



Clinical Efficacy of Fluoride-releasing Dental Adhesive on Restricting White Spot Lesion: An *in vivo* Study

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Article History:

Received on: 03 Feb 2020

Revised on: 24 Apr 2020

Accepted on: 27 Apr 2020

Keywords:

Demineralization,
Fluoride,
Non-fluoride,
White spot lesions,
Orthodontist

ABSTRACT

White spot lesions (WSL) and demineralization is a common complication after the orthodontic treatment. This study aims to explore and evaluate the clinical efficacy of fluoride and-fluoride, releasing self-etching adhesives on enamel demineralization and assess the influence of saliva as a predisposing factor for WSL. The study design is a randomized clinical trial. A sample size of 50 patients was taken, there are two groups for the study-Group A (Control Group)-Teeth on which orthodontic brackets are bonded with non-fluoride releasing self-etching adhesive (G Bond) which will be the control group. Group B (Experimental Group)-Teeth on which orthodontic brackets are bonded with Fluoride releasing self-etching adhesive (Bond Force) which will be the experimental group. Materials containing fluoride help to improve the oral health of the experimental group. However, using Paired t-test get mean and standard deviation values also estimate the correlation coefficient values; the mean effect is improved for non-fluoride patients.



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ISSN: 0975-7538

DOI: <https://doi.org/10.26452/ijrps.v11i3.2586>

Production and Hosted by

IJRPS | www.ijrps.com

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INTRODUCTION

Demineralization of the enamel surface is a common complication of orthodontic treatment which can lead to white spot lesion (WSL), (Hadler-Olsen *et al.*, 2012). The incidence of WSL is 49.6% among patients treated with bonded orthodontic attachments, (Gorelick *et al.*, 1982). It is reported that 97.0% of patients exposed to orthodontic treatment had WSL, (Boersma *et al.*, 2005). It could be due to increased accumulation of plaque around the fixed orthodontic device, Willmot (2008) did that led to minimizing the natural self-cleansing, (Rosenbloom

and Tinanoff, 1991). Further, prolonged orthodontic treatment increases the risk of WSL. Therefore, WSL requires further invasive intervention for treatment.

Various methods to evaluate white spot lesions such as Macroscopic methods, including clinical examination, photographic examination, Light scattering methods, optical fluorescent methods of fluorescent dye uptake, using ultraviolet light, laser fluorescence and quantitative Light-induced fluorescence, (Benson, 2008). Microscopic methods include microhardness testing, polarized light microscopy, microradiography. These microscopic methods utilize extracted teeth for Evaluation which have their drawbacks like treatment delay for the Patient, only Patient requiring extraction can participate, and short duration does not represent the whole treatment period. Among these, fluorescence-based methods like Diagnodent proved to be more efficient in diagnosing lesions invisible to the naked eye and in quantifying the amount of demineralization of the enamel, (Benham et al., 2009; Lodaya et al., 2011).

It is established that Fluoride has been used to decrease the enamel potentiality to decalcification and it can be administered by toothpastes, gels, mouth rinses and varnishes. However, it requires a Patient's compliance to avoid the incidence of WSL. In order to decrease the incompliance, pharmaceutical corporates have integrated the Fluoride into orthodontic cement to help preventing and reducing the decay around the teeth, (Somasundaram et al., 2013). Casein phosphopeptide-amorphous calcium phosphate was also proposed to reduce caries incidence but it is not yet proven (REF). Argon laser enamel surface attenuation can also be used to prevent enamel decalcification, but optimal energy density for administration is to be established (REF). Fluoride-releasing adhesives might aid in the prevention of demineralization adjacent to the orthodontic bracket. In vivo effect of a fluoride-releasing adhesive (Transbond-Plus, Company Name) with non-fluoride releasing adhesive (Transbond-XT, Company Name) on inhibition of enamel demineralization around orthodontic brackets in 20 patients were investigated. It was found that the Fluoride is releasing adhesive resulted in the reduction of demineralization of enamel surface around the bracket, when compared with the traditional adhesive, (Eissaa et al., 2013).

