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Original Research

# Comparative Evaluation of Fluoro Calcium Phosphosilicate, Calcium Sodium Phosphosilicate, and Strontium Chloride Hexahydrate containing Dentifrice for the Treatment of Dentin Hypersensitivity: A Randomized Single-Blind Study

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## Abstract

**Aims and Objectives:** This study aimed to evaluate and compare the clinical effectiveness of dentifrices containing fluoro calcium phosphosilicate, calcium sodium phosphosilicate, and strontium chloride hexahydrate for the treatment of dentin hypersensitivity (DH) when applied twice daily. **Materials and Methods:** Participants with a history of DH and with visual analog scale (VAS) score of ≥5 to a painful test stimuli response (dental explorer) in at least one tooth at the qualifying baseline visit were enrolled in this four-week randomized study. Participants ($n$ = 93) were randomly allocated to one of the following groups: Group 1—fluoro calcium phosphosilicate (BioMin™), Group 2—calcium sodium phosphosilicate (NovaMin®), and Group 3—strontium chloride hexahydrate. Clinical effectiveness (VAS), perceived sensation score (verbal rating scale [VRS]), participants' subjective assessment (four-item questionnaire) and oral health-related quality of life (Oral Health Impact Profile-14 [OHIP-14]) questionnaire) were assessed. **Results:** A significant ($P < 0.0001$) reduction in symptoms over a period of four weeks (from baseline) was noted in all groups; however, the intergroup difference was not statistically significant. At week 2, the percentage reductions in VAS (Group 1: 58.19%; Group 2: 49.18%; Group 3: 52.69%) and VRS (Group 1: 58.19%; Group 2: 47.16%; Group 3: 49.05%) scores were higher in Group 1 as compared with other groups. Subjective assessment results and oral health-related quality of life were comparable in all the three groups at the end of four weeks. **Conclusion:** Fluoro calcium phosphosilicate bioactive glass containing desensitizing dentifrice treatment may provide better treatment response for the treatment of DH because of its early onset of action in relieving hypersensitivity symptoms as compared with other dentifrices (CTRI/2018/04/013481).

**Keywords:** Bioactive glasses, biomin, calcium sodium phosphosilicate, dentinal hypersensitivity, fluoro calcium phosphosilicate, novamin, strontium chloride hexahydrate, verbal rating scale, visual analog scale

## Introduction

Dentin hypersensitivity (DH) is a commonly encountered clinical condition resulting from exposed dentin, causing significant physical and psychological discomfort.[1] By definition, it is a "short, sharp pain arising from exposed dentin in response to stimuli typically thermal, evaporative, tactile, osmotic or chemical and which cannot be ascribed to any other form of dental defect or pathology".[2]

DH is commonly observed in middle-aged adults[3] and factors such as gingival recession and smoking are noted to increase the risk of DH.[1] It is widely prevalent in the general population with varied reported estimates, ranging from 3% to 98% mainly due to differences in diagnostic criteria and study population.[4] A large population scale

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study reported 34% prevalence,[5] which likely reflects the extent to which DH is underreported, despite the painful condition. As DH often leads patients to restrict their dietary choices and brings about adverse behavioral changes, it is known to have a significant adverse impact on health-related quality of life.[1,6] The successful treatment of DH improves both physical comfort and health-related quality of life,[6] highlighting the need to develop and assess effective therapeutic strategies for its management.

Considering the complex and multifactorial etiology of DH, a number of home use and in-office therapeutic approaches have been developed with varied mechanisms of actions. These are based on anti-inflammatory, physical or chemical occlusive, and depolarizing agents.[7] In general, easy-to-use, self-applied, home-care desensitizing agents are recommended as the first line of care in the management of DH.[8] Literature has validated the efficacies of potassium nitrate-, stannous fluoride-, calcium sodium phosphosilicate-, and arginine-containing dentin desensitizing dentifrice as compared with placebo.[9]

