Original Article

Fluoride Release Rate from an Orthodontic Sealant and Its Clinical Implications

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ABSTRACT

The objectives were to measure the rate and amount of fluoride ions released from the sealant over a period of 17 weeks and to determine whether the fluoride-releasing sealant has a recharging ability when fluoride ions are reintroduced into the environment. Disc-shaped specimens were prepared from two types of sealants: (1) 10 discs were made using a fluoride-releasing sealant and (2) 10 discs were made of a nonfluoride adhesive primer (control). An ion analyzer was used to measure the fluoride release using a fluoride ion–specific combination electrode. The results of the repeated measure analysis ($F = 7.76$) indicated that the fluoride-containing sealant released fluoride ions into the solution in sustained but significantly ($P = .014$) decreasing rates from a high of 0.074 $\pm$ 0.04 ppm/week/mm^2 in the first week to a low of 0.015 $\pm$ 0.017 ppm/week/mm^2 at the end of the 17th week. Furthermore, the Pro Seal discs had the ability to be recharged with fluoride ions introduced from a foaming solution of acidulated phosphate fluoride. The mean fluoride release rate one week after recharging was 0.354 $\pm$ 0.095 ppm/week/mm^2 and decreased to 0.014 $\pm$ 0.009 ppm/week/mm^2 after eight weeks. The control sealant showed no significant fluoride release and was unable to absorb the fluoride ions available in the solution. The fluoride-containing sealant Pro Seal released fluoride ions in sustained but significantly decreasing amounts. The Pro Seal discs had the ability to be recharged with fluoride ions. (*Angle Orthod* 2006;76:282–288.)

KEY WORDS: Fluoride release; Composite sealant

INTRODUCTION

The development of a clinically visible carious lesion is a consequence of the interaction between the dental tissues and various variables in the oral environment. As an example, carbohydrate fermentation by the bacteria in the dental plaque causes a decrease in the pH, which in turn results in the loss of mineral ions from the enamel to the oral environment, a process known as demineralization. Through the buffering action of saliva, the pH can increase again allowing the teeth to incorporate free ions, this process is called remineralization.[1,2] Therefore, there is a constant ionic exchange between the dental tissues and the environment, in an attempt to reach an ionic equilibrium. Progressive demineralization without adequate remineralization can result in the development of carious lesions.

A number of studies[3] indicated that the use of fluorides causes a decrease in the caries incidence, particularly when fluoride ions are readily available in the oral environment. More specifically, the presence of fluoride will minimize the ionic loss from the tooth structure until the pH of the plaque becomes as low as 4.5. At that level, even the presence of adequate fluoride concentration in the oral environment will have a minimal beneficial effect on the process of remineralization.[4] But before reaching such a critically low pH level, the availability of fluoride ions in the oral environment will enhance remineralization. In general, the remineralized surface is more resistant to demineralization than the original enamel surface.[5]

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The anticariogenic effects of fluoride compounds incorporated in various restorative materials depend on the amount of fluoride released into the immediate environment and more importantly on the longevity, ie, sustainability of such a release.[6] Therefore, maintaining an adequate and constant presence of fluoride ions in the vicinity of the tooth is critical to the ability of the enamel to remineralize. It has been suggested that fluorides will have a substantial significant effect on the rate of demineralization of dentin and enamel even if it is in the sub-ppm level, ie, as low as 0.02 to 0.06 ppm.[7]

The frequent application of fluorides is the most efficient method for preventing demineralization as well as enhancing remineralization of carious lesions. A potential method of providing a sustained concentration of fluoride ions over a prolonged period is to have a slow fluoride-releasing system incorporated in dental restorative materials. Furthermore, the ability of some restorative materials for recharging fluoride and then releasing it, acting as a fluoride pump, will help interrupt the cariogenic process, thus decreasing the caries risk.[8] Therefore, a number of fluoride-releasing restorative systems have been developed.[8–12] The fluoride ions released from these restorative materials penetrate and defuse into the tooth structure and prevent secondary caries by reinforcing the mineral content of the tooth structure.[9] The most effective fluoride-releasing restorative materials in a descending order are glass ionomer cements, resin-modified glass ionomers, and then compomers.[10] On the other hand, fluoride-releasing composites were not found to be effective in providing a sustained rate of fluoride ions.[10,11]

