

Evaluation of Short Term Fluoride Release from Fluoride Varnishes

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Objective: The aim of this study was to compare the rate of fluoride release from fluoride varnishes over a 48-hour period and ascertain the time at which a plateau occurred. This data provides clinically relevant time points to resume tooth brushing after fluoride varnish application. **Study design:** Four commercially available fluoride varnishes, Premier Enamel ProVarnish (EP), Colgate PreviDent (CP), Omni Vanish (OV) and Omni VanishXT (OVXT) were applied on 40 extracted permanent human teeth. Ten teeth served as controls. The teeth were immersed in artificial saliva. At 1,2,4,8,12,24 and 48 hours, the teeth were sequentially transferred to new vials. TISAB III and ion selective electrode was used to measure fluoride release. Statistical tools were used to compare the rates of fluoride release and plateau of fluoride release. **Results:** CP, EP and OV showed a plateau of fluoride release after 4 hours. OVXT did not show a significant change in fluoride release at any time point. EP had the highest fluoride release in the first 8 hours. **Conclusions:** CP, EP and OV released maximum rate of fluoride release in the first 4 hours whereas OVXT did not have a plateau. The studied varnishes released different concentrations of fluoride despite the fact that they all contained 5% sodium fluoride.

Keywords: Fluoride varnish, fluoride release.

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INTRODUCTION

Professionally applied fluoride in the dental office has traditionally been delivered via fluoride gels and foam, which contain 12,300 ppm fluoride. Fluoride varnish are another means of professionally applied fluoride. Fluoride varnishes available in the United States contain 5% sodium fluoride (22,600 ppm fluoride). While fluoride gels and foams have to be placed in a tray and kept in the mouth for 4 minutes, fluoride varnishes are applied by painting the varnish over the teeth. The ease of application of fluoride varnishes has led to its popularity in the practice of pediatric

dentistry, which involves its use for pre-cooperative children, children with special health care needs, children exposed to head and neck radiation and children who have an exaggerated gag reflex.^{1,2}

There are two essential components in fluoride varnishes. The therapeutic agent is the sodium fluoride. The carrier is the varnish, which is an adherent film that holds the sodium fluoride in contact against a tooth surface. Fluoride varnishes were initially marketed for management of dentin hypersensitivity.^{1,3} Their use for caries prevention was considered off-label use of the product. However, recent studies have shown the use of fluoride varnishes to be effective in the prevention of early childhood caries, and reduce caries by 25-45%.^{4,5} They have been shown to decrease the incidence of root caries, and to be better than other topical fluoride agents.^{6,7}

The in vitro release of fluoride from fluoride varnishes over an extended time period has been investigated. The study methodology of these studies involved single or multiple applications of the varnish and measuring fluoride release over a time periods in the range of 5 months.^{8,9} The teeth specimens were continually immersed in solution during the study period. The investigators reported that fluoride release in the first week, and further in the first 7 hours, to be the most rapid.¹⁰ However, their purpose focused on fluoride release over extended time periods; they did not measure fluoride release in the immediate time period after varnish application. Although information on the long-term fluoride release provides valuable data in understanding the

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fluoride profile of varnishes, the methodology does not reflect the clinical use of the material. In clinical practice, the patient is instructed to resume routine oral hygiene practices, including tooth brushing, after a manufacturer recommended time period. Tooth brushing removes the varnish layer from the tooth, hence it is important to know when the rate of fluoride release plateaus after application of fluoride varnishes. Manufacturers vary in their recommendations for resuming routine oral hygiene after the application of fluoride varnishes (Table 1). They range from waiting 4-6 hours to the next morning. Clinical recommendations by authors on resuming tooth brushing after fluoride varnish application varies from 12 hours² to 24 hours.⁴

Table 1. Manufacturer's recommendations for post-treatment patient instructions after application of fluoride varnish

Product	Brushing & Flossing	Diet	Resume normal oral hygiene	Fluoride supplement
Premier Enamel Pro Varnish	Refrain for 4-6 hours	Soft food	Wait until next day	Interrupt for 2-3 days
Colgate PreviDent	Refrain for 6 hours	Soft diet for 2 hours	Wait until next day	None stated
Omni Vanish	Refrain for 4-6 hours	Soft diet	Wait until next day	None stated
Omni Vanish XT	None stated	None stated	None stated	None stated

The purpose of this study was to measure and compare the rate of release of fluoride from fluoride varnishes from contemporary commercially available fluoride varnishes, and to identify the time point at which the rate of fluoride release plateaus.

