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Review Article

Efficacy of Resin-Modified Glass Ionomer Cement Varnish and Sodium Fluoride Varnish in The Prevention of White Spot Lesions During Fixed Orthodontic Treatment- A Split Mouth Study

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Abstract

Objective: Evaluating efficacy of Resin-Modified Glass Ionomer Varnish and Sodium Fluoride Varnish in prevention of White Spot Lesions (WSLs) during early fixed orthodontic treatment; comparing the incidence of white spot lesions in control teeth and experiment teeth.

Methodology: Design: A Cross-sectional analytical split mouth study.

Setting: Orthodontic Department of Sinhgad Dental College and Hospital.

Participants: A sample size of 288 maxillary and mandibular anterior teeth (24 participants) with newly placed orthodontic brackets, allocated randomly into 4 subgroups, 2 experimental and 2 control.

Interventions: For each experimental quadrant in each patient, respective varnishes were applied on the labial surfaces of anterior teeth. WSLs were recorded before and after 3 months by direct visual inspection following International Caries Detection Assessment System II Criteria.

Results: There was significant difference between pre and post recordings of both the varnishes ($p<0.05$). The control groups showed higher incidence of (WSLs) as compared to the experimental groups ($p<0.05$).

Conclusion: The result obtained from the study suggested that both Sodium Fluoride Varnish (Embrace) and RMGI Varnish (Clinpro XT) will help to prevent WSLs in orthodontic treatments.

Study registration: Scientific advisory committee and institutional ethics committee.

Keywords: Sodium Fluoride Varnish; Resin Modified Glass Ionomer Varnish; White Spot Lesions; Comprehensive Orthodontic Treatment and International Caries Detection System II Criteria

Introduction

The term White Spot Lesion (WSL) was defined as "The first sign of caries like lesions on enamel that can be detected with naked eye [1]. In the absence of adequate oral hygiene, enamel decalcification in the form of white spot lesions is commonly seen during orthodontic treatment, appearing as small lines along the bracket periphery or as large decalcifications with or without cavitations. After the introduction of orthodontic fixed appliances into the oral cavity, there is increases the number of plaque retention sites on the surfaces of the teeth [2]. High levels of bacteria are capable of decreasing the pH of plaque in orthodontic

patients to a greater extent than in non-orthodontic patients [2]. Several studies have reported a significant increase in the prevalence and severity of demineralization after orthodontic therapy compared with controls, with prevalence amongst orthodontic patients ranging 2-96%. The teeth most commonly affected are molars, maxillary lateral incisors, mandibular canines and premolars, especially in the buccal area and gingival region [2-4]. There is no significant relationship between WSL's prevalence as per age and gender or oral hygiene measures [5].

Several methods have been developed over the years for the prevention of WSLs, such as patient compliance dependent traditional approach of mechanical removal of plaque with a fluoridated dentifrice, and daily fluoridated mouthrinses implementing good oral hygiene [6]. Constant use of mouthrinse containing 0.05% sodium fluoride has also shown to reduce the WSLs appearance on buccal surfaces [6]. For less compliant patients' supplemental fluoride such as varnish or fluoride releasing bonding materials can be used [6]. Rose, et al., conducted a study showing that Casein Phosphopeptide (CPP)- Amorphous Calcium Phosphate (ACP) binds to dental plaque, providing a large calcium reservoir inhibiting demineralization and assisting remineralization [7]. However, the evidence level for CPP-ACP paste or ACP resin bonding cement is low [6,7]. Microabrasion with a mixture of hydrochloric acid and pumice leading to a highly polished enamel surface with calcium phosphate packed into the interprismatic enamel surface space is an alternative treatment performed following debanding [6]. Continuous fluoride release from the bonding system around the bracket is another beneficial method to prevent WSLs [6]. Fluoride varnishes are excellent on weakly compliant patients, periodic application of fluoride varnish is much more efficient, reduces demineralization around brackets and promote the remineralization of the carious lesions by delivering the fluoride in a sustained manner over a longer period of time [8].

