

Research Supported by P&G



Thursday, March 17
1310 Anti-plaque Clinical Evaluation of a Paste,
Power Brush, and Rinse

I. MAGNUSSON¹, K. KARPINIA¹, M.L. BARKER², and R.W. GERLACH², ¹College of Dentistry, University of Florida, Gainesville, FL, ²Health Care Research Center, Procter & Gamble Company, Mason, OH

Objectives: A clinical study was conducted to evaluate the anti-plaque level of the combination use of a therapeutic dentifrice and rinse plus power brush.

Methods: Adults who demonstrated disclosed plaque growth overnight were randomly assigned to a combination paste-rinse-brush group or control. Subjects received either the combination treatment with 0.454% stannous fluoride sodium hexametaphosphate dentifrice (Crest® Pro-Health™ Night), a rotating-oscillating powered brush (Oral-B® Vitality™ Precision Clean), and 0.07% cetylpyridinium chloride rinse (Crest Pro-Health Night), or a regular brush and anticavity paste, with use at-home and unsupervised over a 4 week period. After completion of the 4-week study, additional institutional review and informed consent were obtained, and subjects returned for a dental prophylaxis. Digital plaque image analysis of the anterior facial teeth measured fluorescein-disclosed overnight and post-brush plaque at baseline, Weeks 2 & 4, and then immediately after dental prophylaxis.

Results: 29 subjects with a mean (SD) age of 39.8 (13.4) were enrolled, and 72% of the subjects were female. Baseline overnight plaque area% means were approximately 16.0 for each treatment group. Groups differed significantly ($p < 0.005$) at Weeks 2 and 4 for overnight and post-brush plaque, but did not differ significantly ($p = 0.335$) for post-prophy plaque. For the combination group, week 2 mean (SE) post-brush plaque area% was 3.50 (0.37) compared to 3.59 (0.52) for the post-prophy plaque level with no statistical difference ($p = 0.885$). The control group exhibited significantly ($p = 0.003$) higher plaque area% between week 2 and post-prophylaxis with a mean difference of 4.89 demonstrating model sensitivity. Outcomes at week 4 were similar to week 2.

Conclusion: Use of the combination stannous fluoride dentifrice, power brush and rinse demonstrated appreciable anti-plaque benefits as early as 2 weeks and on through 4 weeks.



Thursday, March 17
1311 Gingivitis Treatment with 0.454%
Stannous Fluoride Dentifrice or Prophylaxis

I. MAGNUSSON¹, W. WOLF¹, A.A. WALANSKI², M.L. BARKER², and R.W. GERLACH², ¹College of Dentistry, University of Florida, Gainesville, FL, ²Health Care Research Center, Procter & Gamble Company, Mason, OH

Objectives: A 6-week randomized controlled trial was conducted to evaluate effects of 0.454% stannous fluoride dentifrice on established gingivitis.

Methods: After institutional review and informed consent, healthy adults with established moderate-to-severe gingivitis were randomly assigned in a 1:1 ratio to brushing with a 0.454% stannous fluoride dentifrice (Crest® ProHealth™ Clinical Gum Protection) dentifrice (the experimental group) or a dental prophylaxis plus regular brushing (the positive control). Test products were dispensed in a blinded kit along with a manual brush, oral hygiene was at-home and unsupervised. Clinical response was measured every 2-weeks using the Gingivitis Index (GI), and bleeding sites were derived from site scores of 2+. Treatment comparisons were made using analysis of covariance.

Results: A total of 46 subjects were enrolled, with mean (SD) age of 33.9 (13.5) years, groups were balanced at baseline, and bleeding sites ranged from 20-102 (mean=52). The prophylaxis and dentifrice groups both exhibited significant ($p < 0.001$) improvements at Week 2, with mean changes of -23.6 and -15.2 bleeding sites, respectively. By Week 4, responses were virtually identical, with adjusted mean bleeding site scores differing by less than 0.2%, and with a gingivitis 95% CI of (-0.05, 0.05). Both groups continued to exhibit significant ($p < 0.001$) improvement in gingival health through Week 6. ANCOVA between-group comparisons showed significant differences on gingivitis and bleeding only at Week 2. Responses at other times were similar and not significantly different.

Conclusion: With moderate-to-severe gingivitis, use of a 0.454% stannous fluoride dentifrice or a dental prophylaxis resulted in significant improvements in gingivitis over a 6-week period.