

Comparative efficacy of two treatment regimens combining in-office and at-home programs for dentin hypersensitivity relief: A 24-week clinical study

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ABSTRACT: Purpose: Dentin hypersensitivity is a significant clinical problem that affects numerous individuals. This sharp pain, arising from exposed dentin in response to external stimuli, can be a particularly uncomfortable and unpleasant sensation for patients, because it interferes with their quality of life. The objective of this 24-week, single-center, parallel group, double-blind, stratified and randomized clinical study was to evaluate the clinical efficacy of a single professional treatment with an in-office desensitizing paste followed by twice daily brushing with a desensitizing toothpaste and toothbrush for 24 weeks. **Methods:** 100 adults with confirmed dentin hypersensitivity were randomly assigned into two groups. One group received a single in-office treatment with a desensitizing paste containing 8% arginine and calcium carbonate (marketed as Colgate Sensitive Pro-Relief Desensitizing Paste and Elmex Sensitive Professional desensitizing paste), after dental scaling, followed by 24 weeks of brushing twice daily with a desensitizing toothpaste containing 8% arginine, calcium carbonate with 1450 ppm fluoride as MFP (marketed as Colgate Sensitive Pro-Relief toothpaste and Elmex Sensitive Professional toothpaste) and using the Colgate Sensitive Pro-Relief toothbrush (Test Group). The other group received a single in-office treatment with Nupro-M pumice prophylaxis paste, after dental scaling, followed by 24 weeks of brushing twice daily with a non-desensitizing toothpaste containing 1450 ppm fluoride as MFP and with the Oral-B Indicator toothbrush (Negative Control Group). Hypersensitivity was re-examined immediately after in-office product application and after 8 and 24 weeks of twice daily brushing. **Results:** Immediately after professional product application, and after 8 and 24 weeks, subjects assigned to the Test Group demonstrated statistically significant improvements in dentin hypersensitivity compared to subjects assigned to the Negative Control Group in tactile (49.8%, 57.5% and 32.9%, respectively) and air blast (26.0%, 38.4% and 34.3%, respectively) sensitivity scores. The instant reductions in dentin hypersensitivity provided by the single professional application of a desensitizing paste for in-office use, containing 8% arginine and calcium carbonate were maintained by twice daily brushing with the 8% arginine, calcium carbonate toothpaste with 1450 ppm fluoride as MFP and the Colgate Sensitive Pro-Relief toothbrush for at least 24 weeks. (*Am J Dent* 2012;25:146-152).

CLINICAL SIGNIFICANCE: Based on these clinical results, this novel strategy that uses a two prong regimen to treat dentin hypersensitivity could be a new tool for the dental team in the effective management of this painful condition.

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Introduction

Dentin hypersensitivity has been defined as a short pain arising from exposed dentin in response to stimuli typically thermal, evaporative, tactile, osmotic or chemical and which cannot be ascribed to any form of dental defect or pathology.¹ Dentin hypersensitivity is a painful clinical condition affecting a large part of the population (up to 57%) and associated with exposure of dentin to the oral cavity.^{2,3} It is manifested in a manner that is quite uncomfortable for the patient and it is often described as acute pain of short duration caused by the presence of open dentin tubules on an exposed dentin surface.⁴ This pain is triggered by a variety of stimuli, the most common being the exposure to cold. Pain may also occur by chemical stimuli (acidic food, drinks, etc.) or mechanical stimuli (fingernail, toothbrush bristles, dentist's explorer probe, etc.).⁵ Many theories have been used to explain the mechanism of dentin hypersensitivity. The most commonly accepted is the "hydro-dynamic theory" proposed by Brännström & Åström⁶ in 1964. According to this theory, the presence of a lesion involving the loss of enamel or cementum in the cervical area and the opening of the dentin tubules to the oral aggressions allows the

movement of dentin fluid inside the tubules. This indirectly stimulates the extremities of the pulp nerves, causing the pain sensation. There are also some anatomical variations existing between sensitive and non-sensitive dentin. The sensitive dentin presents widened dentin tubules, two times larger when compared with tubules of normal dentin and in a greater number per area when compared with the dentin without sensitivity.⁷

