Two-Year Caries Clinical Study of the Efficacy of Novel Dentifrices Containing 1.5% Arginine, an Insoluble Calcium Compound and 1450 ppm Fluoride

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Study objective
The objective of the study was to compare the efficacy of two dentifrices containing 1.5% arginine, an insoluble calcium compound (di-calcium phosphate or calcium carbonate) and 1450 ppm fluoride as sodium monofluorophosphate (MFP) to a control dentifrice containing 1450 fluoride as sodium fluoride (NaF) in a silica base in preventing caries progression to cavitation.

Trial conditions and methods

Products under investigation
Test dentifrice 1: 1.5% arginine, di-calcium phosphate, and 1450 ppm fluoride as MFP (Colgate-Palmolive Company, New York, NY)
Test dentifrice 2: 1.5% arginine, calcium carbonate, and 1450 ppm fluoride as MFP (Colgate-Palmolive Company, New York, NY)
Fluoride control dentifrice: 1450 ppm fluoride as NaF in a silica base (Procter & Gamble Company, Cincinnati, OH)

Study subjects
6000 male and female subjects (aged 6 – 12 years) in Thailand with at least four permanent molars fully erupted and at least one permanent central and/or lateral erupted incisor were enrolled.

Methods
In this double-blind, parallel-group study, the 6000 subjects entered into the study were given oral hygiene instructions and were randomly assigned to one of the three study groups (N=2000 per group). Following baseline examination, subjects were instructed to brush twice daily with their assigned toothpaste. Caries efficacy was determined by assessing the status of all tooth surfaces for each permanent tooth, with the exception of third molars. Decayed, missing, and filled teeth (DMFT) and decayed, missing, and filled surfaces (DMFS) scores were calculated for each participant and then the mean DMFT and mean DMFS scores were calculated for each group. Examinations were made at baseline and after 1 and 2 years of product use. Comparisons of the treatment groups with respect to baseline scores were performed using conventional analyses of variance (ANOVA's).
Comparisons among treatment groups with respect to baseline-adjusted incremental DMFT and incremental DMFS scores at the one year and two year examinations were performed using analyses of covariance (ANCOVA’s). Post-ANCOVA pair-wise comparisons of the study treatments were performed using the Tukey test for multiple comparisons. All statistical tests of hypotheses were two-sided and employed a level of significance of $\alpha=0.05$.

**Results**

5055 subjects completed the study. The mean DMFT and DMFS scores did not differ among the three groups at baseline (Mean baseline across the three groups was 0.50 for DMFT and 0.70 for DMFS) or after 1 year. After two years, the two test dentifrices showed statistically significant reductions in both DMFT (21.0% and 17.7%, respectively) and DMFS (16.5% and 16.5%, respectively) as compared to the fluoride control dentifrice. There were no significant differences in DMFT or DMFS scores between the two test dentifrices.

**Conclusion**

The results of this pivotal clinical study support the conclusion that dentifrices containing 1.5% arginine, an insoluble calcium compound, and 1450 ppm fluoride provide superior protection against caries lesion cavitation to dentifrices containing 1450 ppm fluoride alone.