Research Article

NUPRO Sensodyne prophylaxis paste with NovaMin for the treatment of dentin hypersensitivity: A 4-week clinical study

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ABSTRACT: Purpose: The primary objective of this study was to compare the effectiveness of NUPRO Sensodyne Prophylaxis Paste with NovaMin, with and without fluoride, to a standard prophylaxis paste without fluoride (control) in reducing dentin hypersensitivity immediately after a single application following dental scaling and root planing. The secondary objective was to compare the duration of sensitivity relief up to 28 days after a single application of the NUPRO pastes with NovaMin compared to the control paste. **Methods:** This was a randomized, single-center, controlled, three-treatment, parallel-group study conducted at Salus Research in Fort Wayne, Indiana. Male and female subjects who met all inclusion/exclusion criteria and had two non-adjacent sensitive teeth based on tactile (Yeaple probe) and air blast assessments, were enrolled in the study. At baseline, tactile and air blast stimuli were administered and subjects were stratified according to their baseline air blast (Schiff) scores into one of three treatment groups: Group A (NovaMin without fluoride), Group B (NovaMin with fluoride) or Group C (NUPRO classic prophylaxis paste without fluoride). Subjects were then assessed post-treatment and at a 28-day follow-up using tactile and air blast methods. **Results:** A total of 139 patients completed the study. Subjects having received the NovaMin containing prophylaxis pastes (Groups A and B) showed statistically lower (ANOVA, $P < 0.05$) dentin hypersensitivity compared to the control group immediately after the prophylaxis procedure. Group A tactile improvements were 86% immediate, and 88% after 28 days; air blast improvements were 49% immediate, and 50% after 28 days. Group B tactile improvements were 67% immediate, and 65% after 28 days; air blast improvements were 43% immediate, and 34% after 28 days. Group C experienced little improvement in tactile and air blast scores, 9% and 4% respectively, immediately following treatment, and 10% and 1% respectively after 28 days. At both time points, the reduction in sensitivity was meaningful and significantly better than in the group receiving a standard prophylaxis paste as the comparator ($P < 0.05$). Both NovaMin pastes were effective and there was no statistical difference between the pastes with and without fluoride. There were no adverse events reported during the course of this study. (*Am J Dent* 2012;25:262-268).

CLINICAL SIGNIFICANCE: NUPRO Sensodyne Prophylaxis Paste with NovaMin relieves dentin hypersensitivity when applied during a standard prophylaxis procedure and for up to 4 weeks (28 days) after a single application.

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Introduction

Dentin hypersensitivity has been defined as short or transient sharp pain of a rapid onset that arises from exposed dentin. It usually occurs in response to stimuli (typically thermal, evaporative, tactile, osmotic, or chemical) and cannot be ascribed to any other dental defects or pathology.[1] Hypersensitivity affects one in three adults and has 60-98% prevalence in periodontal patients.[2] Dental professionals perceive the number of general population patients experiencing sensitivity to be growing as a result of the escalated usage of tooth whitening products and the expanded consumption of acidic foods and beverages. The mechanism of tooth sensitivity has been theorized to be caused by direct nerve stimulation, irritation of odontoblastic processes and by hydrodynamic flow in open dentin tubules. This latter theory, originally proposed by Gysi and later refined by Brännström, describes the most accepted mechanism for explaining the sensitivity response.[3] Laboratory models of sensitive teeth viewed by scanning electron microscope revealed varying numbers of open or partially occluded dentin tubules.[4-6] Non-sensitive surfaces have been shown to have tubules that are filled with mineral.[7] Therefore, it follows that occluding materials applied to exposed sensitive dentin surfaces should desensitize teeth by preventing stimuli from activating the intra-dental nerves.

Calcium sodium phosphosilicate, known by the trade name NovaMin,[a] has been in use since the late 1960s, and was originally utilized for the development of bone regeneration materials.[8] NovaMin is an inorganic, amorphous melt-derived glass compound that contains calcium, sodium, phosphate, and silica. This compound has been used safely for a number of years in many applications, has been tested repeatedly for biocompatibility, and has been cleared by the United States Food and Drug Administration for use in numerous medical devices.