Jena, et al., conducted a study on 480 maxillary and mandibular anterior teeth by application of Resin-Modified Glass Ionomer (RMGI) cement varnish and concluded that it had a favourable effect in the prevention of WSLs during orthodontic treatment [9]. The RMGI varnish has the potential for more controlled and sustained release of fluoride (Zhou, et al.,) and also has the capacity to protect exposed tooth surfaces from demineralization (Sohn et al., 2012) [10,11]. However, the recently introduced Clinpro XT varnish (3MTM ESPETM) is a light cured Resin-Modified Glass Ionomer Material (RMGI), and the manufacturer claims that it provides a site-specific fluoride- releasing coating for more than 6 months [9].

5% sodium fluoride (NaF) varnishes have a proven track record in caries reduction possessing greater fluoride release over a 48-hour period in comparison to other fluoride products [6]. The positive effects of NaF varnish noted in the current study corroborate the findings of other investigations using Duraphat and Duraflor varnish which contains the same 5% concentration of sodium fluoride as in Embrace varnish [8].

Both these varnishes are independent of patient compliance, easier to apply, and presents sustained release of fluoride over a longer period of time along with a larger duration of action [12]. However, there arises a need to establish which varnish amongst the two shows more effectivity and least disadvantages over the other. So far various preventive methods were based on patient compliance, such as use of fluoridated mouthwashes, gels and tooth-pastes. Thus, the results of the study would be an important adjunct in prevention of WSLs during fixed orthodontic treatment.

Aim

To assess the Efficacy of resin-modified glass ionomer cement varnish and sodium fluoride varnish in the prevention of white spot lesions during fixed orthodontic treatment.

Objectives

- To assess the efficacy of resin modified glass ionomer varnish in prevention of WSLs
- To assess the efficacy of sodium fluoride varnish in prevention of WSLs
- To compare the incidence of white spot lesion in control teeth and experiment teeth

Materials and Methods

In this study, we evaluated the *in-vivo* effectiveness of Naf and RMGI varnish in preventing WSLs surrounding orthodontic

brackets, as measured via visual examination. Before starting with the research, the required approval was taken from the Scientific Advisory Committee and Institutional Ethical Committee, Sinhgad Dental College and Hospital, Pune. Patients visiting Sinhgad Dental College and Hospital for orthodontic treatment and whose orthodontic treatment have started (i.e. both arch banding and bonding) and is not older than a week, fulfilling the inclusion and exclusion criteria were selected for the study. A detailed medical history and an informed consent were obtained from the participants who agreed to undergo the study. The patients, who did not agree or were excluded as per the exclusion criteria, continued their required general treatment.

Twelve anterior teeth of the maxillary and mandibular arch were selected in each patient. Being a split mouth study, these 12 anterior teeth were divided into groups as follows, Group A and Group B are the experimental group and Group C and Group D are control group for each experimental group respectively. Two separate control groups will help us to determine the efficacy of each medicament.

Sample Size

The sample size was determined using appropriate formula and a sample size of 72 teeth in each group was obtained.

Group A: Experimental group- 72 teeth undergoing Clinpro XT - Resin Modified Glass Ionomer (RMGI) Varnish application (manufactured in 2017 at 3M, Australia) on three anterior teeth of any one quadrant in each patient.

Group B: Experimental group- 72 teeth undergoing Embrace - Sodium Fluoride (NAF) Varnish (manufactured in the year 2017 at Watertown, Mass, USA) application on three anterior teeth of any one quadrant in each patient.

Group C: Control group - 72 teeth with no varnish applied, three contralateral anterior teeth each for Group A for each patient.

Group D: Control group - 72 teeth with no varnish applied, three contralateral anterior teeth each for Group B for each patient.

