

# Evaluation of the efficacy of a 5% calcium sodium phosphosilicate (Novamin®) containing dentifrice for the relief of dentinal hypersensitivity: A clinical study

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## ABSTRACT

**Context:** Dentinal hypersensitivity (DH) is a commonly encountered problem. Several products are used in management of DH with varying results. Need is felt in dentistry for a material that chemically reacts, physically occludes and adheres intimately to dentinal tubules to reduce the possibility of its recurrence. One such material is calcium sodium phosphosilicate-Novamin®.

**Aim:** To evaluate an efficacy of a 5% calcium sodium phosphosilicate (Novamin® SHY NM™) containing dentifrice compared to placebo for the relief of DH.

**Settings and Design:** Outpatients visiting Dept of Periodontics, Yenepoya Dental College with DH were deemed eligible for this case-control clinical trial after an informed consent.

**Materials and Methods:** 30 patients having at least 2 sensitive teeth with a VAS (Visual Analogue Scale) of >3 cm after air blast stimulation, qualified to participate in the study. Test (SHY NM™ toothpaste containing 5% calcium sodium phosphosilicate) and control (Pepsodent toothpaste without a desensitizing agent) groups, each containing 15 participants, were subjected to cold water and air blast stimulation for an assessment of DH at baseline, 6<sup>th</sup> and 8<sup>th</sup> week using VAS.

**Statistical analysis used:** Unpaired t-test and repeated measures ANOVA.

**Results:** 5% Novamin® containing dentifrice significantly reduced DH within 6<sup>th</sup> and 8<sup>th</sup> week of usage when compared to a placebo dentifrice.

**Conclusions:** A Novamin® containing dentifrice significantly reduced DH when compared to a placebo dentifrice.

**Key words:** Calcium sodium phosphosilicate, dentinal hypersensitivity, Novamin®

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Several products have been used to manage dentinal hypersensitivity (DH), which either prevent the conduction of pain impulses or mechanically occlude the dentinal tubules, but present highly variable results.<sup>[1-5]</sup> The best way to remineralize enamel is the most natural way, through the saliva. Novamin®(calcium sodium phosphosilicate) is a new material available, which when exposed to water/body fluids (saliva), reacts instantly by releasing billions of mineral ions that become available to the natural remineralization process in the mouth. It deposits hydroxycarbonate apatite

and reduces the possibility of reopening the dentinal tubules. It is made from the same bioactive material, which is used in the most advanced bone regeneration material. And as it is made with the same minerals naturally found in saliva, it is safe and non-toxic.<sup>[6-8]</sup>

The objective of this clinical study was to clinically evaluate an efficacy of a 5% calcium sodium phosphosilicate (Novamin®) containing dentifrice, compared to placebo for the relief of DH.

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## MATERIALS AND METHODS

After obtaining the due clearance from the ethical committee of the Yenepoya University, a total of 30 subjects with DH were recruited from the patients reporting to the Department of Periodontics, Yenepoya Dental College and Hospital, who gave consent to participate in the study. Study period extended upto 11 months.

## Inclusion criteria

- Subjects aged between 18-65 yrs

- At least two sensitive teeth (buccal/facial aspect with recession, abrasion, erosion) with a score of >3 cm using air blast on the Visual Analogue Scale (VAS 10 cm, ranging 0 = no pain, 10 = extreme pain)

### Exclusion criteria

- Subjects with a history of allergy to any of the drugs or chemicals used in the study.
- Any removable appliance (RPD or orthodontic retainer).
- On-going orthodontic treatment with fixed appliances.
- Presence of any large or defective restorations, cracked enamel or caries on the hypersensitive tooth.
- Pregnancy and lactating mothers.
- Dental pathology causing pain similar to dentin hypersensitivity.
- Patients with any systemic problem or mental or physical disability.

Adjacent teeth were isolated using gauze. 2 measures of sensitivity were used in the study: air blast and cold water stimulation.

Air blast stimulation: A 3 seconds air blast from an air syringe held perpendicular and 3 mm away from the exposed dentin at a pressure of 40-65psi.

Cold water stimulation: 1 ml of freshly melted ice cold water was delivered drop wise on to the buccal/facial cervical region using a syringe.

The time interval between measures on a given tooth was 5 minutes. Tooth sensitivity was recorded by marking the degree of discomfort on a 10 cm VAS.

