

## Fluoride Varnish Effect on Preventing Dental Caries in a Sample of 3-6 Years Old Children

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### Abstract:

**Background:** Early childhood caries is one of the most prevalent chronic diseases of children that affect their life and their family in different aspects. Using different types of fluoride is one of the most effective ways for preventing the disease. Fluoride varnish is a topical fluoride product which could use in the community even by non-professional. This study aimed to assess the effect of fluoride varnish on dental caries in a group of children aged 3-6 years old in Kerman kindergarten during 6 month's period.

**Materials and Methods:** This community interventional study recruited a sample of volunteer children from 12 kindergartens through a cluster sampling. Kindergarten randomly allocated to test and control group after matching. Dental examination was performed in three phases of the study by a trained dentist using criteria of Intentional Caries Detection and Assessment System. Fluoride varnish was applied for test group in the first phase after dental examination and also 3 and 6 months after this phase. Control group has received varnish product just after 3 and 6 months after the first dental exam. Mean decayed, missed and filled teeth (dmft) were compared between and within groups using T-test.

**Results:** From 476 children who participated in the study 55% were boys and the 6 years group was the most frequent group with 35% (166). Mean dmft difference was significant between Phase 1 and 2 ( $P = 0.05$ ) in the test group but there was no significant difference between Phase 2 and 3 ( $P = 0.07$ ). The difference was not significant between Phase 1 and 2 ( $P = 0.09$ ) but it was significant between Phase 1 and 3 ( $P = 0.03$ ) in the control group.

**Conclusion:** The study results showed a decrease in mean dmft after applying the fluoride varnish which confirms previous studies.

**Key Words:** Community trial, early childhood caries, fluoride varnish

### Introduction

Oral health is a necessary and integral part of general health. The lack of oral health and untreated oral infections has a vast effect on the quality of life in children.<sup>1</sup> Reliable evidence deduced from different studies has shown the cost effectiveness of preventing methods on oral diseases. Keeping children free from toothaches can reduce the social side effects such as missing school hours.<sup>2</sup> Furthermore, oral diseases render people likely to contract costly chronic diseases such as heart disease, diabetes, respiratory problems and so on.<sup>3</sup>

Dental caries is a disease that can occur in very small children, sometimes as soon as the tooth eruption starts. It can progress rapidly, and cause children to lose their teeth very early on which in turn can lead to many other problems.

The role of fluoride-containing products such as fluoride varnish for preventing dental caries has been reported by many studies and also has been confirmed by systematic reviews and meta-analysis.<sup>4-7</sup> Fluoride varnish was introduced in 1960 in Europe and contained 5% sodium fluoride,<sup>8</sup> it is used on teeth that are dry. The mechanism of action of this substance is the constant and steady release of fluoride ions to the tooth surface. This reduces the demineralization of the tooth and helps with remineralisation. There are microscopic porosities on the surface of the enamel which can be places for fluoride deposition, and from them the steady release of fluoride into the dental plaque can occur which prevents the drop in plaque pH and in turn the demineralization of teeth.

Several studies have shown the effect of fluoride varnish on dental caries. Clinical trial studies have reported numerous results regarding the effect of fluoride varnish on deciduous and permanent dentition.<sup>9-12</sup> Weintraub's clinical study in 2006 also reports the reducing effect of varnish on caries.<sup>13</sup>

Peterson's studies have shown that the use of fluoride varnish is more effective than other topical fluoride in preventing dental caries.<sup>14</sup> In other studies, a 75% effect has been reported.<sup>15</sup> Review studies also point out the positive effect of varnish on caries.<sup>5,16</sup>

Unlike fluoride gels that need certain equipment and attendance at clinic, varnish can be used widely in the community specially the type which will set in proximity to saliva meaning easier application.

Recently the ministry of Health and Medical Education in Iran has started a national program for the use of fluoride varnish in kindergarten. As the plan requires a lot of expense and time, it is necessary to carry out studies to analyze its efficiency. By taking into account the multifactorial nature of dental caries, the role of social and economic factors, and the variety of the food culture in different parts of Iran in causing dental caries, it seems necessary to carry out studies for reassurance of results to be expected from this plan.

Therefore, this study aimed to determine the effect of fluoride varnish application in prevention of caries in a group of 3-6 years old children.

### Materials and Methods

This study was a community intervention which recruited 476 of 3-6 years old children from the kindergarten of Kerman. The study was ethically authenticated by research ethics committee in the Vice-chancellor of research with code k/89/129. Participation to the study was voluntary. Authorization of Kerman oral health unit and social welfare organization was obtained, and target kindergarten was excluded from national varnish program plan.

