

Arginine Versus Calcium Sodium Phosphosilicate in Treating Dentin Hypersensitivity- A Randomized Clinical Trial and Scanning Electron Microscope Study

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ABSTRACT

Objective

To compare the efficacy of a new dentifrice containing arginine to a dentifrice containing calcium sodium phosphosilicate in the management of dentin hypersensitivity using scanning electron microscope (SEM) and randomized clinical trial.

Methods

An eight-week clinical study, with seventy patients, was conducted using a double-blind, two-treatment design. Tactile sensitivity assessments, as well as air blast sensitivity assessments, were used to compare

the efficacy of the two products. An additional scanning electron microscopic study was conducted to assess the tubule occlusion capacity and elemental composition of the test agent.

Results

Highly significant difference in reduction of hypersensitivity was noted at each time interval for both the groups. Maximum fall in sensitivity scores (78.85%) was observed during second to fourth week in group A (ACT). In group B (CSP) maximum fall in

sensitivity scores (83.33%) was seen during 4week to 8-week duration implying faster relief from symptoms in group A Percentage decrease in sensitivity scores at each time interval in group A(ACT) was more than in group B (CSP), suggestive of rapid relief from dentin hypersensitivity as compared to group B (CSP).

Conclusion

A new toothpaste containing 8.0% arginine, calcium carbonate, and 1450 ppm fluoride, as sodium monofluorophosphate (MFP), provided Arginine containing toothpaste provided faster relief from dentin hypersensitivity as compared to calcium sodium phosphosilicate containing toothpaste in response to air blast and cold stimulus as assessed by VAS score. Dentinal tubule occlusion in arginine containing toothpaste was better when compared to calcium sodium phosphosilicate toothpaste as seen in SEM

Keywords

Dentifrice containing calcium sodium phosphosilicate in the management of dentin hypersensitivity, hypersensitivity, monofluorophosphate.

METHODOLOGY

70 subjects were included in the study. Participation of the subjects was voluntary and written informed consent was obtained from the participating subjects. Subjects between 18 to 60 years of age in generally good health with at least 2 hypersensitive teeth demonstrating cervical abrasion, attrition and gingival recession with VAS score of ≥ 4 in response to air blast or thermal stimulus were included in study. Subjects with teeth that were abutments for partial dentures and teeth exhibiting extensive or defective restorations, caries, fractures, excessive mobility or suspected pulpal pathology, subjects with orthodontic

appliances, subjects under medication including analgesics with a potential to mask pain sensation or if they had used commercially available desensitizing agent within three months prior to study were excluded from the study.

To access tooth sensitivity, a controlled air stimulus (evaporative stimulus) and cold water (thermal stimulus) were used. Sensitivity was measured using a 10 cm VAS scale, with score of zero being pain free and score of 10 being excruciating or unbearable pain. Scoring of tooth sensitivity was done first by using controlled air pressure from a standard dental syringe at 40 to 65psi at ambient temperature, directed perpendicular and at a distance of 1 to 3mm from the exposed dentine surface while adjacent teeth were protected with gloved fingers to prevent false positive results. This followed scoring of tooth sensitivity using a drop of ice-cold water from a 22-gauge syringe applied to the exposed dentin surface while neighboring teeth were isolated during testing using operator finger and cotton rolls. A period of at least 5 minutes was allowed between two stimuli. After recording the sensitivity scores at baseline, subjects were given respective toothpaste 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 mouth rinse during the trial but were allowed to continue their normal oral hygiene practice. Sensitivity scores were further recorded at 4-day, 2-week, 4 week and 8-week interval for assessment of relief in dentin hypersensitivity.

The results obtained from this study were collected, tabulated and statistically analyzed using Chi-square test, Freidman's test, Wilcoxon signed rank test and Mann Whitney test.

An additional in vitro study was performed wherein the dentin specimens of dimension 3×2×2 mm were divided into two groups. Each group contained five dentin specimens. Before application of the test agent, the specimens in each group were subjected to scanning electron microscopy (SEM) examination and energy dispersive X-ray (EDX) analysis. Photomicrographs were taken at 1000, 2000 and 5000× magnification to evaluate the number and patency of tubules. EDX analysis was done to assess elemental composition of dentinal tubules. Test dentifrice was applied using a soft bristle toothbrush two times daily for seven days for each test group. Specimens after brushing were stored in saliva substitute. After seven days specimens were again subjected to SEM and EDX analysis to check occlusion and elemental composition of tubules.

