

Treating cervical dentin hypersensitivity with fluoride varnish

A randomized clinical study

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Cervical dentin hypersensitivity is a condition characterized by sharp pain associated with thermal, evaporative, tactile, osmotic or chemical stimuli.¹ This chronic condition is dependent on dentin exposure, as well as on the patency of the dentinal tubules.² It is widely accepted that dentin hypersensitivity is a result of outward fluid movement within the pulp-dentin complex.^{3,4} This phenomenon was first described in the early 20th century,⁵ was later studied by others^{6,7} and became known as the “hydrodynamic theory.”^{8,9}

The prevalence of cervical dentin hypersensitivity varies, depending on the study population and methods used. Several authors have reported that between 14 and 30 percent of the adult population suffers from this condition.¹⁰⁻¹⁶ Because the hydrodynamic mechanism is widely accepted as the principal cause of cervical dentin hypersensitivity, most treatments involve surface and intratubular blocking agents or barriers to reduce dentin permeability. Numerous agents have been proposed for the treatment of dentin hypersensitivity, including corticosteroids, silver nitrate, zinc and strontium chloride, formaldehyde, glutaraldehyde, calcium hydroxide, sodium citrate, potassium oxalate, resin adhesives and fluorides.¹⁷

ABSTRACT

Background. This subject-blind randomized clinical trial tested the efficacy of a new 5 percent sodium fluoride varnish (AllSolutions Fluoride Varnish, Dentsply Professional, York, Pa.) for treatment of cervical dentin hypersensitivity. The authors also compared the test varnish with a control fluoride varnish (Duraphat, Colgate Oral Pharmaceuticals, New York City).

Methods. The study involved application of the test or control varnish to 19 subjects (59 teeth) with tooth sensitivity. The authors applied each product once to each tooth, following manufacturers’ instructions. They used a visual analog scale (VAS) to assess subjects’ responses to compressed air and ice stimuli at six weeks before baseline, at baseline and at two, eight and 24 weeks after treatment.

Results. Mean VAS scores for teeth receiving the test varnish dropped from 34.9 (air) and 68.0 (ice) at baseline to 26.3 (air) and 54.7 (ice) at two weeks after treatment. Mean scores at 24 weeks were 20.6 (air) and 34.8 (ice), representing statistically significant differences from baseline values. For the control varnish, mean VAS scores dropped from 36.9 (air) and 64.2 (ice) at baseline to 32.9 (air) and 47.2 (ice) at two weeks, and to 20.8 (air) and 40.3 (ice) at 24 weeks. The authors analyzed the data for statistical significance, accounting for clustering of teeth within subjects.

Conclusion and Clinical Implications. The test varnish was effective in reducing cervical dentin hypersensitivity. However, the efficacy was not significantly different from that of the control varnish.

Key Words. Dentin hypersensitivity, fluoride varnish.

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BOX

Subject and teeth exclusion criteria.***EXCLUSION CRITERIA FOR SUBJECTS**

- Current and/or previous use of professional desensitizing treatment
- Use of over-the-counter desensitizing products within the previous six weeks
- Long-term use of anti-inflammatory, analgesic and psychotropic drugs
- Pregnancy or breast-feeding
- Allergies and idiosyncratic responses to product ingredients
- Eating disorders
- Systemic conditions that cause or predispose patients to develop dentin hypersensitivity (for example, chronic acid regurgitation)
- Excessive dietary or environmental exposure to acids
- Orthodontic appliance treatment within the previous three months
- Periodontal surgery within the previous three months

EXCLUSION CRITERIA FOR TEETH

- Teeth or supporting structures with any other painful pathology or defects
- Teeth restored in the preceding three months
- Abutment teeth for fixed or removable prostheses
- Crowned teeth
- Extensively restored teeth
- Teeth with restorations extending into the test area
- Carious teeth

* Adapted with permission of Blackwell Publishing from Holland and colleagues.¹

Topical fluoride applications create a barrier by precipitating calcium fluoride (CaF₂) on the tooth surface, blocking patent dentinal tubules and, hence, reducing permeability and hypersensitivity.¹⁷⁻²⁰ One concern with topical fluoride and other barrier treatment agents is the lack of clinical data regarding longevity of the desensitizing effect.²¹ Because cervical dentin hypersensitivity is impossible to test in vitro, clinical trials of safety and both short- and long-term efficacy of desensitizing treatments are required.

