An Evaluation of the Use of Professional (Operator-applied) Topical Fluorides

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Application of fluoride solutions, gels, varnishes, and prophylaxis pastes is reviewed as well as the sequential APF/SnF_2 office-rinse method. The most widely-used technique is with 1.23% APF gel (12,300 ppm F) in trays. Clinical results from this method are similar to those achieved with an APF solution of the same fluoride concentration. A professional APF gel/tray application need not be preceded by a prophylaxis, should last four min, and should not be followed by a water rinse for 30 min. Fluoride varnishes are newer topical fluoride agents, but their relative efficacy, compared with other proven caries-inhibitory methods, remains to be fully determined. In general, fluoride prophylaxis pastes have not been shown to inhibit caries; however, their use is justified by the ability of some to replenish fluoride lost from the abrasive action of the paste on tooth enamel. The sequential office-rinse method has not been tested in randomized clinical trials, and its use cannot be recommended.

Introduction.

Operator-applied topical fluoride products currently in use include fluoride solutions, gels, prophylaxis pastes, and rinses. In Table 1 these products are listed, along with indications as to how they are used. The listing is based on market availability rather than on efficacy which has been substantiated by clinical research.

The decision to use a particular topical fluoride product in a dental office or in a school-based program is determined by both scientific and practical considerations. Of primary importance is that the product must effectively inhibit caries. Such knowledge is derived from the results of properly designed clinical trials (Carlos, 1985; Horowitz, 1984; Horowitz

et al., 1973) and the interpretation of the statistical and clinical significance of the findings (Swango, 1980). A practical consideration is that the product should be convenient to use and be tolerated by patients. An important aspect of publicly funded school-based programs is the cost relative to the expected benefits (Clark et al., 1985a; Manau et al., 1987; Niessen and Douglass, 1984), and another consideration is safety (Ripa, 1987).

It is the purpose of this paper to review the operator-applied topical fluoride methods listed in Table 1 in order to offer recommendations concerning their use. Since the efficacy of some of these procedures has been firmly established in numerous clinical trials, such discussions will be limited primarily to newer products or methods.

Aqueous solutions and gels.

Professional topical fluoride solutions and gels are available as sodium fluoride (NaF), stannous fluoride (SnF_2), and acidulated phosphate fluoride (APF). Although sodium monofluorophosphate has been tested in professionally applied fluoride preventive programs (Goaz et al., 1966; Vrbic et al., 1974; Vrbic and Kosmelj, 1978; Melsen et al., 1979), it has never been marketed as such. While there is as much as a two-fold difference in fluoride concentration between the NaF, SnF_2, and APF preparations shown in Table 1, Ripa (1981), in a review of 35 clinical trials involving 70 treatment groups (Table 2), concluded that the caries inhibitions achieved when these compounds were available as solutions were similar and, from the standpoint of clinical efficacy, could be considered equal.

Personal observation as well as formal (Bradnock and Rock, 1982) and informal surveys (ASDC Forum, 1984) indicate that APF is the topical fluoride used by most practitioners. APF is preferred because it is available as a gel and can be applied in mouth trays, compared with solutions which require a less

TABLE 1
PROFESSIONAL (OPERATOR-APPLIED) TOPICAL FLUORIDE METHODS

Vehicle	Application Technic	Fluoride Compound	Fluoride Concentration	Fluoride Exposure Usual Amount Used	mg F
Aqueous solutions	Paint-on	APF+	12,300	5 mL	61.5
		SnF_2	19,360	5 mL	96.8
		NaF	9040	5 mL	45.2
Gels	Trays	APF	12,300	5 mL	61.5
		NaF	9040	5 mL	45.2
Varnishes	Paint-on	NaF	22,600	0.5 mL	11.3
		Difluorosilane	7000	0.5 mL	3.5
Prophylaxis	Rotary	APF	12,000	3 mL	36.0
Pastes*	Polishers	NaF	10,000 – 20,000		30.0 – 60.0
Sequential	Swish and	APF &	3100 &	30 mL &	93.0 &
Rinses	Expectorate	SnF_2	1000	37.5 mL	37.5

*Other fluoride compounds and concentrations available.

+APF = acidulated phosphate fluoride; the F ion is derived from NaF.

TABLE 2

POOLED RESULTS OF CLINICAL TRIALS OF OPERATOR-APPLIED AQUEOUS SOLUTIONS OF NaF, SnF$_2$, OR APF ON THE PERMANENT TEETH OF CHILDREN RESIDING IN FLUORIDE-DEFICIENT COMMUNITIES

	Number of Treatment Groups	% DMFS Reduction (Averaged Results)
NaF	25	29
SnF$_2$	18	32
APF	27	28

Adapted from Ripa (1981).

convenient paint-on application (ASDC Forum, 1984; Braddock and Rock, 1982). Moreover, tray application appears to be readily accepted by children (Kirkegaard *et al.*, 1980), and the flavoring in gels further enhances patients' acceptance (Stindt, 1983).

Results of clinical trials testing APF gels applied in trays at a concentration of 12,300 ppm F are shown in Table 3. Most of the studies are positive, indicating that it is an effective anticaries technique. Nevertheless, because the method is the most widely used for professional topical fluoride treatments, it is important that it be compared with the one it replaced, *i.e.*, topical application of an APF solution painted on the teeth. In five clinical trials, the amounts of caries inhibition from an APF gel and solution were compared (Table 4), and aggregate results indicate that the gel was not inferior. In addition, two studies that re-examined children one and two years after discontinuation of treatments with an APF gel found that the caries-protective benefits persisted (Bryan and Williams, 1970; Horowitz and Kau, 1974).

Recently, 2% neutral NaF gels have been marketed for professional topical fluoride treatments. These products appeared in response to the concern that the combination of phosphoric acid and sodium fluoride in APF preparations produces hydrofluoric acid (HF) which etches glass filler particles in composite restorations and the surfaces of porcelain crowns (Council on Dental Materials, Instruments and Equipment and Council on Dental Therapeutics, 1988). Although it is conceded that there is little danger to the surfaces of composite

restorations and porcelain crowns from a single fluoride exposure, the cumulative effects of repeated APF treatments could be esthetically damaging; therefore, a neutral topical fluoride preparation has been recommended (Council on Dental Materials, Instruments and Equipment and Council on Dental Therapeutics, 1988).

The concentration of fluoride in neutral gel products (9040 ppm F) is the same as that of neutral NaF solutions which were among the first professional topical fluoride preparations clinically tested. Nevertheless, while 2% neutral NaF solutions have been proven clinically, 2% neutral NaF gels have not. Not only the vehicles but also the methods of usage and application frequency differ between the original and current NaF products. Therefore, results of clinical studies of neutral sodium fluoride solutions should not be extrapolated to gel products. To date, one laboratory study has reported inhibition of artificial caries by a neutral 2% NaF gel (Mellberg *et al.*, 1988), but there are no clinical studies of effectiveness. Although 2% neutral NaF gels may be as effective as solutions, clinicians who use these products should be aware that they lack clinical validation and have yet to receive ADA acceptance.

Method of application. —Topical fluoride solutions are applied to the teeth by use of cotton applicator sticks, and gels are applied in mouth trays. The advantage of trays is that the entire mouth can be treated simultaneously. When solutions are used, teeth are treated on a quadrant or half-mouth basis. However, since the preponderance of operators use gels, only the gel method of application will be discussed.

