CONFERENCE PAPER

Evidence-based Use of Fluoride in Contemporary Pediatric Dental Practice

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Abstract

Fluoride is an important and effective means of reducing the caries incidence in children. Multiple fluoride products are available to dentists for use with their patients at risk for dental caries. The purposes of this paper are to: (1) review clinically salient evidence, primarily systematic reviews and meta-analyses, for the effectiveness of fluoride options and, where possible, combinations of fluoride exposures; and (2) make recommendations to dental practitioners based on the available evidence for the use of these various approaches in contemporary practice, particularly regarding the use of multiple fluoride sources. The available data suggest that therapeutic use of fluoride for children should focus on regimens that maximize topical contact, preferably in lower-dose, higher-frequency approaches. Current best practice includes recommending twice-daily use of a fluoridated dentifrice for children in optimally fluoridated and fluoride-deficient communities, coupled with professional application of topical fluoride gel, foam, or varnish. The addition of other fluoride regimens should be based on periodic caries risk assessments, recognizing that the additive effects of multiple fluoride modalities exhibit diminishing returns. (Pediatr Dent 2006;28:133-142)

KEYWORDS: FLUORIDE, CARIES, PREVENTION, DENTAL PRACTICE

Prevention of dental caries in children is one of the hallmarks of contemporary pediatric dental practice. While there are multiple components of preventive dental programs developed by dentists for their child patients, perhaps none is as important and effective as the appropriate use of fluoride. Dentists have several options for optimizing the fluoride exposure of their child patients.

The purposes of this paper are to:

1. review clinically salient evidence, primarily systematic reviews and meta-analyses, for the effectiveness of fluoride options and, where possible, combinations of fluoride exposures;
2. make recommendations to dental practitioners based on the available evidence for the use of these various approaches in contemporary practice, particularly regarding the use of multiple fluoride sources.

The systemic paradigm

Fluoride's caries-protective action was first discovered in the 1920s and 1930s. Dental epidemiologists and practitioners discovered that naturally occurring fluoride in the water supply led to decreased rates of dental caries in the populations that consumed it.[1,2] They also noted that in areas with high fluoride levels in the water supply, significant numbers of individuals also exhibited a particular form of enamel mottling, later named "fluorosis."[3] From these observations, scientists deduced that fluoride exerts its effects systemically and that it must be ingested for these effects to occur.[4] This paradigm of systemic action led to the notion that significant caries reductions could be achieved in populations that consumed optimally fluoridated water. The success of the water fluoridation trials carried out in the 1940s and 1950s solidified the systemic paradigm for the next several decades.[5,6]

Fluoride dietary supplements

The efforts to extend the systemic benefits of fluoride to populations for whom water-borne fluoride was not available led to the development of fluoride dietary supplements. The intent was to provide a systemic dose of fluoride equivalent to that ingested by a child in an optimally fluoridated community. The developers of fluoride supplements had to wrestle with 2 problems inherent in this approach:

1. How much fluoride does a child in on optimally fluoridated community ingest daily?

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Table 1. Dietary Fluoride Supplementation Schedule[18]

	Water fluoride concentration (ppm)		
Age	**<0.3**	**0.3-0.6**	**>0.6**
Birth <6 mos	0*	0	0
6 mos <3 ys	.25	0	0
3 ys <6 ys	.50	.25	0
6-16 ys	1.00	.50	0

**Dose in mg F ion.*

2. Does a single daily dose of fluoride provide the same protection as the same dose divided into multiple small doses throughout the day?

Reports of trials with various fluoride compounds were published between 1949[7] and the late 1970s.[8,9] Caries reductions of 26% to 80% were reported for decayed, extracted, and filled primary tooth surfaces (defs), and 0% to 93% for decayed, extracted, and filled primary teeth (deft). Reductions in decayed, filled, and extracted permanent tooth surfaces (DFMS) and teeth (DMFT) were 5% to 84% and 6% to 69%, respectively.[7] Statistical significance was not reported in a number of publications. The wide range of the percent caries reductions can be attributed to a variety of factors, including the:

1. subjects' ages;
2. duration of administration;
3. criteria for caries diagnosis; and
4. population under study.

Many studies were marred by design flaws, including:

1. poor or no randomization;
2. lack of concurrent controls or use of historical controls; and
3. differing levels of baseline dental care among study groups.

The majority of the studies were conducted in an era of higher caries rates than those currently experienced by children in developed nations. They were also conducted at a time when other fluoride sources were limited.