RESULTS

Data obtained was statistically analysed by Chi-square test, Friedmann's test,

Wilcoxon signed rank test and Mann Whitney test.

Statistical package for social

sciences (SPSS version 18) and Microsoft Excel 2010 were used to analyse the data.

The results of the randomized clinical trial showed highly significant difference in sensitivity scores at baseline to 8 weeks in both the groups as recorded on VAS in response to air blast and cold stimuli.

Highly significant difference was seen in reduction of hypersensitivity at each time interval for both the groups. In group A maximum fall in sensitivity scores to air blast stimulus (78.85%) was observed during second to 4th week. In group B maximum fall in sensitivity scores (83.33%) was seen during 4 week to 8 week duration suggestive of faster relief from dentin

hypersensitivity in group A (table 1). In group A highly significant fall in sensitivity scores to ice cold stimulus (85.71%) was observed during second to 4th week. In group B fall in sensitivity scores was 36.46 % during 2 weeks to 4-week duration suggestive of faster relief from dentin hypersensitivity in group A (table 2). Results obtained from SEM study showed significantly greater percentage of tubule occlusion in arginine toothpaste group (image 1,2) as compared to calcium sodium phosphosilicate group (image 3,4). EDX analysis showed same elements blocking the tubules as present in the toothpaste confirming their role in tubule occlusion (fig 1,2).

DISCUSSION

The present study was 8 weeks in duration, parallel in design and used methodology that considered the recommendations of the Guidelines for the Design and Conduct of Clinical Trials on dentin hypersensitivity. In particular, diagnosis was based on the internationally accepted definition of dentin hypersensitivity. A power calculation was used to recruit sufficient subjects to show whether a priori decided difference in pain scores, if present, was significant.

Many stimuli can cause dentinal pain, but not all are suited for quantifying dentin sensitivity^{12,13}. Tactile, cold and evaporative air stimuli are recommended, as these are both physiological and controllable⁴. Dentin sensitivity may be different for different stimuli and it is recommended that at least 2 hydrodynamic stimuli should be used^{4,13,14}. Therefore, in the present study two different stimuli were employed, air evaporative and cold water both of which are relevant to the everyday initiation of sensitivity in these subjects.

Attempts to translate subjective feedback to objective data for research purposes have involved both unidimensional and multidimensional pain measurement systems (Flaherty 1996). The most common unidimensional method is the visual analogue scale (VAS). It is widely used in clinical research to assess intensity of acute pain¹⁵. The assessment methods used in the present study were response based using a VAS score completed by the subject rather than a stimulus-based binary response using stimuli of increasing intensity. VAS as measurement of stimuli response was used in this study because the validity and reliability of the VAS for measuring both experimental and clinical pain has been demonstrated by several investigators. Several investigators have compared the VAS with other pain scales and the results indicate that the VAS correlates well with these methods and appears to be more sensitive in discriminating between various treatments and changes in pain intensity^{16,17}.

There was a remarkable pattern toward reduction of dentin hypersensitivity with time for all the variables during the 8 weeks of active phase of the study independent of treatment groups.

In group A, arginine containing toothpaste (ACT) maximum fall in sensitivity scores was observed during second to fourth week. In group B (CSP) maximum fall in sensitivity scores was seen during 4 week to 8-week duration suggestive of faster relief from dentin hypersensitivity symptoms in group A (ACT).

To the best of author's knowledge, only few well-designed clinical trials providing some evidence for the formulation containing all potential active ingredients used in the present study can be found.

The effectiveness of arginine in toothpaste formulations containing 4% and 8% arginine, is supported by data showing significant improvement of dentin hypersensitivity compared with baseline, and superiority in comparison with control toothpastes (Ayad et al. 2009, Docimo et al. 2009, Schiff et al. 2009, Hamlin et al. 2009, Que et al. 2010, Fu et al. 2010)¹⁸⁻²³. The results of the current study are in accordance with other clinical trials conducted to test its effectiveness in treating dentin hypersensitivity.

