

A randomized, parallel group clinical study evaluating the efficacy of three desensitizing dentifrices.

NovaMin Research Report

Abstract

Objective: The purpose of this clinical study was to evaluate the effectiveness of three dentifrices containing 5% potassium nitrate, 0.4% stannous fluoride and 7.5% sodium calcium phosphosilicate (NovaMin®) containing dentifrice respectively in the treatment of dentinal hypersensitivity.

Materials & Methods: The study was a randomized, double-blinded, clinical trial. The study included 120 volunteers, which were balanced for gender and selected based on an evaluation of sensitivity. Sensitivity was measured using a measured cold water and cold air blast onto identified teeth (canines, incisors or pre-molars). Those scoring between 4 and 10 on a visual analogue scale of 0-10 were included (0=no pain, 10= extreme pain). Participants were randomly divided into three groups. Each was given a test dentifrice and instructed to brush twice daily for about 2 minutes. Patients were recalled at 2, 4 and 12 weeks for measurement via the cold air and cold water methods.

Results: For air at weeks 2 and 4, there were significant main effects for group with NovaMin® more effective than the other two groups, which did not differ between themselves. For air at week 12, the effect of group was not significant. For water at weeks 2 and 4, there were significant main effects for group with NovaMin® more effective than the other two groups, which did not differ between themselves. For water at week 12, there was a significant main effect for group with the only significant pair-wise effect being NovaMin more effective than the potassium nitrate group.

Conclusion: All three products reduced sensitivity, with the NovaMin containing product showing much greater reductions at the 2- and 4-week time periods.

Research Institution:
Rmed Forces Medical Center
Delhi, India

Principal Investigator:
Dr. N. Sharma

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INTRODUCTION

The purpose of this clinical study was to evaluate the effectiveness of three dentifrices containing 5% potassium nitrate, 0.4% stannous fluoride and 7.5% sodium calcium phosphosilicate (NovaMin®) containing dentifrice respectively in the treatment of dentinal hypersensitivity. The study was single centre, randomized double blind, parallel group design with duration of 12 weeks. The study included total of 120 subjects and the protocols of the study were followed as per the guidelines for the design and conduct of clinical trials on dentin hypersensitivity.

Patients with a history of tooth hypersensitivity, who were seeking treatment in the out patient dental department of AFMC Pune were

selected for the study with the following inclusion and exclusion criteria.

Inclusion Criteria The inclusion criteria required patients between the ages of 20-50 years. Subjects included in the study were in good general health and had at least 20 natural permanent teeth in their mouth and history of hypersensitivity to hot, cold or sour stimuli on at least two teeth excluding molar teeth. Equal numbers of male and female subjects were selected. All patients were evaluated to insure that they were currently using toothbrush and toothpaste for their oral hygiene procedures.

Exclusion Criteria Patients with active cervical caries or deep abrasion requiring class V filling,

chipped teeth or fractured cusps were excluded from the study. In addition, a tender tooth in the same quadrant as the hypersensitive teeth, and those patients using any type of desensitizing paste or any desensitizing therapy for the last 6 months were excluded. Subjects with history of chronic use of anti-inflammatory and analgesic medication, pregnant or lactating females, those with the history of chronic regurgitation of acids, those who have undergone periodontal surgery in the preceding 6 months, and those with any denture or bridge work that would interfere with the evaluation of hypersensitivity were also excluded.

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. The study was explained to the subjects and informed consent forms for their willingness to be a part of the study for 12 weeks was obtained. All the subjects underwent oral prophylaxis before the study. After a 4 week wash-out phase, baseline visual analogue scale Score (Hurkisson 1974) indicating dentin hypersensitivity levels to cold water stimuli and air blast method was measured. The facial surfaces of sensitive Canine, Incisors and premolars were included. A mean sensitivity score was calculated for each patient by using the stimuli. These mean sensitivity scores became the data that was finally analyzed.

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 1.0 Second and at a distance of about 0.5 cm. A pressure of 60psi was selected with the help of pneumatic pressure control valve. Adjacent teeth were protected by operator's fingers and cotton rolls. Patient response on visual analogue scale of 10cm was measured. The test was repeated three times before a score, using VAS, was noted. Those between VAS score of 4 -10 responses were selected. (10 – Severe pain, 0 – No pain). The cold water test was performed approx 10 minutes after the air blast test. The tooth reported to be sensitive by the patient was isolated with cotton rolls. Cold water stimulus was delivered as 1 ml of freshly melted ice cold water applied immediately to the buccal cervical region using an eppendorf micropipette. Patient response on visual analogue scale of 10cm was measured. The test was repeated

three times before a score, using VAS, was noted. Those between VAS score of 4 -10 responses were selected. (10 – Severe pain, 0 – No pain)

DENTIFRICES TESTED:

Three toothpastes containing following three components respectively as an active agents were used

- 1) 5% Potassium Nitrate
- 2) 0.4% Stannous Fluoride
- 3) 7.5% Sodium Calcium Phosphosilicate (NovaMin®)