Studies conducted in the late 1960s and 1970s using better research designs found DMFS and DMFT reductions on the order of 20% and 45%, respectively.[8,9] The overall effectiveness of fluoride supplements has been estimated to provide 20% to 30% reduction in dental disease.[10] This is roughly half the caries reduction demonstrated in the initial water fluoridation trials, and comparable to the difference in caries rates seen in optimally fluoridated vs fluoride-deficient communities today because of the "halo" effect.[11] The author was unable to find a systematic review or meta-analysis of the effectiveness of fluoride supplements in the literature. This is likely due to the design flaws in many of the early studies.

Fluoride supplements have been associated with the development of dental fluorosis in some, but not all, studies.[12-14] Pendrys et al reported an odds ratio of 23.75 for fluorosis in children residing in optimally fluoridated communities for whom fluoride supplements were inappropriately prescribed.[15] Pendrys and Katz reported that children in fluoride-deficient communities who received fluoride supplements during the first 6 years of life were 4 times as likely to develop fluorosis as those who were not supplemented.[16] Their data indicated that supplementation during ages 3 to 6 carried a higher fluorosis risk than did supplementation during the first year of life. The meta-analysis by Ismail and Bandekar[17] combined the findings of 10 cross-sectional and case-control studies to arrive at an odds ratio of about 2.5 for dental fluorosis in users of fluoride supplements compared to nonusers. In the same paper, they also conducted a meta-analysis of 4 "follow-up" studies and estimated that the relative risk of fluorosis in long-term users ranged between 5.5 and 12.2. They concluded that the use of fluoride supplements during the first 6 years of life in nonfluoridated communities is associated with a significantly increased risk for developing dental fluorosis. The fluorosis severity seen in these instances, however, is typically very mild or mild. The practitioner must weigh the potential benefits of caries reductions vs the risks of mild fluorosis from systemically administered supplements.

Numerous fluoride supplementation schedules were published in the latter half of the 20th century. Each new iteration was an attempt to reduce the dental fluorosis risk while maintaining the caries reduction benefits. The most recent supplementation schedule published in the United States, now over a decade old, appears in Table 1.[18] Supplemental fluoride is prescribed on the basis of age, not body weight. In addition, the sole factor used to determine a child's exposure to other sources of fluoride is the fluoride concentration of the drinking water. The supplementation dosage chart does not mention that fluoride tablets should be chewed or allowed to dissolve in the mouth, and that the resulting fluoride-saliva solution should be swished over the teeth before swallowing.

In recent years, the emphasis placed on the systemic caries protection effect of fluoride has waned significantly. Reanalysis of data from the water fluoridation trials supports the presence of a posteruptive effect of fluoride for those children residing in the optimally fluoridated community. In addition, it appears that teeth erupting during a period of fluoride supplementation receive a measure of caries protection that would most likely be topical in nature. Therefore, while a pre-eruptive systemic effect cannot be completely ruled out, no direct evidence of such an effect has been demonstrated.[4] The paradigm of fluoride's effect has, therefore, shifted from one of systemic action to those of topical effects on the enamel and biological effects on enzyme systems within cariogenic bacteria.

Three major factors have combined to change the way in which fluoride supplements are used in contemporary practice:

1. a shift in our understanding of fluoride's mode of action from systemic to topical;

2. increased exposure among children to other sources of fluoride; and
3. concern for the risk of fluorosis in permanent teeth.

With these factors in mind, the following recommendations are made for the use of fluoride supplements:

1. Prior to prescribing fluoride supplements, assay the child's primary drinking water supply for fluoride content. In addition, practitioners should consider other sources of fluoride exposure for their patients, particularly dentifrice use. For example, children in rural communities may be exposed to fluoride-deficient water at home, but may receive optimally fluoridated water at school or daycare settings. Consider supplementing only those children residing in fluoride-deficient communities with inadequate exposure to other fluoride sources who are at risk for caries, as demonstrated by a caries risk assessment.
2. Consider delaying supplementation until after the eruption of the permanent first molars. Evidence for the effectiveness of systemic fluoride supplementation prior to this age is not strong and does not support a specific recommendation for use prior to age 6.[19] On the other hand, the age group at highest risk for fluorosis from fluoride supplements appears to be 3 to 6 years.[16]
3. Ensure that parents understand the risks and benefits of systemic fluoride supplementation. If supplements are prescribed, ensure that the parents understand the importance of complying with the supplementation regimen.
4. Prescription directions should state that fluoride supplements are to be dissolved in the mouth or chewed and swished prior to swallowing to enhance the topical effect.
5. As a safety factor, a maximum of 120 mg of fluoride ion should be prescribed at one time. This amount would be a certainly lethal dose only for those children weighing less than 8 kg and would be a probably toxic dose for children weighing 24 kg or less.[20]
6. No good evidence exists to support fluoride supplements for pregnant women. Supplementation is not likely to cause harm. Data from a single, randomized, controlled, clinical trial in a fluoride-deficient community, however, indicated that prenatal fluoride supplementation is of no benefit to the primary teeth of the offspring, provided that the children receive postnatal fluoride exposure via dentifrice and supplements.[21]