The mode of action for NovaMin as a desensitizing agent is to physically occlude the dentin tubules. This action occurs rapidly in an aqueous environment, such as saliva, where the NovaMin material immediately releases sodium ions, which in turn increases the local pH. This process allows for the conditions for rapid precipitation of particles and the formation of a calcium hydroxyapatite mineral layer on the dentin surface. In addition, laboratory tests have repeatedly demonstrated that a single application of a sufficient concentration (>3%) of NovaMin will block open dentin tubules and will resist acid challenges.[9] This makes NovaMin an innovative addition to prophylaxis paste, as the procedure typically lasts for a few minutes, and the affects can be seen immediately.

In order to be an effective addition to a dental intervention, NovaMin must not only release ions immediately, but also maintain sufficient concentrations and be able to remain on the dentin surface over a period of time. The interactions of the NovaMin particles with collagen have been studied by a number of research groups in various in vitro models.[10,11] These studies have demonstrated the positive interaction between the reacted surface of the particles with collagen. Because exposed dentin has a high content of exposed collagen, it is reasonable to assume that this is the mechanism that allows it to remain on the dentin surface.[9] This action could provide lasting relief to patients after just one application of prophylaxis paste with NovaMin.

Based on its mode of action, it was hypothesized that prophylaxis paste with NovaMin will give patients immediate sensitivity relief as well as sensitivity relief up to 4 weeks (28 days) after treatment. Therefore, the primary objective of this study was to compare the effectiveness of NUPRO Sensodyne Prophylaxis Paste with NovaMin[b] with and without fluoride, to a standard prophylaxis paste without fluoride, in reducing dentin hypersensitivity immediately after a single application following dental scaling and root planing. Inclusive in the primary objective was the assessment of safety, which was based on intraoral exams and subject responses to the treatment.

The secondary objective of this study was to compare the duration of sensitivity relief up to 28 days after a single application of NUPRO Sensodyne Prophylaxis Paste with NovaMin, with or without fluoride, compared to a NUPRO[b] classic prophylaxis paste without fluoride.

Materials and Methods

Participants - This human clinical study was performed following ISO 14155; 2011, Clinical Investigation of Medical Devices for Human Subjects – Good Clinical Practice (GCP), ICH E6 GCP Guidelines, and the Declaration of Helsinki. The trial documentation was approved by a USA IRB. All subjects enrolled in the trial reviewed and signed informed consent. The study was registered at ClinicalTrials.gov, and key excerpts from the protocol, including all inclusion and exclusion criteria can be found on the website.

Subjects were selected for screening from a patient database located at the research facility in Fort Wayne, Indiana, USA. Inclusion criteria consisted of subjects who had a minimum of 10 natural teeth to be evaluated for sensitivity, and had a minimum of two sensitive teeth that were not adjacent to each other which may have demonstrated cervical erosion, abrasion and/or gingival recession. Qualifying subjects were adult males and females who had a response to tactile stimuli (Yeaple Probe[c]) as defined by a score of $\leq$ 20 grams of pressure and a response to the air blast stimuli as defined by a score of $\geq$ 1 on the Schiff Cold Air Sensitivity Scale. Based on accessibility, the two most sensitive, non-adjacent teeth responding to both stimuli were followed during the study.

Interventions - All enrolled subjects were given non-desensitizing sodium fluoride toothpaste (Crest Regular[d]) and an extra soft adult bristle brush to use for 14 days before the baseline appointment and for 28 days after the application of the prophylaxis paste. Subjects were asked to keep a diary documenting the instructions they were given for brushing (twice a day for 2 minutes each), as well as any medications taken (prescription or OTC). Subjects were also instructed not to use any sort of gum, rinses, whiteners or desensitizing agents for the course of the study. All visits and data collection occurred at Salus Research in Fort Wayne, Indiana, USA.

During the baseline visit, medical history and concomitant medications were updated and reviewed, an intraoral exam was performed and a sensitivity questionnaire was administered. Responses to Yeaple probe and air blast stimuli were documented prior to scaling and root planing. The subjects had their teeth scaled and root planed by a licensed dental hygienist. They were then given a sensitivity questionnaire to complete before the application of the prophylaxis paste. Paste was applied by the hygienist to all teeth using a disposable prophylaxis angle, and left on the teeth for 1 minute per the instructions for use. The pastes used for each treatment group were as follows:

- Test Group A – NUPRO Sensodyne Prophylaxis Paste, with 15% NovaMin, without fluoride, stain removal grit, orange flavor.
- Test Group B - NUPRO Sensodyne Prophylaxis Paste, with 15% NovaMin, with 2.7% fluoride, stain removal grit, orange flavor.
- Control Group C - NUPRO Classic without fluoride, coarse grit, orange flavor.

