Clinical Trial Comparing Plaque Effects of Hygiene Regimen or Prophylaxis

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ABSTRACT

Objectives: A randomized clinical trial compared the effects of a daily oral hygiene combination regimen on overnight plaque accumulation versus a dental prophylaxis.

Methods: After IRB approval and informed consent, baseline measurements were obtained, and subjects with overnight plaque were randomized equally to a daily oral hygiene regimen or dental prophylaxis (the positive control). The regimen group received an advanced manual crossbrush, 0.454% stannous fluoride dentifrice, 0.1% CPC rinse and floss, while the control group received a dental prophylaxis plus a 0.243% sodium fluoride dentifrice and manual brush. Test products (The Procter & Gamble Co.) were dispensed in blinded kits for 7-days at-home use, while subjects assigned to the positive control also received a routine dental prophylaxis. Efficacy was measured instrumentally via image analysis of fluorescein-disclosed plaque coverage from high-resolution images of the anterior facial dentition, while safety was assessed from clinical examination.

Results: 47 subjects were randomized, mean (SD) age was 36.7 (13.6) years, and 46 were evaluated at Day 7. At baseline, mean (SD) overnight plaque area % coverage was 14.1 (10.6) and 14.2 (14.4) in the regimen and control groups, respectively. Relative to baseline, only the oral hygiene regimen group exhibited a significant (p=0.0002) improvement in overnight plaque area at the 1-week recall. Adjusting for baseline, Week 1 means (SE) for overnight plaque area % coverage were 5.19 (0.68) and 12.08 (1.69) in the regimen and prophylaxis groups, respectively. This represented a 57% reduction in plaque with the regimen versus the positive control, with groups differing significantly (p<0.0005). Both treatments were well-tolerated.

Conclusions: Use of a combination daily oral hygiene brush, paste, rinse and floss regimen resulted in significant improvement in overnight plaque accumulation in one week relative to a dental prophylaxis, and as such, may represent a useful approach to achieve sustained plaque control.

MATERIALS AND METHODS

This is a randomized, controlled, single-blind, 2-treatment parallel group study. The target population was approximately 50 healthy adult volunteers with plaque. Following an acclimation period, subjects were randomized to one of two groups: 1) a dental prophylaxis plus a 0.243% sodium fluoride dentifrice and manual brush or, 2) no dental prophylaxis and an advanced manual crossbrush, 0.454% stannous fluoride dentifrice, 0.1% CPC rinse and floss. Overnight (pre-brush) plaque was measured by digital image analysis of fluorescein-disclosed plaque at Baseline and after 1 week of study product use. Analysis of covariance was used to compare treatment groups, and paired difference t-tests were used to assess changes from baseline.

RESULTS

Case Study: Subject 1114 in the Regimen Group was a 26-year-old Caucasian Male. At Baseline, he had 23.1% Overnight Percent Plaque Area and after one week of product use, he had 8.0% Overnight Percent Plaque Area.

CONCLUSIONS

Use of a combination daily oral hygiene brush, paste, rinse and floss regimen resulted in significant improvement in overnight plaque accumulation in one week relative to a dental prophylaxis, and as such, may represent a useful approach to achieve sustained plaque control.