# The Efficiency of Semiannual Silane Fluoride Varnish Applications: a Two-year Clinical Study in Preschool Children

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#### Abstract

Objective: The aim of this two-year community demonstration trial was to study the caries inhibitory effects of semiannual applications of a fluoride varnish in preschool children. Methods: Twenty-four public dental health clinics in the county of Halland, Sweden, with 5,137 preschool children, 4 and 5 years of age, were matched and equally allocated to a fluoride varnish group (n=2,535) and a reference group (n=2,602). The children in the fluoride varnish group were treated every six months with topical applications of a silane fluoride varnish, Fluor Protector (0.1% F), while no fluoride varnish was used in the reference group. Both groups received a basic preventive program at annual checkups consisting of dietary counseling and instructions to parents to brush their children's teeth at least once daily with fluoridated dentifrice. Caries data were collected by clinical examinations at baseline and after one and two years. Results: Caries prevalence at baseline did not differ significantly between the groups. After two years, the mean caries incidence was low and no statistical difference was found in the total number of carious and filled surfaces (dfs) between the two groups. However, the incidence of approximal lesions (dfsa) was significantly lower (P<.05) in the fluoride varnish group than the reference group. Children in the fluoride varnish group with dfs scores of 1–4 and ≥5 at the start of the study exhibited a statistically significant (P<.05) reduction in approximal caries incidence of 19 percent and 25 percent, respectively, when compared with the reference group. Conclusion: Preschool children 4 and 5 years of age with clinical caries who receive semiannual applications of a silane fluoride varnish containing 0.1 percent F experience a reduced incidence of approximal caries over two years. [J Public Health Dent 1998;58(1):57-60]

Key Words: caries prevention, preschool children, silane fluoride varnish.

Under the Public Dental Health Act, all Swedish children and adolescents up to 20 years of age are guaranteed dental care free of charge. The program commences with preventive measures aimed at and designed for prospective parents followed by regular dental health programs for children that begin at 6 to 12 months after birth. The programs, organized by public dental health clinics (PDHCs), consist mainly of dietary measures and the establishment of daily toothbrushing habits with fluoridated dentifrice. These early preventive measures are probably one of the reasons for the low prevalence of dental caries in Sweden. Today, more than 90 percent of 3-year-olds are clinically caries free. Despite subsequent yearly dental recalls, the occurrence of caries in the primary dentition gradually increases, so that by the age of 6 years, more than 50 percent of the children exhibit decay (1). The most likely explanations for this extensive caries incidence in early childhood are the increased intake of refined sugar products with age and the establishment and accumulation of a caries-associated microflora in the oral cavity (2). Hence, intensified efforts to improve preventive oral care in this age group are justified and desirable.

Professionally applied topical fluoride varnishes have been used in Sweden since the mid-1970s. Fluoride varnishes are safe to use in childhood (3) and their caries-inhibiting effects in the permanent dentition generally are acknowledged (4). Their efficacy in the primary dentition, however, is unclear. Some investigators reported a reduced caries incidence in preschool children with low or moderate caries experience when varnish was used alone or in combination with a partial sugar substitution (5,6). Other investigators suggest that subjects with a high caries experience do not benefit from semiannual applications of a sodium fluoride varnish in the primary dentition (7,8).

The purpose of this study was to evaluate the caries-inhibiting effect of a fluoride varnish program conducted over a period of two years within the public dental health care provided for preschool children.

## Methods

All 4- and 5-year-old children who attended the 24 PDHCs in the county of Halland in southwest Sweden were recruited into the study. Before the start of the project in 1991, the PDHCs were matched and equally allocated to a fluoride varnish group (12 clinics; 2,535 children) and a reference group (12 clinics; 2,602 children). The matching procedure was performed using previously collected oral epidemiologic data for the relevant ages and demographic information, including the socioeconomic level and the pro-

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portion of immigrants in the population. Also, the size and organization of the different PDHCs were considered. The number of participants from the clinics ranged from 87 to 409 children. Most children had low fluoride levels (0.1 ppm F) in their piped drinking water. Approximately 10 percent of the children in both groups lived in areas with a natural content of 1.2 ppm F in the water supply. The use of fluoridated dentifrice was almost universal (>90%) in the two groups.