Prior to a professional topical fluoride application, it was recommended that teeth be cleaned for removal of surface integuments which might interfere with fluoride uptake and reduce the clinical effectiveness of the procedure. However, *in vivo* (Tinanoff *et al.*, 1974; Bruun and Stoltze, 1976; Steele *et al.*, 1982; Seppä, 1983) and *in vitro* (Tinanoff *et al.*, 1975; Joyston-Bechal *et al.*, 1976; Klimek *et al.*, 1982) studies have demonstrated that fluoride uptake is not reduced if teeth remain uncleaned (see review by Ripa, 1984), and four independent clinical trials (Houpt *et al.*, 1983; Katz *et al.*, 1984; Ripa *et al.*, 1984; Bijella *et al.*, 1985) have demonstrated that caries inhibition from topical APF gels or solutions is not reduced when the preliminary prophylaxis was omitted (Table 5). Therefore, a patient may simply rinse with water to remove food particles prior to application with stock trays containing gel. McCall *et al.* (1985) have shown that a tray's design can affect the distribution of APF gel on teeth, resulting in incomplete coverage and, presumably, lack of therapeutic effect at uncovered sites. Therefore, it is important that the fit of trays be assessed for each patient.

Gel should be applied to teeth which have been air-dried, because if the teeth are coated with saliva, dilution will occur, and the gel will not be applied at 12,300 ppm F. Furthermore,

TABLE 3

CARIES INHIBITION FROM OPERATOR-APPLIED APF GEL TOPICAL TREATMENTS

Study	No. Applications *per* Year	Study Duration (yr)	% DMFS Reduction
Szwejda *et al.* (1967)	1	1	4
Szwejda (1971)	1	2	3
Horowitz (1969)	1	2	22
Horowitz and Doyle (1971)	1	3	24
Bryan and Williams (1968)	1	1	28
Ingraham and Williams (1970)	1	2	41
Cons *et al.* (1970)	1	4	18
Mainwaring and Naylor (1978)	2	3	14
Cobb *et al.* (1980)	2	2	35
Horowitz and Kau (1974)	*	5	21
Bryan and Williams (1970)	+	2	37
Stern *et al.* (1976)	5‡	2	+ 0.5 (DMFT)
DePaola *et al.* (1980)	10§	2	19

*No additional treatments; examined 2 yr after discontinuation of treatment by Horowitz and Doyle (1971).

+No additional treatments; examined 1 year after discontinuation of treatment by Bryan and Williams (1968).

‡Five treatments on consecutive days during first year only.

§10 treatments on consecutive school days during first year only.

TABLE 4

COMPARISON OF CARIES INHIBITION FROM OPERATOR-APPLIED APF SOLUTIONS AND GELS

	% DMFS Reduction	
Study	Solution	Gel
Cons *et al.* (1970)	0	18
Ingraham and Williams (1970)	12	41
Szwejda (1972)	23*	4*
Horowitz and Doyle (1971)	28	24
Cobb *et al.* (1980)	34	35
Average All Studies	19.4	24.4

*Fluoridated community.

TABLE 5
MEAN DMFS INCREMENTS OF CHILDREN RECEIVING SEMI-
ANNUAL OPERATOR-APPLIED APF TOPICAL FLUORIDE
TREATMENTS: EFFECT OF PRIOR TOOTHCLEANING

		Treatment		
Study	Study Duration (yr)	Prophylaxis + Topical F	Self-brush + Topical F	Topical F only
Bijella et al. (1985)*	1.5	3.30	2.60	+
Houpt et al. (1983)	2.0	2.05	2.48	2.14
Katz et al. (1984)	2.5	2.23	2.33	2.09
Ripa et al. (1984)	3.0	3.33	3.18	3.19

*An APF solution was used in this study; all others used an APF gel.
+A no-treatment control group in this study had a DMFS increment of 9.2.

TABLE 6
RECOMMENDED APPLICATION FREQUENCY FOR
PROFESSIONAL (OPERATOR-APPLIED) TOPICAL FLUORIDE
SOLUTIONS OR GELS

Water Fluoride Status	Caries Status		
	Caries-free	Active Caries	Rampant Caries
F-deficient	2×/yr*	2×/yr	4×/yr
Optimally Fluoridated	0	2×/yr	4×/yr

*To age 16 [adapted from Ripa et al. (1986)].

Hattab (1987) has reported that one-minute air-drying will result in significantly more fluoride uptake by the outer enamel treated with a professional topical fluoride application. In this study, a 2% neutral NaF solution was used, and this effect has yet to be demonstrated with an APF gel.

The gel should be left in contact with teeth for four minutes. Although APF gels have been marketed for which manufacturers recommend an application time of one min, this recommendation lacks clinical verification. Wei and co-workers have shown that enamel fluoride uptake is significantly less when contact is reduced to one min, and recommended that the clinically-proven four-minute contact be continued (Wei and Hattab, 1987; Wei et al., 1988).

After four min, trays are removed and patients instructed not to rinse, eat, or drink for 30 min. Stookey et al. (1986), in an in vivo study, have shown recently that enamel fluoride uptake by artificially induced incipient lesions is reduced by about half when a patient is allowed to rinse immediately following a professional APF gel tray treatment.

Use.—Operator-applied topical fluoride solutions and gels have been used in office-based and school-based preventive programs. However, in the latter, operator-applied programs have generally been supplanted by self-applied methods of fluoride delivery.

There is a dichotomy in the prevalence of dental caries worldwide, with industrialized countries experiencing a caries decline and developing countries a caries increase (Heløe and Haugejorden, 1981). The routine application of topical fluoride, as part of an office caries-preventive program, should only be considered in countries experiencing high caries rates. Where a caries decline is under way, the need for topical fluoride treatments should be decided on an individual basis. Certainly, the application of topically applied fluoride should not be performed routinely on children residing in fluoridated communities, or who have had maximal exposure to fluoride supplements. There are few clinical data to show that topical fluoride treatments are effective when performed on groups of children in fluoridated communities (Mellberg and Ripa, 1983a; Wei, 1974). On the other hand, for individual children who are exposed to systemic fluoride yet are caries-positive, professional topical fluoride treatments should be part of their caries-preventive program. Considering patients' caries activity and exposure to fluoridated drinking water, and recognizing the importance of application frequency on caries inhibition (Grøn and DePaola, 1968), Ripa et al. (1986) developed recommendations, listed in Table 6, for the use of professional topical fluoride applications for individual patients.

The use of operator-applied topical fluorides for community programs has had serious limitations primarily because of the personnel costs associated with this one-to-one method of fluoride delivery. Heifetz (1978) calculated that a hygienist-administered APF gel-tray treatment, given once a year, would cost $10.50 (U.S.). This estimate was based on a treatment time of 24 min and included depreciation costs for capital dental equipment and repairs. It was also calculated that the method would cost $4.40 per surface saved, based upon an estimated 40% caries reduction. Such figures are prohibitive for a school-based program and are probably underestimated because: (a) professionally applied topical fluoride treatments are recommended twice rather than once per year (Grøn and DePaola, 1968; Ripa et al., 1986) and a twice-a-year schedule would nearly double Heifetz's annual cost estimate; and (b) the pooled percent caries inhibition from APF gels clinical trials is only about 60% of the figure used by Heifetz (Ripa, 1981). On the other hand, with the elimination of the prior prophylaxis, the chair time for gel-tray treatment can probably be reduced to 6-8 min, i.e., a quarter to a third of the time used in Heifetz's calculations. Furthermore, several children can be treated simultaneously, or at least in an overlapping sequence; thus, the procedure is no longer a strict "one-to-one" method. Both these changes in the gel-tray procedure would significantly reduce personnel costs, and, taking these into account, cost-effectiveness estimates should be recalculated for the operator-applied method, perhaps using one of the analytical methods described recently (Niessen and Douglass, 1984; Clark et al., 1985a; Tzukert et al., 1986).

