A Clinical Investigation of a Dual Zinc Plus Arginine Dentifrice on Extrinsic Tooth Stain Removal Efficacy

Evaristo Delgado¹, Franklin Garcia-Godoy², Socias Lourdes³, Luis R. Mateo⁴

¹Colgate-Palmolive Company; ²Professor, Department of Bioscience Research College of Dentistry, University of Tennessee; ³Spa Dental, Santo Domingo, Dominican Republic; ⁴LRM Statistical Consulting, LLC

Internal Report

Study objectives

The objective of this clinical study was to evaluate the clinical efficacy of Colgate Total with Dual Zinc plus Arginine in removing extrinsic tooth stains over 6 weeks as compared to regular fluoride toothpaste.

Trial conditions and methods

Products under investigation

Test dentifrice: zinc (zinc oxide, zinc citrate) 0.96%, 1.5% Arginine and 1450 ppm fluoride in a silica base of high cleaning silica (Colgate Total; Colgate-Palmolive Company, New York, NY)

Control dentifrice : regular fluoride dentifrice containing 1450 ppm fluoride (MaxFresh Tea; Colgate-Palmolive Company, New York, NY)

Methods

In this randomized, double-blind, parallel-group clinical study, extrinsic tooth stain removal efficacy was assessed via Lobene Composite Stain Index, Stain Area Index and Stain Intensity Index scores. 102 subjects were randomly assigned to one of two treatment groups and instructed to brush their teeth twice daily for 1 minute with the assigned toothpaste for 6 weeks. The subjects were examined after 3 and after 6 weeks of product usage. Statistical analyses were performed on the Lobene Composite Stain Index, Lobene Stain Area index and Lobene Stain Intensity index scores using analysis of covariance (ANCOVAs). All statistical tests of hypotheses were two sided, and employed a level of significance of α =0.05.



Results

After 3 weeks of product usage the subjects in the test group using Colgate Total were examined to have statistically significant (p<0.001) within treatment reductions of 38.6% in extrinsic tooth stain (Lobene Composite Stain Index), 38.1% in the area stained (Lobene Stain Area Index), and 28.4% in stain intensity (Lobene Stain Intensity Index). This reduction in extrinsic stains was further improved after the full 6 weeks of product usage. At the 6-week examination, subjects assigned to the Test Group exhibited a statistically significant (p< 0.001) within treatment reduction of 61.4% in extrinsic tooth stain (Lobene Stain Area Index), 61.2% in the area stained (Lobene Composite Stain Index), and 51.9% in stain intensity (Lobene Stain Intensity Index). Figure 1 shows the within treatment extrinsic stain reduction at 6 weeks for both the test and control dentifrices.



Figure 1. Within treatment reduction of extrinsic stains after 6 weeks of product use

Conclusion

The results of this study support that Colgate Total with Dual Zinc plus Arginine provides significantly greater extrinsic tooth stain removal as compared to a regular fluoride toothpaste when used over a period of 6 weeks.

