

A randomized, controlled comparison of two professional dentin desensitizing agents immediately post-treatment and 2 months post-treatment

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ABSTRACT: Purpose: To compare the desensitizing effects of two different marketed professional dentin hypersensitivity treatments, a 5% sodium fluoride varnish and an oxalic acid/potassium salt solution, in a single-center, randomized, controlled, subject-blind pilot study. **Methods:** A total of 22 subjects with dentin hypersensitivity on at least two teeth were recruited from a general dentistry practice and randomized 1:1 to treatment with a 5% sodium fluoride varnish (Acclean Fluoride Varnish) group or a 3% oxalic acid/potassium salt solution (Super Seal Desensitizer). The study population was predominantly female (91%) and Caucasian (77%). The mean age was 46.4 years, with ages ranging from 18-73 years. Dentin hypersensitivity was assessed after an air blast challenge by the examiner (Schiff Index Sensitivity Scale) and by the subject [Visual Analog Scale (VAS)] for each tooth tested. Hypersensitivity was assessed immediately post-treatment and at 2 months post-treatment. **Results:** For the sodium fluoride varnish group, the mean Schiff score decreased 61% from baseline immediately post-treatment ($P= 0.0006$) and 41% at Month 2 ($P= 0.0069$). For the oxalic acid/potassium salt solution group, the mean Schiff score decreased 33% from baseline immediately post-treatment ($P= 0.0305$) and 29% at Month 2. Similarly, the mean VAS scores in the sodium fluoride varnish group decreased 41% from baseline immediately post-treatment ($P= 0.0030$) and 34% at Month 2 ($P= 0.0275$). The mean VAS scores in the oxalic acid/potassium salt solution group decreased 35% from baseline immediately post-treatment ($P= 0.0168$) and 33% at Month 2 ($P= 0.0283$). An analysis of covariance found no statistically significant between-group differences in mean Schiff scores or VAS scores immediately post-treatment or at Month 2. Both treatments were well tolerated. There were no reported adverse events in either treatment group. (*Am J Dent* 2018;31:297-302).

CLINICAL SIGNIFICANCE: Both 5% sodium fluoride varnish and an oxalic acid/potassium salt solution are safe and effective options to treat dentin sensitivity in otherwise healthy adults. The examiner-rated Schiff scores and the patient-rated VAS scores consistently demonstrated a reduction in sensitivity with either treatment, both immediately after professional application and at 2 months post-treatment.

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Introduction

Dentin hypersensitivity has been defined as a short, sharp pain that arises from exposed dentin in response to thermal, evaporative, tactile, osmotic or chemical stimuli; this pain cannot be ascribed to any other form of dental defect or pathology.¹ The pain associated with dentin hypersensitivity often disturbs patients while eating, drinking, brushing teeth, and occasionally even while breathing. Studies have demonstrated a significant effect upon patients' health-related quality of life, with a negative correlation between the frequency of painful sensations and health-related quality of life.²⁻⁴ Dentin hypersensitivity is a widespread clinical problem. While studies from various international sites have found rates of dentin hypersensitivity anywhere from 3% to 57%, the prevalence of dentin hypersensitivity in the general adult population of the United States has been less well characterized.⁵ However, one well-designed, cross-sectional survey of 787 adult patients from 37 general dental practices in Northwestern United States reported the prevalence of dentin hypersensitivity at 12.3%.⁶

The etiology of the pain associated with dentin hypersensitivity is complex, but the most commonly accepted model is the hydrodynamic theory. This theory posits that certain stimuli (cold, desiccation, osmotic changes, etc.), alter the fluid flow in dentin tubules, resulting in nociceptor activation

in the pulp/dentin border area.⁷ In support of this model, an early study of extracted, caries-free teeth that were stained with methylene blue dye and visualized using scanning electron microscopy found that the zone of dye-exposed cervical dentin was larger, and the depth of penetration greater, in hypersensitive teeth compared to non-sensitive teeth.⁸ Further, hypersensitive teeth had about eight times the number of tubules per unit area than did non-sensitive teeth, and tubule diameters were about twice as wide in hypersensitive teeth than in non-sensitive teeth. A later study found that an increase in the number of patent tubules as well as a disrupted smear layer were associated with clinically verified dentin hypersensitivity.⁹

