

## A comparison of the anticaries effectiveness of daily and weekly rinsing with sodium fluoride solutions: final results after three years

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### Abstract

*Children in a fluoride-deficient area rinsed their mouths either weekly with a 0.2% NaF solution, weekly with a 0.1% NaCl solution (placebo) or daily with a 0.05% NaF solution. Rinses were conducted in school under the teacher's supervision. Examinations for dental caries were made by two PHS examiners. After three years, incremental caries scores for Examiner 1 showed that subjects in the weekly and daily F rinse groups developed 37.7% and 47.4% fewer DMFS than controls. Corresponding findings for Examiner 2 were 23.5% and 33.6%. For both examiners combined, each regimen of F rinsing was effective in controlling decay, but the observed difference between the two F rinses was not statistically significant. The weekly regimen takes less school time and requires less effort than daily rinses, and costs an average of only 75¢ per child per year, whereas costs of the daily procedure are four times higher. Because of these practical considerations and the lack of clear-cut difference in effectiveness between the two F rinse procedures, the weekly method is preferable as a cost-effective way to reduce children's tooth decay in a public health program.*

This report contains final results of a three-year clinical trial which compared the anticaries effectiveness of daily and weekly mouthrinsing with sodium fluoride solutions. Details of the study design appeared in a previous report of interim findings.<sup>1</sup>

### Methods and Materials

The study was conducted in Biddeford, ME, a non-fluoridated community. Only negligible levels of natural fluoride (0.3 ppm or less) are present in the community's drinking water. At the start of the study in October, 1976, 824 participants in grades 5, 6, and 7 (ages 10 to 12) attending public and parochial schools were examined.

Two Public Health Service examiners, hereinafter identified as Examiners 1 and 2, made the baseline dental examinations. Children were arbitrarily assigned in about equal numbers to each examiner as each classroom reported for examinations. Both examiners used the criteria for diagnosing dental caries (DMFS) that were resented at the ADA's Conference on the Clinical Testing of Cariostatic Agents in 1968.<sup>2</sup> Examiner 1 had limited field experience with the classification system. Examinations were conducted with plane dental mirrors, No. 23 explorers, fiberoptic illumination, and compressed air; radiographs were not taken. Each child was re-examined annually by the same investigator who made the baseline examination. The examiners were unaware of any child's group assignment and did not have access to records from previous examinations.

Within each school, participants randomly were assigned to one of the three following groups: Group C (controls) rinsed once a week with a placebo solution (0.1% NaCl); Group W rinsed once a week with a 0.2% NaF solution; and Group D rinsed daily with a 0.05% NaF solution. Subjects rinsed with 10 ml of solution for 60 seconds.

Participating children in elementary and junior high school, i.e., through 8th grade, rinsed in their classroom under the direct supervision of their teacher. However, during the last year, 9th graders in high school rinsed in the cafeteria under the supervision of lay personnel. These children reported to the cafeteria for rinsing in the brief interval between their arrival at school by bus at the start of homeroom period due to scheduling problems.

Teachers kept a record of each child's participation throughout the study. First- and second-year tallies showed that only a small proportion of the participants: 1.6% and 3.1%, respectively, missed more than 20% their assigned maximum number of treatments. During the third year, records showed that a problem of poor compliance was occurring in the high school third of the study population. Monetary incentives, convenient time for make-up sessions, and liberal use of late passes were offered to improve participation in the high school, but they had little impact. During the third year, 21.6% of participants were absent for more than 20% of the scheduled rinses.

## Results

Of the 824 initial participants, 598, or about 73%, completed the three-year study. Table 1 shows the baseline caries prevalence for these children by examiner and study group. No significant imbalances in mean DMFS scores were found among the study groups either within or across examiners, for any of the comparisons ( $P > 0.05$ ). Across study groups, children examined by Examiner 1 showed a higher mean score than those examined by Examiner 2, but the difference fell short of statistical significance ( $P = 0.07$ ).

Table 1. Baseline DMF surfaces for children remaining after three years by examiner and by study group.

Examiner 1		
Group	No. Subjects	Mean No. DMFS
C (control)	87	7.16 (0.71)*
W (weekly)	97	6.03 (0.57)
D (daily)	88	6.82 (0.68)
Examiner 2		
C	117	6.12 (0.51)
W	102	5.93 (0.47)
D	107	5.44 (0.50)

\* Standard error of the mean.

Results of Examiner 1's findings after one year of study showed a large rate of reversals; the proportion of surfaces reversing from decayed to sound (D0S) to those that potentially could have reversed (D0S + D0D) was about 14%, indicative of inconsistent application of diagnostic criteria between baseline and first-year, follow-up examinations. Smaller, but still inordinately high rates of reversals of about 11% were present in Examiner 2's incremental data after both two and three years of study. Reversals in diagnosis tended to occur fairly equally among the groups at each of the follow-up examinations. Thus, actual differences in incremental caries scores between control and test groups were largely unaffected. However, large reversal rates do bias assessments of proportional preventive effects or percentage reductions† by reducing the size of the denominator or the control group increment, thus tending to produce inflated values.<sup>1,3</sup> Because the examiners had markedly different reversal rates, three-year incremental DMF surface findings in Table 2 are presented for each examiner separately. Results are based on teeth present in the mouth when the study began or teeth that could have received the full three years of treatment. For Examiner 1, children in the weekly and daily fluoride rinse groups developed 37.7% and 47.4% fewer DMFS than control subjects. Corresponding reductions for Examiner 2 were smaller, 23.5% and 33.6%, respectively.

