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Fluorosis and Caries Experience Following Early Post-Natal Fluoride Supplementation: A Report of 19 Cases

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Abstract

Fluorosis and Caries Experience Following Early Post-Natal Fluoride Supplementation: A Report of 19 Cases.

A study of 19 cases of early post-natal supplementation at levels of 0.5 and 1.0 mg of fluoride per day has shown a greater prevalence and severity of very mild fluorosis among those also consuming optimally fluoridated water. Fluorosis was less prevalent among those consuming suboptimally fluoridated water. The authors support the current dosage recommendations of the Council of Dental Theraputics of the American Dental Association, following determination of the fluoride content of the water supply regularly consumed by the child. Pedodontists using these recommendations for their patients are encouraged to report the subsequent dental status of their patients in order that a pool of clinical data may be developed and the efficacy and safety of the recommendations thereby be established.

Introduction

Over the past decade, concerns have been raised that fluorosis of the anterior permanent teeth may be due to the consumption of higher than expected amounts of fluoride by infants and small children from sources such as commercially prepared infant foods and formulas, and from prescribed fluoride supplements.[1,2] The crowns of the permanent incisors calcify during the usual period of consumption of these items.[3]

The concerns have been based upon recent reports of widely ranging fluoride contents of processed baby foods which appear largely dependent on the method of processing.[4,5] It was concluded that the total daily fluoride intake of infants up to six months of age may be significantly higher than the total intake of regarded as optimum.[6] In contrast to fresh cow's milk and human milk which are both low in fluoride, infant formulas in the past may have contained five to twenty times the fluoride concentration.[7-9] The fluoride contents of the formulas may reflect the water fluoride levels where the products were manufactured,[10] and may increase even further in fluoride content when reconstituted with fluoridated water.[11]

Estimates of daily fluoride intake have revealed that infants being fed commercial formulas in the past may have received two to three times in excess of recommended optimum intake.[11] Observations such as these suggest that the previous recommendations for fluoride supplementation may have been greater than desirable since potential dietary sources of fluoride were not taken into consideration.

Dose Schedules for Fluoride Supplementation

The earliest consideration of fluoride supplementation was that of McClure in 1943[12] who recommended "... 0.5 to 1 mg of fluoride daily present in the average diet from the first to the eighth year of life ...".

In 1960, Arnold, McClure and White[13] developed a prescription regimen based upon 1 mgF/day from birth to three years of age which was later modified by Nikiforuk and Fraser[14] to include consideration of the fluoride content of the water and the age of the child. For children consuming water containing 0 - 0.25 ppmF, a dose of 0.25 mgF/day was prescribed from birth to 12 months, increasing to 0.5 mg to age four

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years, 0.75 mg to age eight years and 1 mg thereafter. A water level of 0.25 - 0.5 ppmF required no supplementation before 12 months when 0.25 mgF/day was commenced, increasing to 0.5 mgF/day at four years and 0.75 mg at eight years. A water level of 0.5 - 0.75 ppmF required 0.25 mgF/day supplementation commencing only at age four years, increasing thereafter to 0.5 mg at eight years. No supplementation was prescribed in areas of 0.75 ppmF and above.[14]

Recognition of the potentially high amounts of fluoride that could be ingested by infants from additional dietary sources led Fomon and Wei in 1976[15] to recommend reduction in these dosages. Their schedule recommended no supplementation during the first six months of life, a maximum dose of 0.25 mgF/day between six and 18 months, 0.5 mgF/day between 18 and 36 months and 0.75 mgF/day between three and six years of age.

Since then, the major manufacturers of infant foods and formulas have initiated steps to reduce the fluoride content of these products[16] and the schedule of the Council on Dental Therapeutics of the American Dental Association,[17] based upon both the age of the child and the fluoride level of water consumed, is now generally considered more appropriate and has the support of the American Academy of Pedodontics and the American Academy of Pediatrics (Table I).

