

Fluoride Varnish Concentration Gradient and Its Effect on Enamel Demineralization

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Abstract

Purpose: Two of the 4 fluoride varnishes available on the American market today are sold in 10-mL tubes of 5% NaF varnish (Duraphat and Duraflor). Pilot studies have shown that a separation of contents within these tubes exists. The purpose of the current study was 4-fold: (1) to measure the fluoride concentration gradient in 10-mL tubes of fluoride varnish, based on resting position of the tube prior to use; (2) to compare and contrast fluoride concentration gradients of Duraphat, Duraflor, and CavityShield; (3) to compare this gradient to the ability to inhibit caries in an artificial caries environment; and finally, (4) to determine if quantitative light fluorescence (QLF) can detect differences in lesions developed when exposed to an artificial caries environment and fluoride varnish.

Methods: Human teeth specimens were subjected to a caries challenge and treated with a sample of fluoride varnish from 1 of 5 categories: Duraphat stored horizontally and vertically for 1 week, Duraflor stored horizontally and vertically for 1 week, or a CavityShield 0.4 mL "unidose." All specimens were then analyzed with the QLF system and with confocal microscopy.

Results: Results showed no significant fluoride ppm differences exist between groups ($P=.29$). It was shown that the order in which Duraflor varnish was dispensed from tubes significantly affected the fluoride concentration ($P<.05$). The order effect was not significant for Duraphat ($P=.99$). QLF data analysis showed there was no significant difference ($P>.05$) in the amount of remineralization obtained by using any varnish stored in any position.

Conclusions: These results indicate that all 3 brands of fluoride varnish are able to remineralize incipient in vitro carious lesions, regardless of what part of the 10-mL tube the varnish is taken from. However, a fluoride concentration gradient exists in tubes of Duraflor. Also, QLF is able to detect demineralized and remineralized incipient lesions. (*Pediatr Dent.* 2003;25:119-126)

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Topical fluorides have been available for several decades and have shown positive results as anticaries agents. Topical fluorides are available in several forms, including fluoride-containing dentifrices, topical fluoride gels and foams, rinses, and varnishes. The use of a varnish as a vehicle for topical application of fluoride is intended to prolong the period of contact with the enamel surface. The amount of fluoride permanently retained in the enamel is increased, enhancing the formation of fluoridated hydroxyapatite and reducing the solubility of enamel in acid.¹

The first commercial fluoride varnish product was introduced in 1964 by Schmidt, under the trade name Duraphat (Woelm Pharma Co, Eschwege, Germany). Duraphat contains 5% sodium fluoride or 2.26% weight fluoride (22.6 mg fluoride/mL) in a viscous neutral colophonium base. In 1975, a second fluoride varnish system was introduced by Arends and Schuthof. Under the trade name Fluor Protector (Vivadent, Schaan, Liechtenstein), this product is a polyurethane-based varnish containing 0.1% fluoride (1.0 mg fluoride/mL) in the form of fluorsilane (0.9% weight).² Since then, the formulation of fluoride varnish has not

changed very much. In fact, not only are these 2 products still around today, but only 2 more varnishes have been marketed since. Although now considered to be the standard of care in most of Europe, Scandinavia, and Canada for over the last 25 years, fluoride varnishes, when used for the professional application of topical fluoride, are not as popular in the United States.³

Four fluoride varnishes exist on the American dental consumer market. Two of these varnishes are sold in 10-mL tubes of 5% sodium fluoride in a resin-based solution: Duraphat (distributed in the United States by Colgate Oral Pharmaceuticals, Canton, Ma) and Duraflor (manufactured by Medicom, Montreal, Canada, and distributed in the United States by Medicom, Buffalo, NY). Duraflor is similar in formulation to Duraphat, with the exception that it contains Xylitol, an artificial sweetening agent. Fluor Protector (distributed in the United States by Ivoclar, North America, Amherst, NY) is a polyurethane-carried, 0.1% difluorosilane fluoride varnish and is sold in single-dose vials of 0.4 mL (0.4 mg F). The latest addition into the fluoride varnish marketplace is CavityShield (Omni Products, West Palm Beach, Fla). Like Duraphat and Duraflor, CavityShield is a 5% NaF (22.6 mg fluoride ion/mL) varnish in a resinous base. However, unlike Duraphat and Duraflor, CavityShield is a unit-dosed fluoride varnish. CavityShield is available in 2 doses (depending on the number of teeth to be treated): a 0.25 ml (12.5 mg NaF) package, or a 0.4 mL (20 mg NaF) package. This way, each patient receives a controlled amount of fluoride (preventing overapplication), reducing the chance of overingestion and fluoride toxicity.