Inclusion Criteria

- Subjects in the age range of 12-40 years with Class 1 malocclusion requiring comprehensive orthodontic treatment
- Fully erupted maxillary and mandibular anterior teeth
- Teeth with intact orthodontic bracket

Exclusion Criteria

- Subjects with enamel hypoplasia
- Subjects with any severely malposed anterior teeth
- Subjects with any systemic disease and/or syndrome
- Subjects allergic to Resin modified Glass Ionomer Varnish
- Subjects allergic to Sodium Fluoride Varnish
- Subject under medicaments that can cause initiation of caries, alter salivary flow rate etc.

Rationale

In order to follow the split-mouth study guideline, double-blinding and cross allotment of groups was adopted. An evaluator who had access to all information of participants and did not know the selected treatment and an operator who did not have access to patient information and only perform clinical procedures was determined in the beginning of the study. In all subjects, the varnishes were applied to either the right or left side of the maxillary or mandibular anterior teeth on the basis of cross-random allocation. With the help of random number generator, the sides (control and experimental) and the type of varnish to be applied were allocated before the beginning of study.

For each experimental quadrant in each patient, the varnish was applied to the labial surfaces of the incisors and canines. The contralateral control teeth had the same type of brackets bonded in the same manner, with no varnish applied. All brackets were bonded with a Transbond XT light-cured bonding agent (3M Unitek). For bonding of brackets (MBT 0.022" bracket slot), teeth

were cleaned with pumice, rinsed and dried thoroughly. The area where the bracket was to be placed was etched with a 37% orthophosphoric acid gel (3M ESPE) for 15s and then was rinsed with water. The enamel surface was dried with compressed moisture and oil free air. A layer of Transbond XT primer was applied to the tooth and bracket mesh. Transbond XT adhesive paste was applied to the base of the bracket and was pressed firmly onto the tooth surface. Excess adhesive was removed, and was light cured with the LED curing unit for 20s. For the first three-four months treatment included initial leveling with 0.012", 0.014", 0.016",0.018" Niti following sequence A of MBT. The arch-wire was ligated to the brackets by stainless steel ligature wire.

The Clinpro XT RMGI varnish and Embrace NAF varnish, were applied on the experimental teeth on the same day immediately after the initial bonding. For the Clinpro XT RMGI varnish as per manufacturer's instructions, the polished tooth surface was cleaned and then 37% orthophosphoric acid gel was applied for 15 s over the entire labial enamel surface extending from gingival surface of the bracket to the free gingival margin. Then, the surface was cleaned thoroughly by water spray and dried with compressed moisture and oil free air. The paste and liquid components of the varnish were mixed on a paper pad for 10-15s by a small plastic spatula. When the mix material appeared glossy and smooth in consistency, it was applied as a thin layer over the etched enamel surface by a ball applicator. Care was taken to avoid prolonged contact of uncured material with soft tissues. If accidental contact occurred, the material was immediately wiped off with wet cotton roll. Then, the varnish was light cured with the visible light-curing unit for 20s. Any overhangs or ledges were trimmed with a no. 15 BP blade taking care not to remove any varnish from the study area.

For the application of Embrace Sodium Fluoride Varnish, as per manufacturer's instructions, the polished tooth surfaces were thoroughly cleaned and dried with compressed oil free air. The varnish was applied on the enamel surface with the applicator brush. Care was taken to avoid contact with soft tissues and bracket. If accidental contact occurred, the material was wiped off with wet cotton roll.

Each patient was followed once in every 4 weeks for orthodontic check-up and arch-wire adjustment. Along with this, the participants were also checked for any new signs of WSLs. All patients were explained to maintain good oral hygiene during fixed orthodontic treatment, and at each visit, they were motivated to maintain these. All patients were advised to brush at least 3-min after each meal with a fluoride containing toothpaste (Colgate Total). No other topical fluoride application was used during the study period.

After 3 months of varnish application, the individual tooth surface was initially cleaned of any plaque deposit by compressed air and water, in some cases hand-scaling was also done. At each visit all the groups were examined according to codes given by international caries detection and assessment system II criteria (3), mentioned in Table 1. Individual tooth surface was polished by non-fluoridated pumice powder and were rinsed and dried thoroughly for recording of WSLs. After recording of the WSLs, all the patients were instructed to use sodium fluoride mouth rinse twice daily as an alternative preventive and therapeutic measure for the WSLs. At the end of three months varnish was applied to all teeth for all the patients who participated in the study.

