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A Comparison of Clinical Efficacy of Dentifrices Containing Calcium Sodium Phosphosilicate, Nanoparticle Hydroxyapatite and a Dentifrice Containing Casein Phosphopeptide Amorphous Calcium Phosphate on Dentinal Hypersensitivity- A Comparative Triple Blind Randomized Study

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ABSTRACT

Aim: A considerable number of agents are effective in the treatment of dentin hypersensitivity. This3 month randomized clinical trial compares a dentifrice containing Calcium Sodium Phosphosilicate, Nanoparticle Hydroxyapatite and Casein Phosphopeptide-Amorphous Calicium Phosphate.

Materials and Method: Eighty teeth were selected in each group. The volunteers selected at baseline had a history of dentin hypersensitivity caused by gingival recession or after scaling and root planing. Patients were evaluated for dentin hypersensitivity using visual analog score and Schiff test. Patients were required to have a visual analog scale score of ‡2 to be included in the study. After sensitivity scores for controlled air stimulus and cold water at baseline were recorded, subjects were given toothpastes randomly and sensitivity scores were measured again at 2nd week, 4th week, 2nd month and 3rd month.

Results: All three groups showed reduction in sensitivity scores at 2weeks, 4 weeks and at 3 months for air stimulus and cold water. The nanoparticle hydroxyapatite group was found to be significantly better in reducing the visual analog scale score as well as Schiff test score and at any time point for both measures of sensitivity.

Conclusion: The Nanoparticle Hydroxyapatite group showed comparable reduction in the symptoms of dentin hypersensitivity.

Keywords: Dentifrices, Dentin hypersensitivity, Biocompatible materials.

INTRODUCTION

Dentinal hypersensitivity [DH] has been defined by Holland et al as short, sharp pain arising from exposed dentine as a result of various stimuli such as heat, cold, chemical or osmotic that cannot be ascribed to any other patholog[1]. DH is a painful clinical condition that affects 8% to 35% of the population. The incidence of DH reportedly peaks during the third and fourth decades of life[2]. There are varied

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etiologic and predisposing factors related to DH. Removal of enamel, as a result of attrition, abrasion, erosion and denudation of the root surface by overlying cementum and periodontal tissue loss are commonly cited. Before making a diagnosis of dentinal hypersensitivity, other oral conditions must be ruled out, including occlusal trauma, caries, defective restorations, fractured or cracked teeth, potential reversible or irreversible pulpal pathology or poor gingival conditions[3].

Many theories have been proposed to explain dentinal hypersensitivity. The most accepted view by Astroem in 1964 says that dentin sensitivity is due to a hydrodynamic mechanism where a stimulus produced by inward or outward flow of the content of the dentinal tubules produces, in turn, a mechanical disturbance or cellular perturbation that excites nerves in the tooth[1]. It is also established that interdental myelinated A delta fibers are responsible for dentin sensitivity. The sensitivity of nerve units is dependent on the condition of the dentinal surface, with either open or blocked dentinal tubules and also on the inflammatory changes in the pulp dentin border area.

Evidence indicates that area of hypersensitive dentin have significantly more open dentinal tubules compared with non-sensitive dentin and that these open tubules are patent throughout their length[4]. This enables the fluid to move freely between the oral environment and the pulp. In the hydrodynamic theory, the treatment of hypersensitive teeth should be directed towards reducing the functional diameter of the tubules so as to limit the fluid movement[5]. To achieve this sealing of dentinal tubules with some bonding agents, resins or adhesive material has been suggested. At present most of the home procedures for the treatment of dentin hypersensitivity are aimed at obturating the tubules that provide the patient with immediate and lasting relief[6]. Novamin (Calcium Sodium Phosphosilicate) has been reported to have strong desensitizing effect on patient suffering from dentin hypersensitivity. In this, bioactive glass reacts when exposed to aqueous media and provides calcium and phosphate ions that form a hydroxycarbonate apatite, a mineral that is chemically and structurally similar to the natural enamel and dentine and is resistant to acidic challenges. Hydroxycarbonate apatite can also be used for treating demineralized tooth or preventing further demineralization[2].

Studies have shown effectiveness of G.C Tooth Mousse [Casein Phosphopeptide (CPP)–Amorphous Calcium Phosphate (ACP)] in reducing dentin hypersensitivity following its professional application after ultrasonic / hand scaling and root planing[7,8]. Studies have suggested that CPP is responsible for stabilization, water solubility and incorporation of ACP into plaque and also onto adsorbed macromolecules on tooth surface. The localized CPP-ACP nanocomplexes act to buffer the free calcium phosphate ion activities thereby maintaining a state of super saturation and blocking the patent dentinal tubules[9].