Fluoride dentifrices

Crest, the first commercially available fluoride-containing dentifrice in the United States, was marketed by Procter & Gamble in 1955. This product originally contained stannous fluoride (SnF_2), but the formulation was later changed to sodium fluoride (NaF). Colgate-Palmolive began marketing Colgate with MFP (monofluorophospate) in 1967. The US Food and Drug Administration (FDA) recognizes the effectiveness of all 3 fluoride compounds in dentifrices.

The great majority of dentifrices sold in the United States contain fluoride. The standard concentration is 1,000 to 1,100 parts per million (ppm), which provides approximately 1 mg of fluoride ion (F) per gram of dentifrice. Products containing 1,500 ppm F are marketed in the United States, but may not be available in all areas. Dentifrices containing 250 or 500 to 550 ppm are available in other countries.

Three systematic reviews on the effectiveness of fluoride dentifrices have been published. Marinho et al, in the 2005 update of their review for the Cochrane Database of Systematic Reviews, evaluated 74 papers, of which 70 contributed data for their meta-analysis.[22] They found that in the permanent dentition, the pooled prevented fraction for D(M)FS was 24% (95% confidence interval ([CI] 21% to 28%; $P<.0001$). Pooled prevented fraction is defined as the difference between the mean caries increments in the study and control groups divided by the mean increment in the control group. In a relatively high-risk population with a caries increment of 2.6 DMFS per year, only 1.6 children (number needed to treat [NNT]) need to use a fluoridated dentifrice rather than a fluoride-free dentifrice to prevent 1 DMF surface. In a lower-risk population (1.1 DMFS increment per year), the NNT was 3.7. In this meta-analysis, the caries-preventive effect of fluoridated toothpaste increased with:

1. higher baseline DMFS levels;
2. higher fluoride concentration in the dentifrice;
3. greater frequency of use; and
4. supervised brushing.

The subject's exposure to fluoridated drinking water did not influence the dentifrice's effectiveness. Marinho et al noted that there is little information regarding the effectiveness of fluoridated dentifrice in the primary dentition.

Twetman et al reviewed 905 studies, of which 54 met the criteria for inclusion in their meta-analysis.[23] They found that fluoridated dentifrice provided a DMFS prevented fraction of 25%. They noted that dentifrices with 1,500 ppm F had a greater effect in the young permanent dentition than those with lower fluoride concentrations. As did Marinho et al, Twetman and colleagues found higher caries reductions in studies in which tooth-brushing was supervised. They also found incomplete evidence for the effectiveness of fluoride-containing dentifrices in the primary dentition.

The third meta-analysis of fluoride dentifrices is that of Ammari et al, who compared the effectiveness of dentifrices containing less than 600 ppm F with those containing at least 1,000 ppm.[24] Seven papers met inclusion criteria, and these were further divided into studies of dentifrices with F concentrations of 250 ppm or 500 ppm. Dentifrices with 250 ppm F were significantly ($P<.002$) less effective than standard fluoride dentifrices, with DFS increments .6 to .7 greater than the 1,000-ppm group. Only 2 studies were conducted using dentifrice containing 500 ppm F. The au-

thors were unable to carry out a meta-analysis of dentifrices with that fluoride concentration.

