RESEARCH

Assessing the effect of fluoride varnish on early enamel carious lesions in the primary dentition

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ABSTRACT

Background. The aim of this study was to evaluate the effect of fluoride varnish on enamel caries progression in the primary dentition.

Methods. One hundred forty-two children in Head Start schools (3 to 5 years old) were randomized into the varnish and control groups. Children in the varnish group received fluoride varnish (Duraphat, Colgate-Palmolive Co.) at baseline and after four months, and children in the control group received no professional fluoride applications. Two calibrated examiners performed the examinations at baseline and at nine months.

Results. At nine months, the authors found that in the control group, 37.8 percent of active enamel lesions on occlusal, buccal and lingual surfaces became inactive, 3.6 percent progressed and 36.9 percent did not change. In the varnish group, 81.2 percent became inactive, 2.4 percent progressed and 8.2 percent did not change. The difference between the groups was statistically significant ($P < .0001$). The mean decayed surfaces, or ds, value in the varnish group was significantly lower after nine months than it was at baseline ($P < .0001$). When enamel lesions were included in the data analysis (along with dentinal lesions), the decayed with initial enamel lesions, missing and filled surfaces, or $d_E$mfs, values; decayed with initial enamel lesions, missing and filled teeth, or $d_E$mft, values; and decayed surfaces with initial enamel lesions, or d_Es, values were significantly lower in the varnish group after nine months than they were at baseline ($P < .0001$).

Conclusions. These results suggest that fluoride varnish applications may be an effective measure in reversing active pit-and-fissure enamel lesions in the primary dentition.

Clinical Implications. Fluoride varnishes are safe, easy to apply and well-accepted by patients. This study shows that fluoride varnish may offer an efficient, nonsurgical alternative for the treatment of decay in children.

Despite the decline in the incidence of dental caries in the United States, the disease remains a significant problem for the nation's children, especially children in low-income families.[1] Based on analyses of the data in the National Health and Nutrition Examination, or NHANES, surveys, the mean number of decayed or filled teeth, or dft, among children aged 2 to 5 years decreased from 1.21 (NHANES I, 1971-1974) to 1.01 (NHANES III, 1988-1994).[2] However, the surveys showed no reduction in untreated decay in children who were at or below the poverty level. Unfortunately, the groups at highest risk of developing disease—the poor and minorities—have lower rates of dental care use than the mean rate in the United States.[3] An efficacious, safe, feasible and cost-effective caries preventive treatment for high-risk children is essential.

Fluoride varnish applications may be an effective measure in reversing active pit-and-fissure enamel lesions in the primary dentition.

Acceptance in Europe. Fluoride varnishes have replaced topical gel treatments in many countries. For more than 25 years, fluoride varnishes have been the standard of practice for the professional application of topical fluoride in Europe.[4] The primary reason for the wide acceptance of fluoride varnish is that the procedure is easy, safe, convenient and well-accepted by patients.[5] Patients' exposure to fluoride can be better controlled with varnishes, and less chair time is required than that needed for conventional foams and gels.[5] Fluoride varnish covers the teeth with an adherent film that lasts for up to 24 hours, which is the recommended time before a patient can resume brushing, thereby enhancing the uptake of fluoride ions into the tooth structure. Fluoride is deposited as calcium fluoride, creating a reservoir of fluoride ions, which are slowly released.[6] Thus, the action of fluoride is related to its inhibition of the demineralization processes as well as its promotion of enamel remineralization.

Clinical effectiveness. Numerous studies have shown fluoride varnishes to be clinically effective.[5, 7-11] To our knowledge, Duraphat (Colgate-Palmolive Co.) has been the most extensively studied fluoride varnish.[7, 8-13] A recent review of fluoride varnishes by Beltrán-Aguilar and colleagues[14] summarizes their clinical use, cariostatic mechanism, efficacy, safety and toxicity. However, research on the effect of fluoride varnish on caries reduction in the primary dentition either has not been well-documented or has yielded inconclusive results. Grodzka and colleagues[13] studied the efficacy of semiannual applications of fluoride varnish in 3½-year-old children, but did not find the varnish to be effective after a two-year period.

Numerous studies have shown fluoride varnishes to be clinically effective.

