

# Pit and Fissure Sealant Versus Fluoride Varnish In Prevention of Occlusal Caries

## Original Article

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## Abstract

**Introduction:** It was to compare the efficacy of semiannually fluoride varnish application versus pit and fissure sealant to reduce occlusal caries incidence.

**Materials and methods:** A randomized parallel designed study was conducted with 352 children aged 6-7 years. Participants were allocated into biannual application of varnish (n=179) (NaF 5% (Durafluor, DENTSPLY®, Latin America) or resin-based fissure sealant (n=173) (Eco Seal, Korea®) single application without previous tooth preparation. Two visual-tactile methods including WHO and Nyvad criteria were used for caries detection. The unit of analysis was tooth surface.  $\chi^2$  test, t-test, Fisher exact, and multi-variable logistic regression were used for statistical analysis.

**Results:** Proportion of caries free (DMF=0) were 79.8% and 79.1% among the sealant and varnish groups respectively. By using Nyvad visual-tactile criteria 60.4% and 50.2% of surfaces remained sound in sealant and varnish groups respectively ( $p < 0.001$ ). The prevented fraction of sealant to varnish by two measures was 3.46 and 20.5 respectively. Regression model showed sealant application (OR=0.34) and tooth brushing >2 times/day (OR=0.8) were protective factors while dmfs>4 (OR=0.08), and snack consumption >2 times/day (OR=1.3) were risk factors of caries incidence.

**Conclusion:** The results of this study suggest that semiannual fluoride varnish application can be recommended for preventing and reducing occlusal caries in low caries risk population.

**Key words:** •Fluoride varnish •Fissure sealant •Occlusal Caries.

## Introduction

Global decline in caries incidence is an important achievement of oral health practitioners during the past decades, however more recent studies indicate a warning increase in caries occurrence among children and adults, primary and permanent teeth.<sup>(1)</sup> According to Iranian National Health Surveys DMFT index of 12 year old Iranian children is 1.86. The index is lower in rural areas compared to urban (1.7 versus 1.9); however, treatment is still unavailable to a part of population mainly in rural areas. The main compartment of DMFT index in 12 years of age Iranian children is constituted by decay.<sup>(2)</sup>

Unequal distribution of caries among populations can be attributed to disparities in communities' demographics and life style.<sup>(1,3)</sup> In This public health issue oral health burden with multi-dimensional etiology and predisposing factors, returning to successful Public health remedies may be the best solution.<sup>(1)</sup> Two practical, competing techniques in this area: Fissure sealant and fluoride varnish seem to have the capability of covering population while simultaneously targeting high risk subjects.<sup>(4)</sup> Resin based pit and fissure sealants are the main preventive method in occlusal surfaces. Effectiveness of sealants has long been studied and supported by several investigators.<sup>(2-4)</sup> Effectiveness of sealants is mainly based on retention; hence, it may be declined over time by loss of retention. In addition, there are limitations in sealant application in community based programs. One of the limitations is technique-sensitiveness. Moreover sealant placement relies on equipment and trained personals. Hence, there are limitations to use sealants in community based programs especially in developing countries. Effectiveness of sealants increases in populations with high caries rate.<sup>(5)</sup>

Sodium fluoride varnish has been first developed in 1960s and composed of a lac-

quer or liquid base containing fluoride salts. Fluoride varnishes may be aqueous solutions (e.g. Bifluorid) or non-aqueous solutions of natural resins (e.g. Durafluor). Resin-based varnishes have a sticky texture, which prolongs the contact time between the fluoride and the enamel (12 hours or more) as reservoir of fluoride.<sup>(5)</sup> The concentration of fluoride in varnish ranges from 1,000 ppm to 56,300 ppm.<sup>(6)</sup> Varnish is a safe vehicle of fluoride application for small amount of applied dose estimated about 0.5 ml on average that equals to 3 to 11 mg of fluoride ion per dose that is much lower than the toxic dose of 5 mg/kg.<sup>(7)</sup> The caries preventive effect of fluoride is strongly related to the contact time between fluoride and tooth surface. Highly concentrated products tend to precipitate calcium fluoride as a reservoir of fluoride which is released during pH fall.<sup>(5)</sup>

