

Original Article

Evaluation and comparison of efficacy of three desensitizing dentifrices on dentinal hypersensitivity and salivary biochemical characteristics: A randomized controlled trial

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ABSTRACT

Background: This study aimed to evaluate and compare the efficacy of three desensitizing dentifrices on dentinal hypersensitivity (DH) and salivary biochemical characteristics.

Materials and Methods: A randomized, parallel arm, triple-blinded, clinical trial was conducted over a period of 12 weeks, with a total of three visits: baseline, 6 weeks, and 12 weeks. Calcium sodium phosphosilicate, potassium nitrate and amine fluoride dentifrices were compared. A total of 68 subjects who satisfied the inclusion criteria were included and randomly divided into four groups. Visual analog scale scores for controlled air stimulus were used to assess dentinal sensitivity and salivary pH and buffering capacity were recorded at baseline, 6 and 12 weeks.

Results: All groups showed a reduction in sensitivity scores at 6 and 12 weeks. The calcium sodium phosphosilicate group showed a higher degree of effectiveness in reducing DH than potassium nitrate, amine fluoride dentifrices, and placebo for sensitivity measures. Salivary pH of calcium sodium phosphosilicate group was more toward neutral, and the buffering capacity of the same group showed significant changes from baseline to 6 and 12 weeks compared to the other groups.

Conclusion: The desensitizing toothpaste containing calcium sodium phosphosilicate was found to be more effective in reducing DH and showed improvement in salivary biochemical characteristics over a period of 12 weeks compared to others.

Key Words: Amine fluoride gel, calcium sodium phosphosilicate, Hydrogen ion concentration, potassium nitrate, saliva, sodium bicarbonate capacity, toothpastes

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INTRODUCTION

Dentin hypersensitivity (DH) is defined as short and sharp pain arising from exposed dentin in response to external stimuli, which are typically thermal, evaporative, tactile, osmotic, or chemical, and which cannot be ascribed to any other form of dental defect or disease. The pain is common, transient oral condition resulting immediately on stimulation of

exposed dentine and resolving on stimulus removal.^[1] DH is a multi-factorial disease; risk factors include gingival recession, attrition, abrasion, erosion associated with traumatic tooth brushing, periodontal diseases, diet and erosive lifestyle associated with tooth wear. DH is becoming an increasing problem in

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dentistry with a prevalence rate ranging from 20.6% to 55% in Indian population.^[2-4]

The hydrodynamic theory proposed by Brännstrom *et al.* in 1968 is now widely accepted theory for etiology of dentin sensitivity, which states that flow of fluid in the dentinal tubules trigger receptor within the tooth.^[5] This increased fluid movement in dentin tubules seen in DH is because of open dentin tubules.^[6]

There are different treatment modalities for DH which include self-administered agents and professionally applied agents, of which self-administered toothpaste are effective in pain reduction in DH. These products are divided into two categories: products that block the pulp nerve response and products that occlude open dentine tubules.^[7]

A small amount of unstimulated saliva has a lower pH value and a lower buffer capacity to remove and neutralize acidic food products.^[8-10] As bicarbonate levels in the saliva increase, this will not only increase salivary pH and buffer capacity, and facilitate remineralization, but will also exert ecological effects on the oral flora.^[11] The role of buffer maintenance of acid-base balance or oral homeostasis is one of the most important natural protective functions of saliva. Hence, evaluating the factors in saliva that may increase remineralization of enamel, can pave the way to make recommendations that will cater specific needs of individual.

Considering the aforementioned findings, this study was conducted with an aim to assess and compare the efficacy of three desensitizing dentifrices containing either potassium nitrate or calcium sodium phosphosilicate or amine fluoride in reducing DH and their effects on salivary biochemical characteristics.

