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Effect of professional application of APF foam on caries reduction in permanent first molars in 6-7-year-old children: 24-month clinical trial

Han Jiang[a], BaoJun Tai[a], MinQuan Du[a], Bin Peng[b,*]

[a]*Department of Preventive Dentistry, School of Stomatology, Wuhan University, China*
[b]*Key Lab for Oral Biomedical Engineering of Ministry of Education, School of Stomatology, Wuhan University, Luoyu Road 237, Wuhan City 430079, China*

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Summary *Objectives*. The purpose of the study was to evaluate the effect of 6-monthly professional application of APF foam on caries reduction in permanent first molars in 6–7-year-old children over 24 months, and to compare the caries-preventive effect between APF foam and APF gel.

Methods. In a randomised controlled trial, 661 children aged 6–7-years-old were randomly divided into three groups on a school class basis. The foam group and the gel group received 6-monthly APF foam and APF gel application, respectively, and the control group did not receive any treatment.

Results. The mean caries increment of smooth surfaces of permanent first molars in the foam group was 0.16 while that of the control group was 0.27, resulting in 41% caries reduction (P-value = 0.02), but there was no statistically significant difference between the foam group and the gel group (P-value = 0.10). No difference was found on the mean caries increment of pit and fissure surfaces or all surfaces among the three groups (ANOVA, P-value = 0.89).

Conclusion. Six-monthly professional application of APF foam could effectively reduce the incidence of dental caries in smooth surfaces of permanent first molars in 6–7-year-old children, which was similar to APF gel.

Introduction

Over the past decades, caries prevalence among children in the USA and the most North-West European countries has declined dramatically.[1,2] It is generally accepted that fluoride toothpaste has played an important role in caries reduction in developed countries. In contrast, dental caries in China remains a serious problem. The results of the Second National Survey of Oral Health in China (1995–96) showed that the prevalence of dental caries of children at age 5 was 76.6%, and in 12-year-old the mean DMFT was 1.1. It is worthy noting that the d/D-component constitutes most of the caries index.[3] Meanwhile, a high proportion of

* Corresponding author. Tel.: +86 27 87646384; fax: +86 27 87161397.
E-mail address: phs301@vip.163.com (B. Peng).

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toothpaste marketed in China does not contain fluoride. In fact, most Chinese population do not benefit from the anticaries effectiveness of fluoride toothpaste.[4] Thus, there is an urgent need for taking some appropriate and effective measures of prevention to control caries disease aimed at school children.

Acidulated phosphate fluoride (APF) is an effective cariostatic agent that had been widely investigated in the last half century. APF gels are frequently used in dental clinics and prevention programmes in schools in many countries during recent decades.[5] Fluoride gel can be professionally applied and self-applied under supervision and is usually provided at least every 6 months.[6,7] The effects of APF gel in caries prevention are recently confirmed by two review articles.[5,8] A meta-analysis of clinical studies by Marinho et al.[5] showed the overall caries-inhibiting effect of APF gel treatment was 21% (95%, CI=19–28%), and no evidence was observed that the effect of reduction was dependent on baseline caries level.

APF foam is a relatively recent product, which has the same concentration of fluoride (1.23%) and pH (3–4) as conventional APF gels.[9,10] Whitford et al.[9] found that the two APF products were the same in terms of their abilities to deposit fluoride on the enamel surface. However, compared with the gel, the APF foam required only about one-fifths as much material by weight for adequate coverage of the teeth, which significantly reduced fluoride exposure and retention by the patient.[10] To our knowledge, no clinical studies have investigated the preventive effect of APF foam on caries development in permanent teeth. The primary aim of the present study was to evaluate the effect of 6-monthly professional application of APF foam on caries reduction in permanent first molars in 6–7-year-old children over 24 months. The secondary aim was to compare the caries-preventive effect between APF foam and APF gel.

Materials and methods

The study protocol was reviewed and approved by the Ethics Committee of the School of Dentistry, University of Wuhan, prior to the implementation of this study. The study was implemented in the Hongshan District of Wuhan City, Hubei Province, which is located in central China. Fluoride concentration in drinking water in the district is 0.1–0.3 ppm. Dental care is mainly offered on demand from one dental hospital with about 100 dental units, and no organised oral health care programmes in the primary school are available in the district.

Subjects

The sample size needed to complete the study was calculated to be 198 children per group, with a power of 70% and an alpha level 0.05, to detect the difference of 30% in 2-year caries increment. In total, 661 6–7-years-old children from three primary schools were recruited into the 24-month clinical study. The children were randomly allocated to the three groups based on school class. A total 13 classes from three primary schools were numbered from 1 to 13. Then, all classes were randomly assigned to APF foam group ($n=4$ classes), APF gel group ($n=4$ classes) and control group ($n=5$ classes) by using blocked randomisation. The parents of these children were informed by letter explaining the purposes, design and procedures of the study. Meanwhile, a short questionnaire was sent to the parents who completed it at baseline. The questionnaire included the following items: (1) demographic characteristic, (2) children's toothbrushing behaviour, (3) children's dental visit behaviour, (4) use of fluoride toothpaste, and (5) family's economics status. The informed written consent was obtained from parents of all children. The subjects were blinded to the assignment of group and two dental examiners were blind to all group allocations.