Clinical management of dentin hypersensitivity is based on a proper diagnosis. A correct anamnesis, associated with a careful clinical and radiographic examination, allows dentin hypersensitivity to be differentiated from other pathologies that affect the teeth. Accurate diagnosis is extremely important because the history may be confused with symptomatology associated with incipient caries, defective restorations, pulpal pathology and complete or green-stick fractures of the teeth.⁵ Once the diagnosis is established, there have been traditionally two approaches to treatment, depending on the severity of the symptoms. The first and most conservative approach consists of having the patient use a desensitizing toothpaste (often containing potassium salts) on a twice daily basis until the symptoms subside. This has been widely popular as dentifrices

have the advantage of being readily available products for at-home treatment. The disadvantage is that it takes time for the symptoms to subside (usually 4 weeks). The second approach, if the symptoms persist, is to have the patient come to the dental clinic for an "in-office treatment"⁸ aimed at closing the dentin tubules with one of a number of treatments (varnishes, precipitating agents, resins, etc.). Such treatments, albeit potentially effective, typically have limited efficacy over time and need to be repeated. The recently made available Pro-Argin³ technology is a treatment alternative, using the combination of 8% arginine and calcium carbonate, which has been shown to occlude open dentin tubules, and by so doing has been proven to treat the cause of dentin hypersensitivity (open tubules).⁹⁻¹³ This technology has been formulated into a desensitizing paste for in-office use and a toothpaste for daily at-home use.

This study evaluated the use of a two prong approach in the treatment of dentin hypersensitivity: an initial single professional treatment with the in-office desensitizing paste containing 8% arginine and calcium carbonate, followed by twice daily brushing with an anti-sensitivity toothbrush and the dentifrice containing 8% arginine and calcium carbonate with 1450 ppm fluoride as MFP.

Materials and Methods

This 24-week, single-center, parallel group, double-blind, stratified and randomized clinical study was conducted in Yardley, Pennsylvania. Ninety-five subjects (30 males, 65 females, age range 21-67 years) completed the 24-week clinical exam out of 100 subjects enrolled for voluntary participation in the trial. Participants were selected based on the following criteria:

1. Subjects had to be between the ages of 18-70 (inclusive), and in generally good health.
2. Subjects were required to possess a minimum of two hypersensitive teeth which were anterior to the molars and demonstrated cervical erosion/abrasion or gingival recession; and for which a tactile stimulus-induced hypersensitivity score of 10-50 grams of force (Yeaple Probe^a) and an air blast stimulus-induced hypersensitivity score of 2 or 3 (Schiff Cold Air Sensitivity Scale) were presented at the baseline examination.
3. Subjects were required to be available for the 24-week duration of the study, and to sign an informed consent form.
4. Subjects were excluded from the study if they had gross oral pathology, chronic disease, advanced periodontal disease, treatment for periodontal disease (within the last 12 months), or hypersensitive teeth with a mobility greater than 1. Also excluded from the study were subjects with teeth that had extensive/defective restorations (including prosthetic crowns), suspected pulpitis, caries, cracked enamel or that were used as abutments for removable partial dentures were also excluded from the study.
5. Subjects were excluded from the study if they began to take anticonvulsants, antihistamines, antidepressants, sedatives, tranquilizers, anti-inflammatory drugs, or daily analgesics within 1 month prior to the start of the study or who had to start taking these during the course of the study.
6. Pregnant or lactating women, individuals who were participating in any other clinical study or who had participated in a desensitizing dentifrice study or who used a desensitizing dentifrice within the last 3 months, were not allowed to participate in the study.
7. Subjects with a history of allergy to the test products, or allergies to oral care/personal care consumer products or their ingredients, or subjects with existing medical conditions, which precluded them from not eating and drinking for periods up to 4 hours, were also excluded from the study.

The enrolled subjects reported to the clinical facility having refrained from all oral hygiene procedures, chewing gum for 8 hours, and eating and drinking for 4 hours prior to their examination. All subjects who met the inclusion/exclusion criteria and signed an informed consent form received a baseline tactile hypersensitivity and an air blast hypersensitivity evaluation, along with an oral soft and hard tissue assessment.

For each subject who qualified for participation in the study, two hypersensitive teeth that satisfied the tactile and air blast hypersensitivity enrollment criteria were identified for evaluation throughout the study. Qualifying subjects were stratified based on baseline tactile and air blast hypersensitivity scores and randomly assigned within strata to one of the two study groups.

