Clinical efficacy of ***Colgate® Sensitive Pro-Relief™ toothpaste***

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Comparing the efficacy in providing instant relief of dentin hypersensitivity of a new toothpaste containing 8.0% arginine, calcium carbonate, and 1450 ppm fluoride to a benchmark desensitizing toothpaste containing 2% potassium ion and 1450 ppm fluoride and to a control toothpaste with 1450 ppm fluoride: A three-day clinical study in New Jersey, USA.

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Study objectives

To compare the efficacy in reducing dentin hypersensitivity of toothpaste containing 8.0 % arginine, calcium carbonate, and 1450 ppm fluoride to a desensitizing and to a fluoride control toothpaste, immediately after direct application using a fingertip and after subsequent twice daily brushing for 3 days.

Trial conditions and methods

Products under investigation

Test: Colgate® Sensitive Pro-Relief™ toothpaste containing 8.0% arginine, calcium carbonate, and 1450 ppm fluoride as MFP. KNO_3 control: Toothpaste containing 5% KNO_3 and 1450 ppm fluoride as NaF. Fluoride control: Toothpaste containing 1450 ppm fluoride as MFP (Colgate Palmolive, New York, NY).

Study subjects

125 subjects (aged 18-74 years) with established hypersensitivity (two hypersensitive teeth with a tactile sensitivity score [Yeaple probe] of 10-50 grams of force and an air blast score of 2 or 3 on the Schiff Cold Air Sensitivity Scale).

Methods

In this double-blind, parallel group study, 125 subjects were stratified and randomly assigned to the test (n=42), the KNO_3 (n=41) or the fluoride (n=42) group. Subjects first applied a pea-sized amount of toothpaste directly to the sensitive area of each of the baseline designated teeth with a fingertip and massaged each for 1 minute. Subjects then brushed with their assigned product and a soft bristled toothbrush twice daily for 3 days. Tactile and air blast sensitivity scores were determined immediately after direct topical application and after 3 days of product use.

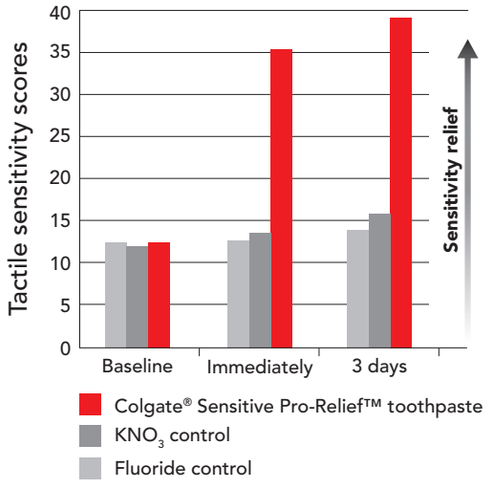
Statistical analyses were performed separately for tactile and air blast scores. Comparisons of treatment groups with respect to baseline were performed using analysis of variance (ANOVA). Comparisons between treatments using baseline adjusted scores were performed using analysis of covariance (ANCOVA).

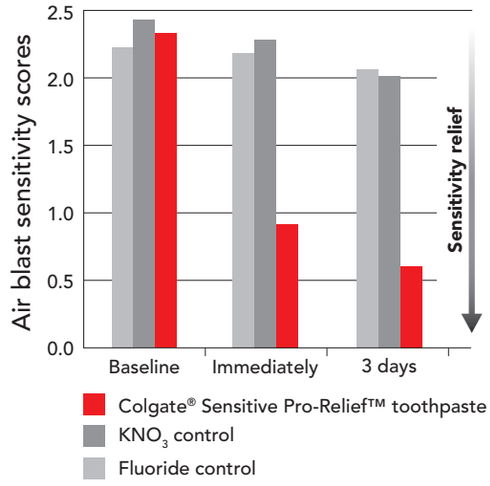
Results

Immediately after direct application and after 3 days, subjects in the test group experienced statistically significant improvements from baseline in tactile (185.6 % and 216.4 %, respectively) and air blast (60.5 % and 74.2 %, respectively) sensitivity scores. Moreover, at the same time points, the test group experienced statistically significant improvements compared to the KNO_3 group in tactile (161.2 % and 147.1 %, respectively) and air blast (59.8 % and 70.1 %, respectively) sensitivity scores, and statistically significant improvements compared to the fluoride group in tactile (180.2 % and 181.2 %, respectively) and air blast (58.0 % and 70.9 %, respectively) sensitivity scores.

In respect of the control groups, subjects in the KNO_3 group experienced statistically significant improvements from baseline in tactile (13.3 % and 32.6 %, respectively) and air blast (5.8 % and 17.3 %, respectively) sensitivity scores, and subjects in the fluoride group experienced statistically significant improvements from baseline in tactile (1.9 % and 12.5 %, respectively) and air blast (1.8 % and 7.6 %, respectively) sensitivity scores. No statistically significant differences between the KNO_3 and the fluoride control groups were indicated immediately after direct application or after 3 days of twice daily brushing.

Effects on dentin hypersensitivity





Conclusion

Colgate® Sensitive Pro-Relief™ toothpaste provides statistically significant relief of dentin hypersensitivity, immediately after direct application with a fingertip, relative to a KNO_3 toothpaste and to a fluoride toothpaste.