Holm[9] evaluated semiannual applications of fluoride varnish in 3-year-old children and found a 44 percent reduction in caries after two years. Peyron and colleagues[11] studied the progression of approximal caries in the primary dentition and the effect of varnish on caries progression in 3- to 6-year-old children. After one year, 51.2 percent of the enamel lesions in the varnish group exhibited progression and 82.8 percent of the lesions in the control group progressed. These authors concluded that the semiannual application of varnish had a cariostatic effect.

Twetman and Petersson[15] studied the effect of fluoride varnish on caries incidence in 4- to 5-year-old children, using the World Health Organization, or WHO, criteria, and observed that the fluoride-silane varnish had a cariostatic effect in the primary dentition. Frostell and colleagues[16] studied the effect of semiannual applications of varnish on caries development in the primary dentition of 4-year-old children and found a 30 percent reduction in caries incidence. The mean caries increment was 2.86 (decayed, missing and filled surfaces, or dmfs) in children in the varnish group and 4.10 (dmfs) in children in the control group. When initial carious lesions were included in the dmfs index, the difference between the groups also was significant.

It is difficult to compare clinical studies because of the wide variation in test conditions and a number of other factors that influence the results. Caries prevalence or incidence in the study population, number and age of subjects, frequency of varnish application, use of additional fluoride products and actual levels of caries risk can influence the outcome of a study.[17] Also, the currently used scoring systems for dental caries (for example, dmfs values) do not consider the dynamic nature of the disease, which can create variations in the results. The traditional measurement of caries at the stage of cavitation, which excludes precavitation stages,[18] no longer accurately reflects changes in the actual disease process. Several studies have shown that the diagnosis of caries at the cavitation stage results in a significant underestimation of the actual caries experience in populations.[19-21] Use of a modified caries scoring system to differentiate the activity of lesions has been tested in the permanent dentition,[22] but not in the primary dentition.

Several studies have shown that fluoride is effective in remineralizing and arresting early carious lesions in the permanent dentition.[7,12] In this study, we used a scoring system that differentiates between active and inactive enamel carious lesions to evaluate the effect of fluoride varnish on early noncavitated lesions in the primary dentition of preschool-aged children.

MATERIALS AND METHODS

Subjects and fluoride treatment. Two hundred twenty-two children aged 3 to 5 years in 10 Head Start schools in Alachua County, Fla., were invited to participate in this study. One hundred eighty-three children in 17 classes accepted and were randomly assigned to the varnish (n = 68) or control (n = 115) groups. We explained the procedures, possible discomforts or risks, as well as possible benefits to the parents, and obtained their informed consent before the investigation began. The research protocol and informed consent forms were reviewed and approved by the University of Florida Health Science Center's Institutional Review Board Involving Human

Subjects. Thirty-five participants dropped out during the trial, leaving 59 participants in the varnish group and 89 in the control group. The main reasons for dropping out included families moving from the area, children withdrawing from the school program and children refusing to continue to participate in the study. An additional six subjects in the control group were excluded because comprehensive restorative treatment was administered immediately after the study began.

The schools were located in areas where the drinking water contained 0.80 milligrams of fluoride per liter. In the varnish group, the subjects received topical applications of fluoride varnish (Duraphat [5 percent sodium fluoride, 22,600 parts per million fluoride]) at baseline and four months later. One of us (J.A.-G.) and a pediatric dental resident performed the baseline applications at the University of Florida dental clinic and the second applications at the children's schools.

In the dental clinic, after cotton roll isolation was completed, the investigators dried the teeth with compressed air and applied the varnish with a small brush to all surfaces of all teeth. At the school visits, each child placed his or her head in the investigator's lap. The dentists then dried the teeth with sterile cotton sponges and applied the varnish with the brush. Each child was advised not to drink for at least two hours or chew for at least four hours and to avoid rough, hard food for the next 24 hours. The investigators told the children to brush their teeth the next morning.

Caries diagnostic criteria and examinations. We differentiated between active and inactive enamel carious lesions on the basis of a combination of visual and tactile criteria. Radiographic bitewings were used to confirm that lesions had not extended into the dentin and to identify interproximal lesions. The box ("Description of the Caries Diagnostic Criteria") shows the scoring criteria for clinical caries assessment.[21] After drying the surface with compressed air, the investigators performed a visual examination, and then used the tip of the explorer to gently check for the loss of surface smoothness or the loss of tooth structure.