Although lack of examiner consistency affects measurements of percentage reductions, when the shift in criteria is applied uniformly to all study groups, the

Table 2. Incremental DMF surfaces in teeth present at baseline by examiner and by study group after three years.

Group	Examiner 1	
	Mean DMFS Increment	% Difference from Control
C (control)	3.61 (0.65)*	—
W (weekly)	2.25 (0.40)	37.7
D (daily)	1.90 (0.43)	47.4
Examiner 2		
C	4.43 (0.46)	—
W	3.39 (0.39)	23.5
D	2.94 (0.33)	33.6

\* Standard error of the mean.

absolute differences among groups are unbiased and therefore, can be used validly to determine statistically significant treatment effects. Therefore, incremental DMFS after three years for both examiners combined were subjected to statistical analyses using a two-way analysis of variance model and the Bonferroni t-statistic. Table 3 summarizes the results. There were significant differences in caries scores by examiner and by treatment, but no significant difference due to examiner by treatment interaction. Statistical comparisons between specific pairs of treatment groups showed that children who rinsed either weekly or daily with the fluoride solutions experienced significantly less decay than did children in the control group ( $P < 0.01$ ). However, a significant difference between the treatment effects of the two fluoride rinses could not be detected ( $P = 0.38$ ). For teeth erupting during the study (data not shown), results with respect to statistical significance at the 0.05 level were the same as those shown in Table 3 for teeth present at baseline.

To determine whether the protection conferred by the daily and weekly fluoride rinses varied by type of surface, the overall mean DMFS increment in teeth present at baseline was separated into its occlusal, mesiodistal and buccal-lingual components. Results of this analysis, by examiner, are shown in Table 4. For each examiner each type of tooth surface in both treatment groups had smaller mean incremental scores than the controls. For Examiner 2, proximal surfaces showed the greatest relative benefits in both treatment groups and caries inhibitions in the daily rinse group exceeded those in the weekly fluoride rinse group for all types of surfaces. These patterns in benefits by type of surface and group were not as clear-cut in Examiner 1's data. For both examiners' data combined, specific comparisons between treatment and control groups by type of surface show that all differences, with the exception of those on buccal-lingual surfaces for weekly fluoride rinsing, were statistically significant ( $P < 0.05$ ). None of the type-surface differences between the weekly and daily fluoride rinse regimens was significant.

Figure 1 shows the incremental DMF surface scores

†  $\frac{\text{control} - \text{test}}{\text{control}}$

**Table 3. Results of statistical analyses of incremental DMFS in teeth present at baseline after three years.**

Two-way analysis of variance	
Source of Variation	P Value
Examiner	.007
Treatment	.001
Treatment by Examiner	.93*
Bonferroni t-statistic	
Specific Comparison	P Value
Control vs Weekly	.008
Control vs Daily	.001
Weekly vs Daily	.38*

\* N.S.  $P > .05$ .

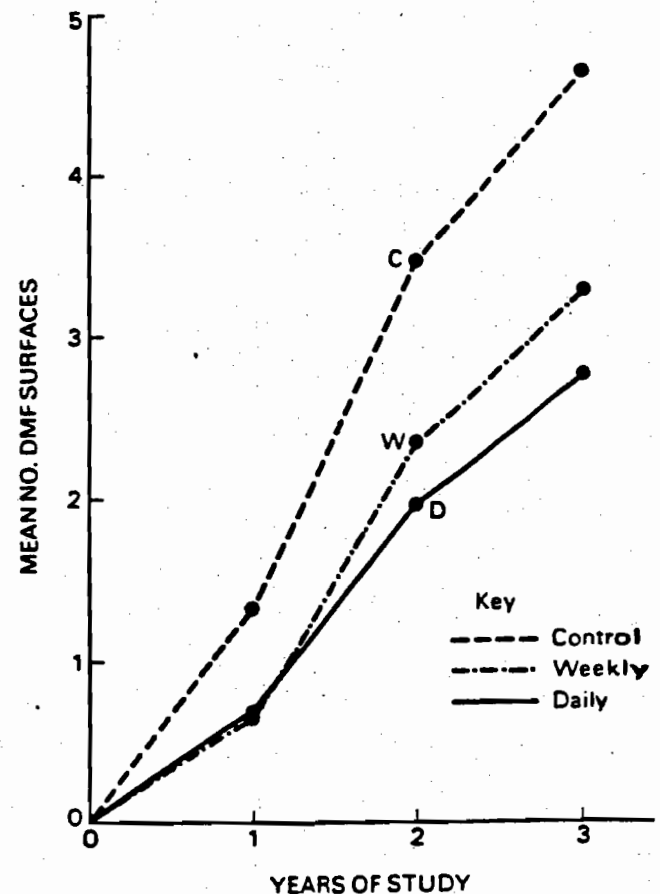
after 1, 2, and 3 years for 519 children who were present at all examinations for both examiners by study group. Findings are based on both baseline and newly erupted teeth. Thus, the results graphically summarize the overall effectiveness of the treatments in all teeth examined for a constant population during the course of the study the weekly and daily fluoride procedures, the slope of the lines connecting cumulative annual incremental scores are nearly identical with the exception of those in the second year of study. None of the differences in mean incremental DMFS between the two fluoride rinses observed after two and three years was statistically significant. However, the differences in mean incremental DMFS between control and test groups at each annual follow-up examination were all statistically significant. After three years, the difference amounted to almost 1.5 and 2 fewer DMFS per child in the weekly and daily fluoride rinse groups, respectively.