Acidic oral cavity increases the demineralization and the risk of having lesions. Therefore, Fluoride helps to inhibit the demineralization of enamel and dentin caries, (Bridi et al., 2016). The pH

level is significantly associated with demineralization level, (dos Santos Noronha et al., 2016). The combination of calcium phosphate and hydroxyapatite affect the pH of the oral cavity and control the bacterial activities, (Chen et al., 2016). Fluoride release from restorative materials has been extensively researched for many years, (Preston et al., 1999; Featherstone, 1994; Ingram and Frazier, 1980). This is because Fluoride has exhibits anti-cariogenic activity by increasing enamel and dentin resistance to subsequent acid attack as well as inhibit carbohydrate metabolism in dental plaque, (Cate, 2001). Currently, composite resins have been selected as the major direct restorative material in clinical dental practice. Against this background, manufacturers have been trying to develop various fluoride-releasing adhesive systems and composite resins, (Imazato et al., 2001).

Basdra et al. (1996), studies show that Fluoride is in the highest level of effect during the first day of treatment used materials containing Fluoride, After this period, a dramatic decline in fluoride release was observed in both adhesives, and after 90 days no fluoride release was detectable (McNeill et al., 2001), compared fluoride release with time from three fluoride-containing orthodontic bonding agents in vitro for six months, In the first days, the fluoride release rates has been high. So, materials containing Fluoride helps to decrease the demineralization of enamel. The availability of Fluoride in the oral cavity helps to decrease the lesions, (Cury et al., 2016). Fluoride-containing materials release different amounts of fluoride ions, depending on the type and composition of the material, (Dionysopoulos et al., 2016).

The purpose of the study is to explore the effect of the Fluoride releasing self-etching bonding system in decreasing the demineralization of enamel surface, as compared to non-fluoride releasing bonding system, in due course of time, in vivo. The study also evaluates the influence of saliva as a predisposing factor for WSL.

METHODS

This study is a randomized, split-mouth, single-blinded clinical trial. Informed consent has been taken from the patient/guardians. Materials used in this study are given below.

1) G Bond (without fluoride content), 2) Bond force (with fluoride content), 3) 3M orthodontic brackets using MBT prescription, 4) LED light-curing unit, 5) Diagnodent unit/pen, 6) Saliva Check1 reactive strip and 7) Saliva Check1 test.

Diagnodent, an electronic caries detecting device, which works on the principle of fluorescence, is to be used for white spot lesion detection; Changes in the digital readings of the Diagnodent are to be collected for analysis, Evaluation of Incisal and gingival aspect of the buccal surface of tooth and Evaluation for the change in the pH and buffering capacity. The amount of fluorescence reflected by demineralized enamel will be shown by the device as a numeric value ranging from (0-99), 3M orthodontic brackets (0.22 MBT) straight wire metal brackets)

Many diagnostic tools have been proposed to diagnose these white spot lesions, like visual inspection, tactile Evaluation using probe, fibre optic transillumination which are not completely reliable or do not quantify the carious lesion. LED Light curing unit, Diagnodent unit, Saliva Check reactive strip, Saliva Check test, Teeth on which orthodontic brackets are bonded with Fluoride releasing self-etching adhesive. (Clear-fell)S³ bond Plus. Patient's saliva is also to be collected at T1, T2 and T3 for measurement of pH and buffering capacity.

Not possible to include all the patients, Teeth with internal and extrinsic stain, Patients on long term medications, Patient planned for surgical procedure, Teeth with defect in histodifferentiation, Teeth with carious lesion/hypoplastic lesion and Glass ionomer restorations on the teeth. Due to More cost to spent patients for treatment because of that not take more patients. Researchers have recommended that fluoride availability should be independent of patient cooperation and that the fluoride ion should diffuse or dissolve over a prolonged period of time. In addition, it would be beneficial if the fluoride ion release were site-specific to those areas most susceptible to demineralization, namely, adjacent to bonded orthodontic brackets.

