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Research Article

EFFICACY OF A FLUORO-CALCIUM PHOSPHOSILICATE DENTRIFICE (ELSENZ®) AS COMPARED TO A POTASSIUM NITRATE DENTRIFICE IN THE TREATMENT OF DENTINAL HYPERSENSITIVITY: A RANDOMIZED CONTROLLED STUDY

Dr.Vaibhavi Bhatt, Dr.Asha Prabhu, Dr.Rahul Mehta, Dr.Meenu Pillai, Dr.Sushmita Bhakk and, Dr.Sweety Agarwal

Department of Pediatric Dentistry, Y.M.T Dental College and Hospital, Kharghar, Navi-Mumbai

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ABSTRACT

Aim: To compare and evaluate the efficacy of two desensitizing dentifrices (Elsenz and potassium nitrate), in presence of a control dentrifice (non-desensitizing) in the treatment of dentinal hypersensitivity.

Material and Methods: 58 patients were evaluated using tactile methods as well as cold air intensity score, along with subjective perception of pain at baseline and at 2weeks and 8weeks. 3 Groups were formed to assess and compare the effectiveness of Elsenz, potassium nitrate, and a control dentrifice respectively.

Results: There was a general decrease in dentinal hypersensitivity levels in both test groups as compared to the control group over the 8-week study period.

Conclusion: This study shows that the novel agent: fluoro-calcium phosphosilicate dentrifice (Elsenz) was successful in reduction of dentin hypersensitivity.

INTRODUCTION

Dentin hypersensitivity (DH) is characterized by a short, sharp pain 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 disease (1–4). This discomfort is a common finding in adult populations (5). Dentinal hypersensitivity poses a major problem as many patients are unable to perform adequate oral hygiene in hypersensitive areas thus leading to further plaque accumulation and degradation in gingival or periodontal health. (6)

Several theories have been proposed to explain the mechanism of dentinal hypersensitivity. Pashley and Parsons in 1987 [7] suggested 3 mechanisms of dentinal sensitivity: Nerve endings or nociceptors that respond directly when dentin is stimulated, located throughout dentin. Odontoblasts, being chemically or electrically related to nerves, function when depolarized as receptors generating nerve impulses. Stimuli applied to dentin producing displacement of dentinal tubule contents which could excite mechanosensitive nerve endings near the pulpal end of the tubules (hydrodynamic mechanism). Current, evidence favours the hydrodynamic theory originally postulated in the 19th century and later developed by Brannstrom in 1963 [8]. This theory suggested that dentinal tubules act as capillary tubes and the fluid within them obeys the laws of fluid movement. The rapid movement of fluid in the dentinal tubules in response to certain stimuli may cause distortion of intradental nerves and generate a response.

Currently, there are many agents used to manage hypersensitivity. Conventional therapy for hypersensitivity is based on using topically applied desensitizing agents, either professionally or at home. A lot of research has been done to evaluate the efficacy of conventional agents such as Potassium nitrate, strontium chloride, Pro-arginine etc. with varying results.

Very limited data exists on the efficacy of a novel desensitising agent containing fluoro-calcium phosphosilicate (Elsenz). Elsenz is a form of bioactive glass that claims to form acid resistant fluoroapatite, thus treating hypersensitivity. Hence, this study was carried out to compare and evaluate the effectiveness of two desensitizing dentifrices (Elsenz and potassium nitrate) in the treatment of dentinal hypersensitivity.

Corresponding author:* **Dr.Vaibhavi Bhatt
Y.M.T Dental College and Hospital, Kharghar, Navi-Mumbai

MATERIALS AND METHOD

Inclusion Criteria

1. Patients with complaint of dentinal hypersensitivity.
2. Patients providing informed consent to accept the treatment and be a part of the said study.

Exclusion Criteria

1. Dental pathoses, which caused pain similar to cervical dentinal hypersensitivity (teeth with caries);
2. Orthodontic appliances or restorations (crowns, cervical restorations, bridgework) that interfered with the evaluation or were a possible cause of pain;
3. Allergy to drugs or chemicals used in the study; or
4. Pregnant at the time of screening

60 patients of both genders from the Department of Periodontics, Dr.G.D.Pol's YMT Dental College and Hospital, Navi Mumbai, were included in the study. The study was approved by the Institute's Ethical Committee.