Over the last 25 years, the fluoride uptake in vitro and in vivo, acid resistance, and caries-preventing effect of fluoride varnishes have been investigated in laboratory, animal, and human experimental studies.³ Laboratory investigations and in vivo experimental studies have shown that varnishes supply fluoride more efficiently than other topical agents.⁴⁻⁹

Lately, there has been a question regarding the homogeneity of fluoride varnishes, and whether or not sodium fluoride may sediment out of solution. Both Duraphat and Duraflor are sold in 10-mL tubes. According to their manufacturers, varnishes that are dispensed from 10-mL tubes are said to contain 14 to 40 “doses” of 0.75 mL to 0.25 mL each. It is speculated that there is a fluoride concentration gradient throughout a 10-mL tube of fluoride varnish and that perhaps the NaF separates out of solution, resulting in a heterogeneous mixture within the tube. How long and in what position a 10-mL tube rests may affect how much NaF is actually dispensed per “dose” of varnish.

It is then reasonable to conclude that, if a fluoride concentration gradient exists within these tubes, the varnishes' ability to inhibit in vitro caries will also be impacted. However, Seppa, et al,¹⁰ investigated the effect of reducing the amount of fluoride in a fluoride varnish on its clinical efficacy. The authors found that no difference in clinical efficacy was noted when a 2.26% NaF varnish was compared with a 1.13% NaF varnish. The authors concluded

that further studies on a less concentrated varnish are indicated, especially considering the use of Duraphat in children. To date, no studies have been conducted to find a “threshold” level of NaF concentration that will make a fluoride varnish more clinically efficacious.

Quantitative light-induced fluorescence

Fluorescence, reflectance, electrical conductance or impedance, and ultrasound transmittal properties of enamel can become altered during demineralization. Many investigators have explored the use of new technologies for detection of early lesions based on these changes that occur in dental enamel during demineralization/remineralization processes.¹¹ According to Verdonschot et al,¹² quantitative methods such as quantitative light-induced fluorescence (QLF), electrical conductance measurements (ECM), and quantitative fiber-optic transillumination (FOTI) have shown the highest correlation with lesion depth and are more suitable to monitor small changes in lesions over time.

QLF was designed to measure the loss of fluorescence of a carious lesion by illuminating the tooth with a beam of light (wavelength=290-450 nm). This light may be absorbed by chromophores in the enamel and/or dentin, causing visible fluorescence. Carious lesions have a lower number of chromophores when compared to sound teeth, and, thus, there is less fluorescence. Therefore, carious lesions appear darker than does sound enamel.¹³

Confocal microscopy

Researchers have examined carious lesions and the effectiveness of interceptive treatments with the use of confocal microscopy.^{14,15} Specimens can be viewed with confocal microscopy by sectioning and then hydrating the tooth with a fluorescent medium (eg, Rhodamine B). Gonzalez-Cabezas et al¹⁶ found that the use of confocal laser-scanning microscopy is an effective technique for measuring in vitro mineral changes in dental tissues. Confocal microscopy operates on the principle that demineralized tooth structure contains larger pores than sound tooth structure. These pores can be penetrated with a dye that will differentially fluoresce, depending on the amount of dye present. Greater demineralization causes the tooth structure to become more porous and allows more dye penetration. Pore volume is the volume of fluid that has penetrated these pores of the tooth. An increase in pore volume may indicate increased demineralization. A decrease in pore volume may indicate less demineralization, or, in some cases, a remineralized type of process. In this study, confocal microscopy was used as the gold standard with which to compare the caries detection properties of QLF.

