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Fluoride retention following topical fluoride foam and gel application

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Abstract

The purpose of this study was to compare the oral fluoride (F) retention following acidulated phosphate fluoride (APF) foam and gel applications in children. Fifty-nine children were divided into two groups, 6–9 years old and 10–13 years old. They each received a randomly assigned sequence of topical F foam and gel applications in two consecutive visits, using either sponge-lined or unlined trays. Approximately 0.6–0.8 g of APF foam, or 3–4 g of APF gel was used in each of the 4-min F applications. The amounts of F applied, recovered from the mouth, and retained were calculated for each treatment. The retention of an average of 1.26 mg F after an APF foam application was significantly less than 2.53 mg F for the APF gel. The sponge-lined trays also reduced significantly the F retention, compared with unlined trays. However, there was no significant difference in the amount of F retained between the two different age groups. The amount of F retained was reduced significantly from 3.65 mg F in the first appointment, to 1.24 mg F in the second appointment when unlined trays were used.

Introduction

Topical applications of fluoride (F) in various formulae and vehicles have shown significant reductions in dental caries increments in children and young adults residing in F-deficient communities. (Wei 1974, 1988; Leverett 1982; Marthaler 1984). However, several studies with adults and children have shown substantial oral retention and ingestion of F following topical application of acidulated phosphate fluoride (APF) gels or solutions, when they were applied professionally using the cotton roll isolation technique and various tray techniques (LeCompte et al. 1982, 1984, 1987). The bioavailability of the ingested F in fasting individuals has been reported to be 100% (Ekstrand et al. 1978). LeCompte and Whitford (1982) reported a peak value of a 26-fold increase in plasma F concentration in children 40–60 min after they received topical APF gel applications. Ekstrand et al. (1981) reported 24- to 115-fold increases in plasma F concentration 1 hr after application. Nausea and vomiting are not uncommon side effects from the excessive ingestion of such high doses of topically applied F (Whitford et al. 1987).

To reduce the systemic ingestion of professionally applied F, several recommendations for topical application of high-potency F products were made at the 63rd General Session of the International Association for Dental Research in March, 1985 (LeCompte 1987). Suggestions also have been made to lower the F concentration of the APF gel (Dijkman et al. 1982; Sluiter and Purdell-Lewis 1984), and rinse following the gel applications (Stookey et al. 1986).

Recently, a new APF foam containing 1.23% fluoride was developed. Wei and Hattab have shown in an in vitro study that the F uptake from this foam was comparable to that of a gel (1988). Since the foam has a much lighter specific weight than a gel, it will take much less foam by weight to completely fill a tray. Hence, the amount of F that potentially can be ingested also would be reduced. It appears that an APF foam may be a useful alternative F agent in this aspect. A pilot study conducted by Wei and Hattab (1989) was carried out on young adults, and no significant difference in oral F retention was found between the APF foam and gel applications. The purpose of the present study was to examine clinically whether this newly developed APF foam would promote less F ingestion than a conventional APF gel in children. In addition, the effects on retention of two application tray systems (sponge-lined and unlined), the age groups, and the appointment sequence on the F retention also were evaluated.

Materials and Methods

The investigation was conducted on 59 children who were under treatment in the Department of Children's Dentistry and Orthodontics at the Prince Philip Dental Hospital, Hong Kong.

The subjects and their parents were informed of the experimental procedures, and each subject was scheduled for two appointments. During each appointment, a randomly assigned combination of one of the APF agents (foam or gel) and application trays was determined and applied to the subject. In the subsequent appointment, the other APF agent was used with the same application technique. The planned distribution of subjects, the F agent, and the application tray systems used are shown in Table 1.

TABLE 1. Experimental design of distribution of number of subjects, age groups, type of trays and fluoride agent (foam or gel)

	APF Foam †		*APF Gel* ††	
	6–9	*10–13*	*6–9*	*10–13*
Sponge-lined trays*	15	15	15	15
Unlined trays**	15	14	15	14

† APF Foam (Batch No. 301-058), Block Drug Company Inc., 257 Cornelison Avenue, Jersey City, NJ, USA.