Bioactive glasses are a group of biomaterials, which are used in the field of dentistry for hypersensitivity treatment. They are generally introduced into various dentifrices as very fine particles to provide calcium and phosphorus to the tooth surface. When these kinds of dentifrices are used, bioactive glass particles adhere to the dentin and form a hydroxycarbonate apatite layer; blocking of the tubules relieves the pain for longer periods.[10] NovaMin® (calcium sodium phosphosilicate [CSPS]) and BioMin™ (fluoro calcium phosphosilicate) are the commonly used bioactive glasses used in the management of DH.[11]

The occlusive desensitizing agent, CSPS, has shown improved outcomes as compared with strontium chloride, potassium nitrate, and regular fluoride dentifrices.[12,13] More recently introduced fluoride-containing bioactive glass, fluoro calcium phosphosilicate, with increased phosphate content and fluoride release, has also shown improved acid demineralization resistance.[14] These properties, along with the small particle size which lowers the abrasive index, make it an attractive agent for occlusion of exposed dentin tubules. Further, studies have shown good efficacy and improved effectiveness with fluoro calcium phosphosilicate, as compared with potassium nitrate and strontium chloride.[15] However, the effectiveness of fluoro calcium phosphosilicate in comparison to conventional CSPS bioactive glass and other conventional desensitizing agent-containing dentifrices such as strontium chloride hexahydrate is less explored.

Hence, the objective of this study was to evaluate and compare the clinical effectiveness of dentifrices containing fluoro calcium phosphosilicate, CSPS, and strontium chloride hexahydrate for the treatment of DH, over a period of four weeks, when applied twice daily. Subjective assessment and oral health-related quality of life was also assessed in these participants over a period of four weeks.

## Materials and Methods

### Patients

Participants aged between 18 to 50 years with a clinical presentation of DH, good general and oral health based on investigator's discretion, attending the Outpatient section of the Department of Conservative Dentistry and Endodontics, Dr. D. Y. Patil Dental College and Hospital, Dr. D. Y. Patil Vidyapeeth, Pimpri, Pune, India, were selected at baseline. The VAS score of at least 5 to a painful test stimuli response (dental exploration) in at least one tooth at baseline was also an inclusion criterion. Participants with any systemic illness and/or dental emergency condition needing urgent treatment or severe generalized periodontitis or presence of active caries, cracks, fractures in cervical areas of affected teeth were excluded. Besides, participants with restorations, prosthesis, orthodontic appliances involving cervical areas of affected teeth or non-surgical or surgical therapy for periodontitis within last 12 months or ongoing use of analgesics, anti-inflammatory or anti-histaminic agents or any use of other home-care desensitizing dentifrices or in-office treatments within 8 weeks were excluded from this study.

Participants who fulfilled the study requirements and were willing to participate provided written informed consent.

### Study Design, Randomization, and Blinding

This single-center, interventional, single-blind, randomized controlled clinical study was conducted between April 2018 and September 2018. The study treatment duration was 4 weeks (28 days).

The clinical investigators were masked to the contents of the dentifrices and remained blinded to the treatment type received by the participant until the completion of the statistical analyses. The dentifrices were placed in an opaque cover to ensure blinding of the clinical investigator. To ensure allocation concealment, the allocation sequence was randomly generated by an independent investigator who was not part of the study and made sure that the blinding remained impeccable. The enrolled participants were randomly assigned to one of the three treatment groups, namely:

Group 1: Fluoro Calcium Phosphosilicate bioactive glass (BioMin™) containing desensitizing dentifrice

Group 2: Calcium Sodium Phosphosilicate bioactive glass (NovaMin®) containing desensitizing dentifrice

Group 3: Strontium Chloride Hexahydrate containing desensitizing dentifrice

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All attempts were made to ensure the clinical examinations and tests were carried out by a single examiner for a given participant to eliminate inter-examiner variability.

## Test stimuli

Sensitivity test stimuli was evaluated by a 1-s application of cold air (40–60 psi at 19–24°C) stimuli on the exposed dentin surface using a standard dental unit air syringe from a distance of 1 cm. Precautions were taken to prevent reporting of a false-positive result by isolating the adjacent teeth.