Clinical Examinations. Examinations for dental caries were carried out at baseline and after one and two years using the diagnostic criteria and methods recommended by the World Health Organization (9). Each PDHC had a trained team consisting of an experienced dentist and a dental assistant who were responsible for the examinations. The registrations were made at the regular clinical checkup using a plane-surface mouth mirror and sharp sickle-shaped explorer under optimal light. The teeth and the surfaces were registered and recorded in a systematic way using the WHO oral assessment forms. No radiographs were exposed on a routine basis. Prior to the study, the responsible teams (n=24) were trained in groups to optimize the clinical recordings. The same examiners performed the baseline and the final clinical examinations at each PDHC. Restorative treatment was performed in both groups as needed according to the decision of the child's regular dentist. Usually, glass ionomer cement was used as the filling material. Caries was expressed as the total number of decayed and filled surfaces (dfs), and as a partial index based on the number of decayed and filled approximal surfaces of the primary molars and the distal surfaces of the cuspids (dfsa). The dfs index excluded missing incisors and the number of extracted teeth was recorded separately and not included in the dfs index.

Fluoride Varnish Group. Children in the fluoride varnish group received four applications of the varnish during the two-year study. The fluoride varnish, Fluor Protector (Vivacare/Vivadent, Schaan, Liechtenstein), contained 0.1 percent F as difluorosilane in a polyurethane varnish base. Prior to the application of fluoride varnish, the smooth surfaces of the teeth were cleaned with a rubber cup using pum-

ice paste and the approximal surfaces with an unwaxed dental floss, followed by careful rinsing with water and drying. The varnish was applied to the entire primary dentition with a small brush and air dried, leaving a clear transparent film on tooth surfaces. The application procedure took approximately five minutes, including the setting time. A standardized amount of varnish (0.25 ml) was used for each application. The children and their accompanying parents were informed that the child should not eat for two to three hours after the varnish application and not brush the teeth until the following day. At a clinical session, the children were given annual toothbrushing instructions together with their parents. Dietary counseling with an emphasis on sugar intake, nocturnal meals, and soft drinks also was provided. Additional fluoride preparations were not given in the fluoride varnish group.

**Reference Group.** The children in the reference group were not treated with fluoride varnish applications, but received the other preventive services provided to the fluoride varnish group at their annual checkup. However, for children determined to be at risk or with previous caries activity, fluoride tablets were recommended.

**Statistical Methods.** All caries data were analyzed using the Wilcoxon nonparametric one-tailed test.

Ethical Considerations. The study was approved by the Ethical Committee at the University of Lund and the Swedish Board of Welfare, Drug Division, Uppsala, Sweden.

#### Results

During the study, one PDHC with 320 children in the reference group was privatized and therefore is excluded. Thus, a total of 4,161 children (2,245 in the fluoride varnish group and 1,916 in the reference group) completed the study (Table 1). The baseline dfs values of the children from the excluded clinic did not differ statistically from those in the remaining clinics.

The baseline caries prevalence is shown by group in Table 2. No statistically significant differences were observed between the groups at baseline. The standard deviations were generally more than double the mean values. A high percentage of caries-free children (74%) was found in both groups. Only 6.5 percent and 6.7 percent of the children in the fluoride varnish group and reference group exhib-

| TABLE 1  |
|--|
| Number and Mean Age of Children Examined in Fluoride Varnish and |
| Reference Groups at Baseline and After Two Years.                |