Screening and Selection Procedures

Subjects who gave their oral and written informed consent and satisfying inclusion criteria were included in the study. A pre-assessment tool was handed over to the patients as a pre-assessment tool (described later). All the participants were subjected to oral examination. Only those teeth demonstrating dentinal hypersensitivity were included in the study. Sensitive teeth were identified with the following methods. Randomization was done using a computer software (Research Randomizer).

Tests for Recording Cervical Dentinal Hypersensitivity

Following methods were used to record cervical dentinal hypersensitivity (9).

Tactile Method-probe Intensity score (PI)

The subject will also be asked to rate the perception of the sensitivity experienced during the scratch process, using a probe. The responses were scored between 0 to 10 (where 0=no pain and 10=excruciating pain) based on a numerical rating visual analog scale (NRS) described by Gillam *et al*. This was considered the "probe intensity score."

Cold air Intensity Score (CAI)

Exactly 10 minutes after the scratch response was recorded, a 2-second application of cold air from a dental unit syringe (at 20° ±3°C at 70-80 psi) were directed perpendicularly to the exposed root surface after isolating the test tooth. The subject was again asked to rate the perception of sensitivity experienced during this test as a score of 0 to 10 (where 0=no pain and 10=excruciating pain). This was recorded as the "cold air intensity score."

Schiff's Score(S)(10)

Patients were also assessed using Schiff's air sensitivity test with following scores:

0- Tooth/subject does not respond to air stimulus
1- Tooth/subject responds to air stimulus but does not request discontinuation of stimulus
2-Tooth/subject responds to air stimulus and requests discontinuation or moves from stimulus
3- Tooth/subject responds to air stimulus, considers stimulus to be painful and requests discontinuation of stimulus

The patients were evaluated at baseline, 2 weeks and 8 weeks.

Subjective Reporting of pain at Baseline-Overall Sensitivity score

Subjects were also asked to rate their perception to hot/cold food and drink, air, tooth-brushing, and to sweet and sour food by providing a score of 0 to 10 (where 0=no pain and 10=excruciating pain). Also, their oral hygiene techniques were evaluated using the same pre-assessment tool.Following screening, subjects were randomly allocated to 1 of 2 treatment groups. All clinical measurements described above were re-recorded at 2 and 8weeks (11).The patients were then randomly distributed into 3 groups of 20 patients each.

Group A: Elsenz
Group B: Potassium nitrate
Group C: Control group

The patients were instructed to follow appropriate brushing techniques with the given dentifrice, twice a day for 2mins, a period of 8weeks. They were asked to return the used/empty toothpaste tubes during their subsequent visits at which time replacement products were provided.

The operators (MP, SB) were blinded to the procedure and similar paste tubes with labels 'A', 'B' and 'C' were provided to them at the time of treatment.

2 patients from Group A dropped out of the study and were hence not considered for statistics.

Statistical Analysis

Data obtained was compiled on a MS Office Excel Sheet (v 2010) & subjected to statistical analysis using Statistical package for social sciences (SPSS v 21.0, IBM).

Normality of data was checked using Kolmogorov Smirnov Test. It was found that since data did not follow a normal curve and was coded as ordinal over a scale of 0 to 10, non parametric tests have been used for testing of hypothesis.

Inter group comparison of all variables was done using Kruskal Wallis ANOVA followed by Mann Whitney U test for pairwise comparisons. Comparison of variables from baseline to follow-ups in each group was done using Friedman's test followed by Wilcoxon Signed Rank test for pairwise comparisons.

For all the statistical tests, $p<0.05$ was considered to be statistically significant, keeping α error at 5% and β error at 20%, thus giving a power to the study as 80%.

