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Comparative Assessment Of Efficacy Of Iontophoresis With Acidulated Phosphate Fluoride (APF) Gel And A Commercially Available Desensitizing Agent-Bifluoride Varnish In The Treatment Of Hypersensitive Teeth."- A Clinical Study

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Abstract:
Purpose: *To evaluate and compare the efficacy of two treatment modalities for dentinal hypersensitivity, iontophoresis with acidulated phosphate gel (APF) gel, and bifluoride varnish application .*
Materials and methods : *This clinical study recruited subjects with a history of hypersensitivity with at least 2 teeth, verified by a light stroke with a dental explorer along the cervical third of the teeth. The patients were subjected to a 1-second air blast and cold water stimuli and their responses were recorded on a visual analogue scale (10- cm scale with 0 to 10 markings) . A total of 80 sites from 40 patients(23males and 17 females) were randomly divided into Group I— APF gel iontophoresis; and Group II—bifluoride varnish. The teeth were evaluated immediately after the treatment and at the end of 2 weeks,4 weeks and 8 weeks.*
Results*: The results were statistically analyzed using independent t test and student paired t test. Group I (APF gel iontophoresis) was more effective clinically, with fewer number of failures compared with Group II(bifluoride varnish) to all the three test stimuli(tactile test,air blast test and cold water test) at the end of 8 weeks.*
Conclusion*: Both the agents showed a statistically significant reduction in sensitivity compared with baseline; however, APF gel iontophoresis was more effective in reducing hypersensitivity over a longer time period.*

I. Introduction

Dentin hypersensitivity (DH) is one of the most common painful conditions affecting oral comfort and function. It is also one of the least successfully resolved problems of the teeth. DH can be defined as temporary pain or an exaggerated response in exposed dentin to stimuli that are typically thermal, evaporative, tactile, osmotic, or chemical, which cannot be explained as arising from other forms of dental defect or pathology.

Primary treatment strategies should undoubtedly aim to eliminate predisposing factors such as abfraction, or erosive components, thereby preventing recurrence. Under normal conditions, dentin is covered by enamel or cementum and does not suffer direct stimulation. However, the exposure of dentinal tubules due to enamel loss by abrasion, erosion, abfraction or root surface exposure caused by gingival recession, periodontal treatment, or a combination of both may produce strong dentinal sensitivity.

Although several hypotheses have been presented to characterize DH, the generally accepted basis for its physiological cause is Brannstorm's hydrodynamic theory. According to its principles, exposed and open dentinal tubules at the tooth surface permit fluid movement inside the tubules that leads to sensorial activation of the nerve cells in the pulp, thus causing pain.

There are many approaches to the treatment and prevention of DH, although no single treatment is accepted universally. Treatment with a chemical agent (eg. potassium nitrate) that penetrates into the dentinal tubules and depolarizes the nerve synapse, thereby reducing sensitivity by preventing the conduction of pain impulses, is a method used in daily use toothpastes. An alternative approach is to treat the tooth with a chemical or physical agent that creates a layer that mechanically occludes the exposed dentinal tubules, thus reducing sensitivity by preventing dentinal fluid flow. This method is used by prophylaxis pastes and varnishes.

Recent studies have focused on non-invasive treatment strategies for early caries lesions. Fluoride treatment is successful in preventing caries. Topical fluoride applications have been widely used for young people in dental clinics. The principle mechanism of topical fluoride applications is to form calcium fluoride (CaF_2) on the enamel surface. The CaF_2 on the tooth surface can act as fluoride reservoir to promote remineralization of enamel. However, CaF_2 on the enamel surface is easily dissolved within 24 h. This problem

could be overcome by penetrating fluoride ions into lesions in a more effective manner. Fluoride iontophoresis (FI) could be an alternative approach to achieve this goal, which is proposed to afford a more effective use of fluoride for caries prevention.[2]

This technique was introduced into dentistry to promote the effect of topical fluoride applications. The FI has been used for prevention of dental caries and to reduce the dentine hypersensitivity. Most studies assessing FI were based on decreasing the dentine hypersensitivity. A previous study (Wilson JM et al 1984) reported that dentine hypersensitivity can be reduced by blocking the dentinal tubules, which are coated with CaF_2. Another previous study (Carlo GT et al 1982) suggested that FI treatment is effective and safe and significantly decreases dentine hypersensitivity. Thus, the aim of the present study was to evaluate and compare the efficacy of two treatment modalities for dentinal hypersensitivity, iontophoresis with acidulated phosphate gel (APF) gel, and bifluoride varnish application.