A number of fluoride-releasing varnishes have been suggested for use during orthodontic treatment in an attempt to prevent decalcification and white spot lesion formation around orthodontic appliances.[12–14] In an in vivo study, Øgaard et al[15] found that the use of a fluoride varnish was as effective in reducing white spot formation as the combined use of chlorhexidine and fluoride varnishes. The only exception was in the maxillary incisors region where the combination of varnishes tended to have a more beneficial effect on white spot lesion reduction.

A highly filled fluoride-releasing sealant was introduced recently with the claim that it will protect the enamel and prevent decalcification around and under orthodontic brackets. The manufacturer also suggests that the sealant will resist toothbrush abrasion for a significant time period (P. Gauge, personal communication). In an earlier study,[16] it was reported that the application of such a sealant did not significantly affect the shear strength of orthodontic brackets bonded to enamel when compared with controls.

A fluoride-releasing sealant intended to protect enamel and prevent decalcification around and under orthodontic brackets was introduced recently. Whether such sealants can also minimize the occurrence of white spot formation is dependent on their continued ability to release fluoride ions over time. Therefore, the purpose of this study was twofold: (1) to measure the rate and amount of fluoride ions released from the sealant over a period of 17 weeks and (2) to determine whether the fluoride-releasing sealant has a recharging ability when fluoride ions are reintroduced into the oral environment.

MATERIALS AND METHODS

Materials used

Disc-shaped specimens were prepared from two types of sealants: (1) 10 discs were made of Pro Seal (Reliance Orthodontic Products Inc, Itasca, Ill), a fluoride-releasing sealant and (2) 10 discs were made of a nonfluoride sealant (control group). This sealant is part of the Transbond XT adhesive system (3M Unitek, Monrovia, Calif). Each disc was one mm thick, five mm in diameter, and with a surface area of 19.64 mm^2 on each side.

When making the discs, the sealants were light cured for 20 seconds according to the manufacturer's instructions. Each disc was then fixed on one of its sides, to the base of a polyethylene tube using sticky wax. A total of 0.5 mL of distilled water was placed in each tube before it was sealed and stored at 37°C.

Fluoride ions–measuring instrument

An ion analyzer (Thermo Orion, model 920A+; Thermo Electron Corporation, Beverly, Mass) was used to measure the fluoride release using a fluoride ion–specific combination electrode. The fluoride release was measured weekly, and at each time interval, the instrument was recalibrated to measure fluoride concentrations between 0.02 and 10 ppm.

Measurement of fluoride release from each material

Fluoride concentration in the solution was measured weekly for five consecutive weeks. The process was repeated again after four weeks and then after another eight weeks of storage, for a total follow-up of 17 weeks (at which point there were no measurable changes in the fluoride ion release).

At each measuring interval, the water in each tube was retrieved and 0.5 mL of total ionic strength adjustment buffer (TISAB) solution was added to it. After calibration of the solution, the fluoride ion concentration was measured by the fluoride-specific ion electrode. After each reading, the tubes containing the

TABLE 1. Descriptive Statistics and the Results of the Repeated Measure Analysis Comparing the Initial Rates of Fluoride Release (in ppm/week/mm²) Between Consecutive Time Intervals. Initial Release of Fluoride From Both Groups

		Time in Weeks						
Material		1	2	3	4	5	9	17
Pro Seal	Mean	0.074	0.067	0.037	0.034	0.023	0.018	0.015
	SD	0.04	0.076	0.032	0.03	0.023	0.013	0.017
	Range	0.01–0.17	0.01–0.28	0.01–0.1	0.01–0.1	0–0.07	0–0.04	0–0.05
	P	.614	.120	.386	.007	.265	.405	
Transbond	Mean	0.001	0.0007	0.0002				
	SD	0.0009	0.0004	0.0004				
	Range	0	0	0				
	P	.089	.001					

discs were thoroughly washed using distilled water. Then, 0.5 mL of fresh distilled water was placed in the tube to cover the disc, which was then stored at 37°C.

