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Case Report

A clinical trial comparing a stannous fluoride based dentifrice and a strontium chloride based dentifrice in alleviating dentinal hypersensitivity

Vinaya Kumar R*, N. Shubhashini, Hema Seshan***, Kranti K******

*MDS ,Senior Lecturer, Periodontics, V.S. Dental College & Hospital, Bangalore ** MDS ,Senior Lecturer,Department of Conservative Dentistry & Endodontics, V.S. Dental College, Bangalore ***MDS, Professor and Head Department Of Periodontics, M.S. Ramaiah Dental College & Hospital, Bangalore. ****MDS , Associate Professor, Periodontics, M.S. Ramaiah Dental College & Hospital, Bangalore. Contact: ramachandravinayakumar@yahoo.in

Abstract

Introduction: Tooth hypersensitivity, or more precisely dentine sensitivity or hypersensitivity, is described clinically as an exaggerated response to non-noxious stimuli and satisfies all the criteria to be classified as a true pain syndrome. According to the widely accepted hydrodynamic theory proposed by Brannstrom in the late 1950s, the displacement of fluids in the dentine and pulp stimulates the nerves causing pain. A considerable number of varied agents are apparently effective in the treatment of dentine hypersensitivity. In particular, the literature supports the efficacy of fluoride and strontium containing formulations. *Objective:* This study was a double-blind parallel group comparison of the efficacy of a strontium chloride and stannous fluoride dentifrice in the

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treatment of dentine hypersensitivity. *Methods:* A total of 107 patients completed the 6-week study and from them, sensitivity gradings were obtained at baseline, 2 and 6 weeks. Sensitivity was scored in response to cold air and scratching with a dental probe Patients also graded their overall sensitivity at each visit, using a visual analogue scale and the effects of treatment on completion. Plaque and gingival indices were recorded at each visit.*Results:* There was an overall and progressive reduction in all sensitivity parameters in the two groups with a significant reduction in hypersensitivity in patients using the stannous fluoride based product. Plaque and gingival scores were already relatively low in this patient group at baseline but improved further as the study continued. *Conclusions:* Under the conditions of this clinical trial, the stannous fluoride dentifrice showed a greater reduction in sensitivity compared to the strontium based desensitizing toothpaste. There is perhaps a need for more studies of potential desensitizing formulations where comparison is made with a conventional fluoride toothpaste product.

Key words: Dentine Hypersensitivity, Fluorides, Strontium, Clinical Trials.

Introduction:

The ever-changing profiles of human diseases in mankind's history have not left dentistry untouched. The improving oral health status of populations, people keeping more teeth for longer, for example, has brought impressive benefits, but at the same time has created or raised awareness of other oral and dental health problems. Following the decline of dental caries, the management of periodontal diseases gained priority, and other, painful dental problems, such as dentine hypersensitivity stepped forward.[(1)] Tooth hypersensitivity, or more precisely dentine hypersensitivity is one of the oldest recorded complaints of discomfort to mankind.[(2)] The term dentine hypersensitivity has been used for many decades to describe a common painful condition of the teeth.

In 1982, Johnson and co-workers stated, "Dentine hypersensitivity is an enigma, being frequently encountered yet ill understood." Dowell and Addy (1983) and Flynn *et al.* (1985), stated that dentine sensitivity may be a more correct descriptor as there is no evidence that dentine is any way different or the pulpal response exaggerated. Pashley (1990) stated that even the terminology for the condition can be inaccurate.[(3)]

A definition for dentine hypersensitivity was suggested in 1983 and, with minor amendment, was adopted by an international workshop on the design and conduct of clinical trials for treatment of the condition. The definition states: "Dentine hypersensitivity is characterized by short, sharp pain arising from exposed dentine 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." The Canadian Advisory Board on Dentine Hypersensitivity in 2002 suggested that it would be more correct to substitute 'disease' for 'pathology.' The definition provides a clinical descriptor for the condition and identifies dentine hypersensitivity as a distinct clinical entity, thereby encouraging

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the clinician to consider a differential diagnosis.[4]

The condition is dependent on exposed dentine that results in the patency of dentinal tubules because of brushing and the changing condition of the oral environment.[5] Dentine exposure increases with age, peaking in young adults and then decreasing with age.[6] Abrasion, attrition, erosion and gingival recession contribute to the loss of enamel and cementum. The estimates of the prevalence of dentinal hypersensitivity vary considerably from 8% to 30% of the adult dentate population; however, these figures are probably an underestimate because not all dental patients report the condition.[5]

