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# Comparative evaluation of effectiveness of two desensitizing tooth pastes for relief in the dentinal hypersensitivity

**[1]Dr. Mudasar Ahad, [2]Dr. Muzafar Ahmad Bhat**

[1]Associate Professor, Department of Dentistry, SKIMS MC/H Bemina, Jammu & Kashmir, India
[2]Registrar, Department of Dentistry, SKIMS MC/H Bemina, Jammu & Kashmir, India

**Corresponding Author:**
Dr. Muzafar Ahmad Bhat

## Abstract

**Background:** Dentine hypersensitivity is a common complaint among dental patients. Recently, a novel stabilized calcium sucrose phosphate dentifrice was introduced that offers a desensitizing benefit. The primary aim of this study was to compare the *in vivo* efficacy of this novel dentifrice with Calcium sodium phosphosilicate and a non-desensitizing dentifrice, on dentin hypersensitivity in a four-week period.
**Methods:** Sixty volunteers with tooth sensitivity were recruited, and a double-blind, randomized, parallel, controlled clinical trial was conducted in a hospital setting. Clinical evaluation for dentin hypersensitivity by 0-10 VAS score was done using air blast, and cold water methods. Following baseline measures, subjects were randomly divided into three groups and treated as follows:
**Group A:** Dentifrice containing calcium sodium phosphosilicate (NovaMin).
**Group B:** Dentifrice containing Calcium sucrose phosphate.
**Group C:** Dentifrice containing no desensitizing ingredients. Clinical evaluations were repeated after two and four weeks of product use.
**Statistical analysis used:** Mean VAS scores were compared among groups at different time points (baseline, and 2 and 4 weeks) and among groups at each time point using one-way analysis of variance.
**Results:** Compared to baseline, there was a clinically significant decrease in dentin hypersensitivity in Groups A and B following four weeks use of the dentifrices containing calcium sodium phosphosilicate and calcium sucrose phosphate, respectively. The Group A dentifrice, however, was found to be significantly better in reducing the VAS score compared to the Group B and Group C dentifrice at any time point for both measures of sensitivity.
**Conclusion:** The results suggest that the dentifrice containing 5% NovaMin provides rapid and significantly more relief from dentin hypersensitivity in four weeks compared to a dentifrice containing calcium sucrose phosphate or a non-desensitizing dentifrice.

**Keywords:** Dentinal hypersensitivity, calcium sucrose phosphate, calcium sodium phosphosilicate.

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## Introduction

According to Addy *et al.* [1] Dentine hypersensitivity (DH) is characterized by 'pain derived from exposed dentine in response to chemical, thermal, tactile or osmotic stimuli which cannot be explained as arising from any other dental defect or pathology.' Dentin hypersensitivity, one of the most commonly encountered dental problems, estimates of its prevalence in the adult dentate population range from 8% to 57% [2, 3]. It was shown to peak in 20-30 year olds and then rise again when people are in their 50s [4]. Most dentin hypersensitivity is a result of abrasion, attrition, erosion, a fraction, gingival recession, and improper brushing habits. Sites of predilection in descending order are the canines, first premolars, incisors, second premolars, and molars [5].
Several theories have been put forward to explain the mechanisms involved in dentin hypersensitivity [6, 7].

1. Odontoblasts and their processes act as dentinal receptor mechanisms.
2. Pulp nerves are stimulated by a hydrodynamic mechanism.
3. Nerve impulses in the pulp are modulated by the release of certain polypeptides during pulp injury.

