

A clinical study of the anti-caries effect of 1.23% and 0.4% APF fluoride gel on primary dentition: One year follow-up

Karam H Jazrawi¹
BDS, MSc (Assist Lect)

Layla A Makani²
BDS, MSc (Assist Prof)

Tarik Y Khamrco²
BDS, DDPH(RCS), MSc (Prof)

¹**Dept of Pedod, Orthod and Prev Dent**
College of Dentistry, University of Mosul

²**Dept of Pedod, Orthod and Prev Dent**
College of Dentistry, Al-Mustansiriya University

ABSTRACT

Aims: To determine the efficacy of acidulated phosphate fluoride (APF) gel in reducing caries increment in a group of pre-school children in Mosul City, and to compare between the anti-caries effect of two different concentrations (full strength-1.23% and half strength-0.4%) after one year of bi-annual application of the gel. **Materials and Methods:** The sample consisted of 363 kindergarten children [192 (52.89%) males and 171 (47.11%) females] aged 4 years -at the initial examination- from 10 randomly selected kindergartens in Mosul City Center. The sample was divided into two experimental groups and one control group. Children in the first group received bi-annual application of full strength (1.23%) APF gel; those in the second group received bi-annual application of half strength (0.4%) APF gel, whereas those in the third group did not receive any fluoride treatment. Dental examinations were done according to WHO criteria using dmft and dmfs indices: One before fluoride application and the other after one year. **Results:** A significant reduction in dental caries increment of the two experimental groups compared with the control group regarding dmft and dmfs indices. The percentage of caries reduction regarding dmft and dmfs indices were 97.25% and 101.15% for the first group, and 95.94% and 85.33% for the second group, respectively. However, the differences between the two concentrations were statistically not significant, although children in the first group who received the full strength fluoride application revealed slightly better reduction in caries increment than those in the second group who received the half strength fluoride application. Therefore, to decrease the risk of ingesting a highly concentrated fluoride gel, the use of the lower concentration APF gel is recommended. **Conclusion:** The use of such a program involving professional APF gel application for pre-school children is advised especially for those with evidence of dental caries.

Key Words: Acidulated phosphate fluoride gel, fluoride concentration.

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INTRODUCTION

Despite great improvements in the oral health of populations across the world, problems still persist. This is particularly so among underprivileged groups in both developed and developing communities.⁽¹⁾ According to the WHO report,⁽²⁾ dental caries remains a major public health problem in most industrialized countries, affecting 60-90% of school children and the vast majority of adults. It is also the most prevalent oral disease in several Asian and Lat-

in American countries. The principal reason for this increase are the growing sugar consumption and inadequate exposure to fluorides.^(3, 4)

Trends in caries experience in the primary dentition are well documented in most countries.⁽⁵⁻⁷⁾ Epidemiological surveys have shown that the prevalence of dental caries was higher in children from less favourable socioeconomic backgrounds than in the general population.^(8, 9)

The need to combat this high prevalence

nance of dental caries in pre-school children leaves the dental profession to a difficult dilemma. On one hand, the importance of the primary dentition as a predecessor for the permanent teeth cannot be neglected. In fact, early extraction of carious primary teeth may create a major orthodontic problem later on. On the other hand, restoration of carious teeth for such young children is not easy; controlling of child being the major difficulty. Moreover, a primary tooth with a restoration is still at risk for additional attacks of dental caries and to inflammation of its supporting tissues.^(1, 2)

The use of fluorides by various means (including professional topical fluoride application) has proven to be effective in preventing dental caries.^(10, 11) Clinical investigations have repeatedly demonstrated the effectiveness of topically applied fluoride gel and solution upon the permanent teeth,⁽¹²⁻¹⁴⁾ but, unfortunately, a paucity of literatures has demonstrated such effect on primary teeth. Most studies conducted on such field evaluated the caries preventive effect of fluoride toothpaste,⁽¹⁵⁾ fluoride varnish,⁽¹⁶⁾ stannous fluoride,⁽¹⁷⁾ amine fluoride,⁽¹⁸⁾ or compared the increment of fluoride in enamel resulting from application of sodium fluoride solution.⁽¹⁹⁾

However, studies have shown that a considerable amount of fluoride may be ingested during the course of a standard professional topical fluoride application,^(20, 21) and that plasma fluoride levels achieved after such an application may reach potentially toxic levels.^(22, 23)