MATERIALS AND METHODS

Study design and sample size

A randomized, parallel arm, triple-blinded (investigator, subjects, and statistician) clinical trial was conducted to assess the efficacy of three desensitizing agents in the dentifrices on DH. The study consisted of four Groups: Group 1: 5% Potassium nitrate, Group 2: 5% Calcium sodium phosphosilicate, Group 3: 3.85% Amine fluoride and Group 4: Placebo. The ethical approval for the study was obtained from the ethics committee of Narayana Dental College, and Hospital, Nellore, and the present Clinical Trial was registered in Clinical Trial Registry-India, CTRI Registration Number:

CTRI/2015/08/006091, (www.ctri.nic.in). Sample size calculation was based on detecting a difference of 30% reduction in visual analog scale (VAS) scores between test and control groups using a two-tailed significance level of 5% with a 90% power.^[12]

Blinding

Desensitizing dentifrices with active ingredients used in the study were given to a pharmacy college for coding. One of the staff in the concerned institution loaded the paste in different coded tubes, and this person was instructed to reveal the decoding once the trial was completed and statistical analysis was performed.

Inclusion and exclusion criteria

The individuals aged 18–75 years with a history of DH with at least 20 natural permanent teeth and at least two teeth with a VAS score of ≥ 4 were included in the study. Teeth with caries, defective restorations, chipped teeth, deep periodontal pockets, periodontal surgery within the previous 6 months, subjects with orthodontic appliances or bridge work that would interfere with evaluation were excluded from this study. Subjects were also excluded if there was the presence of occlusal overload or occlusal adjustment recently made in the tooth to be studied. Subjects who had undertaken treatment with any product that could influence the DH of the patient in the 30 days before baseline were excluded. Subjects were also excluded if they were allergic to ingredients used in the study or exhibited any gross oral pathology, eating disorders, chronic diseases, pregnancy and lactation, medically compromised patients, subjects with poor oral hygiene.

Study procedure

A total of 100 individuals were assessed based on the inclusion and exclusion criteria and a total of 68 subjects who satisfied the criteria and who gave written informed consent were randomized and categorized into four groups. The randomization was done using a computer-generated random table. The intervention period for the study was 12 weeks, with a total of three visits: baseline, 6 weeks, and 12 weeks. The three visits were scheduled at the same time of the day for each individual [Figure 1]. The duration of the study was from March 2015 to July 2015 (till the last patient has completed the 12 weeks of intervention period).

Patients were instructed to use pea size of assigned toothpaste twice daily and with regular oral hygiene practices as explained to the patient.

