

## Fluoride retention following topical application of a new APF foam

Stephen H.Y. Wei, DDS, MS, MDS Faiez N. Hattab, BDS, PhD

### Abstract

*The oral retention of fluoride (F) following the topical application of a newly developed APF foam was compared with a conventional APF gel. Twenty adults aged 16-26 years participated in the study. Ten of the subjects received the F foam and gel treatments, on separate occasions, with a saliva ejector while another 10 subjects received the same treatment without saliva ejector. Approximately 4 g of the gel, and 0.9 g foam, were dispensed for each treatment. The amounts of fluoride applied, recovered from the mouths, and retained in the mouth were calculated for each treatment.*

The mean amounts of F retained following the gel application with and without saliva ejector were 1.4 mg and 2.06 mg, respectively. The corresponding amounts of F retained from the foam application were 1.66 mg and 1.62 mg, respectively. There were no significant differences ( $P > 0.05$ ) in the amounts of F retained from the gel and foam applications. Because of the careful technique used, the use of the saliva ejector did not significantly reduce fluoride retention, especially for the foam application. The thorough expectoration following topical applications seems to overlap the effectiveness of the saliva ejector in reducing the retained F from both the gel and foam applications.

The use of an APF foam would be advantageous in young children or disabled patients where a saliva ejector and thorough expectoration are not feasible.

The last decade has witnessed a sharp decline in the prevalence of dental caries in Western countries (Leverett 1982; Marthaler 1984). The main reasons for the decline in dental caries may be due to the frequent and widespread use of water fluoridation, improved oral hygiene and the use of topical fluorides in various forms. There is some evidence to indicate that there is an increase in the prevalence of enamel fluorosis in optimally fluoridated and above-optimally fluoridated communities (King and Wei 1986; Heifetz et al. 1988). The increase in mild enamel fluorosis probably is due to fluoride (F) overdosage from multiple sources of F. With

the exception of the 1.23% APF gel, the amount of F retained from various topical F treatments seldom exceeds 1 mg per application (Myers 1978; Wei and Hattab 1987; Hattab and Wei 1988c).

Several recent studies have shown substantial oral retention and ingestion of F following professional application of F gels to children and adults (Ekstrand et al. 1981; LeCompte and Whitford 1982; LeCompte 1987). The ingested F from gels may produce side effects such as nausea, vomiting, and sharp elevation in plasma F levels. To minimize the side effects of gels, suggestions have been made to lower the concentration of the F gel (Dijkman et al. 1982; Hattab 1984; Sluiter and Purdell-Lewis 1984). A totally different approach would be to develop a vehicle that is able to dispense F to the entire mouth with a minimum amount of fluoride required.

An experimental 1.23% APF foam preparation (Block Drug Co; Jersey City, NJ) has been developed and the prototype preparation has been shown to be effective in increasing the F concentration in the outer 15  $\mu\text{m}$ -thick enamel to an average of 1736 ppm (Wei and Hattab 1988a). The aim of the present study is to assess the oral retention of F from this new foam preparation compared to a conventional APF gel.

### Materials and Methods

Twenty adults, aged 16-26 years, were requested to refrain from the use of an F dentifrice and eating and drinking of F-rich items for 2 hr prior to the topical F application. The subjects were randomly divided into 2 groups; the assignment was made on whether a saliva ejector was to be utilized or not.

**Group A:** These 10 subjects received a professionally applied conventional 1.23% APF gel (Nupro®, cherry flavor, batch no 6E6364 — Johnson & Johnson; New Brunswick, NJ ) for 4 min. About 4 g of the gel was dispensed in the maxillary and mandibular Discovery® tray (Sybron/Kerr Co; Romulus, MI). After recording the precise weight of the dispensed gel, the maxillary

and mandibular trays were inserted simultaneously. The pooled saliva/gel mixture was collected from the mouth using a saliva ejector connected to a flask collection assembly. Following 4-min of topical application, the trays were placed in a 1-liter plastic bottle containing 250 ml deionized water. The subjects were encouraged to further expectorate into the bottle for 1 min following the topical F application. The saliva ejector and the collection assembly were rinsed with 500 ml deionized water to remove any residual F and the solution was transferred to the bottle, yielding a total volume of 750 ml. The bottles were capped and placed overnight in a rotating shaker. One week later, the same procedure was repeated using the new APF foam preparation. Approximately 0.9 g of the foam was needed to fill the maxillary and mandibular trays.

**Group B:** These 10 subjects received the same F treatments as group A except that no saliva ejector was utilized.

Aliquots of the samples were mixed with 10% by volume of TISAB III (Orion Research Inc; Cambridge, MA). Analysis for F was carried out using a combination F-selective electrode (Orion model 96-09-00 — Orion, MA) as described previously (Wei and Hattab 1988b).