A sample size of 360 was determined ( $\alpha = 0.5$ ) for the study to have 85% power to estimate differences between groups. Considering design effect and also 30% drop outs during 6 months a number of 476 children were enrolled to the study.

Via cluster sampling method, 12 kindergartens from different areas were chosen throughout the city to take part. Parents of 550 children attending the kindergarten signed an informed consent form to be involved in the study after providing necessary information about the nature of the study. Children under 3 years old and those who were uncooperative were excluded from the study. Parents filled a questionnaire including demographic data and oral hygiene habits of their children. First, initial dental examinations were carried out on all the kids whose parents had given consent. Dental examination was recorded according to codes of new International Caries Detection and Assessment System (ICDAS).<sup>17</sup> Examinations were carried out by a dentist who was trained for recording via the new system using a probe with a blunt end and under suitable light. In this system, changes in the enamel from the initial stage, which may be in the form of white spots or demineralized areas with the loss of translucency of the tooth surface, are recorded. The codes in this system are as follows:

- Code 0: Sound tooth and tooth should be examined wet.
- Code 1: First visible changes in enamel and tooth should be examined after drying to detect any change in enamel.
- Code 2: Obvious and visibly diagnosable change in enamel and it is detectable when tooth is wet.

Code 3: Localized enamel breakdown (without clinical visual signs of the dentinal involvement).

Code 4: Underlying dark shadow from dentin.

Code 5: Distinct cavity with visible dentin.

Code 6: Extensive distinct cavity with visible dentin.

Codes 1-6 are recorded as decayed teeth (dt). Filled teeth (ft) and posterior missing teeth due to caries (mt) were also counted and taken into consideration for the calculation of the dmft index. Only deciduous teeth were examined and if in a 6-year-old, the first molar or incisors had erupted, they (the teeth) were ignored in the analysis. Furthermore, the anterior deciduous, if missing, were not considered as teeth lost due to caries.

With taking in mind the whereabouts of the kindergarten were randomly allocated to test and control groups. The kindergartens were matched in a way so that the children would be similar considering dental caries, oral hygiene habits, age and gender.

Then fluoride varnish was applied to test groups by two trained oral hygienist. The varnish used was the Durashield (bubble fun, Sultan Health Care Inc., The American company) which contained 5% sodium fluoride. This varnish was used from the person to person using a special applicator brush on all dried surfaces of the teeth. The varnish sets after reaching of saliva on the teeth. The necessary instructions to not brush and floss and eat stiff and hot food for 4-6 h, after applying the varnish were given to the children. It should be noted that the examiner was different to people applying the varnish; also they were blind to the children allocated group. The parents were instructed to keep children from receiving fluoride product such as mouthwash and professional fluoride therapy during the time of the study. The control group did not receive any intervention in the first phase.

Three months after applying varnish on the teeth of the children in the test group, both groups were examined again, and the rate of caries was recorded using the same system and the same examiner as before. At this time, fluoride varnish was applied to teeth of the control group using the same method and the same instructions were given. The test children were again given fluoride varnish.

Three months later (6 months after this first examination), the children were examined using the same way as before. In this stage, varnish was used again on both groups.

Data analysis for comparing mean dmft between and within groups was carried out using the software SPSS version 17 (Chicago, USA) and *t*-test statistic. Also, the non-parametric Mann-Whitney U-test was used to analyze the difference in the incidence of caries between the two groups. Cluster analysis was

performed to reveal groups design effect on the results.  $P \leq 0.05$  was considered as the level of significance thought the study.

**Results**

In the total of 476 people who took part (Figure 1), 55% were male. The frequency distribution of demographic characteristics of the participants is shown in Table 1. Oral health habits of both groups are shown in Table 2.

The collected data at baseline of the study showed no significant difference between the mean of dental caries and the mean age between test and study groups ( $P > 0.05$ ). Also, there was no significant difference between the two groups for tooth brushing habits and also genders ( $P > 0.05$ ).

The mean of dt, mt due to caries and ft in all of the participants in the first stage of the study was 5.08 and decreased to 4.77 in the third stage.

Table 3 shows the mean dmft in all those who took part, in the test group and control group in the three stages of the study. The independent sample *t*-test showed a significant statistical difference between mean dmft of the test and control group in the second stage of the study but not the first and third stage (Table 4). Comparison of the mean dmft in the test group between the first and second stage was significant but

between the second and third phase it was not significant (Table 5). However, the comparison in the control group between the first and second stage was not significant but between the second and third phase it showed a significant difference (Table 6).

The relationship between dmft and method of tooth brushing in children, the order of children in family, infancy feeding behavior and the type of birth for all the participants in the study is shown in Table 7.

