative to baseline (p ≤ 0.008).

OBJECTIVE
To assess gingivitis after using either a test regimen, consisting of a novel stannous fluoride dentifrice, an oscillating-rotating power toothbrush and floss, or receiving a dental prophylaxis at Baseline followed by use of a regular anti-cavity toothpaste and soft, manual toothbrush.

STUDY DESIGN
This was a randomized, controlled, examiner-blind, 2-treatment parallel group study that involved 46 healthy adult subjects with mild to moderate gingivitis. Subjects were assigned to 1 of 2 groups:

- **Test regimen**: no dental prophylaxis and Crest® Pro-Health Clinical Gum Protection toothpaste (0.454% stannous fluoride), Oral-B® Professional Care SmartSeries 5000 with SmartGuide powered toothbrush with the Oral-B FlossAction® brush head and Oral-B® Glide® Pro-Health Clinical Protection for Professionals floss.
- **Control group**: dental prophylaxis at Baseline followed by use of Crest® Cavity Protection toothpaste and an Oral-B® Indicator regular, soft manual toothbrush.

Subjects in the test regimen were instructed to brush for 2 minutes, using “Daily Clean” mode, twice per day. They were also instructed to floss the whole mouth once daily.

Subjects in the control regimen were instructed to brush thoroughly twice daily. They were asked to refrain from flossing for the duration of the study.

Gingival inflammation and bleeding were assessed clinically after 2, 4 and 6 weeks using the Löe-Silness Gingivitis Index.

Treatment groups were compared using the analysis of covariance method with baseline as a covariate. Statistical tests were two-sided using a 5% significance level.
Fig 1. Depiction of average number of gingival bleeding sites

Dental prophylaxis and standard manual brushing

Crest PRO-HEALTH Test Regimen
(no prophylaxis, SnF₂, dentifrice, power brush and floss)

Baseline (overall mean)

Week 2

Week 4

Week 6

Baseline

12.9

6.1

7.5

10.0

Dental prophylaxis and standard manual brushing

Crest PRO-HEALTH Test Regimen
(no prophylaxis, SnF₂, dentifrice, power brush and floss)

12.9

6.3

2.1

0.5

71% less bleeding

95% less bleeding

Continuing the care that starts in your chair.