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A Clinical Study of the Caries Preventive Effects of an APF Solution and an APF Thixotropic Gel

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Abstract

A clinical trial was conducted to determine the caries inhibitory effects of a "high fluoride release" (solution) and a "low fluoride release" (thixotropic gel) APF topical agent. The test population ranged from 11 to 14 years of age and consumed water containing < 0.2 ppm F^-. Application of the agents once every six months resulted in caries increment reductions of approximately 35% for both agents after 24 months. It is possible that the 1.23% fluoride concentration contained in the products is higher than that required for optimum caries inhibitory effects. Or, the physical properties of the thixotropic gel may compensate for the slower release of fluoride. Fluoride release rates, as determined by a dialysis method, were not useful indicators of clinical effectiveness.

Introduction

The twice-annual topical application of acidulated phosphate fluoride (APF) agents containing 1.23% fluoride (F^-) has been shown to be an effective method of reducing the incidence of dental caries in test populations of children (For review: [1-4]). The use of these agents, particularly as gels, has become popular among dental practitioners. The gels are convenient to apply and seem to be as effective as the solutions.[5]

Most of the APF gels available today employ a cellulose base to achieve the desired viscosity. Recently, some gel products have been introduced which are described as "thixotropic". The term refers to substances which express increased flow under pressure and to which increased viscosity returns when pressure is released.[6] The manufacturers claim that these characteristics make the agents more convenient to use and possibly more effective. To date, these gels have been tested only in the laboratory[7,8] and no clinical trials to evaluate their caries preventive effectiveness have been reported.

In a previously reported study from our laboratory, various APF solutions and gels were tested to determine their rate of F^- release. It was shown that a thixotropic product released significantly less F^- in the first five minutes than did solutions or cellulose gels.[7] However, other investigators have reported that *in vitro* F^- enamel uptake values from two cellulose gels and the thixotropic gel used in our study were similar.[8] Questions concerning the clinical effectiveness of thixotropic gels remain.

The present study was undertaken to evaluate the clinical effectiveness of a "high release" APF agent (solution) and a "low release" APF agent (thixotropic gel), applied once every six months, in reducing the incidence of dental caries in a child population. Our primary interest was to determine if the laboratory test measuring the rate of fluoride release from topical agents was useful in predicting clinical effectiveness.

Methods and Materials

The test population was drawn from three junior high schools in Lenoir County, N.C. Information concerning the study and permission slips were sent home with all seventh grade students. Students undergoing

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orthodontic appliance therapy were excluded from the study, and the remaining 368, who had returned signed permission slips, were randomly assigned to one of three groups: those to be treated with an APF solution (Group A); those to be treated with the APF thixotropic gel (Group B); and those who received no fluoride treatment (Group C).

The Lenoir County Health Department had tested numerous water supplies throughout the county during the last decade. The water from all of those sources contained < 0.2 ppm fluoride.

Prior to examination and application of fluoride, each subject's teeth were stained with a disclosing solution,* and plaque was completely removed with a soft bristle brush and dental floss. Dental hygiene students who had been oriented to the purposes and procedures of the project assisted the subjects to ensure that plaque removal was complete. Each subject was also checked for complete plaque removal by the examining dentist.

A single examiner (H.B.C.) was used throughout the study. The protocol was designed so that the examiner did not know which group the subjects were assigned to until data collection was complete.

A portable dental chair and light were used for the examination. The caries examination was conducted using a sharp #23 explorer and a front surface mirror. Compressed air was used to dry the teeth before tactile and visual examination. Radiographs were not taken.

The decayed, missing, and filled surfaces (DMFS) index was used to record dental caries. A minimum carious lesion was defined as a break in the enamel surface that would "hold" the tip of the explorer. Recurrent decay in filled surfaces was diagnosed by the same criteria. Only permanent teeth were considered in the study, and teeth extracted for orthodontic purposes were not recorded as missing. Findings were recorded on optical scanning forms to facilitate processing and analysis of the data.