Thermal, tactile, chemical and osmotic stimulations cause a painful response if applied to exposed dentine surfaces.[7] Painful stimulus takes place when dentine is exposed to the oral environment or when it is not covered by enamel or periodontal tissues. The flow of fluids inside the dentine tubules indirectly stimulates nerve endings, according to the hydrodynamic theory.[6]

The treatment of dentinal hypersensitivity comprises a variety of regimens, including dentist-applied in-office treatments and patient-applied over-the-counter dentifrices. The latter treatment, which reaches a larger population, is the preferred choice among both patients and dentists. In addition, dentifrices historically have played and continue to play an important role as a vehicle to deliver an active agent. The patients' natural learned behavior to clean their teeth increases the compliance factor if the active agent is in a dentifrice.[5]

A large variety of therapeutic agents have been proposed to reduce sensitivity: strontium chloride, sodium glutaraldehyde, corticosteroids, cavity varnishes, glass ionomers and potassium nitrate. Fluoride, in the form of sodium fluoride or stannous fluoride, has been widely used for this therapy in different application forms, such as toothpaste, gels, mouthrinses or fluoride solutions.[5,6]

Dentifrices containing 10% strontium chloride hexahydrate as the desensitizing agent have been widely available for four decades. The results of early and recent studies demonstrate that home use of a 10% strontium chloride hexahydrate desensitizing dentifrice is effective in relieving the pain of tooth hypersensitivity.[8] Available evidence suggests that strontium chloride acts as a protein precipitant and a tubule occluding agent.[9] The incorporation of strontium chloride in a dentifrice has enjoyed success, some trials claiming 75 - 80% improvement.[8-11]

The use of stannous fluoride (SnF_2) as an oral therapeutic agent dates back to the 1950s when it was used in dentifrices as an anti-caries agent. More recent evidence from *in vitro* and human clinical studies indicate that stannous fluoride also has antibacterial properties as well as the ability to reduce dentinal hypersensitivity.[12] It is postulated that this desensitizing effect is due to

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occlusion of the dentinal tubules, preventing the stimulation of free nerve endings (nociceptors) encased by these tubules, preventing a painful response to thermal, chemical or tactile stimulation.[13]

The objective of this study was to compare the efficacy of two desensitizing dentifrices, namely a stannous fluoride dentifrice and a strontium chloride dentifrice, in alleviating dentine hypersensitivity. The opportunity was taken to monitor the oral hygiene and gingival health of the patients during the study.

Materials and methods

The study was a single-center, double-blind, concurrent parallel treatment group design to compare the efficacy of two desensitizing dentifrices in the treatment of dentine hypersensitivity.

Subjects: The informed consent of all subjects who participated in this clinical investigation was obtained after the possible discomforts, risks and procedures were fully explained. The study population consisted of 110 otherwise healthy individuals (55 males and 55 females), aged 18 to 65 years, who expressed a willingness to participate in the study. The mean age of the subject population was 39 years.

Screening and selection procedures: All subjects were given an oral examination to ensure that all subjects were in good general health except for the symptoms of dentinal hypersensitivity. Detailed clinical and radiographic investigations were performed on all patients to exclude conditions of teeth, which might have caused pain similar to dentine hypersensitivity. Sensitive teeth were identified with a straight explorer cervically evaluating each tooth. The tooth response to cold air was assessed using a standard dental three way syringe at 40 to 60 psi at a temperature of 19ºC ± 3ºC.

Inclusion Criteria:

- Subjects aged between 18 years to 65 years.
- Subjects in whom dentine hypersensitivity was elicited as a recurrent short, sharp pain arising from the buccal cervical margin of teeth in response to stimuli, in particular cold.
- Subjects clinically confirmed to have dentinal hypersensitivity accompanied by cervical abrasion or erosion, gingival recession or both.
- Subjects in whom at least two teeth were identified as hypersensitive by clinical investigations and consequent diagnosis.

Exclusion Criteria:

- Patients with pain elicited from areas of exposed dentine other than the buccal cervical margin of the tooth & teeth suspected to have pulpitis, caries, cracked enamel or defective restorations.
- Patients with teeth being used as abutments for removable partial dentures & patients wearing orthodontic appliances.

