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Dentinal sensitivity: a natural mineral dietary supplement study

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Abstract: The purpose of the investigation was to determine the effect of drinking a natural mineral dietary supplement (NMDS) on gingival health and dentinal hypersensitivity. The NMDS product was from a geothermal source and contained 3.6 mg l^{-1} of fluoride and other minerals. Sample selection included subjects with gingival inflammation and sensitivity as well as screening for exclusion factors. A double-blind randomized parallel approach was used. The investigation was a quasi-experimental pre/post-test design. The experimental group ingested and swished twice a day with the NMDS (1 l) and the control group followed the same regimen with a placebo containing de-ionized water (DIW). Clinical measurements of gingival inflammation and dentinal sensitivity were taken at baseline, 4 and 8 weeks. Gingival inflammation was measured using the Gingival Index. Dentinal hypersensitivity was measured using a tactile stimulus and an evaporative stimulus. After each stimulus was applied, the subjects rated the amount of discomfort on a visual analogue scale from 0 to 10. Each set of data was analysed using anova and a *post hoc* probing technique to determine within- and between-group differences ($P = 0.05$). The experimental and control groups ($n = 70$) experienced a statistically significant decrease in tactile and evaporative sensitivity scores over time; however, the between-group differences were not significant. The gingival inflammation data were not statistically significant with regard to the within- and between-group differences. Therefore the NMDS and DIW were equally effective in reducing dentinal hypersensitivity and neither product effectively reduced gingival inflammation.

Key words: dentin sensitivity; dietary supplement; fluorides; gingivitis; periodontal index

Introduction

The natural mineral dietary supplement (NMDS) evaluated in this study contained 3.6 mg l^{-1} of fluoride and silica, bicarbonate, sodium, chloride, potassium, calcium and various other minerals in trace amounts (pH 9.6). This product was the first to be classified as a NMDS under the US Dietary Supplement Health and Education Act of 1997. The manufacturing company had received unsolicited claims that the product was beneficial in reducing oral pain, alleviating tooth sensitivity and diminishing bleeding of oral soft tissues as well as improving overall oral health. The anecdotal claims were translated into measurable terms; therefore, root sensitivity and gingival inflammation were evaluated by a pilot study. Other types of oral pain and sensitivity were not evaluated by the virtue of exclusion criteria identified in the Study population and methodology section.

The operational definition used for dentinal hypersensitivity was that it 'is characterized by short, sharp pain arising from exposed dentin in response to stimuli such as thermal, evaporative, tactile, osmotic or chemical and which cannot be ascribed to any other form of dentinal defect or pathology' (1). The most accepted explanation for dentin hypersensitivity is the 'hydrodynamic theory', from Brännstrom's original works, that states when an external stimuli causes a rapid outward flow of fluid in the dentinal tubules, the mechanoreceptors are activated at the pulp–dentin interface and pain is caused (2–4). The flow of dentinal fluid is influenced by the linear dimensions, configuration, diameter, and number of open tubules (5). In addition, 'neurogenic inflammation' is recognized as a condition that intensifies and sustains dentin sensitivity (6). Neurotransmitters are released in the pulp during the pain response and the response is spread. Additional study of the role of neurogenic inflammation is suggested (5, 6).

Conventional therapy for dentinal hypersensitivity involves the use of professionally applied and patient self-care topical treatments that are either chemical (desensitizing agents) or physical (restorative resins, varnishes, cement and lasers and grafts). These treatments narrow or occlude the dentinal tubules to reduce or eliminate dentinal hypersensitivity. Choices for treatment are varied, no tested regimes are superior, a large number of diverse agents are effective and choices are arbitrary and practitioner dependent (7). Fluorides are a common desensitizing chemical agent as well as potassium nitrate and silver nitrate. The fluoride and other possible trace chemicals in the NMDS were a possible link to the anecdotal information about decreased tooth sensitivity. A number of studies have tested fluoride as a desensitizing agent and a reduction in sensitivity has been reported (8, 9).