| Group                     | Mean Age | Baseline | After 2 Years | Dropouts (%) |
|---------------------------|----------|----------|---------------|--------------|
| Fluoride varnish<br>group | 4.51     | 2,535    | 2,245         | 289 (11.4)   |
| Reference group           | 4.52     | 2,602    | 1,916         | 686 (26.4)   |
| Total                     |          | 5,137    | 4,161         | 975 (18.9)   |

| TABLE 2  |
|--|
| Total dfs and Approximal dfsa Caries Prevalence at Baseline and Two-year |
| Incidence (dfs, dfsa), by Study Group                                    |

| Fluoride Varnish Group |  | Reference Group   |   | p_   |  |
|------------------------|--|---|---|--|--|
| Mean                   | SD   | Mean  | SD  | value  |  |
| 1.13                   | 2.36   | 1.18  | 3.20  | NS*  |  |
| 1.30                   | 2.46   | 1.39  | 2.66  | NS   |  |
| 0.20                   | 0.92   | 0.23  | 1.00  | NS   |  |
| 0.68                   | 1.49   | 0.81  | 1.66  | <.05   |  |
|                        | Fluoride Van<br>Mean<br>1.13<br>1.30<br>0.20<br>0.68 | Mean SD   1.13 2.36   1.30 2.46   0.20 0.92   0.68 1.49 | Fluoride Varnish Group Reference   Mean SD Mean   1.13 2.36 1.18   1.30 2.46 1.39   0.20 0.92 0.23   0.68 1.49 0.81 | Fluoride Varnish Group Reference Group   Mean SD Mean SD   1.13 2.36 1.18 3.20   1.30 2.46 1.39 2.66   0.20 0.92 0.23 1.00   0.68 1.49 0.81 1.66 |  |

\*NS=not significant.

ited more than five dfs at the start of the study. The mean number of missing teeth per child was low in both groups, being less than 0.1.

A similar proportion (58%) of children in both groups were caries-free after two years, while caries-inactive children were found more often in the fluoride varnish group (64%) than the reference group (59%). Caries-inactive children were those not developing caries, meaning they showed no caries incidence. The incidence of total caries (dfs) was somewhat lower in the fluoride varnish group than in the reference group; however, the difference was not statistically significant (Table 2). The incidence of approximal lesions (dfsa) was significantly lower (P < .05) in the fluoride varnish group than in the reference group. Children in the two study groups who were clinically caries free at baseline did not differ in approximal caries incidence, while children with caries at baseline benefited from the fluoride varnish applications (Table 3). Statistically significant differences (P<.05) in approximal caries incidence were observed between the groups for children with 1–4 dfs and  $\geq 5$  dfs at baseline. The caries reduction after two years was larger in those with the highest caries prevalence at baseline (25%) than in those with the lower level (19%). No side-effects or allergic reactions due to the varnish treatments were reported during the study.

#### Discussion

This clinical trial was planned and implemented as a community demonstration project to determine if a fluoride varnish program would be effective for caries reduction in a low caries population with fully developed, preventive-oriented public dental care. We also were interested in evaluating the effectiveness of varnish in prevent-

ing dental caries in the primary dentition because of conflicting data from previous studies (5-8). The study included 5,137 children, aged 4 and 5 years at baseline, allocated to a fluoride varnish and a reference group. When evaluating the findings, the merits and limitations of such a field trial need consideration. Results obtained from a study of an entire population might be more robust and reliable for community health planners than findings from limited, but controlled and well-monitored study groups. However, the number of examiners involved, problems of calibration, and the subjective clinical diagnostic procedures could bias the results. Moreover, the preventiveoriented health care system itself and the common use of fluoride in the study population is likely to seriously obscure the outcome of an added varnish program.

The number of children in each group was similar at the start of the study; however, the percentage of dropouts varied from 11 percent to 26 percent between the groups (Table 1). The reason for this imbalance was that one PDHC in the reference group was transferred to private ownership during the first year of the trial and was unable to fulfill the study protocol. The other main reason for dropping out was that families moved from the area; however, the rate was similar in the two groups. In the fluoride varnish group, 2.5 percent of the children were excluded because they did not come for the varnish treatments. Considering the baseline caries data, however, it is unlikely that the higher dropout rate in the reference group influenced the results of the study.

