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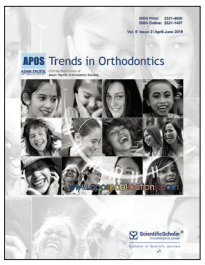

Original Article

Effect of topical fluoride gel and fluoride varnish in the prevention of white spot lesions in patients undergoing fixed orthodontic treatment: An *in vivo* study

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ABSTRACT

Objectives: Our primary objective was to establish the efficacy of fluoride gel and fluoride varnish in the prevention of white spot lesions (WSLs) development during fixed orthodontic treatment.

Materials and Methods: The study sample consisted of 60 adult patients in a prospective split-mouth study design. Interventions, that is, topical fluoride gel and topical fluoride varnish were assigned at the time of bonding to either the right or left halves of the dentition. In all subjects, repeated evaluation of demineralization was done on the facial surfaces of sample teeth in each quadrant. Evaluation using laser fluorescence and by direct visual observation under magnification was carried out at bonding (T0), 3 months (T1), and 6 months (T2).

Results: The distribution of mean DIAGNOdent score at T1 (3.14 ± 1.00 vs. 2.81 ± 0.852) and T2 (4.17 ± 1.41 vs. 3.51 ± 1.13) was observed which is significantly higher in the Gel group compared to the Varnish group. In the Gel group, the distribution of mean DIAGNOdent score at T1 (3.14 ± 1.00) and T2 (4.17 ± 1.41) is significantly higher compared to mean DIAGNOdent score at baseline T0 (2.07 ± 0.66). In the Varnish group, the distribution of mean DIAGNOdent score at T1 (2.81 ± 0.852) and T2 (3.51 ± 1.13) is significantly higher compared to the mean DIAGNOdent score at T0 (2.07 ± 0.66). Visual scores also correlated with DIAGNOdent scores.

Conclusion: Fluoride varnish is more efficacious than fluoride gel in reducing enamel demineralization. Initial application of fluoride varnish around the orthodontic bracket at bonding appointment can offer significant protection against WSLs.

Keywords: White spot lesions, Orthodontic scars, Topical fluorides

INTRODUCTION

In contemporary fixed orthodontic therapy, multibracket appliances are used as literal handles over the tooth surface enamel to bring about efficient tooth movement. Fixed orthodontic appliances comprising bands, brackets, wires, and ligatures increase the retention of debris and plaque on smooth surfaces of the tooth.[1] One of the common side effects of this is the formation of unesthetic incipient carious lesions, known as white spot lesions (WSLs).

The pathogenesis and appearance of WSLs depend on subsurface events of demineralization and remineralization that are directly related to variation in plaque pH. When low pH is maintained for a longer period, it leads to increased demineralization and only short intervals of remineralization. Spontaneous remineralization occurs because of the simultaneous

action of salivary minerals and fluoride from therapeutic intervention.[2] The prevalence of WSLs during orthodontic treatment varies largely, from 38% to 46% from 6 to 12 months post orthodontic treatment.[3] This increased prevalence of WSLs could jeopardize the success of orthodontic treatment.

Considering evaluation of orthodontically induced WSLs, various methods had been suggested in literature including,[3-5] *in vitro* evaluation through light-induced fluorescence, polarized light microscopy, scanning electron microscopy or clinical evaluation techniques such as laser fluorescence method, use of sharp explorer tip, and most commonly used direct visual inspection method along with photographic records. The usefulness of the laser fluorescence technique is well acknowledged in the literature. It is also important to differentiate between developmental enamel lesions and orthodontically induced WSLs.[4]

The treatment of WSLs includes various methods for both preventing demineralization as well as promoting remineralization of existing lesions. Prevention is better than cure, hence preventive steps and procedures take more importance due to the challenges involved in the treatment of already existing lesions. The preventive steps/procedures comprise oral health instructions, patient education, routine professional oral hygiene visits, and the application of fluoride protection.

Optimal protection with fluoride warrants good patient compliance, dearth of patient cooperation is an important aspect of orthodontic care. To overcome this challenge, there are multiple methods available that do not necessitate patient compliance for reducing enamel demineralization.[6] For non-compliant patients, suitable preventive agents, such as topical fluoride application by professionals can help in decreasing the demineralization of enamel surrounding orthodontic brackets.[7,8]

Professionally applied fluoride varnishes and fluoride gels are easy to use and studies have consistently reported a 30–50% decrease in emerging enamel lesions following their applications.[9] A recent randomized controlled trial and another systematic review evaluated the effect of topical fluoride and concluded a statistically significant reduction of dental caries in permanent teeth.[10,11] However, these studies also suggested the requirement of additional research on the topic.