Also, appropriate water fluoridation is an accepted anti-caries agent, enhances desensitization and may be used in controlling gingivitis and plaque accumulation (10). Studies using stannous fluoride have demonstrated a reduction in gingivitis and bleeding (11). Also, there is a documented reduction in existing plaque biofilm and new plaque biofilm accumulation when a stannous rinse is used daily and it is the stannous ion that is thought to have an effect against oral microorganisms (12). It is not conclusive, however, what role fluoride or trace chemicals have in enhancing gingival health. The intent of this pilot study was to determine the effect of drinking a NMDS on gingival health and dentinal hypersensitivity.

Study population and methodology

The sample was recruited from a university campus and community and each subject exhibited some dentinal hypersensitivity and gingival inflammation. The subjects were screened to determine eligibility criteria and randomly assigned to the experimental group or the control group. The experimental group received the NMDS and the control group received the placebo de-ionized water (DIW). The placebo product was the NMDS that was subjected to a chemical de-ionization process to remove all natural ions from the liquid.

The inclusion criteria for the subjects were an adult (18 years and older) with generalized gingival inflammation indicated by a minimum total Gingival Index score of six. The sample or alternative teeth indicated for data collection needed to be present. Also, each subject needed to have a minimum of two teeth sensitive to the tactile or evaporative stimuli defined on the visual analogue scale (VAS) as greater than 0.

Exclusion criteria (1) for subjects included not having periodontal debridement (scaling and/or root planing) within 1 month of the baseline measurement, not having periodontal surgery within 3 months of the baseline measurement and not having uncontrolled diabetes. Subjects could not be pregnant, breast-feeding or using prescription or over-the-counter fluoride therapy (rinse or gel). Also, subjects could not have acute gingival or periodontal condition, a need for emergency dental care, eating disorders, excessive dietary or environmental exposure to acids or systemic conditions that were aetiologic or predisposing to dentin hypersensitive such as chronic acid regurgitation. Additional exclusion criteria were orthodontic hardware, oral contraceptives or hormone replacements, aspirin for anti-inflammatory purposes within 1 month of the study

and antibiotic use within 2 weeks. Also, subjects could not be using other prescription drugs relating to gingival inflammation or perception such as anticonvulsants, prednisone, calcium channel blockers, cyclosporins and mind-altering drugs. Teeth excluded from the sensitivity data collection were those that were non-vital; had crowns, large restorations or restorations extending into the test area; teeth used as abutments for fixed or removable prostheses; and teeth or supporting structures with any other painful pathology or defects.

A total of 70 subjects completed the investigation. Three additional individuals began the study; however, due to non-compliance with the study procedures withdrew from investigation. Table 1 summarizes the characteristics of the experimental and control groups. Both groups were similar when compared with the distribution of sex and age.

A double-blind randomized parallel approach was used. A quasi-experimental pretest/post-test design using an experimental group and a control group was employed. This design used a control group for comparison of the three clinical-dependent variables that were measured at baseline (pretest) and again at 4 and 8 weeks (repeated post-test measurements). Two subjective variables were rated by the participants at baseline and every 2 weeks for the length of the 8-week study.

During the investigation the following conceptual and operational definitions were used. *Tactile sensitivity* was sensitivity originating from touching tooth structure. Subjects rated the amount of sensitivity in individual teeth after a Suter#2 explorer (Suter Dental Manufacturing Co. Inc, Chico, CA, USA) was instrumented using light lateral pressure along the facial surface of the tooth. The sensitivity was rated on a 10-point VAS. The scale ranged from a score of 0 coinciding with no pain or sensitivity to a score of 10 coinciding with intolerable pain and sensitivity.

Evaporative sensitivity was sensitivity resulting from the evaporative action due to air contact. Subjects rated the amount of sensitivity in individual teeth after a timed blast of air from the air/water syringe for 3 s. The sensitivity was rated on a 10-point VAS. The scale ranged from a score of 0 coinciding with no pain or sensitivity to a score of 10 coinciding with intolerable pain and sensitivity.