RESULTS

At Baseline

	Group	Vs group	Mann Whitney U value	Z value	p value
Subjective	1	2	157.500	-0.730	0.466#
reporting at	1	3	132.500	-1.480	.139#
Baseline	2	3	162.500	-1.114	.265#

There was a statistically non-significant difference seen with pair-wise comparison of variables like subjective reporting at baseline between all 3 pairs

Inter Group Comparison of Variables (using Kruskal Wallis test)

Table 1 Showing Inter group comparison of variables (using Kruskal Wallis test)

	Groups	N	Mean	Std. Deviation	Std. Error	Median	Minimum	Maximum	Chi square value	p value of Kruskal Wallis test
Subjective reporting at Baseline	1	18	2.28	.752	.177		1	3	2.663	0.264#
	2	20	2.15	.587	.131		1	3		
	3	20	1.90	.788	.176		1	3		
	Total	58	2.10	.718	.094		1	3		
PIS Baseline	1	18	3.17	1.043	.246		1	5	1.848	0.397#
	2	20	3.10	.718	.161		2	4		
	3	20	2.70	1.261	.282		1	5		
	Total	58	2.98	1.034	.136		1	5		
PIS 2 weeks	1	18	.50	.618	.146		0	2	13.450	0.001**
	2	20	.50	.513	.115		0	1		
	3	20	1.60	1.188	.266		0	4		
	Total	58	.88	.975	.128		0	4		
PIS 8 weeks	1	18	.22	.428	.101		0	1	20.577	0.000**
	2	20	.35	.489	.109		0	1		
	3	20	1.65	1.268	.284		0	4		
	Total	58	.76	1.048	.138		0	4		
CAI Baseline	1	18	3.78	1.263	.298		2	7	4.883	.087#
	2	20	3.50	.889	.199		2	5		
	3	20	2.90	1.373	.307		1	6		
	Total	58	3.38	1.226	.161		1	7		
CAI 2 weeks	1	18	1.00	1.085	.256		0	4	16.964	0.000**
	2	20	.65	.671	.150		0	2		
	3	20	2.30	1.455	.325		0	6		
	Total	58	1.33	1.316	.173		0	6		
CAI 8weeks	1	18	.28	.461	.109		0	1	27.887	0.000**
	2	20	.35	.489	.109		0	1		
	3	20	2.30	1.455	.325		0	6		
	Total	58	1.00	1.325	.174		0	6		
SS Baseline	1	18	2.44	.784	.185		1	3	4.318	0.115#
	2	20	2.15	.745	.167		1	3		
	3	20	1.90	.852	.191		1	3		
	Total	58	2.16	.812	.107		1	3		
SS 2 weeks	1	18	.78	.548	.129		0	2	15.517	0.001**
	2	20	.50	.607	.136		0	2		
	3	20	1.60	.995	.222		0	3		
	Total	58	.97	.878	.115		0	3		
SS 8weeks	1	18	.28	.461	.109		0	1	22.203	0.000**
	2	20	.35	.489	.109		0	1		
	3	20	1.50	.946	.212		0	3		
	Total	58	.72	.874	.115		0	3		

* = statistically significant difference ($p<0.05$)
** = statistically highly significant difference ($p<0.01$)
\# = non significant difference ($p>0.05$)

There was a statistically highly significant difference seen with inter group comparison of variables like

1. PIS at 2 weeks and 8 weeks ($p<0.01$) with highest value for group C at 2 weeks and 8 weeks,
2. CAI at 2 weeks & 8 weeks ($p<0.01$) with highest value for group C at 2 weeks and 8 weeks
3. Schiff's Score at 2 weeks & 8 weeks ($p<0.01$) with highest value for group C at 2 weeks and 8 weeks

However there was a statistically non-significant difference seen with inter group comparison of variables of the variables PIS, CAI, Schiff's Score & subjective reporting at Baseline ($p>0.05$)