II. Materials and Methods:

STUDY DESIGN

The study was a single –centre, single –examiner, randomized, parallel group design with a duration of 8 weeks, conducted at the Department of Periodontics ,Yenepoya Dental College, Yenepoya University Mangalore , India after the study protocol was approved by the Ethics Committee (IRB Approval No -YUEC 205/20/12/12 ,Yenepoya University, Ethics Committee) .

A total of 40 patients, with the tooth sensitivity, were selected from the outpatient department of Periodontics, Yenepoya Dental College, Mangalore. All the patients expressed their willingness to participate in the study and an informed consent was taken.

Adults of either gender (18-60 years) systemically healthy patients who presented hypersensitivity to thermal, mechanical, sweet, or sour stimuli on at least 2 teeth on facial surfaces of the teeth due to abrasion, erosion and attrition.

Exclusion criteria included subjects with fractured or restored teeth,carious teeth, subjects undergoing orthodontic treatment, subjects on analgesics, desensitizing agents,those with a history of periodontal therapy in the last 6 months, pregnant women or lactating mothers and subjects with chronic systemic disease; or a pacemaker.

Qualified subjects who met the study criteria were enrolled and randomized into two treatment groups and provided one of the following study treatments:

Group 1: 20 patients (40 sites) with hypersensitive teeth were treated with iontophoresis using APF gel
Group 2: 20 patients (40 sites) with hypersensitive teeth were treated with bifluoride varnish.

CLINICAL EVALUATION

The tooth to be tested was isolated using cotton rolls and the 3 stimulus tests were performed in order, with the least painful, that is, tactile test first followed by the air blast and finally the cold water test. Each of these tests was performed with an interval of 5 min separating them.

1. Tactile test: An explorer was gently run across the affected surface of the tooth .
2. Air blast test: A blast of air at a pressure of 45–60 psi from a 3-way dental syringe for 1 sec.
3. Cold water test: Ice cold water in a disposable 1-cc syringe was slowly expelled onto the tooth surface.

The subjects were asked to score based on visual analogue scale (VAS), a method which assesses a characteristic or attitude that is believed to range across a continuum of values and cannot be easily objectively measured. Subjects were asked to record their overall sensitivity by marking a point on a 10-cm VAS, where 0 indicated ‘no pain’ and 10 ‘unbearable pain’ experienced due to a blast of air, cold water application, and tactile stimuli .A visual analog scale is a line of 10 cm in length, the extreme of a line representing the limits of pain a patient might experience from an external stimulus.

Group I

The subjects in this group were treated with iontophoresis with APF gel (JONOFLUOR SCIENTIFIC , MEDICAL® Italy[a], APF gel MEDICAL® , Italy[b]). The tooth was isolated with cotton rolls, dried, and a thin layer of APF gel was applied onto the affected site with a sponge. The spoon with the electrode connected to the black spiral cable into the patient’s mouth was fitted above the sponge. The patient was made to hold the manual electrode connected to the red spiral cord avoiding any contact with the metal parts.

The iontophoresis unit was switched on with the circuit being completed and progressively increasing current (maximum 2.5 mA) to the tooth until the patient experienced pain or sensitivity. Once this threshold was reached; the spoon, the electrode in patient’s mouth and the manual electrode in patient’s hand was left for as

long as the application (fluorine gel 2-3 minutes). Once the treatment was over, the knob was turned off and the spoon with the electrode and the sponge was removed from the patient's dental arch. The teeth were evaluated using the test stimuli immediately after the treatment and at the end of 2 weeks , 4 weeks and 8 weeks.

