A 24-month Study Comparing Sealant and Fluoride Varnish in Caries Reduction on Different Permanent First Molar Surfaces

Manuel Bravo, PhD; Pilar Baca, PhD; Juan Carlos Llodra, PhD; Estrella Osorio, PhD

Abstract

Objective: *The aim of this study was to determine the separate effects of dental sealants and fluoride varnish on dental caries in fissured and nonfissured surfaces of permanent first molars.* ***Methods:*** *A clinical trial was conducted with three groups of 6- to 8-year-old schoolchildren: a sealant group (n=100), in which Delton was applied to first molars; a varnish group (n=98), in which Duraphat was applied to first molars; and a control group (n=116), which had no intervention as part of the study. Absolute and percent caries reductions were compared at 24 months.* ***Results:*** *Compared to the controls, sealants resulted in a 68 percent and 87 percent reduction on fissured and nonfissured surfaces, respectively. The corresponding figures for varnish were 38 percent and 66 percent.* ***Conclusion:*** *Sealant and fluoride varnish are effective in preventing caries in both fissured and nonfissured surface. [J Public Health Dent 1997;57(3):184-6]*

Key Words: dental caries, pit and fissure sealants, topical fluorides.

A classic assumption is that fluorides offer greater relative protection against dental caries to smooth surfaces of teeth compared to other surfaces, while sealants protect only the pits and fissures. Sealant studies reporting results on surfaces other than those where sealants were applied always have simultaneously used topical fluorides, and any protection found on nonsealed surfaces was attributed to either the fluoride (1) or to a study design limitation (2). No clinical trial with independent groups comparing both procedures has been carried out in which children in the sealant group received only sealants and those in the fluoride group received only fluoride.

In 1990 a 24-month clinical trial with 6- to 8-year-old children was initiated in Granada, a nonfluoridated city in Andalucía, southern Spain (3). The trial consisted of three groups—a control group, children receiving only sealants, and children receiving only fluoride varnish (3). The mean DMFT score in Andalusian schoolchildren is reported to be 0.66 and 2.70 in 7- and 12-year-old children, respectively, with 95.5 percent and 79.3 percent being the decayed component (4). These data indicate little restorative dental care, a result of a virtual absence of school-based dental programs and the scarcity of dentists in Spain. At the time of the study, no school-based preventive dentistry programs existed in Granada. This paper presents an additional analysis of the data resulting from this clinical trial to compare the caries increment on fissured and nonfissured surfaces of children in the three study groups.

Methods

A detailed description of the study methods has been published elsewhere (3). Five of the 21 primary schools in the city's northern district were selected at random. First-year (n=6) and second-year (n=9) classes were assigned randomly to three independent groups (sealant, varnish, and control). Parents provided informed consent for 84 percent of children selected for participation. Of the 362 children enrolled in the study, none refused to continue in the study during the follow-up; however, 48 moved to other schools. The present analysis is based on the remaining 314 children who were followed for the full 24 months, with 100, 98, and 116 being in the sealant, varnish, and control groups, respectively. No children had any sealants at the start of the trial. Exposures to fluoride at home or dental offices were not investigated, although they probably are not relevant because of the low level of restorative dental attention given to Andalusian schoolchildren (4) and the lack of sealant use outside the study by children in this project (3).

All children received biannual caries examinations by a dentist using standardized criteria (5) and who was unaware of group assignment. For this analysis, initial and final caries scores were used, along with age, sex, and socioeconomic status, determined according to the profession of the father or guardian on a scale from I (high) to V (low) (6). Another dentist with the aid of an assistant applied Delton® light-polymerized opaque fissure sealant (Johnson & Johnson Dental Products, East Windsor, NJ) to all fissured surfaces in all sound permanent first molars (excluding the lower buccal pit) with complete eruption of the occlusal surface using Canguro-CEDIME® portable equipment (CEDIME S.A., Bilbao, Spain) and an ASPIT® suction machine (ORDISI S.A., Barcelona, Spain). After 6, 12, and 18 months, sealants also were applied to molars that were not erupted at previous examinations, and were replaced in cases of partial or total loss, i.e. when the sealant did not cover the

Send correspondence and reprint requests to Dr. Bravo, Departamento de Odontología Preventiva, Facultad de Odontología, Campus de Cartuja s/n, Universidad de Granada, E-18071 Granada, Spain. Internet: mbravo@platon.ugr.es. Drs. Baca and Llodra are also affiliated with the Department of Preventive Dentistry, and Dr. Osorio is with the Department of Dental Materials, all at the School of Dentistry, University of Granada. This study was supported by the Spanish Ministry of Education and Science via grant #PG/89-24199739. Manuscript received: 1/3/95; returned to authors for revision: 4/12/95; accepted for publication: 9/12/96.

main area of the fissures.