Despite the foregoing, it is not recommended that operator-applied gel-tray treatments become a staple of school-based preventive programs in countries with low caries rates. Bohannan et al. (1985a,b) and Klein et al. (1985), for instance, found minimal surface savings from prophylaxis and gel-tray treatments of first, second, and fifth grade children in five fluoridated and five fluoride-deficient U.S. cities. In this study, however, the fluoride gel applications were always used in conjunction with another fluoride method or with sealants, hence the value of the gel-tray method alone could only be conjectured. In another study, Houpt et al. (1983) reported no effect from two years of semi-annual gel-tray applications, but their no-treatment control group may not have been representative, since it consisted of children whose parents elected not to have them participate in the program. However, there are both individual children and groups of children with high caries activity, even when national caries prevalence is low (Graves and Stamm, 1985), and these individuals may benefit from the protection afforded by professional topical fluoride applications. Klock (1980) has pointed out that the cost-effectiveness of preventive dental services could be improved if children with extremely high caries risk could be identified. To date, the most useful caries-risk-predictive factor appears to be a previous history of the disease (Downer and Mitropoulos, 1984). This approach, however, does not identify children who are at high risk, yet are too young to be exposed to the caries challenge for a time sufficient for clinically recognizable lesions to have developed. Studies are under way, and need to be

encouraged, to develop a caries-risk-predictive method that is reliable, sensitive, clinically practical, and economical. Additionally, new clinical studies of the one-step gel-tray treatment, *i.e.*, with no prior prophylaxis, should be conducted specifically on children who demonstrate a high caries risk, by virtue of their DMF score at baseline.

A disadvantage to the use of operator-applied topical fluorides in public health programs has been the difficulty of implementation in areas with a shortage of dental personnel. Thus, the method was impractical in developing countries with escalating caries rates where sufficient dental personnel were unavailable (Murray, 1986). However, the streamlined one-step gel-tray procedure is less technique-critical than the former two-step method, and operators with less dental background than dentists or hygienists could be trained to administer it. In countries experiencing high caries rates, different methods of school-based topical fluoride delivery, including the one-step gel-tray method, should be compared for effectiveness and costs.

Precautions.—The highest concentrations of fluoride are found in those preparations that are intended for professional use (Table 1). One mL of a professional topical fluoride solution or gel contains from 9 to 19 mg F, depending upon the product selected. The most commonly used procedure, the APF gel-tray technic, uses up to 5 mL of gel (2.5 mL/tray) *per* treatment which introduces 61.5 mg F to the mouth. There is the potential that some of the gel can be swallowed, resulting in either acute or chronic toxicity.

Acute toxicity from any agent runs the gamut from a mild systemic reaction to death. Heifetz and Horowitz (1984) calculated that, for a hypothetical two-year-old child weighing 10 kg, the CLD (Certainly Lethal Dose) of fluoride is 320 mg, and the STD (Safely Tolerated Dose)—*i.e.*, the dose that can be ingested without producing serious acute toxicity—is one-fourth the CLD, or 80 mg. Thus, the amount of fluoride in 5 mL of APF gel is less than the STD for even the youngest patient and five times less than the CLD.

The most common acute toxic reactions from professional topical fluoride treatments are nausea and vomiting (Beal and Rock, 1976; Ekstrand and Koch, 1980; Rubenstein and Avent, 1987). Rubenstein and Avent (1987) surveyed 149 children who received professional gel-tray topical fluoride treatments in a school dental clinic, and, of 91 responses, six children (6.6%) reported nausea, vomiting, or headache immediately following or one hour after treatment. Considering that the operators in this study were relatively inexperienced dental students, the prevalence of acute side-effects from this procedure appears to be low when suitable precautions are taken to prevent inadvertent gel swallowing.

The chronic toxicity concern is that the peak plasma fluoride concentrations which occur from fluoride ingestion during these topical treatments (from 15 to 50 μmol/L have been reported, compared with a non-challenge level of 1 μmol/L) could induce enamel fluorosis in age-susceptible children. While Ang-mar-Månsson and Whitford (1983) showed that a single dose of 0.75 mg F/kg body weight produced dental fluorosis in rat incisors, the concern that ingestion of fluoride from infrequent treatments of professional-strength topical fluorides can produce fluorosis in humans has not been clinically substantiated. Larsen *et al.* (1985) examined 269 children, initially 6 years of age and older, who received fluoride gel-tray treatments for up to five years. Approximately 40 mg F was used *per* treatment, and a mean of 7.3 mg F was retained. The treatments did not produce an increased prevalence of fluorosis in the teeth at risk (canines, premolars, and second molars) in spite of retention of up to 0.5 mg F/kg body weight and an application frequency of 4 or 5 times/yr for some children. The

investigators concluded, "Apparently, large acute doses of fluoride at regular intervals do not result in enamel disturbances that can be recorded clinically."

A number of studies have demonstrated that fluoride is retained from professional topical fluoride treatments that use gels (Ekstrand *et al.*, 1978, 1981; Owen *et al.*, 1979; Ekstrand and Koch, 1980; LeCompte and Whitford, 1981, 1982; LeCompte and Doyle, 1982, 1985; McCall *et al.*, 1983a,b; LeCompte and Rubenstein, 1984; Eisen and LeCompte, 1985; Tyler and Andlaw, 1987). Many of these studies were reviewed in a recently published symposium on "Topical Fluorides: Optimizing Safety and Efficacy" (Ekstrand, 1987; LeCompte, 1987; Newbrun, 1987; Whitford, 1987; Whitford *et al.*, 1987; Ripa, 1987), and some are cited in Table 7. The range of fluoride retained varies widely, both in regard to the total amount, and as a percentage of the amount introduced into the mouth. Furthermore, a number of studies have shown that common-sense precautions can significantly reduce the level of fluoride gel retained (Eisen and LeCompte, 1985; LeCompte and Doyle, 1982, 1985; LeCompte and Rubenstein, 1984). Based upon these, prudent administration of professional topical fluoride gel in trays requires the following expedients:

1. Seat the patient upright.
2. Use trays with absorptive liners.
3. Limit the amount of gel placed in the trays to no more than 2.5 mL (0.5 teaspoon) *per* tray.
4. Use suction during and after treatment.
5. Instruct the patient to expectorate after the trays are removed.

Fluoride varnishes.

Substantial leaching of absorbed fluoride from enamel occurs within the first 24 h of application with a solution or gel (Mellberg *et al.*, 1966; Brudevold *et al.*, 1967). Increasing the time of contact between the enamel surface and topical fluoride agent favors the deposition of more permanently bound fluorapatite and fluorohydroxyapatite (Benediktsson *et al.*, 1982). Hence, fluoride varnishes were developed to adhere to the enamel surface for prolonged periods (up to 12 h or more), and to release their fluoride slowly to the teeth. Thus, they increase the contact time between the fluoride and enamel without increasing chair time and also facilitate greater fluoride uptake and retention.

Duraphat, the first fluoride varnish (Heuser and Schmidt, 1968), is a viscous yellowish material, containing 22,600 ppm F as NaF in a neutral colophonium base. A second varnish, Fluor Protector, is a clear polyurethane-based product containing 7000 ppm F from an organic compound, difluorosilane. There have been numerous laboratory and clinical studies of these two varnishes, and they have been the subject of several reviews (Schmidt, 1981; Clark, 1982; Seppä, 1982; Yanover, 1982; Primosch, 1985; DeBruyn and Arends, 1987).

Laboratory data on fluoride varnishes have mainly involved analysis of *in vivo* and *in vitro* enamel fluoride uptake. These were described in the review by DeBruyn and Arends (1987) and need not be repeated here. Of interest, in relation to fluoride use, were the findings of Retief *et al.* (1980) that increasing the fluoride-enamel contact from 1 h to 24 h increased the fluoride uptake, but the optimal contact time identified in a subsequent study was 4 h (Retief *et al.*, 1983).