Given these data, current treatments for dentin hypersensitivity rely on a variety of mechanisms of tubular occlusion for desensitization.^{10,11} One commonly used in-office desensitizing agent is sodium fluoride, which, when used in high concentrations as a varnish, reduces and blocks fluid movements in the dentin tubules through formation of calcium and phosphorous precipitates on the surface of the tubules.^{12,13} Another commonly used strategy is the application of various oxalic acid preparations, which have been shown to result in the deposition of oxalate crystals in exposed tubules.¹⁴ A benefit of oxalates is that they are relatively insoluble in acids,¹⁵ and so are somewhat resistant to dissolution by saliva-

Table 1. The Schiff Index Sensitivity Scale.

Score	Criteria
0	Subject does not respond to stimulus.
1	Subject responds to stimulus, but does not request discontinuation of stimulus.
2	Subject responds to stimulus, and requests discontinuation of stimulus or moves away from stimulus.
3	Subject responds to stimulus, considers stimulus to be painful, and requests discontinuation of the stimulus.

tion, brushing, and dietary acids. Both sodium fluoride preparations^{16,17} and oxalate preparations^{18,19} have been demonstrated to be effective desensitizing agents when applied professionally. However, head-to-head studies have not demonstrated significant efficacy differences between the two classes of agents when evaluated within 4 weeks of application.^{20,21} Longer-term comparative efficacy studies are lacking.

In the current pilot study, we compared the desensitizing effects of two different marketed professional dentin hypersensitivity treatments, a 5% sodium fluoride varnish and a 3% oxalic acid/potassium salt solution, in a study population of otherwise healthy adults. Our study was designed to examine desensitization immediately after professional application, and again at 2 months post-treatment. Dentin hypersensitivity was assessed both by the examiner and the patient at both time points in order to determine if differences between examiner-scored sensitivity and patient-reported sensitivity would be evident for one or both products.

Materials and Methods

Study objectives, assessments, and outcomes - This single-center, randomized, controlled, subject-blind pilot study assessed the effects of two different marketed professional treatments (Acclean Fluoride Varnish,^a 5% sodium fluoride or Super Seal Desensitizer,^b 3% oxalic acid/potassium salt solution) upon dentin hypersensitivity in a study population of otherwise healthy adults. Dentin hypersensitivity was assessed using the air blast challenge in which a 1-second application of air from a standard dental unit syringe is delivered onto a single target tooth. This challenge is perceived as painful for subjects with dentin hypersensitivity.²² To quantify dentin hypersensitivity in response to the air blast challenge, the examiner recorded a score on the Schiff Index Sensitivity Scale²³ for each tooth tested (Table 1). Immediately after the Schiff score was recorded, the examiner asked the subject to look at a Visual Analog Scale (VAS) and to indicate the level of pain experienced as a result of the challenge, where 0 is no pain at all, and 100 is the worst tooth pain ever before experienced. The examiner did not view the VAS scores, nor did the subjects view the Schiff scores.

The two primary outcome measures in this study were the VAS scores and the Schiff scores given in response to the air blast challenge on sensitive teeth. The effects of both treatments upon the VAS scores and Schiff scores were assessed immediately after professional application of the appropriate treatment, and at 2 months post-treatment.

Subjects - Subjects were recruited between June 26, 2013 and September 13, 2013 from the general dental practice at Anderson Dental, Fresno, California. Eligibility was limited

to generally healthy adults 18 years of age or older. During screening, subjects underwent the air blast challenge to identify sensitive teeth. Subjects with a VAS score of ≥ 30 on at least one tooth were eligible for this study. Exclusion criteria were allergy to rosin or pine nuts; pregnancy or nursing; severe periodontal disease; active treatment for periodontitis; or fixed facial orthodontic appliances. Enrolled subjects were required to refrain from dental prophylaxis or any elective dentistry during the study period.