Purpose

The purpose of the current study is 4-fold: (1) to measure the fluoride concentration gradient in 10-mL tubes of fluoride varnish, based on resting position of the tube prior to use; (2) to compare this gradient to the ability to inhibit caries in an artificial caries environment; (3) to compare

and contrast the fluoride concentration gradients and caries-inhibition properties of 3 fluoride varnishes on the American market (Duraphat, Duraflor, and CavityShield); and finally, (4) to determine if QLF can detect differences in lesions developed when exposed to an artificial caries environment and fluoride varnish.

Methods

Tooth selection and preparation

One hundred premolar enamel specimens (3 mm in diameter) were drilled from extracted, human teeth, and disinfected in 10% buffered formalin (pH 6.8-7) for at least 2 weeks. Each specimen was mounted on a polyacrylic rod using denture acrylic and randomly coded with a 3-digit number (000-099). Specimens were then divided at random between 5 groups. All specimens were ground using 600-grade silicon carbide paper to remove approximately 50 μm of the surface and then polished to a high luster with Gamma Alumina (0.05 μm) using standard methods. A strip of nail polish was painted on all specimens, to a width of around 1.0 mm (around 33% of the specimens' surface). This protected "natural" surface was used as a sound reference for QLF analysis.

Initial caries challenge

All of the specimens were placed individually in 14 ml of a 50%-saturated hydroxyapatite (HAP)/0.1 mol lactic acid carbopol solution (pH 5), at 37 °C for 72 hours, so that 30- to 40- μm deep lesions developed. This caused enamel demineralization to occur to the unpainted area of each tooth. Following initial lesion formation, all teeth were rinsed and stored in a beaker lined with a damp paper towel, covered, and then stored in a refrigerator. Once again, a 1 mm-wide strip was painted on each specimen with fingernail polish (which is acid-resistant), so that a grand total of 66% of each specimen's surface was now covered by polish. Thus, 33% of each specimen was initially covered by polish to protect the natural sound tooth, and 33% of each specimen was covered by polish after demineralization to protect a part of the area demineralized by the initial caries challenge (baseline lesion).

Treatment regimens

Group A: Duraflor–horizontal

Twenty tooth specimens each had enough 5% NaF Duraflor painted on them to completely cover their remaining unpainted third. The varnish used in this group was stored in a horizontal position 1 week prior to use.

Group B: Duraflor–vertical

Twenty tooth specimens each had enough 5% NaF Duraflor painted on them to completely cover their remaining unpainted third. The varnish used in this group was stored in a vertical position (cap end upwards) for 1 week prior to use.

Group C: Duraphat–horizontal

Twenty tooth specimens each had enough 5% NaF Duraphat painted on them to completely cover their remaining unpainted third. The varnish used in this group was stored in a horizontal position 1 week prior to use.

Group D: Duraphat–vertical

Twenty tooth specimens each had enough 5% NaF Duraphat painted on them to completely cover their remaining unpainted third. The varnish used in this group was stored in a vertical position (cap end upwards) for 1 week prior to use.

Group E: CavityShield

Ten tooth specimens each had enough 5% NaF CavityShield (from a 0.40 mL unit dose) painted on them to completely cover their remaining unpainted third.

Group F: Negative control

Ten tooth specimens did not have any fluoride varnish placed on their remaining unpainted third. This area remained untouched and uncovered.

The contents of the 4 10-mL tubes of 5% NaF Duraflor were completely dispensed from each tube in the following manner. Each tube was opened immediately before dispensing its varnish. Ten samples (weighing approximately 1 g each) were obtained from each 10-mL tube by means of manual squeezing. Each sample was dispensed into its own plastic dappen dish until varnish weight reached approximately 1 g. Thus, each 10-mL tube delivered 10 samples into 10 separate dappen dishes (creating 40 total samples of Duraflor varnish). This same procedure was repeated for the 4 10-mL tubes of Duraphat varnish, thus creating in total 40 dappen dishes.

All 80 utilized dappen dishes (40 from Duraflor and 40 from Duraphat) were then treated in a similar manner: The contents of each dish were mixed with a disposable, bendable brush. This brush was then used to cover the remaining third (not covered with fingernail polish) of a tooth specimen with fluoride varnish. This same brush was then used to paint a sample of varnish at the bottom of a plastic specimen jar. The weight of this varnish in the jar was recorded and labeled, so as to be identifiable with its corresponding tooth specimen. All 80 plastic specimen jars were then filled with 100 mL of deionized water and allowed to sit for 7 days while occasionally being stirred. The water in these 80 jars was then analyzed for fluoride ion content using direct analysis. The varnished teeth were stored in humid conditions at 4°C for 20 hours. The physical barrier of the fluoride varnish resin base was then removed with a scalpel and checked under a stereo microscope ($\times 10$). All 100 tooth specimens were then subjected to the same caries challenge as described previously (posttreatment lesion).

