

**Fluoride-Associated Caries Initiation, Progression and Remineralization:
A three-year preventive field trial for Mexican-American Hispanic schoolchildren using
fluoride mouthrinse**

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ABSTRACT

Purpose Previous studies on the effectiveness of fluoride mouthrinsing have utilized the DMFT and DMFS indices. The purpose of this study was to evaluate the effectiveness of a fluoride mouthrinse program on the initiation and remineralization of caries in Mexican-American schoolchildren with dfs scores twice the national average.

Methods Two adjacent elementary schools, in the westside barrio of San Antonio, were designated as control and test schools in a field trial from 1987-90. Administration of a weekly 0.2% Sodium Fluoride mouthrinse (FMR) to first graders began in the Fall of 1987. All first grade cohorts through 1990 participated and were given clinical and radiographic examinations annually.

Results There was no significant rise in either caries component, frank or incipient, in the test school over time, versus growing increments in the control school. Leverett's projection of annual savings of decayed tooth surfaces with FMR (0.2 - 0.4 DMFS per year) was confirmed by our finding over all one year periods of 0.28 DMFS per year. Incipient caries represented over 70 percent of the total approximal caries experience, and was largely confined to the control group. The major FMR preventive effect was on incipient caries, especially for permanent teeth erupting during the program. This benefit increased over time with use of FMR. Between the second and third years, over ten percent of first permanent molars of children in the control group showed evidence of progressing caries lesions on mesial surfaces, versus less than two percent of these surfaces in children using FMR.

Conclusions The study is considered to justify FMR programs in these high caries experience Mexican-American children, and others, as a primary preventive method in non-fluoridated communities.

Key words: *fluoride mouthrinse, fluorides, caries, caries initiation, caries progression, remineralization, Mexican-American Hispanic, school-based program, community water fluoridation, primary prevention*

Introduction

A comprehensive review of the efficiency and effectiveness of fluoride mouthrinsing (FMR) in public programs, by Leverett in 1989, estimated the mean savings to be 0.2 - 0.4 decayed, missing, filled surfaces (DMFS) per year.¹ This appears to be a modest but incremental preventive gain, and is based on traditional evaluation of caries advanced to cavitation (D) missing due to caries (M) or filled due to caries (F). It does not evaluate earlier and observable stages of caries initiation and remineralization. Fluorides are known to prevent caries initiation and promote remineralization. To more adequately and fully evaluate these fluoride effects, assessments at earlier stages of the caries process are desirable, and were an objective of this study.

Since Leverett's review in 1989,¹ an eight-year study by Driscoll et al., concluded that combining a FMR and fluoride-tablets in a school program provided no significant benefit over their sole application. The tablet program was the most efficient choice; yet it required daily use in school and the assurance that prescribed tablets were not also consumed at home.² A report on a daily, weak acidic, lower fluoride-content rinse (100ppm F, pH 5.0) for Japanese preschoolers appeared to benefit permanent teeth.³ Ruiken and Truin (1987)⁴ showed a FMR benefit only in the absence of systemic fluorides. According to Widenheim and Birkland (1989),⁵ the benefit appears to be greater in teenagers, probably due to the greater number of approximal permanent surfaces at risk. Marthaler (1981)⁶ concluded that both caries initiation and progression were affected by fluoride, but to differing extents. Groenveld (1985, 1986),⁷ in a longitudinal re-evaluation of the Tiel-Culemborg data (circa 1953-1971), concluded that effects of fluoride on caries initiation, as observed in incipient lesions, were small. The major effects then observed were on caries progression to frank lesions. These conclusions were especially applicable to topical effects of fluoride on approximal surfaces observed during the years of tooth eruption.