Test Group - Subjects received a professionally-administered scaling procedure followed by in-office application of a fluoride-free desensitizing paste containing 8% arginine and calcium carbonate (Colgate Sensitive Pro-Relief Desensitizing Paste^b and Elmex Sensitive Professional^b desensitizing paste). In-office treatment consisted of two consecutive 3-second applications of the product using a rotating prophylaxis cup aimed at the gingivo-facial third of the teeth. At the end of the appointment, subjects were instructed to brush twice daily for 1 minute, for 24 weeks, using an 8% arginine and calcium carbonate toothpaste with 1,450 ppm fluoride as MFP (Colgate Sensitive Pro-Relief toothpaste and Elmex Sensitive Professional toothpaste) and a soft bristle anti-sensitivity toothbrush (Colgate 360° Sensitive Pro-Relief Toothbrush^b).

Negative Control Group - Subjects received a professionally-administered scaling procedure followed by in-office application of a pumice based fluoride-free prophylaxis paste (Nupro-M^c). In-office treatment consisted of two consecutive 3-second applications of the product using a rotating prophylaxis cup aimed at the gingivo-facial third of the teeth. At the end of the appointment, subjects were instructed to brush twice daily for 1 minute, for 24 weeks, using a toothpaste with 1,450 ppm fluoride as MFP (Colgate Cavity Protection toothpaste) and the Oral-B Indicator^d toothbrush.

In-office pastes and take home toothpastes were supplied to the clinical site covered with white overwrapping and toothbrushes were supplied in individual white boxes. All products were labeled with a study group code. A log of the dispensed products was kept and all clinical supplies were replenished as needed. Tactile and air-blast stimulated dentin hypersensitivity, and oral hard and soft tissue condition, were assessed at baseline, immediately after professional application of the in-

Table 1. Summary of age and gender for subjects who completed the 24-week clinical study.

Treatment	Number of subjects			Age ¹	
	Male ¹	Female ¹	Total	Mean	Range
Test Group	15	31	46	45.0	21-67
Negative Control Group	15	34	49	44.9	23-66

¹ No statistically significant difference was indicated between the two treatment groups with respect to either gender or age.

office product (Instant Relief Examination), and after 8 weeks and 24 weeks of toothpaste use.

Subjects were asked to refrain from all oral hygiene procedures and chewing gum for 8 hours, and eating and drinking for 4 hours prior to each examination.

All examinations were performed by the same dental examiner, using the same procedures as employed at baseline.

Tactile hypersensitivity assessment - Tactile hypersensitivity was assessed by use of the Yeaple Model 200A electronic force sensing probe. The application of this probe for dental hypersensitivity testing utilizing a #19 explorer tip at a pre-set force measured in grams was employed.

Teeth were evaluated for tactile hypersensitivity^{14,15} in the following manner:

1. The subject was instructed to respond at the point where he/she first experienced discomfort.
2. The explorer tip of the probe was applied to the buccal surface of each hypersensitive tooth at the CEJ.
3. 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 a force of 50 grams was applied.

Subjectwise scores were calculated by averaging the values measured on the two baseline-designated study teeth. 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 hypersensitivity assessment - Teeth were evaluated for air blast hypersensitivity in the following manner:

1. The evaluated tooth was isolated from the adjacent teeth (mesial and distal) by the placement of the examiner's fingers over the adjacent teeth.
2. Air was delivered from a standard dental unit air syringe at 60 psi (\pm 5 psi) and 70°F (\pm 3°F). The air was directed at the exposed buccal surface of the evaluated tooth for 1 second from a distance of approximately 1 cm.
3. The Schiff Cold Air Sensitivity Scale¹⁶ was used to assess subject response to this stimulus. This scale is scored as follows:
 - 0 = Subject does not respond to air stimulus;
 - 1 = Subject responds to air stimulus but does not request discontinuation of stimulus;
 - 2 = Subject responds to air stimulus and requests discontinuation or moves from stimulus;
 - 3 = Subject responds to air stimulus, considers stimulus to be painful, and requests discontinuation of the stimulus.

Subjectwise scores were calculated by averaging the values obtained from the two baseline-designated study teeth. Only

Table 2. Summary of the baseline tactile and air blast hypersensitivity scores for subjects who completed the 24-week clinical study.

Parameter	Treatment groups	n	Baseline summary (Mean \pm S.D.) ¹
Tactile hypersensitivity	Test	46	16.41 \pm 7.50
	Negative Control	49	17.14 \pm 7.50
Air blast hypersensitivity	Test	46	2.43 \pm 0.27
	Negative Control	49	2.50 \pm 0.29

¹ No statistically significant difference was indicated between the two treatment groups at baseline with respect to either tactile or air blast hypersensitivity.

teeth with a score of 2 or 3 were selected at the baseline examination. Higher scores correspond to higher sensitivity.

