

Clinical evaluation of the efficacy of bioactive glass and strontium chloride for treatment of dentinal hypersensitivity

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ABSTRACT

Objective: Bioactive glass is a calcium sodium phosphosilicate material (24.5% CaO, 24.5% Na₂O, 6.0% P₂O₅, and 45% SiO₂) that was originally developed as an implant material to regenerate bone and recently adapted for use in oral care products (NovaMin[®], NovaMin Technology Inc.). NovaMin reacts rapidly with saliva to release sodium, which increases the salivary pH, as well as calcium and phosphate, creating the ideal conditions for tooth remineralization. NovaMin has been shown to occlude dentinal tubules and remineralize dentin; therefore, it could be used in the treatment of dentinal hypersensitivity. Thus, the aim of this study was to compare *in vivo* the effect of NovaMin and 10% strontium chloride containing dentifrices on dentinal hypersensitivity in a 6-week clinical study. **Materials and Methods:** Forty subjects were evaluated clinically for dentinal hypersensitivity using air blast method (dental air syringe) and cold water method, along with subjective perception of pain (0–10 scale) at baseline and at 2, 4, and 6 weeks. The subjects were then randomly divided into two groups and each group was treated with one of the two test dentifrices. **Results:** There was a general decrease in dentinal hypersensitivity levels in both the groups over 6 weeks, but there was a statistically greater difference in hypersensitivity at 2, 4, and 6 weeks in the group treated with DenShield[™] (NovaMin containing dentifrice) when compared with the Senolin[®] (strontium chloride containing dentifrice) group.

CLINICAL RELEVANCE TO INTERDISCIPLINARY DENTISTRY

- (1) Dentin hypersensitivity is common problem experienced in clinical dental practice.
- (2) It can occur due to changes in the crown, which involve removal of enamel as a result of attrition, abrasion, or erosion. Alternative causes of pain include chipped or fractured teeth, cracked cusps, carious lesions, leaky restorations, and developmental grooves.
- (3) It can also occur due to exposure of root dentin as seen in gingival recession which is caused by chronic trauma from tooth brushing, acute and chronic inflammatory gingival and periodontal diseases, and acute trauma, as with periodontal surgery.
- (4) The problem of dentin hypersensitivity is of concern to the general dental practitioner, the endodontist, and the periodontist, as the treatment requires a multidisciplinary approach very often. Correction could involve desensitizing dentifrices, restoration, crowns, and root coverage.

Key words: Bioactive glass, dentin hypersensitivity, dentinal tubules, strontium chloride

INTRODUCTION

Dentin hypersensitivity is defined as sharp pain arising from the exposed dentin typically in

response to chemical, thermal, tactile, or osmotic stimuli that cannot be explained as arising from any other form of dentinal defect or pathology. As Wycoff^[1,2] stated in 1982, it can be a potential threat to the individual's oral health because such pain may interfere with the maintenance of good oral hygiene.^[1,2] Dentin hypersensitivity is commonly found in adult population and its incidence varies from 4 to 74%.^[3] It occurs during 30–50 years and a peak incidence is found at the end of the third decade.^[4,5] The etiology of dentin hypersensitivity is multifactorial. Dentin hypersensitivity usually is

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diagnosed after other possible conditions have been eliminated. Alternative causes of pain include chipped or fractured teeth, cracked cusps, carious lesions, leaky restorations, and developmental grooves. The etiology of dentin hypersensitivity is multifactorial. Dentin hypersensitivity usually is diagnosed after other possible conditions have been eliminated. For dentin to be sensitive, it must be exposed to the oral environment. This exposure may occur by one or both of two processes: Either removal of the enamel or denudation of the root surface by loss of the overlying cementum and periodontal tissues. Dentin hypersensitivity can occur due to changes in the crown, which involve removal of enamel as a result of attrition, abrasion, or erosion.^[6-8] Alternative causes of pain include chipped or fractured teeth, cracked cusps, carious lesions, leaky restorations, and developmental grooves. It can also occur due to exposure of root dentin as seen in gingival recession which is caused by chronic trauma from tooth brushing, acute and chronic inflammatory gingival and periodontal diseases, and acute trauma, as with periodontal surgery.^[9,10]