Of these, the most widely accepted theory is the so-called "hydrodynamic theory" of sensitivity by Brannstroem and Astroem in 1964. This theory postulates that rapid shifts, in either direction, of fluids within the dentinal tubules following stimulus application result in activation of sensory nerves in the pulp/inner dentin region of the tooth [8].
Treatment for dentin hypersensitivity may include mucogingival surgery, a pulpectomy, and application of resin, lasers, topical desensitizing agents, and desensitizing toothpaste. Desensitizing toothpaste is considered the simplest and most cost-effective treatment for most patients. Toothpastes with ingredients that include stannous fluoride, strontium chloride hexahydrate, aluminum ferric oxalates, potassium ferric oxalates, and fluorides are designed to reduce flow in the dentin tubules by occluding or sclerosing the tubules [6]. One of the latest advances developed for use in oral health care, in reducing dentinal hypersensitivity is calcium sodium phosphosilicate (NovaMin) which physically occludes the dentinal tubules. NovaMin is a bioactive glass in the class of highly biocompatible materials that were originally developed as bone regenerative materials. 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. When incorporated into a dentifrice, particles are deposited onto the dentin surface to mechanically occlude the dentinal tubules. The physical occlusion of NovaMin particles begin when the material is subjected to an aqueous environment where, sodium ions in the particles immediately begin to exchange with hydrogen cations (H+ or HCO3+) [9]. This rapid release of ions allows calcium ions in the particle structure, as well as phosphate ions to be released from the material. This initial series of reactions occurs within seconds of exposure and the release of calcium and phosphorous ions continues as long as the particles are exposed to the aqueous environment. A localized and transient increase in pH occurs during the initial exposure of the material due to the release of sodium. The increase in pH helps to precipitate the calcium and phosphate ions from the NovaMin particle, along with calcium and phosphorous found in saliva, to form a calcium phosphate layer. As the deposition of calcium and phosphorous complexes continues, this layer crystallizes into hydroxycarbonate apatite which is chemically and structurally equivalent to biological apatite [9]. Thus relieving hypersensitivity.
Recently, a new prophylaxis paste (Ena fix, Tooth min) has been brought to the market that contains calcium sucrose phosphate. CSP mainly consist of calcium sucrose 2-phosphate along with other calcium sucrose phosphates (sucrose molecule substituted at other

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positions). This is marketed as an "anticay". Mechanism by which anticay acts as a cariostatic agent is explained in three pathways:

1. Anticay reduces the rate of demineralization of enamel and increases the rate of remineralization by a common ion effect.
2. The sucrose phosphate anion adsorbs directly onto the enamel surface, thereby further inhibiting the process of demineralization.
3. Anticay actively neutralizes plaque acids [10].

A long with acting as an anticay, this paste has also been shown to act as a desensitizing agent, by occluding the dentinal tubules [11].

This study investigates the desensitizing effect of a new toothpaste containing calcium sucrose phosphate on DH over a period of 4 weeks. The efficacy of the new toothpaste was compared to that of a positive control toothpaste containing 5% calcium phosphosilicate and to a placebo.

## Subjects and Methods

The study was a single-centre and longitudinal in design. The study duration was 4 weeks, in which sensitivity scores were measured at baseline, at 2 weeks, and at 4 weeks. The subjects were selected from the outpatient section of the Department of Dentistry SKIMS medical College and Hospital, Srinagar. The three toothpastes studied were

1. A commercially available non-aqueous toothpaste containing 5% calcium sodium phosphosilicate (*Shy-Nm paste*, Group pharmaceuticals) (Group A).
2. A newly available paste containing Calcium sucrose phosphate (Enafix, Group pharmaceuticals) (Group B).
3. A toothpaste containing no desensitizing agent (Group pharmaceuticals) (Group C).

A total of 60 subjects were included in the study and categorized into three groups, each containing 20 subjects. Selected subjects were randomly assigned to one of three treatment groups and were subjected to cold water and air blast stimulation for an assessment of dentine hypersensitivity (DH) at baseline, 2$^{nd}$ and 4$^{th}$ week using 0-10 VAS score. Subjects participating in the study were 20 to 60 years of age. Subjects who were in good general health, could fulfil the scheduled appointment, and gave consent to participate were recruited into the 4-week trial.

