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Original Research

Effect of different fluoride varnishes in prevention of caries on mandibular permanent first molars in pediatric patient- An original research

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ABSTRACT:
Introduction: The purpose of this study was to evaluate the effect of fluoride varnish in preventing dental caries of permanent first molars (PFMs). **Material and Methods**: The study was designed to be a stratified-cluster randomized controlled trial with classes used as the unit of randomization. Classes stratified by district were followed for 36 months. All eligible children of the selected classes were included in the trial. The children in the test group were applied fluoride varnish biannually. The outcomes were measured at the individual level. **Results**: In total, 107 classes (51 in the test group, 56 in the control group) were recruited for the trial. Among the 5,397 total subjects, 5,005 and 4,596 children completed the 24-month and 36-month course, respectively. There were no group differences at baseline (P>0.05). The mean decayed and filled surfaces scores of the test group were significantly lower than those of the control group at the 36-month follow-up (P<0.05). The caries processing speed of PFMs increased from 24 months to 36 months; however, group differences were not significant. **Conclusions**: Biannual application of fluoride varnish can effectively prevent dental caries of six- to seven-year-old children. Nevertheless, the use of fluoride varnish with addi- tional treatments (such as pit and fissure sealants) should be considered for optimized benefit after 24 months.
Keywords: Fluoride Varnishes, Caries Prevention, Pedodontics

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INTRODUCTION

Dental caries is among the most prevalent chronic diseases worldwide.1 Previous studies found that over 90 percent of dental caries occurred on permanent first molars (**PFMs**) among school- aged children, mainly affecting pit and fissures. Previous studies found that fluoride varnish could effectively prevent dental caries from allowing PFMs to erupt.2-10 However, the duration of these clinical trials was limited to less than 24 months. Although these findings are encouraging, they provide no insight into the effect of fluoride varnish for periods longer than 24 months. Some clinical trials reported that the patterns of change in the mean response throughout the longitudinal study is not simply linear.11-15 Intensive changes in the mean response often occur in a short period, while the long- term effect may be relatively minimal.

The purpose of the present study was to evaluate the caries-preventive effect of the semi-annual application of fluoride varnish on permanent first molars in a 36-month study course, with a focus on the effect after 24 months. The null hypothesis was that there was no significant difference in the caries-preventive effect on PFMs between the test group and the control group over 36 months.

MATERIAL AND METHODS

This study was designed as a stratified-cluster randomized controlled trial with classes as the unit of randomization. Eligible participants were six-to seven-year-olds with no acute or chronic systematic disorders.

The fluoride varnish was applied by two dentists and assis- tants at schools in each county-level city. Duraphat (Colgate- Palmolive [UK] Limited, Waltrop, Germany) was used in this study. The children in the test group were scheduled for topical application of fluoride varnish at baseline and then every six months. A total of six applications were given during the 36-month study course. Every child was given 0.25 ml of fluoride varnish according to a standard card, corresponding to 5.65 mg of fluoride per application. After isolating the teeth with cotton rolls and drying with swabs, the varnish was then applied on all accessible tooth surfaces of PFMs using a disposable microbrush and dried by air. The rest of the varnish was applied to other teeth. The child was told not to eat for at least two hours after the application and did not brush their teeth that day.

RANDOMIZATION AND BLINDING

The class randomization was carried out by school administrators according to coin- flipping results. Children from the same class were assigned to the same group. Each child was given an identification (**ID**) number at the first visit and identified by this ID number throughout the study. The examiners, assistants for data rec- ording, and data analyst were blind to the allocation. Allocation lists were provided to the varnish providers and their assistants. However, they did not take part in the dental caries examination, data recording, or analysis. The participants were likely to be aware of the allocation due to the physical nature of Duraphat. Randomization was revealed after statistical analysis to ensure concealment of allocation.

The data were collected at three time points: (1) baseline; (2) at the end of 24 months; and (3) at the end of 36 months. The primary outcome measure was the mean decayed and filled surfaces (**DFS**) of PFMs at each time point (baseline, 24 months, and 36 months). The secondary outcome measure was the change in the mean DFS of PFMs for one unit of time (ΔDFS per year). The statistical significance level for all tests was set at 0.05.

Table 1: Eruption Stages Of Permanent First Molars At Baseline (N=5,397)

Eruption stage	Test group (%)	Control group (%)	*P*-value*
0 Fully erupted occlusal surface and fully exposed crown, established antagonist contact	43.0	41.8	0.26
1 Fully erupted occlusal surface, 13.2 partially exposed crown		13.3	
2 Partially erupted occlusal surface	9.5	10.4	
3 Only cusp erupted	2.0	2.0	
4 No eruption	32.3	32.5	

* Chi-square test.

RESULTS

A total of 107 classes were randomly assigned to a test group or control group. Of these children, 2,657 children were enrolled in the test group and 2,740 children were enrolled in the control group. At baseline, there was no statistically significant difference between the two groups in terms of age, sex, frequency of tooth brushing, frequency of sugar consumption, caries experience of primary dentition, eruption stages, and caries experience of the PFMs ($P>0.05$; Tables 1 and 2).