Treatments

APF foam (Laclede Foam, 1.23% APF, pH 3.5, USA) or APF gel (Xiao tianshi, 1.23% APF, pH 3.5, Shanghai) was professionally applied at schools by two dentists and two assistants. The subjects did not receive professional prophylaxis, nor were the teeth dried by the compressed air, prior to the application. The appropriate sponge-lined trays were used in the procedure of treatment. If the tray did not fit the child, it was trimmed by the operators. The amount of APF foam or APF gel placed in the tray was no more than 40% of the tray's volume. The tray then was placed over the teeth and the child was instructed to close the jaws. The teeth were allowed to be in contact with the foam for 4 min according to the manufacturer's instructions of Laclede APF foam and gel for 4 min. During the time, the child was

seated in an upright position with the head inclined forward and downward to reduce swallow. Meanwhile, the children were told not to swallow but to allow the saliva dropping to a recycling plastic plate directly. At the end of the treatment, the tray was removed from the mouth, and each child was emphasised to expectorate the mixture of saliva and foam or gel for up to 1 min. The children were cautioned not to rinse, eat or drink for at least 30 min. The treatments were provided at approximately 6-monthly interval over 2 years. The maximum number of applications that a child could receive was four times. The children in the control group did not receive any treatment.

Clinical examinations

Oral examination at baseline was carried out in October 2000 and the follow-up examination took place in November 2002. The children were examined by the same two examiners (dentists), who were requested to participate in an initial calibration trial. The kappa statistic was used to assess the inter-examiner reliability and the final kappa scores were higher than 0.90. The clinical examinations were performed in classrooms under natural daylight using sharp explorers and mouth mirrors. Examination criteria for caries diagnosis followed the WHO guidelines (1997). Only cavities with detectable soft wall and floor were recorded as dental caries. In order to test the intra-examiner reliability, about 10% of the children were re-examined as random subjects on the same day in all examinations. The Kappa values of the duplicate examination were over 0.90 at baseline and follow-up evaluations.

Statistics methods

Only those children who were present at baseline examination, four times treatments and follow-up examination were included in the analysis. All data were inputted into the computer and analysed by means of the SPSS 11.0 system for Windows. A one-way analysis of variance (ANOVA) was performed to compare the differences in caries indices at baseline and caries increments among the three groups. Scheffĕ's multiple-comparison was used to compare the significant differences found among the three groups. Chi-square tests were conducted for descriptive variables. The level of statistical significant was set at $\alpha = 0.05$.

Results

A total of 661 children participated in the baseline examination were included in the study. There were 205 (mean age 6.5 ± 0.4 years) children in the APF foam group, 210 (mean age 6.4 ± 0.5 years) in the APF gel group, and 246 (mean age 6.5 ± 0.5 years) in the control group. A total of 612 children completed the study; the drop-out rate was 7%. Most children who were lost from the study were caused by transfer to other schools.

Table 1 presented a description of some baseline demographic characteristics of the three groups. There was no statistically significant difference among the three groups in terms of potentially influential factors such as gender, age, toothbrushing frequency, use of fluoride toothpaste, dental visit, family's economics status and dental caries experience (dmft, dmfs)

The 2-year surface-specific caries increment in permanent first molars of children in three groups was shown in Table 2. The mean caries increment of smooth surfaces of permanent first molars was 0.16 and 0.17 in the foam group and in the gel group, respectively, while that of the control group was 0.27. There was statistically significant difference among the three groups (P-value = 0.01). As compared to the control group, the mean increment of smooth surfaces of permanent first molars was 41% lower in the foam group (P-value = 0.02), and the figure was 37% lower in the gel group (P-value = 0.049). No difference was observed between the foam group and the gel group (P-value = 1.0).

There was no statistically significant difference among the three groups on the mean caries increment of pit and fissure surfaces of permanent first molars (ANOVA, P-value = 0.89). Although the mean DMFS increment of all surfaces in the foam and gel group was lower than that in the control group, it was not statistically significant (ANOVA, P-value = 0.22).

No side effects such as nausea and vomiting were recorded in the present study.

Discussion

The present study was a randomised controlled clinical trial and based on a 2-year follow-up design. One possible bias of this study was that operators were not blind to fluoride application because the physical characteristic between APF foam and APF gel was significantly different. Another limitation of the study derived from the randomisation process on a school class basis, rather than individual, which might lead to selection bias of subjects. However, in China, each child had an equal chance to be

Table 1 Baseline demographic characteristic of the three groups.

