

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

Steven M. Adair, DDS, MS

### 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.<sup>1</sup> With the exception of a few isolated reports in the 1940s, controlled clinical trials began in the 1960s, primarily in Scandinavia.<sup>2,3</sup> After a brief period of ex-

perimentation 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%.<sup>4</sup> 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.<sup>5</sup> Other North American trials followed, with caries reductions centered around 30%.<sup>6,7</sup> 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.<sup>8-10</sup>

Several trials evaluated fluoride mouthrinse in combination with fluoride-containing dentifrices,<sup>11-13</sup> tablets,<sup>14-17</sup> varnishes,<sup>13,18,19</sup> or gels.<sup>20</sup> 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.<sup>20</sup> 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.<sup>21</sup> 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 surfaces<sup>22-24</sup> and on newly erupted teeth<sup>5,25-27</sup> were documented in several studies. Permanent teeth fared better than primary teeth in the few studies that assessed benefits to both dentitions.<sup>21,28-30</sup> Increased duration of participation in mouthrinse studies led to increased benefits.<sup>31,32</sup> Brief interruption (up to 3 years) of

mouthrinse programs was shown to have little adverse impact in one study.<sup>33</sup> Post-treatment benefits declined over several years in those studies that provided long-term follow-up.<sup>22, 34-36</sup>

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.<sup>37-38</sup> Fluoride mouthrinses have also proved efficacious in preventing enamel demineralization and enhancing remineralization around orthodontic brackets and bands.<sup>39, 40</sup>

Fluoride mouthrinses were approved as prescription agents by the United States Food and Drug Administration in 1974.<sup>41</sup> The Council on Dental Therapeutics of the American Dental Association accepted neutral and acidulated NaF mouthrinses in 1975.<sup>42</sup> Recognition was extended to stannous fluoride rinses in 1980.<sup>43</sup> The FDA approved neutral NaF rinses in concentrations of 0.05% or less for over-the-counter sale in 1980.<sup>44</sup> Data from the 1989 National Health Interview Survey indicated that fluoride mouthrinses were used by a minority (about 10%) of children.<sup>45</sup> Spending in the US for fluoride mouthrinses may be only 1% of that spent on dentifrices, virtually all of which contain fluoride.<sup>46</sup>

Few randomized clinical trials with simultaneous controls were undertaken in the US. From these, the efficacy of fluoride rinses was estimated in 1984<sup>47</sup> 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.<sup>47</sup> 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.<sup>47</sup> 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.<sup>48, 49</sup> 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.<sup>49</sup> The "probably toxic dose" of fluoride has been estimated to be 5 mg/kg body weight.<sup>50</sup> 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 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.

Dr. Adair is professor and chair, Department of Pediatric Dentistry, School of Dentistry, Medical College of Georgia, Augusta, Georgia.