The purpose of this study was to evaluate the immediate and 24-week efficacy of a new fluoride varnish product in reducing cervical dentin hypersensitivity. We compared the desensitizing efficacy of the new fluoride varnish with that of another commercially available fluoride varnish.

SUBJECTS, MATERIALS AND METHODS

We conducted this subject-blind randomized clinical trial to test the desensitizing efficacy of a new fluoride varnish (AllSolutions Fluoride Varnish, Dentsply Professional, York, Pa.) in subjects with cervical dentin hypersensitivity. We compared the desensitizing efficacy of the product with that of another commercially available fluoride varnish (Duraphat, Colgate Oral Pharmaceuticals, New York City). (For ethical reasons, we did not include a placebo group in the study.)

Both products have similar active ingredients

(5 percent sodium fluoride [NaF] in an alcohol solution of natural resins, with approximately 22,600 parts per million fluoride). Duraphat is available in 10-milliliter tubes (1 mL contains 50 milligrams of fluoride, equivalent to 22.6 mg fluorine). AllSolutions is supplied in a single-unit-dose delivery system using a self-contained microbrush, which allows for reduced risk of cross-contamination and overdispensing of the product.

The experimental design was based on the American Dental Association's program guidelines for products used to treat dentinal hypersensitivity.²² The Committee on Investigations Involving Human Subjects (Institutional Review Board), The University of North Carolina at Chapel Hill, School of Dentistry, reviewed and approved the consent form and the study protocol. Subjects, who were recruited from the local university community, read and signed the consent form on enrollment into the study.

Study sample. The study sample was composed of subjects who had at least one incisor, canine or premolar tooth with sound exposed cervical dentin on the facial surface that was sensitive to timed applications of compressed air (two seconds) and a cold stimulus (ice stick contact). The box lists the exclusion criteria.

Randomization. We randomized the subject pool to minimize bias. We applied stratified block randomization to assign subjects to test or control groups. To avoid intrasubject cross-contamination from different desensitizing agents' being applied to the same mouth, a single treatment (test varnish or control varnish) was assigned to each subject. We assigned subjects at random to blocks of four subjects. For each block, the first two subjects were treated with either varnish, as determined by a coin flip. The remaining two subjects in the block received the second varnish, generating two subjects per treatment group in each block. Within a block, subjects had approximately the same number of teeth to be treated (two, three or four teeth). Subjects with more than four teeth affected by sensitivity received treatment on

all sensitive teeth, but we included only the four most sensitive teeth at baseline in the analysis. Whenever possible, we selected study teeth in both the maxillary and mandibular arches of each subject.

After enrollment, subjects underwent a six-week period during which they stopped using any desensitizing agents, including desensitizing dentifrices. For standardization, we provided subjects with identical toothbrushes (Oral-B Advantage #40 soft, Procter & Gamble, Cincinnati), dentifrices (Pepsodent Original, Church & Dwight, Princeton, N.J.) and oral hygiene instructions at enrollment.

Examiners. Three trained dentist examiners (A.R., W.D., P.M.) were responsible for qualifying the subjects, applying the stimuli, applying the fluoride varnishes and collecting subjects' responses during recall visits. During the varnish application phase, the study coordinator was responsible for continual assessment of standardization procedures. Because subjects provided subjective study responses, it was not necessary for us to calibrate the examiners in their assessment of the study outcomes. In addition, because the delivery methods differed for the two varnishes, examiner blinding was not viable during the application phase, but was exercised during follow-up visits.

The examiners recorded the subjects' responses to stimuli using magnitude estimation.²³ Magnitude estimation scales allow for the evaluation of absolute differences in pain among groups or conditions or at different time points, thereby being an appropriate method of estimating hypersensitivity. Magnitude estimation requires subjects to indicate the level of pain experienced along a continuum represented by a visual analog scale (VAS).²⁴

VAS. To record subjects' responses to stimuli, the examiners isolated teeth with cotton rolls, wiped them with a cotton pellet to remove any debris and maintained them in a moist condition until they applied the stimuli. The subjects placed a mark on a 100 mm-long line on the VAS that was labeled from "no pain" (0) to "intolerable pain" (100). At each evaluation, subjects recorded on the VAS the sensitivity of each tooth to timed (5 seconds) applications of compressed air (from a three-way dental unit syringe at a distance of approximately 2 centimeters) and a cold stimulus (ice stick contacting the tooth surface). We did not extend air stream and ice contact time longer than

necessary to generate a response. We always applied the air stimulus before the ice stimulus. For data analysis, we obtained a numeric value between 0 and 100 for each observation. We used two scales (one for air, one for ice) for every tooth examined at each visit. The order in which the dentists examined the teeth was different at each visit.