The level of evidence for the effectiveness of fluoridated dentifrices in the permanent dentition is high and sufficient to warrant a strong recommendation for their use to reduce the incidence of caries in the permanent dentition. Unfortunately, there is a dearth of evidence regarding their effectiveness in the primary dentition, but there is no logical reason to assume that fluoridated dentifrices would be substantially less effective in younger patients. Data exist, however, to indicate that:

1. the risk of swallowing a dentifrice is higher among young children;[25] and
2. children may use "child-flavored" dentifrices in greater amounts and for longer periods of brushing.[26,27]

Therefore, the American Academy of Pediatric Dentistry recommends that a pea-sized amount of dentifrice be applied to the brush by the child's caregiver to prevent ingestion of undesirable amounts of toothpaste.[18] Data are scarce, however, on the fluorosis risk from the ingestion of fluoridated dentifrice. One such study found an odds ratio of 1.83 (95% CI=1.05–3.15) for fluorosis from the use of fluoride toothpaste prior to age 6.[28] Among children with fluorosis, those who began brushing with a fluoridated toothpaste prior to age 2 had significantly more severe fluorosis. Other studies have also documented a fluorosis risk from the use of fluoride-containing dentifrices prior to age 2.[29,30]

Based on these findings, the following recommendations are offered for the use of fluoride-containing dentifrices:

1. Oral cleanings after feedings should begin prior to primary tooth eruption, but certainly as soon as teeth have erupted. Nonfluoride, all-natural tooth cleaning gels are available for use in low-caries-risk children at this age. Because of the association between fluorosis and fluoride toothpaste use in children younger than 2, use of fluoridated dentifrices prior to age 2 should be based on a caries risk assessment. Parents should be apprised of the risks and benefits of fluoride dentifrice use in this age group.
2. Tooth-brushing should be supervised by an adult, especially once fluoride dentifrice use has begun. Pea-sized dabs of dentifrice should be used, and the caregiver should brush the child's teeth until this is no longer practicable. At that point, the parent should continue to dispense the dentifrice and the child should have his tooth-brushing checked by the caregiver.
3. Tooth-brushing with a fluoridated toothpaste should be done twice daily. This frequency is associated with additional benefits over once-daily brushing,[31] but the benefits of more frequent cleanings are not well established.[19]
4. Older children who are able to expectorate should use more than a pea-sized dab to increase their salivary fluoride levels.[32]

Fluoride mouthrinses

Fluoride mouthrinses have been available for several decades in the United States as solutions containing:

1. .05% NaF (~225 ppm F) or acidulated phosphate fluoride (APF) for daily use; or
2. .2% NaF (~900 ppm F) solutions for weekly use.

Both concentrations were originally available as prescription-only ingestible solutions, with the .2% formulations reserved primarily for school-based mouthrinse programs.[19] In the 1980s, the FDA permitted the marketing of over-the-counter .05% NaF solutions that were not intended for ingestion.

Two systematic reviews of fluoride mouthrinses have been conducted. Marinho et al conducted the review for the Cochrane Database of Systematic Reviews, most recently updated in February 2004.[33] This analysis was conducted with 36 studies, of which 34 were included in the meta-analysis. The pooled prevented fraction of D(M)FS was 26% (95% CI=23%–30%; p<.0001). There was no significant association between the mouthrinse's effectiveness and the baseline caries severity, background exposure to other sources of fluoride, rinsing frequency, and the mouthrinse's fluoride concentration. The authors noted that there was little information available regarding possible adverse effects or acceptability and compliance with the use of the mouthrinse in the trials, nor was there sufficient data to permit an analysis of the effectiveness of fluoride mouthrinses on the primary dentition.

The second systematic review was conducted by Twetman et al.[34] This study identified 174 papers, 62 of which met inclusion criteria for the meta-analysis. The authors found limited evidence for a DMFS prevented fraction of 29% with daily or weekly use of a NaF mouthrinse compared to a placebo. The data on an additional effect from a fluoride mouthrinse over other fluoride exposure, however, such as a fluoridated dentifrice, were inconclusive. There was no association between the frequency of use and prevented fraction. The authors concluded that fluoride mouthrinses may have a caries-protective effect in children with limited exposure to other sources of fluoride, but that any additional effect is questionable in children who use a fluoridated dentifrice daily. There was insufficient evidence to permit an analysis of the effectiveness of fluoride mouthrinse in the primary dentition. In another systematic review conducted for the Cochrane Database, Marinho et al found no significant difference in the prevented fraction of DMFS afforded by a combination of fluoridated dentifrices and fluoride mouthrinses (or gels) over the dentifrice alone.[35]

Fluoride mouthrinses are commonly recommended for patients undergoing orthodontic treatment. A recent systematic review of various means of reducing demineralization around orthodontic appliances found very limited evidence for an demonstrable effect.[36] The authors concluded that until well-designed trials are conducted, the best practice for orthodontic patients with fixed appliances is

daily use of a .05% NaF mouthrinse. Fluoride mouthrinses are often empirically recommended for children with special health care needs, such as those with reduced salivary flow from medication or radiation treatment and those wearing intraoral prostheses.