Table 1. Current fluoride dosage recommendations (approved by the Council on Dental Therapeutics of the American Dental Association, 1976)[17]

Fluoride Content of Drinking Water (ppm)	Daily dosage (mgF/day)		
	birth to age 2 years	age 2-3 years	age 3-14 years
less than 0.3	0.25	0.50	1.00
0.3 - 0.7	0	0.25	0.50
over 0.7	fluoride dietary supplements unnecessary		

Current recommendations of the Swedish Board of Health and Social Affairs prescribe no supplementation prior to six months when 0.25 mgF/day is commenced, increasing to 0.5 mgF/day at 18 months.[2] The schedule of the Swiss Health Authorities has a dose of 0.25 mgF/day from birth to 24 months when the dose increases to 0.5 mg.[2]

Post Natal Supplementation and Fluorosis

To date, the literature contains few reports of studies of fluorosis occurring subsequent to the regular post natal consumption of fluoride supplements in either suboptimally or optimally fluoridated communities. In part, this is related to the difficulty of establishing retrospectively the doses of fluoride consumed.

Aasenden and Peebles[18] described fluorosis of anterior permanent teeth occuring at levels of fluoride supplementation of 0.5 mgF/day from birth to age three years and 1 mgF/day from three to about 12 years in a non-fluoridated community. Mild to very mild fluorosis was seen in 67% of the children and 14% of these showed moderate fluorosis. Interestingly, in a follow-up study of a group of the same children, a significant reduction in severity of the fluorosis was reported and attributed to continued mineralization or abrasion.[19] These authors recommended reducing the dosage.

Similar observations of mild fluorosis were made in Switzerland[20] where children received a supplement of 0.5 mgF/day from birth to age four years and 1 mg thereafter, and in Sweden[21] following a fluoride-vitamin supplement containing 0.5 mgF/day for the first seven years of life.

In a community with a water supply containing 0.7 ppmF, Hennon, Stookey and Beiswanger[22] reported very mild fluorosis among seven-year-old children who had received sodium fluoride-vitamin preparation daily since an average age of six to seven months. This was significantly higher than among a control group but lower than that reported by Aasenden and Peebles.[18]

Reduction of dosages to 0.25 mgF/day appears effective in minimizing mild fluorosis. At this dosage, Swedish workers found no significant difference in the prevalence of fluorosis between test and control children.[23] More recently, Driscoll and Horowitz[24] surveyed clinical studies employing the recommendations of the American Dental Association,[17] and reported no "objectionable" dental fluorosis.

Methods and Materials

In the course of a larger study of very mildly fluorosed dentitions,[25] the authors were able to examine 19 children (aged eight years to 12 years, eight months), with mixed dentitions, for whom detailed histories of post-natal fluoride supplementation were available. In all cases the parents could recall clearly, or had records of who prescribed the supplement, the brand name and dosages of the supplement, and if any changes had occurred.

No child had a history of pre-natal fluoride supplementation and none had a history of congenital or acquired disease recognized as affecting tooth formation or mineralization. Reliable information was avail-

able on their pattern of feeding (breast, bottle, and commercial baby foods) during infancy and their exposure to optimally or suboptimally fluoridated water. The reliability of the histories was based upon demonstrated internal consistency on the questionnaire, verification of responses by the examiner, and, in some instances, long term personal knowledge of the particular family. The dentition of each child was examined for fluorosis and dental caries in the Pedodontic Clinic of the University of Minnesota School of Dentistry and the present report describes the findings.

The History Questionnaire

Using a recall questionnaire* administered by one author (JLW), information was obtained for each child's pre- and post-natal developmental and medical history, history of post-natal fluoride supplementation, and the places and periods of residence since birth (to verify the consumption of fluoridated water). Also obtained was the history of feeding patterns during infancy (breast and/or bottle feeding, milk or formula, length of feeding pattern) and age at which commercial baby foods (jarred or canned products) were no longer used.

History of Fluoridated Water

For each child, the history of consuming optimally or suboptimally fluoridated water at each place of residence was verified using national and state lists of water supplies.[26,27] In cases where the fluoride content of a community water supply was not available from these sources, direct inquiry was made to the specific water supply authority. The classification of fluoride content of the community water supply as optimal or suboptimal was based upon average annual maximum daily air temperatures according to the definitions of the U.S. Fluoridation Census.[26]

A history of consumption of optimally fluoridated water was defined as continuous use of that water from birth until at least age five years. A history of suboptimally fluoridated water was the continuous or intermittent consumption of that water from birth until at least age five years. The limit of five years was selected since the crowns of the maxillary and mandibular central and lateral incisors are completely calcified by that time.[3]

Differential Diagnosis of Fluorosis

In order to establish the diagnosis and to differentiate fluorosis from other enamel defects, the following definitions were used.