We evaluated dentinal hypersensitivity at five time points:

- enrollment: six weeks before treatment;
- end of the run-in period (baseline);
- two weeks after treatment;
- eight weeks after treatment;
- 24 weeks after treatment.

As much as possible, each examiner followed up with the same subjects during the entire course of the study. In addition to subjects' responses being recorded with the VAS scale, the examiners asked subjects to answer the following question at each evaluation: "Which of the following best describes your perception of the desensitizing treatment you received in this study?":

- no improvement (my teeth are as sensitive as they were before the treatment);
- minor improvement (my teeth are less sensitive than they were before, but they are still sensitive);
- major improvement (my teeth are not sensitive anymore).

The examiners also performed a visual soft-tissue examination at every recall visit, and they recorded any soft-tissue irritation in the subject's progress record.

Before applying the desensitizers, the examiners lightly air-dried the dentin at the cervical area of the tooth with compressed air. They then applied the fluoride varnishes according to the manufacturers' instructions. They applied the varnishes to form a single, uniform and thin coat over the exposed cervical area of the affected teeth. The examiners applied the control varnish with a disposable brush and the test varnish with a single-unit-dose syringe. They instructed subjects to refrain from brushing, flossing and eating for at least two hours after application to avoid removing the varnish mechanically.

We determined the efficacy of the test varnish by comparing baseline VAS scores with posttreatment VAS scores. In addition, we compared the VAS scores for the control varnish against those for the test varnish. We estimated sample size using the following assumptions: statistical power

TABLE 1

Characteristics of subjects.			
VARIABLE	ALLSOLUTIONS VARNISH*	DURAPHAT VARNISH†	P VALUE
Sex (No.)			
Male	0	1	.292
Female	10	8	
Mean (SD) Age (Years)	35.6 (12.4)	47.0 (6.4)	.024
Mean (SD) No. of Study Teeth per Subject	2.9 (0.9)	3.3 (0.7)	.255

* AllSolutions 5% Sodium Fluoride Varnish is manufactured by Dentsply Professional, York, Pa.
 † Duraphat 5% Sodium Fluoride Varnish is manufactured by Colgate Oral Pharmaceuticals, New York City.

TABLE 2

Characteristics of teeth.			
VARIABLE	ALLSOLUTIONS VARNISH* (n = 29)	DURAPHAT VARNISH† (n = 30)	P VALUE
Tooth Type			
Incisors	8	2	.543
Canines	3	12	
Premolars	18	16	
Arch			
Maxillary	14	18	.370
Mandibular	15	12	

* AllSolutions 5% Sodium Fluoride Varnish is manufactured by Dentsply Professional, York, Pa.
 † Duraphat 5% Sodium Fluoride Varnish is manufactured by Colgate Oral Pharmaceuticals, New York City.

equals 0.80, confidence level equals 95 percent and an expected mean difference of 30 VAS units (along the ordinal sensitivity rating scale) between the two comparison groups. We factored in a 25 percent attrition rate to compensate for subjects who might have dropped out during the study.

Statistical analysis. We used statistical tests to make comparisons between treatments and within treatments, and we selected the tests on the basis of whether the variables were categorical or continuous. We used statistical software (SAS Version 8.02, SAS Institute, Cary, N.C.) to generate Mantel-Haenszel χ^2 test statistics for the tooth type, arch, sex and perception variables. For the variables age and study teeth per subject, we used the unpaired Student *t* test. We used statistical software (SUDAAN Release 8.02, Research Triangle Institute, Research Triangle Park, N.C.) to account for clustering of teeth within subjects by generating the following:

- unpaired Student *t* test statistics to compare differences in mean VAS scores across treatment groups;

- paired Student *t* test statistics to compare differences in mean VAS scores from baseline scores within each treatment group;
- Mantel-Haenszel test statistics to compare differences in proportions of categorical variables across treatment groups.

RESULTS

The study results are summarized in Tables 1 through 5 and the figure. Tables 1 and 2 show descriptive characteristics for subjects and teeth. Nineteen subjects were enrolled and

completed the study, including only one male. Ten subjects were treated with the test varnish and nine with the control varnish. Subjects' ages ranged from 18 to 55 years, with a mean age of 41 years. We found a significant difference in the mean age of subjects treated with the test varnish and the mean age of subjects treated with the control varnish. Twenty-nine teeth were treated with the test varnish and 30 with the control varnish. We found no significant differences in the distribution of tooth type (incisors, canines, premolars) or arch (maxillary, mandibular) between the two varnishes. Neither treatment caused any subjective or objective soft-tissue irritation.