As with fluoridated dentifrices, swallowing of fluoride mouthrinses is an issue for children who have not yet mastered their swallowing reflex.[37] Therefore, these products should be recommended for only those children who demonstrate the ability to swish and expectorate without swallowing (generally age 6 or older).

Based on the current literature regarding fluoride mouthrinses, the following recommendations are offered:

1. Fluoride mouthrinses should be reserved for use with children judged to be at moderate or high risk for dental caries, including children with fixed orthodontic or prosthetic appliances and those with reduced salivary flow.
2. Daily use of an over-the-counter .05% NaF rinse in a swish-and-expectorate regimen is as effective as a prescription rinse that is swallowed after rinsing.
3. Little additional benefit should be expected from fluoride mouthrinses in low-caries-risk children who are already using a fluoridated dentifrice.
4. Fluoride mouthrinses should be recommended only for those children who have demonstrated mastery of their swallowing reflex.
5. Where available, alcohol-free preparations should be recommended over those containing alcohol.

Self-applied fluoride gels

Self-applied fluoride gels were originally developed for application via custom mouth trays, though no single application regimen has been considered standard. Fluoride gels are currently available by prescription for self-application as APF and neutral NaF products containing 1.1% NaF (5,000 ppm F ion). Some manufacturers have reformulated their NaF gels with abrasives as a reflection of the increasing use of these products in a brush-on regimen. Glycerin-based SnF_2 products (not true gels) are available with a concentration of 1,000 ppm F.

Most studies of self-applied fluoride gel were conducted in the 1960s and 1970s with NaF or APF containing F concentrations of 5,000 or 12,300 ppm. Application frequencies ranged from 3 to 4 times per week during the school year to 4 times per calendar year. The percent of DMFS reductions in fluoride-deficient communities by tray application and brushing ranged from 0.5% to 80%, with a pooled average of approximately 32%.[38] The dramatic reductions (80%) obtained by Englander et al in a nonfluoridated area[39] have not been replicated in other studies. Caries reductions in trials conducted in optimally fluoridated communities ranged from 7% to 35%.[38] There are no well-designed clinical trials of SnF_2 gels. No systematic reviews of purely self-applied gels have been conducted (see professionally applied fluoride gels and foams section to follow).

Fluoride gels and pastes are often recommended by practitioners for patients:

1. with severe early childhood caries;
2. with rampant caries in the mixed and permanent dentitions;
3. with reduced salivary flow;
4. wearing prosthetic or orthodontic appliances; and
5. who may be at high risk for dental caries.

Fluoride ingestion is obviously a concern with these products.

Recommendations for the use of prescription-strength fluoride gels and pastes for brush-on and custom tray self-application include:

1. These products should be recommended for patients in fluoride-deficient communities who are at high risk for caries.
2. Parents of young children should supervise placement of the product in the custom tray or on the toothbrush. In a brush-on technique with young children, only a pea-sized amount should be used. Brushing should be supervised and, preferably, done by an adult. In tray applications, only the minimum amount of gel necessary to cover the teeth should be used. Tray application should not exceed 4 minutes. Patients should be cautioned against swallowing the gel, and should be allowed to expectorate freely after either type of application. Rinsing, eating, and drinking should be delayed for 30 minutes. Ideally, gel application should occur just prior to bedtime. Caution is advised regarding the use of prescription fluoride gels and pastes in children younger than 6 years.
3. Application regimens should be limited to the minimum time period deemed necessary for control of dental caries, and patients should be evaluated periodically to determine when self-application can be terminated.

Professionally applied fluoride gels and foams

Professionally applied fluoride gels and foams are available in APF formulations containing 1.23% F (12,300 ppm F) and as 2% neutral NaF products containing 9,000 ppm F. The latter product is useful when the practitioner wishes to avoid etching porcelain and composite restorations with low pH compounds. Most trials of professionally applied fluoride gels were conducted in the 1960s and 1970s.[38] Of the relatively few trials conducted in North America, most employed the APF formulation and most evaluated once-yearly applications. The pooled reduction in DMFS among these studies has been estimated to be 20% for once-yearly applications and 26% for twice-yearly applications.[38]

Van Rijkom et al evaluated the effectiveness of professionally applied fluoride gels in low-caries children 4½ to 6½ years old who resided in a fluoride-deficient community.[40] All children were free of caries in their primary and permanent teeth at the start of the study. In this double-blind, randomized, controlled trial, they found

that twice-yearly application of a 1% NaF gel (4,500 ppm F) produced prevented fractions of 26% in the permanent dentition and 20% in the primary dentition. Only the reduction in the permanent dentition was statistically significant, and the authors considered neither reduction to be "clinically relevant."

