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Fluoride in toothpastes for children: suggestion for change

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Abstract

Fluoridated toothpastes were designed to produce a topical caries-preventive effect. Many studies have shown their effectiveness. Recently, researchers have expressed concern that fluorosis may be increasing in the American population. There is speculation that fluoride (F) from fluoridated toothpastes might be a contributing factor when the toothpaste is accidentally swallowed by small children. The objective of this paper is to evaluate the clinical and epidemiological evidence in regard to the relationship between the swallowed fluoride from toothpaste and the presence of fluorosis.

In regard to the epidemiological evidence, the reports in the literature show only a slight increase in the fluorosis index in communities that use fluoridated toothpastes with one or more type of systemic fluoride. However, these are limited, not excluding studies.

The concentration of F in most toothpastes, 1000 ppm, is a "best estimate", empirically derived rather than based on precise scientific study.

The clinical studies concerning ingestion of toothpaste showed that children are ingesting between 0.12 and 0.38 mg of toothpaste per brushing, which represents 0.12-0.38 mg F for the 1.0 mg F/g toothpastes. Children younger than 3 years of age may be ingesting high levels of fluoride from toothpastes. It was clear that the risk of fluorosis increases when children receive systemic fluoride simultaneously from different sources.

It is concluded that small children may accidentally swallow enough fluoride to reach levels considered adequate for the development of fluorosis. Two approaches are recommended to reduce the hazard of fluorosis from ingested toothpastes: (1) manufacture of low-concentration toothpastes for children's use; or (2) encourage parents to supervise children's toothbrushing using a small amount of toothpaste.

It is generally accepted that the presence of fluoride (F) in the enamel, dental plaque, and saliva helps protect teeth against carious attack. At the same time, there is some concern that fluorosis may be increasing in American children as a result of ingestion of excessive amounts of F from a number of sources, during the dentition's formative years. One potential source of swallowed F is fluoridated toothpaste.

In many developed countries, F-containing toothpastes comprise 80-95% of all dentifrice sales (Dowell 1981; Horowitz 1984). In the United States, the American Dental Association publication, *A Guide to the Use of Fluorides*, recommends the use of F dentifrices as soon as the first primary teeth erupt (ADA 1986).

The objective of this paper is to evaluate the evidence for a relationship between the swallowed F from toothpaste and its potential effect on dental fluorosis.

Evidence of Fluorosis

Although recent reviews (Heifetz and Horowitz 1986; Szpunar and Burt 1987) have stressed the lack of clear epidemiologic evidence showing an increase in the prevalence of fluorosis, some reports have pointed out the risk of fluorosis under simultaneous exposure of F from multiple sources (Rozier and Dudney 1981; Ericsson and Ribelius 1971) including fluoridated dentifrices (Ekstrand and Ehrnebo 1980). However, very few controlled studies have addressed the issue of dentifrices and fluorosis (Houwink and Wagg 1979; Holm and Anderson 1982).

Ingestion and Retention of F Through Toothpastes

The literature shows indirect support for an F toothpaste-fluorosis relationship. These studies analyze the oral hygiene habits, amount of toothpaste used, and the amount of toothpaste ingested by infants and children. These data can be used to calculate with a certain degree of confidence the daily intake of F from toothpastes. It is also possible to calculate the amount of F received from combined therapies.

Surveyed mothers reported children brushing with toothpaste, starting as young as 12 months, and swallowing or even eating toothpaste directly from the tube (Blinkhorn 1978; Dowell 1981).

The ingestion of toothpastes during toothbrushing is measured primarily by two methods: using a marker which is recovered from urine or feces (Barnhart et al. 1974); or subtracting the amount of toothpaste recovered from the amount provided ([gravimetric] Hargreaves et al. 1972). The marker method tends to underestimate the amount ingested if samples are not collected carefully and portends difficulties in the determination of the tracer excreted (Barnhart et al. 1974). On the other hand, the gravimetric approach tends to overestimate the values because any loss of toothpaste is recorded as being ingested (Baxter 1980). The "true" value probably lies between the values obtained by the two methods (Hargreaves et al. 1972).