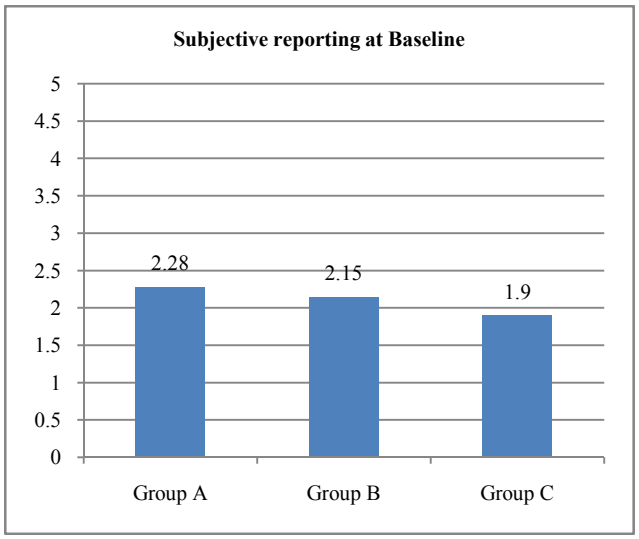

Fig 1 Bar Graph shows the comparative scores of subjective reporting of pain at baseline. Intergroup comparison showed no statistically significant difference between the scores of the three groups.

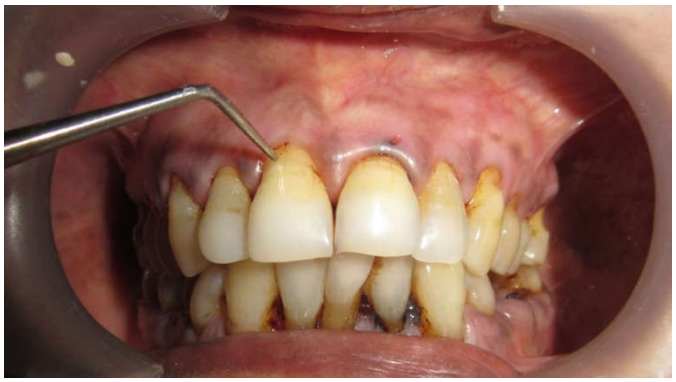

Figure 2 Demonstration of use of tactile method to elicit response of dentinal hypersensitivity.

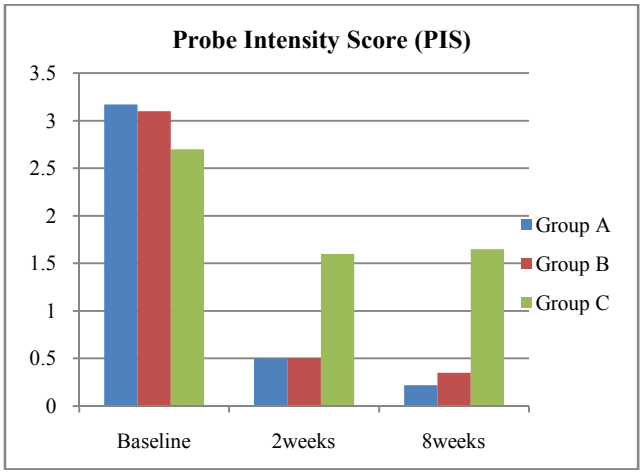

Figure 3 Bar Graph shows the comparative scores of probe intensity score (PIS). Intergroup comparison showed highly statistically significant difference between the scores of the three groups from baseline to 2 weeks and baseline to 8 weeks ($p<0.01$).

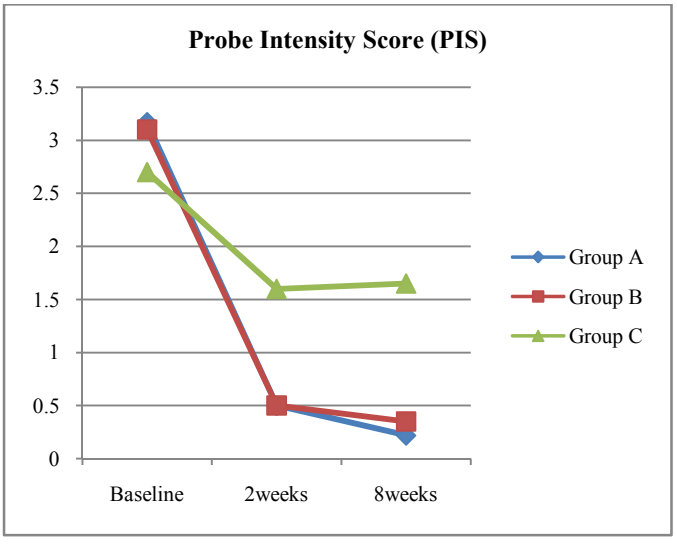

Figure 4 Graph shows the comparative scores of probe intensity score (PIS). Intergroup comparison showed highly statistically significant difference between the scores of the three groups from baseline to 2 weeks and baseline to 8 weeks ($p<0.01$).