The 10 unit doses of 0.40 mL 5% NaF CavityShield were used in the following manner. Each unit dose was opened and mixed, according to manufacturer's instructions. The

Table 1. Fluoride $\mu\text{g/gm}$ (ppm) Measured by Direct Fluoride Analysis

Product	N	Mean	Min	Max
Duraphat vertical*	20	21,838 \pm 2,908	15,346	25,399
Duraflor horizontal*	20	19,331 \pm 32,588	88	124,174
Duraphat horizontal*	20	18,387 \pm 3,096	11,439	24,488
Duraflor vertical*	20	15,333 \pm 27,990	113	99,223
CavityShield*	10	4,992 \pm 968	3,251	6,616

*Not significantly different ($P>.05$).

brush included in each unit dose was then used to cover the remaining third (not covered with fingernail polish) of each tooth specimen in this group. Each of these brushes was then used to paint a sample of varnish onto the bottom of a plastic specimen jar. The weight of the varnish sample was then recorded and labeled, so as to be identifiable with its corresponding tooth specimen. Each tooth specimen was allowed to dry and was stored in humid conditions at 4°C for 20 hours. Next, they were all subjected to the final caries challenge. The 10 specimen jars of CavityShield samples were each filled with 100 mL of deionized water and allowed to sit (with occasional stirring) for 7 days. After this time period, the water in each jar was analyzed for fluoride ion content using direct fluoride analysis.

Direct fluoride analysis

Direct analysis for fluoride was accomplished using a combination fluoride ion-specific electrode (Orion No. 96-09-00) and a pH/ion meter (Accumet 950, Fisher Scientific, Cincinnati, Ohio). The fluoride extract collected from each of the plastic specimen jars was diluted with TISAB II buffer in a ratio of 1:1, and placed directly under the electrode, resulting in a millivolt (mV) measurement. Each assay was duplicated to measure reproducibility. Fluoride content was determined by comparison with a series of known standards similarly analyzed at the same time. This was done for all 80 samples.

QLF analysis

All 100 teeth were analyzed via the QLF system to measure the amount of demineralization. Prior to QLF analysis, the transparent acid-resistant nail polish was carefully removed using acetone, making visually sure the other thirds of the teeth were not contaminated with nail polish during its removal. Each specimen was checked under a stereo microscope ($\times 10$) for complete removal of the nail polish. Images of all specimens' windows were taken using the QLF system (QLF/clin 007, Inspektor Research Systems F.V., The Netherlands). The software provided the average and maximum percentage of fluorescence loss for each

area analyzed. ΔQ was calculated as the average change of fluorescence multiplied by the lesion area. Both the baseline lesion and post-treatment lesion areas were analyzed in the same manner. Then, to obtain the treatment (fluoride varnish) effect for each specimen, the difference between the post-treatment data minus the baseline lesion data was calculated. A negative value resulting from this subtraction indicated more demineralization had occurred, while a positive number indicated remineralization.

Confocal microscopy analysis

After final QLF analysis, all specimens were cut in half so that each half contained a sound area, an initial lesion area, and a post-treatment lesion area. One of these halves from every specimen was placed into storage at 4°C in humid conditions. The other half from every specimen was stained overnight with a freshly prepared water-based 0.1 mmol Rhodamine B solution (Aldrich Chemical Co, Milwaukee, Wis), without further rinsing. Then, the stained demineralized areas of each specimen were analyzed for depth, area, and total lesion fluorescence. The cut, stained surface of each specimen was allowed to dry before being analyzed with the confocal laser scanning microscope (Odyssey, Noran Instruments, Inc, Middleton, Wis) to determine the extent of the lesions (Fontana et al).²⁰ In this case, a negative value indicated remineralization, while a positive value indicated lesions had progressed after treatment.

