Comparison of the Efficacy of a Dentifrice Containing 1.5% Arginine and 1450 ppm Fluoride to a Dentifrice Containing 1450 ppm Fluoride Alone in the Management of Early Coronal Caries as Assessed Using Quantitative Light-induced Fluorescence

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In: J Dent. 2013; 41S: 29-34

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Study objective
The objective of the study was to compare the efficacy of a new dentifrice containing 1.5% arginine, an insoluble calcium compound, and fluoride to a matched positive control dentifrice containing 1450 ppm fluoride in arresting and reversing early coronal caries lesions in children 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 sodium monofluorophosphate (MFP) in a calcium base (Colgate-Palmolive Company, New York, NY)

Study subjects
341 male and female subjects (children aged between 7-14 years) from eight schools in Thailand 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, 331 subjects with an established white spot lesion were given oral hygiene instructions and were randomly assigned to the test group (N=166) or the positive control group (N=165). 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 brushing twice daily for three- and six-months with the assigned product.
The QLF software was used to determine lesion area, loss of fluorescence (ΔF), and lesion volume (ΔQ). The primary outcome was the mean subject ΔQ at the six-month examination. Comparisons between treatments were performed using a linear model controlling for baseline ΔQ value and number of lesions per subject. All statistical tests of hypotheses employed a level of significance of α=0.05.

Results
331 subjects completed the study. There were no statistically significant differences between the two study groups for any of the baseline measurements. For ΔQ, the baseline mean value for the two groups was 28.62. At three-months, mean ΔQ values were 20.53 and 23.38 for the test and positive control, respectively, representing improvements from baseline of 28.0% and 18.0%. At six-months, mean ΔQ values were 15.85 and 20.35 for the test and positive control, respectively, representing improvements from baseline of 44.6% and 28.9%. The difference in ΔQ between test and control groups was statistically significant after six months (p≤0.001). The arginine-containing dentifrice demonstrated an improvement after only three months that was very similar to that achieved by the conventional fluoride dentifrice after six months.

Conclusion
A new dentifrice containing 1.5% arginine, an insoluble calcium compound, and 1450 ppm fluoride, provided statistically significantly superior efficacy in arresting and reversing buccal caries lesions in children than brushing with a matched positive control dentifrice containing fluoride alone.