The *Gingival Index* (GI) (13) was employed to assess the colour and inflammation of the gingiva prior to use of an instrument in the area. The area was dried using compressed air or a gauze to remove saliva from the area. The degree of inflammation was scored using the index scale as follows: 0 = normal gingiva; 1 = mild inflammation, slight change in colour, slight oedema, no bleeding on probing; 2 = moderate inflammation, redness, oedema and glazing, bleeding on probing; 3 = severe inflammation, marked redness, oedema and ulceration.

Table 1. **Characteristics of the experimental and control groups**

Group	Number of males	Number of females	Total	Average age (SD)
Experimental	15	19	34	30.8 (14.4)
Control	18	18	36	30.2 (12.7)

Tendency to spontaneous bleeding

The procedure to measure the bleeding of the gingiva was completed next. A Williams 1-mm calibrated probe (Hu-Friedy, Chicago, IL, USA) was used to assess the sulcus/pocket depth and simultaneously to determine bleeding. Investigators scored bleeding as indicated in the 0–3 GI scale. When the bleeding score was higher than the inflammation score, the higher score was recorded. The GI was scored on teeth 3 (2, 4), 9 (8, 7), 12 (13, 14), 19 (18, 20), 25 (24, 23) and 28 (29, 30). Alternate teeth indicated in the parentheses were used when the test teeth were missing or were used for the sensitivity testing. The maxillary tooth surfaces scored were distobuccal, buccal, mesiobuccal and lingual. The mandibular tooth surfaces scored were buccal, distolingual, lingual and mesiolingual. The GI score was computed for each subject by summing the scores. The maximum score for the GI was 72.

The *Overall Tooth Sensitivity Score* was the subjects' subjective rating of tooth pain experienced from everyday routine from hot and cold food or drink, cold air, tooth brushing or sweet and sour food. The VAS ranged from a score of 0 coinciding with no pain or sensitivity to a score of 10 coinciding with intolerable pain and sensitivity.

The *Overall Bleeding Gum Score* was the subjects subjective rating of gingival bleeding experienced from everyday routine from tooth brushing, flossing and eating. The scale ranged from a score of 0 coinciding with no bleeding to a score of 10 coinciding with all areas bleeding.

The null hypotheses tested were:

1 There is no statistically significant difference in tactile sensitivity between the NMDS group and the DIW group.

2 There is no statistically significant difference in the evaporative sensitivity between the NMDS group and the DIW group.

3 There is no statistically significant difference in the Gingival Index between the NMDS group and the DIW group.

4 There is no statistically significant difference in the Overall Tooth Sensitivity Score between the NMDS group and the DIW group.

5 There is no statistically significant difference in the Overall Bleeding Gum Score between the NMDS group and the DIW group.

A proposal for the pilot study was submitted to the Internal Review Board at Idaho State University and approval was received for Human Subjects Proposal no. 2162. Advertizing for participation in the study occurred on the campus and in private dental practices. Individuals who exhibited hypersensitivity were directed to telephone the campus clinic for a screening appointment. At the appointment, a health history form was completed by the potential subject and reviewed by a dental hygiene investigator to determine if their overall health met the study criteria. Additional questions related to the study criteria were asked before proceeding to the clinical evaluation. Individuals who did not meet the study criteria were provided self-care education, a toothbrush, a desensitizing toothpaste and an interdental aid such as dental floss.

Informed consent was granted from the potential subject to collect the clinical data to determine subject inclusion and the VAS was explained. Within potential subjects, teeth were tested for tactile and evaporative sensitivity. The tactile stimulus was applied first and after 10 min the evaporative stimulus was applied. To determine tactile sensitivity the investigator instrumented the explorer over the facial surface of the tooth using light lateral pressure. The strokes began at the distofacial line angle and proceeded to the mesiofacial line angle. The epithelial attachment level and the cervical third of the facial tooth surface determined the length of the strokes. After each tooth was explored, the subject rated the sensitivity using the 10-point VAS.

To determine the VAS for evaporative stimuli, a 3-s blast of air from a standard air/water syringe was administered. A stopwatch was used to standardize the time intervals between investigators. A research assistant verbally counted the seconds aloud so that the investigators applied a standard stimulus. The air stream was directed at the facial cementoenamel junction, pointed perpendicular to the tooth and placed 5 mm from the tooth surface. The clinician's fingers covered adjacent teeth to ensure sensitivity only on the test site. After each tooth received the air blast, the subject rated the amount of sensitivity. A minimum of two teeth sensitive to either the tactile or evaporative stimuli was necessary for inclusion in the study. A maximum of six different teeth for both sensitivity testing was used for data collection. The data were collected and recorded on standardized forms.