Aclaim Calium phosphate (Nanoparticle hydroxyapatite) has received great attention because of its particle size that is less than 100nm. These nanostructured materials can be kinetically protected on account of their sizes and can remain relatively stable under undersaturated condition, therefore the prevention of enamel erosion is enhanced by the new nano layer and is insensitive to dissolution, thus the enamel surface is protected under the acidic condition. As the hardest biological part, the mechanical strength of the restored enamel surface is the key parameter, which can be examined using nanoindentation[10].

MATERIALS AND METHOD

The study was a single-center, triple masked (investigators, subjects and statistician) study. The study duration was for 3 months in which sensitivity scores were measured at baseline, 2 weeks, 4 weeks, 2 months and 3 months. The research was approved by the Ethical Committee of the Padmashree D.Y. Patil Dental College and Hospital Navi Mumbai, India and patients were selected from the outpatient Department of Periodontics of D.Y. Patil Dental College and Hospital, Navi Mumbai, India. A special proforma format was designed so as to have a systematic and methodical recording of all observations and information. The toothpastes were dispensed in tubes labeled A, B and C, the contents of which were disclosed to the investigators only after completion of the statistical analyses. A total of 80 teeth per group of either sex, aged between 18 to 50 years were selected.

The three toothpastes studied were commercially available non-aqueous toothpastes containing 1) Nanoparticle Hydroxyapatite [SHY-NM, Group Pharmaceuticals, Mumbai, India.] 2) Calcium sodium phosphosilicate [SHY, Group Pharmaceuticals] 3) Casein Phosphopeptide-Amorphous Calcium Phosphate

Subjects who fulfilled the following inclusion and exclusion criteria were considered for the study and an informed written consent was taken.

Inclusion Criteria

1. Patients able to follow verbal or written instructions or commands[11].
2. Patients with postoperative (following scaling and root planing) discomfort or hypersensitivity to thermal stimuli as shown by discomfort elicited by the two test stimuli.

Exclusion Criteria

1. Patients with defective restorations, abrasions, chipped teeth, cracked tooth syndrome, deep dental caries or large restorations showing pulp response, deep periodontal pockets, tender tooth in the same quadrant in which the patient complained of postoperative tooth hypersensitivity.
2. Patients with orthodontic appliances, dentures or bridgework that interferes with the evaluation of hypersensitivity.
3. Patients taking antibiotics and/or anti-inflammatory drugs.
4. Patients already on treatment for hypersensitivity.
5. Pregnant or lactating females.
6. Patients with chronic systemic disease.
7. Patient with any dental pathology causing pain similar to dentine hypersensitivity.

Sensitivity Assessment

To assess tooth sensitivity, a controlled air stimulus (evaporative stimulus) and cold water (thermal stimulus) were used. Sensitivity was measured using a 10-cm VAS score, with the score of zero being a pain-free response and a score of 10 being excruciating pain. Schiff test was also used to evaluate the sensitivity which was noted by operator's observation of patients' facial expression with zero being no response and a score of 3 as patients request for discontinuation of the stimuli. Scoring of tooth sensitivity was done first by using controlled air pressure, from a standard dental syringe at 40 to 65 psi at ambient temperature, directed perpendicularly and at a distance of 1 to 3 m from the exposed dentin surface while adjacent teeth were protected with gloved fingers to prevent false-positive results. This was followed by scoring of tooth sensitivity using 10 ml of ice cold water applied to the exposed dentin surface while neighbouring teeth were isolated during testing using the operator's fingers and cotton rolls. A period of at least 5 minutes was allowed between the two stimuli on each tooth. After the recording of sensitivity scores at baseline, subjects were given respective toothpastes randomly and advised to use the toothpaste with a soft bristle toothbrush twice a day. Subjects were also directed to refrain from any other dentifrice or mouthrinse during the study but were allowed to continue their normal oral hygiene practice.

Statistical Analyses

Mean VAS and Schiff scores and mean ± SD were calculated from VAS and Schiff score from all the subjects in a treatment group. Mean VAS and Schiff scores were compared among groups at different time points (baseline, 2nd week, 4th week, 2 months and 3 months) and the comparison of these difference amongst sample was carried out using Kruskal-Wallis test (non-parametric ANOVA), since the data was of ordinal type. Pair wise multiple comparisons were done using the Mann-Whitney U test ($p<0.05$) and significance was detected using a Chi-square test.