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- Patients with a history of allergy to drugs or chemicals used in the study.
- Patients who are on continuous use of analgesics.
- Patients who are psychologically compromised.

Study Design:

At the baseline visit volunteers underwent a dental examination. Records were taken of the teeth and restorations present and the subject's view of which teeth were sensitive was noted. Gingival recession was recorded from the midbuccal surface of all teeth, and measured in millimeters from the cementoenamel junction (CEJ) to the gingival margin using a William's probe. Cervical dentine abrasion from the same sites was graded as: 0 = no wear; 1 = exposed dentine; 2 = cervical cavity with dentine loss ≤ 1 mm; and 3 = cervical cavity with dentine loss > 1 mm. Enamel loss was also recorded when appropriate as present or absent.

All teeth with clinically detectable exposed buccal cervical dentine were stimulated with 2 tests: a 3-second blast of cold air from an air syringe held 3 mm away from the exposed dentine (Figure 4) and scratching horizontally across the zone of exposed dentine with a modified William's probe tip (Figure 3). The probe was modified and designed to deliver a pre-set force of 25g when the tip was applied perpendicular to the cervical labial surface (Figure 2). Each tooth was isolated with cotton rolls and cellophane matrix strips placed interproximally prior to stimulation.

The subject was asked to subjectively grade the discomfort experienced with each stimulus as: 0 = no discomfort; 1 = discomfort, 2 = pain during stimulation only; 3 = pain during stimulation and persisting after stimulation. A period of at least 5 minutes, to allow for recovery, elapsed between the application of the different stimuli to individual teeth. Finally, the patients were requested to grade their overall sensitivity using a 10 cm Visual Analogue Scale (VAS) labelled at the extremes with "no pain," at the zero cm end of the scale, and "severe pain," at the 10 cm end of the scale. Measurements from the scale were made in millimeters giving a scoring range of 0 to 100.

In an attempt to monitor the overall oral hygiene of the subjects during the study, dental plaque was scored using the criteria of the Silness & Loe index (1964). Gingival health was assessed by the Loe & Silness index (1963).

Subjects were randomly allocated to one of two treatment groups:

1) Strontium chloride group: SC group
2) Stannous fluoride group: SF group

They were then assigned the allocated dentifrice to be used twice daily for a period of 6 weeks.

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The toothpaste products were (Figure 5):

1) a 10% w/w strontium chloride-based desensitizing product, and
2) a 0.4% stannous fluoride-based desensitizing product

Brushing protocol:

Subjects were instructed to brush their teeth with the assigned dentifrice for at least 1 minute twice daily. The unit dose was a strip of dentifrice, 1 inch in length, applied to a wet toothbrush. Subjects were prohibited from using their regular dentifrice but could continue their usual, daily oral hygiene procedures. No specific instructions were provided as to the method of brushing.

At 2 and 6 weeks after baseline assessment and provision of the products, the patients were recalled and assessed for sensitivity, plaque and gingivitis indices. At the end of the treatment phase, week 6, the patients were asked to grade their sensitivity compared to baseline as 1 = much worse; 2 = worse; 3 = the same; 4 = better; and 5 = much better.[5,14,15]

Results:

Of the 110 individuals recruited, 3 subjects did not complete the study due to attendance difficulties and analyses are based on 107 patients. The remaining group was comprised of 53 females and 54 males, age range 18 to 65 years (mean age: 39 years). There were 54 subjects in the strontium chloride toothpaste group (SC) and 53 in the stannous fluoride dentifrice group (SF). The groups appeared well matched for personal and dental details.

In mean terms, at baseline, the SC group had less sensitivity than the SF group. There was a significant difference in the mean cold air sensitivity scores at the 6^{th} week between the two groups ($p<0.05$) by the Student's t-test (Table 1). Further, there was a significant difference in the mean scratch test scores at the 6^{th} week between the two groups ($p<0.001$) by the Student's t-test (Table 2).

Paired Student's t-test was used to test the mean difference in cold air sensitivity scores and scratch test scores at baseline, 2^{nd} week and 6^{th} week. The difference was highly significant ($p<0.001$) in the SC group as well as the SF group (Figure 6 and 7).

