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Comparative Evaluation of Clinical Efficacy of 5% Fluoro Calcium Phosphosilicate Toothpaste with 5% Potassium Nitrate Toothpaste in the Treatment of Dentinal Hypersensitivity

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Abstract

Introduction: Dentinal hypersensitivity is an exaggerated response to non-noxious sensory stimuli which is viewed by individuals as an important health problem. Various desensitizing agents have been introduced to reduce dentine hypersensitivity by either reducing the excitability of the nerve fibres within the pulp or by occluding the open dentinal tubules.

Objectives: To compare the effectiveness of desensitizing toothpaste containing 5% Fluoro Calcium Phosphosilicate toothpaste with 5% Potassium Nitrate toothpaste for the treatment of dentinal hypersensitivity.

Methodology: A total of 60 patients with sensitive teeth were selected and randomly divided into; -

• Group A: 30 patients receiving toothpaste containing 5% Fluoro Calcium Phosphosilicate (Elsenz)TM toothpaste.

• Group B: 30 patients receiving toothpaste containing 5% Potassium Nitrate (Sensodent-K) TM toothpaste.

The Participants teeth were subjectively assessed by means of a VAS (Visual Analogue Scale). This study was a randomised single blind group design with three study visits: Baseline, Week 2, and Week 4.

Results: A statistically significant reduction in the symptoms of Dentinal Hypersensitivity for both the groups was observed from baseline to Week 2 and Week 4. 5% Fluoro Calcium Phosphosilicate toothpaste group showed significant reduction in hypersensitivity compared to 5% Potassium Nitrate toothpaste group for both air stimulus and cold stimulus.

Conclusions: This study demonstrated the effectiveness of 5% Fluoro Calcium Phosphosilicate toothpaste and 5% Potassium Nitrate toothpaste in reduction for the symptoms of dentinal hypersensitivity. Both of these dentrifrices can be recommended for the treatment of Dentinal Hypersensitivity.

Keywords: Dentinal Hypersensitivity; Dentinal tubules; Fluoro Calcium Phosphosilicate; Potassium Nitrate; Toothpaste.

Introduction

Dentinal hypersensitivity (DH) is one of the most commonly encountered dental problems. It can be particularly uncomfortable, unpleasant for patients and can dictate types of foods and drinks ingested. Patients usually described the condition as dull or sharp, vague or specific and intermittent or constant. Dentinal hypersensitivity can be described clinically as an exaggerated response to non-noxious stimuli and is characterized by pain of short duration arising from exposed dentin in response to stimuli, typically thermal, evaporative, tactile, osmotic, or chemical & which cannot be ascribed to any other dental defect or pathology.[1]

A slightly higher incidence of DH is reported in females than in males and affect patient of any age, most affected are age group of 20–50 years, with a peak between 30 and 40 years of age.[2] Regarding the type of teeth involved, canines and premolars of both the arches are the most affected teeth. Buccal aspect of cervical area is the commonly affected site.[3] Brannstrom in 1963 proposed the most widely accepted theory the 'Hydrodynamic theory' where DH is mediated by a hydrodynamic mechanism, where a stimulus results in an increased fluid flow in the dentinal tubules which, in turn, activates nerves located on the pulpal aspect of the tubules, resulting in the generation of action potentials and are interpreted as pain by the patient. [4,5]

Hypersensitivity is caused by loss of enamel covering due to attrition (parafunctional habits), abrasion (improper brushing technique), erosion (dietary components, gastric disorders). Some causes of dentin exposure are; - gingival recession, chronic trauma from faulty restoration, iatrogenic removal of cementum during root planning, curettage, application of citric acid to remove smear layer and surgical periodontal treatment.[6] Attempts have been aimed to reduce dentine hypersensitivity by either reducing the excitability of the nerve fibres within the pulp or by occluding the open dentinal tubules. Various desensitizing agents have been used for the treatment of hypersensitive teeth including silver nitrate, fluoride, formaldehyde, strontium chloride, potassium nitrate and bio glass. [7,8]