Stain removal grit and coarse grit use the same grade of pumice. The only difference is that the NUPRO Sensodyne pastes have 15% of the pumice (by weight) replaced with NovaMin.

Immediately after the application of the prophylaxis paste, Yeaple probe and air blast stimuli were applied by the examiner to the sensitive teeth and the results were documented.

Subjects returned to the study site 28 days after their initial procedure visit and received an intraoral exam, medication review and sensitivity questionnaire. The examiner then applied the Yeaple probe and air blast stimuli and documented the results.

Scoring procedures - One examiner obtained all clinical measures and was experienced in sensitivity studies, as well as calibrated in dentin hypersensitivity using tactile and evaporative assessments within the past year. All study staff were trained on the protocol procedures by the sponsor and the principal investigator prior to the initiation of the trial.

Tactile measurements scored using the Yeaple Probe - The Yeaple probe (electronic force-sensing probe, model 200A[c]) was calibrated, as described,[12] each day that subjects were examined. Testing began at 10 grams and increased by 10 grams with each successive challenge until a "yes" response was recorded or 50 grams was reached. The force setting, which elicited the "yes" response, was then repeated. If a second "yes" was not obtained, the force setting was increased by 10 grams and the process continued until a force was found which elicited two consecutive "yes" responses. The gram setting which elicited the two consecutive "yes" responses was recorded as the threshold. The upper test limit was 50 grams. If no sensitivity was found, the threshold was recorded as >50 grams.

Air blast hypersensitivity (4-point Schiff-score)[13] – An air/water syringe was checked for adequate air pressure (approximately 60 psi) prior to the start of each assessment period. Each

hypersensitive tooth was isolated by the placement of cotton over the adjacent teeth. Air was delivered from a standard dental unit air syringe directed at the exposed buccal surface of the hypersensitive tooth for 1 second from a distance of approximately 1 cm. The examiner scored the subject as follows:

0 = Tooth/Subject does not respond to air stimulus.
1 = Tooth/Subject responds 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 air stimulus, considers stimulus to be painful, and requests discontinuation of stimulus.

Sensitivity questionnaire - The sensitivity questionnaire was given to patients to monitor their perception of overall whole-mouth pain without outside stimuli. The questionnaire had the following format:

How sensitive are your teeth?
0 = No discomfort or awareness of sensitivity.
1 = Mild discomfort/pain from sensitive teeth.
2 = Moderate discomfort/pain from sensitive teeth.
3 = Severe pain from sensitive teeth.

Adverse events - Patients were monitored for adverse events during intraoral examinations performed after paste application and 28 days later. Patients were also instructed to notify the research facility if any events occurred after their baseline appointment.

Outcomes - The primary outcome was the determination of immediate relief from dentin hypersensitivity after a single application of NUPRO Sensodyne Prophylaxis Paste with NovaMin, with or without fluoride, following a standard scaling and root planing procedure. This outcome was measured by the difference in response to tactile and air blast stimuli from baseline to immediately after treatment. A sensitivity questionnaire was also administered to patients to note the overall perception of pain without outside stimuli.

The secondary outcome was dentin hypersensitivity relief measured 28 days after a single application of NUPRO Sensodyne Prophylaxis Paste with NovaMin, with or without fluoride. This outcome was measured by the difference in response to tactile and air blast stimuli from baseline to 28 days later.

Sample size - Based on the findings from a previous study, a sample size of 45 subjects per treatment group was found to be adequate to ensure 0.8 or higher power to detect a statistically significant difference in mean air blast sensitivity scores between a pair of treatments, should the actual difference between those treatments be 0.90 or greater (two-sided comparison, alpha = 0.05). To account for the possibility of up to 10% dropouts (up to 15 subjects), 50 subjects per treatment group were recruited.

Randomization - Excel© software was used for randomization. The function =RAND() which returns a random number was used in Column I to produce 300 random numbers. In Column II the letters A, B and C were placed in groups of three, 100 times (i.e., A, B, C, A, B, C etc.). The cells were then blocked in groups of three and sorted by the number in Column I from smallest to largest, which randomized the letters next to those numbers. Assigning this randomization in blocks of three ensured that the groups were evenly distributed.