Currently, there are many agents used to manage hypersensitivity. Dental professionals have a variety of regimens, including both in-office treatments and patient-applied products for home use. Various chemical compounds, such as silver nitrate, sodium fluoride, stannous fluoride, resins, and strontium chloride, have been used for occlusion of open dentinal tubules.^[11-15] Among these, strontium chloride has been largely used for this purpose, and previously published studies have shown that strontium chloride can effectively occlude the open tubules. The hydrodynamic theory postulates that the most pain provoking stimuli increase the outward flow of the fluid in the tubules. This increased outward flow of the fluid in the tubules in turn causes pressure change across the dentin which activates the A-delta intradental nerves at the pulp-dentin border or within the dentinal tubule.^[1,16,17] According to the hydrodynamic theory the lesion must have the dentinal tubules open at the dentin surface and should be patent to pulp. This has been confirmed by Yoshiyama, Pashley and Absi^[11,18,19]. Bioactive glass is a calcium sodium phosphosilicate material (24.5% CaO, 24.5% Na₂O, 6.0% P₂O₅, and 45% SiO₂) that was originally developed as an implant material to regenerate bone and recently adapted for use in oral care products (NovaMin[®], NovaMin Technology Inc., Alachua, FL, USA). NovaMin reacts rapidly with saliva to release sodium, which increases the salivary pH, as well as calcium and phosphate, creating the ideal conditions for tooth remineralization. NovaMin has been shown to occlude dentinal tubules and remineralize dentin; therefore, it could be used in the treatment of dentinal hypersensitivity. Thus, the aim of this study was to compare *in vivo* the effect of NovaMin and 10% strontium chloride containing dentifrices on dentinal hypersensitivity in a 6-week clinical study.

MATERIALS AND METHODS

Study design

This was an open-label, single-center, parallel-group, blinded, 6-week clinical study that included 40 subjects and was conducted by the Principle Investigator. The protocols for the study were developed as per the guidelines for the design and conduct of clinical trials on dentinal hypersensitivity.^[12]

Selection criteria

Forty patients with a history of tooth hypersensitivity, who were seeking treatment in the out-patient dental department, were selected for the study with the following inclusion and exclusion criteria.

Inclusion criteria

The inclusion criteria required patients between the ages of 20 and 50 years. Subjects included in the study were in good general health and had at least 20 natural permanent teeth in the oral cavity and history of hypersensitivity to hot, cold, or sour stimuli on at least two posterior (pre-molars and molars) teeth. All patients were evaluated to ensure that they were currently using toothbrush and toothpaste for their oral hygiene procedures.

Exclusion criteria

Patients with active cervical caries or deep abrasion requiring Class V filling, chipped teeth, or fractured cusps were excluded from the study. In addition, patients with a tender tooth in the same quadrant as the hypersensitive teeth, as well as those using any type of desensitizing therapy for the last 6 months were excluded. Subjects with a history of chronic use of anti-inflammatory and analgesic medication, pregnant or lactating females, and those with history of chronic regurgitation of acids and/or periodontal surgery in the preceding 6 months were also excluded.

Evaluation of hypersensitivity

The study was explained to the subjects and informed consent forms for their willingness to be a part of the study for 6 weeks were obtained. Teeth that were reported to be hypersensitive by the subject were verified by light strokes of dental explorer along the cervical margins/areas of all the teeth present. All the subjects underwent oral prophylaxis before the study. After a 4-week wash-out period during which time subjects followed their normal hygiene practices, baseline visual analog scale (VAS) scores (Hurkisson 1974) indicating dentinal hypersensitivity level to cold water and air blast were recorded. A mean sensitivity score for each patient was calculated using these stimuli. These mean scores became the data that were later analyzed.

Air blast test

A standard air water syringe with restricted air stream (55 psi) was directed toward the sensitive portion of the tooth perpendicular to the long axis of the tooth for a duration of 1 second and at a distance of about 1 cm. Adjacent teeth were protected by the operator's fingers and cotton rolls. The patient's response to the intensity of pain was captured on a 10-cm VAS. The test was repeated three times and the average final score was recorded. Teeth with a VAS score between 4 and 10 cm were selected (10, severe pain; 0, no pain).

Cold water test

Approximately 15 min after the air blast test, the tooth reported to be sensitive by the patients was isolated with cotton rolls. Cold water stimulus (8°C–10°C) was delivered as 1 ml of cold water applied to the buccal cervical region using a standard micropipette. Patient's response on the VAS was measured. The test was repeated three times and the average final score was recorded. Teeth with a VAS score between 4 and 10 cm were selected (10, severe pain; 0, no pain).