The Hispanic Health and Nutrition Examination Survey of 1982-1984 (H-HANES)⁸ showed that the caries prevalence for Hispanic children reflected the national decline in dental caries (NIDR, 1986-87, NIDR 1979-80),^{9,10} but one-third of the decay found had not been treated. The NHANES III study (1988-1991) showed similar findings of higher rates of decayed surfaces in primary and permanent teeth, but lower rates of filled surfaces in the permanent teeth in Mexican-American children than Non-Hispanic whites.¹¹ The 1982-1984 Texas Department of Health (TDH) Prevalence Survey of Caries revealed that Hispanics had higher mean scores of caries than Anglos and a lower rate of treatment. These data also showed a positive relationship between the rate of caries treatment, educational level and economic status.¹²

Dental caries scores for preschool, primary school children and adolescents were known from prior surveys to be higher in the non-fluoridated city of San Antonio than for equivalent groups in other parts of Texas and the Southwest.¹³

Since the Michigan Workshop on Cost Effectiveness of Dental Prevention and the National Preventive Dentistry Demonstration Program, FMR programs in the United States have been more confined to schools with children at higher risk of caries.^{14,15}

Methods

In order to teach dental students and school students, teachers, administrators and parents the need for caries prevention, and the relative effectiveness and limitations of alternative community preventive methods, this project was devised.¹⁶ It was intended that a 'model' program could be promoted for adoption at other schools. The main purpose was to assess caries in disadvantaged Mexican-American school children from lower income families, to teach first and third year dental students how to operate a school oral prevention program, to educate the community about the need for, operation and value of a school dental prevention program, and specifically for this report to evaluate the current effectiveness of FMR in school children with high dental caries experience.

This evaluation covers the period 1987-90 in the Edgewood Independent School District (ISD) of the westside barrio of San Antonio. The superintendent of the school district chose the Test and Control elementary schools for the program. All schools were within a mile of each other, in what was then the voter precinct of lowest average household income in Bexar County. Over ninety-five percent of children were enrolled in the school lunch program, and over ninety percent of enrolled children were Mexican-American.

This program was planned as a field trial under actual school conditions, rather than as a controlled clinical trial. Thus control and test schools were designated, and the classroom was the operating unit. Incremental entry of first graders into the FMR program, plus any new enrollees in other involved grades, occurred each year.

In the Spring semesters of the years 1987-90, 0.2 percent Sodium Fluoride mouthrinse (Medical Products) was self-administered each Friday morning by schoolchildren with assistance of teachers, teacher aides and parent volunteers, who were trained by the coordinator. Four randomly-selected classrooms were chosen to teach small groups of first-year dental students how to administer FMR. The dental students also gave group-toothbrushing instructions. A record was kept of rinse frequency per child.

Sealants were placed in the Fall semester of second grade by junior dental students, and FMR continued. Annual examinations were made in January of each year. It was decided to evaluate one pair of bitewing radiographs for the FMR effects on incipient approximal caries,

realizing that the increment of frank approximal caries of permanent teeth at these ages would be small. Institutional Review Board and Radiation Safety Committee and parental approvals were obtained. Portable dental equipment was used and included high volume suction, compressed air, and autoclave. Radiographs at the annual examination were made with a portable x-ray unit using a standardized film holder, protective apron with a collar and protective screen.¹⁷ The school nurse was responsible for obtaining written informed parental consent, forwarding the results of the examination and one set of the twin-pack radiographs to parents, and for follow-up when treatment was indicated. The consent rate was over ninety percent in 1987 and remained of this order throughout. A few children switched between these two schools, and were eliminated from the evaluation.

FMR was used according to the protocol of Horowitz.¹⁸ Caries diagnosis followed the World Health Organization (WHO) 1987 protocol,¹⁹ with the additional recording of incipient lesions. Diagnostic criteria were as follows:

Frank Caries

Approximal and Smooth surfaces

Caries was scored when a detectable break in the enamel surface on gentle exploring was observed. White or brown spot lesions were not scored as caries, since without cavitation and under favorable conditions, remineralization can occur, or has occurred. Hypoplasia was excluded. Where caries had invaded the marginal ridge, the occlusal surface was also called carious.

Pit and fissure surfaces

Caries was scored as visible cavitation, or if softening was detectable on gentle exploring. A “catch” or “stick” of the explorer alone, was insufficient to indicate that cavitation had occurred. Softening indicated caries progress into dentin, whereas a catch of the explorer may only have indicated that the explorer was larger than the fissure at that point. Fissure staining was not sufficient, by itself, to record caries. A dark opalescence around a fissure may have indicated caries under the ‘intact’ surface, and frank cavitation or softening to the explorer was then sought. Hypoplasia was not scored as caries.