††Nupro®-Flo APF Gel (Batch No. 7A7411; Code 814012), Johnson and Johnson Dental Products C., E. Windosr, NJ, USA.

* Sponge-lined trays: Discovery Tray, Kerr, Romulus, MI, USA.

**Unlined trays: Disposable Foam Tray, Lorvic, The Lorvic Coroporation, 8810 Frost Avenue, St. Louis, MO, USA.

Clinical Procedures

At each appointment, a pair of upper and lower trays of appropriate size for the subject was placed on an electronic balance, and the weight of the trays was tared. Approximately 1.5–2.0 g of APF gel, or 0.3–0.4 g of APF foam was used to fill each upper and lower tray, and the exact amount was recorded (Figure). Both upper and lower trays were inserted in the child's mouth simultaneously and left in the mouth for 4 min. During the application, a saliva ejector was placed in the floor of the mouth and the aspirated expectorate was collected in a laboratory flask aspiration assembly. After the trays were removed, each subject was instructed to expectorate for up to 1 min, the remaining F agent and the pooled saliva into a coded plastic wide-mouth container (Nalgene Laboratory Quality Bottles — Nalge Co., Division of Sybron Corp., Rochester, NY, 1000 ml) containing 250 ml of deionized water. The trays of the subject, and any portion of the bib that might have been contaminated with saliva overflow, also were placed into the coded container. The laboratory flask aspiration assembly was washed with 500 ml of deionized water, and the content also was collected into the wide-mouth container. The amount of F retained was estimated by subtracting the exact amount of F recovered from the amount used in the topical F application.

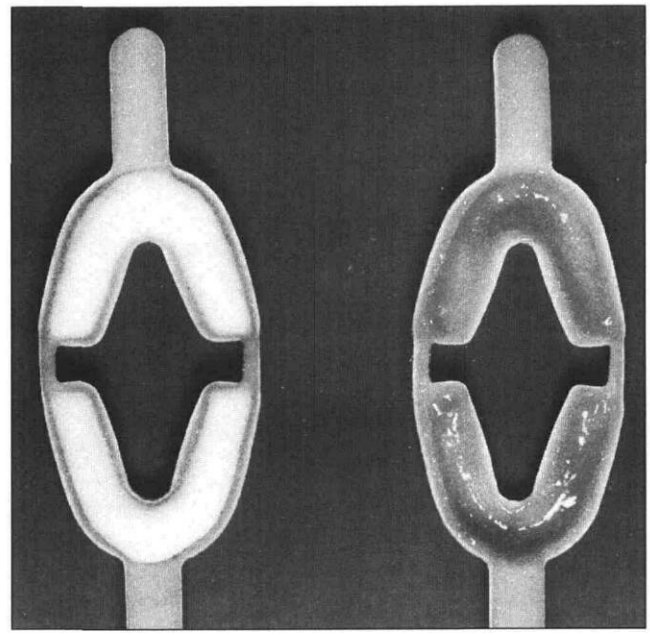

Figure. Approximately 0.6–0.8g of APF foam and 3–4g of APF gel have been placed in Discovery trays.

In a subsequent visit, which was scheduled at least one week later, the same procedures were repeated using the same tray system but with the other F agent.

Laboratory Procedures

The samples collected were shaken vigorously for 2 hr by the Rotary Motion Shaker (GFL® – Gesellschaft für Labortechnik mbH and Co, Bergwedel, West Germany) until the F agent was dissolved completely in the deionized water. Five ml of the homogenized sample was pipetted into a small plastic bottle using a digital micropipette (Finnpipette Digital, LabSystems, Helsinki, Finland). TISAB III (Orion Research Inc., Cambridge, MA, 0.5 ml) was pipetted into the bottle. The buffered sample then was vibrated vigorously for 10 sec using a test tube shaker (Heidolph REAX 2000 — Heidolph Elektro GmbH and CoKG, Kelheim, Germany). F analysis was performed using the standard calibration method with an ionalyzer (Model 901 Microprocessor Ionalyzer — Orion Research, Cambridge, MA) and Combination F Electrode (96–09–00 Combination Fluoride Electrodes — Orion Research, Cambridge, MA).