Two calibrated dentists (J.A.-G. and the pediatric dental resident) performed the examinations at baseline and nine months later. They were unaware of the treatment group to which subjects were assigned. The dentists held preliminary discussions on caries diagnosis and calibration before the initial examinations were performed. Interexaminer reliability of the caries diagnostic criteria was assessed by re-examining 8 to 10 percent of the subjects at each examination period. The results were expressed as percentage agreement and Cohen's κ. The percentage agreement for caries diagnoses was 79 percent at the baseline examination and 99 percent at the nine-month examination. The κ statistic was 0.71 at the baseline examination (substantial level of agreement) and 0.91 at nine months (excellent level of agreement).

DESCRIPTION OF THE CARIES DIAGNOSTIC CRITERIA.*

CODE	CRITERIA
S	Sound, normal enamel translucency and texture.
A	Active enamel caries, surface of enamel is whitish/yellowish opaque with loss of luster; feels soft or rough on probing. Presence of small porosity involving enamel only.
I	Inactive enamel caries, surface of enamel is brownish or black. Enamel may be shiny and feels hard and smooth on probing. Small porosity involving enamel only.
D	Enamel/dental cavity easily visible with the naked eye; surface of cavity feels soft or leathery on probing.
P	Dental cavity with pulpal involvement.

* Source: Nyvad and colleagues.[21]

We defined sites as occlusal, approximal and buccolingual surfaces. Active enamel lesions were considered as decayed (d), and inactive enamel lesions as sound (s) when using our newly developed $d_E$mfs, $d_E$mft and d_Es indexes (that is, decayed with initial enamel lesions, missing and filled surfaces; decayed with initial enamel lesions, missing and filled teeth; and decayed surfaces with initial enamel lesions, respectively). We used these new indexes to simulate a clinical situation, in which active enamel lesions would be restored and inactive lesions would be monitored. When using the traditional dmfs, dmft and ds indexes, we excluded initial enamel lesions, since these indexes do not differentiate between the activity of the lesions.

We analyzed data using STATVIEW 4.0 software (Abacus Concepts, Berkeley, Calif.). Differences in caries prevalence were evaluated with the Mann-Whitney U test. We used the Fisher

TABLE 1

CARIES PREVALENCE (dmfs, dmft, ds)* IN VARNISH AND CONTROL GROUPS.

INDEX	MEAN ± SD† MEASURE AT BASELINE			MEAN ± SD MEASURE AT NINE MONTHS		
	Varnish Group (n = 59)	Control Group (n = 83)	*P* Value	Varnish Group (n = 59)	Control Group (n = 83)	*P* Value
dmfs	2.51 ± 4.02	2.58 ± 3.27	NS‡	3.05 ± 4.25§	4.05 ± 4.40**	< .05
dmft	1.63 ± 2.24	2.07 ± 2.44	NS	1.68 ± 2.27	2.57 ± 2.28††	< .01
ds	1.98 ± 3.60	2.00 ± 2.76	NS	0.76 ± 1.64**	1.44 ± 2.19††	< .05

* dmfs: Decayed, missing and filled surfaces; dmft: decayed, missing and filled teeth; ds: decayed surfaces.
† SD: Standard deviation.
‡ NS: Not significant.
§ $P < .05$.
** $P < .0001$.
†† $P < .001$.

TABLE 2

CARIES PREVALENCE ($d_E$mfs, $d_E$mft, d_Es),* INCLUDING ENAMEL LESIONS, IN THE VARNISH AND CONTROL GROUPS.

INDEX	MEAN ± SD† MEASURE AT BASELINE			MEAN ± SD MEASURE AT NINE MONTHS		
	Varnish Group (n = 59)	Control Group (n = 83)	*P* Value	Varnish Group (n = 59)	Control Group (n = 83)	*P* Value
$d_E$mfs	8.22 ± 7.22	5.33 ± 4.01	< .05	4.63 ± 6.52‡	5.71 ± 5.02	< .01
$d_E$mft	5.22 ± 3.30	4.22 ± 2.86	NS§	2.51 ± 2.74‡	4.02 ± 2.85	< .001
d_Es	7.00 ± 5.72	5.21 ± 3.96	NS	1.20 ± 1.96‡	3.05 ± 2.99‡	< .0001

* $d_E$mfs: Decayed with initial enamel lesions, missing and filled surfaces; $d_E$mft: decayed with initial enamel lesions, missing and filled teeth; d_Es: decayed surfaces with initial enamel lesions.
† SD: Standard deviation.
‡ $P < .0001$.
§ NS: Not significant.

exact test to analyze differences in the distribution of enamel caries.