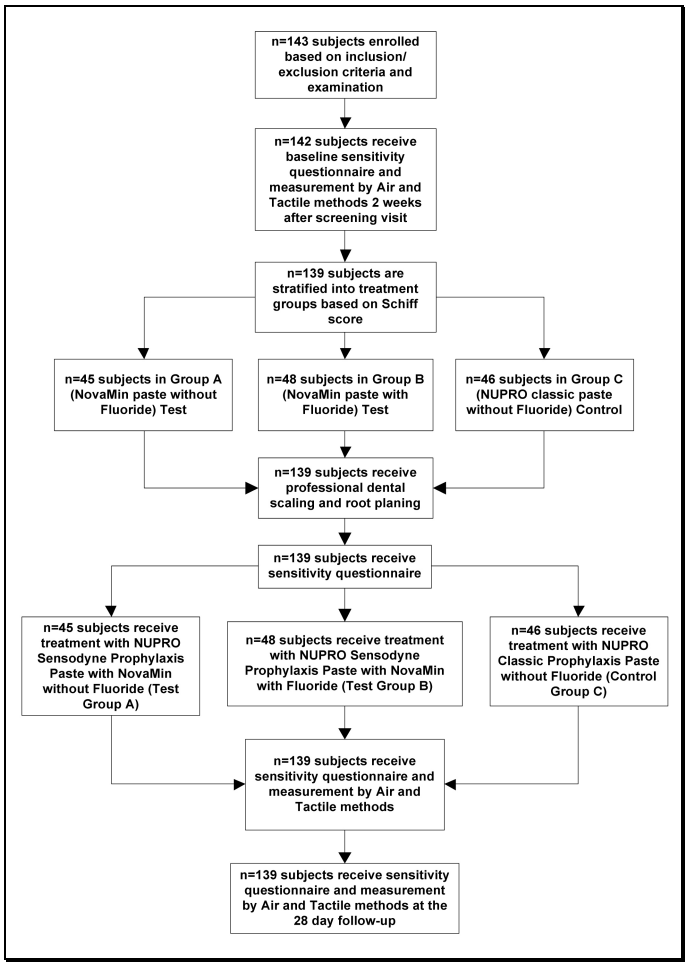

Figure. Participant flow throughout study.

Table 1. Baseline demographics and pre-treatment tactile, air blast and questionnaire data.

	Group A Novamin without fluoride	Group B Novamin with fluoride	Group C NUPRO Classic without fluoride
Total number of subjects	45	48	46
Male	9	9	11
Female	36	39	35
Mean age (years)	44	41	43
Mean (± SD) tactile threshold (gr)	10.56 ±1.59	10.00 ± 0.00*	10.98 ± 2.27
Mean (± SD) Schiff score	1.72 ± 0.58	1.70 ± 0.58	1.65 ± 0.60
Mean (± SD) questionnaire response	0.82 ± 0.72	0.67 ± 0.75	0.76 ± 0.74

*Indicates a significant difference vs Group C (control).

The random allocation sequence was generated by the sponsor and a randomization sheet was given to the study site. From the original list of numbers generated in Excel, 100 randomized letters were used for the subjects who had a Schiff score of 1, the next 100 randomized letters were used for the patients who had a Schiff score of 2 and the last 100 randomized letters were used for the patients who had a Schiff score of 3. As the patients were analyzed during their baseline visit, they were marked (by patient ID #) on the applicable

Table 2. Post-treatment tactile and air blast data (Immediate).

Parameter measured	Treatment	No. of subjects	Immediately after paste application (Mean ± SD)	Change from pre-treatment (Mean ± SD) (% change)	Comparison to pre-treatment P-value	Comparison between treatment groups (P-value)		
						vs. A	vs. B	vs. C
Tactile hypersensitivity (grams)	Group A (NovaMin without fluoride)	45	19.61 ± 11.31	9.06 ± 10.89 (86%)	<0.0001	-	NS	<0.0001
	Group B (NovaMin with fluoride)	48	16.67 ± 9.01	6.67 ± 9.01 (67%)	<0.0001	NS	-	0.0027
	Group C (Control)	46	12.01 ± 5.52	1.03 ± 5.54 (9%)	NS	<0.0001	0.0027	-
Air blast hypersensitivity (Schiff score)	Group A (NovaMin without fluoride)	45	0.88 ± 0.64	-0.84 ± 0.52 (49%)	<0.0001	-	NS	<0.0001
	Group B (NovaMin with fluoride)	48	0.97 ± 0.52	-0.73 ± 0.57 (43%)	<0.0001	NS	-	<0.0001
	Group C (Control)	46	1.72 ± 0.70	0.07 ± 0.52 (4%)	NS	<0.0001	<0.0001	-

