Clinical efficacy of four interventions in the reduction of dentinal hypersensitivity: A 2-month study

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ABSTRACT

Background and Aim: Dentinal hypersensitivity is a relatively common problem experienced in clinical dental practice and is characterized by short, sharp pain in response to stimuli such as tactile, thermal, evaporative, osmotic, or chemical. Several agents and treatment modalities have been used in the treatment of this condition. This study was conducted to compare the efficacy of four commercially available toothpastes in the reduction of dentinal hypersensitivity (DH), based on the hypothesis that calcium sodium phosphosilicate (CSPS) group had a better efficacy of the four.

Settings and Design: This study design was a prospective, single-blind, randomized, parallel clinical design.

Subjects and Methods: A total of 160 cases (93 males and 67 females; aged 20–60 years) were randomly divided into four groups: Group 1 - toothpaste containing 5% potassium nitrate; Group 2 - toothpaste containing 5% CSPS (NovaMin); Group 3 - toothpaste containing 10% strontium chloride; and Group 4 - a herbal formulation. The patients’ DH scores for tactile, thermal, and evaporative stimuli were recorded on a visual analog scale at baseline, 2 weeks, 1 month, and 2 months.

Statistical Analysis Used: The data were analyzed with Wilcoxon signed-rank test, Kruskal–Wallis test, and Mann–Whitney U-test \( (P < 0.05) \).

Results: The four desensitizing kinds of toothpaste containing different active agents were effective in relieving dentinal hypersensitivity. However, CSPS group showed a better clinical response at the end of 2 months.

Conclusions: The CSPS group showed a better reduction in the symptoms of DH.

Key words: Calcium sodium phosphosilicate, dentinal hypersensitivity, herbal, potassium nitrate, strontium chloride, visual analog scale

Dentinal hypersensitivity (DH) is a painful response of a tooth to irritants such as toothbrushing, sweet or sour foods, and thermal changes. It poses a potential threat to the individual’s oral health because such pain may interfere with the maintenance of good oral hygiene.\(^1\) It is characterized by an acute, nonspontaneous, short- or long-lasting pain that appears suddenly in a specific location, which cannot be attributed to any other dental pathology.\(^2\) Owing to its thin cementum layer, the cervical area generally has dentinal tubules that are exposed by toothbrushing, dietary erosion, and abrasive dentifrices. This area is responsible for more than 90% of hypersensitive surfaces.\(^3\) The DH mechanism could perhaps be explained by either the hydrodynamic mechanism or the neural stimulation theory.\(^4\)

The most widely accepted theory is the hydrodynamic theory where DH is mediated by a hydrodynamic mechanism, in which a stimulus results in an increased fluid flow in the...
dentinal tubules. This, in turn, activates nerves located on the pulpal aspect of the tubules, resulting in the generation of action potentials which are interpreted as pain by the patient.\textsuperscript{[5,6]} In support of this theory, clinical evidence shows that individuals with DH have dentinal tubules that are patent from the pulp to the oral environment, and sensitive dentin surfaces have wider and more numerous tubules than nonsensitive surfaces, which are mostly covered by a smear layer.\textsuperscript{[7]}

The incidence of DH may affect patients of any age and peaks during the third and fourth decades of life. Any tooth and tooth surface can be affected, but dentinal hypersensitivity has a predilection for the buccal cervical regions of canines and premolars.\textsuperscript{[8]}

DH may not be a serious dental problem but can be a particularly uncomfortable and unpleasant sensation for patients and can dictate the types of foods and drinks ingested.\textsuperscript{[5]} Many substances have been advocated for the treatment of dentinal hypersensitivity pain with numerous clinical trials reporting their apparent efficacy. The British and American Dental Associations have accredited various formulations for efficacy, including toothpastes incorporating strontium acetate, potassium nitrate, strontium chloride (SC), potassium chloride, fluoride, and sodium citrate.\textsuperscript{[9]}

Attempts to reduce dentinal hypersensitivity have been aimed at either reducing the excitability of the nerve fibers within the pulp or occluding the open dentinal tubules. In the tubular occlusion approach, the tooth is treated with an agent that occludes the dentinal tubules, thus resulting in stoppage of pulpal fluid flow. This leads to a reduction in DH. Treatment strategies such as lasers, dentin sealers, and periodontal soft-tissue grafting work on the same principle.\textsuperscript{[10]}