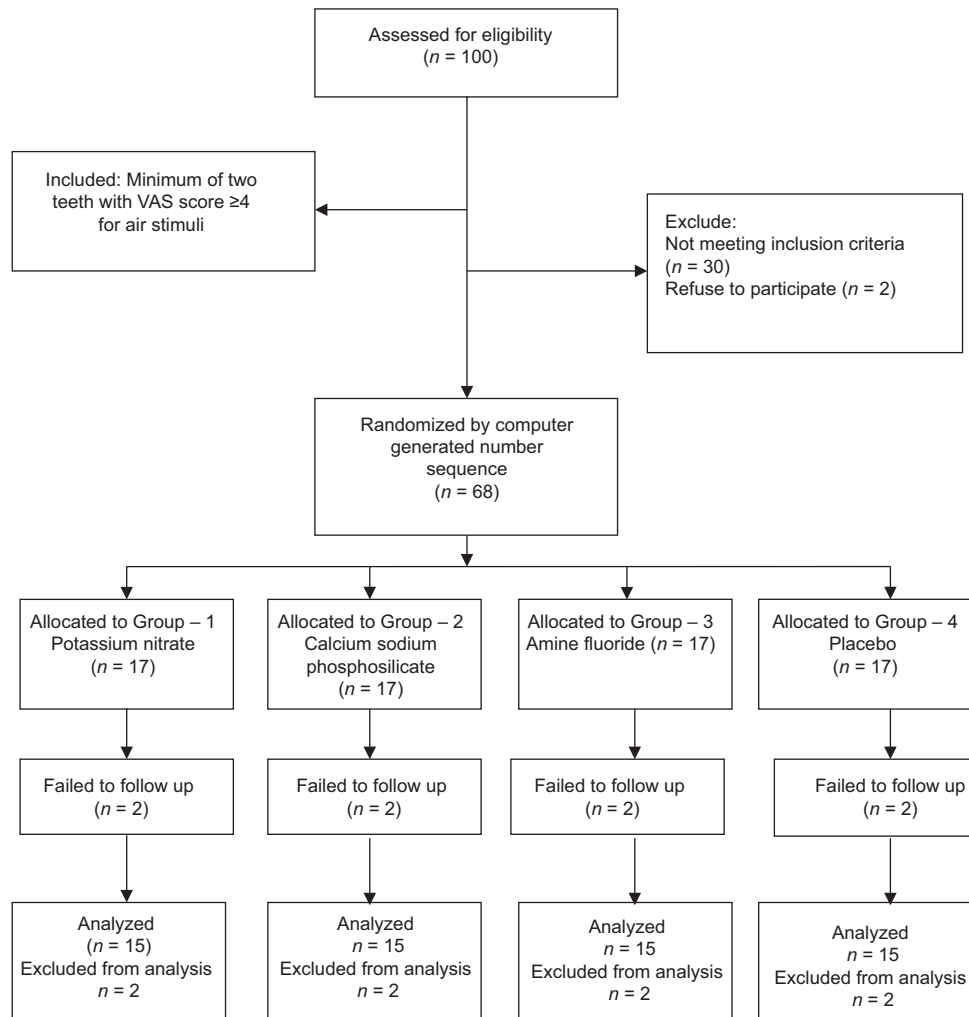


Figure 1: Consort flow diagram.

Subjects were also directed to refrain from using any other dentifrice or mouth rinse during the trial.

Sensitivity assessment

Controlled air stimulus (evaporative stimulus) was used to assess tooth sensitivity. Sensitivity was measured using a 10 cm VAS scale, with the score of zero being a pain-free response and score of 10 being excruciating pain or discomfort. Scoring of tooth sensitivity is first done by using controlled air pressure from a standard dental syringe at 40 to 65 psi directed perpendicularly and at a distance of 1 to 3 mm from the exposed dentine surface while adjacent teeth were protected with gloved fingers to prevent false positive teeth.^[13] The patient was instructed to mark the severity of pain (subject feels) to air evaporative stimulus, on VAS scale in the given sheet representative to that particular patient.

Saliva collection

After sensitivity assessment, saliva samples were collected for salivary biochemical analysis. The patients were instructed not to eat or drink (except water) for at least 1 h before collection and also instructed not to smoke or undergo heavy physical stress before collection. Saliva was collected at the same time of day from the same patient. Samples containing visible blood are discarded. The patients were made to sit in a relaxed position in an ordinary chair and let saliva passively accumulate in the floor of the mouth and then allowed to spit out in a premarked collection tumblers and were stored in refrigerator and the collected samples were transferred for biochemical analysis on the same day.

Salivary biochemical analysis

The salivary analysis was carried out in the Department of Biochemistry, Narayana Medical College and Hospital, Nellore. After collection, pH

of saliva samples was determined using a digital pH meter (SYSTRONICS Company). After measuring pH, 1 ml of 0.1 N lactic acid was added to 1 ml of saliva and centrifuged for 5 min with 3600 g using table top centrifuge REMI-8C. Buffer capacity was calculated according to changes in pH.

Statistical analysis

Mean VAS scores, mean pH and buffering of saliva and mean standard deviation were calculated from raw scores for all individuals in treatment groups. Mauchly test of sphericity indicated that the assumption of sphericity has been violated, hence corrected using Greenhouse-Geisser estimate. Mean VAS scores, pH and buffering of saliva were compared among groups at different time points (baseline, 6 and 12 weeks) and among groups at each time point using Repeated measures ANOVA. Intragroup *post hoc* pairwise multiple comparisons were done using Bonferroni *post hoc* test. Intergroup comparisons of VAS scores, pH of saliva and buffering capacity of saliva at different time intervals was done using Tukey *post hoc* test. Data were entered and analyzed using a software program IBM SPSS version 22 (Armonk, NY: IBM Corp).

RESULTS

Statistical analysis was done for 60 (females 34, males 26) subjects who completed the study and their mean age were estimated as 42.95. Among the

teeth selected for sensitivity assessment, highest representation was from upper premolar 24.6% followed by lower molars 23.0%, upper molars 18.0%, and lower premolars 14.8%.