Dentifrices tested

The dentifrices tested were:

7.5% NovaMin-DenShield NovaMin®, NovaMin Technology Inc., Alachua, FL, USA

10% strontium chloride-Senolin® – Warren, Division of Indoco pharmaceuticals Ltd, Mumbai, India

After the collection of the baseline data, the subjects were randomly divided into two groups of 20 subjects each. Each group was provided with one of the test dentifrices in its commercial package. Each patient was provided with adult soft bristle toothbrush and was advised to apply the dentifrice in an amount equal to about half the length of the bristle head. The patients were instructed to brush their teeth in the usual manner for 3 min, twice daily. Patients were instructed not to eat or drink anything within half an hour of brushing with the dentifrices. They were recalled at 2 weeks, 4 weeks, and 6 weeks for the measurement of tooth sensitivity by the two methods.

At the recall visits, all used dentifrices were returned and new material was dispensed. During the study period, the use of other oral hygiene products as well as any other dental treatment for hypersensitive teeth were not permitted. Drugs, like analgesics, that may have altered the perception of pain perception were not permitted within 24 h of the assessment.

Statistical analysis

Data were analyzed using analysis of variance (ANOVA) and the Bonferroni *post-hoc* test for multiple comparisons.

Since there were three factors in the study, i.e. toothpaste (bioactive glass and strontium chloride), test (air and cold water), and time interval (baseline, 2 weeks, 4 weeks, and 6 weeks), ANOVA was used.

All the samples were independent, i.e. did not take any repeated measurements on the same sample at different time intervals.

RESULTS

No side effects occurred in all the subjects included in the study upon use of the active product. All the 40 subjects were evaluated at baseline and at the recalled intervals of 2, 4, and 6 weeks.

Mean VAS scores are displayed in Tables 1 and 2. The mean change in air scores compared to baseline for both toothpastes are displayed in Figure 1 and for cold water are displayed in Figure 2.

Anova

There was a significant difference between the two toothpastes, NovaMin and strontium chloride, with respect to the mean VAS scores ($P < 0.001$). There was also a significant difference in the mean sensitivity scores between the two test mediums, i.e. air and cold water ($P < 0.001$), and between the time intervals ($P < 0.001$).

Table 1: DenShield® visual analog scale scores for dentifrice containing bioactive glass

Test	Time interval	Mean (cm)	Std. dev.
Air	Baseline	6.35	0.93
	2 weeks	4.5	0.83
	4 weeks	2.5	0.76
	6 weeks	0.45	0.51
	Total	3.45	2.34
Cold water	Baseline	6.55	0.89
	2 weeks	4.7	0.86
	4 weeks	3	0.73
	6 weeks	0.6	0.6
	Total	3.71	2.33

Table 2: Senolin® visual analog scale scores for dentifrice containing strontium chloride

Test	Time interval	Mean (cm)	Std. dev.
Air	Baseline	6.25	0.79
	2 weeks	5.25	0.72
	4 weeks	4.1	0.64
	6 weeks	2.8	0.77
	Total	4.6	1.48
Cold water	Baseline	6.65	0.88
	2 weeks	5.95	0.83
	4 weeks	4.9	0.72
	6 weeks	3.3	0.92
	Total	5.2	1.51