Sampling Techniques

Sample size of 50 patients has been taken.as for the convenience random sampling technique whose are coming to dental College and Hospital and also willing to take treatment. Patients are to be screened at the Department of Orthodontics and Dentofacial Orthopedics, SRM Kattankulathur Dental College and hospital, and suitable patients who fulfilled the criteria are selected for the study. Selected patients are divided into two groups as control and experimental group randomly.

The inclusion criteria for this study were; Patients of age group 15-30 years, patients planned for fixed orthodontic therapy, Dentition without any anatomic anomalies, All permanent teeth should be present, Clinically sound tooth, Periodontal healthy teeth without any bony defects, Patient

willing to participate in the study, The exclusion criteria were:Individuals with no medical problems or systemic illness, Teeth with internal and extrinsic stains, Patients on long term medications, Patient planned for surgical procedure, Teeth with defect in history differentiation, Teeth with carious lesion/hypoplastic lesion, Glass ionomer restorations on the teeth.

The split-mouth study design was used, and quadrant of Fluoride releasing bonding agent and non-fluoride-releasing bonding agent was allocated by random allocation table. There were 2 groups for the study, 25 patients per group were participated.

Pre-Bonding Phase

Patient underwent for complete oral prophylaxis before starting the treatment. Oral hygiene instructions were also given after scaling. Diagnodent, an electronic caries detecting device, which works on the principle of fluorescence, was used for WSL detection. The amount of demineralization shown by the device as a numeric value ranged from 0-99 was recorded for diagnosis. The Diagnodent was calibrated for each Patient with a sound/caries-free site (as recommended by the manufacturer). Baseline Diagnodent readings have to be recorded before attaching the brackets on to the tooth surface. Diagnodent recordings were taken on the incisal and gingival aspect of the buccal surface of control and experimental teeth (T0). The saliva of the Patient was collected and measured for the pH, buffering capacity before the start of the treatment (T0).

Bonding Procedure

The self-etching adhesive (Name, Company) was applied onto the buccal surface of the tooth, at the place of attaching the bracket, for approximately 15s with a disposable applicator. The bracket was placed on to the tooth surface and light-cured for the 20s.

Post- Bonding Phase

The standard orthodontic treatment procedure was carried out, and Patient was called for regular follow up visits 1month, 3months and 6months interval. Diagnodent readings on the gingival and incisal aspect of the bracket were recorded when the Patient came for follow up at one month (T1), three months (T2) and six months (T3). Changes in the digital readings of the Diagnodent were collected for analysis. Patient's saliva has been received at T1, T2 and T3 for measurement of pH and buffering capacity.

DATA ANALYSES

Pearson correlation, Student Paired t-test and ANOVA for data analysis were used.

Descriptive and Inferential Statistics

Descriptive statistics show 22(44%) of male patients participated, and 28(52%) female patient participated in the study. Student Paired t-test and Pearson correlation were used to analyzing the data to compare the mean values and their association for their stages and using ANOVA within the group's comparison.

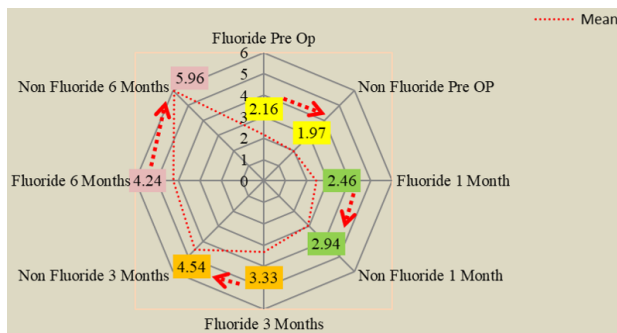


Figure 1: Comparison between Fluoride Pre OP and Non-fluoride Pre OP with 1Month [T1], 3Months [T2] and 6Months [T3].