The participants' enrolment and treatment allocation cohort chart of the study is shown in Figure 1. A total of 93 participants were screened and enrolled into this study, and of those 86 participants completed the study.

Participants were instructed to apply the dentifrice amount equal to about the half the length of the bristle head. Participants were instructed to first apply the dentifrice to the sensitive teeth with a soft-bristled toothbrush, followed by brushing all other areas of the mouth with the dentifrice using their normal oral hygiene method twice a day. Use of other oral hygiene product and any other dental treatment including home remedies for hypersensitive teeth was not allowed throughout the duration of the study. An individual participant diary was provided to collect the details of daily brushing and documenting the symptomology during the treatment period. Entries were made by the participants twice a day.

## Outcome measures

The primary outcome measure was to assess and compare the clinical effectiveness of fluoro calcium phosphosilicate bioactive glass, CSPS bioactive glass, and strontium chloride hexahydrate containing desensitizing dentifrices in the management of DH with twice daily brushing, as measured by adjusted mean change from baseline in pain scores on VAS at week 2. The secondary outcome measure was to assess and compare the clinical effectiveness based on VAS at week 4 and verbal rating scale (VRS) at weeks 1, 2, and 4. Subjective acceptance and participants' oral health-related quality of life with the three dentifrices, as measured by customized four-item questionnaire and Oral Health Impact Profile-14 (OHIP-14) questionnaire, respectively, were also assessed after four weeks of treatment.

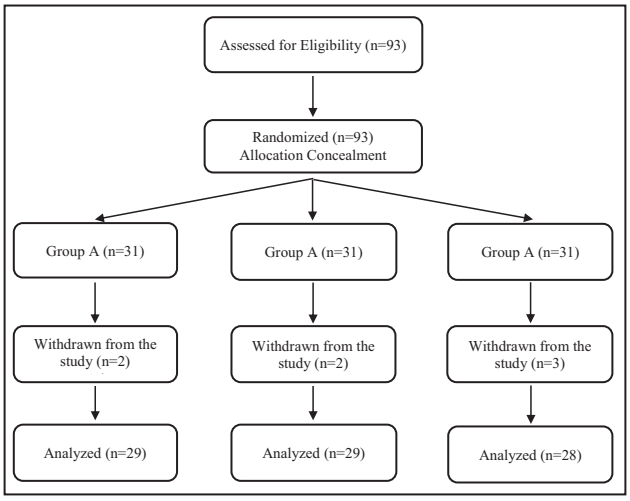


**Figure 1:** Participants' enrolment and treatment allocation cohort chart

## Measures

The measures used to determine the study outcome are as follows:

*VAS*. The VAS scale was used to record the intensity of pain experienced by the participant during the test stimuli (thermal sensitivity). Participants were asked to place a mark on the 10-cm line to indicate the intensity of their current level of DH [0: no pain response; 10: extreme pain or discomfort].[16] The test stimuli was performed during the participants' scheduled clinic visit at baseline, at week 2, and at week 4 of treatment, measured and recorded by VAS.

*VRS*. This scale was used to record the participants' subjective response to pain. In a VRS, adjectives were used to describe different levels of pain (0: no discomfort; 1: mild discomfort; 2: important discomfort; 3: important discomfort lasting more than 10 s).

*OHIP-14*. This is a self-filled questionnaire that describes the impact of oral health conditions in seven domains, namely functional limitation, physical pain, psychological discomfort, physical disability, psychological disability, social disability, and handicap.[17] The responses are recorded on a 5-point Likert's scale (0: never; 1: hardly ever; 2: occasionally; 3: fairly often; and 4: very often), with "never" indicating the least impact and "very often" indicating the maximum impact. It is the short form of the original extended version of 49-items developed by WHO.

*Subjective assessment based on customized four-item questionnaire*. Participants were assessed based on the responses to the following questions:

- QS1. How satisfied are you in terms of effectiveness (pain/ sensitivity relief) of this toothpaste?
- QS2. How satisfied are you in terms of taste and flavor of this toothpaste?
- QS3. How will you rate this toothpaste overall as compared with your regular toothpaste?
- QS4. How likely are you to use this toothpaste in the future?