Incipient Caries

Approximal and smooth surfaces

Incipient approximal caries was separately scored from radiographs as less than half way through the enamel, or from half-way through the enamel up to the dentin enamel junction (DEJ). Caries spreading at the DEJ or into dentin was separately coded as frank caries.

Pit and Fissure surfaces

Visible white or brown spot caries with minimal or no surface changes, which was not soft to the explorer, nor undermined, but may have been stained, chalky or catch the explorer (stick), was coded incipient.

The radiographs were assessed with diminished background lighting, using a masked viewing box and magnifier. One evaluator, trained and calibrated initially and periodically against an experienced examiner, scored all radiographs. If there was doubt about the depth of caries, the lower severity score was assigned. Surfaces which could not be scored for technical reasons were excluded.

Sealants were recorded by surface, and if lost from more than half the fissure were not recorded as present. The whole of the disto-lingual groove of upper molars was recorded as lingual. A sealed surface was regarded as sound. Filled surfaces and teeth missing due to caries were recorded, as were sound, unerupted and otherwise excluded teeth (extracted for other reasons, restored for trauma etc.)

The examinations by tooth surface were recorded directly on to op-scan sheets, and the separately scored radiographic findings were added to the op-scan sheets at a later time, and so were blind to the clinical findings. Demographic and identifying codes were used, so that longitudinal evaluation of children was possible. Inter and intra examiner calibration tests were conducted at the start of each annual examination period, and discrepancies resolved. All clinical exams were made by the same two examiners who worked simultaneously.

The op-scan sheets were read and verified to create a data file, using op-scan card programming. DMFT/S scores and other scores by surface condition were compiled using the Statistical Package for the Social Sciences run on the UTHSCSA VAX system.²⁰ The compilations were downloaded to the Dept. of Community Dentistry Mac Network and analyzed using Statview and Excel.^{21,22}

The analytical methods used were tests of significance between proportions and between mean scores, using the Standard Error Test, Chi-square and t tests. Linear regression of a natural progressive array versus time was also used.

FINDINGS

In the Fall of 1987, ninety-six percent (73 subjects) in the test school, and ninety percent of children (58 subjects) in the control school who entered first grade, participated. Attrition of these subjects occurred each year and by the end of the third year of study, these numbers were reduced to 55 in the test school and 34 in the control. One major focus in analysis for this report was on these subjects, and they are enumerated in Figures 1 and 2.

Incremental entry into first grade occurred each year of the study, and first grade cohorts of 1988 and 1989 were also evaluated over two- and one-year periods respectively. Findings which include these periods of observation will also be discussed, and they are enumerated in Figure 3.

Baseline caries

The baseline mean decayed or filled primary tooth surfaces (dfs) for both schools combined was 10.4 and did not differ significantly between schools. It was determined by parental questionnaire that very few of these children had ever used fluoride tablets or drops. San Antonio water contains 0.3 ppm fluoride. For the control school the extent and distribution of baseline caries of primary teeth can be described and compared with an equivalent socioeconomic and Mexican-American ethnic, but fluoridated population in Table 1.

Baseline caries of permanent teeth was expectedly very low at this age, not equally distributed between test and control schools as is typical of a field trial, but they did not differ significantly.

Caries Increment

When all one-year observational periods were considered for all cohorts, the annual average savings in mean DFS was 0.28 for approximal permanent tooth surfaces in the 263 FMR children over the 255 controls. The number of subjects reflecting this annual savings in DFS is shown in the lower part of Figure 3. Considering only those 55 and 34 subjects who participated for the full three years, this same caries increment in approximal permanent tooth surfaces was not significantly different between FMR and control groups.