Teeth used to determine the sensitivity score were excluded from the GI data collection. The GI was scored using the specified teeth or alternate teeth and surfaces. Participants had to receive a minimum GI score of 6 to meet the inclusion criteria.

When an individual met all the study criteria, the clinician gained final informed consent emphasizing the voluntary nature of the consent and that the subject was free to withdraw from the study at any time without consequence. The subject was encouraged to ask questions about the study and the answers were clarified by the dental hygiene clinician.

The *Overall Tooth Sensitivity Score* and *Bleeding Gum Score* were then determined and a research assistant randomly assigned the subject to either the experimental or control group. All subjects received a code number that was recorded on all the data collection forms. The study was a double-blind investigation. The NMDS and the DIW looked identical with the same label. Each box of water was coded with a batch number. The batch number determined the NMDS and DIW group and was carefully recorded for product distribution at the baseline and midpoint (4-week) appointments.

Each patient received a supply of water for a 4-week period. The subjects were instructed to drink one 1-l bottle of the product per day. In addition, the subjects were instructed to swish the water around his/her mouth for at least 30 s twice a day after brushing. Subjects were instructed to consume the remaining contents of the bottle throughout the day. Investigators did not present information or education on any oral self-care products and techniques. The subjects were instructed to maintain their current self-care routine related to products and techniques. Subjects were taught how to use the compliance diary and rate their *Overall Tooth Sensitivity* and *Bleeding Gum Score* after each 2-week period. Subjects were asked to return the diary at the 4- and 8-week measurements. The unused bottles of water were returned at the end of the study to assist in determining compliance to the study protocol. The dental hygiene clinician made an appointment for the midpoint evaluation at 4 weeks.

The subject returned for the post-test measurements of the sensitivity scores (tactile and evaporative) and the GI on the same test teeth as the previous visit, 4 and 8 weeks after the baseline appointment. The visit window for the 4-week period was ±7 days and the window for the 8-week period was ±12 days. Analgesic medication can mask the symptoms of tooth sensitivity; therefore, subjects were asked to refrain from taking analgesics during a 24-h period prior to the data collection. The subject was asked if any dental appointments or treatment occurred since the previous appointment. If so, the test teeth were evaluated for inclusion or exclusion from the sample. The compliance record was evaluated and collected. To remain in the study the subject must have complied with

the directions 90% of the time (i.e. drink 1 l of water per day and swish twice a day). The same investigator recorded both the pretest and post-test data. At the 4-week appointment the subject was given another 4-week supply of the test or placebo product.

At the 8-week appointment after the data were collected, the subject was provided self-care education, a toothbrush, a desensitizing toothpaste and an interdental aid such as floss. A desensitizing solution was applied to teeth that remained sensitive. Alternative treatment for the sensitive areas was discussed with the subject.

The validity of the Gingival Index to determine gingival inflammation and use of VAS to determine dental hypersensitivity have been established in previous dental research investigations (14). The *Overall Sensitivity Score* has been used to determine subjective information related to dentinal hypersensitivity (14, 15).

The reliability of the study was strengthened by a pilot study to gain intrarater and inter-rater reliability for the five investigators who collected the sensitivity and GI data at the pretest and the two post-test appointments. After the standardization exercise, the clinicians met to discuss the research procedures. A 'Research Procedure Protocol' was distributed to the investigators and research assistant. The research assistant was present at each data collection appointment and responsible for maintaining the standardization of the five investigators.

To ensure reliability with the collection of the data, the same investigator applied the stimuli and collected the data from the subject at the baseline and post-test measurements. At each appointment the investigator collected the data at the same dental unit as the previous visits. This assisted in standardizing the variability of the air pressure administered for the evaporative sensitivity data. The data collection forms from the previous appointment were not available for the investigator or the subject to view.

