



# Anticaries Effectiveness of a Fluoride and Nonfluoride Sealant

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**ABSTRACT** This study compares the retention and anticaries effect of a fluoride and nonfluoride sealant. Two hundred and ninety-four children were divided into two groups. Participants had sealants applied to their first molars. Examinations were conducted after a mean retention of 1¼ years. Mean occlusal retention for both groups was 75 percent. Both groups showed extremely low DMF. The lack of any measurable decay compromised the study's ability to detect any enhanced protection from the fluoride sealant.

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A successful fluoride-containing sealant should meet the requirements of retention comparable or superior to that of conventional nonfluoride sealants, and of constant release of low levels of fluoride for a prolonged period of time. Such ambient fluoride exposure would prove most effective in conferring anticaries benefits.<sup>1</sup> Clinical studies have reported similar rates of retention for a fluoride and nonfluoride sealant, but the latter has not been compared with its chemical analogue.<sup>2</sup>

In vivo findings of the cariostatic effect of fluoride sealants on enamel have shown reduced depth of artificial lesions and decreased enamel solubility.<sup>3,4</sup> However, results of the few clinical trials of the anticaries effects of fluoride sealants have been less than encouraging.<sup>3</sup> The addition of fluoride to a sealant may offer a caries preventive advantage or, as Simonsen has opined, may have

more of a marketing than clinical benefit.<sup>5</sup>

The present investigation was initiated to evaluate the retention and effectiveness of Delton Plus, a fluoride sealant, compared with Delton, its nonfluoride analogue, when included in an ongoing school-based preventive dentistry program. Interim results on retention after eight months of study have been published.<sup>6</sup> Abstracts of final results after 1¼ years on retention and anticaries effects have been presented at IADR and AADR meetings.<sup>7,8</sup> Final results of the study are presented in this report.

## Methods

For the past two decades, the University of Southern California, School of Dentistry, has been conducting a mobile clinic sealant program to improve the dental health of children in inner city schools of Los Angeles.<sup>9</sup> Children in selected schools have limited access to dental care. Details of the study design and retention findings after an average of eight months study