randomization sheet (based on their Schiff Score) and were assigned a random letter (group) on the sheet. Only the sponsor was aware of the randomization code. The code was not broken during the course of this trial.

Blinding - All staff members at the study site and all subjects were blinded. The examiner was not present when the prophylaxis procedures and paste application occurred. The product was prepared and labeled by the sponsor and shipped to the study site. Each product was packaged in a non-printed container, with only a letter written on the blank lid. The details of the groups were unknown to the examiner, the study staff, and the subjects. The statistician was also blinded to the identity of the groups.

Statistical methods - Within treatment comparisons of the baseline versus the follow-up values were performed using paired t-tests. Comparisons between treatment groups at post-baseline time-points were performed using ANCOVA, in which the baseline scores were employed as a covariable. All comparative statistical tests were two-sided, and employed a level of significance of 0.05. All analyses were performed using SAS, release 9.3.[f]

Results

A total of 175 subjects were evaluated and 143 were accepted at the screening exam and appointed for the baseline visit approximately 2 weeks later (Figure). There were four subjects who were lost following the screening exams and at the baseline assessment, one of which withdrew due to a scheduling conflict and the other three were disqualified due to insufficient tactile response with the Yeaple probe. There were no deviations from the protocol during the trial.

Recruitment - After IRB approval, 388 potential subjects were queried from the Salus Research categorized database as subjects with sensitive teeth and were contacted about this study. A total of 175 subjects signed inform consent forms for participation in the study. Study initiation began on March 19, 2012. The study closeout occurred on May 8, 2012.

Demographics and baseline data (Table 1) - The three treatment groups (n = 139) were randomized after the air blast baseline assessment and before treatment began. Test Group A consisted of 45 subjects, Test Group B consisted of 48 subjects, and Control Group C consisted of 46 subjects. A group comparison at baseline resulted in a statistically significant difference between treatment Groups B and C for the tactile assessment, but the groups were evenly distributed based on the air blast assessment.

Efficacy

Immediate (Table 2) - A second exam was completed immediately following the scaling, root planing and polishing procedure. The mean values (i.e. grams of pressure) from the tactile evaluations resulted in statistically significant improvements compared to baseline in Groups A and B. The tactile pressure threshold for Group A ($P< 0.0001$) and Group B ($P= 0.0027$) were greatly improved compared to Group C. The Schiff scale sensitivity values for paste Groups A and B were significantly ($P< 0.0001$) better than baseline and these groups were significantly less sensitive than Group C.

Day 28 (Table 3) - The Day 28 Yeaple probe exams resulted in statistically significant improvements over baseline for Groups A and B. Comparisons of these group scores remained significant compared to Group C.

The Day 28 air blast assessments (i.e. Schiff Scale) for the 139 evaluable subjects resulted in statistically significant decreases in hypersensitivity for Groups A and B compared to baseline and also to Group C. Treatment Group A resulted in a significant reduction ($P= 0.02$) in air blast hypersensitivity compared to Group B at this final assessment.

Ancillary analyses

Sensitivity questionnaire (Table 4) - All subjects completed a questionnaire titled "How sensitive are your teeth?" to assess their whole-mouth tooth sensitivity prior to the baseline assessments, immediately following the scaling and root planing procedures, immediately following the timed, 1-minute prophylaxis paste application, and finally, prior to the 28-day assessments.

The "prior to baseline assessments" categorical summary of

Table 3. 28-day follow-up tactile and air blast data.

