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# The effectiveness of a calcium sodium phosphosilicate desensitizer in reducing cervical dentin hypersensitivity

## A pilot study

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**T**ooth hypersensitivity is a common problem that affects many adults worldwide.<sup>1</sup> The incidence of tooth hypersensitivity increases with age, and the condition is attributed to the general increase in exposure of root surfaces of the teeth as a result of periodontal disease, toothbrush abrasion or cyclic loading fatigue of the thin enamel near the cemento-enamel junction.<sup>2-4</sup> Dentin hypersensitivity is a short, sharp pain arising from exposed dentin in response to various stimuli—such as thermal, tactile, osmotic or chemical—and that cannot be ascribed to any disease.<sup>5</sup>

The accepted theory for tooth hypersensitivity is the “hydrodynamic theory.”<sup>6,7</sup> This theory is based on the belief that open dentinal tubules allow fluid to flow through them, which excites the nerve endings in the dental pulp. Thus, to reduce tooth hypersensitivity, one should prevent the fluid flow across the dentinal tubules.<sup>8</sup>

There are two principal methods of treating dentin hypersensitivity: occluding the tubules and desensitizing the nerve.<sup>9</sup> Several agents and approaches have been investigated, such as potassium nitrate, strontium chloride, resin adhesives, fluoride and laser therapy.<sup>10-13</sup> NovaMin (NovaMin Technology, Alachua, Fla.), which consists of calcium sodium phosphosilicate glasses, has

## ABSTRACT

**Background.** NovaMin (NovaMin Technology, Alachua, Fla.) was introduced into the dental market as a desensitizer in December 2004. However, to the authors’ knowledge, no researchers yet have evaluated the effectiveness of 100 percent NovaMin powder with NovaMin-containing toothpaste in reducing dentin hypersensitivity compared with the effectiveness of NovaMin-containing toothpaste only and a desensitizing toothpaste containing potassium nitrate as a control.

**Methods.** The authors divided 60 participants randomly into three groups: NovaMin powder with NovaMin-containing toothpaste (group 1), a placebo powder with NovaMin-containing toothpaste (group 2) and a placebo powder with the control toothpaste (group 3). The authors used tactile and cold stimuli and a visual analog scale to evaluate participants’ pain at baseline, immediately after powder application and at one week, two weeks and four weeks after powder application. They analyzed data by using Friedman and Wilcoxon signed-rank tests for within-group comparison. They used Kruskal-Wallis and Mann-Whitney *U* tests for between-group comparison. They considered  $P < .05$  to be statistically significant.

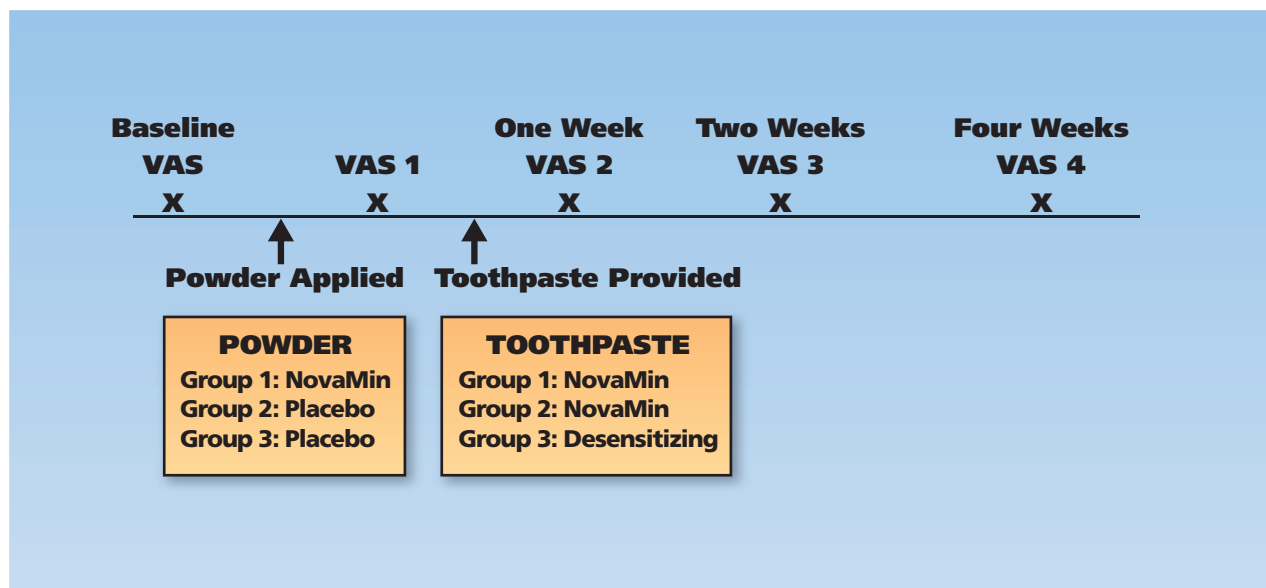
**Results.** Groups 1 and 2 showed significant hypersensitivity reduction over baseline at all time points. Group 3 showed significant hypersensitivity reduction at one week onward. Group 1 showed significant improvement compared with groups 2 and 3, except for response to tactile stimulus at four weeks with group 2. Between groups 2 and 3, there were significant differences at two and four weeks.