Studies have been reported on the effectiveness of different desensitising agents. Dentifrices containing potassium ions increase the potassium ion concentration adjacent to the dentinal nerve terminals, which leads to depolarization and activation of nerve fibres. A prolonged period of depolarization results in inactivation of the action potential. Potassium ions are thought to act by blocking the action potential generated in intradental

nerves and had shown to be effective in reducing dentin hypersensitivity [9]

Dentifrices containing bioactive glass had also been shown by several clinical studies to be effective in reducing dentine hypersensitivity. Bioactive glass adheres to tooth structure through a special polymer, from where it slowly dissolves ion that form fluorapatite, to make teeth more resistant to acids from food over an 8–12-hour period. Bioactive glass toothpaste reduces hypersensitivity by sealing open dentinal tubules by forming fluorapatite. [10,11] Recently, fluoro calcium phosphosilicate, a fluoride-containing bio glass is designed and optimized for desensitizing toothpaste.[12] This formulation differentiates from previous bio glass toothpastes by its higher phosphate content, the presence of Calcium fluoride (CaF2) in the glass and smaller average particle size.[12] It forms fluorapatite, rather than hydroxyapatite, on teeth which is much more resistant to acids produced by bacteria and promotes remineralization, particularly in combination with the calcium and phosphate released from the glass.

So, this study was designed to compare the effectiveness of desensitizing toothpaste containing 5% fluoro calcium phosphosilicate toothpaste with 5% potassium nitrate toothpaste for the treatment of dentinal hypersensitivity.

Materials and Methods

A total of 60 patients for this study were randomly selected by a systematic sampling method in which every 5th subject was selected and was recruited alternatively in each group from the outpatient department of Periodontics, Nair Hospital Dental College, Mumbai.

The study number is EC-57/PERIO-11ND/2017

Inclusion criteria

1) Patients with at least one sensitive tooth with a VAS score of ≥4.

2) Patients age between 25-55 years.

3) Systemically healthy patients.

4) Cooperative patients who can be motivated to maintain good oral hygiene.

5) Patients who consented to participate in the study.

6) Patients with untreated gingival recession having dentinal hypersensitivity.

Exclusion criteria

1) Subjects with history of treatment for dentin hypersensitivity.

2) Patients with poor periodontal condition.

3) Patients having systemic debilitating disease.

4) Patients giving a history of allergy to potassium nitrate. 5) Caries or restoration in the area of hypersensitivity.

6) Patients with orthodontic appliance, crowns, bridges in the area of sensitivity.

Sixty patients was selected with sensitive teeth were randomly divided into group A and group B by a systematic sampling method in which every 5th subject was selected and was recruited alternatively in each group as follows:

• Group A: 30 patients receiving toothpaste containing 5% Fluoro Calcium Phosphosilicate (Elsenz)TM toothpaste.

• Group B: 30 patients receiving toothpaste containing 5% Potassium Nitrate (Sensodent-K) TM toothpaste.

This study was a randomised single blind group design with three study visits: baseline, Week 2, and Week 4.

Clinical Parameter

The participant's teeth were subjectively assessed by means of a VAS (Visual Analogue Scale). The VAS is a 10-cm line with the anchor words "no pain" (0 cm) and "intolerable pain (10 cm)" at the opposite ends. Each participant was asked to place a vertical mark on the VAS to indicate the intensity of his or her level of

sensitivity after receiving stimuli. The parameter was recorded at baseline, Week 2 and Week 4.

Sensitivity Assessment

To assess tooth sensitivity, a controlled air stimulus and cold water was used. Scoring of tooth sensitivity was done first by using controlled air pressure, from a dental unit syringe applied 1 cm away from the affected teeth to determine the participant's baseline response and followed by thermal stimuli i.e., application of ice-cold water in a syringe after 5 minutes to the exposed dentin surface. The parameter was recorded at baseline, Week 2 and Week 4. Sensitivity was measured using a 10 cm VAS score, with the score of 0 being a 'no pain' response and a score of 10 'intolerable pain'

Procedure

All patients were given oral hygiene instructions after oral prophylaxis. Patients were advised to use a new ultrasoft brush for brushing with modified Bass Technique. Patients were randomly divided into group A and group B. Patients under group A was given self-applied 5% fluoro calcium phosphosilicate toothpaste to be used twice daily and was instructed to brush with allocated toothpaste for 2-3 minutes for 4 weeks. Patients under group B was given a self-applied 5% potassium nitrate toothpaste to be used twice daily and was instructed to brush with allocated toothpaste for 2-3 minutes twice daily. All patients were recalled after 2 weeks and 4 weeks for follow up and were evaluated for sensitivity.