The differential diagnosis of fluorosis used was that of Russell.[28] Very mild fluorosis was described as symmetrical small spots or minute, lacy, horizontal lines generally following the incremental lines of enamel development and imperceptibly demarcated from surrounding normal enamel and of a "paper white" color. The incisal or occlusal half of antimere teeth was usually affected with a frosted appearance. The enamel was smooth to an explorer.

Non-hereditary hypoplasia was defined after Russell[28] as a localized, circumscribed pitting, furrowing or absence of enamel which may or may not be associated also with hypomineralization. Non-fluorotic surface enamel defects or hypomineralization defects were asymmetrical round or oval lesions clearly differentiated from adjacent normal enamel and often creamy yellow or brown in color on normally contoured enamel surfaces.[28]

Classification of Fluorosis

The extent of fluorosis for individual dentitions was determined after Moller[29] from his continuum of descriptions and indices assigned as follows: normal or optimal = 0; questionable = 0.25; very mild = 0.5 or 1.0; mild = 1.5 or 2.0; moderate = 2.5 or 3.0; severe = 3.5 or 4.0. The photographs of indexed enamel fluorosis of McClure,[30] as well as the diagnostic and scoring criteria of Moller,[29] were kept at the chairside for confirmation at all examinations.

Fluorosis was scored using the facial surfaces of all erupted maxillary and mandibular central and lateral incisors and cuspids and first permanent molars. For all dentitions an individual score was given to each tooth, and the most severe of these scores became the child's fluorosis index. Ten of the dentitions were re-examined to assess examiner reproducibility; this was determined to be 95%.

Examination for Caries

Each dentition received a visual and tactile examination by one of the authors (JLW) using a chair-mounted dental light* with the child seated in a dental chair in the dental clinic. Pit and fissure caries was defined after Davies and Cadell[31] as an obvious macroscopic lesion in which the explorer point penetrated the enamel. An early carious lesion was characterized by a brown stain with a chalky margin when the tooth was dried; the explorer point+ caught and resisted withdrawal or demonstrated palpable softness. Interproximal lesions, defined after Davies and Cadell,[31] were detected using current intraoral radiographs, a lighted viewbox, and a hand-held magnifying glass, and were interpreted by the same examiner (JLW). An obvious lesion was characterized by a radiolucent area involving dentin, and an initial lesion characterized by a "V" or "U" shaped radiolucent

*Copies available on request from the author.

*Pelton Crane Co., Charlotte, N. Carolina, 28203.

+No. 5DE, Hue Friedy Manufacturing Co., Inc., Chicago, Illinois, 60618.

area in the enamel.

Ten of the dentitions were re-examined after Davies, Kruger and Homan[32] to assess examiner reproducibility. This was determined to be 83% (i.e., 83% of the children were scored similarly on both occasions). This approach is more precise than assessing the percentage of individual surfaces scored the same on two different occasions.

The sum of the carious, extracted and restored primary tooth surfaces was computed for each child as the defs score, and the defs index was computed by dividing the total number of carious, extracted or restored surfaces by the total number of available surfaces. A single tooth was considered to have five surfaces; a stainless steel crown or an extracted tooth was scored as three involved surfaces.

The Student's t-test for unpaired data was used to compare the mean defs indices and mean fluorosis indices for various subgroups of the subjects, and significance was tested at the 0.05 level.

Results

History of Fluoride Supplementation

On the basis of the time of commencing the fluoride supplement and their history of exposure to optimally fluoridated water, the children were divided into two groups: Group I: those beginning supplementation between birth and three months of age (Table 2), and Group II: those commencing supplementation between 18 and 36 months of age (Table 3). Group I contained 12 subjects (six males and six females), and of these, seven had a history of consuming optimally fluoridated water. Group II contained seven children (four males and three females), and of these, two had a history of consuming optimally fluoridated water.

The fluoride supplements had been prescribed variously as follows: by pediatricians to eight children, family physicians to four, family dentists to four, and by pedodontists to three children. The prescription was for fluoride vitamins (as either drops or tablets) for 14 children and as sodium fluoride (drops or tablets) for five children (Tables 2 and 3).