In the other approach, potassium cations of potassium nitrate dentifrice tend to concentrate in the interior of the dentinal tubules, causing a depolarization of the cellular membrane of the nerve terminal and a refractory period with decreased sensitivity.\textsuperscript{[11]} NovaMin is a ceramic material consisting of amorphous sodium-calcium-phosphosilicate which is highly reactive in water and consists of a fine particle size powder which can physically occlude dentinal tubules.\textsuperscript{[12]} SC has been widely used in a dentifrice form for the treatment of cervical DH. SC appears to act both as a protein precipitant as well as a tubule occluding agent.\textsuperscript{[13]}

Recently, there has been a growing interest in natural products, and studies have suggested that herbal-based toothpastes may be effective as the conventionally formulated dentifrice in the control of plaque, gingivitis and in the prevention of dental caries.\textsuperscript{[8]} Hekla lava is a tooth powder which is a fine ash from Mount Hekla, an Iceland Volcano. Hekla is a homeopathy remedy which has the power to treat many oral problems such as gingivitis, abscess of the gums, toothache, and dental sensitivity.\textsuperscript{[14]}

### SUBJECTS AND METHODS

#### Study design

This study was a 2-month single-blind, parallel-group randomized clinical trial. Examinations were conducted at baseline, 2 weeks, 1 month, and 2 months. A pilot study was conducted on seven samples each in NovaMin and potassium nitrate groups, and visual analog scores (VASs) were recorded. Based on the results, the sample size was calculated as 40 in each group under 5% error and 85% power of the test. Following ethical approval, 160 cases (93 males and 67 females of mean age 36.9 ± 10.8 years) \[Tables 1 and 2\] were selected from the outpatient section of the Department of Periodontics. The duration of the study was from October to December 2013. The study protocol was approved by the ethics committee of the institution.

#### Selection criteria

Inclusion criteria were individuals with hypersensitivity to hot, cold, or sour stimuli on facial surfaces of at least two posterior teeth, good periodontal health (no probing depth >4 mm), and with no other conditions that might explain their apparent DH, aged between 20 and 60 years.

Exclusion criteria were chipped teeth, defective restorations, fractured teeth, deep dental caries, orthodontic appliances, dentures, or bridgework that would interfere with the evaluation of hypersensitivity; periodontal surgery within the previous 6 months; ongoing treatment with antibiotics and/or anti-inflammatory drugs; ongoing treatment for tooth hypersensitivity; pregnancy or lactation; uncontrolled metabolic diseases; major psychiatric disorders; and heavy smoking and alcohol or drug abuse.

#### Evaluation of hypersensitivity

The teeth were isolated with cotton rolls, and stimuli were applied in each tooth according to a standard methodology (Tarbet et al. 1979).

### Table 1: Distribution of male and females in four groups

| Groups | Male (%) | Female (%) | Total |
|--------|---------|------------|-------|
| Group 1 | 28 (70.00) | 12 (30.00) | 40 |
| Group 2 | 23 (57.50) | 17 (42.50) | 40 |
| Group 3 | 20 (50.00) | 20 (50.00) | 40 |
| Group 4 | 22 (55.00) | 18 (45.00) | 40 |

Total: 93 (58.13) females and 85% power of the test. Following ethical approval, 160 cases (93 males and 67 females of mean age 36.9 ± 10.8 years) \[Tables 1 and 2\] were selected from the outpatient section of the Department of Periodontics. The duration of the study was from October to December 2013. The study protocol was approved by the ethics committee of the institution.

### Table 2: Comparison of four groups with mean age of male and females

| Groups | Mean±SD | Total |
|--------|---------|-------|
| Group 1 | 38.46±11.04 | 36.75±11.73 | 37.95±11.13 |
| Group 2 | 36.43±11.58 | 33.88±9.23 | 35.35±10.59 |
| Group 3 | 37.55±11.57 | 39.65±11.13 | 38.60±11.26 |
| Group 4 | 37.82±12.07 | 33.94±8.22 | 36.08±10.57 |

Total: 37.61±11.37 | 36.13±10.15 | 36.99±10.87

SD=Standard deviation


**Tactile test**
A sharp dental explorer was passed across the facial area of the tooth, perpendicular to its long axis, at an approximated constant force.

**Airblast test**
A blast of air was directed onto the affected area of the tooth for one second from a distance of 10 mm, using a standard dental unit syringe of 40–65 psi.

