In situ Clinical Effects of New Dentifrices Containing 1.5% Arginine and Fluoride on Enamel De- and Re-mineralization, and Plaque Metabolism

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Study objective

The primary objective of the three studies was to evaluate the effects of new dentifrices containing 1.5% arginine, an insoluble calcium compound and fluoride for their ability to promote remineralization (of demineralized enamel), and to prevent de-mineralization (from sound enamel). A secondary objective was to determine the effects on plaque metabolism with respect to the conversion of arginine to ammonia and sucrose to lactic acid.

Trial conditions and methods

Products under investigation

Test dentifrices: 1.5% arginine and fluoride [1450 (study 1 and 2) or 1000 ppm (study 3)] as sodium monofluorophosphate (MFP) in a calcium [dical (study 1 and 2) and/or calcium carbonate (study 1 and 3)] base (Colgate-Palmolive Company, New York, NY)

Positive control dentifrice: Fluoride [1450 (study 1 and 2) or 1000 ppm (study 3)] as MFP in a calcium [dical (study 1 and 2) and/or calcium carbonate (study 1 and 3)] base (Colgate-Palmolive Company, New York, NY)

Negative control dentifrice: Low-fluoride [250 (Study 1 and 2) or 0 ppm (study 3)] as MFP in a calcium [dical (study 1 and 2) and/or calcium carbonate (study 1 and 3)] base (Colgate-Palmolive Company, New York, NY)

Study subjects

The studies employed 30, 16 and 18 healthy male and female subjects (adults aged 18-70 years), respectively.

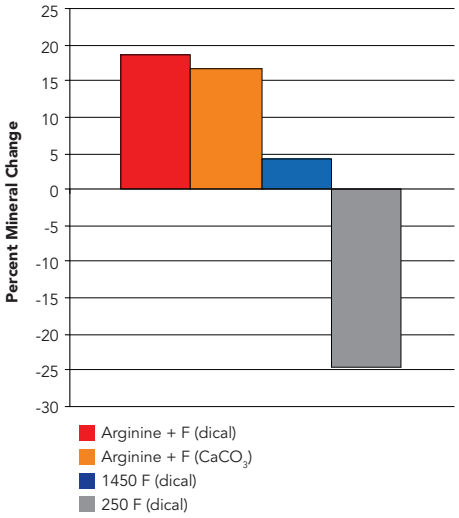
Methods

Study 1, a cross-over design with two-week test periods, compared four dentifrices in a re-min/de-min clinical *in situ* model using acid demineralized enamel thin sections. Microradiography and image analysis were used to measure mineral changes. Studies 2 and 3, cross-over designs with five-day test periods, each compared three dentifrices in de-min/re-min clinical *in situ* models using sound enamel. *Ex vivo* cariogenic challenges (10% sucrose) were utilized four times per day. Micro-hardness was used to assess mineral changes. Plaque samples were harvested to measure the ability to convert arginine to ammonia (studies 2 and 3) and sucrose to lactic acid (study 3).

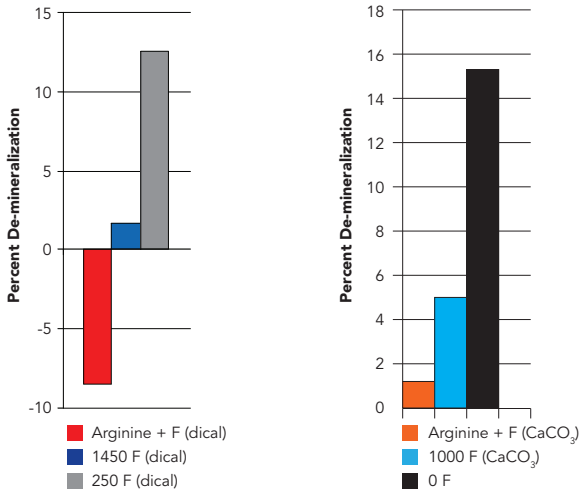
Results

All three studies were successfully validated by demonstrating statistically significant differences between the positive and negative control dentifrices. In study 1, the two arginine-containing dentifrices were statistically significantly more effective than the positive control in re-mineralizing demineralized enamel and were not significantly different from each other indicating that remineralization was independent of the choice of dical or calcium carbonate. Studies 2 and 3 both showed that the arginine-containing dentifrices were statistically significantly more effective than the positive control in preventing de-mineralization of sound enamel. Study 2 showed directionally higher ammonia production after an arginine-sucrose challenge compared to the two controls.

The effect of two dentifrices containing 1.5% arginine, an insoluble calcium compound and 1450 ppm fluoride on re-mineralization of de-mineralized enamel



The effect of dentifrices containing 1.5% arginine an insoluble calcium compound and fluoride on de-mineralization of sound enamel



Additionally, Study 3 showed statistically significantly higher ammonia production after an arginine-sucrose challenge, and directionally lower lactic acid production compared to the two controls, although the difference was not statistically significant.

Conclusion

The results of these studies show that the addition of 1.5% arginine to dical- and calcium carbonate-based fluoride dentifrices provides superior efficacy in promoting remineralization and preventing de-mineralization of enamel relative to dentifrices having the same calcium base and same level of fluoride alone. Further, the results strongly suggest that the arginine-containing dentifrices enhance the ability of plaque to metabolize arginine to ammonia.