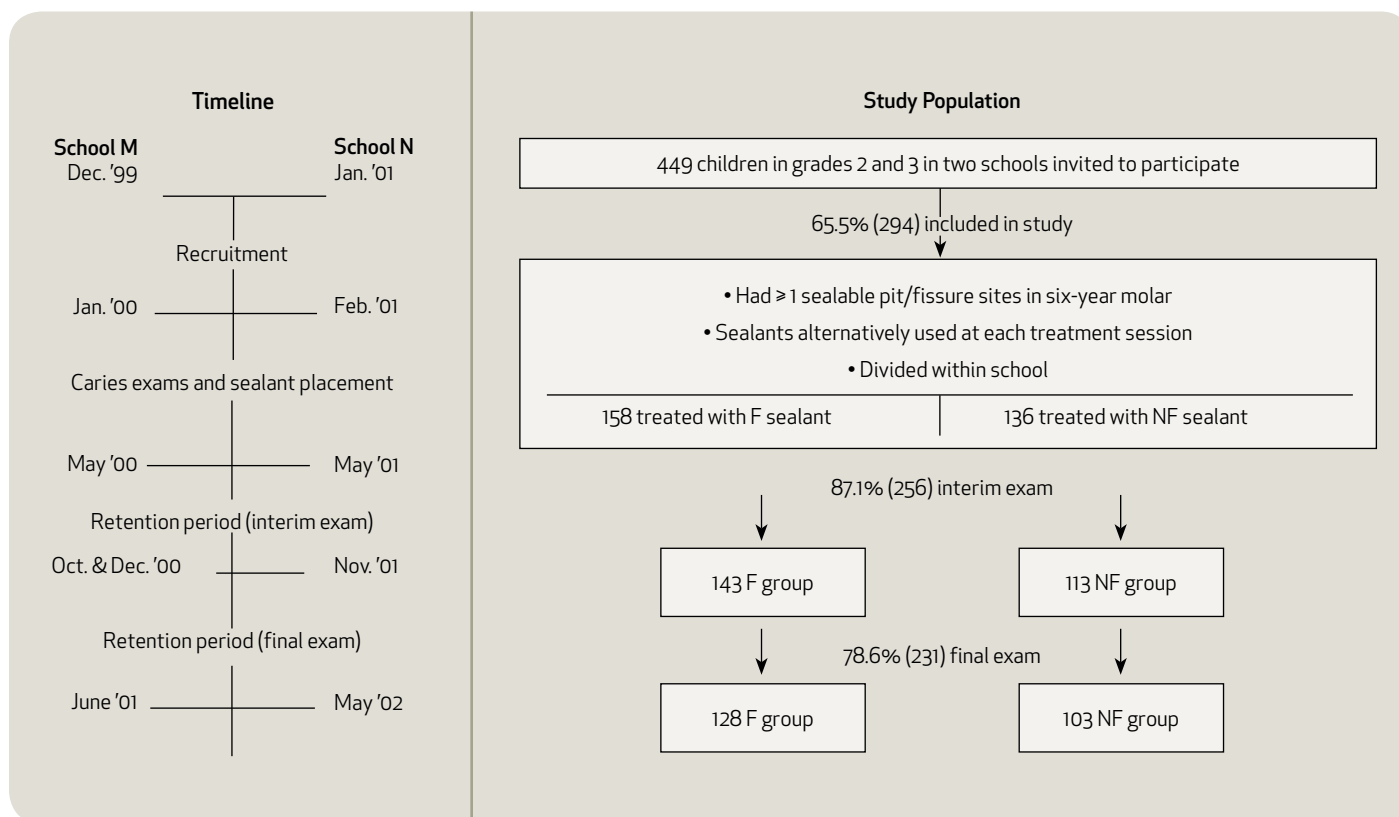


FIGURE 1. Schematic progression of study activities.

have been reported.<sup>6</sup> Donation by the manufacturer of both (Delton) and Delton Plus (2 percent NaF) prompted a study to compare the two types of sealants within the existing program. A total of 294 second and third graders, mainly 7 to 9 years old, in two program schools were divided within their school to receive either the fluoride or nonfluoride sealant. Because the transverse ridge separates the mesial and distal fissure systems of upper six-year molars, the unit of observation was site rather than surface. Subjects had to have one or more occlusal or buccolingual pit and/or fissure sites in six-year molars that were sound, or incipient decayed and sufficiently erupted, to participate in the study.

Supervising faculty determined the sites that were suitable for sealant application. Freshman dental students applied the sealants. They also administered a 1.23 percent APF gel, provided oral hygiene instruction and distributed toothbrushes. Shortly before the study began, the City of Los Angeles fluoridated its water supply (8/99). All clinical examinations in the study were conducted by the same two investigators. Criteria for sealant retention were those of Simonson's and for dental caries those of the ADA's Councils on Dental Research and Dental Therapeutics.<sup>10,11</sup> All first molars were examined but only those that initially received sealant were included in the analyses (FIGURE 1).

FIGURE 1 shows a schematic progression of study activities by timeline and number of study subjects. Because study activities were determined by the fixed schedule of the mobile clinic sealant program, it took approximately 2½ years to complete the study. Of the initial number of participants, 78.6 percent were present for the final exam; 128 in the fluoride; and 103 in the nonfluoride group.

### Statistical Analyses

Chi square tests were performed on demographic data by sealant type. Analyses of variance, ANOVAs, were used for subjectwise assessment of group comparability and for comparison of

TABLE 1

## Summary of Demographic Data Subjects Present at the Final Examination

		F (n=128)	NF (n=103)	p-value
Age (years)	Mean	7.73	8.08	
	S.D.	0.68	0.82	<0.001 <sup>1</sup>
	Range	6-9	6-10	
Gender n (%)	Male	54 (42.2%)	50 (49.0%)	0.301 <sup>2</sup>
	Female	74 (57.8%)	52 (51.0%)	
Ethnicity n (%)	Hispanic	121 (98.4%)	95 (96.0%)	0.130 <sup>3</sup>
	Other	2 (1.6%)	4 (4.0%)	

<sup>1</sup> p-value from t-test.<sup>2</sup> p-value from chi square test.<sup>3</sup> p-value from Fisher's Exact test.