The baseline caries prevalence, expressed as dfs and dfsa, was similar in both groups, indicating that the allocation of PDHCs to the treatment and reference groups was satisfactory. The reason for not including primary incisors in the analysis was the high frequency of dental trauma and exfoliation during the study period. This exclusion might have led to a slight underestimation of the caries prevalence; however, the prevalence of nursing bottle caries was low.

The large percentage of children who were caries free (74%) and small percentage with a high prevalence (7%) in both fluoride varnish group and reference group at baseline illustrate the typically uneven caries distribution of children living in industrialized countries today (1). This polarized situation might be one explanation for the failure of the fluoride varnish program to show any statistically significant reduction in total caries in the study group because a majority of the children (59%-64%) remained caries-inactive during the study. However, a comparison of the caries incidence of the caries-prone approximal surfaces revealed a statistically significant difference in favor of the fluoride varnish group. The difference varied from 19 percent to 25 percent, depending on the level of caries at baseline: the more caries at baseline, the larger the reduction. These data are interesting and in contrast to earlier findings that failed to show any statistically significant preventive effect in preschool children considered at risk or with a high caries activity (7,8).

While no reduction was observed on occlusal and nonapproximal smooth surfaces, the significant approximal effect is encouraging and important in clinical and economical terms. The decayed distal surface of the first primary molar constitutes a well-known clinical management problem. The restorative treatment for this tooth surface is technically de-

| TABLE 3  |       |
|--|-------|
| Mean Approximal Caries Incidence (dfsa) by Total Caries Prevalence (dfs) at Baseline and Study | Group |

| dfs at Baseline | Fluoride Varnish Group |      |      | Reference Group |      |      | <i>p</i> _ | % Caries  |
|-----------------|------------------------|------|------|-----------------|------|------|------------|-----------|
|                 | n                      | Mean | SD   | n               | Mean | SD   | value      | Reduction |
| 0               | 1,755                  | 0.52 | 1.35 | 1,428           | 0.53 | 1.36 | NS*        | 0         |
| 1–4             | 345                    | 1.20 | 1.80 | 330             | 1.48 | 1.95 | <.05       | 19        |
| ≥5              | 145                    | 1.73 | 2.00 | 158             | 2.30 | 1.98 | <.05       | 25        |

\*NS=not significant

manding and time consuming for dentists as well as the children and their parents. Although they must be interpreted with caution, our results indicate that a fluoride varnish program can be beneficial for preschool children with clinical signs of caries, but not for all children living in a low caries community. These findings cannot be generalized to communities with other caries profiles.

The sustained slow release of fluoride after varnish application and its ability to form fluorapatite and calcium fluoride-like compounds on the surface and the subsurface of the enamel are documented (10,11). Our present results indicate that the low fluoride (0.1% F) silane varnish seems to be as effective for children at risk as an earlier tested sodium fluoride varnish with a higher (5% NaF) concentration (7). A number of laboratory studies have suggested that the silane fluoride varnish is better retained on the enamel, resulting in a higher fluoride uptake due to a dissociation and diffusion of HF (12-15). For clinicians, this finding is not unimportant because of their responsibility to use the minimal dose of fluoride preparation to obtain a given effect.

In conclusion, the results of the present community trial of a fluoride varnish program conducted in a preventive-oriented public dental health care system and with a low level of the disease suggest that preschool children with clinical caries experience benefit from the treatments with a statistically significant reduction in the incidence of approximal caries within the range of 19 percent to 25 percent. No caries reduction was observed among children who were caries free at baseline. Thus, silane fluoride varnish treatments can be regarded as a targeted action for use in a low-caries population with a polarized distribution of the disease rather than as a collective measure. This aspect should be considered by professionals and health care administrators when planning and implementing oral preventive programs in the future.

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