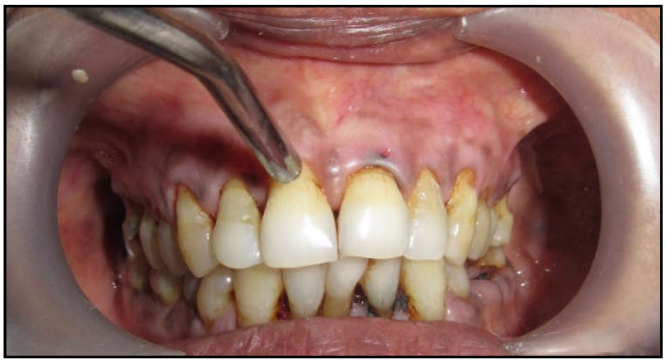

Figure 5 Air-blast applied using dental unit syringe to evaluate dentinal hypersensitivity.

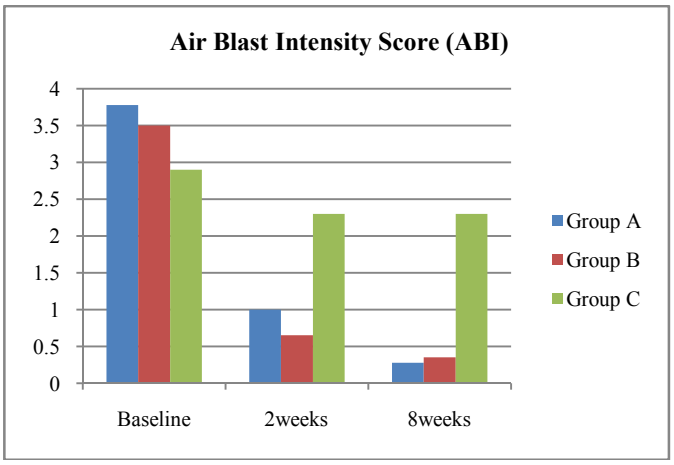

Figure 6 Graph shows the comparative scores of air-blast intensity score (ABI). Intergroup comparison showed highly statistically significant difference between the scores of the three groups from baseline to 2 weeks and baseline to 8 weeks ($p<0.01$).

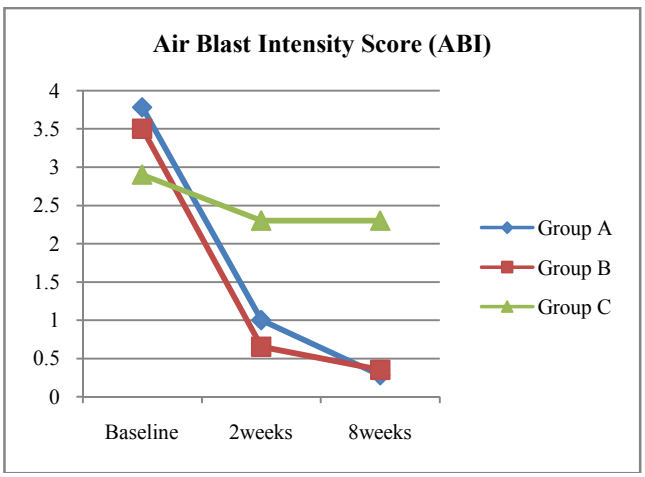

Figure 7 Graph shows the comparative scores of air blast intensity score (ABI). Intergroup comparison showed highly statistically significant difference between the scores of the three groups from baseline to 2 weeks and baseline to 8 weeks ($p<0.01$).

