



**THE USE OF A NOVAMIN[®] CONTAINING PREPARATION FOR THE
REDUCTION OF DENTIN SENSITIVITY IN PATIENTS UNDERGOING
PERIODONTAL MAINTENANCE THERAPY.**

Dr. Cal King, Dr. Richard Oliver, Gainesville, Florida

INTRODUCTION

Tooth hypersensitivity is a common problem that affects between 8% and 30% of the adult population (1,2). The reported incidence of sensitivity is so wide due to various methods used to diagnose the condition. Patients diagnosed with periodontal disease have been reported to have a much higher incidence of tooth sensitivity. Some surveys have reported rates of dentine hypersensitivity as high as 93% in these patients (3). While the etiology of dentine hypersensitivity is multi-factorial (4), it is generally accepted that open dentinal tubules are a major factor in dentine hypersensitivity.

The currently accepted theory for tooth hypersensitivity is the hydrodynamic theory proposed by Brännström (5). This theory is based on the belief that open dentinal tubules allow fluid flow through the tubules, which results in pressure changes that excite the nerve endings in the dental pulp. Clinical replicas and biopsies of sensitive teeth viewed under a Scanning Electron Microscope (SEM) reveal varying numbers of open or partially occluded dentinal tubules (6,7). These studies have also shown that in patients with dentin hypersensitivity, there are a greater number of tubules per area and the diameter of the tubules is greater than in patients with no sensitivity (8). In general, tubules are not seen at the tooth root surface because of the cementum covering the tooth root, or because of a smear layer of dentinal debris 2-5 microns thick that covers the tooth surface and masks the tubules. When the smear layer is present, the fluid flow that can occur through the dentin is only a few percent of that possible following acid removal of the smear layer, which “opens” the tubules.

In patients with periodontally involved teeth, it is believed that bacteria may play a role in the resulting sensitivity in addition to the physical opening of the tubules, which could account for the higher numbers of these patients with sensitivity (9).



In patients undergoing periodontal maintenance therapy, patient compliance has long been known to be a major factor in the success of the treatment plan (10,11). Patients who suffer from severe dentin hypersensitivity are very likely to be less compliant in post-treatment home compliance, resulting in less favorable clinical outcomes.

NovaMin[®] is an amorphous, sodium calcium-phosphosilicate that was developed as a fine particulate to physically occlude dentin tubules (12,13,14). The reaction of NovaMin[®] particles begins when the material is subjected to an aqueous environment. Sodium ions (Na^+) in the particles immediately begin to exchange with hydrogen cations (H^+ or H_3O^+).²³ This rapid release of ions allows calcium (Ca^+) ions in the particle structure, as well as phosphate (PO_4^{3-}) ions to be released from the material. This initial series of reactions occurs within seconds of exposure, and the release of the calcium and phosphate ions continues so long as the particles are exposed to the aqueous environment (15,16). A localized, transient increase in pH occurs during the 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[®] particle, along with calcium and phosphorus found in saliva, to form a calcium phosphate (Ca-P) layer. As the particle reactions continue and the deposition of calcium and phosphorus complexes continue, this layer crystallizes into hydroxycarbonate apatite which is chemically and structurally equivalent to biological apatite (17). The combination of the residual NovaMin[®] particles and the newly formed hydroxycarbonate apatite layer results in the physical occlusion of dentinal tubules, which will relieve hypersensitivity.

Recent studies with NovaMin[®] containing dentifrices and the particulates mixed with water alone have been shown to possess a strong anti-microbial action against periodontal pathogens that could be of significant benefit to the patient in periodontal maintenance therapy, beyond simply desensitizing the root dentin (18,19,20). In one experimental gingivitis study, it was proposed that the material also possesses some local anti-inflammatory action as determined by a reduction in gingival inflammation (21). These properties of NovaMin[®] make the material an attractive candidate for use with periodontal maintenance patients.