The double-blind study and use of a control group helped to control for extraneous variables, especially the Hawthorne effect that has been cited in the literature as being influential on dentinal hypersensitivity investigations (16). The Hawthorne effect is described as the improvement in subjects' self-care methods, plaque scores and gingival health because of participation in a research study. This improvement masks the true effects of the product being tested.

The research design chosen for this investigation was a two-group design with repeated measurements at three time periods (baseline, 4 and 8 weeks). For each set of data, ANOVA and a *post hoc* probing technique were used for the analysis to determine within- and between-group differences. The probability level was established at 0.05 because this investigation was a pilot study. The summed scores of the GI and the tactile and evaporative sensitivity scores were calculated for each subject to determine the measurement per person. Mean values for each set of data for the two groups were determined and analysed.

Results

Seventy -three subjects started the study and 70 subjects completed the 8-week investigation. The retention rate for the study participants was 96%. Three subjects withdrew from the study due to non-compliance with the drinking regimen. Two of the individuals were in the NMDS group and one individual was in the DIW group.

Tables 2 & 3 show the mean sensitivity scores at each assessment. Each of the two groups showed a decrease in the tactile and evaporative sensitivity scores over time. The within-group differences were both statistically significant; however, the between-group differences were not statistically different (refer to Table 4). The results of the GI for the two groups over time are reported in Table 5. The within-group and between-group differences were not statistically different (refer to Table 4).

Tables 6 & 7 report the subjective data recorded by the participants on overall tooth sensitivity and bleeding gums. Each of the two groups showed a decrease in overall tooth sensitivity and bleeding gums scores over time. The within-group differences were both statistically significant; however, the between-group differences were not statistically different (refer to Table 4).

Table 2. **Tactile sensitivity scores (mean and standard deviation by group and visit)**

Group	Baseline	4 weeks	8 weeks
Experimental NMDS	3.23 (0.26)	1.98 (0.23)	1.35 (0.19)
Placebo DIW	3.35 (0.26)	1.78 (0.23)	1.27 (0.19)

Range of possible scores for the visual analogue scale was 0–10.
NMDS, natural mineral dietary supplement; DIW, de-ionized water.

Table 3. **Evaporative sensitivity scores (mean and standard deviation by group and visit)**

Group	Baseline	4 weeks	8 weeks
Experimental NMDS	4.74 (0.34)	3.58 (0.34)	2.80 (0.34)
Placebo DIW	4.31 (0.33)	3.07 (0.33)	2.63 (0.33)

Range of possible scores for the visual analogue scale was 0–10.
NMDS, natural mineral dietary supplement; DIW, de-ionized water.

Table 4. **Significance of the differences ($P < 0.05$)**

Group	Tactile sensitivity	Evaporative sensitivity	Gingival Index	Overall tooth sensitivity	Overall bleeding gums
Within-group difference	Significant	Significant	Not significant	Significant	Significant
Between-group difference	Not significant	Not significant	Not significant	Not significant	Not significant

Table 5. **Gingival Index Scores (mean and standard deviation by group and visit)**

Group	Baseline	4 weeks	8 weeks
Experimental NMDS	35.94 (1.91)	37.79 (1.91)	35.71 (2.20)
Placebo DIW	37.78 (1.86)	37.14 (1.85)	37.14 (2.14)

Range of possible scores was 6–72.
NMDS, natural mineral dietary supplement; DIW, de-ionized water.

Discussion and conclusions

The purpose of the investigation was to conduct a pilot study on the effects of a NMDS on gingival health and dentinal hypersensitivity. The effect of a NMDS on two common dental conditions has not been studied before.

No differences were noted between the NMDS and DIW groups with regard to the results of the tactile and evaporative sensitivity; therefore, the null hypotheses related to these stimuli were accepted. Both groups showed a significant improvement in the sensitivity scores. One explanation for the results could be the placebo effect. An assumption of the study was that the placebo, the DIW, did not have the fluoride and other minerals in the liquid; therefore, the sensitivity reduction in the control group was probably due to the placebo effect. This finding was consistent with other dentinal hypersensitivity investigations (14, 17).