The amount of F retained orally, and potentially ingested, was determined by calculating the difference

TABLE 1. The Mean ( $\pm$  SD) Amount of F (mg) Applied, Recovered, and Retained Following the Applications of Gel and Foam

	Applied (mg F)	Recovered (mg F)	Retained (mg F)
<i>Gel</i>			
With saliva ejector	48.38 $\pm$ 1.57	47.17 $\pm$ 1.85	1.37 $\pm$ 1.19
Without saliva ejector	48.56 $\pm$ 0.56	46.70 $\pm$ 0.73	2.06 $\pm$ 1.03
<i>Foam</i>			
With saliva ejector	10.62 $\pm$ 0.95	8.96 $\pm$ 0.75	1.66 $\pm$ 0.35
Without saliva ejector	10.06 $\pm$ 0.39	8.44 $\pm$ 0.74	1.62 $\pm$ 0.44

between the amount of F applied and the amount recovered. The paired *t*-test was used to determine the statistical differences in F retained from the gel and foam, and with and without the use of a saliva ejector.

## Results

The means and standard deviations for the amounts of F applied, recovered, and retained in the mouth during the APF gel and APF foam applications are shown in Table 1. The data are presented graphically in the Figure. Of the 49.2 mg F in the conventional gel applied to the teeth, an average of 47.17 mg F was recovered while 1.38 mg F was retained in the mouth. Thus, only 2.8% of the applied F was retained in the mouth in cases where the saliva ejector was used during F gel application. When the F gel was applied without a saliva ejector to evacuate oral fluids, about 4.2% of the applied F was retained. This reduction, however, was not statistically significant ( $P > 0.05$ ).

Of the 10.63 mg F in the foam preparation applied to the teeth, an average of 8.96 mg F was recovered; therefore, 1.67 mg F was retained in the mouth. This meant that 15.7% of the applied F was retained. The use of a saliva ejector during an F foam application has no appreciable effect on the amount of retained F (Table 1, Figure).

The present findings indicate that the amounts of F retained from APF gel and APF foam preparations were both very small and ranged from 1.38 to 2.06 mg. This range represents the retained F with or without saliva ejector.

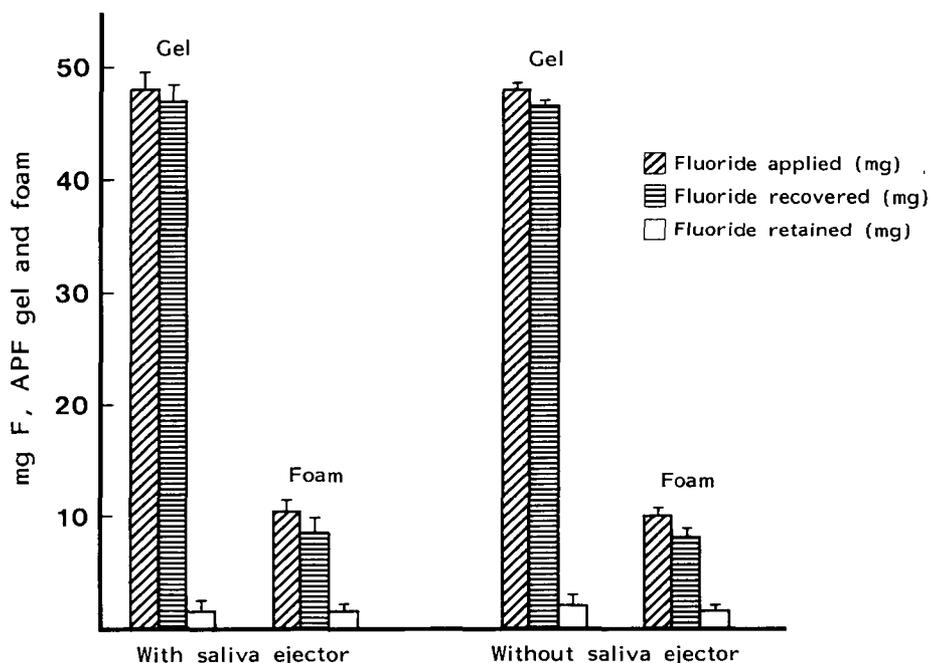


FIG. The amount of fluoride applied, recovered, and retained (mg) when topical fluoride gel or foam are used with and without saliva ejector.