**Cold water test**
A precooled disposable syringe was filled with freshly melted ice-cold water. A volume of 0.2 ml of the water was slowly expelled from the syringe onto the tooth surface. The stimuli were applied in the above order, with a 5–min gap between the application of different stimuli.\

Sensitivity was measured using a 10 cm VAS, with a score of zero being a pain-free response and a score of ten being excruciating pain or discomfort.\

**Dentifrices tested**
The four kinds of toothpaste studied were (1) Group 1 - a commercially available toothpaste containing 5% potassium nitrate (RA Thermoseal, ICPA Health Products Ltd., Ankleshwar, India); (2) Group 2 - a commercially available nonaqueous toothpaste containing 5% calcium sodium phosphosilicate (CSPS) with fused silica (Vantej, Dr. Reddy’s Laboratories Ltd., Hyderabad, India); (3) Group 3 -10% SC (Thermoseal®, ICPA Health Products Ltd., Ankleshwar, India); (4) Group 4 - a herbal toothpaste (Wheezal dental cream, Wheezal Labs (P) Ltd., Dehradun, India) which has herbal extracts such as hekla lava, calendula, kresote, and plantago.

The cases were randomly divided into four groups of forty subjects each. Each group was provided with one of the test dentifrices in its commercial package. Each patient was advised to brush their teeth in the usual manner for 3 min, twice daily, with soft bristle toothbrush, and to apply the dentifrice in an amount equal to about half the length of the bristle head. They were also instructed not to eat or drink anything within half an hour of brushing with the dentifrices. They were recalled at 1 week, 1 month, and 2 months for the assessment of tooth sensitivity. During the study period, the use of other oral hygiene products as well as any other dental treatment for hypersensitive teeth was not permitted. Drugs that may alter the perception of pain were not permitted within 24 h of the assessment.

**Statistical analysis**
Normal distribution of scores was performed by Kolmogorov–Smirnov test. Intergroup comparison of groups with respect to sensitivity scores at different time points was carried out by Kruskal–Wallis test. Pairwise comparisons were carried out by Mann–Whitney U-test. Intragroup comparisons were performed by Wilcoxon matched test. The significance level of this study was set at \( P < 0.05 \).

**RESULTS**
No adverse effects were observed in any of the cases enrolled in the study. Mean VASs for tactile, air, and cold-water stimulus for all four groups at baseline, 2 weeks, 1 month, and 2 months are shown in Table 3. Intragroup comparison showed that all groups recorded a significant improvement from baseline to 2 months [Table 4]. No significant difference between groups at baseline was found for tactile, air, and cold-water stimulus [Table 5].

Group 2 resulted in more improvement at all-time intervals compared to the other groups for all stimuli. Group 1 did not show any statistical significance with Group 3 except for the tactile stimulus test. Although Group 1 showed no statistical difference with Group 4 at 2 weeks, Group 1 fared consistently better than Group 4 at 1 month and 2 months recalls. Group 3 and Group 4 exhibited significant differences at 2 weeks and 1 month, but over a 2 months recall, Group 3 and Group 4 did not show a statistical difference for tactile and cold water stimulus [Table 5].

**Table 3: Intragroup comparison of tactile, airblast, and cold water method for all groups at baseline, 2 weeks, 1 month, and 2 months**

| Toothpaste groups | Tactile method | Baseline | 2 weeks | 1 month | 2 months |
|-------------------|----------------|----------|---------|---------|----------|
| Group 1           | 4.70±0.56      | 3.90±0.84| 2.20±0.85| 1.08±0.83|
| Group 2           | 4.45±0.50      | 2.53±0.64| 1.0±0.56 | 0.20±0.41|
| Group 3           | 4.58±0.55      | 3.53±0.75| 2.70±0.79| 1.65±0.89|
| Group 4           | 4.65±0.98      | 3.70±1.22| 3.13±1.16| 2.00±1.26|

| Airblast method   | Baseline-2 months | 2 weeks | 1 month | 2 months |
|-------------------|--------------------|---------|---------|----------|
| Group 1           | 7.23±1.17          | 6.38±1.44| 4.40±1.39| 2.90±1.15|
| Group 2           | 7.20±1.29          | 4.18±1.20| 2.28±1.09| 0.80±0.76|
| Group 3           | 7.30±1.24          | 5.38±1.08| 4.28±0.96| 2.93±0.83|
| Group 4           | 7.08±1.47          | 6.23±1.62| 5.00±1.34| 3.58±1.06|

| Cold water method | Baseline | 2 weeks | 1 month | 2 months |
|-------------------|----------|---------|---------|----------|
| Group 1           | 7.50±1.09 | 6.35±1.39| 4.40±1.35| 2.95±1.18|
| Group 2           | 7.18±1.13 | 4.63±1.13| 2.68±1.16| 1.03±0.83|
| Group 3           | 7.15±1.23 | 6.08±1.25| 4.85±1.17| 3.30±0.91|
| Group 4           | 7.58±1.15 | 6.73±1.50| 5.45±1.28| 3.75±1.08|