Approximately two dozen articles on clinical studies of fluoride varnishes were summarized in the reviews cited above. Fluoride varnishes have been tested on both primary and permanent teeth. While most studies have involved residents of

TABLE 7
FLUORIDE RETAINED (INGESTED) FROM APF GEL-TRAY TOPICAL TREATMENTS

Study	Subjects		Mean mg F Applied	Mean mg F Retained	% F Retained	Remarks
	No.	Age				
Ekstrand et al. (1981)	8	5–16	40.1	31.2	77.8	vacuum-molded trays; no liners
McCall et al. (1983b)	13	young adults	89.5	10.8	12.0	different tray types; no aspiration
LeCompte and Rubenstein (1984)	10	9–12	49.2	22.7	46.1	without suction or expectoration
			49.2	17.7	36.0	with expectoration
LeCompte and Doyle (1982)	8	8–12	49.2	15.6	31.7	without expectoration
			49.2	4.4	8.9	with expectoration
LeCompte and Doyle (1985)	10	9–12	49.2	16.9	34.3	without suction
			49.2	7.7	15.6	with suction
	8	23–34	49.2	22.0	44.7	without suction
			49.2	10.3	20.9	with suction
Eisen and LeCompte (1985)	10	24–35	51.3	23.0	44.8	without expectoration or suction
			51.3	4.9	9.6	with expectoration and suction
Tyler and Andlaw (1987)	20	5–20	29.5	5.6	18.9	careful technic used

fluoride-deficient communities, fluoride varnishes have also been tested in communities with optimal water fluoridation. Duraphat has been the most tested product, but several trials have also involved Fluor Protector. Although it is evident from these studies that the varnishes can be considered caries-inhibitory agents, because of design flaws in many of the trials (too small sample size; study duration of less than two years; non-standard diagnostic criteria; evaluation of only specific teeth or surfaces; use of a half-mouth treatment method, etc.), hypotheses concerning the relative effectiveness of these varnishes and their position in the plethora of caries-inhibitory agents remain inconclusive.

Clark et al. (1985b,c) reported the results of the only North American fluoride varnish clinical trial. First-grade Canadian schoolchildren, initially 6-7 years old, received semi-annual applications of Duraphat or Fluor Protector for 2.7 years. The study included a placebo control group. The caries inhibitions of each of the fluoride varnish treatment groups were statistically significant for the permanent teeth but not for the primary teeth (Table 8). Clark et al. (1985c) commented on the "modest" results and stressed that the efficiency with both varnishes was low because of the high costs of treatment relative to the tooth surfaces saved.

Method of application and use.—Fluoride varnishes have been applied to teeth that were first professionally cleaned (Koch and Petersson, 1975; Modeer et al., 1984) or self-cleansed (Seppä et al., 1982b, 1983), although laboratory studies have demonstrated that the fluoride from varnishes can be absorbed by uncleaned enamel (Hellwig et al., 1985; Seppä, 1983). Furthermore, while clinical investigators have usually applied a varnish to dried teeth, the manufacturer of Duraphat directs that application may be made to moist teeth, and the author has observed dental students in England being taught to apply Duraphat to saliva-moistened teeth. Thus, it appears that the optimal method of application has yet to be resolved. However, should absolute isolation not be necessary, fluoride varnish might be the professional topical fluoride agent of choice for pre-school children in whom salivary control is difficult.

Also lacking resolution, because the relative efficacy of the two methods has not been studied, is whether a fluoride-varnish or a gel-tray treatment is the preferred method of professional topical fluoride application for individual office patients. Nor is it known whether the high fluoride uptake from a varnish will produce superior caries inhibition, which would make varnish the recommended procedure for high-caries-risk patients. Certainly, available clinical evidence does not support

TABLE 8
CARIES INHIBITION FROM SEMI-ANNUAL FLUORIDE VARNISH APPLICATIONS ON CANADIAN SCHOOLCHILDREN

Study Duration	Treatment	No. of Subjects	dfs		DMFS	
			Increment	Reduction %	Increment	Reduction %
20 months*	Fluor Protector	201	1.56	10	1.70	16
	Duraphat	255	1.62	7	1.73	14
	Placebo	247	1.74	—	2.02	—
32 months**	Fluor Protector	197	1.85	10	2.58	17
	Duraphat	245	1.49	27	2.43	22
	Placebo	234	2.06	—	3.11	—

*Clark et al. (1985b).
**Clark et al. (1985c).

the conclusion that higher fluoride uptake *per se* is associated with higher levels of caries inhibition. Even when the two varnishes were compared, the organic fluoride generally caused the greater enamel fluoride uptake (Edenholm *et al.*, 1977; Retief *et al.*, 1980; Dijkman *et al.*, 1982; Seppä, 1982; Kolehmainen *et al.*, 1978), but it was not associated with a greater caries inhibition when their effectiveness was compared in the same study (Seppä *et al.*, 1981, 1982a,b; Clark *et al.*, 1985b,c).

The role of varnishes in school-based programs also needs clarification. Although fluoride varnish treatment is an operator-intensive technique, especially when a prior prophylaxis and salivary isolation are performed, five clinical trials have compared the effects of fluoride varnish treatment with those of fluoride mouthrinsing (Koch *et al.*, 1979; Hamp *et al.*, 1984; Kirkegaard *et al.*, 1986; Axelsson *et al.*, 1987; Seppä and Pollanen, 1987). In four of the five studies, the treatment cohorts involved fewer than 100 subjects each. In the fifth study, by Kirkegaard *et al.* (1986), where the two treatments were compared for five years in children initially in the third grade, semi-annual application of Duraphat and fortnightly rinsing with a 0.2% neutral NaF solution produced similar caries increments. Therefore, considering the lower costs associated with the mouthrinse procedure, there is no clinical evidence to support its being superseded in public health programs by fluoride varnish applications.

Precautions. —Although fluoride varnishes are topical agents, swallowing most of the applied fluoride is an inevitable consequence of the procedure. This occurs because, once painted on teeth, the film of varnish is allowed to remain until it loosens by itself. The patient is dismissed with instructions not to eat or drink for four hours, nor to use a toothbrush on the treatment day.

Since all the fluoride introduced into the mouth will eventually be swallowed, it is important that the amount used with this method be known. Clark *et al.* (1985c) calculated that they used approximately 0.5 mL of either Duraphat or Fluor Protector *per* patient and that the amount of fluoride used was 11 mg and 3.5 mg, respectively. Koch *et al.* (1979) reported that a similar 0.3–0.5 mL of Duraphat *per* patient was used in their study. Roberts and Longhurst (1987) evaluated the amount of fluoride used when 39 operators applied Duraphat to 111 children, aged 2–14 years. They reported a mean of 5.2 mg F *per* patient with a range of 0.7–14.5 mg, while Ekstrand *et al.* (1980) found fluoride ingestion from the use of Duraphat to be 5.0–5.2 mg/patient. These figures are relatively consistent, and, when compared with fluoride ingestion associated with professional topical fluoride gel treatments (Table 7), amounts are similar. Additionally, fluoride ingestion from a varnish occurs slowly over a period of hours, rather than in a single acute episode. Thus, provided that the amount of varnish applied to the teeth is within the range reported above, no extraordinary precautions need be taken when these products are used.

Fluoride prophylaxis pastes.

Dental prophylaxis pastes are abrasive products for cleaning and polishing the teeth. The addition of fluoride to these pastes is based on the assumption that this will impart a cariostatic benefit. In the dental office, fluoride prophylaxis pastes are used alone or as the preliminary cleaning step before administration of a topical fluoride application.

Most of the studies in which a fluoride prophylaxis paste was used alone, in an infrequent application regimen of once or twice a year, were conducted between 1960 and 1980. These have been reviewed by Ripa (1985). However, the majority involved fluoride prophylaxis pastes which were never marketed. Of those that were marketed in the United States, an APF paste in a silicon dioxide abrasive system and a SnF_2 paste in a zirconium silicate abrasive system received clinical testing (Table 9). DePaola and Mellberg (1973) reported a marginal caries reduction with the APF paste, but Barenie *et al.* (1976) and Schutze *et al.* (1974) failed to detect a caries-protective effect when the paste was applied to permanent or primary teeth, respectively. Beiswanger *et al.* (1980) also failed to find a statistically significant caries inhibition with the SnF_2 paste.