F analysis also was performed on each sample of the F agents used and their actual F concentrations were used in the calculation of the F retention rather than the manufacturers' stated value of 1.23% F, since a range of 1.23 to 1.32% F had been noted by Eisen and LeCompte

TABLE 2. A summary of the effects of agents, trays, age-groups, and appointment sequence on the amount of fluoride retention in children (the values represent both visits of 59 children)

	Agent		*Tray*		*Age-Group*		*Appointment*	
	Foam	*Gel*	*Sponge - lined*	*Unlined*	*6–9*	*10–13*	*1st*	*2nd*
Retention (mgF) N=118	*1.26*	*2.53*	*1.36*	*2.45*	*2.13*	*1.66*	*2.47*	*1.32*

(1985). The mean concentration for both tubes of APF foam was 1.27% F. For the 3 bottles of APF gel used, the F concentrations were found to be 1.18, 1.18, and 1.20%.

Statistical Analysis

The main variables tested were F agents, application tray systems, age groups, and appointment sequence (i.e., experience). An analysis of variance was used to test the main effects, and all possible interactions. The level of significance adopted for the F test was 0.05. However, exact probabilities also were reported.

Results

Fifty-nine children participated in this study, and as much as possible, they were distributed evenly among age and sex. The mean age was 7.33 ± 1.15 for the 6–9-year-old group, and 11.34 ± 1.04 for the 10–13-year-old group. Their body weights were all within the 3rd and 97th percentile of the Southern Chinese growth status (Lau et al. 1987).

A summary of the effects of agents, trays, age groups and appointment sequence on the amount of F retention is tabulated in Table 2.

The ANOVA summary table of results of main and interaction effects is shown in Table 3. Table 4 shows that the two-way interaction between trays and appointment sequence had a significant effect on the amount of F retention at 0.01 level. It can be observed that the retention was reduced significantly from 3.65 mg F in the first appointment to 1.24 mg F in the second appointment when unlined trays were used. The retention over time was not significantly different when sponge-lined trays were used.

Retention of an average of 1.26 mg F of foam was significantly smaller than 2.53 mg F for the gel. Using sponge-lined trays, it was possible to recover more fluoride from the mouth and produce an average of 1.36 mg F retention, which was much smaller than 2.45 mg F retention that occurred when unlined trays were used. Subjects generally showed less retention in the second appointment (mean = 1.32 mg F) than in the first appointment (mean = 2.47 mg F), and the difference was only attributed to the unlined tray group; appointment sequence only had an effect when unlined trays were used. Though the younger age group tended to retain more fluoride orally, the difference was not statistically significant.

TABLE 3. ANOVA summary table of results showing main and interaction effects of agents, trays, age-groups and appointment sequence on the amount of fluoride retention (the F retention values of both visits have been included)

Source	*Sum of Squares*	*DF*	*F*	*P Value*
Main Effects				
agent	26.671	1	14.158	.000*
tray	32.308	1	17.150	.000*
age	4.160	1	2.208	.140
appt.	17.762	1	9.429	.003*
2-Way Interactions				
agent/tray	.208	1	.110	.740
agent/age	2.411	1	1.280	.261
agent/appt.	.851	1	.452	.503
tray/age	4.054	1	2.152	.145
tray/appt.	18.308	1	9.719	.002*
age/appt.	2.303	1	1.222	.272
3-Way Interactions				
agent/tray/age	.482	1	.256	.614
agent/tray/appt.	4.661	1	2.474	.119
agent/age/appt.	.182	1	.097	.757
tray/age/appt.	1.248	1	.663	.418
4-Way Interactions				
agent/tray/age/appt	.583	1	.209	.579
Total	342.638	117		

* Significant at 0.01 level

TABLE 4. 2-Way trays-appointment interaction effect on the mean amount of fluoride retention

	Appointment	
Tray	*1st*	*2nd*
Sponge-lined N=30	1.32	1.41
Unlined N=29	3.65	1.24

When unlined trays were compared with sponge-lined trays during foam and gel applications, the amount of F retained was reduced from 1.41 to 1.21 mg F and 3.49 to 1.61 mg F respectively (Table 5).

