

Evaluation of the Clinical Efficacy of a new Desensitizing Tooth Paste Containing Nano-crystalline Hydroxyapatite in Dentine Hypersensitivity Patients : A Double Blind Randomized Controlled Clinical Trial

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Abstract

Aim: Several dentifrices have been shown to be effective in reducing dentine hypersensitivity (DH). The aim of the present study was to evaluate the desensitizing efficacy of Aclaim[®] toothpaste.

Materials and Method: A double blind randomized controlled clinical trial was performed on 40 subjects in which 20 were asked to use Aclaim[®] toothpaste (test group) and 20 were asked to use fluoridated foaming dentifrice available in market. All subjects were examined at baseline and after 3 weeks and 6 weeks; at each visit only the teeth identified as hypersensitive at baseline were re-evaluated. The hypersensitive teeth were assessed using the commonly used and validated stimuli tests: tactile tests, air blast test and ice stick test and subjective tests.

Results: The results showed that both dentifrices were largely effective; the mean score reduction from baseline to 6 weeks was significant in all the parameters (air blast, tactile, ice stick and subjective test) in both the groups. But, the test group showed a statistically significant mean score reduction in all the parameters recorded.

Conclusion: The results of the present study suggested that there is a significant reduction in dentinal hypersensitivity in subjects advised to use nano-crystalline hydroxyapatite containing dentifrice as compared to subjects using commercially available fluoride based desensitizing toothpaste.

Keywords: Dentinal Hypersensitivity, Remineralizing Agent, Occlusion of Dentinal Tubules.

Introduction

Dentine hypersensitivity (DH) is characterized by a short, sharp pain arising from the exposed dentine in response to thermal, evaporative, tactile, osmotic or chemical stimuli, which cannot be ascribed to any other dental defect or pathology.^{1,2} The condition can arise as a result of enamel loss caused by attrition, abrasion or erosion and can be often associated with exposed root surfaces of canines and premolars.³ Dentine hypersensitivity is a common problem with

prevalence varying widely, with various studies showing that it affects 3% to 57% of adult population.^{4,5} Current evidence explaining dentinal hypersensitivity favors the hydrodynamic theory originally postulated in the 19th century and later developed by Brannstrom in 1963.⁶

A number of treatment regimens have been recommended over the years, and particular attention has been focused on "home use" dentifrices containing various "active" compounds, either blocking the

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hydrodynamic mechanism or the neural response.⁷ According to Lee et al, the variations in DH symptoms occur according to the extent of opened dentinal tubules.⁸ Therefore, an effective method to occlude patent dentinal tubules may prove to be beneficial in treating DH. At one time, strontium salts were the most common desensitizing agents.⁹ Subsequently, potassium salts became the most popular active ingredients of dentifrices advocated for use in DH treatment.^{10,11,12} Most of the products and devices used to treat DH, behave by reducing stimuli conduction and apatite dissolution rather than aiming to promote mineralization through apatite crystallization or the replacement of the lost mineral.^{13,14}

Recently, Aclaim® toothpaste has been advocated for treatment of DH which offers nanocrystals of hydroxyapatite. These nanocrystals mimic natural hydroxyapatite in composition, structure, nano-dimensions as well as functionality. Acting as a filler, nano particles easily penetrate into the exposed dentinal tubules and strongly adsorb to dentine apatite, thus sealing exposed dentinal tubules. The tooth paste releases calcium and phosphate ions, which precipitate and recrystallize to form a biomimetic apatite layer over exposed dentinal tubules. This biomimetic apatite layer has been shown to be impermeable and resistant to acid attack. It also remineralizes micro-sized pores of demineralized enamel, micro cracks, sub-surface lesions and smoothens the enamel surface. This smooth enamel surface reduces the accumulation of plaque and stains.

Thus, the aim of the present study was to compare the clinical efficacy of a dentifrice containing nanocrystalline hydroxyapatite (Aclaim®) to a commercially available

fluoridated desensitizing tooth paste as a positive control in the management of dentinal hypersensitivity over a period of 6 weeks.