Sensitivity improvement. As shown in Table 3, most subjects reported experiencing only a minor improvement in sensitivity at all posttreatment times compared with their perception at baseline. The differences between the responses for the two varnishes were not significant.

VAS scores. As shown in Table 4, teeth treated with the test varnish had significantly lower mean VAS scores when tested with air at

TABLE 3

Subjects' responses to the question, "Which of the following best describes your perception of the desensitizing treatment you received in this study?"

POSTTREATMENT TIME (WEEKS)	LEVEL OF PERCEIVED IMPROVEMENT	ALLSOLUTIONS* (n = 10)	DURAPHAT† (n = 9)	P VALUE‡
Two	Major	1	0	.958
	Minor	7	8	
	None	2	1	
Eight	Major	0	1	.193
	Minor	7	7	
	None	3	1	
24	Major	0	2	.083
	Minor	9	7	
	None	1	0	

* AllSolutions 5% Sodium Fluoride Varnish is manufactured by Dentsply Professional, York, Pa.
 † Duraphat 5% Sodium Fluoride Varnish is manufactured by Colgate Oral Pharmaceuticals, New York City.
 ‡ The P values indicate statistical significance between treatments at each time point ($P > .05$ = nonsignificant difference).

TABLE 4

Differences in visual analog scale (VAS) scores from baseline for teeth in both treatment groups.

STIMULUS	TIME AFTER BASELINE (WEEKS)	DIFFERENCE IN MEAN (SEM)* VAS SCORE FROM BASELINE: ALLSOLUTIONS† (n = 29)	P VALUE‡	DIFFERENCE IN MEAN (SEM) VAS SCORE FROM BASELINE: DURAPHAT§ (n = 30)	P VALUE‡
Air	Two	-7.7 (4.9)	.136	-4.0 (7.1)	.576
	Eight	-11.2 (5.0)	.038	-10.1 (7.9)	.216
	24	-14.3 (3.7)	.001	-16.1 (6.8)	.030
Ice	Two	-13.3 (4.4)	.008	-17.0 (3.7)	< .001
	Eight	-24.6 (8.1)	.007	-23.2 (5.1)	< .001
	24	-33.3 (6.8)	< .001	-24.0 (9.3)	.019

* SEM: Standard error of the mean.
 † AllSolutions 5% Sodium Fluoride Varnish is manufactured by Dentsply Professional, York, Pa.
 ‡ The P values indicate statistical significance within treatment groups at each time point versus baseline ($P > .05$ = nonsignificant difference)
 § Duraphat 5% Sodium Fluoride Varnish is manufactured by Colgate Oral Pharmaceuticals, New York City.

eight and 24 weeks after treatment compared with baseline scores. By comparison, teeth treated with the control varnish had significantly lower mean VAS scores when tested with air only at 24 weeks after treatment compared with baseline scores. When teeth treated with either varnish were tested with ice, mean VAS scores at all posttreatment times were significantly lower than mean VAS scores at baseline. Although we did not compare VAS scores from teeth tested with air with those obtained from teeth tested with ice, it is clear that the ice stimulus elicited more hypersensitivity than did the air stimulus.

Table 5 and the figure (page 1019) show the distribution of mean VAS scores by treatment

and stimulus (ice or air) over time. Table 5 also shows the difference between mean VAS scores for the two varnishes. We found no statistically significant differences in mean VAS scores for teeth treated with the test varnish versus those treated with the control varnish. Mean VAS scores always were lower for the air stimulus than for the ice stimulus, but neither treatment totally eliminated symptoms of pain or discomfort.