TABLE 2

## Number of Occlusal and Buccolingual Sites Sealed at the Final Examination and Duration of Retention

		F (n=128)	NF (n=103)	p-value*
No. occlusal sites sealed per subject	Mean	3.48	3.49	0.978
	S.D.	1.50	1.57	
No. B-L sites sealed per subject	Mean	2.26	2.22	0.819
	S.D.	1.00	1.02	
Duration of retention (months)	Mean	14.25	14.58	0.069
	S.D.	1.21	1.53	

\* p-value from ANOVA

mean percentage retention and caries scores. Where sitewise assessment was used, because of the lack of independence, the analysis was limited to descriptive statistics. All statistical test hypotheses employed a significance level of  $\alpha=0.05$ .

## RESULTS

### Retention

TABLE 1 shows demographic data of the final participants. The two sealant groups were well-balanced with respect to gender and ethnicity; both groups being more

than 96 percent Hispanic. At baseline, subjects in the fluoride group were significantly lower in age than the nonfluoride group by about four months (TABLE 1).

Notwithstanding the small difference in mean age, TABLE 2 shows that the mean number of sealed occlusal sites per child was virtually identical, 3.48 and 3.49. Corresponding scores for buccolingual sites were also comparable. The duration of retention after sealant placement in the fluoride group averaged 14.25 months, and in the nonfluoride group, 14.58 months ( $P=0.07$ ) (TABLE 2).

TABLE 3 shows findings for fluoride and nonfluoride groups by extent of retention on occlusal sites. Mean percentages of sealed occlusal sites per subject for full retention were similar 58 and 55 percent, respectively; for "Any" sealant retention (full or partial), both groups scored 75 percent. Mean subjectwise percentage retention on buccolingual sites (data not shown) were steeply lower than corresponding scores for occlusal sites, as low as 28 percent for Any retention in both groups; "Observed" differences between the groups in "Full" and Any retention were not statistically significant,  $P=0.31$  and  $0.83$ , respectively (TABLE 3).

TABLE 4 shows data of the frequency of sites fully retaining sealant that either was sound or had incipient decay at baseline. No clinical difference is apparent in their respective frequencies of full retention, 45.23 percent and 43.21 percent, respectively. However, results are based on a small proportion of incipient sites; only 7 percent of the 1151 sites were available for study (TABLE 4).

### Anticaries Effectiveness

TABLE 5 shows that for both groups, of the initially sound sites losing their sealant completely or partially during the study period, 90.8 percent remained sound ( $DMF=0$ ); only 9.2 percent experienced decay ( $DMF=1$ ). The tabular data also show numerically greater percent DMF increment of zero for sites with partial sealant loss compared with those of complete loss (TABLE 5).

For the preponderance or 82 percent (190/231) of children who completely or partially lost sealant from initially sound sites, TABLE 6 shows that both the fluoride and nonfluoride groups experienced similar, extremely low mean DMF attack rates, less than 1/10 site per child or  $0.087$  and  $0.094$ , respectively. DMF attack rates

TABLE 3

### Mean Percentage of Occlusal Sites Per Subject Exhibiting Full or Any (Full Or Partial) Sealant Retention at the Final Examination

Study group	Number of subjects	Mean % Occlusal Sites per Subject*	
		Full	Any
F	128	58.07 ± 33.42	74.87 ± 31.76
NF	100	54.65 ± 36.98	74.80 ± 31.10
p-value **		0.309	0.830

\* Mean ± S.D.

\*\* p-value from ANOVA

TABLE 4

### Distribution of Full Retention on Final Exam for Sealed Sites Sound or With Incipient Decay at Baseline

Baseline Diagnosis	Number Sites Sealed	Number Fully Retained	Percent Fully Retained
Sound	1070	484	45.23
Incipient Decay	81	35	43.21
Total	1151	519	45.09

TABLE 5

### Distribution of Sitewise Percent DMF Increment for Initially Sound Sealed Sites by Extent of Sealant Loss by Group

Study Group	Sealant Completely Lost		Sealant Partially Lost		Sealant Completely or Partially Lost	
	DMF=0	DMF=1	DMF=0	DMF=1	DMF=0	DMF=1
F	199 (88.4%)	26 (11.6%)	78 (97.5%)	2 (2.5%)	277 (90.8%)	28 (9.2%)
NF	177 (88.9%)	22 (11.1%)	71 (95.9%)	3 (4.1%)	248 (90.8%)	25 (9.2%)

per subject for sealed sites that initially had incipient decay as expected were much greater, 0.375 for the fluoride group and 0.300 for the nonfluoride group (data not shown). However, subjects in each group numbered 16, too small for the clinical results to be meaningful (TABLE 6).

