Evaluation of Novamin Dentifrice in Reducing Dentinal Hypersensitivity
Shital A. Hungund, Neha Garg, Chaitra Nagaraja.

Abstract

Objective: The purpose of this clinical study was to evaluate the effectiveness of a dentifrice containing 7.5% w/w Novamin in the treatment of dentinal hypersensitivity. Materials and Methods: The study was a multiple site, single blinded, two parallel study groups to assess the efficacy of a 7.5% w/w Novamin dentifrice. Subjects had to have at least two teeth sensitive to air stimulation with a measured Heft Parker’s visual analogue scale > 36 on the scale of 0 - 170 mm. Two measures of testing sensitivity were used in the study: a metered air blast and cold water from three way syringe. Subjects were randomly divided into two groups, with one group receiving the Novamin dentifrice and the other group a placebo dentifrice. Subjects were instructed to brush their teeth in their usual manner for one minute, brushing no more than a total of two times per day for the first two weeks of use. At the two week appointments, patients were instructed to brush only once a week with the test dentifrice for two additional weeks, while returning to their normal dentifrice for daily brushing. In each patient visual analogue scale score were recorded at baseline, first week, second week and fourth week. Results: The Novamin dentifrice was significantly better at reducing sensitivity than placebo dentifrice (p < 0.001). Conclusion: The results of the study demonstrated that a Novamin dentifrice has the ability to significantly reduce dentin sensitivity with noticeable and statistically significant reductions within one week compared to a placebo dentifrice.

Key words: Dentinal Hypersensitivity; Biomedical and Dental Materials; NovaMin; Dentifrice; Cosmetics; Abrasive; Pain Measurement; Visual Analogue Pain Scale.

Introduction

One of the most frequently occurring presenting symptoms in dental practice is the oral pain condition of dentine hypersensitivity, which may be of only minor inconvenience to some patients and yet very disturbing and an issue affecting quality of life to others. Tooth hypersensitivity, or more precisely dentine sensitivity or hypersensitivity, is described clinically as an exaggerated response to non-noxious stimuli and satisfies all the criteria to be classified as a true pain syndrome. According to Addy et al, dentine sensitivity 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”. The prevalence of dental hypersensitivity has been reported over the years and between 8% and 57% of adult dentate population and up to 30% of adults at some point in their lifetime. Dentinal hypersensitivity has been shown to peak in 20 - 30 years old and then rise again when in their 50’s. The condition generally involves the facial surfaces of teeth near the cervical aspect and is very common in premolars and canines. Patients undergoing periodontal treatment are particularly susceptible to the condition because of the recession following periodontal therapy or loss of cementum following non surgical periodontal therapy. In addition periodontal disease and improper brushing habits can also result in gingival recession accompanied by sensitive teeth. The hydrodynamic theory is the most widely demonstrated and accepted physiopathological theory of dentine hypersensitivity. According to this theory, most pain inducing stimuli increase centrifugal fluid flow within the dentinal tubules giving rise to a pressure change throughout the entire dentine. Of all the pain producing stimuli cold appears to be the strongest and causes the greatest problem to those troubled by dentine hypersensitivity. Dentin desensitization may sometimes occur spontaneously as a natural decrease of dentine permeability. However, in most
cases treatment is still necessary. There are numerous treatments for dentine hypersensitivity. Application of anti inflammatory agents, occluding dentinal tubular agents as well as root covering by periodontal surgery are treatment approaches to dentine hypersensitivity that reduce the excitability of the nerve fibres within the pulp.6–7 The objective of this study was to evaluate the efficacy of a 7.5% Novamin dentifrice formulation compared to placebo dentifrices for the relief of dentin hypersensitivity when used daily for two weeks then once a week for an additional two weeks.

**Calcium sodium phosphosilicate (Novamin):** 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 hydroxyapatite, 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 began when the material was subjected to an aqueous environment. Sodium ions in the particles immediately began to exchange with hydrogen cations (H⁺ or HCO₃⁻).8 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 hydroxyapatite, which is chemically and structurally equivalent to biological apatite.8 The combination of the residual Novamin particles and the hydroxyapatite layer results in the physical occlusion of dentinal tubules, which will relieve hypersensitivity.