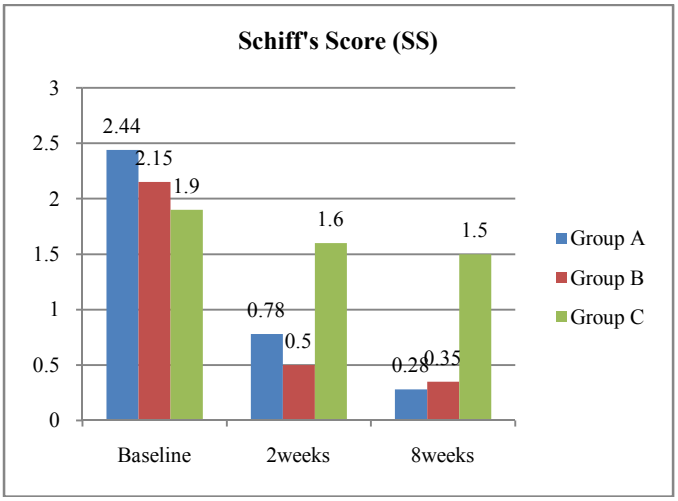

Fig 6 Graph shows the comparative scores of Schiff's score. Intergroup comparison showed highly statistically significant difference between the scores of the three groups from baseline to 2 weeks and baseline to 8 weeks (p<0.01).

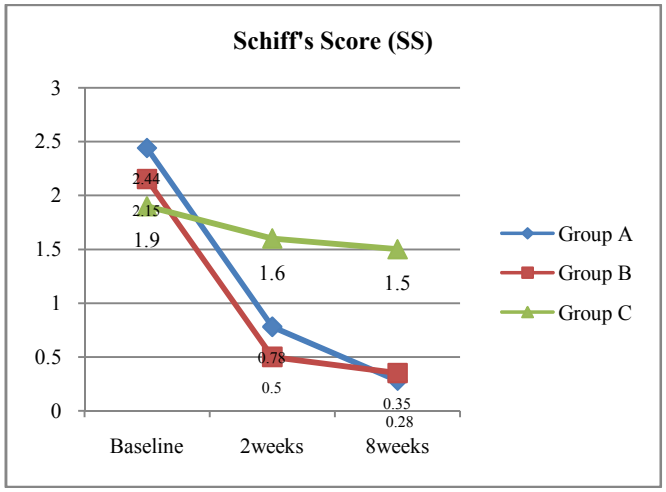

Figure 9 Graph shows the comparative scores of Schiff's score. Intergroup comparison showed highly statistically significant difference between the scores of the three groups from baseline to 2 weeks and baseline to 8 weeks (p<0.01).