DISCUSSION

Cervical dentin hypersensitivity is a significant clinical problem in dentistry because it affects a large percentage of the population, and because there is no completely effective, conservative and

TABLE 5

Visual analog scale (VAS) scores, by stimulus and treatment.					
STIMULUS	TIME	MEAN (SEM)* VAS SCORE FOR TEETH RECEIVING ALLSOLUTIONS† (n = 29)	MEAN (SEM) VAS SCORE FOR TEETH RECEIVING DURAPHAT‡ (n = 30)	ALLSOLUTIONS SCORE MINUS DURAPHAT SCORE§	P VALUE
Air	Six weeks before baseline	27.2 (6.1)	30.3 (5.7)	-3.2	.710
	Baseline	34.9 (7.4)	36.9 (5.5)	-2.0	.830
	Two weeks after baseline	26.3 (7.4)	32.9 (7.1)	-6.6	.525
	Eight weeks after baseline	23.9 (8.4)	26.8 (7.7)	-2.9	.788
	24 weeks after baseline	20.6 (7.1)	20.8 (4.3)	-0.2	.982
Ice	Six weeks before baseline	54.4 (8.5)	58.2 (9.4)	-3.8	.770
	Baseline	68.0 (7.3)	64.2 (7.1)	3.8	.711
	Two weeks after baseline	54.7 (7.1)	47.2 (4.9)	7.5	.396
	Eight weeks after baseline	43.5 (5.7)	41 (7.8)	2.5	.800
	24 weeks after baseline	34.8 (5.7)	40.3 (9.2)	-5.5	.618

* SEM: Standard error of the mean.
 † AllSolutions 5% Sodium Fluoride Varnish is manufactured by Dentsply Professional, York, Pa.
 ‡ Duraphat 5% Sodium Fluoride Varnish is manufactured by Colgate Oral Pharmaceuticals, New York City.
 § The difference in mean VAS scores between the two treatments. The P values indicate statistical significance between treatments at each time point (P > .05 = nonsignificant difference).

permanent treatment for it. Also, as life expectancy increases and patients retain their natural teeth longer because of more effective treatments for caries and periodontal disease, the risk of developing cervical dentin hypersensitivity increases as a result of physiological gingival recession and exposure of cervical dentin.

Use of topical fluorides. Clinicians have attempted several strategies to treat this condition, including topical fluorides, which have been used for at least 60 years to treat dentin hypersensitivity.^{25,26} Topical fluorides are thought to create a barrier by precipitating CaF₂ at the exposed dentin surface, reducing dentin permeability and, consequently, dentin hypersensitivity.^{17,19} The natural resins contained in fluoride varnishes might provide an additional barrier effect, although this has not been tested experimentally.

The results of our study indicate that a single application of topical fluoride varnish reduces

cervical dentin hypersensitivity for 24 weeks. It is possible that the desensitizing effects lasted much longer, but we made no evaluations after 24 weeks. The durability of the results is somewhat surprising, because we might have expected the CaF₂ precipitates formed on the outer dentin to have been washed away by saliva and toothbrush abrasion, reopening the dentinal tubules and triggering hypersensitivity. Castillo and Milgrom²⁷ showed that after topical application of 5 percent NaF, most of the fluoride was released within two weeks, with only small amounts of fluoride being released up to 21 weeks after treatment. However, as the data in this study show, the reduction in mean VAS scores for the entire sample was statistically significant from baseline to 24 weeks after treatment, regardless of the stimulus.

Beecher²⁸ and Morris and colleagues²⁹ cited a placebo effect in pain-reducing studies that used placebo controls. Despite the fact that we did not

use a placebo in this study, a similar effect could be expected. According to this theory, subjects enrolled in a study might experience a reduction in sensitivity even if their treatment product contained no active ingredient. Also, a subject's central pain-inhibiting system might be triggered by emotional and motivational behavior.³⁰ Subjects enrolled in sensitivity clinical trials might be influenced by their desire to obtain relief and their trust in the investigators.²⁹ However, despite the objective data in this study showing a significant reduction in VAS scores from baseline to up to 24 weeks after treatment, the majority of subjects reported experiencing only minor improvement after treatment, and only a few indicated experiencing major improvement (Table 3).

Treatment success. Using a subjective scale to determine success and failure, Hansen³¹ reported a 48 percent success rate at three months and a 41 percent success rate at one year when treating patients with dentin hypersensitivity with the same 5 percent NaF varnish used in this study as the control. If success is defined as a statistically significant reduction in mean VAS scores from baseline, our study results indicate treatment success for both groups at eight and 24 weeks after treatment. Corona and colleagues³² compared the efficacy of a 5 percent NaF varnish in the reduction of cervical dentin hypersensitivity with that of a low-level laser therapy; the results of their study indicated that both treatments may be effective. However, these authors followed up with subjects for only 30 days after treatment. They noted no relapse of sensitivity during the posttreatment evaluation period for either treatment, which is in agreement with the trend noted in our study.