Oral soft and hard tissue assessment - The dental examiner visually examined the oral cavity and peri-oral area using a dental light and dental mirror. This examination included an evaluation of the soft and hard palate, gingival mucosa, buccal mucosa, mucogingival fold areas, tongue, sublingual and sub-mandibular areas, salivary glands, and the tonsillar and pharyngeal areas.

Statistical methods - Statistical analyses were performed separately for the tactile hypersensitivity assessments and air blast hypersensitivity assessments. Comparisons of the treatment groups with respect to gender were performed using a Chi-Square analysis and for age an Independent t-test. Comparisons of the treatment groups with respect to baseline tactile scores and air blast scores were performed using an ANOVA. 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 hypersensitivity and air blast hypersensitivity scores at the follow-up examinations were performed using ANCOVAs. All statistical tests of hypotheses were two sided, and employed a level of significance of $\alpha = 0.05$.

Results

Ninety-five subjects complied with the protocol, and completed the 24-week study. A summary of the gender and age of the study population is presented in Table 1. The treatment groups did not differ significantly with respect to either of these characteristics. Throughout the study, there were no adverse events on the soft or hard tissues of the oral cavity which could be attributed to the products being used.

BASILINE DATA

Table 2 presents a summary of the mean tactile and air blast scores measured at the baseline examination. For tactile hypersensitivity, the mean baseline scores were 16.41 for study subjects assigned to the Test Group and 17.14 for study subjects assigned to the Negative Control Group. For air blast hypersensitivity, the mean baseline scores were 2.43 for the Test Group and 2.50 for the Negative Control Group. No statistically significant difference was indicated between the treatment groups with respect to either hypersensitivity score at baseline.

INSTANT RELIEF DATA

Tactile hypersensitivity

Table 3 presents a summary of the mean tactile hypersensitivity scores measured immediately after professional pro-

Table 3. Summary of the instant relief tactile hypersensitivity and air blast hypersensitivity scores for subjects who completed the 24-week clinical study.

Treatment	n	Post-scaling summary (Mean ± S.D.)	Within-treatment analysis		Between-treatment analysis	
			% change ¹	Significance ²	% difference ³	Significance ⁴
Instant relief - tactile hypersensitivity						
Test Group - In-Office Product	46	39.89 ± 11.57	143.1%	P < 0.05	49.8%	P < 0.05
Negative Control Group - In-Office Product	49	26.63 ± 13.71	55.4%	P < 0.05		
Instant relief - air blast hypersensitivity						
Test Group - In-Office Product	46	1.45 ± 0.64	40.6%	P < 0.05	26.0%	P < 0.05
Negative Control Group - In-Office Product	49	1.96 ± 0.73	21.6%	P < 0.05		

¹ Percent change exhibited by the instant relief mean relative to the baseline mean. A positive value indicates a reduction in either tactile hypersensitivity or air blast hypersensitivity at the instant relief examinations.

² Significance of paired t-test comparing the baseline examinations and the instant relief examinations.

³ Difference between instant relief means expressed as a percentage of the instant relief mean for the Negative Control Group. A positive value indicates a reduction in either tactile hypersensitivity or air blast hypersensitivity for the Test Group relative to the Negative Control Group.

⁴ Significance of ANCOVA comparison of baseline-adjusted means.

Table 4. Summary of the 8-week tactile hypersensitivity and air blast hypersensitivity scores for subjects who completed the 24-week clinical study.

Treatment	n	8-week summary (Mean ± S.D.)	Within-treatment analysis		Between-treatment comparison	
			% change ¹	Significance ²	% difference ³	Significance ⁴
8-week tactile hypersensitivity						
Test Group - In-Office Product	46	37.61 ± 12.46	129.2%	P < 0.05	57.5%	P < 0.05
Negative Control Group - In-Office Product	49	23.88 ± 13.28	39.3%	P < 0.05		
8-week air blast hypersensitivity scores						
Test Group - In-Office Product	46	1.35 ± 0.80	44.7%	P < 0.05	38.4%	P < 0.05
Negative Control Group - In-Office Product	49	2.19 ± 0.62	12.4%	P < 0.05		

¹ Percent change exhibited by the 8-week mean relative to the baseline mean. A positive value indicates a reduction in either tactile hypersensitivity or air blast hypersensitivity at the 8-week examination.

² Significance of paired t-test comparing the baseline examinations and 8-week examinations.

³ Difference between 8-week means expressed as a percentage of the 8-week mean for the Negative Control Group. A positive value indicates a reduction in either tactile hypersensitivity or air blast hypersensitivity for the Test Group relative to the Negative Control Group.