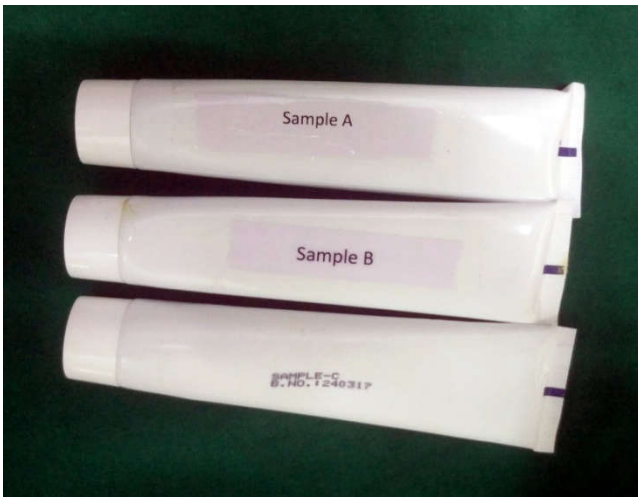

Figure 10 Samples provided for the study

Pair-wise Comparison of the Variables

Variables	Group	Vs group	Mann Whitney U value	Z value	p value
Probe intensity score at baseline	A	B	168.00	-0.372	0.710#
	A	C	141.000	-1.182	.237#
	B	C	161.000	-1.098	.272#
Probe intensity score at 2 weeks	A	B	175.00	-0.167	0.867#
	A	C	81.500	-3.026	.002**
	B	C	90.000	-3.153	.002**
Probe intensity score at 8 weeks	A	B	157.00	-0.856	0.392#
	A	C	56.000	-3.880	.000**
	B	C	75.000	-3.590	.000**
Cold Air Intensity Score at baseline	A	B	160.00	-0.616	0.538#
	A	C	114.000	-1.985	.047*
	B	C	139.500	-1.697	.090#
Cold Air Intensity Score at 2 weeks	A	B	151.500	-0.898	0.369#
	A	C	81.500	-2.967	.003**
	B	C	61.000	-3.878	.000**
Cold Air Intensity Score at 8 weeks	A	B	167.00	-0.472	0.637#
	A	C	37.000	-4.382	.000**
	B	C	44.000	-4.403	.000**
Schiff's Score at baseline	A	B	138.500	-1.318	0.188#
	A	C	117.000	-1.976	.048*
	B	C	166.000	-.977	.329#
Schiff's Score at 2 weeks	A	B	133.00	-1.556	0.120#
	A	C	92.000	-2.751	.006**
	B	C	77.000	-3.496	.000**
Schiff's Score at 8 weeks	A	B	167.00	-0.472	0.637#
	A	C	52.000	-3.972	.000**
	B	C	65.000	-3.875	.000**

This table shows pair-wise comparison of variables between all 3 groups.

There was a statistically highly significant difference (p<0.01) seen with probe intensity score (at 2 weeks) between Group A and C & Group B and C respectively, but statistically non-significant difference seen between Group A & B. Also, there was a statistically highly significant difference (p<0.01) seen with probe intensity score (at 8 weeks) between Group A and C & Group B and C respectively, but statistically non-significant difference seen between Group A & B.

There was a statistically highly significant difference (p<0.01) seen with cold air intensity score (at 2 weeks) between Group A and C & Group B and C respectively, but statistically non-significant difference seen between Group A & B.

Also, there was a statistically highly significant difference (p<0.01) seen with cold air intensity score (at 8 weeks) between Group A and C & Group B and C respectively, but statistically non-significant difference seen between Group A & B. There was a statistically highly significant difference (p<0.01) seen with Schiff's score (at 2 weeks) between Group A and C & Group B and C respectively, but statistically non-significant difference seen between Group A & B.

There was a statistically highly significant difference (p<0.01) seen with Schiff's score (at 8 weeks) between Group A and C, Group A and B & Group B and C respectively.

DISCUSSION

Both the test groups showed a statistically significant reduction in dentinal hypersensitivity at 2 weeks and 8 weeks respectively, as compared to the baseline. There was no statistically significant difference between results of Group A

and Group B. Group C showed consistently higher values as compared to the test groups, depicting the higher efficacy of test products as compared to the control.

Our findings of reduced symptoms in both test and control groups are similar to studies of Pearce *et al*.,(12) Chesters *et al*.,(13) and West *et al*.,(14). This could be explained by the presence of a very large placebo effect of 30 to 40% (15) seen in most of these dentinal hypersensitivity studies. This does not necessarily rule out a therapeutic effect for the test product but clearly demonstrates that individuals participating in a clinical trial on dentinal hypersensitivity often show improvement in symptoms. The mere suggestion to a patient that a prescribed product is an effective treatment can bring about considerable improvement regardless of the formulation's therapeutic potential.

As scratching was completed prior to air blast, one may suppose that the scratching test did not damage the dentin surface to such an extent that it increased sensitivity to air blast. A previous study showed that the dentinal grooves made by a probe under clinically relevant forces were between 20 and 30 lm wide (11,16). The dentin area exposed by scratching was so small compared with the dentin area exposed to air blast that it likely did not influence the prevalence of sensitivity to air blast (16).

The VAS was used to assess the subjective perception of the patients with thermal / evaporative stimuli. The subject response was quantified by using the VAS, which is considered as preferable to a numerical rating scale.(17) This scale has been reported as reliable in the literature for pain assessment (18, 19) and can complement the tactile testing method.

CONCLUSION

The results of this clinical study establish the efficacy of the novel fluoro-calcium phosphosilicate dentrifice (Elsenz) in treating dentin hypersensitivity. Its desensitising action is seen comparable to the conventional potassium nitrate dentrifice.

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Conflict of Interest: Nil

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