

Comparative Evaluation of the Efficacy of Three Commercially Available Toothpastes on Dentin Hypersensitivity Reduction: An Eight-Week Clinical Study

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Abstract

- **Objective:** The objective of this eight-week, single-center, three-cell, double-blind, and randomized clinical study was to evaluate the dentin hypersensitivity reduction efficacy of three commercially available toothpastes: 1) Colgate® Sensitive Pro-Relief™ Toothpaste (also marketed as elmex® Sensitive Professional™); 2) Sensodyne® Rapid Relief Toothpaste; and (3) Crest® Cavity Protection Toothpaste.
- **Methods:** 150 subjects, having two teeth with tactile and air blast hypersensitivity, were assigned to one of the three study groups (50/group). Subjects were then asked to brush their teeth for one minute, twice daily, with the given toothpaste. The dentin hypersensitivity and oral tissues were evaluated at baseline, two weeks, four weeks, and eight weeks. Comparison of the treatment groups with respect to gender was conducted using a chi-square analysis, and with respect to age and baseline hypersensitivity scores was performed using the analysis of variance (ANOVA). Within-treatment effects were analyzed using the paired t-test, while the analysis of covariance (ANCOVA) was used to examine between-treatment effects. The *post hoc* Tukey test was performed for pair-wise comparisons. All statistical tests were two-sided using a significance level of $\alpha = 0.05$.
- **Results:** After two, four, and eight weeks of daily use of the products, all three groups showed a statistically significant reduction from baseline in tactile and air blast dentin hypersensitivity ($p < 0.05$). Colgate Sensitive Pro-Relief toothpaste produced a significant improvement in mean tactile and air blast dentin hypersensitivity scores, and was more effective than Sensodyne Rapid Relief toothpaste and Crest Cavity Protection toothpastes ($p < 0.05$).
- **Conclusion:** Colgate Sensitive Pro-Relief Toothpaste, used twice daily, significantly reduces dentin hypersensitivity, and is significantly more effective in reducing dentin hypersensitivity than Sensodyne Rapid Relief Toothpaste and Crest Cavity Protection Toothpaste.

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Introduction

Dentin hypersensitivity may be experienced after the root surfaces of an individual are exposed to the oral environment via gingival recession or periodontal treatment. Once the root is exposed and the cementum subsequently eroded, the exposed dentin is subjected to exterior stimuli. These stimuli are most commonly of a thermal, osmotic, electrical, chemical, or dehydrating nature. The host then feels a pain, termed “dentinalgia”¹ that has been described as “short, sharp, and cannot be ascribed to any other form of dental defect or pathology.”² This frequent clinical condition has long been a dilemma for both patients and dental practitioners, and with teeth being maintained longer there is an increased demand placed upon the dental practitioner to manage the sensitivity of cervically exposed dentin.

Many theories have been used to explain the mechanisms of dentin hypersensitivity. An early hypothesis was the dentin receptor mechanism theory, which suggested that dentin hypersensitivity is caused by the direct stimulation of sensory nerve endings in dentin;³ today this theory is not well accepted. Another theory was proposed by Rapp, *et al.*⁴ suggesting that odontoblasts act as receptor cells, mediating changes in the membrane potential of the odontoblasts via synaptic junction with nerves. This could result in the sensation of pain from the nerve endings located in the pulpodentinal border. This theory, like the previous one, has some shortcomings, and is not well accepted by the scientific community.

The theory that is widely accepted to explain dentin hypersensitivity-related pain is the “hydrodynamic theory” as described

by Brännström and Astron.⁵ This theory states that the pain sensation is caused by the activation of mechanoreceptors in intratubular nerves or in the superficial pulp due to changes of the flow and/or volume of fluid within dentin tubules.^{5,6}

The management of dentin hypersensitivity has consisted of using dentifrices containing potassium salts for nerve depolarization and disruption of a neural response to pain stimuli as the first line of action. This method, albeit effective, has two shortcomings: 1) it does not address the cause of the problem (open dentin tubules); and 2) it does not provide immediate relief. A number of other agents have been investigated for the treatment of hypersensitive teeth, with varying degrees of effectiveness. They include formaldehyde, sodium fluoride, dibasic sodium citrate, sodium monofluorophosphate, sodium silicofluoride, silver nitrate, calcium hydroxide, and strontium chloride. Some of these compounds have been incorporated into dentifrices for daily use.^{7,8} However, strong evidence of the clinical efficacy of many of these ingredients has been elusive, with some (*i.e.*, formaldehyde) being associated with allergic reactions or soft tissue damage.⁹ In recent years, a novel technology using an amino acid found in saliva (arginine) has shown great promise for the treatment of dentin hypersensitivity as it acts on the open dentin tubules to block the pathway to pain.¹⁰ This new technology utilizes 8.0% arginine and calcium carbonate with 1450 ppm fluoride as sodium monofluorophosphate (MFP) in a toothpaste formula that has been shown to obliterate the dentin tubules, hence reducing the dentin flow and significantly alleviating the pain sensation.¹¹⁻¹³

The objective of this parallel, double-blind, stratified, and randomized clinical study was to compare the clinical efficacy of the new Colgate® Sensitive Pro-Relief™ Toothpaste (also marketed as elmex® Sensitive Professional™) to that of Sensodyne® Rapid Relief Toothpaste and Crest® Cavity Protection Toothpaste in reducing dentin hypersensitivity after two, four, and eight weeks of twice-daily brushing.