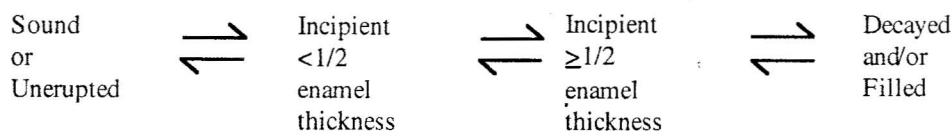
The mean number of incipient approximal carious surfaces of permanent teeth remained low in the FMR group throughout the study (0.02 at baseline, 0.04 after 3 years). For the control group, the mean number of incipient approximal permanent tooth surfaces rose significantly over time (0.18 at baseline, 0.59 after 3 years, $p < 0.05$).

These DFS and incipient caries effects of FMR on permanent approximal surfaces were almost exclusively of the mesial of first permanent molars, and FMR practically eliminated all observable caries, frank and incipient, from this surface.

Caries Progression

The mean DFS is an inadequate measure of FMR effect in this study, because of the skewed caries distribution with a decreasing proportion of the population having an increasing proportion of the caries experience, and because examiner variability and recording errors will inevitably increase as a proportion of true disease as caries declines. Thus a method was sought to describe the change in caries status of individual approximal surfaces over time, taking account of lower rates of caries incidence, severity and progression.

In a time of higher caries prevalence, Grainger (1967)²³ proposed a system of caries severity scoring which was validated by Poulsen and Horowitz (1974)²⁴ and Katz and Meskin²⁵. Only two of Grainger's four caries surface groupings now commonly occur. Therefore a method of assessing not severity but caries progression was devised, based on composite clinical and radiographic caries scores arrayed in a natural progression:



The overall annual change in specific tooth surface conditions could be represented by regression lines. The description of caries progression/remineralization in this way assumes constant error variance, but this was not supported by an F test. Less than 1 percent of variation in the squared residuals, $(O-E)^2$, was associated with variation in the predicted stage of caries. This means that the error variance is time-dependent, as is common to categorical data as Kingman (1979)²⁶ has observed with respect to Grainger's²³ model.

This methodological problem lead next to plotting the percentage of tooth surfaces diagnosed at each examination (Figure 1, 2) for all subjects examined each year. Incipient lesions are thus seen to contribute a major component of the total permanent approximal caries burden in these children: 12 percent of these surfaces with incipient caries and 4 percent with frank caries experience (DFS) in the control school.

Histograms showing the percentage of mesial surfaces of first permanent molars which showed caries progression to any degree over each of three years, and using the same natural progression schema shown above, are illustrated as Figure 3. Progressive lesions were those assessed at a stage to the right of the stage at the beginning of that year of observation. By assessing only progressive lesions, the significant preventive effect of FMR was even more clearly apparent and grew each year. In the third year, 10.3 percent of first permanent molar approximal surfaces showed progressive carious lesions, versus 1.8 percent in the FMR school. Progressive lesions rose with time in the control school but were static with time of FMR use.

Figures 1, 2 and 3 respectively, present evidence for reduced cavitation, lower initiation and lack of progression of caries with weekly school use of a 0.2% NaF mouthrinse by the group under study.

DISCUSSION

Baseline Caries

The initial overall primary tooth caries scores were very high; three times the mean for the Southwestern U.S. and two and a half times the US mean at this age. The overall mean dfs of 10.4 compared with 4.0 nationally, 4.1 in a comparable socioeconomic and predominantly Mexican-American ethnic, but fluoridated community (San Elizario, Texas) and 3.4 in the Southwestern states.^{11,13} The distribution of caries by primary tooth surface (Table 1) was that expected in a past era. This helps to document the high caries prevalence in primary teeth of low income Mexican-American children without fluoridation, such as in San Antonio. These surface distributions for primary teeth were quite different from that for permanent teeth in the population under study.

Two potential overestimates of deciduous caries were recognized. The first results from restoration of incipient caries, and is not controlled for, since restoration occurred independent of the prevention program. The second results from scoring 5 decayed, filled surfaces (dfs) for crowned teeth. Based on our observation of untreated deciduous teeth with ≥ 3 ds, which may be considered indicated for crowns, the mean number of ds per tooth was 3.4. Under these conditions, the fs and dfs would be overestimated by 1.6 for each crown on average. It can be shown that this overestimate of dfs may be of practical effect on mean dfs when the proportion of children receiving crowns is high and/or the number of crowns/child is high. e.g. If 30 percent of children have two crowns each the overestimate in mean fs will be 1.0; if 10 percent of children have eight crown each the overestimate will be 1.8; if 30 percent of children have 8 crowns each the overestimate in mean fs will be 3.8. In fact the rate of caries treatment of Mexican-Americans is lower than for other racial and ethnic groups^{11,12} and so an overestimate of fs due to crowns is less likely to account for the high caries scores than in the general population.