⁴ Significance of ANCOVA comparison of baseline-adjusted means.

duct application (Instant Relief Examination). Product use consisted of post-scaling professional application of the desensitizing paste for in-office use containing 8% arginine and calcium carbonate for the Test Group and identical professional application of the pumice prophylaxis paste for the Negative Control Group.

Comparisons versus baseline - The mean tactile hypersensitivity scores at the Instant Relief Examinations were 39.89 for the Test Group and 26.63 for the Negative Control Group. The percent changes from baseline were 143.1% for the Test Group and 55.4% for the Negative Control Group, of which both groups were statistically significant.

Comparison between treatment groups - Relative to the Negative Control Group, the Test Group exhibited a statistically significant improvement in tactile hypersensitivity scores at the Instant Relief Examination (49.8%).

Air blast hypersensitivity

Table 3 presents a summary of the mean air blast hypersensitivity scores measured at the Instant Relief Examination.

Comparisons versus baseline - The mean air blast hypersensitivity scores at the Instant Relief Examinations were 1.45 for the Test Group and 1.96 for the Negative Control Group. The percent changes from baseline were 40.6% for the Test Group and 21.6% for the Negative Control Group, of which both groups were statistically significant.

Comparison between treatment groups - Relative to the Negative Control Group, the Test Group exhibited a statis-

tically significant reduction in air blast hypersensitivity scores at the Instant Relief Examinations (26.0%).

8-WEEK DATA

Tactile hypersensitivity

Table 4 presents a summary of the mean tactile hypersensitivity scores measured at the 8-week examination.

Comparisons versus baseline - The mean tactile hypersensitivity scores at the 8-week examinations were 37.61 for the Test Group and 23.88 for the Negative Control Group. The percent changes from baseline were 129.2% for Test Group and 39.3% for the Negative Control Group, of which both groups were statistically significant.

Comparison between treatment groups - Relative to the Negative Control Group, the Test Group exhibited a statistically significant improvement in tactile hypersensitivity scores at the 8-week examinations (57.5%).

Air blast hypersensitivity

Table 4 presents a summary of the air blast hypersensitivity scores measured at the 8-week examinations.

Comparisons versus baseline - The mean 8-week air blast hypersensitivity scores were 1.35 for the Test Group and 2.19 for the Negative Control Group. The percent changes from baseline were 44.7% for the Test Group and 12.4% for the Negative Control Group, of which both groups were statistically significant.

Comparison between treatment groups - Relative to the Nega-

Table 5. Summary of the 24-week tactile hypersensitivity and air blast hypersensitivity scores for subjects who completed the 24-week clinical study.

Treatment	n	24-week summary (Mean ± S.D.)	Within-treatment analysis		Between-treatment comparison	
			% reduction ¹	Significance ²	% difference ³	Significance ⁴
24-Week Tactile hypersensitivity						
Test Group - In-Office Product	46	40.00 ± 11.79	143.8%	P < 0.05	32.9%	P < 0.05
Negative Control Group - In-Office Product	49	30.10 ± 13.33	75.8%	P < 0.05		
24-Week Air blast hypersensitivity						
Test Group - In-Office Product	46	1.11 ± 0.81	54.5%	P < 0.05	34.3%	P < 0.05
Negative Control Group - In-Office Product	49	1.69 ± 0.83	32.4%	P < 0.05		

¹ Percent change exhibited by the 24-week mean relative to the baseline mean. A positive value indicates a reduction in either tactile hypersensitivity or air blast hypersensitivity at the 24-week examination.

² Significance of paired t-test comparing the baseline examinations and 24-week examinations.

³ Difference between 24-week means expressed as a percentage of the 24-week mean for the Negative Control Group. A positive value indicates a reduction in either tactile hypersensitivity or air blast hypersensitivity for the Test Group relative to the Negative Control Group.

⁴ Significance of ANCOVA comparison of baseline-adjusted means.

tive Control Group, the Test Group exhibited a statistically significant reduction in air blast hypersensitivity scores at the 8-week examinations (38.4%).

24-WEEK DATA

Tactile hypersensitivity

Table 5 presents a summary of the tactile hypersensitivity scores measured at the 24-week examinations.

Comparisons versus baseline - The mean 24-week tactile hypersensitivity scores were 40.00 for the Test Group and 30.10 for Negative Control Group. The percent changes from baseline were 143.8% for Test Group and 75.8% for the Negative Control Group, of which both groups were statistically significant.