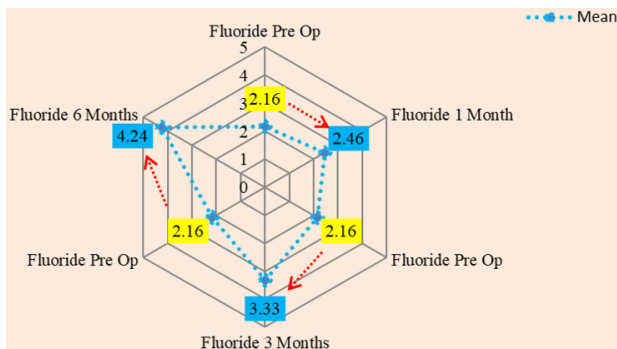


Figure 2: Comparison between Fluoride Pre OP with T1, T2 and T3

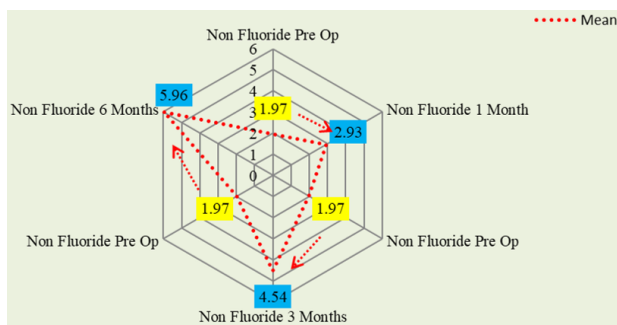


Figure 3: Comparison between Non-fluoride Pre OP with Non-fluoride T1, T2 and T3

It was observed that from the Table 1, Fluoride Pre OP did not show statistical significance difference

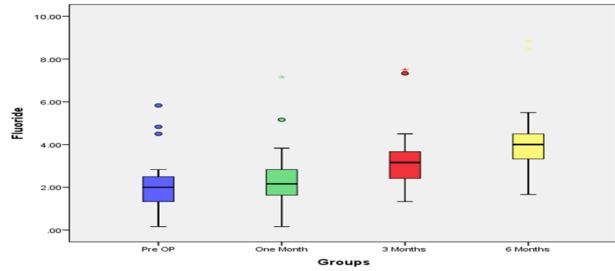


Figure 4: The comparison of their stages from Fluoride Pre OP into T1, T2 and T3 in the Fluoride section

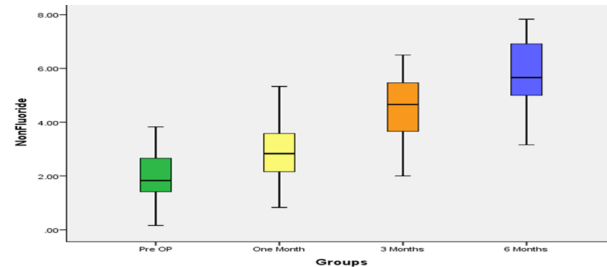


Figure 5: The comparison of their stages from Non-fluoride OP into T1, T2 and T3 in the Non-Fluoride section

with Non-Fluoride Pre OP, and the mean effect difference was 0.19 only. In comparison, the Fluoride T1 with Non-Fluoride T1 showed very highly statistically significant difference and mean effect difference was 0.48. Furthermore, the Fluoride T2 with Non-Fluoride T2 showed very highly statistically significant difference and mean effect difference was 1.21. Similarly, Fluoride T3 showed very highly substantial difference with Non-Fluoride T3 and the mean effect was 1.72. The correlation value between Fluoride Pre OP and Non-Fluoride Pre OP was 0.89, and statistically significant correlated, Fluoride T1 and Non-Fluoride T1 was also significantly correlated, Fluoride T2 and Non-Fluoride T2 were moderately significant correlated, Fluoride T3 and Non-Fluoride T3 were also somewhat significant correlated.

The trajectory graph Figure 1 has shown the comparison about fluoride pre OP and Non-fluoride pre OP [2.16-1.97], which the statistical significance mean difference was very less, whereas fluoride T1 and Non-fluoride T1 [2.46-2.94] showed mean difference was moderate statistical significance difference. However, fluoride T2 and Non-fluoride T2 [3.33-4.54] showed high statistical significance mean difference and Fluoride T3 and Non-fluoride T3 [4.24-5.96] showed very high statistical significance mean difference.