Statistical analysis

Statistical analysis of the groups was done using ANOVA, Tukey's multiple comparisons procedure, paired t test, and intraclass correlation coefficient (ICC). Comparisons were considered to be statistically significant if the P value was less than .05.

Results

Fluoride concentration

Repeatability was found to be good

The ICC for assessing agreement between the repeated mV measurements was 0.92, indicating good repeatability. However, the second reading was consistently lower than the first ($P=.0001$), indicating a possible order effect in the sampling. All results used for statistical analysis for absolute mV were obtained from the first measurement.

Duraflor presented a fluoride concentration gradient

There were no significant F $\mu\text{g/gm}$ differences between the groups ($P=.29$; Table 1). The order effect was significant for Duraflor (stored both horizontally and vertically; $P<.05$): the no. 10 sample was significantly higher than all others, and the no. 9 sample was significantly different from no. 1, 5, 6, 7, and 8 (Figures 1 and 2; Table 2). The order effect was not significant for Duraphat ($P=.99$; Figures 3 and 4; Table 3).

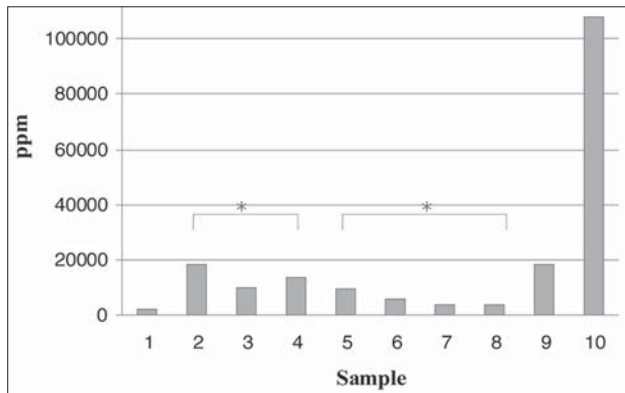


Figure 1. Mean ppm fluoride concentrations from horizontally stored tubes of Duraflor. Sample no. 1 represents the first mL dispensed from the tube; sample no. 10 is the last mL dispensed from the tube.
*Not significantly different ($P>.05$).

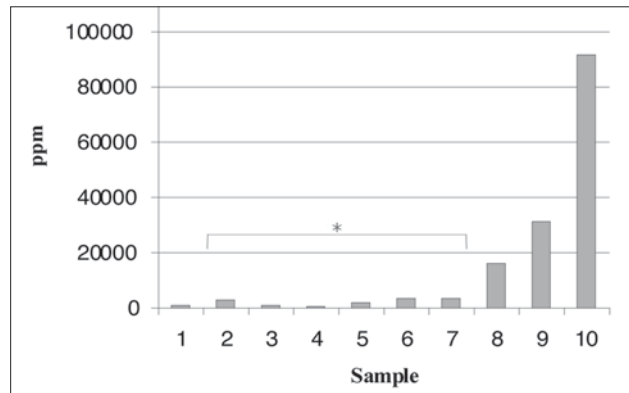


Figure 2. Mean fluoride concentrations from vertically stored tubes of Duraflor. Sample no. 1 represents the first mL dispensed from the tube; sample no. 10 is the last mL dispensed from the tube.
*Not significantly different ($P>.05$).

QLF

There was no significant difference on ΔQ scores due to storage method ($P=.81$) or product used ($P=.87$). All groups showed remineralization (shown by a positive mean value) except the negative control (shown by a negative mean value; Table 4).

Confocal microscopy Total lesion fluorescence

All groups were significantly different from the negative control ($P=.0001$). No other significant differences were found between groups ($P>.81$; Table 5). The order effect was not significant ($P=.99$).

Discussion

Several pilot studies were conducted prior to experimentation. The purpose of the studies was to determine the best method of extracting fluoride ion out of a varnish solution, resulting in the most accurate (closest to theoretical value) reading with a fluoride ionometer (direct fluoride analysis). A 5% sodium fluoride varnish contains 50 mg of NaF per mL of varnish. Specifically, 1 mL of varnish contains 22.6 mg of fluoride ion. The standard abbreviation “ppm” (parts per million) for fluoride represents the number of μg of fluoride ion per g (or mL) of solute. Therefore, a solution of 5% NaF should theoretically contain 22,600 ppm fluoride ion.