Table 5. Effects of trays on the amount of F applied and retained during APF foam and gel applications

		Tray	
		Sponge-lined	*Unlined*
Foam	F Applied (mgF)	82.8 ± 0.73	8.86 ± 0.74
	F Retained (mg F)	1.12 ± 0.33 N=30	1.42 ± 0.64 N=29
Gel	F Applied (mg F)	41.64 ± 3.59	42.22 ± 3.27
	F Retained (mg F)	1.61 ± 1.02 N=30	3.49± 2.65 N=29

Discussion

Recent investigations have reported that oral retention of 2–31 mg of F can occur from the professional topical applications of 1.23% gels in children and adults (Table 6). Retention and swallowing of the topical F can involve as much as 76% of the amount applied to the teeth (Ekstrand et al. 1981), which can explain the occasional complaints of nausea or vomiting associated with professional topical F applications. Since practically all of the F ingested is absorbed, it is feared that the peak plasma fluoride concentrations (15–50 μmol/L have been reported, compared with a control level of 1 μmol/L) may result in dental fluorosis in age-susceptible children or cause a transient urinary syndrome. Disturbances in the physiologic and biochemical processes in relation to topical F application also have been reported (Whitford et al. 1987). Consequently, the smaller the amount of fluoride used for topical application, the more acceptable the procedure would be. When an APF-based foam was available in a prototype

Table 6. Summary review of previous studies on retention of fluoride following 1.23% APF gel applications

Authors	*Year*	*Age of Subjects (year)*	*No. of Subjects*	*Gel Applied (g)*	*Fluoride Applied (mg)*	*Fluoride Retained (mg)*	*% Retention (%)*	*Remarks*
Owen et al.	1979		15			11.2		
Ekstrand et al.	1981	5–16	8	3.3	41.0	31.2	76	Vacuum-moulded trays
LeCompte & Doyle	1982	8–12	10	4.0	49.2	9.9	20	Sponge-lined trays without expectoration
						3.1	6	Sponge-lined trays with expectoration
						4.1	8	Paper-lined trays with expectoration
						6.9	14	Paint-on technique with expectoration
						5.9	12	Custom vinyl trays with expectoration
LeCompte & Whitford	1982	9–13	5	3.0	37.4	17.4	47	Paint-on technique
Heeres & Purdell-Lewis	1983	6–13	50	10.7	131.6	23.6	18	Disposable trays
McCall et al.	1983	Adults	13	7.8	95.7	1.3–23.2	1–24	Different disposable trays
More et al.	1983	4–14	60	4.0	49.2	16.2	33	Tray with suctioning

form, we were interested in estimating its potential clinical value. In a previous publication by Wei and Hattab (1988), the estimated fluoride uptake from a new APF foam was compared to that of a conventional APF gel; both contained 1.23% fluoride. Using 40 sound human premolars extracted for orthodontic reasons, the fluoride uptake from the new foam and a conventional gel were tested and found to be very comparable. The differences in fluoride uptake at 5 μm were not significantly different. Furthermore, in another assessment of fluoride retention in adults following topical application of the new foam and a conventional gel (Wei and Hattab 1989), it was found that the amount of fluoride retained from the gel and foam applications could be considered to be within acceptable limits, especially when appropriate expectoration was carried out.