Following plaque removal and examination, the subjects in Groups A and B received a four minute application of topical fluoride. The dental hygiene students isolated the teeth with cotton rolls, thoroughly dried the teeth with compressed air, and applied the fluoride agent with cotton swabs using floss to carry the material into the interproximal areas. Group A received application of an APF solution,† and Group B was treated with an APF thixotropic gel.§ Shortly before the study was initiated the manufacturer modified the original thixotropic product and analyses showed that the new agent** released F^- about as rapidly as an APF solution. Upon request, the supplier provided thixotropic gel based on the old formulation for use in this study. Both the solution and the gel contained 1.23% fluoride. Subjects in Group C had plaque removed from their teeth but had no fluoride application. Participants receiving fluoride were instructed not to eat or drink for 30 minutes following treatment.

Subsequent examinations and fluoride applications were made at six month intervals (±2 weeks) through 24 months, at which time the study was terminated.

The data were evaluated by application of the t-test, comparing the mean DMFS increments of each group to each of the others.

Fluoride release from the solution and the thixotropic gel was measured according to the method of Congleton *et al.*[7]

Results

The subjects ranged in age from 11 to 14 years. There were no significant differences among the groups according to age, sex, race, or the proportion of subjects who reported regularly visiting a dentist. Neither were there significant differences in the loss of subjects from the groups during the course of the study.

Table 1 shows the mean DMFS scores for the test groups at the baseline and the mean cumulative DMFS increments at six, 12, 18 and 24 months. Figure 1 is a graphic display of the cumulative six-month DMFS increments for the three groups. It can be seen that the no-treatment group (Group C) experienced a greater cumulative DMFS increment at each observation period than did either treatment group (Groups A and B). However, these differences were significant at the 95% level of confidence only at the 18 and 24 month intervals. While the cumulative increments for Group B (APF thixotropic gel) were always lower than for Group A (APF solution), the differences were not statistically significant at any of the observation times. The DMFS increments in the control might be considered high in comparison to other study groups. However, the increments are typical of populations in that region of the state.[9]

The results of analyses for F^- release from the solution and the thixotropic gel by continuous flow dialysis showed that the gel released 56% as much F^- as did the solution in the first five minutes.

Discussion

A previous study from our laboratory had shown, using a continuous flow dialysis method, that F^- diffu-

*Trace Dental Disclosing Solution, Lorvic Corp., St. Louis, MO.

†Luride APF Topical Solution, Hoyt Laboratories, Needham, MA.

§Gel II (original formulation), Pacemaker Corp., Portland, OR.

**Gel II (current formulation), Pacemaker Corp., Portland, OR.

Table 1. DMFS baseline and six month cumulative increment scores for control group (Group C) and fluoride treated groups (Group A — solution; Group B — thixotropic gel)

	Baseline		6 Mo.		12 Mo.		18 Mo.		24 Mo.	
Group	N	DMFS	N	DMFS Increment	N	DMFS Increment	N	DMFS Increment	N	DMFS Increment
A	131	5.17 (0.44)*	117	1.62 (0.22)	118	2.86 (0.33)	107	4.32 (0.53)	102	5.35 (0.58)
B	130	6.01 (0.46)	124	1.28 (0.23)	123	2.60 (0.39)	116	3.72 (0.49)	115	5.28 (0.66)
C	107	5.38 (0.46)	97	1.69 (0.22)	92	3.35 (0.35)	86	6.17 (0.67)	78	8.15 (0.87)

* x (± standard error of the mean)

sion across a membrane from APF solutions occurred in accordance with Fick's law of diffusion. In the first five minutes, the typical cellulose gel released only 60% as much F^- as did the solutions, and the thixotropic gel released only 17% as much F^-.[7] It was of interest to determine if these data had clinical relevance. This was particularly so in view of a report by Wefel and Wei[8] which indicated that enamel uptake of F^- *in vitro* was similar when enamel was exposed to cellulose gels or a thixotropic gel having the same fluoride concentration.

It was originally intended that three topical fluoride agents (an APF solution, an APF cellulose gel, and an APF thixotropic gel) would be evaluated in the current study. However, the number of subjects available allowed inclusion of only two treatment groups. The decision was made to use a "high F^- release" product (solution), a "low release" product (thixotropic gel), and to omit the "intermediate release" agent (cellulose gel).

Analyses revealed that the batch of thixotropic gel used in this study released 56% as much F^- as did the APF solution. This was considerably higher than the product we had tested in our previous study, but substantially lower than the test solution.

Since the primary purpose of this study was to determine the value of a laboratory test in predicting clinical effectiveness, the fluoride agents were both applied with cotton tipped applicators to more closely simulate laboratory conditions. The method was also more similar to conditions used in the study reported by Wefel and Wei.[8] Thixotropic gels are usually applied in trays when used clinically. That method could well result in levels of effectiveness different than those reported here.