**Table 4: Intragroup comparison of tactile, airblast, and cold water scores between different visits**

| Groups | Visits       | \( P \)  |
|--------|--------------|---------|
| Group 1| Baseline-2 weeks | 0.0001* |
| Group 1| Baseline-1 month | 0.0001* |
| Group 1| Baseline-2 months | 0.0001* |
| Group 2| Baseline-2 weeks | 0.0001* |
| Group 2| Baseline-1 month | 0.0001* |
| Group 2| Baseline-2 months | 0.0001* |
| Group 3| Baseline-2 weeks | 0.0001* |
| Group 3| Baseline-1 month | 0.0001* |
| Group 3| Baseline-2 months | 0.0001* |
| Group 4| Baseline-2 weeks | 0.0001* |
| Group 4| Baseline-1 month | 0.0001* |
| Group 4| Baseline-2 months | 0.0001* |

\*\( P<0.05 \) statistically significant
Table 5: Intergroup comparison of tactile, airblast, and cold water stimulus at baseline, 2 weeks, 1 month, and 2 months

| Comparison between groups | Baseline (P) | 2 weeks (P) | 1 month (P) | 2 months (P) |
|---------------------------|--------------|-------------|-------------|--------------|
| Tactile method            |              |             |             |              |
| Group 1-Group 2           | 0.0868*      | 0.0001*     | 0.0001*     | 0.0001*      |
| Group 1-Group 3           | 0.3918       | 0.0001*     | 0.0001*     | 0.0001*      |
| Group 2-Group 3           | 0.2145*      | 0.0001*     | 0.0001*     | 0.0001*      |
| Group 2-Group 4           | 0.8099*      | 0.0001*     | 0.0001*     | 0.0001*      |
| Group 3-Group 4           | 0.6168       | 0.7545      | 0.1436      | 0.2748       |
| Airblast method           |              |             |             |              |
| Group 1-Group 2           | 0.8211*      | 0.0001*     | 0.0001*     | 0.0001*      |
| Group 1-Group 3           | 0.8814*      | 0.0013*     | 0.5605      | 0.8625       |
| Group 2-Group 3           | 0.3607       | 0.4764      | 0.1081      | 0.0168*      |
| Group 2-Group 4           | 0.6932*      | 0.0001*     | 0.0001*     | 0.0001*      |
| Group 3-Group 4           | 0.6033*      | 0.0001*     | 0.0001*     | 0.0001*      |
| Cold water method         |              |             |             |              |
| Group 1-Group 2           | 0.2443*      | 0.0001*     | 0.0001*     | 0.0001*      |
| Group 1-Group 3           | 0.1358       | 0.2217      | 0.1703      | 0.2163       |
| Group 2-Group 3           | 0.7218       | 0.3146      | 0.0014*     | 0.0073*      |
| Group 2-Group 4           | 0.6861       | 0.0001*     | 0.0001*     | 0.0001*      |
| Group 3-Group 4           | 0.1384       | 0.0001*     | 0.0001*     | 0.0001*      |

*p<0.05 statistically significant

**DISCUSSION**

It is evident that DH is not only a troublesome condition for dental professionals to effectively diagnose and manage but it may also have a profound effect on the quality of life of those who suffer with the problem. A number of treatment regimens have been recommended over the years, and particular attention has been focused on home use dentifrices containing various active compounds, which act by either blocking the hydrodynamic mechanism or the neural response.

This study compared four commercially available dentifrices. The NovaMin group showed a higher degree of effectiveness at reducing DH compared to the other dentifrices for all sensitivity measures.

CSPS (NovaMin) is a bioactive glass in the class of highly biocompatible materials that were originally developed as bone-regenerative materials. In saliva, sodium ions (Na⁺) in CSPS particles immediately begin to exchange with hydrogen cations (H⁺ or H₂O). This rapid exchange of ions allows calcium (Ca²⁺) and phosphate (PO₄³⁻) species to be released from the particle surface. A modest, localized, transient increase in pH occurs that facilitates the precipitation of calcium and phosphate from the particles and from saliva to form a calcium phosphate (Ca-P) layer on tooth surfaces. As the reactions and the deposition of Ca-P complexes continue, this layer crystallizes into hydroxycarbonate apatite, which is chemically and structurally similar to biological apatite.