The deciduous caries scores in these children are two to three times higher than national and regional scores. Permanent caries scores, are also higher, but by a factor of less than two. No adequate hypothesis for this difference in susceptibility of the dentitions is available. Diet cannot reasonably be said to change on eruption of permanent teeth, parental questionnaires on fluoride toothpaste use were not discriminating, and suggested explanations of caries proneness of primary versus permanent teeth based on enamel thickness seem quite inadequate, given that the permanent teeth with thinnest enamel are least caries prone.

Fluoride bioavailability for remineralization in response to caries challenge, with high frequency at low dose, is currently considered important for fluoride effect to be optimal. The most plausible explanation may be that many of these children are fluoride deficient, but testing of this hypotheses would be difficult because enamel biopsies do not differ greatly between fluoridated and non-fluoridated communities and are difficult to control for depth of enamel

sampled. Parental questionnaires on fluoride toothpaste use tend to be answered according to expectations, and in-home availability of fluoride toothpaste would have to be ascertained frequently over a sustained period, but in a covert way. The inquiry itself would easily bias the result.

It is generally held that high deciduous caries predisposes to high permanent caries.^{27,28} Opinions to the contrary, based on a hypothesis of self-immunization by high levels of cariogenic bacteria in the preschool years are speculative at best, and not in accord with the observations that infants who acquire Mutans Streptococci earlier, go on to develop more caries. Thus the high primary caries experience and low family SES levels of these children indicate they are a group at high risk of future caries. As such they are a suitable group for testing FMR and Sealants to prevent caries of permanent teeth in a community-based program.

Fluoride Mouthrinse and Caries of Approximal Permanent Tooth Surfaces

Approximal frank caries represented only 12 percent of the all surfaces scored DFS. Incipient caries represented over 70 percent of the total approximal caries experience. There was no significant rise in either caries component, frank or incipient, in the test school over time, versus growing increments in the control school.

A traditionalist objection to analysis of incipient lesions may be raised as to how many would ever require restoration, since not all progress. This may be answered by affirming that prevention of incipient caries is primary prevention, and preferred over the secondary prevention of restoration, which breaches tooth integrity and often has to be retreated. Also, progressive lesions were separately assessed in this study, and found to be lower in the FMR group. All lesions should currently be thought of as requiring treatment; remineralization or sealant treatment if incipient or minimal, restoration if frank or cavitated (Bader and Brown 1993, Brown 1993).^{30, 31} This value judgment therefore led to an assessment of caries progression in this study, and is in keeping with contemporary concepts of the biology of caries and its management. Caries is now understood to be a reversible, multifactorial, infectious, diet dependent disease of the mouth, manifest in teeth.

This discussion hinges on an acceptance of the implied distinction of caries initiation and caries progression. Caries initiation actually takes place at the crystal level, not the light level, in accord with the physical chemistry of enamel solubility. Nevertheless, it is true that incipient lesions are both observable at an earlier stage and reversible, while frankly cavitated lesions are less often arrestable, and involve loss of form and potentially of function.

As newer, validated caries detection methods are adopted e.g. tooth separation, fiber optic transillumination (FOTI) and electrical resistance (ER), and other promising methods commercially developed e.g. quantitative light fluorescence (QLF) and electrical impedance spectroscopy (EIS), caries will be diagnosed earlier.³² Arrest of progression and enhancement of

remineralization will grow in importance and be better understood and managed. Newer methods of evaluating these preventive outcomes based on enhanced detection technology and applied prior to the development of frank caries will replace evaluation of frank caries.³³ This study shows we are well down such a path, because evaluation of frank caries was not an adequate outcome measure of FMR, even in this high caries risk group.