**Conclusions and Clinical Implications.** The use of NovaMin powder and NovaMin-containing toothpaste for hypersensitivity reduction is more effective than the use of a desensitizing toothpaste containing potassium nitrate and fluoride.

**Key Words.** Dentin sensitivity; randomized controlled clinical trials; toothpaste.

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**Figure.** Study design. VAS: Visual analog scale. NovaMin is manufactured by NovaMin Technology, Alachua, Fla.

been reported to be effective in relieving dentin hypersensitivity when added to dentrifice.<sup>7,14</sup>

We conducted a study to evaluate the effectiveness of the application of 100 percent NovaMin powder followed by use of a toothpaste containing 7.5 percent NovaMin in reducing dentin hypersensitivity compared with the use of only a toothpaste containing 7.5 percent NovaMin or of a commercially available desensitizing toothpaste containing potassium nitrate twice daily for four weeks. The null hypotheses were these:

- there is no difference between NovaMin-containing toothpaste and a desensitizing toothpaste in terms of relieving dentin hypersensitivity;
- the use of NovaMin powder does not affect the reduction of dentin hypersensitivity.

**PARTICIPANTS, METHODS AND MATERIALS**

We designed the study as a randomized, single-site, double-masked controlled clinical trial and conducted it in the Dentistry Department at Chulalongkorn Hospital, Bangkok. The ethics committee of the faculty of medicine of Chulalongkorn University, Patumwan, Thailand, reviewed and approved the study protocol.

**Participants.** We recruited the 60 participants, men and women between the ages of 26 and 70 years (mean age, 44.8 years), from the Dentistry Department at Chulalongkorn Hospital. One of the authors (T.N.) evaluated participants clinically to confirm that they had dentin hypersensitivity caused by gingival recession or cervical erosion. We

excluded from the study any teeth with cracked enamel, caries, defective restorations or crowns; teeth used as abutments; and teeth that had orthodontic appliances. In addition, we excluded participants who had chronic diseases, oral manifestations of systemic diseases or active infectious diseases such as hepatitis, human immunodeficiency virus or tuberculosis; women who may have been pregnant or lactating; patients taking anti-inflammatory drugs; and patients who had used any desensitizing compounds within the three months preceding the study. Each participant signed an informed consent form before beginning the trial.

**Testing.** We used cold water and tactile stimuli to identify tooth hypersensitivity. To measure pain, we used a 10-centimeter visual analog scale (VAS) that ranged from 0 (no pain) to 10 (severe pain). The time after each stimulus for each given tooth was at least five minutes. We evaluated the patient’s measurement of tooth sensitivity first by using an explorer, with approximately 40 g of force delivered perpendicular to the exposed cervical root surface. After waiting five minutes, we performed the second evaluation by using a cotton pellet (approximate diameter, 4 millimeters) soaked in ice water and applied to the exposed root surface. At the screening evaluation, we required that, to be accepted into the study, participants have a VAS score of at least 3 for each stimulus.

