Comparing the Efficacy in Reducing Dentin Hypersensitivity of a New Toothpaste Containing 8.0% Arginine, Calcium Carbonate, and 1450 ppm Fluoride to a Commercial Sensitive Toothpaste Containing 2% Potassium Ion: An Eight-Week Clinical Study in Rome, Italy

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Abstract

- **Objective:** This paper presents the results of one of two eight-week dentin hypersensitivity clinical studies in which the efficacy of a novel toothpaste containing 8.0% arginine, calcium carbonate, and 1450 ppm fluoride as sodium monofluorophosphate (MFP) was compared to that of a benchmark commercial toothpaste containing 2% potassium ion, dosed as 3.75% potassium chloride, and 1450 ppm fluoride as sodium fluoride (NaF).
- **Methods:** An eight-week clinical study, with eighty patients, was conducted in Rome, Italy using a double-blind, stratified, two-treatment design. Tactile sensitivity assessments, as well as air blast sensitivity assessments, were used to compare the efficacy of the two products.
- **Results:** This clinical study showed that the new toothpaste containing 8.0% arginine and 1450 ppm fluoride as MFP in a calcium carbonate base provided a significant reduction in dentin hypersensitivity when used over a period of eight weeks. The study also showed that this new arginine toothpaste provided significantly greater reductions ($p < 0.05$) in dentin hypersensitivity in response to tactile (37.0%, 30.0%, and 12.2%) and air blast (23.9%, 32.0%, and 29.3%) stimuli than the commercial sensitive toothpaste containing 2% potassium ion and 1450 ppm fluoride as NaF in a silica base, after two weeks, four weeks, and eight weeks of product use, respectively.
- **Conclusion:** A new toothpaste containing 8.0% arginine, calcium carbonate, and 1450 ppm fluoride as sodium monofluorophosphate (MFP) provides significantly increased dentin hypersensitivity relief ($p < 0.05$) compared to a commercial sensitive toothpaste containing 2% potassium ion after two weeks, four weeks, and eight weeks of product use.

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Introduction

Dentin hypersensitivity is distinguished as a sudden pain arising from exposed dentin that cannot be explained by any other form of dental pathology. This pain is generally triggered by an external stimulus, such as a thermal (cold temperature), tactile (toothbrush or dental instrument), osmotic (sweet), or evaporative (air blast) stimulus.[1] Dentin hypersensitivity is a common problem in adult populations, and it may well increase as people live and maintain their dentitions longer. As a consequence, there is a significant demand on dental professionals to manage dentin hypersensitivity, as well as address any secondary issues that may arise from its associated discomfort. More specifically, dentin hypersensitivity may render tooth brushing very difficult in some individuals, with the result that persistent and continued accumulation of dental plaque in hypersensitive areas may increase the risk of cavities, gingival inflammation, and further periodontal

problems.[2] Dentin hypersensitivity is a common problem in patients with chronic periodontal disease because the root surface can become exposed as part of the disease process, or as a result of periodontal treatment. In fact, dentin hypersensitivity occurs most frequently in the cervical area of the root, where the cementum is very thin. Periodontal procedures, such as scaling and root planing, may entirely remove this thin cementum layer and induce hypersensitivity.

Several theories have been proposed over the years to explain the mechanism of dentin hypersensitivity.[3,4] Whereas each of these theories has been scientifically investigated, the hydrodynamic theory is the only one that has stood the test of time and, as such, is generally favored by the dental community to explain hypersensitivity. In essence, the hydrodynamic theory[5] (modified by Brännström[6] in 1963) attributes fluid movement within exposed dentin tubules to the transmission of painful sensations. Specifically, non-noxious stimuli at the tooth surface can trigger fluid movement within the dentin tubules affecting the pulpal mechanoreceptors and resulting in the sensation of pain. In 1994, Nähri, *et al*.[7] added to the hydrodynamic theory by suggesting that the perception and sensation of pain are directly related to the stimulation of the nerves within the pulp via electrical current.