The volunteers selected at baseline had a history of DH caused by gingival recession or cervical erosion. Patients were required to have at least two teeth with a VAS score of $\geq$4 to be included in the study. Teeth included in the study had small or no occlusal restoration. Teeth with caries, defective restorations, and subjects with orthodontic appliances or bridge work that would interfere with evaluation were excluded. In addition, subjects were also excluded if they were allergic to ingredients used in the study or exhibited any gross oral pathology, eating disorders, chronic disease or any disease requiring repeated or regular analgesia, anti-inflammatory drugs or antihistamines.

To assess tooth sensitivity, a controlled air stimulus (evaporative stimulus) and cold water (thermal stimulus) were used. Sensitivity was measured using a 10-cm VAS score, with the score of zero being a pain-free response and a score of 10 being excruciating pain or discomfort. Scoring of tooth sensitivity was done first by using controlled air pressure, from a standard dental syringe at 40 to 65 psi at ambient temperature, directed perpendicularly and at a distance of 1 to 3 mm from the exposed dentin surface while adjacent teeth were protected with gloved fingers to prevent false-positive results. This was followed by scoring of tooth sensitivity using 10 ml of ice cold water applied to the exposed dentin surface while neighbouring teeth were isolated during testing using the operator's fingers and cotton rolls.

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A period of at least 5 minutes was allowed between the two stimuli on each tooth. After the recording of sensitivity scores at baseline, subjects were given respective toothpastes randomly and advised to use the toothpaste with a soft bristle toothbrush twice a day. Subjects were also directed to refrain from any other dentifrice or mouth rinse during the trial but were allowed to continue their normal oral hygiene practice.

Mean VAS scores and mean SE were calculated from raw VAS scores from all the subjects in a treatment group. Mean VAS scores were compared among groups at different time points (baseline, and 2 and 4 weeks) and among groups at each time point using one-way analysis of variance. Post hoc pairwise multiple comparisons were done using the Holm-Sidak method ($P < 0.05$) when significance was detected. Data were statistically analyzed using a software program.

## Results

Mean VAS scores for air stimulus for the calcium sodium phosphosilicate group (Group A), the calcium sucrose phosphate group (Group B), and the placebo group (Group C) at baseline, and 2 and 4 weeks are shown in Table 1. VAS scores for air stimulus of all three groups were not statistically different from each other at baseline. Although all three groups showed reduction in sensitivity scores at 2 and 4 weeks, the calcium sodium phosphosilicate (Group A) group was found to be significantly better in reducing VAS scores compared to the calcium sucrose phosphate group (Group B) at 2 and 4 weeks and the placebo group (Group C) at 4 weeks. Mean VAS scores for water stimulus for the calcium sodium phosphosilicate group, the calcium sucrose phosphate group, and the placebo group at baseline, and 2 and 4 weeks are shown in Table 2. VAS scores for water stimulus were not statistically different among the groups at baseline. There was greater reduction in mean sensitivity score for the calcium sodium phosphosilicate group compared to the placebo and calcium sucrose phosphate groups at 2 and 4 weeks. The calcium sodium phosphosilicate group showed significant reduction at 4 weeks compared to the other groups.

Percentage change in mean sensitivity scores for all three groups at all-time points for both measures is shown in Table 3 & 4. Percentage change in sensitivity score for the calcium sodium phosphosilicate group was 64.2% and 61.9% for air and water stimulus, respectively, at 4 weeks. This change in score was statistically significant compared to the other groups. Negative value in all percentage change in sensitivity scores showed that there was a reduction in sensitivity score from baseline to 2 and 4 weeks.

Intergroup comparison of percentage change in air and water sensitivity scores at all-time points is shown in Table 5 and Table 6, respectively. The calcium sodium phosphosilicate group showed a statistically significant difference in percentage change for both air and water sensitivity from both the calcium sucrose phosphate and placebo groups at all-time points, but the percentage change difference was greater for air stimulus at all-time points.