Determination of the recharging ability of the materials

After completion of the first part of the study, the 10 Pro Seal discs were divided into two equal subgroups to simulate two different methods of fluoride application to the teeth, namely, brushing with a fluoride-containing toothpaste and after the topical application of fluoride foam.

Tooth brushing subgroup

Each disc was brushed for two minutes with a slurry prepared from one g of a fluoride-containingtoothpaste (Colgate-Palmolive Co, New York, NY) and three mL of distilled water. The fluoride toothpaste contains 0.24% sodium fluoride. Each sample was then carefully rinsed for two minutes with distilled water and then stored for 24 hours in 0.5 mL of distilled water at 37°C. This procedure was repeated daily for seven days. At that point, each sample was placed in a new container with 0.5 mL of distilled water and stored for a week at 37°C. At the end of the week, the fluoride ion release was measured.

Topical fluoride subgroup

Each Pro Seal disc was immersed for five minutes in a foaming solution of acidulated phosphate fluoride (Oral-B, Belmont, Calif), which contained 1.23% wt/vol fluoride ion. Each disc was then rinsed for two minutes and placed in a tube with 0.5 mL of distilled water. As in the first subgroup, each sample was then stored for a week before the fluoride ion release was measured.

Control group

Discs of the nonfluoride sealant were immersed in a foaming solution of acidulated phosphate fluoride as explained above, and fluoride ion release was measured after one week storage in distilled water at 37°C.

Statistical analysis

Descriptive statistics including the means, standard deviations, and minimum and maximum values were calculated for the rate of fluoride release at each measuring interval for both the control and fluoride-releasing sealants.

The repeated measure analysis (analysis of variance) was used to determine whether there was a significant change in the rate of fluoride release with time.

Student's *t*-tests were used to compare the rate of fluoride release between the two sealants tested at the corresponding weekly intervals. Significance for all statistical tests was predetermined at $P \leq .05$.

RESULTS

Rate of fluoride release from the control (nonfluoride) sealant

The descriptive statistics for the rates of fluoride ion released from the control sealant are shown in Tables 1 and 2.

Initial fluoride release. With the Transbond sealant, there was no measurable fluoride release after the third week. The readings over the three-week period ranged from 0 to 0.01 ppm/week/mm² (Figure 1; Table 1).

Recharging effect. After the application of the topical fluoride foam, there was no significant increase in the fluoride ion released. The mean of fluoride released was 0.034 ± 0.009 ppm/week/mm² in the first week and then decreased to 0 ppm/week/mm² in the third week (Figure 2; Table 2).

Rate of fluoride release from Pro Seal

The descriptive statistics for the rates of fluoride ion release from the Pro Seal are shown in Tables 1 and 2.

Initial fluoride release. There was a sustained fluo-

TABLE 2. Descriptive Statistics and the Results of the Repeated Measure Analysis Comparing the Rates of Fluoride Release (in ppm/week/mm²) Between Consecutive Time Intervals. Release of Fluoride From Both Groups After Topical Fluoride Application

		Time in Weeks							
Material		1	2	3	4	5	6	7	8
Pro Seal	Mean	0.354	0.100	0.044	0.028	0.025	0.027	0.020	0.014
	SD	0.095	0.044	0.022	0.010	0.008	0.011	0.009	0.009
	Range	0.22–0.45	0.03–0.15	0.01–0.07	0.02–0.04	0.02–0.03	0.01–0.04	0.01–0.03	0–0.03
	P		.002	.019	.075	.433	.560	.069	.053
Transbond	Mean	0.034	0.009	0.001					
	SD	0.009	0.009	0.001					
	Range	0.02–0.04	0–0.03	0					
	P		.001	.132					