## Statistical Analyses

The sample size was estimated using the "balanced one-way analysis of variance test" in the R software package "pwr".[18] Considering a dropout rate of 15% per group, the total sample size calculated was 93 subjects for the study, that is, 31 participants per treatment arm.

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Descriptive analysis of all study parameters was performed. One-way analysis of variance (ANOVA) test followed by adjusted mean analysis was used to compare the mean VRS and VAS scores. Paired *t*-test analysis was used to compare the mean VAS and VRS scores between different time intervals within each study group. The level of statistical significance was set at $P < 0.05$. The dataset analyzed for the purpose of this study was intent-to-treat (ITT) population.

Statistical analyses of the study data were performed using SAS version 9.4 software package for Windows (SAS Institute, Cary, NC).

## Results

A total of 86 (92.47%) of 93 enrolled participants (31 participants in each group) completed the study. A total of seven participants discontinued from this study because of protocol violation ($n = 1$), lost to follow-up ($n = 3$), and adverse events (AE; $n = 3$). The mean (standard deviation [SD]) age of the participants in each group was 34.71 (8.21) years, 33.23 (7.15) years, and 33.81 (9.10) years, respectively, with an overall female preponderance (52 female and 41 male).

A significant ($P < 0.0001$) reduction in symptoms based on VAS scores from baseline to weeks 2 and 4 was noted in all treatment groups. At week 2, percentage reduction in VAS score (58.19%) was higher in Group 1 (mean [SD]: –4.03[1.84]; 95% CI: –4.74: –3.33) as compared with Group 2 (49.18%) and Group 3 (52.69%). In week 4, the percentage reduction in VAS score was higher in Group 3 (87.76%), followed by Group 1 (83.33%) and Group 2 (77.34%). However, no statistically significant difference in VAS scores between the three treatment groups was noted at weeks 2 and 4 of treatment [Table 1].

A significant reduction ($P < 0.0001$) in VRS scores was observed in all the three groups at weeks 1, 2, and 4 as compared with baseline. At weeks 1 and 2, percentage reduction in VRS score was higher in Group 1 (week 1: 34.48%; week 2: 58.19%) as compared with Group 2 (week 1: 27.07%; week 2: 47.16%) and Group 3 (week 1: 30.00%; week 2: 49.05%). However, in week 4, the percentage reduction was higher in Group 3 (84.76%) as compared with Group 1 (76.29%) and Group 2 (72.93%). The intergroup difference was not statistically significant at weeks 1, 2, and 4 of treatment [Table 2].

Subjective assessment based on four-item questionnaire indicated that majority of the participants were satisfied in terms of effectiveness (sensitivity relief), taste, and flavor of the dentifrice, across all the groups. However, in terms of effectiveness (hypersensitivity relief), higher number of participants in Group 1 reported "very satisfied" as compared with other groups (Group 1: 38.71%; Group 2: 22.58%; Group 3: 30%). No statistically significant difference was observed between the three treatment groups. Further, participants reported a significant improvement in oral health-related quality of life in all the three treatment groups [Table 3].

### Safety

Three AEs (headache [$n = 1$ in Group 1]; malaise with discomfort [$n = 1$ in Group 2]; vomiting [$n = 1$ in Group 3])

**Table 1: Comparison between the three treatment groups showing the change in visual analogue scale (VAS) score for pain from baseline to weeks 2 and 4 of treatment (ITT population)**