Fluoride varnish application is easy, with greater patient acceptability" as compared to other fluoride products, especially fluoride gel.<sup>(5)</sup>

There are more than 30 fluoride containing varnish products available with different compositions and delivery systems. Evidence favors providing 2-4 applications yearly in children and adolescents 6-18 years of age.<sup>(8)</sup> The anti-caries effect of fluoride is implemented through its action in enamel/plaque interface mainly through remineralization of early carious lesions and reducing enamel solubility.<sup>(5)</sup>

The last published Cochrane review on this issue concluded that an absolute recommendation cannot be advised relying on present evidence.<sup>(9)</sup>

Considering the importance of caries prevention in child population, there is a need to seek new approaches to cover public needs. The aim of the present study was to compare the effectiveness of pit and fissure Sealant and Fluoride Varnish in prevention of occlusal caries" and to investigate the impact of probable risk factors on outcome.

## Materials and Methods

This study was approved and granted by Institutional Review Board and Ethical Committee of Guilan University of Medical Sciences, Rasht, IRAN, (Grant number 6051 and IRCT reference number 138802091861 IRCT) conducted from July 2009 to July 2012. The trial comprises a two-arm double cluster randomised parallel design. Twelve primary schools from different areas of Rasht having at least two classes from each grade were selected from sixty eight. According to the study protocol, school hygienists were actively involved in the study including case selection, parental interview, follow-up visits and oral health education. Fluoride content of water during the years of 2009-2012 was in the range of 0.45-0.8 ppm based on seasonal changes.

After discussing the risks and benefits of intervention with all parents, six hundred twenty two 6-7 years of age children (grade 1 and 2) were invited for initial screening. A sample of 170 teeth per group was determined based on a %5 statistical significance, with a power of 90%, and a 17% difference between FV and FS groups according to the study of Bravo 1996. With estimation of 35% dropout and predicting at least one eligible molar per person, 250 subjects were determined for each group. Written informed consent was obtained from parents and they were assured that their children could withdraw from the study at any time without negative consequences. The children were randomly assigned to sealant and varnish groups. In each school, one class from each grade was assigned to sealant and the other to varnish by coin tossing.

Inclusion criteria for enrollment were: age 6-7 at the beginning of the study, presence of at least one sound newly and completely erupted first permanent molar with deep occlusal fissures, and cooperative behavior. Children were excluded in case of any history of any chronic diseases.

## Clinical examination:

Children were examined in dental clinic using unit light, saliva ejector. One trained dentist (K.S) who was blind to the study design performed all examinations using WHO criteria<sup>(10)</sup> and Nyvad visual-tactile criteria.<sup>(11)</sup> The Nyvad criteria divide the lesions in two main categories of active and inactive lesions and at the same time are classified by lesion's severity in a continuum from sound to intact, enamel discontinuity, cavity, and fillings respectively (Table 1). Prior to the clinical examination, all the children were given the same types of toothbrush (Jordan, Malaysia) and brushed their teeth. To determine caries status by Nyvad classification; teeth were kept isolated by cotton roll and saliva ejector, rinsed and dried for 3-5 s with a blast of air. Explorer was used to remove any remaining debris and to inspect the surface texture if visual inspection was not conclusive. The Inter-examiner kappa value for Nyvad and WHO criteria were 0.79 and 0.81. Sealant retention was determined according to "CCC sealant evaluation system" (Deery et al 2001). Four categories of: A-complete retention, B-partially retained (more than 50%), C-partially retained (less than 50%), and D-lost sealants.<sup>(12)</sup>

## Intervention:

All children and their parents participated in oral hygiene education sessions including restriction of sugary snacks and regular tooth brushing and received toothbrush and 1450 ppm Fluoride toothpaste in Sodium Monofluorophosphate composition (Pooneh jelly toothpaste, Paxan, Iran) in every visit. The Nyvad classification is presented in table 2. During the study, the participants did not receive any supplementary fluoride resources except regular tooth brushing by fluoride jelly toothpaste. Routine oral health instruction continued during the study by school hygienists.