Study limitations. This study had some limitations that we should acknowledge. First, the lack of a placebo-control group limits the interpretation of the results. A placebo-control group

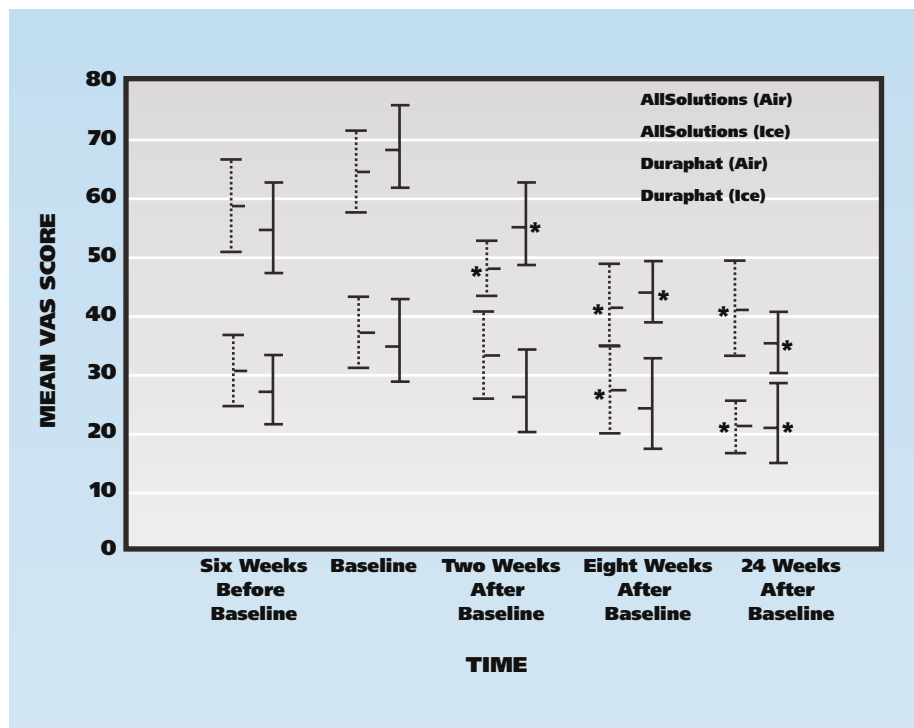


Figure. Mean visual analog scale (VAS) scores (“no pain” equals 0 and “intolerable pain” equals 100) as a function of treatment and stimulus over time. The vertical bars indicate the standard error of the mean. The asterisk indicates $P < .05$ (different from baseline value for that treatment). No statistically significant differences were found between the test varnish (AllSolutions Fluoride Varnish, Dentsply Professional, York, Pa.) and the control varnish (Duraphat, Colgate Oral Pharmaceuticals, New York City) at any time for a given stimulus.

might have enabled us to determine more clearly whether any of the results obtained were due to a placebo effect.

Second, we enrolled significantly older subjects in the control group than in the test group, which should have been avoided. We assigned subjects to specific groups randomly and did not use age as a factor for stratified randomization. Therefore, it is not totally surprising that the mean age of subjects differed between comparison groups. A multivariable regression analysis revealed that this age difference had no significant effect on the study outcomes (data not shown).

Finally, we should have included similar numbers of men and women as subjects. Although other studies of cervical dentin hypersensitivity also have included more women than men,³¹ the almost exclusive enrollment of women in our study was not planned. We screened prospective subjects on a “first-come, first-served” basis and enrolled them if they met the inclusion criteria. The influence of the sex imbalance on the outcome of the study is difficult to assess, but it

should be investigated further.

The new delivery system for the test varnish proved to be effective and convenient for a single-patient application, with no drawbacks regarding handling and/or ease of application. In addition to their desensitizing effect, topical fluoride varnishes help prevent caries.³³⁻³⁶ On the other hand, one disadvantage of using fluoride varnishes is their potential to stain esthetic restorations^{37,38}; however, one study³⁷ showed that the color changes are visually imperceptible.

The efficacy of fluoride varnish in treating cervical dentin hypersensitivity should be studied further by extending the evaluation time while maintaining similar conditions of hygiene, diet and use of over-the-counter desensitizing agents. However difficult and expensive these long-term clinical trials are, they are the ultimate test for a material and/or technique in the treatment of an oral condition.

CONCLUSION

The results of this study show that the new fluoride varnish effectively reduced cervical dentin hypersensitivity. However, we found no statistically significant differences between the desensitizing efficacy of this varnish and that of the control varnish. ■

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