Tables 2 and 3 show the period of fluoride supplementation for each subject. For Group I, this ranged from four to 132 months (mean 26.7 mo. ± 35.1 SD), and for Group II from 12 to 84 months (mean 39.4 mo. ± 31.5 SD).

The birthdays for all children studied were between 1964 and 1969. Based on formulations and dosages described by the parents and the then current pharmaceutical recommendations, all children in Group II, and 10 of those in Group I, probably received 1 mgF/day. The exceptions were subjects K and L, for whom doses of 0.5 mgF/day were verified.

Infant Feeding Patterns

The majority of children in Group I, and all of those in Group II, had been breast fed for short time periods, ranging from one and one-half to four months (Tables 2 and 3). Thereafter, all had been bottle-fed, the majority for at least nine months. Since most children had received both milk and formula in the bottle at different times, the predominant fluid only was recorded. All children had been fed commercial baby foods and most consumed these for approximately one year.

Table 2. Fluorosis and caries experience of children who received fluoride supplementation commencing between birth and 3 months of age (Group I, N = 12; 6 males, 6 females).

Water Hist.	Subj. code	Age at exam (mo)	Fluoride Supplement begun at (mo)	form	total time	Feeding Pattern breast (mo)	bottle (mo)	comm.fd.[a] (mo)	Fluor. Index[b]	Caries (Prim teeth) defs	no. teeth	defs index	Caries (Permt teeth) DEFS	no. teeth	DEFS index
Optimal F	A	98	birth	FV[c]	4	4	8(m)[e]	12	0.50	0	12	0	0	12	0
	B	103	birth	FV	24	0	15(m)	18	0.50	10	12	0.17	0	12	0
	C	104	birth	FV	9	0	6(f)[f]	12	0.25	15	10	0.30	3	12	0.05
	D	120	birth	FV	4	4	8(m)	12	0.50	0	12	0	0	12	0
	E	127	birth	FV	12	1.5	18(m)	10	0	4	12	0.07	5	12	0.08
	F	130	birth	FV	10	0	12(f)	12	0.50	0	12	0	0	12	0
	G	134	birth	FV	12	1.5	9(f)	12	0.50	2	12	0.03	6	12	0.10
Sub-Optimal F	H	126	birth	FV	24	4	4(f)	3	0.25	6	12	0.10	2	12	0.03
	I	132	birth	NaF[d]	132	2	12(m)	12	1.00	0	0	0	4	28	0.03
	J	145	birth	FV	24	2	8(f)	4	0	0	8	0	0	16	0
	K	152	3	FV	21	3	12(f)	9	0	19	12	0.32	6	12	0.10
	L	152	3	FV	45	3	9(f)	9	0	9	4	0.45	4	20	0.04

[a]age at which commercial baby foods no longer used
[b]Fluorosis index: Moller[29]
[c]fluoride vitamins (drops or tablets)
[d]sodium fluoride (drops or tablets)
[e]bottle-fed with cow's milk
[f]bottle-fed with infant formula

Table 3. Fluorosis and caries experience of children who received fluoride supplementation commencing between 18 and 36 months of age (Group II, N = 7; 4 males, 3 females).

Water Hist.	Subj. code	Age at exam (mo)	Fluoride begun at (mo)	Supplement form	Supplement total time	Feeding Pattern breast (mo)	bottle (mo)	comm.fd. (mo)	Fluor Index[b]	Caries (Prim teeth) defs	no. teeth	defs index	Caries (Permt teeth) DEFS	no. teeth	DEFS index
Optimal	M	97	24	NaF	12	3	9(m)[e]	12	0	8	11	0.14	0	12	0
F	N	135	18	NaF	24	2	7(f)[f]	4	0.50	0	8	0	0	15	0
Sub-	0	96	24	NaF[c]	12	2	14(f)	9	0	7	12	0.12	4	12	0.07
Optimal	P	111	24	FV[d]	60	3	9(m)	12	0.25	4	12	0.07	1	12	0.02
F	Q	117	36	NaF	12	3	9(m)	12	0.25	17	12	0.28	1	12	0.02
	R	128	24	FV	72	3	9(m)	12	0	0	10	0	0	12	0
	S	152	36	FV	84	3	9(m)	12	0	4	3	0.27	3	25	0.02

[a]age at which commercial baby foods no longer used
[b]Fluorosis index: Moller[29]
[c]fluoride vitamins (drops or tablets)
[d]sodium fluoride (drops or tablets)
[e]bottle-fed with cow's milk
[f]bottle-fed with infant formula