From Table 2, it was observed that there was a statistically significant difference among Fluoride Pre

Table 1: Comparison between Fluoride Pre OP and Non-fluoride Pre OP with T1, T2 and T3.

	Mean	SD	Paired t -Test	P-Value	95% CI		Correlatio (r)	P-Value
					Lower	Upper		
Fluoride Pre OP	2.16	1.33	1.46	0.159	- 0.08	0.46	0.89	0.001 ***
Non- Fluoride Pre OP	1.97	1.05						
Fluoride T1	2.46	1.45	2.89	0.009	- 0.82	- 0.14	0.84	0.001 ***
Non- Fluoride T1	2.94	1.11		***				***
Fluoride T2	3.33	1.51	5.54	0.001	- 1.66	- 0.76	0.73	0.001 ***
Non- Fluoride T2	4.54	1.19		***				***
Fluoride T3	4.24	1.65	7.87	0.001	- 2.18	- 1.27	0.78	0.001 ***
Non- Fluoride T3	5.96	1.23		***				***

ns-There was statistical insignificance difference between Fluoride Pre OP and Non-fluoride Pre OP ($p > 0.05$), *** There was very highly statistical significance difference between Fluoride T1,T2,T3 and Non-Fluoride T1,T2,T3 ($p < 0.01$).

Table 2: Comparison between Fluoride Pre OP with 1 Month [T1], 3 Months [T2] and 6Months [T3]

	Mean	SD	Paired t -Test	P-Value	95% CI		Correlatio (r)	P-Value
					Lower	Upper		
Fluoride Pre OP	2.16	1.33	3.45	0.002	- 0.47	- 0.12	0.96	0.001 ***
Fluoride T1	2.46	1.45						
Fluoride Pre OP	2.16	1.33	8.13	0.001	- 1.46	- 0.87	0.89	0.001 ***
Fluoride T2	3.33	1.51						
Fluoride Pre OP	2.16	1.33	12.43	0.001	- 2.42	- 1.73	0.88	0.001 ***
Fluoride T3	4.24	12.45						

OP and Fluoride T1, T2, and T3 and where the mean differences were 0.3, 1.17, and 2.08 respectively. Comparison of three groups relationship (Fluoride Pre OP and Fluoride T1, Fluoride Pre OP and Fluoride T2 and Fluoride Pre OP and Fluoride T3 showed highly statistical significance correlated values, i.e. $r > 0.88$).

The trajectory graph Figure 2 has shown less statistical significance difference between fluoride pre OP and fluoride T1 [2.16-2.46], whereas, moderate

statistical significance difference for fluoride pre OP with T2 [2.16-3.33] and high statistical significance difference between fluoride pre OP with T3 [2.16-4.24]. All were shown the statistically significant difference. Based on this analysis, we can conclude that there is a statistical significance effect difference during the time of this six months study period.

There is a statistical significance difference between Non-fluoride OP and Non-fluoride T1, T2, T3 as shown in Table 3. Among these statistical difference

Table 3: Comparison between Non-Fluoride Pre OP with T1, T2 and T3

	Mean	SD	Paired t -Test	P-Value	95% CI		Correlatio (r)	P-Value
					Lower	Upper		
Non-Fluoride Pre OP	1.97	1.04	10.39	0.001***	- 0.77	- 1.16	0.92	0.001***
Non-Fluoride T1	2.93	1.11						
Non-Fluoride Pre OP	1.97	1.05	20.04	0.001***	- 2.29	- 2.83	0.86	0.001***
Non-Fluoride T2	4.54	1.19						
Non-Fluoride Pre OP	1.97	1.05	27.86	0.001***	- 3.69	- 4.28	0.83	0.001***
Non-Fluoride T3	5.96	1.23						