Novamin can prevent demineralization and promote remineralization of the enamel surface. In a study done by Alaudin and Fontana (2007) who compared a dentifrice containing 5% Novamin and Fluoride to a commercially available dentifrice, in remineralization of subsurface carious lesions in human tooth enamel. They used confocal laser scanning microscopy, which was able to distinguish between sound enamel and demineralized enamel using a fluorescent dye. The authors came to the conclusion that Novamin-containing dentifrice was statistically more significant in decreasing the lesional area than the commercial dentifrice containing fluoride alone.5

According to Anora Burwell, scanning electron microscopic (SEM) analysis showed that Novamin totally occludes the dentinal tubules by forming a hydroxyl carbonate apatite (HCA) layer. This HCA layer is chemically and structurally similar to natural enamel and dentin and is more resistant to acid challenges than the amorphous calcium phosphate deposited by the GC Tooth Mousse.8

**Materials and Methods**

The study was conducted in the Darshan Dental College and Hospital, Udaipur. All the patients were randomly selected between the ages of 18 to 65 years with complaint of sensitivity from hot and cold beverages. At the initial screening procedure they were subjected for oral soft tissue examination, clinical assessment and controlled stimuli to identify sensitive teeth. The study was explained to the subjects and informed consent forms for their willingness to be a part of the study for four weeks was obtained. All the subjects underwent oral prophylaxis before the study and then baseline visual analogue scale (VAS) score indicating dentin hypersensitivity levels to cold water stimuli and air blast method was used.

**Inclusion Criteria:** All subjects who have at least two teeth sensitive to air and water stimulation with a measured Heft Parker’s visual analogue scale more than 36 on the scale of 0 - 170 mm were included in the present study (Figure 1).
Exclusion Criteria: Patients with active cervical caries, deep abrasion requiring class V filling, chipped tooth, fractured cusps, using any type of desensitizing paste or using any desensitizing therapy for the last six months, anti-inflammatory and analgesic medication, pregnant or lactating females, history of chronic regurgitation of acids, undergone periodontal surgery in the preceding six months or undergoing orthodontic therapy, smokers and those with any denture or bridge work that would interfere with the evaluation of hypersensitivity were excluded from the present study.

Evaluation of Sensitivity: The reported hypersensitive teeth in the subjects were verified by light strokes of dental explorer along the cervical areas of all teeth present following enrollment in the study. For the air method, a standard air water syringe with restricted air stream (60 psi) was directed towards the sensitive portion of the tooth perpendicular to the long axis of the tooth for duration of approximately four seconds and at a distance of about 0.5 cm. Adjacent teeth were protected by operator’s fingers and cotton rolls. Patient response on visual analogue scale of 0 - 170 was measured. The test was repeated two times before a score was finally accepted. For the cold water testing method, approximately 5 min after the air blast test, the tooth reported to be sensitive by the patient was isolated with cotton rolls. Patient response on visual analogue scale of 0 - 170 was measured. The test was repeated three times before a score was finally accepted. In both the methods those between VAS score of 36 - 170 responses were selected.

After the collection of the baseline data, the subjects were divided randomly into two groups with 15 subjects each. Group one received the Novamin dentifrice and the other group a placebo. These test dentifrices were dispensed to the subjects of both the groups personally in order to avoid the disclosure of the contents. Subjects were instructed to brush their teeth in their usual manner for one minute, brushing no more than a total of two times per day for the first two weeks of use. At the two week appointments, patients were instructed to brush only once a week with the test dentifrices for two additional weeks, while returning to their normal dentifrice for daily brushing.

The patients were instructed not to eat or drink anything within half an hour of brushing with the dentifrice. The patients were recalled at first week, second week and fourth week for the measurement of tooth sensitivity by the cold water test and the air blast method. During the study period, the use of other oral hygiene products, any other dental treatment to sensitive teeth and drugs like analgesics which might influence pain perception within 24 hrs of assessment days were not permitted.

Statistical Analysis: The results of the Heft Parker VAS scale averaged across the cold water and air pressure methods and were analyzed using student t test.

Results
The mean VAS at baseline for Novamin was 112.13 while for the placebo group it was 100.41. Then a significant reduction was observed in first and second weeks for VAS mean i.e., 86.53 and 63.87 for Novamin and 103.76 and 88.41 for placebo group respectively. At the end of fourth week VAS mean for Novamin was 44.93 while for placebo it was 85.00 and standard deviation at the end of fourth for Novamin was 28.47 while for placebo it was 0.00 (Graph 1). The Novamin dentifrice was statistically better at reducing sensitivity than placebo and that the effects were statistically significant over all the time periods as well (p < 0.001).