Mean VAS scores between the four groups at baseline were not statistically significant, indicating that baseline VAS scores for all groups were nearly equal. Subjects in Group 2 showed greater reduction in VAS scores from a mean of 8.06–3.37 by the end of 12 weeks and least reduction was seen in Group 4 (7.46, 7.13) [Table 1]. VAS scores decreased with an increase in mean difference in VAS scores from baseline to 6 weeks, 12 weeks for Group 1 (1.00, 2.20), Group 2 (2.56, 4.68), and Group 3 (1.73, 3.06) which was statistically significant, indicating that DH reduced with time. The mean difference for VAS scores was highest for Group 2 (2.56, 4.68) compared to other groups and a very negligible difference was seen in Group 4 (0.06, 0.33), which was not statistically significant [Table 2]. At 6 weeks interval, statistically significant difference was noted only between Group 2 and Group 4 ($P < 0.001$), at 12 weeks there was statistically significant difference between all groups except Group 1 and Group 3 ($P = 1.00$) [Table 3].

Mean pH values between the four groups at baseline were statistically significant. Mean pH values of Group 2 was more toward neutral (6.93, 7.08) by the end of 12 weeks compared to other groups and

Table 1: Mean±standard deviation visual analog scale sensitivity scores to air blast stimulus, pH and buffering capacity of saliva for all groups at baseline, 6 weeks and 12 weeks

	Tooth paste group	Baseline	6 weeks	12 weeks	P
VAS scores	Group 1	7.20±1.47	6.20±1.32	5.00±1.60	<0.001*
	Group 2	8.06±1.38	5.50±1.46	3.37±1.20	<0.001*
	Group 3	8.20±1.08	6.46±0.99	5.13±0.91	<0.001*
	Group 4	7.46±1.06	7.40±1.12	7.13±1.35	<0.049*
	F	2.14	6.19	21.89	
	P	0.104 (NS)	0.001*	<0.001*	
pH of saliva	Group 1	6.73±0.24	6.76±0.23	6.77±0.23	0.003*
	Group 2	6.93±0.24	7.03±0.18	7.08±0.18	0.005*
	Group 3	6.69±0.23	6.76±0.22	6.78±0.21	0.001*
	Group 4	6.89±0.24	6.88±0.25	6.88±0.24	0.25 (NS)
	F	3.63	4.92	6.57	
	P	0.01*	0.004*	0.001*	
Buffering capacity of saliva	Group 1	4.45±0.43	4.51±0.33	4.50±0.33	0.31 (NS)
	Group 2	4.37±0.28	4.43±0.27	4.47±0.28	<0.001*
	Group 3	4.43±0.33	4.49±0.34	4.52±0.33	<0.001*
	Group 4	4.41±0.27	4.42±0.28	4.41±0.27	0.49 (NS)
	F	0.443	0.326	0.338	
	P	0.72 (NS)	0.80 (NS)	0.79 (NS)	

ANOVA. * $P < 0.05$ statistically significant. $P > 0.05$ NS. Repeated measures ANOVA. NS: Nonsignificant

Table 2: Intragroup comparison of visual analog scale scores, pH and buffering capacity of saliva between different visits