In the end, an average of 0.030 g of varnish was placed in 100 mL of deionized water to achieve the theoretical values. This same protocol for extracting fluoride ion of its varnish solution is now being used at other universities for similar purposes.

One purpose of this study was to measure the fluoride concentration gradient in 10-mL tubes of fluoride varnish, based on the resting position of the tube prior to use. It was theorized that the resting position of a tube will create a wide fluoride ion concentration gradient. However, it was found that, regardless of storage position and which part

Table 2. Mean ppm Fluoride Concentrations from Horizontally and Vertically Stored Tubes of Duraflor

Storage	Order	N	Mean	Min	Max
Horizontal	1	2	2,003±982	1,308	2,698
	2*	2	18,127±25,511	88	36,165
	3*	2	10,100±14,093	135	20,065
	4*	2	13,713±18,413	693	26,733
	5*	2	9,455±7,267	4,317	14,594
	6*	2	5,871±1,771	4,618	7,123
	7*	2	3,699±1,351	2,744	4,655
	8*	2	3,835±616	3,400	4,271
	9	2	18,372±16,671	6,584	30,160
	10	2	108,137±22,680	92,100	124,174
Vertical	1*	2	892±573	487	1,297
	2*	2	3,135±2,956	1,044	5,226
	3*	2	797±422	499	1,095
	4*	2	520±576	113	927
	5*	2	1,812±1,523	735	2,888
	6*	2	3,359±90	3,295	3,423
	7*	2	3,649±1,196	2,803	4,495
	8	2	16,172±5,585	12,223	20,121
	9	2	31,395±8,524	25,367	37,422
	10	2	91,599±10,781	83,975	99,223

*Not significantly different ($P>.05$).

of the tube varnish came from, Duraphat tubes consistently provided varnish with a fluoride concentration similar to theoretical values. In essence, no concentration gradient exists within tubes of Duraphat. On the other hand, Duraflor varnish does seem to have a fluoride ion concentration gradient not only based on its resting position, but also perhaps on the way each tube is mechanically filled with varnish.

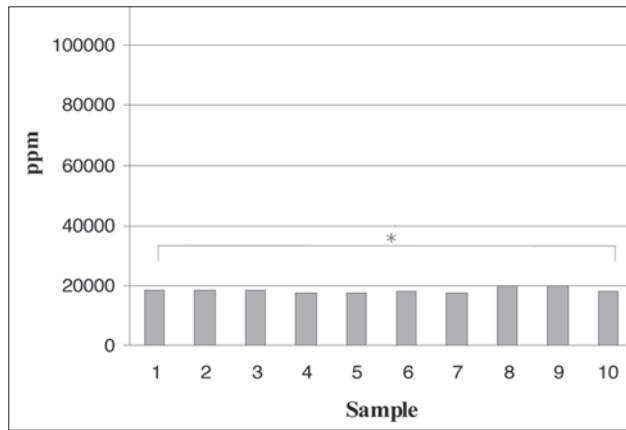


Figure 3. Mean fluoride concentrations from horizontally stored tubes of Duraphat. Sample no. 1 represents the first mL dispensed from the tube; sample no. 10 is the last mL dispensed from the tube.
*Not significantly different ($P>.05$).

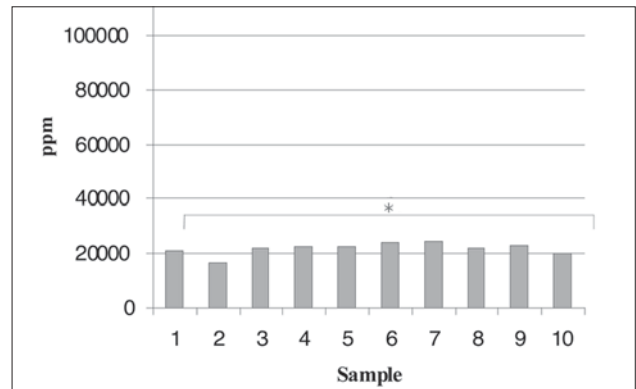


Figure 4. Mean fluoride concentrations from vertically stored tubes of Duraphat. Sample no. 1 represents the first mL dispensed from the tube; sample no. 10 is the last mL dispensed from the tube.
*Not significantly different ($P>.05$).