RESULTS

We excluded six subjects with multiple anterior decayed teeth from this study, because comprehensive treatment was initiated immediately and all lesions were restored. After these exclusions, the varnish group consisted of 59 children, and the control group consisted of 83 children. Fifty-four percent of subjects in the varnish group were female and 53 percent of subjects in the control group were female. There were no significant differences in caries prevalence between girls and boys at baseline or nine months later; only the d_Es value was slightly larger in girls at baseline ($P < .05$).

The racial composition of the groups also was similar. In the varnish group, 71.2 percent of subjects were African-American, 25.4 percent were white, 1.7 percent were Hispanic and 1.7 percent were Asian. In the control group, 72.8 percent of subjects were African-American, 24.7 percent were white, 1.2 percent were Hispanic and 1.2 percent were Asian. We found no significant differences in caries prevalence between subjects of different races at baseline or after nine months. The mean age of subjects was 5.5 years in the varnish group and 5.6 years in the control group.

Caries prevalence. Tables 1 and 2 show baseline data and changes in caries prevalence. No statistically significant differences in dmfs, dmft or ds values between the test and control groups could be seen at baseline. We observed a slight increase in caries prevalence in the control group when compared with the varnish group at nine months ($P < .01$ for dmft and $P < .05$ for dmfs and ds, Mann-Whitney U test) (Table 1). The mean dmfs value also was significantly higher in the control group at nine months than it was at baseline ($P < .0001$, Mann-Whitney U test) (Table 1). The mean ds value in the varnish group was significantly lower at nine months compared with the baseline value ($P < .0001$, Mann-Whitney U test) (Table 1).

When enamel lesions were included in the data analysis, the mean $d_E$mfs, $d_E$mft and d_Es values were significantly lower in the varnish group after nine months than they were at baseline ($P < .0001$, Mann-Whitney U test), while the mean $d_E$mfs and $d_E$mft values in the control group remained constant (Table 2). After nine months, the mean $d_E$mfs value ($P < .01$), the mean $d_E$mft value ($P < .001$)

and the mean d_Es value ($P < .0001$) were higher in the control group than they were in the varnish group ($P < .001$, Mann-Whitney U test) (Table 2). These differences are significant because of the decrease in caries prevalence in the varnish group.

As shown in Table 3, 153 (60 percent) of 255 active enamel lesions were on the occlusal surfaces in the varnish group, while 177 (78.7 percent) of 225 active enamel lesions were on the occlusal surfaces in the control group. We did not provide data for radiographic approximal enamel caries because the radiographic caries incidence was so low. In the varnish group, 81.2 percent of active enamel lesions were inactive after nine months ($P < .0001$), compared with 37.8 percent of active enamel lesions in the control group (Table 3). In the control group, 36.9 percent of all active enamel lesions were still active at nine months ($P < .0001$), whereas only 8.2 percent of all active enamel lesions in the varnish group were still active (Table 3). We found significantly more inactive lesions in the varnish group after nine months on all surfaces ($P < .0001$) than we did in the control group. Clearly, remineralization in the control group was less evident.

TABLE 3

DISTRIBUTION OF ACTIVE ENAMEL LESIONS AT NINE MONTHS.

TOOTH SURFACE	GROUP	NUMBER (%) OF ACTIVE LESIONS				
		No Change	Inactive	Progressed	Filled	TOTAL
Occlusal	Varnish	10 (6.5)*	119 (77.8)*	6 (3.9)	18 (11.8)*	**153** (60.0)
	Control	63 (35.6)	67 (37.9)	8 (4.5)	39 (22.0)	**177** (78.7)
Buccal	Varnish	7 (9.9)	62 (87.3)*	0	2 (2.8)	**71** (27.8)
	Control	10 (41.7)	9 (37.5)	0	5 (20.8)	**24** (10.9)
Lingual	Varnish	4 (12.9)	26 (83.9)*	0	1 (3.2)	**31** (12.2)
	Control	10 (41.7)	9 (37.5)	0	5 (20.8)	**24** (10.9)
TOTAL	Varnish	21 (8.2)	207 (81.2)*	6 (2.4)	21 (8.2)	**255 (100)**
	Control	83 (36.9)*	85 (37.8)	8 (3.6)	49 (21.8)	**225 (100)**

* $P < .0001$.