Materials And Method

Study Population

The study was conducted in the outpatient Department of Periodontology and Oral Implantology, I.T.S-CDSR, Ghaziabad. For this randomised controlled trial, 40 patients were selected. Following inclusion criteria was used 1) Patients aged 18 to 60 years, 2) Hypersensitive area on facial surfaces with at least two teeth scoring one or more on the air blast sensitivity test, 3) Periodontally healthy patients, 4) Systemically healthy patients 5) Patients with gingival recession and 6) No other condition that might explain their apparent DH. The exclusion criteria were 1) Deep dental caries or large restorations showing pulpal response, 2) Defective restorations, 3) Deep periodontal pockets, 4) Orthodontic appliances, 5) Patients with dentures or bridge work that would interfere with the evaluation of hypersensitivity, 6) Patients who had undergone periodontal surgery within the previous 6 months, 7) Patients who were undergoing treatment with antibiotics or anti-inflammatory drugs and treatment for tooth hypersensitivity, 8) Heavy smokers, alcohol or drug abusers and 9) Patients with any systemic disease. The subjects were randomly categorized into two groups, i.e. the test group and the control group. The test group included 20 subjects, who were advised to use Aclaim® toothpaste and the control group received a fluoride containing desensitizing toothpaste, Sensodent KF® The randomization process was made externally by the statistical unit using a computer generated random table. The investigator was neither involved during the

randomization process nor were they aware of which group the subject belongs to in the evaluation phase. Informed written consent was taken from all the patients prior to the study.

Initial Therapy

The patients initially completed a plaque control program, including oral hygiene instruction, scaling and root planing. The patients were instructed to perform non traumatic brushing technique twice a day for 2 min and not to use any other desensitizing agent or dentifrice. Only those patients maintaining optimum oral hygiene as well as showing compliance towards the correct brushing technique were included in the study.

Clinical Parameters

All subjects were examined at baseline, 3 weeks and 6 weeks. At each visit only the teeth identified as hypersensitive at baseline were re-evaluated. During the visits minimum of two and up to four hypersensitive teeth were assessed using stimuli tests: tactile tests, air blast test and ice stick test.¹⁵ the teeth were isolated with cotton rolls and stimuli were applied on each tooth.

Air Blast Test

A blast of air was directed onto the affected area of the tooth for 1 sec from a distance of 10mm, while the adjacent teeth were isolated using cotton rolls, using standard dental unit air syringe. Sensitivity was recorded using the air sensitivity scale.

0 = tooth/ subject does not respond to air stimulus.

1 = tooth/ subject responds to air stimulus but subject does not request discontinuation of the stimulus.

2 = tooth/ subject responds to air stimulus and requests discontinuation or moves from the

stimulus

3 = tooth/ subject responds to air stimulus, considers stimulus to be painful, and requests discontinuation of the stimulus

Tactile Test

The test was carried out using a sharp dental explorer. The explorer was passed across the facial surfaces of the tooth perpendicular to its long axis, at an approximated constant force. The test was repeated three times before a score was recorded. The subjects were asked to rate the perception of sensitivity as a score '0-10' where '0' meant no pain and '10' meant excruciating pain, based on a visual analog scale (VAS). This was the "probe intensity score."¹⁶

Ice Stick Test

Ice sticks were kept at the facial surface of the tooth after proper isolation for a 5 sec. Sensitivity was measured using a 10 cm VAS score.

0 = no pain

10 = excruciating pain or discomfort

The above stimuli tests were applied in the above order with a minimum of 5 min gap between the applications of different stimuli.¹⁷

Subjective Tests

In addition to stimuli tests, the subject's subjective perception was investigated using an overall sensitivity score. Subjects were asked to rate their perception to hot/ cold food and drink, air, tooth brushing and too sweet and sour food by providing a score of 0-10.¹⁸

All assessments were made by two investigators, after receiving a 5 hours specific training programme and were unaware of the subjects group. Each subject was evaluated by the same investigator throughout the trial. During each visit, the occurrences of potential adverse effects were

assessed by investigators through both clinical survey and participants enquiry.