Table 4: Comparison of mean values within the Fluoride and the Non-Fluoride

		Mean	SD	95% CI		ANOVA	P-Value	
				Lower Bound	Upper Bound			
Fluoride	Pre OP	23	2.16	1.33	1.59	2.74	9.007	0.001***
	T1	23	2.46*	1.46	1.83	3.09		
	T2	23	3.33	1.51	2.68	3.98		
	T3	23	4.24**	1.66	3.52	4.95		
	Total	92	3.05	1.68	2.69	3.39		
Non-Fluoride	Pre OP	23	1.97	1.05	1.52	2.43	53.941	0.001***
	T1	23	2.94*	1.11	2.46	3.42		
	T2	23	4.54**	1.19	4.02	5.05		
	T3	23	5.96***	1.23	5.42	6.49		
	Total	92	3.85	1.90	3.46	4.25		

Table 5: The comparison between Pre Salivary and Salivary T1, T2 and T3

	Mean	SD	Paired Samples Statistics				Correlatio (r)	P-Value
			Paired t -Test	P-Value	95% CI			
					Lower	Upper		
Pre Salivary	7.32	0.38	0.643	0.53	- 0.09	0.19	0.66	0.001***
Salivary T1	7.28	0.37						
Salivary T2	7.32	0.38	0.189	0.85	- 0.14	0.12	0.61	0.001***
Salivary T3	7.33	0.33						
Pre Salivary	7.32	0.38	0.509	0.62	- 0.12	0.09	0.61	0.001***
Salivary T1	7.32	0.38						
Salivary T2	7.35	0.32						
Salivary T3								

Table 6: The comparison between pre Salivary, Non-Fluoride and Fluoride for T1, T2 and T3

	Paired Samples Statistics							
	Salivary	Non-Fluoride	Paired t	P-Value	Salivary	Fluoride	Paired t	P-Value
	Mean \pm SD		-test		Mean \pm SD		-test	
Pre	7.3 \pm 0.37	1.95 \pm 1.0	27.202	0.001 ***	7.3 \pm 0.37	2.12 \pm 0.38	20.059	0.001 ***
T1	7.3 \pm 0.37	2.91 \pm 1.07	22.419	0.001 ***	7.3 \pm 0.37	2.41 \pm 1.41	18.871	0.001 ***
T2	7.3 \pm 0.33	4.51 \pm 1.15	13.444	0.001 ***	7.3 \pm 0.33	3.29 \pm 1.46	14.895	0.001 ***
T3	7.4 \pm 0.32	5.94 \pm 1.19	5.774	0.001 ***	7.4 \pm 0.32	4.23 \pm 1.59	9.832	0.001 ***

was found, and the mean difference was 0.96, 2.58, and 3.99 respectively, and the correlation (association) value was statistically significant correlated i.e.r > 0.83.

The trajectory graph Figure 3 showed the comparison between non-fluoride pre OP and non-fluoride T1 [1.97-2.93], which was decidedly less statistical significance difference, non-fluoride pre OP with non-fluoride T2 [1.97-4.54] was moderate statistical significance difference and non-fluoride pre OP with non-fluoride T3 [1.97-5.96] showed very high statistical significance difference. All were statistical significant difference. Based on this analysis, we can conclude that there is a statistical significance effect difference during the time of this six months study period.

There is a statistical significant difference among the Fluoride and non-fluoride, Table 4 showed a substantial difference within the group of Fluoride and Non-fluoride groups. From the Pre OP fluoride mean was 2.16, T1(2.46), T2(3.33) and T3(4.24) and statistical significance was found in their progression. From the Pre OP Non-fluoride mean was 1.97, T1(2.94), T2(4.54) and T3(5.96) and statistical significance progression was obtained.

Box and whisker plot graph Figure 4, shows mean and standard deviation values in their different periods among the fluoride patterns, in the pre OP (2.16 \pm 1.33), after T1 (2.46 \pm 1.46), after T2 (3.33 \pm 1.57 and after T3 (4.24 \pm 1.19). A statistical significant difference was found among these groups.