Group	Time (I)	Time (J)	Mean difference (I-J)	95% CI	P
VAS scores					
Group 1	Base line	6 weeks	1.00	0.73-1.26	<0.001*
		12 weeks	2.20	1.65-2.74	<0.001*
Group 2	6 weeks	12 weeks	1.20	0.80-1.59	<0.001*
		Base line	6 weeks	2.56	2.13-2.98
Group 3	Baseline	12 weeks	4.68	4.28-5.09	<0.001*
		6 weeks	2.12	1.64-2.60	<0.001*
Group 4	Base line	6 weeks	1.73	1.31-2.15	<0.001*
		12 weeks	3.06	2.34-3.79	<0.001*
		12 weeks	0.33	-0.10-0.76	0.16 (NS)
	6 weeks	12 weeks	0.26	-0.05-0.58	0.12 (NS)
pH					
Group 1	Baseline	6 weeks	-0.03	-0.05--0.005	0.01*
		12 weeks	-0.03	-0.06--0.009	0.008*
Group 2	6 weeks	12 weeks	-0.005	-0.01--0.0001	0.04*
		Baseline	6 weeks	-0.09	-0.19--0.008
Group 3	Baseline	12 weeks	-0.14	-0.27--0.02	0.01*
		6 weeks	12 weeks	-0.04	-0.19--0.001
Group 4	6 weeks	12 weeks	-0.07	-0.12--0.02	0.006*
		Baseline	6 weeks	-0.08	-0.14--0.03
Group 4	Baseline	12 weeks	-0.01	-0.03--0.0003	0.04*
		6 weeks	12 weeks	0.01	-0.01-0.03
	6 weeks	12 weeks	0.003	-0.004-0.01	0.62 (NS)
	6 weeks	12 weeks	-0.007	-0.02-0.01	0.94 (NS)
Buffering capacity					
Group 1	Baseline	6 weeks	-0.009	-0.02-0.005	0.30 (NS)
		12 weeks	-0.002	-0.01-0.01	1.00 (NS)
Group 2	6 weeks	12 weeks	0.007	-0.01-0.02	0.97 (NS)
		Baseline	6 weeks	-0.05	-0.09--0.01
Group 3	Baseline	12 weeks	-0.09	-0.14--0.05	<0.001*
		6 weeks	12 weeks	-0.04	-0.07--0.007
Group 4	Baseline	6 weeks	-0.06	-0.12--0.01	0.02*
		12 weeks	-0.09	-0.12--0.02	0.006*
Group 4	6 weeks	12 weeks	-0.02	-0.06-0.007	0.13 (NS)
		Baseline	12 weeks	-0.003	-0.01-0.008
	12 weeks	12 weeks	-0.001	-0.008-0.007	1.00 (NS)
	6 weeks	12 weeks	0.003	-0.004-0.009	0.90 (NS)

* $P < 0.05$ statistically significant, $P > 0.05$ NS. Bonferroni *post hoc* test. VAS: Visual analog scale; NS: Nonsignificant; CI: Confidence interval

statistically significant difference was not seen in Group 4 ($P = 0.25$) by the end of 12 weeks [Table 1]. The mean difference in pH values was highest for Group 2 (-0.09, -0.14) compared to other groups and a very negligible difference was seen in Group 4 (0.01, 0.003) which was not statistically significant [Table 2]. Tukey *post hoc* assessment for intergroup comparison of pH of saliva showed statistically significant difference between Group 1 and 2, Group 2 and 3 compared to other groups [Table 3].

Mean buffering capacity between the four groups at baseline, 6 and 12 weeks was not statistically significant. Subjects in Group 2 (4.37, 4.47) and Group 3 (4.43, 4.52) showed statistically significant improvement in buffering capacity of saliva by the end of 12 weeks [Table 1]. The mean difference in buffering capacity of saliva scores of Group 2 ($P < 0.001$) and Group 3 (0.006) were statistically significant from baseline to 12 weeks, and group 3 was not statistically significant ($P = 0.13$) at 6 weeks to 12 weeks interval [Table 2]. Buffering

Table 3: Intergroup comparison of visual analog scale sensitivity scores, pH and buffering capacity of saliva scores at baseline, 6 and 12 weeks