Statistical Analysis

The data was subjected to statistical analysis. Paired 't' test was used to evaluate intra group scores. Unpaired 't' test was used for assessing inter group results. A two-tailed p-value of 0.05 was considered significant for all analyses.

Results

Table 1 shows the mean value for all the parameters recorded, i.e., air blast, tactile, ice stick and subjective test for both the groups. The mean value for tactile test in control group at baseline, 3 weeks and 6 weeks was 5.26 ± 0.76 , 4.1 ± 0.72 and 3.46 ± 0.80 while at test site was 4.84 ± 1.12 , 1.28 ± 0.92 , and 0.50 ± 0.52 . The mean value for air blast test in control group at baseline, 3 weeks and 6 weeks was 1.84 ± 0.49 , 1.51 ± 0.29 and 1.29 ± 0.22 while at test site was 1.98 ± 0.29 , 1.29 ± 0.22 and 0.96 ± 0.12 respectively. Ice stick test showed mean value at baseline, 3 and 6 week were 7.08 ± 1.76 , 4.44 ± 0.96 and 3.32 ± 0.98 at control site while at test site they were 7.44 ± 1.80 , 3.14 ± 1.34 and 2.4 ± 1.16 . Also, subjective test showed mean value at baseline, 3 and 6 weeks 7.2 ± 1.18 , 3.94 ± 1.3 and 1.94 ± 1.04 at control site. At test site, the values were 6.92 ± 1.48 , 1.6 ± 1.0 , and 1.02 ± 0.96 , respectively. In control group the mean reduction value was 1.8 in tactile test as compared to 4.34 in test site. This reduction was statistically significant on comparison. In control group the mean reduction value was 0.59 in air blast test as compared to 1.02 in test site. This reduction was found statistically significant on comparison. In control group the mean reduction value was 3.76 in ice stick test as compared to 4.3 in test site. This reduction was statistically significant on

comparison. In control group the mean reduction value was 5.26 in subjective test as compared to 5.9 in test site. On comparison this reduction was statistically significant.

Bar diagram shows mean value reduction in all the parameters including air blast test, tactile test, ice stick test and subjective test at base line, from base line to 3 weeks and from baseline to 6 weeks respectively.

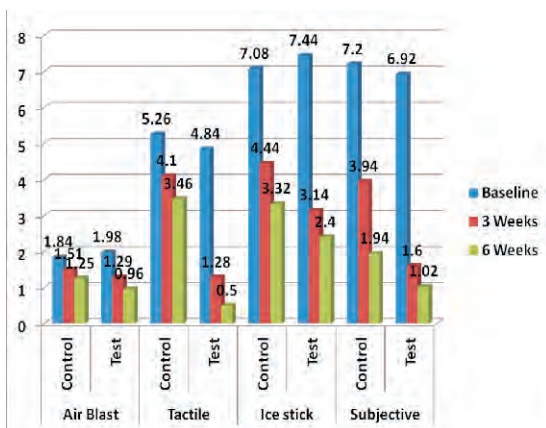
Discussion

Dentine hypersensitivity might be reduced physiologically by formation of intratubular crystals from the dentinal fluid and saliva minerals or by the application of therapeutic chemical agent to occlude the exposed dentinal tubules.¹⁹ Clinically treatment of dentinal hypersensitivity with agents that promote the occlusion of dentinal tubules aims to cause the precipitation of crystals which may subsequently reduce the movement of dentinal fluids. But there has been no gold standard for treatment of dentinal hypersensitivity. It may be achieved by home use of various desensitizing dentifrices which contains various ingredients i.e strontium chloride, sodium fluoride, pro argenine, potassium nitrate. A recent addition to this category is nano- hydroxy appetite crystals in the form of toothpaste which due to its nano sized particle occludes well inside the exposed dentinal tubules. To evaluate the threshold of response to pain elicited by various stimuli, it should be quantified and established. DH has been mainly evaluated on the basis of the patient's subjective response to the presenting stimulus, for example, in the form of verbal rating and VAS and questionnaires.¹⁶ DH may be evaluated either in terms of the stimulus intensity required to evoke pain (stimulus-based assessment), or as the subjective evaluation of the pain produced by a stimulus