Acute fluoride toxicity is of particular concern when administering a topical fluoride treatment to the small child patient because of the exposure to a relatively higher fluoride dose per body weight than in the case of an adult receiving the same treatment. Since most currently used gels are both flavoured and acidulated, saliva-fluoride mixture generally occurs during gel application. The amount ingested by a young child may be increased if the use of saliva ejector is impractical. This potential for toxicity would be diminished if the fluoride concentration of the currently used 1.23% APF gels could be reduced without compromising clinical effectiveness.⁽²⁴⁾

So, the purposes of the present research were to determine the efficacy of profes-

sionally applied topical acidulated phosphate fluoride gel in reducing caries increment over one year period in a group of pre-school children aged 4-5 years old in Mosul City, and to compare between the anti-carries effect of full- and half-strength gels.

MATERIALS AND METHODS

The study was conducted in 2001-2002 with 412 kindergartens children aged 4 years at the initial examination from 10 randomly selected kindergartens in Mosul City, Ninevah Governorate, Iraq. These kindergartens were chosen from both sides of the Tigris River depending on the cooperation of the kindergarten's authority.

The parents of each child received detailed explanatory letters concerning the aims and benefits of the study and including their approval about the research. The letter also included two questions regarding the child: The medical health and the history of fluoride intake (whether systemic or topical). Any child with known history of fluoride intake, systemic and/or topical, was excluded from the study.

All the children were clinically examined two times during the study: 1) At the beginning of the study, and 2) after one year (at the end of the study). The children were examined in good natural daylight with a probe and mirror according to the WHO criteria using dmft and dmfs indices,⁽²⁵⁾ with the exception that a score for the initial caries (white or chalky spots) was included in the scoring of decayed teeth.⁽¹⁵⁾ The missing primary molar teeth were scored as extracted. One extracted molar tooth was counted as 4 extracted surfaces according to Dunning.⁽²⁶⁾ Missing incisor teeth were assumed as being exfoliated and not included in the scoring of the index. Radiographs were not taken because of the practical limitations which make radiography for each child very difficult.

After the first clinical examination, the entire sample was randomly divided into three groups. The first group received topical application of conventional full-strength acidulated phosphate fluoride (APF) gel (1.23% APF thixotropic gel "Protect, USA") every 6 months (2 times a year); the second group received topical application of half-strength APF gel

(0.4% APF thixotropic gel “Dentaclean, UK”) every 6 months (2 times a year); and the third group was the control group that received no application of fluoride.

All applications of fluoride were accomplished by teams consisting of 10 persons representing the researchers and students from the fifth grade of College of Dentistry, University of Mosul. The experimental groups received no prior prophylaxis. Five children at a time were treated following the standard procedure for professional fluoride gel application.⁽²⁷⁾

It should be emphasized that, in order to minimize the amount of fluoride inadvertently swallowed by the children and decrease the hazard of fluoride toxicity, the Workshop on Changing Patterns of Fluoride Intake (WCPFI) recommendations⁽²⁸⁾ were strictly followed during each application session.

The daily “work orders” for the specific treatments and their date of application for each child were registered.

The results were statistically expressed as two whole-mouth dmft and dmfs indices. The mean baseline indices, their standard deviation (SD), and the mean 1-year indices with SD were calculated. The statistical evaluation of the differences between the mean 1-year caries increments for the experimental and control groups was performed using F-test, whereas one-way analysis of variance (ANOVA) followed by Duncan’s Multiple Range Test were used to estimate the difference among the three groups in the first and second examinations, both for dmft and dmfs indices. Percentage of caries reductions and caries increments were calculated according to Rugg-Gunn⁽²⁹⁾ as follows:

$$\frac{\left(\text{Mean of caries increment of the control group} \right) - \left(\text{Mean of caries increment of the experimental group} \right)}{\text{Mean of caries increment of the control group}} \times 100$$

$$\frac{\left(\text{Mean of caries at the second examination} \right) - \left(\text{Mean of caries at the first examination} \right)}{\text{Mean of caries at the first examination}} \times 100$$

RESULTS

In the beginning, 412 children were included in the trial and 363 of them remained by the end of the study, which represents a loss of 11.89%.