Parameter measured	Treatment	No. of subjects	Immediately after paste application (Mean ± SD)	Change from pre-treatment (Mean ± SD) (% change)	Comparison to pre-treatment P-value	Comparison between treatment groups (P-value)		
						vs. A	vs. B	vs. C
Tactile hypersensitivity (grams)	Group A (NovaMin without fluoride)	45	19.89 ± 11.46	9.33 ± 11.24 (88%)	<0.0001	-	NS	<0.0001
	Group B (NovaMin with fluoride)	48	16.51 ± 10.35	6.51 ± 10.35 (65%)	<0.0001	NS	-	0.0069
	Group C (Control)	46	12.07 ± 5.20	1.09 ± 4.91 (10%)	NS	<0.0001	0.0069	-
Air blast hypersensitivity (Schiff score)	Group A (NovaMin without fluoride)	45	0.87 ± 0.63	-0.86 ± 0.66 (50%)	<0.0001	-	0.0265	<0.0001
	Group B (NovaMin with fluoride)	48	1.11 ± 0.61	-0.58 ± 0.51 (34%)	<0.0001	0.0265	-	<0.0001
	Group C (Control)	46	1.67 ± 0.67	0.02 ± 0.69 (1%)	NS	<0.0001	<0.0001	-

Table 4. Patient sensitivity questionnaire data.

Questionnaire assessment	Treatment	No. of subjects	Mean ± SD	Change from pre-treatment Mean ± SD	Comparison to pre-treatment P-value
Post-scaling	Group A (NovaMin without fluoride)	45	1.31 ± 0.79	0.49 ± 0.73	<0.0001
	Group B (NovaMin with fluoride)	48	0.98 ± 0.67	0.31 ± 0.75	0.0058
	Group C (Control)	46	1.28 ± 0.72	0.52 ± 0.86	0.0002
Post-prophy	Group A (NovaMin without fluoride)	45	1.00 ± 0.90	0.18 ± 1.01	NS
	Group B (NovaMin with fluoride)	48	0.90 ± 0.81	0.23 ± 0.97	NS
	Group C (Control)	46	1.09 ± 0.69	0.33 ± 0.84	0.0120
Day 28	Group A (NovaMin without fluoride)	45	0.60 ± 0.62	-0.22 ± 0.70	0.0398
	Group B (NovaMin with fluoride)	48	0.50 ± 0.71	-0.17 ± 0.56	0.0443
	Group C (Control)	46	0.72 ± 0.69	-0.04 ± 0.70	NS

questionnaire scores demonstrated that the test groups were not significantly different from one another. Immediately following the scaling and root planing procedures categorical summary of questionnaire scores demonstrated that all three treatment groups had a statistically significant increase in sensitivity awareness compared to pre-treatment. The 1-minute prophylaxis paste application resulted in an overall decrease in self-reported, whole-mouth tooth sensitivity for the three treatment groups. Groups A and B were not significantly different than the pre-treatment values following the single prophylaxis paste application and Group C remained statistically more sensitive compared to pre-treatment. Lastly, the 28-day assessments revealed a statistically significant decrease in self-reported, whole-mouth tooth sensitivity for Groups A and B compared to their pre-treatment scores. However, subjects in Group C returned to their pre-treatment value for self-reported hypersensitivity.

When between-group comparisons of these data were made, no statistically significant differences were found. The fact that the study was designed and sized primarily on objective measures of sensitivity rather than questionnaire data may have contributed to this finding.

Safety - There were no adverse events or reactions to the product noted during this clinical trial.

Discussion

The inclusion of NovaMin in the prophylaxis paste represents a recent innovation for the in-office treatment of dentin hypersensitivity. The concentration needed for efficacy in this format was determined by the application of prototype formulations containing increasing concentrations (3.25%, 7.5%, 15% and 21% by weight) of NovaMin to bovine dentin samples. Examination of the surfaces with SEM, EDS spectra and FTIR demonstrated an increasing level of tubule occlusion with in-

creasing concentration. Formulations containing 15% and 21% NovaMin produced the most complete and reproducible levels of tubule occlusion.[14] Prior to clinical testing, and to confirm the efficacy of tubule occlusion by NUPRO Sensodyne Prophylaxis Paste with NovaMin (15%), bovine samples were ground, etched and treated with TRIS buffer. The samples were then polished with the commercially available product for 30 seconds, let stand for 1 minute, and rinsed with water and brushed until all pumice was removed. The SEM photos showed the bovine sample before and after treatment with the NovaMin containing prophylaxis paste under ×2000 magnification, which confirms that tubule occlusion occurred.[15]