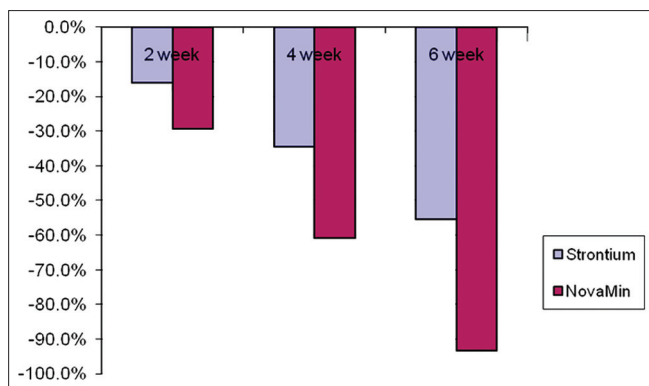


Figure 1: Change versus baseline – air

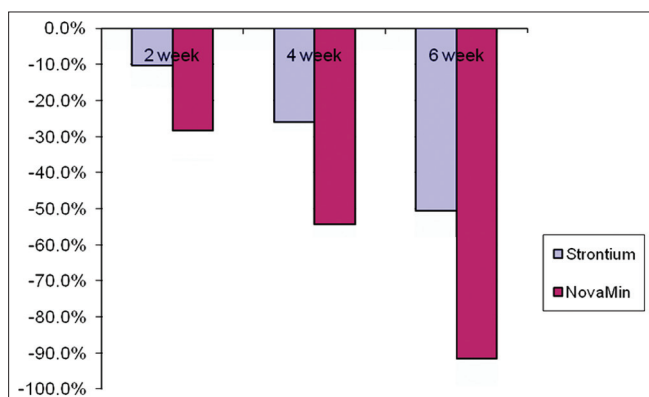


Figure 2: Change versus baseline – water

The interaction between the type of toothpaste and the test medium (air and water) was found to be insignificant ($P = 0.054$), i.e. the toothpastes did not behave differently when used in different test mediums, either air or cold water. Similarly, there was no interaction effect between the test medium and the time intervals ($P = 0.474$), whereas there was a significant interaction effect between the toothpaste and time intervals ($P < 0.001$). The interaction between all the three factors, viz. toothpaste, test medium, and time intervals, was also not significant ($P = 0.943$).

It can also be concluded that subjects treated with the dentifrice containing NovaMin showed less sensitivity compared to subjects treated with the dentifrice containing strontium chloride at all the tested time intervals.

When tested in “air” medium, the sensitivity was low, compared to “cold water.” Graphs 1 and 2 indicate gradual decrease in the sensitivity levels from baseline to 6 weeks time period. The sensitivity was lowest at the end of 6 weeks.

Multiple comparisons

In order to find out the time intervals test at which the sensitivity changes were significant, a post-hoc test using the Bonferroni method was conducted. For air, at weeks

2, 4, and 6, there were significant main effects for the group with NovaMin, which was more effective than the group with strontium chloride. For water at weeks 2, 4, and 6, there were significant main effects for group with NovaMin, which was more effective compared to the strontium chloride group.

DISCUSSION

The objectives of this study were to evaluate the desensitizing efficacy, safety, and relative effectiveness of a dentifrice formulation, DenShield, containing 7.5% calcium sodium phosphosilicate (NovaMin), and Sensolin, a dentifrice containing 10% strontium chloride as the desensitizing ingredient. The results of this clinical trial demonstrate that both dentifrices have cumulative effects over a 6-week period and are well tolerated. In addition, the desensitizing efficacy of DenShield, with 7.5% calcium sodium phosphosilicate dentifrice (NovaMin), was found to be significantly greater when compared with Sensolin, containing 10% strontium chloride dentifrice.

Strontium chloride is one of the many desensitizing agents that have been used to treat sensitivity with varying degrees of success.^[20] Lower reduction in sensitivity by strontium chloride may be due to its mechanism of action. Skurnick^[20] in an uncontrolled study has shown decreased dentinal sensitivity is only short term in 93% of the cases, and is mostly produced by abrasive fillers occluding the open dentinal tubule.

Studies by Henry O Trowbridge *et al.*^[21] and Hodge and colleagues showed that strontium strongly absorbs to calcified tissues. It has been suggested that strontium deposits are produced by an exchange with calcium in the dentin, resulting in recrystallization in the form of a strontium apatite complex.^[12,21,22] This type of precipitation is known to reduce the diameter of the open tubules. When the desensitizing agent is delivered in a dentifrice, partial tubule occlusion may also be achieved by means of both strontium apatite complex and silica abrasive particles.^[12,23] The presence of abrasives can produce tubule occlusion with varying degrees of success.^[24,25] Studies by Addy and Mustafa^[26] have shown that the abrasive silica particles in the therapeutic dentifrices can also occlude the open dentinal tubule, but this is dependent on the specific composition of the dentifrice vehicle, especially with respect to the choice of surfactant. Addy’s work suggests that silica in combination with a non-ionic detergent will adhere to the dentin surface. In this study, we used a commercially available dentifrice containing strontium chloride; therefore, the exact composition of the vehicle and choice of surfactant is not known for certain.