Patients were divided into 2 groups, each containing 15 participants. This study being a single blind clinical trial, the first examiner performed the designated tests and collected the readings and the second examiner distributed the sample products. One group was given product A (test-SHY NM™ toothpaste with 5% calcium sodium phosphosilicate) and the other group was given product B (control- Pepsodent toothpaste, without a desensitizing agent) alternatively to each patient by the second examiner. Both groups were instructed to brush twice daily with soft toothbrush and toothpaste (2 cm in length) using Modified Stillman's method as explained and standardized by the second examiner.

At the end of the 6<sup>th</sup> and 8<sup>th</sup> week, VAS scores were collected by the first examiner as the subjects recorded their responses to air blast and cold water stimulus.

### RESULTS

The results from the study were statistically analyzed using SPSS17 and MS Excel. Unpaired t-test and

repeated measures ANOVA was used to test the significance.

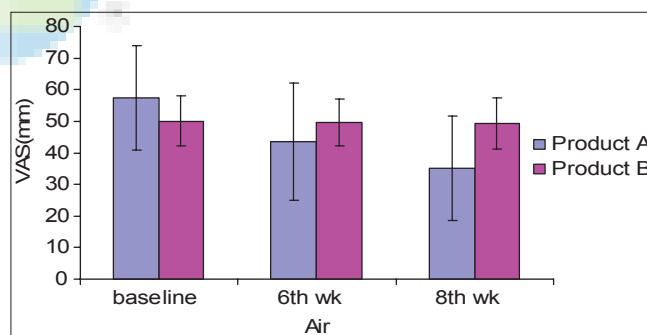
- It showed that there were significant effects of the treatment with Novamin® dentifrice, which were statistically better at reducing the sensitivity than placebo, particularly in the 8<sup>th</sup> week. The effects were statistically significant over the other time periods as well.

[Table 1 and Graph 1] shows that, when product A and product B were compared for air stimulation at baseline and 6<sup>th</sup> week, there was no statistically significant reduction in DH for both the groups. But in the 8<sup>th</sup> week, product A showed significant reduction in DH with *P* value = 0.007.

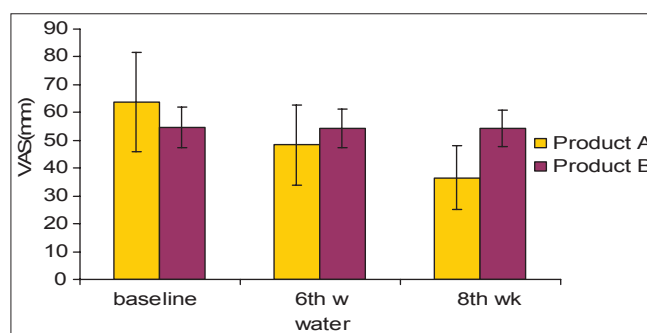
[Table 2 and Graph 2] shows that, when product A and product B were compared for water stimulation at baseline and 6<sup>th</sup> week, there was no statistically significant reduction in DH for both the groups. But in the 8<sup>th</sup> week, product A showed significant reduction in DH with *P* value <0.0005.

[Table 3 and 4] shows comparison of the results between baseline, 6<sup>th</sup> and 8<sup>th</sup> week for product A in response to air and water stimulation, and a statistically significant reduction in DH was noted with *P* value <0.0005.

[Table 5 and 6] shows comparison of the results between baseline, 6<sup>th</sup> and 8<sup>th</sup> week for product B in response to air and



Graph 1: Comparison between Product A and Product B - Air stimulation



Graph 2: Comparison between Product A and Product B -Water stimulation

water stimulation. The *P* value = 0.183 for air stimulation and 0.168 for water stimulation. The product B showed no statistically significant reduction in DH in response to air and water stimuli.

**Table 1: Comparison between Product A and Product B - Air stimulation**

Group	N	Mean	Std. deviation	<i>P</i>	Significance
Baseline Product A	15	57.40	16.578	.138	Not significant
Product B	15	50.07	7.896		
6 <sup>th</sup> week Product A	15	43.47	18.578	.240	Not significant
Product B	15	49.67	7.403		
8 <sup>th</sup> week Product A	15	35.13	16.535	.007	Statistically significant
Product B	15	49.27	8.049		

**Table 2: Comparison between Product A and Product B - Water stimulation**

Group	N	Mean	Std. deviation	<i>P</i>	Significance
Baseline Product A	15	63.80	17.773	.084	Not significant
Product B	15	54.73	7.285		
6 <sup>th</sup> week Product A	15	48.33	14.311	.154	Not significant
Product B	15	54.33	6.821		
8 <sup>th</sup> week Product A	15	36.60	11.444	<.0005	Statistically significant
Product B	15	54.20	6.494		