WSLs can become noticeable around the brackets within 1 month of bracket placement, demineralization continue to increase in the subsequent months leading to formation of regular caries which usually takes at least 6 months [1,2]. Intervention on or before three months will help greatly in the reduction of WSLs. A study conducted by Demito, et al. using fluoride varnishes indicated that at three months the unvarnished group showed a tendency toward greater demineralization than in the varnished group, which developed to more severe demineralization at six months. Thus, WSLs were recorded for individual tooth on a standard proforma before the varnish application (T0) and approximately after 3 months of varnish application (T1) by using visual analysis with the help of international caries detection and assessment system II criteria (3), according to Table 1.

Code	Description
0	Sound tooth
1	First visual change in enamel

2	Distinct visual change in enamel
3	Localized enamel breakdown
4	Underlying dark shadows from dentin
5	Distinct cavity with visible dentin
6	Extensive cavity with visible dentin (more than ½ tooth surface)

Table 1: Standard proforma before the varnish application.

Statistical Analysis

Data were analyzed using SPSS software (Version 16). Frequency analysis and Chi square test were used to measure the percentage and proportions. Paired t-test and ANOVA tests were used for comparison and to determine statistical differences between experimental and control sides. A P-value of 0.05 was considered as a statistically significant level.

Results

The description of visual measurements for WSLs is given in Table 1. There was significant statistical difference ($p<0.05$) as mentioned in Table 2 for pair 1,2,3 and 6. The control group showed higher evidence of WSLs after a duration of three months as compared to the experimental group, Table 2 pair 8 and 10($p<0.05$) (Fig. 1). There was no significant statistical difference between the effectiveness of Group A and Group B group (p value> 0.05) in Table no. 3. There was also no statistically significant difference between the four groups with ANOVA test as per Table 3 $p>0.05$).

Pair (Pre and Post)	Mean	Paired differences (95% Confidence Interval of the Difference)	t	Sig. (2-tailed) p
Pair 1	Pre Clinpro XT - Post Clinpro XT	-.026	-2.304	.031
Pair 2	Pre Clinpro XT - Post Clinpro XT	-.006	-2.145	.043
Pair 3	Pre Clinpro XT - Post Clinpro XT	-.064	-2.564	.018
Pair 4	Pre Embrace - Post Embrace	.036	-1.446	.162
Pair 5	Pre Embrace - Post Embrace	.089	-1.000	.328
Pair 6	Pre Embrace - Post Embrace	-.033	-2.460	.022
Pair 7	Pre Clinpro Control - Post Clinpro Control	.018	-1.813	.083
Pair 8	Pre Clinpro Control - Post Clinpro Control	-.012	-2.145	.043
Pair 9	Pre Clinpro Control - Post Clinpro Control	.110	-.569	.575
Pair 10	Pre Embrace Control - Post Embrace Control	-.064	-2.563	.017
Pair 11	Pre Embrace Control - Post Embrace Control	-.251	-4.153	.000
Pair 12	Pre Embrace Control - Post Embrace Control	.037	-1.696	.103

Table 2: Paired Sample Analysis for pre and post results of the study.

(I) Groups	(J) Groups	Mean Difference (I-J)	Std. Error	Sig.	Lower Bound (95% Confidence Interval)	Upper Bound (95% Confidence Interval)
Group A	Group B	.042	.076	.948	-.16	.24
Group A	Group C	-.042	.076	.948	-.24	.16
Group A	Group D	-.153	.076	.191	-.35	.04
Group B	Group A	-.042	.076	.948	-.24	.16
Group B	Group C	-.083	.076	.696	-.28	.11
Group B	Group D	-.194	.076	.055	-.39	.00
Group C	Group A	.042	.076	.948	-.16	.24
Group C	Group B	.083	.076	.696	-.11	.28
Group C	Group D	-.111	.076	.467	-.31	.09
Group D	Group A	.153	.076	.191	-.04	.35
Group D	Group B	.194	.076	.055	.00	.39
Group D	Group C	.111	.076	.467	-.09	.31

Table 3: Tukey HSD for evaluating the relationship between all the groups.