Materials and Methods

After Institutional Review Board (IRB) approval of the protocol and the letter of informed consent, a total of 150 healthy adults, ages 20 to 69 years, participated in the study. Subjects were required to be available for the study duration and to sign the informed consent form. To be eligible for participation in the study, each subject had to have a minimum of two teeth with dentin hypersensitivity among incisors, canines, and premolars, with cervical erosion/abrasion or gingival recession, as determined by a tactile hypersensitivity stimulus score of 10 to 50 grams of force using a calibrated Yeaple Electronic Pressure Sensitive Probe (Model 200A; Yeaple Research, Pittsford, NY, USA), and an air blast stimulus score of 2 or 3 (Schiff Cold Air Sensitivity Scale). Subjects with any of the following conditions were excluded from the study: gross oral pathology; chronic oral diseases; advanced periodontal disease; treatment for periodontal disease within one year; sensitive teeth with mild mobility (mobility index > 1), extensive or defective restorations, suspected pulpitis, caries, cracked enamel; or teeth used as abutments for removable partial dentures. The exclusion also applied to the following conditions: current use of anticonvulsants, antihistamines, antidepressants, sedatives, tranquilizers, anti-inflammatory drugs,

or daily analgesics; pregnant or lactating women; participation in a desensitizing dentifrice study or use of a desensitizing dentifrice within the last three months; currently participating in another clinical study; history of allergy to oral care/personal care consumer products or the test products of the present study; or any existing medical conditions that precluded them from not eating and drinking for a period of four hours.

The study was a three-cell, double-blind, parallel-group, stratified, and randomized clinical investigation. Each enrolled study participant was randomly assigned to one of the three treatment groups which were balanced using the baseline tactile and air blast hypersensitivity scores. The three toothpastes were: 1) Colgate Sensitive Pro-Relief containing 8.0% arginine, calcium carbonate, and 1450 ppm fluoride as MFP (Colgate-Palmolive Co., New York, NY, USA); 2) Sensodyne Rapid Relief containing 8% strontium acetate and 1040 ppm fluoride as NaF (Glaxo-SmithKline Co., Weybridge, Surrey, UK); and 3) Crest Cavity Protection containing 1100 ppm fluoride as NaF (Procter & Gamble Co., Cincinnati, OH, USA).

Subjects were instructed to refrain from oral hygiene procedures and chewing gum for eight hours, and from eating and drinking for four hours prior to their scheduled baseline examination. After the baseline evaluation of oral tissues and dentin hypersensitivity of the two identified teeth using the Yeaple tactile probe and Schiff cold air blast method,¹⁴ each subject was given their assigned toothbrush and toothpaste to use for the duration of the study. At-home instructions consisted of brushing their teeth for one minute, twice daily, using only the toothpaste and toothbrush provided, and to refrain from any other oral hygiene products and procedures throughout the duration of the study.

All tested dentifrices were supplied in their original packaging and overwrapped with a white label to mask the identity of the product. A log of the dispensed products was kept and all clinical supplies were refurbished as needed. There were no restrictions regarding diet or smoking habits. Subjects returned to the clinic after two weeks, four weeks, and eight weeks, again refraining from oral hygiene procedures and chewing gum for eight hours, and eating and drinking for four hours prior to their scheduled examinations. Assessments of oral tissues and tactile and air blast dentin hypersensitivity were repeated by the same examiner using the same methods. At each visit, each subject was also interviewed regarding adverse events and the use of concomitant medications.

For the measurement of Yeaple tactile hypersensitivity, the instrument was calibrated daily following manufacturer's instructions. Scores were recorded in terms of the quantified reproducible force (grams applied using a #19 explorer tip) that was required to elicit discomfort with the established procedures.^{15,16} Briefly, the subject was instructed to respond at the point where he or she first experienced discomfort. The explorer tip of the probe was applied to the buccal surface of each hypersensitive tooth at the CEJ. The explorer tip was stroked perpendicular to the tooth beginning at a pre-set force of 10 grams, and increased by 10-gram increments until the subject experienced discomfort, or until 50 grams of force was applied.