The present study is of a high caries experience sample, following major decline of caries in the overall population. The results are in marked contrast to the Tiel-Culemborg fluoridation study reports of prior decades which indicated the major effect was then on lack of caries progression to frank lesions. In the present study the major effect was on lack of initiation of incipient lesions. A similar but smaller effect was noted for primary teeth, but not reported here.

The primary teeth in this study erupted 3 to 4 years before the start of FMR, and the permanent teeth during the use of FMR. The benefits after three years favor availability of fluoride from the time of eruption. This is consistent with fluoride uptake during post-eruptive enamel maturation and with the bio-availability of fluoride which enhances remineralization of enamel undergoing repeated caries challenge.

Our results, for all one year observation periods combined, showed an average annual saving of decayed surfaces of 0.28 for approximal surfaces - confirming Leverett's estimation in 1989 of 0.2-0.4 DMFS per year. Recently Morgan, Crowley and Wright (1998)³⁴ reported an economic analysis of FMR and Sealants in 12-13 year olds in nonfluoridated communities of Victoria, Australia, and showed a mean annual savings of 0.14 DMF smooth surfaces per year. These authors showed that a combined FMR and sealant program became more cost effective each year of operation.

When incipient plus frank approximal caries were considered together, the percentage of approximal tooth surfaces which progressed in the third year of FMR was 1.8 percent versus 10.3 percent ($p<0.001$) for first permanent molars in the control school, and 5.1 percent versus 9.4 percent ($p<0.012$) respectively for deciduous posterior teeth. This represents approximal caries progression in 34 fewer first permanent molar mesial surfaces per 100 subjects, and 86 fewer deciduous posterior approximal surfaces per 100 subjects in the third year of FMR; an average of 1.2 fewer progressing caries lesions per subject using FMR.

FMR effects on pit and fissure surfaces are not assessed in this report. Fluorides are known to be more effective on smooth surfaces, but since 88 percent of the caries now occurs on pit and fissure surfaces of permanent teeth of Texas children and adolescents,¹¹ fluoride effects on these surfaces may still be of major importance in those programs when FMR is not combined with sealants. Molina and Rodriguez (1989)³⁵ presented some data of relevance to this point, but clear and detailed data is lacking. Although the numbers of children we observed in school over three full years was limited by enrollment and attrition in schools, their response was consistent

with that of larger numbers of subjects we observed and evaluated over one and two year periods, and over successive yearly periods. The method of analysis was an efficient use of data from a field trial with progressive cohort recruitment of subjects each school year.

Conclusion

With the caries decline, it is more readily observable that fluorides reduce caries initiation. This is a highly desirable primary preventive effect, which was not so apparent when caries rates were higher overall. FMR in this non-fluoridated, low income Mexican-American community was an effective caries preventive measure, and Leverett's estimate of annual savings of tooth surfaces from caries were confirmed. However, the contemporary full effect was not apparent by observing DFS. The major FMR preventive effect was to prevent initiation of incipient caries and inhibit caries progression, especially for permanent teeth erupting during the program. This benefit increased over time of use of FMR. The study is considered to justify FMR programs in high caries experience, low income, minority children living in non-fluoridated communities. FMR is a primary preventive method - it prevents caries initiation, as well as caries progression to cavitation.

The project has been used to promote oral health in San Antonio. Nevertheless it has proven difficult to influence community, school district and city officials to act on the implications of the findings that (a) school prevention programs are effective and justified in many other schools, and (b) that community water fluoridation would convey a community wide benefit at far lower cost than FMR, and make fluoride universally bio-available for caries prevention and remineralization for all age groups, including those not part of this study - preschoolers, adolescents, adults and seniors.

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This Program continues to be a training program in community oral health for junior and freshmen dental students, under the supervision and training of Martha Baez, RDH, MPH. In addition, UTHSCSA dental students in 1993 independently raised funds through a fun run and corporate sponsorship to operate their own school FMR programs. Presently over 6,200 children in 32 schools participate. They have provided continuity to their program by continuing the leadership, fund- raising and program operation to the present.