Box and whisker plot graph Figure 5, showed the mean and standard deviation presented in their different periods among the non-fluoride patterns, in the pre OP (1.97 \pm 1.05), after T1 (2.94 \pm 1.11), after T2 (4.54 \pm 1.19) and after T3 (5.96 \pm 1.23). Among the non-fluoride groups, also statistically significant

difference was found.

From Table 5, ns-Not statistical significance difference between Pre Salivary with Salivary T1, T2 and salivary T3 at 95% (p > 0.05). *** there is a statistically significant correlation between Pre Salivary with Salivary T1, Salivary T2 and Salivary T3 at 95% (p < 0.01). It was found that pre-Salivary mean value was 7.32 compared to Salivary T1 (7.28), Salivary T2 (7.33) and Salivary T3 (7.35), and the difference was insignificant. The correlation value for pre-Salivary was 0.66 and compared with Salivary T1, T2 and T3, where the values were 0.61 for each group, and all were statistically significant.

From the above Table 6, all the comparison have a statistically significant difference; Salivary compare to non-fluoride and Fluoride, we conclude that non-fluoride more significance.

DISCUSSION

50 patients participated in the study, 100 % of the patients responded, they are following the instruction as per the dental doctor suggestions and their food habit are Non-Vegetarian, Overall OH level was very good in this study. Patient has to undergo complete oral prophylaxis before starting the treatment. Oral Hygiene instructions are also given after scaling. Standard orthodontic treatment procedure is to be carried out, and Patient has to be re-called for regular follow up visits, No patient missed the appointments between the treatment periods.

The clinical efficacy of Fluoride and non-fluoride releasing self-etching adhesives on enamel demineralization. The influence of saliva as a predisposing factor for white spot lesions. A variety of mechanisms are involved in the anti-cariogenic effect of Fluoride. The mechanisms include reduction of demineralization, enhancement of demineraliza-

tion, inhibition of pellicle and plaque formation, and inhibition of microbial growth and metabolism. Fluoride released from restorative materials may possibly inhibit caries via all of these mechanisms.

Many in vitro studies have shown that fluoride-releasing restoratives can inhibit the enamel demineralization induced by acidic gels or demineralizing buffer solutions. This ability depends on the amount of Fluoride released from the materials. In the present study, all fluoride-releasing materials tested had an inhibitory effect on the development of experimental lesions around the fluoride-releasing materials when compared with a non-fluoridated composite. This inhibitory effect may be due to the presence of fluoride ions around restorations and was dependent on the concentration of fluoride ions released.

The formation of white spot lesions or enamel demineralization around fixed orthodontic attachments is a common complication during and following fixed orthodontic treatment, which mars the result of a successfully completed case. This study is a contemporary review of the risk factors, preventive methods and fate of these orthodontics scars. The importance of excellent oral hygiene practice during fixed orthodontic treatment must be explained. Preventive programs must be emphasized to all orthodontic patients. Suggestions are offered in the literature for ways to prevent this condition from manifesting itself.

CONCLUSION

Randomized clinical trial conduct as many evidences show the importance of investigating the functions of Fluoride and the influence of saliva to treat white spot lesions among patients in India. WSL are one of the common complications of fixed orthodontic treatment. It is the responsibility of an orthodontist to minimize the risk of the Patient having decalcification as a consequence of orthodontic treatment by educating and motivating the patients for excellent oral hygiene practice. Different regimens suggested by various authors can be prescribed to the patients to control WSL along with topical fluoride application. Now Salivary compare to non-fluoride and Fluoride, we conclude that non-fluoride more significance effect compare to others.

There are several products containing Fluoride available to clinicians and their patients. Unfortunately, the evidence for the effectiveness of these products is weak. However, to date, using fluoride varnish in high concentration and with regular applications is the most effective way to avoid WSL appearance. This should be implemented in

close association with the control of caries risk factors. Indeed, It is still crucial to emphasize that prevention of these lesions is the furthestmost desirable outcome aesthetically and also the least costly for patients. Clinicians can benefit from the study by using products containing florid. Further, the decision-makers and the government require allocating resources and exempt tax for products containing florid.

Conflict of Interest

None.

Funding Support

None.

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