Storage	Order	N	Mean	Min	Max
Horizontal	1*	2	18,367±295	18,158	18,576
	2*	2	18,410±4,300	15,369	21,450
	3	2	18,281±3,827	15,575	20,987
	4*	2	17,382±1,980	15,982	18,782
	5*	2	17,688±3,122	15,480	19,896
	6*	2	17,963±9,227	11,439	24,488
	7*	2	17,558±3,229	15,275	19,842
	8*	2	20,045±2,643	18,176	21,914
	9*	2	20,037±1,946	18,661	21,413
	10*	2	18,143±3,616	15,586	20,700
Vertical	1*	2	21,272±2,545	19,473	23,072
	2*	2	16,796±2,051	15,346	18,246
	3*	2	21,871±3,704	19,251	24,490
	4*	2	22,599±402	22,314	22,883
	5*	2	22,319±3,304	19,983	24,655
	6*	2	23,868±130	23,776	23,960
	7*	2	24,675±1,023	23,952	25,399
	8*	2	21,897±4,379	18,801	24,994
	9*	2	23,120±268	22,930	23,309
	10*	2	19,965±4,144	17,035	22,895

*Not significantly different ($P>.05$).

A tube of Duraflor stored horizontally does seem to have an even fluoride ion concentration for the first 9 mL dispensed, with some values close to theoretical values. However, the last 1 mL dispensed from these tubes consistently had fluoride concentration values close to 100,000 ppm. This leads one to believe that this bolus of fluoride may be “trapped” at the end portion of a tube after manufacturing. A future study to help solve this problem would entail storing the tubes 3 ways: (1) horizontally, (2) cap end up,

Product	N	Mean	Min	Max
Duraphat vertical†	20	6,005.5±8,163.7	-8,126.3	19,437.6
Duraflor vertical†	20	4,480.4±9,833.0	-11,698.3	21,164.1
Duraflor horizontal†	20	4,438.0±8,394.4	-12,055.5	19,684.5
Duraphat horizontal†	19	4,168.9±10,604.8	-16,074.0	26,177.1
CavityShield†	9	4,167.0±11,853.4	-6,608.2	33,660.4
Negative control†	10	-4,488.6±7,256.7	-12,859.2	10,423.7

*A positive number indicates remineralization. A negative value indicates lesion progression.
†Not significantly different ($P>.05$).

and (3) cap end down. A tube of Duraflor stored vertically with its capped end up appears to house a fluoride ion concentration gradient. Fluoride concentration readings from the first several milliliters dispensed were very low, around the range of 700 ppm. This value is less than most fluoride-containing dentifrices (1,100 ppm) in the United States. As varnish from the last half of the tube was measured, it was noted that the fluoride concentration consistently increased from about 3,400 ppm up to about 92,000 ppm. Therefore, it is concluded that a fluoride ion concentration does exist in tubes of Duraflor based on resting position.

These findings have several clinical implications. First and foremost is the thought of fluoride toxicity in children. Fluoride varnish contains the highest fluoride concentration of any vehicle. It has been reported by Cameron and Widmer¹⁷ that gastrointestinal symptoms were noted in children after ingestion of 3 to 5 mg F/kg. Fatalities have been documented of children who ingested fluoride at doses of 16 mg F/kg. According to manufacturers, each “dose” of fluoride varnish given per patient should only be from 0.3 to 0.5 mL. At a theoretical value of 22,600 ppm,

Table 5. Total Lesion Fluorescence (Posttreatment Minus Baseline Data)*

Product	N	Mean	Min	Max
Duraphat horizontal†	19	-558,730±986,570	-2,346,500	1,341,100
Duraflor vertical†	20	-437,155±862,383	-2,948,000	560,700
CavityShield†	10	-304,850±623,194	-1,826,100	362,000
Duraflor horizontal†	19	-221,511±847,339	-1,760,700	2,050,600
Duraphat vertical†	20	-175,910±978,501	-1,796,000	1,869,200
Negative control†	10	1,700,810±1,415,827	0	4,134,000

*A positive number indicates remineralization. A negative value indicates lesion progression.