For evaluating the air blast hypersensitivity, the tooth to be examined was isolated from the adjacent teeth by placing the

examiner's fingers over the adjacent teeth. Air was delivered from a standard dental unit air syringe at 60 psi (± 5 psi) and 70°F ($\pm 3^\circ\text{F}$), directed at the exposed buccal surface of the hypersensitive tooth for one second from a distance of approximately one cm. The Schiff Cold Air Sensitivity Scale¹⁴ was used to assess subject response to this stimulus, as follows:

- 0 = Subject did not respond to air stimulus;
- 1 = Subject responded to air stimulus but did not request discontinuation of stimulus;
- 2 = Subject responded to air stimulus and requested discontinuation or moved from stimulus;
- 3 = Subject responded to air stimulus, considered stimulus to be painful, and requested discontinuation of the stimulus.

The oral tissue examination included visual assessment of the soft and hard palate, gingival and buccal mucosa, mucogingival fold areas, tongue, sublingual and submandibular areas, salivary glands, and the tonsillar and pharyngeal areas.

Comparisons of the treatment groups with respect to gender were performed using a chi-square analysis; for age, the analysis of variance (ANOVA) was used. The tactile and air blast scores were calculated separately by averaging the values measured on the two qualified teeth for each subject, and the data were analyzed using the ANOVA. The paired t-test was performed to examine within-treatment effects. The treatment groups, with respect to baseline-adjusted tactile hypersensitivity and air blast hypersensitivity scores at the follow-up examinations, were compared using the analysis of covariance (ANCOVA). If a statistically significant difference was detected among the treatment groups by the ANCOVA analysis, a *post hoc* Tukey Multiple Comparison test was performed on the pair-wise comparisons. All statistical tests were two-sided using a significance level of $\alpha = 0.05$.

Results

All one-hundred and fifty (150) subjects complied with the protocol and completed the eight-week clinical study. A summary of the gender and age of the study population is presented in Table I. Throughout the study, there were no adverse events on the soft or hard tissues of the oral cavity observed by the examiner or reported by the subjects when questioned. Table II presents a summary of the mean tactile and air blast hypersensitivity scores measured at the baseline examination. For tactile hypersensitivity, the mean baseline scores were 11.60 for the Colgate Sensitive Pro-Relief Toothpaste group, 11.90 for the Sensodyne Rapid Relief Toothpaste group, and 12.10 for the Crest Cavity Protection Toothpaste group. For air blast hypersensitivity, the mean baseline scores were 2.50 for the Colgate Sensitive Pro-Relief Toothpaste group, 2.43 for the Sensodyne Rapid Relief Toothpaste group, and 2.37 for the Crest Cavity Protection Toothpaste group. No statistically significant differences were indicated among the treatment groups with respect to either tactile or air blast hypersensitivity scores at baseline.

Two-Week Clinical Data—Tactile Hypersensitivity

Table III presents a summary of the tactile hypersensitivity scores measured after two weeks of product use.

Comparisons versus Baseline. The mean two-week tactile

Table I
Summary of Age and Gender for Subjects Who Completed the Eight-Week Clinical Study

Treatment	Number of Subjects			Age	
	Male	Female	Total	Mean	Range
Colgate Sensitive Pro-Relief* Toothpaste	15	35	50	39.4	20–69
Sensodyne Rapid Relief Toothpaste	14	36	50	37.6	23–61
Crest Cavity Protection Toothpaste	17	33	50	39.8	23–65

*Also marketed as elmex Sensitive Professional.

Table II
Summary of the Baseline Tactile Hypersensitivity and Air Blast Hypersensitivity Scores for Subjects Who Completed the Eight-Week Clinical Study

Parameter	Treatment	n	Baseline Summary (Mean \pm SD) ¹
Tactile Sensitivity	Colgate Sensitive Pro-Relief* Toothpaste	50	11.60 \pm 3.26
	Sensodyne Rapid Relief Toothpaste	50	11.90 \pm 3.63
	Crest Cavity Protection Toothpaste	50	12.10 \pm 3.79
Air Blast Sensitivity	Colgate Sensitive Pro-Relief Toothpaste	50	2.50 \pm 0.43
	Sensodyne Rapid Relief Toothpaste	50	2.43 \pm 0.38
	Crest Cavity Protection Toothpaste	50	2.37 \pm 0.41

*Also marketed as elmex Sensitive Professional.

¹No statistically significant differences were indicated among the three treatment groups at baseline with respect to either tactile hypersensitivity or air blast hypersensitivity scores.

hypersensitivity scores were 27.20 for the Colgate Sensitive Pro-Relief Toothpaste group, 19.20 for the Sensodyne Rapid Relief Toothpaste group, and 16.30 for the Crest Cavity Protection Toothpaste group. The percent changes from baseline were 134.5% for the Colgate Sensitive Pro-Relief Toothpaste group, 61.3% for the Sensodyne Rapid Relief Toothpaste group, and 34.7% for the Crest Cavity Protection Toothpaste group, all of which were statistically significant.