Study design - Institutional review and approval were obtained from Schulman Associates IRB (IRB number: 201306100). The study was conducted in compliance with the International Conference on Harmonization's Good Clinical Practice Consolidated Guidelines. All subjects provided written, informed consent.

Enrolled subjects participated in two study visits. At the first visit, subjects gave informed consent and documented their demographic information and personal medical history. The oral examiner then conducted a comprehensive clinical examination of the oral and perioral regions, including the hard and soft tissues. The air blast challenge was conducted in order to identify up to two target teeth with dentin sensitivity, defined as a VAS score of ≥ 30 points and a Schiff score of ≥ 1 , in different quadrants. Subjects were stratified by the examiner based on baseline VAS score and age, and randomized 1:1 using block randomization to either receive a single, professional treatment of the sensitive tooth or teeth with either a 5% sodium fluoride varnish (Acclean Fluoride Varnish) or a 3% oxalic acid/potassium salt solution (Super Seal Desensitizer). These marketed treatments were professionally applied by the examiner according to the manufacturer's instructions for use. Test products were dispensed in marketed packaging and subjects were blinded to their assignment. Immediately following the sensitivity treatment, the examiner performed the air blast challenge to the treated teeth, followed by subject self-assessment of pain using the VAS and examiner's assessment of clinical sensitivity using the Schiff Index.

At the second study visit, which occurred at Month 2, a comprehensive oral examination was conducted to evaluate the oral and perioral region, including hard and soft tissues. The air blast challenge was then performed to the teeth that had been treated at Visit 1, followed by subject self-assessment of pain using the VAS and examiner's assessment of clinical sensitivity using the Schiff Index.

During the course of the study, subjects were permitted to perform their daily oral care regimen using their usual products as desired. The use of non-study oral care products was not monitored, as this study was designed to be performed in the setting of a general dentistry practice.

Adverse events - General comments and adverse events could be recorded at any time during the study. An adverse event was defined as any unfavorable or unintended sign, symptom, or disease that appeared or worsened in a subject during the study period. Adverse events were collected from examination and interview. On dental examination, an adverse event was recorded if a new abnormal finding was noted after product distribution or if any previously noted abnormal finding increased in severity during the treatment period. All serious

Table 2. Subject demographics.

Statistic or category	Sodium fluoride varnish (n=11)	Oxalic acid/potassium salt solution (n=11)	Overall (n=22)	P-value
Age (Years)				
Mean (SD)	48.1 (19.71)	44.6 (9.84)	46.4 (15.30)	0.6087 ^a
Min. - Max.	18 - 73	28 - 65	18 - 73	
Ethnicity				
Asian ^b	1 (9%)	1 (9%)	2 (9%)	0.7243 ^c
Black/African American ^b	1 (9%)	0 (0%)	1 (5%)	
Caucasian ^b	9 (82%)	8 (73%)	17 (77%)	
Hispanic ^b	0 (0%)	2 (18%)	2 (9%)	
Sex				
Female ^b	11 (100%)	9 (82%)	20 (91%)	0.1380 ^d
Male ^b	0 (0%)	2 (18%)	2 (9%)	

^a Two-sided ANOVA P-value for the treatment comparison.

^b The number (percent) of subjects in each category.

^c Two-sided Fisher's exact test P-value for the treatment comparison.

^d Two-sided chi-square P-value for the treatment comparison.