Table (1) presents distribution of the sample regarding sex for the three groups.

The sample consisted of 192 (52.89%) males and 171 (47.11%) females. The first group contained 165 (45.45%) children, second group included 108 (29.75%) children, while the third (control) group contained 90 (24.80%) children.

Table (1): Distribution of the sample according to sex and different groups

Sex	Group 1		Group 2		Group 3		Total	
	No.	%	No.	%	No.	%		
Males	No.	81	42.19	69	35.94	42	21.87	192
	%	49.1	████████	63.89	████████	46.67	████████	52.89
Females	No.	84	49.12	39	22.81	48	28.07	171
	%	50.9	████████	36.11	████████	53.33	████████	47.11
Total		165	45.45	108	29.75	90	24.80	363

Table (2) shows the mean age of the sample according to sex of the three groups. The mean ages for males, females and total sample were 4.516, 4.483 and 4.5, re-

spectively. It is worth to clarify that the difference between the mean age of males and females was very slight.

Tables (3) and (4) reveal the mean

dmft and dmfs, respectively, in the first and second examinations for each group. Regarding the experimental groups, the differences between the first and second examinations was statistically not significant; while for the control group, the difference was significant ($p = 0.0002$).

Tables (3) and (4) also show the percentage of caries increment for the groups

regarding dmft and dmfs, respectively. From these results, it could be found that the highest caries increment was found in the third (control) group, followed by the second then the first group. The negative score for the first group regarding dmfs index indicated that there was a decline in the incidence of dental caries.

Table (2): The mean age of the sample for the different groups

Groups	Males		Females		Total	
	Mean (Years)	± SD	Mean (Years)	± SD	Mean (Years)	± SD
1	4.574	0.448	4.518	0.512	4.546	0.481
2	4.500	0.630	4.500	0.488	4.500	0.580
3	4.429	0.422	4.406	0.480	4.417	0.451
Total	4.516	0.517	4.483	0.497	4.500	0.507

SD: Standard deviation.

Table (3): Comparison of dmft index between the two examinations with percentage of caries increment for each group

Group	Examination	Mean ± SD	F-test	% Caries Increment
1	First	6.96 ± 3.87	-0.12	0.86
	Second	7.02 ± 4.07	df= 328 $p= 0.90, NS$	
2	First	7.08 ± 3.90	-0.16	1.27
	Second	7.17 ± 3.70	df= 214 $p= 0.87, NS$	
3	First	7.03 ± 3.89	-3.74	31.29
	Second	9.23 ± 4.00	df= 178 $p= 0.0002, S$	

SD: Standard deviation; NS: Not significant; S: Significant.

Table (4): Comparison of dmfs index between the two examinations with percentage of caries increment for each group

Group	Examination	Mean ± SD	F-test	% Caries Increment
1	First	12.02 ± 9.03	0.06	-0.50*
	Second	11.96 ± 8.90	df= 328 $p= 0.96, NS$	
2	First	11.44 ± 7.77	-0.69	6.38
	Second	12.17 ± 7.56	df= 214 $p= 0.49, NS$	
3	First	11.13 ± 7.96	-3.85	43.49
	Second	15.97 ± 8.87	df= 178 $p= 0.0002, S$	

SD: Standard deviation; NS: Not significant; S: Significant.

* Minus score indicates caries reduction.

Tables (5) and (6) demonstrate the differences among the three groups in the

first and second examinations regarding dmft and dmfs indices, respectively. In the

first examination, there was no statistical significance among the three groups; whereas in the second examination, the third (control) group reported a significant difference from the experimental groups. Ho-

wever, the difference between the experimental groups in the second examination was statistically not significant for both dmft and dmfs indices.

Table (5): Comparison of dmft index in the first and second examinations among the groups

Examination	One-way ANOVA			Group	Duncan's Multiple Range Test*	
	No.	F-value	p-value		No.	Mean ± SD
First	363	0.03	0.968	1	165	6.964 ± 3.868 ^A
				2	108	7.083 ± 3.901 ^A
				3	90	7.033 ± 3.890 ^A
Second	363	10.16	0.000	1	165	7.018 ± 4.069 ^A
				2	108	7.167 ± 3.695 ^A
				3	90	9.233 ± 4.003 ^B

SD: Standard deviation.