## References

1. Mellberg JR, Ripa LW: Self-applied topical fluoride. In *Fluoride in Preventive Dentistry. Theory and Clinical Applications*. JR Mellberg, LW Ripa EDS. Chicago: Quintessence Pub Co, pp 248-74, 1983.
2. Fjaestad-Seger M, Norstedt-Larsson K, Torell P: Forsök med enkla metoder för klinisk fluorapplikation. *Sverige Tandlak-Forb Tidn* 53:169-80, 1961.
3. Lundstam R: Teachers administering mouthwash with fluorides in Jamtland, Sweden. *Sverige Tandlak-Forb Tidn* 56:681-82, 1964.
4. Forsman B: Effect of mouth rinses with sodium fluoride in schools at Vixjo. *Sverige Tandlak-Forb Tidn* 57:705-709, 1965.
5. Horowitz HS, Creighton WE, McLendon BJ: The effect on human dental caries of weekly oral rinsing with a sodium fluoride mouthwash: a final report. *Arch Oral Biol* 16:609-616, 1971.
6. Aasenden R, DePaola PF, Brudevold F: Effects of daily rinsing and ingestion of fluoride solutions upon dental caries and enamel fluoride. *Arch Oral Biol* 17:1705-1714, 1972.
7. Heifetz SB, Driscoll WS, Creighton WE: The effect on dental caries of weekly rinsing with a neutral sodium fluoride or an acidulated phosphate-fluoride mouthwash. *J Am Dent Assoc* 87:364-68, 1973.
8. Radike AW, Gish CW, Peterson JK, King JD, Segreto VA: Clinical evaluation of stannous fluoride as an anticaries mouthrinse. *J Am Dent Assoc* 86:404-408, 1973.
9. Laswell HR, Pacher MW, Wiggs JS: Cariostatic effects of fluoride mouthrinses in a fluoridated community. *J Tenn Dent Assoc* 55:198, 1975.
10. Driscoll WS, Swango PA, Horowitz AM, Kingman A: Caries-preventive effects of daily and weekly fluoride mouthrinsing in a fluoridated community: final results after 30 months. *J Am Dent Assoc* 105:1010-13, 1982.
11. Ashley FP, Mainwairing PJ, Emslie RD, Naylor MN: Clinical testing of a mouthrinse and a dentifrice containing fluoride. A two-year supervised study in school children. *Br Dent J* 143:333-38, 1977.
12. Blinkhorn AS, Holloway PJ, Davies TG: Combined effects of a fluoride dentifrice and mouthrinse on the incidence of dental caries. *Community Dent Oral Epidemiol* 11:7-11, 1983.
13. Axelsson P, Paulander J, Nordkvist K, Karlsson R: Effect of fluoride containing dentifrice, mouthrinsing, and varnish on approximal dental caries in a 3-year clinical trial. *Community Dent Oral Epidemiol* 15:177-80, 1987.
14. Holm G-B, Holst K, Koch G, Widenheim J: Fluoridtabletter nytt hjälpmedel i karies-profylaktiken. *Tandläkartidningen* 67:354-61, 1975.
15. Poulsen S, Gadegaard E, Mortensen B: Cariostatic effect of daily use of fluoride-containing lozenges compared to fortnightly rinses with 0.2% sodium fluoride. *Caries Res* 15:236-42, 1981.
16. Heifetz SB, Horowitz HS, Meyers RJ, Li SH: Evaluation of the comparative effectiveness of fluoride mouthrinsing, fluoride tablets, and both procedures in combination: interim findings after two years. *Pediatr Dent* 9:121-25, 1987.
17. Stephen KW, Kay EJ, Tullis JI: Combined fluoride therapies. A 6-year double-blind school-based preventive dentistry study in Inverness, Scotland. *Community Dent Oral Epidemiol* 18:244-48, 1990.
18. Bruun C, Bille J, Hansen KT, Kann J, Qvist V, Thylstrup A: Three-year caries increments after fluoride rinses or topical applications with a fluoride varnish. *Community Dent Oral Epidemiol* 13:299-303, 1985.
19. Kirkegaard E, Petersen G, Poulsen S, Holm SA, Heidmann J: Caries-preventive effect of Duraphat varnish applications versus fluoride mouthrinses: 5-year data. *Caries Res* 20:548-55, 1986.
20. Heifetz SB, Franchi GJ, Mosley GW, MacDougall O, Brunelle J: Combined anticariogenic effect of fluoride gel-trays and fluoride mouthrinsing in an optimally fluoridated community. *Clin Prev Dent* 1:21-23, 1979.
21. Miller AJ, Brunelle JA: A summary of the NIDR community caries prevention demonstration program. *J Am Dent Assoc* 107:265-69, 1983.
22. Koch G: Caries increment in schoolchildren during and two years after end of supervised rinsing of the mouth with sodium fluoride solution. *Odontol Revy* 20:323-30, 1969.
23. Rugg-Gunn AJ, Holloway PJ, Davies TG: Caries prevention by daily fluoride mouthrinsing. Report of a three-year clinical trial. *Br Dent J* 135:353-60, 1973.
24. Ripa LW, Leske GS, Levinson A: Supervised weekly rinsing with a 0.2% neutral NaF solution: results from a demonstration program after two school years. *J Am Dent Assoc* 97:793-98, 1978.