**ABBREVIATION KEY.** **M:** Changes in mean visual analog scale scores from baseline. **VAS:** Visual analog scale.

We randomly divided the 60 participants into three groups. The figure shows the study design.

■ We treated group 1 participants with 100 percent by weight NovaMin powder at baseline and instructed them to brush at home for the duration of the study with a toothpaste containing 7.5 percent by weight NovaMin. We mixed the NovaMin powder with distilled water until it formed a monostructured paste, applied it with a small brush to the tooth surface, left it for two minutes and rinsed it off. We performed this procedure under a rubber dam.

■ We treated group 2 participants with placebo powder (sodium bicarbonate) at baseline and instructed them to brush at home for the duration of the study with a toothpaste containing 7.5 percent by weight NovaMin. We prepared placebo powder and applied it to the tooth surface in the same manner as that with the NovaMin powder.

■ We treated participants in group 3, the positive control group, with placebo powder at baseline and instructed them to brush at home for the duration of the study with a desensitizing toothpaste containing 5 percent by weight potassium nitrate with 1,000 parts per million fluoride.

We provided all toothpastes to the participants. Table 1 shows the materials used in the study.

Immediately after the application of either the NovaMin powder or the placebo powder, we asked the participants to score their pain on the VAS. At the powder treatment visit, we provided participants with soft-bristled toothbrushes and toothpastes to be used at home during the study, according to the group to which they belonged. We instructed the participants to brush twice daily with the toothpaste provided and to refrain from using any other mouthrinse or toothpaste. We recalled participants and asked them to provide VAS scores at one, two and four weeks after the powder application. None of the participants failed to complete the study, and none of them reported any adverse reactions.

**TABLE 1**

| Materials used in the study.         |                                   |         |  |
|--------------------------------------|-----------------------------------|---------|--|
| MATERIAL                             | MANUFACTURER                      | LOT NO. | ACTIVE INGREDIENT  |
| <b>NovaMin Powder</b>                | NovaMin Technology, Alachua, Fla. | 08190   | 100 percent by weight calcium sodium phosphosilicate                           |
| <b>NovaMin-Containing Toothpaste</b> | NovaMin Technology                | 08094   | 7.5 percent by weight calcium sodium phosphosilicate                           |
| <b>Desensitizing Toothpaste</b>      | Neocosmed, Pathumthani, Thailand  | 390809  | 5 percent by weight potassium nitrate, 0.221 percent by weight sodium fluoride |

**TABLE 2**

| Participants' mean (standard deviation) visual analog scale scores.* |               |             |             |                  |             |             |
|--|---------------|-------------|-------------|------------------|-------------|-------------|
| TIME POINT   | COLD STIMULUS |             |             | TACTILE STIMULUS |             |             |
|  | Group 1       | Group 2     | Group 3     | Group 1          | Group 2     | Group 3     |
| <b>Baseline</b>  | 8.10 (1.02)   | 7.65 (1.93) | 6.75 (1.65) | 6.40 (1.05)      | 6.00 (1.65) | 5.40 (1.19) |
| <b>After Powder Application</b>                                      |               |             |             |                  |             |             |
| <b>Immediately</b>   | 4.75 (1.83)   | 6.90 (1.89) | 6.45 (1.64) | 3.25 (1.55)      | 5.40 (1.60) | 5.25 (1.16) |
| <b>One week</b>  | 3.50 (1.40)   | 5.95 (1.91) | 5.95 (1.57) | 1.80 (1.47)      | 4.10 (2.07) | 4.75 (1.21) |
| <b>Two weeks</b>   | 2.45 (1.36)   | 4.40 (2.60) | 5.45 (1.55) | 0.90 (1.25)      | 2.40 (1.90) | 3.80 (1.58) |
| <b>Four weeks</b>  | 1.25 (1.37)   | 2.65 (2.32) | 4.25 (1.68) | 0.10 (0.30)      | 0.90 (1.41) | 2.60 (1.66) |

\* Scores ranged from 0 (no pain) to 10 (severe pain).