Keeping the various advantages and disadvantages of both fluoride gels and varnishes and the lacunae of evidence in the literature of their success potential, a study was designed to evaluate the effect of topical fluoride gel and fluoride varnish on enamel mineralization during orthodontic treatment.

The null hypothesis for the study was: There is no difference in the efficacy of topical fluoride gel and fluoride varnish in preventing the development of WSLs on enamel in patients undergoing orthodontic treatment.

Aim of the study

This study aims to evaluate the efficacy of topical fluoride gel and fluoride varnish in preventing the development of WSLs on enamel in patients undergoing orthodontic treatment using pre-adjusted edgewise appliance (PEA) by use of laser fluorescence and visual method under magnification.

MATERIALS AND METHODS

This prospective study was carried out in the Department of Orthodontics and Dentofacial Orthopedics of a tertiary care Government hospital, providing free treatment to patients. The study sample consisted of 60 adult patients with permanent dentition scheduled to undergo fixed orthodontic treatment, fulfilling the following inclusion and exclusion criteria.

Inclusion criteria

- Permanent dentition
- No smooth surface caries on the selected sample teeth
- No dental fluorosis
- No hypocalcified teeth or visible demineralization

Exclusion criteria

- Syndromic cases
- Patients with Cleft lip and palate
- Patient with poor hand dexterity
- Oral Hygiene Index-Simplified score >3 (more than three)
- Previous h/o orthodontic treatment

Sample size calculation

The minimum required sample size worked out was 60 in each group, taking $\alpha = 0.05$ and power of 80%. Sample size calculation is done based on the master article data from Perrini *et al*.; the mean and standard deviations are taken ($\mu_1 = 5.28$, SD1 = 7.08 and $\mu_2 = 2.67$, SD2 = 1.39).[12]

Consent and ethics

The research protocols described in this study were reviewed and approved by the Institutional Ethical Committee. Written informed consent duly endorsed by a witness was obtained from each participant at the enrollment stage after explaining the nature and purpose of the study to the participants.

Methodology

On commencement of the study all selected patients received a professional sitting of oral prophylaxis (scaling and

polishing) and standard oral hygiene instructions were given to every patient.

A split-mouth study technique was adopted to conduct this study. Each of two interventions, that is, topical fluoride gel (Fluocal, Septodont, Septodont Healthcare India Pvt. Ltd. C-1/2, MIDC Industrial Area, Maharashtra, India) and topical fluoride varnish (Fluor Protector, Ivoclar Vivadent, 175 Pineview Drive Amherst, NY 14228 USA) were randomly assigned to either the right or left halves of the dentition utilizing chit system, which included one-half of the maxillary dentition and one-half of the mandibular dentition in all subjects. Central incisor, canine and second premolar in each quadrant were selected as sample teeth for evaluation, being anterior, middle, and posterior teeth respectively in the dental arch. The armamentarium used in the study is shown in the picture [Figure 1].

The selected patients were subjected to standard orthodontic bonding procedures and measurements for enamel mineralization of sample teeth were obtained T0 (at the time of bonding/baseline), using the following two methods [Figure 2]:

Evaluation using laser fluorescence

Mineralization of all sample teeth (maxillary and mandibular central incisors, canines, and second premolars) was measured with a DIAGNOdent pen 2190 (Kaltenbach and Voigt GmbH, KaVo Dental GmbH, Biberach). The laser was calibrated for each patient according to the manufacturer's guidelines and readings were taken at 04 labial sites: M-mesial, D-distal, O-occlusal, and G- gingival. Each 1 mm distance from the bracket. Laser fluorescence from the wand tip is reflected off the tooth surface to measure the mineralized content of the enamel, higher readings indicate greater demineralization. Usually, DIAGNOdent score for healthy tooth substance = 10–12, initial demineralization = 13–24, strong demineralization = >25, However, any readings from 2 to 9 can signify incipient decalcification.[13]

Evaluation by direct visual observation under magnification

Using surgical loupe for visual evaluation under magnification (×2.5), decalcification scores in each of the four areas (gingival, occlusal, mesial, and distal edges of the bracket) on all sample teeth were recorded as per the following index:

Enamel decalcification index

Score 0 = no decalcification.