Group II

The subjects in this group were treated with bifluoride varnish (Bifluorid 12,containing NaF 6% and CaF_2 6% ,VOCO Company , Germany [C]) .The teeth to be treated were isolated with cotton rolls, cleaned and dried with cotton pledges. The solution was dropped on the brush or preferably on Pele Tim foam pellets (provided by the manufacturer). The surface should be thinly painted. Adequate dilution should be done, if the solution seems viscous. For 10-20 seconds, the varnish applied should be allowed to dry, using air syringe. The teeth were evaluated using the test stimuli immediately after the treatment and at the end of 2 weeks, 4 weeks and 8 weeks.

III. Results:

The results of the study were compiled as follows**:**

The statistical analysis was performed using independent "t" test and paired "t" test. The mean discomfort score was compared using independent "t" test .Both the agents showed a statistically significant reduction in sensitivity compared with baseline. Statistically significant difference was seen at all the time period compared to the baseline in all three test stimuli (Table 4,5 and 6)

Air Blast Test: The baseline mean VAS score to air blast test was 4.3 for both the groups. Both the agents were equally effective immediately after treatment in reducing dentine hypersensitivity in response to the air blast test with mean scores of 0.5 and 0.8 for group I and group II respectively. However, after 2 weeks,4 weeks and 8 weeks ,there was statistically significant differences in the two test groups with group I showing greater reduction in dentine hypersensitivity ($p<0.05$) . (Table 1, Fig.1)

Cold Water Test

The baseline mean VAS scores to cold water test were 5.4 and 5.5 in group I and group II respectively. There was statistically significant reduction in dentine hypersensitivity to cold stimulus post treatment in both the groups . However, there was statistically significant difference between the two groups in all the post treatment periods with group I showing a better outcome in this regard as compared to group II. Immediately after application, the mean VAS scores were 0.7 and 1.4 in group I and II respectively, 0.8 and 1.8 after 2 weeks, 1.3 and 2.8 after 4 weeks, 1.6 and 3.2 after 8 weeks. (Table 2, Fig.2)

Tactile Test

The baseline mean VAS scores to tactile test were 1.8 and 1.7 in group I and II respectively. There was a statistically significant reduction in dentine hypersensitivity after application of the agents in both groups as evaluated by the tactile stimuli .Although the difference between the two groups was not statistically significant immediately after treatment (0.2 and 0.4 in group I and II respectively) and 2 weeks follow up(0.3 and 0.5) , outcome was better in group I compared to group II at the end of 4 weeks (0.4 and 1) and 8 weeks.(0.5 and 1.3) (Table 3, Fig.3)

		Group	N	Mean	Std. Deviation	t	df	P VALUE
air blast test	Baseline	IONTOPHORESIS	40	4.3	1.506	078		1
		BIFLUORIDE VARNISH	40	4.3	1.698			
	immediately after application	IONTOPHORESIS	40	0.5	0.816	-1.393	72.263	0.168
		BIFLUORIDE VARNISH	40	0.8	1.091			
	2 weeks	IONTOPHORESIS	40	0.6	1.033	-2.239	73.162	**0.028**
		BIFLUORIDE VARNISH	40	1.2	1.344			
	4 weeks	IONTOPHORESIS	40	1	1.569	-2.316	75.417	**0.023**
		BIFLUORIDE VARNISH	40	1.9	1.892			
	8 weeks	IONTOPHORESIS	40	1.3	1.814	-2.708	76.008	**0.008**
		BIFLUORIDE VARNISH	40	2.5	2.136			

Table 1: comparison between pre and post treatment scores in group I and group II to air blast test by Independent T test .