| Visit baseline | Group 1 ($N = 31$) | Group 2 ($N = 31$) | Group 3 ($N = 30$) | Intergroup *P* value# |
|---|---|---|---|---|
| *n* | 31 | 31 | 30 | |
| Mean(SD) | 6.84 (1.16) | 6.71 (1.27) | 6.70 (1.32) | |
| Median | 7 | 6 | 6 | |
| Min | 5.00 | 5.00 | 5.00 | |
| Max | 9.00 | 10.00 | 10.00 | |
| Week 2 | | | | |
| *n* | 29 | 29 | 29 | 0.2317 |
| Mean(SD) | 2.86 (1.53) | 3.41 (1.62) | 3.17 (1.42) | |
| Median | 3 | 3 | 3 | |
| Min | 0.00 | 1.00 | 0.00 | |
| Max | 6.00 | 8.00 | 6.00 | |
| Intragroup *P* value* | <0.0001 | <0.0001 | <0.0001 | |
| Week 4 | | | | |
| *n* | 29 | 29 | 28 | 0.0974 |
| Mean(SD) | 1.14 (1.19) | 1.52 (1.38) | 0.82 (1.19) | |
| Median | 1 | 1 | 0 | |
| Min | 0.00 | 0.00 | 0.00 | |
| Max | 4.00 | 5.00 | 4.00 | |
| Intragroup *P* value* | <0.0001 | <0.0001 | <0.0001 | |

**P*-value for difference between score from baseline to week 2 and baseline to week 4.
*#P*-value for change from baseline to week 2 and week 4 between treatment groups.

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**Table 2: Comparison between the three treatment groups showing the change in Verbal Rating Scale from baseline to week1, week 2 and week 4 of treatment (ITT Population)**

| Visit baseline | Group 1 (*N* = 31) | Group 2 (*N* = 31) | Group 3 (*N* = 30) | Intergroup *P* value# |
|---|---|---|---|---|
| *n* | 31 | 31 | 30 | |
| Mean(SD) | 2.32 (0.75) | 2.29 (0.69) | 2.10 (0.71) | |
| Median | 2.00 | 2.00 | 2.00 | |
| Min | 1.00 | 1.00 | 1.00 | |
| Max | 3.00 | 3.00 | 3.00 | |
| Week 1 | | | | |
| *n* | 31 | 30 | 30 | 0.5349 |
| Mean(SD) | 1.52 (0.68) | 1.67 (0.80) | 1.47 (0.63) | |
| Median | 1.00 | 2.00 | 1.00 | |
| Min | 0.00 | 0.00 | 1.00 | |
| Max | 3.00 | 3.00 | 3.00 | |
| Intragroup *P* value* | <0.0001 | <0.0001 | <0.0001 | |
| Week 2 | | | | |
| *n* | 29 | 29 | 29 | 0.2119 |
| Mean(SD) | 0.97 (0.63) | 1.21 (0.62) | 1.07 (0.80) | |
| Median | 1.00 | 1.00 | 1.00 | |
| Min | 0.00 | 0.00 | 0.00 | |
| Max | 2.00 | 3.00 | 3.00 | |
| Intragroup *P* value* | <0.0001 | <0.0001 | <0.0001 | |
| Week 4 | | | | |
| *n* | 29 | 29 | 28 | 0.7663 |
| Mean(SD) | 0.55 (0.57) | 0.62 (0.62) | 0.32 (0.48) | |
| Median | 1.00 | 1.00 | 0.00 | |
| Min | 0.00 | 0.00 | 0.00 | |
| Max | 2.00 | 2.00 | 1.00 | |
| Intragroup *P* value* | <0.0001 | <0.0001 | <0.0001 | |

**P*-value for difference between score from baseline to week 1, baseline to week 2 and baseline to week 4.
#*P*-value for change from baseline to week 1, week 2 and week 4 between treatment groups.

**Table 3: Comparison of change in mean score for the oral health impact profile-14 (OHIP-14) questionnaire at week 4 (ITT population)**

| Visit baseline | Group 1 (*N* = 31) | Group 2 (*N* = 31) | Group 3 (*N* = 30) | Intergroup *P* value# |
|---|---|---|---|---|
| *n* | 31 | 31 | 30 | |
| Mean(SD) | 12.97 (8.89) | 14.81 (11.67) | 12.47 (10.30) | |
| Median | 11.00 | 12.00 | 8.00 | |
| Min | 4.00 | 2.00 | 1.00 | |
| Max | 46.00 | 37.00 | 36.00 | |
| Week 4 | | | | |
| *n* | 29 | 29 | 28 | 0.9977 |
| Mean(SD) | 1.59 (2.13) | 2.66 (5.91) | 1.43 (2.13) | |
| Median | 1.00 | 1.00 | 0.00 | |
| Min | 0.00 | 0.00 | 0.00 | |
| Max | 8.00 | 31.00 | 7.00 | |
| Intragroup *P* value* | <0.0001 | <0.0001 | <0.0001 | |

**P*-value for difference between OHIP-14 score from baseline to week 4.
#*P*-value for change from baseline to week 4 between the treatment groups.

were reported in this study. However, these were not related to study dentifrices.