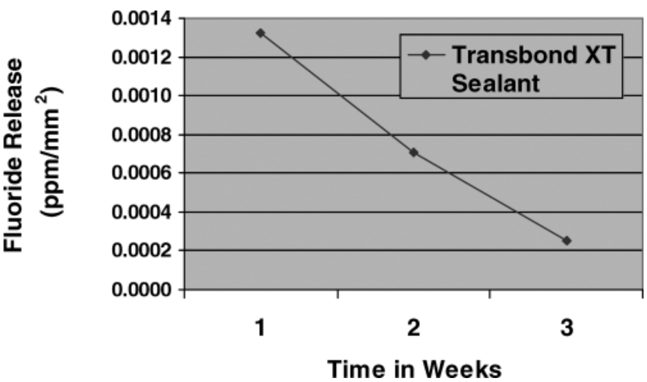

FIGURE 1. Fluoride release from Transbond in a three-week period.

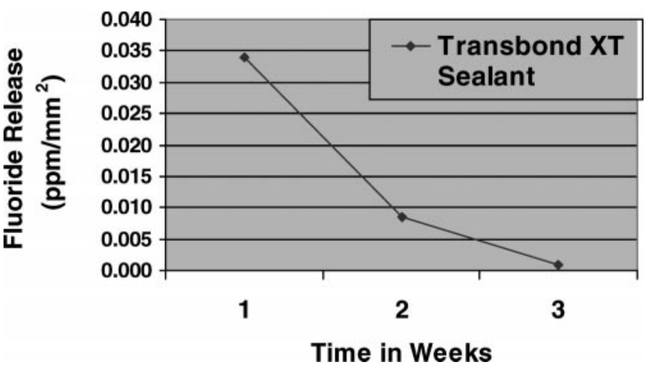

FIGURE 2. Fluoride release from Transbond in a three-week period after fluoride foam application.

ride ion release from the Pro Seal discs, but the rate steadily decreased over the 17-week observation period (Figure 3; Table 1). The mean fluoride released during the first week was 0.074 ± 0.04 ppm/week/mm², which gradually decreased to 0.015 ± 0.017 ppm/week/mm² at week 17. The results of the repeated measure analysis (F ratio = 7.76) indicated that there was a significant (P = .014) change in the rate of fluoride release from the first week to the 17th week. Comparison of the rate of fluoride release between each two consecutive weeks (Table 1) indicated that there was a significant difference between weeks 4 and 5 (P = .007).

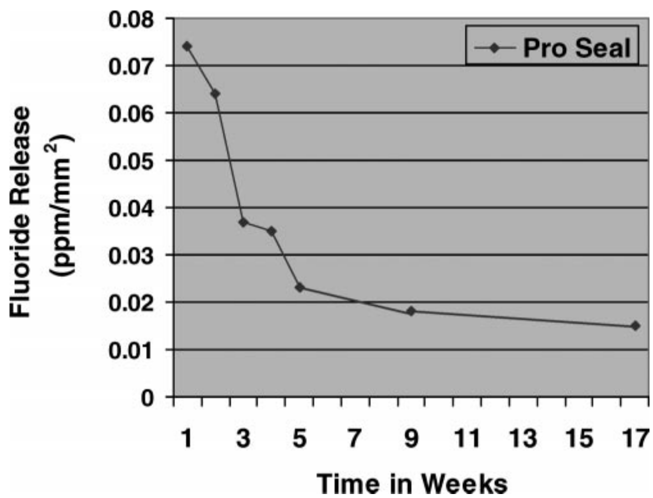

FIGURE 3. Fluoride release from Pro Seal over a 17-week period.

Recharging effect. Introduction of fluoride ions through the tooth brushing approach did not result in a significant increase in fluoride release from the Pro Seal discs. The mean fluoride release/week/ mm² after one week of storage was 0.007 ± 0.004 ppm/week/mm².