**Table 3: Air stimulation - Product A within the group from Baseline to 8<sup>th</sup> week**

	Mean	Std. deviation	<i>P</i>	Significance
Baseline	57.40	16.578	<.0005	Statistically significant
6 <sup>th</sup> week	43.47	18.578		
8 <sup>th</sup> week	35.13	16.535		

**Table 4: Water stimulation - Product A within the group from Baseline to 8<sup>th</sup> week**

	Mean	Std. deviation	<i>P</i>	Significance
Baseline	63.80	17.773	<.0005	Statistically significant
6 <sup>th</sup> week	48.33	14.311		
8 <sup>th</sup> week	36.60	11.444		

**Table 5: Air stimulation - Product B within the group from Baseline to 8<sup>th</sup> week**

	Mean	Std. deviation	<i>P</i>	Significance
Baseline	50.07	7.896	.183	Not significant
6 <sup>th</sup> week	49.67	7.403		
8 <sup>th</sup> week	49.27	8.049		

**Table 6: Water stimulation - Product B within the group from Baseline to 8<sup>th</sup> week**

	Mean	Std. deviation	<i>P</i>	Significance
Baseline	54.73	7.285	.168	Not significant
6 <sup>th</sup> week	54.33	6.821		
8 <sup>th</sup> week	54.20	6.494		

## DISCUSSION

Dentin hypersensitivity is defined as a sharp pain arising from the exposed dentin as a result of various stimuli like heat, cold, chemicals, or due to bacteria.<sup>[9]</sup> It is an enigma, being frequently encountered but poorly understood.<sup>[10]</sup> Lack of knowledge regarding the etiology, nature of the lesion and status of the pulp makes the management of the condition difficult and recurrences appear commonly.<sup>[11-13]</sup> Abrasion and erosion of the teeth or denudation of the root surfaces due to gingival recession or periodontal treatment results in dentin exposure.<sup>[9]</sup>

DH commonly affects 8-57% of the population with an increased prevalence of 72-98% in periodontal patients aged between 30-40 years, mostly women.<sup>[11,13,14]</sup>

The currently accepted Brännstrom theory for tooth hypersensitivity proposes that, open dentinal tubules allow fluid to flow through the tubules, which excite nerve endings in the dental pulp.<sup>[15]</sup>

There have been 2 basic approaches to the treatment and prevention of DH.

- A chemical agent that penetrate into the dentinal tubules, depolarizes the nerve synapse and, thereby prevents the conduction of pain impulses (e.g., potassium nitrate).<sup>[1]</sup>
- A chemical or physical agent that creates a deposition layer and mechanically occludes dentinal tubules, which prevents pulpal fluid flow (e.g., potassium oxalate, ferric oxalate, strontium chloride).<sup>[2,3]</sup>

Although both approaches are effective at reducing or eliminating the hypersensitivity, the duration of relief is highly variable. Hypersensitivity usually reappears due to toothbrush abrasion, the presence of acid challenges in the mouth, and/or degradation of the coating material.<sup>[4,5]</sup>

Therefore, there is a need in the dental field for a material that will chemically react with the surface of dentin, will intimately adhere to the tooth structure and will significantly reduce the possibility of reopening the dentinal tubules. Novamin<sup>®</sup> (calcium sodium phosphosilicate) is one such material, which reacts when exposed to the body fluids, and deposits hydroxycarbonate apatite, a mineral that is chemically similar to the mineral in enamel and dentin.<sup>[6,7]</sup> It is a bioactive glass, which is highly biocompatible that is originally developed as bone regenerative material.<sup>[6]</sup>

The physical occlusion of Novamin<sup>®</sup> particles begins when the material is subjected to an aqueous environment. Sodium ions (Na<sup>+</sup>) in the particles immediately begin to exchange with hydrogen cations (H<sup>+</sup> or H<sub>3</sub>O<sup>+</sup>). This rapid release of ions allows calcium (Ca<sup>+</sup>) ions in the particle structure,

as well as phosphate ( $\text{PO}_4^{3-}$ ) ions to be released from the material. This initial series of reactions occurs within the seconds of exposure, and the release of the calcium and phosphate ions continues so long as the particles are exposed to an aqueous environment.<sup>[6]</sup>

A localized, transient increase in pH occurs during an 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<sup>®</sup> particle, along with the calcium and phosphorus found in saliva, to form a calcium phosphate (Ca-P) layer.