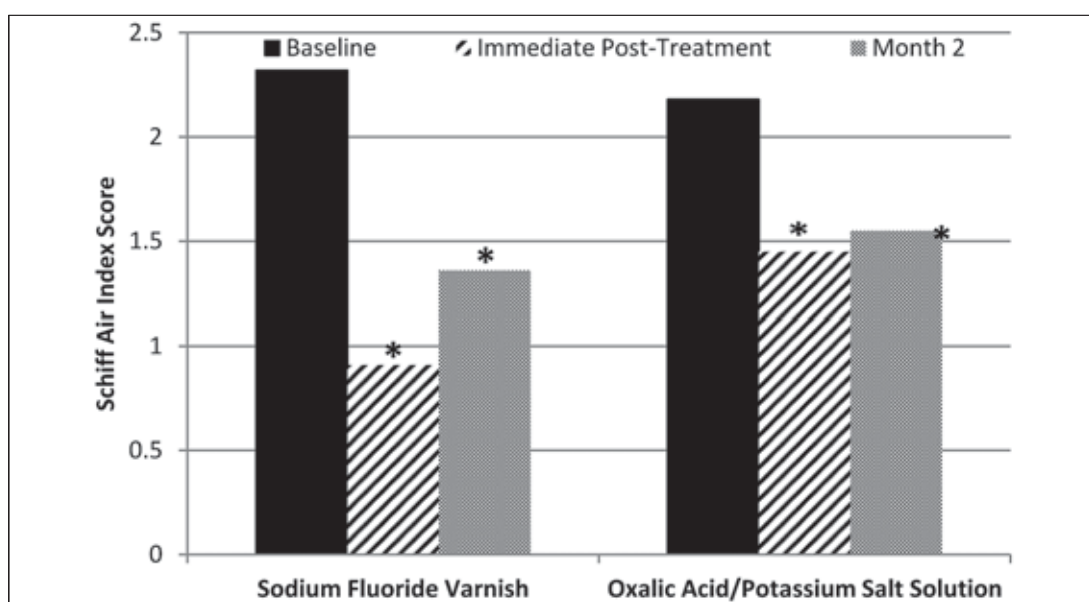


Fig. 1. The effects of sodium fluoride varnish treatment and oxalic acid/potassium salt solution treatment on mean Schiff Air Index scores immediately post-treatment and at Month 2. * P<0.05 when compared with baseline.

and non-serious oral-related adverse events were recorded. Only serious non-oral-related adverse events were recorded.

Statistical analysis - A sample size of 10 subjects per group in this pilot study yielded 80% power to detect an effect size of 1.0 versus baseline, and between-group differences of 1.3, using two-sided testing at 5% significance levels. A sample size of 22 was selected to allow for a 10% dropout rate. Summary statistics of the demographic characteristics and measurements were calculated for each treatment group and overall. Sensitivity scores were averaged among target teeth for each subject and assessment. For each treatment group and assessment, mean comparisons to Baseline were performed using paired difference t-tests. For each assessment, mean comparisons between treatment groups were analyzed using ANCOVA with the Baseline score as a covariate. Statistical comparisons utilized two-sided testing with a 5% significance level.

Results

Baseline demographics and clinical characteristics - A total of 22 subjects were enrolled in this study and randomized 1:1

into the sodium fluoride varnish group and the oxalic acid/potassium salt solution group (Table 2). The study population was predominantly female (91%) and Caucasian (77%). The mean age was 46.4 years, with ages ranging from 18-73 years. There were no significant differences in demographic characteristics, baseline Schiff Air Index scores, or baseline VAS scores between the groups.

All subjects participated in the first study visit and received the appropriate treatment per protocol. At the second visit, one subject in the oxalic acid/potassium salt solution group was deemed non-evaluable because crowns had been placed on both test teeth between the two study visits by an unaffiliated practitioner. Therefore, the completion rate was 95%.

Response to treatment: Schiff Air Index - Dentin hypersensitivity was assessed by the examiner after the 1-second air blast challenge using the Schiff Air Index (Table 1). Both treatments produced immediate beneficial effects upon dentin hypersensitivity, and beneficial effects of treatment were still evident at Month 2 (Fig. 1). For the sodium fluoride varnish group, the pre-treatment mean Schiff score was 2.32± 0.72.