Score 1 = mild, but clinically visible decalcification affecting <50% area.

Score 2 = moderate to severe decalcification more than 50% area.

Score 3 = decalcification covering the complete area or surface breakdown and caries.

Total score per tooth was calculated by adding up individual area scores for each sample tooth.[14] After baseline observations were recorded on the day of bonding T0, the dental arches were isolated for following topical fluoride intervention [Figure 3].

Fluoride gel half (A) - topical fluoride gel was applied to the enamel around the brackets of one-half of the maxillary dentition and one-half of the mandibular dentition as per the manufacturer's recommendations at T0 under controlled clinical settings, high volume suction utilizing split carrier gel trays.

While in, fluoride varnish half (B) - topical fluoride varnish was applied to the other remaining half of

Figure 1: Study Armamentarium (a) Lip and cheek retractor (b) Application trays for fluoride gel (c) Dappen dish with brush applicator sticks for fluoride varnish (d) Fluocal fluoride gel (e) Fluor Protector fluoride varnish (f) DIAGNOdent pen 2190 with autoclavable tips (g) Magnifying surgical loupe.

Figure 2: DIAGNOdent scoring.

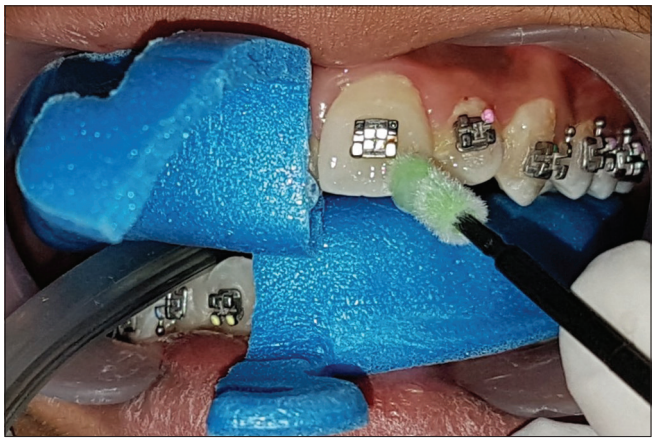

Figure 3: Split-mouth application of fluoride gel and varnish.

maxillary and mandibular dentition as per manufacturer's recommendations at T0 under controlled clinical settings, high volume suction utilizing applicator tips. In follow-up visits, enamel demineralization was evaluated using above mentioned two methods (laser fluorescence and direct visual observation) at T1 = at 3 months of fixed orthodontic therapy, T2 = at 6 months of fixed orthodontic therapy.

The direct visual observation and readings of Laser fluorescence were recorded after cleaning the labial surfaces of all teeth using a brush mounted on a low-velocity handpiece.

Data compilation and statistical analysis

The entire data were statistically analyzed using Statistical Package for Social Sciences (SPSS ver 21.0, IBM Corporation, USA) for MS Windows, the $P < 0.05$ were considered to be statistically significant. The inter-group statistical comparison of categorical variables was done using the Chi-square test. The inter-group statistical comparison of means of continuous variables was done using an independent sample *t*-test for the two groups, ANOVA with *post hoc* Bonferroni's correction for multiple group comparisons was used for more than two groups. The intra-group comparison of categorical variables was done using Wilcoxon's signed rank test. The intra-group comparison of means of continuous variables was done using repeated measures ANOVA. The underlying normality assumption was tested before subjecting the study variable to a *t*-test or ANOVA.

RESULTS

Analyzing the data considering in maxillary and mandibular arches, all selected teeth and all quadrants combined following are the results.

The overall inter-group comparison of mean diagnodent score

The distribution of mean baseline DIAGNOdent score did not differ significantly between the two study groups ($P > 0.05$). The distribution of mean DIAGNOdent score at T1 (3.14 ± 1.00 vs. 2.81 ± 0.852) and T2 (4.17 ± 1.41 vs. 3.51 ± 1.13) is significantly higher in the Gel group compared to the Varnish group ($P < 0.001$ for both). The distribution of mean % change in DIAGNOdent score at 6-months (117.57% vs. 83.06%) is significantly higher in the Gel group compared to the Varnish group ($P < 0.001$) [Table 1].