Fluorosis of Permanent Teeth

Eight subjects in Group I and three subjects in Group II showed questionable to mild fluorosis (Tables 1 and 2). The prevalence and severity of the condition was greatest among those children beginning supplementation at birth and also consuming optimally fluoridated water. The severity of the fluorosis was greater among children consuming optimally fluoridated water and supplements (n = 9, mean fluorosis index 0.34 + 0.23 SD) than among children consuming suboptimally fluoridated water and supplements (n = 10, mean fluorosis index 0.17 + 0.31 SD), but the difference was not statistically significant. Those receiving the supplement for 24 months or longer showed a higher fluorosis index (n = 9, mean index 0.36 + 0.35 SD) than those consuming supplements for 21 months or less (n = 10, mean index 0.22 + 0.23 SD), but the difference was not statistically significant.

Three subjects who had consumed suboptimally fluoridated water showed questionable fluorosis (subjects H, P, and Q). A fourth subject (I in Group I) was of particular interest since she has consumed one mgF-/day for more than 11 years since birth. Her fluorosis score was based on all the maxillary incisors, each of which showed mild fluorosis involving the entire labial surface.

No clear association could be seen between the prevalence of fluorosis and the history of being bottle-fed with milk (six of ten subjects showed questionable to mild fluorosis) or formula (five of nine subjects showed questionable to very mild fluorosis). The three children who had been bottle-fed exclusively (B, C, and F in Group I) all showed questionable to very mild fluorosis.

Caries Experience of Primary Teeth

The prevalence of caries among primary teeth was less for children consuming optimally fluoridated water and fluoride supplements (n = 0, mean defs index 0.08 ± 0.10 SD) than for those consuming suboptimally fluoridated water in addition to fluoride supplements (n = 9, mean defs index 0.16 ± 0.16 SD), but this difference was not statistically significant (Tables 2 and 3). Children beginning supplementation at birth showed a lower prevalence of caries (n = 9, mean defs index 0.07 ± 0.10 SD) than those beginning it between three and 36 months (n = 9, mean defs index 0.18 + 0.15 SD), but the difference was not significant statistically.

Children receiving supplementation for 24 months or longer showed a caries experience (n = 9, means defs index 0.13 ± 0.16 SD) similar to that of children taking supplements for 21 months or less (n = 10, mean defs, index 0.13 ± 0.13 SD).

Caries Experience of Permanent Teeth

Tables 2 and 3 show that the prevalence of caries among permanent teeth for children consuming optimally fluoridated water and supplements (n = 9, mean DEFS index 0.02 ± 0.04 SD) was similar to that of those consuming suboptimally fluoridated water and supplements (n = 10, mean DEFS index 0.03 ± 0.03 SD). Children beginning supplementation at birth showed a caries prevalence (n = 10, mean DEFS index 0.03 ± 0.04 SD) similar to that of children commencing supplementation between three and 36 months (n = 9, mean DEFS index 0.03 ± 0.03 SD). Children receiving supplementation for 24 months or longer showed a lower caries experience (n = 9, mean DEFS index 0.01 ± 0.01 SD) than that of those taking supplements for 21 months or less (n = 10, mean DEFS index 0.04 ± 0.04 SD), but the difference was not statistically significant.

Discussion

A study of case reports of fluorosis performed retrospectively presents several difficulties. First, the information is gained largely by parental recall, which may not be reliable. The fact that dental observations are being made, and correlations being attempted with retrospective information relating to the period of infancy for the child, may also bias the information obtained.

For each of the 19 cases described, the information on fluoride supplementation and infancy feeding patterns appeared to be reliably provided by the parents. None of the children came from large families where a parent possibly could confuse the histories of different children and none of the cases had a history of receiving any other long-term medications during the years under consideration. Although the individual responsible for prescribing the fluoride supplement could not be contacted in all instances for confirmation, verification of the fluoride content of the water supplies was possible for all subjects. The report, then, does offer observations on children where the fluoride supplement actually was consumed. Larger epidemiological studies suffer from the disadvantage that it is not possible to verify that the supplement was used as prescribed for every child.