Regardless of the etiology, the problem of dentin hypersensitivity needs to be addressed in order to provide patients with improved oral comfort and quality of life. The clinical management of the condition varies widely from products that are applied by the dental professional in office, such as varnishes (resins), to everyday home-use products, the most common of which are desensitizing toothpastes. The products share the same goal: to relieve the patient's discomfort. One approach to accomplish this goal is to limit the possibility of fluid displacement within dentin tubules (decrease hydrodynamic flow) by reducing the diameter of exposed tubules, blocking neurotransmission, and decreasing the response to painful stimuli. According to Trowbridge and Silver,[8] this could be achieved by forming a smear layer on the exposed dentin, either by the use of topical agents that form insoluble precipitates within the tubules, or by blocking the entrance to tubules with plastic resins. Another approach, which has become popular and convenient for the patient, is the use of potassium salts in desensitizing toothpastes. Potassium nitrate, potassium citrate, and potassium chloride have each been used extensively and universally as desensitizing agents. Clinical and mechanism of action studies have shown that 2% potassium ion is the active entity, and this can be dosed as any one of the three commonly used salts. In effect, the potassium ion is believed to have a depolarizing effect on electrical nerve conduction, causing nerve fibers to be less excitable to external stimuli,[9] thereby reducing the patient's sensation of pain.

Arginine, an amino acid, has been studied by Kleinberg and coworkers for its potential oral health benefits. Specifically, a combination of arginine bicarbonate and calcium carbonate has been shown to deposit on exposed dentin surfaces to physically block and seal open dentin tubules.[10] This concept has recently been further evaluated by the Colgate-Palmolive Company, and a novel toothpaste was developed containing 8% arginine in a calcium carbonate base, with 1450 ppm fluoride as sodium monofluorophosphate. Clinical studies have demonstrated that this toothpaste is highly efficacious in reducing dentin hypersensitivity, and *in vitro* mechanism of action studies have shown that this novel technology works by occluding dentin tubules.[11]

The objective of this clinical study was to compare the efficacy in reducing dentin hypersensitivity of a new toothpaste containing 8.0% arginine and 1450 ppm fluoride as MFP in a calcium carbonate base (Colgate-Palmolive Co., New York, NY, USA; Test Dentifrice) to a commercial sensitive toothpaste containing 2% potassium ion, as 3.75% potassium chloride, and 1450 ppm fluoride as NaF in a silica base (Sensodyne® Total Care F toothpaste, GlaxoSmithKline, Middlesex, UK; Control Dentifrice) over an eight-week period. This study essentially replicates an eight-week clinical study conducted in Canada, which was reported in the previous paper in this issue.[12]

Materials and Methods

This eight-week, single-center, parallel-group, double-blind, stratified, and randomized clinical study was conducted in a private practice setting in Rome, Italy. Subjects were recruited from the patient population in a nearby hospital, as well as by advertisement. Eighty patients (24 males and 56 females with a mean age of 42.2 ± 10.6 years) were selected based on the following criteria:

- Subjects had to be between 18 and 70 years of age, in generally good health, with no history of allergies or idiosyncrasies to dentifrice ingredients.
- Subjects were required to possess a minimum of two hypersensitive teeth which were anterior to the molars, demonstrated cervical erosion/abrasion or gingival recession, and for which a tactile hypersensitivity stimulus score of 10 to 50 grams of force (Yeaple probe) and an air blast stimulus score of 2 or 3 (Schiff Cold Air Sensitivity Scale) were presented at the baseline examination.
- Subjects needed to be available for the duration of the study, and to sign an informed consent form.
- Teeth that were abutments for partial dentures, and teeth exhibiting extensive or defective restorations, caries, fractures, excessive mobility, or suspected pulpal pathology were not included in the study.
- Subjects who had orthodontic appliances, more than one incisor with a prosthetic crown or veneer, tumors of the soft or hard oral tissues, moderate or advanced periodontal disease, or more than one carious lesion were excluded from the study.
- Subjects were also excluded from the study if they were concurrently using medications, including analgesics with a potential to mask pain sensation, or if they had used commercially available desensitizing agents within the three months prior to the study.
- Pregnant women and individuals who were participating in another clinical trial were also excluded.