The overall intra-group comparison of mean diagnodent score

In the Gel group, the distribution of mean DIAGNOdent score at T1 (3.14 ± 1.00) and T2 (4.17 ± 1.41) is significantly higher compared to mean DIAGNOdent score at baseline T0 (2.07 ± 0.66) $P < 0.001$ for both. In the Gel group, the distribution of mean DIAGNOdent score at T2 (4.17 ± 1.41) is significantly higher compared to mean DIAGNOdent score at T1 (3.14 ± 1.00) $P < 0.001$. In Varnish group, the distribution of mean DIAGNOdent score at T1 (2.81 ± 0.852) and T2 (3.51 ± 1.13) is significantly higher compared to mean DIAGNOdent score at T0 (2.07 ± 0.66) $P < 0.001$ for both. In the Varnish group, the distribution of mean DIAGNOdent score at T2 (3.51 ± 1.13) is significantly higher compared to the mean DIAGNOdent score at T1 (2.81 ± 0.852) $P < 0.001$ [Table 2].

The overall inter-group comparison of visual scores under magnification

The distribution of baseline visual score did not differ significantly between the two study groups ($P > 0.05$). The distribution of visual score at T1 (Gel: Score 1 [3.6%] vs. Varnish: Score 1 [0.6%]) and T2 (Gel: Score 1 + Score 2 [22.2%] vs. Varnish: Score 1 + Score 2 [5%]) differs significantly between two study groups, $P < 0.01$ for both [Table 3].

Table 1: The overall inter-group comparison of mean DIAGNOdent score.

Follow-up	Gel Group (*n*=60) (Total no. of readings=1440)		Varnish Group (*n*=60) (Total number of readings=1440)		*P*-value (Inter-Group)
	Mean	SD	Mean	SD	
Baseline	2.07	0.66	2.07	0.66	0.887^{NS}
3-Months	3.14	1.00	2.81	0.852	0.001***
6-Months	4.17	1.41	3.51	1.13	0.001***
% Change (at 6-Months)	117.57%	--	83.06%	--	0.001***

P-values (Inter-group) by independent sample *t*-test. *P*<0.05 is considered to be statistically significant. ***P*<0.001, NS: Statistically non-significant

Table 2: The overall intra-group comparison of mean DIAGNOdent score.

	Gel Group (*n*=60) (Total no. of readings=1440)		Varnish Group (*n*=60) (Total number of readings=1440)	
	Mean	SD	Mean	SD
Follow-up				
Baseline	2.07	0.66	2.07	0.66
3-Months	3.14	1.00	2.81	0.852
6-Months	4.17	1.41	3.51	1.13
P-value (Intra-Group)				
Baseline vs. 3-Months	0.001***		0.001***	
Baseline vs. 6-Months	0.001***		0.001***	
3-Months vs. 6-Months	0.001***		0.001***	

P-values (intra-group) by repeated measures ANOVA. *P*<0.05 is considered to be statistically significant. ***P*<0.001, NS: Statistically non-significant, vs.: Versus

The overall intra-group comparison of visual scores

In Gel group, the distribution of visual score at T1 (Score 1 + Score 2: 3.6%) and T2 (Score 1 + Score 2: 22.2%) differs significantly compared to visual score at baseline (Score 1 + Score 2: 0.0%) ($P < 0.001$ for both). The distribution of visual score at 6-months (Score 1 + Score 2: 22.2%) differs significantly compared to visual score at 3-months (Score 1 + Score 2: 3.6%), $P < 0.001$. In Varnish group, the distribution of visual score at T2 (Score 1 + Score 2: 5.0%) differs significantly compared to visual score at baseline (Score 1 + Score 2: 0.0%) ($P < 0.001$). The distribution of visual score at T2 (Score 1 + Score 2: 5.0%) differs significantly compared to visual score at T1 (Score 1 + Score 2: 0.6%), $P < 0.001$ [Table 4].

DISCUSSION

WSLs are incipient enamel caries and one of the clinically significant side effects of fixed orthodontic therapy. Preventing the development of these lesions would be the best possible strategy to deal with WSLs. Various preventive measures have been suggested in the past; however, the most commonly used prevention protocol includes the use of topical fluorides in their different forms, apart from patient education and oral hygiene practices.[15,16]

The present split-mouth study involved the application of two different forms of fluoride, that is, fluoride in Gel form (Fluocal, Septodont [active fluoride nearly 11,900 ppm]) and Varnish form (Fluor Protector, Ivoclar Vivadent [active fluoride nearly 10,000 ppm]). As both forms of fluoride are professionally applied, they do not rely on patient compliance and also deliver relatively high fluoride concentrations.[10] Most studies suggest that biannual/annual applications are effective in the prevention of demineralization.[10,13,17]