Following the treatment, the patients were given another form and a self-addressed, stamped envelop and asked to rate their sensitivity 24 hours post procedure (i.e., the following day) and to make any other comments they felt appropriate. They were asked to send back the form. No further follow-up was performed with the patients. Data were collected, and a statistical analysis using a two-tailed Student's *t*-Test was conducted. The analysis assumed no difference in expected means. The data is reported as the mean and standard error of the mean (SEM).

The current in-office clinical study uses NovaMin[®] Tooth Root Conditioner (NTRC), applied to the supragingival root surfaces immediately following periodontal maintenance therapy in patients with known dentin hypersensitivity. The objective of the clinical study was to evaluate the ability of the NTRC to give immediate relief of sensitivity following routine periodontal maintenance therapy in a group of patients with known dentin sensitivity.

MATERIAL AND METHODS

The study was designed as an open label, prospective study to evaluate the desensitization ability of the NovaMin[®] Tooth Root Conditioner product in the normal course of a periodontal office practice. One periodontal office was chosen as the site for the study. Fifty (50) patients undergoing normal periodontal maintenance therapy, with moderate periodontal disease and a known history of tooth hypersensitivity, were identified by the dental hygienists at their regularly scheduled scaling and root planing appointment. At the time of the office visit the patient was presented with a simple form and asked to rate their overall tooth sensitivity on a scale from zero (0) to ten (10), with 0 being 'no sensitivity' and 10 being 'severe sensitivity'. Following completion of the form, normal scaling and root planing was performed. Since the patients being scaled and root planed were in a periodontal maintenance program, the SRP was a full mouth procedure.

Immediately following the completion of the SRP maintenance, the TRC was applied to the gingival margins. The product was supplied in two syringes, one containing 1 cc of NovaMin[®] particulate (2 μ m average particle size) and one containing 0.7 mL of a 1% wt/vol. of NovaMin[®] particulate in sterile water. These two syringes were mixed according to manufacturers instructions, and the material immediately applied to the gingival surfaces.

The material was allowed to remain on the dentin surface for two minutes, and then gently rinsed for 15 seconds to remove excess material. The patient were instructed not to eat or drink for an hour, and given on other special instructions.

Following the treatment, the patients were given another form and a self-addressed, stamped envelop and asked to rate their sensitivity 24 hours post procedure (i.e., the following day) and to make any other comments they felt appropriate. They were asked to send back the form. No further follow-up was performed with the patients. Data were collected, and a statistical analysis using a two-tailed Students *t*-Test was conducted. The analysis assumed no difference in expected means. The data is reported as the mean and standard error of the mean (SEM).

RESULTS

Forty-three (43) patients sent back the forms marking their sensitivity 24 hours post-treatment. The data for the initial (pre-treatment) sensitivity and 24-hour post-treatment sensitivity are shown in Table 1 and Figure 1.

Table 1. Statistical analysis of sensitivity data.

Baseline	24-Hours post SRP	
<i>n</i>	43	43
Mean	8.023	3.884
Std. Error (SEM)	0.281	0.455
Significance (<i>p</i>)	<i>p</i> <0.001	

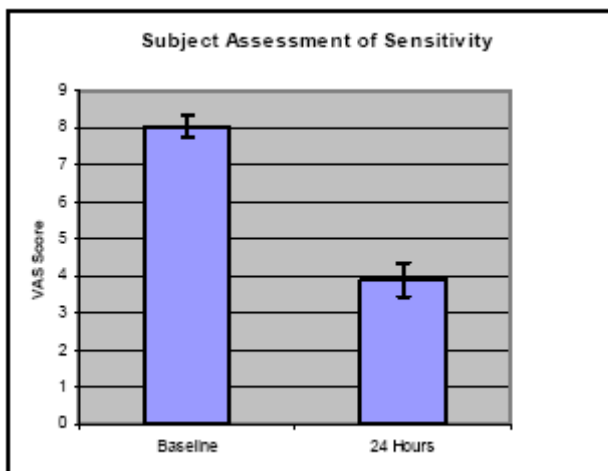
Of the 43 patients enrolled in the study, 79% of the patients (34 out of 43) showed significant relief of sensitivity 24 hours after treatment, as determined by a reduction of at least 2 units on the reported sensitivity scale. Nine (9) patients reported no reduction in post-treatment sensitivity.