Dependent variable	Group (I)	Group (J)	P		
			Baseline	6 weeks	12 weeks
VAS sensitivity score	Group 1	Group 2	0.37 (NS)	0.73 (NS)	<0.005*
		Group 3	0.20 (NS)	1.00 (NS)	1.00 (NS)
		Group 4	1.00 (NS)	0.06 (NS)	<0.001*
	Group 2	Group 3	1.00 (NS)	0.20 (NS)	<0.002*
		Group 4	1.00 (NS)	<0.001*	<0.001*
		Group 3	Group 4	0.71 (NS)	0.26 (NS)
pH of saliva	Group 1	Group 2	0.15 (NS)	<0.01*	<0.002*
		Group 3	1.00 (NS)	1.00 (NS)	1.00 (NS)
		Group 4	0.51 (NS)	1.00 (NS)	1.00 (NS)
	Group 2	Group 3	<0.04*	<0.009*	<0.002*
		Group 4	1.00 (NS)	0.36 (NS)	0.10 (NS)
		Group 3	Group 4	0.17 (NS)	1.00 (NS)
Buffering capacity of saliva	Group 1	Group 2	1.00 (NS)	1.00 (NS)	1.00 (NS)
		Group 3	1.00 (NS)	1.00 (NS)	1.00 (NS)
		Group 4	1.00 (NS)	1.00 (NS)	1.00 (NS)
	Group 2	Group 3	1.00 (NS)	1.00 (NS)	1.00 (NS)
		Group 4	1.00 (NS)	1.00 (NS)	1.00 (NS)
		Group 3	Group 4	1.00 (NS)	1.00 (NS)

* $P < 0.05$ statistically significant, $P > 0.05$ NS. Tukey *post hoc* test. VAS: Visual analog scale; NS: Nonsignificant

capacity of saliva between the entire groups at different time intervals was not statistically significant [Table 3].

DISCUSSION

The present clinical trial was designed to compare three desensitizing dentifrices and a placebo for a 12-week duration to achieve maximal desensitizing effect, although that 8 weeks could be a suitable duration for most of the clinical trials as suggested by Holland *et al.*^[1]

After obtaining the results, decoding for the blinding procedure was done, and it was found that the Group 1 represented 5% potassium nitrate, Group 2 represented 5% calcium sodium phosphosilicate, Group 3 represented 3.85% amine fluoride, and Group 4 the placebo dentifrice. The examiner was unaware about the subject allocation into groups; the subjects did not know which dentifrice they were using, and the statistician did not know which group each code represents, thereby completing the triple blinding procedure along with randomization.

The mean age of 42.95 years of the study sample correlated with the data which was reported by

other researchers, which indicated that DH primarily affected adults who were aged 20–50 years.^[4,14]

It is observed in the present study that premolars were commonly affected by DH which coincides with other studies,^[13,15] and in contrary one of the study reported canines^[16] and another study reported lower anterior as commonly affected teeth.^[4]

In the present study, salivary pH values of calcium sodium phosphosilicate group were more toward neutral (7.03 at 6 weeks and 7.08 at 12 weeks) as time varied compared to potassium nitrate and amine fluoride dentifrices and placebo groups. Salivary Buffering capacity of calcium sodium phosphosilicate group showed better improvement from baseline to 6 and 12 weeks compared to the other groups. Many components from saliva as well as from sources outside the oral cavity allow enamel to undergo remineralization after demineralization. Optimal remineralization depends on the enamel surface's being exposed to low concentrations of calcium, phosphate, and fluoride for prolonged periods.^[17] In the aqueous environment of the tooth, sodium ions from the calcium sodium phosphosilicate particles rapidly exchange with hydrogen cations (in the form of H_3O^+), and this brings about the release of calcium and phosphate (PO_4^{3-}) ions from the glass (calcium sodium phosphosilicate).^[18] A localized, transient increase in pH occurs during the initial exposure of the material to water due to the release of sodium. This increase in pH helps to precipitate the extra calcium and phosphate ions provided by the calcium sodium phosphosilicate to form a calcium phosphate layer. As these reactions continue, this layer crystallizes into carbonate enriched hydroxyapatite (HCA).^[19] The combination of the residual calcium sodium phosphosilicate particles and the newly formed HCA layer results in remineralization of the enamel surface and prevents further demineralization. In the present study, statistically significant improvement was observed for salivary buffering capacity values for calcium sodium phosphosilicate group.