MATERIALS AND METHODS

The four fluoride varnishes tested in this study were (1) Premiere Enamel Pro Varnish (EP), (2) Colgate PreviDent (CP), (3) Omni Vanish (OV), (4) Omni Vanish XT (OVXT). All the tested products contain 5% sodium fluoride varnish. Fifty extracted permanent teeth were cleaned and dried with gauze. The tooth surfaces were covered with OPI nail varnish except for a 5x5 window, where the test material was to be applied. The weight of each tooth was recorded. The teeth were randomly divided into 5 groups of 10 each. Four groups corresponded to the test products and the fifth group comprised of untreated controls. In each group, the test material was applied following the manufacturer's instructions. EP, CP and OV were placed by painted with the provided brush inside the package. OVXT was mixed as per manufacturer's instructions, applied on the tooth and then light cured for 20 seconds. The teeth were weighed again after the application of the varnishes, and then placed in individual vials containing 3ml of artificial saliva, at pH 7.2 and room temperature.

The teeth were removed from vials and placed in new vials containing fresh artificial saliva sequentially at 1, 2, 4,

8, 12, 24, and 48 hours after the application of fluoride varnish. After the transfer, 1.8 ml of solution from preceding vial was added to 0.2 ml of total ionic strength adjusting buffer (TISAB) III for fluoride analysis. Fluoride ion concentration was measured by ion selective electrode for fluoride, calibrated with TISAB III and fluoride standards. This method measured fluoride ion concentration (in parts per million) in solution, which corresponds to the fluoride ion released by the fluoride varnish.

RESULTS

All the test products showed a decline in the rate of fluoride release over the time period of study. The fluoride ion concentration in the control specimens ranged from 0.005-0.009 ppm and did not show variation with time; therefore the data from the control specimens are not included in the subsequent tables. The mean hourly rate of release of fluoride is reported in Table 2. When adjusted for the weight of fluoride applied on each tooth, the fluoride release of each product at each time point of measurement is shown in Table 3. The rate of release of fluoride is graphically shown in Figure 1. The data show that the release of fluoride was the highest in EP group at baseline. The rate of release of fluoride by EP was also highest in the initial hours (up to 8 hours). The rate of release of fluoride by OVXT was low in the initial 4 hours, but was higher than other tested products after the initial 4 hours. Repeated measures ANOVA (analysis of variance) indicated significant differences in the products' fluoride release over time ($F_{3,36}=153, p<0.0001$).

This is also shown in Table 4. The time beyond which there was no further significant change in the rate of release

Table 2. Mean hourly rate of fluoride release

Group	N	Mean (ppm)	Std Dev (ppm)
Premier Enamel Pro Varnish	10	358.467	124.712
Colgate PreviDent	10	52.244	10.081
Omni Vanish	10	18.470	5.959
Omni Vanish XT	10	188.676	106.484

Table 3. Weight adjusted fluoride (ppm) release rate

Group	Time						
	Hr 1	Hr 2	Hr 4	Hr 8	Hr 12	Hr 24	Hr 48
Premier Enamel Pro Varnish	1730.2	545.1	118.9	76.7	30.7	6.5	1.2
Colgate PreviDent	163.5	121.9	39.1	17.8	16.2	4.2	3.1
Omni Vanish	45.8	34.8	13.5	11.1	14.7	5.5	3.9
Omni Vanish XT	487.1	386.1	188.7	121.9	72.6	41.8	22.5

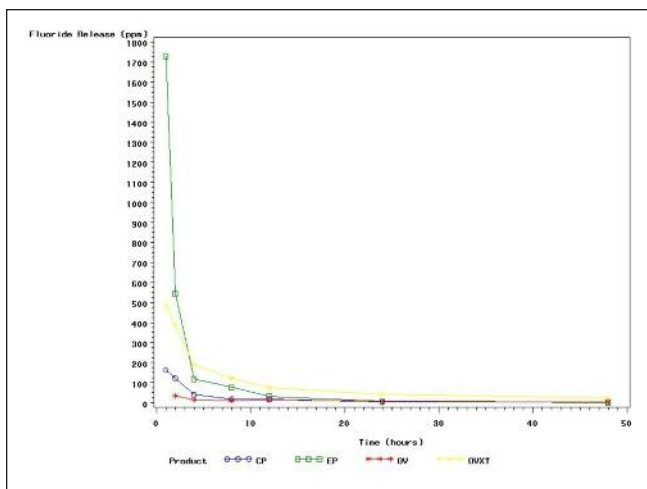


Figure 1. Fluoride release rate from test products

Table 4. Pairwise comparison of test products (Tukey Kramer test)