### Discussion

Interim results after one and two years of study showed that children who rinsed either weekly or daily with the fluoride solutions experienced significantly fewer new DMFS than did controls. However, significant differences between the two fluoride rinses could not be detected. Three-year findings of the present report confirm the results obtained after one and two years, i.e., both fluoride regimens were effective in controlling dental decay, but they did not differ significantly from each other. Both examiners showed only a small difference of about 10 percentage points between daily and weekly

fluoride rinsing. Despite the unimpressive size of the difference, a conclusion that the two treatments produce similar benefits must be reserved because of the large  $\beta$  error in this study. A large  $\beta$  error offers a good likelihood of falsely accepting the null hypothesis when a real difference exists.

More important than a simple comparison of efficacy of the two treatments is a comparison of cost-effectiveness for the purpose of public health programming. In a three-year study of daily rinsing in school with a 0.05% NaF solution, Rugg-Gunn and coworkers observed a 36% reduction in incremental decay.<sup>4</sup> However, their accounting of costs of the procedure led them to conclude that its cost-effectiveness was debatable. In con-



**Figure 1. Incremental caries scores in all teeth after 1, 2, and 3 years for both examiners by group.**

**Table 4. Mean incremental DMF surfaces in teeth present at baseline by examiner and type of surface and by study group after three years.**

Group	Examiner 1			Examiner 2		
	Occlusal	% Difference	%	Proximal	% Difference	%
C	1.51	—	—	1.39	—	—
W	1.07	29.1	—	0.76	45.3	42.3
D	0.74	51.0	—	0.86	38.1	57.7
				Examiner 2		
C	1.71	—	—	1.70	—	—
W	1.37	19.9	—	1.21	28.8	20.6
D	1.23	28.1	—	0.93	45.3	22.5

First, weekly fluoride mouthrinsing has been shown to be clearly cost-effective.<sup>5</sup> The materials for weekly rinsing cost about one-fourth as much as for daily rinsing. The weekly procedure requires considerably less school time and effort. Assuming a caries reduction of only 20-25% for weekly rinsing, which is at the lower boundary of reported efficacy,<sup>6</sup> the protection provided by daily rinsing would have to be substantially greater to duplicate the cost-effectiveness of the weekly regimen. Understandably, there is presently little debate over the weekly fluoride mouthrinse being the procedure of choice for public health programs.

The NaF solution used by the daily rinse group in the present study contained a fluoride concentration of 230 ppm. Recently, NaF and SnF<sub>2</sub> rinse products containing approximately the same fluoride concentration have been made commercially available to the public on a nonprescription basis. When used daily according to directions, there is little doubt that the home rinse procedure can confer benefits equal to, if not greater than, the weekly regimen of fluoride rinsing in school. We support the use of these over-the-counter rinse products as a bona fide preventive measure. However, some fluoride rinsing should not be used to supplant programs of weekly rinsing in school because the home procedure is not as feasible a public health measure. Costs for the daily use of the commercial rinse product greatly exceed the low cost of 75¢ per child per year for the materials required for a school-based weekly procedure.

Moreover, judging from the problems of compliance experienced in many home-based programs of daily administration of fluoride tablets,<sup>7</sup> it is doubtful that we can depend on large numbers of children carrying out the daily home rinse for an extended period.

The over-the-counter fluoride rinses have been recognized as safe and effective in controlling dental decay by the Council on Dental Therapeutics of the ADA.<sup>8</sup> However, the Council's recommendation links the effectiveness of the fluoride rinse products to their use in conjunction with a recognized fluoride dentifrice and a program of oral hygiene. Because sales of fluoride dentifrices comprise more than 80% of total dentifrice sales in this country, current fluoride mouthrinse studies in-

herently represent evaluations of the additive effects of mouthrinsing in populations that use fluoride dentifrices. Evidence linking the effectiveness of fluoride mouthrinsing with the maintenance of good oral hygiene, however, is lacking. Attempts were not made to clean the teeth prior to rinsing in the Biddeford study or in most other reported studies of mouthrinsing with fluoride solutions. A thorough toothbrushing before either daily or weekly mouthrinsing with fluoride may enhance their respective benefits, but, at present, the value of a prior toothcleaning remains to be demonstrated. Investigators are presently studying this question under contract-supported research of the National Caries Program, National Institute of Dental Research.

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