Qualifying subjects were stratified according to baseline tactile and air blast sensitivity scores and were randomly assigned within strata to one of the following two study treatments: the new toothpaste containing 8% arginine, calcium carbonate, and 1450 ppm fluoride, or Sensodyne Total Care F toothpaste. Both toothpastes were provided in original tubes, over-wrapped with

opaque white paper to ensure the double-blind design. Subjects were also given a soft bristle toothbrush, and instructed to brush their teeth twice a day (morning and evening) for one minute each time. A log of the dispensed products was kept, and all clinical supplies were refurbished as needed.

After the baseline evaluation, the subjects were re-evaluated at two, four, and eight weeks. At each time point, they received a thorough oral examination of their hard and soft tissues, followed by a careful evaluation of their dentin hypersensitivity using the Yeaple probe and the air/water syringe.

All examinations were performed by the same investigator throughout the study.

Tactile Sensitivity Assessment

This assessment was conducted using a calibrated Model 200A Yeaple Electronic Pressure Sensitive Probe (Yeaple Research, Pittsford, NY, USA). Scores were recorded in terms of a quantified, reproducible force (grams).[13-15] After presetting the initial force to 10 grams, the probe tip was passed over the exposed dentin on the buccal surface of the selected teeth, apical to the cemento-enamel junction. Subsequent passes were made, each time with the applied force increased by 10 grams until the subject indicated that he/she was experiencing discomfort, or until the maximum force of 50 grams was reached. A force of 50 grams was considered the cut-off point; higher scores on this index correspond to lower levels of dentin hypersensitivity.

Air Blast Sensitivity Assessment

This assessment was conducted by directing a one-second blast of air onto the exposed buccal root surface of the sensitive tooth, from a distance of one centimeter using the air component of a dental air/water syringe. After shielding the adjacent proximal teeth from the air blast through the placement of two fingers, the air blast was applied with a pressure of 60 p.s.i. (± 5 p.s.i) and a temperature of 70°F (± 3°F) for one second.

Sensitivity was recorded in accordance with the air sensitivity scale described by Schiff, *et al.*[15] as follows:

0 = Tooth/Subject sensitivity does not respond to air stimulation;
1 = Tooth/Subject respond to air stimulus, but does not request discontinuation of stimulus;
2 = Tooth/Subject responds to air stimulus, and requests discontinuation or moves from stimulus;
3 = Tooth/Subject responds to stimulus, considers stimulus to be painful, and requests discontinuation of the stimulus.

Only teeth with a score of 2 or 3 were selected at the baseline examination; the higher the score, the higher the sensitivity.

Statistical Methods

Statistical analyses were performed separately for the tactile sensitivity assessments and air blast sensitivity assessments, respectively. Comparisons of the treatment groups with respect to baseline tactile scores and air blast scores were performed using an independent t-test. Within-treatment comparisons of the baseline versus follow-up tactile sensitivity and air blast sensitivity scores were performed using paired t-tests. Comparisons of the treatment groups with respect to baseline-adjusted tactile sensitivity and air blast sensitivity scores at the follow-up examinations were performed using Analyses of Covariance (ANCOVA). All statistical tests of hypothesis were two-sided, and employed a level of significance of $\alpha = 0.05$.

Results

All eighty (80) subjects who were enrolled at baseline complied with the protocol and completed the eight-week clinical study. A summary of the baseline sensitivity data is presented in Table I. The treatment groups did not differ significantly with respect to either tactile or air blast scores at baseline.