## Discussion

The most commonly used APF agent for professional application is the APF gel containing 1.23% F. Because of the high F concentration and the acidity (pH < 4) of these products, adverse systemic effects such as nausea, vomiting, epigastric pain, and sharp elevations of plasma F concentrations have been reported following routine topical F applications (Beal and Rock 1976; Ekstrand et al. 1981; LeCompte and Whitford 1982; Whitford et al. 1987; Wei and Hattab 1988c). Following topical application of gels a variable amount of F is not recovered from the mouth, but is retained and swallowed. The amount of F ingested depends on the product's F concentration, the physicochemical properties (solubility, pH, and viscosity), the amount used, the age of the subject, and the application technique. Table 2 summarizes previous findings on F retention and ingestion from 1.23% APF gels of many different age groups. It also has been shown that systemic absorption (bioavailability) of the ingested F dose is complete in fasting subjects (Ekstrand et al. 1981).

Following topical application of an F gel, the average amount of F retained in the mouth was 2.06 mg (4.2% of the applied dose). In this part of the study no saliva ejector was used and the gel/saliva mixture was collected with a 1-min expectoration following the topical application (Table 1). When a saliva ejector was used in addition to a 1-min expectoration, the retained F from orally applied gel was reduced by one-third (Table 1, Figure). In a study on the retention of APF gel

in children aged 8-12 years, LeCompte and Doyle (1982) found that 3.1 mg F or 6.3% of the applied F dose was retained following suctioning and a 1-min expectoration period (Table 2). Comparison of our findings with those of LeCompte and Doyle (1982) indicated that children may retain about twice as much F compared to adults.

The present study indicated that the retained ingested F doses from the gel and foam applications averaged about 0.037 and 0.030 mg F/kg of body weight, respectively. These findings are much less than previously reported in which the ingested F dose in 5- to 16-year-old subjects ranged from about 0.3 to 1.8 mg F/kg of body weight (Table 2). It seems that the thorough 1-min expectoration performed by the subjects in our study is the main reason for the reduction of retained F. It should be emphasized, however, that the age group of our study, namely young adults, are also different from children of various ages reported by other studies. The nonsignificant differences in the retention of F from the gel and foam applications could be due to the effectiveness of expectoration to reduce the orally retained F to a minimum level, whereby no appreciable differences in the retention of F from the foam and gel was detected. Further studies on the retention of F from foam without patient expectoration is recommended. Additional data also are needed concerning oral retention in children in order to identify the least orally retained product.

Of special concern are the amounts of F ingested by young children with developing teeth because of the risk of enamel fluorosis. The present study indicates that the orally retained F from an F gel treatment can be reduced substantially if: (1) no more than 2 g of gel is dispensed by tray; (2) foam-lined trays are used; (3) a saliva ejector is used during the application procedure; and (4) thorough expectoration is done following gel application. Other suggestions to minimize the ingestion of applied F gel include shortening the application time to 1 min as for the Minute-Gel™ (Oral B Laboratories Inc; Redwood City, CA; 1985) or by asking the patient to rinse with water immediately after topical F treatment. How-

**TABLE 2. Review of Previous Studies on Fluoride Retention From 1.23% APF Gel Applications**

Age Subject (Year)	No Subjects	Gel Applied (g)	Applied (mg)	Fluoride Retained (mg)	Retained (%)	Remarks	Author and Year
—	15	—	—	11.2	—	—	Owen et al. '79
5-16	8	3.3	41.0	3.12	78	Vacuum molded trays	Ekstrand et al. '81
9-13	5	3.0	37.4	17.4	47	Cotton-roll technique	LeCompte & Whitford '82
8-12	10	4.0	49.2	9.9	20	Foam-lined trays, suctioning	LeCompte & Doyle '82
8-12	10	4.0	49.2	3.1	6	Foam-lined trays, suctioning and expectoration	LeCompte & Doyle '82
6-13	50	10.7	131.6	23.6	18	Disposable tray	Heeres & Purdell-Lewis '83
Adults	13	7.8	95.7	1.3-23.2	1.4-24	Different disposable trays	McCall et al. '83
4-14	60	4.0	49.2	16.2	33	Tray with suction device	More et al. '83
9-12	10	4.0	49.2	22.7	46	Non expectoration	LeCompte & Rubenstein '84
9-12	10	4.0	49.2	4.9	10	Expectoration	LeCompte & Rubenstein '84

ever, recent evidence has shown that both of these suggestions significantly may reduce the efficacy of the topical F therapy (Stookey et al. 1986; Wei and Hattab 1987, 1988; Wei et al. 1988).

Collectively, the present data indicated that the risk of excessive ingestion of F from professionally applied APF gels can be reduced to a minimum by using a saliva ejector during the topical application and by encouraging the patient to expectorate thoroughly following the application procedure. The new APF foam preparation has the advantage of dispensing a minimum F dose for each topical F application and not requiring suctioning to reduce the orally retained F. The APF foam will offer advantages for home use as well as for the treatment of young children and disabled persons where saliva evacuation may not be feasible.