**Table 1:** Sensitivity scores to air stimulus for all treatment groups at different intervals of time

| Group | Sensitivity Scores (Mean ± SD) | | |
|---|---|---|---|
| | Baseline | 2 Weeks | 4 Weeks |
| Group A | 5.80±1.01 | 3.89±0.87 | 2.08±0.59 |
| Group B | 5.60±0.88 | 4.45±0.86 | 3.07±0.76 |
| Group C | 5.30±0.92 | 4.35±0.91 | 3.20±0.88 |

**Table 2:** Sensitivity scores to water stimulus for all treatment groups at different intervals of time

| Group | Sensitivity Scores (Mean±SD) | | |
|---|---|---|---|
| | Baseline | 2 Weeks | 4 Weeks |
| Group A | 6.10±0.85 | 4.25±0.79 | 2.35±0.75 |

| | | | |
|---|---|---|---|
| Group B | 5.55±0.95 | 4.40±0.84 | 3.35±0.74 |
| Group C | 5.60±0.94 | 4.73±0.76 | 3.76±0.85 |

**Table 3:** Percentage change in mean sensitivity scores to air stimulus for all the three groups at different intervals of time

| Group | Baseline to 2 weeks | | | Baseline to 4 weeks | | |
|---|---|---|---|---|---|---|
| | Mean | SD | P-value (ANOVA) | Mean | SD | P-value (ANOVA) |
| Group A | -32.7 | 12.05 | <0.001* | -64.2 | 8.28 | <0.001* |
| Group B | -20.6 | 8.64 | | -45.2 | 9.80 | |
| Group C | -18.0 | 8.38 | | -41.9 | 10.17 | |

*Statistically Significant at 0.05 level.

**Table 4:** Percentage change in mean sensitivity scores to water stimulus for all the three groups at different intervals of time

| Group | Baseline to 2 weeks | | | Baseline to 4 weeks | | |
|---|---|---|---|---|---|---|
| | Mean | SD | P-value (ANOVA) | Mean | SD | P-value (ANOVA) |
| Group A | -30.0 | 10.79 | <0.001* | -61.9 | 9.47 | <0.001* |
| Group B | -19.5 | 11.31 | | -40.6 | 12.56 | |
| Group C | -15.7 | 4.58 | | -33.4 | 8.37 | |

*Statistically Significant at 0.05 level

**Table 5:** Holm-Sidak method for intergroup comparison of mean percentage change in air sensitivity scores

| Groups Compared | Baseline to 2 weeks | | Baseline to 4 weeks | |
|---|---|---|---|---|
| | Mean difference | P-value | Mean difference | P-value |
| Group A versus Group B | -12.1 | 0.002* | -19.0 | <0.001* |
| Group A versus Group C | -14.7 | <0.001* | -22.3 | <0.001* |
| Group B versus Group C | -2.7 | 0.779 | -3.3 | 0.611 |

*Statistically Significant at 0.05 level

**Table 6:** Holm-Sidak method for intergroup comparison of mean percentage change in water sensitivity scores

| Groups Compared | Baseline to 2 weeks | | Baseline to 4 weeks | |
|---|---|---|---|---|
| | Mean difference | P-value | Mean difference | P-value |
| Group A versus Group B | -10.5 | 0.003* | -21.4 | <0.001* |
| Group A versus Group C | -14.3 | <0.001* | -28.5 | <0.001* |
| Group B versus Group C | -3.8 | 0.484 | -7.19 | 0.090 |

*Statistically Significant at 0.05 level

## Discussion

This study compared calcium sodium phosphosilicate toothpaste to a new calcium sucrose phosphate and placebo toothpastes. The trial was designed and reported in accordance with good clinical practice. The results of the present study demonstrate reduction in symptoms for all treatment groups from baseline to 2 and 4 weeks for both measures of sensitivity. There was a remarkable pattern toward reduction of DH with time for all the variables during the 4 weeks of active phase of the study independent of treatment groups. The calcium sodium phosphosilicate group showed a higher degree of effectiveness at reducing DH than newly available calcium sucrose phosphate paste available and a placebo for both sensitivity measures. Percentage reduction in sensitivity score was greater for air stimulus compared to water stimulus from baseline to 2 and 4 weeks.