After the collection of the baseline data, the subjects were divided randomly into three groups. Each group had 40 subjects with equal number of males and females. Each group designated A, B and C was provided with one of the dentifrices. The dentifrices were dispensed by an examiner to the subjects of three groups so that neither the examiner nor the patient knew the content of the toothpaste. Each patient was provided with adult soft bristle toothbrush and was advised to put about half an inch of dentifrice on the brush. Patients were instructed to brush their teeth in a usual manner for about 2 minutes, twice daily with their respective dentifrice. The patients were instructed to not to eat or drink anything within half an hour of brushing with the dentifrice. The patients were recalled at 2 weeks, 4 weeks and 12 weeks for the measurement of tooth sensitivity by the cold water test and the air blast method. At the recall visit all the used dentifrice was returned and new material was dispensed. During the study period following were not permitted: 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.

STATISTICAL METHODS:

ANOVA analysis of groups was performed to determine any significant differences in the stratification of the groups. Paired t-tests were performed for each group to determine differences at each time point. ANCOVA analysis of the group effects at each time point was conducted. In addition, a within group analysis of each dentifrice was performed. A Tukey post-hoc pair-wise comparison was carried out to determine differences between groups at each time point, using a $p < 0.05$ as a significance level. All analyses were performed using Sigma Stat and Sigma Plot 9.0.

RESULTS:

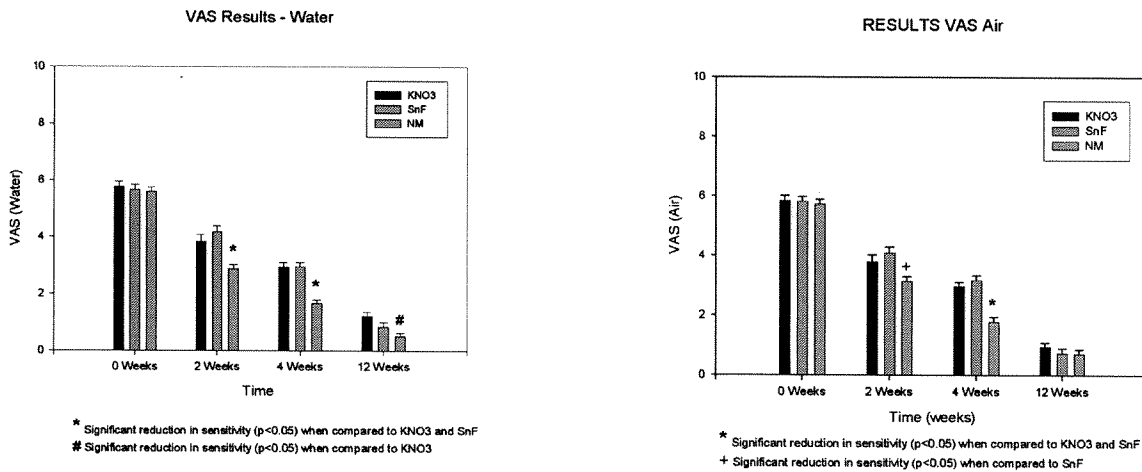
Stratified assignment by gender was successful and there were 20 males and 20 females in each group. An ANOVA on age indicated the absence of a significant main effect for group (mean age = 32.03, 30.70, and 32.43 years for potassium nitrate, stannous fluoride, and NovaMin groups, respectively; $P = 0.461$). ANOVAs of baseline air sensitivity and baseline water sensitivity indicated no significant main effects for group ($P_s = 0.842$ and 0.757 for air and water, respectively). Paired t-tests, for each group, were done comparing sensitivity for water and air at time points 2, 4, and 12, to baseline. Figures 1a and 1b show that all products resulted in significantly reduced sensitivity compared to baseline for both water and air tests, and that the clear trend was for increasing reductions in sensitivity over time. ANCOVAs for the group effect were done for air and water at times 2, 4, and 12, with baseline as the covariate (in all ANCOVAs, the effect of the covariate was significant at $P < 0.001$). Post-hoc pair-wise comparisons were done using Tukey. For air at weeks 2 and 4, there were significant main

effects for group with NovaMin[®] more effective than the other two groups, which did not differ between themselves. For air at week 12, the effect of group was not significant. For water at weeks

2 and 4, there were significant main effects for group with NovaMin[®] more effective than the other two groups, which did not differ between themselves. For water at week 12, there was a significant

main effect for group with the only significant pair-wise effect being NovaMin more effective than the potassium nitrate group.

Figures 1a. and 1b.: VAS reduction results across three test dentifrices at 2-, 4- and 12-weeks



The absence of some significant group effects at 12 weeks may be due to a floor effect. That is, NovaMin results in more rapid reductions in sensitivity but, at 12 weeks, the other dentifrices

approach similar reductions in sensitivity with no room on the measurement scale for further improvement. The results of this study demonstrated that a NovaMin[®]

containing dentifrice provides significantly more rapid relief from sensitivity than did two leading commercial active ingredients used in dentifrice formulations to treat dentinal hypersensitivity.