At the 24-month follow-up examination, 98.5 percent of the PFMs had fully erupted. The mean DFS scores of the PFMs in the test group were 0.41 (SD 1.22) and 0.64 (SD 1.64) for the control group. There was a statistically significant difference molars based on data collected at baseline examination. *P*-values for slope one are for slope estimates in comparison to zero, indicating whether there was a significant change in phase one for the control group, test group, or a comparison between the control group and test group slopes (difference), respectively. At the 36-month follow-up examination, all PFMs had fully erupted. The mean DFS scores of the PFMs were 0.67 (1.64) and 1.03 (2.07) for the test group and control group, respectively. There was a statistically significant difference between the two groups ($P<0.001$; Table 3).

As shown in Table 4, PLME models also confirmed that there was no significant difference in mean DFS scores of PFMs at baseline between the test group and the control group.

Table 2: Baseline Characteristics Of The Participants

Variables	Test group (N=2,657)	Control group (N=2,740)	P-value
Age (years)			
Mean±(SD)	6.81±0.42	6.85±0.42	0.87*
Sex (%)			
Males	55.3	53.0	0.09†

Females	44.7	47.0	
Toothbrushing habit (%)			
≥2x/day	28.7	28.9	0.85†
<2x/day	71.3	71.1	
Sweet consumption (%)			
≥1x/day	42.8	44.4	0.25†
<1x/day	57.2	55.6	
Caries experience of primary dentition			
Prevalence (%)	87.3	85.7	0.096†
Caries experience of permanent first molars			
Decayed filled surfaces (Mean± [SD])	0.03±0.35	0.04±0.32	0.49*

* Two-sample *t*-test. † Chi-square test.

Table 3: Mean Decayed And Filled Scores (DFS) Of Permanent First Molars At The 24-Month Follow-Up And 36-Month Follow-Up

	Test group	Control group	t-value	P-values*
24-month follow-up				
n	2,385	2,620		
DFS (mean±[SD])	0.41±1.22	0.64±1.64	-6.53	<0.001
36-month follow-up				
n	2,235	2,361		
DFS (mean±[SD])	0.67±1.64	1.03±2.07	-5.68	<0.001

* *t*-test.

Table 4. Piecewise Linear Mixed-Effects (PLME) Models With Random Intercept

Randomization		Parameter estimate	Standard error	*P*-values*
Intercept	Control	0.04	0.01	<0.001
	Test	0.03	0.01	<0.001
	Difference	-0.01	0.01	0.49
Slope 1	Control	0.30	0.01	<0.001
	Test	0.19	0.01	<0.001
	Difference	-0.11	0.02	<0.001
Slope 2	Control	0.38	0.02	<0.001
	Test	0.25	0.02	<0.001
	Difference	-0.13	0.03	<0.001
Slope 3	Control	-0.08	0.03	0.004
	Test	-0.06	0.03	0.02
	Difference	0.01	0.04	0.71

* *P*-values are from PLME models. *P*-values for intercept are for baseline estimates relative to the mean decayed and filled scores for permanent first

DISCUSSION

The study evaluated the effect of fluoride varnish in large groups of children and produced powerful statistical results. Instead of randomizing individual participants, a higher-level unit (classes) facilitated the organization and promotion of the trial at primary schools. The results of the study showed that five percent NaF varnish prevented dental caries of PFMs among children aged six to seven years over 36 months. However, there was no significant difference in caries prevention between the two groups beyond the 24-month intervention. Therefore, the caries-preventive effect of five percent NaF varnish on PFMs was non- linear over a long-term monitoring period. A notable effect with a significant difference was achieved only at the beginning of 24 months. It could then be concluded that the observed caries-preventive effect of five percent NaF varnish on PFMs at the 36-month follow-up was mainly ascribed to the first 24 months of the 36-month period. The null hypothesis was rejected.

Both Milsom and Hardman failed to demonstrate that biannual application of five percent NaF varnish provided at school could reduce dental caries in school-aged children. The authors attributed their failed outcome to high dropout rates and a lower-than-expected caries increment16,17 However, the present study had a large sample size and low dropout rate. The eruption stages of PFMs may be correlated to the patterns of change. Approximately 60 percent of PFMs were in the erupting stages in phase one, while all PFMs had fully erupted in phase two. The partially erupted PFMs were more susceptible to caries than PFMs with full occlusion.5, 17, 18 It can be deduced that the fully erupted PFMs may suffer a relatively lower risk for dental caries

than the erupting ones. Therefore, once PFMs reach full occlusion they may be less sensitive to five percent NaF for caries prevention.19 However, Liu et al. reported that five percent NaF varnish could effectively prevent dental caries in fully erupted PFMs.20 The

According to the findings of the current study, an additional 12-month application of five percent NaF varnish on PFMs after initial 24-month intervention seemed less meaningful since only a modest benefit was found at the expense of clinical material and time involved. To maintain a prolonged caries-preventive effect, the use of fluoride varnish with additional treatments, such as pit and fissure sealants, should be considered to optimize benefits after a 24-month intervention.

The present study provides some initial evidence for the 36-month effect of five percent NaF varnish on caries prevention of PFMs among children aged six to seven years. More studies that demonstrate the 36-month effect, as well as a generalization of the results, is needed. In addition, whether the 24 months was the inflection point in the nonlinear trajectory should also be ascertained in future studies.

CONCLUSIONS

Based on the present study's results, the following conclusions can be made:

- Semiannual application of five percent sodium fluoride varnish can effectively prevent dental caries in permanent first molars among six- to seven-year-olds.
- To maintain a prolonged caries-preventive effect, the use of fluoride varnish with additional treatments, such as pit and fissure sealants, should be considered for optimized benefit after 24 months of semiannual application of fluoride varnish on PFMs.

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