## Discussion and Conclusions

Final results after 1¼ years are consistent with those after eight months of study in that the fluoride and nonfluoride

sealants continued to show no difference in retention and are in agreement with reviews comparing the two types of sealants.<sup>2,5,12</sup> Also in agreement with other studies is the relatively poor sealant retention on buccolingual sites compared with occlusal sites.<sup>13-15</sup> Concerning anticaries results, at baseline, the 294 subjects had a caries prevalence on six-year molars of 1.6 DMFS/child. Because of the moderate past caries experience, a measurable amount of new decay could be anticipated

among study subjects. However, it was unanticipated that the additive effect of the combined preventive measures included in the sealant program might be so profound as to inhibit further decay, compromising the capability of the study to detect any enhanced protection from the fluoride sealant. Another possible plausible explanation for the minimal decay is that the remaining eligible sound six-year molars that lost sealant were less caries prone to begin with.

For a sound fissure, when the sealant remains fully intact, the fissure is completely protected from decay; and when fully or partially lost, the fissure is equally at risk as if it was never sealed.<sup>12</sup> But there is equivocal evidence to also show that when a sealant is partially retained, some anticaries benefits are conferred, compared with unsealed control sites.<sup>13,16,17</sup> In the present study, sites with partial sealant lost had numerically greater zero increment than sites with complete or partial sealant loss, ≥ 96 percent compared with 91 percent, respectively (TABLE 5).

Concern is still sometimes heard about sealing teeth with incipient decay as done in the present study. A large body of evidence has accumulated showing that when the sealant remains intact no further progression of the incipient lesion occurs.<sup>5,12</sup> However, that leaves the question of whether teeth with incipient lesions that partially lose their sealant are more, less, or equally at risk than teeth with incipient lesions that were never sealed. As for retention itself, in the present study, no clinical difference was observed in the frequency of full retention between sound teeth and teeth with incipient decay that were sealed (TABLE 4). However, results are based on only a small proportion of incipient sites, 7 percent of the 1151 sites were sealed. Therefore, the issue in question cannot be authorita-

TABLE 6

### DMF Attack Rate per Child for Sealed Sites Initially Sound That Completely or Partially Lost Sealant by Group

Study Group	Sealant Completely or Partially Lost	
	Number of subjects	DMF rate/child*
F	106	0.087 (0.241)
NF	84	0.094 (0.247)

\* p-value=0.875 from ANOVA  
( ) Standard Deviation

tively addressed by the data in this study. However, the current method of clinically diagnosing incipient pit and fissure caries is fraught with poor sensitivity, correctly calling from 20 percent to 80 percent of true enamel caries; the reciprocal being the falsely negative range.<sup>18,19</sup>

One can, therefore, assume that purportedly sound fissures that partially lose sealant erroneously include a certain unknown proportion with incipient decay, this study being no exception. That “sound” fissures with partial sealant loss have, in the few studies previously reported herein, shown anticaries benefits, suggests that fissure sites with incipient decay that partially lose sealant, at best, may receive some anticaries protection and at worst, appear to be at no more at increased risk of further caries progression than unsealed fissures with incipient decay. Further research is needed to determine the fate of incipient caries in fissures where the sealant has been partially lost.