RESULTS

Mean VAS and Schiff scores for air stimulus for the nanoparticle hydroxyapatite, calcium sodium phosphosilicate group and casein phosphopeptide group at baseline, 2 weeks, 4 weeks, 2 months and after three months are shown in Table1 and 2. VAS and Schiff scores for air stimulus of all three groups were not statistically different from each other at baseline. Although all three groups showed reduction in sensitivity scores at 2 weeks, 4 weeks, 2months and 3 months. The Nanoparticle Hydroxyapatite group was found to be significantly better in reducing VAS as well as Schiff scores compared to other two dentifrices. Mean VAS and Schiff scores of water stimulus for the

Nanoparticle particle Hydroxyapatite, Calcium sodium phosphosilicate group and Casein Phosphopeptide group at baseline, 2weeks, 4 weeks, 2months and after 3 months are shown in Table 3 and 4 respectively. There was greater reduction in mean sensitivity score for the Nanoparticle Hydroxyapatite as compared to the Calcium sodium phosphosilicate and Casein Phosphopeptide groups.

Table 1: Sensitivity score to air stimulus for all the groups at all time points using visual analog score.

VAS SCORE					
	BASELINE	2 WEEKS	4 WEEKS	2 MONTH	3 MONTH
Sample A	7.19 ± 0.98	5.21 ± 1.06	4.06 ± 0.459	2.04± 0.21	0.21± 0.61
Sample B	6.22 ± 1.22	4.62 ± 1.25	2.75 ± 1.11	1.67± 0.92	0.00± 0.00
Sample C	6.26 ± 1.38	5.19 ± 0.98	3.90 ± 0.75	2.30 ± 0.72	1.19 ± 1.03

Table 2: Sensitivity score to air stimulus for all the groups at all time points using Schiff test.

SCHIFF TEST					
	BASELINE	2 WEEKS	4 WEEKS	2 MONTH	3 MONTH
Sample A	2.52± 0.50	1.63 ± 0.56	1.19 ± 0.42	0.61 ± 0.588	0.08 ± 0.28
Sample B	2.17 ± 0.38	1.61 ± 0.49	1.16 ± 0.51	0.31 ± 0.46	0.00 ± 0.00
Sample C	2.35 ± 0.48	1.97 ± 0.34	1.33 ± 0.47	0.92 ± 0.55	0.65 ± 0.47

Table 3: Sensitivity scores to cold water stimulus for all the groups at all time points using VAS score.

VAS SCORE					
	BASELINE	2 WEEKS	4 WEEKS	2 MONTH	3 MONTH
Sample A	8.19 ± 0.59	6.14 ± 0.73	4.82± 1.07	2.76 ± 0.97	0.97 ± 1.00
Sample B	7.65 ± 0.82	5.8 ± 0.98	3.9 ± 1.05	2.72 ± 1.20	0.70 ± 0.95
Sample C	7.42 ± 1.10	6.19 ± 1.05	4.83 ± 0.99	4.83 ± 0.99	1.69 ± 0.90

Table 4: Sensitivity scores to cold water stimulus for all the groups at all time points using Schiff test score.

SCHIFF TEST					
	BASELINE	2 WEEKS	4 WEEKS	2 MONTH	3 MONTH
Sample A	2.91±0.28	1.98 ±0.31	1.62 ±0.50	1.12±0.44	0.51±0.50
Sample B	2.77±0.42	2.02 ±0.44	1.71 ± 0.455	0.67±0.47	0.28±0.455
Sample C	2.82±0.38	2.41 ±0.49	1.76 ±0.42	1.20±0.57	0.94±0.588

The change in sensitivity score for Nanoparticle Hydroxyapatite group for air and water stimulus was statistically significant compared to the other groups. To find the effective sample amongst all three groups following procedure was done:-

Difference Scores of Baseline to 3 months: The difference in the scores at baseline and after three months is calculated to find the effective sample.

D1: Baseline VAS score values – After 3 months VAS score values (Air Blast test).

D2: Baseline VAS score values – After 3 months VAS score values (Cold water test).

D3: Baseline Schiff test score values –After 3 months Schiff test score values (Air Blast test).

D4: Baseline Schiff test score values –After 3 months Schiff test score values (Cold water test).

The comparison of these differences amongst sample was carried out using Kruskal-Wallis test and the level of significance was set at 5%.

Table 5: Mean rank value stating the intergroup differences.

	RANKS		
	GROUP	NUMBER	MEAN RANK
D1	Sample A	80	158.56
	Sample B	80	142.78
	Sample C	80	84.34
D2	Sample A	80	154.95
	Sample B	80	142.72
	Sample C	80	88.43
D3	Sample A	80	162.35
	Sample B	80	133.31
	Sample C	80	89.11
D4	Sample A	80	142.34
	Sample B	80	151.69
	Sample C	80	94.00

On observing the mean rank table above one can conclude that Sample A is more effective than rest of the samples in D1, D2, D3. But mean rank value for sample B is higher in case of D4 thus sample B is more effective than that of other samples for pain reduction in D4 test. These results were even confirmed using Mann-Whitney test.