To determine whether a preliminary prophylaxis performed with a fluoride-containing paste provided additive cariostatic benefits to a professional topical fluoride application, this combination would have to be tested against a similar regimen in which the prophylaxis paste was fluoride-free. Only two reported studies were so designed (Beiswanger *et al.*, 1980; Horowitz and Lucye, 1966), and neither found the combination of fluoride treatments to be superior (Table 10), although in one study none of the treatment groups benefited from the different fluoride applications.

Thus, there are no clinical studies which support a conclusion that fluoride prophylaxis pastes, as commonly used in dental offices, improve caries protection. This statement is consistent with the absence of fluoride prophylaxis pastes from the lists of accepted therapeutic fluoride products of either the U.S. Food & Drug Administration or the American Dental Association.

Use. —The principal reasons to undertake a professional dental cleaning are to remove extrinsic stains from the teeth and to establish a baseline level of oral hygiene in individuals with gingival disease. In these instances, it is recommended that fluoride paste be used, even though they are not proven anti-caries agents. During a professional cleaning, several μm of fluoride-rich surface enamel are abraded from the teeth (Vrbic *et al.*, 1967; Zuniga and Caldwell, 1969; Stookey, 1978; Biller *et al.*, 1980). Although the clinical implications of this loss are unknown, it is deemed undesirable. If a prophylaxis paste containing fluoride is used, the fluoride that is lost by abrasion may be replaced. Mellberg *et al.* (1976) demonstrated that, while there was no long-term increase of enamel fluoride from semi-annual professional treatment with an $APF-SiO_2$ paste, neither was there any loss, indicating that fluoride removed during the polishing procedure had been replaced. Therefore, inclusion of fluoride in dental cleaning pastes can be justified on the basis of their ability to replenish fluoride lost during polishing. However, because the ingredients of a prophylaxis paste can restrict the availability of its fluoride, it is important that bioavailability be established for each product (Mellberg and Ripa, 1983b).

Sequential fluoride rinses.

Within the last decade, some companies have promoted what is termed a sequential office-rinse method whereby a patient rinses with a 0.31% APF solution (3100 ppm F) followed by a 0.4% SnF_2 solution (1000 ppm F).

Since its introduction, this method has undergone modifications. The amount of fluoride used for rinsing has been reduced to its present level following complaints of potential acute toxic effects from the original dose (Wade, 1981). In addition, the user is offered a choice of three rinse sequences: *viz.*, two one-minute rinses with APF solution followed by two one-minute rinses with SnF_2; a one-minute rinse with APF followed by a one-minute rinse with SnF_2; or two one-minute rinses with a combined solution of APF and SnF_2.

TABLE 9
CARIES INHIBITION FROM PROFESSIONALLY APPLIED FLUORIDE PROPHYLAXIS PASTES

Study	F Compound and Abrasive	Duration (yr)	No. Applications per year	% DMFS Reduction
DePaola and Mellberg (1973)	1.2% APF SiO_2	2	2	21
Barenie et al. (1976)	1.2% APF SiO_2	2	2	+5 (+8)*
Schutze et al. (1974)	1.2% APF SiO_2	1	3	+16+
Beiswanger et al. (1980)	9.0% SnF_2 $ZrSiO_4$	3	2	15

*Two independent examiners.
+defs primary teeth; optimally fluoridated community.
APF = acidulated phosphate fluoride; SiO_2 = silicon dioxide; SnF_2 = stannous fluoride; $ZrSiO_4$ = zirconium silicate.

The impetus for this method was derived from studies by Shannon (1970a,b) in which sequential applications of APF and SnF_2 to enamel produced greater protection against acid dissolution than when either fluoride compound was used alone. Shannon's original solutions contained 1.23% APF and 0.5% SnF_2, which were later changed to the lower fluoride concentrations mentioned above (Magness et al., 1979).

Both APF and SnF_2 have been sequentially applied in studies examining enamel solubility reduction (Shannon, 1970a,b; Shannon et al., 1974), artificial caries inhibition (Crall et al., 1982), enamel fluoride uptake (Crall et al., 1982; Crall and Bjerga, 1984), and effects on dental plaque (Yankell et al., 1982). While these laboratory studies were generally favorable, depending upon the concentration of fluoride tested, there have been no randomized double-blind clinical studies of caries inhibition with the sequential rinse method. In fact, the only clinical report in which this method was exclusively used appears to be confined to a study of enamel decalcification in 22 orthodontic patients (Magness et al., 1979). Despite several favorable laboratory reports of this method, especially when the original concentration solutions were used, the almost complete absence of supporting clinical data on caries inhibition makes the sequential rinse procedure one that cannot be recommended for office use. Furthermore, one must question the caries-inhibitory potential of a procedure that can be employed only a few times a year yet uses products with fluoride concentrations normally used or tested in daily (fluoride dentifrices) or weekly (Heifetz et al., 1973) preventive programs.

TABLE 10
CARIES INHIBITION FROM PROFESSIONALLY APPLIED FLUORIDE PROPHYLAXIS PASTE COMBINED WITH PROFESSIONAL TOPICAL FLUORIDE APPLICATION

Study	Fluoride Treatment	Duration (yr)	No. Applications per Year	% DMFS Reduction
Horowitz and Lucye (1966)	P_F T_F $P_F + T_F$	2	1	+6 +8 1
Beiswanger et al. (1980)	P_F T_F $P_F + T_F$	3	2	15 52 52

SnF_2 active ingredient in both studies.
P_F = fluoride prophylaxis paste professional treatment.
T_F = professional topical fluoride application.

Discussion.

Professional (operator-applied) topical fluoride products used in North America include solutions, gels, varnishes, prophylaxis pastes, and sequential rinses.

The most popular operator-applied fluoride method uses 1.23% APF gel in mouth trays. This technique superseded the solution paint-on protocol principally because of its convenience, patient acceptance, and reduced chairside time. Limited clinical evidence (Table 4) indicates that the two methods are equally effective. A recent change has been the elimination of the need for routine prophylaxis before a topical fluoride application. By reducing the method from a traditional two-step procedure to a one-step four-minute simultaneous treatment of the whole mouth, the cost-effectiveness ratio of a once-labor-intensive procedure should be improved considerably.

In North America and other industrialized regions, caries activity is declining, whereas in developing countries it is increasing. Where there is a low caries prevalence, the gel-tray method should not be considered for across-the-board application in school-based programs, because the absolute number of tooth surfaces saved would be expected to be low.

In countries with high caries rates, the assumption seems justified that the results achieved by this method should parallel the absolute and relative caries inhibitions reported during the 1960's and 1970's, when U.S. caries prevalence was higher. These data form the basis of scientific evidence supporting this method of caries inhibition. Since a preliminary prophylaxis is no longer needed, a single operator, or operating team, can treat simultaneously at least eight children in under ten min. The recent study by Bijella et al. (1985), on Brazilian schoolchildren, with a mean annual caries increment of 6.1 surfaces, found that semi-annual operator-applied topical fluoride treatments produced a 64 to 72% caries inhibition. This dramatic result suggests the potential for this method in countries with high caries rates.

For office-based programs, use of this method should be decided on an individual basis in which the principal criteria are a patient's caries activity and the level of fluoride in the drinking water (Table 6).