Overall, both the treatments resulted in progressive and proportionately large intra-group improvements in sensitivity scores throughout the 6-week treatment period. Intergroup comparisons revealed that the improvements were significantly different by treatment. Significance was obtained at 6 weeks for the cold air sensitivity scores ($p<0.05$) and for the scratch test scores ($p<0.001$), where the SC group improvement was significantly less than the SF group.

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Table 1. Cold air stimulation (Mean & SD by treatment and visit)

Time	**SC Group** *(n = 54)*	***SF Group*** *(n = 53)*
Baseline	2.44 (0.664)	2.70 (0.463)
Week 2	1.81 (0.646)	1.94 (0.569)
Week 6	1.26 (0.620)	1.06 (0.362)

Table 2.Manual scratching with probe tip (Mean & SD by treatment and visit)

Time	**SC Group** *(n = 54)*	***SF Group*** *(n = 53)*
Baseline	2.13 (0.584)	2.21 (0.567)
Week 2	1.41 (0.599)	1.21 (0.743)
Week 6	0.78 (0.538)	0.36 (0.522)

Table 3. Visual analogue scores of overall discomfort

Time	**SC Group** *(n = 54)*	***SF Group*** *(n = 53)*
Baseline	58.33 (23.005)	65.28 (19.695)
Week 2	36.11 (19.969)	42.36 (19.990)
Week 6	20.83 (17.204)	15.38 (12.628)

Table 4. Silness & Loe plaque index scores (Mean & SD by treatment and visit)

Time	**SC Group** *(n = 54)*	***SF Group*** *(n = 53)*
Baseline	1.4233 (0.214)	1.3719 (0.149)
Week 2	1.2839 (0.182)	1.2279 (0.112)
Week 6	1.14 (0.158)	1.10 (0.077)

Table 5. Loe & Silness gingival index scores (Mean & SD by treatment and visit)

Time	**SC Group** *(n = 54)*	***SF Group*** *(n = 53)*
Baseline	1.256 (0.171)	1.263 (0.146)
Week 2	1.17 (0.131)	1.17 (0.128)
Week 6	1.07 (0.093)	1.06 (0.069)

Table 6. End of treatment evaluation of overall effect

Overall effect	**SC Group** *(n = 54)*	***SF Group*** *(n = 53)*
Much Better	12	19
Slightly Better	40	34
No Change	2	0