Comparison Between Treatment Groups. Relative to the Sensodyne Rapid Relief Toothpaste group and Crest Cavity Protection Toothpaste group, the Colgate Sensitive Pro-Relief Toothpaste group exhibited statistically significant improvements in tactile hypersensitivity scores after two weeks of product use (41.7% and 66.9%, respectively).

Relative to the Crest Cavity Protection Toothpaste group, the Sensodyne Rapid Relief Toothpaste group exhibited a small, but statistically significant improvement in tactile hypersensitivity scores after two weeks of product use (17.8%).

Table III
Summary of the Two-Week Tactile Hypersensitivity Scores for Subjects Who Completed the Eight-Week Clinical Study

Treatment	n	Two-Week Summary (Mean ± SD)	Within-Treatment Analysis		Between-Treatment Comparison			
			Percent Change ¹	Sig. ²	vs. Sensodyne Rapid Relief Toothpaste		vs. Crest Cavity Protection Toothpaste	
					Percent Difference ³	Sig. ⁵	Percent Difference ⁴	Sig. ⁵
Colgate Sensitive Pro-Relief* Toothpaste	50	27.20 ± 8.76	134.5%	p < 0.05	41.7%	p < 0.05	66.9%	p < 0.05
Sensodyne Rapid Relief Toothpaste	50	19.20 ± 5.19	61.3%	p < 0.05	—	—	17.8%	p < 0.05
Crest Cavity Protection Toothpaste	50	16.30 ± 4.61	34.7%	p < 0.05	—	—	—	—

*Also marketed as elmex Sensitive Professional.

¹Percent change exhibited by the two-week mean relative to the baseline mean. A positive value indicates an improvement in tactile hypersensitivity at the two-week examination.

²Significance of paired t-test comparing the baseline and the two-week examinations.

³Difference between the two-week means expressed as a percentage of the two-week mean for the Sensodyne Rapid Relief Toothpaste. A positive value indicates an improvement in tactile hypersensitivity scores relative to the Sensodyne Rapid Relief Toothpaste.

⁴Difference between the two-week means expressed as a percentage of the two-week mean for the Crest Cavity Protection Toothpaste. A positive value indicates an improvement in tactile hypersensitivity scores relative to the Crest Cavity Protection Toothpaste.

⁵Significance of ANCOVA comparison of baseline-adjusted means.

Two-Week Clinical Data—Air Blast Hypersensitivity

Table IV presents a summary of the air blast hypersensitivity scores measured after two weeks of product use.

Comparisons versus Baseline. The mean two-week air blast hypersensitivity scores were 1.45 for the Colgate Sensitive Pro-Relief Toothpaste group, 1.93 for the Sensodyne Rapid Relief Toothpaste group, and 2.04 for the Crest Cavity Protection Toothpaste group. The percent changes from baseline were 42.0% for the Colgate Sensitive Pro-Relief Toothpaste group, 20.6% for the Sensodyne Rapid Relief Toothpaste group, and 13.9% for the Crest Cavity Protection Toothpaste group, all of which were statistically significant.

Comparison Between Treatment Groups. Relative to the Sensodyne Rapid Relief Toothpaste group and Crest Cavity Protection Toothpaste group, the Colgate Sensitive Pro-Relief Toothpaste group exhibited statistically significant reductions in air blast hypersensitivity scores after two weeks of product use (24.9% and 28.9%, respectively).

Relative to the Crest Cavity Protection Toothpaste group, the Sensodyne Rapid Relief Toothpaste group did not exhibit a

statistically significant reduction in air blast hypersensitivity scores after two weeks of product use (5.4%).

Four-Week Clinical Data—Tactile Hypersensitivity

Table V presents a summary of the tactile hypersensitivity scores measured after four weeks of product use.

Comparisons versus Baseline. The mean four-week tactile hypersensitivity scores were 42.50 for the Colgate Sensitive Pro-Relief Toothpaste group, 27.90 for the Sensodyne Rapid Relief Toothpaste group, and 17.70 for the Crest Cavity Protection Toothpaste group. The percent changes from baseline were 266.4% for the Colgate Sensitive Pro-Relief Toothpaste group, 134.5% for the Sensodyne Rapid Relief Toothpaste group, and 46.3% for the Crest Cavity Protection Toothpaste group, all of which were statistically significant.

