In Vivo Effects of a New Dentifrice Containing 1.5% Arginine and 1450 ppm Fluoride on Plaque Metabolism

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Study objective

The objective of the study was to assess the in vivo effects on plaque metabolism of a new dentifrice containing 1.5% arginine, an insoluble calcium compound, and 1450 ppm fluoride compared to a commercially available dentifrice containing 1450 ppm fluoride alone.

Trial conditions and methods

Products under investigation

Test dentifrices: 1.5% arginine and 1450 ppm fluoride as sodium monofluorophosphate (MFP) in a calcium base (Colgate-Palmolive Company, New York, NY)
Control dentifrice: 1450 ppm fluoride as sodium fluoride (NaF) in a silica base (Crest Calcident, Procter and Gamble, Cincinnati, OH, USA)

Study subjects

60 healthy subjects participated in the study.

Methods

This was a four-week, parallel, randomized, double-blind clinical study. Following a one-week washout period using the control dentifrice, subjects were instructed to brush for two-weeks, twice daily with their assigned dentifrice for 1 minute. The test period was followed by two weeks use of the control product by both groups. Plaque collection was carried out at baseline, after one- and two-week’s use of the test and control products, and after two-week’s use of the control product. Plaque samples (after fasting) were collected for measurement of resting plaque pH and ammonia production capacity. Each subject then rinsed with a 10% sucrose solution for two minutes, eight minutes following which plaque samples were collected for measurement of terminal pH and lactic acid analysis. Data from the treatment phase were analyzed using Repeated Measures Analysis (RMA) including treatment, time and treatment* time interaction and baseline values as covariates. One-sided upper tests were used for pH and ammonia production and one-sided lower tests for lactic acid. Data from the post-treatment phase were analyzed using ANCOVA. Differences were considered significant if 95% confidence level was achieved.
**Results**

51 subjects completed the study. Subjects using the test dentifrice, containing 1.5% arginine, an insoluble calcium compound, and 1450 ppm fluoride, during the treatment phase had significantly higher pH values before the sucrose challenge than those using the control dentifrice (p≤0.01). The least squares mean resting pH values were 7.28 and 7.09 for the test and control groups, respectively. Plaque samples from subjects using the arginine-containing dentifrice during the treatment phase also produced significantly higher levels of ammonia (p≤0.01). The least squares mean ammonia production values were 108.9 and 81.4 for the test and control groups, respectively. Subjects using the arginine-containing dentifrice also had directionally higher plaque pH after sucrose challenge, with least squares mean terminal pH values of 5.96 and 5.84 for the test and control groups, respectively, and their plaque samples produced a directionally lower level of lactate, with least squares mean lactic acid production values of 4.03 and 4.59 for the test and control groups, respectively. Following two-week’s subsequent use of the control product, there were no significant differences in plaque metabolism measures between groups.

**Conclusion**

A new dentifrice containing 1.5% arginine, an insoluble calcium compound, and 1450 ppm fluoride has been shown in this study to modulate plaque metabolism by increasing plaque pH through increased ammonia production and decreased lactate production.