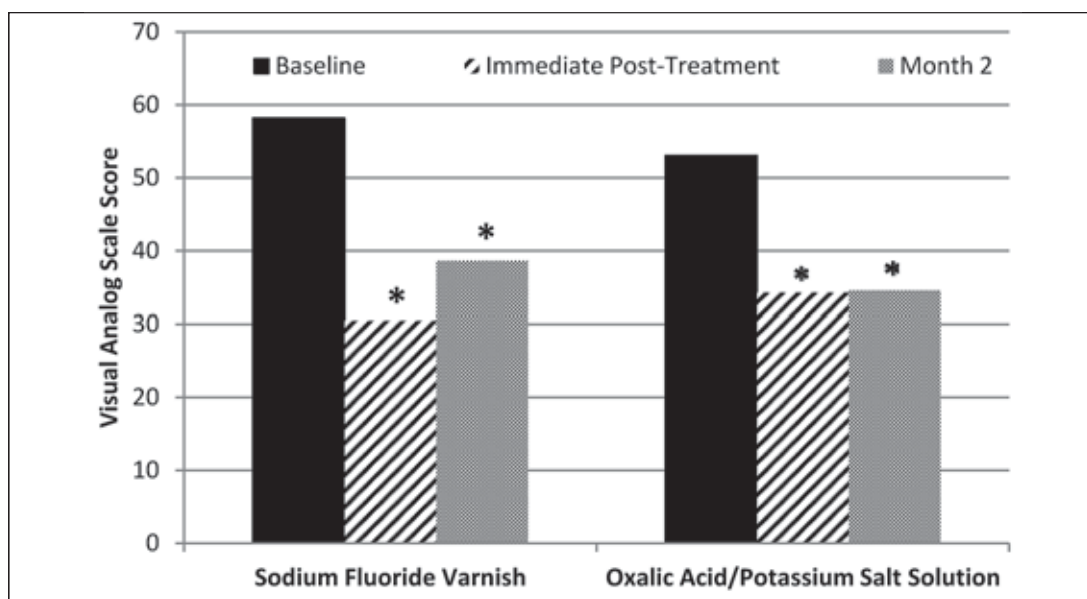


Fig. 2. The effects of sodium fluoride varnish treatment and oxalic acid/potassium salt solution treatment on mean Visual Analog Scale scores immediately post-treatment and at Month 2. * $P < 0.05$ when compared with baseline

Table 3. ANCOVA summary at Month 2.

Treatment	N	Adjusted mean (SE)	Treatment difference (95% confidence interval)	Two-sided P-value
Schiff Air Index (Baseline Mean = 2.21)				
Sodium fluoride varnish	11	1.276 (0.255)	-0.371 (-1.152, 0.409)	0.3308
Oxalic acid/Potassium salt	11	1.647 (0.267)		
Visual Analog Scale (Baseline Mean = 55.31)				
Sodium fluoride varnish	11	36.234 (7.291)	-0.959 (-23.415, 21.497)	0.9295
Oxalic acid/Potassium salt	10	37.193 (7.655)		

Immediately post-treatment, the mean Schiff score decreased to 0.91 ± 1.00 , representing a 61% reduction from baseline ($P = 0.0006$). The beneficial effect of treatment was still evident at Month 2, at which point the mean Schiff score was 1.36 ± 1.14 , representing a 41% reduction from baseline ($P = 0.0069$). For the oxalic acid/potassium salt solution group, the pre-treatment mean Schiff score was 2.18 ± 0.78 , and the immediate post-treatment mean score was 1.45 ± 1.25 , representing a 33% reduction from baseline ($P = 0.0305$). At Month 2, the mean Schiff score was 1.55 ± 0.90 , representing a 29% reduction from baseline ($P = 0.0318$).

Response to treatment: Visual Analog Scale scores - Dentin hypersensitivity was assessed by the subjects after the 1-second air blast challenge using the VAS. As with the mean Schiff scores, both treatments produced immediate beneficial effects upon mean VAS scores that were still evident at Month 2 (Fig. 2). For the sodium fluoride varnish group, the pre-treatment mean VAS score was 58.18 ± 15.46 , which decreased to 30.50 ± 28.51 immediately post treatment, representing a 41% reduction from baseline ($P = 0.0030$). At Month 2, the mean VAS score was 38.64 ± 26.67 , representing a 34% reduction from baseline ($P = 0.0275$). For the oxalic acid/potassium salt solution group, the pre-treatment mean VAS score was 53.05 ± 13.72 , and the immediate post-treatment mean score was 34.27 ± 28.27 , representing a 35% reduction from baseline ($P = 0.0168$). At Month 2, the mean VAS score was 34.55 ± 26.08 , representing a 33% reduction

from baseline ($P = 0.0283$).

