The role of fluoride mouthrinses in the control of dental caries: a brief review

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Abstract

Fluoride mouthrinses have generally proved to be effective in controlling caries in clinical studies. Caries reductions in North American studies have averaged about 30%. Large-scale school-based mouthrinse programs conducted during the 1970s, however, used historical controls at a time when caries rates were now known to be declining. Post-hoc analysis of the absolute (not relative) caries reductions in these studies showed that school-based fluoride mouthrinse programs were of questionable benefit from a cost standpoint.

Fluoride mouthrinses have been shown to reduce demineralization and enhance remineralization of enamel adjacent to orthodontic bands and brackets. Benefits in adults have been less well documented. Use of fluoride mouthrinses by young children is discouraged until they have mastery of their swallowing reflexes.

This paper recommends the use of fluoride mouthrinses for patients at increased or high risk for dental caries, but cautions that school-based programs be undertaken only in communities with a high population caries rate (Pediatr Dent 20:2 101-104, 1998).

The Oral Health Program at the Centers for Disease Control and Prevention (CDC) established a Fluoride Work Group in 1996, comprising a number of individuals from across the US with expertise in aspects of fluoride’s role in controlling dental caries. The purpose of the Work Group was to review the mechanism of actions of fluoride, the various modes of delivery (intake from foods and beverages, community and school water fluoridation, dentifrices, topical applications, mouthrinses, dietary supplements, and fluoride-containing restorative materials), and the risks of fluorosis. This paper is a summary of the review of fluoride mouthrinses provided to the CDC as part of the Fluoride Work Group’s deliberations.

Fluoride mouthrinses generally have been found efficacious as a means of controlling dental caries incidence.1 With the exception of a few isolated reports in the 1940s, controlled clinical trials began in the 1960s, primarily in Scandinavia.2,3 After a brief period of experimentation with other compounds, sodium fluoride (NaF), either neutral or acidulated, became the standard. Low potency/high frequency regimens assessed the daily use of a 0.05% NaF solution (230 ppm F) or a 0.44% APF solution, while high potency/low frequency protocols tested weekly or biweekly use of a 0.2% NaF rinse (900 ppm F). Stannous and amine fluoride rinses received some limited attention as well. The early Scandinavian trials obtained reductions in caries increments of up to 80%.4 Evaluations of fluoride mouthrinses using historical controls in North America began after 1970 when a significant effect for a weekly rinse regimen was demonstrated in a fifth-grade cohort.5 Other North American trials followed, with caries reductions centered around 30%.6,7 Most of these studies were conducted in fluoride-deficient communities, but more than a dozen studies demonstrated varying degrees of efficacy (0-55%) in optimally fluoridated communities.8-10

Several trials evaluated fluoride mouthrinse in combination with fluoride-containing dentifrices,11-13 tablets,14-17 varnishes,13,18,19 or gels.20 Results were conflicting, but a general interpretation of these studies suggests that for most children, fluoride rinses offered little benefit over the use of fluoride-containing dentifrices, tablets (in a “chew, swish, swallow” regimen), or varnishes. The combination of mouthrinse and gel was impressive, given a 30% caries reduction in an optimally fluoridated community.20 Neither regimen was tested separately in that study, however.

Large-scale demonstration programs involving almost 75,000 schoolchildren took place in the United States and Guam in the mid-1970s.21 These evaluations of weekly use of 0.2% NaF were conducted using historical rather than concurrent controls. Caries reductions for children in grades 1 through 6 ranged from 11 to 54%, with a mean for all 17 sites of 34%.

The preferential effects of fluoride on smooth tooth surfaces22-24 and on newly erupted teeth5,25-27 were documented in several studies. Permanent teeth fared better than primary teeth in the few studies that assessed benefits to both dentitions.21,28-30 Increased duration of participation in mouthrinse studies led to increased benefits.31,32 Brief interruption (up to 3 years) of
mouthrinse programs was shown to have little adverse impact in one study. Post-treatment benefits declined over several years in those studies that provided long-term follow-up.

Fluoride mouthrinse benefits in adults have not been well documented, but there is evidence that caries increments, including root surface caries, can be reduced in older patients. Fluoride mouthrinses have also proved efficacious in preventing enamel demineralization and enhancing remineralization around orthodontic brackets and bands.

Fluoride mouthrinses were approved as prescription agents by the United States Food and Drug Administration in 1974. The Council on Dental Therapeutics of the American Dental Association accepted neutral and acidulated NaF mouthrinses in 1975. Recognition was extended to stannous fluoride rinses in 1980. The FDA approved neutral NaF rinses in concentrations of 0.05% or less for over-the-counter sale in 1980. Data from the 1989 National Health Interview Survey indicated that fluoride mouthrinses were used by a minority (about 10%) of children. Spending in the US for fluoride mouthrinses may be only 1% of that spent on dentifrices, virtually all of which contain fluoride.