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Figure 1. Armamentarium

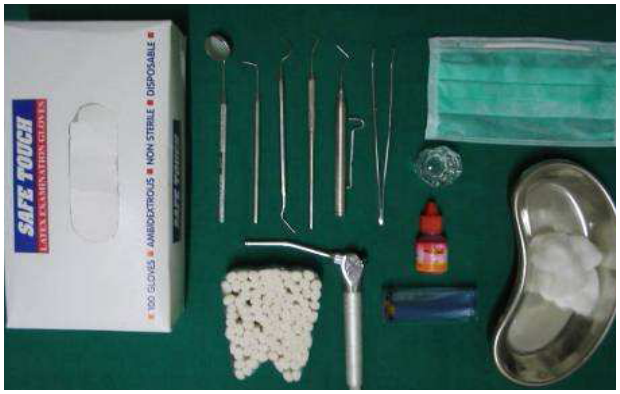

Figure 2. Modified williams probe

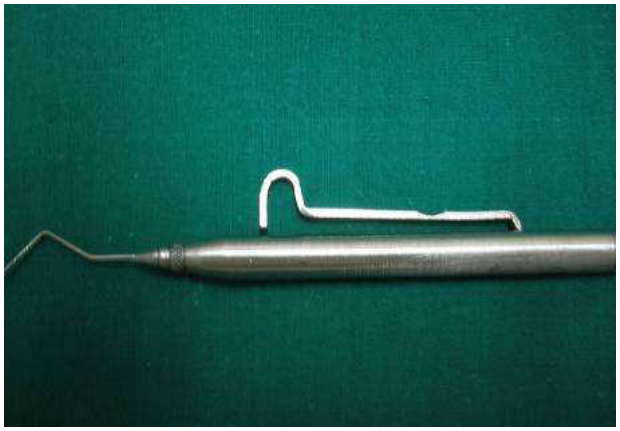

Figure 3. Manual scratch test

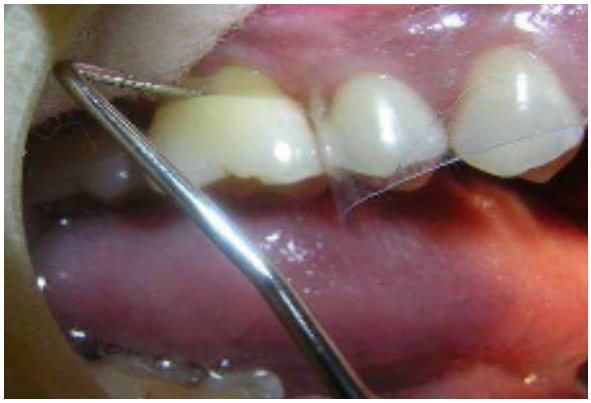

Figure 4. Cold air blast test

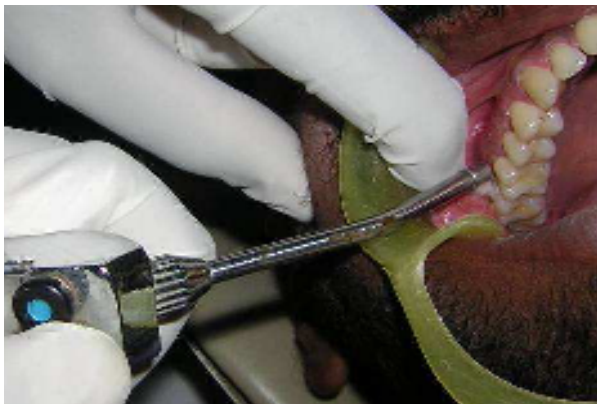

Figure 5. Desensitizing dentifrices

Figure 6. Cold air stimulation

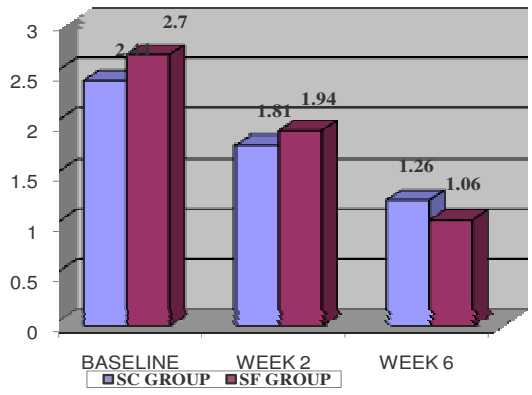

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Figure 7. Manual scratching with probe tip