Statistical Analysis

Data collected was entered into a computer and analyzed using the SPSS software. Results on continuous measurements were presented on Mean ± Standard deviation followed by Student unpaired' test to compare the mean VAS scores between different time intervals among the groups . Repeated measures of ANOVA test were used to compare the mean VAS scores between different time intervals within each study group. Level of significance were fixed at p=0.05 and any value less than or equal to 0.05 were considered to be statistically significant.

Results

There were no drop outs and no adverse effects were reported in any of the groups. Mean VAS scores in terms of Mean (SD) for measures of sensitivity to air and cold stimulus for 5% Fluoro Calcium Phosphosilicate group and 5% Potassium Nitrate group at baseline, week 2 and week 4 are shown in Tables 1,2 and 3.

Intergroup analysis

For measures of sensitivity to Air Stimulus (Table 1/graph 1)

The mean VAS score of 5.37 and 5.43 was found at baseline for Group A and B respectively.

In 2 weeks, significant difference and improvement in VAS scores dropping to 2.70 in Group A and 2.80 for Group B was observed.

In 4 weeks, statistically significant difference and improvement of VAS scores of 0.93 and 1.47 was seen in Group A and Group B respectively.

For measures of Sensitivity to Cold water stimulus (Table 1/graph 2)

Mean VAS score of 5.57 and 5.77 was found at baseline for Group A and B respectively.

In 2 weeks, significant difference and improvement in VAS scores for Group A and B was found to be 2.87 and 3 respectively.

In 4 weeks, statistically significant difference and improvement of VAS scores of 0.90 and 1.73 was seen in Group A and Group B respectively.

There was no significant difference between Group A (5% Fluoro Calcium Phosphosilicate) and Group B (5% potassium nitrate) at baseline. On comparison to

measures of sensitivity between air and cold-water stimulus, 5% Fluoro Calcium Phosphosilicate group was significantly better in reducing VAS scores at 2 weeks and 4 weeks. Furthermore, 5% Fluoro Calcium Phosphosilicate group showed statistically significant reduction and higher degree of effectiveness in reducing the symptoms of dentinal hypersensitivity when compared to 5% Potassium Nitrate group.

Table 1: Comparison of the visual analogue scale score in terms of {Mean (SD)} at different time intervals among both the groups using unpaired t test.

(Air stimulus)						
Time Intervals	Group	N	Mean	Std. Deviation	t value	P value
Baseline	Group A	30	5.37	1.066	0.238	0.813
	Group B	30	5.43	1.104		
2 weeks	Group A	30	2.70	0.877	0.439	0.662
	Group B	30	2.80	0.887		
4 weeks	Group A	30	0.93	0.691	2.447	0.017*
	Group B	30	1.47	0.973		
(Cold Stimulus)						
Baseline	Group A	30	5.57	1.040	0.797	0.428
	Group B	30	5.77	0.898		
2 weeks	Group A	30	2.87	0.937	0.548	0.586
	Group B	30	3.00	0.947		
4 weeks	Group A	30	0.90	0.759	3.767	<0.001**
	Group B	30	1.73	0.944		

($p < 0.05$ - Significant*, $p < 0.001$ - Highly significant)

- Comparison of the visual analogue scale score in terms of {Mean (SD)} at different time intervals among both the groups using unpaired t test and repeated measures ANOVA test.

Graph; -1(Air Stimulus)

Graph 2 ;-(Cold water stimulus)

Intragroup analysis

Group A (5% Fluoro Calcium Phosphosilicate) showed statistically significant improvement in VAS scores from baseline to 2 weeks and between baseline to 4 weeks. For measures of sensitivity to air stimulus, VAS scores of 5.37 at baseline was reduced to 2.70 at end of 2 weeks and VAS scores reducing to 0.93 was observed at the end of 4 weeks. For Cold water stimulus, VAS scores of 5.57 at baseline was reduced to 2.87 in 2 weeks and at the end of 4 weeks VAS scores reducing to 0.90 was observed. Thus, statistically significant reduction in VAS scores to measures of sensitivity to both air and cold-water stimulus was seen at baseline, 2 weeks and 4 weeks as shown in table 2/Graph 1/Graph 2.