Calcium sodium phosphosilicate was used as a positive control in the present study because it has been proved to be clinically efficient in the treatment of dentin hypersensitivity. Originally developed as a bone regenerative material, it has been shown to be effective at physically occluding dentinal tubules through the development of a hydroxyapatite like mineral layer²⁴. Clinical evaluations of calcium sodium phosphosilicate for the treatment of dentin hypersensitivity have shown statistically significant and clinically positive results²⁵.

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 prevention of demineralization of tooth structures, especially dentin. Moreover, it has demonstrated strong antimicrobial behavior in vitro, which reduces symptoms of dentin hypersensitivity by preventing bacteria to induce pulpal response²⁶.

The effectiveness of CSP in toothpaste formulations containing 5% and 7.5% NovaMin®, is supported by data showing significant improvement of dentin hypersensitivity compared with baseline, and superiority in comparison with control toothpastes

(Du et al. 2008, Salian et al. 2010, Pradeep et al. 2010 Litkowsky and Greenspan 2010, Sharma 2010)^{24,25}.

Several studies have been conducted to test the efficacy of calcium sodium phosphosilicate containing toothpaste to other desensitizing dentifrices. However, there is paucity of literature comparing efficacy of arginine containing toothpaste to calcium sodium phosphosilicate. In the author's knowledge, present study is the first to compare the arginine toothpaste and calcium sodium phosphosilicate toothpaste both in vitro and in vivo.

CONCLUSION

Scanning electron microscopy results showed better tubule occlusion on brushing the dentin specimen with arginine containing toothpaste for seven days as against calcium sodium phosphosilicate containing toothpaste. The results of SEM thus substantiate the results obtained from randomized clinical trial. Energy dispersive x-ray results further confirmed that the elements occluding the tubules have the same elemental composition as present in the respective toothpaste.

Dentin hypersensitivity studies are fraught with difficulty as they are subject based. Therefore, several factors can influence the measurement of pain. To date, none of the methods used to assess the measurements have been seen to be completely successful. Nonetheless, in the light of current observations of in vitro and clinical trial using arginine containing toothpaste to calcium sodium phosphosilicate, arginine containing toothpaste appears to be a significant advancement in the treatment of dentin hypersensitivity.

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Table 1: Pair wise intergroup comparison of percentage change in sensitivity scores in response to air blast stimulus between group A and group B at different time intervals

			Mean Difference	Percentage	P Value	
Base line	4 days	Group A	2.200	37.75	.081	NS
		Group B	1.588	28.93		
	2 weeks	Group A	4.343	74.51	.024	S
		Group B	3.324	59.90		
	4 weeks	Group A	5.514	94.61	.001	HS
		Group B	4.176	75.63		
8 weeks	Group A	5.829	100.00	.239	NS	
	Group B	5.353	95.94			
4 days	2 weeks	Group A	2.143	59.06	.071	NS
		Group B	1.735	43.57		
	4 weeks	Group A	3.314	91.34	.009	HS
		Group B	2.588	65.71		
	8 weeks	Group A	3.629	100.00	.754	NS
		Group B	3.765	94.29		
2 weeks	4 weeks	Group A	1.171	78.85	.221	NS
		Group B	.853	39.24		
	8 weeks	Group A	1.486	100.00	.087	NS
		Group B	2.029	89.87		
4 weeks	8 weeks	Group A	.314	100	.000	HS
		Group B	1.176	83.33		

NS- Non significant S- Significant HS- Highly significant

Table 8: pair wise intergroup comparison of percentage change in sensitivity scores in response to ice cold stimulus between group A and group B at different time intervals.