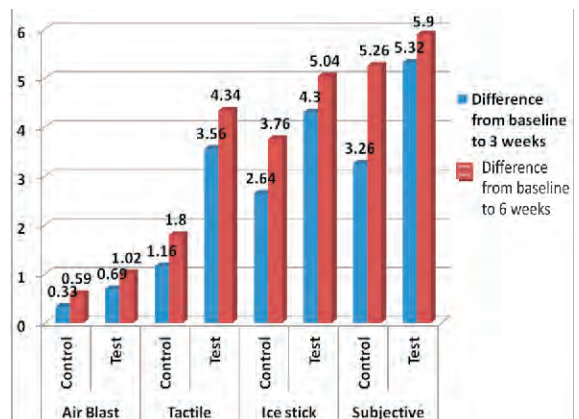
Table 1: Mean values of control and test group at baseline, three weeks and six weeks for tactile airblast, ice stick and subjective test.

Clinical Test	Groups	N	Baseline		3 Weeks		6 Weeks	
Air Blast	Control	20	1.84 ± 0.49	0.3	1.51 ± 0.29	0.009*	1.25 ± 0.28	0.000*
	Test	20	1.98 ± 0.29		1.29 ± 0.22		0.96 ± 0.12	
Tactile	Control	20	5.26 ± 0.76	0.4	4.1 ± 0.72	0.000*	3.46 ± 0.80	0.000*
	Test	20	4.84 ± 1.12		1.28 ± 0.92		0.50 ± 0.52	
Ice stick	Control	20	7.08 ± 1.76	0.5	4.44 ± 0.96	0.048*	3.32 ± 0.98	0.010*
	Test	20	7.44 ± 1.80		3.14 ± 1.34		2.4 ± 1.16	
Subjective	Control	20	7.2 ± 1.18	0.4	3.94 ± 1.3	0.000*	1.94 ± 1.04	0.007*
	Test	20	6.92 ± 1.48		1.6 ± 1		1.02 ± 0.96	

*p<0.05



Bar Diagram 1: mean values of control and test group at baseline, three weeks and six weeks for tactile, air blast, ice stick and subjective test.



Bar diagram 2:- Bar diagram show the mean value reduction after baseline to 3 weeks, baseline to 6 weeks for tactile test, airblast test, ice stick test and subjective test.

(response-based assessment).²

In the present study, assessment of stimuli for all patients was done by VAS without any bias. Compliance was enhanced by regular follow-up of patients. No side effects were observed in any patient during the conduction of the clinical trial. Orisini et al 2010²⁰ documented that the new dentifrice containing zinc-CHA nanocrystals significantly reduced dentinal hypersensitivity after 4 and 8 weeks, supporting its utility in clinical practice. OHTA K et al, demonstrated that nano-HAP could be an effective agent for occluding dental tubules and may be useful in treatment of hypersensitivity.²¹ It is noteworthy that the benefits seen in the present study were obtained by simple home use of the products in the form of dentifrices, rather than by more complex in-office interventions.