Systematic reviews of fluoride gels' effectiveness were published by van Rijkom et al in 1998[41] and by Marinho et al in 2003.[42] Both reviews included studies of self-applied and professionally applied gel. Study designs evaluated in both reviews were diverse in the number of fluoride gel treatment groups, study duration, and application frequency. Van Rijkom et al found a reduction in caries incidence relative to the incidence in the control group of 22%. They found no significant effect on the outcome for baseline caries prevalence, "general fluoride regimen," application method, and application frequency. Marinho et al found a pooled prevented fraction for DMFS of 28%. Studies that utilized placebo control groups demonstrated 21% reductions. Regression analysis did not reveal any statistically significant associations between treatment effectiveness and a multitude of factors, including: (1) baseline caries level; (2) self vs professional application; (3) fluoride concentration; (4) background exposure to fluoridated water; and (5) other sources of fluoride.

Marinho et al stated that there is clear evidence of a caries-inhibiting effect of fluoride gel, but cautioned that there is scant information available on the effectiveness in the primary dentition.

Fluoride foams are available as 1.23% APF or 2% neutral NaF formulations. They offer the advantages of requiring only about 20% as much product in the application tray to achieve a topical fluoride deposition equivalent to that of the amount of fluoride gel typically used in a professional application.[43]

The cost-effectiveness of professionally applied fluoride is a function of the patient's or population's caries risk level, and the application's cost. Each of the systematic reviews previously cited found no significant difference in the fluoride gel applications' effectiveness in high and low caries groups. While the prevented DMFS fractions in high and low caries groups were similar, the absolute number of caries surfaces saved per application of fluoride gel was substantially lower among low-caries risk groups. This was demonstrated in the reviews by their calculations of the NNT. In the Marinho et al study,[42] the NNT in a population with an annual caries increment of .2 DMFS per year was 24. In a population with an annual caries increment of 2.2 DMFS, however, the NNT was only 3. van Rijkom et al[41] found an NNT of 18 in a population with a caries incidence of .25 DMFS per year, but an NNT of only 3 if the caries incidence was .5 DMFS per year. Therefore, a caries risk assessment should form the basis of a decision to provide an in-office topical fluoride treatment.

Recommendations for the clinical use of fluoride gels and foams include:

1. Use a caries risk assessment to determine the need for and frequency of professionally applied fluoride gel/foam.
2. Follow a pumice prophylaxis with a topical fluoride application to replace the surface fluoride layer removed by the prophylaxis.
3. During professional application of fluoride gel or foam, reduce the likelihood of unwanted ingestion by using properly fitted application trays. Fill the trays with only enough product to cover the teeth. Seat the patient upright, and place a saliva ejector in the mouth between the upper and lower trays during administration. Have the patient lean forward slightly, and allow excess saliva to drip into a cup. Apply the fluoride gel/foam for 4 minutes.
4. Allow the patient to expectorate freely after application. Have the patient refrain from eating or drinking for 30 minutes following the application.

Professionally applied fluoride varnish

Fluoride varnish was introduced in 1964[44] and has been employed widely in Europe since the 1980s. These products became available in the United States after receiving FDA approval in 1994 for use as a desensitizing agent and as a cavity liner. Use as a caries-preventive agent is considered off-label, but legal.[19] Two formulations are available in the United States. One contains 5% NaF by weight, resulting in an F concentration of 22,600 ppm. The other contains difluorosilane, with an F concentration of 1,000 ppm. Fluoride varnish is easily applied to the teeth, and it sets relatively quickly in contact with moisture. A typical application requires .2 to .5 mL, resulting in a total fluoride ion application of approximately 5 to 11 mg. The primary side effect has been the temporary yellow-brown discoloration of the teeth while the varnish adheres, but this has been eliminated in newly marketed tooth-colored varnishes.