(A) (B) (C)

Figure 1: Clinical view of white spot lesions which developed during 3 months of fixed orthodontic treatment. (A) Areas of demineralization seen between the bracket attachment sites and gingival margins, of 32,33 and on the mesial aspect of 31; (B) Areas of demineralization are particularly evident between the bracket attachment sites and gingival margins, on the mesial aspect of canine and on the maxillary lateral incisors; (C) Areas of demineralization seen between the bracket attachment sites and gingival margins of 41 and 42.

Discussion

Until now, the general protocol for preventing WSLs in patients undergoing orthodontic treatment is prescribing fluoride mouthwashes and toothpastes, but their effectiveness is highly based on patient compliance. As yet there is no gold standard to prevent WSLs during orthodontic treatment. Geiger, et al., reported a 25% reduction in the number of WSLs using fluoride rinse, fluorie gel and/or fluoride toothpaste [13,14].

Fluoride varnish adheres to the tooth surface in a thin layer and releases fluoride for a period of 5-6 months (Castillo, et al.,). There are various types of fluoride and fluoride releasing varnish which are used by the dentists. Zabokova in her study concluded that the level of fluoride in enamel before and after bonding the brackets with composite resin (Dentaurum, Germany), and application of a fluoride varnish was significantly increased [15].

The Clinpro XT varnish is a resin-modified glass ionomer that contains calciumglycerophosphate, which can provide calcium and phosphate release over the life of the coating (3-6 months; Pianotti, et al.,). Embrace sodium fluoride varnish releases bioavailable calcium and phosphate ions, the essential building blocks of teeth. Saliva dissolves the xylitol coating and releases the calcium and phosphate ions, which react with the fluoride ions in saliva to form protective fluorapatite on the teeth. It provides a sustained time-release varnish with uniform dosage that delivers 10 times more fluoride.

Another helpful finding from this study was; Embrace sodium fluoride varnish and Clinpro XT RMGIC varnish were moderately effective in preventing the white spot lesions when compared to the control group. Also, a study conducted by Demito, et al.,

found there was an increase of 32% in demineralization in areas where varnish was not applied in comparison with a 30-50% reduction in WSLs in areas where Duraphat was applied twice annually [16]. Jena AK, et al., found that the Clinpro XT RMGIC varnish was moderately effective in preventing the white spot lesions. Sohn, et al., also reported that the Clinpro XT varnish protected the exposed root surfaces from demineralization [3,17].

Although the role of saliva in the physiological regression of the WSLs is not to be ignored, many of the lesions remain stable [11]. Several professionally and home applied products contain fluorides and/or casein phosphopeptide-amorphous calcium phosphate, with evidence for varying degrees of success to be found in the dental literature [18,19]. The varnish used in this study helped us to determine that varnishes can be applied to prevent WSLs and is independent of patient compliance. However further research needs to be carried out using similar parameter but for a longer duration of time to evaluate the effectiveness of varnish in preventing WSL during orthodontic treatment.

Conclusion

White spot lesions are one of the most common iatrogenic effects of orthodontic treatment which hampers the esthetics and health of sound teeth. This widespread problem poses an alarming concern and demands significant attention from orthodontists that should result in increased emphasis on effective caries prevention. The result obtained from the study suggested that both Sodium Fluoride Varnish (Embrace) and Resin Modified Glass Ionomer Varnish (Clinpro XT) will help to prevent these white spot lesions and have the potential to prevent the further breakdown of enamel around the brackets exposed to cariogenic conditions.

Ethical Approval

Approval Letter obtained from Institutional Ethics Committee (IEC).

Conflict of Interest

The author has no conflict of interest to declare.

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