Varnishes are relatively new fluoride vehicles. Their advantage is that they increase fluoride/tooth contact time without increasing chairside time and produce a relatively high enamel surface fluoride level. However, whether this ultimately translates into clinical superiority in terms of caries inhibition is not

clear. Another advantage, at least according to the manufacturer of one commercial product, is that meticulous attention to the maintenance of a dry field is not essential. This technical advantage can be important in the treatment of young children or disabled patients in whom saliva control may be difficult. Since the varnish loosens from the coated teeth after a patient is dismissed, most of the topically applied fluoride would be swallowed. Duraphat has the highest fluoride concentration (22,600 ppm) of all fluoride products; however, because the volume applied can be small (Roberts and Longhurst, 1987), the amount of fluoride ingestion has been reported to be no greater than when a lower concentration (12,300 ppm) fluoride gel is used (Ekstrand et al., 1980).

Fluoride varnishes have received scant attention in North America, with only one reported study of Canadian schoolchildren (Clark et al., 1985b,c). Additional studies of this method, in countries with both low and high caries prevalence, are indicated. However, the important consideration regarding fluoride varnishes is not whether they can be accepted as true caries-inhibitory agents, which has already been ascertained, but how they compare in clinical efficacy and cost/effectiveness with other established methods of caries control, such as fluoride gel-trays and fluoride rinses (Kirkegaard et al., 1986).

Fluoride prophylaxis pastes have been available for years, yet lack clinical substantiation of efficacy as caries-inhibitory agents. They should not be relied upon as vehicles for caries control in infrequent office or school-based programs. Evidence from studies that employed the so-called "Karlstad" model of frequent professional prophylaxis suggests that when a fluoride prophylaxis paste is professionally administered as often as once every two weeks, this vehicle may be effective in caries control (Ripa, 1985). However, the frequency of professional intervention makes this an impractical approach. It certainly could not be used in countries where funds and/or personnel for dental preventive programs are limited. Nonetheless, marketing of fluoride prophylaxis pastes is justified because they may replace fluoride abraded from the enamel surface during polishing. Hence, whenever a professional cleaning is indicated for plaque control or stain removal, a fluoride-containing prophylaxis paste should be used.

A sequential rinse method using APF and SnF_2 is being promoted for dental office use. Its advantage is its simplicity, whereby professional supervision replaces professional application. There is evidence of enamel fluoride uptake from this method, depending upon the particular rinse sequence or concentration of fluoride used (Crall et al., 1982; Crall and Bjerga, 1984). However, the relationship between enamel fluoride levels and clinical caries inhibition is not clear-cut, nor can laboratory studies substitute for the lack of clinical trials. Considering the positive laboratory studies, a controlled clinical trial comparing the relative caries inhibition from the sequential rinse method and a 0.2% neutral NaF rinse in a weekly school-based program would be of interest. However, because of the lack of clinical substantiation of this method, it should be shunned by dental practitioners and not used as a substitute for accepted methods of caries control in infrequent office-based caries-preventive programs.

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Discussion of Session V: Rational Use of Fluorides in Prevention and Therapy

Compiled by K.W. STEPHEN

Dr. Manji was asked by *Dr. Evans* whether he would explain what was implied by "caries without cavitation", and he answered that caries should be considered as a process rather than simply as an event at a particular stage, *i.e.*, a cavity requiring restoration. He reminded participants of the Dutch water fluoridation studies which showed that where diagnosis included enamel lesions, under those conditions, no differences were found between fluoridated and non-fluoridated areas. It was only when cavitation lesions were considered that major differences were evident. *Dr. Carlos* said that *à propos Dr. Manji's* caries diagnostic criteria, it was important to distinguish between descriptive or analytical studies of the kind under discussion, and clinical trials or experimental studies. In descriptive studies, much more conservative diagnostic criteria were employed, since potentially reversible enamel lesions were not diagnosed as carious. Evidence of frank cavitation was required for the diagnosis. There were two reasons for this, one being that from the public health standpoint, there was little interest in lesions which have no effect on a person in terms of requirements for treatment or restoration. He reminded the audience that a few years earlier, Silverstone had stated that when a "caries-free individual" was talked of, in fact, were diagnostic abilities sufficient, it would be found that such an individual had many pre-cavitational lesions approximally. However, epidemiologically it was of little concern if that person went through life without frank cavitation. The other reason was that much better diagnostic reproducibility could be obtained among multiple examiners when a more conservative criterion was employed.

Dr. Horowitz asked of *Dr. Carlos* what action was taken to correlate residence histories with caries prevalence in the U.S. fluoridated *vs.* non-fluoridated areas, since in many regions which were considered to be non-fluoridated, recent surveys had shown there to be fluoride pockets, particularly where individual water supplies were found. As a result, to an unmeasured extent, he stated that these existed within the recent U.S. national data; hence the differences between these two types of communities might be conservative. With these points, *Dr. Carlos* agreed.

Dr. Horowitz also asked *Dr. Manji* to comment on the fact that, for many years, the literature had been replete with reports of isolated populations who had excellent caries resistance until civilization arrived with its processed foods, candy, etc., ranging from Tristan da Cunhans to Eskimos. However, in the light of *Dr. Manji's* contention that caries was not declining, or not increasing in developing countries, was this because dietary practices had not deteriorated, or had there been implementation of preventive measures to overcome such dietary deterioration? To these points *Dr. Manji* stated he did not think caries was declining, but that he felt there was heterogeneity over the African continent. There were some places where caries was increasing, and some places where it was declining. There was also the impact of dietary changes, and these had been considerable. In Kenya, for example, *per capita* sugar consumption had increased two-fold since 1963, yet caries levels over that same period apparently had not followed, even given the non-comparability of much of the data. However, *Dr. Manji* could not provide an answer to *Dr. Horowitz* as to why caries should not increase in these situations and

asserted that detailed studies were required. On the same topic, *Dr. Stephen* observed that he had witnessed the opposite situation in the Middle East, where, in a relatively isolated Jordanian township, the 18-year-olds and 12-year-olds were virtually caries-free, while their 6-7-year-old siblings had more than 50% caries.

In response to a question from *Dr. Øgaard* regarding the fact that the U.S. national caries DMFS score could well correspond solely to fissure caries of the first and second molars, and that, since the effect of fluoride was mainly on smooth surfaces, would a further decline in caries prevalence actually be expected with present fluoride agents, *Dr. Carlos* observed that the answer was unknown. However, he said that in the U.S., smooth-surface caries was close to disappearing, and that such caries as still occurred was primarily on pit and fissure surfaces. Hence the reaction to these data had been to try to increase the use of pit and fissure surface prevention, *i.e.*, through the use of sealants. By so doing, the overall caries rate should come down, but whether the "point of no return" had been reached with fluoride, he did not know. However, he felt that to keep caries at the current level, fluoride exposure must be maintained.

Dr. Holloway stated that he was very concerned about the comparison which *Dr. Carlos* made between those children on lifelong fluoridation, and those who had had no fluoridation. *Dr. Holloway* thought that this was a wholly invalid comparison in the U.S., where 60% of the population was covered by a fluoridated water supply. There were so many factors that made these two populations incomparable that *Dr. Holloway* did not think it should be undertaken.

Dr. Whitford asked *Dr. Carlos* to comment on the fact that a 30% DMF reduction had been found between 1981 and the most recent U.S. study, although it was unlikely that exposure to fluoride had changed over the nine-year period. In addition, he enquired whether any comments could be made about fluorosis trends on the basis of the latest U.S. survey? In reply, *Dr. Carlos* said that the question as to why caries should continue to decline if fluoride exposure had not increased dramatically was an obvious one. As far as he was aware, the only thing which had increased in that time interval was the market share of fluoride dentifrices. However, he did not think anyone knew the answer to the question. He thought the data were very similar to those from other countries where the percentage of fluoride dentifrice in use had remained rather steady, yet caries was declining where there was no water fluoridation. As to the point about mottling, he stated that he recollected that there had been an increase in the "mild" and "very mild" forms of fluorosis as compared with data from small isolated studies, but there were no recent national figures. No alarming change in the "moderate" and "severe" fluorosis categories had emerged; hence there was no evidence from children to cause alarm. Nonetheless, he agreed that monitoring must be on a continuing basis.