**Table 1: Demographic characteristic of participants.**

Characters	Frequency (%)
Age in year (N=476)	
3 year	75 (16)
4 year	86 (18)
5 year	149 (31)
6 year	166 (35)
Gender (N=476)	
Male	262 (55)
Female	214 (55)
Birth type (N=443)	
Natural	204 (44)
C-section	299 (50)
Premature	10 (0.2)
Child birth order (N=448)	
1 <sup>st</sup>	179 (48)
2 <sup>nd</sup>	237 (52)
3 <sup>rd</sup>	18 (4)
>3 <sup>rd</sup>	14 (3.2)
Infancy feeding habits	
Breast feeding	343 (75)
Bottle feeding	85 (18.5)
Both	26 (5.7)

**Table 2: Oral hygiene habits of participants.**

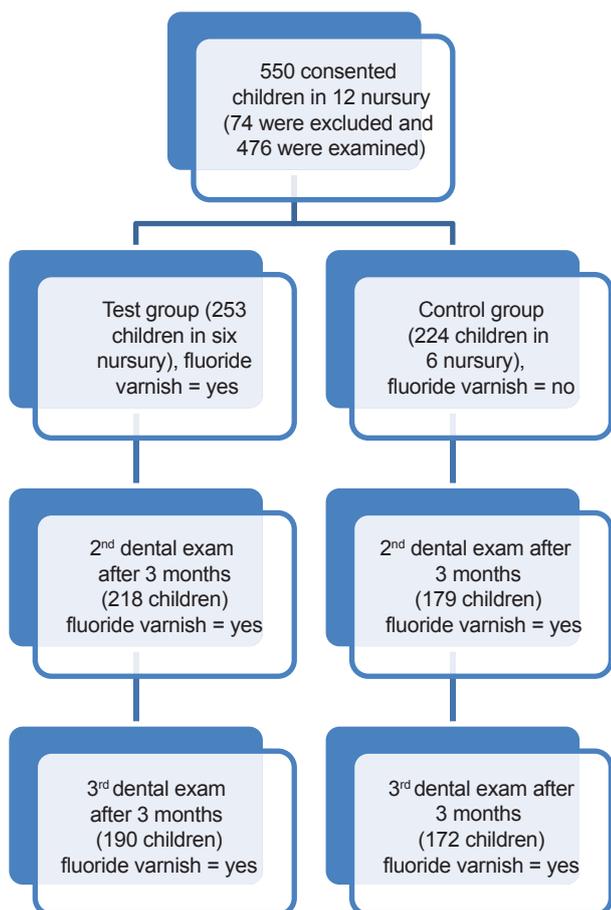
Oral hygiene habits	Frequency (%)
Tooth brushing (N=428)	
Does not brushed	140 (33)
Sometimes it does	125 (30)
Once a day makes	153 (36)
Twice a day	10 (3/2)
Using dental floss (N=425)	
Yes	37 (8)
No	338 (76)
I do not know	50 (2/21)

dmft: Decayed, missed and filled teeth

**Table 3: Mean±SD of dmft for all participants, test and control groups in three stages of the study.**

	All participants (N)	Test group (N)	Control group (N)
The first stage	5.08±4.14	5.23±4.23	4.91±4.04
	476	253	224
The second stage	4.78±3.4	5.15±4.05	4.33±3.88
	394	218	179
The third stage	4.77±4.08	4.87±4.24	4.65±3.89
	359	190	172

dmft: Decayed, missed and filled teeth, SD: Standard deviation



**Figure 1:** Flowchart of the study phases and participants.

**Table 4: Comparing mean dmft in different stages between test and control group.**

	Group	Mean difference and standard error of the difference	Degrees of freedom	Significant (2-tailed)
The first stage	Test group	0.314, 0.381	474	0.4 NS
	Control group			
The second stage	Test group	0.82, 0.40	391	0.043 S
	Control group			
The third stage	Test group	0.22, 0.43	360	0.57 NS
	Control group			

S: Significant, NS: Not significant, dmft: Decayed, missed and filled teeth

**Table 5: Paired t-test of mean dmft within test group in different stages of the study.**

	Number of pairs	Mean difference of the pairs±SD	Degrees of freedom	Significant (2-tailed)
Pair 1				
First stage dmft	216	0.13±0.1	215	0.05 S
Second stage dmft				
Pair 2				
Second stage dmft	190	0.21±0.77	189	0.07 NS
Third stage dmft				

S: Significant, NS: Not significant, dmft: Decayed, missed and filled teeth, SD: Standard deviation

**Table 6: Paired t-test of mean dmft within control group in different stages of the study.**

	Number of pairs	Mean difference of the pairs±SD	Degrees of freedom	Significant (2-tailed)
Pair 1				
First stage dmft	177	0.08±0.67	176	0 NS
Second stage dmft				
Pair 2				
Second stage dmft	138	-1.38±0.74	137	0.03 S
Third stage dmft				