Dr. Wei is a professor and head, children's dentistry and orthodontics, Prince Philip Dental Hospital, Hong Kong, and Dr. Hattab is an assistant professor, cariology and pedodontics, Jordan University of Science and Technology, Irbid, Jordan. Reprint requests should be sent to: Dr. Stephen H.Y. Wei, Dept. of Children's Dentistry and Orthodontics, University of Hong Kong Faculty of Dentistry, Prince Philip Dental Hospital, 34 Hospital Rd., Hong Kong.

Beal JF, Rock WP: Fluoride gels. A laboratory and clinical investigation. *Br Dent J* 140: 307-10, 1976.

Dijkman AG, Tak J, Arends J: Comparison of fluoride uptake of human enamel from acidulated phosphate fluoride gels with different fluoride concentrations. *Caries Res* 16:197-200, 1982.

Ekstrand J, Koch G, Lindgren LE, Petersson LG: Pharmacokinetics of fluoride gels in children and adults. *Caries Res* 15: 213-20, 1981.

LeCompte EJ, Whitford GM: Pharmacokinetics of fluoride from APF gel and fluoride tablets in children. *J Dent Res* 61: 469-72, 1982.

LeCompte EJ, Doyle TE: Oral fluoride retention following various application techniques in children. *J Dent Res* 61:1397-1400, 1982.

LeCompte EJ, Rubenstein LK: Oral fluoride retention with thixotropic and APF gels and foam-lined and unlined trays. *J Dent Res* 63:69-70, 1984.

LeCompte EJ: Clinical application of topical fluoride products—risks, benefits, and recommendations. *J Dent Res* 66: 1066-71, 1987.

Leverett DH: Fluorides and the changing prevalence of dental caries. *Science* 217:26-30, 1982.

Marthaler TM: Explanation for changing patterns of disease in the Western world, in *Cariology Today*, Guggenheim B, ed. Zurich; S Karger, 1984 pp 13-23.

Hattab FN: Effect of fluoride-containing alginates and gels on the

acid resistance of demineralized human enamel. *Acta Odontol Scand* 42:175-81, 1984.

Hattab FN, Wei SHY: Dietary sources of fluoride for infants and children in Hong Kong. *Pediatr Dent* 10:13-18, 1988.

Heeres GJ, Purdell-Lewis DJ: Fluoride ingestion by school children during routine gel application. *Caries Res* 17:174 (abstr 44), 1983.

Heifetz SB, Driscoll WS, Horowitz HS, Kingman A: Prevalence of dental caries and dental fluorosis in areas with optimal and above-optimal water fluoride concentrations: a 5-year follow-up survey. *J Am Dent Assoc* 116:490-95, 1988.

King NM, Wei SHY: Developmental defects of enamel: a study of 12-year-old children in Hong Kong. *J Am Dent Assoc* 112:835-39, 1986.

McCall DR, Watkins TR, Stephen KW, Collins WJN, Smalls MJ: Fluoride ingestion following APF gel application. *Br Dent J* 155:333-36, 1983.

More F, Grimaloo J, Corporon R, Loesche W: Ingestion of fluoride during a topical application. *J Dent Res* 62 (abstr 837), 1983.

Myers HM: Fluorides and dental fluorosis. Monographs in oral science, vol 7. Basel; S Karger, 1978 p 76.

Owen D, Morris M, Adair J, Bakker V: Monitoring ingestion and urinary excretion of topical fluoride. *IADR Program and Abstracts* 58 (abstr 1256), 1979.

Sluiter JA, Purdell-Lewis DJ: Lower fluoride concentrations for topical application. In vitro study on human dental enamel. *Caries Res* 18:56-62, 1984.

Stookey GK, Schemehorn BR, Drook CA, Cheetham BL: The effect of rinsing with water immediately after a professional fluoride gel application on fluoride uptake in demineralized enamel: an in vivo study. *Pediatr Dent* 8:153-57, 1986.

Wei SHY, Hattab FN: Relation between enamel fluoride uptake and time of topical application. *J Dent Res* 66 (abstr 1086), 1987.

Wei SHY, Hattab FN: Enamel fluoride uptake from a new APF foam. *Pediatr Dent* 10:111-14, 1988a.

Wei SHY, Hattab FN: Time dependence of enamel fluoride acquisition from APF gels. I. An in vitro study. *Pediatr Dent* 10:168-72, 1988b.

Wei SHY, Hattab FN: Water fluoridation, systemic fluoride, and fluoride metabolism, in *Pediatric Dentistry: Total Patient Care*, chapter 5, Wei SHY, ed. Philadelphia; Lea and Febiger, 1988c.

Wei SHY, Lau EWS, Hattab FN: Time dependence of enamel fluoride acquisition from APF gels. II. An in vivo study. *Pediatr Dent* 10:173-77, 1988.

Whitford GM, Allman DW, Shahed AR: Topical fluorides: effects on physiologic and biochemical process. *J Dent Res* 66: 1072-78, 1987.