Throughout the study, there were no adverse events on the soft or hard tissues of the oral cavity which were observed by the examiner, or reported by the subjects when questioned.

This double-blind clinical study provided an investigative comparison of the efficacy of two dentifrices with respect to the dentin hypersensitivity scores over an eight-week period.

After two, four, and eight weeks of dentifrice use (Tables II, IV, and VI), subjects assigned to the Test Dentifrice group (the

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

Parameter	Treatment	n	Sensitivity Scores (Mean ± SD)[3]
Tactile Sensitivity	Test Dentifrice[1]	40	12.13 ± 3.74
	Control Dentifrice[2]	40	13.63 ± 4.38
Air Blast Sensitivity	Test Dentifrice[1]	40	2.49 ± 0.37
	Control Dentifrice[2]	40	2.51 ± 0.40

[1] Colgate toothpaste containing 8.0% arginine and 1450 ppm fluoride as MFP in a calcium carbonate base.
[2] Sensodyne Total Care F toothpaste containing 2% potassium ion as 3.75%, potassium chloride, and 1450 ppm fluoride as NaF in a silica base.
[3] No statistically significant difference was indicated between the two treatment groups at baseline with respect to either mean tactile sensitivity or mean air blast sensitivity scores.

Table II
Summary of the Two-Week Baseline-Adjusted Mean Tactile Sensitivity Scores for Subjects Who Completed the Eight-Week Clinical Study

		Baseline-adjusted Tactile Sensitivity Scores	Within Treatment Analysis		Between Treatment Comparison	
Treatment	n	(Mean ± SD)	Percent Change[3]	Sig.[4]	Percent Difference[5]	Sig.[6]
Test Dentifrice[1]	40	26.45 ± 6.99	105.4%	$p < 0.05$	37.0%	$p < 0.05$
Control Dentifrice[2]	40	19.30 ± 6.99	49.8%	$p < 0.05$		

[1] Colgate toothpaste containing 8.0% arginine and 1450 ppm fluoride as MFP in a calcium carbonate base.
[2] Sensodyne Total Care F toothpaste containing 2% potassium ion as 3.75%, potassium chloride, and 1450 ppm fluoride as NaF in a silica base.
[3] Percent change exhibited by the two-week baseline-adjusted mean relative to the baseline mean. A positive value indicates an improvement in tactile sensitivity at the two-week examination.
[4] Significance of paired t-test comparing the baseline and two-week examinations.
[5] Difference between two-week baseline-adjusted means expressed as a percentage of the two-week baseline-adjusted mean for the Control Dentifrice. A positive value indicates an improvement in tactile sensitivity for the Test Dentifrice containing 8.0% arginine relative to the Control Dentifrice.
[6] Significance of ANCOVA comparison of baseline-adjusted means.

Table III
Summary of the Two-Week Baseline-Adjusted Mean Air Blast Sensitivity Scores for Subjects Who Completed the Eight-Week Clinical Study

Treatment	n	Baseline-adjusted Air Blast Sensitivity Scores (Mean ± SD)	Within Treatment Analysis: Percent Change[3]	Sig.[4]	Between Treatment Comparison: Percent Difference[5]	Sig.[6]
Test Dentifrice[1]	40	1.65 ± 0.51	34.0%	$p < 0.05$	23.9%	$p < 0.05$
Control Dentifrice[2]	40	2.17 ± 0.51	13.4%	$p < 0.05$		

[1] Colgate toothpaste containing 8.0% arginine and 1450 ppm fluoride as MFP in a calcium carbonate base.
[2] Sensodyne Total Care F toothpaste containing 2% potassium ion as 3.75%, potassium chloride, and 1450 ppm fluoride as NaF in a silica base.
[3] Percent change exhibited by the two-week baseline-adjusted mean relative to the baseline mean. A positive value indicates an improvement in air blast sensitivity at the two-week examination.
[4] Significance of paired t-test comparing the baseline and two-week examinations.
[5] Difference between two-week baseline-adjusted means expressed as a percentage of the two-week baseline-adjusted mean for the Control Dentifrice. A positive value indicates an improvement in air blast sensitivity for the Test Dentifrice containing 8.0% arginine relative to the Control Dentifrice.
[6] Significance of ANCOVA comparison of baseline-adjusted means.