Comparison between treatment groups - Relative to the Negative Control Group, the Test Group exhibited a statistically significant improvement in tactile hypersensitivity scores at the 24-week examinations (32.9%).

Air blast hypersensitivity

Table 5 presents a summary of the air blast hypersensitivity scores measured at the 24-week examinations.

Comparisons versus baseline - The mean 24-week air blast hypersensitivity scores were 1.11 for the Test Group and 1.69 for the Negative Control Group. The percent changes from baseline were 54.5% for the Test Group and 32.4% for the Negative Control Group, of which both groups were statistically significant.

Comparison between treatment groups - Relative to the Negative Control Group, the Test Group exhibited a statistically significant reduction in air blast hypersensitivity scores at the 24-week examinations (34.3%).

Discussion

The existing literature reports a prevalence range for dentin hypersensitivity ranging from 4-57%.^{3,4} This percentage increases in periodontal patients, reaching 72-98%.¹⁷ Most affected patients are in the 20-50 year-old range, with a peak reported to be in the age range 30-40.¹⁸ Interestingly enough, although dentin hypersensitivity is a common problem that is seen daily in clinical practice, it is widely underreported and undertreated. A reason for this seems to be a certain level of discomfort in the dental profession when it comes to diagnosing and treating dentin hypersensitivity.¹⁹

Grossman²⁰ reported in 1935 some requirements of the ideal treatment for dentin hypersensitivity, that are still valid today: fast therapeutic action, effective for long periods of time, easy to apply, not irritating to the pulp, not causing pain, not staining the teeth and be constantly effective. To these requirements, it would be prudent to add that the product should have a pleasant taste to increase patient compliance. Desensitizing toothpastes for at-home use are often self prescribed or recommended by dental care professionals as the first line of treatment for the control of dentin hypersensitivity, given that this option is simple to use, non-invasive, widely available and cost-effective.

Arginine, a semi-essential amino acid naturally found in saliva, was first isolated from a lupin seedling extract in 1886 by the Swiss chemist Ernst Schultze. A new technology comprising 8% arginine and calcium carbonate, known as Pro-Argin, has been developed and validated as both an in-office desensitizing treatment, as well as a daily-use toothpaste.⁹⁻¹³ Research has demonstrated that arginine and calcium carbonate work together to accelerate the natural mechanisms of desensitization by depositing a dentin-like material containing calcium and phosphate within the dentin tubules to form robust tubular occlusion and a protective layer on the dentin surface.^{21,22} The in-office desensitizing paste with Pro-Argin technology has been clinically proven to provide instant sensitivity relief when applied with a prophylaxis cup before or after a professional cleaning procedure, and that the benefit of a single post-cleaning treatment lasts for at least 28 days.^{23,24} The desensitizing toothpaste with Pro-Argin technology and 1,450 ppm fluoride as sodium monofluorophosphate has been clinically proven to provide, with twice daily routine brushing, significantly better and faster relief than regular fluoride toothpaste,²⁵ and 2% potassium ion toothpastes or an 8% strontium acetate toothpaste.²⁶⁻³⁰ Moreover, it has been clinically proven that dentifrices with the Pro-Argin technology provide instant relief of dentin hypersensitivity when applied directly to each sensitive tooth and massaged for 1 minute, and the afforded relief is maintained with continued twice daily brushing.³¹⁻³⁵

This study evaluated the use of a two prong treatment regimen for instant and long-lasting (6 months) relief of dentin hypersensitivity: a single in-office professional treatment with the desensitizing paste containing 8% arginine and calcium carbonate, followed by twice daily brushing at home with an anti-sensitivity toothbrush and the dentifrice containing 8% arginine and calcium carbonate with 1,450 ppm fluoride as

MFP. The results of this 24-week clinical experiment did show that immediately after professional product application (at the Instant Relief Examinations), subjects in the Test Group (8% arginine and calcium carbonate) exhibited a statistically significant improvement in mean tactile and air blast hypersensitivity scores as compared to subjects in the Negative Control Group (49.8% and 26.0% respectively).

After 8 weeks and 24 weeks of twice daily brushing with the assigned toothpaste and toothbrush, subsequent to in-office product application, subjects in the Test Group (8% arginine and calcium carbonate with 1,450 ppm fluoride as MFP) exhibited a statistically significant improvement in mean tactile hypersensitivity scores as compared to the Negative Control Group (57.5% and 32.9% respectively). In addition, after 8 weeks and 24 weeks of twice daily brushing, subjects in the Test Group exhibited a statistically significant improvement in mean air blast hypersensitivity scores as compared to the Negative Control Group (38.4% and 34.3% respectively).

