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Thursday, March 17
1316 Three-Month Clinical Trial on the
Anti-Calculus Effects of Two Dentifrices

J.L. MILLEMAN[1], M.S. PUTT[1], A. WINTERGERST[2], M.L. BARKER[3], and T. HE[3], [1]University Park Research Center, Fort Wayne, IN, [2]Universidad Nacional Autonoma de Mexico, Mexico City DF, Mexico, [3]The Procter & Gamble Company, Mason, OH

Objectives: Supra-gingival dental calculus formation is a common problem for consumers. The present study was undertaken to evaluate the anti-calculus efficacy of a 0.454% Stannous Fluoride (SnF_2)/sodium hexametaphosphate dentifrice relative to a marketed positive control dentifrice.

Methods: This was a 3-month, parallel-group, double-blind, randomized and controlled clinical trial in which the SnF_2 dentifrice (Oral-B Pro-Salud®) was compared to a marketed positive control dentifrice (Colgate Total 12 Professional Clean®). Subjects received a dental prophylaxis and then entered a 2-month run-in phase, during which they brushed unsupervised with a cavity protection dentifrice. At the end of the 2 months, subjects received Volpe Manhold Index (V-MI) calculus examination. Qualified subjects who formed a minimum of 9mm of calculus on the lingual surfaces of the six mandibular anterior teeth were re-prophied and randomly assigned to one of the two treatments. Subjects brushed with their assigned product twice daily using a standard manual toothbrush, one minute each time, over the 3-month duration. Safety and efficacy measurements were taken via V-MI and OST exams at Baseline, Week 6 and Month 3. Non-parametric analysis with treatment as a factor and baseline V-MI score as the covariate was used to assess treatment differences.

Results: Of the 77 subjects who were randomized to treatment, 75 completed the study. The calculus score for the SnF_2 dentifrice group was statistically significantly lower than that of the positive control group, at both post-treatment visits ($p<0.01$). At Week 6 and Month 3, the SnF_2 dentifrice group demonstrated 30.3% and a 26.5% lower median levels, respectively, of calculus build-up than the positive control. Both test products were well tolerated.

Conclusions: The research demonstrated superior anti-calculus efficacy of the SnF_2 dentifrice relative to the positive control dentifrice in this 3-month clinical trial.

Thursday, March 17
1319 Comparative Overnight Plaque Response to
Therapeutic Dentifrices in Twins

W.A. BRETZ[1], P.M. CORBY[1], A.L. CORBY[1], A. MOREIRA[1], M.L. BARKER[2], R.W. GERLACH[2], and A.R. BIESBROCK[2], [1]New York University, New York, NY, [2]Health Care Research Center, Procter & Gamble Company, Mason, OH

Objective: A crossover study was conducted to compare plaque treatment effects with antimicrobial dentifrices among twins.

Methods: After informed consent and child assent (where indicated), twin pairs were randomly assigned to a 3-period crossover sequence, where each period involved 2-weeks use of one of two therapeutic dentifrices. Subjects used a regular anticavity dentifrice for acclimation and washout. During treatment, subjects received either a stannous fluoride (Oral-B® Pro-Saude) or triclosan copolymer (Colgate® Total) dentifrice. Test products were dispensed over-labeled in a blinded kit with a regular manual brush. At the end of each treatment period, overnight plaque was measured instrumentally by digital plaque image analysis. With this method, subjects rinsed with 5mL of a 1240ppm fluorescein rinse, digital images were collected under standardized lighting, and image analysis was used to derive plaque area% coverage. A general linear mixed model was used to compare treatments with age group and treatment as factors and subject as a random effect.

Results: There were 25 twin pairs ranging from 14-32 years of age, and 49/50 subjects completed the crossover study. For both therapeutic dentifrices, overnight mean plaque levels were significantly ($p<0.03$) higher and there was a 9-fold higher residual variance with teen twins compared to adult twins. For the teen twins, overnight plaque mean (SE) area% was 14.9 (2.5) for the stannous fluoride group compared to 15.3 (2.5) for the triclosan copolymer, while for adult twins, mean (SE) area% was 7.0 (1.3) for the stannous fluoride group and 8.8 (1.3) for the triclosan copolymer group. Treatments differed significantly ($p=0.029$) on overnight plaque in adult twins, favoring the stannous fluoride dentifrice. Both treatments were well-tolerated.

Conclusion: Over a two-week period, use of a stannous fluoride dentifrice resulted in significant 20% reductions in plaque levels in adult twins compared to a triclosan copolymer dentifrice.

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