Sealant and varnish application was performed by a trained dentist (F.S). The teeth

were sealed if the tooth was completely erupted without any gingival impingement on occlusal surface. Neither tooth preparation nor bonding agents were used prior to the sealant application. Sealants (Eco-seal, Korea) placed according to the manufacturer were cured for 40 s by Halogen type Light cure device [Astralis 3(Ivoclar Vivadent Liechtenstein)]. Partially or completely lost sealants were repaired /reapplied once if necessary after six months. Sealants were evaluated every 6 months until the end of study, and the final retention rate was reported.

Fluoride varnish (Durafluor, DENTSP-LY®, Latin America, 22600 ppm) was used without prior prophylaxis. The tooth was rinsed and dried by air syringe, and the area was kept dry by cotton rolls. A thin layer of Fluoride varnish was painted on total tooth surfaces and kept isolated for 15 seconds. The patients were asked to avoid chewing for 2 hours and not to brush their teeth until the next day. Fluoride varnish application was repeated every six months until the end of study. During the study, all participants were reexamined biannually and in case of any caries occurrence, they were offered to receive appropriate treatment.

For statistical analysis, only occlusal surface was taken as the unit of analysis. Data were analyzed using SPSS 21. Independent t-test (alternatively Mann-Whitney for skewed distributions), chi-square (alternatively fisher exact) and backward stepwise regression were used for statistical analysis. Independent variables included those at the participant and tooth level treatment (sealant, varnish), snacking (frequency), tooth brushing (frequency), and baseline dmft score. The prevented fraction was calculated as Arruda et al.<sup>(13)</sup> The significant level was set at 0.05.

## Results

From 400 children, three hundred fifty two were reexamined during 24 months re-

presenting an overall follow-up rate of 88% (352/400). Flow diagram of study population is presented in figure 1. All subjects were aged 6-7 at the beginning, 134 females (38%) and 218 males (62%). There was similar numbers of two genders at baseline however at final examination sealant group included more females and fewer males in compare to varnish. The majority of children reported brushing their teeth once daily and sugary snacks 1-2 times without significant difference between groups. Sealant group consisted of 173 subjects (691 occlusal sites) and Fluoride varnish group included 179 subjects (716 occlusal sites) at the final examination. Sealants as the main preventive method in occlusal caries prevention were considered as the control group.

Retention rate of sealants during twenty four months was evaluated using 4 –point CCC score completely retained (code A) to completely loss (code D). At final examination, 43.3% of sealants were completely retained. Partial retention of more or less half of the tooth surface (code B and C) was observed in 37% and 8.7% of occlusal surfaces respectively and 11% of sealants were completely lost (Table 2).

Caries status was determined by two visual –tactile measures: WHO criteria (DMF) and Nyvad criteria. At final examination, the mean DMFT and DMFS scores were not significantly different between sealant and varnish groups (Table 3).

When the groups were compared by means of Nyvad criteria, more sound as well as active lesions were found in sealant group when compared to varnish, chi-square  $P < 0.001$ . Distribution of lesions according to severity is demonstrated in Figure 2.

**Table1.** Definition of clinical scores (according to Nyvad et al.1999)

Score	Category	Criteria
0	Sound	Normal enamel translucency and texture(slight staining allowed in otherwise sound fissure).
1	Active caries (Intact surfaces)	Whitish/yellowish opaque with loss of luster; feels rough under explorer touch; generally covered with plaque; intact fissure morphology
2	Active caries (surface discontinuity)	Same criteria to score 1; localized surface defect in enamel only(micro cavity )
3	Active caries (cavity)	Enamel/dentin cavity easily visible with naked eye.
4	Inactive caries (intact surface)	Surface of enamel is whitish, brownish or black. Enamel seems shiny and feels smooth with tip of probe.
5	Inactive caries (surface discontinuity)	Same criteria as score 4. Localized surface defect (microcavity) in enamel only. No undermined enamel or softened floor detectable with the explorer.
6	Inactive caries(cavity)	Undermined Enamel/dentine cavity easily visible with the naked eye; surface of the cavity feels shiny and feels hard on gentle probing. No pulpal involvement. Filling (sound surface)
7	Filling (sound surface)	
8	Filling + active caries	Caries lesion may be cavitated or non-cavitated.
9	Filling + inactive caries	Caries lesion may be cavitated or non-cavitated.