A study by Neuhaus et al. demonstrated that single application of both fluoridated and nonfluoridated prophylaxis pastes containing 15% CSPS (NovaMin) provided a significant reduction of dentinal hypersensitivity up to at least 28 days. NovaMin application was more effective in providing relief from DH when compared with hydroxethyl methacrylate and glutaraldehyde (Gluma Desensitizer) in a study by Joshi et al. A recent study showed that NovaMin incorporated into a nonaqueous dentifrice was able to reduce the viability of planktonic bacterial cultures of Streptococcus mutans, Fusobacterium nucleatum, Actinomyces naeslundii, and Streptococcus sanguis.

In the present study, the higher effectiveness of NovaMin group is in accordance with a study by Ananthakrishna et al., which revealed that CSPS performed better than a 10% SC containing toothpaste at 2, 4, and 6 weeks. The 5% CSPS showed prolonged desensitizing effect even after discontinuation as compared to 5% potassium nitrate.

Potassium nitrate group was not more effective than SC group for airblast and cold water stimuli at different time intervals. Evidence from experiments on nerve excitability indicates that potassium–induced effects are transient and reversible. Potassium ions may reduce intradental nerve excitability by raising the concentration of local extracellular potassium ions and causing depolarization of the pulpal sensory nerves, thereby interrupting pain transmission. Hodosh stated that topical applications of 1–15% potassium nitrate (KNO₃) or a paste containing 10% KNO₃ were effective in reducing dentinal hypersensitivity. Furthermore, potassium nitrate does not induce any pulpal change.

SC is a protein precipitant, and its mechanism of action is through organic precipitation forming a sealing film that prevents fluid movement and also has an occlusive action. A study by Minkoff and Axelrod as reported by Porto IC et al. concluded that regular home use of dentifrices with 10% SC is an efficient means of reducing DH. Kishore et al. evaluated the efficacy of desensitizing agents and concluded that 10% SC showed a significant reduction in dentinal sensitivity whereas 5% potassium nitrate solution could not. The application of SC containing dentifrice showed significantly better results than the placebo at 24 weeks and pain relief was observed in 72% of all patients in a study by Kobler et al.

Although the potassium nitrate group did not reveal a better reduction in sensitivity as compared to the herbal group up to 2 weeks, at 1 month and 2 months recalls, patients using potassium nitrate evidenced lesser sensitivity. The effect of the potassium nitrate is cumulative and it may take several weeks for patients to appreciate pain relief.

Although SC group was more effective at 1 month when compared to the herbal group, there was no significant difference between the two groups at 2 months.
lava is a tooth powder which can be used as intracanal medicament in root canal treatment since it contains large amount of sulfur, silica, lime, magnesia, ferrous oxide, and fluoride. It has anti-inflammatory effect which helps in treating gingivitis, chronic periodontitis, etc. Hekla lava has been used as a natural remedy for treating neuralgia and pyorrhea, bad breath, and as a breath freshener. Being herbal in nature, it has no side effects. There is currently not much evidence in support of this herbal extract in the treatment of DH. Its role presumably in the occlusion of dentinal tubules stays as an attractive hypothesis.

Holland et al. have indicated in their guidelines for the design and conduct of clinical trials on dentinal hypersensitivity that trials should last for at least 8 weeks. The present study also evaluated the reduction in tooth hypersensitivity in cases over a period of 8 weeks. Furthermore, in the present study, the most common and validated stimuli, to assess tooth sensitivity including tactile test, airblast test, and cold water test were used as these are both physiological and controllable. The 0–10 numerical rating VAS has been shown to be a more efficacious alternative to the continuous VAS due to it being simpler in application and patient comprehension.

Limitations of the study
Single-blind nature of the study can be considered a limitation in the study. In any clinical trial in which a patient’s pain response is evaluated, a placebo is required to provide a baseline against which to measure active treatments against. However, in the present study, a placebo or a negative control group was not included.

CONCLUSION
After 2 months of clinical evaluation, all treatments showed lower VAS sensitivity values compared with baseline, independent of their different modes of action. This study demonstrated that the CSPS group showed significantly better results compared to either potassium nitrate, SC, or a herbal dentifrice in reducing DH symptoms. Further, long-term clinical trials are needed.

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Conflicts of interest
There are no conflicts of interest.
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