The study was conducted according to methods generally accepted for investigations of this kind. The results show that application of both APF agents resulted in caries reductions when compared to the contol group, and that these differences were statistically significant at 18 and 24 months. Even though the thixotropic gel resulted in greater caries reductions

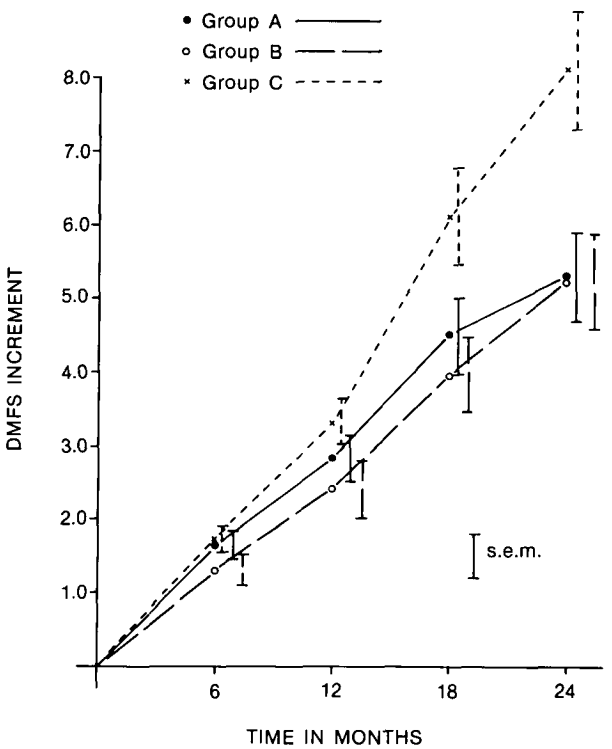

Figure 1. Cumulative DMFS increments for control group (C), APF solution treated group (A) and APF thixotropic gel treated group (B)

than the solution at six, 12, and 18 months, none of the differences were statistically significant and the reductions were nearly the same at 24 months. It is clear that the clinical results were unrelated to data concerning the rate of F^- release from the two products. The results are consistent with the *in vitro* findings of Wefel and Wei,[8] although the F^- release rate of the agents they used was not measured.

There are two possible explanations from these results. The first is that the 1.23% fluoride concentration contained in the APF agents may be substantially higher than that required to obtain the maximum caries inhibitory effect, even when applied only once every six months. This possibility has been mentioned

by other investigators.[8]

Concern has been expressed about children who experience nausea following topical fluoride application.[10] A recent study showed that under optimum conditions children may swallow an average of about 11 mg of fluoride as the result of a topical application.[11] Less than optimum application methods could result in ingestion of considerably more fluoride. Use of an agent with a lower concentration would reduce the amount of fluoride ingested. If the clinical effectiveness of a topical fluoride agent with a lower concentration was similar to that obtained with a 1.23% concentration, the use of the former would be indicated. This possibility should be pursued in a clinical trial using identical agents except for their fluoride content.

The second possible explanation for our results is that the physical characteristics of the thixotropic gel may enhance the enamel uptake of available fluoride and, thus, compensate for the lower rate of fluoride release.

It should be considered that about 25% of the children in the control group (Group C) reported visiting a dentist on a regular basis and some of them probably received fluoride applications, thus reducing the apparent effectiveness of fluoride treatments given during the study.

Nevertheless, the caries increment reductions observed in this study at 18 and 24 months are fairly typical for reported investigations using APF agents of this fluoride concentration under these general conditions (30-50%).[3] The reductions seen in the current study were observed even though the toothbrush and floss prophylaxis was substituted for the traditional rubber cup and paste prophylaxis. Tinanoff and coworkers[12] have reported laboratory findings which indicate that a traditional prophylaxis did not enhance fluoride uptake by enamel. The usefulness of the rubber cup and prophy paste prophylaxis prior to the application of an APF 1.23% fluoride agent seems open to question. Plaque removal with a brush and floss may be just as effective. However, this study did not directly address that question and the findings in that respect are only suggestive.

It is obvious that measuring the rate of fluoride release from two topical agents containing the same concentration of fluoride was not a useful indicator of clinical effectiveness under the conditions of this study.

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