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CLINICAL COMPARISON OF 5% FLUORO CALCIUM PHOSPHOSILICATE VERSUS 5% CALCIUM SODIUM PHOSPHOSILICATE IN THE TREATMENT OF DENTINAL HYPERSENSITIVITY

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Abstract:
Dentinal hypersensitivity is a perplexing problem for the patient as well as clinician. Among the plethora of pharmacological agents developed for the management of this rather common affliction, tubule occluding agents form the mainstay of treatment. Bioglasses (phosphosilicates) with evolving chemical and biological properties, are widely used, with the latest modification being the addition of fluoride to conventional calcium sodium phosphosilicate (Novamin) to result in fluoro calcium phosphosilicate (Biomin), purported to have superior tubule occlusive properties. The present study was designed as randomized clinical trial to compare the efficacy of Biomin and Novamin in reducing the subjective and provoked (thermal) experience of dentinal hypersensitivity. Sixty subjects were randomly prescribed three dentifrices after oral prophylaxis: *Group A* (20 patients): dentifrice containing 5% fluoro calcium phosphosilicate (Biomin); *Group B* (20 patients): dentifrice containing 5% calcium sodium phosphosilicate (Novamin); *Group C* (20 patients): standard dentifrice containing fluoride. Subjective and thermal sensitivity was assessed using a 10 point VAS score at baseline, at 15 days, 30 days and 60 days of treatment. It was found that though significant reduction in hypersensitivity was observed for all three groups over time, flouro calcium phosphosilicate was most effective in reducing the VAS score, followed by calcium sodium phosphosilicate and fluoride. It was concluded that fluoro calcium phosphosilicate is a promising agent for clinical management of dentinal hypersensitivity.

Introduction

Dentin hypersensitivity (DH) is a global oral health problem, affecting 10-42% of the general population [1]. It commonly presents as a transient sharp pain occurring as a response to thermal, physical, or chemical stimuli, and resulting from stimulation of exposed dentinal tubules. The condition may potentially affect the quality of life and represents a perplexing clinical problem[2] .Currently two treatment approaches are widely applied for DH, namely tubular occlusion and blockage of nerve activity. While the superiority of no method or agent has yet been established, tubule occluding agents are the mainstay of contemporary research, due to their long term safety and efficacy.

Among these agents, bioglasses offer unique properties and proven clinical efficacy. Recently introduced calcium sodium phosphosilicate (Novamin), is a particulate bioactive glass[3] which preferentially binds to exposed tubules [4] ; on exposure to the aqueous oral environment, it provides calcium and phosphate ions to form a hydroxycarbonate apatite‐like layer on the dentine surface and within the tubules resulting in tubular occlusion.[5]

A novel modification of Novamin, fluoro- calcium phosphosilicate, or Biomin was introduced in 2016. It contains fluoride, and higher phosphate content, besides having a smaller average particle size[6].Upon contact with the exposed tubules, it forms fluorapatite, rather than hydroxyapatite, which is much more resistant to acids and promotes

remineralization, particularly in combination with the calcium and phosphate released from the glass. The fluoro calcium phosphosilicate containing toothpaste was launched in 2016 in the UK (online only) and pharmacies in Germany and India. However, the clinical evidence for its efficacy in treating dentinal hypersensitivity is limited.

Hence, this study aimed to comparatively evaluate the clinical desensitizing efficacy of dentifrice containing 5% fluoro-calcium phosphosilicate (Biomin) versus 5% calcium sodium phosphosilicate (Novamin) in participants with sensitive teeth.

MATERIALS AND METHODS

The study was conducted as a single-center, interventional randomized controlled clinical trial involving sixty patients within the age group of 18-55 years. Prior to commencement, ethical clearance was obtained from the institutional ethical committee. Patients were selected from the OPD of the Department of Periodontology, GDC, Srinagar, based on the inclusion criteria, and provision of informed consent.

Inclusion Criteria:

- Systemically healthy
- Visual analog scale (VAS) score of ≥4 to both subjective and thermal stimuli in at least two teeth at baseline

Exclusion Criteria:

- Active cervical caries/ attrited teeth/caries/ chipped teeth/faulty restorations/pulpal causes of sensitivity
- Regular use of a desensitizing dentifrice within 2 months
- Periodontal surgery in the preceding 6 months
- Oral prophylaxis within 2 weeks
- Patients on daily doses of analgesics/ anticonvulsants/antihistamines/sedatives/ tranquilizers/ mood-altering drugs/ anti-inflammatory drugs,
- Pregnant and lactating females
- Allergic to ingredients used in the study
- Smokers and alcoholics.