Comparison Between Treatment Groups. Relative to the Sensodyne Rapid Relief Toothpaste group and Crest Cavity Protection Toothpaste group, the Colgate Sensitive Pro-Relief Toothpaste group exhibited statistically significant improvements in tactile hypersensitivity scores after four weeks of product use

Table IV
Summary of the Two-Week Air Blast Hypersensitivity Scores for Subjects Who Completed the Eight-Week Clinical Study

Treatment	n	Two-Week Summary (Mean ± SD)	Within-Treatment Analysis		Between-Treatment Comparison			
			Percent Change ¹	Sig. ²	vs. Sensodyne Rapid Relief Toothpaste		vs. Crest Cavity Protection Toothpaste	
					Percent Difference ³	Sig. ⁵	Percent Difference ⁴	Sig. ⁵
Colgate Sensitive Pro-Relief* Toothpaste	50	1.45 ± 0.62	42.0%	p < 0.05	24.9%	p < 0.05	28.9%	p < 0.05
Sensodyne Rapid Relief Toothpaste	50	1.93 ± 0.42	20.6%	p < 0.05	—	—	5.4%	NS
Crest Cavity Protection Toothpaste	50	2.04 ± 0.38	13.9%	p < 0.05	—	—	—	—

*Also marketed as elmex Sensitive Professional.¹

¹Percent change exhibited by the two-week mean relative to the baseline mean. A positive value indicates a reduction in air blast hypersensitivity at the two-week examination.

²Significance of paired t-test comparing the baseline and the two-week examinations.

³Difference between the two-week means expressed as a percentage of the two-week mean for the Sensodyne Rapid Relief Toothpaste. A positive value indicates a reduction in air blast hypersensitivity scores relative to the Sensodyne Rapid Relief Toothpaste.

⁴Difference between the two-week means expressed as a percentage of the two-week mean for the Crest Cavity Protection Toothpaste. A positive value indicates a reduction in air blast hypersensitivity scores relative to the Crest Cavity Protection Toothpaste.

⁵Significance of ANCOVA comparison of baseline-adjusted means.

Table V
Summary of the Four-Week Tactile Hypersensitivity Scores for Subjects Who Completed the Eight-Week Clinical Study

Treatment	n	Four-Week Summary (Mean ± SD)	Within-Treatment Analysis		Between-Treatment Comparison			
			Percent Change ¹	Sig. ²	vs. Sensodyne Rapid Relief Toothpaste		vs. Crest Cavity Protection Toothpaste	
					Percent Difference ³	Sig. ⁵	Percent Difference ⁴	Sig. ⁵
Colgate Sensitive Pro-Relief* Toothpaste	50	42.50 ± 5.91	266.4%	p < 0.05	52.3%	p < 0.05	140.1%	p < 0.05
Sensodyne Rapid Relief Toothpaste	50	27.90 ± 6.23	134.5%	p < 0.05	—	—	57.6%	p < 0.05
Crest Cavity Protection Toothpaste	50	17.70 ± 4.19	46.3%	p < 0.05	—	—	—	—

*Also marketed as elmex Sensitive Professional.

¹Percent change exhibited by the four-week mean relative to the baseline mean. A positive value indicates an improvement in tactile hypersensitivity at the four-week examination.

²Significance of paired t-test comparing the baseline and four-week examinations.

³Difference between the four-week means expressed as a percentage of the four-week mean for the Sensodyne Rapid Relief Toothpaste. A positive value indicates an improvement in tactile hypersensitivity scores relative to the Sensodyne Rapid Relief Toothpaste.

⁴Difference between the four-week means expressed as a percentage of the four-week mean for the Crest Cavity Protection Toothpaste. A positive value indicates an improvement in tactile hypersensitivity scores relative to the Crest Cavity Protection Toothpaste.

⁵Significance of ANCOVA comparison of baseline-adjusted means.

(52.3% and 140.1%, respectively).

Relative to the Crest Cavity Protection Toothpaste group, the Sensodyne Rapid Relief Toothpaste group exhibited a statistically significant improvement in tactile hypersensitivity scores after four weeks of product use (57.6%).

Four-Week Clinical Data—Air Blast Hypersensitivity

Table VI presents a summary of the air blast hypersensitivity scores measured after four weeks of product use.

Comparisons versus Baseline. The mean four-week air blast hypersensitivity scores were 0.60 for the Colgate Sensitive Pro-Relief Toothpaste group, 1.44 for the Sensodyne Rapid Relief Toothpaste group, and 1.99 for the Crest Cavity Protection Toothpaste group. The percent changes from baseline were 76.0% for the Colgate Sensitive Pro-Relief Toothpaste group, 40.7% for the Sensodyne Rapid Relief Toothpaste group, and 16.0% for the Crest Cavity Protection Toothpaste group, all of which were statistically significant.

Comparison Between Treatment Groups. Relative to the Sensodyne Rapid Relief Toothpaste group and Crest Cavity Protection Toothpaste group, the Colgate Sensitive Pro-Relief Tooth-

paste group exhibited statistically significant reductions in air blast hypersensitivity scores after four weeks of product use (58.3% and 69.8%, respectively).