Because the data were not normally distributed, we analyzed them with nonparametric methods by using software (SPSS 17.0 for Windows, SPSS, Chicago). We used the changes in mean VAS scores from baseline ( $\Delta M$ ) for statistical comparison. We compared the within-group differences at different time points by using the Friedman and Wilcoxon signed rank tests with the Bonferroni method. We compared the between-group differences at each time point by using the Kruskal Wallis and Mann-Whitney *U* tests with the Bonferroni method to analyze the differences in  $\Delta M$ . We adjusted (by means of the Bonferroni method) *P* values for four families of multiple comparisons by using an overall experimentwise error rate of .05 for  $\alpha$ .

**RESULTS**

Table 2 shows the participants' mean VAS scores and standard deviations. Table 3 shows  $\Delta M$  at different time points. The group that used the NovaMin powder with NovaMin-containing toothpaste (group 1) and the group that used placebo powder with NovaMin-containing toothpaste (group 2) showed a statistically significant improvement over baseline at every time point (*P* < .05). The positive control group (group 3) showed a statistically significant improvement

**TABLE 3**

| Changes in participants' mean visual analog scores from baseline at each time point. |                              |         |         |                  |         |         |
|--|------------------------------|---------|---------|------------------|---------|---------|
| TIME POINT AFTER POWDER APPLICATION  | GROUP, ACCORDING TO STIMULUS |         |         |                  |         |         |
|  | Cold Stimulus                |         |         | Tactile Stimulus |         |         |
|  | Group 1                      | Group 2 | Group 3 | Group 1          | Group 2 | Group 3 |
| Immediately  | 3.35*                        | 0.75*   | 0.30    | 3.15*            | 0.60*   | 0.15    |
| One Week   | 4.60*                        | 1.70*   | 0.80*   | 4.60*            | 1.90*   | 0.65*   |
| Two Weeks  | 5.65*                        | 3.25*   | 1.30*   | 5.50*            | 3.60*   | 1.60*   |
| Four Weeks   | 6.85*                        | 5.00*   | 2.50*   | 6.30*            | 5.10*   | 2.80*   |

\* Statistically significant difference within each group at different time points ( $P < .013$  according to Bonferroni method).

**TABLE 4**

| Differences in changes in participants' mean visual analog scores from baseline between groups at each time point. |                              |                        |                        |                        |                        |                        |
|--|------------------------------|------------------------|------------------------|------------------------|------------------------|------------------------|
| TIME POINT AFTER POWDER APPLICATION  | GROUP, ACCORDING TO STIMULUS |                        |                        |                        |                        |                        |
|  | Cold Stimulus                |                        |                        | Tactile Stimulus       |                        |                        |
|  | Group 1 versus group 2       | Group 1 versus group 3 | Group 2 versus group 3 | Group 1 versus group 2 | Group 1 versus group 3 | Group 2 versus group 3 |
| Immediately  | 2.60*                        | 3.05*                  | 0.45                   | 2.55*                  | 3.00*                  | 0.45                   |
| One Week   | 2.90*                        | 3.80*                  | 0.90                   | 2.70*                  | 3.95*                  | 1.25                   |
| Two Weeks  | 2.40*                        | 4.35*                  | 1.95*                  | 1.90*                  | 3.90*                  | 2.00*                  |
| Four Weeks   | 1.85*                        | 4.35*                  | 2.50*                  | 1.20                   | 3.50*                  | 2.30*                  |

\* Statistically significant difference within each group at different time points ( $P < .013$  according to Bonferroni method).

( $P < .05$ ) over baseline from one week onward. The results from both cold and tactile stimuli demonstrated the same pattern.

Table 4 shows the differences in  $\Delta M$  between groups at each time point. When we compared groups 1 and 2, group 1 showed significantly more improvement than did group 2, except for response to the tactile stimulus at four weeks after powder application. Group 1 also showed more reduction in tooth hypersensitivity than did group 3 at every time point for both stimuli. The improvement of group 2 was significantly greater than that of group 3 from two weeks after powder application onward.