As with other fluoride modalities, the study designs employed with fluoride varnish vary greatly, making direct comparisons difficult. Results of clinical trials indicate that fluoride varnish provides caries incidence reductions of 18% to 70%,[45] though the quality of the clinical trials is generally poor. The 4 systematic reviews of fluoride varnish all found substantial caries reduction effects in their analyses of fluoride varnish studies. Helfenstein and Steiner[46] included 8 studies in their meta-analysis and determined that fluoride varnish provided a 38% overall reduction in permanent dentition caries compared to patients in control groups. Because topical fluoride effects tend to diminish over time, the authors also calculated a 45% duration-adjusted effect size for the mean study duration of 2.5 years. Only 3 studies met inclusion criteria for the meta-analysis conducted by Strohmenger and Brambilla.[45] All compared twice-yearly application of fluoride varnish with control groups that used a .2% NaF mouthrinse every 2 weeks. The pooled estimate of the treatment effect indicated an insignificant advantage for fluoride varnish.

Table 2. Summary of the Author's Recommendations for the Use of Fluoride Regimens in Contemporary Pediatric Dental Practice*

Fluoride regimen	Recommendations
Dietary supplements	• Assay patient's primary source of drinking water; consider other sources of fluoride intake • Consider delaying supplementation until after eruption of permanent first molars • Ensure that parents understand risks/benefits of supplementation • Instruct patient to chew/swish supplement prior to swallowing • Prescribe no more than 120 mg F • No benefit to prenatal administration
Dentifrices	• Use in children <2 ys old should be based on caries risk assessment • Tooth-brushing for young child should be done by adult; brushing by older child should be supervised by adult • Use pea-sized dab of dentifrice in children with immature swallowing reflexes; older children can use larger amounts • Brush with fluoride toothpaste twice daily
Mouthrinses	• Reserve for use in children with moderate/high caries risk • Reserve for use in children who have mastered swallowing reflex • Recommend alcohol-free preparations
Self-applied gels/pastes (5000 ppm F)	• Reserve for patients in fluoride-deficient communities who are at increased risk for caries • Application should be done by adult for young child, and supervised by adult for older child • Application period should be 4 minutes • Allow patient to expectorate freely after application; postpone eating/drinking for 30 minutes • Use with caution in children who have not mastered swallowing reflex • Monitor effectiveness; terminate regimen when feasible
Professionally applied gel/foam (12,300 ppm F)	• Application frequency based on caries risk assessment • Follow a pumice prophylaxis with fluoride application • Use minimum amount of gel/foam necessary to cover teeth • Seat patient upright, use suction to reduce swallowing of product • Apply for 4 minutes • Allow patient to expectorate freely after application; postpone eating/drinking for 30 minutes
Fluoride varnish (22,600 ppm F)	• Use after pumice prophylaxis as noted for gel/foam application • Use in alternative restorative technique to arrest lesions in young, precooperative patients • Have patient refrain from eating/drinking for 30 minutes after application • Have patient postpone brushing teeth until following morning

**Table assumes that the baseline recommendation for all patients is twice daily use of a fluoridated dentifrice coupled with once- or twice-yearly professional application of fluoride gel/foam/varnish. Use of all regimens except fluoride dentifrice should be based on a caries risk assessment.*

Petersson et al included 24 papers in their meta-analysis.[47] They determined that compared to placebo or untreated control groups, the mean prevented fraction afforded by fluoride varnish was 30%. In studies in which fluoride varnish was compared to other fluoride regimens, however, the mean prevented fraction was 18%. The authors considered that the level of evidence from these studies was limited. They also evaluated 3 clinical trials that took place in the primary dentition and found inconclusive evidence for a caries-reduction effect by varnish.

Marinho et al conducted a systematic review for the Cochrane Database of Systematic Reviews, with the most recent findings published in 2005.[48] Nine studies were included in the meta-analysis. The pooled prevented fraction was 46% for permanent teeth and 33% for primary teeth. No significant associations were found between the caries-preventive effect in the permanent dentition and baseline caries severity or background exposure to fluoride. The authors concluded that fluoride varnish provides a substantial caries-inhibiting effect in both dentitions, but that the quality of the available studies is relatively poor.

Based on the available evidence to date, the following recommendations are offered for fluoride varnish use:

1. The current best practice with fluoride varnish is application at 6-month intervals for reducing the caries incidence in the permanent teeth of children residing in optimally fluoridated and fluoride-deficient communities. The evidence for fluoride varnish's effective-

ness in the primary dentition is inconclusive, but there is no reason currently to assume that it would not provide a similar level of caries protection in younger children.
2. Have the patient refrain from eating or drinking for 30 minutes after the application. Have the patient postpone brushing the teeth until the morning following varnish application.
3. Until further evidence suggests otherwise, frequent periodic applications of fluoride varnish to open caries lesions in very young children (as often employed in the "alternative restorative technique") should continue to be utilized as a means of controlling early childhood caries.
4. When a choice of professionally applied fluoride is available, it appears that fluoride varnish may be superior to fluoride gels and foams in caries reductions.