Time Interval		Group	Mean Difference	Percentage	P Value	
Base line	4 days	Group A	3.086	41.86	.286	NS
		Group B	2.743	38.25		
	2 weeks	Group A	5.371	72.87	.032	S
		Group B	4.429	61.75		
	4 weeks	Group A	7.086	96.12	.000	HS
		Group B	5.429	75.70		
8 weeks	Group A	7.343	99.61	.128	NS	
	Group B	6.629	92.43			
4 days	2 weeks	Group A	2.286	53.33	.020	S
		Group B	1.686	38.06		
	4 weeks	Group A	4.000	93.33	.000	HS
		Group B	2.686	60.65		
	8 weeks	Group A	4.257	99.33	.454	NS
		Group B	3.886	87.74		
2 weeks	4 weeks	Group A	1.714	85.71	.005	HS
		Group B	1.000	36.46		
	8 weeks	Group A	1.971	98.57	.213	NS
		Group B	2.200	80.21		
4 weeks	8 weeks	Group A	.257	90.00	.000	HS
		Group B	1.200	68.85		

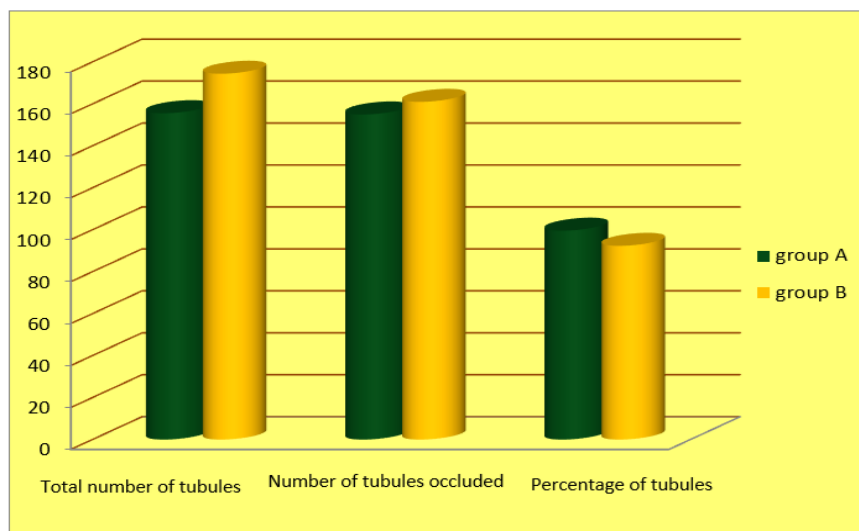


Image 1: Micrograph showing open dentinal tubules before application of arginine containing dentifrice (group A)