Discussion
The results of the current study demonstrate that a Novamin dentifrice has the ability to significantly reduce dentine hypersensitivity with noticeable and statistically significant reductions within one week compared to a placebo dentifrice. Moreover, the data showed that after an initial daily use period of two weeks, brushing only once a week still resulted in further reductions in measured sensitivity in patients using the Novamin dentifrice. There was the expected placebo effect in the control dentifrice with reductions in sensitivity at fourth week compared to baseline and even with this reduction, the Novamin dentifrice showed better results at all-time points.

The rationale for the non-traditional usage regimen of twice daily for the first two weeks; followed by a once a week brushing in this study was to evaluate how persistent the occlusion of the dentin tubules would be using the Novamin dentifrice. Since in-vitro studies have demonstrated a significant
hydroxyl carbonate apatite layer formation on dentin blocks after brushing with Novamin. It has been postulated that this layer would be persistent for some time after the applications of Novamin containing dentifrice has been discontinued. In addition once a week application of Novamin that would continue to bring relief from sensitivity would also allow the patient to use their regular fluoride containing dentifrice with anti-cariogenic property for maintaining their routine oral hygiene since the formulation used in this study was free from fluoride.

According to Greenspan et al., dentifrice containing Novamin significantly improves oral health as measured by a reduction in gingival bleeding and reduction in the supra-gingival plaque compared to negative or placebo dentifrice. In the current in-vivo study the reduction in sensitivity at the fourth week time point in Novamin using group was approximately 60%.

According to Tirapelli et al., among the four materials tested, biosilicate demonstrated the best clinical performance and provided the fastest treatment to reduce dentine hypersensitivity. Distilled water proved to be an adequate vehicle to disperse biosilicate. Low dentine hypersensitivity scores were maintained during the six months follow-up period. The hypothesis that the novel bioactive glass-ceramic may be an efficient treatment for dentine hypersensitivity was confirmed.

Gjorgievska ES et al., subjected the human permanent molar teeth for three consecutive demineralization cycles followed by remineralization of the experimental groups by dentifrices containing Recaldent and Novamin. The samples were analyzed by Scanning Electron Microscope and energy-dispersive X-ray spectroscopy (EDX). Extensive demineralization was noted in the control group (without remineralization) while the groups treated with the dentifrices demonstrated various degrees of remineralization, as shown by formation of different types of deposits on the enamel surface. The EDX analysis showed increased amounts of Ca, P, Si and Zn in the enamel of the experimental groups, compared to the control one. Dentifrices containing Recaldent and especially Novamin have the potential to remineralize enamel, a property which might be important in finding a substitute to pit and fissure sealing.

Wang et al., evaluated the in-vitro effectiveness of a new bio-glass containing and two commercial desensitizing dentifrices on dentinal tubule occlusion after citric acid challenge or artificial saliva immersion. They concluded that all three desensitizing dentifrices significantly reduced dentine permeability and created precipitates on the treated dentine surfaces. Moreover, the reductions in dentine permeability showed partial recovery after a citric acid and artificial saliva immersion. Sensodyne showed significant resistant to acid attack

Graph 1: Effects of two treatments on VAS scores averaged across methods at four time points.
and Novamin exhibited the lowest permeability after artificial saliva immersion for 24h.12

Conclusion
The results of the study demonstrated that a Novamin dentifrice has the ability to significantly reduce dentin sensitivity with noticeable and statistically significant reductions within one week compared to a placebo dentifrice. Moreover, the dentifrice appeared to be effective at maintaining and further decreasing sensitivity even as once per week therapy.

Author Affiliations
1. Dr. Shital A Hungund, Professor and Head, 2. Dr. Neha Garg, Post Graduate Student, 3. Dr. Chaitra Nagaraja, Reader, Department of Periodontology and Implants, Darshan Dental College and Hospital, Udaipur, Rajasthan State, India.

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References

Corresponding Author
Dr. Shital A. Hungund, Professor and Head, Department of Periodontology, Darshan Dental College and Hospital, Loyara, Udaipur, Rajasthan State, India.
E mail: drhungund@hotmail.com
Ph: +919660977604

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