Overall, the reduction in post-treatment sensitivity was 52% from baseline. The resulting reduction in sensitivity was highly significant ($p < 0.001$).

In order to determine the magnitude of the reduction in sensitivity in those patients who recorded a reduction greater than 2 units on the VAS scale, the nine patients who did not record a reduction in sensitivity were removed from the data set and the data for the remaining 34 was recalculated.

For these patients, the baseline sensitivity was 8.303 and the 24-hour sensitivity was 2.969, or a reduction of 65% in total sensitivity. The baseline sensitivity in this group was not statistically different from that of the overall cohort

Figure 1. Patient reported sensitivity, before and 24-hours after SRP.



DISCUSSION

It is generally accepted that patients with periodontal disease have a higher incidence of dentin hypersensitivity than does the general population (3). Rates of sensitivity among periodontal patients have been reported to range from over 50% to as high as 93% (22). The periodontal procedures used to remove plaque and associated damaged tissue is known to increase sensitivity in a transient manner (23).

The etiology of the sensitivity experienced by periodontally involved patients may be somewhat different than that experienced by the general population. The role of bacterial infection, both in the gingival tissue and within dentin tubules has been proposed as a possible source of sensitivity (9). The inflammation associated with periodontal disease may also be another source of the perception of pain that is noted as sensitivity.

It is recognized that patient compliance is a critical factor in the outcome of periodontal maintenance therapy. If a patient is suffering from severe, or even moderate dentin hypersensitivity, that patient may not be as compliant with home care, jeopardizing the ultimate outcome of the periodontal therapy. Therefore, a simple post-scaling treatment that can relieve the sensitivity post-treatment will make the patient more comfortable, and may help with patient compliance in their home care regimen.



In the current study, NovaMin[®] Tooth Root Conditioner was used to physically occlude tubules immediately following periodontal maintenance therapy. This study was conducted as an open-label, unblinded study to assess the patients' self-evaluation of their sensitivity, both before and after periodontal maintenance therapy. The patients selected were those with known sensitivity who routinely have difficulty with post-treatment home care due to pain from the sensitivity, or who are reluctant patients due to the fact that they know they will suffer post-treatment pain for a significant amount of time.

The results of the current study showed this group of patients' self assessment of their sensitivity as rather significant, averaging 8.023 on a scale from zero to ten. This figure is in contrast to baseline figures of sensitivity in many clinical studies where specific stimuli are used on sensitive teeth only. Many of these assessments show a baseline score of sensitivity from about 5 to 7 on a VAS scale. Often, a subjective, self assessment will be higher than the specific sensitivity numbers generated using a specific stimulus such as cold-air or water on a specific tooth. Since it is the patients' own perception of sensitivity that will drive them to either comply or not comply with home care instructions, it was felt that the subjective assessment in this study has significant value to the clinician in determining the efficacy of such a treatment.

The data clearly show a significant reduction in patient sensitivity 24-hours post-treatment. The reduction for the group was greater than 50%. Interestingly, the baseline data showed a very small standard error, giving a high degree of confidence that the mean values reported by the patients are in line with their perception of the sensitivity they suffer. Nearly 80% of the patients reported significant relief from sensitivity at the 24-hour post treatment time point.

Overall sensitivity was reduced from 8.023 at baseline to 3.884 at the 24-hour time point. The standard error at the 24-hour time point was also quite small (0.445) given a high degree of confidence that the reported reductions are significant.

This study has demonstrated that NovaMin[®] Tooth Root Conditioner is effective at reducing sensitivity following periodontal maintenance in a group of patients with pre-existing sensitivity. While the results of this study are very positive, additional studies are being planned, using a broad group of patients, both sensitive and non-sensitive, and to use a placebo to determine the breadth and extent of the sensitivity relief found in this study.

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