S: Significant, NS: Not significant, dmft: Decayed, missed and filled teeth, SD: Standard deviation

**Table 7: Relationship between dmft and some characteristics of all participant children.**

Child characteristic	Tooth brushing	Child birth order	Infancy feeding habits	Birth type
dmft				
Pearson coefficient	0.054	0.19	0.018	0.046
Significant (2-tailed)	0.2 NS	0.05 S	0.7 NS	0.32 NS
Number	428	448	454	457

S: Significant, NS: Not significant, dmft: Decayed, missed and filled teeth

The Mann–Whitney U-test shows a significant difference between mean dmft of the test and control group in the second stage of the study. Although, this test showed no significant difference between the first and third stage. Cluster analysis confirmed the study results analysis.

**Discussion**

The results showed the positive effect of fluoride varnish in preventing caries in the participants after 6 months. The mean of dmft of those who took part in the study, in the first stage was 5.08, which reached 4.77 in the third stage, which shows a 14% reduction. This reduction is more evident within the test group who were exposed twice to fluoride varnish. It showed a significant statistical difference between the first and second stage ( $P = 0.05$ ) when varnish was applied to the teeth but between the second and third stage showed no significant difference ( $P = 0.07$ ) which showed the effect of the varnish. This difference in the control group, between the first and second stage where no varnish was applied was not significant ( $P = 0.09$ ) but between the second and third after applying varnish, it was significant ( $P = 0.03$ ). The results are in line with other studies worldwide.

Many studies have published worldwide about the benefits of using fluoride varnish to prevent caries.<sup>9-13</sup> Fluoride varnishes have been used for over 30 years in Europe.<sup>8</sup>

In 2004, a systematic review on clinical trials based on the efficiency of use of fluoride was carried out by Peterson *et al.*<sup>18</sup> This study showed the efficacy of fluoride varnish to reduce caries in deciduous teeth by 30%. This research was carried out in time periods of 6 months to 3 years. Therefore the result of 14% reduction for this study taking in mind the time period of the study is acceptable. Quinonez *et al.* also reported a 28% decrease in childhood caries yearly, by using fluoride varnish that is consistent with the results of this study.<sup>19</sup>

Mehran *et al.* in 1997 reported an increase in caries in the control group of 1-3 year old children of 21% compared to the test group who were given fluoride varnish which also coincides with the results of this study.<sup>20</sup>

In the reported study dental caries were assessed using ICDAS to record demineralization from the initial stages of white spots to cavities that were an important aspect of the study. White spots were considered caries to enable us to analyze the progress of the lesion or its remineralization. Although due to the high volume and complication of the results obtaining the dmft had to be sufficient and recording the minor details of the lesions, and different codes was not possible to report in here. However most other studies carried out in this field also reported results based on dmft.

Using fluoride varnish compared with other methods of using fluoride, seemed to be more accepted for patients.

In this study, the comparison of different fluoride products was not intended, and choosing fluoride was due to the fact that fluoride varnishes were to be used throughout the country in kindergarten according to nationwide plan by the government.

The aim of this study was to analyze the efficacy of fluoride varnish and how it could help the plan.

The benefits of using fluoride varnish in preventing caries are easy use in different population groups without the need of having a dental clinic, lower risk of swallowing of fluoride by children and ease of use for patients. Also for use of fluoride varnish, the same prophylaxis and preparation which is needed for using fluoride gels is not necessary, and a simple brushing will suffice. There is no need for isolation and it sets in contact with saliva, and there is no toxicity reported by this product.

Taking in mind the lack of significant difference between caries incidence in control and test groups and other factors such as age, gender, brushing technique and amount of caries prior to the study, the reduction in caries can be related to the use of fluoride varnish.

This study was able to show the effect of fluoride varnish in reducing caries in deciduous teeth in community level but it could be investigated in a cohort study in longer time and also for predicting the effects of fluoride varnish on permanent teeth.

It is obvious that due to population movement, carrying out this kind of study is always challenging, and in this certain study, although it was short term, 17% of the sample in second stage and 24% in the third was lost.

### Conclusion

Results of this study prove those of previous studies that show the preventive effect of fluoride varnish on dental caries. Even though this study was a short-term one a reduction in caries is evident, therefore we are hopeful that the continued use of varnish in kindergarten, which fortunately has been put into motion by the Iranian Ministry of Health, will help to promote oral health of children.

Thus it is suggested that the effect of varnish on permanent teeth in children should be studied on a long term basis in a cohort study in larger samples across the country.

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