For Group B (5% potassium nitrate), showed statistically significant improvement in VAS scores from baseline to

2 weeks and between baseline to 4 weeks. For measures of sensitivity to air stimulus, At baseline the VAS scores of 5.43 reduced to 2.80 at end of 2 weeks and VAS scores reducing to 1.47 was observed at the end of 4 weeks.

For Cold water stimulus, VAS scores of 5.77 at baseline was reduced to 3 in 2 weeks and at the end of 4 weeks VAS scores reducing to 1.73 was observed. Thus, statistically significant reduction in VAS scores to measures of sensitivity to both air and cold-water stimulus was seen at baseline,2 weeks and 4 weeks as shown in table 3/Graph 1 /Graph 2.

- Comparison of the visual analogue scale score in terms of {Mean (SD)} at different time intervals in group A and B using repeated measures ANOVA test

Table 2: Group A: 5% Fluoro Calcium Phosphosilicate (Elsenz) TM

(Air stimulus)					
Time interval	N	Mean	Std. Deviation	Wilk's Lambda value	P value
Baseline	30	5.37	1.066	214.318	<0.001**
2 weeks	30	2.70	0.877		
4 weeks	30	0.93	0.691		
(Cold water stimulus)					
Time interval	N	Mean	Std. Deviation	Wilk's Lambda value	P value
Baseline	30	5.57	1.040	160.949	<0.001**
2 weeks	30	2.87	0.937		
4 weeks	30	0.90	0.759		

(p < 0.05 - Significant*, p < 0.001 - Highly significant)

Table 3: Group B: 5% Potassium Nitrate Toothpaste (Sensodent-K) TM

(Air stimulus)					
Time interval	N	Mean	Std. Deviation	Wilk's Lambda value	P value
Baseline	30	5.43	1.104	93.218	<0.001 **
2 weeks	30	2.80	0.887		
4 weeks	30	1.47	0.973		
(Cold water stimulus)					
Time interval	N	Mean	Std. Deviation	Wilk's Lambda value	P value
Baseline	30	5.77	0.898	133.165	<0.001
2 weeks	30	3.00	0.947		**
4 weeks	30	1.73	0.944		

(p < 0.05 - Significant*, p < 0.001 - Highly significant**)

Discussion

Dentin hypersensitivity is a painful experience which generates a very unpleasant perception. Dentin hypersensitivity is characterized by a high prevalence of exposed cervical dentin which varies from 8% to 57%,[13] affecting different age groups with the majority of sufferers aged between 20 to 40 years. Treatment of dentin hypersensitivity becomes a challenge for both the patient and the healthcare provider. Most hypersensitive teeth are accompanied by gingival recession presumably resulting from periodontal disease, periodontal therapy, or improper brushing habits. There are two principal treatment options: - plug the dentinal tubules, thereby preventing fluid flow, or desensitize the nerve responsive to stimulation.[14] Among the therapeutic procedures developed to reduce or eliminate dentinal hypersensitivity related pain is the use of chemical agents aiming at sealing dentinal tubular entrances by making them less susceptible to painful stimuli.[7]

This study compared the Clinical Efficacy Of 5% Fluoro Calcium Phosphosilicate Toothpaste (Elsenz)TM with 5% Potassium Nitrate Toothpaste (Sensodent-K)TM in the treatment of Dentinal Hypersensitivity. The sensitivity level of this study was determined by translating the subjective feedback scale into objective data using VAS scale. The results of the present study revealed statistically significant reduction in symptoms for both the groups from baseline to week 2 and week 4 for both measures of sensitivity to air and cold-water stimulus. There was no significant difference between Group A (5% Fluoro Calcium Phosphosilicate) and Group B (5% Potassium Nitrate) at baseline. For measures of sensitivity to Air stimulus, At 2 weeks, significant difference and improvement in VAS scores dropping to 2.70 in Group A and 2.80 for Group B was observed. At the end of 4 weeks, statistically significant difference and reduction of VAS scores to 0.93 and 1.47 was seen in Group A and Group B respectively. For Cold stimulus, In 2 weeks, significant difference and improvement in VAS scores for Group A and B was found to be 2.87 and 3 respectively. At the end of 4 weeks, statistically significant difference and improvement of VAS scores of 0.90 and 1.73 was observed in Group A and Group B respectively.