Referring to a publication by Dr. Larsen, *Dr. O'Mullane* wished to draw attention to the fact that technical problems could be associated with water fluoridation in urban communities. In Ireland, such difficulties occurred 10 to 20 years previously, but the evidence was that these mainly had been overcome and that the equipment was now very sophisticated.

Dr. Stephen added that, since most large schemes now ran on liquid fluorosilicic acid, rather than powder, this had been a great improvement from a technical point of view.

Replying to these points, *Dr. Larsen* commented that his group had studied fluoride concentrations in water supplies over a period of years and had observed that they varied, both upward and downward, by as much as 50% either way.

In response to a question by *Dr. Rugg-Gunn* relating to the effect of pre- and post-eruptive fluoride at both the beginning and end of the Dutch fluoridation study, *Dr. Groeneveld* confirmed that on approximal surfaces, the results were comparable, as detailed in the manuscript. *Dr. Ingram* then enquired as to the Dutch diagnostic criteria for early enamel caries, and *Dr. Groeneveld* stated that, initially, the enamel lesion was diagnosed in two ways: first, as a white-spot lesion with a glossy appearance, and second, as a white-spot lesion with a rough appearance. However, as the study continued, five or six different categories were identified—*e.g.*, a glossy appearance that could be seen if the surface was wet but could not be seen when it was dried, etc.

Dr. Moss asked of *Dr. Thylstrup* why he assumed that pre-eruptive fluoride did not help the primary dentition, since tooth maturation had to have some effect on enamel lesion progression. Furthermore, in the primary dentition, a strong clinical impression existed that early enamel lesions progressed slower in teeth with pre-eruptive fluoride within the lesion. He thus expressed concern that *Dr. Thylstrup's* data were concerned only with the permanent dentition, a statement which was backed up by *Dr. Stephen*, who reinforced these anxieties regarding the desire simply to dismiss the deciduous dentition. He felt the attainment of caries-free status for 3-, 4-, and 5-year-olds was as important as for older children and expressed regret that few international data sets existed in relation to the status of deciduous dentitions.

Dr. Thylstrup replied that if topical fluorides or post-eruptive fluorides were available, caries would also progress more slowly in deciduous teeth, whereon *Dr. Moss* responded by stating that the data which *Dr. Carlos* presented could not be explained unless there was some pre-eruptive benefit. Thereafter, when *Dr. Stephen* enquired of *Dr. Thylstrup* whether there was any evidence that there was *not* a pre-eruptive effect in deciduous teeth, the latter agreed he knew of no such information.

Dr. Horowitz then congratulated *Dr. Groeneveld* on the elegant design of this study which did show the pre-eruptive effects of fluoride, as did *Dr. Marthaler's* analysis of the Grand Rapids' data. This also showed that children exposed to fluoridated water from birth fared much better than those who were exposed at year one, year two, or year three, even though all had topical exposure from the time of eruption. Other information from school water-fluoridation studies demonstrated that teeth which had both systemic and pre-eruptive effects of fluoride did better than teeth in children who started school at 6 years of age and already had their first molars erupting. Thus, there was a body of convincing evidence to show that pre-eruptive fluoride was of value with respect to the total caries-preventive effect.

Dr. Rugg-Gunn then stated that *Dr. Thylstrup* gave only one piece of evidence for the lack of a pre-eruptive effect. That was relating to a study of three communities in Denmark. Here, in one community which had a school-based topical fluoride program, caries came down to the same level as in the naturally fluoridated area. However, he said it was quite possible to reduce caries by several topical methods. For example, Englander showed an 80% reduction in caries using daily gel applications at school. However, that did not necessarily mean there was no systemic mechanism and, as a result, he asked *Dr. Thylstrup* if he knew of any other epidemiological evidence, since *Dr. Thylstrup's* own data did not show that there was an unimportant pre-eruptive effect. However, *Dr. Thylstrup* again provided no clinical information of the type sought by *Dr. Rugg-Gunn*.

Dr. Rugg-Gunn enquired of *Dr. Hargreaves* whether it was the dosage of dietary fluoride supplements which could be incorrect, and whether these should not be corrected rather than seek blanket condemnation of dietary supplement usage? *Dr. Hargreaves* replied that he thought this was an important question and that he had looked seriously at it when arriving at his recommendation. Beverage consumption studies in the U.K., which were typical of Europe, and his own studies in Canada were very similar, suggesting about 600 mL *per* day intake. Therefore, while he thought the dosage was wrong, he was more worried with respect to compliance, since this was very poor in these areas in which he had been involved, although much effort had been put into dispensing correct information. Thus there were three options to be considered—*i.e.*, either (1) reduce the dosage and confirm these supplement levels; (2) delay their introduction until the maturation stage was over to try to avoid severe fluorosis which might occur, or (3) stop their usage altogether, since there was now evidence about the widespread availability of dentifrices and the effects of daily, low, topical fluoride levels.

Dr. J. Clarkson then stated that he wished to clarify some of the data which *Dr. O'Mullane* produced on fluorosis in Ireland. When these figures had been analyzed, all subjects receiving fluoride supplements were excluded, and only 6% of children who had fluorosis according to Dean's Index were receiving fluoridated water alone. Hence, it did not seem that there was a problem with fluorosis in Ireland. However, since *Dr. Hargreaves* had mentioned that 53-56% of children receiving supplements had fluorosis, he wished to ask him to which index did these figures apply? *Dr. Hargreaves* responded that these data came from the T.F. index. There was a slightly lower level of involvement with the T.S.I.F. index (48-49%). However, he wished to emphasize that when clinical fluorosis was described with both indices, it was only apparent to the examiners at a very mild level and, apart from 8%, was of no consequence to most of the children and their parents.

Dr. Bawden stated that, in relation to supplement dosage schedules, he thought it should be considered that the dose may be too high at the three-year age level, rather than earlier, although it tended to be reduced at early ages. Nonetheless, Dr. Hargreaves showed no difference in fluorosis by commencing supplements early on, and, while the evidence was clear that fluorosis might occur by exposure only during the maturation phase, it was difficult to run an experiment to indicate that it could arise during the secretory phase. Furthermore, there were laboratory data to indicate that fluoride supplements could be given more safely during the first two years with less risk of fluorosis than might be obtained by ingestion at 2.5 years, or maybe three years of age. To this, *Dr. Hargreaves* agreed, since his findings confirmed that fluorosis' involvement was not occurring in the maturation stage, and he thought the other end of the dosage scale should be considered if doses were to be altered.

With respect to salt fluoridation, *Dr. Whitford* said that he was concerned about a remark which *Dr. Horowitz* had made regarding salt being used less frequently during the day, which might mitigate against it as a fluoride-delivery vehicle. However, clinical studies all showed that salt fluoridation was as effective as water fluoridation in reducing caries; hence, actual frequency might not be too important. Second, with regard to the introduction of low-concentration fluoride dentifrices, in

the U.S. there would be a problem if this was attempted, since the F.D.A. would require a New Drug Application, which could cost millions of dollars, and he felt that talks ought to be held about the rationale.

In response, *Dr. Horowitz* stated that he agreed that salt was as suitable a vehicle for fluoride as was water, although there were very few salt fluoridation clinical studies. His worry related to the fact that frequency of fluoride application was known to be extremely important in remineralization, and he thought that the consumption of water and foods was likely to be a more frequent source of ambient fluoride than was the eating of salted food. During this discussion, *Dr. Iragoyem* stated that, in Mexico, salt fluoridation was chosen in preference to water fluoridation for several reasons, in spite of the fact that their urban population was larger than their rural population. This was because salt fluoridation was much easier to deliver under Mexican conditions, since there were approximately 1000 water wells in operation. Hence, it would be very difficult for Mexico to keep track of the fluoride in each of these water sources. In addition, some of these areas already had more than 0.3-0.4 ppm F in their water supplies. Furthermore, with fluoridated salt, a lower fluorosis rate had been produced in upper anterior teeth than had been found in children who received fluoride from other sources, such as mouth-rinsing, etc. However, *Dr. Horowitz* enquired whether he would be correct in assuming that *Dr. Iragoyem* could only state that she *thought* there was less fluorosis since, at present, no surveys relating to this matter had actually been carried out? In response, *Dr. Iragoyem* stated that *Dr. Horowitz* was correct with this assumption, since the basis for her statement related to long-term findings from Switzerland.