**Table2.** Retention rate of sealants at 24 months

	Tooth type				total
	16	26	36	46	
<b>Optimal coverage code A</b>	79(45.6%)	78(45%)	75(43.7%)	68(39.3%)	299(43.3%)
<b>More than 50% coverage code B</b>	69(40%)	64(37.2%)	57(33.1%)	66(38.1%)	256(37%)
<b>Less than 50% coverage code C</b>	11(6.4%)	13(7.6%)	20(11.6%)	16(9.2%)	60(8.7%)
<b>Lost sealant code D</b>	14(8 %)	18(10.2%)	20(11.6%)	23(13.4%)	76(11%)
<b>Total</b>	173	173	172	173	691

**Table3.** Mean DMFS-DMFT index in sealant and varnish groups

		N	Mean(SD)	F*	T**	P value ¥	SE Difference
DMFT	Sealant	691	0.41(0.92)	3.64	0.89	0.37	-0.90, 95%CI[-0.097-0.259]
	Varnish	716	0.33(0.77)				
DMFS	Sealant	691	0.51(1.47)	5.20	1.77	0.27	0.13, 95%CI [-0.104-0.406]
	Varnish	716	0.36(0.88)				

\*F=F value, \*\*t=t value, ¥ Independent Samples Test

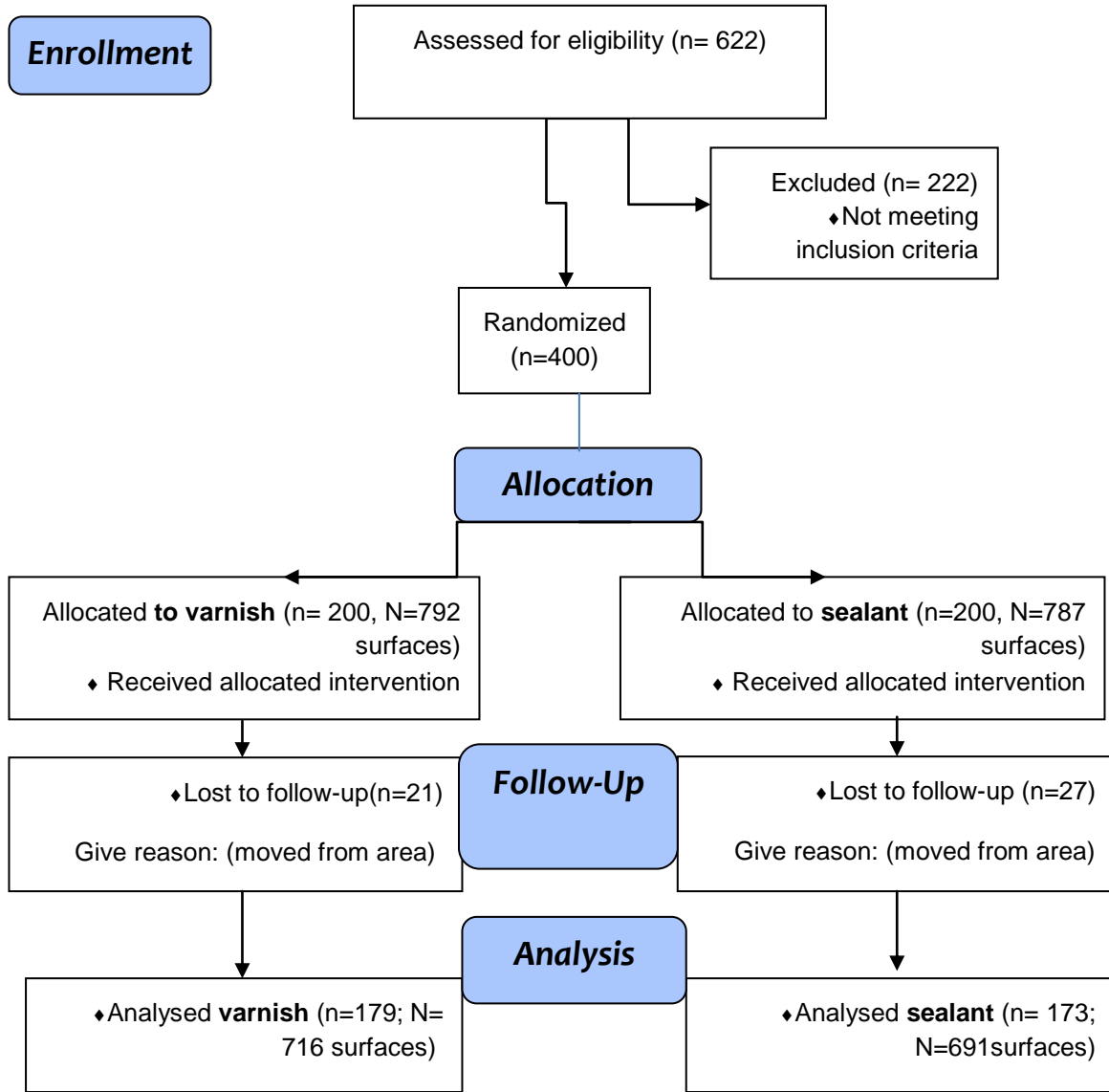
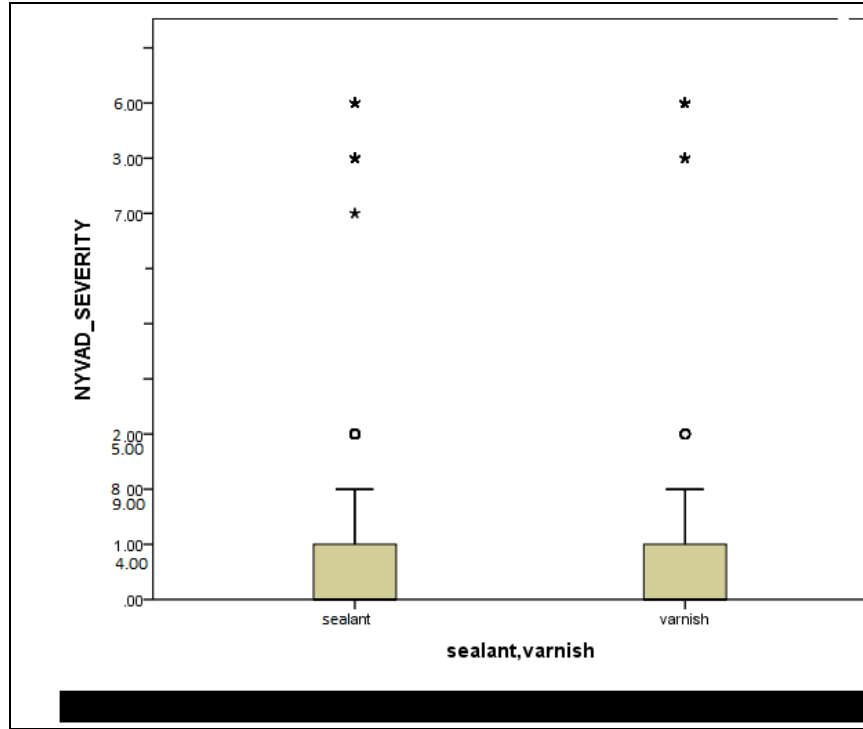


Figure 1. Flow diagram of study population





**Figure2.** Box plot representing the distribution of lesions according to severity; the median and minimum scores indicated sound surfaces that constituted 75% of all surfaces (upper box limit /third quartiles). Surface discontinuities in enamel are demonstrated as outliers. The fillings were the next prevalent type of lesions (whiskers). Cavities (score 3, 6) were scarce.