Table IV
Summary of the Four-Week Baseline-Adjusted Mean Tactile Sensitivity Scores for Subjects Who Completed the Eight-Week Clinical Study

Treatment	n	Baseline-adjusted Tactile Sensitivity Scores (Mean ± SD)	Within Treatment Analysis: Percent Change[3]	Sig.[4]	Between Treatment Comparison: Percent Difference[5]	Sig.[6]
Test Dentifrice[1]	40	40.98 ± 7.87	218.2%	$p < 0.05$	30.0%	$p < 0.05$
Control Dentifrice[2]	40	31.52 ± 7.87	144.7%	$p < 0.05$		

[1] Colgate toothpaste containing 8.0% arginine and 1450 ppm fluoride as MFP in a calcium carbonate base.
[2] Sensodyne Total Care F toothpaste containing 2% potassium ion as 3.75%, potassium chloride, and 1450 ppm fluoride as NaF in a silica base.
[3] Percent change exhibited by the four-week baseline-adjusted mean relative to the baseline mean. A positive value indicates an improvement in tactile sensitivity at the four-week examination.
[4] Significance of paired t-test comparing the baseline and four-week examinations.
[5] Difference between four-week baseline-adjusted means expressed as a percentage of the four-week baseline-adjusted mean for the Control Dentifrice. A positive value indicates an improvement in tactile sensitivity for the Test Dentifrice containing 8.0% arginine relative to the Control Dentifrice.
[6] Significance of ANCOVA comparison of baseline-adjusted means.

new toothpaste with 8% arginine, calcium carbonate, and 1450 ppm fluoride) exhibited statistically significant improvements from baseline in baseline-adjusted mean tactile sensitivity scores of 105.4%, 218.2%, and 252.2%, respectively. Additionally, after two, four, and eight weeks of dentifrice use (Tables III, V, and VII), subjects assigned to the Test Dentifrice group exhibited statistically significant reductions from baseline in baseline-adjusted mean air blast sensitivity scores of 34.0%, 63.4%, and 80.5%, respectively.

After two, four, and eight weeks of dentifrice use (Tables II, IV, and VI), subjects assigned to the Control Dentifrice group (Sensodyne Total Care F) exhibited statistically significant improvements from baseline in baseline-adjusted mean tactile sensitivity scores of 49.8%, 144.7%, and 214.2%, respectively.

Table V
Summary of the Four-Week Baseline-Adjusted Mean Air Blast Sensitivity Scores for Subjects Who Completed the Eight-Week Clinical Study

Treatment	n	Baseline-adjusted Air Blast Sensitivity Scores (Mean ± SD)	Within Treatment Analysis: Percent Change[3]	Sig.[4]	Between Treatment Comparison: Percent Difference[5]	Sig.[6]
Test Dentifrice[1]	40	0.92 ± 0.56	63.4%	$p < 0.05$	32.0%	$p < 0.05$
Control Dentifrice[2]	40	1.35 ± 0.56	46.1%	$p < 0.05$		

[1] Colgate toothpaste containing 8.0% arginine and 1450 ppm fluoride as MFP in a calcium carbonate base.
[2] Sensodyne Total Care F toothpaste containing 2% potassium ion as 3.75%, potassium chloride, and 1450 ppm fluoride as NaF in a silica base.
[3] Percent change exhibited by the four-week baseline-adjusted mean relative to the baseline mean. A positive value indicates an improvement in air blast sensitivity at the four-week examination.
[4] Significance of paired t-test comparing the baseline and four-week examinations.
[5] Difference between four-week baseline-adjusted means expressed as a percentage of the four-week baseline-adjusted mean for the Control Dentifrice. A positive value indicates an improvement in air blast sensitivity for the Test Dentifrice containing 8.0% arginine relative to the Control Dentifrice.
[6] Significance of ANCOVA comparison of baseline-adjusted means.