Few randomized clinical trials with simultaneous controls were undertaken in the US. From these, the efficacy of fluoride rinses was estimated in 1984 to save 0.12 permanent tooth surface per year in first- and second-grade children, and 0.28 surface per year in fifth- and sixth-grade children in fluoride-deficient communities, given caries patterns at the time. These are estimates of the absolute caries reductions, in contrast to the relative caries reductions reported in most studies of that type. The best available data for estimating real-world effectiveness are the less scientifically rigorous school-based demonstration programs. These studies included all volunteers, and thus relied on historical controls at a time when caries prevalence is now known to have been declining. The caries increment savings in fifth- and sixth-grade children may have been only 0.21 surface per year in studies conducted from the mid-1970s to the mid-1980s. These data call into question the efficiency of fluoride mouthrinse programs. Stamm et al. estimated that a 4-year mouthrinse program beginning in grades one and two might cost $20.00 in 1981 dollars to save less than 0.5 surface of decay per child. The 1981 average fee for a one-surface amalgam was $19.92, although the surfaces most likely to be protected, proximals, must generally be restored by more expensive multiple surface restorations. The efficiency of fluoride mouthrinsing is also a function of the value placed by program administrators on sound tooth surfaces.

Several studies have documented the inability of young children to rinse without ingesting some or all of the fluoride introduced into the oral cavity. Wei and Kanellis found that with a 0.05% NaF rinse, children ages 3–5 might retain 0.25–0.41 mg F, depending on age. The "probably toxic dose" of fluoride has been estimated to be 5 mg/kg body weight. Twenty-two mL of a 0.05% solution would be required to deliver 5 mg F. A 12-month-old female weighing 7.8 to 11.2 kg (the 5th and 95th percentiles) would have to consume 172–247 mL of a 0.05% NaF rinse to receive a probably toxic dose. This is 1–1.5 times the amount contained in a small bottle (180 mL) of mouthrinse. For children old enough to use over-the-counter products (about age 6), considerably more mouthrinse would have to be ingested to approach a toxic fluoride dose.

**Recommendations**

Fluoride mouthrinses are a safe means of providing a measure of caries protection to children and adults in fluoride-deficient and, to a lesser extent, in optimally fluoridated communities. Aside from school-based programs, these products are used by only about 10% of children; in addition, their use is not equitably distributed across socioeconomic and ethnic/racial lines (e.g., African-American and lower-income children are more likely to be involved in a school mouthrinse program, while children from lower income families may be less likely to use over-the-counter products). The following recommendations for fluoride mouthrinses are made in the context of their integration with multiple fluoride modalities:

1. **School-based fluoride mouthrinse programs** should be employed only in communities with a population caries rate high enough to warrant a cost-effective outcome. For ease of handling and administration, fluoride tablets in a "chew and swish" program may be substituted for mouthrinse.

2. **Dentists should consider recommending fluoride mouthrinses only for individuals who are at increased or high risk for dental caries.** Topical fluoride mouthrinses can be recommended for these patients regardless of whether they use a fluoride-containing dentifrice, take fluoride dietary supplements, and/or live in a fluoridated community.
   - Daily use of a 0.05% NaF rinse should be considered for individuals at increased or high risk for dental caries. This category includes, but is not limited to, individuals with: active coronal and/or root surface caries; impaired ability to maintain oral hygiene; space maintainers, orthodontic appliances, or prostheses; exposed root surfaces.
   - Daily use of a 0.05% or 0.2% NaF (prescription) mouthrinse should be considered for...
individuals at very high risk for dental caries. This category includes, but is not limited to, individuals with reduced salivary flow from disease, medications, chemotherapy, and/or radiation treatment.

- Laboratory tests (salivary mutans streptococci counts, salivary buffering capacity) can be combined with clinical findings (medical history, caries history, level of oral hygiene, diet, fluoride exposure) to monitor disease activity and determine the need for mouthrinse therapy.

3. Over-the-counter fluoride rinses for children should be recommended only for those who have demonstrated mastery of their swallowing reflexes (about age 6 years). High-dose (0.2% NaF) prescription rinses should not be used in children younger than age 6.

4. Alcohol-free over-the-counter rinses should be the products of choice for children and for adults with alcohol dependency.

5. The following aspects of fluoride mouthrinse warrant further investigation: a) the absolute effectiveness in high caries risk groups; b) the efficacy and cost-effectiveness of weekly 0.2% fluoride mouthrinses in fluoridated and nonfluoridated communities; c) oral clearance of 0.05% and 0.2% NaF mouthrinses; and d) the cost-effectiveness of fluoride mouthrinse used in private practices.

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References