## Discussion

DH, a common condition because of tooth wear and gingival recession, has a significant impact on the quality of life. There are various therapies and agents developed for the management of DH. Over the years, more attention has been provided to develop home-use dentifrices with various active compounds for the management of DH.

The strategies used for the management of DH are to desensitize the nerve tissue within the dentin tubules using

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agents such as potassium nitrate, or plug the tubules using compounds that can precipitate together into a large enough mass to occlude them.[19] The latter strategy of tubular occlusion as a method of dentin desensitization is a logical conclusion to the widely accepted "hydrodynamic theory" developed by Brännström. The three dentifrices chosen for this study use tubular occlusion as the mechanism of action, which decrease both dentin permeability and fluid movement, thereby reducing DH.[20]

Strontium chloride hexahydrate and CSPS are widely used traditional dentin desensitizing agent. The effectiveness of newly introduced bioactive glass containing dentifrices such as fluoro calcium phosphosilicate bioactive glass in comparison to CSPS bioactive glass and strontium chloride hexahydrate desensitizing agent-containing dentifrices is less explored. Hence, this study was designed to compare the clinical effectiveness of dentifrices containing fluoro calcium phosphosilicate, CSPS, and strontium chloride hexahydrate for the treatment of DH.

A total of 93 participants were enrolled into the study and 86 (92.47%) completed the study. Participants were equally distributed (31 in each group) into the three treatment groups. The mean age of the participants was 33.92 years, with an overall female preponderance of 52 (55.91%), which is in line with currently published literature.[21]

The severity of dentin sensitivity was determined by translating the subjective feedback into objective data using VAS and VRS scores. The reliability and validity of VAS for measuring clinical pain has already been shown.[20,22,23] The results of this study revealed statistically significant ($P < 0.0001$) reduction in symptoms in all treatment groups from baseline to week 2 (Group 1: 58.19; Group 2: 49.18%; Group 3: 52.69%) and week 4 (Group 1: 83.33%; Group 2: 77.34%; Group 3: 87.76%) based on VAS scores.

The study also revealed statistically significant ($P < 0.0001$) reduction in DH symptoms in all three treatment groups from baseline to week 1 (Group 1: 34.48%; Group 2: 27.07%; Group 3: 30.00%), week 2 (Group 1: 58.19%; Group 2: 47.16%; Group 3: 49.05%), and week 4 (Group 1: 76.29%; Group 2: 72.93%; Group 3: 84.76%) of treatment based on the VRS scores.

Thus, a significant reduction in DH was observed with time in all the variables during the four weeks of the active treatment period in all the three treatment groups. Participants in fluoro calcium phosphosilicate treatment group showed rapid and sustained relief as compared with participants in CSPS, and strontium chloride hexahydrate-containing dentifrices. This was evidenced by a higher degree of clinical effectiveness as shown by the reduction of symptoms and severity of pain at week 2. This early onset of action may be attributed to the unique mechanism of action of fluoro calcium phosphosilicate, a fluoride-containing bioactive glass integrated into the dentin desensitizing dentifrices. During dissolution, fluoride ions are released by fluoride-containing bioactive glasses[24] resulting in the formation of fluorapatite.[22] Fluoro calcium phosphosilicate is different as compared with the conventional CSPS because of the presence of higher phosphate content, smaller average particle size ($D_{50}$ of 6 μm) and $CaF_2$ in the glass.[25] Apatite crystal formation is enhanced because of the presence of higher phosphate content and $CaF_2$.[25,26] In essence, fluoro calcium phosphosilicate works by slowly releasing calcium, phosphate, and fluoride ions over a period of 8–12 h[27] and pushing the dynamic equilibrium between enamel and saliva. This forms fluorapatite to rebuild, strengthen, and protect the tooth structure.[27] This inhibits the loss of appetite and favors remineralization by apatite formation to reduce the risk of acid erosion and tooth decay.