WSLs cause changes in the fluorescence value of enamel and when a clean enamel surface is subjected to irradiation of a specific wavelength, tooth structure emits fluorescence related to the amount of mineralization. This phenomenon was utilized for the evaluation of demineralization in the laser fluorescence method (DIAGNOdent pen 2190 [KaVo]), which functions at 655 nm wavelength. Minimal or no fluorescence was shown on clean and healthy enamel surfaces. Whereas, demineralized enamel surface showed increased fluorescence proportionate to the amount of demineralization. DIAGNOdent is a valuable tool to evaluate WSL.[13,16]

Another method used for evaluation of WSLs was a clinical visual examination that has been used classically in various studies, Geiger *et al.* have given basic scoring for assessing the severity of acquired WSLs.[18] The present study employed the

Table 3: The overall inter-group comparison of visual scores under magnification.

Scoring	Gel Group (*n*=60) (Total number of readings=360)		Varnish Group (*n*=60) (Total number of readings=360)		*P*-value (Inter-Group)
	n	%	n	%	
Baseline					
Score 0 (No Decalcification)	360	100.0	360	100.0	0.999^{NS}
Score 1 (Mild but clinically visible Decalcification)	0	0.0	0	0.0	
Score 2 (Moderate to severe Decalcification)	0	0.0	0	0.0	
Score 3 (Decalcification covering whole area)	0	0.0	0	0.0	
3-Months					
Score 0 (No Decalcification)	347	96.4	358	99.4	0.007**
Score 1 (Mild Decalcification)	13	3.6	2	0.6	
Score 2 (Moderate to severe Decalcification)	0	0.0	0	0.0	
Score 3 (Decalcification covering whole area)	0	0.0	0	0.0	
6-Months					
Score 0 (No Decalcification)	280	77.8	342	95.0	0.001***
Score 1 (Mild Decalcification)	77	21.4	17	4.7	
Score 2 (Moderate to severe Decalcification)	3	0.8	1	0.3	
Score 3 (Decalcification covering whole area)	0	0.0	0	0.0	

P-values (inter-group) by Chi-square test. $P<0.05$ is considered to be statistically significant. **$P<0.01$, ***$P<0.001$, NS: Statistically non-significant

Table 4: The overall intra-group comparison of visual scores**.**

Scoring	Gel Group (*n*=60) (Total number of readings=360)		Varnish Group (*n*=60) (Total number of readings=360)	
	n	%	*n*	%
Baseline				
Score 0 (No Decalcification)	360	100.0	360	100.0
Score 1 (Mild but clinically visible Decalcification)	0	0.0	0	0.0
Score 2 (Moderate to severe Decalcification)	0	0.0	0	0.0
Score 3 (Decalcification covering whole area)	0	0.0	0	0.0
3-Months				
Score 0 (No Decalcification)	347	96.4	358	99.4
Score 1 (Mild but clinically visible Decalcification)	13	3.6	2	0.6
Score 2 (Moderate to severe Decalcification)	0	0.0	0	0.0
Score 3 (Decalcification covering whole area)	0	0.0	0	0.0
6-Months				
Score 0 (No Decalcification)	280	77.8	342	95.0
Score 1 (Mild but clinically visible Decalcification)	77	21.4	17	4.7
Score 2 (Moderate to severe Decalcification)	3	0.8	1	0.3
Score 3 (Decalcification covering whole area)	0	0.0	0	0.0
P-value (Intra-Group				
Baseline vs. 3-Months	0.001***		0.157^{NS}	
Baseline vs. 3-Months	0.001***		0.001***	
3-Months vs. 6-Months	0.001***		0.001***	

P-values (intra-group) by Wilcoxon's signed rank test. $P<0.05$ is considered to be statisticallysignificant. ***$P<0.001$, NS: Statistically non-significant, vs.: Versus

Enamel Decalcification Index[14] as recommended by Banks and Richmond, along with surgical loupe magnification (×2.5) for better visual inspection around the orthodontic bracket. The baseline evaluation of DIAGNOdent and visual scores showed no significant difference between the two groups studied (Gel and Varnish). This suggests that both the groups were comparable and there was no selection bias in the present study.