Pairwise comparison	Premier Enamel Pro Varnish	Colgate PreviDent	Omni Varnish	Omni Varnish XT
Premier Enamel Pro Varnish	-	<.0001*	<.0001*	<.0228
Colgate PreviDent	<.0001*	-	0.9440	0.0990
Omni Varnish	<.0001*	0.9440	-	0.0231
Omni Varnish XT	<.0228	0.0990	0.0231	-

of fluoride from the products was 4 hours for EP, CP and OV. OVXT did not exhibit a specific time point beyond which there was a significant decline in the rate of fluoride release (Table 4). None of the control samples exhibited fluoride release.

DISCUSSION

The fluoride concentration of the 4 test products was identical. However, they had significantly different fluoride release profiles ($p < 0.0001$). Hence, there are inherent differences in the carrier for the sodium fluoride in the commercially available fluoride varnishes, which affects the rate of release of fluoride. This variation in fluoride release by different varnishes has been previously reported.¹⁰ Uniformity of fluoride release varies among different brands of fluoride varnishes and leaves the practicing clinician with the decision to make the appropriate choice of commercially available fluoride varnish. The carrier in the varnish is the component which is held proprietary by the manufacturers, and properties of this component of the fluoride varnish is what appears to make the difference in the fluoride release. The rate of fluoride release from EP, PD and OV showed a plateau at 4 hours. EP showed the highest rate of fluoride release in the first 8 hours, among the products tested. It can be inferred that in a clinical scenario, the maximum rate of

release of fluoride would have occurred by 4 hours after application if PD and OV are used and by 8 hours if EP is used. These are critical time points in the use of these products when considering instructions on resuming oral hygiene practices after professional fluoride applications.

OVXT is a glass ionomer based extended release fluoride varnish. Manufacturers recommend light curing for 20 seconds after application. The extended release feature of this product was confirmed in our study. It was the only varnish to exhibit a sustained release of fluoride, although the initial rate of release in the first 4 hours was lower than EP.

The question is whether the product which releases more fluoride is the better one. Intuitively, it appears that the more fluoride a product releases, the more fluoride is available for enamel uptake. However, this needs to be confirmed by studies that specifically measure fluoride uptake by enamel after fluoride varnish application. Although OVXT demonstrated sustained release of fluoride, systemic safety needs to be taken into consideration. As fluoride release by EP, PD and OV declines precipitously after 4 hours, it implies that systemic ingestion of fluoride also declines. With prolonged fluoride release from OVXT, there is longer systemic exposure to the released fluoride.

From a clinical perspective, it is important to know the scientific time frame for resuming tooth brushing after application of fluoride varnish. Instructing parents to not brush their children's teeth for a certain duration may be misinterpreted and lead to failure of compliance in tooth brushing for a longer period of time. This would prove counterproductive to oral health. There was lack of scientific data on the short term fluoride release profile of commercially available fluoride varnishes, nor a simultaneous comparison of contemporary fluoride varnishes.

There are limitations to using the data from our study directly in a clinical practice. This *in vitro* study measured only the rate of fluoride release. It did not study the fluoride uptake by enamel. By virtue of it being an *in vitro* study, the dynamics of human saliva affecting the rate of release were not evaluated. Further, it is not known how much fluoride is required for caries prevention, nor what the appropriate rate of fluoride release ought to be for caries prevention. However, the data from this study provides the clinician with specific times to recommend to patients for resuming regular oral hygiene practices, based on the type of fluoride varnish being used.

CONCLUSIONS

Each of the investigated fluoride varnishes had a fluoride release profile, which was significantly different from the other products.

EP, CP and OV showed a plateau in the rate of fluoride release at 4 hours.

OVXT did not exhibit a plateau in the rate of fluoride release, and demonstrated its sustained release feature when compared to EP, CP and OV.

EP showed the most fluoride release in the first 8 hours after application of the varnish.

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