In the fluoride varnish group, Duraphat® (Rorer GmbH, Cologne, Germany) was applied by the same team on all surfaces of all sound permanent first molars with partially or totally erupted occlusal surfaces (approximately 0.1 ml/molar). After 6, 12, and 18 months, varnish was applied to molars newly erupted since the last examination, and reapplied to all those that were still sound.

Absolute and percent caries reductions were calculated for each preventive technique by comparing each treatment group to the control group and to each other. Absolute reduction was calculated as the difference in DMFS increment between two groups using a priori contrasts. Percent reduction of one group compared to another is $((\bar{x}_2-\bar{x}_1)/\bar{x}_1) \times 100$, where $\bar{x}_1$ and $\bar{x}_2$ are the mean DMFS increments in the two groups being compared (see Ref. 7 for the standard error formula). Bonferroni's correction was used to adjust for three comparisons. Separate analyses were performed for fissured surfaces, i.e., occlusal (O) and lingual (L) of upper molars, and O and buccal (B) of lower molars; and nonfissured surfaces, i.e., mesial (M), distal (D), and B of upper molars, and M, D, and L of lower molars. Lesions on L and B surfaces were assumed to be fissured caries on upper and lower molars, respectively.

Two multiple linear regression models were constructed using the 24-month DMFS increments on fissured or nonfissured surfaces as the dependent variables. Affiliation group and the initial dft index were forced into each model, the latter because it is an accepted caries risk predictor at this age (8). Other terms in the model were: initial DMFS index (including fissured and nonfissured surfaces), socioeconomic status, sex, age, and the "initial DMFS x Group" interaction term. Also, due to the random assignment based on school classes rather than individuals, the school was considered as another potential variable. These variables were included in the model if they, alone or together, produced a change of at least 10 percent in the estimated coefficients of the forced variables. An exception to this rule was used for inclusion of the interaction term, which was based on its statistical significance ($P<.05$) (9). Variables correlated with other variables at 0.75 or greater were not included in the models to avoid a multicollinearity effect. Data were analyzed using SPSS-PC+ V.4.0 (SPSS Inc., Chicago, IL).

TABLE 1
Initial Values and Caries Increments in Permanent First Molars Over 24 Months (n=314)

	Sealant (n=100) $\bar{x}$ (SD)	Varnish (n=98) $\bar{x}$ (SD)	Control (n=116) $\bar{x}$ (SD)	Comparison (ANOVA) $F_{exp(2,311\ df)}$	*P*-value
Initial DMFS	0.57 (1.29)	0.45 (0.99)	0.74 (1.43)	1.46	.233
Fissured surfaces	0.54 (1.14)	0.45 (0.99)	0.72 (1.36)	1.52	.221
Nonfissured surfaces	0.03 (0.30)	0.00 (0.00)	0.02 (0.19)	0.54	.582
DMFS increments over 24 months*					
Fissured surfaces	0.69 (1.24)	1.33 (1.82)	2.13 (2.06)	18.19	<.001
Nonfissured surfaces	0.06 (0.34)	0.15 (0.83)	0.45 (1.22)	5.67	.004

$\bar{x}$=arithmetical mean. SD=standard deviation. df=degrees of freedom.
*Comparisons in pairs are shown in Table 2.

TABLE 2
Absolute and Percent Reduction in Caries Increment of Permanent First Molars Over 24 Months Comparing Control, Sealed, and Varnished Children (n=314)

	Sealant vs Control		Varnish vs Control		Sealant vs Varnish	
Reduction	$\bar{x}$ (SE)	*P*-value*	$\bar{x}$ (SE)	*P*-value*	$\bar{x}$ (SE)	*P*-value*
Absolute†						
Fissured surfaces‡	1.44 (0.24)	<.001	0.80 (0.24)	.003	0.64 (0.25)	.033
Nonfissured surfaces¶	0.39 (0.12)	.006	0.30 (0.12)	.050	0.09 (0.13)	≈1.000
Percent§						
Fissured surfaces	67.6 (6.5)	<.001	37.7 (10.3)	<.001	48.0 (11.8)	<.001
Nonfissured surfaces	86.6 (8.4)	<.001	65.8 (20.6)	.004	60.8 (31.0)	.149