The results of inter-group comparisons in the present study showed that DIAGNOdent and visual scores are significantly

higher in the gel group than in the varnish group both at 3-months (T1) and 6-months (T2). These results indicate lesser demineralization with varnish application compared to the gel application. However, results of intragroup comparisons for both gel and varnish groups showed that DIAGNOdent and visual scores are significantly higher at T1 and T2 compared to baseline (T0) values, also the scores at T2 are significantly higher compared to T1. Indicating that demineralization occurred in both the groups, and it increases with the duration of fixed orthodontic treatment after initial one-time baseline application at the time of bonding. Adriaens *et al*.[19] showed high effectiveness of Fluor Protector fluoride varnish for preventing WSL; the present study also indicates that Fluor Protector fluoride varnish is highly effective in reducing enamel demineralization.

A report from American Dental Association which was based on various systematic reviews and clinical trials related to in-office fluoride interventions, suggested that half-yearly fluoride varnish is very effective in reducing caries incidence.[20] Similarly, Hawkins and Locker[21] also recommends the six-monthly application of professionally applied topical fluoride. Agrawal *et al*.[22] concluded that the biannual application of APF gel significantly reduces enamel demineralization. The results of the present study corroborate with the findings of the above-mentioned studies and both Fluocal Gel and Fluor Protector varnish reduces the caries incidence during the first 6 months after one-time application.

Comparative evaluation between the fluoride gel and fluoride Varnish was carried out by Seppa *et al*.[23] in terms of caries preventive effect of both the agents. They concluded that the difference between varnish and gel was statistically not significant and larger studies were required for comparative evaluation. In the present study, a significant difference between both the group in terms of reducing demineralization is evident. It may be because of the sensitivity of methods used for the evaluation of WSLs.

As evident with the results and also during the examination, laser fluorescence is more sensitive compared to visual examination under magnification as a detection method for enamel demineralization. DIAGNOdent was able to detect changes on the enamel surface and the demineralization scores were reproducible. Findings of DIAGNOdent were corroborated with the visual findings of WSLs. However, many incipient lesions were detected by DIAGNOdent that were clinically not visible even under ×2.5 magnification. The findings of the present study are in tandem with the findings of Aljehani *et al*.,[24] they reported a high correlation between DIAGNOdent and visual findings and concluded that DIAGNOdent is a valuable, objective and quantitative detection tool whereas visual examination is a subjective method. DIAGNOdent can be used for quantification of demineralization and to find out long-term changes with WSL prevention protocols.

Clinical implications

Preventive measures always take precedence, specifically for an iatrogenic problem such as WSLs. Therefore, prophylactic measures in form of topical fluorides are recommended. In patients with poor oral hygiene, it is mandatory not to rely on measures requiring patient compliance. There is a wide array of fluoride preparations available commercially and choices are to be made based on efficiency, ease of application, esthetic considerations, patient's safety, and acceptance. Considering the above facts following clinical implications can be drawn from the present study:

- Initial months with fixed orthodontic appliances are most crucial in terms of susceptibility to enamel demineralization.[25] Hence, it is important to add a topical fluoride application after bonding.
- Both fluoride gel and varnish are professionally applied; however, handling and application of fluoride varnish is easier than fluoride gel, making fluoride varnish a better clinical choice.
- As very less clinically visible lesions were reported in the present study. showing that initial one-time in-office fluoride application is very effective in preventing WSLs during the first 6 months.
- Comparing Fluocal gel and Fluor Protector varnish, the latter showed better results.
- Esthetically, no discoloration of the enamel surface was evident after Fluocal gel or Fluor Protector varnish application.

Limitations of the study

Split-mouth study design with inherent potential for cross-contamination or carry-over effect of fluoride during and after application however it also nullifies the other confounding factors related to oral hygiene, bonding technique, eating and drinking habits. Another limitation is the short prospective study duration of 6 months.

CONCLUSION

This prospective clinical study was conducted to evaluate the efficacy of topical fluoride gel and fluoride varnish in preventing the development of WSLs on enamel in patients undergoing orthodontic treatment using PEA by testing the null hypothesis that there is no difference in the efficacy of two materials being tested. The following conclusions can be drawn from the study:

1. The null hypothesis is rejected as there is a significant difference in the two materials studied to prevent the development of WSLs.
2. Fluoride varnish (Fluor Protector) is more efficacious than fluoride gel (Fluocal) in reducing enamel demineralization, but both the agents could not completely eliminate chances of enamel demineralization.

3. Initial application of fluoride varnish around the orthodontic bracket at bonding appointment may be recommended for every patient as a standard prophylactic procedure to reduce the chances of development of WSLs.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

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