Table VI
Summary of the Eight-Week Baseline-Adjusted Mean Tactile Sensitivity Scores for Subjects Who Completed the Eight-Week Clinical Study

Treatment	n	Baseline-adjusted Tactile Sensitivity Scores (Mean ± SD)	Within Treatment Analysis: Percent Change[3]	Sig.[4]	Between Treatment Comparison: Percent Difference[5]	Sig.[6]
Test Dentifrice[1]	40	45.40 ± 5.30	252.5%	$p < 0.05$	12.2%	$p < 0.05$
Control Dentifrice[2]	40	40.47 ± 5.30	214.2%	$p < 0.05$		

[1] Colgate toothpaste containing 8.0% arginine and 1450 ppm fluoride as MFP in a calcium carbonate base.
[2] Sensodyne Total Care F toothpaste containing 2% potassium ion as 3.75%, potassium chloride, and 1450 ppm fluoride as NaF in a silica base.
[3] Percent change exhibited by the eight-week baseline-adjusted mean relative to the baseline mean. A positive value indicates an improvement in tactile sensitivity at the eight-week examination.
[4] Significance of paired t-test comparing the baseline and eight-week examinations.
[5] Difference between eight-week baseline-adjusted means expressed as a percentage of the eight-week baseline-adjusted mean for the Control Dentifrice. A positive value indicates an improvement in tactile sensitivity for the Test Dentifrice containing 8.0% arginine relative to the Control Dentifrice.
[6] Significance of ANCOVA comparison of baseline-adjusted means.

Additionally, after two, four, and eight weeks of dentifrice use (Tables III, V, and VII), subjects assigned to the Control Dentifrice group exhibited statistically significant reductions from baseline in baseline-adjusted mean air blast sensitivity scores of 13.4%, 46.1%, and 72.5%, respectively.

Relative to the Control Dentifrice group, after two, four, and eight weeks of dentifrice use, the Test Dentifrice group exhibited statistically significant improvements in baseline-adjusted mean tactile sensitivity scores of 37.0%, 30.0%, and 12.2%, respectively. Relative to the Control Dentifrice group, after two, four, and eight weeks of dentifrice use, the Test Dentifrice group exhibited statistically significant reductions in baseline-adjusted mean air blast sensitivity scores of 23.9%, 32.0%, and 29.3%, respectively.

Table VII
Summary of the Eight-Week Baseline-Adjusted Mean Air Blast Sensitivity Scores for Subjects Who Completed the Eight-Week Clinical Study

Treatment	n	Baseline-adjusted Air Blast Sensitivity Scores (Mean ± SD)	Within Treatment Analysis		Between Treatment Comparison	
			Percent Change[3]	Sig.[4]	Percent Difference[5]	Sig.[6]
Test Dentifrice[1]	40	0.49 ± 0.39	80.5%	$p < 0.05$	29.3%	$p < 0.05$
Control Dentifrice[2]	40	0.69 ± 0.39	72.5%	$p < 0.05$		

[1] Colgate toothpaste containing 8.0% arginine and 1450 ppm fluoride as MFP in a calcium carbonate base.
[2] Sensodyne Total Care F toothpaste containing 2% potassium ion as 3.75%, potassium chloride, and 1450 ppm fluoride as NaF in a silica base.
[3] Percent change exhibited by the eight-week baseline-adjusted mean relative to the baseline mean. A positive value indicates an improvement in air blast sensitivity at the eight-week examination.
[4] Significance of paired t-test comparing the baseline and eight-week examinations.
[5] Difference between eight-week baseline-adjusted means expressed as a percentage of the eight-week baseline-adjusted mean for the Control Dentifrice. A positive value indicates an improvement in air blast sensitivity for the Test Dentifrice containing 8.0% arginine relative to the Control Dentifrice.
[6] Significance of ANCOVA comparison of baseline-adjusted means.