All patients underwent oral prophylaxis as indicated. Thereafter, they were randomly prescribed any of the toothpastes:

1. **Group A** (20 patients): A commercially available dentifrice containing 5% fluoro calcium phosphosilicate (Biomin)(*Elsenz*, Group pharmaceutical Ltd, Bengaluru)
2. **Group B** (20 patients): A commercially available dentifrice containing 5% calcium sodium phosphosilicate (Novamin)(*Vantej*, Dr. Reddy's Labs)
3. **Group C** (20 patients): A standard dentifrice containing fluoride

All patients were instructed to brush with a soft toothbrush, using the bass technique. They were instructed to apply dentifrice in an amount equal to about half the length of the bristle head and to brush for 2 min and no more than a total of 2 times/day. They were also directed to refrain from any other dentifrice or mouth rinse during the trial but were allowed to continue their normal oral hygiene practice.

Sensitivity assessment

The following assessments were made by a single examiner at baseline, 15 days, 30 days, and 60 days after initial treatment:

- Subjective sensitivity: Individuals were asked to evaluate their typical perceived pain level due to dentine hypersensitivity using a 0-10 VAS score.

- Thermal sensitivity: By one-second application of cold air from a standard dental air syringe at 40–65 psi at ambient temperature, directed perpendicular and at a distance of 1–3 mm from the exposed dentin surface (evaporative stimulus). The adjacent teeth were isolated with cotton rolls and protected by gloved fingers before applying the stimuli to prevent false-positive results. The intensity of pain evoked was marked by the subject on a 10 cm VAS, with the score of 0 being a no-pain response and a score of 10 being extreme pain or discomfort[7].

Statistical analysis

One way ANOVA test followed by Bonferroni's post hoc analysis was used to compare the mean VAS scores by subjective and thermal sensitivity between the three groups at different time intervals. Repeated measures of ANOVA followed by Bonferroni's post hoc analysis were used to compare the mean VAS scores of subjective and thermal sensitivity between different time intervals within each study group. The level of statistical significance was set at $P < 0.05$.

Results

Mean VAS scores for subjective sensitivity and thermal sensitivity for the fluoro calcium phosphosilicate (Biomin) group, the calcium sodium phosphosilicate (novamin)group, and the fluoride group at baseline, 15, 30, and 60 days are shown in Figures 1&2 respectively. VAS scores for subjective

and thermal sensitivity of all three groups were not statistically different from each other at baseline. Intragroup comparison of mean VAS scores for subjective sensitivity and thermal sensitivity scores between different intervals revealed a statistically significant reduction from baseline to 60 days in all the three groups. Meanwhile, intergroup comparison for these parameters showed that the efficacy of fluoro calcium phosphosilicate was significantly better in reducing VAS scores than the calcium sodium phosphosilicate and fluoride at 15, 30, and 60 days. Furthermore, calcium sodium phosphosilicate group showed statistically significant reduction in the scores when compared to the fluoride group (Table 1&2).

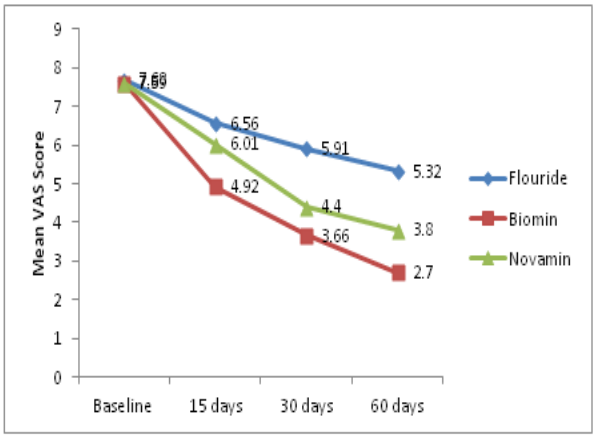

Figure 1: Changes in mean Visual Analog Scale scores for subjective sensitivity over time

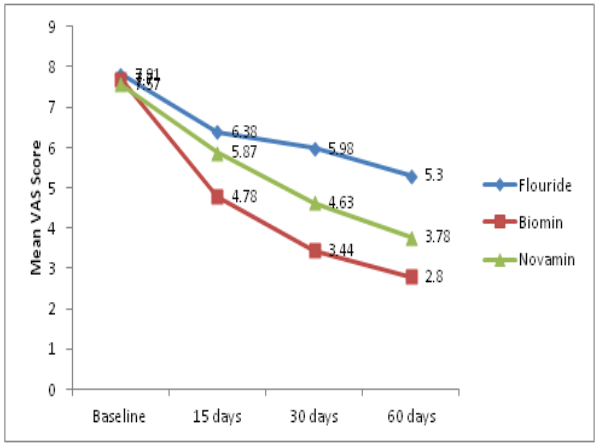

Figure 2: Changes in mean Visual Analog Scale scores for thermal sensitivity over time