On the other hand, the application of the topical fluoride foam resulted in a significant increase in the fluoride released from the Pro Seal discs (Figure 4; Table 2). The mean fluoride release after a week was 0.354 ± 0.095 ppm/week/mm². Over the eight-week period, the rate of fluoride release progressively decreased to reach a mean of 0.014 ± ppm/week/mm².

Comparisons of fluoride release rate between the two sealants

All the *t*-test comparisons between Pro Seal and the nonfluoridated sealant Transbond were significantly different (range, 0.02 and 0.0001). These results indicated that, as expected, there was little or no fluoride release from the Transbond sealant both initially (Table 3) and after the fluoride foam application (Table 4).

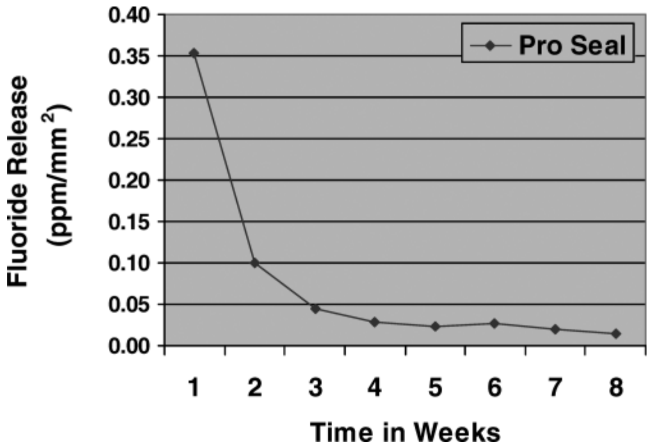

FIGURE 4. Fluoride release from Pro Seal over an eight-week period after fluoride foam application.

DISCUSSION

The application of fluoride varnishes and gels has a significant effect in minimizing demineralization.[15] However, it is still important to emphasize that during orthodontic treatment maintenance of good oral hygiene is the most crucial factor for preventing and minimizing the accumulation of plaque that causes demineralization.[16]

Øgaard et al[15] found that during orthodontic treatment the use of a fluoride varnish was as effective in reducing white spot formation as the combined use of both chlorhexidine and fluoride varnishes. The only exception was in the maxillary incisors region where the combination of varnishes tended to have a more significant effect on white spot lesion reduction.

A fluoride-containing sealant, Pro Seal, used to protect the enamel and prevent decalcification was introduced recently. In an earlier study,[16] it was reported that the application of the Pro Seal sealant did not adversely affect the shear strength of orthodontic brackets bonded to enamel. On the other hand, the ability of sealants to minimize the occurrence of white spot lesion formation is dependent on their continued ability to release fluoride ions over time.

In this study, the fluoride-containing adhesive Pro Seal was tested to measure the rate and amounts of fluoride release and also the ability of the sealant to reabsorb and release fluoride ions after being exposed to a fluoride source (toothpaste or foam). The results indicated that the fluoride-containing sealants released fluoride ions into the solution in a sustained but significantly decreasing rate from a high of 0.07 ppm/week/mm^2 in the first week to a low of 0.01 ppm/week/mm^2 at the end of the 17th week. These amounts of fluoride release are considered to be sub-ppm. On the other hand, Ten Cate[7] suggested that even a sub-ppm fluoride release will have a significant effect on the demineralization/remineralization process. It is also known that fluoride-releasing materials when subjected to a decreasing pH will significantly increase the amount of fluoride they release.[17–19]

These findings indicated that Pro Seal discs have the ability to be recharged with fluorides introduced from a foaming solution of acidulated phosphate fluo-

TABLE 3. *t*-test Comparison of the Rate of Fluoride Release (in ppm/week/mm^2) the Initial Three Weeks From Pro Seal and Transbond Sealants

	Time											
	First Week				Second Week				Third Week			
Material	Mean	SD	*t*[a]	*P*	Mean	SD	*t*	*P*	Mean	SD	*t*	*P*
Pro Seal	0.074	0.040	5.74	.0001	0.067	0.075	2.78	.021	0.037	0.032	3.67	.005
Transbond	0.001	0.001			0.001	0.000			0.000	0.000		

[a] *t* indicates *t*-test.