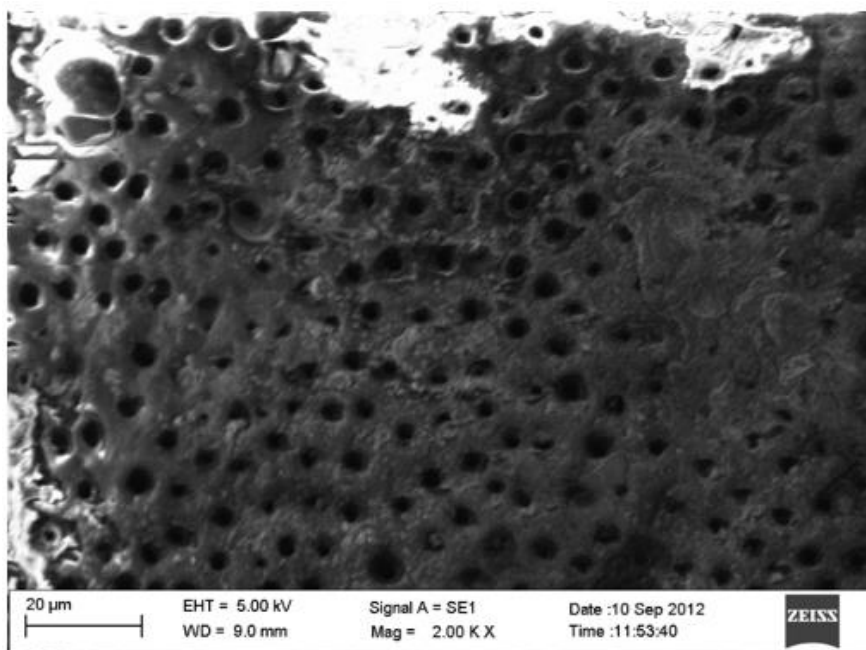


Image 2: Micrograph showing occluded dentinal tubules after application of (g

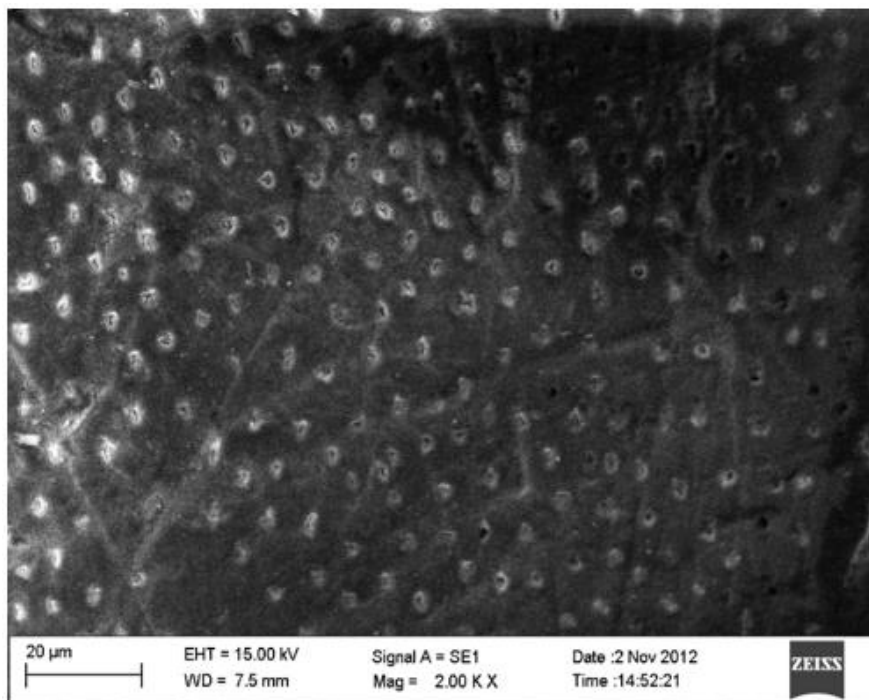


Image 3: Micrograph showing open dentinal tubules before application of calcium sodium phosphosilicate dentifrice (group B)

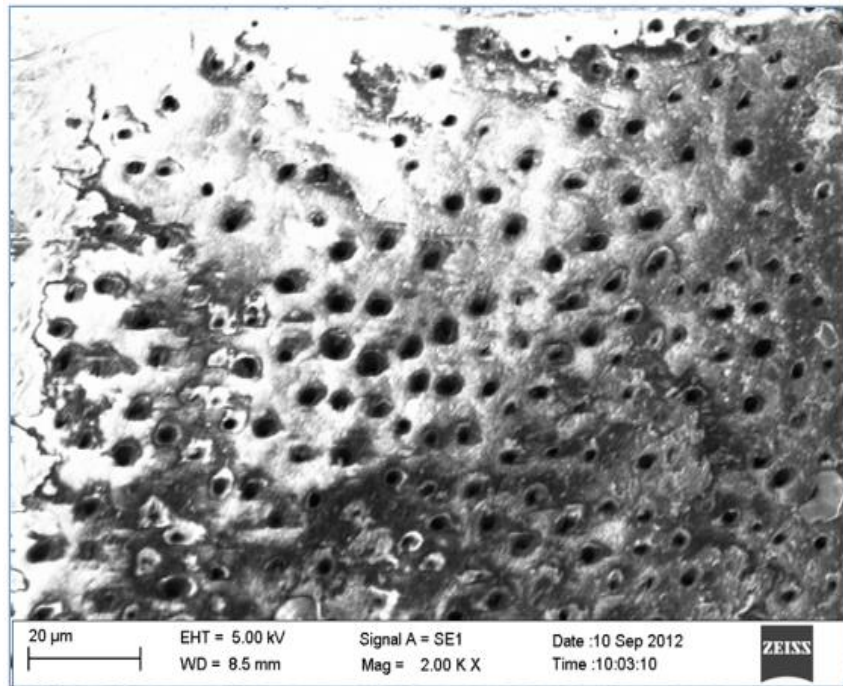


Image 4: Micrograph showing occluded dentinal tubules after application of calcium sodium phosphosilicate dentifrice (group B)