Relative to the Crest Cavity Protection Toothpaste group, the Sensodyne Rapid Relief Toothpaste group exhibited a statistically significant reduction in air blast hypersensitivity scores after four weeks of product use (27.6%).

Eight-Week Clinical Data—Tactile Hypersensitivity

Table VII presents a summary of the tactile hypersensitivity scores measured after eight weeks of product use.

Comparisons versus Baseline. The mean eight-week tactile hypersensitivity scores were 46.60 for the Colgate Sensitive Pro-Relief Toothpaste group, 36.30 for the Sensodyne Rapid Relief Toothpaste group, and 18.90 for the Crest Cavity Protection Toothpaste group. The percent changes from baseline were 301.7% for the Colgate Sensitive Pro-Relief Toothpaste group, 205.0% for the Sensodyne Rapid Relief Toothpaste group, and 56.2% for the Crest Cavity Protection Toothpaste group, all of which were statistically significant.

Table VI
Summary of the Four-Week Air Blast Hypersensitivity Scores for Subjects Who Completed the Eight-Week Clinical Study

Treatment	n	Four-Week Summary (Mean ± SD)	Within-Treatment Analysis		Between-Treatment Comparison			
			Percent Change ¹	Sig. ²	vs. Sensodyne Rapid Relief Toothpaste		vs. Crest Cavity Protection Toothpaste	
					Percent Difference ³	Sig. ⁵	Percent Difference ⁴	Sig. ⁵
Colgate Sensitive Pro-Relief* Toothpaste	50	0.60 ± 0.35	76.0%	p < 0.05	58.3%	p < 0.05	69.8%	p < 0.05
Sensodyne Rapid Relief Toothpaste	50	1.44 ± 0.39	40.7%	p < 0.05	—	—	27.6%	p < 0.05
Crest Cavity Protection Toothpaste	50	1.99 ± 0.38	16.0%	p < 0.05	—	—	—	—

*Also marketed as elmex Sensitive Professional.

¹Percent change exhibited by the four-week mean relative to the baseline mean. A positive value indicates a reduction in air blast hypersensitivity at the four-week examination.

²Significance of paired t-test comparing the baseline and the four-week examinations.

³Difference between the four-week means expressed as a percentage of the four-week mean for the Sensodyne Rapid Relief Toothpaste. A positive value indicates a reduction in air blast hypersensitivity scores relative to the Sensodyne Rapid Relief Toothpaste.

⁴Difference between the four-week means expressed as a percentage of the four-week mean for the Crest Cavity Protection Toothpaste. A positive value indicates a reduction in air blast hypersensitivity scores relative to the Crest Cavity Protection Toothpaste.

⁵Significance of ANCOVA comparison of baseline-adjusted means.

Table VII
Summary of the Eight-Week Tactile Hypersensitivity Scores for Subjects Who Completed the Eight-Week Clinical Study

Treatment	n	Eight-Week Summary (Mean ± SD)	Within-Treatment Analysis		Between-Treatment Comparison			
			Percent Change ¹	Sig. ²	vs. Sensodyne Rapid Relief Toothpaste		vs. Crest Cavity Protection Toothpaste	
					Percent Difference ³	Sig. ⁵	Percent Difference ⁴	Sig. ⁵
Colgate Sensitive Pro-Relief* Toothpaste	50	46.60 ± 3.97	301.7%	p < 0.05	28.4%	p < 0.05	146.6%	p < 0.05
Sensodyne Rapid Relief Toothpaste	50	36.30 ± 7.20	205.0%	p < 0.05	—	—	92.1%	p < 0.05
Crest Cavity Protection Toothpaste	50	18.90 ± 4.20	56.2%	p < 0.05	—	—	—	—

*Also marketed as elmex Sensitive Professional.

¹Percent change exhibited by the eight-week mean relative to the baseline mean. A positive value indicates an improvement in tactile hypersensitivity at the eight-week examination.

²Significance of paired t-test comparing the baseline and the eight-week examinations.

³Difference between the eight-week means expressed as a percentage of the eight-week mean for the Sensodyne Rapid Relief Toothpaste. A positive value indicates an improvement in tactile hypersensitivity scores relative to the Sensodyne Rapid Relief Toothpaste.

⁴Difference between the eight-week means expressed as a percentage of the eight-week mean for the Crest Cavity Protection Toothpaste. A positive value indicates an improvement in tactile hypersensitivity scores relative to the Crest Cavity Protection Toothpaste.

⁵Significance of ANCOVA comparison of baseline-adjusted means.

