

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 Mississauga, Canada.

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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. KNO₃ control: Toothpaste containing 5% KNO₃ and 1450 ppm fluoride as NaF. Fluoride control: Toothpaste containing 1450 ppm fluoride as MFP (Colgate Palmolive, New York, NY).

Study subjects

120 subjects (aged 18-66 years) with established dentin 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, 120 subjects were stratified and randomly assigned to the test (n=41), the KNO₃ (n=40) or the fluoride (n=39) 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.

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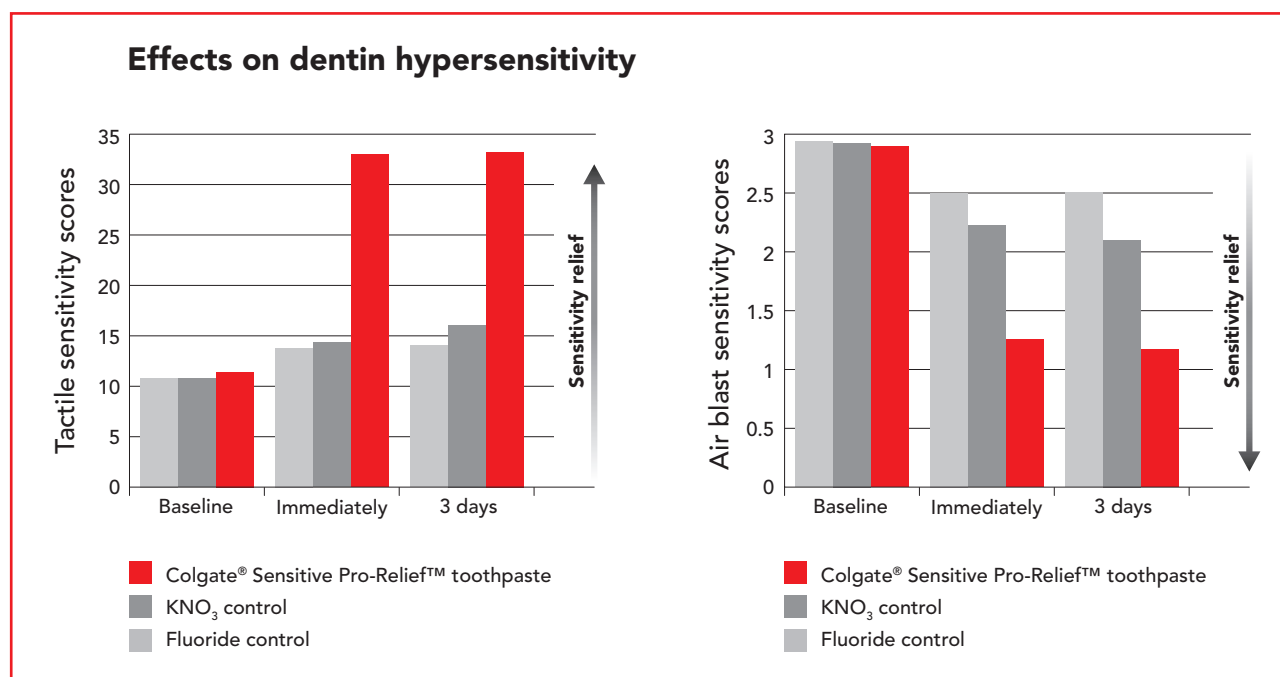
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Statistical analyses were performed separately for tactile and air blast scores. Comparisons of treatment groups with respect to baseline were performed using analysis of variance (ANOVA). Comparisons between treatments using baseline adjusted scores 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 (189.4% and 190.4%, respectively) and air blast (56.6% and 59.7%, respectively) sensitivity scores. Moreover, at the same time points, the test group experienced statistically significant improvements compared to the KNO₃ group in tactile (130.7% and 104.9%, respectively) and air blast (43.8% and 44.5%, respectively) sensitivity scores, and statistically significant improvements compared to the fluoride group in tactile (139.5% and 136.1%, respectively) and air blast (49.6% and 53.2%, respectively) sensitivity scores.

In respect of the control groups, subjects in the KNO₃ group experienced statistically significant improvements from baseline in tactile (32.2% and 49.4%, respectively) and air blast (23.5% and 28.4%, respectively) sensitivity scores immediately after direct application and after 3 days use. Subjects in the fluoride group experienced statistically significant improvements from baseline in tactile (27.1% and 29.4%, respectively) and air blast (15.3% and 15.5%, respectively) sensitivity scores. No statistically significant differences between the two control groups were indicated immediately after direct application. After 3 days use, the KNO₃ group demonstrated a significant reduction in mean air blast scores (15.6%) relative to the fluoride group, but there was no significant difference in tactile sensitivity scores.



Conclusion

Colgate® Sensitive Pro-Relief™ toothpaste provides statistically significant relief of dentin hypersensitivity, immediately after direct application with a fingertip, relative to a KNO₃ toothpaste and to a fluoride toothpaste.

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