**DISCUSSION**

Tooth hypersensitivity is a subjective symptom that is difficult to quantify. Nevertheless, the VAS scale is an accepted method of pain measurement.<sup>15</sup> In this study, we used cold and tactile stimuli to evaluate tooth hypersensitivity, because patients often experience this symptom when drinking cold water and sometimes complain about hypersensi-

tivity when they rub the cervical dentin with a toothbrush or fingernail.

In this study, the positive control agent was a desensitizing toothpaste that contains potassium nitrate and fluoride. Desensitizing toothpastes are the products most commonly used for reducing tooth hypersensitivity, as they are inexpensive and easy to use.<sup>16</sup> Potassium nitrate is believed to reduce hypersensitivity by depolarization of the nerve impulse, thus preventing the conduction of pain sensation.<sup>17</sup> Moreover, fluoride in the toothpaste also helps reduce hypersensitivity.<sup>16,18</sup>

We used sodium bicarbonate as the placebo powder because it does not have a residual effect on the oral cavity,<sup>19</sup> and its color, grain size and mixture characteristics are identical to those of the NovaMin powder. Thus,

the operator and the participants were not able to identify the different powders. The grain size of the two powders is similar; in addition, like NovaMin, sodium bicarbonate is highly soluble and is cleared easily by rinsing with water.<sup>20</sup>

In our study, we detected a reduction in dentin hypersensitivity immediately after powder application in all groups. This may result from a placebo effect in participants whose pain response might alter across time, especially when they realize that they are participating in a study regarding hypersensitivity.<sup>21</sup> However, the sensitivity reduction in group 3 participants was not statistically significantly different, possibly because the baseline VAS scores were low, so the  $\Delta M$ s were not large enough to be statistically significant.

NovaMin-containing toothpaste includes calcium sodium phosphosilicate particles and does not contain any fluoride.<sup>22</sup> When NovaMin is incorporated into a toothpaste, the calcium sodium phosphosilicate particles are deposited onto the dentin surface to occlude the dentinal tubules mechanically. The

physical occlusion by NovaMin begins when the material encounters an aqueous environment.<sup>23</sup> Sodium ions in the particles immediately begin to exchange with hydrogen or hydronium cations in the tooth. 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 to saliva, and the release of the calcium and phosphate ions continues as long as the particles are exposed to the aqueous environment. A localized, transient increase in oral pH occurs during the initial exposure of the material because of its release of sodium. This increase in pH helps to precipitate the calcium and phosphate ions from the NovaMin particles, along with calcium and phosphorus found in saliva, to form a calcium phosphate layer. As the particle reactions continue and the deposition of calcium and phosphate complexes continues, this layer crystallizes into hydroxycarbonate apatite, which is chemically and structurally equivalent to biological apatite. The combination of the residual NovaMin particles and the hydroxycarbonate apatite layer results in the physical occlusion of dentinal tubules,<sup>23</sup> which relieves hypersensitivity.

NovaMin-containing toothpaste was superior to the positive control dentifrice for both methods of evaluation of hypersensitivity after two to four weeks' use, which is in agreement with findings from a previous study.<sup>14</sup>

When evaluated by means of both cold and tactile stimuli, the use of 100 percent NovaMin powder followed by daily use of NovaMin-containing toothpaste proved superior to the daily use of NovaMin-containing toothpaste alone for four weeks. This probably was because the higher concentration of NovaMin may be more effective in hypersensitivity reduction. However, researchers should perform further investigations of the effectiveness of 100 percent NovaMin powder and NovaMin-containing toothpaste for treating dentin hypersensitivity by extending the evaluation time to demonstrate the materials' long-term effects.

## CONCLUSION

NovaMin-containing toothpaste showed better performance in relieving tooth hypersensitivity than did the desensitizing toothpaste containing potassium nitrate. Moreover, the application of 100 percent NovaMin powder enhanced the effectiveness of the NovaMin-containing toothpaste. Thus, the hypotheses we set were rejected. ■

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