A Clinical Investigation Using Quantitative Light-induced Fluorescence (QLF) of the Anti-caries Efficacy of a Dentifrice Containing 1.5% Arginine and 1450 ppm Fluoride as Sodium Monofluorophosphate

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Study objective
The objective of the study was to assess the ability of a dentifrice containing 1.5% arginine, an insoluble calcium compound and fluoride to arrest or reverse naturally occurring buccal caries lesions in children measured using Quantitative Light-induced Fluorescence (QLF).

Trial conditions and methods

Products under investigation
Test dentifrice: 1.5% arginine and 1450 ppm fluoride as sodium monofluorophosphate (MFP) in a calcium base (Colgate-Palmolive Company, New York, NY)

Positive control dentifrice: 1450 ppm fluoride as MFP in a calcium base (Colgate-Palmolive Company, New York, NY)

Negative control dentifrice: Non-fluoride toothpaste in a calcium base (Colgate-Palmolive Company, New York, NY)

Study subjects
450 male and female subjects (children aged 10-12 years) from three schools in China with at least one visible white spot lesion on the buccal surface of one of the six upper anterior teeth.

Methods
In this double-blind, parallel-group study, 450 subjects with a visible white spot lesion were given oral hygiene instructions and were randomly assigned to the test group, the positive or the negative control group (N=150 for each group). Following baseline examination, subjects were instructed to brush at least twice per day with their assigned toothpaste and toothbrush. On school days, subjects brushed in the afternoon, under supervision, for two minutes. Three to five images per subject were taken of the upper anterior teeth, using a QLF imaging system, so that clear views of any lesions could be captured. The camera and illuminator were mounted in a stabilizing unit. Together with video repositioning software, this enabled subjects to be accurately repositioned at each visit. Images were taken at baseline, and after three- and six-months use of the assigned product.
The QLF software was used to determine lesion area, loss of fluorescence ($\Delta F$), and lesion volume ($\Delta Q$). The primary outcome was the mean subject $\Delta Q$ at the six-month examination. Comparisons between treatments were performed using a linear model controlling for baseline $\Delta Q$ value and number of lesions per subject and applying a Bonferroni adjustment to the pair wise comparisons. All statistical tests of hypotheses employed a level of significance of $\alpha=0.05$.

**Results**

446 subjects completed the study. There were no statistically significant differences between the three study groups for any of the baseline measurements. For $\Delta Q$, the baseline mean value for the three groups was 27.30. At three-months, mean $\Delta Q$ values were 16.76, 19.25, and 25.89 for the test, positive control and negative control, respectively, representing improvements from baseline of 38.6%, 29.5% and 5.2%. At six-months, mean $\Delta Q$ values were 13.46, 18.47, and 24.18 for the test, positive control and negative control, respectively, representing improvements from baseline of 50.7%, 32.3% and 11.4%. For all QLF measures, the differences between the negative control and both the test and positive control groups were statistically significant ($p \leq 0.01$). The difference between the test and positive control groups for $\Delta Q$ was statistically significant at the six-month examination ($p \leq 0.003$).

**Conclusion**

Both fluoride-containing dentifrices are significantly better at arresting and reversing buccal caries lesions than the non-fluoride dentifrice. Furthermore, it is concluded that the new dentifrice containing arginine, an insoluble calcium compound, and fluoride provides significantly greater anti-caries benefit than a dentifrice containing fluoride alone.