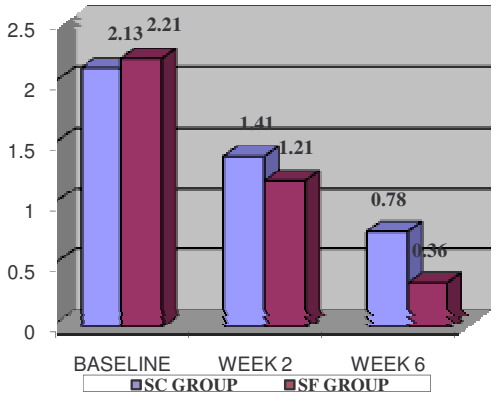


Figure 8. Visual analogue scores

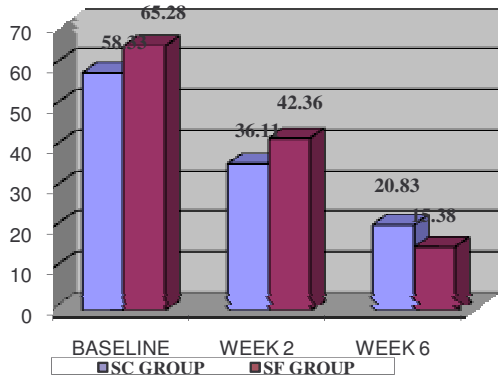


Figure 9. Silness and loe plaque index

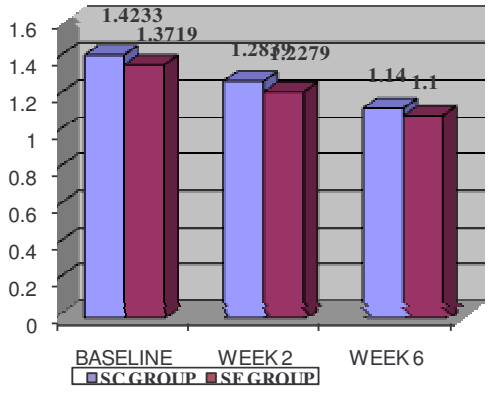


Figure 10. Loe & silness gingival index

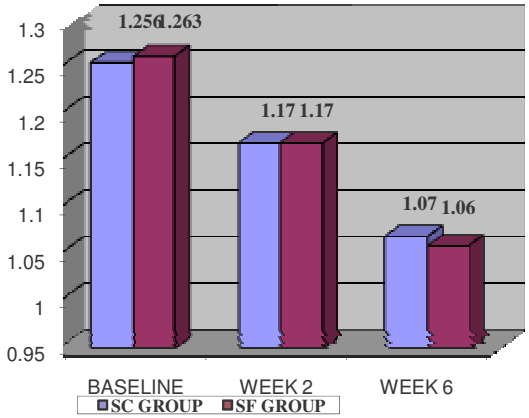
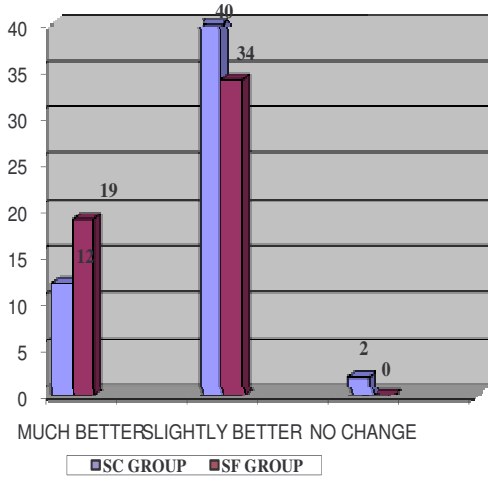


Figure 11. Evaluation of overall effect at end of treatment



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In the case of visual analogue scores, there were improvements in both the groups at each subsequent visit, which was in mean terms progressive at increasing time from baseline. Student's t-test showed no significant difference in the mean visual analogue scores between the two groups at baseline, 2nd week and 6th week (Table 3).

However, Paired Student's t-test used to test the mean difference in visual analogue scores at baseline, 2nd week and 6th week was highly significant ($p<0.001$) in the SC group as well as the SF group (Figure 8). Intergroup analyses revealed no significant differences in the improvement between the two treatments at any visit ($p>0.05$).

Observationally, two features concerning the data from plaque scores are apparent. Firstly, the plaque scores at baseline indicate fair oral hygiene and secondly, the indices show overall progressive reductions during the study. However, Student's t-test showed no difference in the plaque scores at baseline, 2nd week and 6th week between the two groups (Table 4).

On the other hand, the Paired Student's t-test showed a highly significant difference ($p<0.001$) in the mean plaque scores at baseline, 2nd week and 6th week for both the groups (Figure 9).

Similar observations as for plaque can be made, with moderate gingivitis in this population at baseline and progressive reductions in scores throughout the study. Student's t-test showed no difference in the gingival scores at baseline, 2nd week and 6th week between the two groups (Table 5).

Paired Student's t-test however, showed a highly significant difference ($p<0.001$) in the mean gingival index scores at baseline, 2nd week and 6th week for both the groups (Figure 10).

For the total patient group, 98.13% of the subjects reported an improvement, 1.87% no change while none of the subjects reported a deterioration of symptoms. Further, 19 subjects in the SF group felt that the overall effect at the end of treatment was much better when compared to 12 subjects from the SC group (Table 6 & Figure 11).

There were no significant differences between treatment groups for the number of patients in any category.

Discussion:

Much has been written on the subject of dentine hypersensitivity; yet it would seem justifiable to agree that the condition is "an enigma being frequently encountered but poorly understood." Dentine hypersensitivity continues to be a problem in the adult dentate population. Relatively little is known of the etiology of dentine hypersensitivity, the nature of the lesion, or the status of the pulp. This lack of knowledge makes the management of the condition difficult and recurrences appear common.[14]

Not many studies are available in literature that have compared the efficacy of stannous fluoride and strontium chloride dentifrices in reducing dentine hypersensitivity. The results of this study demonstrated that the reductions in symptoms was greater for the

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group of patients using the stannous fluoride dentifrice formulated for the treatment of dentine hypersensitivity when compared to those using a strontium chloride dentifrice. This study, consistent with recent clinical trials, used group sizes which would have revealed statistical significance for clinically meaningful differences. The differences were statistically significant at week 6 for both the objective assessments (Manual scratch test and Cold air blast) of dentine hypersensitivity in favour of the stannous fluoride dentifrice.