In conclusion, based on these clinical results, this novel strategy that uses a two prong regimen to treat dentin hypersensitivity could be a new tool in the effective management of this painful condition by the dental team. The Pro-Argin technology used as a treatment continuum, with a single in-office application and, as a follow-up, at home twice daily brushing with the dentifrice and toothbrush could be the dawn of a new era in the treatment of dentin hypersensitivity.

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- c. Dentsply International, York, PA, USA
- d. Procter & Gamble Company, Cincinnati, OH, USA.

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References

1. Dowell P, Addy M. Dentine hypersensitivity. A review. Aetiology, symptoms and theories of pain production. *J Clin Periodontol* 1983;10:341-350.
2. Markowitz K, Pashley DH. Personal reflections on a sensitive subject. *J Dent Res* 2007;86:292-295.
3. Addy M. Dentine hypersensitivity: Definition, prevalence, distribution and etiology. In: Addy M, Embery G, Edgar WM, Orchardson R. *Tooth wear and sensitivity: Clinical advances in restorative dentistry*. London: Martin Dunitz, 2000;239-248.
4. Rees JS, Lin LJ, Lam S, Kudanowska I, Vowles R. The prevalence of dentine hypersensitivity in a hospital clinical population in Hong Kong. *J Dent* 2003;31:453-461.
5. Porto ICCM, Andrade AKM, Montes MAJR. Diagnosis and treatment of dentinal hypersensitivity. *J Oral Sci* 2009;51:323-332.
6. Brännström M, Åström A. A study on the mechanism of pain elicited by the dentin. *J Dent Res* 1964;43:619-625.
7. Yoshiyama M, Noiri Y, Ozaki K, Uchida A, Ishikawa Y, Ishida H. Transmission electron microscopic characterization of hypersensitive human radicular dentine. *J Dent Res* 1990;69:1293-1297.
8. Orchardson R, Gillam DG. Managing dentin hypersensitivity. *J Am Dent Assoc* 2006;137:990-998.
9. Cummins D. Dentin hypersensitivity: From diagnosis to breakthrough therapy for everyday sensitivity relief. *J Clin Dent* 2009;20 (Sp Is):1-9.
10. 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 (Sp Is A):3A-7A.
11. Cummins D. The efficacy of a new dentifrice containing 8.0% arginine, calcium carbonate, and 1450 ppm fluoride in delivering instant and lasting relief of dentin hypersensitivity. *J Clin Dent* 2009;20 (Sp Is):109-114.
12. Cummins D. Recent advances in dentin hypersensitivity: Clinically proven treatments for instant and lasting sensitivity relief. *Am J Dent* 2010;23 (Sp Is A):3A-13A.
13. Cummins D. Advances in the clinical management of dentin hypersensitivity: A review of recent evidence for the efficacy of dentifrices in providing instant and lasting relief. *J Clin Dent* 2011;22 (Sp Is):100-107.
14. Clark GE, Troullos ES. Designing hypersensitivity clinical studies. *Dent Clin North Am* 1990;34:531-544.
15. Gillam DG, Bulman JS, Jackson RJ, Newman HN. Efficacy of a potassium nitrate mouthwash in alleviating cervical dentine sensitivity (CDS). *J Clin Periodontol* 1996;23:993-997.
16. 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 (Sp Is):87-92.
17. Chabanski MB, Gillam DG, Bulman JS, Newman HN. Prevalence of cervical dentine sensitivity in a population of patients referred to a specialist Periodontology department: A pilot study. *J Clin Periodontol* 1996;23:989-992.
18. Gillam DG, Seo HS, Bulman JS, Newman HN. Perceptions of dentin hypersensitivity in a general practice population. *J Oral Rehabil* 1999; 26:710-714.
19. Canadian Advisory Board on Dentin Hypersensitivity: Consensus based recommendations for the diagnosis and management of dentin hypersensitivity. *J Can Dent Assoc* 2003;69:221-226.
20. Grossman L. A systematic method for the treatment of hypersensitive dentine. *J Am Dent Assoc* 1935;22:592-598.
21. Petrou I, Heu R, Stranick M, Lavender S, Zaidel L, Cummins D, Sullivan RJ, Hsueh C, Gimzewski 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 (Sp Is):23-31.
22. Lavender S, Petrou I, Heu R, Stranick M, Cummins D, Kilpatrick-Liverman L, Sullivan R, Santarpia III RP. Mode of action studies on a new desensitizing dentifrice containing 8.0% arginine, a high cleaning calcium carbonate system and 450 ppm fluoride. *Am J Dent* 2010;23 (Sp Is A):14A-19A.
23. Schiff T, Delgado E, Zhang YP, Cummins D, DeVizio W, Mateo LR. Clinical evaluation of the efficacy of an in-office desensitizing paste containing 8% arginine and calcium carbonate in providing instant and lasting relief of dentin hypersensitivity. *Am J Dent* 2009;22 (Sp Is A):8A-15A.
24. Hamlin D, Willians KP, Delgado E, Zhang YF, DeVizio W, Mateo LR. Clinical evaluation of the efficacy of a desensitizing paste containing 8% arginine and calcium carbonate for the in-office relief of dentin hypersensitivity associated with dental prophylaxis. *Am J Dent* 2009;22 (Sp Is A):16A-20A.
25. Que K, Fu Y, Lin L, Hu D, Zhang YP, Panagakos FS, DeVizio W, Mateo LR. Dentin hypersensitivity reduction of a new toothpaste containing 8.0% arginine and 1450 ppm fluoride: An 8-week clinical study on Chinese adults. *Am J Dent* 2010;23 (Sp Is A):28A-35A.
26. Ayad F, Ayad N, Zhang YP, DeVizio W, Cummins D, Mateo LR. Comparing the efficacy in reducing dentin hypersensitivity of 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 on Canadian adults. *J Clin Dent* 2009;20 (Sp Is):10-16.
27. Docimo R, Montesani L, Maturo P, Costacurta M, Bartolino M, De Vizio W, Zhang YP, Cummins D, Dibart S, Mateo LR. Comparing the efficacy in reducing dentin hypersensitivity of 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. *J Clin Dent* 2009;20 (Sp Is):17-22.
28. Docimo R, Montesani L, Maturo P, Costacurta M, Bartolino M, Zhang YP, DeVizio W, Delgado E, Cummins D, Dibart S, Mateo LR. Comparing the efficacy in reducing dentin hypersensitivity of a new toothpaste containing 8.0% arginine, calcium carbonate, and 1450 ppm fluoride to a benchmark commercial desensitizing toothpaste containing 2% potassium ion: An eight-week clinical study in Rome, Italy. *J Clin Dent* 2009;20 (Sp Is):137-143.