$\bar{x}$=arithmetical mean. SE=standard error.
*After Bonferroni's corrections for three comparisons.
†Difference in DMFS increment between two groups (e.g., sealant and control).
‡Adjusted absolute reductions for sealant and varnish vs control were 1.33 and 0.78, respectively (with regression equation: increment fissures= 1.52 + 0.23 x initial dft − 1.33 x sealant − 0.78 x varnish, with adjusted R^2=0.22).
¶Adjusted absolute reductions for sealant and varnish vs control were 0.31 and 0.19, respectively (with regression equation: increment nonfissured=0.09 + 0.04 x initial dft + 0.34 x initial DMFS − 0.31 x sealant − 0.19 x varnish, with adjusted R^2=0.30).
§Percent reduction of one group compared with another is $[(\bar{x}_2 - \bar{x}_1) / \bar{x}_1) \times 100$, where $\bar{x}_1$, $\bar{x}_2$ are the mean DMFS increments in the two groups being compared.

The study was approved by the University of Granada Faculty of Dentistry Ethics Committee.

Results

At the beginning of the trial, the mean age of children was 7.28 years, 51 percent were male, the median socioeconomic level was class IV, the mean dft index per child was 2.52 (SD=2.90), the percentage of DMF molars that were restored was 4.3 percent, and no permanent molars were missing. No statistically significant differences among the three groups were found for any of these variables at baseline (results not shown). During the follow-up, a mean of 3.26 and 3.48 sound molars per child were sealed or varnished in the sealant and varnish groups, respectively.

Statistically significant differences in caries increments were found among the three groups for both the fissured and nonfissured surfaces (Table 1). Absolute and percent reductions were statistically significant in all paired group comparisons except for nonfissured surfaces in the sealant-varnish comparison (Table 2).

The multiple linear regression models (footnote in Table 2) provide adjusted estimates of absolute reductions for both the sealant and the varnish groups compared to the control group. These figures are only slightly lower than those of the previous crude analysis, which would suggest that possible confounding in the crude results is minimal, at least when adjusted by potential confounders available in this study.

Discussion

While caries reduction figures obtained from the comparison of varnish and control children agree with present knowledge, the effect of sealants on nonfissured surfaces has not been reported previously in children receiving no other organized preventive dentistry program. We found a correlation in the control group between the initial number of fissure caries and nonfissure caries increments (r=0.58, P<.001). Thus, the observed sealant protection on nonfissured surfaces could be indirect, i.e., derived from the reduction in fissured caries.

Further analysis of the caries progression in the control group during the 24-month follow-up period revealed that 213 molars contributed to the DMFS increment, and of these, 188 developed new fissure caries only, eight new nonfissure caries only (all with fissure caries at baseline), and 17 fissure and nonfissure new caries. These 25 molars (8+17) accumulated 52 new carious lesions in nonfissured surfaces during the follow-up. The lesions appeared as primary caries in 19 cases and the origin (primary or secondary to fissure caries) could not be established in the other 33 because they were joined to fissure caries. Thus, the sealants could prevent either the development of primary caries in nonfissured surfaces or caries progression from fissured to nonfissured surfaces, although the latter possibility cannot be established.

This unusual finding should be considered with some caution. A possible explanation could be a carryover or Hawthorne effect. Children in the sealant group could have been more motivated in their self-care because they had visible signs of dental care (sealants) in their mouths. Nevertheless, the control group received the same number of examinations, and the level of dental care in Spain is low (4). Another consideration is the increment in DMF scores due to fillings placed by dentists using caries diagnostic criteria different from those used by the study examiner. Of the 73 nonfissured surfaces that became DMF in 24 months (six, 15, and 52 in the sealant, varnish, and control groups, respectively), six were fillings, and of these, five (all in the control group) were placed in surfaces that were declared sound on the visit immediately before the one during which the filling was first detected. Thus, a maximum bias of 9.6 percent (5/52) in the caries incidence for the control group can be inferred, a magnitude that does not seem to be particularly large.

Examiner bias also could be argued, particularly for the sealant group, which had obvious signs of the intervention. Examiner reliability for caries diagnosis of occlusal surfaces are presented elsewhere (3). Additional analysis of examiner reliability for caries in nonfissured surfaces were done for this paper. At the end of the study, 182 molars (times three surfaces = 546 nonfissured surfaces) and 122 molars (times three surfaces = 366 nonfissured surfaces) were reexamined for intra- and interexaminer reliability, respectively. For fissured and nonfissured surfaces, kappa coefficients were 0.821 and 0.808, respectively—estimates considered almost "perfect agreement" (10).

The results of this study indicate that sealants could provide an indirect protection on nonfissured surfaces. The use of sealants and fluoride together is considered the best way to reduce caries in children. However, if the results of this study are confirmed by other investigators, the amount of additional effect of topical fluorides over the use of sealants only should be investigated.

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