		Group	N	Mean	Std. Deviation	t	df	P VALUE
cold water	Baseline	IONTOPHORESIS	40	5.4	1.707	-0.249	78	0.804
		BIFLUORIDE VARNISH	40	5.5	1.881			
	immediately after application	IONTOPHORESIS	40	0.7	1.114	-2.072	64.564	**0.042**
		BIFLUORIDE VARNISH	40	1.4	1.823			
	2 weeks	IONTOPHORESIS	40	0.8	1.265	-2.76	67.674	**0.007**
		BIFLUORIDE VARNISH	40	1.8	1.911			
	4 weeks	IONTOPHORESIS	40	1.3	1.87	-2.997	71.483	**0.004**
		BIFLUORIDE VARNISH	40	2.8	2.554			
	8 weeks	IONTOPHORESIS	40	1.6	2.228	-2.838	74.419	**0.006**
		BIFLUORIDE VARNISH	40	3.2	2.785			

Table 2: comparison between pre and post treatment scores in group I and group II to cold water test by Independent T test .

		Group	N	Mean	Std. Deviation	t	df	P VALUE
tactile test	Baseline	IONTOPHORESIS	40	1.8	1.091	0.424	78	0.673
		BIFLUORIDE VARNISH	40	1.7	1.018			
	immediately after application	IONTOPHORESIS	40	0.2	0.405	-1.975	75	0.052
		BIFLUORIDE VARNISH	40	0.4	0.496			
	2 wks	IONTOPHORESIS	40	0.3	0.464	-1.842	77.415	0.069
		BIFLUORIDE VARNISH	40	0.5	0.506			
	4 wks	IONTOPHORESIS	40	0.4	0.672	-3.122	67.753	0.003
		BIFLUORIDE VARNISH	40	1	1.013			
	8 wks	IONTOPHORESIS	40	0.5	0.679	-3.878	64.484	<0.001
		BIFLUORIDE VARNISH	40	1.3	1.114			

Table 3: comparison between pre and post treatment scores in group I and group II to tactile test by Independent T test .

Paired Samples Test								
TEST	Group			Paired Differences		t	df	P VALUE
				Mean	Std. Deviation			
air blast test	IONTOPHORESIS	Pair 1	before application - immediately after application	3.800	1.556	15.448	39	**<0.001**
		Pair 2	before application - 2 wks	3.700	1.572	14.884	39	**<0.001**
		Pair 3	before application - 4 wks	3.300	1.698	12.294	39	**<0.001**
		Pair 4	before application - 8 wks	3.000	1.867	10.160	39	**<0.001**
	BIFLUORIDE VARNISH	Pair 1	before application - immediately after application	3.500	1.377	16.070	39	**<0.001**
		Pair 2	before application - 2 wks	3.100	1.533	12.793	39	**<0.001**
		Pair 3	before application - 4 wks	2.400	1.766	8.596	39	**<0.001**
		Pair 4	before application - 8 wks	1.800	1.742	6.534	39	**<0.001**

Table 4. Mean and standard deviation of hypersensitivity assessment of APF gel iontophoresis and bifluoride varnish to air blast test at different periods of observation by paired sample test .

TEST	Group			Paired Differences		t	df	P VALUE
				Mean	Std. Deviation			
cold water	IONTOPHORESIS	Pair 1	before application - immediately after application	4.700	1.698	17.510	39	**<0.001**
		Pair 2	before application - 2wks	4.600	1.707	17.046	39	**<0.001**
		Pair 3	before application - 4 wks	4.100	1.945	13.329	39	**<0.001**
		Pair 4	before application - 8 wks	3.800	2.210	10.877	39	**<0.001**
	BIFLUORIDE VARNISH	Pair 1	before application - immediately after application	4.100	1.945	13.329	39	**<0.001**
		Pair 2	before application - 2 wks	3.700	1.698	13.784	39	**<0.001**
		Pair 3	before application - 4 wks	2.700	2.028	8.420	39	**<0.001**
		Pair 4	before application - 8 wks	2.300	2.174	6.690	39	**<0.001**

Table 5. Mean and standard deviation of hypersensitivity assessment of APF gel iontophoresis and bifluoride varnish to cold water test at different periods of observation by paired sample test .