TABLE 4. *t*-test Comparison of the Rate of Fluoride Release (in ppm/week/mm^2) From Pro Seal and Transbond Sealants After Fluoride Foam Application

	Time											
	First Week				Second Week				Third Week			
Material	Mean	SD	*t*[a]	*P*	Mean	SD	*t*	*P*	Mean	SD	*t*	*P*
Pro Seal	0.35	0.09	7.46	.002	0.10	0.04	4.48	.009	0.04	0.02	4.28	.013
Transbond	0.03	0.009			0.008	0.009			0.0009	0.0007		

[a] *t* indicates *t*-test.

ride but not from toothpastes. Thus, the use of topical fluorides needs to be considered especially after the fourth week of appliance placement because it might have a significant effect on increasing the amount of fluoride released from Pro Seal. The regular application of a fluoride foam in addition to the sealant is beneficial in high caries risk patients, where all preventive measures need to be considered. Under such conditions, the clinician needs to consider the cost/benefit ratio of the whole approach.

Other important observations

In this study, tooth brushing with a fluoride-containing toothpaste did not have a significant effect on recharging the Pro Seal discs. Yet, Marinho et al[20] found that the use of fluoride-containing toothpastes is as effective as the use of fluoride-containing mouthwashes and varnishes in caries prevention. Therefore, although the use of fluoride-containing toothpaste in this study did not have a significant recharging effect of Pro Seal, it is imperative to advise the patient to use fluoride-containing toothpastes. These products have a beneficial effect by altering the demineralization/remineralization process occurring in the oral cavity and thus minimizing white spot formation.

With the Pro Seal sealant, there was a sharp decline in the rate of fluoride release in the first three weeks (Figure 3) from a mean of 0.074 to 0.037 ppm/week/mm^2. This drop was not reflected in the statistical comparisons (Table 1). This discrepancy is partly related to the large variation in the rate of fluoride release from the various specimens, eg, in the third week, the standard deviation was as large as the mean value (0.037 vs 0.032, respectively).

It needs to be emphasized that the data in this study are reported as fluoride released/week/mm^2; therefore, on a daily basis, the rate of fluoride release would be significantly lower. In addition, the oral environment will affect the fluoride ion availability by either diluting it with saliva and other fluids or increasing their concentration from the application of fluoride gels, foams, or tooth brushing.

It is important for the manufacturers to provide more detailed information on the rate of fluoride ion release as well as the duration of its release from sealants and adhesives that contain fluorides. This will allow clinicians to compare the efficacy of different products available on the market.

Two important clinical questions remain unanswered and still need to be investigated, namely (1) Would the low and decreasing levels of fluoride released from Pro Seal have an effect on decreasing white spot lesion formation around orthodontic appliances? and (2) How much of the Pro Seal layer applied during the bonding procedure remains on the tooth when it is subjected to the rigors of the oral environment?

CONCLUSIONS

- The fluoride-containing sealant Pro Seal released fluoride ions in a sustained but significantly decreasing amounts from a high of 0.07 ppm/week/mm^2 in the first week to a low of 0.01 ppm/week/mm^2 at the end of the 17th week.
- The Pro Seal discs had the ability to be recharged with fluoride ions introduced from a foaming solution of acidulated phosphate fluoride.
- After recharging, the mean fluoride ions release during the first week was 0.354 ± 0.095 ppm/week/mm^2 but significantly decreased to 0.014 ± 0.009 ppm/week/mm^2 on the eighth week.
- There was no significant fluoride release registered in the control sealant and, in addition, it did not absorb fluoride ions that were made available.

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