Dentifrices containing strontium chloride have been available for over four decades. Consequently, clinical studies testing the efficacy of the products span a range of designs, from simple monadic studies that utilize only subjective perception as assessments to double-blind placebo-controlled studies that utilize application of controlled stimuli to evoke a response. Many, but not all, of these studies support the home use of dentifrices containing 10% strontium chloride for the treatment of dentinal hypersensitivity, including sensitivity as a result of periodontal surgery. While the weight of evidence supports its use, the degree of efficacy of strontium compared to other agents and the duration of its effect have been considered uncertain by some authors.^[11]

As Figures 1 and 2 illustrate, both dentifrices were effective in this study, with greater than 50% reduction in baseline scores for pain intensity after 6 weeks in the strontium toothpaste group and 90% reduction in the calcium sodium phosphosilicate group.

In this study, the toothpaste containing NovaMin outperformed the toothpaste containing strontium chloride. NovaMin is a relatively new material based on the bioactive glass originally used as bone graft material, and therefore is known to be highly biocompatible. Recently, it has been used for treating dentin hypersensitivity and known to occlude the open tubules by depositing hydroxycarbonate apatite, a mineral that is chemically and structurally similar to the mineral in enamel and dentin.^[27,28]

In this study, it was shown that the efficacy of NovaMin was comparatively higher than that of strontium chloride at all the tested time intervals. The reason for this could be explained, in part, by mechanistic factors that lead to surface deposition and tubule occlusion by NovaMin. These materials are reactive when exposed to body fluids and deposit hydroxycarbonate apatite, a mineral that is chemically similar to the mineral in enamel and dentin.^[29] In this study, the therapeutic response occurred within 2 weeks and increased with time.

The reaction of NovaMin particles begins when the material is subjected to an aqueous environment. Sodium ions (Na⁺) in the particles immediately begin to exchange with hydrogen cations (H⁺ or H₃O⁺).^[23] This rapid release of ions allows calcium (Ca⁺) ions in the particle structure, as well as phosphate (PO₄³⁻) ions to be released from the material. This initial series of reactions occurs within seconds of exposure, and the release of the calcium and phosphate ions continues so long as the particles are exposed to the aqueous environment.^[19,30] A localized, transient increase in pH occurs during the initial exposure of the material due to the release of sodium. This increase in pH helps to precipitate the calcium and phosphate ions from the NovaMin particle, along with calcium and

phosphorus found in saliva, to form a calcium phosphate (Ca-P) layer. As the particle reactions and the deposition of calcium and phosphorus complexes continue, this layer crystallizes into hydroxycarbonate apatite, which is chemically and structurally equivalent to biological apatite.^[23] The combination of the residual particles and the newly formed hydroxycarbonate apatite layer results in the physical occlusion of dentinal tubules, which will relieve hypersensitivity. The tubular orifices are completely obliterated by formation of hydroxycarbonate apatite. *In vitro* studies have shown that this layer is resistant to acid challenges and is mechanically strong. Continuous release of calcium from this layer may help to maintain the protective effects on dentin and continual occlusion of the dentin tubules. These findings help to distinguish NovaMin from strontium chloride. The results of this study are consistent with the results of previously published *in vitro* and *in vivo* studies.^[31-33] The results of this study are in accordance with other studies,^[31,32] which suggests that dentifrice containing NovaMin occludes dentin tubules and provides rapid and significantly more relief from dentin hypersensitivity compared to a dentifrice containing 5% potassium nitrate. The NovaMin group was found to be significantly better in reducing the VAS score compared to the potassium nitrate group at any time point for both the controlled air group and cold water stimulus.

NovaMin containing dentifrice has also shown to reduce the sensitivity significantly more than the dentifrice containing 0.4% stannous fluoride and potassium nitrate.^[33]

Study by Anora Burwell *et al.*^[34] demonstrated the ability of novaMin to rapidly occlude dentinal tubules, remain on the dentin surface in the face of acid challenges, and form a biologically stable hydroxycarbonate apatite layer on the surface of dentin.

CONCLUSION

Both NovaMin and strontium chloride containing dentifrices exhibited significant reduction in dentin hypersensitivity when used for 6 weeks, with NovaMin exhibiting significantly higher reduction in sensitivity at the tested time intervals of 2, 4, and 6 weeks.

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