The strongest evidence of efficacy comes from controlled clinical trials. Based on promising findings from laboratory studies and the widespread use of NovaMin in other product formats such as toothpaste, this double-blind, randomized, three-arm parallel study was conducted among a group of study participants typical of individuals for whom application of desensitizing prophylaxis paste would be intended. While the age-range for dentin hypersensitivity is broad; its peak incidence is between 20-40 years. Numerical gender differences are reported in some surveys with proportionately more females affected than males.[16] The demographics of the study participants fall into this spectrum. Research also indicates that a majority of individuals with sensitive teeth do not seek treatment.[17] The subtle onset of sensitivity allows for the unconscious development of coping strategies, such as avoidance of ice, drinking through straws, and brushing with warm water to minimize the discomfort.[18] Participants recruited for this trial were not treating their sensitive teeth, yet expressed interest in participating in a 28-day study of a relatively new treatment for sensitive teeth. In addition, each had multiple sensitive teeth making treatment with a product that is conveniently applied to all teeth, sensitive or at risk for sensitivity, an attractive solution.

The instrumentation performed during adult prophylaxis and periodontal maintenance and debridement procedures can be painful at pre-existing hypersensitivity sites and may result in new sites of transient hypersensitivity on previously exposed dentin. Patient responses to the sensitivity questionnaire used in this study demonstrated that the scaling and root planing procedure elevated their perception of pain or discomfort from sensitive teeth. However, immediately following treatment with desensitizing prophylaxis paste, levels of pain perception were found to be no different than pre-instrumentation.

The participants in this study presented with hypersensitivity prior to scaling and root planing and treatment with prophylaxis paste, and the results of subsequent clinical assessments with tactile and air stimuli were compared to pre-scaling treatment values. The results of the tactile and air blast testing, as well as patient questionnaire data, confirm the hypotheses that NUPRO Sensodyne Prophylaxis Paste with NovaMin will immediately relieve dentin hypersensitivity, regardless of cause, when it is applied following a scaling and root planing procedure. Test Group A (NovaMin paste without Fluoride) participants experienced an 86% improvement in tactile and a 49% improvement in air blast responses. Test Group B (NovaMin paste with fluoride) experienced a 67% improvement in tactile and a 43% improvement in air blast scores. Control Group C (NUPRO classic prophylaxis paste without fluoride) experienced some improvement in tactile and air blast scores (9% and 4% respectively), most likely due to the action of the polishing procedure distributing particles from the paste (such as silica) into the dentin tubules.

Relief was also measured 4 weeks (28 days) after application. At this time point, Test Group A participants experienced an 88% improvement in tactile over their pre-treatment scores and a 50% improvement in air blast responses. Test Group B experienced a 65% improvement in tactile and a 34% improvement in air blast scores. Control Group C experienced some improvement in tactile and air blast scores (10% and 1% respectively). This effect is reasonably noticeable considering that dentin hypersensitivity is episodic and can improve over time with natural remineralization. At both time points, the reduction in sensitivity was meaningful and significantly better than in the group receiving a standard prophylaxis paste as the comparator ($P < 0.05$). Both NovaMin pastes were effective and there was no statistical difference between the pastes with and without fluoride.

The availability of prophylaxis paste with NovaMin will enable dental professionals to implement a continuous care strategy to manage hypersensitivity. Using prophylaxis paste as a delivery vehicle for NovaMin is likely to be economical and requires no additional steps or techniques to apply the treatment. Therefore, a desensitizing treatment can easily be incorporated into the standard prophylaxis routine as part of preventive and periodontal procedures. For care beyond 28 days, the dental professional could offer an at-home treatment that includes NovaMin.

When considering patient benefits of this kind of care as opposed to risk, the history of the product is well established. The occurrence of allergic reaction to NUPRO prophylaxis paste products is rare, and no reported incidence led to any adverse events in the present study. In addition, results from an extended 8-week treatment period of twice daily use of a toothpaste among 285 subjects provides further evidence of tolerability.[19] Therefore, the risks associated with the use of NUPRO Sensodyne prophylaxis paste containing NovaMin, a medical device, are minimal and are outweighed by the benefit the patient will receive from immediate and long term sensitivity relief as well as clean and polished teeth.

This was a single use study that compared test products to a negative control. Further clinical studies are necessary to explore additional benefits provided by NUPRO Sensodyne Prophylaxis Paste with NovaMin.

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