*Means with the same letter were statistically not significant.

Table (6): Comparison of dmfs index in the first and second examinations among the groups

Examination	One-way ANOVA			Group	Duncan's Multiple Range Test*	
	No.	F-value	p-value		No.	Mean ± SD
First	363	0.36	0.699	1	165	12.018 ± 9.029 ^A
				2	108	11.444 ± 7.769 ^A
				3	90	11.133 ± 7.955 ^A
Second	363	7.20	0.001	1	165	11.964 ± 8.898 ^A
				2	108	12.167 ± 7.561 ^A
				3	90	15.967 ± 8.868 ^B

SD: Standard deviation.

*Means with the same letter were statistically not significant.

Finally, the percentage of caries reduction for each of the experimental groups compared with the control group regarding dmft and dmfs indices (Table 7) revealed that the first group achieved the best results, followed by the second group. The percentage of caries reduction regarding dmft and dmfs indices was 97.25% and 101.15% for the first group, and 95.94% and 85.33% for the second group, respectively.

Table (7): The percentage of caries reduction for the two experimental groups compared with the control group regarding dmft and dmfs indices

Index	Group 1	Group 2
dmft	97.25	95.94
dmfs	101.15	85.33

DISCUSSION

In Iraq, the prevalence of dental caries, especially for younger age groups, is increased due mainly to the increase in sugar consumption and paucity of preventive programs conducted at schools.⁽³⁰⁻³²⁾ So, we need to enhance an effective program to be used in Iraqi kindergartens and schools to control dental caries focused on prevention, where the preventive approach is an essential recommendation.

In this study, some of the children were excluded; the percentage of loss being 11.89%. This is due to the fact that some of them either moved from the area or were repeatedly absent from the kindergarten at the time of applications of topical fluoride gel or at the time of the second examination.

During this study, the topical fluoride applications were conducted on deciduous teeth without prior professional cleaning, since *in vivo* studies have demonstrated that fluoride uptake and caries inhibition are not reduced if teeth remained uncleaned.⁽³³⁻³⁶⁾ Consequently, the improvement in cost regarding the elimination of this step as well as the decrease in chair-side time for each treatment is making the single step procedure for application of fluoride more suitable for public health programs as well as those programs conducted at kindergartens.

The purpose of professional fluoride treatment is to benefit the tooth surface by a topical effect, and care should be taken to limit ingestion of professionally applied products. It should be emphasized that all possible precautions were taken during the fluoride application in this study to prevent accidental ingestion of fluoride by the children. The use of these procedures has been shown to reduce the amount of inadvertently swallowed fluoride to less than 2 mg, which may be expected to be of little consequences.⁽³⁷⁾ At the same time, it is noteworthy to document that children were advised not to eat, drink or rinse for 30 minutes following each fluoride treatment session. This is because fluoride levels in treated enamel were found to be about 50% lower if the subjects rinsed immediately after the application.⁽³⁸⁾

In this study, the anticaries effect of half-strength APF gel (0.4% fluoride) has been shown to be nearly similar to the full-strength one (1.23% fluoride). These results were in agreement with those of Hagan *et al.*⁽²⁴⁾ There are two possible explanations for 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 desired caries inhibitory effect, even when applied only once every six months. This possibility is in agreement with a study carried out by Wefel and Wei.⁽³⁹⁾

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

The use of low-strength fluoride gel carries a benefit in that it decreases the potential risk for children who inadvertently swallow a quantity of the gel. A study showed that under optimum conditions, children may swallow an average of 11 mg of fluoride as the result of topical application.⁽⁴⁰⁾ Use of an agent with a lower concentration would reduce the amount of fluoride ingested.

CONCLUSION

The findings of this clinical trial indicate that both the full- (1.23% APF) and half-strength (0.4% APF) gels were effective in reducing caries increment in the sample of pre-school children, although there were indications that the full-strength agent is more effective.

In cases where acute fluoride toxicity and exposure to high levels of fluoride are of special concern (as in case of very young child), the reduced strength concentration gel can be used and may be expected to impart a significant caries-reducing effect. Hence, the use of the low fluoride concentration is recommended over the high fluoride concentration.

The planning of such a fluoride therapy as a pre-school-based program is advised for all children with evidence of dental caries.

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