Comparison Between Treatment Groups. Relative to the Sensodyne Rapid Relief Toothpaste group and Crest Cavity Protection Toothpaste group, the Colgate Sensitive Pro-Relief Toothpaste group exhibited statistically significant improvements in tactile hypersensitivity scores after eight weeks of product use (28.4% and 146.6%, respectively).

Relative to the Crest Cavity Protection Toothpaste group, the Sensodyne Rapid Relief Toothpaste group exhibited a statistically significant improvement in tactile hypersensitivity scores after eight weeks of product use (92.1%).

Eight-Week Clinical Data—Air Blast Hypersensitivity

Table VIII presents a summary of the air blast hypersensitivity scores measured after eight weeks of product use.

Comparisons versus Baseline. The mean eight-week air blast hypersensitivity scores were 0.35 for the Colgate Sensitive Pro-Relief Toothpaste group, 0.89 for the Sensodyne Rapid Relief Toothpaste group, and 1.92 for the Crest Cavity Protection Toothpaste group. The percent changes from baseline were 86.0% for

the Colgate Sensitive Pro-Relief Toothpaste group, 63.4% for the Sensodyne Rapid Relief Toothpaste group, and 19.0% for the Crest Cavity Protection Toothpaste group, all of which were statistically significant.

Comparison Between Treatment Groups. Relative to the Sensodyne Rapid Relief Toothpaste group and Crest Cavity Protection Toothpaste group, the Colgate Sensitive Pro-Relief Toothpaste group exhibited statistically significant reductions in air blast hypersensitivity scores after eight weeks of product use (60.7% and 81.8%, respectively).

Relative to the Crest Cavity Protection Toothpaste group, the Sensodyne Rapid Relief Toothpaste group exhibited a statistically significant reduction in air blast hypersensitivity scores after eight weeks of product use (53.6%).

Discussion

This double-blind clinical study provided an investigative comparison of the efficacy of three commercially available toothpastes with respect to dentin hypersensitivity reduction after

Table VIII
Summary of the Eight-Week Air Blast Hypersensitivity Scores for Subjects Who Completed the Eight-Week Clinical Study

Treatment	n	Eight-Week Summary (Mean ± SD)	Within-Treatment Analysis		Between-Treatment Comparison			
			Percent Change ¹	Sig. ²	vs. Sensodyne Rapid Relief Toothpaste		vs. Crest Cavity Protection Toothpaste	
					Percent Difference ³	Sig. ⁵	Percent Difference ⁴	Sig. ⁵
Colgate Sensitive Pro-Relief* Toothpaste	50	0.35 ± 0.35	86.0%	p < 0.05	60.7%	p < 0.05	81.8%	p < 0.05
Sensodyne Rapid Relief Toothpaste	50	0.89 ± 0.38	63.4%	p < 0.05	—	—	53.6%	p < 0.05
Crest Cavity Protection Toothpaste	50	1.92 ± 0.36	19.0%	p < 0.05	—	—	—	—

*Also marketed as elmex Sensitive Professional.

¹Percent change exhibited by the eight-week mean relative to the baseline mean. A positive value indicates a reduction in air blast hypersensitivity at the eight-week examination.

²Significance of paired t-test comparing the baseline and eight-week examinations.

³Difference between the eight-week means expressed as a percentage of the eight-week mean for the Sensodyne Rapid Relief Toothpaste. A positive value indicates a reduction in air blast hypersensitivity scores relative to the Sensodyne Rapid Relief Toothpaste.

⁴Difference between the eight-week means expressed as a percentage of the eight-week mean for the Crest Cavity Protection Toothpaste. A positive value indicates a reduction in air blast hypersensitivity scores relative to the Crest Cavity Protection Toothpaste.

⁵Significance of ANCOVA comparison of baseline-adjusted means.

two, four, and eight weeks of at-home brushing, two times per day over an eight-week period.

Toothpastes have been widely used in the treatment of dentin hypersensitivity because of their low cost and ease of use for home application. The mechanism of action of a desensitizing toothpaste is either nerve depolarization (potassium-based toothpaste) or the obliteration of dentin tubules by the precipitation of insoluble deposits on the dentin surface. Potassium-based toothpastes, when used for several weeks, have been reported to alleviate the discomfort associated with dentin hypersensitivity. Although widely popular among dental professionals, the real efficacy of these potassium-based products is still open to question.⁶

The present study compared Colgate Sensitive Pro-Relief Toothpaste to Sensodyne Rapid Relief and Crest Cavity Protection Toothpastes regarding their clinical effectiveness in reducing dentin hypersensitivity after two, four, and eight weeks of twice-daily brushing. Relative to the Sensodyne Rapid Relief Toothpaste group and Crest Cavity Protection Toothpaste group, subjects assigned to the Colgate Sensitive Pro-Relief Toothpaste group exhibited superior efficacy, providing statistically significant improvements in tactile hypersensitivity scores after two weeks (41.7% and 66.9%, respectively), four weeks (52.3% and 140.1%, respectively), and eight weeks (28.4% and 146.6%, respectively).