The results of the present study demonstrated a remarkable reduction in symptoms for all the treatment groups with time for measures of sensitivity. The calcium sodium phosphosilicate group showed a higher degree of effectiveness at reducing DH than potassium nitrate and amine fluoride dentifrices and a placebo for sensitivity measures. There was no statistically significant difference between the results

of the potassium nitrate toothpaste and the amine fluoride toothpaste in the reduction of symptoms by the end of 12 weeks, similar results were found in one of the clinical trial which was done only for 6 weeks with no salivary analysis comparing calcium sodium phosphosilicate, amine fluoride, potassium nitrate, and a placebo.^[15]

Enough evidence can be found from well-designed clinical trials for all active ingredients used in this study. The mode of action of calcium sodium phospho-silicate (CSPS) has been investigated *in vitro* and was described to occlude dentinal tubules by the formation of apatite-like calcium phosphate hydroxycarbonate layer and resist acid challenge that aid in the treatment of treatment of DH and dentine remineralization.^[20,21] Local precipitation of apatite-like material was attributed to the immediate release of sodium ions when CSPS comes in contact with water or saliva. This induces a rise of the local environmental pH, which subsequently facilitates release of calcium and phosphate ions.^[18] Moreover, it also exerts antibacterial effect on certain oral bacteria *in vitro*, possibly by virtue of the alkaline nature of its surface reactions, which reduces symptoms of DH by preventing bacteria to induce pulpal response.

In this study, calcium sodium phosphosilicate group showed a higher degree of effectiveness at reducing DH than commercially available potassium nitrate and amine fluoride dentifrices and a placebo, similar results were demonstrated by other studies.^[13,15,22-24] Potassium nitrate as active ingredient in toothpaste has proved to be clinically efficient in treatment of DH,^[25,26] there is the difference in sensitivity reduction between potassium nitrate and calcium sodium phosphosilicate and this can be explained by their mechanism of action. Potassium nitrate blocks intradental nerves by increasing the extracellular potassium ion concentration.^[27] Evidence from experiments on nerve excitability indicates that potassium induced effects are transient and reversible. Calcium sodium phosphosilicate directly blocks dentinal tubules by forming apatite crystals and has better desensitizing effects than potassium nitrate.

In vitro studies have demonstrated that fluoride ions in amine fluoride enhance remineralization of surface enamel by the formation of calcium fluoride crystals.^[28] Amine fluoride is an organic fluoride, the distribution of organic material is increased in demineralized enamel and this explains the higher

uptake of organic fluoride. In addition, amine fluoride also demonstrated to have effective inhibitory effect on oral bacterial isolates,^[29] which reduces symptoms of DH by preventing bacteria to induce pulpal response. A mouthrinse containing amine fluoride as active agent has been evaluated for the treatment of DH and was found to be effective.^[30] The results of the present study, comparing amine fluoride as an active ingredient in dentifrice to calcium sodium phosphosilicate and potassium nitrate are in agreement with other study.^[15]

In the present study, the placebo group also reported a reduction in mean sensitivity scores over time. One probable factor may be the patients were aware about the clinical trial to determine the efficacy of desensitizing products. The Hawthorne effect can also be responsible for the same. Subjects may show improved oral hygiene due to frequent examinations. The scope for showing an improvement either by a chemical product and/or Hawthorne effect, is very small.^[30] Data of previous clinical trials on DH clearly indicate that a placebo response occurs in DH studies.

Salivary analysis for calcium and phosphate levels was not done in this clinical trial, which could be one of the limitations. Evaluation of salivary pH, calcium, and phosphate levels are important to determine an individual suffering from a demineralization-remineralization dysfunction. Another limitation is that VAS assessment is clearly highly subjective, these scales are of most value when looking at change within individuals, and are of less value for comparing across a group of individuals at one-time point.

Further research in this field is needed, by conducting long-term clinical trials with follow-up, with large sample size, ideally randomized, placebo-controlled, triple-blinded studies which should also include many salivary biochemical analyses to support the subjective variation of sensitivity assessment.

CONCLUSION

The data of the present study indicate that with twice daily use, all three products would be expected to bring about the considerable relief of symptoms during product use. Among three desensitizing dentifrices, calcium sodium phosphosilicate was found to be more effective in reducing DH and showed better improvement in salivary biochemical characteristics over a period of 12 weeks compared to others.

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Conflicts of interest

The authors of this manuscript declare that they have no conflicts of interest, real or perceived, financial or nonfinancial in this article.

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