TEST	group			Paired Differences		t	df	P VALUE
				Mean	Std. Deviation			
tactile test	IONTOPHORESIS	Pair 1	before application - immediately after application	1.600	1.033	9.798	39	**<0.001**
		Pair 2	before application - 2 wks	1.500	.934	10.160	39	**<0.001**
		Pair 3	before application - 4 wks	1.400	.928	9.539	39	**<0.001**
		Pair 4	before application - 8 wks	1.300	.791	10.395	39	**<0.001**
	BIFLUORIDE VARNISH	Pair 1	before application - immediately after application	1.300	.911	9.021	39	**<0.001**
		Pair 2	before application - 2 wks	1.200	.758	10.014	39	**<0.001**
		Pair 3	before application - 4 wks	.700	.648	6.827	39	**<0.001**
		Pair 4	before application - 8 wks	.400	.672	3.766	39	**.001**

Table 6. Mean and standard deviation of hypersensitivity assessment of APF gel iontophoresis and bifluoride varnish to tactile test at different periods of observation by paired sample test .

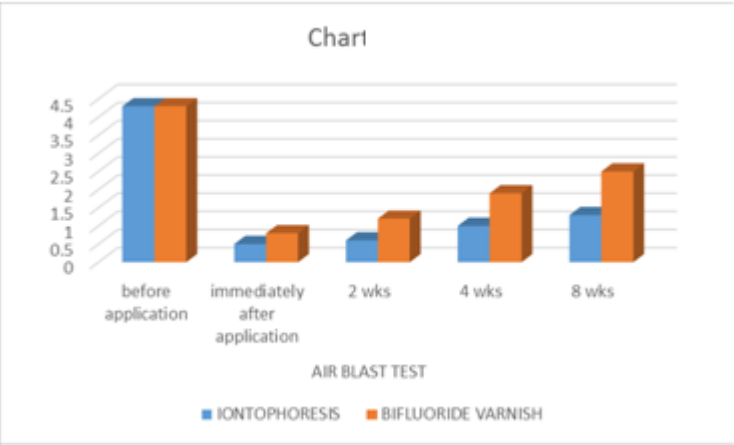

Fig .1 Comparison of scores between iontophoresis and bifluoride varnish groups for air blast test.

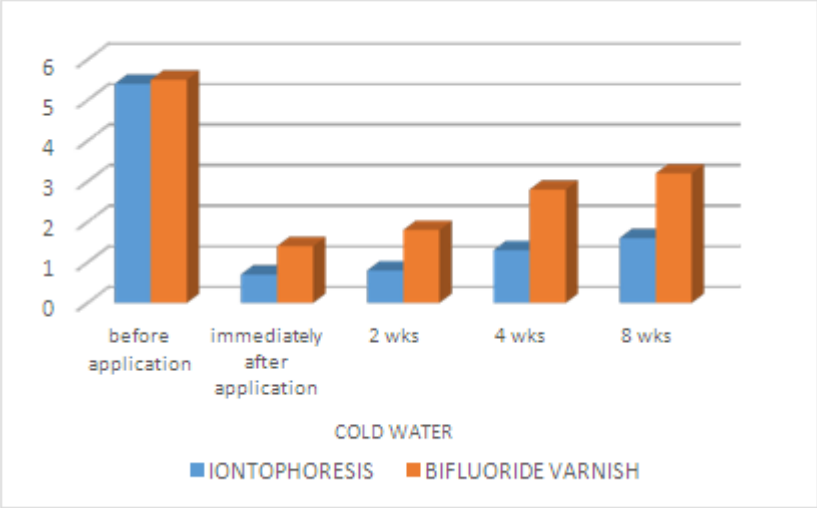

Fig. 2 Comparison of scores between iontophoresis and bifluoride varnish groups for cold water test.