†Not significantly different ($P>.05$).

a 0.5 mL dose of varnish contains 11.3 mg of fluoride ion. Using a toxic dose of 3 mg F/kg body weight, a 20 kg (44 lb) child would need to ingest 60 mg of fluoride to accrue symptoms. One 0.5 mL dose of varnish does not come close to this level. However, when treated with 0.5 mL of varnish with a concentration of 100,000 ppm (as seen in some “doses” of both storage methods of Duraflor), a child comes much closer to the toxic level of 60 mg. 0.5 mL of varnish at this concentration contains 50 mg of fluoride ion. A full 1 mL of this varnish would obviously contain 100 mg, well above the toxic dose. To reach a fatal dose (16 mg F/kg), a 20 kg child would need to ingest 6.4 mL of varnish containing 100,000 ppm fluoride. The chances of this occurring seem unlikely, but are still noteworthy. No child should ever be left alone in an operatory for any reason with such potential hazards as high-dosed fluoride varnishes made available to them. Perhaps Duraflor tubes should be discarded when approximately 1 mL of its varnish is left.

The hazard of fluoride toxicity/accidental ingestion has led many to begin using unit-dosed packaged fluoride varnishes, such as CavityShield. This brand of fluoride varnish is available in either a 0.25 mL package or a 0.4 mL package. The theoretical total amount of fluoride in a 0.25 mL package is 5.65 mg, and in a 0.4 mL package the total is 9.05 mg F. In the current study, recovered concentrations of fluoride from CavityShield were lower than the theoretical value. Perhaps mixing the varnish better within its mixing well would result in a higher ppm value. Also, CavityShield unit doses used in this study were prototypes packaged in clear mixing wells, allowing one to visualize the varnish without opening the package. Light passing through the mixing well may allow congealing of the varnish, rendering some of its fluoride unreadable with direct fluoride ion analysis. CavityShield is now exclusively packaged in opaque black mixing wells.

This study also attempted to compare and contrast the caries inhibition properties of Duraphat, Duraflor, and CavityShield and determine whether or not a fluoride

concentration gradient affected these properties. Using confocal microscopy as the gold standard, it was found that all 3 brands of varnish, regardless of how they were stored and from what part of the tube a sample came, were able to inhibit an in vitro caries process. On average, remineralization of enamel occurred in every treatment group, whereas lesion progression occurred in the negative control group. This is clinically relevant for those using Duraflor varnish in that, even though a large concentration gradient exists within tubes, the in vitro caries process can still be halted. However, it was noted numerically that the higher the fluoride concentration was used to treat a tooth, the more the remineralization process took place. The differences were not statistically significant, probably due to the small sample sizes used. Whether these numerical differences are clinically relevant remains to be proved. Also, the data presented here strengthen the notion that the fluoride concentration in fluoride varnishes could be reduced without compromising fluoride’s ability to prevent enamel demineralization. This idea is supported by the findings that different samples of Duraflor (containing a wide range of fluoride concentrations) had similar effects on preventing demineralization. Further studies are needed to investigate this matter.

A final purpose of this study was to determine if QLF can detect differences in lesions developed when exposed to an artificial caries environment and fluoride varnish. It was hypothesized that QLF does have this ability. After data analysis, it was noted that the ΔQ (described earlier) of treated lesions vs nontreated lesions was not statistically significant. However, it is noted that mean values of every treatment group indicate enamel remineralization and that the mean value of untreated lesions indicate lesion progress (further demineralization). The differences between all groups were not statistically significant probably due to the small sample sizes used. It may be concluded that QLF is an effective technique that is able to detect and monitor the early enamel lesions created and treated under the in vitro conditions used in this study. Clinically this is important if the operator is able to use a handheld QLF intraoral device and detect early lesions before cavitation. Then, treatment of these early lesions with topical fluorides may be monitored to prevent future demineralization without the need for operative cavity preparation and restoration.

Conclusions

1. A fluoride concentration gradient exists within 10-mL tubes of Duraflor, but no gradient exists within Duraphat tubes.
2. A fluoride concentration gradient did not significantly affect Duraflor’s ability to inhibit in vitro caries formation.
3. All 3 brands of varnish had similar caries inhibition properties.
4. QLF was able to detect demineralized and remineralized incipient lesions.

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