29. Docimo R, Perugia C, Bartolino M, Maturo P, Montesani L, Zhang YP, DeVizio W, Mateo LR, Dibart S. Comparative evaluation of the efficacy of three commercially available toothpastes on dentin hypersensitivity reduction: An eight-week clinical study. *J Clin Dent* 2011;22 (Sp Is):121-127.
30. Schiff T, Mateo LR, Delgado E, Cummins D, Zhang YP, DeVizio W. Clinical efficacy in reducing dentin hypersensitivity of a dentifrice containing 8.0% arginine, calcium carbonate, and 1450 ppm fluoride compared to a dentifrice containing 8% strontium acetate and 1040 ppm fluoride under consumer usage conditions before and after switch-over. *J Clin Dent* 2011;22 (Sp Is):128-138.
31. Nathoo S, Delgado E, Zhang YP, DeVizio W, Cummins D, Mateo LR. Comparing the efficacy in providing instant relief of dentin hypersensitivity of a new toothpaste containing 8.0% arginine, calcium carbonate, and 1450 ppm fluoride relative 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. *J Clin Dent* 2009;20 (Sp Is):123-130.
32. Fu Y, Li X, Que K, Wang M, Hu D, Mateo LR, DeVizio W, Zhang YP. Instant dentin hypersensitivity relief of a new desensitizing dentifrice containing 8.0% arginine, a high cleaning calcium carbonate system and 1450 ppm fluoride: A 3-day clinical study in Chengdu, China. *Am J Dent* 2010;23 (Sp Is A):20A-27A.
33. Ayad F, Ayad N, Delgado E, Zhang YP, DeVizio W, Cummins D, Mateo LR. Comparing the efficacy in providing instant relief of dentin hypersensitivity of a new toothpaste 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. *J Clin Dent* 2009;20 (Sp Is 4):115-122.
34. Schiff T, Delgado E, Zhang YP, DeVizio, 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 (Sp Is):131-136.
35. Li Y, Lee S, Zhang YP, Delgado E, DeVizio, W, Mateo LR. Comparison of clinical efficacy of three toothpastes in reducing dentin hypersensitivity. *J Clin Dent* 2011;22 (Sp Is):113-120.