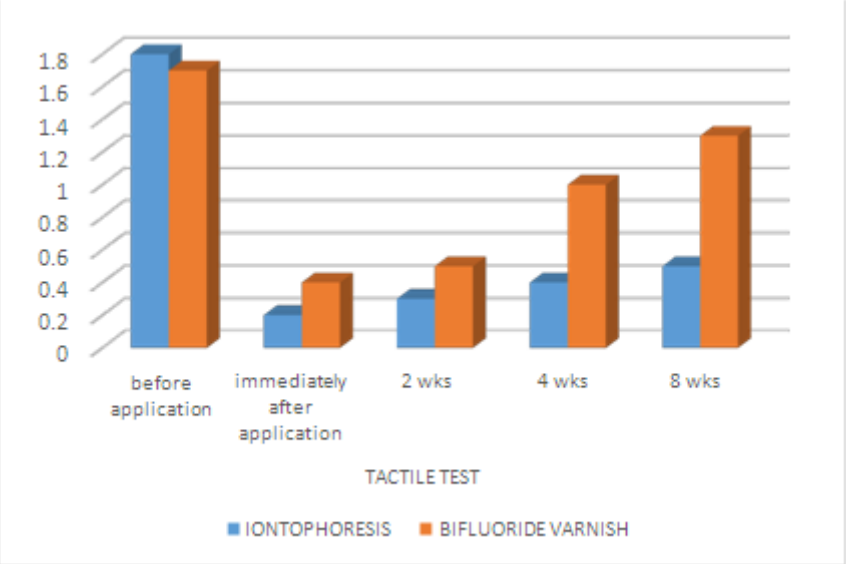

Fig 3.Comparison of scores between iontophoresis and bifluoride varnish groups for tactile test.

IV. Discussion

Dentinal hypersensitivity is described clinically as an exaggerated response to non noxious sensory stimuli. It is a painful response of a tooth to different stimuli such as dental brushing, food or thermal changes. Various theories proposed are direct receptor theory, gate control theory, transducer theory, modulation theory and hydrodynamic theory. Currently, hydrodynamic theory is the most widely accepted theory.

In this study, the in-office application of agents were done because they may be far more effective and this also allows professional control and monitoring, which enhances patients' satisfaction. More than one stimulus to assess pain was used, according to the recommendation of Holland *et al* (1997). This recommendation arises from the fact that different stimuli can elicit different pain sensations and could lead to more reliable conclusions. Blasts of water and air were used as thermal and thermal/ evaporative stimuli, respectively.

The method of iontophoresis was described by Pivati in 1747. Iontophoresis was first used in the early 1960s to treat dentin hypersensitivity. This procedure allows a concentrated application of the drug in a desired localized area. By applying the appropriately charged electrical current, ionized drugs can be driven into tissue based on the principle that like charges repel and opposite charges attract.

The exact mechanism of this desensitization is not yet clearly understood. Several hypotheses have been proposed to explain the desensitization by iontophoresis . One, involves the formation of reparative dentin following application of current to dentin, which results in dead tracts. The second mechanism proposed is that electrical current produces paresthesia by altering the sensory mechanism of pain conduction and the third is

that iontophoresis probably causes microprecipitation of calcium fluoride that may block the hydrodynamically mediated stimuli that induce pain. McBride *et al* demonstrated that iontophoretically treated teeth had a fluoride concentration twice that of topically applied and 20 times that of control teeth. APF gel, when applied on dentin forms calcium fluoride, fluorhydroxyapatite, and phosphate ions. The phosphoric acid provides for a low pH, which favors the formation of fluorhydroxyapatite and prevents loss of phosphate ions from the enamel surface.

In iontophoresis, this has resulted in an immediate significant and for many patients, a permanent reduction in hypersensitivity. Iontophoresis has been found to cause significant improvement in 70% - 80% of the patients, and has been found to meet most of the criteria of an ideal desensitizing agent.

The teeth in group II were treated with fluoride varnish applied topically. Fluoride varnish mainly acts by its ability to form calcium fluoride and, to some extent, by formation of fluorapatite, thus blocking the transmission of stimuli to the pulp. In a study done by Shen and Jaana, it was found that after fluoride application, a significant elevation of fluoride level in whole saliva occurred with Bifluorid 12. Due to the presence of significant amount of fluoride in saliva, high fluoride uptake in the surface and sub surface layer has been reported by Gedalia, *et al.* Ehrlich, *et al.*

In the present study it was observed that both the desensitising agents were successful in reducing the sensitivity of the patients. Both the agents showed a statistically significant reduction in sensitivity compared with baseline . In the present study 24 out of 40(60%) sites in iontophoresis group and 16 out of 40 (40%) sites in bifluoride varnish group showed complete relief from dentine sensitivity from the time of application until 8 weeks of follow up while in the remaining sites ,there was reduction in sensitivity but not completely .There were lesser number of failures in group I compared to group II. 13(32.5%) sites in group I whereas 24(60%) sites in group II showed recurrence of sensitivity over a period of 8 weeks..