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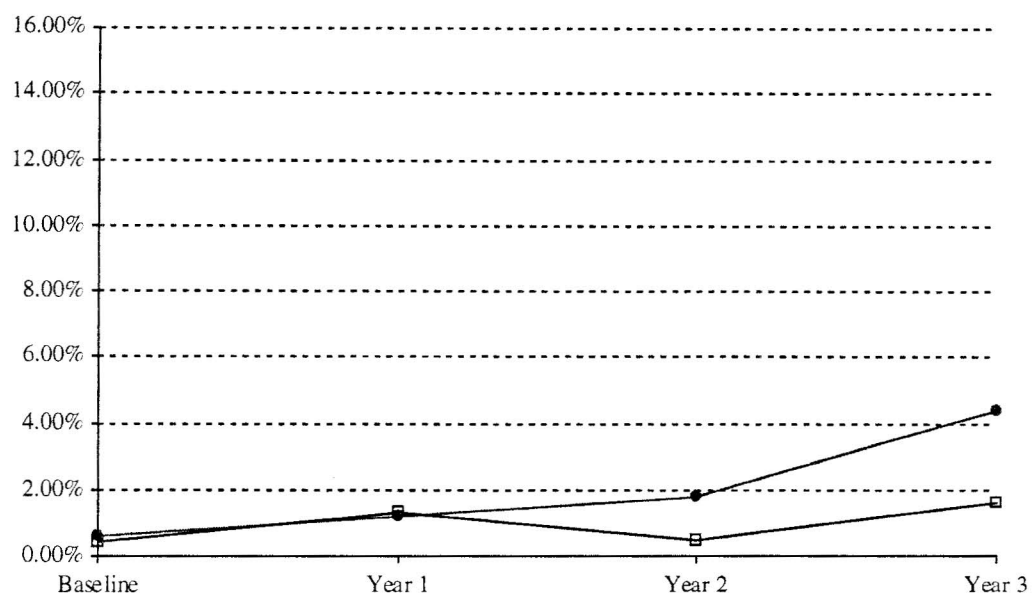
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Table 1
Mean dfs and its tooth surface distribution in two predominantly Mexican-American communities

Location	Age	Water Fluoride Level	Mean dfs \pm sd	Occlusal	Buccal and Lingual	Approximal
San Antonio Tx (1987)	6-8	0.3ppm	10.1 \pm 12.2	28%	31%	40%
San Elizario Tx (1988)	7-9	0.7 to 1.2ppm	4.1 \pm 5.0	47%	25%	28%

FIGURE 1

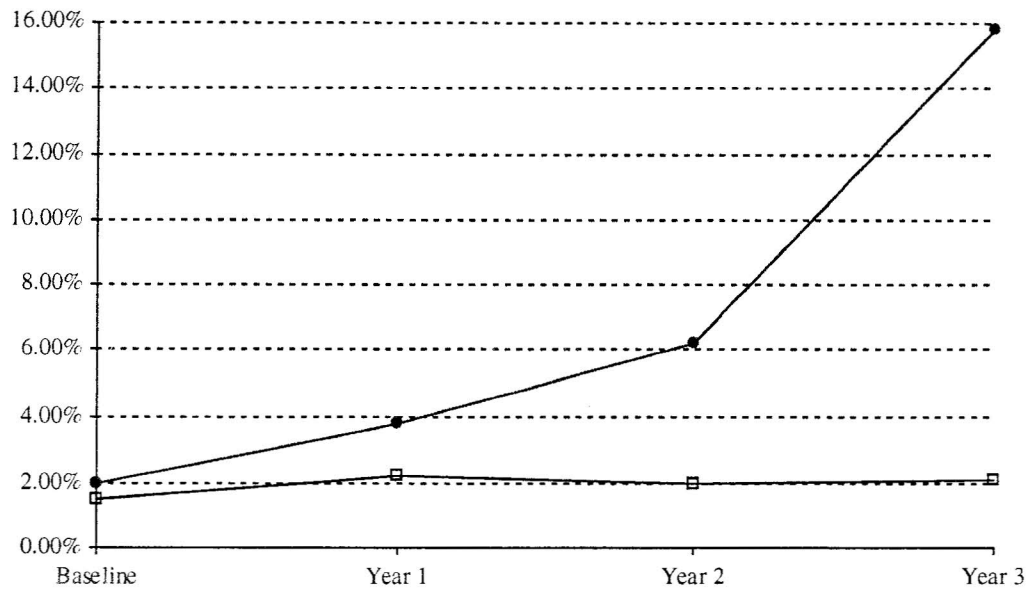
% Frankly Decayed plus Filled Permanent Approximal Surfaces