Combinations of fluoride modalities

Analyses of studies that employed combinations of fluoride modalities have provided mixed results. Axelsson et al[49] conducted a systematic review of a number of combined caries preventive methods, including: (1) fluoride; (2) patient education; (3) supervised brushing; (4) professional prophylaxis; and (5) others. They found that combination approaches using professional tooth-cleaning, fluoride products, and supervised tooth-brushing were superior to regimens using placebo products. Petersson et al,[50] however, found no differences in treatment effect on 3-year-old children between various combinations of fluoridated and placebo tablets, dentifrice, and varnish. Stephen et al[51] found no difference in caries increments between a group using fluoride mouthrinse and a test group using fluoride mouthrinse and fluoride tablets. Marinho et al[35] found that fluoride mouthrinses, gels, or varnishes combined with fluoride dentifrice provided a 10% pooled prevented fraction over the use of fluoride dentifrice alone. No significant results were found, however, in separate meta-analyses of fluoride dentifrice vs fluoride gel or mouthrinse combined with fluoride dentifrice. A significant result was seen in favor of the combined use of fluoride gel and mouthrinse compared to the use of fluoride gel alone. The pooled prevented fraction was 23%, but the analysis was based on only 2 trials.

It is likely that patients experience a "diminishing returns" effect as fluoride modalities are combined. Further, it appears that the combination of once- or twice-yearly professional fluoride applications and twice-daily use of fluoride dentifrice is an acceptable baseline program for low caries-risk children. The addition of other fluoride regimens, such as systemic supplements, mouthrinses, and self-applied gels should be considered only after a thorough caries risk assessment. If additional fluoride regimens seem warranted, they should be introduced in a stepwise fashion with careful follow-up to determine if additional fluoride exposures are necessary.

Conclusions

The primary caries-preventive effects of fluoride result from its topical contact with enamel and through its antibacterial actions. Therefore, therapeutic use of fluoride for children should focus on regimens that maximize topical contact, preferably in lower-dose, higher-frequency approaches. Clinicians should be aware that the level of evidence for most fluoride regimens is fair at best. Until stronger evidence is available, current best practice includes recommending twice-daily use of a dentifrice containing 1,000 ppm F for children in optimally fluoridated and fluoride-deficient communities, coupled with professional application of topical fluoride gel, foam, or varnish. The addition of other fluoride regimens—supplements, mouthrinses, and self-applied gels—should be based on periodic caries risk assessments. A summary of the author's recommendations appears in Table 2. Clinicians should keep in mind that the additive effects of multiple fluoride modalities exhibit diminishing returns. Fluoride products should be used in proven, approved regimens, and steps should be taken to reduce the unnecessary ingestion of fluoride by young children.

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Abstract of the Scientific Literature

General Anesthesia for Developmentally Disabled Dental Care Patients: Use of Reinforced Laryngeal Mask Airway (LMA)

The purpose of this study was to compare the efficacy of endotracheal anesthesia and reinforced laryngeal mask airway (LMA) for dental care of developmentally disabled patients under general anesthesia. The LMA has been used to provide general anesthesia for many types of procedures. Modifications of the original LMA have been made to use a flexible reinforced tube, and this has made it useful for some dental procedures. The device is designed to be placed in the hypopharynx and the junction of the gastrointestinal tract and respiratory tract where it seals the glottis. A retrospective analysis of the data concerning the postoperative course of 687 patients with a mean age of 16.1 was performed. Patients who had LMA used had a significantly shorter recovery period and lower postoperative complication rates when compared to those with endotracheal anesthesia. Nausea and vomiting during the post anesthesia phase and after discharge was significantly higher in the intubated group.

Comments: The fewer postoperative complications reported with LMA show that this may be an option for older special needs children. This technique may warrant further investigation. Access to the oral cavity, however, is usually more limited with a LMA. Additional care must be taken, as the LMA may become dislodged during the procedure. **JCS**

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Hung WT, Hsu SC, Kao CT. General anesthesia for developmentally disabled dental care patients: a comparison of reinforced laryngeal mask airway and endotracheal intubation anesthesia. Spec Care Dentist 2003;23:135-138.

23 references