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Researching the literature, well-designed clinical trials providing some evidence for the formulation containing all potential active ingredients used in this study can be found. Calcium sodium phosphosilicate, originally developed as a bone regenerative material, has been shown to be effective at physically occluding dentinal tubules through the development of a hydroxyapatite-like mineral layer [12, 13]. Clinical evaluations of calcium sodium phosphosilicate for the treatment of DH have shown statistically significant and clinically positive results [14]. The significant clinical treatment of hypersensitivity through the formation of crystalline apatite led researchers to hypothesize that calcium sodium phosphosilicate could be useful in remineralization and the prevention of demineralization of tooth structures, especially dentin. Moreover, it has demonstrated strong antimicrobial behaviour *in vitro* [15] which reduces symptoms of DH by preventing bacteria to induce pulpal response.

Studies on sugar phosphates [16, 17, 18] on the dissolution of hydroxyapatite and on the hardening of human tooth enamel [19] demonstrated that a complex mixture of calcium sucrose phosphate and calcium orthophosphate not only reduced dissolution but could effectively remineralize enamel. Furthermore when this complex was incorporated in a toothpaste the re-hardening, *in vitro*, was rapid. A later report [20] showed that this calcium sucrose phosphate-calcium orthophosphate complex (CSP) produces a surface effect on the tooth enamel. Craig [21] studied the effect of CSP incorporated in a dentifrice and as a gel when applied to cervical areas of the teeth of 12 patients who had suffered from hypersensitivity in the cervical areas of teeth and reduction in sensitivity was observed.

Dentin sensitivity may differ for different stimuli [22], and it is recommended that at least two hydrodynamic stimuli be used in the clinical trial. We used evaporative air stimulus and cold water in our study because these are both physiologic and controllable. Evaporative air stimulus was used first for sensitivity assessment followed by water stimuli in our study because the least severe stimulus should be applied first to prevent interpretation error. The interval of $\geq 5$ minutes was allowed between the two stimuli to minimize inter- actions between stimuli.

In the present study, the placebo group also reported greater reduction in mean sensitivity scores over time. One probable factor may be the environment under which this study was performed. The patients knowingly participated in a clinical trial to determine the efficacy of desensitizing products. Despite randomization and stratification effects to homogenize sample characteristics, enrolled volunteers often try to please the investigators. Furthermore, positive emotional and motivational behavioural responses can activate the body's central pain-inhibiting system, which can modulate painful stimuli from the periphery through the release of endorphins centrally [23]. Many investigators have described patients obtaining relief without any treatment because of placebo effect, which varies from 20% to 60% in DH clinical trials [24, 25]. Yet another possible phenomenon, which could cause such change, is the Hawthorne effect. This effect is a response to non-intervention procedures, such as improved oral hygiene or frequent examinations. Improved oral hygiene would decrease the pain because this may allow greater saliva access to patent dentinal tubules, which in turn may enhance tubule obliteration through the deposition of salivary calcium, phosphate, and proteins.

With the present state of knowledge and technical skills, evaluation of compounds for the treatment of DH is based on clinical trials [6]. To date no standard technology has been developed to test products designed for treatment of DH. To prevent the placebo effect, which can mask any treatment effects, clinical trial designs for DH should be modified.

## Conclusion

After the 4 weeks of clinical evaluation, all treatments showed lower VAS sensitivity values

compared with baseline, independent of their different modes of action. It can be concluded that under the conditions of a clinical trial, the calcium sodium phosphosilicate group will show comparable, tremendous reductions in dentine hypersensitivity symptoms. Although calcium sucrose phosphate has a role in reducing sensitivity in hypersensitive teeth, but it is better to be used as an "Anticaries" because Novamin has shown much greater reduction in hypersensitivity than this dentrifice in this present study. For future prospects, longer-term studies with scanning electron microscope evaluations should be undertaken to ascertain the efficacy of this novel calcium sucrose phosphate paste.

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