CSPS was initially developed as a bone regenerative and repair material, which was later formulated as a dentifrice for the management of DH. CSPS bioactive glass is a ceramic material containing amorphous sodium calcium phosphosilicate, which is highly reactive in water. It has fine particle that can physically occlude the dentinal tubules.[28] In saliva, there is a rapid exchange of sodium ions (Na+) in CSPS particles with hydrogen cations (H+ or H3O+) which releases calcium (Ca2+) and phosphate ($PO_4^{3-}$) species from the particle structure. This leads to the formation of a calcium phosphate (Ca–P) layer on tooth surfaces, which crystallizes into hydroxycarbonate apatite.[28]

Strontium chloride hexahydrate is believed to work by partially occluding the open dentin tubules by precipitating insoluble metal compounds on the dentin surfaces.[29]

A study by Shaikh *et al.*[30] has shown that fluoro calcium phosphosilicate-containing dentifrices has significantly better resistance to citric acid challenge as compared with the CSPS -containing dentifrice. Further, studies by Shaikh *et al.*[30] and Amruta *et al.*[31] showed that fluoro calcium phosphosilicate-containing dentifrice was found to produce more completely occluded tubules than dentifrice containing CSPS on initial application. Also, the variation in the mechanism of action between the two bioactive glass containing dentifrices and strontium chloride hexahydrate dentifrices explains the difference in the higher reduction of VAS and VRS scores at week 2 of treatment for treatment Group 1. However, at week 4, the percentage reduction was higher in Group 3 (VAS—87.76% and VRS—84.76%), followed by Group 1 (VAS—83.33% and VRS—76.29%) and Group 2 (VAS—77.34% and VRS—72.93%), although not statistically significant. This higher percentage reduction in treatment Group 3 at week 4 of treatment may be attributed to better compliance in treatment and oral hygiene. However, in the subjective assessment

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questionnaire, more participants in Group 1 (38.71%) responded that they are "very satisfied" with respect to effectiveness, as compared with other groups (Group 2: 22.58%; Group 3: 30%).

The subjective four-item questionnaire measured the participants' self-reported satisfaction in terms of effectiveness, taste, and likeliness to continue the use of the dentifrice in the future after week 4 of treatment. However, no statistically significant difference was observed between the three treatment groups based on the responses to subjective four-item questionnaire.

Treatment Group 3 (88.53%) has a higher reduction in OHIP-14 scores, followed by Group 1 (87.74%) and Group 2 (82.04%) as compared with baseline, which is consistent with the reduction in VAS and VRS scores at week 4. There was a statistically significant intragroup reduction in OHIP-14 scores in all the three treatment groups after four weeks of treatment. However, there was no statistically significant difference observed in the OHIP-14 questionnaire after four weeks of treatment when compared between the three treatment groups.

One of the limitations of the study was the absence of control group or placebo. Further, this was a single-bind study. Hence, further studies in larger population are warranted to understand the best treatment strategy.

## Conclusion

Fluoro calcium phosphosilicate bioactive glass containing desensitizing dentifrice treatment may provide better treatment response for the treatment of DH because of its early onset of action in relieving hypersensitivity, as compared with other dentifrices. Overall, this study provides evidence of a higher therapeutic value of fluoro calcium phosphosilicate in the treatment of DH.

### Ethical policy and institutional review board statement

The research protocol was reviewed and approved by the institutional ethics committees of Dr. D. Y. Patil Dental College & Hospital, Dr. D. Y. Patil Vidyapeeth, Pune, Maharashtra, India (Reg. No.EC R-/361/Inst/MH/2013/RR/-16). The trial details are available at the CTRI website (CTRI/2018/04/013481).

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### Conflicts of interest

There are no conflicts of interest.

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