Table 6: Intergroup comparisons between all the three groups

	I	J	Mann-Whitney U test p-Value
D1	Sample A	Sample B	0.077
		Sample C	0.000*
	Sample B	Sample C	0.000*
D2	Sample A	Sample B	0.206
		Sample C	0.000*
	Sample B	Sample C	0.000*
D2	Sample A	Sample B	0.000*
		Sample C	0.000*
	Sample B	Sample C	0.000*
D4	Sample A	Sample B	0.318
		Sample C	0.000*
	Sample B	Sample C	0.000*

Table 7: intergroup comparisons of pain reduction.

Groups	Sample A	Sample B	Sample C
D1	6.9787	6.65	5.0714
D2	7.2128	6.95	5.7381
D3	2.4362	2.175	1.7024
D4	2.4043	2.4875	1.881

Table 6 states that for Sample A and Sample C and Sample B and Sample C, p-values were less than that of 0.05 indicating significance of difference. But to find which of this sample was better in pain reduction mean pain reduction for all the tests were compared.

It can be observed from Table 7 that Sample A has shown maximum pain reduction after three months for tests D1, D2 and D3. But Sample B has shown maximum pain reduction for D4. Sample C has shown the least amongst all the three samples for the entire test considered here.

DISCUSSION

This study compared Nanoparticle Hydroxyapatite, Calcium sodium phosphosilicate and Casein Phosphopeptide toothpastes. The results of the present study demonstrate reduction in symptoms for all treatment groups from baseline to 4 weeks, 2 months and 3 months for both measures of sensitivity. The Nanoparticle Hydroxyapatite group showed a higher degree of effectiveness at reducing DH than commercially available Calcium sodium phosphosilicate and Casein Phosphopeptide for both sensitivity measures.

Nanoparticle Hydroxyapatite the material chosen for the study is always considered as a model compound of enamel due to the chemical similarity. Therefore, the remineralization of enamel minerals by using synthetic apatite or metastable calcium phosphate is always suggested in dental research[12]. The formed nano HAP layer can even prevent the demineralization of hard tissue. It is also important that the mechanical strength of the restored enamel surface is maintained after the treatment. These in vitro results imply that 20 nm sized HAP is a better candidate than any restorative material used to date and a perfect repair of enamel can be achieved. The underlying enamel surface can be well protected under the acidic condition[10].

Calcium sodium phosphosilicate, originally developed as a bone regenerative material, has been shown to be effective in physically occluding dentinal tubules through the development of a hydroxyapatite-like mineral layer[13]. The significant clinical treatment of hypersensitivity through the formation of crystalline apatite led researchers to hypothesize that calcium sodium phosphosilicate could be useful in remineralization and the prevention of demineralization of tooth structures, especially dentin.

A milk Casein derived molecule called Casein phosphopeptide-amorphous calcium phosphate (CPP-ACP) which when applied on to the tooth binds with the bioflims, hydroxyapatite of the tooth, soft tissues, plaque and acts as a buffer to the free calcium and phosphate ion thereby maintaining a state of supersaturation of Ca2 and PO4 within the oral environment. This supersaturated environment with respect to Ca2 and P043 has been claimed to remineralize the initial carious lesions[14,15] and to provide relief from the dentinal hypersensitivity after scaling and root planing.

In the present study two different stimuli were used. It has been recommended that a minimum of two methods[16] were required to test product or clinical procedure in vivo as sensitive teeth often respond to one type of stimulus and not to another[17]. It has also been recommended that least disturbing stimulus should be used first, with the most disturbing stimulus to be used at last so that each stimulus does not interfere with the other stimuli used in measuring procedure[18]. Accordingly in the present study air blast stimulus, least disturbing stimulus was used first, followed by cold water, with 5 minutes gap in between these test stimuli[17]. In the present study a visual analogue scale and Schiff test was used as criteria for

sensitivity assessment which is a subjective criteria as recommended by Tarbel et al (1982)[19] and Dayton et al (1974)[20].

Further more significant differences were found at baseline, 2 weeks, 4 weeks , 2nd month and 3rd month between sample A, B and C for air blast test and cold water which showed that Nanoparticle Hydroxyapatite, Calcium sodium phosphosilicate are comparable in providing the relief to hypersensitive teeth while CPP was least effective in providing the immediate relief .

CONCLUSION

Long-term follow-up studies are required to assess the efficacy of the treatment procedures. The mechanisms underlying dentine hypersensitivity should be explored further so more effective therapies can be developed. Further, clinical education should provide greater focus on the predisposing factors, diagnosis and management of dentine hypersensitivity and other forms of chronic pain. Thus we can conclude from this study that Nanoparticle Hydroxyapatite and calcium sodium phosphosilicate has better effect on relieving dentinal hypersensitivity as compared to Casein Phosphopeptide on evaluating the discomfort score after three months.

CONFLICT OF INTEREST

No potential conflict of interest relevant to this article was reported.

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