In the present study, the amount of F retained was 1.26 mg F for the foam and 2.53 mg F for the gel, which

Table 6. Summary review of previous studies on retention of fluoride following 1.23% APF gel applications

Authors	Year	Age of Subjects (year)	No. of Subjects	Gel Applied (g)	Fluoride Applied (mg)	Fluoride Retained (mg)	% Retention (%)	Remarks
LeCompte & Rubenstein	1984	9–12	10	4.0	49.2	22.7	46	Non expectoration
						4.9	10	Expectoration
						4.1	8	Foam-lined trays
						5.7	12	Unlined trays
						6.4	13	Gel
						3.4	7	Thixotropic gel
Eisen & LeCompte	1985	Adults	10	4.0	49.2–51.8	1.7–7.4	3–14	Gel with different viscoity, lined and with or without suctioning and expectoration
LeCompte & Doyle	1985	9–12	10	4.0	49.2	7.7	16	Sponge-lined trays with suctioning
						1.6	3	Sponge-lined trays with suctioning & expectoration
		Adults	8	4.0	49.2	10.3	21	Sponge-lined trays with suctioning
Tyler & Andlaw	1987	5–13 and Adults	13 7	2.4	29.5	5.6	19	Air-cushion trays with absorbent paper insert
Wei & Hattab	1988	Young Adults	10	3.9	48.4	1.4	3	Sponge-lined trays with suctioning
				4.0	48.6	2.1	4	Without suctioning
				Foam				
				0.9	10.6	1.7	16	Sponge-lined trays with suctioning
			10	0.8	10.1	1.6	16	Without suctioning

was the lowest among any of the reported F retention studies (Table 6).

The retention of 2.53 mg F in children following APF gel applications appeared slightly higher than that of 1.6 mg F in LeCompte and Doyle's study (1985) in which saliva ejector, patient expectoration, and sponge-lined trays were used. The retention for the APF gel applied with sponge-lined trays in this study was 1.61 mg F (Table 5), highly consistent with LeCompte and Doyle's result. The F retention for the foam group would be reduced further if the trays were not completely filled with the APF foam.

The maximum amount of retention for one subject was 3.76 mg F for foam and 10.01 mg F for gel. The 10.01 mg F ingested in a child weighing 23.8 kg would mean a dose of 0.42 mg F/kg body weight. This dose was still smaller than the lowest single dose of 0.75 mg F/kg body weight that might produce dental fluorosis in the rat (AngmaR-Mansson and Whitford 1985). As the probable toxic dose for F toxicity is 5 mg F/kg body weight (Whitford 1987), the retention of such a small amount suggests that topical F application is a relatively safe caries prevention procedure, if the guidelines recommended for the reduction of oral F retention have been followed carefully (LeCompte 1987).

The use of sponge-lined trays significantly reduced the F retention in both foam and gel applications. This was consistent with the findings of Doyle and LeCompte (1982), LeCompte and Doyle (1982), and LeCompte and Rubenstein (1984).

The different age groups did not have an effect on F retention. This might suggest that the 6-year-old children were old enough to receive topical F therapy without increased risks.

The appointment sequence (i.e. the experience with topical F application) exerted a significant effect on the F retained only when unlined trays were used. The safety of the procedure would be increased with repeated applications as the children became more familiar with the procedure.

On the whole, the APF foam was a good alternative F agent to the gel in topical F treatment. The exceptionally small amount of F applied and retained makes it potentially an excellent home-use fluoride agent, and the agent of choice for special patients for whom routine tray application techniques or the use of saliva evacuation may not be feasible.

There are still technical problems associated with the manufacture of a stable foam preparation in commercial quantities. In addition, the taste and flavor of the foam need to be improved further. The theoretical advantages of the foam appear to be established firmly by this and other studies reported previously.

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Vitamin C touted for healing

Vitamin C seems to hasten healing of the wound from dental extractions, according to a report in *Miami Today*.

Two researchers found that 277 tooth-extraction patients given vitamin C after dental surgery "exhibited significantly more rapid healing than the 175 control subjects who received none."

Taking vitamin D was "statistically associated with more rapid clinical healing and reduced likelihood of post-surgical complications," they reported.

Moreover, the incidence of alvollagia (dry socket) was five times less frequent in those taking vitamin C.

Although it is not known precisely how vitamin C achieves its beneficial effects, as far back as 1979 research has suggested that dietary supplements of vitamin C. might help reduce infection in hospitalized patients. One possible avenue is stimulation of the immune system.