Clinical Study to Evaluate the Dentin Hypersensitivity Reduction Efficacy of Mouthwash Containing 0.8% Arginine in Adults over a Six-Week Period

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Study objective
The objective of this six-week study was to evaluate the dentin hypersensitivity reduction efficacy of a mouthwash containing 0.8% arginine, PVM/MA copolymer, pyrophosphates, and 0.05% sodium fluoride (“Arginine”) as compared to a commercial mouthwash containing 2.4% potassium nitrate and 0.022% sodium fluoride (“Potassium Nitrate”) and to a control mouthwash containing 0.05% sodium fluoride (“Negative Control”) at various time points up to six weeks.

Trial conditions and methods

Products under investigation
Test Mouthwash (Arginine): 0.8% arginine, PVM/MA copolymer, pyrophosphates, and 0.05% sodium fluoride (Colgate-Palmolive Company, New York, NY)

Commercial Sensitive Mouthwash (Potassium Nitrate): 2.4% potassium nitrate and 0.022% sodium fluoride (Johnson & Johnson, New Brunswick, NJ)

Negative Control Mouthwash: 0.05% sodium fluoride (Colgate-Palmolive Company, New York, NY)

Study subjects
75 male and female adults in Santo Domingo, Dominican Republic, with established dentin hypersensitivity (two hypersensitive teeth with a tactile score [Yeaple probe] of 10–50 grams of force and air blast score of 2 or 3 on the Schiff Cold Air Sensitivity Scale) were enrolled.

Methods
In this double-blind, parallel-group study, 69 subjects with established dentin hypersensitivity were randomly assigned to one of the test groups, complied with the protocol, and completed the six-week study. Dentin hypersensitivity assessments were conducted at baseline, 30 minutes post an initial rinsing, and again after two, four, and six weeks of twice-daily product use.
**Results**

Thirty minutes after a single use, there were no differences among the subjects in the three groups with respect to mean tactile and air blast hypersensitivity scores. After two weeks, four weeks, and six weeks of product use, subjects using the Arginine Mouthwash exhibited a statistically significant improvement in mean tactile hypersensitivity (higher score is better) and air blast hypersensitivity (lower score is better) as compared to users of both the Potassium Nitrate Mouthwash and Negative Control Mouthwash.

**Conclusions**

The results of this double-blind clinical study support the conclusions that the Test Mouthwash containing 0.8% arginine, PVM/MA copolymer, pyrophosphates, and 0.05% sodium fluoride provides a significant and superior reduction in dentin hypersensitivity as compared to a commercial sensitive mouthwash containing 2.4% potassium nitrate and 0.022% sodium fluoride, and to a negative control mouthwash containing 0.05% sodium fluoride.