A review of the reports on ingestion of toothpaste shows considerable variation in the amount of toothpaste ingested (Ericsson and Forsman 1969; Hargreaves et al. 1970, 1972; Naylor et al. 1971; Barnhart et al. 1974; Glass et al. 1975; Baxter 1980). Results may be conflicting due to the different ages and methods used. What appears to be a consistent pattern is the ingestion of higher amounts of F at lower ages.

Some of these studies have pointed out inter- and intrasubject changing patterns in brushing behavior (Baxter 1980; Hargreaves et al. 1970, 1972; Naylor et al. 1971). In addition, there appears to be no correlation between the amount of toothpaste taken and the amount swallowed (Hargreaves et al. 1972). Several factors may influence the amount of dentifrice used and the amount retained; these include the length of the toothbrush head, the diameter of the orifice of the tube (Glass et al. 1975), the pleasant flavor of the dentifrices (Baxter 1980), and most importantly, the ability of the child to avoid swallowing.

Amount of Fluoride Swallowed from Toothpaste

It is necessary to question whether the quantity of F obtained from toothpaste could be large enough to be a risk factor for fluorosis. Due to the variability of the data on dentifrice ingestion, minimum and maximum values of ingested toothpaste were selected from the reports in the literature. The selected values were: 0.12 (Ericsson and Forsman 1969) and 0.38 g (Hargreaves et al. 1972) of toothpaste/brushing which represent 0.12-0.38 mg of F per brushing for the 1 mg F/g toothpaste formulations (Table 1).

Total Amount of Fluoride Ingested

The comparison of these theoretical values with the "optimal" levels of F (0.022 mg/kg) between birth and 6 years reported by Galagan et al. (1957, Table 2) indicates that children who brush their teeth once a day with a fluoridated toothpaste might be ingesting optimal amounts of F if they follow the described pattern of swallowing. Children who brush two or three times per day clearly exceed these values. It is also clear that children who either live in a community with fluoridated drinking water or who receive dietary F supplements, and/or simultaneously ingest F from other sources, are ingesting amounts of F that exceed Galagan's optimal level. For example, Table 3 reports the theoretical values for combined exposure to F toothpastes and dietary F supplements under current recommendations. Interestingly, the total amount of F exposure in this table attains and surpasses the values which were reported by Aasenden and Peebles (1978) as causing fluorosis.

It is important to note that not all the F ingested by fluoridated toothpastes is absorbed (Glass et al. 1975). Although minimal interference between dentifrice and abrasives is currently accepted (Forward 1980), it is impossible to estimate to what extent the type of abrasive and the food already in the digestive tract affect F absorption.

Discussion

The objective of any F preventive therapy is to attain the maximum anticaries benefit with minimum risk of fluorosis. For therapeutic purposes, it would be helpful to have reliable information concerning the amount of F a child needs for a given age or body weight (maximum effect). Unfortunately, this is not possible because of our incomplete understanding of the cariostatic mechanisms of F, and the many sources of F to which the individual is exposed. On the other hand, there is no sharp threshold for fluorosis (minimum risk), and some degree of fluorosis is considered esthetic or acceptable. Clearly, our objective to attain maximum effect with

TABLE 1. Theoretical Range of Fluoride Ingested from Toothpaste[a]

	Number of Toothbrushings per Day		
	One	*Two*	*Three*
Amount fluoride	0.12 – 0.38[b]	0.24 – 0.76	0.36 – 1.14

[a] In mgs of fluoride.
[b] From Ericsson and Forsman 1969 and Hargreaves et al. 1972, respectively.

TABLE 2. Theoretical Optimal Amount of Fluoride[a]

Age	*Weight*[b]	*Optimum Level of Fluoride*[c]
0-2	3.4-12.3	0.07-0.27
2-3	12.3-13.4	0.27-0.29
3-6	13.4-21.1	0.29-0.46

[a] Modified from Infante (1975) based on 0.022 mg/kg.
[b] Mean weight in Kg for each age limit.
[c] In mgs of fluoride.