Discussion

Dentin hypersensitivity is a significant problem and a "quality of life" concern for many individuals. It is characterized by a sharp, transient pain which occurs in response to a sensory stimulus that affects eating, drinking, brushing teeth, and breathing.[16] This painful condition affects nearly 40 million Americans,[17] and can be seen in all age groups.[18] Epidemiology research suggests that prevalence peaks between 30 and 40 years of age, and that women experience a higher incidence of dentin hypersensitivity at a younger age than men.[18] Patients who have received periodontal therapy are four times more likely to develop hypersensitivity then the general population.[19] This is because gingival recession and exposed root surfaces occur as a result of periodontal disease and its associated therapy. The cementum on these exposed roots is partially or totally removed during scaling and root planing, with the result that the dentin tubules are exposed to the oral environment. Any change in fluid pressure within the tubule is detected by the odontoblast, the nerve becomes polarized, and the patient feels pain.

The treatment choices available to relieve dentin hypersensitivity are to occlude the dentin tubules or to desensitize the nerves so that they are not responsive to stimulation. Potassium salts have been added to dentifrices as sensitivity-reducing agents for many years. A number of clinical studies have demonstrated that toothpastes containing 2% potassium ion, as potassium nitrate, potassium citrate, and potassium chloride, are more effective in reducing dentin hypersensitivity than a regular fluoride toothpaste,[20] yet the detailed mechanism of action of potassium ions is not fully elucidated. It is believed that delivering and maintaining a high concentration of extracellular potassium ion deep in the dentin tubules and around the nerve endings causes depolarization of nerve fiber membranes and prevents repolarization.[9]

A second route that has been investigated by the dental research community is to occlude dentin tubules or reduce their diameter with a technology that coats the dentin surface and blocks the tubules, such as a varnish or material which precipitates *in situ*, such as calcium phosphate.[21] This approach impairs or limits the displacement of fluids in the dentin tubule, *i.e.*, hydrodynamic flow and the blockage of painful stimuli. While several *in vitro* studies have shown occlusion of dentinal tubules with calcium phosphate,[21-24] there is a paucity of clinical data proving efficacy *in vivo*.

An essential amino acid, arginine, first isolated from a lupin seedling extract in 1886 by the Swiss chemist Ernst Schultze, has been investigated in combination with bicarbonate and calcium carbonate for its ability to occlude dentin tubules and reduce pain from dentin hypersensitivity.[10] This technology has recently been further developed and formulated into a toothpaste containing 8% arginine, calcium carbonate, and 1450 ppm fluoride as sodium monofluorophosphate.[20]

The results of the present clinical investigation confirm the results of a previous study conducted in Canada.[12] It shows that a new toothpaste containing 8% arginine, calcium carbonate, and 1450 ppm fluoride as sodium monofluorophosphate, and Sensodyne Total Care F toothpaste, containing 2% potassium ion as potassium chloride, both provide significant reductions in dentin hypersensitivity when used twice daily for a period of eight weeks. More importantly, this double-blind clinical study clearly shows that this new arginine toothpaste provides significantly superior control of dentin hypersensitivity ($p < 0.05$) compared to Sensodyne Total Care F toothpaste, after two, four and eight weeks of use.

The clinical results reported in this study, together with the results of the study conducted in Canada and reported in the previous paper in this issue,[12] confirm the superior efficacy of a new toothpaste containing 8% arginine, calcium carbonate, and 1450 ppm fluoride in treating dentin hypersensitivity compared to Sensodyne Total Care F toothpaste.

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