Distribution of different categorizes of lesions according to Nyvad criteria is summarized in table 4. There was a significant difference between groups  $P < 0.001$ . More sound surfaces were observed in sealant than in varnish group; while more intact surfaces among varnish group. When the clinical scores were dichotomized to carious and non-carious lesions, as showed in table 5, the difference between groups was not significant (fisher exact test  $P = 0.331$ ). In order to estimate the probability of preserving non-carious tooth surfaces (score 0+4), when fissure sealants were applied; Mantel-Haenszel Common Odds Ratio Estimate were used. (OR=0.92;  $P = 0.611$ , 95% CI

[0.698-1.23]). Net gain, the prevalence of preserved tooth surfaces in every 100 treated teeth, was calculated in both DMFT and NYVAD indices. The prevalence of caries free subjects (DMFT=0) was 79.1% and 79.8% in varnish and sealant groups respectively, hence the Net gain of sealant to varnish calculated by:  $79.8 - 79.1 = 0.7$ . The prevented fraction (PF) of varnish to sealant was derived by calculating the difference between the incidence of caries (DMFT) in varnish group and the incidence of caries in sealant group (as the base of comparisons):  $100 - 79.8 = 20.2$ ,  $100 - 79.1 = 20.9$  divided by the incidence of caries in the sealant group.<sup>(13)</sup> PF was:  $100(20.9 - 20.2) / 20.2 = 3.46$ .

**Table4.** Distribution of Nyvad scores among sealant and varnish groups

Category	Group		P-Value
	Sealant	Varnish	
0	417(60.4%)	360(50.2%)	0.001¶
1	25(3.6%)	40 (5.5%)	
2	18(2.6%)	5(0.9%)	
3	12 (1.7%)	7 (1%)	
4	157(22.8%)	250(34.8%)	
5	13(1.9%)	22(3.1%)	
6	1(0.1%)	5(0.7%)	
7	1(0.1%)	0(0%)	
8	14(2%)	7(1%)	
9	33(4.8%)	20(2.8%)	
<b>total</b>	<b>691(100%)</b>	<b>716(100%)</b>	

¶ Chi-Square

0: Sound, 1: Active intact, 2: Active enamel surface discontinuity, 3: Active cavity, 4: Inactive intact, 5: Inactive enamel surface discontinuity, 6: Inactive cavity, 7: Filling, 8: Filling +active caries, 9: Filling +inactive caries

**Table5 .**Dichotomized classification of caries status according to presence or absence of caries

Group	Without caries score(0+4)	Caries (other scores)	Total	Pvalue
Sealant	577(83.5%)	114(16.5%)	691	0.33*
Varnish	605(84.5%)	11(15.5%)	716	

\*Fisher exact test

The prevalence of Nyvad's sound surfaces was 60.4% and 50.2% in sealant and varnish, respectively. Also, the prevented fraction of sealant over varnish was 20.5% in sound surfaces.

The agreement between DMF index and Nyvad criteria was calculated by Cohen Kappa value. There was a weak but significant agreement between DMFS index and caries score in distinction carious surface Frank cavities by DMF versus discontinuity/cavity (Nyvad scores 2, 5, 3, 6 and 7-9):  $p < 0.001$ , kappa=0.15.

Binary (caries/no caries) Backward Stepwise Multivariate Logistic Regression determines the covariates of caries incidence among study population. There were two effective protective variables on caries incidence variables: sealant application and tooth brushing more than twice daily.

## Discussion

During the present study two different caries detection methods were used. Due to low prevalence of caries in this population, DMF index was used in combination with a more detailed diagnostic measure to provide sufficient information about the outcome of intervention. The findings of this study indicated that when DMF index was used, or in other words when a Frank occlusal lesion was determined as caries lesion; the efficacy of pit and fissure sealant and fluoride varnish were similar. When the surfaces were evaluated by Nyvad visual-tactile criteria the predominance of sound surfaces in sealant group and intact surfaces among varnish group was observed. In fact the latter criteria attempt to detect every slight surface changes. Due to dynamic nature of caries these surface changes may progress to other types of lesions or in contrast be reversed. Intact lesions imply to surfaces with initial demineralization without loss of tooth substance and intact-inactive lesions are inferred to those surfaces with remineralization of early lesion. Hence in a second analysis we made a combination of sound and intact-inactive lesions together as non-carious lesions category. The comparison of the new category of non-carious lesions between groups, demonstrated that the efficacy of both interventions was similar. At dentinal level, again similar caries rate was observed in two groups as shown by the proportion of cavities and fillings. This finding was in agreement with that of Liu et al<sup>(5)</sup>, and Uma et al.<sup>(14)</sup>, both reported similar efficacy of sealant and varnish at dentinal level. The diagnosis criteria were ICDAS (code 4-6 /dentinal caries) in the study of Liu and DMF was used by Uma.