Studies have found that toothpastes containing 5% Potassium Nitrate significantly decreased Dentinal Hypersensitivity. By increasing the potassium ion concentration adjacent to the dentinal nerve terminals. Divalent cation solutions stabilize the nerve membrane without changing the membrane potential. This Potassium Nitrate toothpastes must be used for a minimum of 4 weeks, twice daily to bring about a reduction of sensitivity. [15,16] In this study, we found that 5% Potassium Nitrate group showed statistically significant results in reducing the symptoms of Dentinal Hypersensitivity from baseline to week 4. However, On comparision, with 5% Fluoro Calcium Phosphosilicate showed statistically significant results and a high degree of effectiveness in measures of sensitivity to both air and cold water stimulus than 5% Potassium Nitrate.

Fluoro Calcium Phosphosilicate is a fluoride-releasing bioactive glass recently incorporated in desensitizing dentifrices. It differs from the conventional bio glass dentifrices by the presence of calcium fluoride (CaF2) in the glass, higher phosphate content and smaller average particle size (D50 of 6 μm).[12] Fluoride ions are released by fluoride-containing bioactive glasses during dissolution [17] resulting in the formation of fluorapatite.[18] Moreover, the presence of CaF2 increases glass dissolution and higher phosphate content enhances the ability to form apatite crystal. [12,19]

Fluoro Calcium Phosphosilicate dentifrices have shown to instantly occlude some of the dentinal tubules, after 2 min of brushing. Even after washing with 6% citric acid for 30 s, the tubules were reported to remain occluded.[12]

The mechanism of action of Fluoro Calcium Phosphosilicate toothpaste which offered long lasting relief and protection from dentinal hypersensitivity is described in following four steps.[20]

Step 1: Chemical Bonding: its particles chemically bind to the tooth surface

Step 2: Release of minerals: components slowly dissolve to release calcium, phosphate and fluoride ions into saliva.

Step 3: Rapid Apatite Formation: ions precipitate and crystallize to form fluor hydroxyapatite over dentin surface and within dentinal tubules. These highly acid resistant crystals provide deep occlusion within dentinal tubules

Step 4: Enamel Remineralization: sustained release of fluoride ions rebuilds and strengthens enamel

The significant clinical improvement of hypersensitivity through the formation of fluorapatite in the present study may aid to hypothesize that Fluoro Calcium Phosphosilicate could be useful in remineralization and the prevention of demineralization of tooth structures, especially dentin. Besides, it also inhibits the metabolism of bacteria associated with caries, by preventing their metabolic acid production.[12]

Clinical studies demonstrating the efficacy of Fluoro Calcium Phosphosilicate as a desensitizing agent are limited.

The data from this study provide evidence of the therapeutic value Of Fluoro Calcium Phosphosilicate dentifrices, suggestive that it can be used in the reduction of and symptoms/pain due to dentine hypersensitivity in comparable to other conventional desensitizing agents.

Since both the dentifrices revealed significant reduction to symptoms of dentinal hypersensitivity to measures of sensitivity to air and cold-water stimulus, these products can provide a good treatment modality for Dentinal hypersensitivity.

Limitations

In the present study, there was no control group or placebo included, thus there is possibility of biased results. More numbers of clinical trials done over a larger population are essential in future to find out best treatment strategy.

Conclusion

This study demonstrated the effectiveness of 5% Fluoro Calcium Phosphosilicate toothpaste and 5% Potassium Nitrate toothpaste in reduction for the symptoms of dentinal hypersensitivity.

Both of these dentrifrices can be recommended for the treatment of Dentinal Hypersensitivity.

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