Dr. Caslavska made the observation that, 10 years ago, biopsies taken from incisors which were treated semi-annually with ammonium fluoride and sodium fluoride indicated that substantial quantities of calcium fluoride were found still to be present in teeth of the ammonium-fluoride-treated group 18 months later. She then asked of *Dr. Mellberg*, in view of his statement on the effect of viscosity, if he would speculate whether toothbrushing with a mouthrinse solution (which would contain a low concentration of fluoride and possibly a suitable surfactant) would be a good system of fluoride delivery. To this point, *Dr. Mellberg* replied by stating that he did not see any disadvantage to using an F^--containing solution as long as the fluoride could be guaranteed distribution around the mouth.

Dr. Rølla was then asked by *Dr. Caslavska* if he had also applied topical fluoride solution at pH 1.9 to shark teeth and, if so, was there any effect on demineralization? To this point, *Dr. Rølla* replied in the affirmative but that the topical fluoride application had no effect. His interpretation of these data was that to have such a marked effect *via* calcium fluoride would demand the presence of a continuous layer, such as is obtained on human enamel, and from which calcium ions are fairly easily available. In relation to shark's teeth, there appear to be more scattered deposits of calcium-fluoride-like material.

Dr. Rølla was also asked by *Dr. Chow* about the point he had made that pH may have an important effect where calcium fluoride is involved. Was that because the surface area was smaller or because more was formed? The question was prompted by data which *Dr. Chow* had presented at the 1989 San Francisco AADR meeting on the dissolution of calcium fluoride under constant-composition conditions, where he had tried to dissolve calcium-fluoride-compressed pellets and compare the rates of dissolution with those of calcium fluoride formed on tooth surfaces by APF gel treatment. Here, with the calcium fluoride pellets, dissolution slowed down progressively until it eventually stopped in the saliva-like conditions.

However, with the calcium fluoride formed on the tooth surface, dissolution also slowed down, but, primarily because calcium fluoride was lost, the $t_{1/2}$ was 3-4 h. It therefore seemed that there was a lot of calcium fluoride present and possibly before it had all gone, a protective coating could be formed. On the other hand, perhaps it would be dissolved before the coating could be formed. In reply, *Dr. Rølla* stated that the surface area of a low-pH fluoride product is much larger than those obtained at neutral pH, so that could not be a factor. His interpretation was that the amount of phosphate was much lower; hence, it was much closer to the pure chemical. He then cited some of their work over the previous 10-year period, where *Dr. Øgaard* had treated premolars, which were going to be extracted, with 2% sodium fluoride. After extraction, the presence of alkali-soluble fluoride was measured. They had also presented data where calcium fluoride was produced on pieces of enamel and placed in the mouth, after which they showed that some was lost at the beginning, but the study ran for up to eight days. However, according to the current hypothesis that calcium fluoride is as soluble in saliva as in water, he said they should have lost several hundred times the amount which actually disappeared. Hence, he stated, the point raised was of interest but, in the mouth, there was still so much phosphate that even this dissolution of calcium fluoride on the teeth could be arrested. Furthermore, it has also been shown that protein has to be taken into account, since albumin inhibits dissolution. Thus, he concluded that the principle works in the mouth and that his group had shown it in many systems.

Dr. LeGeros stated that she was happy to inform *Dr. Rølla* that *in vitro* work confirmed what he found *in vivo*. Concentration, pH, and time all affected the formation of calcium fluoride. However, for calcium fluoride to form, a high level of fluoride has to be available, and for that to be clinically relevant, was there not cause for concern about possible toxicological levels such as those to which *Dr. Whitford* had referred? In response, *Dr. Rølla* stated that 15 mg of calcium fluoride would dissolve in 1 liter of water. However, with 7 ppm of fluoride and 8 ppm of calcium, the system would be saturated. As a result, with 40 or maybe even 80 ppm calcium in saliva, and 1000 ppm fluoride available from a mouthrinse, he was certain that during the rinsing period there would be saturation for calcium fluoride formation. Also, with regard to toothpaste, if 1 mg was placed into the volume of saliva of which *Dr. Dawes* talked earlier, then the saliva would definitely be saturated as well.

Dr. Ericsson stated that he wished to emphasize a point on which *Dr. Mellberg* had touched, *i.e.*, that even with very thorough brushing, it must be assumed that some plaque would remain, particularly in the fissures and interproximal areas. Hence, fluoride uptake in the remaining plaque may be as important as, or perhaps even more important than, fluoride uptake by surface enamel. Hence, fluoride diffusion into plaque and the binding of fluoride to the plaque, particularly the calcium phosphate particles, might be of great importance. In reply, *Dr. Mellberg* agreed with *Dr. Ericsson's* thoughts that fluoride must be made available to those remaining plaque-covered areas and be kept there in high enough concentration so that it was available when required. There was little evidence that it was required during actual brushing, but it was certainly going to be needed several hours later.

Dr. Rølla then commented that, as was discussed earlier in the Symposium, the conditions for calcium fluoride formation in plaque were present, and that the product behaved like calcium fluoride, *i.e.*, it had to be dissolved in perchloric acid. Certainly, one experiment which he had carried out with salivary sediment had shown that calcium fluoride could form there.

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Dr. ten Cate then addressed *Dr. Mellberg* and reminded the audience that *Dr. Mellberg* had suggested that more attention should be given to *in situ* models to assist with the prediction of topical fluoride effects. However, while agreeing with these sentiments, he was concerned as to what would be the best design of such a system, since many existed at present. In particular, the time during which *in situ* studies were carried out tended to be short. Furthermore, lesions which were commonly placed in the mouth were very reactive, and whatever could be determined in a one-week intra-oral period did not necessarily reflect the long-term treatment effects. In addition, many *in situ* models used frequent sucrose challenges which did not reflect the natural situation. Hence, he agreed with *Dr. Mellberg's* recommendation and suggested that there was need for a consensus as to what constituted the best model system.

Replying, *Dr. Mellberg* stated that he thought a mini-conference on *in situ* models might be appropriate. Nonetheless, he did not believe the time-frame need be long, because, even though lesions which were not quite the same as natural lesions were used, what was being demonstrated was whether a remineralizing environment or a demineralizing environment was present or not. Beyond that, he felt it was of less importance because, if a remineralizing environment was developed, then little problem would exist. Thus, regardless of the type of lesion, or for how long it was going to be exposed to a treatment, he felt that these points were irrelevant, as long as it could be shown that a remineralizing system existed. Nonetheless, he did not like to compare "Study A" with "Study B" as far as percentage remineralization, etc., was concerned. He felt that percentage numbers were all relative and should only be looked at within any one experiment.

Finally, *Dr. Thylstrup* commented on *Dr. Mellberg's* data where it was stated that caries reductions of around 20% were to be found in different clinical trials. However, *Dr. Thylstrup* thought it was important to underline that such results came from short-term studies and, had these been initiated at the time of tooth eruption, then reductions similar to (or even greater than) those obtained by a long-term administration, *e.g.*, as of water fluoridation, could be obtained.

Note: Due to technical failure of the recording device, the remaining parts of the Discussion of this Session regretfully cannot be reproduced. The organizers and Editors of these Proceedings apologize for this unfortunate circumstance.