The predominance of sound surfaces in sealant group implies a better protective effect of sealants in preserving sound surfaces, while more intact surfaces among varnish group may demonstrate the therapeutic role



of fluoride varnish in remineralising initial lesions.<sup>(15)</sup> Hence, one may conclude that both methods are effective in different ways.

Despite the similarity of groups in the main results, it was observed that sealant application was more likely to prevent the new lesions.

The Prevented Fraction of sealant to varnish was 3.46 by using DMFT index. The crude preventive fraction of sealant and varnish by DMFT index were 20.9 and 20.1%, respectively. When the sound surfaces were considered as described by the Nyvad clinical criteria, the prevented Fraction of sealant over varnish was 25.5. These findings imply the better protective effect of sealants on occlusal surfaces. Liu et al, reported the prevented fractions for sealant and varnish in compare to the controls 65% and 48% at dentinal level respectively.<sup>(5)</sup>

When the severity of lesions was considered, majority of surfaces remained sound or intact among both sealant and Fluoride varnish groups. The next prevalent figures were Fillings, surface discontinuities and cavities that constituted a cumulative percent of 13.2% and 12% in sealant and varnish groups respectively, representing the protective effect of both sealant and varnish. There are few published similar studies on this issue. The latest published studies [Bravo 1996, Bravo 2005, Uma 2011, Liu 2012] could not reached a strict conclusion of superiority of sealants over varnish due to several reasons including protection of other surfaces and feasibility of use in public health programs.

At 24 months, the complete retention was 49%. In a non-replacement protocol Liu et al. reported the rate of fully or partially retained sealants as much as 46% at 24 months. Bravo et al. reported an 84.5% complete retention at 24 months with periodic repairs. They reported an average of 0.39 times replacement need during 24 month period.

To investigate the probable predictors of caries incidence multivariate logistic regression was used. Sealant placement and tooth-brushing more than twice a day were protective variables, whilst frequent Snack consumption (more 2 times /day) and dmfs>4 were promoted caries occurrence. Caries risk Assessment Tool (CAT) places the history of previous decay and more than 3 between meal exposures to cariogenic snacks as a high caries risk indicator, whereas accessibility to fluoride supplements places the subject in low risk category.<sup>(16)</sup> Hence, the study population may basically place in belong to low caries risk category. The relationship between dft and risk of sealant failure has been reported by Bravo et al.<sup>(17)</sup>

The dropout rate of this study was very low. The reason was establishing a close collaboration with school organizers and nurses. Their involvement in the study increased the participation of parents and encouraged the children not to lose their periodical appointments.

One of the limitations of this study was the single application of sealants. We applied sealants once and reapplied/repared only once after 6 months that should be considered in Preventive fraction. However even if the follow-up cannot be ensured sealant application is advocated [Gooch et al 2009].<sup>(18)</sup> Clinical diagnosis is the base of any caries detection in daily practice. Hence, seeking practical while precise criteria helps the dental professionals to assess the lesion at its earliest stage. Moreover, any preventive/interceptive method should be tailored to special needs of the targeted population. Two elements of successful management prevention are early detection and appropriate preventive method. Any effort in preserving the integrity of tooth structure should not be ignored specially in pediatric patients.

## Conclusion

In conclusion, dynamic nature of caries process provides an opportunity to prevent and/or reverse the lesions before forming a true cavity. Based on the present study, considering the low caries risk population and the limitations of the study, Fluoride varnish is recommended as an effective and feasible preventive method to reduce caries incidence.

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