As the particle reactions continue and the deposition of Ca and P complexes continue, this layer crystallizes into hydroxycarbonate apatite, which is chemically and structurally equivalent to biological apatite.

The combination of the residual Novamin<sup>®</sup> particles and the hydroxycarbonate apatite layer results in the physical occlusion of dentinal tubules, which will relieve the hypersensitivity.<sup>[16]</sup>

The results of the current study demonstrated that, a Novamin<sup>®</sup> containing dentifrice has an ability to significantly reduce the dentin hypersensitivity when compared to a placebo dentifrice.

The result of this study is in accordance with the observation of a double-blind, placebo-controlled trial conducted by Litkowski L, in which an ability of calcium sodium phosphosilicate (CSP) in reducing the dental hypersensitivity was evaluated at baseline, 2, 4 and 8 weeks by using cold air and tactile stimulation using 3 different formulations of 7.5%, 2.5% and 0%. The clinical observations revealed that, dentifrice containing 2.5% and 7.5% CSP reported a statistically significant reduction in sensitivity. The 7.5% showed a more rapid and greater magnitude of reduction in sensitivity.<sup>[17]</sup>

In a scanning electron microscope study, original Bioglass<sup>®</sup> and 3 coded dentifrices containing 0, 2.5 and 7.5% Bioglass<sup>®</sup> were compared using dentin discs, and the results revealed that, dentifrice formulations with different ratios of Bioglass<sup>®</sup> provided greater surface coverage and tubule occlusion.<sup>[18]</sup>

A similar *in vitro* study was performed by Litkowski *et al.* in 1997, where dentin slabs were evaluated using scanning electron microscope and fourier transform infrared spectroscopy, and the results showed an increase in tubular occlusion compared with non-Novamin<sup>®</sup> containing controls.<sup>[16]</sup>

A randomized, double-blind, parallel group study was performed where a dentifrice containing 5% CSP (test

group) was compared to a dentifrice containing strontium chloride (positive control group) and a dentifrice without CSP (negative group). 39% and 22% reduction in DH was found in the test group and positive control group respectively, revealing that 5% CSP was more effective in reducing DH than  $\text{SrCl}_2$ .<sup>[19]</sup>

A 6-week, randomized, parallel-arm, double-blind clinical study evaluated the efficacy of a dentifrice containing calcium sodium phosphosilicate (Novamin<sup>®</sup>) v/s a placebo and a commercially-available strontium chloride containing dentifrice in 71 subjects for the treatment of dentin hypersensitivity. The percentage reduction in sensitivity at 6 weeks for the Novamin<sup>®</sup> test group was 35% for air and 39% for cold water stimulus, v/s 11% for air and 22% for cold water for the strontium chloride dentifrice. The reductions for the placebo dentifrice were 21% for the air stimulus and 18% for the water stimulus. The results demonstrated that the Novamin<sup>®</sup> dentifrice was more effective at reducing the sensitivity compared with a commercial dentifrice and placebo control.<sup>[20]</sup>

In a recent randomized clinical trial, CSP was compared with potassium nitrate and a placebo. A total of 110 subjects were included into the trial and their sensitivity scores were recorded on a VAS at baseline, 2<sup>nd</sup> and 6<sup>th</sup> week. The CSP group, however, was found to be significantly better in reducing the VAS score compared to the potassium nitrate group and the placebo group.<sup>[21]</sup>

In a case-control clinical trial, 13 patients with chronic generalized periodontitis who underwent periodontal flap surgery, used a Novamin<sup>®</sup> containing dentifrice in 1 quadrant and 5% potassium nitrate in another quadrant. VAS scores were recorded on day 1 (next day of surgery) and day 7. Mean sensitivity was significantly lower with Novamin<sup>®</sup> containing dentifrice than with 5% potassium nitrate containing dentifrice. 60% of patients using Novamin<sup>®</sup> containing dentifrice got more than 2 score benefit on the VAS, while that with 5% potassium nitrate containing dentifrice was nil.<sup>[22]</sup>

The present study demonstrates that, a 5% Novamin<sup>®</sup> dentifrice has the ability to significantly reduce the dentin hypersensitivity with noticeable and statistically significant reductions within 6<sup>th</sup> and 8<sup>th</sup> week when compared to a placebo dentifrice.

Further long term clinical trials with a larger sample size, comparison with positive controls and different concentration of Novamin<sup>®</sup> should be taken into account to validate the outcome of this new product as an efficacious desensitizing agent. However, the results were consistent in demonstrating a significant effect in reducing the sensitivity with the Novamin<sup>®</sup> dentifrice.

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