Background variables	APF foam group	APF gel group	Control group	*P*-value
Total number of subjects	205	210	246	
Age, years (SD)	6.5 (0.4)	6.4 (0.5)	6.5 (0.5)	>0.05
Gender, *n* (%)				
Male	109 (53.2)	112 (53.3)	127 (51.6)	
Female	96 (46.8)	98 (46.7)	119 (48.4)	>0.05
Toothbrushing frequency (%)				
Less than once a day	38.5	36.7	31.7	
Once a day	32.2	30.5	37.1	
At least twice a day	29.3	32.8	31.2	>0.05
Use of fluoride toothpaste (%)				
Yes	42.4	45.7	40.2	
No	57.6	54.3	59.8	>0.05
Dental visit (%)				
Within the last 12 month	20.5	24.3	22.4	
Over one year	21.0	20.5	20.3	
Never	58.5	55.2	57.3	>0.05
Family's economics status (%)				
High	38.5	31.4	35.8	
Medium	33.2	37.6	31.3	
Low	28.3	31.0	32.9	>0.05
Dental caries at baseline, mean (SD)				
Dmft	4.0 (4.4)	3.7 (4.0)	3.6 (4.1)	>0.05
Dmfs	8.1 (10.9)	8.3 (10.1)	7.7 (9.9)	>0.05

allocated to either class in every primary school since assignment was not based on academic ability and parent's income level. Meanwhile, no significant differences were observed among the three groups with regard to gender, age, dental health behaviour, family's economics status and caries indices at baseline. Furthermore, the drop-out level was low, and results from inter- and intra-examiner agreement indicated excellent reliability of the examination. The subjects were blind to the assignment of group and two dental examiners were blind to all group allocations throughout the study. It was concluded that the findings were valid.

The effectiveness of 1.23% APF gels on caries reduction had been widely documented in numerous clinical studies.[5,7,8] It was widely accepted that topical fluoride can ensure protection on smooth surfaces, but had limited effect on the pits and fissures of teeth.[11] Results of the study by van Rijkom et al.[7] showed that a reduction of about 60% on caries increment of smooth surfaces was achieved in low-caries children initially aged

Table 2 Mean (±SD) caries (DMFS) increment by tooth surface types of permanent first molars over 24-month study period.

	n	Baseline mean (SD)	Follow-up mean (SD)	New caries increment mean (SD)
Smooth surface				
Foam	191	0.03 (0.21)	0.19 (0.44)	0.16 (0.39)
Gel	200	0.04 (0.30)	0.21 (0.41)	0.17 (0.38)
Control	221	0.03 (0.20)	0.30 (0.48)	0.27 (0.45)*
Pit and fissure surface				
Foam	191	0.09 (0.34)	0.31 (0.77)	0.22 (0.66)
Gel	200	0.07 (0.31)	0.27 (0.63)	0.20 (0.55)
Control	221	0.08 (0.37)	0.31 (0.68)	0.23 (0.60) NS
All surface				
Foam	191	0.12 (0.40)	0.51 (0.87)	0.39 (0.65)
Gel	200	0.10 (0.35)	0.48 (0.81)	0.38 (0.69)
Control	221	0.11 (0.46)	0.61 (1.01)	0.50 (0.87) NS

*$P<0.05$ (ANOVA). NS, not statistically significant (ANOVA).

4.5–6.5 years by using 1.23% APF gel over 4 years, but no reduction was observed on pit and fissure surfaces. This finding was in accordance with the present study. Six-monthly professional application of APF foam and APF gel were found to be effective in preventing caries in smooth surfaces of permanent first molars. The reduction of new dental caries development was 41 and 37%, respectively, when compared to the control group. In a recently systematic meta-analysis of gel trials by Marinho et al.[5] including 14 studies of APF gels published between 1964 and 1996, the overall average preventive effect was 21% (95%, CI = 19–28%), showing the effectiveness in permanent teeth, but estimate of treatment effect on the main outcome in no-treatment control group employed was 19% higher than that in the placebo control group employed. The result was in agreement with the findings of the current study, in which the DMFS pooled prevention fraction of APF foam and APF gel was higher than that of the above meta-analysis. Although it was unclear why the type of control group was associated with differences in outcome, the results should be considered with caution.

Another similar clinical trial reported that 6-monthly application of APF gel was significantly efficacious in reducing caries on pit and fissure surfaces among the children aged 6–7 of 3–14 baseline dmfs, but no reduction on smooth surfaces and among children having initially more than 14 dmfs.[6] However, the statistical limitation of the study, especially the low level of power achieved in the separate analysis of the two groups according to the different dmfs at baseline might produce the bias in the results.[12]

It was likely that the effectiveness of APF foam on caries prevention in permanent teeth was equivalent to APF gel because the chemical characteristic and application method of APF foam were similar to gel.[13] This null hypothesis was supported by the 24-month findings. However, compared with gel, the risk of using APF foam was reduced because a smaller amount was needed for application. The fluoride exposure and retention of APF foam by the patient might be significantly reduced compared with APF gel application.[9,10] Thus, APF foam may be a better alternative to APF gel, especially for young children.

In conclusion, based on the 24 mouths results of this study, it is concluded that 6-monthly professional application of APF foam is as effective as APF gel in reducing the incidence of dental caries in smooth surfaces of permanent first molars in 6–7-year-old children. Taking into account reduced risk of fluoride over-ingestion, the application of APF foam should be recommended. Future clinical studies are needed to assess the relations between the caries-inhibiting effect of APF foam and costs in the Chinese population.

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