TABLE 3. **Theoretical Range of Children's Fluoride Exposure**[a]

	Number of Toothbrushings per Day			
	mgF[b]	*One*	*Two*	*Three*
0-2	0.25	0.37 – 0.63	0.49 – 1.01	0.61 – 1.39
2-3	0.50	0.62 – 0.88	0.74 – 1.26	0.88 – 1.64
3-14	1.00	1.12 – 1.38	1.24 – 1.76	1.36 – 2.14

[a] Based on the theoretical amount of fluoride ingested from toothpaste plus maximal dosage of daily fluoride supplements for 0.3 ppm F in the water supply.

[b] According to the schedule recommended by the American Dental Association (1984) and the American Academy of Pediatrics (1986).

minimum risk is confronted with these inherent problems.

Fluoridated toothpastes were designed to produce a topical caries preventive effect. The efficacy of F dentifrices has been demonstrated in many studies; two excellent reviews include those of DePaola (1983) and Volpe (1982). The F concentration of American toothpastes was established to provide 1.0 mg F for each toothbrushing (American Dental Association 1986). Higher F formulations are not necessarily associated with increased benefit (Ripa et al. 1987).

The present analysis shows that young children may be receiving amounts of F large enough to be considered a risk for developing fluorosis specifically through the accidental swallowing of fluoridated toothpaste. Many researchers have expressed concern in this regard (Forsman and Ericsson 1973; Glass et al. 1975; Houwink and Wagg 1979; Ekstrand and Ehrnebo 1980; Dowell 1981; Feigal 1983; Horowitz 1984). Theoretical values indicate that even if toothpaste is the only source of F, children younger than 3 years of age still may be ingesting high levels of F from the dentifrice, depending on the pattern of swallowing and brushing. It is also clear that the risk of fluorosis increases when children receive F simultaneously from different sources. Yet, these values are based on assumptions that the behavior of children in toothpaste studies can be generalized and that the entire amount of F ingested is retained. These assumptions may not be entirely valid.

The following policy recommendations are proposed:

1. Compound fluoridated toothpaste with a lower F content, package it in a box and tube color-coded and with the label "for children's use only." A potential drawback is the possibility of reduced fluoridated toothpaste efficacy as shown by Forsman (1974) and Mitropoulus et al. (1984).
2. Direct parental toothbrushing instruction and/or supervision. The use of a very small amount of toothpaste should be stressed. This alternative has been recommended by many researchers (Horowitz 1984). Moreover, Feigal (1983) and Ericsson and Forsman (1969) propose toothbrushing with a fluoridated toothpaste only once a day. The recommendation to use nonfluoridated toothpaste for the second or third toothbrushing (Feigal 1983) does not appear practical.

Although these alternatives have been proposed for children who are exposed to optimally fluoridated water or dietary supplements, the evidence supports the extension of the recommendation for children receiving F from toothpaste only.

It is recognized that small children may accidentally swallow large enough amounts of fluoridated toothpastes to produce levels of F consumption associated with an increased risk of developing fluorosis. To avoid this hazard, the manufacture of low F concentration toothpastes, and parental instruction and supervision of children's toothbrushing, using a small amount of toothpaste, are recommended. It is interesting to note that, contrary to these recommendations and the current interest in fluorosis, a fluoridated toothpaste that claims increased benefit recently has been introduced in the market. This toothpaste contain 1.5 mg F/g, an increase of 50% over the actual ADA-recommended concentration (ADA 1984). The amount of F ingested by children would be increased by 50% if these dentifrices are used with the pattern described in this review.

Finally, more research is necessary in the area of absorption of F from toothpastes, and in the epidemiology of fluorosis in populations receiving fluoridated toothpastes alone or combined with other sources of F.

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Advertising dentists increase

Almost half of dentists participating in a recent survey are using some sort of advertising to promote their practices to the public. The numbers of advertising dentists increased from similar studies reported in the past.

Dentists new to practice are advertising more than established dentists. Two-thirds of the surveyed dentists who have been in practice fewer than 5 years reported they use some form of advertising, compared with half the dentists in practice 5-14 years; 32% of dentists in practice 15-24 years; and 30% of dentists who have been practicing 25 years or more.

The most popular form of promotion was advertising in the Yellow Pages.® Other methods mentioned by survey respondents include: direct mail to attract new patients, newspaper ads, Welcome Wagon, and coupons. Only 1% said they advertise their practices on radio or TV.