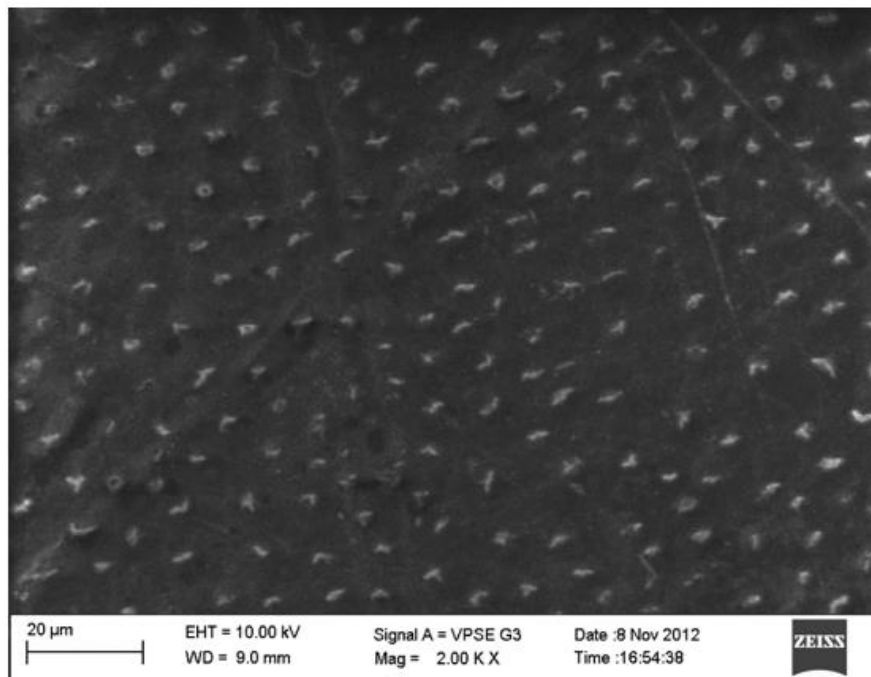


Fig 1: Elements present in dentinal tubule as detected by energy dispersive x-ray after application of arginine containing toothpaste (group A)

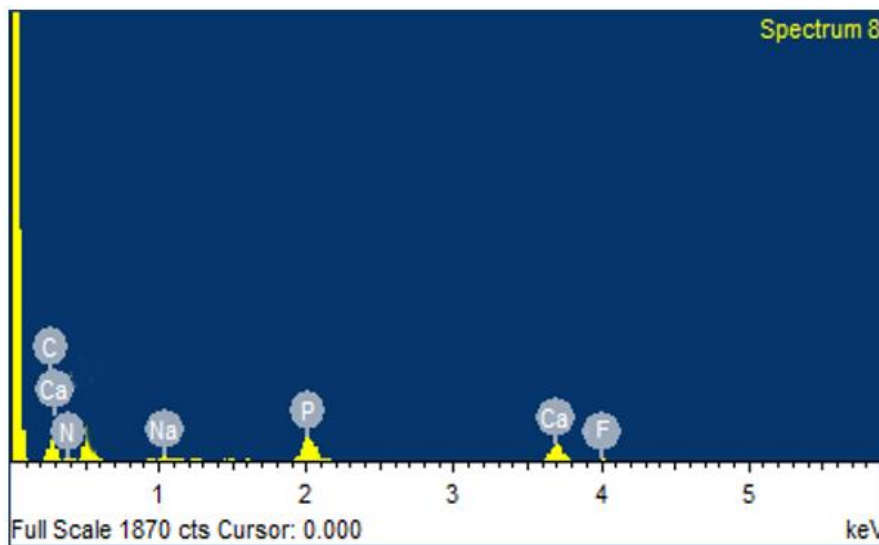


Fig 2: Elements present in dentinal tubule as detected by energy dispersive x-ray after application of calcium sodium phosphosilicate dentifrice (group b)