Between-group differences in efficacy - An ANCOVA was used to determine if there were any between-group differences in mean Schiff scores or VAS scores immediately post-treatment and at Month 2 (Table 3). Although the mean Schiff scores and VAS scores were directionally better for the sodium fluoride varnish group than for the oxalic acid/potassium salt group at both post-treatment time points, these differences were not statistically significant ($P \geq 0.1281$ and $P \geq 0.3388$, respectively).

Safety - Both treatments were well tolerated. There were no reported adverse events in either treatment group.

Discussion

This randomized, single-blind pilot study provides evidence to support the efficacy of both 5% sodium fluoride varnish and a 3% oxalic acid/potassium salt solution to treat dentin sensitivity in otherwise healthy adults. The examiner-rated Schiff scores and the patient-rated VAS scores consistently demonstrated a reduction in sensitivity with either treatment, both immediately after professional application and at 2 months post-treatment. When the differences between groups were analyzed, we found that the mean Schiff scores and VAS scores were directionally better for the sodium fluoride varnish group than for the oxalic acid/potassium salt group at both time points, but that these differences were not

statistically significant. Both treatments were very well tolerated by the subjects.

Effective pain management for patients with dentin hypersensitivity may require multiple approaches, using both in-office and at-home treatments. Many in-home treatment options, such as desensitizing toothpaste or mouthrinses, are available, and evidence indicates that most of these options provide a desensitizing benefit.^{24,25} While some options have been shown to work relatively quickly (e.g., stannous fluoride dentifrice),^{26,27} others such as potassium nitrate may require a few weeks for the full desensitizing effects to be felt by patients.²⁸⁻³¹ Generally, the effects of in-home desensitizing treatment are not durable, requiring indefinite, twice-daily use to maintain efficacy.^{24,25} When considering professional, in-office treatment options, dentists are faced with an ever-expanding and confusing array of choices.³² Our study adds further evidence in support of the efficacy and durability of in-office treatment with both sodium fluoride varnish and an oxalic acid/potassium salt solution. Of course, the effectiveness of ingredients can be impacted by delivery, contact time, formulation and other factors, so results for an ingredient in one product cannot necessarily be generalized to another product with the same ingredient.

One of the strengths of the current study is the use of a patient population recruited from a general dentistry practice. Studies on dentin hypersensitivity are often restricted to highly selected, convenience populations such as patients from periodontal offices, students, or hospitalized patients, which limits the generalizability of the findings.⁵ Further, the mean age of our population was 46.4 years, which is consistent with the reported peak age range of dentin hypersensitivity.³³⁻³⁷ Regarding gender, our patient population was heavily female (91%), which is one limitation of this study, but research has shown that women tend to be more frequently affected with dentin hypersensitivity than men.^{6,38} Many explanations for the gender difference have been offered. Compared with men, women tend to brush more intensively, eat more fruit servings per day, visit the dentist more frequently, and articulate health problems more willingly.⁵ Finally, in order to model response after dental treatment, this pilot study did not monitor daily oral care. Any treatment effects, then, were observed against the variable background of normal daily oral care typical of the routine dental practice patients.

In conclusion, the current randomized, single-blind pilot study shows that a 5% sodium fluoride varnish can reduce examiner-graded dentin sensitivity in otherwise healthy adults by 61% immediately after treatment, and by 41% at post-treatment Month 2, while a 3% oxalic acid/potassium salt solution can reduce dentin sensitivity by 33% immediately after treatment, and by 29% at post-treatment Month 2. The patient-graded results indicate that a 5% sodium fluoride varnish can reduce dentin hypersensitivity by 41% immediately post-treatment, and by 34% at post-treatment Month 2, while a 3% oxalic acid/potassium salt solution can reduce dentin hypersensitivity by 35% immediately post-treatment and by 33% at post-treatment Month 2. Both options are effective, with no significant differences between the groups at either time point.

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