The result of the present study is in agreement with an earlier finding of increased efficacy of a fluoride toothpaste over a strontium chloride toothpaste.[16] On the other hand, the result is in contrast to findings of a study which stated that stannous fluoride dentifrice was less effective than strontium chloride toothpaste in providing relief to a cold stimulus.[17]

The literature contains considerable evidence for the value of stannous fluoride and strontium chloride, contained in the products employed in the present study, in the treatment of dentine hypersensitivity. Several studies have shown the effectiveness of stannous fluoride in the control of dentine hypersensitivity[18-20] while reports on the efficacy of strontium chloride dentifrices are contradictory.[8-11]

There is at present no agent or product for sensitive teeth that can be considered as a standard and used as a positive control, nor is it likely that any toothpaste would behave as a true placebo.[14] In our present status of knowledge and technical skills, evaluations of compounds for the treatment of dentine hypersensitivity are based on clinical trials.[21] In turn the clinical trials are dependent on the measurement of a single parameter, namely pain. There are at present no objective measurements applicable to dentine hypersensitivity trials and the mode of action of apparently effective toothpaste products of their ingredients can only be surmised. Evidence is available from studies *in vitro*, but can only be interpreted with caution.[22] Based on the hydrodynamic theory of stimulus transmission across dentine, and more direct evidence,[23] teeth exhibiting dentine hypersensitivity must have tubules open at the surface and patent to the pulp. For stannous fluoride and strontium chloride, blockage of tubules has been suggested as the mode of action for both agents, but evidence *in vitro* does not support this direct effect.[14] Most toothpastes could be capable of blocking dentinal tubules directly with abrasive particles and active ingredients, indirectly by the formation of a smear layer, or both. Such observations would suggest that any toothpaste base, devoid of active ingredients such as fluoride or strontium salts, should be equally effective. Certainly, considerable improvements with minus active toothpastes are reported,[21] although to a lesser degree than with the active product.[16,24,25]

The results for the fluoride dentifrice in this study raise the question of why dentine hypersensitivity is so prevalent, despite the widespread use of fluoride toothpastes. One probable factor, already alluded to, must be the environment under which studies are performed. The patients are knowingly

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participating in a clinical trial to determine the efficacy of desensitizing products and several phenomena associated with clinical trials are well known. Behavioural changes are common producing a so-called Hawthorne effect. Thus, the oral hygiene and gingival health, already of a good standard, improved progressively throughout the study. This could have effects on sensitivity, since if brushing were even more effective, tubule occlusion might be promoted, or the activity of strontium and fluoride increased. Additionally, and not unusual in painful conditions, spontaneous improvement may have occurred. This regression to the mode may be a natural phenomenon or encouraged by the close and regular supervision of the patients.[14]

Finally, a true placebo effect may occur, and has been alluded to in many dentine hypersensitivity treatment studies.[21]

As stated above, the oral hygiene and gingival health of the subjects improved with the use of both the products. This is largely in agreement with a previous study, in which the plaque scores and gingival condition improved with the use of all 3 toothpastes.[14] However, the number of variables that could conceivably influence studies of this type are numerous and make comparisons between any two studies difficult.

In conclusion, under the conditions of the clinical trial, the patient group using the stannous fluoride dentifrice showed significant reductions in dentine hypersensitivity when compared to those using the strontium chloride dentifrice. The data provide further evidence of the therapeutic value of fluoride and strontium containing products, but suggest that use of a stannous fluoride dentifrice may bring about a greater reduction in the symptoms of dentine hypersensitivity.

Lastly, unless clinical trial designs for dentine hypersensitivity are modified, the placebo effect can mask any treatment effects.[26] Consistent with other studies, significant placebo responses can be expected in dentine hypersensitivity treatment studies and these may overshadow the treatment effects of known actives such as strontium and fluoride salts. This should not be used to undermine the value of desensitizing products since it must be the perception of using an effective agent, even when not, that triggers the placebo response. It would of value to develop protocols that avoid the perception that the formulation in use is a desensitizing product: a task that certainly is not impossible.[27] There is perhaps a need for more studies of potential desensitizing formulations where the comparison is made with a conventional fluoride toothpaste product.[14]

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