Excessive daily dose of fluoride, resulting in mild fluorosis of the anterior permanent teeth, can occur in infants residing in an optimally fluoridated community and taking supplements at the level of 1 mgF/day. However, even within the wide ranges possible for dietary intake of fluoride from a variety of additional sources, no objectionable fluorosis was seen. In all cases, the fluorosis was quite esthetic in appearance and of no apparent cosmetic concern to either the child or parent.

Flurosis was more prevalent and more severe among children receiving fluoride supplements in addition to consuming optimally fluoridated water (seven affected children of nine) than among those consuming suboptimally fluoridated water (four affected children of ten). This trend was noted especially for those commencing fluoride supplementation at birth. These observations support those of others,[18,19,22] and support the reduction in dosages.

Questionable fluorosis was a variable finding in the suboptimally fluoridated groups, and showed little relationship to either the age of commencing the supplement or the length of time of supplementation. The three cases with questionable fluorosis may have experienced a high cumulative dose of fluoride from a variety of dietary sources. Alternatively, the individual variability may reflect a variable susceptibility of ameloblasts to fluoride or impairment of enamel maturation,[33] as has been seen in animal studies where a variable production of fluorosis occurred following exposure to systemic fluoride. Brudevold, Bakhos, and Aasenden[34] reported a consistent trend of increase in incisor fluoride content with increasing fluorosis score in rat incisors, but some incisors had the same level of fluoride as teeth with moderate fluorosis.

Even though infant formulas and commercial baby foods in the past may have contained high contents of fluoride, no indication was seen in the cases reviewed here of an additive effect of fluoridated water, fluoride supplements, formula feeding and commercial baby foods in producing clinical evidence of fluorosis. Clearly, a prospective study with the maintenance of daily dietary records, rather than a retrospective study, is needed to determine any synergistic effects.

At present, direct comparisons of the relative severities of fluorosis observed in clinical and epidemiological studies are hampered by a lack of uniformity of indices for assessment. At least three indices[29,35,36] are in present usage. The five-point index of Dean[35] offers inadequate discrimination for the diagnosis of the milder forms of fluorosis and apportions only three points to questionable or mild fluorosis.

The classification of Moller[29] provides better discrimination by apportioning five points between 0.25 and 2.00 to these forms and employing a continuum of descriptions. These minimize overlap of criteria, especially when used in conjuction with the clinical photographs of McClure.[30] Identifying a similar problem with Dean's index in diagnosing the more severe forms of fluorosis, Thylstrup and Fejerskov[36] developed and used a ten-point scale which primarily expanded the index at the severe end.

The low dental caries experience of both the primary dentitions (predominantly molars and cuspids) and permanent dentitions (incisors and first molars) in this report is not unexpected. Marked reductions in dental caries experience of both primary and permanent dentitions have been reported in a number of studies following fluoride supplementation.[18,22,23] In contrast to most of these studies which employed prolonged administration, the cases observed here showed considerable variation in total time of supplementation (ranging from four months to 132 months) with longer supplementation times for those in suboptimally fluoridated communities.

Regardless of their fluoride histories, each child appeared to have parents highly motivated toward preventive dental health care. This was evidenced by the ready recall by the parents of the information sought (frequently recorded in "baby books"), the early and regular seeking of dental care for the child for non-emergency reasons, and the conscientious efforts of the parents in complying with and renewing the fluoride supplement prescriptions.

Conclusion

The present report demonstrates the importance of fluoride levels in the early years and underscores the need for pedodontists and pediatricians to be aware of all the potential sources of fluoride in a child's diet before prescribing additional supplementation.

In evaluating current dosage recommendations, additional clinical data is required on dentitions where reliable histories of diet patterns and fluoride supplementation are available. Ideally, these should be prospective studies.

More uniformity is desirable in the clinical assessment of the milder forms of fluorosis. The authors recommend the use of the index of Moller[29] in conjunction with the clinical photographs of fluorosis of McClure.[30]

Pending any clinical evidence to the contrary, the current dosage recommendations (1976) of the Council on Dental Therapeutics of the American Dental Association[17] appear satisfactory. The correct usage of these recommendations requires determining the fluoride content of the water supply regularly consumed by the individual. This usually can be performed by the local department of health or water supply authority. Pedodontists using these recommendations for their patients are encouraged to report the subsequent dental status of their patients, in order that a pool of clinical data can be developed so that the efficacy and safety of the recommendations can thereby be established.

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