The present investigation, it should be noted, is the result of a relatively short-term sealant study. There is consensus that sealant therapy does not impart long-term effective anticaries protection unless the sealant remains fully intact and most effective when applied to those pits and fissures in the earliest stages of the carious process. Moreover, the routine application of fissure sealant to sound surfaces is viewed as overtreatment in some European countries.<sup>10</sup> The targeting of fissures at highest risk for sealant therapy has been recommended by investigators in this country.<sup>13,20</sup> And as far back

as the mid 1980s, the NIDR was advocating the sealing of incipient lesions.<sup>21</sup> The challenges of improved sealant chemistry and of increased sensitivity in diagnostic methods for the clinical detection of incipient caries must be met if the cost-benefit ratio of sealants is to become appreciably more favorable. ■■■■■

#### REFERENCES

1. Curzon MEJ, Toumba KJ, In vitro and in vivo assessment of a glass slow fluoride-releasing device: a pilot study. *Brit Dent J* 196;543-6, 2004.
2. Morphis TL, Toumba KJ, Lygidakis NA, Fluoride pit and fissure sealants: a review. *Int J Paediatr Dent* 10:90-8, 2000.
3. Jensen ME, Wefel JS, et al, Effects of a fluoride-releasing fissure sealant on artificial enamel caries. *Am J Dent* 3:75-8, 1990.
4. Hicks MJ, Flaitz CM, Garcia-Godoy F, Fluoride-releasing sealant and caries-like enamel lesion formation in vitro. *J Clin Pediatr Dent* 24:215-9, 2000.
5. Simonsen RJ, Pit and fissure sealant: review of the literature. *Pediatr Dent* 24:393-414, 2000.
6. Heifetz SB, Yaari A, Proskin HM, Retention of a fluoride-releasing sealant compared with its nonfluoride analogue: interim results of a clinical study after an average of eight months. *J Clin Dent* 15:1-5, 2004.
7. IADR/AADR/CADR 83rd general session in Baltimore, Md.: Heifetz SB Yaari A, Proskin HM, Fluoride and nonfluoride sealant retention: results after 1¼ years. *J Dent Res* 84(Spec Iss A): 1789, 2005.
8. AADR/ADEA 35th annual meeting in Orlando, Fla.: Heifetz S, Yaari A, Proskin HM, Anticaries effectiveness of fluoride and nonfluoride sealant after sealant loss. *J Dent Res* 85 (Spec Iss A): 491, 2006.
9. University of Southern California, School of Dentistry: community programs sealant project, www.usc.edu/hsc/dental/community/sealant\_project.htm (Accessed June 14, 2007).
10. Simonsen RJ, Retention and effectiveness of a single application of white sealant after 10 years. *J Am Dent Assoc* 115:31-6, 1987.
11. American Dental Association, Council on Dental Research and Council on Dental Therapeutics: proceedings of the conference on the clinical testing of cariostatic agents, ADA, Chicago, pp. 87-8, 1972.
12. Feigal RJ, The use of pit and fissure sealants. *Pediatr Dent* 24: 415-22, 2000.
13. Feigal RJ, Sealants and preventive restorations: review of effectiveness and clinical changes for improvement. *Pediatr*

*Dent* 20:85-92, 1998.

14. Barrie AM, Stephan KW, Kay EJ, Fissure sealant retention: a comparison of three sealant types under field conditions. *Community Dent Health* 7:273-277, 1990.

15. Ripa L, Occlusal sealants: rational and review of clinical trials. *Clin Prev Dent* 4:3-10, 1982.

16. Horowitz HS, Heifetz SB, Poulson S, Retention and effectiveness of a single application of an adhesive sealant in preventing occlusal caries: final report after five years of study in Kalispell, Mont. *J Am Dent Assoc* 95:1133-9, 1977.

17. Charbeneau GT, Dennison JB, Ryge G, A filled pit and fissure sealant: 18-month results. *J Am Dent Assoc* 95:299-306, 1977.

18. Ekstrand KR, Ricketts DNJ, et al, Detection, monitoring, and logical treatment of occlusal caries in relation to lesion activity and severity: an in vitro examination with histological validation. *Caries Res* 32:247-54, 1998.

19. Lussi A, Validity of diagnostic and treatment decisions of fissure caries. *Caries Res* 25:296-303, 1998.

20. Heller KE, Reed SG, et al, Longitudinal evaluation of sealing molars with and without incipient dental caries in a public health program. *J Publ Health Dent* 55:148-53, 1995.

21. National Institutes of Health, Consensus development conference statement on dental sealants in the prevention of tooth decay. *J Am Dent Assoc* 108:233-6, 1984.

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