The superior efficacy of Colgate Sensitive Pro-Relief was confirmed by the air blast sensitivity test results. Relative to the Sensodyne Rapid Relief Toothpaste group and Crest Cavity Protection Toothpaste group, subjects assigned to the Colgate Sensitive Pro-Relief Toothpaste group exhibited statistically significant reductions in air blast hypersensitivity scores after two weeks of twice-daily product use (24.9% and 28.9%, respectively), four weeks of twice-daily product use (58.3% and 69.8%, respectively), and eight weeks of twice-daily product use (60.7% and 81.8%, respectively).

Conclusion

Colgate Sensitive Pro-Relief Toothpaste, used twice daily, significantly reduces dentin hypersensitivity and is significantly more effective than Sensodyne Rapid Relief Toothpaste and Crest Cavity Protection Toothpaste. Colgate Sensitive Pro-Relief Toothpaste is the latest new tool in the armament of the modern dentist.

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References

1. Berman LH. Dentinal sensation and hypersensitivity. A review of mechanisms and treatment alternatives. *J Periodontol* 1985;56:216-22.
2. Ajcharanukul O, Kraivaphan P, Wanachantararak S, Vongsavan N, Matthews B. Effects of potassium ions on dentine sensitivity in man. *Arch Oral Biol* 2007;52:632-9.
3. Irvine JH. Root surface sensitivity: a review of aetiology and management. *J New Zealand Soc Periodontol* 1988;66:15-8.
4. Rapp R, Avery JK, Strachan DS. Possible role of the acetylcholinesterase in neural conduction within the dental pulp. In: *Biology of the Dental Pulp Organ*, Finn SB, ed. University of Alabama Press, Birmingham, pp. 309-11, 1968.
5. Brännström M, Åström A. A study on the mechanism of pain elicited by the dentin. *J Dent Res* 1964;43:619-25.
6. Pashley DH, Tay FR, Haywood VB, Collins MA, Drisko CL. Consensus-based recommendations for the diagnosis and management of dentin hypersensitivity. *Inside Dent* 2008;4(Spec Iss):1-35.
7. Markowitz K. The original desensitizers: Strontium and potassium salts. *J Clin Dent* 2009;20(Spec Iss):145-51.
8. Day T, Einwag J, Hermann JS, He T, Anastasia MK, Barker M, Zhang Y. A clinical assessment of the efficacy of a stannous-containing sodium fluoride dentifrice on dentinal hypersensitivity. *J Contemp Dent Pract* 2010;11:E001-8.
9. McFall WT, Morgan WC. Effectiveness of a dentifrice containing formalin and sodium monofluorophosphate on dental hypersensitivity. *J Periodontol* 1985;56:288-92.
10. Cummins D. Dentin hypersensitivity: from diagnosis to a breakthrough therapy for everyday sensitivity relief. *J Clin Dent* 2009;20(Spec Iss):1-9.
11. Panagakos F, Schiff T, Guignon A. Dentin hypersensitivity: effective treatment with an in-office desensitizing paste containing 8% arginine and calcium carbonate. *Am J Dent* 2009;22(Spec Iss A):3A-7A.
12. Petrou I, Heu R, Stranick M, Lavender S, Zaidel L, Cummins D, Sullivan RJ, Hsueh C, Girnzewski JK. A breakthrough therapy for dentin hypersensitivity: how dental products containing 8% arginine and calcium carbonate work to deliver effective relief of sensitive teeth. *J Clin Dent* 2009;20(Spec Iss):23-31.
13. Schiff T, Delgado E, Zhang YP, DeVizio W, Cummins D, Mateo LR. The clinical effect of a single direct topical application of a dentifrice containing 8.0% arginine, calcium carbonate, and 1450 ppm fluoride on dentin hypersensitivity: the use of a cotton swab applicator versus the use of a fingertip. *J Clin Dent* 2009;20(Spec Iss):131-6.
14. Schiff T, Dotson M, Cohen S, DeVizio W, McCool J, Volpe A. Efficacy of a dentifrice containing potassium nitrate, soluble pyrophosphate, PVM/MA copolymer, and sodium fluoride on dentinal hypersensitivity: A twelve-week clinical study. *J Clin Dent* 1994;5(Spec Iss):87-92.
15. Clark GE, Troullos ES. Designing hypersensitivity studies. *Dent Clin North Am* 1990;34:531-3.
16. Gillam DG, Bulman JS, Jackson RJ, Newman HN. Efficacy of a potassium nitrate mouthwash in alleviating cervical dentine sensitivity (CDS). *J Clin Periodontol* 1996;23:993-7.