It was seen that there was no statistically significant difference between groups I and group II at baseline and immediately after treatment in response to the air blast test. However, after 2 weeks,4 weeks and 8 weeks ,there was statistically significant differences in the two test groups with group I showing greater reduction in dentine hypersensitivity. (Table 1, Fig.1)

There was statistically significant reduction in dentine hypersensitivity to cold stimulus post treatment in both the groups . However, there was statistically significant difference between the two groups in all the post treatment periods with group I showing a better outcome in this regard as compared to group II .(Table 2, Fig.2)

Both the agents were equally effective immediately after treatment and 2 weeks follow up. However, outcome after use of APF gel iontophoresis showed better results in reducing dentine hypersensitivity in response to tactile stimuli as compared to bifluoride varnish at the end of 4 weeks and 8 weeks .(Table 3, Fig.3)
These results are in accordance with previous studies by Murthy KS *et al* (1973), Kern
DA *et al* (1989), Pankaj Singal *et al* (2005) and Aparna S *et al* (2010) wherein there was a significant reduction in the sensitivity with application of fluoride iontophoresis. Kern DA *et al* (1989) used single application of sodium fluoride with or without iontophoresis concluded that 2% sodium fluoride with iontophoresis proved more effective than 2% sodium fluoride alone over 6 months post treatment measurements. Murthy KS *et al* (1973) also found that sodium fluoride with iontophoresis provided immediate relief after one application. Both the agents, revealed significant reduction in the sensitivity at different time intervals to all the three test stimuli when compared to the baseline as assessed by paired t test (Table 4,5 and 6).

The effectiveness of bifluoride varnish was statistically no different from iontophoresis. However, there was a definite clinical difference. Immediately after the application, bifluoride varnish did provide relief but the effects were short lived compared with iontophoresis, probably as a result of the washing away of the varnish layer. APF iontophoresis probably has a better penetration of fluoride ions into the tubules, thus providing relief for a longer time.

V. Summary and Conclusion

The following conclusions can be drawn from the present study:

1. Both the treatment modalities, iontophoresis with APF gel and bifluoride varnish application provided immediate relief from dentinal hypersensitivity to tactile test and air blast test.
2. APF gel iontophoresis showed better results in reducing dentine hypersensitivity in response to tactile stimuli as compared to bifluoride varnish at the end of 4 weeks and 8 weeks.
3. APF gel iontophoresis showed significant reduction in dentine hypersensitivity in response to air blast stimuli as compared to bifluoride varnish at the end of 2 weeks, 4 weeks and 8 weeks.
4. APF gel iontophoresis also showed significant improvement in dentine hypersensitivity in response to cold water stimuli as compared to bifluoride varnish immediately after treatment and at the end of 2weeks,4 weeks and 8 weeks.
5. Both the agents, revealed significant reduction in the sensitivity at different time intervals to all the three test stimuli when compared to the baseline. Hence, they both can be considered as potential desensitizers.

Thus, fluoride iontophoresis appeared to be more effective in providing long‐ term relief against all the three test stimuli. Thus, the results of the present study suggest that fluoride iontophoresis provides relief for the majority of patients suffering from dentine hypersensitivity and that the therapy has clinical significance because it is fast, economical and safe. It is therefore suggested that fluoride iontophoresis be used as a first line treatment, before other therapeutic steps like resin primers and low laser treatment are considered for the treatment of dentine hypersensitivity.

a. Jonofluor scientific, Medical S.r.l company, Via Olivera ,42; San Vendemiano ; Italy.
b. APF gel , , Medical S.r.l company, Via Olivera ,42; San Vendemiano ; Italy.
c. Bifluorid 12, VOCO ,Germany.

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