No. of Subjects				
Control	58	53	41	34
Test	73	73	63	55

FIGURE 2

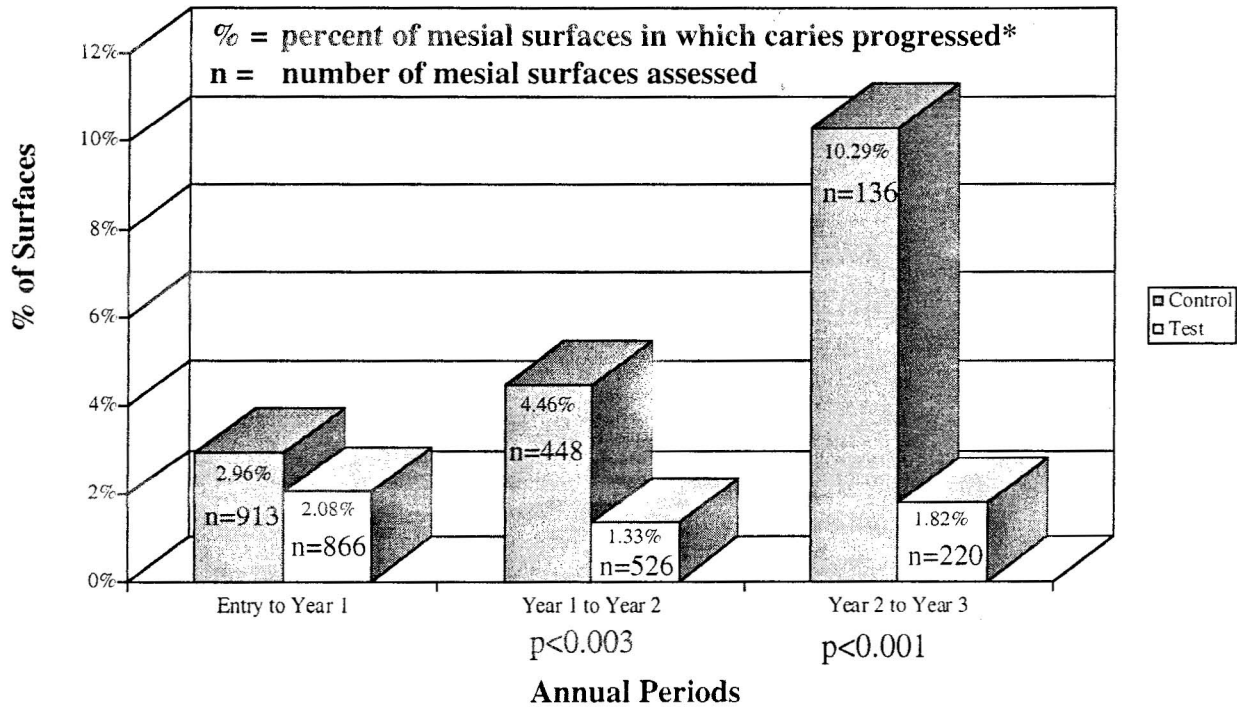
% Incipient plus Frankly Decayed plus Filled Permanent Approximal Surfaces



No. of Subjects				
Control	58	53	41	34
Test	73	73	63	55

FIGURE 3

% of Mesial Surfaces of First Permanent Molar Teeth in Which Caries Progressed During Each of Three Annual Periods



Subjects:

255	263
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113	135
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34	55
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With incremental entry to this field study, the number of subjects available for observation from entry to Year 1, and from Year 1 to Year 2 is greater than those shown in Figure 1 over a full three-year period.

*Progressive lesions are defined under Findings.