DISCUSSION

Baseline caries measurements indicate that randomization was performed successfully (Tables 1 and 2). The κ-statistics indicate that calibration and standardization also were performed successfully.

We administered the second fluoride varnish applications in the schools, and subjects in the control group did not receive any professionally applied fluoride treatments. Other topical fluoride products, such as gel or foam, require trays, suction and means of expectoration. Since the study was designed to be performed in the schools, subjects in the control group could not receive any other fluoride applications, which would have enabled us to compare the efficacy of varnish with that of other topical fluoride products.

The results of this study indicate that two applications of fluoride varnish may be effective in arresting early active enamel lesions in the primary dentition. Zimmer and colleagues[10] studied the effect of fluoride varnish in a community with a low socioeconomic status and generally high caries level. Children who received a minimum of two applications of fluoride varnish per year for two years exhibited a significantly lower caries increment when compared with children in the control group, who received no professional fluoride application. However, data in the study were restricted to the permanent dentition. Our study supports the conclusion of Zimmer and colleagues that fluoride varnish applications may be a feasible and effective method of preventing caries in economically deprived children who are at high risk of developing caries.

During the 1990s, scientists have emphasized the importance of remineralization of noncavitated carious lesions.[23,24] This finding is partially associated with the ability of fluoride to remineralize and arrest lesions.[23] Preventive dentistry in the United States has long been based primarily on oral prophylaxis; fluoride applications in the form of rinses, gels or foams; and diet counseling. Little attention has been given to identifying and managing initial enamel lesions, because of the variability of the test results reported in the literature. Part of the variability in fluoride varnish studies in regard to reducing the caries increment may be associated with the diagnostic criteria used.[23] Diagnostic criteria can be used to make distinctions in the activity status of lesions.[22]

Nyvad and colleagues[21] described caries diagnostic criteria that differentiates between active and inactive carious lesions at both cavitated and noncavitated sites in the permanent dentition. They concluded that use of criteria based on an activity assessment could be highly reliable, even when noncavitated carious lesions are included in the scoring system. In our study, we used a modified version of their scoring system,[21] which also differentiates between active and inactive carious lesions with high reliability, to evaluate the effect of fluoride on early noncavitated lesions in the primary dentition.

Some studies have addressed the progression rate of interproximal carious lesions or the distribution of carious lesions in the primary dentition.[11,25,26] However, differentiation between active and inactive pit and fissure enamel caries in the primary dentition has not been documented. Gizani and colleagues[27] studied the distribution of carious lesions among the various tooth surfaces in the primary dentition, but did not differentiate between active and inactive lesions. The occlusal surfaces of the primary molars exhibited the highest attack rates, as confirmed in our study.

Grindefjord and colleagues[28] studied the development of dental caries in children aged 2½ to 3½ years and found that the majority of new lesions were located on the occlusal surfaces of the second molars. Our study focused on the effect of fluoride varnish on early enamel lesions located on occlusal surfaces. Although the effect of varnish on approximal surfaces is not reported here, a halo effect may be anticipated. Additional studies are needed to elucidate the effects of fluoride varnish on early approximal caries.

Caries progression in the primary dentition is reportedly rapid, and within 12 months enamel caries may progress into the dentin.[11] Therefore, nine months should be a sufficient period to study the progression rate of enamel carious lesions. Also, because traditional restorative treatment decisions often are based on the presence and extent of enamel lesions, it is important to show that active enamel lesions can be arrested. Our study shows that fluoride varnish can arrest early enamel lesions in the primary dentition.

As stated above, we performed the second fluoride varnish applications in 10 Head Start schools. Teachers and children readily accepted the visits and fluoride treatments. It is widely accepted that children at high risk of developing caries need extra protection and often are not compliant enough to undertake fluoride therapy themselves. This study supports the proposal that varnish applications may be a practical preventive treatment that can be performed in the school environment, which would allow more high-risk children to be reached. Since the goal of prevention is to ensure that a disease process never starts or to reverse the disease in its early stages, health care authorities should recommend administering preventive therapy to children in kindergartens and elementary schools who are at high risk of developing caries.

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CONCLUSION

Fluoride varnish may offer an effective means of arresting early enamel lesions in the primary dentition. While detecting and monitoring these lesions are critical in determining effectiveness, this study suggests that fluoride varnish applications may offer an efficient, nonsurgical approach to the treatment of decay in children. ■

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