Comparing 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 Primary Root Caries

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Study objectives:
The objective of the study was to compare the efficacy of a new dentifrice containing 1.5% arginine, an insoluble calcium compound and 1450 ppm fluoride to a positive control dentifrice containing fluoride alone in arresting and reversing primary root caries lesions in adults.

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)

Study subjects
284 male and female subjects (adults aged 30-69 years) in Brazil with at least one non-cavitated primary root caries lesion, one of which was selected and followed throughout the study.

Methods
In this double-blind, parallel-group study, 284 subjects with an established primary root caries lesion were given oral hygiene instructions and were randomly assigned to the test group or the positive control group (N=140-144 per group). Following baseline examination, subjects were instructed to brush at least twice per day with their assigned toothpaste and toothbrush. Efficacy for arresting and reversal of primary root caries lesions was assessed by clinical hardness measures. The primary outcome was the number of lesions becoming hard at the six-month examination. The results for the two groups were compared using a chi-square test. The level of statistical significance was set at α=0.05.
Results
253 subjects completed the study. There was some evidence of baseline imbalance with lesions tending to be larger in area (p=0.022) in the arginine-containing dentifrice group than in the positive control group. After six-months, clinical hardness measures showed that 70.5% of lesions improved in subjects using the arginine-containing dentifrice compared to 58.1% in the positive control group. The difference in the number of lesions becoming hard in the two groups was statistically significant (p=0.038), and the difference increased (p=0.004) when logistic regression analysis was applied to adjust for the slight baseline imbalance.

Conclusions
A new dentifrice containing 1.5% arginine, and insoluble calcium compound, and fluoride, provided statistically significantly superior efficacy in arresting and reversing active root caries lesions in adults compared to a matched control dentifrice containing fluoride alone.

1. One subject left the study for reasons unrelated to the trial.