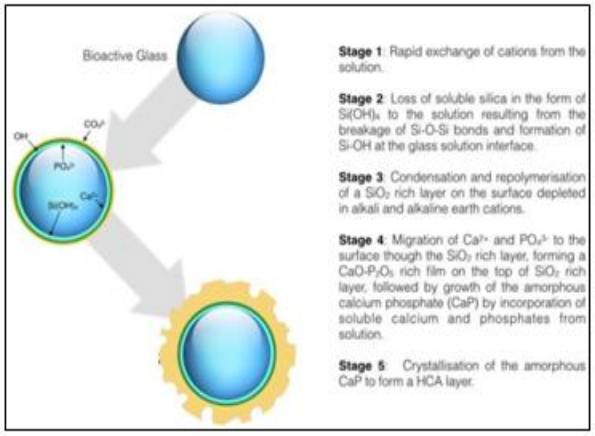

Figure 3: Mechanism of action of bioglass

Table 1: Comparison of mean visual analog scale scores between groups for subjective sensitivity (Bonferroni's post hoc analysis)				
Time		**Group A vs Group B**	**Group A vs Group C**	**Group B vs Group C**
15 days	*P*	0.002*	<0.001*	0.004*
30 days	*P*	<0.001*	<0.001*	0.002*
60 days	*P*	<0.001*	<0.001*	0.001*

Table 2: Comparison of mean visual analog scale scores between groups for thermal sensitivity (Bonferroni's post hoc analysis)				
Time		**Group A vs Group B**	**Group A vs Group C**	**Group B vs Group C**
15 days	*P*	0.002*	<0.001*	0.004*
30 days	*P*	0.001*	<0.001*	0.003*
60 days	*P*	<0.001*	<0.001*	0.001*

Discussion

This study compared the desensitizing efficacy of fluoro calcium phosphosilicate (biomin) to calcium sodium phosphosilicate (novamin) and standard fluoride dentifrice. VAS score was used to assess the patient perceived sensitivity as well as the provoked thermal sensitivity. The validity and reliability of the VAS for measuring both experimental and clinical pain have been demonstrated by several investigators. [8,9,10]

It was found that flourocalcium phosphosilicate had the best efficacy as compared to calcium phosphosilicate or fluoride. The phosphosilcates are a family of bioactive glasses that have a unique biological property of surface dissolution upon contact with body fluids, which results in the precipitation and crystallisation of a biocompatible hydroxyapatite like layer around the bioglass particle (Figure 3). [11] When used for bone regeneration, this layer facilitates the adhesion and subsequent activity of osteoblasts, and, in context of dentinal sensitivity, it aids in the occlusion of exposed dentinal tubules, thereby preventing fluid ingress and sensitivity. The addition of fluoride to the bioactive glass results in the release of fluoride ions upon dissolution and cause the formation of florapatite, which is more stable and resistant to action of acids.[12] Moreover, Flouro calcium phosphosilicate also has a higher phosphate content, and a smaller average particle size (D50 of 6 µm),[12] which might enable a deeper penetration into dentinal tubules and occlusion of smaller tubules. In fact, SEM studies have shown that the number of completely occluded dentinal tubules was higher with fluorocalcium phosphosilicate as compared to calcium phosphosiliscate which caused only partial occlusion.[13] This could explain the difference in desensitizing efficacy seen between the two bioglasses. Similar findings have been reported by Prithyani et al [14] and Ashwini et al.[8]

With regard to the reduction in sensitivity seen with the use of fluoride containing dentrifice, it is known that fluoride aids in the remineralization of the tooth surface, making it more resistant to acid dissolution [15]. However, in context of managing dentinal sensitivity, this mechanism is of limited value. As follows from the hydrodynamic theory of hypersensitivity [16], effective desensitization can be achieved by occlusion of the patent dentinal tubules, which prevents ingress of fluids and odontoblastic stimulation. Hence, the observed effect may be due to better plaque control of the subjects subsequent to oral prophylaxis and oral hygiene instructions.

Conclusions

Within the limitations of this study, it can be concluded that flouro calcium phosphosilicate is a promising agent for the management of dentinal hypersensitivity, as evidenced by the earlier reduction in patient perceived as well as objective experience of sensitivity, as compared to the conventionally used calcium sodium phosphosilicate. Further trials are implicated to evaluate the difference in biochemical mechanisms of the two compounds, and the persistence of relief after treatment.

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