At the beginning of the study the NMDS and the DIW group exhibited gingival inflammation with an average score of 36, which approximated half the amount of the maximum score (72). Throughout the 8-week study the scores remained relatively unchanged. The null hypothesis was accepted indicating that there was no difference in the GI between the NMDS and the DIW group. No change in the gingival condition may be linked to the need for mechanical plaque removal to enhance the gingival health.

The Hawthorne effect was not evidenced in this study. The gingival health of the control group did not improve over the 8-week period. This finding is consistent with the investigation completed by Yates *et al.* (17).

Holland *et al.* (1) reported 8 weeks as the median length of time of 45 investigations conducted between 1956 and 1992. 'While 8 weeks may be a suitable duration for most clinical trials, the optimum course of the product action should first be established in pilot studies' (p. 811). Perhaps the length of this investigation, 8 weeks, was not sufficient in length to determine significant differences between the NMDS and DIW groups.

Holland *et al.* (1) also noted that evaluation of products should include a subjective evaluation of changes in the individual's overall sensitivity to everyday stimuli. In this investigation, the subjects rated the severity of tooth pain experienced during everyday routine from hot and cold food or drink, cold air, toothbrushing or sweet and sour food. The rating was completed on a VAS from 0 to 10 every 2 weeks. Both groups experienced a reduction in their overall tooth sensitivity; however, the differences noted between the two groups

Table 6. **Overall Tooth Sensitivity Scores (mean and standard deviation by group and visit)**

Group	Baseline	2 weeks	4 weeks	6 weeks	8 weeks
Experimental NMDS	4.04 (0.40)	2.81 (0.38)	2.58 (0.35)	2.25 (0.32)	2.28 (0.31)
Placebo DIW	4.06 (0.38)	3.12 (0.36)	2.96 (0.33)	2.51 (0.30)	2.31 (0.30)

Range of possible scores for the visual analogue scale was 0–10.
NMDS, natural mineral dietary supplement; DIW, de-ionized water.

Table 7. **Overall Bleeding Gums Scores (mean and standard deviation by group and visit)**

Group	Baseline	2 weeks	4 weeks	6 weeks	8 weeks
Experimental NMDS	2.02 (0.30)	1.21 (0.29)	1.09 (0.26)	1.15 (0.26)	1.02 (0.23)
Placebo DIW	2.57 (0.28)	1.64 (0.28)	1.55 (0.25)	1.31 (0.25)	0.98 (0.22)

Range of possible scores for the visual analogue scale was 0–10.
NMDS, natural mineral dietary supplement; DIW, de-ionized water.

were not significantly different. Considering the episodic nature and the localized nature of tooth sensitivity, the results might be explained.

The Overall Bleeding Gum Index also showed similar results. The null hypothesis was accepted because there were no differences between the NMDS and DIW group. Subjects rated the severity of bleeding gums in their mouth experienced during everyday routine from brushing, flossing and eating. The rating was completed on a VAS from 0 to 10 every 2 weeks. The subjects in the NMDS and DIW group rated their overall bleeding gum score at 2.02 and 2.57, respectively, at baseline. These scores were initially low which may indicate that subjective evaluation of gingival bleeding was not a reliable measure of this condition. The use of the GI as a clinical measure of gingival health was a more reliable and valid measure of gingival health. Both groups did experience a significant difference in their Overall Bleeding Gum Index during the 8-week period; however, this finding is not consistent with the GI results previously reported in this study.

Future investigations could include subjects with a higher sensitivity level on the VAS at the baseline measurement, such as 4 or 5. Perhaps a study longer than 8 weeks would produce a therapeutic effect of the NMDS. Another recommendation is to have a separate investigation for gingival outcomes and another for dentinal hypersensitivity outcomes. The exclusion criteria for a study involving gingival outcomes is involved; therefore, subjects that meet the sensitivity criteria are sometimes eliminated from the study due to the gingival exclusion criteria.

All null hypotheses were accepted meaning there was no statistically significant difference between the experimental and control groups. This finding was evidenced with all the clinical variables as well as the subjective variables related to gingival health and dentinal hypersensitivity.

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