Kim et al in 2006 evaluated the effect of nano-hydroxyapatite toothpaste, which was produced by nano- technology, on the remineralization of human enamel. The authors reported Vickers hardness number values between those obtained before and after the remineralization steps were significant. The results showed that the remineralization effect increased with increasing immersing time. However, there were no significant differences in VHN values between the two groups. SEM also demonstrated differences in the micro surface at each step. Hence they concluded that a toothpaste containing nano-hydroxyapatite has the potential to remineralize an incipient caries lesion. In addition, the addition of fluoride had no synergistic effect on remineralization.²² Peter et al in 2011,²³ evaluated the effects of nano-hydroxyapatite (n-HAp) toothpastes on remineralization of bovine enamel and dentine subsurface lesions. In that study, the

specimens were demineralized, randomly divided into five groups, and exposed to an aqueous remineralizing solution for two and five weeks (37 °C). Brushing procedures were performed with the respective toothpaste/storage solution slurry twice daily (2 × 5 s; total contact time of the slurries 2 × 120 s/d): storage in remineralizing solution only (0); additional brushing with B (20 wt% zinc carbonate nano-hydroxyapatite, ZnCO₃/n-HAp); BS (24 wt% ZnCO₃/n-HAp); E (0.14 wt% amine fluoride); or A (7 wt% pure n-HAp). Differences in mineral loss before and after storage/treatment were microradiographically evaluated. The author reported that the Dentine groups 0, B, BS, and A showed significantly higher values compared to E. Enamel values of group A were significantly higher compared to group E, whilst no significant differences of these groups could be observed compared to 0, B, and BS. They concluded that, toothpastes containing n-HAp revealed higher remineralizing effects compared to amine fluoride toothpastes with bovine dentine, and comparable trends were obtained for enamel.

In a study done by Lee et al⁸, the effects of the short-term use of a dentifrice containing nano-sized carbonate apatite (n-CAP) on the occlusion of the dentinal tubules using a scanning electron microscope (SEM) and an image analyser in vitro was evaluated. One hundred human dentine specimens were wet ground with a silicone carbide papers and etched with 6% citric acid for 1 min to allow complete opening of the dentinal tubule. Specimens showing complete opening tubules were used as the baseline. The specimens were divided randomly into five groups: G1: 0% n-CAP, G2: 5% n-CAP, G3: 10% n-CAP, G4: 20% n-CAP and G5: 10% strontium chloride

(SrCl₂). Five specimens from each group were brushed by applying 50, 100, 250 and 500 strokes, respectively. All the specimens were evaluated by a SEM ($\times 3000$), and the degree of occlusion of the dentinal tubules was quantified using an image analyser. The results were analysed by one-way anova and a Tukey's test using the spss 12.0 statistical package program. The dentifrice containing 20% n-CAP for 50 strokes, which indicated 2-day use, showed the highest tubular occlusion than the other groups ($P < 0.05$). Moreover, this group showed 79.5% and 77.4% less open tubular area than the baseline and 0% n-CAP group, respectively. The groups containing various concentrations of n-CAP showed significant differences in the SrCl₂ group after tooth-brushing for 500 strokes, which indicated 17-day use. According to this examination of the short-term use of desensitizing dentifrices *in vitro*, the dentifrice containing 20% n-CAP was the most effective in occluding the dentinal tubules.

The results of the present study demonstrate that home use of desensitizing toothpastes can be effective in the management of dentinal hypersensitivity. Moreover, the use of these agents is safe and effective and can provide relief within a few days. Occlusion of the dentinal tubules is thus an effective way to tackle this common complaint of the patient. For this, the newly available toothpaste i.e. Aclaim[®] seems to be an effective method to achieve remineralization. As evident from the study, there was an improvement in both the objective and the subjective symptoms of dentinal hypersensitivity.

Conclusion

The results of the present study suggest that there is a significant reduction in dentinal hypersensitivity in subjects advised to use

NHA crystals containing dentifrice as compared to subjects using commercially available fluoride-based desensitizing toothpaste. This may be due to the increased bioavailability of hydroxyapatite, promoting remineralization of exposed dentinal tubules, thereby reducing hypersensitivity. However, long-term clinical trials studies, along with SEM analysis are suggested to establish the exact mechanism of its effectiveness in the management of dentinal hypersensitivity.

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