25. McConchie JM, Richardson AS, Hole LW, McCombie F, Kolthammer J: Caries-preventive effect of two concentrations of stannous fluoride mouthrinse. *Community Dent Oral Epidemiol* 5:278-83, 1977.
26. DePaola PF, Soparker P, Foley S, Bookstein F, Bakhos Y: Effect of high-concentration ammonium and sodium fluoride rinses on dental caries in schoolchildren. *Community Dent Oral Epidemiol* 5:7-14, 1977.
27. Poulsen S, Kirkegaard E, Bangsbo G, Bro K: Caries clinical trial of fluoride rinses in a Danish Public Child Dental Service. *Community Dent Oral Epidemiol* 12:283-87, 1984.
28. Ripa LW, Leske GS: Two years' effect on the primary dentition of mouthrinsing with a 0.2% neutral NaF solution. *Community Dent Oral Epidemiol* 7:151-53, 1979.
29. Ripa LW, Leske GS, Varma A: Effect of mouthrinsing with a 0.2 per cent neutral NaF solution on the deciduous dentition of first to third grade school children. *Pediatr Dent* 6:93-97, 1984.
30. Leverett DH, Sveen OB, Jensen OE: Weekly rinsing with a fluoride mouthrinse in an unfluoridated community: results after seven years. *J Public Health Dent* 45:95-100, 1985.
31. Ripa LW, Leske GS, Sposato A, Rebich T Jr: Supervised weekly rinsing with a 0.2% neutral NaF solution: results after 5 years. *Community Dent Oral Epidemiol* 11:1-6, 1983.
32. Ripa LW, Leske GS, Sposato A, Rebich T: Supervised weekly rinsing with 0.2 percent neutral NaF solution: final results of a demonstration program after six years. *J Public Health Dent* 43:53-62, 1983.
33. Widenheim J, Birkhed D, Hase JC, Olavi G: Effect on approximal caries in teenagers of interrupting a school-based weekly NaF mouthrinse program for 3 years. *Community Dent Oral Epidemiol* 17:83-86, 1989.
34. Leske GS, Ripa LW, Green E: Posttreatment benefits in a school-based fluoride mouthrinsing program. Final results after 7 years of rinsing by all participants. *Clin Prev Dent* 8:19-23, 1986.
35. Haugejorden O, Lervik T, Birkeland JM, Jorkjend L: An 11-year follow-up study of dental caries after discontinuation of school-based fluoride programs. *Acta Odontol Scand* 48:257-63, 1990.
36. Heidmann J, Poulsen S, Arnbjerg D, Kirkegaard E, Laurberg L: Caries development after termination of a fluoride rinsing program. *Community Dent Oral Epidemiol* 20:118-21, 1992.
37. Ripa LW, Leske GS, Forte F, Varma A: Effect of a 0.05% neutral NaF mouthrinse on coronal and root caries of adults. *Gerodontology* 6:131-36, 1987.
38. Wallace MC, Retief DH, Bradley EL: The 48-month increment of root caries in an urban population of older adults participating in a preventive dental program. *J Public Health Dent* 53:133-37, 1993.
39. O'Reilly MM, Featherstone JD: Demineralization and remineralization around orthodontic appliances: an in vivo study. *Am J Orthod Dentofacial Orthop* 92:33-40, 1987.
40. Øgaard B, Rølla G, Arends J, ten Cate JM: Orthodontic appliances and enamel demineralization. Part 2. Prevention and treatment of lesions. *Am J Orthod Dentofacial Orthop* 94:123-28, 1988.
41. US Food and Drug Administration: Fed Reg 39:17, 1974.
42. Council classifies fluoride mouthrinses. Council on Dental Therapeutics. *J Am Dent Assoc* 91:1250-51, 1975.
43. American Dental Association: Association recognizes OTC fluoride rinses. *ADA News*, July 7-14, 1980.
44. US Food and Drug Administration: Fed Reg 45:20690, 1980.
45. Gift HC, Newman JF: Oral health activities of US children: results of a national health interview survey. *J Am Dent Assoc* 123:96-106, 1992.
46. Stamm JW: The value of dentifrices and mouthrinses in caries prevention. *Int Dent J* 43:517-27, 1993.
47. Stamm JW, Bohannon HM, Graves RC, Disney JA: The efficiency of caries prevention with weekly fluoride mouthrinses. *J Dent Educ* 48:617-26, 1984.
48. Ericsson Y, Forsman B: Fluoride retained from mouthrinses and dentifrices in preschool children. *Caries Res* 3:290-99, 1969.
49. Wei SH, Kanellis MJ: Fluoride retention after sodium fluoride mouthrinsing by preschool children. *J Am Dent Assoc* 106:626-29, 1983.
50. Whitford GM: Fluoride in dental products: safety considerations. *J Dent Res* 66:1056-60, 1987.

## **Pediatric Dentistry can communicate on line!**

Please direct questions, comments, or letters to the editor to:

**Dr. Milton I. Houpt, Editor-in-Chief**  
houpt@umdnj.edu (*Internet*)

You may also send correspondence or questions about manuscript preparation or status to:

**Diana Dodge, Journal Editor**  
ddodge@aapd.org (*Internet*)

We welcome your comments and questions. However, please follow the Instructions to Contributors on the web at <http://aapd.org> for manuscript submission procedures.

